

## Mixture SDS generation

The **Lead Component IDentification**  
(**LCID**)–based inclusion method

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1

### Outline

- A bit of history around the LCID
- Purpose of the LCID and how it works
- Current work of the CEFIC/VCI Task Force
- Task Force report

2

2

## Requirement & approach

### 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.“



### The basic premise of the LCID

- 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.

Supplier SDSs  
(including exposure scenarios)

Mixture SDS

3



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## Development of the methodology



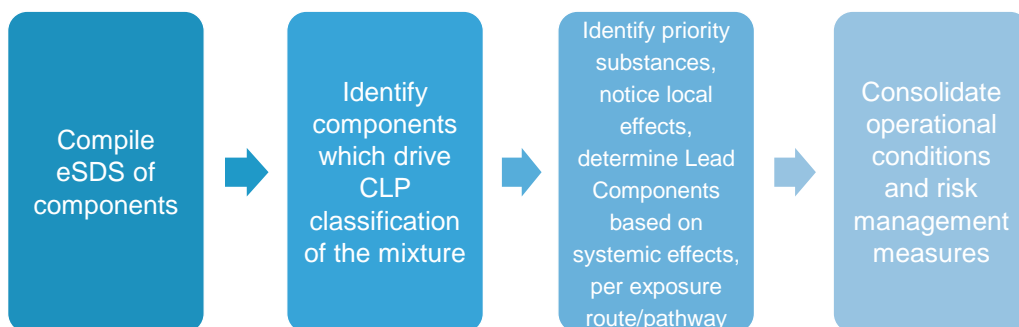
- Development started back in 2013 (based on DPDplus methodology)
- Several iterations of consultation with ENES community
- “Round-robin” to demonstrate validity and robustness of the methodology
- Publication of “Practical Guide” in 2016, Update in 2018
- Focus on workflow, not on communication



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4

## High level workflow of deriving safe use information



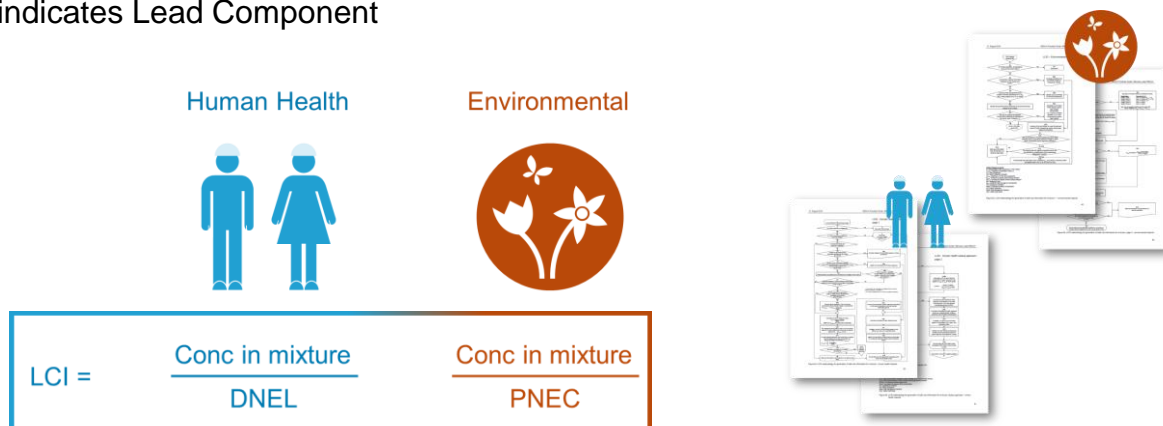
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## Determination of Lead Component Indicator (LCI)

- LCI is calculated for each relevant component of the mixture, highest LCI indicates Lead Component



<sup>6</sup> DNEL = Derived No Effect Level ## PNEC = Predicted No Effect Concentration



6

## Key questions for current work

- How to handle if conditions of safe use differ
  - ▶ between the different uses of the mixture (if relevant), and/or
  - ▶ across the contributing activities within one use.
- How to consolidate data/information resulting from applying the LCID methodology?
- How to include safe use information by integration within the body of the SDS?
- How to include safe use information as an annex to the SDS?
- What terminology is appropriate and to what level of detail?

7



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## Options to communicate via the Safety Data sheet



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Guidance developed on which of the following options may be appropriate for a given situation:

- Attach the (relevant) exposure scenario(s) of the lead components as they are to the SDS of the mixture
- Consolidate/merge the exposure scenarios of the lead components, to derive the safe use advice for the mixture,
  - ▶ and attach it to the mixture SDS or
  - ▶ embed it into section 7 and of the mixture SDS.



8

## What has been done

- Selection of case studies/project examples that cover different kind of hazards, uses and communication options
- Drafting of safety data sheet examples, whereas these include two parts
  - ▶ an introduction to each example to explain its characteristics, the data decisive for running the LCID method, the LCID output, and the option chosen for communication in the supply chain (in the body of the SDS or an annex to the SDS)
  - ▶ the safety data sheet of the mixture itself. Thereby, parts of the SDS not relevant with regard to LCID application and communication of safe use condition might be omitted

9

9



## Report content

- 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 ESs
  - ▶ Existing information in sections 7 and 8 of the SDS

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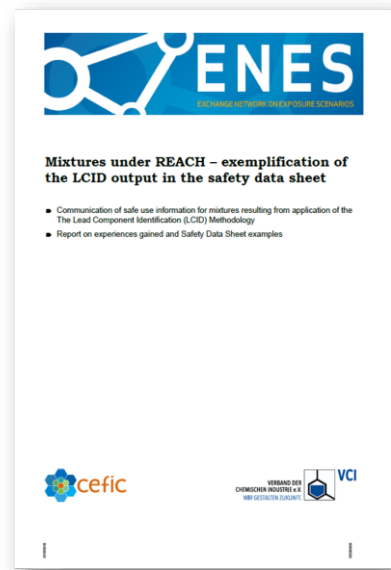
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## Task Force Report

### Available for download @

- [https://echa.europa.eu/documents/10162/28491047/Mixtures-under-REACH\\_exemplification-of-LCID-output-in-the-SDS.pdf/334726a6-aa08-72b6-4ccf-369425ce9386](https://echa.europa.eu/documents/10162/28491047/Mixtures-under-REACH_exemplification-of-LCID-output-in-the-SDS.pdf/334726a6-aa08-72b6-4ccf-369425ce9386)
- <https://cefic.org/guidance/reach-implementation/es-csr-csr-guidance/>
- <http://www.vci.de/vci-online/themen/chemikaliensicherheit/reach/cefic-vci-issue-practical-guide-on-safe-use-of-mixtures-under-reach-lead-component-identification-methodology.jsp>



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11

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12