Evaluation of Tier 1 Exposure Assessment Models under REACH (eteam) Project

Substudy Report on Gathering of Background Information and Conceptual Evaluation

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The responsibility for the contents of this publication lies with the authors.

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Abstract

In this part of the eteam Project a general evaluation of the models‘ concepts was conducted.
This included the tools ECETOC TRA (version 2 and 3), MEASE (version 1.02.01), the EMKG-EXPO-TOOL, STOFFENMANAGER® (version 4.5) and RISKOFDERM (version 2.1), but also EASE (version 2), which has been used as a basis during the development of ECETOC TRA and MEASE.
In the course of the conceptual evaluation each tool was described concerning design, functionalities and structure of use. Model development and background information were summarised as far as publicly available. The model algorithms were analysed and explained including underlying data and principles. In addition information about the models' scope was collected.
The results of this evaluation were used to develop an applicability matrix. This applicability matrix is intended to help model users to choose the appropriate tool for their purpose that is able to describe an exposure situation in a sufficiently detailed way by offering necessary parameters whose scope includes the assessed situation.
In addition, a use map was derived that can be used to convert different use description parameters into each other. This use map will therefore help model users to do exposure assessments with different models in a correct and consistent way.
Overall, the conceptual evaluation was not used to prioritise the evaluated models, as model concepts, scopes and backgrounds are mostly too different to be compared in a direct way.
However, the outcomes of this work package give users the possibility to compare different tools concerning scope and use and serve as a basis for other parts of the project where detailed knowledge of the model algorithms is needed.

Key words:
Exposure assessment; exposure modelling; validation; REACH; risk assessment

Teilbericht zur Sammlung von Hintergrundinformation und der konzeptionellen Evaluierung

Kurzreferat

Dieser Teil des eteam-Projektes beinhaltet eine generelle konzeptuelle Evaluierung der zur Registrierung von Stoffen unter REACH verwendeten Tier 1-Tools.
Dazu zählen ECETOC TRA (Version 2 und 3), MEASE (Version 1.02.01), das EMKG-EXPO-TOOL, STOFFENMANAGER® (Version 4.5) und RISKOFDERM (Version 2.1), aber auch EASE (Version 2), das bei der Modellentwicklung von ECETOC TRA und MEASE als Basis diente.
Die konzeptuelle Evaluierung umfasst zuerst die Beschreibung von Design, Funktionalitäten und Verwendung eines jeden Tools. Soweit entsprechende Informationen verfügbar waren, sind Modellentwicklung und Hintergrundinformation zusammengefasst. Weiterhin analysiert und erklärt die Evaluierung Modellalgorithmen (einschließlich der ihnen zu Grunde liegenden Daten und Prinzipien). Die Evaluierung wird mit einer Sammlung von Informationen bezüglich der Geltungsbereiche der verschiedenen Modelle ergänzt.
Die Ergebnisse dieser Evaluierung flossen in die Entwicklung eine Anwendungsmatrix („applicability matrix“) ein. Diese Anwendungsmatrix soll Benutzern dabei helfen, ein angemessenes Tool für ihren Zweck auszuwählen, das die notwendigen Parameter bezüglich der Umgebungsbedingungen berücksichtigt, und dessen Geltungsbereich die untersuchte Situation umfasst.
Außerdem wurde eine sogenannte Prozesszuordnungshilfe („use map“) entwickelt, die verwendet werden soll, um verschiedene Parametersets zur Beschreibung der Prozesse/Aufgaben am Arbeitsplatz ineinander umzusetzen. Die Zuordnungshilfe dient Modellnutzern dazu, ihre Expositionsabschätzungen mit verschiedenen Modellen auf korrekte und konsistente Weise durchzuführen.
Die konzeptuelle Evaluierung zielt nicht auf eine Priorisierung der Modelle ab, da Modellkonzepte, Geltungsbereiche und Hintergründe überwiegend zu unterschiedlich sind, um einen direkten Vergleich zu erlauben.
Die Ergebnisse geben dem Anwender allerdings die Möglichkeit, verschiedene Tools bezüglich Geltungsbereich und Anwendung zu vergleichen und dienen somit auch als Basis für andere Teile des Projektes, die ein detailliertes Verständnis der Modellalgorithmen erfordern.

Schlagwörter:
Expositionsabschätzung, Expositionsberechnung, Validierung, REACH, Risikobewertung

1 Introduction

In the context of the European Regulation concerning Registration, Evaluation, Authorization, and Restriction of CHemicals (REACH), Chemical Safety Reports (CSRs) are developed by registrants for registration dossiers. CSRs include a risk characterization based on hazard and exposure assessments. The exposure assessment needs to be carried out for each relevant exposure situation for the chemical substance, which may include manufacture of the chemical, industrial or professional downstream use of the chemical to produce formulations or articles, and the use of formulations or articles containing the chemical by professionals or consumers.

Exposure estimations are required for all routes relevant corresponding to human health (inhalation, dermal and ingestion) and for the environment. For human exposure, inhalation and dermal exposure should be included; other exposure routes (e.g. exposure through inadvertent ingestion and exposure to the eyes) must be considered if hazard is identified by these routes (ECHA, 2011).

Ideally, the exposure estimation should be based on measured values for the corresponding workplace and work activities or - if this is not possible - on analogous data. However, measurement data of sufficient quality and quantity are only available for relatively few exposure situations. Exposure calculation tools have been designed to fill this gap by allowing the user to estimate exposure without measurements, using some information about the substance and the exposure situation. Several tools are available which differ in terms of scope and applicability.

The overall aim of this project is to evaluate the generic first tier or screening exposure tools that are currently widely used for chemical safety assessments for workers under REACH, in order to determine/confirm the applicable domains of the models and to achieve more confidence about the accuracy and reliability of model predictions.

Tier 1 models are simple tools which provide conservative estimates of exposure levels at workplaces without the need to gather detailed information or to perform exposure measurements. According to ECHA (2010b) the following determinants need to be available for Tier 1 exposure assessments:

- physical state of the substance;
- physical state of the product handled;
- vapour pressure (for liquids);
- “dustiness” (for solids);
- the concentration of the substance in the preparation;
- the level of containment;
- presence and efficiency of local exhaust ventilation (LEV);
- duration of activity; and
- process and activity (what is done with the substance, covering parameters related to energy exerted on the substance or product, surface area of source in contact with air).

Use of personal protective equipment is generally not considered for the first tier exposure estimation. The exposure-reducing effect of PPE is considered as a next step (ECHA, 2010b, ECETOC (2004). However in ECHA (2010b) in the introduction of different tier 1 tools (e.g. ECETOC TRA) it is considered to be a limitation if no

options for specifying personal protective equipment are available. Thus, the information provided by the REACH guidance is not clearly defined.
The Tier 1 tools ECETOC TRA, MEASE, the EMKG-EXPO-TOOL, STOFFENMANAGER© and RISKOFDERM and partly EASE will be evaluated in this project. All of them except EASE are intended to be used in the context of REACH and are also described in REACH guidance R14 (ECHA, 2010b). Although some tools include options for estimating consumer and environmental exposures (e.g. ECETOC TRA), only the model parts, which assess exposure at workplaces, shall be evaluated.
In this report each tool will be discussed in a separate chapter that will be divided into the following parts:

- An introduction, where the history of the tool development will be summarised;
- A full description of the tool, where the concept, additional contributing algorithms and the scope will be given;
- A description of the underlying database from which the tool was developed and a summary of its limitations;
- The derivation of the final exposure output;
- A discussion of the transparency of the model development and implementation; and
- A conclusion, where the different parts of the model concept will be summarised and an overview about the covered determinants will be given.

An overall discussion (see Chapter 10) will compare the different tools and present an applicability matrix (Appendix 5) which gives a general overview of all tools and a use map (Appendix 6). Both tables may help the user to decide, which of the tools fits best to his specific situation.

2 Gathering of information

To achieve a comprehensive overview of all available tools, several well-known literature databases were searched. The result of these searches are summarised in Table 2.1. Further refinement options of the keywords were implemented in case of EASE to reduce the number of results without losing important publications: Exposure AND Assessment AND (EASE OR "Estimation and Assessment of Substance Exposure") AND (workplace OR worker OR inhalation OR dermal). This refinement led to a total of 88 references for EASE.
The resulting lists of references were revised carefully and publications which are not relevant for this project were discarded. Further information was obtained via cross references in the available articles and reports. All publications which were considered to be relevant were stored in EndNote. Additionally, we asked the eteam Project Advisory Board, which includes representation from all of the tool developers, to provide any additional information which had not previously been made public.

Table 2.1 Literature search results

	Toxline			
	without PubMed	**with PubMed**	**PubMed**	**Web of Science**
Exposure AND Assessment AND (EASE OR "Estimation and Assessment of Substance Exposure") AND (workplace OR worker OR inhalation OR dermal)	64	141	139	241
Exposure AND Assessment AND ECETOC	0	1	19	19
Exposure AND Assessment AND MEASE	0	0	0	0
Exposure AND Assessment AND STOFFENMANAGER©	0	5	1	14
Exposure AND Assessment AND EMKG	0	0	0	0
Exposure AND Assessment AND RISKOFDERM	0	14	3	10
	overall (without duplicates)			**416**

3 Conceptual models of Exposure

In the following paragraphs, different concepts of occupational exposure modelling as published in scientific literature will be summarised. Conceptual models for inhalation exposure were described by Cherrie et al. (1996) and Tielemans et al. (2008), while Schneider et al. (1999) describes a conceptual model for dermal exposure.[1] The main components of these conceptual models are the source and the receptor (i.e. the exposed person) and various pathways between these two.

3.1 Cherrie et al., 1996

According to Cherrie et al. (1996) the intrinsic emission (i.e. attributes of substance: dustiness, vapour pressure etc.), the method of handling or processing, occupational hygiene controls (i.e. localized controls) and personal protection (gloves, respiratory protection etc.) are the four main areas which should be covered in some way to successfully predict exposure. Cherrie et al. (1996) propose that the workplace exposure can be described by the following equations:

$$\varepsilon_a = \varepsilon_i \cdot h \cdot \eta_{LC} \qquad \textbf{(3.1)}$$

- ε_a: active emission score
- ε_i: intrinsic emission score
- h: handling score
- η_{LC}: local controls at source, e.g. LEV

$$\varepsilon_T = \varepsilon_a + \varepsilon_p \qquad \textbf{(3.2)}$$

- ε_T: total emission;
- ε_p: passive emission; e.g. re-suspension of settled dust.

$$C_{NF} = \varepsilon_{t,NF} \cdot t_{a,NF} \cdot \eta_{PPE} \qquad \textbf{(3.3)}$$

- C_{NF}: exposure score for near field emission; a cube of 8 m^3 around the head (1 m distance in any direction (Cherrie et al., 1999)
- η_{PPE}: score for personal protective equipment
- $t_{a,NF}$: duration of source activity

$$C_{FF} = \varepsilon_{t,FF} \cdot t_{a,FF} \cdot \eta_{PPE} \cdot d_{gv} \qquad \textbf{(3.4)}$$

- C_{FF}: Concentration score for far field emissions (all sources which are not within 1 m)
- d_{gv}: dilution factor, based on the efficiency of general ventilation

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[1] Naming of constants and variables may differ from those defined in the corresponding publications, to standardise terminology within this report.

$$C_T = \sum_{i=1}^{n} (C_{NF,i} + C_{FF,i})$$

(3.5)

C_T represents the total exposure to a substance that is used in n tasks. It is recommended that the scores (ε_i, h etc.) increase in equal steps on the log-scale. Values and short explanations on the assignment of scores are given in Cherrie et al. (1996) (e.g. η_{LC} = 1 if no control was present).

3.2 Tielemans et al., 2008a

Tielemans et al. (2008a) describes a modified version of conceptual model, which uses the same basic approach as described in Cherrie et al., 1996.
provides a schematic overview of this source-receptor model, including the various compartments and pathways between the compartments.

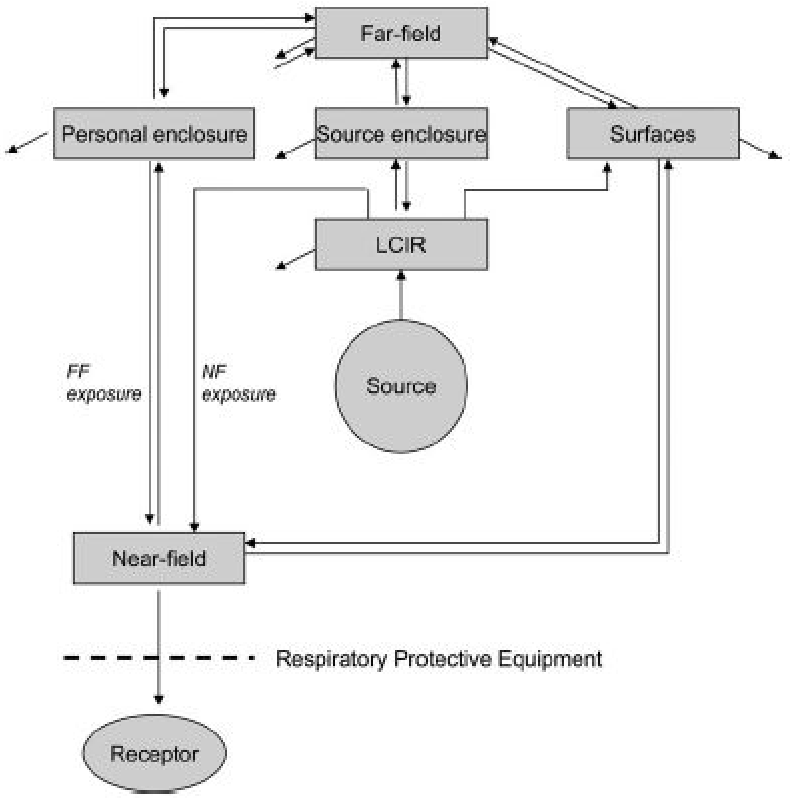


Figure 3.1 Conceptual model for inhalation exposure including sources, compartments and receptor and transport between these (Tielemans et al., 2008b; LCIR = local control influence region).

Compared to the model described by Cherrie et al. (1996) the following changes were proposed:

- introduction of personal behaviour factor P_{nf} (e.g. working direction upwards or downwards);
- segregation of source (h_{seg}) instead of general localised control for far field exposure;

- introduction of separation of the worker (Sep_{ff}) for far field exposure as organisational control; and
- dilution also for near field exposure.

The model is represented by the following equations (definition of variables identical to Cherrie et al. (1996)):

$$C_T = (C_{NF} + C_{FF}) \cdot \eta_{PPE} \tag{3.6}$$

$$C_{NF} = (\varepsilon_{t,NF} \cdot t_{a,NF} \cdot \eta_{lc} \cdot P_{nf} + \varepsilon_{p,NF}) \cdot d_{gv,NF} \tag{3.7}$$

$$C_{FF} = (\varepsilon_{t,FF} \cdot t_{a,NF} \cdot \eta_{seg} \cdot \eta_{LC} + \varepsilon_{p,FF}) \cdot d_{gv,FF} \cdot Sep_{ff} \tag{3.8}$$

3.3 Schneider et al., 1999

Schneider et al. (1999) presented a similar conceptual model for dermal exposure. The different compartments and pathways between them are illustrated in Figure 3.2.

The proposed conceptual model for dermal exposure includes 6 compartments:

i) the source (S);
ii) the surrounding air;
iii) the surface contaminant layer (Su);
iv) the outer clothing contaminant layer (CloOut);
v) the inner clothing contaminant layer (CloIn); and
vi) the skin contaminant layer (Sk).

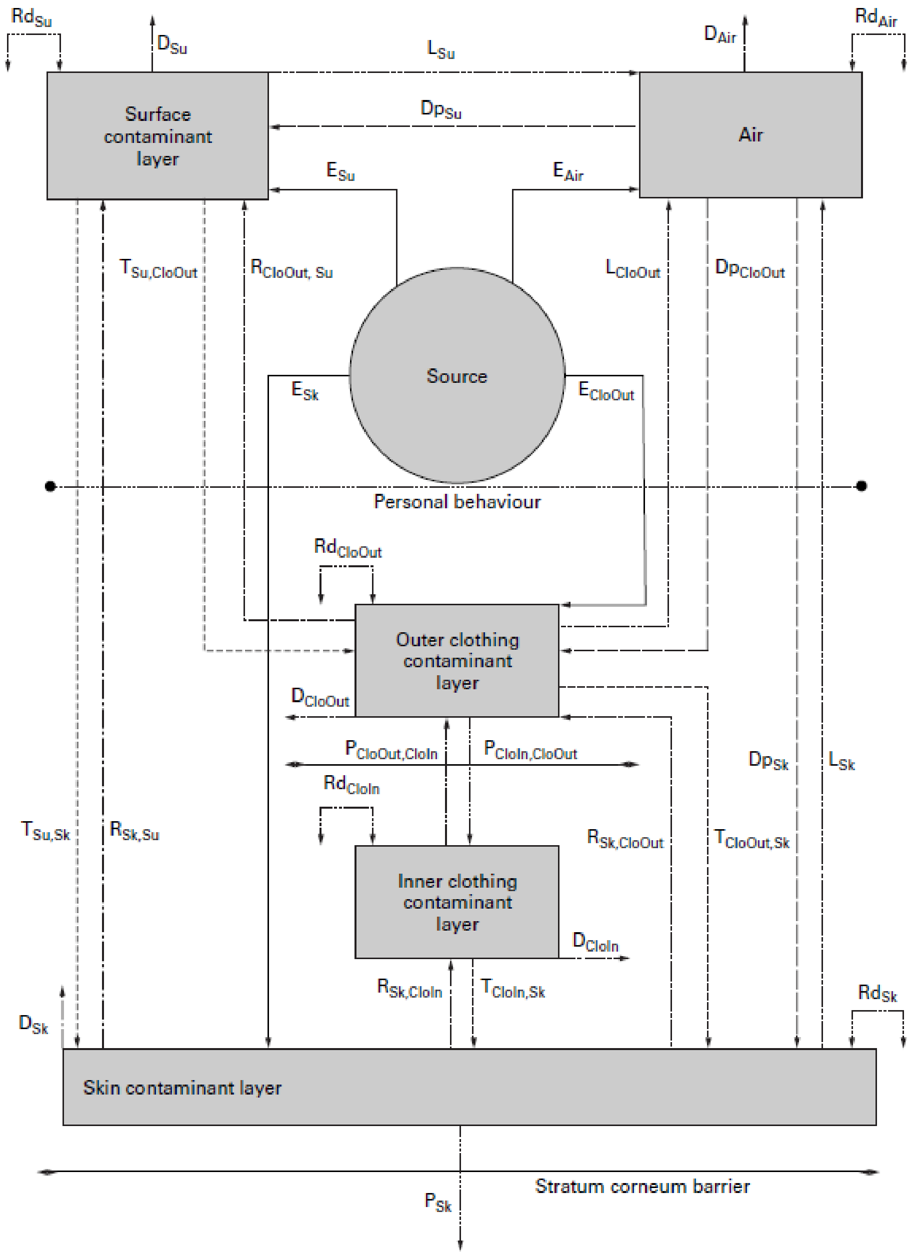
The various mass transport processes are categorised as

i) emission from primary sources (E);
ii) deposition from air to surfaces (Dp);
iii) resuspension or evaporation of substances from surfaces, clothing etc. (L);
iv) transfer by direct contact (T) in direction towards to the worker;
v) removal (R) of substance by direct contact in direction away from the worker;
vi) redistribution (Rd) e.g. between different parts of the body or any other compartment;
vii) decontamination (D) of contaminated air or surfaces by ventilation or other cleaning procedures; and
viii) penetration (P) through barriers like clothing or skin.

Examples of methods to estimate or measure the corresponding parameters are given in Schneider et al. (1999). This conceptual model formed the basisfor the development of a semi-quantitative model for estimating dermal exposure (DREAM) (van-Wendel-de-Joode et al., 2003).

A general problem of dermal exposure is that it is multidirectional and multi-compartmental. Furthermore, it is difficult to measure and no standardised strategy for sampling exists with different sampling methods potentially giving very different results. For these reasons, the dermal models within this project tend to be less-refined and more simplistic than similar tools for inhalation exposure (see also

Kromhout et al., 2004). More complex tier 1 models exist (e.g. BEAT), however no higher Tier dermal models are currently available.



Overview of the conceptual model, compartments and rate constants. E=emission (——); Dp=deposition (——); L=resuspension or evaporation (_._._._); T=transfer (- - -); R=removal (-·-·-); Rd=redistribution (·········); D=decontamination (-·-·-·-); P=penetration and permeation (········).

Figure 3.2 Overview of the conceptual model for dermal exposure as published in Schneider et al., 1999[2].

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[2] S: Source; Su: Surface contamination layer; CloOut, CloIn: Outer and inner clothing contaminant layer; E: Emission; Sk: Skin contaminant layer; Dp: Deposition; L: Resuspension or evaporation; T: Transfer; R: Removal; Rd: Redistribution; D: Decontamination; P: Penetration and permeation.

3.4 Conceptual evaluation method

It is obvious that the concept models for inhalation and dermal exposure are too complex and detailed to be used directly for Tier 1 models. Nevertheless, the concepts described in these publications can give a useful overview of the kind of information that is needed in theory for accurately estimating exposure. Tier 1 models not containing all of the parameters described in the conceptual model may still provide appropriate estimates, as long as uncertainty factors are included to ensure that the models are sufficiently conservative.

In this report a common approach of conceptual evaluation will be used. The conceptual basis of the tool will be evaluated in relation to the underlying empirical evidence, the model algorithm and the documentation of the tool. A short description of the underlying equations will be given and the scope – including the structure of use - will be analysed.

None of the conceptual models mentioned above should be regarded as a “gold standard”, as the tools in this project are too different to be forced into such limitations. Moreover, for their current purposes of use, Tier 1 tools are not expected to fulfil all requirements listed in these publications.

An overview of exposure determinants used as model parameters will be given separately for each of the tools, grouped by the four main exposure defining elements (intrinsic substance properties, process description/operational conditions, risk management measures at the source, personal protective equipment).

Additionally, an overview of the different tools and their implemented determinants will be provided in Chapter 0, to give the reader an impression of the scope of each tool. Although a higher number of determinants does not guarantee a better performance and higher accuracy, identification of the relevant required parameters can be helpful in deciding which tool covers the areas and determinants that are important for each specific exposure situation, company or user.

4 EASE

4.1 Introduction

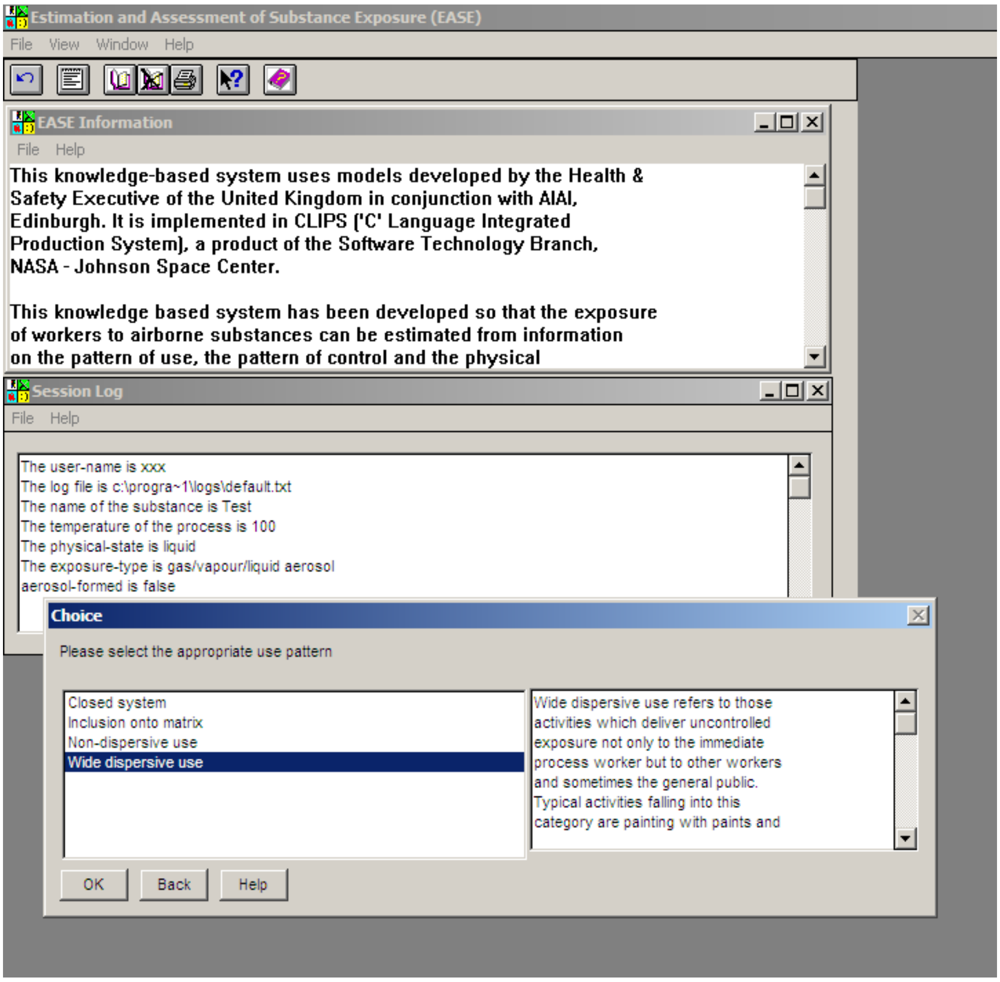

Figure 4.1 Screenshot of the EASE tool, version 2

EASE was one of the first generic tools available for the estimation of exposure concentrations at workplaces. It was originally developed for screening assessments of exposure for substances new to the European marketplace where no or little information about uses would be available (i.e. notification of new substances = NONS; HSE, 2003; Creely et al., 2005).

Initial, generalised ideas, which were later used in the underlying structure of EASE, were published in OECD, 1993. It was here stated that the concentration of a substance in a workroom might be predicted by analogy with similar situations and calibration using measured exposure data. Two general determinants of exposure, the containment level and the tendency of substance to become airborne (physical properties) were included in this first approach.

The model itself was developed in the early 1990s. The tool development was initiated by HSE (“Health and Safety Executive”) in collaboration with the HSL (“Health and Safety Laboratory”) (Tickner et al., 2005). It is based on a series of logic criteria which assign each situation/ substance combination to a certain output range.

The latest published version of EASE (Version 2) includes a module for predicting inhalation exposure and one for predicting dermal exposure. The dermal exposure module was acknowledged to be cruder and less specific than the inhalation part of the tool (HSE, 2003; Tickner et al., 2005).
EASE was intended to be a flexible model with adjustments to its output ranges being made as and when newer and better data became available. However, the output ranges of EASE have not been updated since the first version of EASE was published in 1994 (Tickner et al., 2005; ECETOC, 2004).
Whilst EASE is no longer used, several Tier 1 tools are derived from this model (ECETOC TRA, MEASE), and therefore it was considered appropriate to evaluate its underlying concepts within this project. EASE is a standalone tool that was initially distributed by floppy disk. Version 2 of the tool and its manual (HSE, 1999) can still can be obtained from HSE on request (Northage, 2012; personal communication). No special software is required for installation of EASE, however there are problems with installation of the programme under the Windows Vista and Windows 7 operating systems. Some problems which are described in the following chapters were addressed in EASE Version 3, but this package was never distributed following interpretation problems identified during the user trial (HSE, 2003).

Publications
A large number of publications about EASE, its structure of use, advantages and disadvantages are available: The development of EASE has been described by Tickner et al. (2005), Creely et al. (2005) and HSE (2003). The underlying concept, usability and limitations of the tool were evaluated by the HSE in 2003.
Several external validations can be found which compare EASE results with measured data - Kindler et al. (2010); HSE (2003); Devillers et al. (1997); Bredendiek-Kämper et al. (2001); Johnston et al. (2005); Creely et al. (2005); Cherrie and Hughson (2005); Hughson and Cherrie (2005) and Cherrie et al. (2005). These validations are briefly summarised in Appendix 2.

4.2 Tool description

4.2.1 Scope

The tool is designed to estimate exposure from gases, solids and liquids. The model also allows for the estimation of exposures to fibrous and non-fibrous dusts. EASE should not be used for estimating exposure to mists and fumes, such as arise from processes like welding, soldering, spray painting and decomposition of products (EC, 2003).The dermal exposure is estimated for hands and forearms. Estimation of mixtures is not implemented in EASE but a suggestion is made in the manual to reduce the estimated exposure by a factor equivalent to the concentration of the substance in the mixture. No further guidance for additional modifications is given in the manual or the other available publications (HSE, 1999; HSE, 2003).

4.2.2 Model, parameters and structure of use

The EASE tool is based on an empirical model, where categories are assigned to different, fixed exposure ranges by using a series of criteria. This "logic tree" is implemented within a computer-based expert system (Tickner et al., 2005; HSE, 2003).
EASE applies a number of use categories to provide the basis for an exposure situation description which were adopted from the HEDSET system[3] (HSE, 2003). This system originally applied to releases into the environment, but short explanations referring to the worker specific definition are given in several publications (e.g. HSE, 1999) and the tool itself. Summary of the use categories, control strategies and other parameters implemented in EASE are given in Table 4.1 - 5 below (see also the usemap in Appendix 6 and the applicability matrix in Appendix 5).
The number of combinations of use categories and control approaches is restricted to reasonable possibilities within the model algorithm (EASE manual) (see Table 4.5).
In version 2 of EASE, the decision tree (see Appendix 1) is implemented in a series of windows, which include short descriptions of the different steps, e.g. definitions of the handling categories and control strategies, as well as some instructions and help comments. In each window, the user must select the most appropriate category which finally leads to the corresponding exposure range.

Table 4.1 Determinants for inhalation exposure to gas, vapour or aerosol

tendency to become airborne		use pattern	pattern of control
Gas		closed system	full containment
Liquid/ solid with	high vapour pressure	inclusion into matrix	LEV
	moderate to high vapour pressure	non-dispersive use	segregation
	moderate vapour pressure	wide-dispersive use	direct handling with dilution ventilation
	moderate to low vapour pressure		direct handling
	low vapour pressure		
Aerosol			

Table 4.2 Determinants for inhalation exposure to dust

		fibrous dust			non-fibrous dust[4]
particle size	**type of dust**	**tendency to become airborne**	**use pattern**	**LEV**	**aggregation tendency**
granular	fibrous	high inherent dustiness	dry crushing and grinding	yes	non aggregating
respirable/ inhalable	non-fibrous	moderate inherent dustiness	dry manipulation	no	aggregating
		low inherent dustiness	low dust techniques		

[3] HEDSET EC/OECD Harmonised Electronic Data Set (for data collection of existing substances
[4] Categories for use pattern and the presence of LEV identical to the categories implemented for fibrous dust are also included for non-fibrous dust.

Table 4.3 Use categories of EASE

liquid	
wide dispersive use	Wide dispersive use refers to those activities which deliver uncontrolled exposure not only to the immediate process worker but to other workers and sometimes the general public. Typical activities falling into this category are painting with paints and the spraying of pesticides.
non-dispersive use	Non-dispersive use refers to processes in which substances are used in such a way that only certain group of workers, with the knowledge of the processes, come into contact with these chemicals. Procedures are normally worked out to achieve adequate control of exposure commensurate with the risk. This category is intended to cover most occupational use not specifically assignable to other categories.
inclusion into a matrix	Use consisting of inclusion into or onto matrices means all processes where chemicals are incorporated into products or articles from which release into the environment is substantially curtailed. Within the workplace, examples include the dispersion of solids in water (with wet solids less dust is produced), the use of the raw material in pellet form and the use of elastomer master batches. During the preparation of the matrix, for example mixing powdered dyestuff with water, significant quantities of the substance may be released into the workplace environment. Such processes will need to be assigned to the "non-dispersive use" category.
closed system	A process should be assigned to this category if the substance remains within a reactor or is transferred from vessel to vessel through closed pipework. Intermediates in the process are restricted to the reaction vessel and its dedicated equipment. Isolated products are stored on-site or are transported under controlled conditions. Where substances are used in closed systems but might be released into the environment after production, or where significant discharges into the environment cannot be excluded during production, the use pattern should be usually assigned to the "non-dispersive use" or the "wide dispersive use" category. Because of the need sometimes to enter a closed system, for example to carry out sampling or maintenance, the option is given to consider these systems in other use categories.
solid	
dry crushing and grinding	This category includes cleaning with compressed air, hand sanding and machine sanding as well as dry crushing and grinding. The user is asked later whether LEV is present or absent.
dry manipulation	This category includes any manipulation of the dry material. Dry brushing of the material is included.
low dust techniques	"Low dust" techniques include wet processing and any other technique where sufficient care is exercised to substantially reduce potential exposures

Table 4.4 Determinants for dermal exposure

use pattern	handling	contact level
closed system	direct	none: 0/day
Inclusion into matrix/non-dispersive	not direct	incidental: 2/day
wide-dispersive		intermittent: 2-10/day
		extensive: >10/day

Table 4.5 Possible combinations of input parameters for inhalation of vapour*****

Use pattern	Possible control pattern
Closed system without breach	Fully contained
Closed system with breach	LEV, Segregation or Direct handling
Non-dispersive use, Inclusion into matrix	Containment, LEV, Segregation and Direct handling
Wide-dispersive use	Segregation, Direct handling

** All combinations of use pattern and control pattern are possible for inhalation of dust and dermal exposure*

The various pathways within the logic tree lead to 18 different exposure ranges for vapour, gas or aerosol, 11 different ranges for fibrous dust, 10 for non-fibrous dust and 5 for dermal exposure. The limited number of exposure outcomes reflects the relative crudeness of EASE, in particular for the dermal model part, and the broadness of its output ranges. The full exposure range is 0-1000 ppm for vapour inhalation, 0-500 mg/m^3 for dusts, 0-3000 fibres/ml for fibrous dust and for dermal exposure 0-15 mg/cm^2/day. According to Tickner et al. (2005) the exposure estimates should represent both task-specific and time-weighted averages equally well, as the model would not be precise enough to reflect those differences.
A printable log file summarising the different steps included in the exposure assessment is generated by the programme.

4.2.3 Additional contributing algorithms

The programme uses a combination of the Clausius-Clapeyron equation and Trouton's rule to calculate the vapour pressure if it was not measured at the process temperature. If necessary and appropriate, a derivative of the Antoine equation which is based on the chemical class and the number of carbon atoms is used (see HSE, 1999 and Lyman, 1990):

$$\ln P_{vp} = \frac{\Delta H_{vb}(T_b - C_2)^2}{\Delta Z_b R T_b^{\,2}} \left[\frac{1}{(T_b - C_2)} - \frac{1}{(T - C_2)} \right] \quad \textbf{(4.1)}$$

with $$\frac{\Delta H_{vb}}{T_b} = \Delta S_{vb} = K_F (8.75 + R \ln T_b) \quad \textbf{(4.2)}$$

P_{vp}: vapour pressure
ΔH_{vb}: heat of vaporisation at the boiling point
T_b: boiling temperature
ΔZ_b: compression factor at the boiling point, assumed to be 0.97
R: gas constant
C_2: empirical constant; $C_2 = -18 + 0.19\ T_b$
T: process temperature
K_F is a value that is derived from a consideration of the dipole moments of polar and nonpolar molecules. Examples are listed in Lyman (1990).

4.3 Empirical exposure data used for model development

4.3.1 Description of datasets

Three different data sources were used to develop EASE, which refer to the inhalation exposure part for liquids and non-fibrous dusts (NEDB: “National Exposure Database”), the inhalation exposure part for fibrous dusts (Guidance Note EH35) and the dermal exposure part of the tool (US EPA; see HSE, 2003).
All underlying datasets were measured during the 1980s and 1990s (NEDB: 1980s/1990s; dermal data: older than 1992; fibres: 1980s; see HSE, 2003).

Dermal datasets
The dermal database includes mostly pesticides and was obtained by the US EPA (US Environmental Protection Agency) (HSE, 2003). Thus, it is not of European origin. Neither the number of dermal datasets, the industries covered nor the units of exposure results have been published.

Inhalation datasets
Most of the inhalation data sets which provide the basis of EASE’s output ranges are from the NEDB. The description published in HSE, 2003 (“Firstly, using the vapour ranges a series of “equivalent” ranges for dusts (e.g. 50-100 ppm equivalent to ~5-10 mg/m^3) were postulated.”) does not provide clear information on wether only liquids or also dust measurements from NEDB where used for the calibration of EASE output ranges. The purpose of this database was to provide reliable information on compliance with exposure limits under COSHH (Control of Substances Hazardous to Health Regulations). It contained approximately 100,000 measurements in the early 1990s, divided into approximately 400 substances, 150 industries, 750 processes (e.g. degreasing, spray painting, degreasing (hot), shoe production, cleaning, vapour degreasing, assembly, coating, casting, painting, plant maintenance, polyurethane components production, gasket production, hand tool production, motor repair, powder handling) and 750 different jobs which were reduced to 10 exposure ranges to be included in the first version of the later EASE model (HSE, 2003 and Tickner et al., 2005). The number of datasets in fact used for the calibration of EASE has not been published. The exact number of data points, industries and exposure situations have not been published (HSE, 2003).
Some additional inhalation data for fibrous dusts were obtained from HSE’s Guidance Note EH35-Probable Concentrations of Asbestos Dust (now out of print) and include manufacturing and stripping (i.e. removing of asbestos) processes which were undertaken in the mid-1980s (Tickner et al., 2005). The number of asbestos datasets, covered industries or the unit of exposure results are not published.
All inhalation data (i.e. NEDB and fibrous dust data) were collected in the UK.

4.3.2 Limitations of the datasets

General
As there is very little information published about the underlying datasets, no detailed description of missing industries or scenarios with few data points can be given.
It is not clear if there are matching datasets for exposure to gases in the underlying datasets (HSE, 2003).

Dermal datasets
An important deficiency of the EASE underlying database is the small number of dermal datasets (HSE, 2003).

Inhalation datasets
As the NEDB data were influenced by HSE's enforcement strategy in the 1980s and 1990s the corresponding datasets might be positively biased (i.e. show higher exposure values than the average workplace) – even if compared to historical common workplace measurements performed at the same time (HSE, 2003).

Concerning the interpretation of inhalation exposure values (i.e. NEDB), the measured data were always treated as if the source were the pure substance (HSE, 1999). It is stated that if the data could not be treated in such a way it was rejected, but no additional explanation of this procedure or the corresponding criteria for rejection are provided. The description in the manual and the given examples (oil mist or foundry particulate) suggests that only measurements which also provided exposure to the complete mixture were included, so underestimations of exposure due to this procedure are not expected.[5]

4.4 Derivation of the final exposure result

Dermal exposure
The dermal exposure part of the EASE tool is partly based on experiments done with liquids in the USA (US EPA) and partly on scientific knowledge of the model developers (EC, 2003). The exposure estimates are based on the physical state, pattern of use and pattern of control. The latter two are given in simplified form because of a lack of reliable data (see also Table 4.6). The categories "inclusion onto matrix" and "non-dispersive use" lead to the same exposure range and the pattern of control includes only two categories: direct or not direct handling (Tickner et al., 2005). The dermal exposure output is not influenced by the volatility or tendency to become airborne of a substance, as it is assumed to depend predominantly on direct contact with the substance. Dermal exposure from vapours or gases was considered to be very low (HSE, 1999; HSE, 2003).

Inhalation exposure
The available exposure data for solvents and other liquids were grouped (i.e. processes which were considered to have similar potential for exposure were treated together) and summarised in graphical form ("box-and-whiskers" plots, with 25-75th percentile, 10th and 90th percentile and median (50th percentile) marked). An iterative discussion and refinement process led to output ranges for vapour exposure and the structure of the first version of EASE in 1994 (Tickner et al., 2005, HSE, 2003; HSE, 1999).

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[5] "Some substances are in fact always measured as mixtures, for example, oil mist or foundry particulate. Nevertheless, it was assumed for the purposes of the model that measured data could be treated as if the source was the "pure" substance and data which could not be treated in this way was rejected." (HSE, 1999)

Table 4.6 EASE Descriptions of control approaches

level of control: vapour inhalation	
full containment	If the level of control is full containment, the process is in effect a closed system.
LEV	The presence of effective local exhaust ventilation (LEV) will have a profound effect on the level of exposure. Effective LEV removes the contaminant at the point of origin or generation and therefore prevents the contaminant from entering the air of the workroom where it might subsequently be inhaled. The user is asked if effective LEV is present; this means that if LEV is to qualify as being present it must be appropriate for the purpose and operating at or about its design effectiveness. If it is not, one of the other patterns of control should be chosen.
Segregation	In the absence of other control measures, such as LEV, exposure may be minimised by segregating the worker from the substance by means of space or time or by using some other procedural controls. A typical process is one where the operator is separated by a few metres from the source of exposure. Procedures typically require such separation to be maintained by supervision rather than by physical barriers.
level of control: dust inhalation	
LEV	description see text above
level of control: dermal	
direct handling	In the absence of any other control procedures it is assumed that the worker handles the substance directly.
not direct handling	If the level of control is full containment, or there is effective local exhaust ventilation (LEV), or the worker is segregated from the substance by means of space or time or by using some other procedural controls, then this option should be chosen.

The vapour exposure results of the model were tested initially by comparing them with further searches of the NEDB data. In some cases the ranges were adjusted to agree with the NEDB data (HSE, 2003). It was recognised by the developers that it introduced a degree of circularity that the same database was used to determine the ranges of the model and then to carry out its validation, however the absence of an alternative data source precluded a different approach (HSE, 2003).
The output ranges for inhalation exposure to non-fibrous dust were obtained postulating a series of "equivalent" ranges for dusts (e.g. 50-100 ppm equivalent to ~5-10 mg/m^3, HSE, 2003, Tickner et al., 2005). The model for non-fibrous dust is only based on materials handling and control, not on the "intrinsic dustiness" (HSE, 2003). However; some particles have a tendency to stick together (from addition of waxy substrates or electrostatic effects); therefore an additional category relating to particles' ability to aggregate was included.
The particle size has to be entered during the modelling process (inhalable, respirable, granular). In case of granular particle size, the exposure is assessed to be zero. Even though the user can identify inhalation or respirable dust, no differentiation is made in the estimated exposure level between these two size fraction and identical estimates are obtained (Tickner et al., 2005).

For fibrous dusts, judgement about the exposure values is based on the ability of the fibres to become airborne, which in turn is based on knowledge about fibre-size distributions and practical experience (Tickner et al., 2005, HSE, 2003).

Underlying assumptions

- The dermal exposure was assumed to be assessed as the quantity of contaminant in milligrams that was deposited on this area of skin during a working day, i.e. no account was taken of the effects of hand washing or evaporation or other possibilities of losing contaminant from skin (HSE, 2003);
- EASE assumes tonne quantities to be routinely handled, which may be significantly higher than in those exposure situations where the model was likely to be used (ECETOC, 2004);
- A continuous process is sampled (Johnston et al., 2005);
- The presence of standard atmospheric pressure with usual exposure levels and engineering controls (Johnston et al., 2005);
- A constant vaporisation rate (Johnston et al., 2005); and
- A uniform exposure for all workers (Johnston et al., 2005).

4.5 Transparency

Tool development and datasets

EASE has been used since 1994 but the first publication of its development, concepts and principles did not occur until 2005 (Tickner et al.). Unfortunately, not all of the documentary record of model development had survived and the documentation was inadequate (Tickner et al., 2005).

A short description of the program is also included in the manual (HSE, 1999), which is available together with the tool. According to Tickner et al. the main part of the development of EASE was an unstructured expert discussion without formal procedures and documentation. It is unclear how the output ranges were derived, especially for gases where it is not known if corresponding measurements exist (compare HSE, 2003, see also Chapter 4.3).

The sampling duration used for the measurements taken from NEDB (i.e. inhalation exposure) is not documented in a clear way. According to HSE (2003) and Tickner et al. (2005) the original data used was restricted to 8-hour time weighted average information, usually calculated from task-specific exposures and knowledge of the work patterns, breaks etc. This approach was later abandoned as it was recognised that the model would work better if it predicted task exposure, which could then be adapted to any required pattern of work (HSE, 2003; Tickner et al., 2005). Thus, it is unclear if the resulting inhalation ranges are based on task based data, 8 hour averaged data or both.

Sampling durations for fibrous substances or dermal exposure are not published.

Scope and algorithm

The underlying decision tree is published by HSE (1999) and also by Kindler et al. (2010) as well as the derivation of the volatility from vapour pressure and process temperature. The EASE logic tree is a unique structure among the group of Tier 1 tools included in this project, as it does not provide an actual equation but rather output ranges for a set of defined exposure situations. It makes the model algorithm very transparent and easy to follow.

Deficiencies of the tool and the underlying model are addressed in detail in a number of publications (e.g. HSE, 2003; Tickner et al., 2005; Creely et al., 2005) although they are not mentioned in the manual or the tool itself. Several comparisons with measured values are available (see also Appendix 2). It is known that the model is crude in many aspects.

Structure of use

EASE offers a quite simple and clear structure of use. The user is guided via comments and additional information through the logic tree until he reaches the final exposure result. However; the tool includes some potential sources of confusion, e.g. it is not clear if task or full-shift specific exposures are estimated, as the type of result is not defined in the tool.

The skin area which has been used for the dermal exposure estimation is not defined in the tool and the particle size for dust exposure is only partly taken into account. A differentiation between inhalable and respirable dust is however suggested by the options within the tool itself.

Overall, it can be concluded that the tool algorithm is easy to understand. The logic tree is published in Kindler et al., 2010 and the EASE manual, which - together with the tool itself – is available on request directly from HSE. However, neither the underlying data sources nor the derivation method of the model estimates are documented. Therefore, the transparency of the EASE tool is considered to be insufficient.

4.6 Conclusion

EASE is a widely applicable, generic model, which was originally designed for providing exposure estimates under the Notification of New Substances Regulation. It is not a recommended tool for use in REACH (HSE, 2003).

The output ranges of EASE have never been updated since the first version of EASE was published in 1994. Hence, the estimates provided by EASE are unlikely to be representative of current exposure situations (HSE, 2003; Tickner et al., 2005; ECETOC, 2004).

Both the exposure ranges and the model itself are quite widely defined and the system is not always able to categorise a situation correctly. The dermal model in particular is less defined and less detailed.

The EASE's exposure decision tool contains some sources of uncertainty, which will be discussed in detail in a later work package and include amongst others the crude and rough division into handling categories, the missing exposure estimation for body parts other than the hands and forearms, and the assumption of tonne quantities being routinely handled (ECETOC, 2004).

Several potential sources of confusion (e.g. the missing differentiation between respirable and inhalable dust, see Chapter 4.4) and deficiencies (e.g. the generally low level of transparency and the age of the underlying database, see Chapter 4.5) may lead to incorrect use of the tool and results.

It is known that the term "inclusion into a matrix" caused some confusion on the user side as it referred originally to products and consumer uses. It is – according to HSE (2003) – not used commonly in industry and might therefore lead to misunderstandings. Although examples or short descriptions are implemented in the tool and given in the manual (HSE, 1999) these problems have remained (HSE, 2003).

Dustiness of solids is only taken into account to a limited extent - only three “ability to become airborne” categories for fibrous dust are provided and the options “readily aggregating” and “not readily aggregating” for non-fibrous dust. In contrast to this a common approach for determination of volatility is implemented for liquids.

Although EASE is quite a crude model, many aspects of a successful exposure tool are already covered at least in a rudimentary way. Table 4.7 provides the determinants included in EASE and their assignment to the four main exposure defining elements. The number of categories per determinant and the influenced exposure routes (i = inhalation, d = dermal) are given in brackets. All areas are described by at least one determinant, which is considered to be the basic requirement for a Tier 1 model (see Chapter 3 and ECHA, 2010b). EASE does not provide very exact results but it tends to overestimate exposure, thus erring on the side of caution (HSE, 2003; see also Appendix 2).

In summary, it can be stated that, although three of the four main elements of an exposure situation are covered to some extent, definitions for the inhalation and dermal route are imprecise and the model provides insufficient information to fully characterise the exposure. However, the inclusion of process temperature into the derivation of volatility is comparatively advanced.

The logic tree seems reasonable but the derivation of input ranges from the underlying datasets remains unclear.

Table 4.7 Number of categories per exposure determinant (in brackets) and assignment to the different broad exposure defining elements.[6] (see also Chapter 3).

Intrinsic substance properties[7]	Process description / operational conditions (7)	Risk management measures at source (7)
physical state (i+d, 2 categories)	exposure to gas, vapour, aerosols (i, 4 categories)	LEV (i, 1 category)
vapour pressure at process temperature (either direct or calculated) (i, 6 categories)	exposure to fibrous dust (i, 3 categories)	full containment (i, 1 category)
type of dust (i, fibrous or not)	all physical states (d, 3 categories)	segregation (i, 1 category)
non-fibrous dust: aggregating or not (i)	contact level (d, number of events per day, 4 categories)	direct handling with dilution ventilation (i, 1 category)
fibrous dust: tendency to become airborne / intrinsic dustiness (i, 3 categories)	good occupational hygiene is assumed	direct handling without dilution ventilation (i, 1 category)
particle size of non-fibrous dust (i, 3 categories, indeed only 2 categories)		type of handling (d, 2 categories: direct/not direct handling)

[6] Personal protective equipment is not implemented.
[7] i: parameter influences inhalation exposure. d: parameter influences dermal exposure.

