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Technical rules for hazardous substances	Substitution	TRGS 600
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The Technical Rules for Hazardous Substances (TRGS) reflect the state of the technology, occupational medicine and occupational hygiene as well as other verified scientific knowledge for activities involving hazardous substances, including their classification and labelling.

They are established by the

Committee on Hazardous Substances (AGS)

and announced by the Federal Ministry of Labour and Social Affairs (BMAS) in the Joint Ministerial Gazette (GMBI).

Within its scope of application, this TRGS specifies requirements of the Ordinance on Hazardous Substances (GefStoffV). If the technical rules are observed, the employer can assume that the corresponding requirements of the Ordinance are fulfilled. If the employer chooses a different solution, he must achieve at least the same level of safety and health protection for the employees.

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*) Note: The TRGS 600 has been completely revised, including

- Updating to the state of the art of regulations and rules, in particular GefStoffV and TRGS 400,
- Demarcation from the REACH Regulation (brief clarification of definitions, relationship between REACH authorisation and substitution),
- with regard to classification under the CLP Regulation when determining the urgency of substitution,
- Conversion of the column model to the CLP Regulation and deletion of the impact factor model.

- Annex 1: Flow chart substitution with example cleaning/degreasing of plant components in workshops
- Annex 2: Comparative assessment of health and safety hazards (column model)
- Annex 3: Criteria for the realisation of substitution - reasons for weighing up the operational use of substitute solutions and for extended evaluation

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1 Scope of application

(1) Within the framework of the information gathering and risk assessment according to § 6 of the Ordinance on Hazardous Substances, the employer must also assess the hazards identified as relevant from the point of view of the possibilities of substitution. The employer has the obligation to determine and assess the substitution possibilities, to carry out assessments of substitution and to document them.

(2) This TRGS is intended to support the employer in this,

1. To avoid activities involving hazardous substances,
2. to replace hazardous substances by substances, mixtures or processes which, under the conditions of use in question, present no risk or a lesser risk to workers, or
3. to replace dangerous procedures with less dangerous procedures.

(3) If the employer has established within the scope of the risk assessment that there is a low risk according to the criteria of § 6 para. 13 GefStoffV in conjunction with section 6.2 para. 6 and 7 of TRGS 400 "Risk assessment for activities involving hazardous substances", an assessment of substitution can be dispensed with.

(4) The aim of substitution is to eliminate or reduce to a minimum the hazards associated

with all activities involving hazardous substances, including maintenance, operating and monitoring activities. As a priority measure for the protection of employees working with hazardous substances, the employer must examine the possibilities of substitution within the framework of information gathering and risk assessment in accordance with the Ordinance on Hazardous Substances (§ 6 GefStoffV, see also TRGS 400) and implement them in accordance with the requirements described in more detail in this TRGS.

(5) The assessment of substitution in accordance with the requirements of these TRGS must also be applied if the use of new substances and processes is planned for economic or technological reasons.

(6) This TRGS does not describe the requirements that are set out in Regulation (EC) No 1907/2006 (REACH Regulation) for the evaluation of substitution solutions in the context of authorisation and restriction procedures. If an operational and process-related authorisation for the use of a substance has been granted under the REACH Regulation, reference can be made to the REACH documentation when examining the possibilities of substitution.

(7) Annex 1 contains a flowchart with the individual steps to be followed in the determination and implementation of substitution solutions. Annex 1 also contains a simplified case study of this procedure as an illustration. Annex 2 contains a comparative assessment of the health and safety hazards (column model).

2 Definition of terms

(1) In this TRGS, terms are used as they are defined in the "Glossary of Terms for the Regulations of the Ordinance on Industrial Safety and Health (BetrSichV), the Ordinance on Biological Substances (BioStoffV) and the Ordinance on Hazardous Substances (GefStoffV) of the AGS and ABS.

(2) Substitution within the meaning of these TRGS refers to the replacement of a hazardous substance or a process by a substance, a mixture, a product or a process that leads to an overall lower risk for employees (substitution solution).

(3) Substitution solutions in the sense of these TRGS designate substances or mixtures or products or processes that reduce the overall hazards of hazardous substances in the workplace. At the same time, they should not increase the risk to other protected goods (environmental protection, consumer protection).

(4) The examination of substitution possibilities refers to the process of identifying and comparing potential chemical and non-chemical substitution solutions.

(5) Low-emission uses of a substance or mixture are those where the potential for release to air or the likelihood of dermal contact has been reduced by shaping or packaging in such a way that special protective measures are no longer necessary in activities. Examples of proven methods for the manufacture of low-emission forms of use are granulation, pelletisation and tableting, coating, master batches, stock solutions/concentrates, pastes, dissolving/lost packaging, multi-component containers with integrated mixing function. In the case of lost packaging, the hazardous substance is contained in suitable packaging and is introduced into a reaction system with the packaging without opening it. See also TRGS 561 "Activities involving carcinogenic metals and their compounds" and TRGS 500 "Protective measures" section 5.2.2.

3 Identification of substitution possibilities

(1) The determination of substitution possibilities is part of the risk assessment according to § 6 paragraph 1 GefStoffV. In the case of activities involving hazardous substances that may pose a risk, the employer must always check whether there are possibilities of substitution.

(2) Sources of information for the identification of substitution options are listed below (for more detailed information and references see references):

1. TRGS on substitute materials (TRGS 500 ff. and TRGS 600 ff.),
2. Sector- or activity-specific guidance which contains statements on substitution, e.g.
 - a) DGUV information with statements on substitution,
 - b) Information systems, e.g. WINGIS (see product codes) and publications of accident insurance institutions and the Länder,
 - c) other sector-specific guidance issued by associations and accident insurance institutions (UVT), eg a database of permissible washing and cleaning agents in offset
3. Safety data sheet (in particular section 7.3; reference to sector-specific guidance, e.g. product codes) and additional information from suppliers and/or manufacturers, e.g. technical data sheets,
4. Information and experience reports from networks with other entrepreneurs, technology transfer offices, positive/negative lists from expert sources,
5. Information on substitution solutions from other regulatory areas,
6. Information on substitution solutions from other sectors which have proved their worth in practice.

