European Automobile Manufacturers Association

Expectations from end-users of mixtures with SME suppliers

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Exposure scenarios for mixtures?

COUNCIL OF
THE EUROPEAN UNION

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Interinstitutional File:
2003/0256 (COD)
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STATEMENT OF THE COUNCIL'S REASONS

Finally, the Council has in its Common Position decided to delete Annex Ib (Chemical Safety Assessments for Preparations) given that the scientific methodology underpinning this Annex is still being developed.

No exposure scenarios for mixtures!

REACH, article 31.2

If the safety data sheet is developed for a preparation **and the actor in the supply chain has prepared a chemical safety assessment for that preparation**, it is sufficient if the information in the safety data sheet is consistent with the chemical safety report for the preparation instead of with the chemical safety report for each substance in the preparation.

There is no annex Ib describing how to create A CSR for a mixture!

Downstream-user obligations …

…if they receive an „ext. SDS“ for mixtures

… resulting from REACH, TITLE V: refer only to registered substances (used as such or used as a component) - not to mixtures!

Question:
Is there a legal requirement for REACH compliance check after receiving consolidated ES for mixtures? If yes, which and based on which legal reference?

Answer:
None, see REACH Art 31(4) and be aware of the fact, that the full registration number is not provided for components of mixtures

Downstream-user obligations …

…if a substance is used but the ES does not fit

… include in future also plausibility check of ES if registered substances are used (lengthy ext. SDS difficult to analyse)

… ES specifications are often parallel to already existing workplace safety instruments, like risk assessment, work place safety instructions, TLV, other national technical standards.

… prefer upstream communication if SDS resp. RMMs and/or other data are not adequate or not consistent (Art. 34, also for mixtures) …

… require identification of use from supplier if use is missing or conditions are not reasonable (Art. 37 (3), substances only)

… create DU-CSR only if use is not yet registered and CBI shall be protected (Art. 37 (3), only for substances not for mixtures!)

ECHA SDS Guidance Version 1.1, 3.23

Option 2 for mixture SDS (include information into main body of SDS) preferred by end-users

- RMMs for workplace and environmental protection result anyhow mainly from a correct (CLP) classification of a mixture and should be therefore already part of a normal mixture SDS.

- Special OCs (if any) might be included in the main body SDS in the appropriate RMM SECTIONs (e.g. 7 and 8).

- DNEL/PNEC are already requested for subsection 8.1 (control parameters).
Note: No requirement for non-hazardous ingredients!

- Scaling tools* and ES for the ingredients may be made available via Internet/data base. Note: substance manufacturer should use spERCs instead of ERCs to avoid any incompliance at customer side that might occur when using worst-case generic ES estimation tools.

* preferable only 1 tool and NOT many tools!

Characteristics of extended SDS

… are often too complex, are too long (too much paper) and not understandable.

… ES contain redundant and sometimes superfluous information resulting from different generic exposure estimation tool (e.g. ECETOC, Stoffenmanager etc.) and are often not comparable.

… show sometimes prosa text only, no real data and many different standard formats (output)

… ES are generic or created by models and cannot be transferred 1:1 to workplaces

… ES are not in national language (but*)

… are not better than „normal“ SDS regarding basic elements, like CLP classification, quality of data in sections 9,11 and 12

* Note: because it‘s for experts only one should discuss whether it‘s acceptable to receive the ES in English until the whole ES communication process is consolidated and standardised (ESCom project); many ECHA Guidance documents are also available in English only.

Experiences with extended SDS

…Ext. SDS / ES contain errors or are not complete resp. inconsistent

….DU need special expertise/knowledge for reading and understanding ext. SDS and for the REACH compliance check.

… difficult to check whether the own identified uses and the uses of own customers are covered by an exposure scenario

… end-users , who want to be REACH-compliant have difficulties to communicate on REACH obligations with their SME-suppliers

…the terms „Identified use“ and „Use“ are difficult to distinguish.

…Use descriptors are difficult to understand.
Note: for mixtures it‘s better to have a general description of use instead of use descriptors.

FAZIT: there is no real safety improvement compared to already existing inhouse workplace and environmental safety management.

Example of „ext. SDS for mixtures“

1.2. Relevante identifizierte Verwendungen des Stoffs oder Gemischs und Verwendungen, von denen abgeraten wird

Identifizierte Verwendungen

Basierend auf dem “use descriptor system” gemäß der Vorgabe der europäischen Chemikalienagentur EChA

Verwendungssektor	SU 3, SU 22
Produktkategorie	PC9a, PC9b

Weitere Informationen vgl. Abschnitt Expositionsszenario

If the end-ser consults Guidance R12
He might find out:
“Coatings and Paints”

Use advised against

Das Produkt ist ausschließlich für den industriellen und/oder gewerbsmäßigen Gebrauch bestimmt, und nicht für den privaten Verbraucher.