5 ECETOC TRA

5.1 Introduction

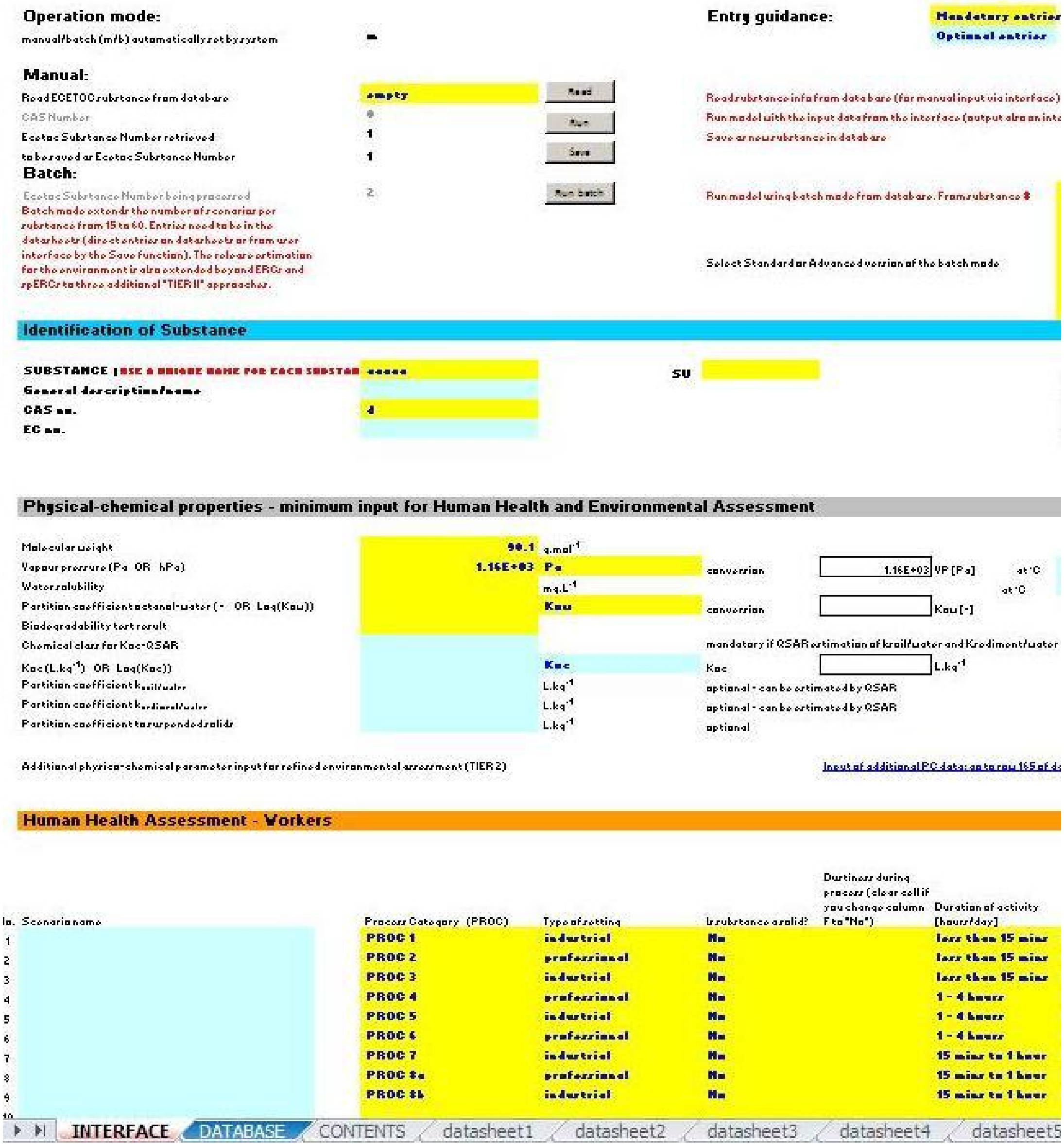

Figure 5.1 Screenshot of the ECETOC tool, Version 2, integrated version.

The ECETOC TRA (targeted risk assessment) tool was developed by ECETOC[8] to be used by chemical manufacturers and suppliers as a screening tool for a first Tier assessment under REACH (Money et al, 2007, ECETOC, 2009). Version 1 of ECETOC TRA was published in 2003 and followed by version 2 in 2009 while version 3 was published in April 2012. In both versions 2 and 3 of the tool, the descriptor system introduced under REACH (ECHA, 2010a, see Appendix 3) is used.

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[8] European Centre for Ecotoxicology and Toxicology of Chemicals

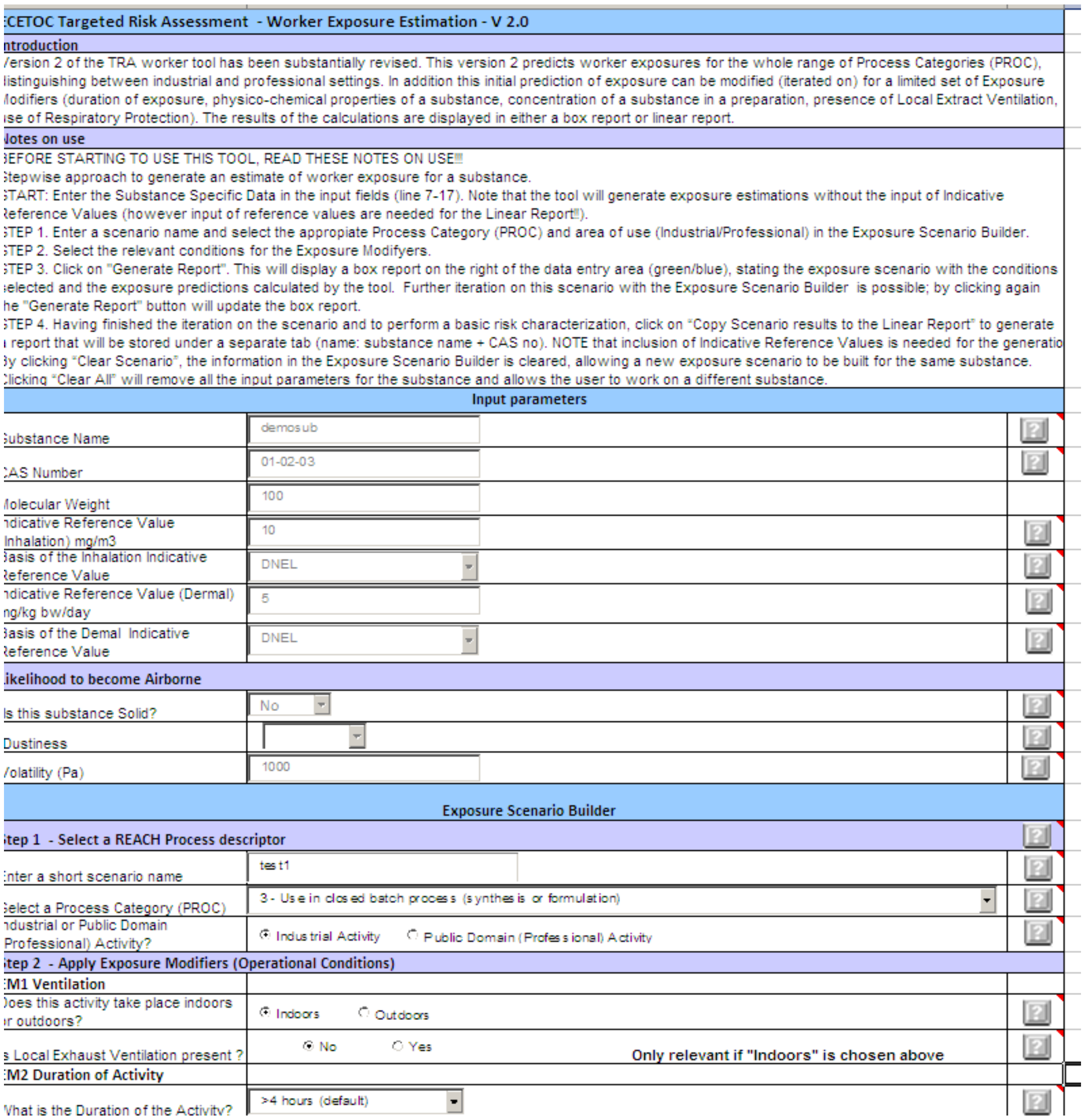

Figure 5.2 Screenshot of the ECETOC TRA tool, worker standalone version 2.

ECETOC TRA version 2 and 3 are both implemented in MS Excel and are designed to provide exposure estimates for worker, consumer and also for the environment (via EUSES).
The tool is available in an integrated form, which includes all three parts. Additionally the version 2 consumer and worker exposure modules are available as standalone tools. However, in version 3 the worker exposure module is only available as part of the integrated tool. In the context of this project only the version 2 and version 3 worker modules of ECETOC TRA will be analysed.
The latest version of the tool can be downloaded free of charge at www.ecetoc.org/tra after a short registration process. The corresponding web page can be found very easily: A simple Google-search with "ECETOC TRA" as keyword leads directly to the corresponding part of the ECETOC homepage.
The main structure of use as well as the underlying principles are basically the same for version 2 and version 3 of the tool. Thus, they will be discussed together in Chapters 5.2 and 5.3. A summary of modifications concerning the algorithm will be given in Chapter 5.4.

Publications
To assist users, there are a number of guidance documents available from the TRA webpage. These include short user guides and two technical reports by ECETOC – TR 107 (2009) which relates to v.2 of the TRA and the more detailed TR 93 (2004) which covers the web-based v.1 of the TRA. However it should be noted that the former document (ECETOC, 2009) predominantly describes the differences between v.1 and v.2, rather than a comprehensive description of the tool. The corresponding draft technical report and a beta-version of the upcoming v.3 of the ECETOC TRA were supplied to the ITEM project team for consideration in this work package, prior to the information being made public (ECETOC, 2012). In addition, a list of frequently asked questions has been made available for users on the TRA webpage, www.ecetoc.org/tra.
The underlying concept of the ECETOC TRA, i.e. a basic summary of the workflow of the tool, was summarised by Money et al. (2007). Two further validation studies for the ECETOC TRA v.2 have also been published (Vink et al., 2010 and Dobecka et al., 2011). A summary of the major findings from these published studies is given in Appendix 2.

5.2 Tool description

5.2.1 Scope

The tool covers both liquids and solids but not gases, although ECETOC (2009) gives some additional advice how to deal with volatiles with vapour pressures above 30 kPa during the estimation of dermal exposure (see also Chapter 4.4).
ECETOC TRA is not directly applicable to molten solids (i.e. non-mineral solids) used at elevated temperature (ECHA, 2010b) and it cannot be used to assess exposure to fibres (Money, 2012; personal communication).
Inhalation exposure to liquid aerosols is not covered in any of the evaluated versions of ECETOC TRA although it is only indicated explicitly in version 3 (ECETOC, 2004; ECETOC, 2012). In case of spray processes using liquids, only vapour exposure will be estimated (see also Chapter 5.4). For liquid products with dissolved or suspended solid ingredients, ECETOC, 2004 suggests using the highest fugacity class ("very dusty") to take account of the particle formation.
The dermal exposure estimation is limited to hands and forearms, with the exact skin area depending on the process number (see ECETOC, 2009 and lookup table in tool).
In ECHA, 2010b (and also Vink et al., 2010) it is suggested that LEV should not be used in combination with dermal exposure within ECETOC TRA v.2 as this leads to underestimation of exposure (comparison with RISKOFDERM data revealed this). In consequence of this the implementation of dermal LEV efficiencies has been modified for ECETOC TRA v.3 (see Chapter 5.4.2).
In general it is stated that ECETOC TRA shows some of the limitations present in EASE, which has been accounted for in the development of ECETOC TRA (Money, 2012; personal communication, see also Chapter 4 and Appendix 5). This refers for example to the treatment of process fumes, which are explicitly not covered by all versions of ECETOC TRA (Money, 2012; personal communication).

Some processes are restricted either to liquids or to solids[9]. The combinations which are not applicable are indicated by the tool (v.2 and v.3) for inhalation and partly also for dermal (v.3 of the integrated tool and the v.2 stand-alone version; e.g. by the message “not for solids” in the result fields).

5.2.2 Model, parameters and structure of use

In the ECETOC TRA v.1, the initial predicted airborne and dermal exposure was calculated by applying the EASE model to workplace exposure scenarios (ECETOC, 2004, App. J) and reviewing/refining the results in the light of newer exposure data to produce more accurate results. In version 2, these scenarios were re-named as the Process Categories (i.e. PROC numbers, see Appendix 3), in line with those published by the ECHA (ECHA, 2010a) to be used under REACH. However, the exposure prediction remained to be “based upon EASE” (ECETOC, 2009; see also usemap in Appendix 6 and applicability matrix in Appendix 5).

The integrated versions (2 and 3) of ECETOC TRA are structured by coloured fields, with mandatory information in yellow and optional fields in light blue. Up to 15 PROCs can be entered and calculated at once. In the stand-alone version (only v.2) no colour coding has been implemented and only one scenario (PROC) per sheet can be calculated.

Two different modes of running are possible for version 2 and 3 of the integrated version: manual or batch mode, where batch mode means that several substances can be calculated in one run.

Initial dermal exposure estimates of ECETOC TRA v.2 and v.3 are defined by the PROC number, whereas initial inhalation exposures are based on the PROC number, the setting (industrial or professional) and substance properties (tendency to become airborne, molecular weight[10], physical state).

These initial values are then modified in version 2 by factors based on information about duration, ventilation, respiratory protection and the substance concentration in the preparation. Version 3 also takes into account the effect of general ventilation and gloves on dermal exposure. However, not every determinant is relevant for both exposure routes and each physical state (Table 5.1).

The tendency to become airborne depends on the substance’s intrinsic properties and is estimated by using volatility or dustiness bands (high, medium or low, see Chapter 4.4). The volatility bands are precisely defined by vapour pressure ranges and the dustiness can be assigned by comparison with commonly known materials (sugar, talc, flour). Help on the choice of dustiness is provided in the tool itself and the tool documentation (ECETOC, 2004 and 2009, Table 5.2).

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[9] PROC 12 only liquid, PROC 21-25 only solid

[10] Only for conversion of units from ppm into mg/mg^3 in case of vapour exposure.

Table 5.1 Summary of the different categories for each determinant and the relevant exposure routes and physical states. Italicised text refers to differences between v.2 and v.3.

		modifying factor	**exposure route**	**physical state**
molecular weight[28]	free number	linear dependence (ideal gas law)	inhalation	liquid
dustiness	high / medium / low	included in initial exposure estimate	inhalation/ *(dermal)*	solid
vapour pressure	high / medium / low / very low	included in initial exposure estimate	inhalation/ *(dermal)*	liquid
process description (PROC no)	PROC 1-25 according to the descriptor system	included in initial exposure estimate	inhalation/ dermal	liquid/solid
process temperature (PROC 22-25)	process temperature relative to melting point*	included in initial exposure estimate via fugacity	inhalation	liquid/solid
process temperature (PROCs 1-21)	*vapour pressure at process temperature is entered high / medium / low / very low*	*included in initial exposure estimate*	*inhalation/ (dermal)*	*liquid*
type of setting	industrial / professional	included in initial exposure estimate and LEV efficiency	inhalation/ *dermal*	liquid/solid
ventilation	indoor without LEV indoor with LEV	1 PROC specific	inhalation/ dermal	liquid/solid
	good general ventilation *enhanced general ventilation* *good general ventilation + LEV* *enhanced general ventilation + LEV*	*0.3* *0.7* *PROC specific* *PROC specific*	*inhalation*	*liquid/solid*
	outdoor	0.7	inhalation	liquid/solid
RPE, respiratory protection equipment[11]	90 % efficiency 95 % efficiency	0.1 0.05	inhalation	liquid/ solid
gloves	*80 % efficiency* *90 % efficiency* *95 % efficiency*	*0.2* *0.1* *0.05*	*dermal*	*liquid/solid*

[11] According to Reach Guidance R14 one should refer to http://www.oehc.uchc.edu/news/Control_Guidance_Factsheets.pdf (COSHH) for the choice of respiratory protection with appropriate reduction level.

		modifying factor	exposure route	physical state
Concentration (w/w)	< 1% 1-5% 5-25% > 25%	0.1 0.2 0.6 1	inhalation/ *dermal*	liquid/*solid*
duration	< 15 min 15-60 min 1-4 h > 4 h	0.1 0.2 0.6 1	inhalation/ *dermal*	liquid/solid
	Short term 15 min	*4*	*inhalation*	*liquid/solid*

*leads to splitting of PROCs into a, b, c for low, medium, high volatility.

Table 5.2 Help on fugacity selection criteria

General description	**Relative dustiness potential**	**Typical materials**	**TRA Selection Value**
Not dusty	1	Plastic granules[12], pelleted fertilisers	Low
Slightly dusty[13]	10 - 100 times dustier	Dry garden peat, sugar, salt	Low or Medium
Dusty	100 - 1,000 times dustier	Talc, graphite	Medium
Very/extremely dusty	More than 1,000 times dustier	Cement dust, milled powders, plaster, flour, lyophilised powders, (process fumes[14])	High

[12] Exposures to materials where a substance is contained and bound in a matrix (e.g. pigment within plastic, filler within paint) should also be included in this category. Although the real exposure is actually determined by a combination of physical form and the bioavailability of the substance within the matrix, because the bioavailability is very low under such circumstances, then this will result in a low exposure potential.

[13] The assignment of this material to one of the three dustiness categories is described ambiguously – in case of doubts medium dustiness should be chosen.

[14] Process fumes (e.g. rubber, welding, soldering) behave like gases and would be considered within this category if exposures to such complex mixtures are considered in any risk assessment.

The user should be aware that for the PROCs 2, 3 and 4 sampling of product or mixture from the reaction vessel is included as sub-activity but not for the higher PROCs (ECETOC FAQ).
The term “LEV” in the ECETOC TRA tool can refer to both local exhaust ventilation and containment in case of dermal exposure (ECETOC, 2009) – a fact that is mentioned in the documentation but not in the tool itself.
In the integrated versions of ECETOC TRA, the unit of predicted exposure estimates is mg/m^3 for inhalation exposure (solids and also liquids) and ppm (only liquids), for dermal exposure it is mg/kg/day and $\mu g/cm^2$ (only version 3). Version 2 of ECETOC TRA also provides the total exposure estimate (i.e. combined exposure routes) in $mg\ kg^{-1}\ day^{-1}$.
A risk characterisation ratio (RCR = exposure value · limit $value^{-1}$) is provided whose interpretation depends on the type of limit value that has been entered (e.g. DNEL, occupational exposure limit, other regulatory limit, experimental result NO(A)EL). A list of results including all exposure values (air concentration, dermal dose, final dose) and RCRs is given within the tool. No functionality for conversion of the DNEL units is implemented in any of the tool versions.
The units of exposure are mostly the same for the stand-alone version of the ECETOC TRA, but additional information about the skin area used for extrapolation of the dermal dose and a small summary of the estimation history (initial exposure estimate, changes due to RMMs and PPE) is given in a small report table together with the exposure values. No dermal exposure in mass per skin area is given, however the tool provides the total exposure (i.e. combined exposure routes) in $mg\ kg^{-1}\ day^{-1}$. This information of course is also included in the integrated version, however it is less obvious through its location in one of the look-up tables.
Additionally, a linear report, i.e. a list of all assessed scenarios for one substance can be stored in the stand-alone version. This report also includes the RCR values (i.e. the exposure divided by limit value for inhalation, dermal and combinded exposure routes), which is, however, called “margin of exposure”. Both types of reports implemented in the stand-alone version of ECETOC TRA do not contain any physico-chemical data of the substance (e.g. physical state, vapour pressure).
The estimates of the ECETOC TRA are assumed by ECHA (2010b) to represent the 90^{th} percentile of the full-shift exposure distribution, while they are described as the 75^{th} percentile in the TR114 documentation for TRA v.3.

Technical aspects of the integrated and the stand-alone versions

- ❖ A notification of a programming error in the calculations of the integrated v.2 worker part of the ECETOC TRA has been published on www.ecetoc.org. This error leads to wrong results being generated for substances with very low vapour pressure (< 0.00001 kPa) and for non-solids for some PROCs. The error does not however affect the standalone version of the TRA and has been rectified in version 3;
- ❖ In the worker stand-alone version it is important to enter the button “Clear all” before starting the assessment, as pull down menus which define substance properties etc. are inoperable otherwise; and
- ❖ The decimal separator has to be in UK setting for a correct use of ECETOC TRA v. 2 (i.e. points instead of commata), otherwise errors occur.

5.3 Empirical exposure data used for model development

5.3.1 Description of datasets

No additional datasets have been mentioned for v.3 of the tool, thus, all information in this chapter applies to both versions evaluated in this project.

PROCs 1-20: General information
The data from which the ECETOC TRA predictions are generated vary with the PROCs (see Table 5.3). For the larger part of the tool (PROCs 1-20), no specific measurements are reported. It is stated that the initial exposure estimates (exposure without modifying factors) and the effect of LEV are derived from EASE outputs in the light of more recent exposure experiences (ECETOC, 2009) for both the inhalation and dermal routes.

PROCs 1-20: Dermal datasets
Some of the datasets used for the adaption of dermal output ranges were collected within the RISKOFDERM project (see Chapter 9).

Table 5.3 ECETOC TRA: Sources of ECETOC initial exposure estimates, underlying datasets

PROC numbers	inhalation	dermal
1-20	Adapted EASE outputs	Adapted EASE outputs
21-25	EEC[15], three metals (Zn, Sb, Pb)	EEC, three metals (Zn, Sb, Pb)

Table 5.4 PROC numbers which refer to the RISKOFDERM project (ECETOC, 2009).

PROC number	PROC description	Interpretation in RISKOFDERM according to Usemap (see Appendix 6)
PROC 1	Use in closed process, no likelihood of exposure	assignment of DEO unclear
PROC 3	Use in closed batch process (synthesis or formulation)	"filling, mixing, loading"
PROC 12	Use of blowing agents in manufacture of foam	assignment of DEO unclear
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation	"mechanical treatment"
PROC 15	Use as laboratory reagent	"filling, mixing, loading"
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	assignment of DEO unclear
PROC 19	Hand-mixing with intimate contact and only PPE available	not applicable

[15] Existing Substances Regulation (EEC) 793/93

However it is not clear why certain PROCs have been chosen for comparison with RISKOFDERM data and which exact measurements or publications are referred to (ECETOC, 2009). For some PROCs (Table 5.4), a comparison with RISKOFDERM data has been explicitly mentioned in ECETOC (2009).
According to our usemap[16] for PROC 1, 12 and 16 the assignment of RISKOFDERM DEO units is unclear. PROC 19 is not covered and PROC 3, 14 and 15 ("filling, mixing, loading", "mechanical treatment") are difficult to compare with RISKOFDERM without further information about the exposure situation (e.g. application rate, duration) or analysing the RISKOFDERM datasets individually. Therefore the connection between both tools will not be reproduced at this point.
For PROCs 4, 8a and 20 dermal exposure data from EBRC were used for calibration and "rounded up" to ensure reasonable worst case estimations (ECETOC, 2009).

PROCs 1-20: Inhalation datasets
For PROC20 the inhalation initial exposure values have been derived from the EBRC exposure data. (ECETOC, 2009).

PROCs 21-25: General information
For the metal/mineral specific PROCs (21 to 25), exposure data on zinc, lead, antimony trioxide and nickel were available from EU Risk assessments and Eurometaux (and its consultant EBRC) (ECETOC, 2009; HERAG, 2007). However, in the tables where measurement data are assigned to PROC numbers, no nickel measurements are listed (see Table 5.5 and Table 5.6) and it is stated that they are only included for comparative purposes (ECETOC, 2009).
A detailed description of the circumstances of measurement (e.g. compliance check) is not provided, but as the datasets were prepared in the context of Risk Assessments under the "Existing Substances Regulation (EEC) 793/93", quality, extent and representative nature of collected data had previously been assessed and agreed between member states and industry.

PROCs 21-25: Dermal datasets
The underlying publications originated from the UK and were published between 1999 and 2005 (ECETOC, 2009). The dermal data is also included in the HERAG fact sheet on dermal exposure which is the basis of the later MEASE tool (HERAG, 2007; see also Chapter 6).
According to ECETOC (2009) only dermal exposure data collected using a removal technique, i.e. moist wipes, were used. As a result, some dermal exposure data for lead, calcium carbonate and diantimony trioxide from downstream user industries were not considered due to the use of different sampling methods which would preclude direct comparisons (ECETOC, 2009). However, according to HERAG, 2007 some studies included in ECETOC TRA were performed with the bag wash method. Both the wipe and the bag wash method determine the actual exposure on the skin, and therefore are taking account of the effect of any personal protective equipment as well as any removal of contaminant from the skin, for example due to hand washing.
The dermal datasets underlying MEASE and ECETOC for the metal specific PROCs are not completely identical, therefore statistical outputs (e.g. overall percentiles and

[16] = comparison of the process description of the different tools and assignment to each other, see Appendix 6

median values published) in HERAG, 2007 can only provide rough impressions and are no exact results concerning the data included in ECETOC. Some graphical analyses of single datasets divided into EASE categories containing the 10th, 25th, 75th and 90th percentile as well as the median, the mean and points for the single datasets, are included in both ECETOC, 2009 and HERAG, 2007.

PROCs 21-25: Inhalation datasets
The underlying publications originated from the UK and Sweden and the data were originally published between 2003 and 2008. No information on the sampling method for measuring inhalation results is documented.
Some workplaces not related to metal exposure (e.g. production of animal feed and fertilizers, cleaning and maintenance) were not included. Graphical analysis results of the inhalation data are not published (ECETOC, 2009).

5.3.2 Limitations of the datasets

General information
The size of the overall dataset is summarised in Table 5.5 and Table 5.6 together with the corresponding process descriptions, industries and the division into PROC numbers.
The number of data points varies greatly between the different PROC numbers and between the exposure routes. For inhalation exposure, the smallest number of datapoints is 146 for PROC 24, while the largest is 2544 for PROC 23.
In case of dermal exposure, the smallest numbers of datapoints is 0 for PROC 25 and 25 for PROC 21, while the largest is number of data points is 146 for PROC 22.
Some process numbers rely on datasets based only on one metal (PROC numbers 21 and 24 only lead in case of inhalation exposure; PROC 23 only Zinc oxide in case of dermal exposure; PROC 25 only zinc oxide in case of inhalation and no data at all in case of dermal exposure[17]).

According to ECETOC (2009) the three metals (zinc, antimony and lead) are representative of metals with high, moderate and low occupational exposure limits (OELs) and therefore should also be representative of exposure situations with different levels of controls for both exposure routes. These circumstances have to be considered carefully, as some RMMs may also be present later in the tool. This may lead to overadjustment for the affect of RMMs and hence can possibly result in underestimation of.

According to the ECETOC, 2009 all available data for the different metals have been pooled to derive the implemented exposure values although they tend to vary between the three different metals for one process. The inhalation exposure values implemented in ECETOC TRA for PROCs 21-25 are higher than the highest measured results (ECETOC, 2009) but neither the derivation of the initial exposure values nor how organisational controls present at the measured workplaces were considered is provided.

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[17] Hot temperatures in this process should prevent dermal contact and thus, dermal exposure should be minimal.

Table 5.5 Number of data points referring to the PROCs 21-25 for inhalation exposure.

		Workplaces (number of values)		
PROC	**Process description**	**Zinc**	**Lead**	**Antimony trioxide**
21	Forming operations on substances/metals as such or bound in materials and/or articles		shredding and sorting / milling / plate treatment / assembly / forming processes / abatement, demolition, scrap (1839[19])	
22	Potentially closed operations with minerals/metals at elevated temperature	pyrometallurgic process / kiln/furnace operation / kiln maintenance (63[18])	sintering / smelting / melting and smelting / melting and refining (1019)	oxidation (production) (47)
23	Open processing and transfer of minerals/metals at elevated temperature	Die casting / brass casting / galvanising (22[19])	refining and casting / plate manufacturing (2522)	
24	High (mechanical) energy workup of substances bound in materials and/or articles or of massive metal		sawing and slitting / cutting processes (146)	
25	Other hot work operations with metals	welding (datasets according to footnote 19)		

Table 5.6 Number of data points referring to the PROCs 21-25 for dermal exposure.

		Workplaces		
PROC	**Process description**	**Zinc**	**Lead**	**Antimony trioxide**
21	Forming operations on substances/metals as such or bound in materials and/or articles		crystal glass / battery (78)	
22	Potentially closed operations with minerals/metals at elevated temperature	Furnace (12)	Refinery (59)	refuming / converter (54)
23	Open processing and transfer of minerals/metals at elevated temperature	galvanising (62)		
24	High (mechanical) energy workup of substances bound in materials and/or articles or of massive metal		crystal glass / battery (78)	
25	Other hot work operations with metals	negligible exposure		

[18] + extrapolated data as reported by the Dutch rapporteur in the Zinc Metal RAR
[19] + additional datasets, were raw data was not available and the 90th percentile or the next highest value was used

Dermal datasets

As mentioned previously, dermal exposure estimates were based on measurements of actual dermal exposure (i.e. on the skin) which would have been affected by the use of any personal protective equipment, such as the rigger gloves, that have been used at some of the workplaces included in HERAG, 2007 (see also Chapter 6.3[20]). If these datasets have been used for the derivation of ECETOC outputs, any further adjustment of these exposure estimates within the model for use of gloves, could potentially lead to underestimations of the exposure.

Inhalation datasets

Although according to ECETOC (2009) only risk assessments for three metals with "full access to the underlying raw data" were used, some inhalation datasets without a known number of data points (where the raw data were not available at EBRC) are mentioned in TR 107.

5.4 Derivation of the final exposure result

For both versions of ECETOC TRA evaluated in this project initial exposure values have been implemented for each PROC, which are subsequently modified by the parameters in the model. In Chapter 5.4.1 the basic algorithm of ECETOC TRA v2 will be summarised while Chapter 5.4.2 will focus on the modifications of v.3 relative to v.2.

5.4.1 ECETOC TRA version 2

Initial exposure estimates and LEV efficiencies: PROCs 1-20 (inhalation and dermal)

A large part of the model (i.e. initial dermal and inhalation exposure estimates and LEV efficiencies for PROCs 1-20, see Table 5.3) is connected to the EASE categories which were reviewed in the light of newer exposure data (ECETOC, 2009; see also Chapter 5.3). Short justifications for the chosen values are given within ECETOC, 2004 (Appendix T and U) and ECETOC, 2009 (Appendix A and C). None of the available newer datasets are explicitly cited. Two examples of the provided justifications for inhalation exposure are summarised in Table 5.7.

Assignments to the corresponding EASE categories are given for the dermal part in ECETOC (2009) and for the inhalation part in ECETOC (2004), so it is possible to retrace the history of the initial exposure estimates. However a detailed derivation of ECETOC TRA outputs is not available.

The initial inhalation exposure values are defined for a certain combination of volatility, type of setting (professional/industrial), physical state and process number. Initial exposure estimates, efficiency of LEV for each PROC, differences between

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[20] HERAG, 2007: "The majority of the other exposure scenarios (lead, nickel and zinc refineries, hot dip galvanizing, lead battery and glass production, and antimony trioxide production) are all either hot production processes or the potential adverse health risks from dermal exposure dictate the use of gloves, thus producing dermal exposures that are generally lower than for unprotected hands (such as in zinc oxide production). However, it should be noted that the gloves worn are usually of the "rigger" type and thus do not fulfil the requirements of chemical protective equipment designed to effectively minimise exposure."

professional and industrial use and the corresponding EASE suggestions are documented in Appendix A of ECETOC (2009) for inhalation exposure. Changes made relative to Version 1 of ECETOC are indicated.
For dermal exposure this initial exposure is only influenced by the PROC number. Initial exposure estimates together with LEV efficiency, EASE suggestions, changes in version 2 relative to version 1 of ECETOC and the exposed skin area are provided in Appendix C of ECETOC (2009).

Initial exposure estimates and LEV efficiencies: PROCs 21-25 (inhalation and dermal)

The initial estimates for metal specific processes (PROCs 21-25) are not derived from EASE outputs.
A summary of available metal related datasets (Vetter & Battersby, 2008) including summary statistics and proposed initial concentrations for dermal and inhalation exposure were provided by Eurometaux (through their technical consultants, EBRC, see also Chapter 5.3 and HERAG, 2007). Reasonable outputs were derived by these statistical analyses (typical values, i.e. 50th percentile, corresponding to “exposure with LEV” and worst case values, i.e. 90th percentile, corresponding to “exposure without LEV”) (ECETOC, 2009). Assignments of those datasets to PROC numbers and the resulting exposure estimates are given in ECETOC (2009).
However, the outputs provided in Appendix B of TR107 are not the same as the estimates obtained from the tool itself for inhalation exposure. Smaller inconsistencies are also present for dermal exposure (only PROC 23).
Moreover ECETOC estimates are different from corresponding exposure values in MEASE although both are based on Vetter & Battersby (2008), i.e. there have to be differences either in the underlying datasets or the interpretation of these datasets.

Table 5.7 Derivation of ECETOC outputs – examples

	PROC 15: Use as a laboratory reagent, high volatility, dust inhalation exposure	
ECETOC, 2004	"EASE Assumes respirable, low dust technique, non-fibrous, non-readily aggregating dust". EASE results: 1 and 5 mg/m^3 with and without LEV.	Comment: EASE prediction clearly inappropriate for laboratory situation. The effectiveness of LEV (fume cupboard) is not adequately addressed. Result of ECETOC v. 1: 0.5 and 5 mg/m^3 with and without LEV.
ECETOC, 2009		Comment: EASE offers 80% (as LEV effectiveness). Results of ECETOC v. 2: 0.5 and 5 mg/m^3 with and without LEV.
	PROC 7: Spraying, high volatility, liquids	
ECETOC, 2004	"EASE assumes aerosol formation, 50 KPa vapour pressure, wide dispersive use. Where no LEV then direct handling with general ventilation assumed" EASE results: 500 and 1000 ppm (with and without LEV)	Comment: EASE does not appear to account for effectiveness of LEV. Revisions made (prediction/5-10) to account for fact that predictions significantly overestimate actual data. Results of ECETOC v. 1: 100 and 1000 ppm with and without LEV.
ECETOC, 2009		Comment: EASE offers 50% (as LEV effectiveness) Results of ECETOC v. 2: 25 and 500 ppm with and without LEV

Fugacity (included in initial exposure estimates, inhalation)
The fugacity for PROC numbers 1-21 is based on the vapour pressure for liquids and the dustiness for solids. One of three (or four in case of liquids) fugacity bands is assigned to each substance according to Table 5.8 (see also Table 5.2 for the definition of dustiness categories). The process temperature is not a tool parameter for these PROCs, however according to ECETOC, 2009, the vapour pressure at the corresponding temperature should be used. Initial exposure estimates for liquids are not documented for the "very low volatility" category within ECETOC, 2009. They are however documented in ECOTOC, 2012 for v.3 (see Chapter 5.4.2).

Table 5.8 Definition of fugacity bands.

resulting fugacity class	**PROC 22-25[21] process temperature**	**PROC 1-21 Vapour pressure (kPa)**	**PROC 1-21 Dustiness**
very low	-	< 0.00001	-
Low	process temp < melting point	≥ 0.00001 to <0.5	Low
Medium	process temp ≈ melting point	0.5 to 10	Medium
High	process temp > melting point	>10	High

For PROC numbers with "material-invasive" processes included (hot-forming and melting, PROC numbers 22-25) the fugacity is classified by the relation between the process temperature and the melting point (see Table 5.8). For temperatures below the melting point dust exposure will play a major role, while for temperatures close to

[21] In drilling or "abrasion" techniques (e.g. grinding) the temperature of the "tool-material contact area" may be used instead of the process temperature.

the melting point vaporisation of oxide layers on the surface of the metal is the most important source of exposure and for higher temperatures it is fumes (ECETOC, 2009).

Type of setting (included in initial exposure estimates; inhalation)
The terms “industrial” and “professional” are - according to ECETOC, 2009 – analogous to “wide dispersive” and “non-dispersive” EASE categories[22]. However, using EASE (and also the later MEASE tool) “wide dispersive use” results in higher exposure estimates in most cases, but industrial use in ECETOC (and also MEASE) leads to lower exposure estimates than for professional use. Both widely dispersive and non-dispersive EASE categories are already included in the derivation of ECETOC TRA v.1 outputs, where no distinction between professional and industrial was yet made. The manner by which the differences between the EASE categories and the terms professional/industrial were taken into account during the tool development is not explained in detail. Both wide dispersive and non-dispersive descriptions are used for both exposure routes (dermal and inhalation (ECETOC, 2004; ECETOC, 2009)), although for dermal exposure no discrimination between dispersive and non-dispersive uses takes place (unlike EASE, see ECETOC, 2009).

Modifiers (inhalation and dermal)
The modifying factors implemented in ECETOC TRA represent refinements of the exposure situations, e.g. concentration of the substance in a preparation and RMMs (summarised in Table 5.1). The derivation of most modifiers (except respiratory protection) is not documented.

Beyond the tool (inhalation and dermal)
In the Appendices of ECETOC (2009) some options are provided which enable the user to improve and refine the results of the Tier 1 assessment by the application of alternative procedures:

Inhalation exposure

- ❖ Handling of substances of very low volatility (Jayjocks model): The estimation of a “saturated vapour concentration” is suggested instead of ECETOC inhalation default results which have shown to represent an overestimation of exposure; and
- ❖ If the process takes place at different temperatures, several exposure assessments should be performed, each with the vapour pressure at the corresponding temperature.

[22] “It should be noted that, unlike EASE, the revised dermal TRA does not discriminate between dispersive and non-dispersive uses (which are considered as the equivalent to the industrial and professional uses described in the ‘inhalation’ portion of the model).” (ECETOC, 2009)

Dermal exposure

- ❖ Some modifiers for glove usage are suggested (four categories: “no glove or any glove without permeation data and without special training”; ”gloves with available permeation data but without training”; “chemically resistant gloves with basic employee training” and “chemically resistant gloves with specific training” have efficiencies assigned of 0%, 80%, 90%, 95%, respectively);
- ❖ For operating temperatures above 60°C dermal exposure is assumed to be negligible due to avoidance of contact with hot materials and surfaces. The same is true for substances with boiling points below 0°C – PROCs 1 and 3 may be used for these cases;
- ❖ In case of vapour pressures above 30 kPa also the PROCs 1 (“use in closed process”) and 3 (“use in closed batch process”) may be used as the substance will not be in contact with the skin for a long time. A Tier 2 alternative is suggested for adaptions concerning the duration of skin contact for substances of high vapours; and
- ❖ Refinement of dermal exposure by adding concentration factors is suggested (“As the dermal exposure will normally be to the bulk mixture, however, correction on the basis of actual (typical high-end) percentage in the mixture can be applied rather than resorting to bands.” ECETOC, 2009). Thus, the actual concentration of a component in a mixture can be used to extract an exposure reduction factor.

5.4.2 ECETOC TRA Version 3

The following issues were modified in the exposure algorithm (information in brackets refers to the exposure route(s) which are influenced by these changes, see ECETOC, 2012):

Initial exposure estimates and LEV efficiencies (inhalation and dermal)

The LEV efficiencies for inhalation and dermal exposure are now identical, i.e. large parts of dermal LEV efficiencies have been revised and split up into professional and industrial use. For PROC numbers which include direct substance handling (10 and 19), the influence of LEV has been removed completely for dermal exposure. The same applies to PROC 1. LEV effectiveness can also be switched off for the dermal exposure route.

Initial dermal exposure for PROC 3 and for initial inhalation exposure for PROCs 2 and 3 have been revised.

Initial exposure values as well as LEV efficiencies and changes relative to version 2 are indicated in Appendices AA (inhalation) and BB (dermal) of ECETOC, 2012.

Initial exposure estimates for ECETOC TRA v.3 depend on the PROC number, the type of setting, physical state and the fugacity for inhalation on the PROC number for dermal exposure.

Fugacity: Liquids with very low volatility (inhalation)

The treatment of liquids with very low volatility, which were already included in ECETOC TRA v.2, is clarified. The Appendix includes now initial exposure values for these substances and the derivation of exposure is explained. The algorithm includes a cut-off value of 0.1 ppm as a maximum for these substances and most PROCs (based on a saturated vapour pressure of 0.01 Pa). 0.1 ppm represents the initial exposure estimate and this value will not be exceeded, not even for the calculation of short term exposure (see below). Exceptions from the cut-off value are given in Table 5.9.

Fugacity: Process temperature (inhalation and dermal (via duration modifier))
ECETOC TRA version 3 explicitly allows for the opportunity to use the vapour pressure at process temperature but does not provide an algorithm to estimate vapour pressures within the tool.

Modifiers: Short-term exposures (inhalation)
Short-term inhalation exposures (i.e. the expected peak concentration corresponding to 15 minutes duration assigned to a given full shift value) can be estimated with version 3. According to ECHA, 2010b the required factor depends on the process:

- for process based PROC numbers (1-4, 12, 16 and 20) a factor of 4 times the full shift value is considered to be reasonable;
- for other PROC numbers which are more task- than process-related, the estimated short-term value is expected to be independent of time and a modifier of once or twice the full shift value, if a 95^{th} percentile is required; and
- For the metal specific PROC numbers 21-25 a multiplier of 4 is considered to be reasonable as these are again activity based PROC numbers.

However, ECETOC decided to implement a pragmatic and conservative factor of 4 for all PROC numbers.
For liquids with very low volatility the maximum short-term exposure level is set at 0.1 ppm (i.e. the cut-off value for these substances). Exceptions are PROCs 7, 11, 17, 18 (where aerosol generation may appear, see paragraph above) and PROCs 10 and 19 in the absence of LEV (see Table 5.9). For these PROCs the short-term exposure estimate is calculated as explained above by multiplying the inhalation full-shift exposure result by four. PROC 12 also shows initial long-term and short-term exposure estimates above 0.1 for liquids of very low volatility in the corresponding table of the draft report but is not mentioned as one of the exceptions.

Table 5.9 Exceptions from cut-off value for maximal exposure estimates referring to liquids of very low volatility.

Cut-off value does not apply	Comment
PROCs 7, 11, 12, 17, 18	Enlarged exposure values (i.e. higher than being achieved as a saturated vapour for a substance of very low volatility are implemented to prevent an underestimation of the risk. ➔ Individual initial exposure estimates according to ECETOC, 2012
PROC 10 and 19	10 ppm in the absence of LEV and 0.1 ppm with LEV for liquids with very low vapour pressure. This was implemented already in v.2 to flag that a LEV is likely needed to cover aerosol exposures (which are not addressed in ECETOC TRA). The tool now states that only vapour exposure is covered and efficiencies of 80 or 90% are applied for LEV.
PROCs 21-25	Liquids are not applicable

This option should not be confused with general exposure durations less than 15 minutes that refer to the average exposure estimate if a process is only carried out for 15 minutes during one 8 hour shift.

Modifiers: Duration modifiers (dermal)

Duration modifiers as presented in Table 5.1 are applied to all PROCs for dermal exposure to high and moderate volatility liquids and non-dusty solid substances but not to low (or very low) volatility liquids or moderate and high dusty solids. Duration does not influence dermal exposure to these types of substances as they may remain on the skin even after finishing the task. Exposure controls such as hand washing are not reflected in this simple screening approach.

Modifiers: General ventilation (inhalation)

Different forms of general ventilation were implemented for inhalation exposure in version 3. Influence of general ventilation in case of EASE (2-3 ACH) and COSHH (5-15 air changes per hour - ACH) are discussed and led to an implemented efficiency of 30% exposure reduction (2-5 ACH) for good general ventilation and an exposure reduction of 70 % for mechanical or enhanced general ventilation systems (5-10 ACH).

These options cannot be used together with the "outdoors" option. A combination of enhanced or good general ventilation and LEV is possible, but enhanced ventilation and LEV apply only for industrial setting. An additional table provided in the draft report suggests that enhanced ventilation is in general not applicable to professional settings (see also Table 5.10). None of those options influences the dermal exposure.

Table 5.10 Implementation of general ventilation in ECETOC TRA version 3.

Type of General Ventilation	**Industrial setting**	**Professional setting**	**Ventilation Effectiveness (Modifier to Initial Inhalation Estimate)**
'Basic' general ventilation is assumed in the base TRAv1 and v2 estimates	Corresponds to: ▪ Basic natural ventilation (i.e. normal GV arising from incidental activities within a workplace) ▪ Typically 1-3 air exchange per hour		0% (1.0 x)
'Good' general ventilation is not assumed in the TRA estimates and can be applied as an exposure modifier for indoor activities (exposure reduction consistent with 'use outdoors')	Corresponds to: ▪ good natural (e.g. intentional opening of doors and windows) and/or 'non-engineered' mechanical ventilation ▪ Typically 3-5 air exchange per hour ▪ TRA does not support use in combination with LEV or 'use outdoors'		30% (0.7 x)
Enhanced general ventilation	Corresponds to: ▪ Engineered mechanical ventilation for the workplace ▪ At least 5-10 air exchanges per hour ▪ TRA does not support use in combination with LEV or 'use outdoors'	Only applicable to industrial settings	70% (0.3 x)

Table 5.11 Implementation of personal protective equipment for dermal exposure in ECETOC TRA version 3.

Dermal Protection Characteristics	Indicated Efficiency %	Affected User Groups
a. Any glove/gauntlet without permeation data and without employee training	0	Applies to both industrial and professional users
b. Gloves with available permeation data indicating that the material of construction offers good protection for the substance	80	
c. Chemically resistant gloves (i.e. as #b above) with 'basic' employee training	90	
d. Chemically resistant gloves in combination with specific activity training (e.g. procedures for glove removal and disposal) for tasks where dermal exposure can be expected to occur	95	Industrial users only

Modifiers: Concentration of substance in preparation (inhalation and dermal)
Concentration modifiers do now also apply to solid mixtures and to dermal exposure. For suspensions of solids in liquids they should not be applied.

Modifiers: Gloves (dermal)
Personal protective equipment, i.e. gloves, is implemented for dermal exposure (see Table 5.11). Two levels of efficiency (80 and 90%) are implemented for professional workers and three (80, 90 and 95%) for industrial workers.

5.4.3 Underlying assumptions (ECETOC TRA v.2 and v.3)

The following assumptions / default values are used in ECETOC TRA:

- A body weight of 70 kg;
- 100% absorption through skin for dermal exposure, although this has only to be considered if one wishes to refine the exposure assessment without including absorption factors into the DNEL derivation (ECETOC, 2009 and ECETOC, 2004); and
- For the conversion from ppm to mg/m^3 ideal gas behaviour is assumed which results in a linear dependence of the air concentration in mg/m^3 on the molecular weight.

5.5 Transparency

Tool development
The development of ECETOC TRA version 1 to 3 is documented to a high level of detail, although some users might be overwhelmed by the amount of information provided in ECETOC, 2004 and 2009. EASE scenarios from which initial exposure estimates originate are given in ECETOC, 2009 (dermal) and ECETOC, 2004 (inhalation). It is also documented if the resulting output of ECETOC v.2 (v.3) is higher or lower compared to ECETOC v.1 (v.2) results or compared to the former EASE results.

Datasets

The underlying data, which might have led to the initial exposure estimates, are only partly documented (see also Chapter 5.3); the specific datasets are only given for PROCs 21-25. For these processes the assignment of the different publications to PROC numbers is provided in ECETOC, 2009 for inhalation and dermal exposure.

The analysis and interpretation of the datasets is summarised but no detailed information is given and some contradictions within the description of datasets can be found (see Chapter 5.3). For a more detailed overview of the dermal datasets one should refer to HERAG, 2007 although not all datasets published in this document have been used in ECETOC TRA.

Scope and algorithm

Information about most limitations of the TRA is spread over various publications (ECETOC, 2004 and 2009, comments in the tool, ECHA, 2010b).

Some contradictory information can be found in the tool itself or the associated documentation. An example is the treatment of process fumes, which is not defined unambiguously in the tool and its reports. In ECETOC (2009) it is stated that "at process temperatures well above the melting point, generation of fumes can be assumed to occur, which for example will be emitted from the surface of molten metals or slags during tapping or casting operations."

This is relevant to the higher PROC numbers 22-25, introduced for metal specific uses. According to the tool itself, the dustiness should be set to "very high" for cases where fumes are expected. However, according to ECETOC, 2009 the tool (as EASE) is not capable of calculating fume exposure. Although it has to be noted that fumes are explicitly not covered (Money, 2012; personal communication), this point should also be clarified within the tool to assist users.

The model algorithms are easy to understand and the relevant factors for the corresponding modifiers can be found also in the tool itself but some of the implemented parameters are not explained in a detailed manner (e.g. how the initial exposure values and modifiers are derived).

Concerning the descriptor system (see ECHA, 2010a) and its implementation into the tool, some minor inconsistencies could be identified:

- Process description and type of setting are partly mixed, e.g. the combination of PROC 20 and industrial use leads to the result "industrial use covered by PROC 2";
- In v.2, the dermal exposure result of PROC 1 (Use in closed process, no likelihood of exposure) is influenced by LEV whereas the inhalation exposure does not depend on this factor. In v.3 neither inhalation nor dermal exposure are influenced by LEV for PROC 1;
- For medium volatility substances, the ppm inhalation exposure values seem to suggest greater exposure from PROC 3 than PROC 4 processes, whereas for low volatility substances the exposure increases from PROC 1 to PROC 4. According to ECETOC (ECETOC FAQ) this is a slight anomaly in version 2 that has been corrected in version 3 of the tool; and
- General issues as described in Chapter 10.7 also apply here.

Appendix C in ECETOC, 2009 offers some contradictory information concerning the derivation of skin areas. Sometimes "2 hands" refer to 480 cm^2, sometimes to 960 cm^2 (e.g. for PROC 8a and 8b). A list of identified skin areas is provided in Table 5.12 while contradictions found in this context are provided in Table 5.13.

Table 5.12 Assignment of skin area to different body parts as implemented in ECETOC TRA (ECETOC, 2009).

one hand palm	240 cm^2
palms of both hands	480 cm^2
both hands (back and palm)	960 cm^2
two hands (back and palm) and one forearm[23]	1500 cm^2
both hands (back and palm) and forearms	1980 cm^2

Table 5.13 Inconsistent definition of skin areas within ECETOC TRA

Process / task	**Assumed body surface according to ECETOC, 2009**	**Assigned area**
6	2 hands palm only	960
7 & 11	2 hands (back and palm)and forearms	1500
8b[24]	2 hands (back and palm)	480
19	2 hands (back and palm)	1980

It is always made clear in ECETOC, 2009 that ECETOC TRA is only a screening tool and it was designed to provide conservative results.

Structure of use

The integrated and the stand-alone versions of ECETOC TRA offer somewhat different structures of use, with differing levels of transparency, although the basic principles are the same.

The stand-alone version is more clearly arranged while the integrated version needs some practice to extract certain parts of information. However the main input fields are clearly marked and the user is able to create an exposure assessment without spending too much time with preparations. Short user guides are available at www.ecetoc.org, where the basic structure of use is shown without much background information.

Some potential sources of confusion are present within the tool and its documentation. For example, the number of dustiness and volatility bands are explained and defined in an incomplete way.

For solids, only three dustiness categories exist although four different sets of examples are given to define them. One set of examples is labelled with “low or medium dustiness” and one of those two options (i.e. "low" or "medium") has to be chosen for substances matching the description (see Table 5.2).

For volatiles, four categories exist, although in the table within the excel sheet and ECETOC, 2009 only three areas for vapour pressure are mentioned. An additional category (“very low volatility”) exists below the lowest defined vapour pressure limit (<0.00001 kPa). However, the next report version describing ECETOC TRA version 3 will provide additional information about substances of very low volatility. (ECETOC, 2012)

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[23]No unambiguous information provided in ECETOC, 2009 for this area – assignment of two hands and one forearm seemed reasonable at this point.

[24]This inconsistency has been corrected: In ECETOC v.3 PROC8b is assigned to a skin surface of 960 cm^2 according to 2 hands.