(3) In order to determine the possibilities of substitution, the employer must check TRGS, sector- or activity-specific guidance and safety data sheets. In particular, he should also ask the supplier for less hazardous solutions in the context of the procurement of hazardous substances. In order to prepare far-reaching decisions, more in-depth research/examinations may be necessary with additional use of the above-mentioned sources. Far-reaching decisions are necessary for

1. high risk, or
2. large number of vulnerable persons.

4 Pre-selection of promising substitution possibilities: Guiding criteria

(1) If several possibilities of substitution have been identified in the course of information gathering, guiding criteria for the pre-selection of promising possibilities of substitution are useful if it is not possible to fall back on model solutions as described in Section 3, paragraph 2, points 1 to 2. A preselection is particularly helpful if, in the case of several possibilities identified, not all of them can be examined with the same priority with regard to the suitability criteria specified in Section 5.2 and 5.3. If only a few substitution possibilities have been found during the information search, the preselection can also be skipped.

(2) As criteria for a pre-selection of substitution options, both the health hazards and the physico-chemical hazards as well as the potential for release must be considered. The latter

is influenced by the physico-chemical properties and the process and use conditions (paragraphs 3 to 7). When deciding which possibilities should be further investigated, all criteria must be considered in their entirety and considerations of skin hazards must also be taken into account (paragraph 7). Since the criteria of the pre-selection are intended for cases where many possibilities have to be examined, the criteria are not finely differentiated. It is possible that possibilities that did not initially appear to be promising in the pre-selection may be taken up again in the later course of the assessment.

(3) The risk due to health hazards of a hazardous substance can be assessed using the column model described in more detail in Annex 2. This distinguishes between acute health hazards that may arise from a single exposure and chronic health hazards that may arise from repeated exposure, e.g. during activities involving carcinogenic, germ cell mutagenic or reprotoxic hazardous substances. Substitution is carried out in the order listed within a column (Very High -> High -> Medium -> Low -> Negligible).

(4) The hazard due to physico-chemical impacts of a hazardous substance may also be assessed using the column model described in Annex 2.

(5) The potential for release of a hazardous substance into the air at the workplace can generally be reduced by substitution along the sequence shown in the respective line:

1. high concentration/large quantities > low concentration/small quantities,
2. Process with wetting of large areas > Process with wetting of small areas,
3. Gas > Liquid > Paste,
4. dusty solid > non-dusty solid,
5. sublimating solid > non-sublimating solid,
6. low boiling point (high vapour pressure) > high boiling point (low vapour pressure),
7. open process > process with integrated extraction > closed process > chambered system (closed process in its own enclosed space),
8. Process at high temperatures > Process at room temperature,
9. Processes under pressure > Unpressurised processes,
10. Processes involving the production of aerosols > aerosol-free processes,
11. solvent-based systems > aqueous systems etc.

(6) Low-emission forms of use can be taken into account when assessing a substance with regard to its release behaviour. Dissolvable/lost packaging and safe to use equipment (e.g. forced mixing in closed containers) may be relevant in the assessment of processes.

(7) With regard to skin exposure, the criteria for the pre-selection of substances, mixtures, articles or work processes may differ from the above-mentioned criteria in individual cases and must therefore be individually reviewed and, if necessary, adapted. This applies in particular to the criteria for release potential. Here, properties that lead to an increased release into the air may well have the opposite effect for dermal exposure. For example, pastes remain on the skin longer than liquids or gases, but reduce inhalation exposure. TRGS 401 "Hazards due to skin contact - determination, assessment, measures" should be used for a comparison of the hazards due to skin contact.

(8) In the overall consideration within the framework of the preselection, the employer has to weigh up all guiding criteria against each other in order to identify which substitutes and

under which process or use conditions an overall elimination or minimisation of the hazard can be expected. For example, in individual cases it may lead to an overall lower health risk to use a hazardous substance with more hazardous properties, which is available in a non-dusting form or which has a very low vapour pressure, rather than a hazardous substance with less hazardous properties, but which is only available on the market in a dusty form or which has a considerably higher vapour pressure.

5 Decision on substitution

5.1 Basic information

(1) The substitution solution must reduce the overall risk of exposure to hazardous substances in the workplace. At the same time, it should not lead to an increase in other workplace hazards or to an increased impairment of other protected goods.

(2) Those substitution options that have proved to be promising in the preselection process can be examined even more thoroughly for their technical, health and physico-chemical suitability using the criteria and methodological tools mentioned in sections 5.2 and 5.3. Section 5.4 describes the regulatory requirements and operational decision criteria for the operational realisation of substitution options found.

(3) Possibilities of substitution from TRGS and sector-specific guidance (Section 3 para. 2 nos. 1 and 2) are to be regarded as suitable from a technical point of view as well as from a health, physico-chemical and economic point of view. If the employer deviates from these recommendations, it must justify this in writing.

(4) For substitution decisions within the framework of the Ordinance on Hazardous Substances, the integrated decision according to the criteria of the following sections focuses on safety and health at work, but in specific cases it may also be necessary and relevant to the decision to consider other objects of protection.

5.2 Criteria for technical suitability

(1) Substitution recommendations given in the sources of information referred to in Section 3.2 (1) and (2) for specific uses are generally technically appropriate. If the employer deviates from these recommendations despite comparable operational conditions of use, he must justify this in writing.

(2) In other cases, the technical suitability of a substitution option must be assessed on a case-by-case basis by the user of the substance or process in question. Among other things, the following must be taken into account:

1. the state of the art (Section 2 (15) of the Hazardous Substances Ordinance),
2. the function of the dangerous substance (auxiliary substance in the production process or indispensable component of the product/process or raw material of the production process or indispensable component of the product),
3. the technical consequences of substitution on the own production process and product quality,
4. the resulting technical consequences for the downstream processing/application of the product in the value chain and
5. the impact of substitution on product characteristics and the quality of the final product

(including consumer acceptance, conformity with standards, loss of approvals).

