

# Deriving Surrogate DNELs for Preparations under the Scope of REACH



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## Abstract

FEICA has recognized that for risk assessments of mixtures there will be a long interim period lasting until 2019: during this time, DNEL values will not be available for all ingredients in a formulation. Yet, annexes to the safety data sheets of preparations have to be produced based on the then already existing limited information. The FEICA scheme therefore makes use of toxicological hazard information indicated by R-phrases to assign substances to hazard bands. Furthermore, the proposal includes a critical component approach (i.e., the substances in the mixture with the highest risk potential represent the whole preparation) and a tiered approach for inhalative and dermal pathway to sort out the ingredients requiring a more detailed examination. If neither OEL nor scientific sound DNEL values are available for inhalation and dermal exposure the hazard banding schemes available from I.M. Brooke (1998) and from the German AGS may be employed as a basis for Tier 1 DNEL derivations.

## Background Information

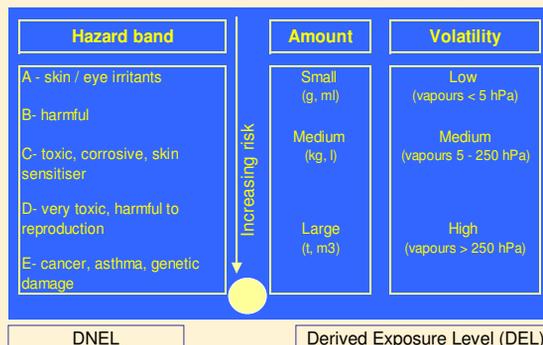
REACH will require exposure, hazard, and risk assessments of ca. 30000 registered substances nearly always occurring in mixtures. The main criterion for safe use of chemicals is:

Exposure Level  $\leq$  DNEL (Derived No Effect Level)

However, at least in the beginning of the REACH process for most of the ingredients in a preparation neither DNELs nor exposure values will be available. Only ca. 700 of these chemicals already have TLV/OEL- values. For major components in a preparation DNELs will not be available before the last registration under REACH after 11 years. Furthermore, the way in which DNELs for preparations are derived cannot be addressed simply by extrapolation of the approaches developed for pure substances.

In the absence of DNELs for at least the critical components a safety assessment of mixtures can lead to false negative conclusions.

## Outline of the Banding Methodology for Liquids



## Hazard Group Allocation

Hazard ranking and banding are not new concepts. The COSHH Essentials Concept (Brooke, 1998), the BAUA protection levels (e.g. Packroff et al. 2006), the ILO Chemical Control Toolkit, the TNO Stoffenmanager, and the ECETOC TRA already have banding models included. Banding tools are recommended for use within the reference REACH Implementation Project 3.2-2 P-TGD.

Categorization of hazards is based upon EU classification criteria. The separation of endpoints accounts for the relative importance that different endpoints have in terms of adverse health effects (whether they are life threatening, irreversible, etc.). The ranking scheme proposed for vapours (s. Table) and dusts is taken from Brooke (1998). The system is compatible with the future GHS system.

The DNEL band is a health based limit of a temporary nature based on the available hazard data and using a precautionary approach.

These bands should be seen as the best estimate of the upper limit of an acceptable exposure. If available, more reliable OELs/DNELs replace initial category values.

Corresponding EU R-Phrases	Hazard Band	Target airborne concentration range (DNEL)
R10-12,19, R36, R38, R50-53, R59, R65, R66. Substances not allocated to another band	A	>50 to 500 ppm
R20, R21, R22, R21/22, R20/21/22, R67	B	>5 to 50 ppm
R23/24/25, R33, R34, R35, R37, R39/23/24/25, R40/20/21/22, R41, R43, R48/20/21/22	C	>0.5 to 5 ppm
R48/23/24/25, R26/27/28, R39/26/27/28, R40 Carc. Cat. 3, R68 Muta cat 3 (formerly R40 Muta cat 3), R62, R63, R64	D	<0.5 ppm
R42, R45, R46, R49, R60, R61, R68	E	Carcinogens or asthmagens: Seek specialist advice

For carcinogens, mutagens, and asthmagens (Group E): "As Low As Reasonably Achievable" (ALARA). Therefore, seek the advice of a specialist.

## Do R-Phrases underestimate Hazard?

R-Phrases and German MAK Values:

Character	R-Phrases (also in combination)	Arithmetic mean & standard deviation (No. of MAK-values)*	Bands (ppm)
(F+), O, N.E)	R 10, 11, 12, 19, 50-53, 59, 65-67 :	1627,7 ± 635,3 (25) mg/m <sup>3</sup>	50-500
Xi	R 36,37,38:	182,3 ± 132,1 (19) mg/m <sup>3</sup>	50-500
Xn	R 20,21,22:	125,8 ± 94,8 (27) mg/m <sup>3</sup>	5-50
T	R 23,24,25:	27,8 ± 24,9 (9) mg/m <sup>3</sup>	0,5 - 5
C(Xi)	R 34, R41:	25,4 ± 18,6 (13) mg/m <sup>3</sup>	0,5 - 5
C	R 35 :	8,4 ± 7,1 (15) mg/m <sup>3</sup>	0,5 - 5
Xi	R 43:	4,8 ± 2,6 (9) mg/m <sup>3</sup>	0,5 - 5
Xn	R 40 (Carc. Cat. 3):	7,0 ± 6,7 (16) mg/m <sup>3</sup>	< 0,5
T+	R 26,27,28:	3,9 ± 3,1 (16) mg/m <sup>3</sup>	< 0,5
T(+)	R 45:	0,78 ± 1,36 (36) mg/m <sup>3</sup>	Specialist adv.
Xn	R 42:	0,5 ± 0,3 (6) mg/m <sup>3</sup>	Specialist adv.
T(+)	R 49:	0,071 ± 0,066 (4) mg/m <sup>3</sup>	Specialist adv.

For well investigated substances occupational exposure limits tend to fall within an appropriate band, but in a few cases (ca. 2% - mainly irritant effects) may be less than the lower end of the band. To minimize a false sense of security it is necessary to deal with uncertainty

## The Critical Component Approach

Focusing on the substances with the highest risks (critical component approach) is a valuable instrument to overcome the complexity in assessing preparations.

General concept:

- Use of the banding system to identify the critical component based on hazard-, exposure-, and risk- assessment for all substances in a mixture.
- If necessary, additivity of effects has to be taken into account.
- For all relevant exposure pathways focus on the substance(s) in the highest risk band(s).
- Apply adequate risk measures to control the critical components risks. De facto, any lesser risk levels will also be controlled.

## Conclusions

DNELs derived from Banding models may assist industry

- in developing Chemical Safety Assessments and Risk Reduction Measures for preparations under the scope of REACH,
- to screen preparations for substances of concern demanding a higher tiered approach,
- to ease communication in the supply chain,
- and to draw up anticipated workplace risk assessments to accompany products.
- Main elements of existing banding models (Inhalation: Brooke 1998; Skin: German AGS) have been adapted to REACH requirements and successfully tested as Level I in the IT tool "HEAL" within the RIP 3.2 FEICA – Case Study