Exemplification of LCID output in the safety data sheet

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The challenge

- REACH Article 31(7):
  "Any downstream user shall include relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses."
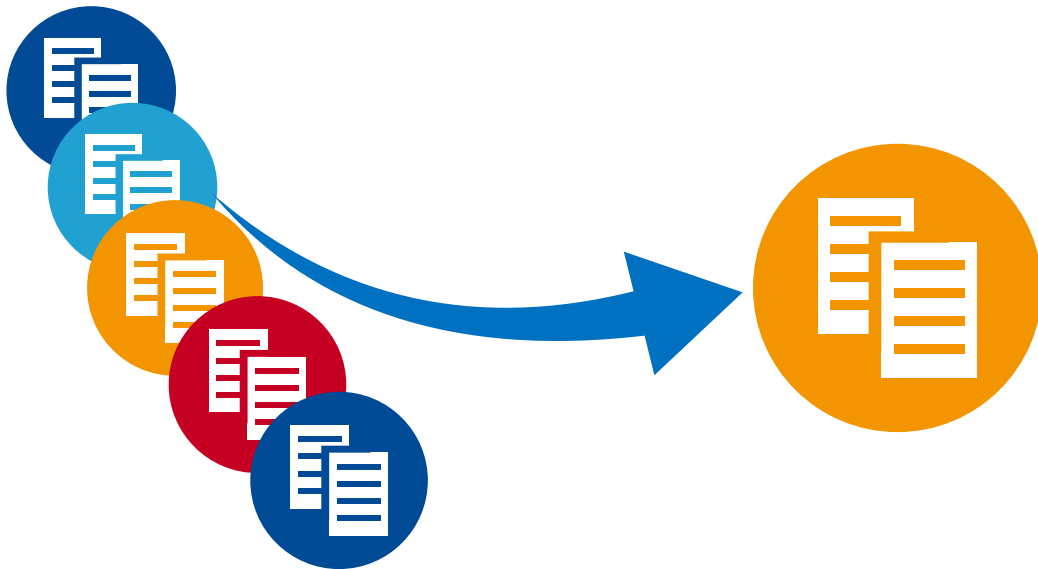
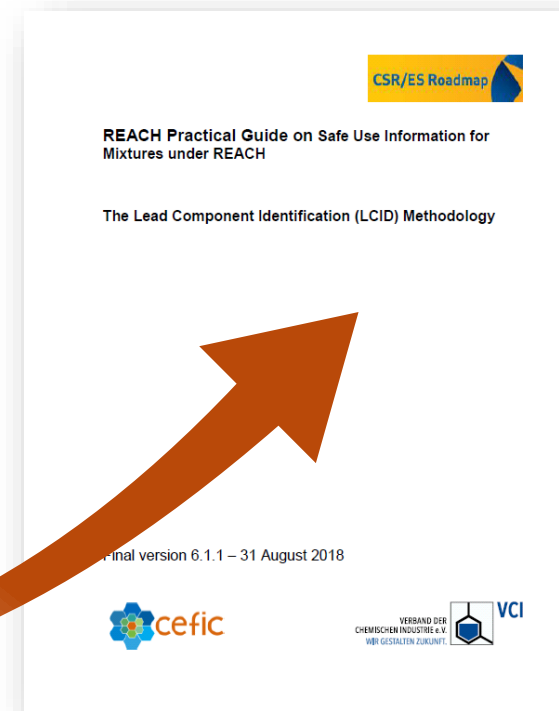Suppliers' SDSs with ESs   Mixture SDS

The basic premise

If the risks are controlled for the most hazardous component, then the risks from the other substances in the mixture are also likely controlled.

LCID methodology (2nd rev. 2018)

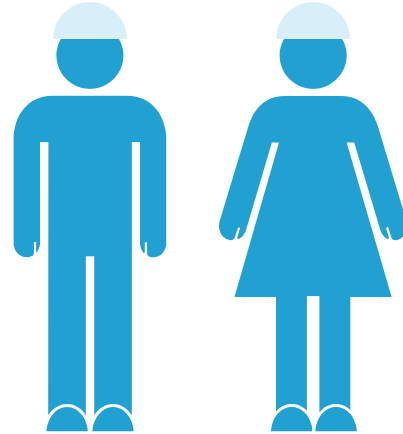Use chemicals? These tools will help you

Determination of Lead Component Indicator (LCI)

Human Health

Environmental

$$LCI = \frac{\text{Conc in mixture}}{\text{DNEL}} \qquad \frac{\text{Conc in mixture}}{\text{PNEC}}$$

Additional determinant =   Vapour pressure   Biodegradability

DNEL = Derived No Effect Level; PNEC = Predicted No Effect Concentration

High level workflow of deriving safe use information

Compile eSDS of components

→

Identify components which drive CLP classification of the mixture

→

Identify priority substances, notice local effects, determine Lead Components based on systemic effects, per exposure route/pathway