5.3 Criteria for health and physico-chemical hazards

(1) If the available guidance cannot be applied when deciding on the suitability of a substitution option or if the assessment of the risk is not clear, specific estimation models should be used first. Particular reference is made to the column model mentioned in Annex 2.

(2) In addition, it must be noted that the assessment of mixtures may require further knowledge, e.g. the ability to identify critical constituents relevant to the decision. Depending on the complexity of the individual case, a more extensive and thorough examination of possible substitution solutions may be necessary. In addition to a thorough search in the sources for literature references, the involvement of experts may then also be necessary.

(3) Data for substitutes must be at least as good as for the hazardous substance to be replaced in terms of their health and physico-chemical hazards. This applies to substitutes also in case that the safety data sheet does not make qualified statements on the hazardous properties - see TRGS 400 section 5.2 paragraph 8.

(4) Before a substitution solution is finally selected, it should also be checked whether it releases dangerous decomposition or reaction products during use or later in its life cycle. Such information may be available as industry sector knowledge or in the scientific literature. For individual substances or groups of substances information is usually only available from experience, as such information is not generated during registration under REACH.

(5) Whether tests or assessments of health hazards have been carried out can be checked in the safety data sheet (there section 11 "Toxicological information") or must be determined otherwise, in particular by asking the supplier. In the case of substances registered under the REACH Regulation, it can be assumed that all relevant data are available.

(6) At least test data or equivalent meaningful information on acute toxicity, irritation, skin sensitisation, germ cell mutagenicity and specific target organ toxicity on repeated exposure must be available. In the absence of specific information, the following hazard categories must be assumed by default:

1. Acute Tox. 3 (Acute toxicity category 3; H301, H311, H331),
2. Skin irritation. 2 (skin irritation category 2; H315),
3. Muta. 2 (germ cell mutagenicity category 2; H341),
4. Skin Sens. 1 (skin sensitizing category 1; H317) and
5. STOT RE 2 (Specific target organ toxicity on repeated exposure category 2; H373).

(7) Hazards arising from the physico-chemical properties of dangerous substances which may cause fire and explosion hazards must also be taken into account. In particular, it must be assessed whether it is possible to use substitutes which do not have any classification based on physico-chemical properties or which do not lead to fire or explosion hazards.

(8) It must be checked whether the safety data sheet (there section 9 "Physical and chemical properties") on physical hazards or on fire or explosion hazards, e.g. due to explosive mixtures, contains appropriate information and safety parameters. For example, the following information in the safety data sheet is relevant:

1. Boiling point,

2. Vapour pressure,
 3. Relative density in relation to air (gases and vapours),
 4. Lower and upper explosion limits,
 5. Flash point,
 6. Ignition temperature (gases and liquids),
 7. Auto-ignition temperature (solids),
 8. Pyrophoric properties,
 9. Burn-up rate,
 10. Maximum rate of gas evolution when reacting with water and indication of the gas formed,
 11. Grain size and grain size distribution (relevant is the fine grain portion smaller than 0.5 mm),
 12. Oxidizing power compared to the reference mixture,
 13. Active oxygen content for organic peroxides,
 14. exothermic decomposition energy,
 15. Test results on thermal sensitivity (BAM steel sleeve test according to Regulation (EC) No. 440/2008, Method A.14 or Koenen test according to UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, (UN RTDG), Manual of Tests and Criteria" stating the test series) as well as on impact and friction sensitivity.
- (9) Further guidance may also be given in the safety data sheet in Section 5 "Fire Fighting Measures", Section 7 "Handling and Storage" and Section 10 "Stability and Reactivity".
- (10) If information on physical hazards is not available or if, after a plausibility check, information seems to be missing, for example information on flammability in the case of a highly volatile organic solvent, this information must be requested as part of the information gathering process. The supplier must provide the classifications according to the CLP Regulation.

5.4 Decision on the implementation of substitution

- (1) If a hazard exists in activities involving hazardous substances, the employer shall – based on the assessment as described - give priority to substitution. This applies in particular to activities involving carcinogenic, germ cell mutagenic and reprotoxic substances and mixtures of categories 1A or 1B and acutely toxic substances and mixtures of category 1, if alternatives are technically possible and lead to an overall lower risk for the employees.
- (2) It can be assumed that substitution options from TRGS on substitutes (TRGS 600 ff.) and sector- or activity-specific guidance containing statements on substitution are basically suitable for application. Therefore, the employer must generally implement them.
- (3) The employer can make the integrated decision taking into account the economic evaluation criteria (see also Annex 1 "Flow chart"). Guidance on which aspects the employer should take into account in the weighing process is given in Annex 3 "Criteria for the realisation of substitution".
- (4) The substitution solution must be used if the operational factors examined in accordance with Annex 3 are essentially positively influenced. Higher costs of a substitution solution do not

automatically exclude substitution.

(5) The integrated decision must also take into account influences on other protected interests, especially the environment. For this purpose, ecotoxicological parameters must be taken into account in particular: e.g. the potential for release and dispersion in the environment, the partition coefficient between water and n-octanol (log Kow) and the persistence and bioaccumulation potential (PBT, vPvB). These provide measures of the capacity of infiltration e.g. into groundwater, of persistence in the environment and of accumulation.

6 Documentation

(1) The result of the assessment of substitution possibilities must be documented.

(2) The documentation of the result of the assessment substitution possibilities is sensibly carried out in connection with the documentation of the other parts of the risk assessment (see TRGS 400). A form is not prescribed. For example, the list of hazardous substances can be supplemented by further columns/fields indicating the time of the check, the result and the location of supplementary documents. The results of the substitution check can be described by standard phrases, e.g:

1. "Possibilities for substitution are ...",
2. "No possibility of substitution. ",
3. "Solution is already substitution solution. ".

(3) If the assessment of substitution reveals possibilities of substitution and these solutions are not implemented while supplementary protective measures outlined in Section 9 and 10 of the Ordinance on Hazardous Substances are applied, the employer has to document the reasons for this. This can be done in the form of standard phrases, e.g.