There are also some inconsistencies noted within the explanatory documentation (i.e. ECETOC, 2009) and in the tool relating to the assignment of the surface areas of body parts when estimating dermal exposure. While the general assignment of skin areas to body parts used in ECETOC TRA is shown in Table 20 the identified inconsistencies are summarised in Table 21.
The term “volatiles” which is used in the tool may be misleading as it can refer also to gases in a general way, but the ECETOC TRA FAQ[25] make clear that the tool is not able to handle exposure situations referring to gases not emitted from volatile liquids.
The reports on the development of the tool are publicly available (ECETOC, 2004 and ECETOC, 2009) as well as user guides for each part (integrated and stand-alone versions). The documentation includes all parts of the tool, i.e. the worker part and also information about environmental exposure and consumer exposure. Sometimes this can lead to problems concerning the quick localisation of information.
Some contradictions and deficiencies exist within the documentations. The fact that large parts of the tool cannot be retraced to specific datasets and some potential sources of confusion in combination with the voluminous collection of excel sheets in the integrated version make it hard to understand the tool and its algorithm in detail. Thus, although in principle a large part of the necessary information is included either in the tool itself or one of the reports, some users might have difficulties in finding appropriate information and guidance.

5.6 Conclusion

ECETOC TRA is a widely applicable tool. The dermal estimation process is more crude than that for inhalation and in version 2 the exposure estimates are only modifiable by the presence or absence of LEV. However, this has been changed in version 3 and dermal exposure is, in addition to LEV, also affected by duration and concentration of the substance in a preparation.
The tool documentation is sufficiently detailed, although some inconsistencies and sources of potential misunderstanding remain within the tool (see Chapter 5.5).
A general limitation of ECETOC TRA is that the process temperature is inconsistently considered within the PROCs. It is included for the PROCs 22-25 (metals, minerals, substances in articles), where the user has to choose the appropriate subcategory of these PROCs by comparing process temperature and melting point (see also Table 5.8). Otherwise, it is suggested to use vapour pressures at the process temperature in ECETOC, 2009, but this information is not explicitly given in version 2 of the tool. As the process temperature is not mentioned in the use descriptions of PROCs 1-21 the false assumption might occur that it is not necessary for these processes.
Some underlying assumptions (see Chapter 5.4.3) might influence the quality of the result.
A list of model determinants and their division into the four main exposure defining elements (see Chapter 3) with the number of categories per determinant (in brackets) is given in Table 5.14. The four areas (substance properties, process description / organisational conditions, process related RMMs, PPE) are basically covered.

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[25] http://www.ecetoc.org/uploads/Documents/TRA/Frequently-asked%20questions%20on%20using%20the%20tool.pdf

Moreover ECETOC TRA is based on the descriptor system used in REACH (ECHA, 2010a) which provides a detailed and pragmatic approach of describing processes or tasks occurring at workplaces.

Some of the issues which are not addressed or only via the Appendices in ECETOC, 2009 for version 2 of the tool are already addressed in version 3 (process temperature, gloves, general ventilation; see also Chapter 4.4).

Although the tool is appears to be complex at first sight due to the size (and in case of the integrated tool) number of the excel sheet(s), it does not take much time to learn the basic principles. Much information is already included in the excel sheet itself if the user knows where this information can be found. However, for a first start with ECETOC TRA the standalone version might be more suitable than the integrated one, as it offers the same functionalities but – due to the smaller input and output sections – with a more clearly arranged design and an easier overview.

Suggestions:

- The ECETOC documentation (ECETOC, 2009) is not completely clear about the exact definition and implementation of industrial/professional or widely dispersive/non dispersive categories. A detailed explanation of this issue and its consequences on exposure would be desirable.
- Clarify the treatment and coverage of fumes in the tool. There are some contradictions in the information concerning this issue (ECETOC, 2009: fumes are not covered; the tool itself: fumes should be implemented via “high dustiness”).

Table 5.14 Number of categories per determinants (in brackets) and assignment to four broad exposure defining elements (see also Chapter 3).

Intrinsic substance properties	**Process description / operational conditions**	**Risk management measures at source**	**Personal protective equipment**
physical state (2 categories)	PROCs (25 of 27) (ECHA, 2010b)	LEV (1 category)	respiratory protection (2 categories)
dustiness (3 categories)	duration (4 categories)	General ventilation[26] (2 categories + additional LEV)	gloves[26] (3 categories)
volatility (4 categories)	short term exposure[26]		
concentration in preparation (4 categories)	process temperature for PROC 21-25 (3 categories)		
molecular weight (free text)	good occupational hygiene is assumed		
	outdoors (1 category)		

[26] Only implemented in version 3.

6 MEASE

6.1 Introduction

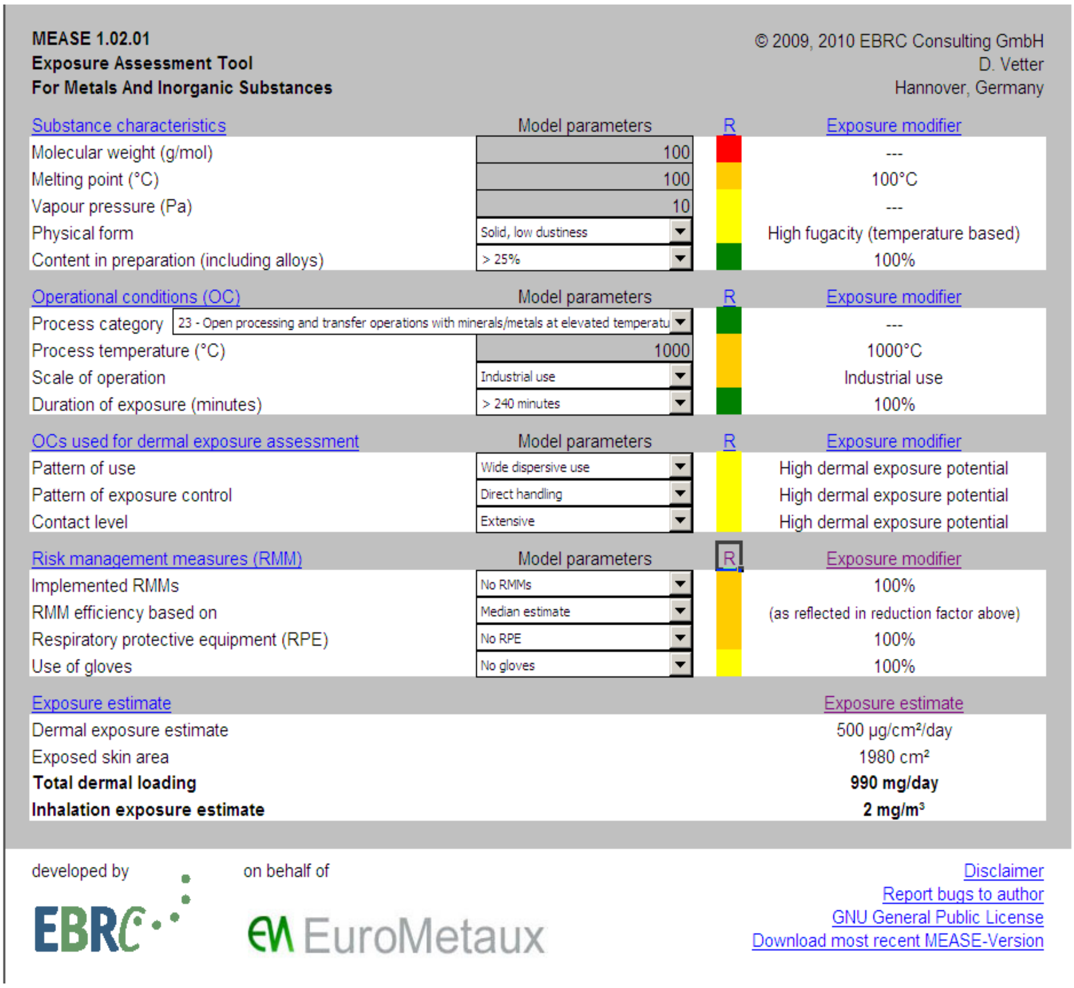

Figure 6.1 Screenshot of the MEASE tool, Version 1.02.01

EBRC developed MEASE ("the metals' EASE") on behalf of EUROMETAUX to address specific needs of the metal industry. The current version of MEASE (version 1.02.01) is an MS Excel based tool and is designed to assess workers' dermal and inhalation exposure. The tool combines approaches from the EASE expert system, the ECETOC TRA tool (version 2) and the Health Risk Assessment Guidance for Metals (HERAG, 2007, www.ebrc.de). The dermal exposure part is based on an adapted EASE algorithm while the inhalation part relies on a modified version of the ECETOC TRA. MEASE is freely available on the internet[27], together with a glossary (included in the tool), short documentation (Vetter, 2010a) and a changelog (Vetter, 2010b). References and the HERAG fact sheet (HERAG, 2007) are also available here. The tool is very easy to find (first result in a simple Google-search).

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[27] http://www.ebrc.de/mease.html

Publications
The dermal datasets are presented in HERAG, 2007 ("Health Assessment Guidance for Metals – Assessment of occupational dermal exposure and dermal Absorption for Metals and Inorganic Metal Compounds"), while the RMM efficiencies for inhalation exposure are based on the publication of Fransman et al., 2008 (see also Fransman et al., 2009). Additional published literature about the tool itself is currently not available. No validation of the model has been published to date.

6.2 Tool description

6.2.1 Scope

MEASE was designed to assess inhalation and dermal exposure in situations where metals and/or inorganic substances are used or manufactured. The tool aims to fulfil the specific requirements arising from this specialisation (e.g. exposure resulting from the emission of fumes, work with massive objects; Vetter and Battersby, 2012; personal communication; www.ebrc.de and glossary).
In principle, inhalation exposure can be estimated for liquids, solids (solids of high, medium or low dustiness and massive objects), gases and aqueous solutions but the possible combinations are restricted to reasonable exposure situations (see PROCs in Table 6.1).
A general overview of the scope of MEASE is given in the draft documentation which is available at www.ebrc.de (Vetter, 2010a; see Table 6.1). It contains a list of all PROC numbers and the physical states and types of setting for which they are applicable. An equivalent table for dermal exposure categories has not been published. In contrast to ECETOC TRA v.2, MEASE also covers the PROCs 26, 27a and 27b.
The dermal exposure estimation is limited to hands and forearms with the exact exposed skin area depending on the PROC number.

6.2.2 Model, parameters and structure of use

To fulfil the specific needs of the metal industry (e.g. the extremely low fugacity of massive objects) both underlying models (ECETOC TRA and EASE) were modified. The ECETOC TRA v.2 algorithm for inhalation was further developed and extended to cover exposure to dust resulting from the emission of fumes (Vetter and Battersby, 2012; personal communication), whilst the EASE ranges for dermal exposure were adapted to suitable datasets from the metal industry. The following major differences between MEASE and ECETOC TRA v.2 and/or EASE were identified (see also usemap in Appendix 6 and applicability matrix in Appendix 5):

1. Inhalation and dermal exposure situations are described in distinct ways in MEASE (PROC codes (ECHA, 2010a, Appendix 3) for inhalation, and EASE categories plus PROC codes for dermal). For the dermal exposure assessment, the exposed skin area varies between PROC codes.
2. MEASE also covers PROC numbers 26 ("Handling of solid inorganic substances at ambient temperature"), 27a ("Production of metal powders (hot processes)") and 27b ("Production of metal powders (wet processes)").
3. Additional fugacity range for metal objects and aqueous solutions are included in MEASE.

Table 6.1 MEASE documentation (Vetter, 2010a; downloadable at www. EBRC.de): Applicability of MEASE for different physical forms and scales of operation.

PROC / Physical form	Massive object	Solid, low dustiness	Solid, medium dustiness	Solid, high dustiness	Aqueous solution	Liquid	Gaseous	Scale of operation
1 - Use in closed process, no likelihood of exposure	X	X	X	X	X	X	X	I
2 - Use in closed, continuous process with occasional controlled exposure	X	X	X	X	X	X	X	B
3 - Use in closed batch process (synthesis or formulation)	X	X	X	X	X	X	X	B
4 - Use in batch and other process (synthesis) where opportunity for exposure arises	X	X	X	X	X	X	X	B
5 - Mixing or blending in batch processes for formulation of preparation and articles	X	X	X	X	X	X	X	B
6 - Calendering operations	X	X	X	X	O	O	O	B
7 - Industrial spraying	O	X	X	X	X	X	X	I
8a - Transfer of subst. or prep. from/to vessels/large containers at non-dedicated facilities	A	B	B	B	X	X	X	B
8b - Transfer of subst. or prep. from/to vessels/large containers at dedicated facilities	A	B	B	B	X	X	X	B
9 - Transfer of subst. or prep. into small containers (dedicated filling line, including weighing)	A	B	B	B	X	X	X	B
10 - Roller application or brushing	O	X	X	X	X	X	O	B
11 - Non industrial spraying	O	X	X	X	X	X	X	P
12 - Use of blowing agents in manufacture of foam	O	O	O	O	X	X	X	B
13 - Treatment of articles by dipping and pouring	X	X	X	X	X	X	O	B
14 - Production of preparations or articles by tabletting, compression, extrusion, pelletisation	X	X	X	X	X	X	O	B
15 - Use as laboratory reagent	X	X	X	X	X	X	X	B
16 - Using material as fuel sources, limited exposure to unburned product to be expected	X	X	X	X	X	X	X	B
17 - Lubrication at high energy conditions and in partly open process	O	X	X	X	X	X	O	B
18 - Greasing at high energy conditions	O	X	X	X	X	X	O	B
19 - Hand-mixing with intimate contact and only PPE available	O	X	X	X	X	X	O	B
20 - Heat and pressure transfer fluids in dispersive, professional use but closed systems	O	O	O	O	X	X	O	B
21 - Low energy manipulation of substances bound in materials and/or articles	X	X	O	O	O	O	O	B
22 - Potentially closed processing operations with minerals/metals at elevated temperature	X	X	X	X	O	O	O	B
23 - Open processing and transfer operations with minerals/metals at elevated temperature	X	X	X	X	O	O	O	B
24 - High (mechanical) energy work-up of substances bound in materials and/or articles	X	X	X	X	O	O	O	B
25 - Other hot work operations with metals	X	X	X	X	O	O	O	B
26 - Handling of solid inorganic substances at ambient temperature	O	X	X	X	O	O	O	B
27a - Production of metal powders (hot processes)	X	X	X	X	O	O	O	I
27b - Production of metal powders (wet processes)	X	X	X	X	X	X	O	I

Legend	
X	Combination of physical form and PROC is covered in MEASE
O	Combination of physical form and PROC is __not__ covered in MEASE
A	Combination of physical form and PROC is covered in MEASE, but PROC 21 could considered as being more appropriate
B	Combination of physical form and PROC is covered in MEASE, but PROC 26 could considered as being more appropriate

Legend	
B	PROC is applicable to industrial and professional uses
I	PROC is only applicable to industrial uses
P	PROC is only applicable to professional uses

4. Additional inhalation RMMs (enclosure, general ventilation, wet suppression, separation of workers) are introduced together with a corresponding additional set of efficacy values that were not included in ECETOC TRA.
5. The resulting exposure ranges of the dermal EASE algorithm were modified based on the new data sets.
6. Use of gloves as RMM for the dermal route was introduced.
7. In contrast to both ECETOC TRA v.2 and EASE, the concentration of the substance in the mixture and the duration of task affects dermal exposure in MEASE.
8. “Type of setting” (industrial / professional) was renamed to “Scale of operation” (industrial / professional use).
9. The combination of PROC1 and professional use is out of scope.

The tool is neatly arranged on one spreadsheet with some free text fields and several pull down menus which define the details of the exposure situation. A full list of determinants and the corresponding categories is given in Table 6.2. The spreadsheet includes various hyperlinks to the glossary. A relevance indicator (colour coded beside the pull down menus) indicates if the determinant influences the dermal and/or inhalation exposure result. The chosen entry value is directly translated into the category used for the exposure estimation (e.g. the final fugacity class, dermal exposure potential, efficiency of the RMMs) and is listed beside the relevance indicator.

The determinant “process temperature” is implemented for processes at “elevated temperature” or “hot processes” (PROC numbers 22, 23, 25 and 27a). An approach similar to ECETOC TRA is used to derive the fugacity band of a certain substance/process combination (see Table 6.3 and also Chapter 5). In contrast to ECETOC TRA the fugacity for PROC24 does not depend on the process temperature.

An additional category for very low fugacity in case of solids is available that also applies to aqueous solutions of inorganic solids, but unlike ECETOC TRA, no corresponding category exists for pure liquids.

As MEASE also uses the descriptor system as published in ECHA, 2010b general facts described in Chapter 10.7 also apply here (e.g. type of setting and process description are mixed). However there are small differences concerning the specific applicability compared to ECETOC TRA (PROC1 not applicable with professional setting, PROC20 also applicable with industrial setting; see also Chapter 5).

If the tool is applied to melting processes or in other cases where the physical form of a substance may change, the MEASE glossary recommends that an additional step (exposure scenario) for “raw material handling” should be introduced.

For dermal exposure, the exposure situation is defined by the pattern of use, the exposure control and the level of contact. All four dermal use patterns can be combined with all physical states, whereby “non-dispersive” and “inclusion into matrix” lead to the same result. Dermal exposure estimates for gaseous substances are independent from the pattern of use.

Table 6.2 Influence of different tool parameters on the exposure estimation

	Determinant	Categories	Influenced exposure routes
Physical characteristics	molecular weight[28]	linear relationship	inhalation
	fugacity[29,30]	up to four bands (see Table 6.3)	inhalation
	content in preparation[31]	four bands, identical to ECETOC	inhalation + dermal
Operational conditions	process category[31]	29 PROCs	inhalation
	scale of operation[31]	industrial and professional	inhalation
	duration of exposure[31]	four bands, identical to ECETOC	inhalation + dermal
	pattern of use[32]	wide dispersive, non-dispersive/inclusion into matrix, closed system	dermal
	contact level[32]	extensive, intermittent, incidental, none	dermal
	pattern of control[32]	direct or non-direct handling	dermal
RMMs (inhalation)[33]	enclosure/containment[31]	upper & lower confidence limit, average with median confidence (labelled "median")	inhalation
	generic LEV[31]	upper & lower confidence limit, average with median confidence (labelled "median") + ECETOC TRA v2 efficiency	inhalation
	exterior LEV (capturing hood close to source but not enclosing it) [31]	upper & lower confidence limit, average with median confidence (labelled "median")	inhalation
	interior LEV (enclosing hood combined with fixed LEV) [31]	upper & lower confidence limit, average with median confidence (labelled "median")	inhalation
	general ventilation[31]	upper & lower confidence limit, average with median confidence (labelled "median")	inhalation

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[28] The molecular weight is used only for conversion of ppm into mg/m^3 for inhalation exposure estimates for liquids and gases. See also Chapter 0.
[29] A more detailed overview of physical states, the different levels of dustiness and their applicability to different PROC numbers is given in Table 6.1).
[30] Influences exposure estimates for all physical states (see also
Table ***6.3***)
[31] Influences exposure estimates for all physical states.
[32] Influences exposure estimates for to all physical states except gases.
[33] For confidence limits see **Fehler! Verweisquelle konnte nicht gefunden werden.**. According to the MEASE glossary the lower confidence level should be used for a first tier risk assessment.

	Determinant	Categories	Influenced exposure routes
	wet suppression of contaminant (after emission)[31]	upper & lower confidence limit, average with median confidence (labelled "median")	inhalation
	capture sprays (wetting systems at point of release)[31]	upper & lower confidence limit, average with median confidence (labelled "median")	inhalation
	generic suppression[31]	upper & lower confidence limit, average with median confidence (labelled "median")	inhalation
	separation of workers[31]	upper & lower confidence limit, average with median confidence (labelled "median")	inhalation
PPE	respiratory protection[31]	APF[34] 4, 5, 10, 20 or 40	inhalation
	gloves[31]	yes/no, 90% efficiency	dermal

Table 6.3 Definition of fugacity bands*

aggregation state	very low fugacity	low fugacity	medium fugacity	high fugacity
liquid		p_{vap}= 0-500 Pa	p_{vap} = 501-10000 Pa	p_{vap}> 10000 Pa
solid	massive object	low dustiness	medium dustiness	high dustiness
solid: hot processes		$T_{proc}<T_{melt}$	$T_{melt}\leq T_{proc}<T_{melt}\cdot 1.5$	$T_{proc}\geq T_{melt}\cdot 1.5$
gas				vapour pressure based
aqueous solution	dustiness based		PROC7 and PROC11 (dustiness based)	

*Green fields: combination is covered; red fields: combination is not covered

[34] APF: assigned protection factor according to EN 529:2005 for APFs at or below 40 (as given in the MEASE glossary)

The dermal exposure estimates are given in µg/day/cm^2 (dermal) in combination with the exposed skin area and in form of a total dermal loading in mg/day (see also Chapter 6.4.1 and Table 10.3). The inhalation exposure is presented in mg/m^3. All input parameters as well as the results are summarised on the input sheet in a clearly arranged way. To store the results a copy of the tool can be saved or the screen can be printed on a single A4 paper.

6.3 Empirical exposure data used for model development

6.3.1 Description of datasets

Initial dermal exposure estimates – HERAG, 2007

The report includes results of 617 dermal measurements for metals or inorganics; 51 correspond to $CaCO_3$ which have not been used for the development of MEASE (see also Chapter 6.4) (Table 25). Single datasets and the corresponding underlying publications[35] are listed in HERAG, 2007 and exposure results per cm^2 referring to both the analysed metal (e.g. Zn) and the actual contaminant (e.g. ZnO). Results are presented as full shift average values in µg/cm^2 and refer to hands and forearms (HERAG, 2007).

Consistent sampling and analytical methods were not used within HERAG, 2007. Most studies contain data resulting from wipe sampling (hands and forearms), although in two studies the bag washing method was used for determining dermal load on the hands. However, it is noted that no significant differences (i.e. at least one order of magnitude) could be found after visual inspection between both sampling types (Vetter and Battersby, 2012; personal communication, see e.g. Chapter 2.2.1.2 of HERAG, 2007).

The maximum dermal loading mentioned in HERAG, 2007 is 0.7 mg/cm^2 and refers to zinc oxide. However, this may not correspond to a realistic exposure level, as the measurements were done after immersion of the hands into a bowl filled with the substance. The corresponding measurement is marked to be a “supplemental investigation”. A definition of the limit of detection and the limit of quantification is not given, but the lowest measured value in the HERAG publication is 0.001 mg/cm^2.

Results of statistical analysis of the data, including the median, the 90th percentile and a presentation of different percentiles in graphical form, are published in HERAG, 2007. As mentioned previously in Chapter 5 the dermal datasets in this publication partly overlap with the ECETOC database for the PROC numbers 21-25. The corresponding measurements are marked in Table 6.4.

The exposure situations are divided into EASE categories (see HERAG, 2007) and the exposure values are compared with EASE-predicted exposures. No detailed information is provided regarding the assignment of datasets to categories.

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[35] published 1996-2005 in the UK, IOM reports are available at http://www.iom-world.org/, also published in various EU RARs and VRAs for Ni, Zn, Sb_2O_3, and Pb

Some basic information about the dermal datasets is also included in Vetter and Battersby, 2008 ("Proposed metal-specific refinements ECETOC TRA", unpublished draft report, was made available for this project).

Table 6.4 Number of dermal measurements for each situation and metal (HERAG, 2007)

	Zinc*	Lead**	Antimony***	Nickel****
Handling of chemicals	32	43		
Furnace	12			
Galvanising	31			
Refinery	14	59		134
Crystal		25		
Battery		53		
Packing			51	
Refuming			18	
Converting			36	
Powder metallurgy				24
Stainless steel production				34

Marked data sets are also included in the ECETOC TRA database (metal specific PROCs, see Chapter 5).
* ZnO, $ZnNH_4Cl$, $ZnCl_2$
** $nPbO \cdot PbSO_4$
*** Sb_2O_3
**** Ni, NiO, $NiCl_2 \cdot 6H_2O$, $NiSO_4 \cdot 6H_2O$, $NiCO_3 \cdot 2Ni(OH)_2 \cdot 4H_2O$

Inhalation initial exposure estimates – Vetter and Battersby, 2008
Initial inhalation exposure estimates are partly identical to the ECETOC TRA defaults (PROC 1-20, see also Chapter 5), whilst for PROCs 21-27a they are derived from datasets provided by the industry for their individual EU Risk Assessments (i.e. Zn, Pb and Sb; see Vetter and Battersby, 2008). Datasets have undergone peer review by the respective rapporteur member states, and have been endorsed at EU level by approval at the Technical Committee for New and Existing Substances (TCNES) and published in EU Risk Assessment Reports (Vetter, 2012; personal communication; see also Chapter 6.4.1 and MEASE glossary).
An intermediate summary of the measurement data used for the development of MEASE is given in Vetter and Battersby, 2008, however this report does not provide a complete overview of the data used for the development of MEASE, as additional datasets, which became available since the creation of the draft report, have been used.

RMM efficiencies – Fransman et al., 2008 and Fransman et al., 2009 (for additional information see Appendix 4)
In Fransman et al., 2008 overall 433 efficiency values are included for six RMM groups, which in turn are collected from 90 publications. It is stated that the creation of this "Exposure Control Efficiency Library (ECEL)" was the result of a PubMed search and a journal specific search for 2000-2007[36] although apparently not all underlying publications are listed in the references of this publication. Neither age nor countries of origin of the datasets are documented in detail in Fransman et al., 2008.

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[36] Annals of Occupational Hygiene, American Industrial Hygiene Association Journal, Applied Occupational and Environmental Hygiene and Journal of Occupational and Environmental Hygiene

A general overview about recent publications and the history of RMM efficiency research is provided.
Information concerning the efficiency results can be found in **Appendix 4, Table 1**.
Substantial variation in efficiency values within a particular RMM category was observed. The results given in this publication include the 95% confidence intervals of efficiencies and the average values. A detailed explanation of the performed analyses is not included.
No detailed information about the covered industries, workplaces and substances is published by Fransman et al. and no description of the corresponding measurement techniques is provided. As the underlying data were extracted from various publications it cannot be determined if comparable measurement techniques or study designs have been used. These circumstances should be noted of as they could also influence the level of uncertainty of any exposure model using their findings.
MEASE addresses the uncertainty in the efficiency values by using the lower confidence value of the efficiency value (see also Footnote 96).
According to the MEASE glossary only RMMs with at least 12 measurements are incorporated into MEASE. Furthermore, if the confidence interval of the efficiency estimate extended below zero, the corresponding RMMs were not included in MEASE (see Glossary). However not all RMMs in Fransman et al., 2008 meeting these criteria are implemented, as some of them were not considered to be relevant for the Tier 1 assessment of metals and inorganic substances (Vetter and Battersby, 2012; personal communication).
Fransman et al., 2009, which describes the development of the ART tool, also refers to Fransman et al., 2008 and the included datasets. The publication does not contain a full list of underlying datasets either, however it offers additional detailed descriptions of various RMMs.

6.3.2 Limitations of the datasets

Dermal datasets – HERAG, 2007

As already mentioned in Chapter 5, HERAG, 2007 states that many workplaces dictate the use of gloves. The methods of measurement included in this publication are all referring to actual exposure, therefore the results of these measurements will have been affected by the use of any personal protective equipment. As a consequence, there is a potential for underestimating exposure if during the use of the model the effect of gloves is included again. It is not mentioned if these exposure situations were excluded from the MEASE model or if the influence of these gloves was taken into account in any other way, so there remain some doubts if the resulting model will be able to reflect initial concentrations and the effect of gloves in a correct way.

Inhalation initial exposure estimates

Initial inhalation exposure estimates are partly identical to the ECETOC TRA defaults, (PROC 1-20, see also Chapter 5) for which no specific information about underlying datasets is provided. Inhalation exposure estimates for PROCs 21-27a are derived from measurement data provided by the industry for their individual EU Risk Assessments (Vetter and Battersby, 2012; personal communication and glossary; see also Chapter 6.3 and Vetter and Battersby, 2008). Further information about the exposure scenarios in the EU Risk Assessments or measurement results are not provided in any of the cited publications but are given in the corresponding EU Risk assessments.

Inhalation RMM efficiencies – Fransman et al, 2008 and 2009

In some cases negative efficiency values were observed (according to Fransman et al. this may be caused by bad work practice or bias) which were not excluded from the study. RMMs were not included into MEASE if the lower limit of the 95th percent confidence interval was below zero (see MEASE glossary). However, single observations of negative efficiencies are still present in case of some RMMs.

The Exposure Control Efficacy Library (ECEL) as developed by Fransman et al. is not specific to metal exposure, but is based on evidence from other agents (e.g. wood dust) and work places (e.g. rubber industry). However, Fransman et al (2008) observed similar control efficiencies for dusts, fumes, vapours and mists, which indicates that the efficiencies should be applicable to metal specific exposure situations. No information about any temperature dependence of the RMM efficiencies is included.

A possible general problem that is mentioned in the discussion of Fransman et al., 2008 might be an overestimation of the RMM efficiencies due to publication bias (i.e. the common tendency to publish only the "best" experimental results, see Fransman et al., 2008). However, this statement is not further explained and the fact that there are also negative control efficiencies included in ECEL suggest that this may not be the case.

Some RMMs (enclosure and separation of workers) are based on a small - and therefore not representative - number (*N* = 14 for "enclosure", "specialised ventilation" and "separation of workers") of measurements which leads most likely[37] to larger confidence intervals than it would be the case for a higher number of datasets.

6.4 Derivation of final exposure output

Some parts of the model are based on measured values (interpreted via statistical analysis) while the derivation of some parts is not documented in detail (e.g. ECETOC initial concentrations, RMM efficiency value for professional setting is reduced by 25% based on scientific knowledge of the model developers). For each situation an initial dermal and inhalation exposure estimate is derived which can then be refined by a set of modifiers. The exposure estimates for dermal and inhalation exposure are defined by different sets of parameters. While the inhalation algorithm is based on the use descriptor system (PROC 1-27b) the dermal part refers to four EASE categories and the use descriptor system which defines the exposed skin area.

[37] The wideness of confidence intervals depends on the number of datasets and their variability.

6.4.1 Initial exposure estimates

Dermal initial exposure estimates

Initial estimates for dermal exposure (only hands and forearms, see Chapter 6.3) are derived from HERAG, 2007, where three exposure ranges referring to three groups of exposure situations are shown:

- low dermal loading (0-0.005 $mg/cm^2/day$), i.e. no direct handling (I);
- medium dermal loading (0.005-0.05 $mg/cm^2/day$), i.e. limited direct handling (II); and
- high dermal loading (0.05-0.5 $mg/cm^2/day$), i.e. direct handling (III).

Organisational controls already implemented in the measurements are reflected in the separation of single datasets into these categories (see Table 15 of HERAG, 2007). The exposure ranges replace (according to the tool developers) three of the five EASE output ranges (0.1-1, 1-5, 5-15 $mg/cm^2/day$, see Table 6.5) to calibrate the EASE results with actual metal specific data. In order to create a conservative exposure estimate the MEASE results represent the upper border of these exposure ranges, i.e. the reasonable worst case which represents approximately the 90th percentile exposure values (HERAG, 2007).

Table 6.5 Comparison of EASE and MEASE output ranges.

Exposure situation	Closed system[38]	Non dispersive us/inclusion into matrix + direct handling			
		extensive contact	**intermittent contact**	**incidental contact**	**no contact**
EASE output / mg cm^{-2} day^{-1}	very low	1-5	0.1-1	0-0.1	very low
MEASE output / mg cm^{-2} day^{-1}	0.0005	0.05	0.005	0.005	0.0005
Exposure situation	**all handling classes + not direct handling**	**wide dispersive use + direct handling**			
	all types of contact	**extensive contact**	**intermittent contact**	**incidental contact**	**no contact**
EASE output / mg cm^{-2} day^{-1}	very low	5-15	1-5	0.1-1	very low
MEASE output / mg cm^{-2} day^{-1}	0.0005	0.5	0.05	0.005	0.0005

Since in HERAG no measured values were available for "very low" exposure situations (i.e. the EASE categories “closed system”, “no direct handling”, gases, massive objects or “no contact”), exposure was estimated to be 10% of the lowest available output (i.e. 0.0005 $mg/cm^2/day$). The combination of incidental contact and non-dispersive use (original EASE output: 0-0.1 $mg/cm^2/day$), which is also not covered by measured data, is estimated to be equal to the next highest exposure

[38] equivalent to other use patterns in combination with “no contact”

range which results in a MEASE output of 0.005 mg/cm^2/day (Vetter, 2012; personal communication).

Inhalation initial exposure estimates

Most initial concentrations for inhalation exposure are identical to the ones implemented in ECETOC TRA (see also Table 6.6). For the lower PROC numbers (PROC 1-20) only two details are not identical: PROC1 in combination with professional setting is not applicable in MEASE and PROC20 is also applicable in combination with industrial setting (contradiction within MEASE draft documentation: Table 1 vs. Table 2 for PROC20). The non-identical values concerning metal specific processes (PROC 21-27b) are marked green and yellow in Table 6.6. Their derivation has not been documented in a detailed way: PROC 21-27a refer to the 90th percentile of measured data of the inhalable fraction[39], while the initial concentration for PROC 27b is based on scientific experience of the model developers (Vetter and Battersby, 2008; Vetter, 2010a, see also Table 6.6).

To obtain the initial exposure estimates for PROCs 21-27a the original measured values were normalised (i.e. corrected) for the impact of any control measures following a procedure similar to the one described in Fransman et al., 2009. The inverse of the expected control efficiency (based on Fransman et al, 2008) for any RMM present during the measurement was applied to the measurement result to obtain an exposure estimate for the workplace if no RMM was present (Vetter and Battersby, 2012; personal communication).

Concerning the fugacity, similar (but not identical) categories as for ECETOC TRA are implemented: high, medium, low and very low fugacity (massive objects and aqueous solution). While for liquids the volatility is based on the vapour pressure the fugacity of solids in cold processes is derived via dustiness.

Inhalation exposures to gases are identical to the ones derived for liquids with very high vapour pressure. The derivation of the initial inhalation exposure estimates for massive objects are not given in the documentation (Vetter, 2010a). However according to the MEASE glossary they correspond to a 90% reduction on the value for the low fugacity exposure estimate.[40]

For the “high temperature” PROCs the fugacity is defined by a combination of melting point and process temperature (PROCs 22, 23, 25, 27a); process temperature is not used as a determined for the other PROC numbers. The borders of the different fugacity classes are summarised in Table 6.3.

Concerning the scale of operation (industrial or professional use) it is assumed that professional use generally involves less contained processes and less effective RMMs which leads to higher inhalation exposure values compared to industrial processes. In MEASE, all combinations between the dermal "pattern of use" and the

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[39] Reference given in draft documentation: EBRC, 2009. This reference refers to unpublished datasets for inhalation exposure and RMM efficiencies and the corresponding statistical analysis including the normalisation procedure in Excel format. To take account of the variability of the underlying datasets additional safety factors based on the scientific knowledge of the model developers were applied to the statistical results before implementing them into MEASE (Vetter and Battersby, 2012; personal communication).

[40] Exeptions are hot processes (see MEASE glossary): PROC22 (both 7 mg/m^3), PROC23, 24, 25 (both 2 mg/m^3), PROC27a (both 5 mg/m^3), PROC27b (both 0.1 mg/m^3) and all PROCs where massive objects are out of scope.

"scale of operation" which is used in the inhalation exposure algorithm are possible (see Table 6.1, Table 6.2 and MEASE glossary).

6.4.2 Algorithm and modifiers

The different determinants, their modifiers, their impact on exposure routes and the possible physical state are summarised in Table 6.2. Some modifiers were adopted from ECETOC TRA v.2 (see Table 6.7) but also additional measures and influences are implemented.

Table 6.6 MEASE documentation (Vetter, 2010a; download from www.EBRC.de): Initial concentrations of inhalation exposure and default efficiencies of LEV (option "ECETOC default")

		Industrial												Professional											
		Solids						Volatiles						Solids						Volatiles					
#	PROC	low	LEV	med	LEV	high	LEV	low	LEV	med	LEV	high	LEV	low	LEV	med	LEV	high	LEV	low	LEV	med	LEV	high	LEV
1	1	0.01	0%	0.01	0%	0.01	0%	0.01	0%	0.01	0%	0.01	0%												
2	2	0.01	90%	0.5	90%	1	90%	1	90%	10	90%	50	90%	0.01	80%	1	80%	5	80%	5	80%	20	80%	50	80%
3	3	0.1	90%	1	90%	1	90%	3	90%	25	90%	100	90%	0.1	80%	1	80%	5	80%	3	80%	25	80%	100	80%
4	4	0.5	90%	5	90%	25	90%	5	90%	20	90%	100	90%	1	80%	5	80%	50	80%	10	80%	50	80%	250	80%
5	5	0.5	90%	5	90%	25	90%	5	90%	50	90%	250	90%	1	80%	5	80%	50	80%	10	80%	100	80%	500	80%
6	6	0.1	90%	5	90%	25	90%	5	90%	50	90%	250	90%	1	80%	5	80%	50	80%	10	80%	100	80%	500	80%
7	7	1	95%	20	95%	100	95%	100	95%	250	95%	500	95%												
8	8a	0.5	90%	5	90%	50	90%	10	90%	50	90%	250	90%	0.5	80%	5	80%	50	80%	25	80%	100	80%	500	80%
9	8b	0.1	95%	5	95%	25	95%	5	97%	50	97%	150	97%	0.5	80%	5	80%	50	80%	10	90%	50	90%	250	90%
10	9	0.1	90%	5	90%	20	90%	5	90%	50	90%	200	90%	0.5	80%	5	80%	20	80%	10	80%	100	80%	250	80%
11	10	0.5	90%	5	90%	10	90%	10	90%	50	90%	250	90%	0.5	80%	5	80%	10	80%	25	80%	100	80%	500	80%
12	11													1	80%	20	80%	200	80%	100	80%	500	80%	1000	80%
13	12							2	80%	20	80%	100	80%							10	80%	100	80%	500	80%
14	13	0.1	90%	1	90%	5	90%	10	90%	50	90%	250	90%	0.5	80%	5	80%	5	80%	10	80%	100	80%	250	80%
15	14	0.1	90%	1	90%	10	90%	5	90%	50	90%	250	90%	1	80%	5	80%	50	80%	10	80%	100	80%	500	80%
16	15	0.1	90%	0.5	90%	5	90%	5	90%	10	90%	50	90%	0.1	80%	0.5	80%	5	80%	5	80%	10	80%	50	80%
17	16	0.1	90%	5	90%	10	90%	1	90%	5	90%	25	90%	5	80%	20	80%	50	80%	1	80%	10	80%	50	80%
18	17	1	95%	20	95%	50	95%	20	95%	50	95%	100	95%	10	90%	50	90%	200	90%	50	90%	200	90%	500	90%
19	18	1	95%	20	95%	50	95%	20	95%	50	95%	100	95%	5	90%	50	90%	200	90%	50	90%	200	90%	500	90%
20	19	0.5	90%	5	90%	25	90%	10	90%	50	90%	250	90%	0.5	80%	5	80%	50	80%	25	80%	100	80%	500	80%
21	20													0.01	80%	1	80%	5	80%	5	80%	20	80%	50	80%
22	21	0.5	90%		90%		90%							0.5	80%		80%		80%						
23	22	1	90%	3.5	90%	7	90%							1	0%	5	0%	10	0%						
24	23	0.5	90%	1.5	90%	2	90%							0.5	80%	1.5	80%	5	80%						
25	24	2	80%	3	80%	5.5	80%							2	75%	3	75%	5.5	75%						
26	25	0.5	90%	1	90%	2	90%							1	80%	2	80%	4	80%						
27	26	1.5	0%	4	0%	10	0%							3	0%	8	0%	20	0%						
28	27a	1	0%	3	0%	5	0%																		
29	27b	0.1	0%	0.5	0%	2.5	0%																		

Legend for background colours

White	Original ECETOC TRA defaults
Grey	Not applicable
Green	EBRC (2009) proposed values (partly modified, further modified (comparing to version 0.9.04), see documentation)
Yellow	Values based on expert judgement (for recently established PROCs)

Dermal exposure

The dermal part offers the same categories as EASE (handling classes, control measures, contact level) and some new influences and refinement methods are added, i.e. properly designed/selected gloves, duration modifiers and concentration modifiers (Table 6.7). The presence of LEV does not influence the dermal exposure.
For gloves only one category exists that results in 90% exposure reduction (according to EC, 2003) while concentration and duration modifiers are identical to values used in ECETOC TRA and the inhalation part of MEASE.

Table 6.7 Modifiers for the concentration of a substance in a mixture (A) and the duration of activity (B)

A			B	
Concentration in mixture (w/w)	**Exposure modifying factor**		**Duration of activity**	**Exposure modifying factor**
Not in a mixture or > 25%	1		>4 h (default)	1
5 – 25%	0.6		1 - 4 h	0.6
1 – 5%	0.2		15 min to 1 h	0.2
< 1 %	0.1		less than 15 min	0.1

Corresponding modifiers for the control strategy (direct or indirect handling) and the level of contact (extensive, intermittent, incidental, none) are also based on HERAG, 2007 as presented in Chapter 6.4.1. Assignments of dermal MEASE results to the corresponding EASE output ranges are given in Table 6.5.
The dermal part of MEASE assumes skin areas that are mostly identical to ECETOC TRA defaults (see Chapter 5 and Table 10.3) and are assigned depending on the PROC number.
It is stated in the Glossary that “the exposed skin area for the handling of massive objects, aqueous solutions and liquids is limited to 480 cm^2 (but could even be lower according to the PROC-specific TRA default-area).” This sentence is inconsistent, as massive objects (e.g. for PROC 26) can also include skin areas up to 1980 cm^2 within MEASE.

Inhalation exposure

Beside LEV, additional risk management measures (see Table 6.2) can be selected to modify the inhalation exposure. The implemented measures are summarised in **Appendix 4, Table 1** together with the 95% confidence intervals of the control efficiency and the average efficiency estimates (average with median confidence, labelled “median” in the tool) which were obtained from Fransman et al., 2008. The user is advised by the glossary to use the lower confidence limit as a default.
The values listed in **Appendix 4, Table 1** represent efficiencies for industrial type of setting. According to the glossary a reduction factor of 25% is applied to the efficiency for professional tasks, whereas this reduction only applies to inhalation RMMs and not to gloves. Operational conditions, i.e. duration of exposure and the concentration, are also not affected. This value has been derived by scientific knowledge of the model developers.
The option “containment” (= enclosure) shows a remarkably wide confidence interval. This is caused by the fact that “partly contained systems” were also included (Fransman et al., 2008).

ECETOC default LEV efficiencies are also implemented but are only intended for comparative purposes (see glossary). In contrast to ECETOC TRA v.2 the LEV efficiencies depend on the type of LEV and are not process specific.
As for ECETOC, the ideal gas equation is used for conversion of units from ppm to mg/m^3 in case of inhalation exposure estimates of volatiles. If the user does not provide a molecular weight then a default value of 24.45 g/mol is used, which leads to a 1:1 conversion between the two units. This default value has been chosen for debugging reasons as documented in the MEASE glossary.
According to the glossary only PPE is considered for PROC20. However, this sentence represents a typo in the MEASE glossary: It refers to PROC19 and all options except ECETOC efficiencies are still working for PROC20.

6.4.3 Underlying assumptions

The model algorithm is based on the following assumptions:

- ❖ The efficiencies of RMMs are identical for dusts, vapour and gases (Fransman et al., 2008) and are not process dependent;
- ❖ Aqueous solutions of inorganic solids offer a fugacity equal to very low dustiness (massive objects);
- ❖ Inhalation exposure to liquids and gases is converted from ppm to mg/m^3 using the ideal gas law, which is common way of conversion from ppm to mg/m^3 amongst occupational hygienists[41]; and
- ❖ Some PROCs are assumed only to be applicable either for professional or industrial type of setting (see Table 6.6 and Chapter 6.4.1).

6.5 Transparency

Tool development
The tool development is only documented in a limited way. Some information is available in the implemented glossary and parts of the tools background are published in HERAG, 2007 and Fransman et al., 2008/Fransman et al., 2009. However, a detailed report, a user guide or sufficient documentation is currently not available and not all information that would be necessary for a complete tool description can be found in the currently available publications. Modifying factors are shown within the tool itself, but documentation where the different factors originate from and where they can also be found (e.g. comparison with ECETOC TRA, EASE) would be helpful. A changelog document[27] (Vetter, 2010b), including the numbers of the different versions as well as dates and changes, is also available at the EBRC homepage.

[41] see e.g. http://www.cdc.gov/niosh/docs/2004-101/calc.htm

Datasets

In the glossary of the tool it is claimed that “in contrast to the TRA tool, the initial exposure estimates in MEASE are based on measured data from the metals industry.”[42] This phrase may be misleading, as ECETOC TRA also refers to measured values, although only datasets for PROCs 21-26 are documented. As the derivation of some determinants (e.g. implementation of duration, influence of LEV) and initial exposure estimates for ECETOC TRA were not documented (see Chapter 5) and additional estimations were used in MEASE itself (e.g. duration modifiers, partly derivation of output ranges for dermal exposure, efficiencies for RMMs in case of professional use, see also Chapter 3.4), the distinction between “based on data” and “not based on data” may not be perfectly clear. The initial inhalation exposure estimates are adopted from ECETOC TRA v.2 for PROCs 1-20 and thus, the corresponding MEASE outputs show similar limitations, but the inhalation exposure values for PROCs 21-27a and the dermal exposure estimations are based on actual metal data (see HERAG, 2007). This has already been made clearer on www.ebrc.de in the meantime and was indicated to be made clearer in the tool glossary in the next version of the tool (personal communication, Vetter and Battersby, 2012).

Information about the efficiencies of RMMs applicable to inhalation exposure (i.e. Fransman et al., 2008) is not directly available, as Fransman et al., 2008 does not contain all important information. It is stated that “433 records from 90 publications” are included in the publication, but not all of them are listed in the references. The age of the underlying datasets and covered industries is not exactly given, neither are physical states of the substances which were measured.
The underlying publications with measurements of dermal exposure, the number of datasets and the different substances are given in HERAG, 2007. Raw data are given in this publication (without exact measuring times, but HERAG, 2007 refers to full shift average exposures).

Scope and algorithm

A rough overview and explanations of the implemented features, their meaning and a set of examples for the implemented PROC numbers are provided in the integrated glossary. Limitations of the tool are partly addressed in the documentation[27] (Vetter, 2010a) where a list of the different PROC numbers, if they are generally applicable and if they are applicable in certain combinations with physical properties/task types (industrial, professional, both) is given.
RMM efficiencies (i.e. ECETOC defaults and values taken from Fransman et al., 2008) are clearly visible on the input screen and explained in the glossary, however they are not mentioned in the draft documentation (see also Chapter 6.4), which includes only two tables without further text or explanations.
The development of MEASE or the calculations within the tool are not explained in great detail (e.g. implementation of process temperature). However basic information about modifiers and parameters is directly visible on the input screen and can be found in the glossary.

Structure of use
As the term “inclusion into matrix” is not commonly used in industry the same possible source of confusion as in case of EASE exists. However explanations are given in the glossary for this handling category (see also Chapter 4), thus, an attentive user will be able to use the correct assignment.
The default setting for the molecular weight (24.45 g/mol) is a much smaller value than would be expected for typical, metal containing substances. It is documented in the glossary that this value has been chosen for debugging reasons which are not obvious to the user (identical results in mg/m^3 and ppm). It has to be exchanged in the course of a REACH exposure assessment for which the molecular weight has to be known anyway.
Warning messages are also shown within the tool, if a combination of substance properties and process is entered which is not covered by the tool and no exposure estimate is provided in these cases. Together with the relevance indicator and the presentation of modifiers and input parameters on the input screen this leads to a quite clear structure of use.
Concerning the applicability, for which PROC numbers, substances and physical states MEASE can be used, this tool is quite transparent. It is always made clear which of the modifiers / RMMs influence the results (dermal or inhalation) and by how much, although the correctness of the relevance indices should be checked (i.e. for influence of molecular weight and vapour pressure on dermal exposure to liquids and gases).

Minor parts of the tool development and exposure calculation algorithm are not given in publicly available data sources. However, further information has been made available by the tool developers for this project (specific assignment of 2 of 5 dermal exposure outcomes to measured values, borders of fugacity ranges for high temperature PROCs). While according to the introduction of the glossary and the website[42] the tool is based on measured data from the metals industry this is in fact only the case for the dermal exposure part and some of the inhalation initial exposure estimates (metal specific PROCs 21-27). So overall MEASE and its background can be considered to be of medium transparency.

6.6 Conclusion

MEASE is constructed in a logical way but some uncertainty exists (see also work WP II.1). Examples for these sources of uncertainties are the underlying assumptions (e.g. same LEV efficiencies for dust and vapour, see Chapter 6.4). For the inhalation part MEASE uses the use descriptor system (published in ECHA, 2010a; see also Chapter 10.7) which bears some inconsistencies (e.g. that the type of setting and process description are mixed) but overall provides a quite detailed concept of handling descriptions. Moreover the implementation of this approach increases the usability under REACH.
For the dermal part of MEASE, parameters of the EASE model (see also Chapter 4), and some additional modifiers (see Table 23) are used, which lead to a less detailed scenario description than for the inhalation part.

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[42] Information at website has already been made clearer during the revision process of this report.

As dermal and inhalation exposure estimation parts are separated within the tool the user has to define the exposure situation in two different ways which is a potential source of error to the exposure result.
Although some parts of the model are not metal specific (e.g. initial inhalation exposure estimates for PROCs 1-20 (except for massive objects and aqueous solutions) and inhalation RMM efficiencies) the complete dermal exposure part as well as PROCs 21-27, which are considered to reflect the most important processes in the metals industry, are based on measured data from metal specific workplaces.
A summary of the covered determinants and exposure defining elements (intrinsic substance properties, risk management measures, process description/operational conditions, personal protective equipment, see Chapter 3) is given in Table 6.8. The inhalation part of MEASE is quite detailed (especially the RMMs) and might even be assigned to a higher tier approach.
Compared to the inhalation part the dermal part is coarser but relies on real workplace measurements and should therefore be able to give realistic impression of actual workplace exposures. As some of the dermal datasets rely on measurements carried out under gloves, the implementation of gloves as RMM may be problematic.
Details of both algorithm parts (inhalation and dermal) are spread over different publications.
Overall it can be stated that some modifications and additional documentation would be advisable for the tool but it is easy to use and the implemented determinants offer a sufficient level of detail.