→

Consolidate operational conditions and risk management measures
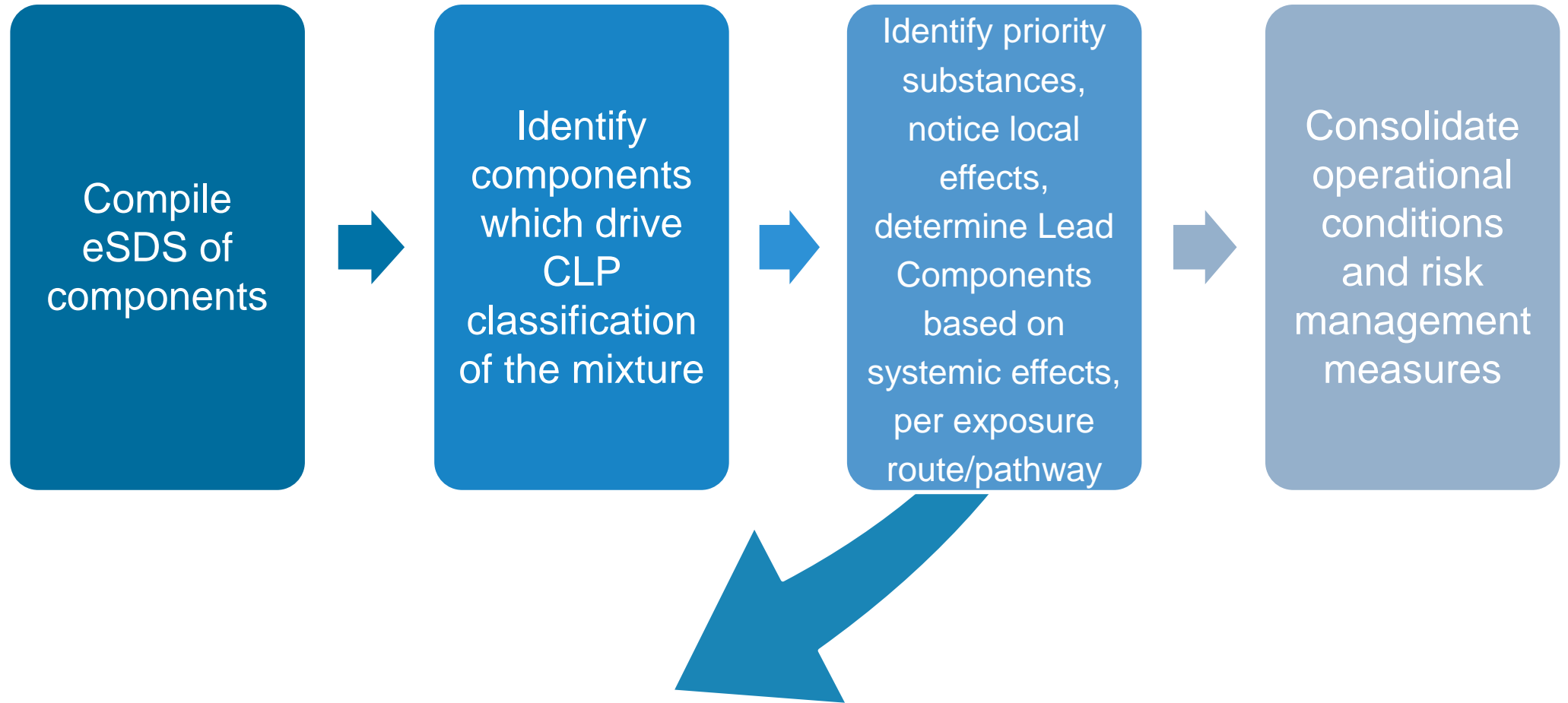
If the risks are controlled for the most hazardous component(s), then the risks from the other substances in the mixture are also likely controlled

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Exemplification of the LCID output in the safety data sheet (2019)

- Seven different examples:
  - Mixtures classified as hazardous to human health and/or environment
  - Representation of different sectors, uses and applications
  - Description of LCID methodology outcome
  - Examples of different format/layout options of the annex with Pros and Cons

- Decision tree to support reason for selection of the safe use communication format:
  - Based on the classification of the mixture
  - Based on diversity of uses and conditions of use per activity
  - Based on position in the supply chain

- Considerations on consolidating information:
  - Two or more lead components ES
  - Existing information in section 7 and 8 of the SDS

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Conclusions

Conclusions 1/2

- LCID is an efficient method to focus on the risk driving ingredient substances.

- **Annexing** safe use advice might be preferred:
  - when multiple uses or contributing activities are covered in an SDS for a mixture and require different OCs/RMMs and/or,
  - when long-term systemic effects drive the exposure controls (and require different OC/RMM per activity),
  - when the recipient of the mixture SDS is a formulator and needs to receive ES on substances as they are.
- **Embedding** safe use advice might be preferred when a mixture:
  - Is only classified for local effects related to skin and eye and/or;
  - Has limited/specific end use therefore,
  - limited set of safe use information items is communicated to an end-user.

- Inclusion of proper safe use advice for the mixture (by a formulator) requires that the received ESs are relevant and consistent <u>before</u> applying the LCID.

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Conclusions 2/2

Findings with regard to the application of the **LCID method itself**:

- The expert judgement "safety net" steps of the method (E16 and E17) are applicable to the situations below. To consider whether rules could be included into the method, addressing:
  - Substances with low DNEL, but not contributing to the classification of mixture;
  - Low vapour pressure substances with low DNELs in aerosol forming processes/activities (risk driver is operational condition not vapour pressure).
  - For the environment, the OC/RMM for the non-Lead Component may possibly need to be carried forward to the mixture SDS.

- If a systemic long-term DNEL for inhalation is missing, but a local long-term DNEL for inhalation is available, this should be sufficient to run the LCID algorithm.

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To be published in October 2019

- Mixtures under REACH – exemplification of the LCID output in the safety data sheet
  - Communication of safe use information for mixtures resulting from application of The Lead Component Identification (LCID) Methodology
  - Report on experiences gained and Safety Data Sheet examples

- On Cefic and VCI websites

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THANK YOU!