1. "Substitution solution technically not suitable because ...",
2. "Substitution solution does not sufficiently reduce risk because ...",
3. "Substitution solution operationally not suitable because...",
4. "Substitution solution initiated, re-examination until ... ".

(4) If a substitution with less hazardous substances, mixtures, articles or processes which is technically possible is not implemented for economic reasons, the underlying arguments must be verifiably documented. Annex 3 of this document, for example, is suitable for this purpose.

(5) If no possibilities of substitution have been identified during the assessment of substitution possibilities for activities for which protective measures are to be taken in accordance with Section 10 of the Ordinance on Hazardous Substances, the information sources that have been consulted shall be named.

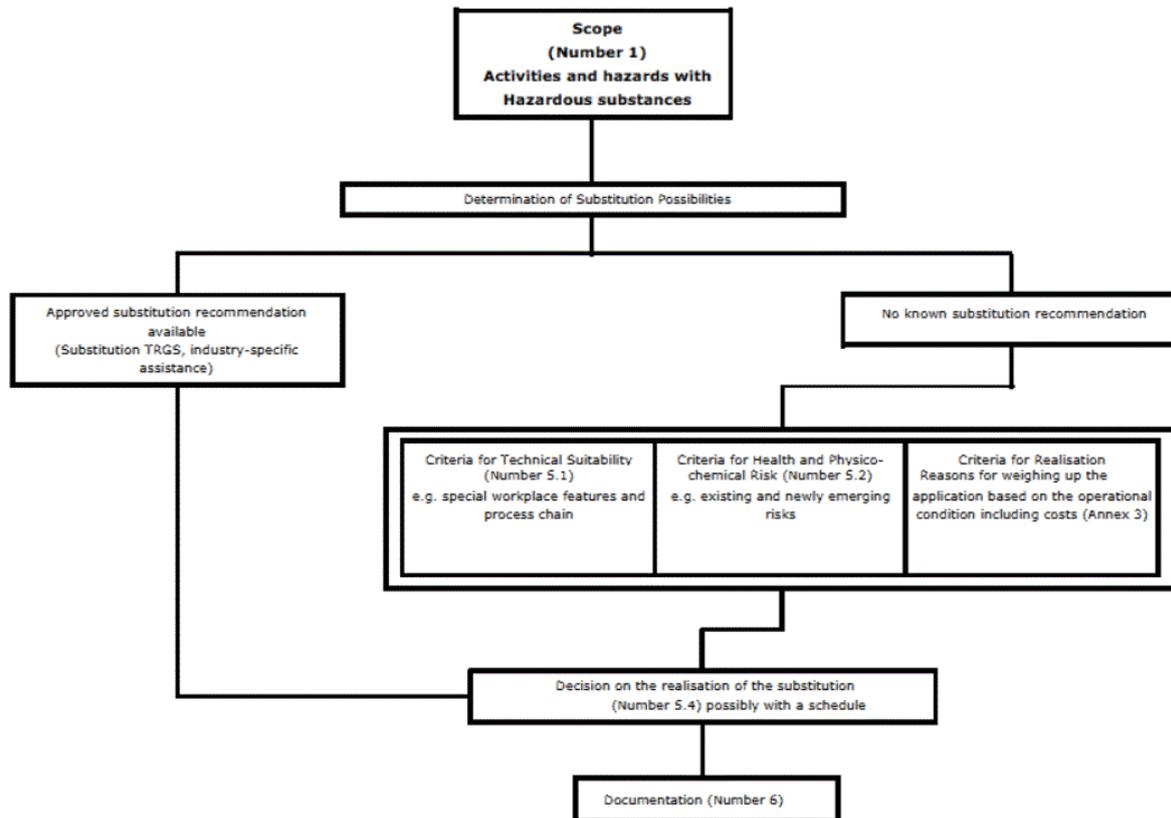
(6) The employer responsible for activities involving carcinogenic, germ cell mutagenic or reprotoxic hazardous substances of categories 1A and 1B must, in accordance with § Section 18 (3) of the Ordinance on Hazardous Substances inform the competent authorities on request of the results of the assessment of substitution and cases of substitution.

(7) For detailed documentation or instead of a freely formulated justification, templates such as those in Annex 3 can also be used. These and other documents can be archived separately.

Annex 1 Flow chart substitution with example cleaning/degreasing of system parts in workshops

1 Flow chart substitution

Figure 1: Flowchart Substitution



2 Example cleaning/degreasing of plant components in workshops

2.1 Preliminary remark

(1) In this annex an example is given of how TRGS 600 can be applied to a concrete substitution case. The example does not claim to have examined all conceivable possibilities or to describe in full the selection and weighting of the assessment criteria.

(2) Cleaning and degreasing work on plant components such as parts of machines or vehicles is carried out e.g. in workshops such as locksmiths or service workshops. Often flammable low-boiling solvents such as aromatic-free white spirit, e.g. in spray cans, are used for this purpose.

2.2 Risk assessment of the existing solution: Cleaning with volatile solvents

Starting point: handicraft-structured workshop, 10 employees, highly volatile cleaning agent in spray cans, on average approx. 5 compressed gas packs á 400 ml per shift, post-cleaning/wiping with rags

Table 1: Overview risk assessment existing example

<p>health hazard</p> <p>Solvent release into the air at the workplace, inhalation exposure and skin contact with degreasing solvents</p>
<p>Hazards arising from physico-chemical agents</p> <p>(here: fire and explosion hazards)</p> <p>Danger from explosive atmosphere due to solvent vapours</p> <p>Fire hazard due to cleaning cloths</p>
<p>Environment: emission of solvents into the environment</p>
<p>other hazards: not relevant in this example</p>
<p>Decision: There is a risk to health and risks of fire and explosion. A substitution solution must be tested.</p>

2.3 Determination of substitution possibilities (Section 3 TRGS 600)

- (1) There is no recognised substitution recommendation (substitute TRGS, activity or sector-specific solution) in accordance with Section 3 (2) (1) and (2) of TRGS 600.
- (2) Possible alternative solutions to replace highly volatile detergents are
 1. Change in working method: use of a mobile cleaning unit with aqueous detergent,
 2. Use of substitutes:
Low-volatile cleaning agent containing hydrocarbons, pump spray bottle (air as propellant).