Suggestions:

- Publish a sufficient documentation which includes information about the origin of the different parts of the model.
- Provide a logic tree similar to the EASE model but with updated output ranges, so the user is able to reproduce similarities and differences between the approaches.
- Document how the usage of gloves was reflected in the dermal datasets.

Table 6.8 Number of categories per determinants and assignment to the different exposure defining elements (see also Chapter 3)*.

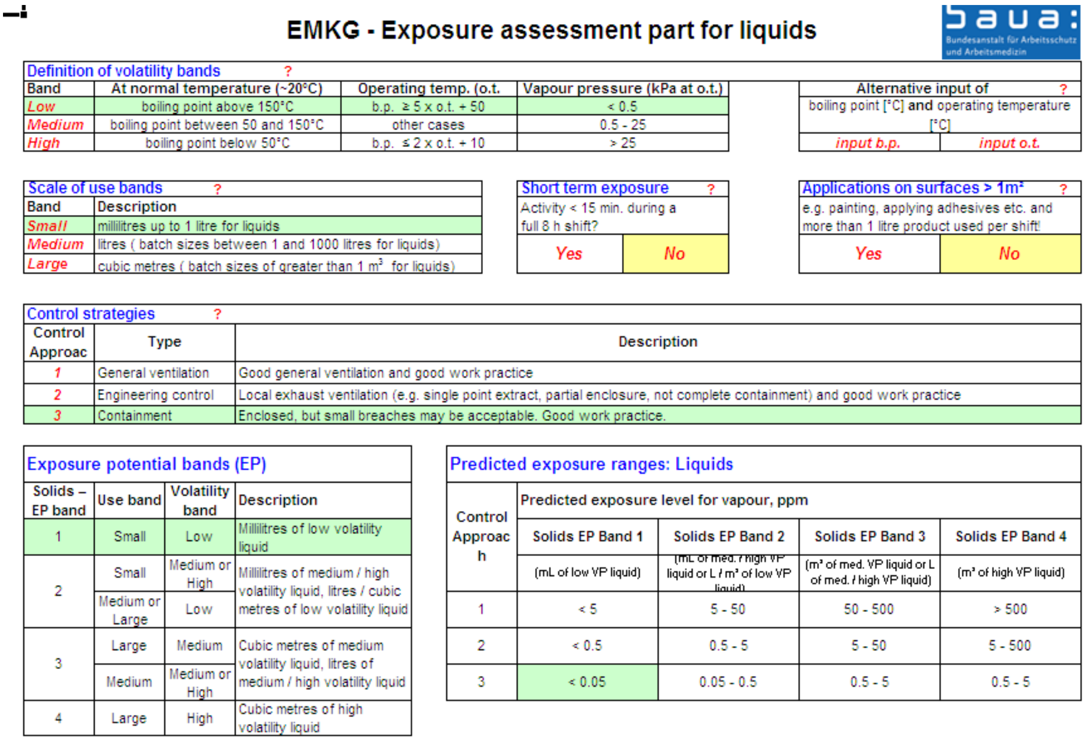
Intrinsic substance properties[43]	**Process description /operational conditions (inhalation)**	**Process description /operational conditions (dermal)**	**Risk management measures at source (inhalation)**[44]	**Risk management measures at source (dermal)**	**Personal protective equipment**
molecular weight (i, free text)	PROC numbers corresponding to the REACH descriptor system (29 categories)	rescaled EASE (4 categories, indeed only 3 category)	Enclosure (1 category)	pattern of exposure control (direct and non-direct handling)	Gloves (1 category)
melting point (i+d, 3 categories)	process temperature (3 categories)	contact level (4 categories)	LEV (3 categories)		Respiratory protection (5 categories)
vapour pressure (i+d, 3 categories)	scale of operation (industrial vs. professional)		general ventilation (1 category)		
dustiness (i+d, 4 categories)	duration of exposure (4 categories)		suppression techniques (3 categories)		
physical state (i+d, two categories)	good occupational hygiene is assumed		separation of workers (1 category)		
content in preparation (i+d, 4 categories)					

*The numbers of categories per model parameter are given in brackets behind the corresponding determinant and the influence route of exposure is indicated by “i” (inhalation) and “d” (dermal) if necessary.

[43] i: substance property influences inhalation exposure; d: substance property influences dermal exposure.
[44] Each RMM additionally can be modified concerning the confidence limit, see chapter 6.4.

7 EMKG-EXPO-TOOL

7.1 Introduction



EMKG - Exposure assessment part for liquids

Definition of volatility bands ?			
Band	At normal temperature (~20°C)	Operating temp. (o.t.	Vapour pressure (kPa at o.t.)
Low	boiling point above 150°C	b.p. ≥ 5 x o.t. + 50	< 0.5
Medium	boiling point between 50 and 150°C	other cases	0.5 - 25
High	boiling point below 50°C	b.p. ≤ 2 x o.t. + 10	> 25

Alternative input of ?	
boiling point [°C] and operating temperature [°C]	
input b.p.	input o.t.

Scale of use bands ?	
Band	Description
Small	millilitres up to 1 litre for liquids
Medium	litres (batch sizes between 1 and 1000 litres for liquids)
Large	cubic metres (batch sizes of greater than 1 m³ for liquids)

Short term exposure ?	
Activity < 15 min. during a full 8 h shift?	
Yes	No

Applications on surfaces > 1m² ?	
e.g. painting, applying adhesives etc. and more than 1 litre product used per shift!	
Yes	No

Control strategies ?		
Control Approac	Type	Description
1	General ventilation	Good general ventilation and good work practice
2	Engineering control	Local exhaust ventilation (e.g. single point extract, partial enclosure, not complete containment) and good work practice
3	Containment	Enclosed, but small breaches may be acceptable. Good work practice.

Exposure potential bands (EP)			
Solids – EP band	Use band	Volatility band	Description
1	Small	Low	Millilitres of low volatility liquid
2	Small	Medium or High	Millilitres of medium / high volatility liquid, litres / cubic metres of low volatility liquid
	Medium or Large	Low	
3	Large	Medium	Cubic metres of medium volatility liquid, litres of medium / high volatility liquid
	Medium	Medium or High	
4	Large	High	Cubic metres of high volatility liquid

Predicted exposure ranges: Liquids				
Control Approach	Predicted exposure level for vapour, ppm			
	Solids EP Band 1	Solids EP Band 2	Solids EP Band 3	Solids EP Band 4
	(mL of low VP liquid)	(mL of med. / high VP liquid or L / m³ of low VP liquid)	(m³ of med. VP liquid or L of med. / high VP liquid)	(m³ of high VP liquid)
1	< 5	5 - 50	50 - 500	> 500
2	< 0.5	0.5 - 5	5 - 50	5 - 500
3	< 0.05	0.05 - 0.5	0.5 - 5	0.5 - 5

Figure 7.1 Screenshot of the EMKG-EXPO-TOOL (version number not available)

The EMKG-EXPO-TOOL is another MS Excel based tool (MS Excel 97 or younger, MS Excel 2002 has not been tested yet according to the reach helpdesk[45]). It was developed to estimate inhalation exposure for workplaces, especially in small and medium sized enterprises. It is part of the EMKG,[46] which has been developed by the BAuA[47], the German authority for occupational safety & medicine, to provide advice to small and medium size enterprises (see Kahl et al., 2008 and 2011) As the EMKG provides the basis for the EMKG-EXPO-TOOL it will be summarised in Chapter 7.2. EMKG is based on COSHH Essentials ("Control of Substances Hazardous to Health"; Kahl et al., 2008 and 2011), a control banding tool that was developed by HSE (Health and Safety Executive), in collaboration with the TUC (Trades Union Congress) and CBI (Confederation of British Industry)[48]. The EMKG-EXPO-TOOL is almost identical to the exposure estimation part of COSHH Essentials (see Chapter 7.2.3).

The difference between EMKG and EMKG-EXPO can be summarised as followed:

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[45] http://www.reach-clp-helpdesk.de/de/Themen/Expositionen/Expositionen.html or http://www.reach-clp-helpdesk.de/en/Exposure/Exposure.html

[46] "Einfaches Maßnahmenkonzept Gefahrstoffe", or "Easy to use workplace control scheme for hazardous substances"

[47] "Bundesanstalt für Arbeitsschutz und Arbeitsmedizin", or "Federal Institute for Occupational Safety and Health"

[48] http://www.hse.gov.uk/coshh/essentials/index.htm

The EMKG can be used to determine a safe control strategy for a substance if hazard (R/S phrases), amount of substance used, and exposure potential are known. An exposure assessment is not provided. The EMKG-EXPO-TOOL on the other hand can be provides an estimated range of exposure if the amount of substance, the control strategy and the exposure potential are known (i.e. the exposure result refers to the situation that may already have been described within EMKG).
The tool can be found easily: A simple Google search (keyword “EMKG-EXPO”) leads directly to the download page where it can be obtained free of charge.[45]

Publications
The EMKG concept is described in detail by Kahl et al., 2008 and 2011. For the EMKG-EXPO-TOOL only one specific publication has been found, which compares the EMKG-EXPO-TOOL with EASE (Kindler et al., 2010). A general description of the tool and its use is provided in ECHA (2010b). A validation study of EMKG was carried out by Tischer et al., 2007 (see also Tischer et al., 2009).
Relevant studies of EMKG(-Expo) and a selection of publications about COSHH are briefly summarised in Appendix 2.

7.2 Tool description

7.2.1 Scope

The EMKG-EXPO-TOOL is designed specifically for the needs of small and medium enterprises so it should be easy to use and to understand (Tischer et al., 2003a; Russell et al., 1998).
The tool only provides inhalation exposure estimates and it can be used for both solids and liquids but not for gases.
The tool is not appropriate for activities where dusts are formed through abrasive techniques, aerosol exposure resulting from open spray applications[49], gases and pesticides.
Operations with generation of fumes (soldering, welding) and wood dusts are outside the scope as well. Further special activities like e.g. restoration, recycling or cleaning, where unexpected exposure to hazardous substances may occur are not covered (ECHA, 2010b; Kahl et al., 2008; see also tool itself). Moreover the tool is not suited for CMR substances (information given in the tool itself but no justification is provided).
Some additional information is provided in the help section at www.coshh-essentials.org.uk and in HSE, 2009. This information refers to COSHH, but as both concepts use almost the same way of exposure estimation the limitations are relevant to both. It is stated that COSHH essentials covers some process dust and fumes (e.g. wood dust[50] and flour, foundry, rubber and some soldering fumes) but does not cover other process fumes (e.g. welding), other process dust (e.g. quarry dust), veterinary medicines, pharmaceuticals, (Russel et al., 1998) lead and asbestos[51].

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[49] Only vapour exposure resulting from spray applications is covered as long as the corresponding control guidance sheets are used (Tischer, 2012; personal communication).
[50] This information contradicts the limitations given for EMKG-EXPO, see paragraph above.
[51] http://www.coshh-essentials.org.uk/help/

If the boiling point is < 20°C or the vapour pressure is ≥ 1atm the tool should not be used, as gases cannot be handled (HSE, 2009). No warning message is provided by the tool in these cases.
The tool is only valid within the ranges given by the limited number of control guidance sheets, i.e. only for the tasks described there (see Table 7.1 and Table 7.2).
An exposure assessment completely without control measures is not possible as the minimum control approach already refers to general ventilation.

7.2.2 Model, parameters and structure of use

EMKG
The underlying principles and development of the toxicological and exposure estimation parts of COSHH, on which the EMKG-EXPO-TOOL is based, are published in Brooke et al., 1998 and Maidment, 1998.
The substance is assigned to one of five hazard bands according to its occupational exposure level or (if no such OEL exists) according to its R and S phrases according to the Dangerous Substance Directive. This part of COSHH has been modified slightly before implementing it into EMKG, but as it does not influence the exposure estimation it will not be discussed at this point. If the OELs are used for classification they are divided into five concentration ranges – one for each hazard band – which are identical to the later output ranges of the EMKG-EXPO-TOOL although the EMKG concept (without the tool) does not provide exposure estimations. The Globally Harmonized System of Classification and Labeling of Chemicals ("GHS classification") is not implemented yet in the EMKG.
Each substance is assigned to an exposure potential band using the amount handled and the volatility. The combination of this exposure potential band and the hazard band lead to a certain control approach which has to be followed to ensure safe use of the substance. The control approaches are explained for various tasks in the German control guidance sheets ("Schutzleitfäden"), which are in large parts German translations of the control guidance sheets of the COSHH essentials.

The EMKG-EXPO-TOOL
The EMKG-EXPO-TOOL is based on the assumption that exposure is determined by two principle factors: *exposure potential* of the substance and *control strategy* (Tischer et al., 2003b).

The options within the tool are
- the scale of use (= amount of substance per event):
  - liquids: < 1 l, 1 l -1000 l, > 1000 l ;
  - solids: < 1 kg, 1 kg – 1 t, > 1 t ;
- fugacity (via boiling point, process temperature, vapour pressure for liquids or dustiness for solids);
- control approach (level 1, 2 or 3; according to one of the COSHH control guidance sheets or the German "Schutzleitfäden"):
  - general ventilation (good general ventilation and work practice);
  - engineering control (local exhaust ventilation and good work practice);
  - containment (enclosed, but small breaches may be acceptable);
- size of the surface in case of application on surfaces (only liquids, larger or smaller than 1 m^2); and

❖ duration of exposure (short or long-term exposure).
The amount of substance is assumed to be the most important parameter (Maidment, 1998).

Table 7.1 Tasks included in "Schutzleitfäden" and control guidance sheet, number of sub-scenarios and included control levels.

Unit Operation	**number of sub-scenarios within unit operation**	**Control levels covered**[52]
General tasks	7	1, 2, 3
General measures	3	1, 2
Storage	2	1
Printing, Copying	1	1
Dust extraction	1	1, 2, 3
Transfer	15	1, 2, 3
Weighing	3	2, 3
Mixing	3	2, 3
Sieving	1	2
Screening	1	2
Surface coating	5	2, 3
Lamination	2	2
Dipping	3	2, 3
Drying	3	2, 3
Palletizing	2	2
Dust workplaces	1	2
Service and maintenance	1	2

[52] Level 1: low level of control ("General ventilation"); Level 2: medium level of control ("Engineering control"); Level 3: high level of control ("Containment"). See also Table 7.2.

Table 7.2 List of general control guidance sheets/"Schutzleitfäden" available for COSHH and EMKG*.

Control Approach 1: General ventilation			
Sheet No.	**Sheet title**	**COSHH**[53]	**EMKG**
100	General ventilation	x	x
101	General storage	x	x
102	Open bulk storage	x	x
103	Removing waste from dust extraction unit	x	
110	Organisation and hygiene measures "breathing"		x
120	Organisation and hygiene measures "skin"		x (also in english)
130	Printing, Copying		x (also in english)
7 sheets			

Control Approach 2: Local exhaust ventilation			
Sheet No.(s)	**Sheet title**	**COSHH**[53]	**EMKG**
200	Local exhaust ventilation	x	x
201	Fume cupboard	x	x
202	Laminar flow booth	x	
203	Ventilated workbench	x	x
204	Removing waste from dust extraction unit	x	x
205	Conveyor transfer	x	x
206	Sack filling	x	x
207	High throughput sack filling	x	
208	Sack emptying	x	x
209	Filling kegs	x	
210	Charging reactors / mixers from a sack or keg	x	x
211	IBC filling and emptying	x	x
212	Drum filling	x	x
213	Drum emptying (drum pump)	x	x
214	Weighing	x	x
215	Mixing solids with other solids or liquids	x	x
216	Mixing solids	x	
217	Mixing liquids with other liquids or solids	x	x
218	Sieving (+ filtering)	x	
219	Screening	x	
220	Spray painting small scale	x	
221	Spray painting medium scale		
222	Powder coating	x	x
223	Batch lamination	x	x
224	Continuous lamination	x	
225	Pickling bath (medium scale)	x	
226	Pickling bath (large scale)	x	
227	Vapour degreasing bath	x	
228	Tray drying oven	x	x
229	Continuous drying labyrinth oven	x	
230	Palletizing	x	x

[53] „general" cgs; labelled g*cgs number*.pdf

231	Tablet press	x	
240	Dust workplaces		x
250	Extended measures "skin"		x (also in english)
260	Service and maintenance of printers		x (also in english)
35 sheets			
Control Approach 3: Containment			
Sheet No.(s)	**Sheet title**	**COSHH**[53]	**EMKG**
300	Containment	x	x
301	Glove box	x	x
302	Removing waste from dust extraction unit	x	
303	Transferring solids	x	
304	Sack emptying	x	
305	Drum filling	x	x
306	Drum emptying	x	x
307	IBC filling and emptying (solids)	x	x
308	IBC filling and emptying (liquids)	x	x
309	Tanker filling and emptying (solids)	x	
310	Tanker filling and emptying (liquids)	x	x
311	Filling kegs	x	
312	Transferring liquid by pump	x	x
313	Packet filling	x	
314	Bottle filling	x	
315	Weighing (liquids)	x	
316	Weighing (solids)	x	
317	Mixing (solids)	x	
318	Mixing (liquids)	x	
319	Robot spray booth	x	
320	Automated powder coating	x	
321	Vapour degreasing bath	x	
322	Spray drying	x	
23 sheets			
*Not task based sheets are marked yellow			

The EMKG-EXPO-TOOL is a tool that is easy to overview and thus fast to learn. Only a small number of input fields (see above and also Chapter 7.4) is implemented and options can be chosen by a simple click. But it is important to work according to the control guidance sheets with the corresponding control measures (level 1, 2 or 3), otherwise the exposure estimation is not considered to be valid.[54]

If no appropriate control guidance sheet is available the exposure cannot be estimated.

Control guidance sheets are available at the BAuA homepage[55] and the COSHH homepage[56].

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[54]Information given in the tool itself (help function).

[55]http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/EMKG/Schutzleitfaeden_content.html

[56]http://www.coshh-essentials.org.uk/assets/live/G***.pdf . A full list of English control guidance sheets (= cgs, originally referring to COSHH) can be downloaded free of charge at http://oehc.uchc.edu/news/Control_Guidance_Factsheets.pdf. (state of affairs 20.01.2012)

In conjunction with control guidance sheets detailed descriptions of exposure situations and necessary RMMs, access to work area, maintenance of equipment etc. are implemented (Tischer et al., 2003b). However, these detailed scenarios are broken down to a limited set of exposure output ranges.
If the estimated exposure range lies below the limit value of the substance the use is considered to be safe, if the limit value lies within the predicted range or below it, a more detailed exposure assessment using other tools or concepts is necessary.
The options implemented in the EMKG-EXPO-TOOL cannot be directly translated into the REACH descriptor PROC system as – without the control guidance sheet – they refer only to control measures. However, in the usemap which was designed to link the PROC system to handling classes of other tools (see Appendix 6) a selection of possible guidance sheets is assigned to each PROC number.
A short overview of the included tasks is also available in HSE, 2009 (see also Table 7.1 and Table 7.2). More detailed information can only be found inside the corresponding control guidance sheets.
If a control guidance sheet exists in both the German and the English (i.e. COSHH) version numbering and content for both sets of sheets ("Schutzleitfäden" and control guidance sheets) are identical, but not all sheets are represented in both sets (see Table 7.2). A 4th category ("special" – special expert advice is needed) is implemented in COSHH in case of CMR substances but not in the EMKG-EXPO-TOOL (HSE, 2009 and information provided in control guidance sheet g400). In these cases the combination of substance and use is considered to be beyond the scope of the tool.
The exposure result is presented as range with the unit ppm (liquids) or mg/m^3 (solids) and it refers to time weighted full shift average values (ECHA, 2010b). Red, yellow and green colour coding of input parameters and results indicate if the exposure is high, medium or low, respectively. The number of possible output ranges varies between 6 for solids and 9 for liquids.
No option to export any kind of report is implemented.

In the COSHH documentation (HSE, 2009[57]) some additional advice for special cases can be found:

- how to deal with mixtures: use major component for volatility/dustiness;
- aerosol formation: special control guidance sheets for some spray applications exist. In doubt the higher control approach should be applied. The propellant should be ignored as gases are not covered. According to the help section of http://www.hse.gov.uk/coshh/essentials/index.htm for aerosols (spray application) a more stringent control approach should be used than indicated by COSHH;
- volatile solids: compare control guidance sheets for solid and liquid approach and use the more stringent one; and
- solids in liquids: treat like liquids with low volatility in water, like solids-in-liquids with volatility of solvent for other solvents.

[57] www.coshh-essentials.org.uk/assets/live/CETB.pdf and http://oehc.uchc.edu/news/Control_Guidance_Factsheets.pdf. (state of affairs 20.01.2012)

7.2.3 Additional contributing algorithms

Volatility

The volatility of liquids is defined via the vapour pressure at operating temperature or the relation between operating temperature and boiling point (Tischer et al., 2003b). The borders of the volatility bands are the same as for the EASE model but result in only three volatility ranges instead of six: low, medium and high volatility refer to boiling points lower than 50°C, between 50 and 150°C and above 150°C if the process temperature is around 20°C (Tischer et al., 2003b). The border between the low and medium volatility band is defined by “boiling point = 5 x process temperature + 50”, while the border between the medium and high volatility band is defined by “boiling point = 2 x process temperature + 10” (Maidment, 1998, see Figure 7.2). This grouping of substances also agrees with the subjective assessments of these solvents provided by the members of the working group established for the development of the model (Maidment, 1998).

The influence of boiling point (T_{bp}, [K]) and process temperature (T, [K]), if the process temperature is not around 20°C, is implemented via a combination of Clausius Clapeyron and the Trouton rule (ΔH_{vap} T_{bp}^{-1} = 86.4 J mol^{-1}), although overestimations are likely for this procedure (Tischer et al., 2003b):

$$\ln P_{Pa} = -10.6\left(\frac{T_{bp}}{T} - 1\right).$$

(Tischer et al., 2003b, HSE; 2009; vapour pressure given in atm)

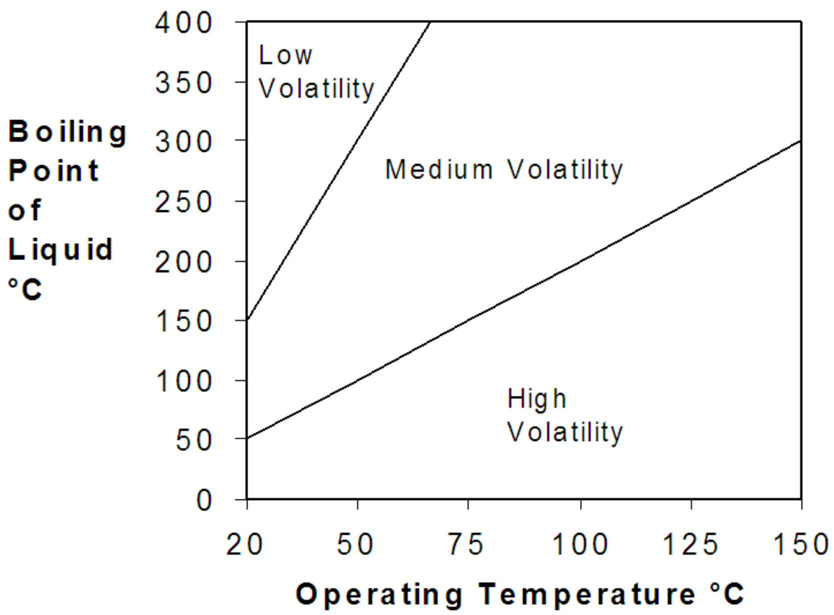

Figure 7.2 Graph to select volatility of liquids (Maidment, 1998)

For mixtures it is suggested to use the lowest boiling point included in the given range (conservative approach) (Tischer et al., 2003a). It is assumed that all mixtures show ideal behaviour, i.e. no modifications of the vapour pressure due to other components in the mixture is taken into account. This can induce mistakes up to an order of magnitude, as a demonstration with various test mixtures has shown

(Krafczyk et al., 2000[58]). Thus, the tendency of the core model towards conservative estimates (through the use of the lowest boiling point) can be overcompensated by concentration-dependent factors - the core model approach for mixtures is too simple to model all possible situations realistically.
Alternatively, the vapour pressure at process temperature can be used for defining the volatility band of a substance. Again the ranges refer to EASE categories and result in the vapour pressure categories < 0.5 kPa, 0.5 – 25 kPa and > 25 kPa (corresponding to the EASE ranges "very low or low"; "low/moderate, moderate or moderate/high" and "high").

Differences between COSHH and the EMKG-EXPO-TOOL: Application of liquids on large surfaces
A mechanistic, external modelling of situations which refer to application of liquids on large surfaces was performed during the development of the EMKG-EXPO-TOOL (Tischer, 2011). The study revealed that COSHH is not reliable in those cases and tends to underestimate exposure. Therefore a new option - "application on surfaces larger than 1 square metre" - was introduced. The modelling procedure that refers partly to Gmehling et al, 1989a and b will be summarised in the following paragraphs and is compared with EMKG-EXPO estimations at control level 1 (i.e. general ventilation).
Two situations have been simulated with this model in the process of tool development – one of a substance with low vapour pressure (250 Pa, *situation 1*) and one with medium or high vapour pressure (> 500 Pa, *situation* 2). For small and medium scale processes, use of medium and high vapour pressures result in the same exposure prediction by the EMKK-EXPO-TOOL (see Table 7.4). Therefore they are both included in situation 2. Large amounts of substance (i.e. more than 1 m^3) are not covered.

For **situation 1** the evaporation of chemicals from a mixture and resulting air concentration is estimated based on the Gmehling-Weidlich-Model (Gmehling et al., 1989a and Gmehling et al., 1989b), which is a mechanistic model based on evaporation rates and transport coefficients above liquid, plane surfaces. The following equations can be obtained (based on a time dependent box model for a well-mixed room):

The substance flow $\dot{n}_i$ induced by evaporation (mol/h) is defined by:

$$\dot{n}_i = x_i \cdot \gamma \cdot \frac{P_i^S}{RT} \cdot 0.0111 \frac{v_{surface}^{0.96} \cdot D_i^{0.19}}{v^{0.14} \cdot X^{0.04}} \cdot A$$

This leads to the following concentration $c_{i,evap}(t)$ (ppm) which is induced by the evaporation of the substance:

[58] Reference given in Tischer et al., 2003a but not publicly available: Krafczyk J, Gmehling J, Fischer K (2000). Empfehlungen zur thermodynamischen Behandlung komplexer Multikomponentensysteme in Zusammenhang mit Expositionsabschätzungen, Anhang 5 zum Endbericht des Forschungsvorhabens "Bewertung und Fortentwicklung der Regelsetzung: Anwendbarkeit der TRGS 440.". Teil 2: 60p.

$$c_{i,evap}(t) = \frac{\dot{m}_i}{M_i \cdot \dot{V}}(1-\exp(-\lambda \cdot t)) \cdot 1000 \cdot 24.1 l \cdot mol^{-1}$$ with $\lambda = \dot{V} / V_R$

In parallel, the concentration decrease $c_{i,dilution}(t)$ after the time of exposure (ppm/h) is determined by the ventilation and can be described by the following equation:

$$c_{i,dilution}(t) = c_{i,dilution}(t_0) \cdot \exp(-\lambda \cdot (t - t_0))$$

Both processes together give the total concentration change of substance *i* at the time *t* $c_{i,ges}(t)$:

$$c_{i,ges}(t) = c_{i,evap}(t) \cdot H[t_0 - t] + c_{i,dilution}(t) \cdot H[t - t_0]$$

Time weighted average of room concentration $c_{i,twa}(t)$:

$$c_{i,twa}(t) = \int_0^t \frac{1}{t} c_{i,ges}(t) dt$$

The following physical constants and properties have been used:

- *H[n]*: Heaviside (or unit step) function; *H[n]* = 0 for *n* < 0 and *H[n]* = 1 for *n* larger or equal to 0.
- x_i = 1: mole fraction
- t_0= 4 h: emission time
- γ= 1: activity coefficient
- P_i^S = 250 Pa: vapour Pressure
- R = 8.314510 J mol^{-1} K^{-1}
- A = 1 m^2: surface area of liquid
- T = 293.15 K: process temperature
- $v_{surface}$= 360 m h^{-1}: air velocity above liquid surface
- D_i = 0.05 m^2 h^{-1}: diffusion constant of substance i in the gas phase
- v_i = 0.055 m^2 h^{-1}: viscosity of air
- X = 1 m: length of surface area
- M_i = 100 g mol^{-1}: molecular weight
- V_R = 200 m^3: room volume
- $\dot{V} = 1000$ m^3 h^{-1}: flow of fresh air
- molar volume of an ideal gas at 293.15 K: 24.1 l mol^{-1}
- λ: ventilation rate $\lambda = \frac{\dot{V}}{V_R}$
- v_L = 360 m/h, air velocity above liquid surface
- $\dot{m}_i(V)$ = mass flow
- t_{exp}= exposure time; assumed to be 8 h (i.e. shift length)

The model calculation results in exposure values below 5 ppm for surface areas up to 1 m^2, which is the upper border of the corresponding exposure band in the EMKG-EXPO-TOOL without the “large surfaces” option. For larger areas the “large surfaces” option should be used and results in the next higher exposure band. This model is independent of the amount of substance but the already mentioned border of 1 m^2 has to be considered.

For **situation 2** another approximation is used:

$$c_i(V_{liq}) = \frac{\dot{m}_i(V_{liq})}{V_R \cdot \lambda} \frac{24.1l \cdot mol^{-1}}{M_i}$$

$$\dot{m}_i(V_{liq}) \approx \frac{m_i}{t_{\exp}}$$

- t_{exp}= exposure time; assumed to be 8 h (i.e. shift length)
- V_{liq} = overall volume of liquid
- m_i = amount of substance in mass units

Situation 2 reflects the use of substances on large (>1 m^2) surface areas. Due to the large surface it is assumed that the whole liquid evaporates instantaneously (conservative assumption) and is diluted in the room air. The exposure time is assumed to be 8 h (Tischer, 2011).

Table 7.3 Comparison of external model with EMKG-EXPO results*.

	Exposure situation	**Result of EMKG-EXPO without "surface application" option**
Situation 1: result of external model does not depend on amount of substance; p_{vap} = 250 Pa	surface area > 1 m^2	(red)
	surface area ≤ 1 m^2	(green)
Situation 2: result of external model does not depend on surface area; p_{vap}> 500 Pa	substance amounts > 1 l surface area > 1 m^2	(red)
	substance amounts < 1 l surface area > 1 m^2	(green)

*Red = EMKG-EXPO-TOOL without surface option underestimates Exposure; Green = EMKG-EXPO-TOOL is consistent with external model.

In contrast to situation 1 the result is independent of the surface but dependant on the amount of substance. For the lowest tested ventilation number (2/h) the upper level (50 ppm) of the corresponding concentration band without the “large surfaces”-option was exceeded with amounts of substance less than 1 l. For ventilation numbers of 5/h or higher the upper concentration level was not exceeded for less than 1 l. Thus, one of the inherent tool assumptions is a sufficiently high ventilation rate, otherwise false results might be obtained. With higher amounts of substance than 1 l the upper level (i.e. 50 ppm) is exceeded, therefore the integrated “surface” option is necessary (Tischer, 2011).
A summary of the external model results in comparison with EMKG-EXPO results is given in Table 7.3. It is not published how the exact wording of the included option

(i.e. “application on surfaces larger than 1 m^2 *and* more than 1 l per shift”) was derived from these external model results.
The resulting "doubling" of possible input about the amount of substance (i.e. the three "scale of use" bands and the amount mentioned in the surface option) may lead to misunderstandings, thus, it is important to note that the "scale of use" refers to amounts of substance per event. Therefore during one shift several events including small amounts may be added up to result in overall amounts above 1 litre.

7.3 Empirical exposure data used for model development

The output ranges have been derived by debate among the occupational hygienists in the working group without any underlying database (Maidment, 1998).

7.4 Derivation of final exposure output

The combination of fugacity bands and scale of use leads to four different exposure predictor bands for each physical state (see Table 7.4, Maidment, 1998). The tool has a set of 12 output fields for each liquids and solids (see Table 7.5). If short term exposure is chosen, a smaller range is added, the highest range is removed and all other ranges are shifted to smaller values accordingly (except exposure predictor band 1 + control approach 3 which represents the minimal implemented exposure range). Each result range refers to certain combinations of exposure potential band and control approach (see Table 7.5). The overall number of possible determinants and options for each of them is summarised in Table 7.6.
No scientific justification for the produced definitions (i.e. the aggregation of physical and operational factors to exposure predictor bands and the ranking of the corresponding EPS and EPL) in the tool is provided (Tischer et al., 2003b).
If the exposure duration is <15 minutes per day for a given control approach the concentration range decreases by a factor of 10) (HSE, 2009). If this option is not chosen a task duration of 8 h (shift length) is assumed (ECHA, 2010b).

According to Maidment, 1998 the COSHH Essentials tool was “arrived at by debate amongst the occupational hygienists” working on the project. The values have been validated by comparison with measured data or by wider peer review within the British Occupational Hygiene Society (BOHS) and the British Institute of Occupational Hygienists (BIOH) (Maidment, 1998). A list of criteria documents which were used for the comparison with measured data is given in Maidment, 1998, however, for this comparison already the final exposure ranges have been used. No further explanation of the derivation of exposure ranges is provided.
A general observation is that upon changing the control approach or the exposure predictor band to the next band the exposure result of the EMKG-EXPO-TOOL is modified by a factor of 10.

Table 7.4 Derivation of exposure predictor bands (HSE, 2009)

Solids			
Low dustiness	**Medium dustiness**	**High dustiness**	**Exposure Predictor Band**
Grams	Grams		EP1 Solid
Kilograms and tonnes		Grams	EP2 Solid
	Kilograms	Kilograms	EP3 Solid
	Tonnes	Tonnes	EP4 Solid
Liquids			
Low volatility	**Medium volatility**	**High volatility**	**Exposure Predictor Band**
Millilitres			EP1 Liquid
Litres and cubic metres	Millilitres	Millilitres	EP2 Liquid
	Litres and cubic metres	Litres	EP3 Liquid
		Cubic metres	EP4 Liquid

Table 7.5 Output ranges of the EMKG-EXPO-TOOL/COSHH (HSE, 2009)

Solids Predicted exposure level for dust, mg/m^3				
Control approach	**EP Band 1 (g of low / medium dustiness solid)**	**EP Band 2 (g of high dusty solid, kg / t of low dustiness solid)**	**Band 3 (kg of medium/high dustiness solid,**	**EP Band 4 (t of medium / high dustiness solid)**
1	0.01 - 0.1	0.1 – 1	1 - 10	>10
2	0.001 - 0.01	0.01 - 0.1	0.1 - 1	1 - 10
3	<0.001	0.001 - 0.01	0.01 - 0.1	0.1 - 1
Liquids: Predicted exposure level for vapour, ppm				
Control approach	**EP Band 1 (mL of low VP liquid)**	**EP Band 2 (mL of medium / high VP liquid, L / m^3 of low VP liquid)**	**EP Band 3 (m^3 of medium VP liquid, L of medium / high VP liquid)**	**EP Band 4 (m^3 of high VP liquid)**
1	<5	5 - 50	50 - 500	>500
2	<0.5	0.5 – 5	5 - 50	5 - 500
3	<0.05	0.05 - 0.5	0.5 - 5	0.5 - 5

Table 7.6 Overall number of determinants and options within one determinant of the EMKG-EXPO-TOOL

	volatility/ dustiness	**scale of use**	**control strategy**	**short term exposure**	**application on surfaces**
solids	low/medium/ high	small/ medium/ large	general ventilation/ engineering control/ containment	yes/no	
liquids	low/medium/ high	small/ medium/ large	general ventilation/ engineering control/ containment	yes/no	yes/no

7.4.1 Underlying assumptions

An assumption within the tool is that the substance concentration in products is assumed to be 100% (ECHA, 2010b), thus, in case of mixtures a worst case scenario would be modelled. It is possible to pool several components within a product if they can be assigned to the same volatility band; otherwise they have to be treated separately (Tischer, 2012, personal communication).

7.5 Transparency

Tool development and datasets
A general description of the EMKG concept is available (Kahl et al., 2008 and 2011), but the EMKG-EXPO-TOOL is not described in this publication in detail. The publications of Kahl et al, (2008 and 2011) are only available in German language. Some additional information can be found in a validation study published by Tischer et al., 2007 but it is important that almost all publications on this topic (except Kindler et al., 2010) describe the concept (i.e. EMKG) and not the tool (i.e. EMKG-EXPO-TOOL). Thus a general documentation of the tool is not available.
For a thorough understanding of the tool it is crucial to refer to publications about COSHH essentials (e.g. HSE, 2009), although even here not all information has been documented. The exact process of model development and the derivation of output ranges or any kind of underlying dataset is not available (see Chapter 7.4 and Maidment, 1998).

Scope and algorithm
The differences between COSHH and the EMKG-EXPO-TOOL, i.e. changes derivation of the exposure estimate, are not publicly available at the moment. The external modelling procedure for application on large surfaces required some assumptions (e.g. control level 1, sufficiently high ventilation rates, only two test situations were modelled, compare Chapter 7.2.3) which are reflected in the applicability of the newly introduced option. However via personal communication (Tischer, 2011) the crucial differences could be identified.
Deficiencies of the prediction quality of the EMKG-EXPO-TOOL, EMKG or COSHH are addressed via several validation studies (see Chapter 7.1 and Appendix 2). Most publications refer to the comparison with measured values – the model concept is discussed in Tischer et al., 2003a and 2003b.
There are some German control guidance sheets ("Schutzleitfäden") which are published separately[59] but a direct link to the download-page of the EMKG-EXPO-TOOL is not given at the BAuA-homepage and no direct link to the "Schutzleitfäden" or one of the COSHH-relevant pages is given at the download page of EMKG-EXPO. It is not clear, if all control guidance sheets are also usable for the EMKG-EXPO-TOOL, as there is only a limited number of "Schutzleitfäden", a much larger number of (partly branch specific) COSHH control guidance sheets and a very small number (4) of English written "Schutzleitfäden" (not included in the COSHH control guidance sheets) at the BAuA homepage.

[59] http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/EMKG/Schutzleitfaeden_content.html

It seems reasonable that the EMKG-EXPO-TOOL works also accurate for the branch specific control guidance sheets as COSHH and the EMKG-EXPO-TOOL use almost the same logic to estimate exposure but the link implemented in the EMKG-EXPO-TOOL refers only to general control guidance sheet (label "G*sheet number*"). It is not mentioned if the presence of the additional option "application on large surfaces" within the EMKG-EXPO-TOOL might influence the applicability of certain control guidance sheets together with the tool.

Structure of use

The EMKG-EXPO-TOOL is easy to overlook and the structure of use is quite straightforward. However no user guidance or manual for the tool is provided, so the user has to rely on the information provided within the tool itself (introductory text and help function) and the available publications.

An important potential source of confusion is that the connection between COSHH and the EMKG-EXPO-TOOL is not obvious at first sight (mentioned in Tischer et al., 2009 and Tischer et al., 2007), so an inexperienced or inattentive user might miss this critical link. A pop-up help window within the EMKG-EXPO-TOOL leads to the COSHH control guidance sheets but only the direct link is provided and no list of possible sheet numbers[60].

The link cannot be copied directly but has to be written down by hand and inserted into the browser – a fact that decreases the user friendliness.

The help function is mentioned in the "limitations" worksheet, however if a user does not use the EMKG-EXPO help function (i.e. the red "?" button), it is not unlikely that he completely misses the necessity of any further advice and only refers to the short descriptions of the control levels implemented within the tool (general ventilation, engineering control, closed system).

The control guidance sheets are mentioned in the help function within the tool but not in the introductory text, and not at www.reach-clp-helpdesk.de, where the tool can be downloaded. On the other hand the EMKG-EXPO-TOOL is not mentioned on the BAuA homepage, where German versions of the control guidance sheet are available.

Some control guidance sheet-numbers in the list provided at the OEHC webpage (http://oehc.uchc.edu/news/Control_Guidance_Factsheets.pdf) contradict the assigned control approach, e.g. control guidance sheet G204 is also listed under control approach 3. Some control guidance sheet refer to general control approaches (e.g. general ventilation) while others describe a specific task. Some "Schutzleitfäden" refer only to one exposure route (e.g. skin). Control guidance sheets for a forth level of control exist (HSE, 2009) but this level is not covered in EMKG-EXPO.

[60] http://www.coshh-essentials.org.uk/assets/live/g###.pdf

7.6 Conclusion

A general summary of covered determinants and their assignment to the different elements (personal protective equipment, process description and operational conditions, risk management measures, intrinsic substances properties) defining exposure (Cherrie et al., 1996, see also Chapter 3) is shown in Table 7.7. The number of categories per tool parameter is given in brackets after each determinant.

It can be stated that the basic elements except PPE are covered, although the process description is only implemented via external control guidance sheets.

One conceptual evaluation (referring to COSHH) was published by Tischer et al. (2003b) and came to the result that, although the concept and combination of input parameters make intuitive sense no stringent scientific justification for the allocation to exposure categories within the tool is provided. This statement is supported by this evaluation. The basic requirements for a Tier 1 model are fulfilled for the EMKG-EXPO-TOOL but the transparency of the model and its development is very low and can therefore not be reproduced.

The structure of use of EMKG-EXPO-TOOL is very clear. The tool is easy to oversee and easy to handle. But as no documentation or any tool-specific advice is provided neither derivation of the exposure estimate nor tool development can be called transparent.

Some sources of uncertainty exist within the tool which includes among others the vagueness of input parameters like the dustiness, and the assumptions underpinning the “application on large surfaces” option (see also Chapter 7.2.3).

The exposure result is quite rough and in range format, which might lead to misunderstandings corresponding to the correct interpretation of this range in relation to a certain limit value.

Overall it can be summarised, that if the user is aware of its crudeness and limitations this tool can be very useful for Tier 1 screening purposes. It is important to create more transparency, make clearer that control guidance sheets are mandatory for a successful use of the tool and provide a sufficient documentation and user guidance that can be found easily.

However, if the user refers to control guidance sheets he has access to very clearly described exposure situations and thus, the possibility of an error caused by an imprecisely defined workplace is very low.

Table 7.7 Number of categories per determinants (in brackets) and assignment to four broad exposure defining elements (see also Chapter 3).

Intrinsic substance properties	**Process description / operational conditions**	**Risk management measures at source**
dustiness (3 categories)	process temperature (3 categories)	level of control (3 categories)
boiling point or vapour pressure (3 categories)	duration (2 categories)	
	amount of substance (3 categories)	
	application on large surfaces for liquids (1 category)	
	process description (only via control guidance sheets)	
	good occupational hygiene is assumed	

Suggestions:

- Clarify the connection between control guidance sheets and the EMKG-EXPO-TOOL - perhaps via implementation of direct links to the corresponding pages.
- Publish a documentation or manual that refers exclusively to the tool (to prevent confusion with the EMKG) and includes the background to tool development, a list of control guidance sheets, the most important features which were adopted and adapted from COSHH, differences between both approaches and the underlying assumptions.

8 STOFFENMANAGER©

8.1 Introduction

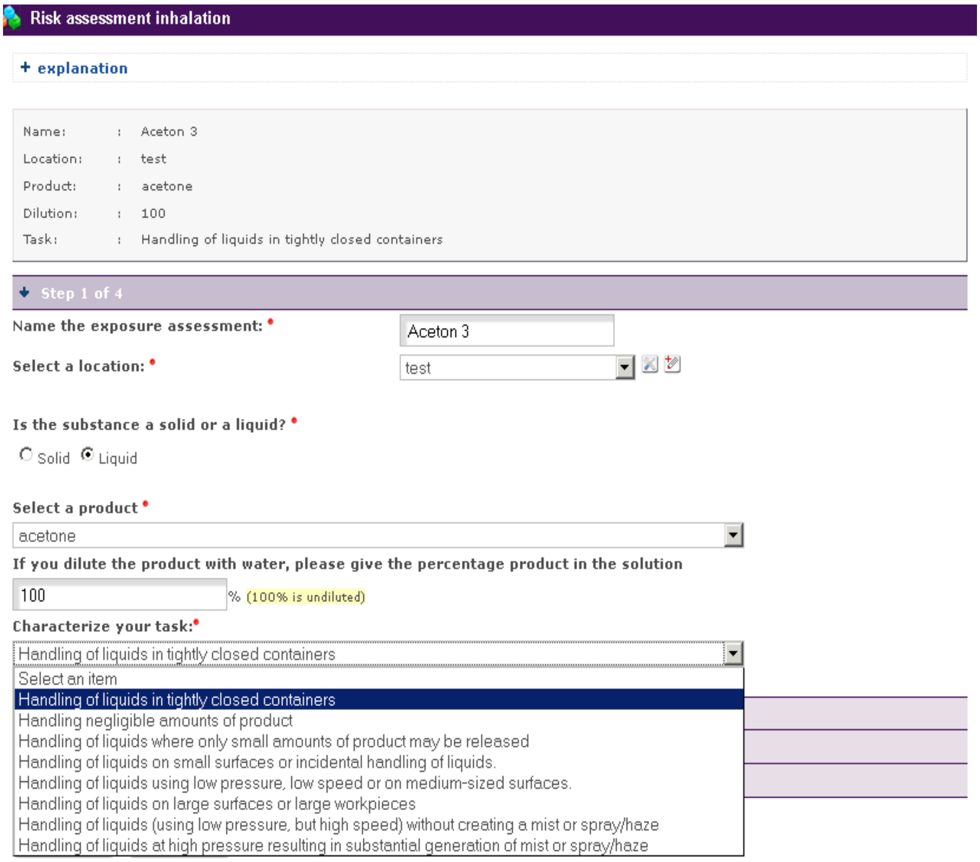

Figure 8.1 Screenshot of the STOFFENMANAGER© tool, Version 4.5 (28.11.2011)

STOFFENMANAGER© was developed by TNO (Netherlands Organisation for Applied Scientific Research) and Arbo Unie (Occupational Health Service), Expert Centre for Chemical Risk Management, with the project numbers V7714/EC345-07[61] and V7714/EC346-07[62] (TNO, 2007a and TNO, 2007b). The tool is connected to the so called "VASt programme", a program that was established by the Dutch Ministry of Social Affairs and Employment (SZW) to assist small and medium sized enterprises in reinforcing the working condition policy on hazardous substances (see also Chapter 8.3).

STOFFENMANAGER© is a web-based tool, consisting of several distinct parts;

- a control banding tool which combines a hazard banding scheme similar to EMKG and COSHH Essentials with an exposure banding scheme and covers both dermal and inhalation exposure;

[61] V7714/EC345-07 - Stoffenmanager, a web-based control banding tool using an exposure process model

[62] V7714/EC346-07 - Stoffenmanager exposure model: development of a quantitative algorithm

- a control banding part designed especially for exposure to engineered nanomaterials (online since version 4.5 of STOFFENMANAGER©);
- a quantitative inhalation exposure assessment tool for estimating occupational exposure; and
- a quantitative inhalation exposure assessment tool for estimating occupational exposure, specifically designed for REACH.

Both quantitative parts share the same algorithm for estimating inhalation exposure (see Chapter 8.2 and 8.4) but show some differences concerning the specific design and implemented functionalities. In this project, only the quantitative REACH worker part will be evaluated.

STOFFENMANAGER© is available free of charge after registration on the STOFFENMANAGER© homepage[63]. It is easy to find via a simple Google search. The tool offers English, Finnish (as off 1st July 2012) and Dutch versions (version 4.5) at https://www.stoffenmanager.nl/Default.aspx and also a German translation (only version 4.0) at https://gestis-stoffmanager.dguv.de/.

Publications

A number of publications concerning the development and further refinement of STOFFENMANAGER© are available. In Marquart et al., 2008 (and the corresponding project report TNO, 2007a) the development of the underlying model basis, which is the same for control banding and the quantitative part of STOFFENMANAGER©, is described, while in Tielemans et al., 2008b (and project report TNO, 2007b) the quantification of the model algorithms (i.e. the calibration with measured data) is summarised.

Schinkel et al., 2010 published a validation of STOFFENMANAGER© and described the refinement of STOFFENMANAGER© by including the validation datasets into the underlying database. Koppisch et al., 2012 described another validation. In Van der Ven et al., 2010 further development of the STOFFENMANAGER© algorithm with a company-specific Bayesian methodology is described. The results of the available validation studies are summarised in Appendix 2.

8.2 Tool description

8.2.1 Scope

STOFFENMANAGER© was designed to be used by small and medium sized enterprises for risk assessment purposes. It was not originally intended to be used under REACH but offers a REACH specific exposure part and suggestions for "translations" into the use descriptor system according to ECHA, 2010a shall be implemented in one of the subsequent versions of STOFFENMANAGER©.

It is a task-based tool, thus, for an exposure estimation of the whole workflow the different tasks contributing to the corresponding process have to be added up (Koppisch et al., 2012). STOFFENMANAGER© can take into account near-field and far field sources ("Is there more than one employee carrying out the *same* task

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[63] A new version version of Stoffenmanager is planned for 2012, whose REACH part will only be available in a paid subscription form. The other parts of the tool will still be available free of charge.

simultaneously?"; "Is the task followed by a period of evaporation, drying or curing?"). Other sources in the same room are not considered.

Table 8.1 Parameters for the definition of "components" and "products" within STOFFENMANAGER© (www.stoffenmanager.nl)[64]

	Parameter	**Comment**
Component	Name	only for documentation
	CAS-number	only for documentation
	molecular weight	only for documentation
	exposure limit (mg/m3)	
	type of the exposure limit	e.g. DNEL
	vapour pressure (Pa)	No default value will be used. If no vapour pressure is entered then no calculation will be made and an error message will occur. The unit is mentioned only in the general quantitative section and not in the REACH specific part.
Product	product name	only for documentation
	date of MSDS (material safety data sheet) creation	only for documentation
	supplier + contact data	only for documentation
	Additional information about hazard statements and precautionary statements	Not mandatory. "Not applicable" can be chosen if no information about H- and P-phrases is available.
	concentrations of the different components within a product (free number)	It is not defined if the concentration should be provided as mole % or weight %, although the underlying publications (Marquart 2008, Tielemans 2008b) suggest the latter.
	vapour pressure (Pa) or dustiness	Vapour pressure (used for the control banding part but only for documentation in the REACH worker part). If the vapour pressure is not known the vapour pressure of water at 20°C will be used as a default.

Some limitations of the tool are listed on the STOFFENMANAGER© homepage[65]. Exposures to fibres, gases or substances released into the air as an effect of welding or soldering are outside the scope of the tool. Assessments for abrasion and impact of solid objects are only possible for stone and wood. Exposure to respirable dusts is only implemented for comminuting activities on stone (since April 2012). A summary of STOFFENMANAGER©'s applicability domain can be found in Figure 8.2.

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[64] It is planned for the next version of Stoffenmanager to implement only input fields which are actually needed for the exposure assessment (state of affairs on 20.04.2012).

