



Handling exposure scenario related information in Safety Data Sheets for mixtures

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DUCC = platform for associations whose member companies use chemicals to formulate mixtures as finished products for end users (consumers and professional users)

DUCC focuses on DU needs, rights, duties and specificities under REACH and CLP



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Presentation outline

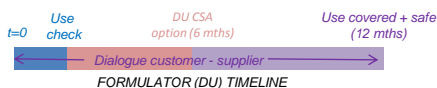
- Scene setting
 - Practical difficulties, conclusion of ENES 1
- DUCC recommendations (different options for different types of mixtures)
 - Handling ES information in SDS for mixtures (5 cases)
- Existing methodologies
 - Current method and way forward

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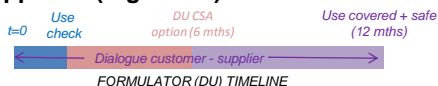


The headache at formulator level: deadlines and communication duties

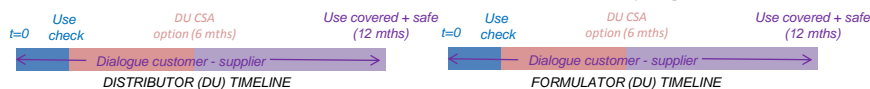
Substance A, supplier 1 (registrant)



Substance A, supplier 2 (registrant)



Substance B, supplier 3 (distributor who is a DU, supplying formulator)



Substance C, supplier 4 (registrant): no ext-SDS received

SDS not updated yet? Substance not registered? Substance not subject to CSR/ES?

Mixture A + B + C ??

Mixtures of mixtures ???



Passing on ES information – ENES1, 24-25/11/2011

- The terminology “ES for mixtures” does not exist in the regulation. ES concept applies only to **substances**, as such or in mixtures (or articles)
- The legal text does not prescribe **how to transmit** ES information for substances in mixtures
 - An annex is not obligatory for mixtures
 - Practical options: add annex(es) or integrate into SDS main body ?
- ES information triggers specific **DU duties**, so this information needs to be clear in the SDS
- Automation (IT tool) is not yet available

Challenge: As formulator, find a way to communicate understandable information to your DUs

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DUCC recommendation on how ES information on substances can be converted into information for the safe use of mixtures

In brief: after checking use coverage

Case	Need for an ES?
1. Formulation of mixtures (at own site)	NO. SDS not legally required because no placing on the market. Workers safety legislation governs safety communication to workers.

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DUCC recommendation on how ES information on substances can be converted into information for the safe use of mixtures

Case	Need for an ES?
2. Intermediary & End-use mixtures used by professional or industrial users	MAYBE. Formulators need to forward relevant information. For classified mixtures an SDS is mandatory which reflects incoming ES (of substances or mixtures). 3 options:
Option 1	Forward the ES of the relevant substance(s) Intermediary mixture
Option 2	Consolidate ES of relevant substances contained in the mixture into an annex to the SDS of the mixture Intermediary mixture
Option 3	Integrate the information on OC/RMM into the main body of the SDS of the mixture End-use mixture

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Downstream Users of Chemicals Co-ordination group

DUCC recommendation on how ES information on substances can be converted into information for the safe use of mixtures

Case	Need for an ES?
3. End-use mixtures intended for consumers (general public)	NO. No need to include ES-related information in SDS supplied to retailers* as relevant OC/RMM for them are in the main body. Sufficient safety information to be communicated to consumers via the label.

* SDS supplied as common practice, not a legal requirement except if requested

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DUCC recommendation on how ES information on substances can be converted into information for the safe use of mixtures

Case	Need for an ES?
4. R&D Samples	NO. SDS must be provided for samples placed on the market. Due to the nature of R&D (use or conditions of uses may not be known yet) <u>no need to annex ES</u> , as long as the requirements for the protection of human health and environment are in place.

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DUCC recommendation on how ES information on substances can be converted into information for the safe use of mixtures

Case	Need for an ES?
5. Non-classified mixtures	NO . SDS must be provided for non-classified mixtures under certain conditions <u>and</u> if requested. No need to annex ES- related information.

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Possible approaches to “consolidate” received information

“Case by case” approach - DPD+ methodology

- Starts with classification of mixture (DPD+)
- **Lead substance** to be assessed per endpoint
- Once the Lead Substance(s) is/are identified → Relevant set of OC/RMM controlling exposure
- Limitations of DPD+*
 - Additional assessment necessary for CMRs, respiratory sensitisers, PBT/vPvB
 - Expertise is needed to fill gaps
- See Cefic/VCI practical guide “**Part 3-Mixtures under REACH**” and Cefic/DUCC industry guidance document “**REACH: Exposure scenarios for preparations**” (June 2009)

* OKOPOL assessment of DPD+ methodology for environment, will be evaluated once fully published ¹³



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Possible approaches to “consolidate” received information

“Generic exposure scenario” concept

- Sector specific approach
- Consists in **condensing many mixtures** with a common use into a **representative** one with a “typical ES”
- Define domain of applicability for each GES – map OCs/RMMs VS hazard classifications
- Requires good knowledge of product compositions & characteristics, well organised supply chain
- Relies on existing (pre-REACH) substance information

Others approaches like Risk Determining Substance, Critical Component Approach, step by step etc...

For more details, see break-out groups

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Way forward (1)

- **Manageable solutions** are necessary (substance information prioritisation as starting point); still requires considerable effort
- Find appropriate means to manage transitional period until 2018 – **short term fix**
 1. Compare current mixture SDS with new available substance information ⇨ does the SDS need to be updated?
 2. Prioritise SDS update in case of new information and major change on substances: C&L, RMM
 3. Focus on lead and priority substances
 4. Priority should not only be given to substances classification but also to new information related to SVHC / authorisation / restrictions

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Way forward (2)

- Good **quality and clarity of substances' ES** is essential
- **Agreed approaches** needed for dealing with inconsistency in ES from suppliers (scaling, DU CSA...)
- Checking **consistency with the ES** of separate ingredients should not be forgotten before finalising ES for mixture
- **Automation** (IT tool) is needed in the medium to long-run
- **Training to support DUs**, sector organisations can act on that
- Full implementation will **TAKE TIME!**

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Thank you

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All documents available on <http://www.duccplatform.org/>

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