2.4 Assessment of Substitution

2.4.1 Criteria for existing and possibly emerging hazards must be observed (Sections 4 and 5.3 of TRGS 600)

- (1) Here the criteria from sections 4 and 5.3 of TRGS 600 or the column model in Annex 2 to TRGS can be selected and applied.
- (2) Hazard factors other than substance-bound hazards (e.g. hazards due to noise, vibrations) shall also be considered in accordance with the Occupational Health and Safety Act.
- (3) The promising solutions should be investigated and the results documented.

Table 2: Comparison of hazards between existing example and alternatives

Hazards	Present solution/practice	Alternative 1	Alternative 2
Designation (substance or process)	Volatile Detergents	Low-volatility Detergents	mobile cleaning plant
Characterization	Hydrocarbon-based cleaner Flash point < 23°C, propellant: propane/butane	Hydrocarbon-based cleaner, Flash point > 60°C Pump spray bottle	mobile cleaning system with aqueous cleaning agent
Health hazards from inhalation and dermal exposure	Inhalation exposure to hydrocarbon vapours and aerosols, skin contact with degreasing solvents.	Lower inhalation exposure to hydrocarbon vapours and aerosols than with highly volatile products, dermal exposure (degreasing) higher than with highly volatile products.	No volatile hazardous substances are used. Little skin contact.
Hazards due to physical-chemical properties (here: fire and explosion hazards)	Risk of fire and explosion due to flammable solvents and propellant gas	Fire and explosion hazard due to flammable solvents, lower than at flash point < 23°C. Fire hazard due to rags and solvent residues	None
Environmental hazard	Emission of solvents into the environment	Due to the lower vapour pressure (or higher boiling point) lower emission of solvents into the environment. Collecting container and disposal necessary	Collecting container and disposal necessary
other hazards: (not subject of the Hazardous Substances Ordinance, but relevant to operations)	Not relevant	Not relevant	Not relevant
Decision	High hazard from vapours and aerosols of volatile hydrocarbons	Less risk from hydrocarbons than with current solution	no hazards from volatile hazardous substances to be expected

2.4.2 Select criteria for technical suitability (Section 5.2 of TRGS 600)

The alternatives are based on the relevant criteria, e.g. technical requirements and suitability in the process chain, and to document the results.

Table 3: Comparison of technical suitability of existing example with alternatives

Technical assessment	Present solution/practice	Alternative 1	Alternative 2
Designation	Volatile Detergents	Low volatile detergents	mobile cleaning plant
Technical requirement: Components clean and dry	Yes	Yes, but longer drying time than with highly volatile cleaning agents	Yes, but longer drying time than with highly volatile cleaning agents
Suitability in the process chain especially here: Manufacturer specifications for cleaning components	Given	Given	Given
Can it be realised in the existing rooms?	Yes, but observe explosion protection	Yes, but drip tray necessary	Yes, but drip tray necessary
Decision	Technically suitable, but observe explosion protection	Technically suitable	Technically suitable

2.4.3 Criteria for the realisation of substitution (Section 5.4 and Annex 3 of TRGS 600)

It is qualitatively documented whether the substitution solution has a very positive (++), positive (+), negative (-), very negative (--) or neutral (0) effect.

Table 4: Comparison of substitution solutions for highly flammable detergents

Influencing factors	Change through the substitution solution	
	++/+/0/-/--	++/+/0/-/--
	Alternative 2: mobile cleaning system	Alternative 1: Low volatile detergents
Material costs	+	0
Investment costs		
– Investment costs	--	-
– Energy costs	0	0
Labour costs	-	0
Technical protection measures		
– Ventilation measures	+	+
– Fire/Ex-Protection	+	+
Personal protection measures	+	+
Occupational medical precaution	0	0
Transport costs	0	0
– Freight tariffs, packaging ...		
Storage costs	0	0
Disposal costs	0	0
– Recycling, waste water, exhaust air		
Costs for organisation	0	0
Insurance costs	0	0
Reduction of risk (not to be described in costs)	++	+
Other influencing factors (operational factors not to be described in costs)		
– Company image	+	+
– Employee satisfaction	0	0
– Future viability/planning security	+	0
Final evaluation:		
Alternative 2 is to be preferred because of the greater reduction in risk (no use of volatile hazardous substances).		

Annex 2 Comparative assessment of health and safety hazards (column model)

The column model

(1) The column model (see Table 5) allows for a quick comparison of substances and mixtures based on less information.

(2) A comparative assessment of a product and a potential substitution solution is carried out separately for each of the two solutions in the five columns:

1. Acute health hazards (single exposure),
2. chronic health hazards (repeated exposure),
3. Environmental hazards,
4. physical-chemical effects (fire, explosion, corrosion etc.),
5. Release behaviour and
6. Procedure.

(3) The evaluation of the results should take the following criteria into account:

1. Comparative assessments may only ever be made within a column and never within a line.
2. It may only be used if the manufacturer has evaluated the substances or mixtures (with regard to the health hazard at least in terms of acute toxicity, skin irritation, mucous membrane irritation, mutagenic potential and skin sensitisation) on the basis of available data and experience, taking into account existing data gaps (see safety data sheet sections 9 and 11).
3. In principle, small differences in hazard levels are only an argument in favour of a substitute if the data situation for the substitute is as good as for the substance to be substituted.
4. If the potential substitution solution performs better in all five columns than the product or process used, the level of risk is clearly identified.
5. A difference of one hazard level may sometimes lead to the substitute not being used if there are conflicting reasons.
6. If there are differences of two or more hazard levels, there must be important reasons not to use the substitute.
7. However, as a general rule, the potential substitute will have a lower hazard level in some columns, but also a higher hazard level in one or two columns. It is then up to the user to assess which hazard characteristics, i.e. which columns have the greater weight in the specific case.
 - a) If, for example, ignition sources cannot be excluded during product processing, greater attention will have to be paid to the fire and explosion properties and the release behaviour of the products.
 - b) If larger quantities of waste are produced during processing, the environmental risks are more significant, etc.
8. The result of the substitution check shall be documented.