[65] www.stoffenmanager.nl

8.2.2 Model, parameters and structure of use

STOFFENMANAGER© is based on a refined version of the conceptual model described by Tielemans et al., 2008a (see Chapter 3) which has been published in Marquart et al., 2008. It applies a scoring system based on a logarithmic scale to the exposure determinants (e.g. intrinsic properties, control measures).The combination of these scores leads to an overall concentration score C_T. These model scores are converted from semi-quantitative outputs into quantitative following calibration of the algorithms using a set of exposure measurement data (see Chapter 8.4).

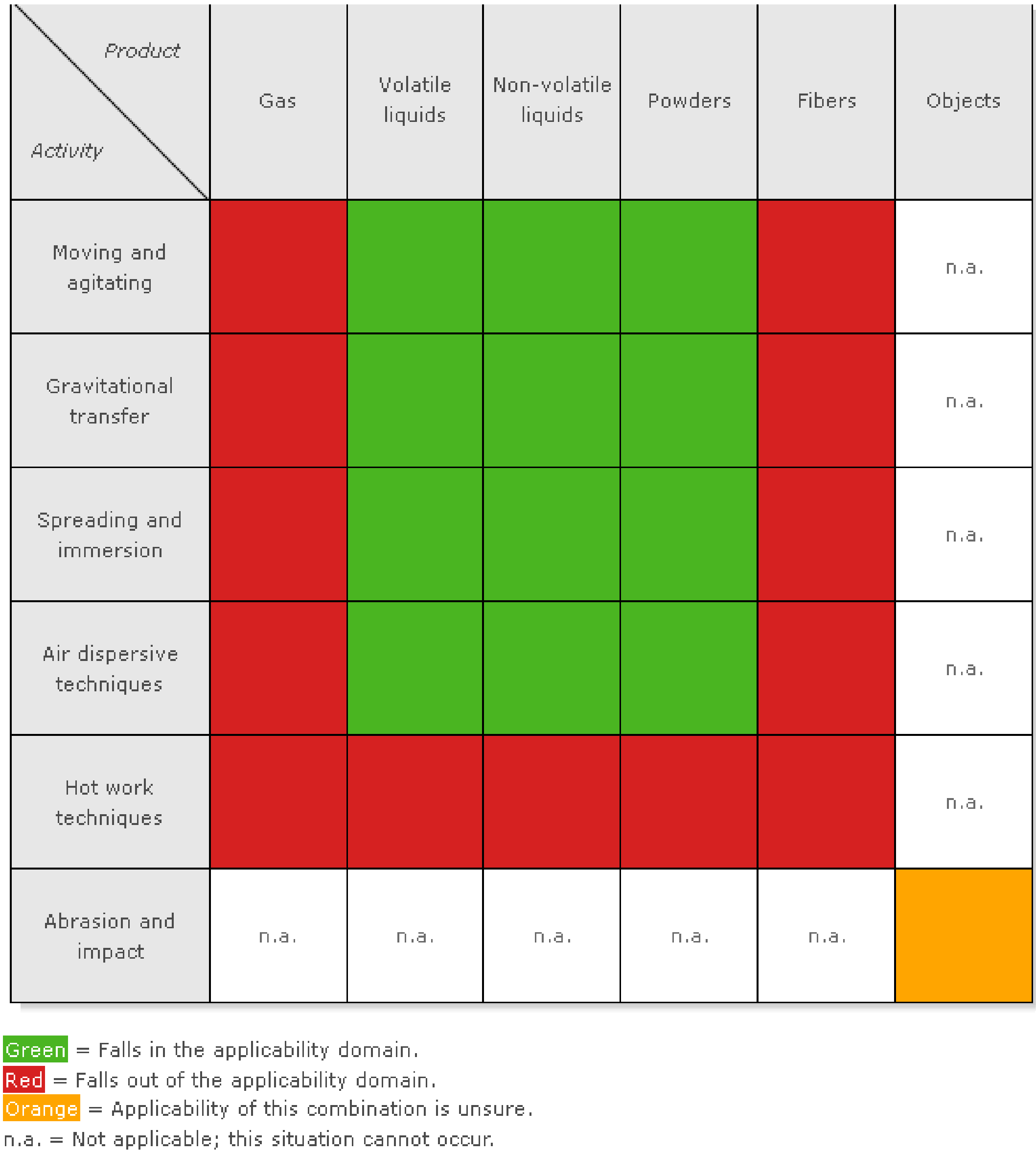

Figure 8.2 The applicability domain for the qualitative inhalation exposure model (www.stoffenmanager.nl)

Table 8.2 List of handling categories (www.stoffenmanager.nl)

handling categories			
Solid			**liquid**
no cutting or removing of material	**shaping by removing or cutting of material: wood**	**shaping by removing or cutting of material: stone**	
handling of product in closed containers	mechanical sanding of wood	mechanical sawing and sanding of stone	handling of liquids in tightly closed containers
handling of product in negligible amounts	mechanical handling of wood resulting in fine dust	mechanical handling and demolition of stone resulting in fine dust	handling negligible amounts of products
handling of product in very small amounts or in situations where release is highly unlikely	mechanical handling of wood resulting in coarse dust of chips	low energy mechanical handling of stone	handling of liquids where only small amounts of product may be released
handling of product in small amounts or in situations where only small quantities of products are likely to be released	manual sanding of wood	low energy mechanical handling of stone resulting in less dust	handling of liquids on small surfaces or incidental handling of liquids
handling of product with low speed or with little force in medium quantities	low energy mechanical handling of wood resulting in less dust		handling of liquids using low pressure, low speed and/or[66] on medium-sized surfaces
handling of product or treatment of objects with a relatively high speed/force which may lead to some dispersion of dust	other manual handling of wood		handling of liquids on large surfaces or large work pieces
handling of product or treatment of objects, where due to high pressure, speed or force large quantities of dust are generated and dispersed			handling of liquids (using low pressure, but high speed) without creating a mist or spray/haze
handling of very large amounts of product			handling of liquids at high pressure resulting in substantial generation of mist or spray/haze

To estimate exposure, the user is first asked to describe the relevant components (i.e. single substances) and to define the corresponding product that may contain one or more of the components. Mandatory input parameters are summarised in Table 8.1, although not all of the parameters are used in the exposure estimation algorithm. Next, the fugacity is defined using either the vapour pressure of the component in case of liquid product, or the dustiness in case of solid products. The dustiness of the

[66]The English version of Stoffenmanager uses “or” and the Dutch version “and” – which word leads to the correct description of the use category still has to be clarified. The fact, that in Marquart et al., 2008 also “and” is used, suggests that this option is the correct one.

product is divided into six categories (objects, solid granules/grains/flakes, granules/grains/flakes, coarse dust, fine dust, extremely dusty products).
STOFFENMANAGER© relies on generic task descriptions. Task categories and options for control measures available within the tool are summarised in Table 8.2, Table 8.3 and Table 8.4. Examples for the different tasks are provided via small help-texts. In STOFFENMANAGER©, the task description ("handling of…") is mixed with information about the amount of substance. They differ between products of different physical states. Additionally, the tool is able to differentiate between chemicals in general and wood- or stone related tasks.

The current version of STOFFENMANAGER© (21.06.2012) does not use the use descriptor system according to ECHA, 2010a. The model developers are planning to include a table suggesting relations between PROCs and handling classes. However, all combinations of handling classes and PROC numbers will still be possible. A draft version of the conversion system between STOFFENMANAGER© handling categories and PROC numbers was made available for this project and could be used for comparison purposes (Marquart, 2011; see also Appendix 6, Appendix 5 and Introduction).
The exposure assessment for a liquid product (inclusive solids solved in liquids) contains the exposure results for each component of the product based on their vapour pressure. In case of solid products, the overall dust of the product is estimated.
The results of the exposure assessment are presented in graphical form (unit mg/m^3) including a table with the exposure values corresponding to the 50^{th}, 75^{th} and 95^{th} percentile (see also Figure 8.3)[67].
It is possible to create reports of the assessment in *.doc format, which contain tables with the main information. Although a limit value like the DNEL can be entered no calculation of the RCR is implemented.

Two minor problems have been identified:
- The help function (pop-up window) for limit values did not work (state of affairs 01.02.2012).
- No unit for vapour pressure of the components is provided.

8.3 Empirical exposure data used for model development

8.3.1 Description of datasets

Published information (Tielemans et al., 2008b and Schinkel et al., 2010):
The original database of STOFFENMANAGER© is described in Tielemans et al., 2008b and resulted in the first quantitative version of this tool. After a validation study in 2010 (Schinkel et al., 2010) it has been extended with the corresponding validation measurements and a refinement of the model algorithms was performed.

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[67] It is planned to implement numerical results for the 50^{th}, 75^{th}, 90^{th} and 95^{th} percentile in the a later version of Stoffenmanager. No graphical output will be provided in this version anymore (Marquart, 2012; personal communication).

A database (STEAMbase[68]) was created for the collection of datasets for the STOFFENMANAGER© calibration and validation. The data within this database originated from three sources:

- ❖ Measurement surveys carried out in SMEs in The Netherlands especially for the use in the calibration of STOFFENMANAGER©. No details about the age of these data are given.
- ❖ Additional occupational exposure data sets from the archives of TNO from research projects funded by the Dutch Government in past years. Some underlying publications (published between 1994 and 2007) where details about the datasets can be found are listed in Tielemans et al., 2008b. In Schinkel et al., 2010 no information about the age of the datasets or underlying publications is given or on the size of companies (e.g. whether the data are from SMEs).
- ❖ The network of the VASt program was used to collect exposure data. This program was established by the Dutch ministry of social affairs and employment to assist SMEs in reinforcing the working condition policy on hazardous substances. A link to the homepage is given in Tielemans et al., 2008b (http://vast.szw.nl/)[69]. Further information about this program is not provided. The year the data were collected is not mentioned.

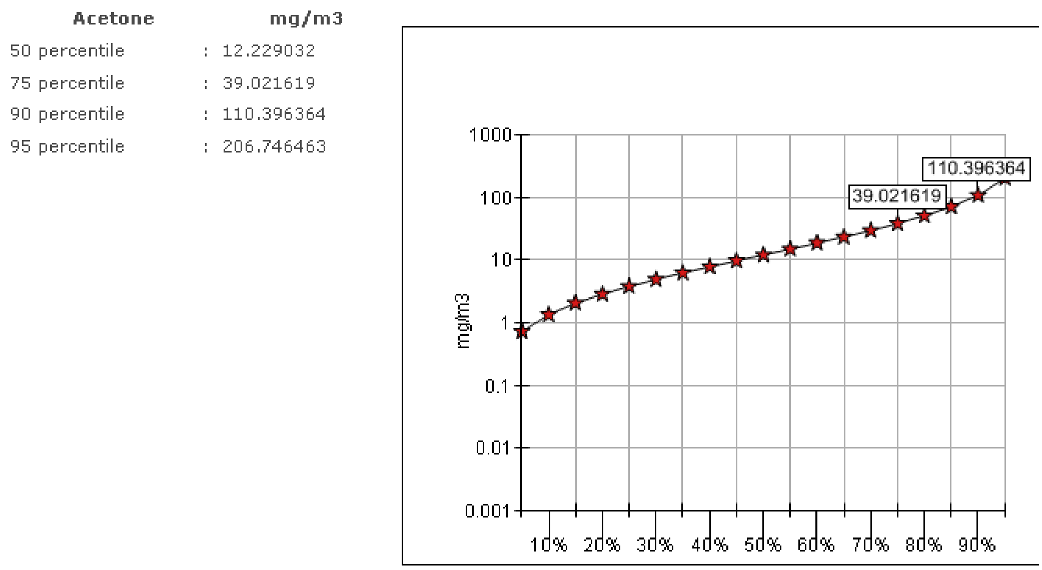

Figure 8.3 Screenshot of the graphical output of the quantitative exposure part of STOFFENMANAGER©

[68] STEAMBASE is an inhalation exposure database, whose structure follows the principles and parameters of the Stoffenmanager algorithm. It can be found at http://steambase.stoffenmanager.nl/but there is no open access to the database and no registration is possible, so details of the datasets are not publicly available. STEAMbase refers to“SToffenmanager Exposure and Modelling database”.

[69] At the time of writing, this website no longer appeared to be live

Table 8.3 Additional options to describe the exposure situation: RMMs, PPE, worker situation, information about room and ventilation, frequency of handling and duration of handling

duration of handling[70,71]	frequency of handling[70]	room size	ventilation	RMMs	worker situation	PPE
0-30 min	once per year	<100 m^3	no ventilation	LEV	worker is in separated room with fresh air supply	Filter mask (FFP2, FFP3)
30-120 min	once per month	100-1000 m^3	open windows	use of product that reduces emission	worker is in open or closed cabin without special ventilation system	Half mask respirator with filter (P2L, P3L)
2-4 h	once every two weeks	>1000 m^3	mechanical general ventilation	containment of source	The worker is not working in a cabin (default and not changeable if task is carried out in breathing zone of worker)	Full face respirator with filter (P2L, P3L)
4-8 h	once per week	Outdoors	spraying booth	containment of source and LEV		Half/full face powered air respirator (part.cartridge) (TMP1, TMP2, TMP3)
	2-3 times per week			no RMM		Full face powered air respirator (TMP3)
	4-5 times per week					Hood or helmet with supplied air system (TH1, TH2, TH3).

Table 8.4 Additional options for the description of the exposure situation

Is the working room being cleaned daily?
Take inspections or maintenance of machines place once monthly?
Is the task carried out in the breathing zone of an employee? (if “no” is chosen, the next two options (more than one employee is carrying out the task, period of evaporation) are not applicable anymore. If 'yes' is chosen, the option 'the employee does not work in a cabin' is chosen automatically
Is more than one employee is carrying out the task?
Is the task followed by a period of evaporation, drying or curing?
Is the product diluted with water? (free text field)

[70] These options do not influence the exposure estimation.
[71] Will be implemented in the next version of Stoffenmanager (state of affairs on 20.04.2012).

The data collected for Tielemans et al., 2008b were ranked into one of three quality categories and only good measurements were used for the analyses and published in Tielemans et al., 2008b and stored in STEAMbase. Datasets were only labelled as "good", if core information was available (see e.g. Tielemans et al., 2002); all STOFFENMANAGER© parameters could be retrieved and if the time registration was accurate.
The samples had to be personal exposure measurements taken from the breathing zone of a worker (Tielemans et al., 2008b; Schinkel et al., 2010). Sampling methods are described in Tielemans et al., 2008b. STEAMbase contains both task-based and shift-based measurements. For the evaluation and refinement of the tool in Schinkel et al., 2010, all data in this database, that were not already in the STOFFENMANAGER© calibration database and matched the quality criteria (sufficient contextual information, sample strategy and sample technique had to be documented) were used.

The limit of detection (LOD) was defined as the average weight difference of the blank filters plus three times the standard deviation. For exposure values below this detection limit a value of 0.5 x LOD was used. Schinkel et al., 2010 does not include a description of approaches used to deal with results below the LOD.
The covered types of industries, the numbers of measurements and some statistical data on the corresponding exposure measurements as published in Tielemans et al., 2008b and Schinkel et al., 2010 are summarised in Table 8.5 and Table 8.5. Overall STOFFENMANAGER© is based now on 951 measurements (520 for solids, 431 for liquids) which are spread over various industries, substances and exposure situations. The dust measurements refer to overall inhalable dust concentrations. Some additional statistical output (e.g. bias and precision) are provided by Tielemans et al. (2008) and Schinkel et al. (2010).
Exposures to respirable dust, gases or fibres were not part of the studies currently published and thus, they are mostly beyond the validity of STOFFENMANAGER© (Tielemans et al, 2008b, Schinkel et al., 2010, see also paragraph about "Recent changes" later in this chapter.

Recent changes (Marquart, 2012; personal communication)
Since April, 2012 STOFFENMANAGER© is able to estimate exposure to respirable dust for comminuting activities on stone. For this purpose it has been calibrated with a set of measurements collected from TNO, Arbo Unie, Arbouw, IOM and the MEGA database. 146 measurements from 35 different companies have been fitted to the STOFFENMANAGER© model equation (see Chapter 8.4) to provide a separate exposure result for respirable dust. These datasets have not been used to modify the inhalable dust algorithm of STOFFENMANAGER©. Some preliminary information about this development has been provided by Hans Marquart (2012, personal communication), however, as this modification of the tool was not published yet when this report was created it will not be discussed here in detail.

8.3.2 Limitations of the datasets

Most if not all of the measurements on which the calibration of STOFFENMANAGER© is based were performed in SMEs in the Netherlands. Some parameter classes present within the STOFFENMANAGER© algorithm (see Chapter 8.4) are not or only to a limited extent covered by data. This applies for example to the following areas (Tielemans et al., 2008b):

- For solids: outside work, solids with very low intrinsic emission scores (e.g. firm granules or flakes), enclosure, LEV in combination with enclosure and wetting, no respirable dust concentration.
- For liquids: handling score 0.1 (small amounts of substances/release highly unlikely), enclosure and LEV in combination with enclosure.
- No glove boxes were within the database, no wet suppression techniques, no processing of melted or burning materials, no hot work techniques.

Respirable dust measurements are only available for a limited number of scenarios (comminuting activities on stone, see Chapter 8.3). All other samples represent inhalable dust exposure.
No gases or fibres are present in the database.

8.4 Derivation of final exposure output

The basis of the quantitative STOFFENMANAGER© algorithm is identical to the control banding part of the tool, which is described in Marquart et al., 2008. It is based on the conceptual model published in Tielemans et al., 2008a, which in turn is based on the earlier work of Cherrie et al., 1996 (see Chapter 3). The approach differs only in the following details from the model described previously in Tielemans et al., 2008a:

- a frequency of handling f_h, is introduced
- slight differences concerning the implementation and definition of passive emission ε_p and duration of task $t_a$exist:passive emission scores for near field and far field are now treated together and $t_{a,NF} = t_{a,FF}$
- the “near field” is defined by a sphere around head instead of a cube
- no separate consideration of segregation, separation and personal behaviour

A scoring system was applied for the exposure determinants (e.g. intrinsic properties, control measures). The scores are on a logarithmic scale and are used to discriminate between different exposure situations. The combination of those scores leads to an overall concentration score C_T that describes the exposure at a workplace (see below). Categorization of the parameters and the allocation of scores for categories in STOFFENMANAGER© are partly taken from Cherrie et al., 1996. Some categories or definitions have been changed by Marquart et al. In these cases the final allocations were largely based on scientific knowledge of the model developers All scores representing handling, RMMs or other parameters of the exposure situation implemented in STOFFENMANAGER© are provided in Marquart et al, 2008. Thus, they enable the recalculation of C_T.

In the following paragraphs the underlying principles and equations which lead to the final exposure score are summarised (Marquart et al., 2008):

Table 8.5 Descriptive statistics of available measured exposure data: Solids[72] (Schinkel et al., 2010; Tielemans et al, 2008b)

Type of industry / study	N	K	Median sampling time (min)	AM (mg m^{-3})	GM (mg m^{-3})	GSD	Range (mg m^{-3})
Overall	*520*	*104*					*0.0004-646.4*
Pharmacies[73]	78	9	14	0.17	0.05	5.55	0.0004–2.63
Bakeries[73]	56	17	382	2.75	1.31	3.18	0.05–48.0
Construction industry[73]	74	20	230	28.4	14	3.02	1.31–310
Experimental study[73]	36	1	15	84.3	36.2	4.01	5.22–313
Woodworking industry[73]	23	5	250	2.18	1.27	3.11	0.20–7.20
Fertilizer industry[73]	6	1	465	1.76	1.16	2.7	0.42–5.12
Dairy industry[73]	3	1	391	1	0.73	2.85	0.24–1.92
Animal feed industry[73]	40	4	248	4.53	1.62	4.1	0.18–54.5
Metal industry[73]	4	3	199	32.3	7.99	10	0.74–94.6
Transshipment industry[73]	5	2	301	11.3	7.97	3.11	1.20–21.3
Transshipment industry[74]	38	3	173	90.7	12.4	9.19	0.25-646.4
Rubber / plastic industry[73]	4	1	147	19.4	12.2	3.05	3.50–51.8
Textile industry[73]	28	6	233	0.5	0.25	3.04	0.06–4.82
Publishing company[73]	1	1	447	0.53	0.53	—	—
Paint industry[73]	20	10	53	74.3	31.9	4.26	1.90–420
Carbon black industry[74]	10	1	115	6.09	2.34	4.69	0.2-30.8
Cardboard industry[74]	2	1	395	0.35	0.32	1.91	0.2-0.5
Cement industry[74]	12	1	121	9.54	5.75	2.52	1.8-49.5
Chemical production industry[74]	1	1		10	79.9	79.9	79.9-79.9
Metal industry[74]	3	2	348	10.4	5.99	3.5	2.82-25.4
Paving[74]	20	1	227	0.32	0.28	1.68	0.13-0.63
Pottery[74]	4	1	323	1.37	1.17	1.84	0.71-2.8
Waste processing[74]	4	1	330	13.1	5.51	5.16	0.87-39.1
Railway maintenance[74]	10	1	105	4.19	2.55	2.93	0.61-16
Refinishing[74]	8	1	58	11	1.41	19.7	0.03-39
Woodworking industry[74]	30	9	307	4.22	1.84	2.79	0.3-60.5

[72] N: Number of samples, K: number of companies, AM: Arithmetic mean, GM: Geometric mean, GSD: Geometric standad deviation
[73] Tielemans et al, 2008b
[74] Schinkel et al, 2010

Table 8.6 Descriptive statistics of available measured exposure data: Liquids[1] (Schinkel et al., 2010; Tielemans et al, 2008b)

Type of industry / study	**N**	**K**	**Median sampling time (min)**	**AM (mg m^{-3})**	**GM (mg m^{-3})**	**GSD**	**Range (mg m^{-3})**
Overall	*432*	*141*					*0.0002-2762*
Pest and control/disinfection[73]	16	9	92	0.03	0.003	6.66	0.0003–0.34
Pest and control/disinfection[73]	29	1	61	0.03	0.02	2.64	0.004–0.21
Pest and control/disinfection[73]	14	10	32	0.09	0.05	2.93	0.01–0.42
Pest control[74]	21	10	305	0.05	0.02	4.28	0.004-0.34
Boatyards (antifouling paint)[73]	31	8	70	1.32	0.38	6.29	0.007–9.03
Agriculture[73]	19	9	41	0.004	0.003	2.43	0.0005–0.01
Agriculture[73]	17	17	69	0.01	0.004	5.14	0.0002–0.03
Agriculture[74]	9	1	7	0.02	0.01	2.4	0.002-0.06
Car body repair shops[73]	90	17	9	0.58	0.08	13.6	0.0006–4.52
Car body repair shops[73]	15	8	10	59.3	4.67	9.98	0.36–563
Car body repair shops[74]	1	1	19	135.9	135.9		135.9-135.9
Car body repair shops[74]	7	3	6	0.82	0.07	21.3	0.004-2.87
Metal industry[73]	56	14	24	175	56.7	5.9	1.06–1572
Orthopaedic shoe manufacturing[73]	26	10	510	257	128	3.5	10.4–1762
Orthopaedic shoe manufacturing[74]	7	6	510	89.2	77.5	1.79	37.5-152.3
Silkscreen printing industry[73]	7	2	293	8.84	4.72	5	0.23–17.2
Silkscreen printing industry[74]	1	1	452	16.3	16.3		16.3-16.3
Metal industry[74]	6	1	74	123.8	87.1	2.58	31.8-299.8
Shoe repair industry[74]	24	4	510	43.1	34	2.06	6.37-121
Chemical production industry[74]	15	2	62	37.7	6.79	7.28	0.43-210
Furniture industry[74]	13	4	145	118	67.2	4.06	2.7-252.7
Transport[74]	1	1	40	189.6	189.6		189.6-189.6
Cleaning industry[74]	5	1	354	0.08	0.04	5.24	0.01-0.15
Textile industry[74]	2	1	214	0.01	0.01	1.47	0.01-0.02

$B = C_T \cdot t_a \cdot f_h$:

- B: exposure score
- C_T: total concentration score
- t_a: duration of handling/source activity
- f_h: frequency of handling

$C_T = (\varepsilon_p + C_{NF} + C_{FF}) \cdot \eta_{PPE}$

- ε_p: background concentration (=”diffusive sources”, e.g. dirt and dust on not regularly cleaned surfaces), passive emission
- C_{NF}: concentration score due to near field emission
- C_{FF}: concentration score due to far field emission
- η_{PPE}: modifier for the reduction of exposure due to control measure at the worker

$\varepsilon_p = \varepsilon_i \cdot a$

- ε_i: intrinsic emission score of substance i
- a: multiplier for the relative influence of background sources. Three categories for this parameter are provided. a depends on regular inspections and cleaning which are not covered by far-field sources. Examples for this type of exposure are spills that have not been cleaned up, leaking machinery and contaminated rags. a is multiplied by the intrinsic emission potential ε_i of the substance to obtain ε_p, thus, a highly volatile substance will always give higher background exposure values than substances with low volatility.

$C_{NF} = \varepsilon_i \cdot h \cdot \eta_{lc} \cdot d_{gv,NF}$

- h: handling (or task) score. STOFFENMANAGER© aimed to provide descriptions and discriminating categories assigned to this score that are understandable by small and medium sized enterprises
- η_{lc}: multiplier for the effect of local control measures
- $d_{gv,NF}$: multiplier for the effect of general ventilation in relation to the room size on the exposure due to near-field sources

$C_{FF} = \varepsilon_i \cdot h \cdot \eta_{lc} \cdot d_{gv,FF}$

- $d_{gv,FF}$: multiplier for the effect of general ventilation in relation to the room size on the exposure due to far-field sources

Final equation:

$B = [(\varepsilon_i \cdot h \cdot \eta_{lc} \cdot d_{gv,NF}) + (\varepsilon_i \cdot h \cdot \eta_{lc} \cdot d_{gv,FF}) + (\varepsilon_i \cdot a)] \cdot \eta_{PPE} \cdot t_h \cdot f_h$

B is the final, semi-quantitative exposure score.

All parameters, except ε_i in case of liquids which is derived directly from the vapour pressure, are categorical parameters. The derivation of ε_i follows a simple approach:

$\varepsilon_i = p_{vap} \cdot 30000^{-1}\ Pa^{-1}$ (p_{vap} = vapour pressure)

This equation is based on the principle that substances with a vapour pressure of 30000 Pa (= 0.3 bar) or more are fully evaporated, so the ratio should give a type of “relative evaporation factor”. All substances with p_{vap} smaller or equal to 10 Pa show

the minimum score for vapour pressure (10), all substances with p_{vap} larger or equal to 30000 Pa the maximum score (i.e. 30000) (Tielemans et al., 2008b).
For mixtures ε_i is represented by the sum of the percentage weighted emission potentials of the single components.

$$\varepsilon_i = \frac{P_1}{30000} f_1 + \frac{P_2}{30000} f_2 + \ldots + \frac{P_n}{30000} f_n$$

For solids a table is provided that describes the dustiness scores ε_i with weighing factors (0, 0.01, 0.03, 0.1, 0.3, 1) and short, qualitative descriptions of typical materials for each category.
To provide quantitative exposure predictions (i.e. with units in mg/m^3) the semi-quantitative exposure scores were calibrated with measured data. Thus, concentration scores (C_T) were derived for each situation included in the underlying database (see Chapter 8.3) and the final exposure outputs of STOFFENMANAGER© were arrived by linking these concentration scores C_T to the measurements of the STEAMbase database (Tielemans et al., 2008b; Schinkel et al., 2010). Scores were assigned to the measurements based on the contextual information by one occupational hygienist and reviewed by a second one who was also involved in the development of the exposure algorithm. In case of inconsistencies a discussion with two additional experts took place. If multiple tasks appeared during a measurement, scores were calculated for each task and combined as time-weighted summation. After the assignment of scores (C_T) mixed-effect regression modelling with natural log-transformed exposure scores C_T as independent parameter and the natural log of exposure measurements as dependent variable was performed. Random between- and within-company components of variance were included. While the derivation of the C_T values is explained in Marquart et al. (2008) and the resulting C_T values are shown in two figures, no list of the single measurement values is published.

The following general model equation is used for the fitting process:

$$\text{Ln}(Y_{ij}) = X_{ij} = \beta_0 + \beta_1 \cdot \text{Ln}(C_T) + \delta_i + \varepsilon_{ij}$$

- Y_{ij}: exposure level for ith company and the jth worker
- X_{ij}: log-transformed exposure level
- β_0: intercept
- β_1: represents the fixed effect of the log of STOFFENMANAGER© scores, slope of the regression line
- δ_i: random effect of the ith company, variance σ^2_{bc}
- ε_{ij}: random effect for the jth worker in the ith company, variance σ^2_{wc}

In the first approach published in Tielemans et al., 2008b, the calibration resulted in two different model equations – one for solids and one for liquids. After the validation and model refinement published in Schinkel et al., 2010 the database was split up into four data sets, i.e. for “handling powders and granules” (n = 408 measurements), “handling resulting in comminuting” (n = 112 measurements), “handling low-volatile substances” (n = 256 measurements) and “handling volatile substances” (n = 176 measurements). Separate calibrations were carried for these four categories.

Following the calibration, the range of the handling parameter score was increased as the tool did not reflect the whole range of measured dust exposure which covered seven orders of magnitude (Schinkel et al., 2010). Therefore, the range of the handling parameter score was increased from two to three orders of magnitude (*h* = 0.03-30 instead of 0.1-10). A similar adjustment was performed for the handling of liquids (*h* = 0.03-10 instead of 0.1-10).

The model can be used to predict a geometric mean exposure $\hat{Y}$ using the following equation:

$$\hat{Y} = \exp[\beta_0 + \beta_1 \cdot \mathrm{Ln}(C_T)]$$

STOFFENMANAGER© uses the estimates of the variance in the empirical exposure data to describe the exposure distribution, thereby allowing the estimation of different percentiles of the exposure distribution. Assuming a lognormal distribution of the exposures, the geometric mean is multiplied with an uncertainty factor (*M*), for example M_{90}, to produce a 90th percentile:

$$M_{90} = \exp\left[1.28 \cdot \sqrt{\sigma_{bc}^2 + \sigma_{wc}^2}\right]$$

- σ_{bc}^2 : between company variance
- σ_{wc}^2 : within-company variance

It is stated in Tielemans et al, 2008b that the data used for tool development show substantial variability in exposure measurements within a certain STOFFENMANAGER© score.

8.4.1 Underlying assumptions

STOFFENMANAGER© is based on the following assumptions:

- It is assumed that the task duration is equal to the exposure duration (Marquart et al., 2008);
- A logarithmic scale is used for most variables (exception: fraction of substance, volatility);
- It is assumed that the exposure score is linearly dependent on the fraction of substance in a mixture (Tielemans et al., 2008b)[75];
- As information on the mole-fraction for a liquid mixture is usually not available, the mass fraction is used to predict partial vapour pressure (Tielemans et al., 2008b); and
- It is assumed that the exposure levels follow a log-normal distribution (Tielemans et al., 2008b).

[75] The same assumption applies to the exposure duration and frequency, which are not implemented in the REACH relevant part of Stoffenmanager.

8.5 Transparency

Tool development and datasets

A lot of information about the model algorithm, the underlying database, its deficiencies and the tool development is published in a number of peer-reviewed scientific articles (Tielemans et al., 2008b, Marquart et al., 2008, Schinkel et al., 2010) which are also cited at the STOFFENMANAGER© homepage (www.stoffenmanager.nl). The STOFFENMANAGER© homepage includes some information about recent changes in the “news” section, but this information is presented in a more general way and no details about extensions of the database or modifications in the model algorithm are given. No documentation of the different STOFFENMANAGER© versions or the changes in between these versions is available.

Scope and algorithm

A general impression of the quality of prediction can be extracted from statistical data about the measurements as published in Tielemans et al., 2008b and Schinkel et al., 2010 (e.g. Spearman correlation coefficients, explained total variance) but no user friendly summary of these results has been published.

Concerning the algorithm there is a lack of transparency that – although the equations and scores are all published in Marquart et al., 2008 – no efficiency or actual protection factor of the different RMMs has been provided that would make it easier to overlook the exposure estimation and to get an impression of the different results. This fact is caused by the composition of the model algorithm that includes background factors which are not influenced by RMMs and different algorithms for different types of substances[76].

The basis of the upper and lower vapour pressure borders (30000 Pa vs. 10 Pa, see Chapter 8.4) value is not explained.

The duration and frequency of a task can be entered during the description of the task and the measures surrounding it, but are not used for any type of calculation.

Although according to Tielemans et al., 2008b and Marquart et al., 2008 the exposure is linearly dependent on the fraction of substance in mixture, it is noted that it does not drop by a factor of two if the fraction of a component is lowered to 50% by diluting the product with water or by creating a mixed product. This phenomenon can be explained by the fact that the slope defining the relationship between the STOFFENMANAGER© score (which indeed drops about 50% if the concentration of the concentration of the component is reduced about 50%) and exposure value does not cross the origin.

Structure of use

The tool itself provides tips and help via the help function and small explanatory text passages. No user guide or documentation which summarises the most important facts in a user-friendly way has been provided.

A possible source of confusion is that two different quantitative exposure tool parts exist – the general and the REACH specific part. The general part offers some

[76] It is the intention that a future version will contain an output in REACH Exposure Scenario format that does include the actual protection factors assuming no background source and separate values for each algorithm calculated in the calibration of scores versus values (Marquart, 2012; personal communication)..

options which might also be useful in REACH context (e.g. estimation of daily average values). On the other hand it includes a set of additional control measures which can be applied after the risk assessment is finished. Some of them are already implemented in the regular measures describing the exposure situation which results in a doubling of model parameters.

In general it is not indicated within the tool, which parameters influence the exposure algorithm and which parameters are only entered for documentation reasons.

The tool includes some inconsistencies concerning the translation process from Dutch to English (typos and other errors).

The model algorithm and information about the underlying database (number of data points for different areas, background information) are presented in Tielemans et al., 2008b, Marquart et al., 2008 and Schinkel et al., 2010 in a transparent way and sufficient level of detail. The concept of linear mixed effect models may be difficult to grasp for many users who are not familiar with this topic.

Information about resulting efficiencies of different measures and the general use of the tool (i.e. a general user guidance and/or documentation) is also unpublished. The tool contains several sources of confusion (e.g. implementation of fraction of substance, existence of two quantitative exposure tools, see paragraphs above). Thus, although in principle all core information about the model basis is published, a user guide and/or documentation that includes some basic information about the major changes during the last years would be helpful.

8.6 Conclusion

In general STOFFENMANAGER© offers – for a Tier 1 tool – a high level of detail and thus, allows for a good description of the exposure situation. An overview of the implemented determinants and their division into the main elements defining exposure (see Chapter 3 and Cherrie et al., 1996) is given in Table 8.7. The number of categories per model determinant is given in brackets behind the corresponding parameter.

Sources of uncertainty like the definition and treatment of the limit of detection, other limitations of the database (see Chapter 8.3.2) and the underlying assumptions of the model algorithm (see Chapter 8.4) are present which will be discussed in detail in Work package II of this project.

As all tools which are fitted to a collection of measured datasets STOFFENMANAGER© should only be used for situations that are reflected within this database, otherwise accurate exposure estimations might not be guaranteed.

STOFFENMANAGER© is the only tool within this project which describes background factors and far-field factors in a transparent way and covers all relevant elements of an exposure assessment (Cherrie et al., 1996) using a reasonable set of determinants.

Both the STOFFENMANAGER© database and the development of the tool are well documented in different publications and project reports, although it requires some effort for non-experts to understand the model basis. Unfortunately no user guide or corresponding manual is available. This together with the fact that neither the changes between the different STOFFENMANAGER© versions nor initial concentrations within the exposure assessment or the efficiencies of RMMs are documented leads to a not perfect but still high transparency.

Thus, although the tool still has some room for optimisation it is quite transparent and useful in the exposure assessment process.

Table 8.7 Number of categories per determinants (in brackets) and assignment to four broad exposure defining elements (see also Chapter 3).

Intrinsic substance properties	**Process description / operational conditions**	**Risk management measures at source**	**Personal protective equipment**
volatility: vapour pressure (free text), dustiness (6 categories)	task descriptions (6 categories for wood, 4 for stone, 8 for liquids and solids (no removing or cutting of material))	ventilation (3 categories)	Filter mask (FFP2, FFP3)
physical state (solid/liquid)	room size (3 categories) or outdoors (1 category)	LEV (1 category)	Half mask respirator with filter (P2L, P3L)
concentration of component in product (free text)	worker situation (3 categories)	containment of source (1 category)	Full face respirator with filter (P2L, P3L)
dilution factor of product with water (free text)	task carried out in breathing zone (1 category)	containment of source and LEV (1 category)	Half/full face powered air respirator (part.cartridge) (TMP1, TMP2, TMP3)
	background influences, 1 category each: cleaning of room, inspections and maintenance, period of drying	use of a product that reduces emission (1 category)	Full face powered air respirator (TMP3)
	far-field influences, 1 category: other workers performing the same task		Hood or helmet with supplied air system (TH1, TH2, TH3).

Suggestions[77]:

- Publish a manual, which summarises the main aspects of the tool and its exposure algorithm in a user friendly way. Make clear what the differences between the common quantitative exposure part and the REACH specific part are and why this separation has been implemented. Mark parameters that are only implemented for administrative reasons.
- Consider implementing duration and frequency.
- Check and complement the English translation of STOFFENMANAGER©. Some small parts (single words or sentences, some features in the general quantitative algorithm) are still in Dutch.
- Consider to provide more detailed updates of the “News” section at https://www.stoffenmanager.nl including a detailed version number (e.g. “4.5.x”) and all recent changes of the tool features and the model algorithm.

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[77] Some of these suggestions (implementation of duration and daily average exposure estimates, removal of parameters which are only for documentation) will be taken account of in the next version of Stoffenmanager (state of affairs on 20.04.2012).

9 RISKOFDERM

9.1 Introduction

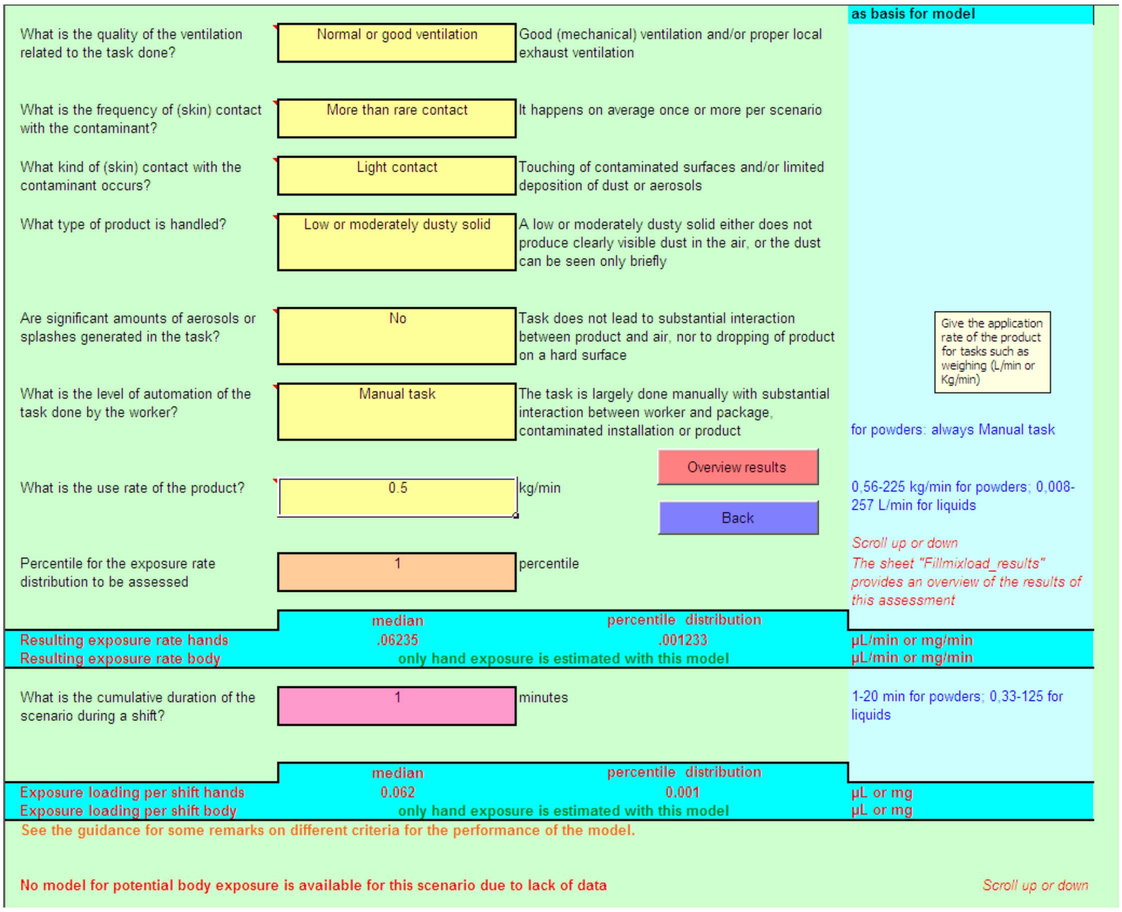

Figure 9.1 Screenshot of the RISKOFDERM tool, version 2.1, DEO unit 1 ("Mixing, filling, loading")

The RISKOFDERM tool is an MS Excel based tool for estimating dermal exposure, which was developed within the RISKOFDERM project (EU fifth Framework Program, project QLK4-CT-1999-01107) (Warren et al., 2006). It is based on a database of exposure measurements, which were used to develop linear mixed effects models. Somewhat confusingly, there is also a RISKOFDERM toolkit, which is a qualitative control banding tool designed for risk management of dermal exposure in small and medium-sized enterprises. In contrast to the tool it is not based on a mathematical fitting procedure to measured values. This qualitative toolkit will not be evaluated in this report.

The RISKOFDERM tool was designed for expert use, which covers the dermal route for both hands and body exposure. It is often described as a "Tier 1.5" tool, as it offers more parameters to describe the exposure situation than listed in ECHA, 2010b (see also Chapter 0, 9.2 and 9.4). The RISKOFDERM tool is Excel based and freely available at the TNO homepage[78].

Publications

A number of publications is available about the RISKOFDERM project. The development of the qualitative toolkit is described in detail in Goede et al., 2003, Oppl et al., 2003, Schuhmacher-Wolz et al., 2003, van Hemmen et al., 2003, Warren et al., 2003, Oppl et al., 2004 and Auffarth et al., 2003. The algorithm of the quantitative RISKOFDERM tool has been published in Warren et al., 2006. An additional publication (Marquart et al., 2006) describes how the given data set can be used to obtain default values for standard scenarios. Project reports for the qualitative toolkit (Oppl et al., 2004) as well as a user manual for the quantitative tool (TNO, 2006[79]) are also available. The datasets used for this project are described and analysed in Rajan-Sithamparanadarajah et al., 2004 and Kromhout et al., 2004.
A limited number of validation attempts are available, which are summarised in the Appendix 2

9.2 Tool description

9.2.1 Scope

As the tool is based on a set of measured data its abilities and limitations are closely connected with the quality and boundaries of the data that were available for the different DEO units (see also Chapter 9.3). Valid ranges for the parameters application rate and duration are given within the tool and summarised in
Table 9.1. To obtain reasonable results the user should remain within these ranges. If they are exceeded the possibility of overestimated exposure values arises, i.e. the result would be higher than the results that are found when the skin is fully immersed in viscous liquids (Warren et al., 2006). This source of error is also indicated within the tool via warning messages, but the creation of an exposure output is still possible.
An overview of the DEO units and their applicability to different physical states or hands/body exposure is given in
Table 9.1 and Table 9.2. Gases are not covered. The tool is – due to a lack of highly volatile substances in its database – not able to cover evaporation from the skin and thus, not optimally suitable for very volatile substances (ECHA, 2010b, see also Chapter 9.3.2).

[78] www.tno.nl/downloads/RISKOFDERM%20potential%20dermal%20exposure%20model%20vs%202.1t.xls
[79] http://www.tno.nl/downloads/The%20RISKOFDERM%20Dermal%20Exposure%20Model%20-%20Guidance%20document.doc

The quality of the exposure prediction of each DEO unit depends on the underlying number and quality of datasets for hand and body exposure, thus, for one scenario hands and body exposure can show different accuracy for both skin areas. These differences are not indicated within the tool.

Table 9.1 Valid ranges of the RISKOFDERM tool (TNO, 2006)

	Use rate (L/min or kg/min)		**Duration (minutes)**	
Process	**Solids**	**Liquids**	**Solids**	**Liquids**
Filling, mixing and loading	0.56-225	0.008-257	1-20	0.33-125
Wiping[80]	no data	0.0017-1.18	no data	5-35
Dispersion hand-held tools[80]	no data	0.0001-1.1	no data	1- 445
Spraying[80]	0.02-0.12	0.04-50.4	4-90	3- 600
Immersion	not relevant	not relevant	no data	4- 483
Mechanical treatment	not relevant	not relevant	18–154	47- 214

Table 9.2 Number of data points for the different DEO units and possible physical states (Warren et al., 2006).

		Number of data points		
	Description	**Hands**	**Body**	**Possible physical states**
DEO unit 1	mixing, filling, loading	195	0	liquid and solid
DEO unit 2	wiping	79	57	liquid
DEO unit 3	dispersion with hand held tool	117	107	liquid
DEO unit 4	spraying	140	331	liquid and solid
DEO unit 5	immersion	13	68	liquid
DEO unit 6	mechanical treatment	0	97	liquid and solid

Some general information concerning the quality of prediction for the different DEO units can be found in Chapter 9.5.

9.2.2 Model, parameters and structure of use

RISKOFDERM is based on a set of measured dermal exposure data which are fitted to model equations (see Chapter 9.4). The data were assigned to six different tasks, the so-called DEO units (Dermal Exposure Operation units). The tool offers a short explanation of its correct use and a summary of the implemented changes and the validity of the underlying model within the excel sheet itself. At the start of an exposure assessment the user is asked to select the most appropriate DEO unit. The DEO units are “Filling, mixing, loading”, “Wiping”, “Dispersion of product with hand-held tools”, “Spraying”, “Immersion” and “Mechanical treatment” (see also Table 9.3). After choosing the DEO, several refinement options (see Table 9.4) can be selected in a second step (see also usemap in Appendix 6 and applicability matrix in Appendix 5). Duration of task is the only common model parameter that is available for all DEOs; the number and type of the remaining parameters depend on the DEO unit.

[80]For these DEO units also a boundary for the occurring combinations of use rate and duration exists. High use rates generally do not occur with high durations.If these boundaries are exceeded the user is cautioned via warning messages.

The DEO unit 1 (“Mixing, filling, loading”) is the most broadly defined within the tool. Originally this DEO unit was called “handling of contaminated objects”, but it was realised that a predominance of special exposure situations within the large variety in this DEO unit existed. Therefore only mixing, filling and loading are covered by DEO unit 1 (Warren et al., 2006).
It is noted that - depending on the use rate - the parameter “automation” in the DEO unit “filling, mixing, loading” not necessarily leads to lower exposure results. This is caused by the specifics of the underlying datasets and the specific choice of algorithm. The parameter should not be confused with a “closed system”, as it might as well represent open processes performed by some kind of machinery.
The user is guided via small pop-up messages that provide short descriptions and help with the completion of the excel sheet. Whenever application rates or durations are entered which lie beyond the reasonable boundaries of the tool (i.e. higher values than represented in the underlying database), a short warning message is provided. The exposure estimation can be performed anyway, but the user is cautioned that the results may not be reliable. No warning messages appear if the value lies below the boundaries dictated by the database.
Results of the assessment are given as a short summary including the median of exposure and a freely selectable percentile, with the unit of exposure being volume per time for liquids and mass per time for solids. A more detailed report can be created where details of the scenario are summarized and a graphical analysis of the assessment is provided. Different percentile results are given.
The RISKOFDERM tool provides task based exposure estimates. In case of multiple tasks the user is advised to sum up the exposures of different tasks to get an overall exposure for a certain process (TNO, 2006).

Table 9.3 Description of the different DEO units and major exposure paths

DEO unit	Exposure path (Warren et al., 2006)	Description within tool
Mixing, filling, loading[81]	primary source of exposure is the contact with contaminated objects and surfaces, but also aerosols, some direct contact or immersion may happen	Weighing of powders, dumping of powders from bags of drums, pumping of liquids, pouring of liquids, scooping of liquids or pastes etc. The purpose is to transfer product from one container to another.
Wiping	predominantly through direct contact	Wiping surfaces with a liquid (preparation), including e.g. cleaning agents. Wiping is done with a sponge or cloth or rag, or another tool without handle. The purpose is to spread the product over the surface.
Dispersion with hand-held tools	mostly due to contact with contaminated surfaces, also some direct contact via splashing or dripping	Dispersion of products or substances by using a brush, comb, rake, roller or other tool with a handle. The purpose is to spread the product over a surface.
Spraying	aerosols and contact with contaminated surfaces	Spray application of products such as paints, glues, cleaning agents. Hosing down with water using a normal water line under normal pressure is not included.
Immersion	direct contact and contaminated surfaces	Immersing objects in chemicals, where the exposure is to chemicals in which the product is immersed and not to substances coming from the object.
Mechanical treatment	aerosols and contact with contaminated surfaces	Treatment of solid objects leading to emission of substances. This relates to substances emitted from the solid objects, e.g. wood dust, but also to substances used in the process of treatment, e.g. metal working fluids.

[81] This DEO was originally intended to represent “handling of contaminated objects”. It has been constricted due to a lack of datasets for some of the included scenarios but the term “handling of contaminated objects” is mentioned in some of the underlying publications.