<u>REACH, Annex II, No 1.2:</u>

At least the identified uses relevant for the recipient(s) of the substance or mixture shall be indicated.

This shall be a brief description of what the substance or mixture is intended to do, such as “flame retardant”, “anti-oxidant”.

Identified use – SECTION 1

Where a chemical safety report is required, the information in this subsection of the safety data sheet shall be consistent with the identified uses in the chemical safety report and the exposure scenarios from the chemical safety report set out in the annex to the safety data sheet.

Question: **Is a CSR required for a mixture?**
Answer: **No!**

Question: **Is REACH annex I dealing with CSR for mixtures?**
Answer: **No!**

Question: **Why making the world of REACH more complex than legally required?**
Answer: **?**

ES for non hazardous mixtures?

SICHERHEITSDATENBLATT
nach 1907/2006/EG

Abschnitt 2. Mögliche Gefahren

The mixture is not classified as dangerous according to 1999/45/EC

1. Expositionsszenario (Typ 1) für das Auftragen von Beschichtungen durch Versprühen

DU obligations are not clear!

Freie Kurzbezeichnung:

Industrielle oder handwerkliche Anwendung von Beschichtungsstoffen durch Versprühen (handwerkliche Verwendung in industrieähnlichem Umfeld)

Systematische Bezeichnung auf Grundlage von Verwendungsdeskriptoren:

Verwendungssektor	SU 22, SU 3
Produktkategorie	PC9a, PC9b
Verfahrenskategorie	PROC 4 (umfasst PROC 2), PROC 5 (umfasst PROC 3), PROC 8a (umfasst PROC 8b), PROC 7 or PROC 11
Umweltfreisetzungskategorie	ERC 4, ERC 5

Data required for mixtures

Data description	SDS Section	Remark
DNEL/PNEC of hazardous ingredients	8.1	First priority: national TLV
Hazardous ingredients theirself	3	Including CORRECT (!) CLP classification, SCLs and M-factors of the single substances
CLP Classification	2.1	Including classification method used for mixtures
CLP Labeling	2.2	H- and P-phrases, EUH-Statements, other labeling
Other hazards	2.3	**Which are NOT covered by classification (will be less frequent under CLP, because better description of hazards)**
data of the hazardous ingredients ,relevant for classification (eco)tox.	9, 11, 12	Every member of the supplier chain should use the same data: therefore it would be good to have **an official EU data base with all classification relevant data**
Transport classification	14	Consistency with CLP Physical Hazards (SECTION 9)
RMMs (OCs special cases)	4, 5, 6, 7, 8, 10, 13	**Resulting from CORRECT(!) CLP classification**
General description of use of the mixture (no descriptors)	1 and 2	Brief description of what the mixture is intended to do, such as “flame retardant”, “anti-oxidant”. The uses which the supplier advises against and why shall, where applicable, be stated.

Summary

Work processes require more qualified manpower at DU (SME supplier AND end-user side), because

...increase of information (ext. SDS) without any real safety gain
...implementation problems of REACH / CLP at production plants
➔ increased plausibility check/rework of in-/outcoming SDS
➔ time consuming questions back to suppliers
➔ increased training requirements

Open questions remaining...
...scaling vs. Identification of additional use/ DU-CSR for substances?
...dealing with (consolidated) ES for mixtures (if any) at DU side?

CLP classification is describing the hazards of mixtures well enough, there is no need for mixture ES and no safety gain!

There is no need for mixture ES for end-users and their SME Tier 1 supplier! They should NOT receive any mixture ES

Recommended path forward

- Develop/offer method to include information of ES / RMMs into SDS main body based on CLP classification (DPD+ not needed anymore!)
- Develop/offer harmonised output format for est. SDS and support XML for communication along the supply-chain (incl. main body)
- Develop/offer harmonised exposure estimation and/or scaling tools
- Develop/offer a comprehensive data base with all substance ES available and searchable
- offer a data base with classification relevant data (CLP), especially for “Acute Toxicity” (define the EU valid $LD(C)_{50}$ for calculation of the ATE_{mix}.

Free Download of Version 3.1:

http://www.acea.be/reach/

Thank you!

European Automobile Manufacturers Association
www.acea.be