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Case study on the different options for mixture (e)SDS

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Motivation: Open questions on mixture SDS

Actors are insecure about SDS for mixtures with registered ingredients

- Broad agreement on how to deal with ingredient exposure scenarios...
 - a) forward unmodified ingredient ES as attachment to mixture SDS
 - b) create ES for the whole mixture and attach them to SDS
 - c) integrate consolidated information into main body of mixture SDS
 - (note: options are in accordance with ECHA DU Guidance, although there options are structured differently)
- Yet no experience in consolidation
 - comparability of different options?
 - technical feasibility



Idea: Practical example to illustrate existing guidances

- Mandate of VCI Project Group „Safety Data Sheets“ for preparation of procedural guidelines
 - decision to create a leaflet depicting the different methods based on real ES
- Conditions:
 - leaflet should be rather short for better understanding; no detailed discussion of individual aspects of the mixture
 - leaflet should complement, not replace or repeat existing guidance
 - each (e)SDS option processed by another company, to reveal aspects that depend on the individual point-of-view

Result: 3 SDS with same content but different level of detail

- ▶ Leaflet uses color to make references to ingredients

2.3 Contributing scenario controlling worker exposure:
PROC4; PROC5

Concentration of substance in preparation/mixture or article:

- <=100% Polyether polyol
- <=20% Alkylamino carboxamide
- <=100% 2-Ethylhexanol

Physical state during application:
liquid

Amounts used:
Not of relevance.

Duration and frequency of use:
Exposure time.....: 1-4 h; per day

Risk management measures related to human health (worker):

- If dermal exposure cannot be excluded, appropriate gloves and protective clothing have to be worn.
- Wear eye protection if exposure to the eye cannot be excluded, e.g. during spraying, overhead work, or where the face is in close proximity to source of exposure.
- Provide extract ventilation to points where emissions occur. (Effectiveness: 90%)

Example: Such a detail in option b)
would be omitted in option c)

- ▶ This presentation will not focus on the resulting leaflet, but on the steps we made on our way

Step #1: A suitable mixture

■ Specifications:

- mixture with different ingredients with real eSDS, but not too complex
 - ingredients with different classifications, suitable for a DPD+ approach
 - no relevant ingredients without exposure scenarios
 - ingredients from different suppliers
- ⇒ no suitable real mixture found that suited our needs

■ Fictitious mixture

Ingredient	Conc.	R-phrases
Polyether polyol	30%	R36
2-Ethylhexanol	19%	R20-36/37/38
Diethyltoluenediamine (DETDA)	10%	R21/22-36-48/22-50/53
Alkylamino carboxamide	1%	R34-43-50/53
Non-classified polyether	40%	-



Step #2: Identified uses

- Uses of mixture vs. intersection of ingredient uses
 - not discussed here, but important for real mixtures
 - intersection may ease SDS generation, but:
 - - higher chance of missing some DU uses in the mixture SDS
 - - intersection may lead to description of unnecessary PROCs
- Decision to process only one use for the mixture
 - **industrial end use** (e.g. in coatings); ERC6c; PROC1,3,4,5,8a,8b,9,15

Ingredient	Exposure scenarios (selection)
Polyetherpolyol	<ul style="list-style-type: none">■ ES2: Formulation■ ES3: Industrial end uses (ERCs 2,3,5,6c / PROCs 1,2,3,4,5,8a,8b,9,10,13,14,15,21)
2-Ethylhexanol	<ul style="list-style-type: none">■ ES1: Formulation■ ES2: Coatings (ERC 4 ⇔ SpERC / PROCs 1,2,3,4,5,7,8a,8b,9,10,13,14,15)■ ES5: Functional fluids (industrial)
Diethyltoluenediamine (DETDA)	<ul style="list-style-type: none">■ ES1: Formulation■ ES2: PUR parts (ERCs 6c,8c,8f / PROCs 1,2,3,4,5,7,8a,8b,9,11,13,14,15)■ ES3: Coatings (ERCs 6c,8c,8f / PROCs 1,2,3,4,5,7,8a,8b,9,10,11,13,15)■ ES4: Glues and sealants (ERC 6c,8c,8f / PROCs 1,2,3,4,5,7,8a,8b,9,10,11,13,14,15)
Alkylaminocarboxamide	<ul style="list-style-type: none">■ ES2: Formulation (ERC2)■ ES3: Industrial end uses (ERC 5 with zero emission / PROCs 1,2,3,4,5,8a,8b,9,15,21)
Non-classified polyether	-

ES2 and ES4 are suitable, too

Step #3: Lead substances (LS)

- Identification of lead substances required to reduce complexity
 - DPD+ chosen as most appropriate method
 - oral route: not relevant for industrial use

Route	DPD+ lead substances
inhalation	carboxamide; 2-ethylhexanol
dermal	carboxamide; 2-ethylhexanol
eye	polyetherpolyol
aquatic env.	DETDA

■ Considerations beyond DPD+

- inhalation:

STOT RE 2 classification of DETDA indicates a low inhalative DNEL. Indeed the value of 0.13 mg/m³ is the lowest.

