

Overview of the LCID Methodology

Practical Guide and Excel-based Tool

Cefic/VCI Workshop on the LCID methodology

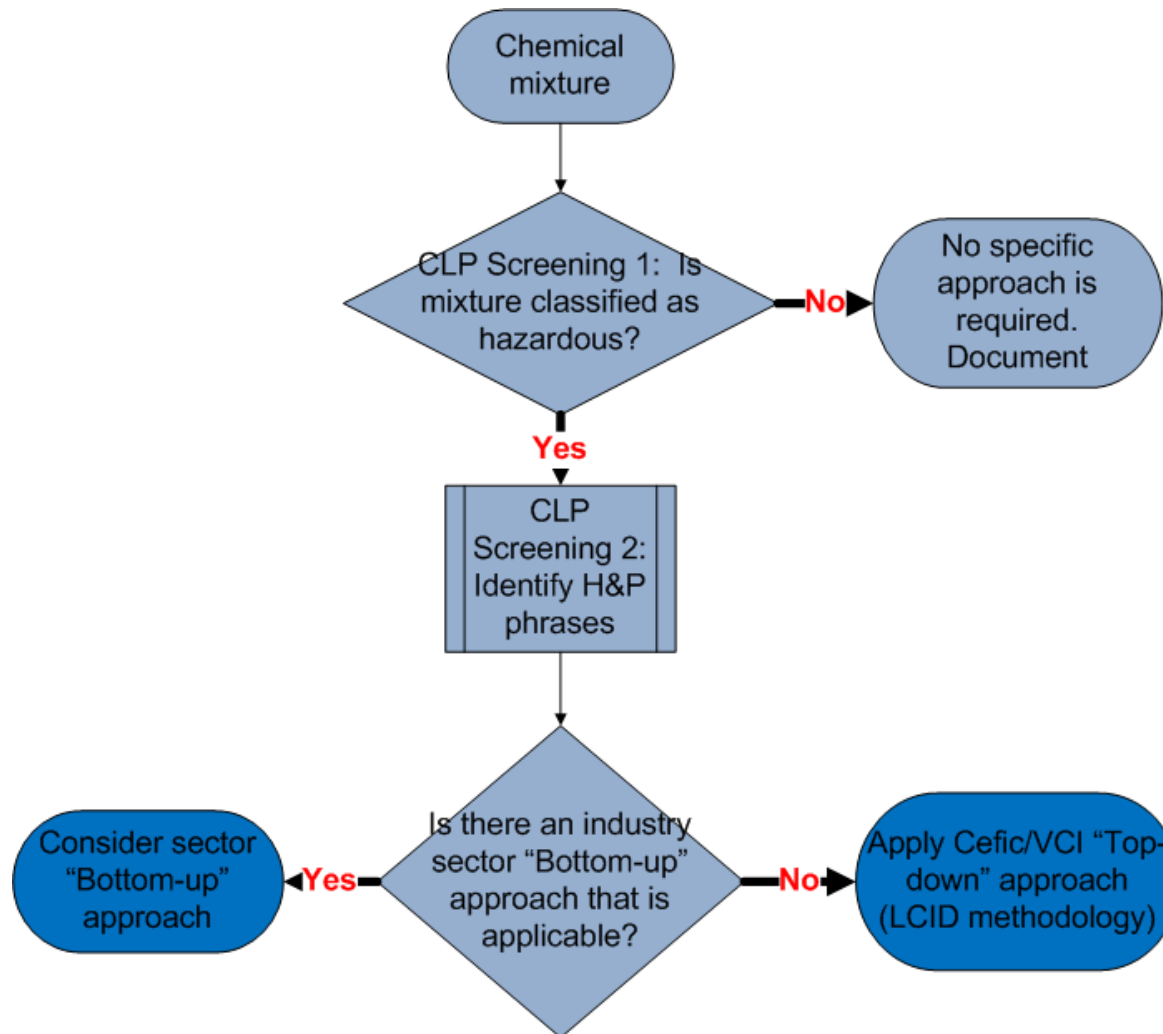
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- Deliverables