(3) In the case of mixtures, no evaluation is carried out with regard to the ingredients. This pragmatic approach means that certain disadvantages are accepted, e.g. those resulting from the existence of classification limits for mixtures.

Table 5: Column model

1 Risk	2a Acute health hazards (single exposure)	2b Chronic health hazards (repeated exposure)
Very high	<ul style="list-style-type: none"> •Acutely toxic substances/mixtures, categories 1 or 2 (H300, H310, H330) •Substances/mixtures which may emit very toxic gases in contact with acids (EUH032) 	<ul style="list-style-type: none"> •Carcinogenic substances/mixtures, categories 1A or 1B (H350, H350i) •Carcinogenic activities or processes according to TRGS 906 •Germ cell mutagenic substances/mixtures, categories 1A or 1B (H340)
High	<ul style="list-style-type: none"> •Acutely toxic substances/mixtures, category 3 (H301, H311, H331) •Substances/mixtures which are toxic in contact with the eyes (EUH070) •Substances/mixtures which, in contact with water or acids, may emit toxic gases (EUH029, EUH031) •Substances/mixtures with specific target organ toxicity at single exposure, category 1: organ damage (H370) •Skin sensitising substances/mixtures (H317, Sh) •Respiratory sensitising substances/mixtures (H334, Sa) •Skin-etching substances/mixtures, Cat. 1, 1A (H314) 	<ul style="list-style-type: none"> •Reproduction toxic substances/mixtures, categories 1A or 1B (H360, H360F, H360D, H360FD, H360Fd, H360Df) •Carcinogenic substances/mixtures, category 2 (H351) •Germ cell mutagenic substances/mixtures, category 2 (H341) •Substances/mixtures with specific target organ toxicity on repeated exposure, category 1: organ damage (H372)
Medium	<ul style="list-style-type: none"> •Acutely toxic substances/mixtures, category 4 (H302, H312, H332) •Substances/mixtures with specific target organ toxicity at single exposure, category 2: Possible organ damage (H371) •Skin corrosive substances/mixtures, cat. 1B, 1C (H314, pH ≥ 11.5, pH ≤ 2) •Eye damaging substances/mixtures (H318) •Substances/mixtures which are corrosive to the respiratory tract (EUH071) •Non-toxic gases which can cause suffocation due to air displacement (e.g. nitrogen) 	<ul style="list-style-type: none"> •Reproduction toxic substances/mixtures, category 2 (H361, H361f, H361d, H361fd) •Substances/mixtures with specific target organ toxicity on repeated exposure, category 2: Possible organ damage (H373) •Substances/mixtures which may cause harm to babies via breast milk (H362)
Low	<ul style="list-style-type: none"> •Skin irritant substances/mixtures (H315) •Eye irritant substances/mixtures (H319) •Skin damage in wet work •Substances/mixtures with aspiration hazard (H304) •Skin damaging substances/mixtures (EUH066) •Substances/mixtures with specific target organ toxicity at single exposure, category 3: respiratory irritation (H335) •Substances/mixtures with specific target organ Single exposure toxicity, category 3: drowsiness, dizziness (H336) 	<ul style="list-style-type: none"> •Substances that are otherwise chronically harmful (no H-phrase, but still hazardous!)
Negligible	<ul style="list-style-type: none"> •Experience has shown that substances are harmless (e.g. water, sugar, paraffin, etc.) 	

1 Risk	3 Environmental hazards ¹	4 Physico-chemical effects (fire, explosion ² , ³ corrosion, etc.) <i>Bold and italic H-phrases occur several times.</i> ⁴
Very high	<ul style="list-style-type: none"> •Substances/mixtures acutely hazardous to water, category 1 (H400) •Chronic water-polluting substances/mixtures, category 1 (H410) •Substances/mixtures of water hazard class WGK 3 •PBT substances •vPvB substances 	<ul style="list-style-type: none"> •Unstable explosive substances/mixtures (H200) •Explosive substances/mixtures/articles, subclasses 1.1 (H201), 1.2 (H202), 1.3 (H203), 1.4 (H204), 1.5 (H205) and 1.6 (without H-phrase) •Flammable gases, category 1 A (H220), category 1B and category 2 (H221) •Pyrophoric gases (H232) •Chemically unstable gases, category A (H230) and B (H231) •Flammable liquids, category 1 (H224) •Self-reactive substances/mixtures, types A (<i>H240</i>) and B (<i>H241</i>) •Organic peroxides, types A (<i>H240</i>) and B (<i>H241</i>) •Pyrophoric liquids or solids, category 1 (H250) •substances/mixtures which, in contact with water, emit flammable gases, category 1 (H260) •Oxidising liquids or solids, category 1 (H271)
High	<ul style="list-style-type: none"> •Substances/mixtures chronically hazardous to water, category 2 (H411) •Substances that deplete the ozone layer (H420) 	<ul style="list-style-type: none"> •Aerosols, category 1 (H222 and <i>H229</i>) •Flammable liquids, category 2 (H225) •Flammable solids, category 1 (<i>H228</i>) •Self-reactive substances/mixtures, types C and D (<i>H242</i>) •Organic peroxide types C and D (<i>H242</i>) •Self-heating substances/mixtures category 1 (H251) •substances/mixtures which, in contact with water, emit flammable gases, category 2 (<i>H261</i>) •Oxidising gases, category 1 (H270) •Oxidising liquids or solids, category 2 (<i>H272</i>) •Desensitised explosive substances/mixtures, category 1 (H206) and category 2 (H207) •substances/mixtures with specific properties (EUH014, EUH018, EUH019, EUH044)

¹ The water hazard class is only used as an evaluation criterion for those substances/mixtures that are not (yet) classified with regard to environmentally hazardous properties.

² Substances/mixtures may have explosive properties in the sense of the tests according to section 5.3 paragraph 8 point 15 even without appropriate classification. This has to be taken into account in each individual case.

³ Due to their specific problems, explosive dusts have to be expertly examined in each individual case and are therefore not assigned to any hazard level.