- aquatic:

carboxamide is not lead substance, but would lead to a classification.

⇒ Additional ES check showed that relevant measures are typically covered by lead substances

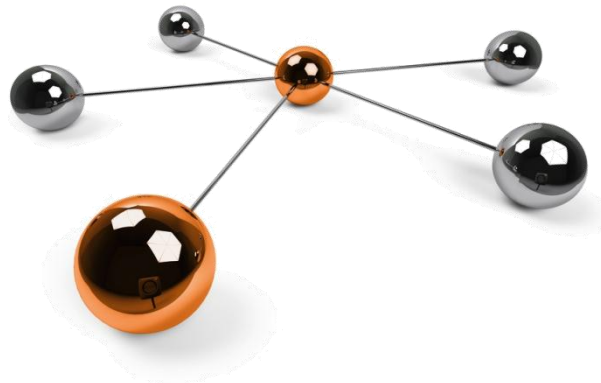
Step #4: OCs and RMMs for communication

Some issues that caught the eye:

- **Gloves**
 - materials/details typically only given in Section 8
 - no efficiency given for dermal lead substance
- LEV for one substance only required for higher temperatures
- **Emission factors: zero emission beats ERC defaults**
 - communication should be in form of RMM, especially for option c)
 - “surfaces must be sealed”; “emergency plans for spill/leakage/storm water required”: necessary RMM or just best practice?
- **Conditions described in ES of non-lead substances**
 - e.g. carboxamide would have most restrictive env. RMM for a different use
 - inconsistencies could be neglected, since ES of different ingredients were not prepared for a common use in our fictitious mixture
- Amounts used per day/year may be converted for the mixture

Step #5: Adaptions for a reduced complexity

- Reduction of number of forwarded substance ES in option a)
 - no quantitative assessment for eye exposure
⇒ inclusion of RMM only in main body
 - measures of 2-ethylhexanol cover both inhalative and dermal exposure
⇒ neglection of scenario of carboxamide
 - only one full exposure scenario by use of contributing scenarios (DETDA for environment; 2-ethylhexanol for worker)
- Harmonization of measures
 - exposure time *1–4 h (high concentration)* could be adapted to match *>4 h (low concentration)*; ⇒ alignment with RMM of other LS



Step #6: Level of detail

- Level of information varies
 - option a)
full information in forwarded substance ES
 - option b)
selected information in mixture ES (see below)
 - option c)
only OC/RMM without efficiencies in main body,
plus selected DNEL/PNEC



- Selection of exposure estimates, RCR, DNEL/PNEC for option b)
 - exposure values can hardly be scaled to the mixture \Rightarrow only for substances
 - for clarity, only most critical RCR should be communicated
 - RCRs for non-LS may be higher than those for LS in original scenario (but are usually lower when scaled with the conditions for the LS)
 - DNEL/PNEC should be restricted to substances for which conditions are communicated (i.e. mainly the lead substances)

Summary: Lessons learned

- Identification of lead substances helps to reduce complexity
 - DPD+ gives a suitable picture
- Basic scaling useful for consolidation
 - sometimes parameters of “neighbour” scenarios can be adopted
- OC/RMM wording may differ between ES of different substances
 - alignment of different wording for same measure is possible
 - usage of standard phrases is recommended for better harmonization
- Specific experience on ES required for the process, especially to determine relevance of information
- High effort with little improvement of safety information
 - OC/RMM comparison and harmonization takes up most of the time
 - RMM can typically be reduced to a few “classic” types: shorter exposure duration, PPE, LEV
 - often measures will not differ from those already given in the mixture SDS
 - no big difference for the three options

Outlook: Issues that should be further pursued

- Strategies for a high throughput in revision of mixture SDS
 - acceptance of lead substance approaches, e.g. DPD+
 - no unnecessary hurdles like flagging of ES information in main body
- Separation of mandatory RMM and best practice advices
 - overview on basic RMM of common assessment tools
 - acceptance of expert judgement
- Harmonization of different RMM combinations with similar protection
 - concentrations much lower than described in the ES
 - different and complicated descriptions for the same basic measure
- More flexibility for expert amendments without DU CSR duty