Table 9.4 Determinants in RISKOFDERM (Warren et al., 2006)

Determinant	DEO unit	Description used in RISKOFDERM
Formulation details		
Physical state of formulation	1	highly dusty solids (solid particles with high tendency to become airborne)† low or moderately dusty solids* liquid formulations†
	4	(just for transferring unit of result, not a fixed effects, no influence on resulting exposure magnitude): solid liquid
	6	solids† liquid*
Aerosol generation	1	processes leading to significant aerosol generation† no aerosol generation*
Viscosity	3	similar to water* similar to syrup/honey† similar to oil†
Volatility	4	highly volatile liquid formulations† not highly volatile*
Working environment and working task details		
Work environment (Outdoors/ Confined/restricted space)	4	work environment is outdoors† work environment is indoors*
Automation	1	automated or semi-automated processes† manual process*
Ventilation	1	normal or good ventilation* poor or no ventilation†
	4, 5	adequate LEV / directed airflow away from the worker† no adequate LEV / not away from the worker (by ventilation system or by movement)*
Segregation	4	physical barrier separating worker from spray aerosol, e.g. a tractor cab† no physical barrier*
Surface area of contact	2	extensive body contact [1] with treated surface† no extensive body contact with treated surface*
	2, 3, 4, 5,	exposure to the body, excluding hands (implemented automatically, no option within the tool) †
Kind of skin contact	1	light contact [2] (surfaces, limited deposition of dust and aerosols) † more than light contact (splashes and drops)*
Frequency of contact	1	infrequent/rare contact [3]† frequent/more than rare contact*
	6	rare or irregular contact* frequent or continuous contact[4]†
Application/use rate	1, 2, 3, 4	rate at which the formulation is handled or dispersed ($l \cdot min^{-1}$ or kg $l \cdot min^{-1}$), free text (determinant implemented linearly)†
Distance to source (Proximity, length of tool handle)	4, 6	>100 cm from primary source of exposure (more than one arm's length) † <100 cm from primary source of exposure (within one arm's length) *
	3	>30 cm from primary source of exposure* <30 cm from primary source of exposure†
	5	<30 cm from primary source of exposure† >30 cm from primary source of exposure but <100 cm*

Determinant	DEO unit	Description used in RISKOFDERM
		>100 cm from primary source of exposure†
Orientation	3, 4	level or overhead* downwards†
	4	level* overhead† downwards†
Duration	1, 2, 3, 4, 5, 6	duration of exposure (min), free text (not a fixed effect but determinant implemented linearly)
Definitions for types of contact provided in the tool RISKOFDERM: [1]extensive: worker tends to lean against wet surfaces or has to work in areas with extensive contact with freshly wiped surfaces. Otherwise select not extensive. [2]light: touching contaminated surfaces and/or limited deposition of dust or aerosol more than light: splashes and drops. part of the worker is in direct contact with stream of substance [3]frequent/more than rare: happens on average once or more per scenario infrequent/rare: happens sometimes but on average less than once per scenario [4] frequent: contact happens with a high frequency, prolonged or constantly or has a clear regular pattern rare or irregular: contact happens with a low frequency and without regular pattern * Descriptions marked with a star are included in α_0. Deviations from this condition (α_0) are implemented as fixed effects (α_n). Hands exposure is also included in α_0, while body exposure is implemented via a fixed effect, which is not optional but calculated automatically for each DEO unit where it is possible. † fixed effects (α_n)		

9.3 Empirical exposure data used for model development

9.3.1 Description of datasets

The exposure data on which the tool is based were collected between 1996 and 2005. In total, 544 measurements for hands and 660 for body exposure in the final tool, with varying numbers of data points for the different DEO units (Warren et al., 2006). They were collected in five different European countries (Finland, Spain, Sweden, Netherlands and UK) and by seven research institutions[82] (Rajan-Sithamparanadarajah et al., 2004).

The majority of the data were collected specifically for the RISKOFDERM project, but some additional data were obtained from the literature (see underlying publications in Warren et al., 2006). The covered workplaces as listed in Warren et al., 2006 are summarised in Table 9.5 while an overview of industrial sectors can be found in Rajan-Sithamparanadarajah et al., 2004.

[82] KRIOH –Kuopio Regional Institute of Occupational Health, INSHT – National Institute for Occupational Safety and Hygiene, NIWL – National Institute for Working Life, TNO – Nutrition and Food Research, UU – University of Utrecht, HSL – Health and Safety Laboratory, IOM – Institute of Occupational Medicine; see Rajan-Sithamparanadarajah et al., 2004.

Some other analyses of a large part of the underlying database were published by Kromhout et al., 2004 and Rajan-Sithamparanadarajah et al., 2004. Rajan-Sithamparanadarajah described data sources, sampling methods and the grouping into exposure situations and DEO units, while Kromhout provides the results of detailed statistical analyses of the data (Table 9.6). The original data sources are cited in Warren et al., 2006 and Rajan-Sithamparanadarajah et al., 2004. Although much information about the underlying datasets can be extracted from Rajan-Sithamparanadarajah et al., 2004 and Kromhout et al., 2004 these publications do not contain all exposure values included in the later RISKOFDERM tool.
The grouping of exposure situations into DEO units is based on similarities of the exposure paths, on the tasks, and on professional experience and judgement. The underlying workplaces are summarised in Rajan-Sithamparanadarajah et al., 2004 and Warren et al., 2006 and can be found in Table 9.5.

Table 9.5 Underlying datasets, covered exposure situations and number of data for hands and body exposure.

DEO unit	Measured exposure situations	Number of data Hand	Body
(1) Mixing, loading and filling	Mixing antifouling paint	9	–
	Pouring of urine	26	–
	Loading, bagging and weighing calcium carbonate	61	–
	Loading and filling operations with 2-(2-butoxyetoxy)ethanol	58	–
	Loading zinc oxide	12	–
	Filling spray paint guns	29	–
(2) Wiping	Wiping of hospital patients	26	–
	Car washing	12	12
	Graffiti removal	11	15
	Small scale wiping of biocides	6	6
	Large scale wiping of biocides	24	24
(3) Dispersion with a hand tool	Antifouling paint	2	10
	Timber preservatives	10	15
	Styrene rolling	30	45
	Painting	24	–
	Silk screen printing	16	20
	Parquet lacquer	30	12
	Brush application of NMP	5	5
(4) Spray dispersion	Remedial biocides	67	
	Public hygiene insecticides	9	85
	Orchard spraying	1	29
	Antifouling paint	6	27
	Controlled droplet applicator	–	12
	Antifouling paint	25	35
	Car body painting	30	30
	Dry powder coating	22	18
	Pest control	16	16
	Cleaning foam	12	12
(5) Immersion	Electroplating	–	29
	Electroplating	–	26
	Degreasing using NMP	13	13
(6) Mechanical treatment	Metal working fluids	31	
	Machining	–	8
	Sawing and carpentry	–	29
	Grinding of acid-proof steel	–	29

Certain qualities were considered to be desirable of a DEO unit and its underlying scenarios: The dermal exposure within scenarios should be observable (i.e. the scenario should have a clear beginning and end), measureable with respect to dermal exposure, attributable to the task within the scenario and applicable to many industries. At least two scenarios should be selected for workplace exposure assessment in each DEO unit (Rajan-Sithamparanadarajah et al., 2004; van Hemmen et al., 2003).

Tasks should not be mixed with others ("isolated"), so the advice was to stop sampling whenever a change of the scenario took place (Rajan-Sithamparanadarajah et al., 2004). This led often to short measurement durations, increasing the number of measurement results below the limit of detection. The resulting sampling times range from 0.33 minutes ("mixing, filling, loading") up to 600 minutes ("spraying")[83]. Wherever possible, sites have been visited on two occasions (Rajan-Sithamparanadarajah et al., 2004).
The used sampling methods presented in Rajan-Sithamparanadarajah et al, 2004 include "surrogate skin" methods (gloves and patches or whole body suits) and "removal" methods (washing or wiping). Whole body suits were analysed either by cutting out patches, by non-destructive techniques or by solvent extraction of the whole suit (Rajan-Sithamparanadarajah et al., 2004). The results of these measurements are interpreted as either potential exposure (e.g. when the measurements were carried out on the outside of protective gloves or clothing) or actual exposure (when measurements were carried directly on the skin, thereby taking into account the effect of personal protective equipment and personal hygiene).
Although in Rajan-Sithamparanadarajah et al., 2004 values for potential and actual dermal exposure are included the publication of Warren et al., 2006 refers only to potential exposure.
The sampling and analytical methods varied between surveys as no standardised techniques of dermal sampling and methods of measurement exist (i.e. position of patches, material etc., varied nature of analytes, cost of analysis, work situations and work clothing regimes) (Rajan-Sithamparanadarajah et al., 2004). This is a general problem of dermal exposure and represents a major source of uncertainty in the resulting exposure model (see also Introduction and Chapter 0).
Values below the limit of detection are addressed via multiple imputation, i.e. a random sample of exposures is created drawn from a log-normal distribution conditional upon being less than their LOD to substitute for non-detected values (Warren et al., 2006)[84].

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[83] Sampling times are not given in the available publications but in the tool itself.
[84] In contrast to this in Rajan-Sithamparanadarajah et al., 2004 values below the LOD are replaced by half of the LOD.

Table 9.6 Underlying datasets - summary of important publications.

	number of datasets		
	Hands	**Body**	**Summary of results**
Kromhout et al., 2004	170 under protective clothing		Grouping of measurements into DEO units and scenarios (e.g. smaller subunits of DEO units). Statistical analysis (e.g. median, GM, GSD, range of exposure estimates). The grouping was found to be useful but still a large variability within each DEO and even within one scenario was found.
	404 not under protective clothing	419	
Rajan-Sithamparanadarajah et al., 2004	437	419[85]	
Warren et al., 2006	544	660	Linear mixed effects modelling was performed and exposure estimation algorithms for the RISKOFDERM tool were developed.

Definitions of the LOD (mean plus three times the arithmetic standard deviation of a blank sample)and the LOQ (mean plus 10 times the standard deviation of the blank samples) are given in Rajan-Sithamparanadarajah et al., 2004 but it is not clear if the same definitions also apply to the RISKOFDERM tool, i.e. were used in Warren et al., 2006.
According to Rajan-Sithamparanadarajah et al., 2004 DEO unit 1 showed the highest number of non-detects while DEO unit 4 showed the fewest. It is not clear if these numbers apply also to the database used for developing RISKOFDERM tool. However, as large parts of the datasets included in Warren et al., 2006 and Rajan-Sithamparanadarajah et al., 2004 are overlapping, it can be assumed that at least the relative frequency of non-detects corresponding to the different DEO units in both publications will be comparable.
The unit of exposure in Warren et al., 2006 and Kromhout et al., 2004 is mg/min, while in Rajan-Sithamparanadarajah et al., 2004 $\mu g/h/cm^2$ is used.
The skin areas represented by the different sampling patches were according to Rajan-Sithamparanadarajah et al., 2004 surface areas of the body standardised to represent an 80^{th} percentile man (18720 cm^2 for the total body and 410 cm^2 for each hand, compare OECD, 1997) (Rajan-Sithamparanadarajah 2004).

9.3.2 Limitations of the datasets

The number of datasets per DEO unit is summarised in Table 9.2. Body exposure estimates were not available for DEO unit 1, while no hand exposure measurements were available for DEO unit 6 (see Table 3). For DEO units 2, 3 and 5 only data for liquids were available (see also Chapter 9.2.1).
The DEO unit with the smallest dataset is “Immersion”. The majority of measurements for body exposure in this DEO unit was collected from two studies of electroplating containing widely differing exposures. One explanation for this level of scattering is that in one study only the specific immersing tasks were measured while in the other study longer periods, possibly including also other activities that might lead to decreased or even increased exposure, were sampled. Additional reasons

85 including one without sampling time

might have been differences in the methodologies for sampling of dermal exposure and chemical analysis (Warren et al., 2006).
As no substances with very high vapour pressure are included in the overall database, evaporation from the skin surface is not addressed in the model for the exposure estimation (ECHA, 2010b, see also Chapter 9.2.1). A comparison with biomonitoring data published by Boogaard et al., 2008 suggests that the RISKOFDERM estimates may indeed overestimate relevant exposures for volatiles, but the comparison of internal values with external values introduces several additional uncertainties that preclude a firm conclusion.
According to the exposure ranges given in Warren et al., 2006 even for a given DEO unit exposure values sometimes vary by several orders of magnitude.
For DEO unit 5 all available data are for machining tasks, so the tool should not be applied to low energy processes (Warren et al., 2006).
The number and type of the implemented parameters (see Chapter 9.4) heavily depends on the underlying datasets. Only for determinants that were represented in the corresponding sub-database could an effect be modelled. For example, for "Wiping" the viscosity could not be studied due to a lack of data (only water based substances were included in the database, see also Table 9.7) (Warren et al., 2006).
It is possible that there are other limitations of this type that have not been explicitly mentioned in any of the available publications, so in general it is advisable to have a rough overview of the underlying datasets to decide if a specific situation is at least close to one of the implemented scenarios (see e.g. Table 9.5 and Table 9.7).
Overall it can be summarised that the quality and number of the data sets varies between the DEO units (see Table 9.5). The data collection was complicated by the general difficulties of dermal exposure sampling (no standardised sampling method etc., see Chapter 1), however already a comparatively large area of tasks and workplaces could be covered.

Table 9.7 Determinants whose influence could not be studied due to a lack of data according to Warren et al. 2006.

DEO unit 1	mixing, filling, loading	nothing published
DEO unit 2	wiping	viscosity
DEO unit 3	dispersion using a hand-held tool	overhead (only 12 data points)
DEO unit 4	spraying	nothing published
DEO unit 5	immersion	level of automation (proximity was used instead)
DEO unit 6	mechanical treatment of objects	particle size, manual tasks

9.4 Derivation of final exposure output

The RISKOFDERM tool is based on a set of linear mixed effects models which are fitted to the measured data (Warren et al., 2006). The equations, the fitting process and the tool development are described in detail in Warren et al., 2006 and the generic form of the linear mixed effect models is given as follows:

$$Y_{i,j} = \alpha_0 + \alpha_1 X_1 + \alpha_2 I_{2,ij} + ... + \beta_i + \Sigma_{ij}$$

- $Y_{i,j}$: j^{th} log-transformed measurement on the i^{th} worker
- α_0: mean log-transformed potential dermal exposure for the corresponding DEO unit. $\alpha_{i,0}$ includes a default setting for each implemented determinant.

- α_n: n^{th} fixed effect (n = 1,2, ...; defines the determinants of an exposure setting, e.g. quality of ventilation)
- $I_{1,ij}$: becomes 1, if the first fixed effect was present for the jth measurement on the ith worker and 0 otherwise.
- X_1: logarithm of the application rate
- β_i: random effect for the ith worker; describes the scattering of exposure values caused by the fact that different individuals were measured.
- Σ_{ij} : random error associated with the jth measurement on the ith individual; describes the scattering of exposure values caused by the fact that different measurements on one single individual were performed.

Σ_{ij} and β_i are independent and normal distributed with means of zero and standard deviations of σ_{BW} and σ_{WW}, respectively (between-worker and within-worker variability).
The within worker variability is allowed to differ between hand and body exposures. The connection between both variance components is described by the following equation:

$$\sigma_{ww} = \sigma_{ww,Hand}(1 - I_{body,i,j}) + \sigma_{ww,body} I_{body,i,j}$$

The number of statistically significant fixed effects (excluding one fixed effect for the estimation of body exposure) implemented within the models ranges from 3 in DEO unit 2 to 9 in DEO unit 4 (Table 9.8 and Table 9.4).
One determinant (e.g. viscosity) can be represented by several fixed effects (e.g. viscosity like oil). If none of the fixed effects (α_n) is included in the scenario description, the exposure situation is described by a set of default conditions included in α_0. Which settings are assigned to fixed effects and which are included in α_0 is indicated in Table 9.4.

Table 9.8 Number of fixed effects per DEO unit*.

	Number of fixed effects
DEO unit 1	8
DEO unit 2	3
DEO unit 3	6
DEO unit 4	9
DEO unit 5	4
DEO unit 6	3
*see Table 48 for settings assigned to fixed effects.	

The DEO unit with the highest number of implemented exposure fixed effects is “Spraying” (nine fixed effects including “body exposure”) while the DEO unit with the smallest number is “wiping” (three fixed effects). It is important to keep in mind that only for properties with a sufficient set of underlying measurements fixed effects could be modelled (see also Chapter 9.3). Thus, for DEO unit 6 no fixed effects relating to PC-properties such as particle size or viscosity could be implemented. In case of the particle size this was caused by a lack of variation within the datasets, whereas varying viscosities seemed to cause no difference in the exposure result (Warren et al., 2006). The spray pressure in case of “Spraying” showed no influence on the exposure result – the most likely reason for this is the observation that the highest spray pressure is often associated with a high viscosity.
The orientation of work is important for “Dispersion with hand held tool” and “Spray dispersion”, thus, both DEO units have fixed effects for downward application implemented. On the other hand only “Spray dispersion” shows significant effects for overhead application – this possibly relates to the small number of data points (12) for the combination of DEO unit 3 (“Dispersion using hand held tool”) and overhead application).
DEO unit 5, “Immersion” has only fixed effects describing the proximity and ventilation and shows large residual errors for hands and body exposure. The level of automation in the underlying measurements is not always documented. Therefore the model is based on proximity. “Automated” processes have an effect comparable with “proximity > 1 m”, whilst manual dipping has a magnitude of effect comparable to “proximity < 30 cm”.

9.4.1 Underlying assumptions

The tool relies on the following assumptions:

- ❖ The exposure to a chemical agent is proportional to its weight fraction in the formulation (Warren et al., 2006). This assumption is not implemented within the tool but according to the manual (TNO, 2006) it can be applied manually after the exposure estimation with the tool;
- ❖ The average exposure increases linearly with duration of the task (Warren et al., 2006). It has to be noted that how the duration of a task exactly influences the dermal exposure has not been shown in experiments yet and an implementation of this parameter for dermal exposure has always to be used with caution (see also Chapter 10.3); and

- The density of liquid substances is assumed to be 1 mg/ml (Warren et al., 2006).

9.5 Transparency

Tool development and datasets

The RISKOFDERM tool includes a short description of changes compared to Version 1.1 and 2.0, the ranges of validity and explanations of the most important features of the tool. A lot of additional background information can be found in the corresponding publications (Warren et al., 2006; TNO, 2006).
A high amount of information is available about the underlying database. Two publications (Kromhout et al., 2004 and Rajan-Sithamparanadarajah et al., 2004) with detailed analysis of a large part of the measured data points can be consulted and Warren et al., 2006 also lists the number of data sets, underlying publications, background information and some additional statistical information. Basic information about the database as well as a list of the valid ranges is also given in the guidance document (TNO, 2006). Information about the different scenarios which together form the less defined DEO units can be found in Marquart et al., 2006 and include also more information on e.g. the amounts of product used during the measurements, providing an indication of the applicability domain.

Scope and algorithm

The tool algorithm represents a relatively complex mathematical model but in principle all important information is documented in a reproducible way.
Datagaps, geometric standard deviation and the variance of the model (within and between worker, fixed effects) are given in Warren et al., 2006 and TNO, 2006 and therefore allow for insight into the quality of performance (see also Chapter 9.5). Limitations of the different models are also clearly discussed in the user manual (TNO, 2006).

Structure of use

Although the tool is available free of charge a simple Google search might lead to misunderstandings: The Eurofins homepage provides information about the RISKOFDERM project, but offers only a download for the toolkit[86]. The RISKOFDERM tool (version 2.1) can be downloaded at www.tno.nl, but the direct link could only be found via Google. A search on the TNO homepage itself led to no result.
Short statements about quality of performance are provided for each DEO unit (i.e. model) within the tool. Some advice on the best choice of percentile is given in TNO, 2006.
The tool offers a high level of transparency via short warning messages that indicate if the user enters values beyond the scope of the underlying database or if the result exceeds what is considered to be a reasonable maximum exposure.

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[86] www.eurofins.com/product-testing-services/services/research--development/projects-on-skin-exposure-and-protection/riskofderm---skin-exposure-and-risk-assessment.aspx

The skin surface assumed for the estimation of overall exposure is not mentioned within the tool.
The major source of confusion is the implementation of the parameter “automation”, which may deduce some users into believing that this represents a description related to an improved system with less exposure.
Overall it can be summarised that the development of the six task specific models is transparently described in Warren et al., 2006, although due to the complexity of the calculations and the underlying linear mixed effects models it is difficult to reproduce “by hand”. The user might need some time and technical knowledge to understand the mathematical models but nevertheless RISKOFDERM is a tool of very high transparency.

9.6 Conclusion

RISKOFDERM offers a dermal exposure algorithm with a very high level of detail. As summarised in Chapter 9.5 its development is described with a very high transparency and it gives the user the possibility to see many of the database induced limitations directly during the creation of a scenario.
A general limitation of the RISKOFDERM tool is the quite rough process description that only includes 6 different DEO units. Moreover the level of detail implemented for the different scenario descriptions varies between the different DEO units. The tool includes some sources of uncertainty (e.g. the varying number of fixed effects for each DEO unit, not uniform measurement techniques for the underlying datasets, no substance with high vapour pressure in the database) which will be discussed in detail in WP II of this project. Another important issue is that like all dermal exposure tools RISKOFDERM suffers from the general problem of dermal exposure that no standardised measurement techniques exist and the differences between the existing measurement techniques are not well explored yet.
The performance of the different model equations can be judged by the percentage of variance that can be explained by fixed effects, the 95% percentile confidence interval of the anti-log of the intercept term which equals the confidence intervals for median exposures without the presence of any fixed effects and the overall geometric standard deviation. In particular a good model should have a high percentage of explained variance, a small confidence interval and a small geometric standard deviation (TNO, 2006). Taking into account these three factors, DEO units 1, 2 and 6 are performing good, DEO units 3 and 4 moderate and DEO unit 5, “Immersion”, shows a poor performance (Warren et al., 2006; TNO, 2006; see also Table 9.9).
The implemented determinants and their division into the different elements defining exposure (see Chapter 3 and Cherrie et al., 1996) are summarised in Table 9.10. The number of categories per determinants is given in brackets behind each parameter. In principle all important areas are covered but the user should keep in mind that not all of those determinants apply to all DEO units. Personal protective equipment is the only area of an exposure situation as described in Cherrie et al., 1996 that is not implemented in any of the DEO units. But – as PPE does not belong to the Tier 1 definition as published in ECHA, 2010b (see also Introduction) – RISKOFDERM still fulfils the needs of a Tier 1 model.

Table 9.9 Quality of performance for different DEO units – summary (TNO, 2006)

Process	Percentage explained variance	Geometric standard deviation		95 % confidence interval for intercept	Remarks
		Body	Hands		
Filling, mixing and loading	61%	-	5.4	0.06 - 1.73	Overall good performance
Wiping	50%	5.8	3.5	453 - 1464	Overall good performance
Dispersion hand-held tools	75%	5.9	11.2	20.4 - 181	High GSD for hands; other parameters reasonable to good
Spraying	31%	6.0	6.0	14.7 - 39.3	Moderate percentage explained variance; other parameters good
Immersion	29%	9.4	34.2	0.8 -76.7	Poor performance in all of the parameters
Mechanical treatment	53%	4.9	-	6.4 - 34.4	Overall good performance

It can be summarized that the tool has its limitations but still offers a high level of detail. The level of transparency is also very high – limitations are clearly addressed in TNO, 2006 and Warren et al., 2006 and therefore the tool allows the user to decide on the basis of statistical facts and the underlying database if the tool can be safely applied in his specific situation.

Table 9.10 Number of categories per determinants (in brackets) and assignment to four broad exposure defining elements (see also Chapter 3).[87]

Intrinsic substance properties	Process description / operational conditions	Risk management measures at source
Dustiness (2 categories: normal, highly dusty solids)	DEO units (6 categories)	Ventilation (poor or normal)
Aggregate state (2 categories)	Type of contact (light, extensive)	LEV (1 category)
Viscosity (3 categories)	Application rate (free text)	Outdoors (1 category)
Volatility (2 categories)	Automation (manual/automated task)	Segregation (1 category)
	Direction of work (3 categories)	directed airflow (away or not away from the worker)
	Duration of task (free text)	
	Aerosol generation (1 category)	
	Contact frequency (2 categories)	
	Proximity (<30 cm, 30-100 cm, >100 cm)	
	good occupational hygiene is assumed	

[87] Not every determinant refers to all DEO units. Compare

Table 9.4. PPE is not implemented.

10 Summary and Conclusions

In this project we compare six different tools: EASE, ECETOC TRA, the EMKG-EXPO-TOOL, MEASE, RISKOFDERM and STOFFENMANAGER©. Except EASE, they are all recommended under REACH for Tier 1 exposure assessments. The various findings about the conceptual basis of these Tier 1 tools shall be summarised and compared in this chapter.

Under REACH a system of use descriptors was introduced to standardise the description of substance usage. The descriptor system simplifies or enables the up- and downstream communication. This is necessary as the manufacturer or importer of a substance has to develop, assess and communicate exposure scenarios, covering the entire life cycle of the substance. The system is based on five separate descriptor sets (sector of use category – SU, chemical product category - PC, process category – PROC, environmental release category – ERC and article category – AC) which in combination with each other form a brief description of use or an exposure scenario. The process categories are generic use descriptions and can be directly linked to standard worker exposure assessment tools.

Each registrant is also obliged to include a brief general description of all identified uses in his Technical Dossier and in the Chemical safety report. It is recommended to base this description on the descriptor system.

In ECETOC TRA and MEASE the PROC codes are already implemented as these tools were designed for exposure assessment under REACH in the first place. The EMKG-EXPO-TOOL, RISKOFDERM and STOFFENMANAGER© were designed for other purposes and do therefore not contain the PROC codes. To bridge this gap, we developed a “usemap”, i.e. a look-up table for several exposure situations (see Appendix 6). The usemap was created by comparing the use descriptions implemented in the different tools and “translating” them into each other. Thus its final version, which has been authorised by the tool developers, contains the process categories in terms of PROC codes and the corresponding use description of the other tools. Users who want to switch between different tools can use this table to choose the correct process description and to decide, if a certain task can be described within the tool(s) or not. Thus, it allows for an easy comparison between the tools and provides an overview about the covered exposure situations. The usemap can help to prevent the assignment of false process descriptions and compensate at least a part of the uncertainty connected with use assignment.

All tools contain specific features, reflecting their suitability for certain exposure situations. Therefore we derived a general applicability matrix (see Appendix 5) in this project. It can be used to decide if a tool covers certain substances and exposure routes and gives an overview of the implemented exposure determinants and the level of detail that has been used. Thus, the applicability matrix provides further help with the correct assignment of exposure situations to tools with an appropriate scope. As EASE is not used anymore it is included neither in the usemap nor in the applicability matrix.

Both tables, i.e. usemap and applicability matrix, can be used to extract general differences and similarities between the tools:

- The highest level of detail for the implemented exposure determinants is offered by MEASE and STOFFENMANAGER© - a more detailed level than is expected for Tier 1 tools (ECHA, 2010b (R14), see also Introduction).

- The models offer very different numbers of use categories which influence the level of detail that can be used to describe an exposure situation. However, as many of categories are mixed with other operational conditions (e.g. level of containment, amount of substance) a simple comparison is not possible.
- The tools show very different applicabilities, i.e. restrictions of the reasonable area of use.
- Exposure to dust resulting in the emission of fumes is only addressed in MEASE.
- Inhalation exposure to liquid aerosols is only covered by MEASE and STOFFENMANAGER©.
- Usage of the EMKG-EXPO-TOOL is restricted to the control guidance sheets.
- Although in some cases only one physical state is covered in a specific tool some common scenarios were identified: The PROC numbers 3, 4, 5, 7, 8a, 8b, 9, 10, 11, 13, 14 and 15 can be described in all tools and thus, are good candidates for the later comparison with measured values. However the comparison of the scope of all tools within this project is only one of several aspects which will lead to the final decision about the extent of the external validation.

An overview of all determinants as implemented in the various Tier 1 tools is given in Table 10.1. In principle it is possible to obtain more accurate results with tools that are able to provide a more detailed description of an exposure situation but the accuracy of the results also depends on the way the determinants are implemented and if they are applied by the user correctly. Thus, the simple number of parameters cannot represent a scale for the quality of model predictions, especially as many determinants are not mandatory for a Tier 1 tool as defined in ECHA, 2010b (see also Introduction).
The tools have been analysed in detail concerning their underlying algorithms and database. In the following paragraphs, some important features will be discussed.

10.1 User Guidance

Implemented hints and help during the exposure assessment are available for all evaluated tools in varying level of detail, i.e. in MEASE via its glossary, in ECETOC TRA via comments and information in the underlying Excel sheets, in the EMKG-EXPO-TOOL, STOFFENMANAGER©, RISKOFDERM and EASE via help texts appearing during tool usage (e.g. pop-up windows).
RISKOFDERM is the only tool that additionally gives instantaneous advice if the user’s input values are inside the specified boundaries of the model and if the resulting exposure outcome is beyond what is considered to be a reasonable maximum exposure. Specific user manuals and/or reports are only available for RISKOFDERM, EASE and ECETOC TRA. The EMKG-EXPO-TOOL, MEASE and STOFFENMANAGER© refer to a set of underlying publications – a circumstance that lowers the user friendliness and makes the extraction of information less straightforward.

10.2 Transparency/Tool background

The level of transparency with which the development, algorithms and database of the different tools are documented and described is, like the existence of a user

friendly user guidance (see Chapter 10.1), a very important factor influencing the correct application.
The tools included in this project offer very different amounts of information about their development and the underlying model algorithms. About EASE only a part of the relevant information is published and so only limited insight into the algorithm and its derivation is possible. The EMKG-EXPO-TOOL offers more information, but a large part of the information is only available via COSHH specific literature. Differences between COSHH and the EMKG-EXPO-TOOL were not publicly available until this project. About ECETOC TRA a lot of information concerning the algorithm and tool development is available via project reports and the tool itself. However, the number of published details and the amount of information may overstrain some users. Thus, they might not be able to extract the most important facts. Information about MEASE is available via underlying publications but not via specific documentation or report files. Some parts of the tool development are not documented in a transparent way. Detailed publications containing information about the underlying model algorithms and their derivation are available for RISKOFDERM and STOFFENMANAGER©.
All tools are empirically derived, i.e. the quality of their performance heavily depends on comparison with measured exposure values. The tools are to a varying extent adapted to real exposure measurements, but these measurements differ in many features (quality, methodology, age, country, exposure situation), thus, a sufficient amount of information about the underlying datasets is an important part of a transparent tool concept. However the exposure situation descriptions assigned to the available measurements differ widely in quality and level of detail as measurements are usually not performed with the intention of model development.
While STOFFENMANAGER© and RISKOFDERM are based on a mathematical fitting procedure applied to a well-documented set of measured data the tools EASE and MEASE can only partly be retraced to certain datasets that are documented in a less detailed and transparent way. For the EMKG-EXPO-TOOL and ECETOC TRA no specific datasets are published.

10.3 Algorithm and Exposure determinants

A central parameter of all tools is the volatility of the corresponding substance. It is noted here that the definition of volatility bands is not uniform for all tools. The definition of fugacity bands for the different tools depending on vapour pressure and process temperature is summarised in Table 10.2. If the process temperature increases about 10°C, the vapour pressure increases by approximately a factor of two (rule of thumb), thus, it is easily reproducible that this parameter has a high influence on the outcome of any exposure assessment.

Similar differences concerning the definition of dustiness exist, i.e. ECETOC TRA and the EMKG-EXPO-TOOL refer to three bands, MEASE to four bands, STOFFENMANAGER© to six bands, RISKOFDERM uses two bands and EASE only allows for a separation into dusty (i.e. inhalable or respirable particle size) and not dusty solids (i.e. granular particle size that results in negligible inhalation exposure). EASE is the only tool which offers using the vapour pressure to define the fugacity of a solid.

Table 10.1 Overview of determinants and separation into the four main areas of an exposure situation (see Introduction)*.

		Inhalation						Dermal				
		EASE	**ECETOC TRA v.2**	**ECETOC TRA v.3**	**MEASE**	**EMKG-EXPO-TOOL**	**STOFFEN-MANAGER©**	**EASE**	**ECETOC TRA v.2**	**ECETOC TRA v.3**	**MEASE**	**RISKOF-DERM**
Intrinsic substance properties	physical state											
	dust description (fibrous or not)											
	volatility / solids (dustiness based)											
	volatility / solids (vapour pressure based)											
	volatility / liquids											
	molecular weight[88]											
	concentration of component in product / preparation											
	viscosity											
Process description / operational conditions	generic process categorisation											
	descriptor system											
	process temperature											
	automation rate											
	duration of task											
	frequency of task / contact frequency											
	direction of work (e.g. downwards)											
	type of contact (light, extensive)	not relevant										

[88] Only needed for conversion of units from ppm into mg/m^3.

		Inhalation						Dermal				
		EASE	**ECETOC TRA v.2**	**ECETOC TRA v.3**	**MEASE**	**EMKG-EXPO-TOOL**	**STOFFEN-MANAGER ©**	**EASE**	**ECETOC TRA v.2**	**ECETOC TRA v.3**	**MEASE**	**RISKOF-DERM**
	professional / industrial	red	green/yellow	green/yellow	green/yellow	red	red	red	red	green/yellow	red	red
	amount of substance	red	red	red	red	green	yellow	red	red	red	red	red
	background exposure (e.g. other workers in the same room)	red	red	red	red	red	green	red	red	red	red	red
	passive exposure	red	red	red	red	red	green	red	red	red	red	red
	application outdoors	red	green	green	red	red	green	red	red	red	red	red
Risk management Measures	LEV	green	green	green	green	green	green	red	green	green	red	green
	general ventilation	green	red	green	green	green	green	red	red	red	red	green
	suppression techniques (e.g. wetting the source)	red	red	red	green	red	green	red	red	red	red	red
	segregation (cabin, other room)	green	red	red	red	red	green	red	red	red	red	green
	containment	green	yellow	yellow	yellow	green	green	yellow	yellow	yellow	yellow	red
	direct / not direct handling	not relevant						green	red	red	green	red
	distance to worker	red	red	red	red	red	green	red	red	red	red	green
	room size	red	red	red	red	red	green	red	red	red	red	red
PPE	respiratory protection / gloves	red	green	green	green	red	green	red	red	green	green	red

*green fields: determinant implemented in corresponding tool; red fields: determinant not implemented; yellow fields: "mixed determinants", included in process description. Determinants marked with blue text fall under the Tier 1 definition as described in ECHA, 2010b (see section 1).

Another issue is the question which physical states are covered by the different tools. Most tools refrain from estimating exposure values for gases. The only exceptions are MEASE and EASE. Solutions of solids in liquids are only addressed explicitly in STOFFENMANAGER© (all solutions) and in MEASE (aqueous solutions of inorganics), but with different approaches concerning the fugacity. The parameter "very low dustiness" is reintroduced in case of MEASE (see Chapter 6) and the vapour pressure of the solid substance is used in case of STOFFENMANAGER© (see Chapter 8).

Table 10.2 Volatility borders of different Tier 1 tools - vapour pressure ranges and influence of process temperature

EASE (very low / low / medium-low / medium-high / high / very high)[89]	p_{vap} ≤ 1 Pa	1 < p_{vap} ≤ 500 Pa	500 < p_{vap} ≤ 1500 Pa	1500 < p_{vap} ≤ 10000 Pa	10000 < p_{vap} ≤ 25000 Pa	p_{vap} > 25000 Pa
ECETOC TRA (very low / low / medium / high)[90] PROCs 1-21	p_{vap} < 0.01 Pa	0.01 ≤ Pa p_{vap} < 500 Pa	500 ≤ p_{vap} ≤ 10000 Pa		p_{vap} >10000 Pa[91]	
ECETOC TRA (low / medium / high) PROCs 22 - 25	$T_{process}$<T_{melt}		$T_{process}$ ≈ T_{melt}		$T_{process}$>T_{melt}	
MEASE (low / medium / high)[90] PROCs 1-21, 24, 27b	p_{vap}≤ 500 Pa		500 ≤ p_{vap}< 10000 Pa		p_{vap} >10000 Pa	
MEASE (low / medium / high) PROCs 22, 23, 25, 27a	$T_{process}$<T_{melt}		T_{melt}≤T_{proc}<T_{melt} ·1.5		T_{proc} ≥ T_{melt}· 1.5	
EMKG-EXPO (low / medium / high)[92]	p_{vap} < 500 Pa		500 Pa ≤ p_{vap}≤ 25000 Pa			p_{vap} > 25000 Pa
EMKG-EXPO-TOOL (low / medium / high)	T_{boil} < (2 x $T_{process}$ + 10) °C		(2 x $T_{process}$ + 10 °C) ≤ T_{boil} ≤ (5 x $T_{process}$ + 50) °C			T_{boil} > (5 x $T_{process}$ + 50) °C
STOFFENMANAGER©[90]	p_{vap} < 10 Pa	linear scaling, no categorisation				p_{vap} > 30000 Pa
RISKOFDERM	"not highly volatile"			"highly volatile"		

It is important to note that the molecular weight in fact does not influence the exposure in ppm in any of the tools but the value is needed for the conversion into mg/m³ in case of inhalation exposure to gases/vapours. Thus, it does not represent an actual determinant for the exposure estimation.

Exposure determinants related to far field factors and background exposure, i.e. exposure induced by other workers in the same room or by a lack of cleaning,

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[89] vapour pressure at process temperature

[90] no information about temperature of vapour pressure

[91] p_{vap}> 30000 Pa: Advice in Appendix of TR 107 to use PROC 1 or 3 for dermal exposure, as the substance will not be in contact with skin. Same number as in Stoffenmanager but again not reference or discussion.

[92] vapour pressure at room temperature (~20°C), applicable if the process is also at room temperature

respectively are only implemented in STOFFENMANAGER©. For all other tools good occupational hygiene practice is assumed to be present.
The dermal exposure parts of the different tools are always less detailed and provide rougher results than inhalation exposure models. This is caused by the fact that for many substances no standardised sampling methods for dermal exposure exist. In many cases the number of datasets with sufficient quality is too small for model development or refinement of the influence of specific exposure determinants, respectively. Moreover exposure values obtained with different sampling techniques are often not directly comparable. The duration of exposure is implemented in the dermal exposure algorithms of MEASE, RISKOFDERM and ECETOC TRA v.3. Although it has been shown that the dermal exposure level increases over time until it reaches a certain "saturation level" (HERAG, 2007; Hughson and Cherrie, 2003), it should be noted that no exact algorithm defining the influence of task duration on the dermal exposure for substances of different fugacity and for different processes has been experimentally proven yet.
Some parameters which are needed to describe specific situations accurately are not included in any of the tools within this project or are only represented by simplified assumptions (e.g. "very high dustiness" instead of droplet spectrum in case of aerosol formation with ECETOC, see Chapter 5 and WP II.1 of this project). These parameters are required for higher Tier tools (e.g. SprayExpo) that offer more options and are assumed to provide a more accurate estimation of exposure. However insights that have been gained during the development and validation of such higher Tier tools may be of future relevance for the improvement and revision of the Tier 1 models.
Depending on the task different skin surface areas are considered to be relevant, but not all tools use identical definitions of the appropriate areas for certain parts of the body. Moreover the level of differentiation is not the same, e.g. ECETOC TRA also allows for exposure only to the hand palms while RISKOFDERM uses always the whole hands' surface and EASE results always reflect exposure to hands and both forearms. While for RISKOFDERM and EASE the covered body areas are based on the available measurements it is not documented how the connection between exposed skin areas and the PROC codes in case of ECETOC TRA and MEASE was arrived at.
Skin areas as implemented in the different tools are summarised in Table 10.3. RISKOFDERM is the only tool, which is able to estimate whole body exposure. EASE, MEASE and ECETOC TRA neglect whole body exposure which may represent a source of error, even if the exposure loading on the hands might be estimated correctly.

Table 10.3 Skin areas implemented in different tools (cm^2).

RISKOFDERM	ECETOC TRA	MEASE	EASE	body part
	240	240		one palm of hand
	480	480		both palms of hands
820	960	960*		both hands
	1500	1500*		hands and one forearm
	1980	1980*	2000	hands and both forearms
18720				body except hands
* not implemented for liquids and aqueous solutions				

10.4 Vagueness

All tools compared in this project are based on algorithms using quantitative as well as qualitative input parameters. While quantitative measurable parameters (e.g. molecular weight, vapour pressure) usually refer to distinctly separated categories, qualitative determinants are more difficult to characterise, i.e. no clear borders between two adjacent categories within one attribute exist.
Vagueness is a parameter that describes the difficulty to distinguish between these qualitatively described categories. Comparing the input parameters of the different tools (see Table 10.1), some examples of parameters with a high vagueness can easily be identified (e.g. viscosity, the descriptor system, automation rate, containment, passive exposure (i.e. GOHP)). These properties do not offer categories with clearly defined borders, and hence misclassification in some cases is more likely. In the following paragraphs the vagueness of the different parameters shall be discussed.
The parameter dustiness is defined within most tools by a set of descriptions and examples, partly different for each tool. Thus, the potential source of error increases if the user switches between the tools, e.g. from ECETOC TRA (low, medium high dustiness) to STOFFENMANAGER© (objects, solid granules/grains/flakes, granules/grains/flakes, coarse dust, fine dust, extremely dusty). Another example where vagueness might influence the outcome is the input parameter viscosity in RISKOFDERM which is also defined in a descriptive way (e.g. viscous like oil). Thus, it represents a parameter of comparable vagueness, although in this case established experimental procedures exist.
The vagueness of the process description or use category depends on the level of detail that has been used to define the categories within the tool and therefore to a certain extent on the number of implemented exposure situations. Every process description bares a certain level of vagueness as it is impossible to capture all details of a real-life working area. The most detailed and least vague description for the process description is available for the EMKG-EXPO-TOOL in form of control guidance sheets. However, these guidance sheets are not directly implemented into the tool and the user must be aware of their existence for a valid exposure assessment.
In general the terms “industrial/professional” and “wide dispersive/non-dispersive” show a relatively high level of vagueness concerning the connection between both pairs of setting description. Although a short explanation of these terms is given in ECHA, 2010b (i.e. professional = skilled trade premises and industrial = industrial process), a clearer definition would be desirable in this case.
For risk management measures only a “yes/no” decision is required.
However, the definition and description of these risk management measures implies a high level of vagueness in almost all tools evaluated in this project. For most measures (e.g. LEV, general ventilation, wetting of sources) no efficiency is given that is connected directly to the RMM design (except for MEASE). Thus, the specific setup of the exposure situations that were considered for the model development (e.g. type of LEV, air change rate) is not defined. Identical risk management measures in different tools lead not to identical exposure reductions, e.g. the general ventilation in case of EASE assumes 2-3 ACH, in case of the EMKG-EXPO-TOOL (and COSHH) it assumes 5-15 ACH and for ECETOC v. 3 3-5 ACH are implemented (ECETOC, 2012). Similar differences can be found for LEV, which shows 78% efficiency for industrial and 72% efficiency for professional uses in case of MEASE

(lower confidence limit) and varies between 80 and 95% efficiency in case of ECETOC TRA, depending on type of setting and the specific PROC number.

Another source of vagueness is the interpretation and definition of results. For all tools within this project exposure results are given in a quantitative way. However, some tools (RISKOFDERM, STOFFENMANAGER©) provide information on various percentiles of the exposure distribution, while other tools (EMKG-EXPO-TOOL, EASE) simply provide an estimated range of exposure. Thus, although the level of vagueness may not be high the output format still provides a source of uncertainty as the user has to choose the correct interpretation for his specific situation. A clear advice via documentation or manuals in these cases is very important.

Another issue related to the vagueness of inhalation exposure results is the treatment of different dust fractions in the tools. For earlier versions of STOFFENMANAGER© it is stated, that only inhalable dust measurements are covered (validation study in Schinkel et al., 2010, see Chapter 5), however since April 2012 for comminuting activities on stone also the respirable dust fraction can be estimated (Marquart, 2012). MEASE provides estimates of the inhalable fraction for all PROCs (90^{th} percentile for PROCs 21-27a, for other PROCs percentiles are defined as in ECETOC version 2; Vetter and Battersby, 2012; personal communication, MEASE glossary; see also Chapter 6) and EASE leaves the impression to differentiate between inhalable and respirable dust (see Chapter 5) although both options lead to the same results. For the other tools no corresponding information has been published.

For all tools it is important to study available literature and manuals to ensure a safe use and a correct description of the actual exposure situation with the tool parameters. If certain factors (e.g. the exact efficiency and construction of a ventilation system) are not defined, the result has to be conservative enough to cover all possible exposure situations related to the respective factor.

Overall it can be summarised that there are many sources of error due to vagueness of the implemented parameters. In WP I.6 the between user variability will be evaluated which is directly influenced by the vagueness of input parameters and can be used to measure the influence of this aspect. During the external validation of the tools it would be desirable to ensure that worst case scenarios within the “vagueness boundaries” are selected from the validation datasets.

10.5 Application under REACH

Depending on the specific hazard characterisation (chronic vs. acute effects) of a substance risk assessments may be necessary for both long term and short term exposure under REACH.

Long term exposure corresponds to full shift average concentrations and can be predicted by all models discussed in this project. This includes full shift average exposures for short task durations within one shift for RISKOFDERM, MEASE, ECETOC TRA v.2 and v.3 and the EMKG-EXPO-TOOL.

In contrast to this, short term exposure refers to peak exposure values within an average working day. Procedures to extrapolate short term values from long term exposure are suggested in ECHA, 2010b, however predictions are only directly provided by one of the models within this project, ECETOC TRA v.3.

While average exposure estimates should be compared with long-term occupational limit values, short term exposures (i.e. peak values) are important for risk assessments referring to acute toxicity.

In general it can be stated that the output format of exposure estimates varies between the different tools (see Chapter 10.4). Only ECETOC TRA is able to directly calculate a risk characterisation ratio. Thus, if this risk characterisation ratio is >1 suitable RMMs can be selected to derive a generic scenario of safe conditions. This represents an advantage in REACH context.

STOFFENMANAGER© also offers the option to enter a limit value for the assessed substance but does not provide the corresponding risk characterisation ratio.

None of the evaluated Tier 1 tools is able to produce report files that offer a full description of an exposure scenario as it is needed for the chemical safety report (CSR). However there are additional tools and templates using the same model algorithm that are able to fill this gap.

Examples for these are the CEFIC GES/ES template and Chesar (current version 1.2).

The CEFIC template (release 2010) is available as Excel spreadsheet and can be used for developing generic exposure scenarios for occupational exposure, translating available sector-specific GES's into substance-specific exposure scenarios and transferring data into certain IT systems. It can be used together with ECETOC TRA v.2.[93]

Chesar (Chemical Safety Assessment and Reporting tool) is a plug-in available for the widely used IUCLID (International Uniform Chemical Information Database) software which is able to store and exchange various information related to chemicals. The first version of the Chesar plug-in has been released in 2010 by the European Chemicals Agency (ECHA) and is used to carry out chemical safety assessments (CSAs) and prepare chemical safety reports and exposure scenarios (ES) for communication in the supply chain.[94]

The model algorithm of ECETOC TRA is already implemented in Chesar, furthermore it is planned to implement also other models in a later version.

One example for these models is MEASE. Although the MEASE model algorithm will (in contrast to ECETOC) not be a part of Chesar the corresponding model input parameters will be available as options within the IUCLID plug-in and form a template that is able to simulate the MEASE inherent scenario design. Moreover it will be possible to create xml-files with MEASE which can directly be imported into Chesar and facilitate the conversion process (Vetter and Battersby, 2012; personal communication).

Concerning the EMKG-EXPO-TOOL a similar conversion process is planned: It is intended that the Chesar user is able to upload an xml-file containing the assessment related information and the results of the exposure assessment carried out with the EMKG-EXPO-TOOL. The necessary functionality to upload exposure assessment results from EMKG-EXPO-TOOL is already set up in the Chesar version 2.0.1 by means of pull-down menus together with alternative Tier 1 exposure assessment tools.

Currently, the determinants (= systematically described conditions driving the exposure) of the EMKG-EXPO-TOOL are associated to the determinants of Chesar with support of the Chesar team of ECHA.

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93 www.cefic.org.

94 for more information see http://iuclid.eu and http://chesar.echa.europa.eu.

Initially, EMKG-EXPO-TOOL parameters were assigned to corresponding Chesar data.
On this basis an additional feature will be developed for the EMKG-EXPO-TOOL to create an export file with the results from the exposure assessment.
The xml-format of the potential EMKG-EXPO-TOOL report file is currently being adapted to the Chesar xml-format in collaboration with ECHA.
There are considerations to implement the EMKG–EXPO-TOOL as a plug-in into Chesar in a second step in future. For this purpose, it will be necessary to recode the tool in Chesar (Walendzik, 2012; personal communication).

10.6 Risk management measures

Some simple RMMs are implemented in several of the tools included in this project, e.g. the option "LEV" is implemented in all tools with varying level of detail and the option "general ventilation" can be used in all tools except ECETOC TRA v.2.
More specific control measures at the process level, e.g. wetting of powders to prevent the release of dust, are addressed in MEASE and STOFFENMANAGER©.
In general, it is desirable to use exposure assessment tools with refined options concerning the selection of organisational measures, as in practice reducing release from the source with the help of organisational measures should be favoured over using PPE, which is however included in some tools as RMM.
ECHA, 2010b provides contradicting information about the implementation of PPE (see INtroduction) – a clear advice, if its use is considered to be adequate without a further exploration of the possibilities of exposure reduction via organisational measures would be desirable.

10.7 Additional remarks on the use descriptor system

The use descriptor system as described in the REACH guidance R12 (ECHA, 2010a) takes a special role within the different approaches of handling categories as it is recommended to use it to describe exposure situations within the chemical safety report and the safety data sheets. Thus, for tools which shall be used in REACH context the implementation of the descriptor system increases the usability. In the following paragraphs some details of the PROC system are listed that are somehow inconsistent or may be a source of misinterpretation:

- Some PROCs describe general process designs/settings (e.g. "closed system") whereas other PROCs contain task descriptions.
- Control approach and task description are sometimes integrated (e.g. in case of PROCs 22 and 23) and in doubt all available possibilities should be covered to ensure a safe use of the corresponding substance.
- The implementation of process temperature is not homogeneous: For some PROCs it is part of the short title (PROCs 22, 23, 26), for some it is considered in the explanation (PROCs 6, 17,18) and for the rest it is not mentioned at all.
- In case of spraying the setting (industrial/professional) is part of the use description and not a subsequent determinant as for the other PROCs, therefore two PROC numbers exist (PROC 7 and 11).

- Although PROC 19 (Hand-mixing with intimate contact and only PPE available) can be combined with both types of setting (i.e. professional and industrial) it may not represent actual state of the art technology.

Nevertheless, the system of standardised process descriptions is a useful tool which offers a large variety of possibilities to model a common working day and which shows a sufficiently low level of vagueness to present a suitable standard collection of handling descriptions.

10.8 Conclusion

Overall it can be concluded that the choice of the tool with the “best” concept heavily depends on the specific situation (substance, use and route) that shall be assessed and the personal preferences of the user. Underlying concepts, strengths and limitations of the various tools within this project show large differences and are hardly comparable in many areas.

As all evaluated tools can be classified to be at Tier 1 or 1.5 level, it cannot be expected that all details of an exposure situation are described in a realistic way. However, as long as the user is informed about the tool’s limitations he will be able to produce risk assessments which lead to a safe use.

Thus, the most important advice for a potential user is to obtain a maximum of information about his preferred tool and not to use it outside of its designated scope (see also Appendix 5).