⁴ In the case of physico-chemical hazards, it must be taken into account that a change to a different hazard class results in a different type of hazard which, even if the hazard level is reduced, does not necessarily lead to a reduction of the hazard in the individual case under consideration. An example is the replacement of a flammable liquid of category 2 by a self-reactive substance of type E, where the hazard due to thermal instability must also be taken into account.

Medium	<ul style="list-style-type: none"> •Chronic water-polluting substances/mixtures, category 3 (H412) •Substances/mixtures in water hazard class WGK 2 	<ul style="list-style-type: none"> •Aerosols, category 2 (H223 and H229) •Flammable liquids, category 3 (H226) •Flammable solids, category 2 (H228) •Self-reactive substances/mixtures, types E and F (H242) •Organic peroxides, types E and F (H242) •Self-heating substances/mixtures, category 2 (H252) •substances/mixtures which, in contact with water, emit flammable gases, category 3 (H261) •Oxidising liquids or solids, category 3 (H272) •Gases under pressure (H280, H281) •Corrosive to metals (H290) •Desensitised explosive substances/mixtures, category 3 (H207) and category 4 (H208)
Low	<ul style="list-style-type: none"> •Substances/mixtures chronically hazardous to water, category 4 (H413) •Substances/mixtures of water hazard class WGK 1 •Generally water-hazardous substances/mixtures (awg) 	<ul style="list-style-type: none"> •Aerosols, category 3 (H229 without H222, H223) •Flammable substances/mixtures (Flash point > 60 ... 100 °C, no H-phrase) •Self-reactive substances/mixtures, type G (no H phrase) •Organic peroxides, type G (no H phrase)
Negligible	<ul style="list-style-type: none"> •Substances/mixtures not hazardous to water (nwg) 	<ul style="list-style-type: none"> •Non-flammable or very hardly inflammable substances/mixtures (for liquids flash point > 100 °C, no H-phrase)

1 Risk	5 Hazards from re-release behaviour	6 Process-related hazards
Very high	<ul style="list-style-type: none"> •Gases •Liquids with a vapour pressure > 250 hPa (mbar) (e.g. dichloromethane) •Dusty solids •Aerosols 	<ul style="list-style-type: none"> •Open processing •Possibility of direct skin contact •Large area application •Process index 4 according to TRGS 500 (open construction or partially open construction, natural ventilation)
High	<ul style="list-style-type: none"> •Liquids with a vapour pressure 50 - 250 hPa (mbar) (e.g. methanol) 	<ul style="list-style-type: none"> •Process index 2 according to TRGS 500 (partially open design, opening as intended with simple extraction, open with simple extraction)
Medium	<ul style="list-style-type: none"> •Liquids with a vapour pressure of 10 - 50 hPa (mbar), with the exception of water (e.g. toluene) 	<ul style="list-style-type: none"> •Closed processing with exposure possibilities e.g. during filling, sampling or cleaning •Process index 1 according to TRGS 500 (closed design, leak tightness not guaranteed, partially open design with effective extraction)
Low	<ul style="list-style-type: none"> •Liquids with a vapour pressure of 2 - 10 hPa (mbar) (e.g. xylene) 	<ul style="list-style-type: none"> •Process index 0.5 according to TRGS 500 (closed design, tightness guaranteed, partly closed design with integrated extraction, partly open design with highly effective extraction)
Negligible	<ul style="list-style-type: none"> •Liquids with vapour pressure < 2 hPa (mbar) (e.g. glycol) •Non-dusting solids 	<ul style="list-style-type: none"> •Process index 0.25 according to TRGS 500

Annex 3 Criteria for the realisation of substitution - reasons for weighing up the implementation of substitution solutions and for extended evaluation

1 Considerations for the operational use of substitution solutions

(1) The following explanations are intended to provide employers in particular with reasons for weighing up the operational use of substitution solutions (see Section 5.4 of TRGS 600). The examination is carried out when it has been established that the possible changes

1. actually reduce the material hazard (see section 5.3 of TRGS 600) and
2. are technically suitable (see section 5.2 of TRGS 600).

(2) The following Table 6 shows relevant operational factors (with examples of sub-items) that can be influenced by the use of substitutes and substitute processes.

(3) In business management terms, costs are divided into variable and fixed costs. The table gives the user an indication of which costs may be affected by the substitution solution.

(4) The allocation of the cost blocks to the variable or fixed portion depends largely on the organisation of the company and must be adapted individually.

(5) In addition to costs, the table includes other factors that are difficult to capture in terms of costs but which may well be relevant to long-term effective decisions.

(6) The influencing factors shown can be applied to all types of substitution solutions, i.e. for

1. of substitutes, or
2. the use of substitute procedures.

(7) In most cases it is sufficient to describe the influencing factors qualitatively (positive influence/no influence/negative influence). It is important that all applicable factors are considered and that the applicable sub-items are selected and documented, even if they prove to be irrelevant in the specific case or if there is no change in the factor. A comparison of selected individual costs (e.g. price of the currently used substance against price of the substitute) is generally not sufficient.

(8) Based on a qualitative description of the influencing factors, a clear decision can already be made in many cases, otherwise individual or several of the factors should be examined more closely.

(9) If none of the influencing factors are changed to the negative, the advantage of the substitution solution is obvious. The changes must be initiated immediately.

(10) Even if individual influencing factors are negatively influenced, the substitution solution as a whole can still be advantageous. If a number of factors are negatively influenced, it depends on the operational boundary conditions which relative weight is attached to the positively and negatively influenced factors in the final decision. Rigid assessment rules cannot be formulated.

(11) Higher costs of a substitution solution cannot automatically lead to the assessment "not applicable". Particularly if the substances to be substituted cause a high risk, great importance must be attached to reducing the risk.

2 Considerations for the extended assessment

- (1) For far-reaching decisions (e.g. inter-operational substitution targets, development of new product lines, group-wide restrictions), the above described operational criteria are not sufficient.
- (2) Before using expert methods, it should be checked whether and how the models capture economic, ecological and social criteria, convert them into indicators and evaluate them. In order to be able to make sustainable decisions, it is of great importance that these criteria are applied to all relevant stages of the life cycle of a substance.
- (3) The models should take into account the following stages of the life cycle:
 1. Production, extraction and transport of the raw material,
 2. Further processing of the raw material into products,
 3. Use or consumption of the products including the care and maintenance effort,
 4. Recycling, recovery or disposal of material or products.
- (4) Basically relevant criteria are, for example, the toxicological profile of the input materials and/or intermediate products, energy consumption, emissions, the ecotoxicological profile, the availability of the substances, and, depending on the problem, other more specific criteria.
- (5) Depending on the number of phases in the life cycle of the substance that have been investigated and the data available or used, different levels of description of the substance and the opportunities and risks associated with its use are possible.
- (6) Expert models can support decisions on the substitution or establishment of a product line in the fields of marketing, research, strategy and also politics.

Table 6: Considerations for the implementation of substitution solutions

As far as possible, all influencing factors should be considered and appropriate sub-items selected. For each influencing factor, if necessary broken down by sub-items, it should be documented at least qualitatively whether the substitution solution has a positive (+), negative (-) or neutral (0) effect. If there are several conceivable substitution solutions, the table can be extended or created several times.

Influencing factors		Change due to the substitution solution ++/+/0/-- or cost estimate	Remarks
variable costs:			
1.	Input material costs If necessary, take into account costs for auxiliary materials and consumables.		
2.	Storage costs		
3.	Transport costs e.g. costs for packaging, freight tariffs, etc.		
4.	Disposal costs e.g. costs for material recycling, waste, waste water and exhaust air treatment		
5.	Energy costs		
6.	Insurance costs etc.		
fixed costs:			
7.	Research and development costs Development and adaptation of the substitution solution in the value chain		
8.	Investment costs Investment in the production plant		
9.	Personnel costs e.g. salaries, costs for continuing education, etc.		
10.	Risk management costs: - technical measures, - organisational measures - personal measures e.g. structural measures, ventilation measures, if necessary, need for additional personnel, workstation		
11.	Costs for occupational health care		
12.	Costs of labour management systems and compliance with legal requirements e.g. ISO certification, list of hazardous substances, registrations, approvals, permits, etc.		
13.	Distribution costs etc.		
further influencing factors (if applicable, operational factors that cannot be described in costs):			
14.	public perception, corporate image, etc.		
15.	Employee satisfaction, motivation, etc.		
16.	advantageous product labelling, quality seal, etc.		
17.	Life cycle assessment etc.		
other relevant factors (if necessary, add operational and case-related factors)			
final evaluation:			
-	Alternative solution not suitable for operation, because, ...		
-	Substitution solution initiated,		
-	renewed check until		
-	or free text		

References

In addition to the involvement of experts, research in generally accessible knowledge sources should also be carried out when developing substitution solutions. Examples of such knowledge sources are given below. They make different demands on the user's prior knowledge, some of them should only be used if the user has sufficient technical qualification. The following collection is not exhaustive (status 2019).

1 Databases on substitutes and substitution procedures

1. the hazardous materials information system of BG BAU - GISBAU with comprehensive information on hazardous materials in construction, renovation and cleaning

<https://www.wingisonline.de/>

2. BG ETEM- sector initiative for the reduction of solvent emissions in offset printing - The product lists should enable the user to select the washing agent permitted or recommended for his machines.

<http://praevention-dp-bgetem.bg-kooperation.de/>

3. The VKIS-VSI-IGM-BGHM substance list contains the substances which should or may not be used in cooling lubricants by the manufacturers or which are subject to declaration. This list of substances is regularly updated by the Consumer Group Industrial Lubricants (VKIS), the Lubricant Industry Association e.V. (VSI) and the IG Metall (IGM) with the help of the Berufsgenossenschaft Holz und Metall (BGHM).

<http://www.vsi-schmierstoffe.de/regelwerke/vkis-vsi-igm-bghm-stoffliste.html>

4. ECHA's general database on substitution

<https://echa.europa.eu/de/substitution-to-safer-chemicals>; <https://echa.europa.eu/de/search-for-alternatives-for-substitution>

5. Haz-Map Information on Hazardous Chemicals and Occupational Diseases: toxicological information, but access is possible via substance groups, so that possible alternative substances are offered.

<https://haz-map.com/>

2 Databases with substance information

1. GESTIS - Substance database: introduction to the substance; substance information; references to "good practice", some specific references to restrictions on use and substitution solutions

www.dguv.de/ifa/stoffdatenbank

2. GSBL - Joint Substance Data Pool of the Federal Government and the Länder: Access via the substance; substance information in the structure of the safety data sheet; information on uses, but no information on substitution solutions

<http://www.gsbl.de/>

3. IGS - Information system for hazardous substances

<https://igsvtu.lanuv.nrw.de>

4. BG RCI - GisChem hazardous substance information system: entry via the substance or some activities, product groups, sectors; substance information; few references to "good practice", no concrete references to substitution solutions

<http://www.gischem.de/>

3 International databases (mostly on the effects of substances)

1. US EPA Database - Substance information; access via the substance

<https://www.epa.gov/aegl/access-acute-exposure-guideline-levels-aegls-values#chemicals>

2. IPCS INCHEM - Substance Information; access via the substance or CAS number: Fast international access to an assessment of chemicals in common use worldwide, which may also occur as environmental and food contamination, as an aid to substitution decisions very helpful (Lead is the Canadian Centre for Occupational Health and Safety (CCOHS), English and French)

<http://www.inchem.org/>

3. Pubmed - Service of the U.S. National Library of Medicine including over 17 million citations from MEDLINE and other life science journals for biomedical articles back to the 1950s.

<https://www.ncbi.nlm.nih.gov/pubmed>

4. EU-OSHA - Practical tools and guidelines on dangerous substances

<https://osha.europa.eu/de/themes/dangerous-substances/practical-tools-dangerous-substances>

5. eChemPortal provides free public access to information on properties of chemicals:

<https://www.echemportal.org/echemportal/>