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Abbreviations

AC	Article category
ACH	Air changes per hour
AM	Arithmetic mean
APF	Assigned protection factor
BAuA	“Bundesanstalt für Arbeitsschutz und Arbeitsmedizin“ (Federal Institute for Occupational Safety and Health)
BIOH	British Institute of Occupational Hygienists
BOHS	British Occupational Hygiene Society
BWI	“Bewertungsindex” (quotient of measured 5 exposure value and occupational exposure limits)
CBI	Confederation of British Industry
CEFIC	“Conseil Européen de l'Industrie Chimique“ (European Chemical Industry Counsil)
CGS	control guidance sheet
Chesar	Chemical Safety Assessment and Reporting tool
COSHH	Control of Substances Hazardous to Health
CSR	chemical safety report
DEO unit	dermal exposure operation unit
DNEL	Derived no effect level
EASE	Estimation and Assessment of Substance Exposure
ECHA	European Chemicals Agency
ECEL	Exposure Control Efficiency Library
ECETOC	ECETOC – European Centre for Ecotoxicology and Toxicology of Chemicals
EMKG	“Einfaches Maßnahmenkonzept Gefahrstoffe” (Easy to use workplace control scheme for hazardous substances)
EPL	Exposure potential band for liquids
EPS	Exposure potential band for solids
ERC	Environmental release category
ES	Exposure Scenario
EUSES	European Union System for the Evaluation of Substances
FAQ	Frequently asked questions
GES	Generic Exposure Scenario
GM	Geometric mean
GOHP	Good occupational hygiene practice
GSD	Geometric standard deviation
HEDSET	Harmonised Electronic Data Set
HERAG	Health Risk Assessment Guidance
HSE	Health and Safety Executive
HSL	Health and Safety Laboratory
INSHT	“Instituto nacional de seguridad e higiene en el trabajo” (National Institute for Occupational Safety and Hygiene)
IOM	Institute of Occupational Medicine
ITEM	Institute of Toxicology and Experimental medicine
IUCLID	International Uniform Chemical Information Database
KRIOH	Kuopio Regional Institute of Occupational Health

LEV	Local exhaust ventilation
LOD	Limit of detection
LOQ	Limit of quantification
MEASE	The metals' EASE
MEGA	"Messdaten zur Exposition gegenüber Gefahrstoffen" (Measurement data relating to workplace exposure to hazardous substances)
MoE	Margin of Exposure
NEDB	National Exposure Database
NIOSH	National Institute for Occupational Safety and Health
NIWL	National Institute for Working Life
NO(A)EL	No observed (adverse) effect level
NONS	Notification of new substances
OC	Operational condition
OECD	Organisation for Economic Co-operation and Development
OEHC	Occupational and Environmental Health Center
OEL	Occupational exposure limit
PC	Physico-chemical *or* product category
PPE	Personal protective equipment
PROC	Process category
RAR	Risk assessment report
RCR	Risk characterisation ratio
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk management measures
SMEs	Small and medium sized enterprises
Steambase	STOFFENMANAGER Exposure and Modelling database
SU	Sector of use
SZW	"Ministerie van Sociale Zaken en Werkgelegenheid" (Dutch Ministry of Social Affairs and Employment)
TCNES	Technical Committee for New and Existing Substances
TNO	"Nederlandse Organisatie voor Toegepast Natuurwetenschappelijk Onderzoek" (Netherlands Organization for Applied Scientific Research)
TUC	Trades Union Congress
TRA	Targeted Risk Assessment
US EPA	US Environmental Protection Agency
VRA	Voluntary risk assessment

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Appendix 1 EASE logic tree

Logic diagrams for EASE (version 2 for windows)

Appendix 1, Table 1 EASE - Abbreviations

P.T.	Process temperature
B.P.	Boiling point
M.P.	Melting point
V.P.	Vapour pressure
TBA	Tendency to become airborne
Mod	Moderate
P.T.	Page
LEV	Local exhaust ventilation
Seg	Segregation
DV	Dilution ventilation
DV+DH	Dilution ventilation + Direct handling
DH	Direct handling
DC+G	Dry crushing and grinding
DM	Dry manipulation
LDT	Low dust techniques

Chart 2: Route of exposure

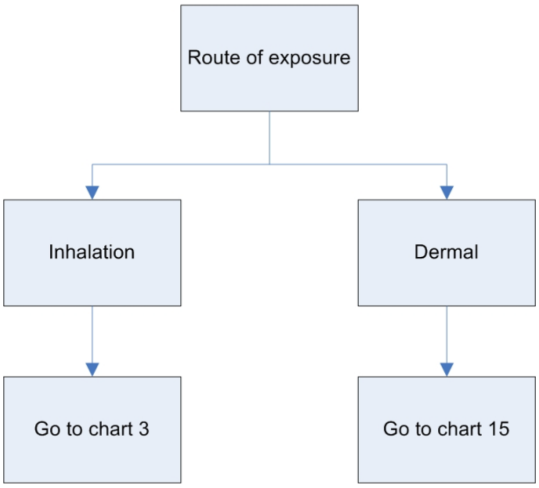


Chart 3: Determination of type of inhalation exposure

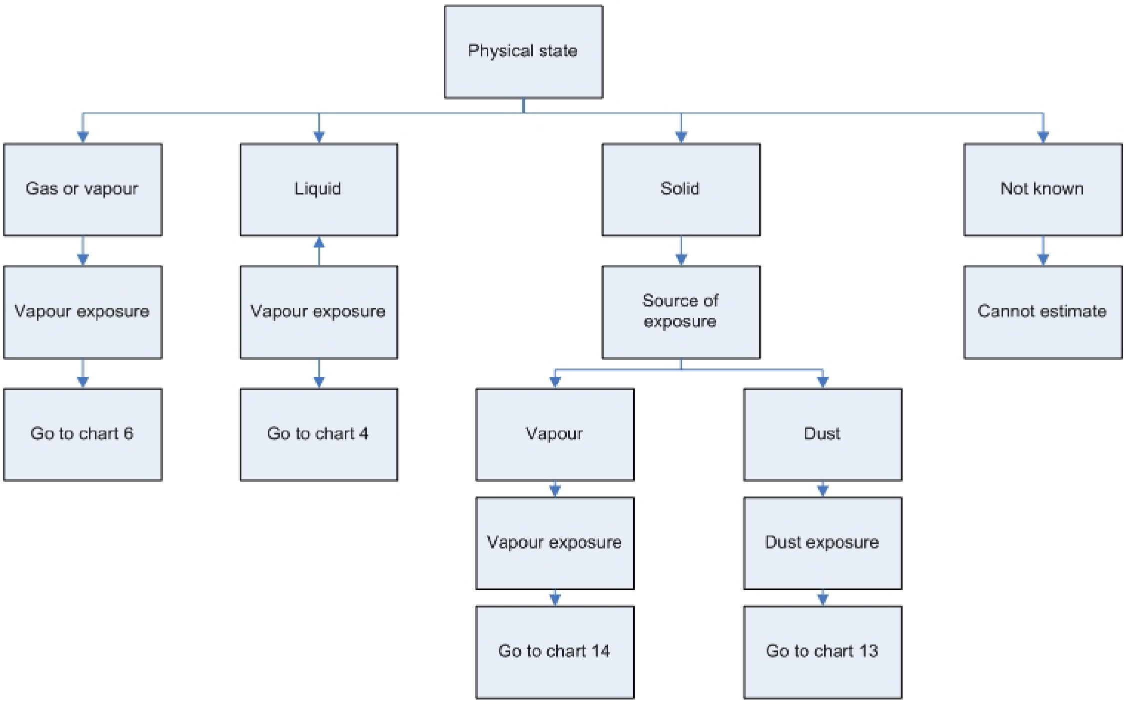


Chart 4: Determination of vapour pressure

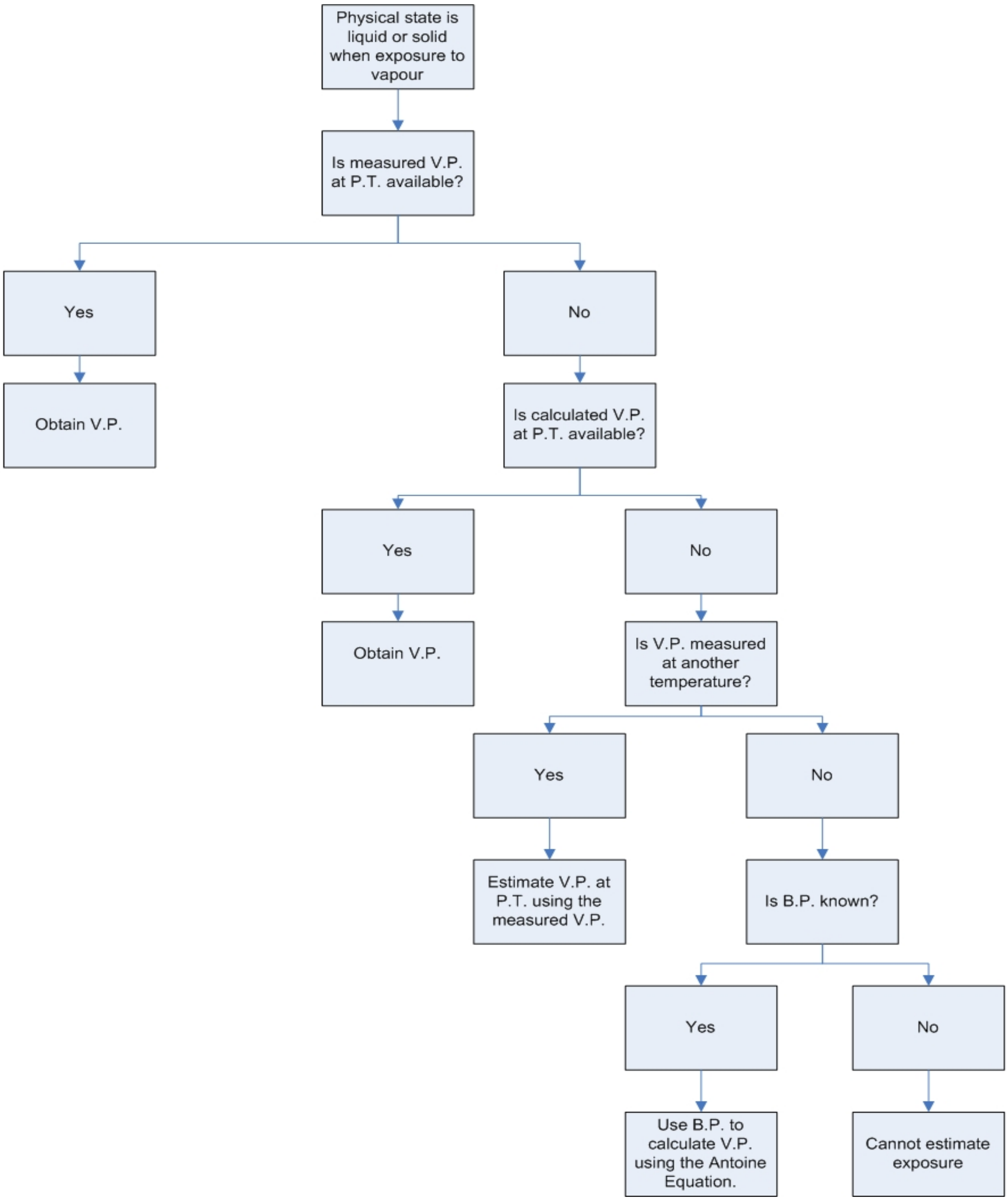


Chart 5: Determination of volatility

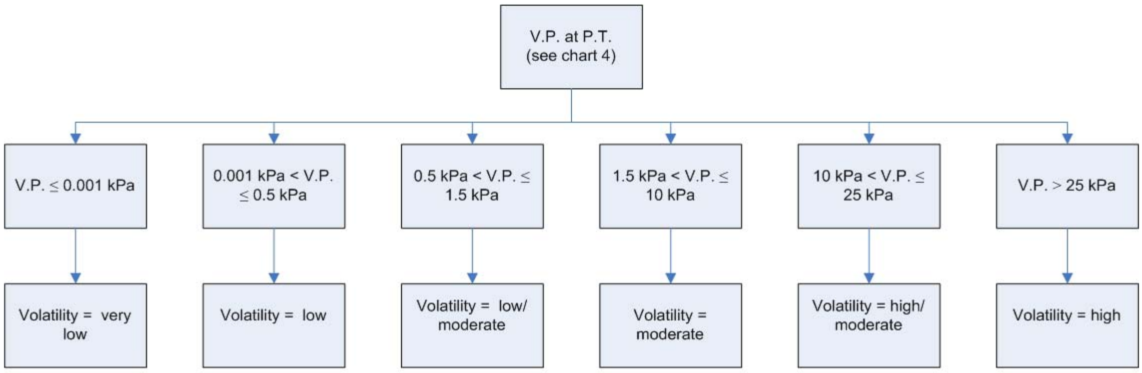


Chart 6: Determination of tendency to become airborne

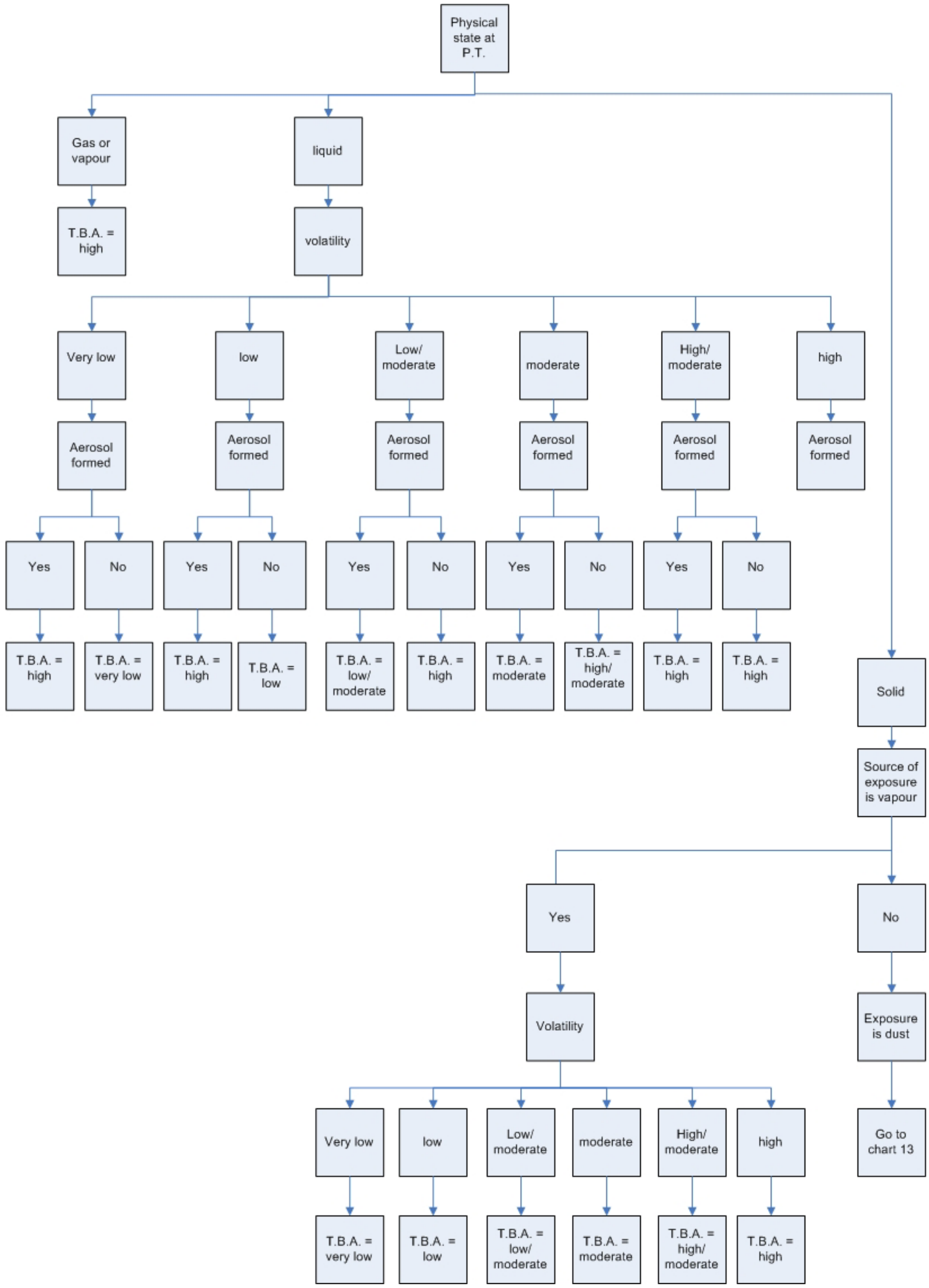


Chart 7: Determination of pattern of control

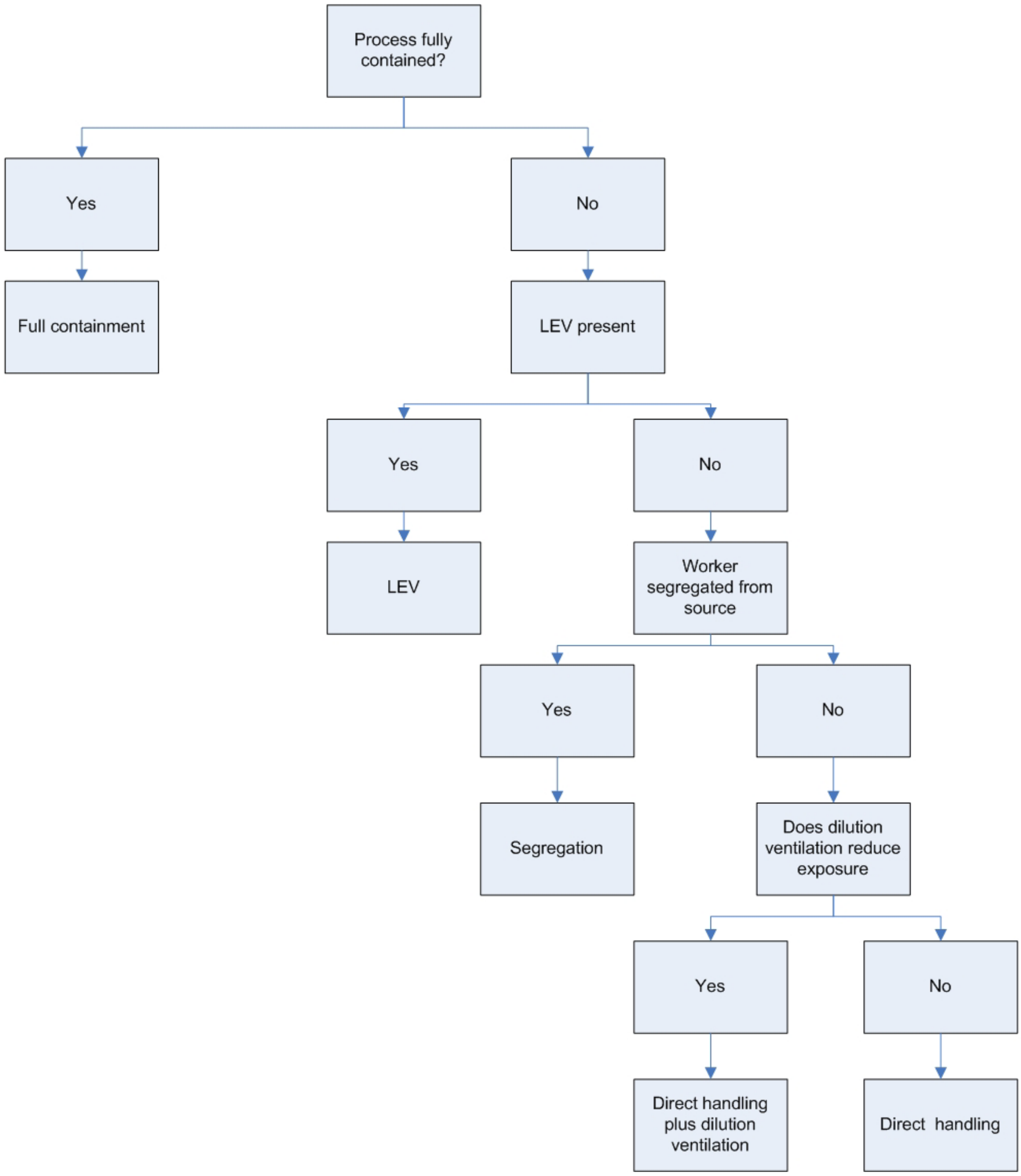


Chart 8: Determination of pattern of use

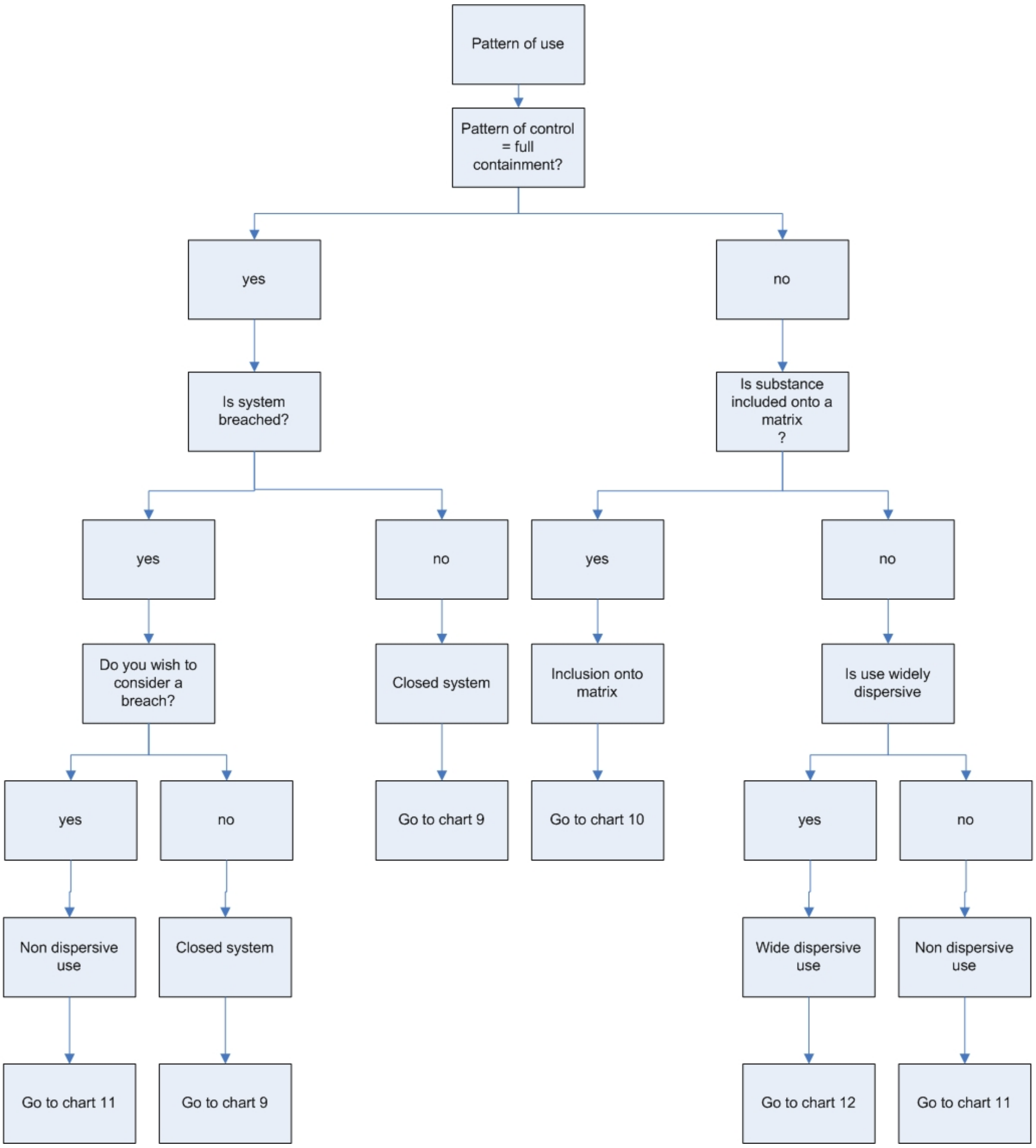


Chart 9: Determination of vapour exposure use pattern is closed system

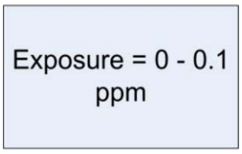


Chart 10: Determination of vapour exposure use pattern is inclusion onto matrix

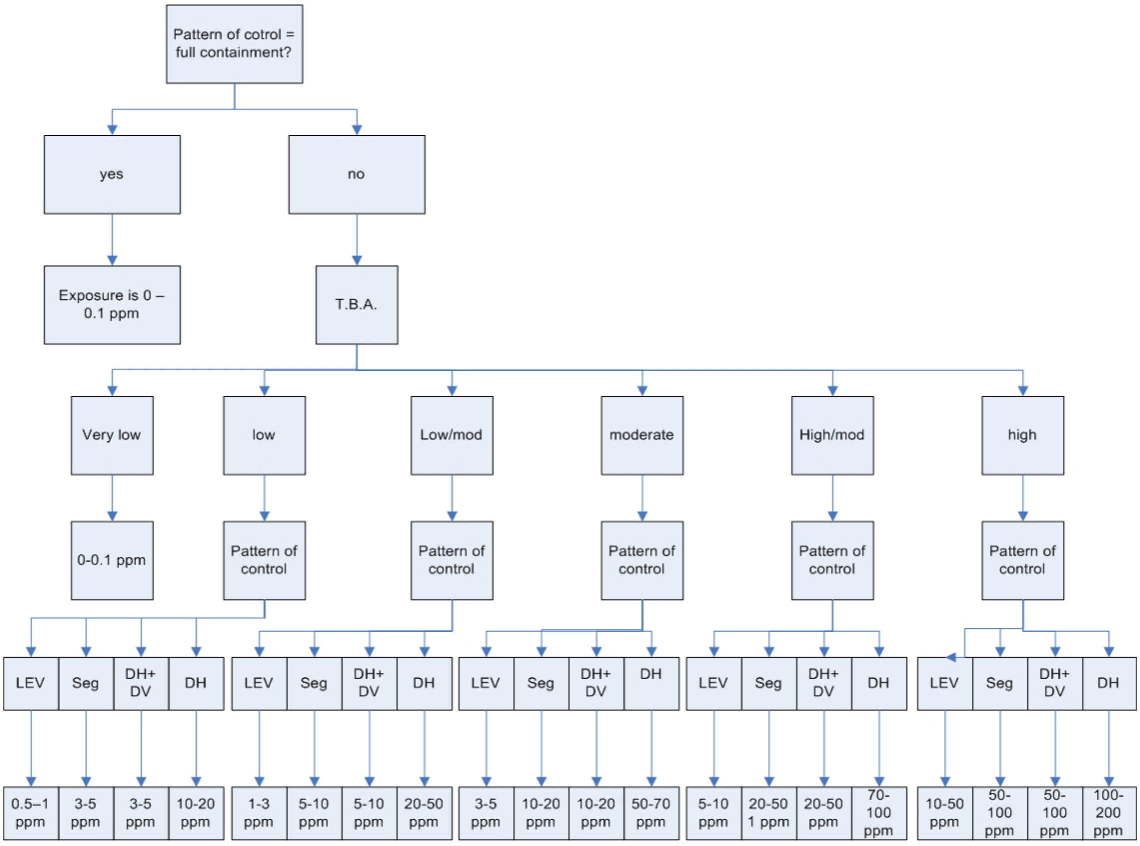


Chart 11: Determination of vapour exposure use pattern is non dispersive

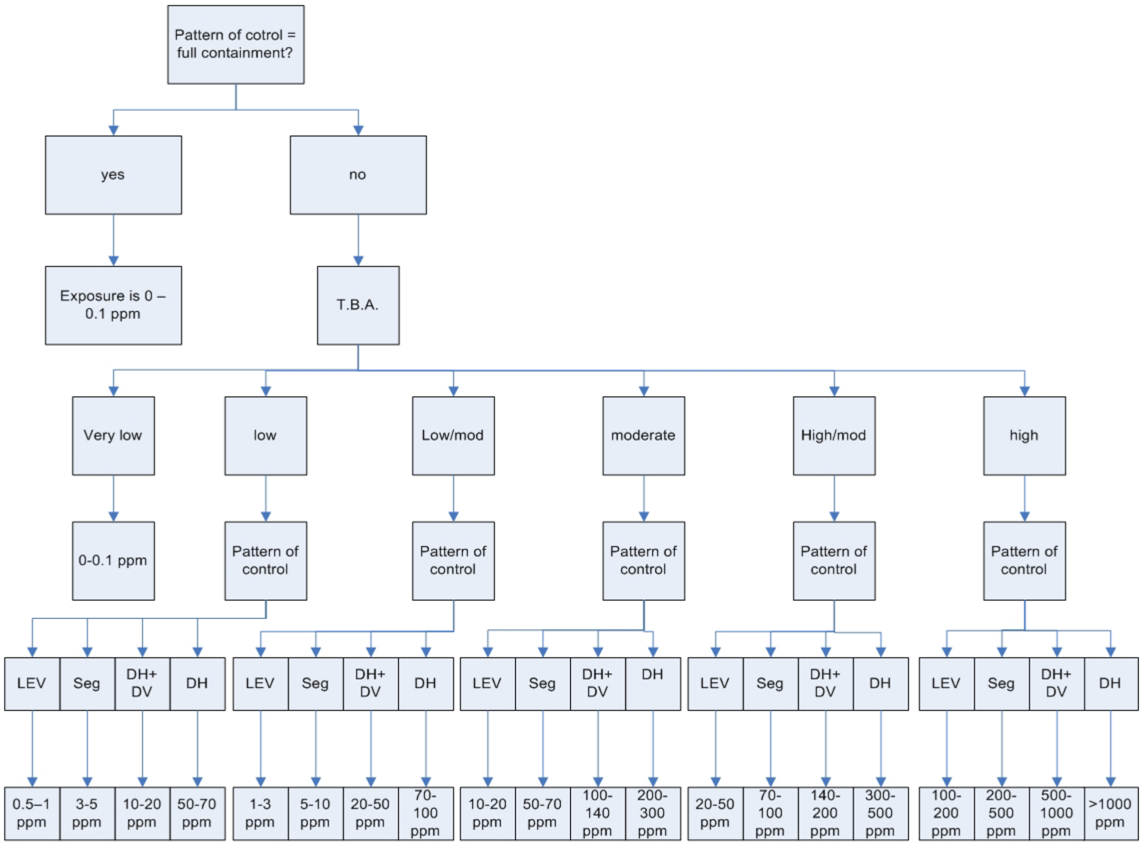


Chart 12: Determination of vapour exposure use pattern is widely dispersive

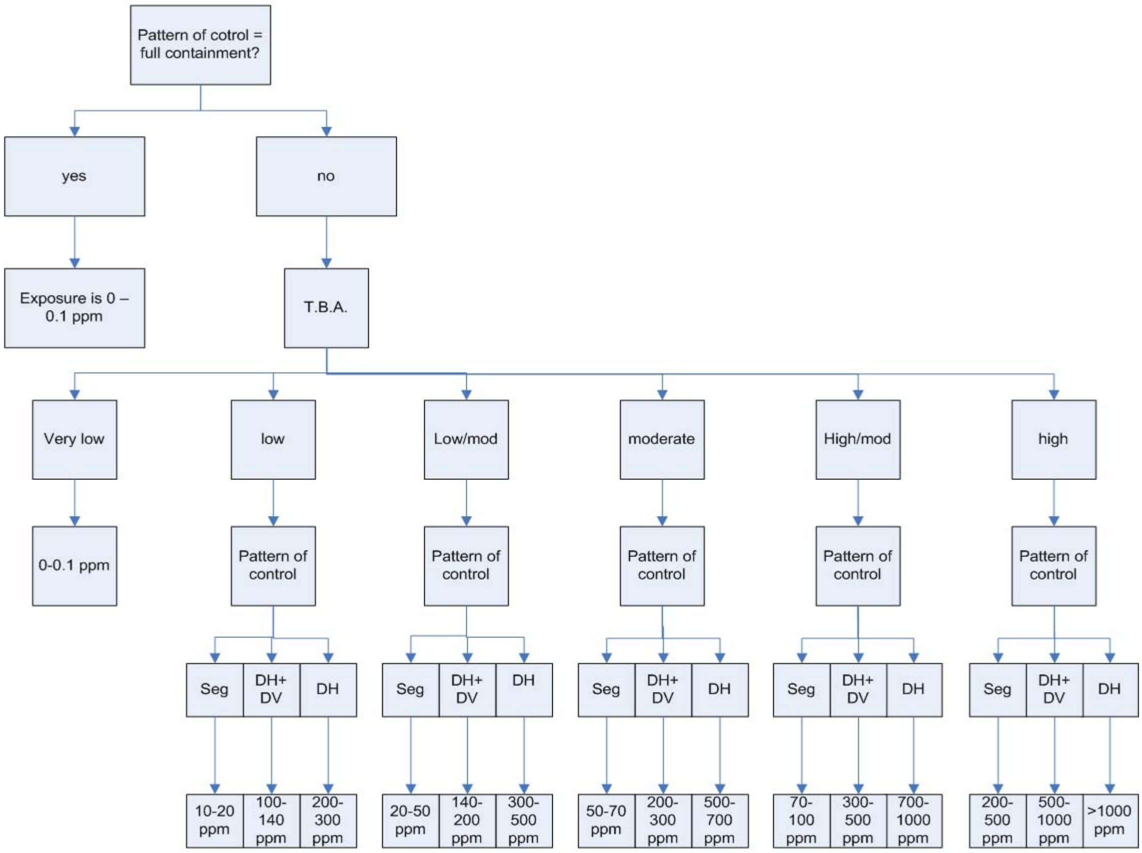


Chart 13: Determination of Dust exposure

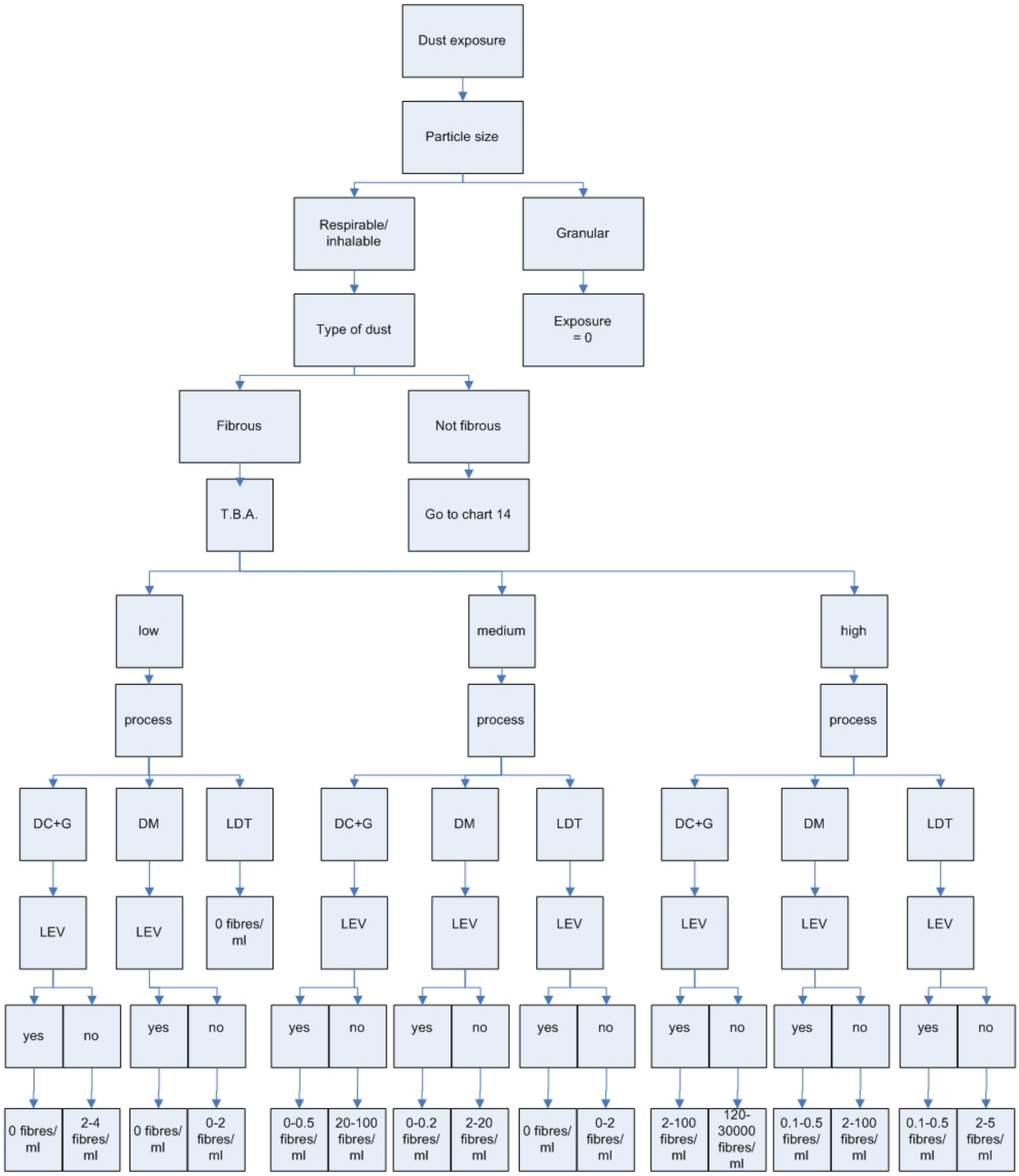


Chart 14: Determination of Dust exposure – Dust is non-fibrous

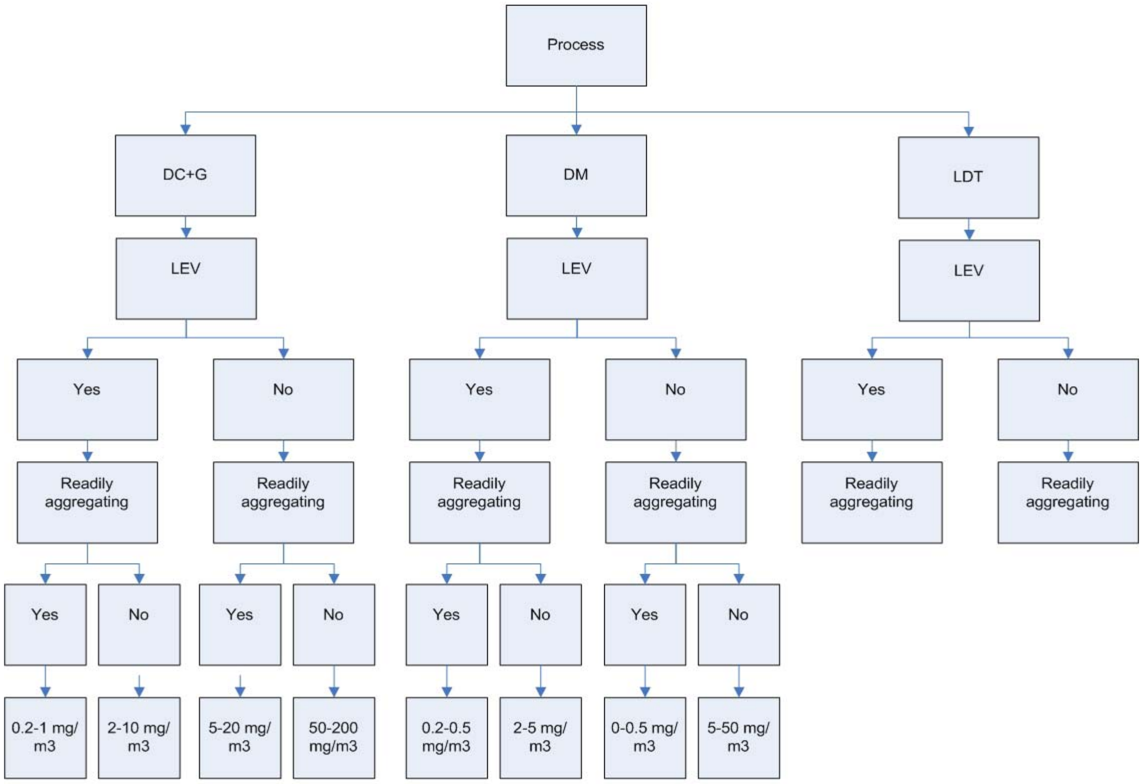
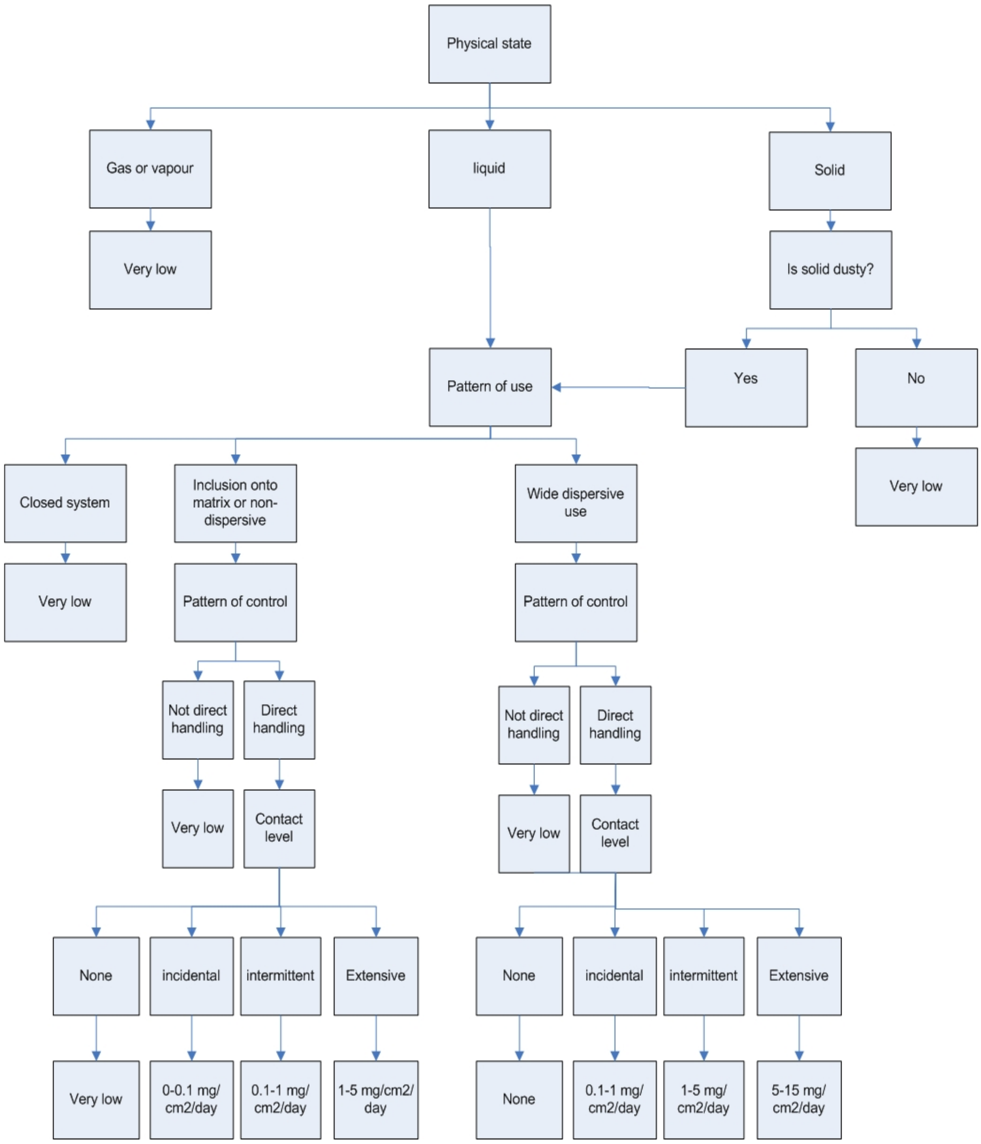


Chart 15: Determination of dermal exposure



Appendix 2 Available validation studies

2.1 EASE

- Bredendiek-Kämper et al., 2001: Exposures to low volatility organic solvents are reflected more accurately than exposures to highly volatile organic solvents.
- HSE, 2003; Creely et al., 2005: The model generally either predicts close to the measured exposures or overestimates exposure. It considerably overestimates dermal exposure. The end-point range for low-dust technique and use of LEV is too large (0-1 mg/m^3). The performance is highly variable.
- ECETOC, 2004: In most cases EASE overestimates exposure, but in some cases underestimation takes place – mostly for handling of solids if the material is dusty. The consideration of LEV effectiveness is insufficient but the authors realise that this maybe representative for the time where EASE was developed. Dermal exposure may be overestimated by a factor of 50 (e.g. in the case of exposure to zinc). Inhalation values are also highly overestimated.
- Johnston et al., 2005: The overestimation may be due to invalid assumptions of uniform exposure situations. EASE is good as screening tool, because only minimal inputs are required.
- Tickner et al., 2005: In the absence of an alternative database, the NEDB database was used for calibration of the model as well as for validation after finishing the first version, by comparing the predictions with further searches of the NEDB data and adjusting the ranges when necessary.
- Boogaard et al, 2008**:** Comparison of biomonitoring data with dermal exposure estimations of EASE and RISKOFDERM (taken from EU risk assessments). The investigated substances were styrene, 2-butoxyethanol and 1-methoxy-2-propanol. It was concluded that for EASE the measured values mostly lie within the predicted range.
- Kindler et al., 2010: Exposure estimation for dusts gives reasonable results, but the tool is not appropriate for exposure estimation of substances with high vapour pressure (prediction either too low or too high) and exposure to low vapour pressure substances is overestimated.

2.2 ECECTOC TRA

- ECETOC, 2004: Some comparisons between the ECETOC TRA v.1 with EU risk assessment results were performed by ECETOC (2004) but no evaluation against actual measured data took place (see also ECHA, 2010b). The extraction of information from the comparison is hindered by the lack of a standard procedure for exposure estimation within the EU risk assessment process.
- Dobecka et al, 2011: An evaluation study for inhalation workplace exposure to organic solvents (toluene, ethyl acetate, acetone, o-xylene) was carried out in Poland. A paints and lacquers factory (section filtration and decanting room), a shoe factory (sole manipulation, sewing section, assembling), and a refinery (supervisor, process controller, operator and mechanic work tasks) were tested. The processes codes (PROCs) 1 (Use in closed process, no likelihood of exposure), 2 (Use in closed, continuous process with occasional controlled exposure) and 10 (Roller application or brushing) were assigned to these

workplaces, although the selected process categories did not precisely describe the studied applications. The outcome of this comparison ranges from underestimation (shoe factory) to correct results (i.e. measurements lying within the interval between exposure with and without LEV).

- Vink et al,2010: The outputs from the ECETOC TRA v.2 were compared with other models (STOFFENMANAGER© and RISKOFDERM). The inhalation exposure estimates (full shift) were also compared with the 90th percentile of 745 datasets on propylene glycol monomethyl ether (1-methoxypropan-2-ol, PGME) measurements selected from the MEGA database (1996-2000). Model estimates obtained without LEV and the assumption that the product contains 30% PGME led to a substantial overestimation of the real workplace exposure in case of ECETOC TRA. The PROCs 8a, 11, 13 were assigned to homogenizing and filling, spraying and cleaning respectively.

2.3 MEASE

No validation studies are published so far.

2.4 EMKG-EXPO

- Lee et al., 2011: The COSHH essentials model was evaluated using full-shift exposure measurements of five chemicals in a mixture (i.e. acetone, ethyl-benzene, methyl ethyl ketone, toluene and xylene) at a plant producing paint materials. The tasks "batch-making" and "bucket-washing" were evaluated for all three control levels and indicated a significant amount of underestimations for bucket washing in case of acetone (control level 2 and 3), methyl ethyl ketone and Xylenes (both control level 3).
- Kindler et al., 2010: 42 scenarios are evaluated within EMKG-EXPO and EASE. Result: Exposure to substances of low vapour pressure is overestimated. The efficiency of LEV is overestimated (which means that exposure may be underestimated). The model development is not well documented. No chemicals in mixtures are addressed. Only minimal information is required for using the tool. Exposure predictions for substances with high vapour pressure appear to be fine.
- Lee et al., 2009: COSHH essentials was evaluated for short-term and full shift exposures in a printing plant. 188 measurements of isopropanol and 187 measurements of acetone (each ~60 min) were collected and time-weighted average concentrations were evaluated for methylene chloride. Overall the study suggests the COSHH essentials provides reasonable results, however there are some cases (cleaning with acetone or isopropanol, print preparation with isopropanol, full shift exposure to acetone) where the probability of underestimations is larger than 10%.
- Tischer et al., 2007 and Tischer et al., 2009: It is evaluated by probabilistic modelling if the activity concepts of EMKG provide a sufficient level of safety. A Monte-Carlo simulation of the BWI (“Bewertungsindex”; ratio of measured exposure value and occupational exposure limits (OEL)) distribution is performed. Overall 732 measurements with data for two control banding scenarios were used. It was found that control banding does not guarantee a safe use. However

the generic simulation showed that compliance for volatile liquids in closed systems and solids in presence of LEV was high.

It has to be stated that OELs could vary between different countries. This represents a potential source of error within the study as it also influences the BWI.

In this publication several earlier evaluations of COSHH and the EMKG concept are cited which show different results but did not lead to an update of exposure ranges or the EMKG scheme.

- Hashimoto et al., 2007: COSHH essentials was applied to 12 petroleum company workplaces and its results were compared with comprehensive risk assessments. These risk assessments were based on exposure estimations which were created by measurements or expert judgement (depending on the workplace) and their comparison with OELs. For seven of the workplaces an over-controlled situation was predicted. No under-controlled situations were identified.
- Jones et al., 2006a: Evaluation of COSHH essentials for vapour degreasing and bag filling operations. 78% of the exposure situations in case of vapour degreasing and 48% in case of bag filling operations are "under-controlled", i.e. the actual concentration exceeded the predicted upper limit within COSHH.
- Tischer et al., 2003a and Tischer et al., 2003b: Evaluation of a small subset of the possible scenarios within COSHH essentials. 18 different branch specific situations. Most of the exposure situations are at least represented in a safe way, as the error is on the side of caution. The external evaluation showed good agreements for solids/dusts. For liquids (larger amounts/litres) agreement is good, for millilitre quantities of liquids and dispersive processes (e.g. painting or applying adhesives), the exposure levels may exceed the predicted range.

  "Application on large surfaces" is included in the EMKG-EXPO-TOOL as additional option, but only for quantities larger than 1 l, so this problem (i.e. underestimations in case of dispersive processes with liquids) may remain (see also Chapter 7.2.3). There is a lack of exposure data for higher levels of control in the evaluation set.

2.5 STOFFENMANAGER©

- Koppisch et al., 2012: Validation of STOFFENMANAGER© with data from the MEGA exposure database (1984-2007). Evaluation of two model equations: handling of powders/granules (n=390 data points, 15 scenarios) and machining (n=1133 data points, 22 scenarios) for exposure to inhalable dust. Tasks: grinding, sanding, milling, sawing or cutting of wood, stone or asphalt for machining; filling/dumping, mixing, sweeping, chimney cleaning, plastering for the handling of powders/granules. Result: 11% and 7% of the MEGA data were above the estimated 90th percentile of STOFFENMANAGER©, respectively.
- Schinkel et al., 2010 (see also Chapter 8.3): Correlations between measured and predicted values, bias and precision were calculated for a set of measurements. The scenarios "handling of powders and granules" (n=82 data points), "handling solids resulting in comminuting" (n=60), "handling of low-volatile liquids" (n=40), "handling of volatile liquids" (n=72) were evaluated separately. The predicted 90th percentile exposure for "handling of powders and granules" was not sufficiently conservative.

- Vink et al., 2010: This publication includes a comparison of STOFFENMANAGER© and ECETOC TRA predictions for inhalation exposure with full-shift exposure values derived from the MEGA database on PGME (1-methoxypropan-2-ol, 90th percentile of 745 datasets (1990 - 2000)[95]. STOFFENMANAGER© results were about half of the reasonable worst case derived from the measured values.

Additional remark

Concerning the publication of Vink et al, 2010 it has to be noted that the process descriptions within the publication are not identical with the ones derived from the usemap developed within the current study, which is explained in Chapter 0 and can be found in Appendix 6. Appendix 2, Table summarises these contraditions: “Spraying” (i.e. PROC 11) is assigned to the STOFFENMANAGER© handling category “handling liquids at high pressure resulting in substantial generation of mist or spray/haze” in both Vink et al., 2010 and Appendix 6 while “Homogenizing and filling” (PROC 8a) and “Cleaning” (PROC 13) are assigned to different Stoffenmanger handling categories in Vink et al., and Appendix 6.

[95] Summary of datasets provided in Vink et al., 2010: http://www.dguv.de/ifa/de/pub/rep/pdf/rep01/bgar0199/mega.zip

Appendix 2, Table 1 Comparison of task descriptions, STOFFENMANAGER© and handling categories as published in Vink et al., 2010 with STOFFENMANAGER© handling categories as assigned to a certain PROC number according to usemap (see Appendix 6)

Task (general description as published in Vink et al., 2010)	**Homogenizing and filling**	**Spraying**	**Cleaning**
Descriptor (as assigned by Vink et al., 2010)	**PROC 8a:** Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	**PROC 11:** Non-industrial spraying	**PROC 13:** Treatment of articles by dipping andpouring
STOFFENMANAGER© task description as published in Vink et al., 2010	Handling liquids, low pressure, low speed, medium–large surfaces	Handling liquids, high pressure, substantial generation of mist/spray/ haze	Handling liquids, low pressure, low speed. medium–large surfaces
STOFFENMANAGER© task description according to usemap (see Appendix 6)	handling of liquids (using low pressure, but high speed) without creating a mist or spray/haze	handling of liquids at high pressure resulting in substantial generation of mist or spray/haze	handling of liquids on large surfaces or large workpieces

Green: Assignment of Vink et al. and Usemap are identical
Red: Assignment of Vink et al., and Usemap not identical

2.6 RISKOFDERM

- Vink et al., 2010: The publication contains a comparison of results from STOFFENMANAGER©, ECETOC TRA and RISKOFDERM with full-shift exposure values derived from MEGA on PGME (1-methoxypropan-2-ol, 90th percentile of 745 datasets). As no dermal exposure data are stored in MEGA the results of RISKOFDERM were only compared with results of ECETOC TRA. It was shown that RISKOFDERM results are higher than ECETOC results, in both cases with and without the exposure reducing factor apllied for the risk management measure “LEV” in ECETOC.
- Boogaard et al, 2008: The publication summarises a comparison of biomonitoring data with dermal exposure estimations of EASE and RISKOFDERM taken from EU risk assessments. The investigated substances were Styrene, 2-Butoxyethanol and 1-methoxy-2-propanol. It was concluded that overall RISKOFDERM tends to overestimate exposure.
- TNO, 2006; Warren et al., 2006: A benchmark study with a small set of data was performed during the process of tool development, which resulted in quite reasonable results.The underlying data were later integrated into the tool. More detailed information about these benchmark data and the corresponding validation results are not available.

Appendix 3 The use descriptor system – PROCs

PROC no	short description
1	Use in closed process, no likelihood of exposure
2	Use in closed, continuous process with occasional controlled exposure
3	Use in closed batch process (synthesis or formulation)
4	Use in batch and other process (synthesis) where opportunity for exposure arises
5	Mixing or blending in batch processes (multistage and/or significant contact)
6	Calendering operations
7	Industrial spraying
8a	Transfer of chemicals from/to vessels/ large containers at non dedicated facilities
8b	Transfer of chemicals from/to vessels/ large containers at dedicated facilities
9	Transfer of chemicals into small containers (dedicated filling line)
10	Roller application or brushing
11	Non industrial spraying
12	Use of blowing agents for foam production
13	Treatment of articles by dipping and pouring
14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation
15	Use of laboratory reagents in small scale laboratories
16	Using material as fuel sources, limited exposure to unburned product to be expected
17	Lubrication at high energy conditions and in partly open process
18	Greasing at high energy conditions
19	Hand-mixing with intimate contact (only PPE available)
20	Heat and pressure transfer fluids (closed systems) in dispersive use
21	Low energy manipulation of substances bound in materials and/or articles
22	Potentially closed operations with minerals at elevated temperature
23	Open processing and transfer of minerals at elevated temperature
24	High (mechanical) energy work-up of substances bound in materials and/or articles
25	Hot work operations with metals
26	Handling of solid inorganic substances at ambient temperature
27a	Production of metal powders (hot proc-esses)
27b	Production of metal powders (wet proc-esses)

Appendix 4 Fransman et al., 2008 - details

Appendix 4, Table 1 Estimated average efficiency values and 95% confidence intervals for individual RMMs (Fransman et al., 2008)*.

RMM	*n*	Estimated efficiency (%)	95% confidence interval (%)[96]		
Enclosure	14	50	4	to	74
Complete	3	86	30	to	97
Partial	6	23	-103	to	70
LEV	280	82	78	to	84
Exterior	65	81	75	to	86
LEV + Enclosure	9	86	69	to	94
Integrated	133	87	84	to	90
Mobile	4	61	-28	to	88
Vapour collection	19	64	23	to	83
Specialized ventilation	14	87	73	to	94
Specialized booth	1	94	37	to	99
Clean-zone worker	6	86	64	to	95
Miscellaneous	7	85	47	to	96
General ventilation	42	43	17	to	61
Natural	9	31	-56	to	70
Mechanical	31	46	17	to	65
Suppression techniques	69	83	77	to	88
Wet suppression	32	84	75	to	89
Capture sprays	25	88	80	to	93
Stabilization	12	58	-3	to	83
Separation of workers	14	87	71	to	94
Complete	9	90	75	to	96
Partial	5	71	-31	to	94

*RMMs which were implemented in the inhalation part of MEASE are marked in blue.

According to Fransman et al., 2008 experimental values included in the database had to fulfil a number of requirements:

- Efficiency had to be based on quantitative measurement data and appropriate descriptive statistics had to be available
- Efficiency of RMMs had to be determined either in terms of pre- and post-comparisons or as a cross-sectional comparison of situations with and without RMM. “Optimization data” (e.g. a comparison of old and new LEV) were marked and excluded from the analyses as well as data sets where one of the exposure values was below the limit of detection.
- Efficiency values have to be based on only one RMM.
- Suitable data were represented by studies where a quantitative factor could be distilled that represented the reduction effect of a particular RMM (no “chaotic” data sets or sets with contradictions between the different data points).

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[96] Confidence intervals based on statistical analyses performed by Fransman et al. are implemented in MEASE except RMMs with negative confidence intervals. However it should be noted that single negative measurement results were not excluded from these analyses (Fransman et al., 2008).

- If the mean exposure in situation with RMM or in situation without RMM was below the level of detection, the data sets were excluded.

Appendix 5 Applicability matrix

Inhalation exposure

Applicability	EMKG	STOFFENMANAGER©	ECETOC-TRA v2	ECETOC-TRA v3	MEASE
Route	Inhalation	Inhalation	Inhalation	Inhalation	Inhalation
PROC Code	Not included	Not included; however, a suggested relation between PROCs and Handling Classes is presented	Yes	Yes	Yes
Task / Process	implemented via control guidance sheets	handling classes	Yes	Yes	Yes
Covered physical state	solid liquid	solid liquide	solid liquid = volatile	solid liquid = volatile	solid liquid gaseous
Beyond Scope	dusts by abrasive techniques, open spray, gases, pesticides, fumes (soldering, welding, acid fumes), wood dusts, CMR substances	fibres, gases or hot working techniques (welding, soldering, acid fumes); abrasion and impact of solid objects not recommended	Fibres, liquid aerosols or emissions from hot processes (e.g. fumes). Caution also needs to be exercised when applying to CMRs	Fibres, liquid aerosols or emissions from hot processes (e.g. fumes). Caution also needs to be exercised when applying to CMRs	organic substances & some restrictions concerning special combinations of PROC/physical properties
Type of enterprises	SME	industrial & professional	industrial & professional	industrial & professional	industrial & professional
Substance emission potential Volatility / Dustiness	3 categories for solids low / medium / high 3 categories for liquids low / medium / high	6 categories for solids Objects Solid granules, graines & flakes Granules, grains & flakes Coarse dust Fine dust Extremely dusty products 1 category for liquids: 0-30.000 Pa (vapour pressure of component)	3 categories for solids low / medium / high 4 categories for liquids very low / low / medium / high	3 categories for solids low / medium / high 4 categories for liquids very low / low / medium / high	5 categories for solids massive objects solids, low dustiness solids, medium dustiness solids, high dustiness aqueous solution 3 categories for liquids low / medium / high
Amount of substance	3 categories	Qualitative user decision	Not included	Not included	Not included
Concentration of the substance	Not included	for liquids	Modifying factors (4 bands) for liquids and solids	Modifying factors (4 bands) for liquids and solids	Modifying factors (4 bands)

Duration		8 h or 15 min	categories without effect	Modifying factors (4 bands)	Modifying factors (4 bands)	Modifying factors (4 bands)
Use description		task based	task based	process based	process based	process based
Frequency / Contact level		Not included	categories without effect	Not included	Not included	Not included
Farfield factors		partly included via cgs sheets	same task by other workers	Not included	Not included	Not included
Background factors		GOHP* assumed	cleaned daily inspections and maintenance at least monthly	GOHP* assumed	GOHP* assumed	GOHP* assumed
RMM	**Operational conditions (OC)**	General ventilation	Emission control measures (7 categories)	PROC-inherent OC	PROC-inherent OC	PROC-inherent OC
		Engineered control	Adaptation of worker situation (2 categories)	Local Exhaust Ventilation	Local Exhaust Ventilation	Enclosure
		Containment	Local control measures (4 categories)	Outdoor uses	Outdoor uses	General ventilation
			General ventilation(3 categories)		General ventilation (2 levels)	Local Exhaust Ventilation - three types
						Supression techniques
						Separation of worker
	PPE	No	Yes (13 categories)	Yes (2 categories)	Yes (2 categories)	Yes (5 categories)

*GOHP: Good occupational hygiene practice

Dermal exposure

Applicability	ECETOC-TRA v2	ECETOC-TRA v3	MEASE	RISKOFDERM
Route	Dermal	Dermal	Dermal	Dermal
PROC Code	Yes	Yes	Yes	Not included
Task / Process	Yes	Yes	Yes	6 tasks
Covered physical state	solid liquid = volatile	solid liquid = volatile	solid liquid gaseous	solids liquids
Beyond Scope	Fibres, liquid aerosols or emissions from hot processes (e.g. fumes). Caution also needs to be exercised when applying to CMRs	Fibres, liquid aerosols or emissions from hot processes (e.g. fumes). Caution also needs to be exercised when applying to CMRs	organic substances	sometimes restrictions due to original data set ("only on manual tasks for powders") fumes not covered
Type of enterprises	industrial & professional	industrial & professional	industrial & professional	industrial & professional
Substance emission potential Volatility / Dustiness	Not included	Yes. Modifying factors (4 bands)	2 categories gaseous non-gaseous	They were included. If insufficient data were available to study the effect of a determinant, it was not included.
Amount of substance	Not included	Not included	Not included	Application rate 4 x to be entered 2 x inherent level
Concentration of the substance	Not included	Yes. Modifying factors (4 bands)	Modifying factors (4 bands)	Not included; the model estimated exposure to a full product handled and not to a substance in a product
Duration	Not included	Yes. Modifying factors (4 bands)	Modifying factors (4 bands)	Cumulative duration approach
Use description	process based	process based	process based	task based
Frequency / Contact level	Not included	Not included	4 categories / modifying factors / bands	Not included
Farfield factors	Not included	Not included	Not included	Not included
Background factors	GOHP* assumed	GOHP* assumed	GOHP* assumed	GOHP* assumed

Applicability		ECETOC-TRA v2	ECETOC-TRA v3	MEASE	RISKOFDERM
RMM	**Operational conditions (OC)**	PROC-inherent OC	PROC-inherent OC	PROC-inherent OC	Ventilation Distance to source Direction of application (in relation to worker) Level of automation *All of these above for one or more of the tasks only*
		Local Exhaust Ventilation	Local exhaust ventilation	Pattern of use (3 bands)	
				Pattern of exposure control (2 bands)	
				-	
	PPE	No	Yes (3 categories)	Yes (1 category)	No

Appendix 6 Usemap

Red fields indicate processes that cannot be converted accurately into the system of task descriptions of the corresponding tool.
Grey fields indicate processes which are not applicable due to general restrictions.

ECETOC TRA v. 2 and 3
Definition of processes according to the use descriptor system.
For details refer to the Excel Version of the usemap.

MEASE
Inhalation route:
According to the use descriptor system.
For details refer to the Excel Version of the usemap.

Dermal route:

OC	short version	Description	PROC	Examples/Explanation	solid	liquid
closed system	manufacturing of substances/preparations	Use in closed process, no likelihood of exposure	PROC 1	Use of the substances in high integrity contained system where little potential exists for exposures, e.g. any sampling via closed loop systems	closed system	closed system
closed system	manufacturing of substances/preparations	Use in closed, continuous process with occasional controlled exposure	PROC 2	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions. It is not high integrity and occasional exposure will arise e.g. through maintenance, sampling and equipment breakages	closed system	closed system
closed system	manufacturing of substances/preparations	Use in closed batch process (synthesis or formulation)	PROC 3	Batch manufacture of a chemical or formulation where the predominant handling is in a contained manner, e.g. through enclosed transfers, but where some opportunity for contact with chemicals occurs, e.g. through sampling	inclusion onto matrix/non-dispersive use	inclusion onto matrix/non-dispersive use

OC	short version	Description	PROC	Examples/Explanation	solid	liquid
open or closed system	manufacturing of substances/preparations	Use in batch and other process (synthesis) where opportunity for exposure arises	PROC 4	Use in batch manufacture of a chemical where significant opportunity for exposure arises, e.g. during charging, sampling or discharge of material, and when the nature of the design is likely to result in exposure	wide / non-dispersive; decision needed	wide / non-dispersive; decision needed
open or closed system	manufacturing of substances/preparations	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	PROC 5	Manufacture or formulation of chemical products or articles using technologies related to mixing and blending of solid or liquid materials, and where the process is in stages and provides the opportunity for significant contact at any stage	wide / non-dispersive; decision needed	wide / non-dispersive; decision needed
open or closed system	coating	Calendering operations	PROC 6	Processing of product matrix Calendering at elevated temperature and large exposed surface	wide / non-dispersive; decision needed	not applicable
open or closed system	spraying	Industrial spraying	PROC 7	Air dispersive techniques. Spraying for surface coating, adhesives, polishes/cleaners, air care products, sandblasting. Substances can be inhaled as aerosols. The energy of the aerosol particles may require advanced exposure controls; in case of coating, overspray may lead to waste water and waste.	wide / non-dispersive; decision needed	wide / non-dispersive; decision needed
open or closed system	transfer of substances or preparations	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	PROC 8a	Sampling, loading, filling, transfer, dumping, bagging in non-dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.	wide / non-dispersive; decision needed	wide / non-dispersive; decision needed
open or closed system	transfer of substances or preparations	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	PROC 8b	Sampling, loading, filling, transfer, dumping, bagging in dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.	wide / non-dispersive; decision needed	wide / non-dispersive; decision needed

OC	short version	Description	PROC	Examples/Explanation	solid	liquid
open or closed system	transfer of substances or preparations	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	PROC 9	Filling lines specifically designed to both capture vapour and aerosol emissions and minimise spillage	wide / non-dispersive; decision needed	wide / non-dispersive; decision needed
open or closed system	coating	Roller application or brushing	PROC 10	Low energy spreading of e.g. coatings. Including cleaning of surfaces. Substance can be inhaled as vapours, skin contact can occur through droplets, splashes, working with wipes and handling of treated surfaces.	wide / non-dispersive; decision needed	wide / non-dispersive; decision needed
open or closed system	spraying	Non industrial spraying	PROC 11	Air dispersive techniques. Spraying for surface coating, adhesives, polishes/cleaners, air care products, sandblasting. Substances can be inhaled as aerosols. The energy of the aerosol particles may require advanced exposure controls.	wide / non-dispersive; decision needed	wide / non-dispersive; decision needed
open or closed system	use of blowing agents	Use of blowing agents in manufacture of foam	PROC 12		not applicable	wide dispersive use
open or closed system	coating	Treatment of articles by dipping and pouring	PROC 13	Immersion operations. Treatment of articles by dipping, pouring, immersing, soaking, washing out or washing in substances; including cold formation or resin type matrix. Includes handling of treated objects (e.g. after dying, plating,). Substance is applied to a surface by low energy techniques such as dipping the article into a bath or pouring a preparation onto a surface.	wide / non-dispersive; decision needed	wide / non-dispersive; decision needed
open or closed system	shaping by pressure	Production of preparations or articles by tabletting, compression, extrusion, pelletisation	PROC 14	Processing of preparations and/or substances (liquid and solid) into preparations or articles. Substances in the chemical matrix may be exposed to elevated mechanical and/or thermal energy conditions. Exposure is predominantly related to volatiles and/or generated fumes, dust may be formed as well.	inclusion onto matrix/non-dispersive use	inclusion onto matrix/non-dispersive use

OC	short version	Description	PROC	Examples/Explanation	solid	liquid
open or closed system	transfer of substances or preparations	Use as laboratory reagent	PROC 15	Use of substances at small scale laboratory (< 1 l or 1 kg present at workplace). Larger laboratories and R+D installations should be treated as industrial processes.	wide / non-dispersive; decision needed	wide / non-dispersive; decision needed
open or closed system	transfer of substances or preparations	Using material as fuel sources, limited exposure to unburned product to be expected	PROC 16	Covers the use of material as fuel sources (including additives) where limited exposure to the product in its unburned form is expected. Does not cover exposure as a consequence of spillage or combustion.	wide / non-dispersive; decision needed	wide / non-dispersive; decision needed
open or closed system	cooling of high energy processes	Lubrication at high energy conditions and in partly open process	PROC 17	Lubrication at high energy conditions (temperature, friction) between moving parts and substance; significant part of process is open to workers. The metal working fluid may form aerosols or fumes due to rapidly moving metal parts.	wide / non-dispersive; decision needed	wide / non-dispersive; decision needed
open or closed system	cooling of high energy processes	Greasing at high energy conditions	PROC 18	Use as lubricant where significant energy or temperature is applied between the substance and the moving parts	wide / non-dispersive; decision needed	wide / non-dispersive; decision needed
open system	hand-mixing	Hand-mixing with intimate contact and only PPE available	PROC 19	Addresses occupations where intimate and intentional contact with substances occurs without any specific exposure controls other than PPE.	wide dispersive use	wide dispersive use
open or closed system	transfer of substances or preparations	Heat and pressure transfer fluids in dispersive, professional use but closed systems	PROC 20	Motor and engine oils, brake fluids. Also in these applications, the lubricant may be exposed to high energy conditions and chemical reactions may take place during use. Exhausted fluids need to be disposed of as waste. Repair and maintenance may lead to skin contact.	not applicable	wide / non-dispersive; decision needed
open or closed system	low energy abrasion processes	Low energy manipulation of substances bound in materials and/or articles	PROC 21	Manual cutting, cold rolling or assembly/disassembly of material/article (including metals in massive form), possibly resulting in the release of fibres, metal fumes or dust	wide / non-dispersive; decision needed	not applicable

OC	short version	Description	PROC	Examples/Explanation	solid	liquid
closed system	manufacturing of substances/preparations	Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting	PROC 22	Activities at smelters, furnaces, refineries, coke ovens. Exposure related to dust and fumes to be expected. Emission from direct cooling may be relevant.	inclusion onto matrix/non-dispersive use	not applicable
open system	transfer of substances or preparations	Open processing and transfer operations with minerals/metals at elevated temperature	PROC 23	Sand and die casting, tapping and casting melted solids, drossing of melted solids, hot dip galvanising, raking of melted solids in paving. Exposure related to dust and fumes to be expected.	wide dispersive use	not applicable
open or closed system	high energy abrasion processes	High (mechanical) energy work-up of substances bound in materials and/or articles	PROC 24	Substantial thermal or kinetic energy applied to substance (including metals in massive form) by hot rolling/forming, grinding, mechanical cutting, drilling or sanding. Exposure is predominantly expected to be to dust. Dust or aerosol emission as result of direct cooling may be expected.	wide / non-dispersive; decision needed	not applicable
open or closed system	Other hot work operations with metals	Other hot work operations with metals	PROC 25	Welding, soldering, gouging, brazing, flame cutting. Exposure is predominantly expected to fumes and gases.	wide / non-dispersive; decision needed	not applicable
open or closed system	transfer of substances or preparations	Handling of solid inorganic substances at ambient temperature	PROC 26	Transfer and handling of ores, concentrates, raw metal oxides and scrap; packaging, unpackaging, mixing/blending and weighing of metal powders or other minerals	wide / non-dispersive; decision needed	not applicable
open or closed system	manufacturing of substances/preparations	Production of metal powders (hot processes)	PROC 27a	Production of metal powders by hot metallurgical processes (atomisation, dry dispersion)	wide / non-dispersive; decision needed	not applicable
open or closed system	manufacturing of substances/preparations	Production of metal powders (wet processes)	PROC 27b	Production of metal powders by wet metallurgical processes (electrolysis, wet dispersion)	wide / non-dispersive; decision needed	wide / non-dispersive; decision needed

EMKG-EXPO-TOOL

OC	short version	Description	PROC	Examples/Explanation	liquid + solid	
closed system	manufacturing of substances/preparations	Use in closed process, no likelihood of exposure	PROC 1	Use of the substances in high integrity contained system where little potential exists for exposures, e.g. any sampling via closed loop systems	3: containment (enclosed, but small breaches may be acceptable), good work practice	G300 (Containment)
closed system	manufacturing of substances/preparations	Use in closed, continuous process with occasional controlled exposure	PROC 2	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions. It is not high integrity and occasional exposure will arise e.g. through maintenance, sampling and equipment breakages	3: containment (enclosed, but small breaches may be acceptable), good work practice	G300 (Containment)
closed system	manufacturing of substances/preparations	Use in closed batch process (synthesis or formulation)	PROC 3	Batch manufacture of a chemical or formulation where the predominant handling is in a contained manner, e.g. through enclosed transfers, but where some opportunity for contact with chemicals occurs, e.g. through sampling	3: containment (enclosed, but small breaches may be acceptable), good work practice	G300 (Containment), G303 (transferring solids), G304 (sack emptying), G305 (Drum filling), G306 (Drum emptying), G210 (Infrequent charging reactors / mixers from a sack or keg), G307 or G308 (IBC filling and emptying, G311 (filling kegs), G312 (transferring liquid by pump), G315 or G316 (weighing), G317 or G318 (Mixing)
open or closed system	manufacturing of substances/preparations	Use in batch and other process (synthesis) where opportunity for exposure arises	PROC 4	Use in batch manufacture of a chemical where significant opportunity for exposure arises, e.g. during charging, sampling or discharge of material, and when the nature of the design is likely to result in exposure	1: general ventilation or 2: engineering control	G100 (general ventilation); G200 (local exhaust ventilation), G206 or G207 (sack filling), G208 (sack emptying), G209 (filling kegs), G210 (charging reactors / mixers from a keg

OC	short version	Description	PROC	Examples/Explanation	liquid + solid	
						or sack), G211 (IBC filling and emptying), G212 (drum filling), G213 (drum emptying), G202 or G214 (weighing), G216 or G217 (mixing), G218 (sieving and filtering)
open or closed system	manufacturing of substances/preparations	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	PROC 5	Manufacture or formulation of chemical products or articles using technologies related to mixing and blending of solid or liquid materials, and where the process is in stages and provides the opportunity for significant contact at any stage	1: general ventilation or 2: engineering control	G100 (general ventilation); G200 (local exhaust ventilation), G210 (charging reactors / mixers from a keg or sack), G211 (IBC filling and emptying), G202 or G214 (weighing), G216 or G217 (mixing), G218 (sieving and filtering)
open or closed system	coating	Calendering operations	PROC 6	Processing of product matrix Calendering at elevated temperature and large exposed surface	not applicable	not applicable
open or closed system	spraying	Industrial spraying	PROC 7	Air dispersive techniques. Spraying for surface coating, adhesives, polishes/cleaners, air care products, sandblasting. Substances can be inhaled as aerosols. The energy of the aerosol particles may require advanced exposure controls; in case of coating, overspray may lead to waste water and waste.	2: engineering control (local exhaust ventilation (e.g. single point extract, partial enclosure, not complete containment) and good work practice	G220 or G217 (surface coating)
open or closed system	transfer of substances or preparations	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	PROC 8a	Sampling, loading, filling, transfer, dumping, bagging in non-dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be	1: general ventilation or 2: engineering control	G100 (general ventilation), G200 (local exhaust ventilation), G206 or G207 (sack filling), G208 (sack emptying), G209 (filling kegs), G210 (charging

OC	short version	Description	PROC	Examples/Explanation	liquid + solid	
				expected.		reactors / mixers from a keg or sack), G211 (IBC filling and emptying), G212 (drum filling), G213 (drum emptying), G205 (conveyor transfer), G202 (laminar flow booth)
open or closed system	transfer of substances or preparations	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	PROC 8b	Sampling, loading, filling, transfer, dumping, bagging in dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.	1: general ventilation or 2: engineering control	G100 (general ventilation), G200 (local exhaust ventilation), G206 or G207 (sack filling), G208 (sack emptying), G209 (filling kegs), G210 (charging reactors / mixers from a keg or sack), G211 (IBC filling and emptying), G212 (drum filling), G213 (drum emptying), G205 (conveyor transfer), G202 (laminar flow booth)
open or closed system	transfer of substances or preparations	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	PROC 9	Filling lines specifically designed to both capture vapour and aerosol emissions and minimise spillage	2: engineering control (local exhaust ventilation (e.g. single point extract, partial enclosure, not complete containment) and good work practice	G209 (filling kegs), G202 or G214 (weighing)
open or closed system	coating	Roller application or brushing	PROC 10	Low energy spreading of e.g. coatings. Including cleaning of surfaces. Substance can be inhaled as vapours, skin contact can occur through droplets, splashes, working with wipes and handling of treated	1: general ventilation (good general ventilation and good work practice)	G100 (general ventilation)

OC	short version	Description	PROC	Examples/Explanation	liquid + solid	
				surfaces.		
open or closed system	spraying	Non industrial spraying	PROC 11	Air dispersive techniques. Spraying for surface coating, adhesives, polishes/cleaners, air care products, sandblasting. Substances can be inhaled as aerosols. The energy of the aerosol particles may require advanced exposure controls.	2: engineering control (local exhaust ventilation (e.g. single point extract, partial enclosure, not complete containment) and good work practice	G220 or G221 (spray painting)
open or closed system	use of blowing agents	Use of blowing agents in manufacture of foam	PROC 12		not applicable	not applicable
open or closed system	coating	Treatment of articles by dipping and pouring	PROC 13	Immersion operations. Treatment of articles by dipping, pouring, immersing, soaking, washing out or washing in substances; including cold formation or resin type matrix. Includes handling of treated objects (e.g. after dying, plating,). Substance is applied to a surface by low energy techniques such as dipping the article into a bath or pouring a preparation onto a surface.	2: engineering control (local exhaust ventilation (e.g. single point extract, partial enclosure, not complete containment) and good work practice	G225 or G226 (pickling bath, vapour degreasing bath)

OC	short version	Description	PROC	Examples/Explanation	liquid + solid	
open or closed system	shaping by pressure	Production of preparations or articles by tabletting, compression, extrusion, pelletisation	PROC 14	Processing of preparations and/or substances (liquid and solid) into preparations or articles. Substances in the chemical matrix may be exposed to elevated mechanical and/or thermal energy conditions. Exposure is predominantly related to volatiles and/or generated fumes, dust may be formed as well.	2: engineering control (local exhaust ventilation (e.g. single point extract, partial enclosure, not complete containment) and good work practice	G230 palletizing; G231 tablet press
open or closed system	transfer of substances or preparations	Use as laboratory reagent	PROC 15	Use of substances at small scale laboratory (< 1 l or 1 kg present at workplace). Larger laboratories and R+D installations should be treated as industrial processes.	1: general ventilation or 2: engineering control or 3: containment	G100 (general ventilation); G201 (fume cupboard), G202 (laminar flow booth), G203 (ventilated workbench), G301 (glove box)
open or closed system	transfer of substances or preparations	Using material as fuel sources, limited exposure to unburned product to be expected	PROC 16	Covers the use of material as fuel sources (including additives) where limited exposure to the product in its unburned form is expected. Does not cover exposure as a consequence of spillage or combustion.	not applicable	not applicable
open or closed system	cooling of high energy processes	Lubrication at high energy conditions and in partly open process	PROC 17	Lubrication at high energy conditions (temperature, friction) between moving parts and substance; significant part of process is open to workers. The metal working fluid may form aerosols or fumes due to rapidly moving metal parts.	not applicable	not applicable
open or closed	cooling of high energy processes	Greasing at high energy conditions	PROC 18	Use as lubricant where significant energy or temperature is applied between	not applicable	not applicable

OC	short version	Description	PROC	Examples/Explanation	liquid + solid	
system				the substance and the moving parts		
open system	hand-mixing	Hand-mixing with intimate contact and only PPE available	PROC 19	Addresses occupations where intimate and intentional contact with substances occurs without any specific exposure controls other than PPE.	not applicable	not applicable
open or closed system	transfer of substances or preparations	Heat and pressure transfer fluids in dispersive, professional use but closed systems	PROC 20	Motor and engine oils, brake fluids. Also in these applications, the lubricant may be exposed to high energy conditions and chemical reactions may take place during use. Exhausted fluids need to be disposed of as waste. Repair and maintenance may lead to skin contact.	not applicable	not applicable
open or closed system	low energy abrasion processes	Low energy manipulation of substances bound in materials and/or articles	PROC 21	Manual cutting, cold rolling or assembly/disassembly of material/article (including metals in massive form), possibly resulting in the release of fibres, metal fumes or dust	not applicable	not applicable
closed system	manufacturing of substances/preparations	Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting	PROC 22	Activities at smelters, furnaces, refineries, coke ovens. Exposure related to dust and fumes to be expected. Emission from direct cooling may be relevant.	not applicable	not applicable
open system	transfer of substances or preparations	Open processing and transfer operations with minerals/metals at elevated temperature	PROC 23	Sand and die casting, tapping and casting melted solids, drossing of melted solids, hot dip galvanising, raking of melted solids in paving. Exposure related to dust and fumes to be expected.	not applicable	not applicable

OC	short version	Description	PROC	Examples/Explanation	liquid + solid	
open or closed system	high energy abrasion processes	High (mechanical) energy work-up of substances bound in materials and/or articles	PROC 24	Substantial thermal or kinetic energy applied to substance (including metals in massive form) by hot rolling/forming, grinding, mechanical cutting, drilling or sanding. Exposure is predominantly expected to be to dust. Dust or aerosol emission as result of direct cooling may be expected.	not applicable	not applicable
open or closed system	Other hot work operations with metals	Other hot work operations with metals	PROC 25	Welding, soldering, gouging, brazing, flame cutting. Exposure is predominantly expected to fumes and gases.	not applicable	not applicable
open or closed system	transfer of substances or preparations	Handling of solid inorganic substances at ambient temperature	PROC 26	Transfer and handling of ores, concentrates, raw metal oxides and scrap; packaging, unpackaging, mixing/blending and weighing of metal powders or other minerals	1: general ventilation or 2: engineering control	G100 (general ventilation); G200 (local exhaust ventilation), G206 or G207 (sack filling), G208 (sack emptying), G209 (filling kegs), G210 (charging reactors / mixers from a keg or sack), G211 (IBC filling and emptying), G212 (drum filling), G213 (drum emptying), G202 or G214 (weighing), G216 or G217 (mixing), G218 (sieving and filtering)
open or closed system	manufacturing of substances/preparations	Production of metal powders (hot processes)	PROC 27a	Production of metal powders by hot metallurgical processes (atomisation, dry dispersion)	not applicable	not applicable
open or closed system	manufacturing of substances/preparations	Production of metal powders (wet processes)	PROC 27b	Production of metal powders by wet metallurgical processes (electrolysis, wet dispersion)	not applicable	not applicable

RISKOFDERM

OC	short version	Description	PROC	Examples/Explanation	solid	liquid
closed system	manufacturing of substances/preparations	Use in closed process, no likelihood of exposure	PROC 1	Use of the substances in high integrity contained system where little potential exists for exposures, e.g. any sampling via closed loop systems		
closed system	manufacturing of substances/preparations	Use in closed, continuous process with occasional controlled exposure	PROC 2	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions. It is not high integrity and occasional exposure will arise e.g. through maintenance, sampling and equipment breakages		
closed system	manufacturing of substances/preparations	Use in closed batch process (synthesis or formulation)	PROC 3	Batch manufacture of a chemical or formulation where the predominant handling is in a contained manner, e.g. through enclosed transfers, but where some opportunity for contact with chemicals occurs, e.g. through sampling	Filling, mixing, loading	Filling, mixing, loading
open or closed system	manufacturing of substances/preparations	Use in batch and other process (synthesis) where opportunity for exposure arises	PROC 4	Use in batch manufacture of a chemical where significant opportunity for exposure arises, e.g. during charging, sampling or discharge of material, and when the nature of the design is likely to result in exposure	Filling, mixing, loading	Filling, mixing, loading
open or closed system	manufacturing of substances/preparations	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	PROC 5	Manufacture or formulation of chemical products or articles using technologies related to mixing and blending of solid or liquid materials, and where the process is in stages and provides the opportunity for significant contact at any stage	Filling, mixing, loading	Filling, mixing, loading
open or closed system	coating	Calendering operations	PROC 6	Processing of product matrix Calendering at elevated temperature and large exposed surface		

OC	short version	Description	PROC	Examples/Explanation	solid	liquid
open or closed system	spraying	Industrial spraying	PROC 7	Air dispersive techniques. Spraying for surface coating, adhesives, polishes/cleaners, air care products, sandblasting. Substances can be inhaled as aerosols. The energy of the aerosol particles may require advanced exposure controls; in case of coating, overspray may lead to waste water and waste.	Spraying	Spraying
open or closed system	transfer of substances or preparations	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	PROC 8a	Sampling, loading, filling, transfer, dumping, bagging in non-dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.	Filling, mixing, loading	Filling, mixing, loading
open or closed system	transfer of substances or preparations	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	PROC 8b	Sampling, loading, filling, transfer, dumping, bagging in dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.	Filling, mixing, loading	Filling, mixing, loading
open or closed system	transfer of substances or preparations	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	PROC 9	Filling lines specifically designed to both capture vapour and aerosol emissions and minimise spillage	Filling, mixing, loading	Filling, mixing, loading
open or closed system	coating	Roller application or brushing	PROC 10	Low energy spreading of e.g. coatings. Including cleaning of surfaces. Substance can be inhaled as vapours, skin contact can occur through droplets, splashes, working with wipes and handling of treated surfaces.		Dispersion of product with hand-held tools
open or closed system	spraying	Non industrial spraying	PROC 11	Air dispersive techniques. Spraying for surface coating, adhesives, polishes/cleaners, air care products, sandblasting. Substances can be inhaled as aerosols. The energy of the aerosol particles may require advanced exposure controls.	Spraying	Spraying
open or closed system	use of blowing agents	Use of blowing agents in manufacture of foam	PROC 12			

OC	short version	Description	PROC	Examples/Explanation	solid	liquid
open or closed system	coating	Treatment of articles by dipping and pouring	PROC 13	Immersion operations. Treatment of articles by dipping, pouring, immersing, soaking, washing out or washing in substances; including cold formation or resin type matrix. Includes handling of treated objects (e.g. after dying, plating,). Substance is applied to a surface by low energy techniques such as dipping the article into a bath or pouring a preparation onto a surface.		Immersion
open or closed system	shaping by pressure	Production of preparations or articles by tabletting, compression, extrusion, pelletisation	PROC 14	Processing of preparations and/or substances (liquid and solid) into preparations or articles. Substances in the chemical matrix may be exposed to elevated mechanical and/or thermal energy conditions. Exposure is predominantly related to volatiles and/or generated fumes, dust may be formed as well.	Mechanical treatment	Mechanical treatment
open or closed system	transfer of substances or preparations	Use as laboratory reagent	PROC 15	Use of substances at small scale laboratory (< 1 l or 1 kg present at workplace). Larger laboratories and R+D installations should be treated as industrial processes.	Filling, mixing, loading	Filling, mixing, loading
open or closed system	transfer of substances or preparations	Using material as fuel sources, limited exposure to unburned product to be expected	PROC 16	Covers the use of material as fuel sources (including additives) where limited exposure to the product in its unburned form is expected. Does not cover exposure as a consequence of spillage or combustion.		
open or closed system	cooling of high energy processes	Lubrication at high energy conditions and in partly open process	PROC 17	Lubrication at high energy conditions (temperature, friction) between moving parts and substance; significant part of process is open to workers. The metal working fluid may form aerosols or fumes due to rapidly moving metal parts.	Mechanical treatment	Mechanical treatment
open or closed system	cooling of high energy processes	Greasing at high energy conditions	PROC 18	Use as lubricant where significant energy or temperature is applied between the substance and the moving parts	Mechanical treatment	Mechanical treatment
open system	hand-mixing	Hand-mixing with intimate contact and only PPE available	PROC 19	Addresses occupations where intimate and intentional contact with substances occurs without any specific exposure controls other than PPE.	not applicable	not applicable

OC	short version	Description	PROC	Examples/Explanation	solid	liquid
open or closed system	transfer of substances or preparations	Heat and pressure transfer fluids in dispersive, professional use but closed systems	PROC 20	Motor and engine oils, brake fluids. Also in these applications, the lubricant may be exposed to high energy conditions and chemical reactions may take place during use. Exhausted fluids need to be disposed of as waste. Repair and maintenance may lead to skin contact.		
open or closed system	low energy abrasion processes	Low energy manipulation of substances bound in materials and/or articles	PROC 21	Manual cutting, cold rolling or assembly/disassembly of material/article (including metals in massive form), possibly resulting in the release of fibres, metal fumes or dust		Mechanical treatment
closed system	manufacturing of substances/preparations	Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting	PROC 22	Activities at smelters, furnaces, refineries, coke ovens. Exposure related to dust and fumes to be expected. Emission from direct cooling may be relevant.		
open system	transfer of substances or preparations	Open processing and transfer operations with minerals/metals at elevated temperature	PROC 23	Sand and die casting, tapping and casting melted solids, drossing of melted solids, hot dip galvanising, raking of melted solids in paving. Exposure related to dust and fumes to be expected.		
open or closed system	high energy abrasion processes	High (mechanical) energy work-up of substances bound in materials and/or articles	PROC 24	Substantial thermal or kinetic energy applied to substance (including metals in massive form) by hot rolling/forming, grinding, mechanical cutting, drilling or sanding. Exposure is predominantly expected to be to dust. Dust or aerosol emission as result of direct cooling may be expected.		
open or closed system	Other hot work operations with metals	Other hot work operations with metals	PROC 25	Welding, soldering, gouging, brazing, flame cutting. Exposure is predominantly expected to fumes and gases.	not applicable	not applicable

OC	short version	Description	PROC	Examples/Explanation	solid	liquid
open or closed system	transfer of substances or preparations	Handling of solid inorganic substances at ambient temperature	PROC 26	Transfer and handling of ores, concentrates, raw metal oxides and scrap; packaging, unpackaging, mixing/blending and weighing of metal powders or other minerals		not applicable
open or closed system	manufacturing of substances/preparations	Production of metal powders (hot processes)	PROC 27a	Production of metal powders by hot metallurgical processes (atomisation, dry dispersion)		not applicable
open or closed system	manufacturing of substances/preparations	Production of metal powders (wet processes)	PROC 27b	Production of metal powders by wet metallurgical processes (electrolysis, wet dispersion)		

STOFFENMANAGER©

OC	short version	Description	PROC	Examples/Explanation	solid	liquid
closed system	manufacturing of substances/preparations	Use in closed process, no likelihood of exposure	PROC 1	Use of the substances in high integrity contained system where little potential exists for exposures, e.g. any sampling via closed loop systems	handling of product in closed containers	handling of liquids in tightly closed containers
closed system	manufacturing of substances/preparations	Use in closed, continuous process with occasional controlled exposure	PROC 2	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions. It is not high integrity and occasional exposure will arise e.g. through maintenance, sampling and equipment breakages	handling of product in very small amounts or in situations where release is highly unlikely	handling of liquids where only small amounts of product may be released
closed system	manufacturing of substances/preparations	Use in closed batch process (synthesis or formulation)	PROC 3	Batch manufacture of a chemical or formulation where the predominant handling is in a contained manner, e.g. through enclosed transfers, but where some opportunity for contact with chemicals occurs, e.g. through sampling	handling of product in small amounts or in situations where only slow quantities of products are likely to be released	handling of liquids where only small amounts of product may be released
open or closed system	manufacturing of substances/preparations	Use in batch and other process (synthesis) where opportunity for exposure arises	PROC 4	Use in batch manufacture of a chemical where significant opportunity for exposure arises, e.g. during charging, sampling or discharge of material, and when the nature of the design is likely to result in exposure	handling of product or treatment of objects with a relatively high speed/force which may lead to some dispersion of dust	handling of liquids using low pressure, low speed or on medium-sized surfaces
open or closed system	manufacturing of substances/preparations	Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	PROC 5	Manufacture or formulation of chemical products or articles using technologies related to mixing and blending of solid or liquid materials, and where the process is in stages and provides the opportunity for significant contact at any stage	handling of product or treatment of objects with a relatively high speed/force which may lead	handling of liquids using low pressure, low speed or on medium-sized surfaces

OC	short version	Description	PROC	Examples/Explanation	solid	liquid
					to some dispersion of dust	
open or closed system	coating	Calendering operations	PROC 6	Processing of product matrix Calendering at elevated temperature and large exposed surface	handling of product with low speed or with little force in medium quantities	not applicable
open or closed system	spraying	Industrial spraying	PROC 7	Air dispersive techniques. Spraying for surface coating, adhesives, polishes/cleaners, air care products, sandblasting. Substances can be inhaled as aerosols. The energy of the aerosol particles may require advanced exposure controls; in case of coating, overspray may lead to waste water and waste.	handling of product or treatment of objects, where due to high pressure, speed or force large quantities of dust are generated and dispersed	handling of liquids at high pressure resulting in substantial generation of mist or spray/haze
open or closed system	transfer of substances or preparations	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	PROC 8a	Sampling, loading, filling, transfer, dumping, bagging in non-dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.	handling of product or treatment of objects, where due to high pressure, speed or force large quantities of dust are generated and dispersed	handling of liquids (using low pressure, but high speed) without creating a mist or spray/haze
open or closed system	transfer of substances or preparations	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	PROC 8b	Sampling, loading, filling, transfer, dumping, bagging in dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.	handling of very large amounts of product	handling of liquids (using low pressure, but high speed) without creating a mist or spray/haze

OC	short version	Description	PROC	Examples/Explanation	solid	liquid
open or closed system	transfer of substances or preparations	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	PROC 9	Filling lines specifically designed to both capture vapour and aerosol emissions and minimise spillage	handling of product with low speed or with little force in medium quantities	handling of liquids using low pressure, low speed and on medium-sized surfaces
open or closed system	coating	Roller application or brushing	PROC 10	Low energy spreading of e.g. coatings. Including cleaning of surfaces. Substance can be inhaled as vapours, skin contact can occur through droplets, splashes, working with wipes and handling of treated surfaces.	not applicable	handling of liquids on large surfaces or large workpieces
open or closed system	spraying	Non industrial spraying	PROC 11	Air dispersive techniques. Spraying for surface coating, adhesives, polishes/cleaners, air care products, sandblasting. Substances can be inhaled as aerosols. The energy of the aerosol particles may require advanced exposure controls.	handling of product or treatment of objects, where due to high pressure, speed or force large quantities of dust are generated and dispersed	handling of liquids at high pressure resulting in substantial generation of mist or spray/haze
open or closed system	use of blowing agents	Use of blowing agents in manufacture of foam	PROC 12		not applicable	not applicable
open or closed system	coating	Treatment of articles by dipping and pouring	PROC 13	Immersion operations. Treatment of articles by dipping, pouring, immersing, soaking, washing out or washing in substances; including cold formation or resin type matrix. Includes handling of treated objects (e.g. after dying, plating,). Substance is applied to a surface by low energy techniques such as dipping the article into a bath or pouring a preparation onto a surface.	handling of product with low speed or with little force in medium quantities	handling of liquids on large surfaces or large workpieces

OC	short version	Description	PROC	Examples/Explanation	solid	liquid
open or closed system	shaping by pressure	Production of preparations or articles by tabletting, compression, extrusion, pelletisation	PROC 14	Processing of preparations and/or substances (liquid and solid) into preparations or articles. Substances in the chemical matrix may be exposed to elevated mechanical and/or thermal energy conditions. Exposure is predominantly related to volatiles and/or generated fumes, dust may be formed as well.	handling of product or treatment of objects with a relatively high speed/force which may lead to some dispersion of dust	not applicable
open or closed system	transfer of substances or preparations	Use as laboratory reagent	PROC 15	Use of substances at small scale laboratory (< 1 l or 1 kg present at workplace). Larger laboratories and R+D installations should be treated as industrial processes.	handling of product in very small amounts or in situations where release is highly unlikely	handling of liquids where only small amounts of product may be released
open or closed system	transfer of substances or preparations	Using material as fuel sources, limited exposure to unburned product to be expected	PROC 16	Covers the use of material as fuel sources (including additives) where limited exposure to the product in its unburned form is expected. Does not cover exposure as a consequence of spillage or combustion.	not applicable	not applicable
open or closed system	cooling of high energy processes	Lubrication at high energy conditions and in partly open process	PROC 17	Lubrication at high energy conditions (temperature, friction) between moving parts and substance; significant part of process is open to workers. The metal working fluid may form aerosols or fumes due to rapidly moving metal parts.	not applicable	handling of liquids at high pressure resulting in substantial generation of mist or spray/haze
open or closed system	cooling of high energy processes	Greasing at high energy conditions	PROC 18	Use as lubricant where significant energy or temperature is applied between the substance and the moving parts	not applicable	handling of liquids (using low pressure, but high speed) without creating a mist or spray/haze

OC	short version	Description	PROC	Examples/Explanation	solid	liquid
open system	hand-mixing	Hand-mixing with intimate contact and only PPE available	PROC 19	Addresses occupations where intimate and intentional contact with substances occurs without any specific exposure controls other than PPE.	handling of product with low speed or with little force in medium quantities	handling of liquids using low pressure, low speed or on medium-sized surfaces
open or closed system	transfer of substances or preparations	Heat and pressure transfer fluids in dispersive, professional use but closed systems	PROC 20	Motor and engine oils, brake fluids. Also in these applications, the lubricant may be exposed to high energy conditions and chemical reactions may take place during use. Exhausted fluids need to be disposed of as waste. Repair and maintenance may lead to skin contact.	not applicable	not applicable
open or closed system	low energy abrasion processes	Low energy manipulation of substances bound in materials and/or articles	PROC 21	Manual cutting, cold rolling or assembly/disassembly of material/article (including metals in massive form), possibly resulting in the release of fibres, metal fumes or dust	handling of product in very small amounts or in situations where release is highly unlikely	not applicable
					low energy mechanical handling of wood resulting in less dust	
					low energy mechanical handling of stone resulting in less dust	
closed system	manufacturing of substances/preparations	Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting	PROC 22	Activities at smelters, furnaces, refineries, coke ovens. Exposure related to dust and fumes to be expected. Emission from direct cooling may be relevant.	not applicable	not applicable

OC	short version	Description	PROC	Examples/Explanation	solid	liquid
open system	transfer of substances or preparations	Open processing and transfer operations with minerals/metals at elevated temperature	PROC 23	Sand and die casting, tapping and casting melted solids, drossing of melted solids, hot dip galvanising, raking of melted solids in paving. Exposure related to dust and fumes to be expected.	not applicable	not applicable
open or closed system	high energy abrasion processes	High (mechanical) energy work-up of substances bound in materials and/or articles	PROC 24	Substantial thermal or kinetic energy applied to substance (including metals in massive form) by hot rolling/forming, grinding, mechanical cutting, drilling or sanding. Exposure is predominantly expected to be to dust. Dust or aerosol emission as result of direct cooling may be expected.	mechanical sanding of wood or mechanical sawing and sanding of stone	not applicable
open or closed system	Other hot work operations with metals	Other hot work operations with metals	PROC 25	Welding, soldering, gouging, brazing, flame cutting. Exposure is predominantly expected to fumes and gases.	not applicable	not applicable
open or closed system	transfer of substances or preparations	Handling of solid inorganic substances at ambient temperature	PROC 26	Transfer and handling of ores, concentrates, raw metal oxides and scrap; packaging, unpackaging, mixing/blending and weighing of metal powders or other minerals		not applicable
open or closed system	manufacturing of substances/preparations	Production of metal powders (hot processes)	PROC 27a	Production of metal powders by hot metallurgical processes (atomisation, dry dispersion)		not applicable
open or closed system	manufacturing of substances/preparations	Production of metal powders (wet processes)	PROC 27b	Production of metal powders by wet metallurgical processes (electrolysis, wet dispersion)		not applicable