Safe Use Information for Mixtures



Safe Use Information for Mixtures

LCID Methodology Top-down

Sector-Specific Bottom-up

Recipients

Formulators, distributors

End-users

Formulations

All concentration bands

Sector-specific

Environmental

Environmental hazard

If expected to be released

OCs & RMMs

All applicable

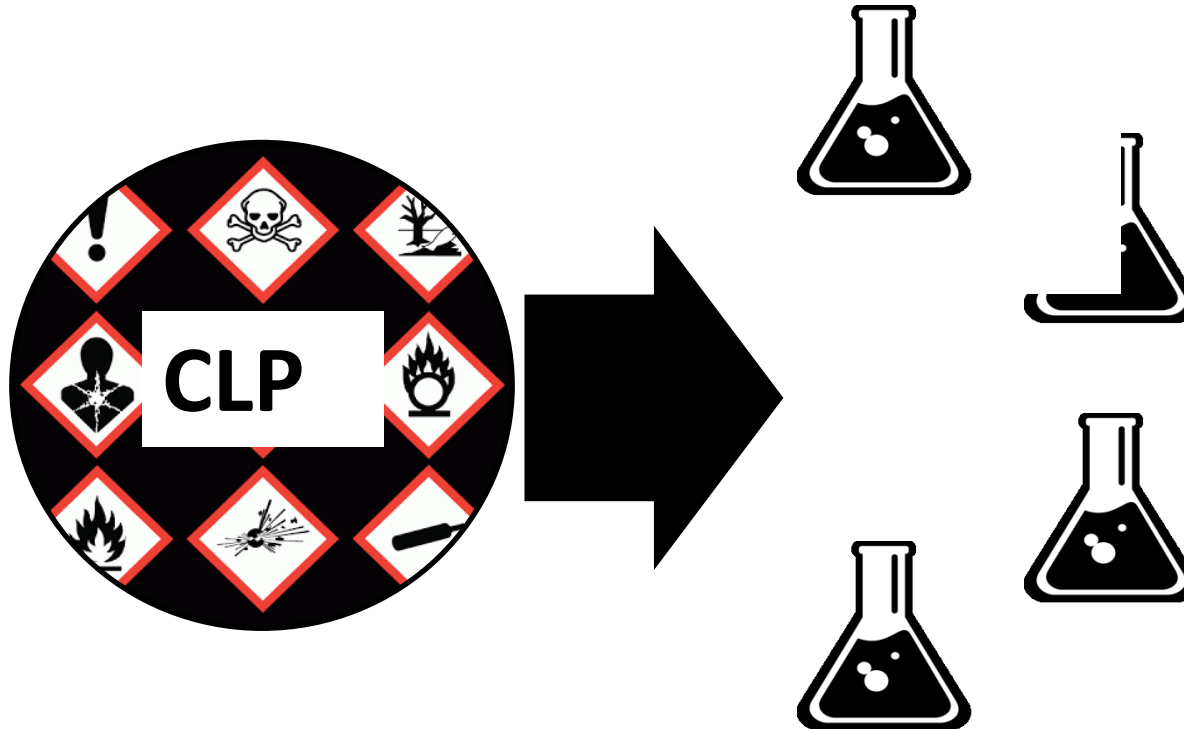
Sector use maps, SWEDs, SCEDs, SUMIs

Scaling

Full

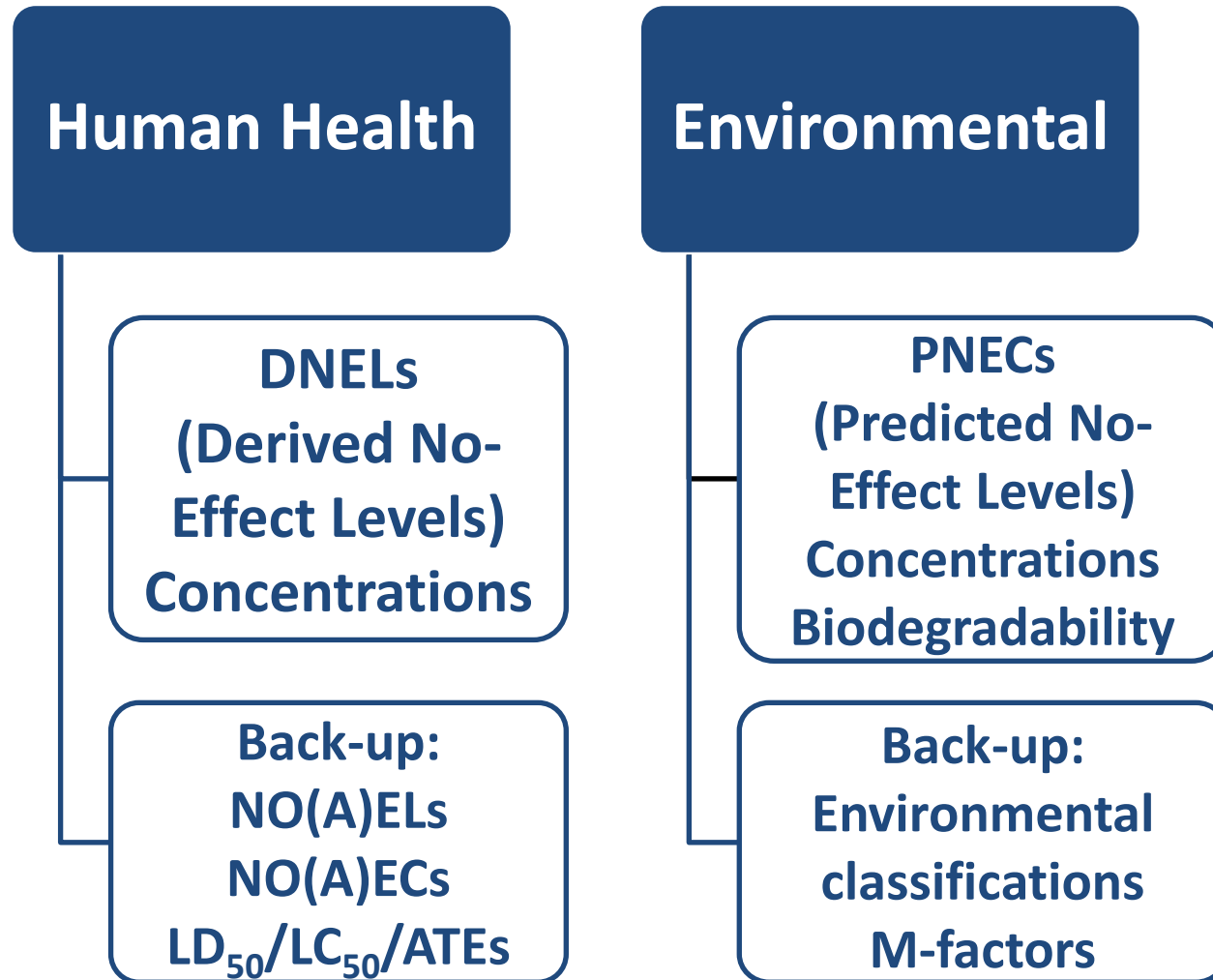
Restricted or unable

LCID Methodology Uses the CLP Classification



to identify relevant components that drive the hazard classification of the mixture

DNELs and PNECs from Exposure Scenarios of Relevant Components



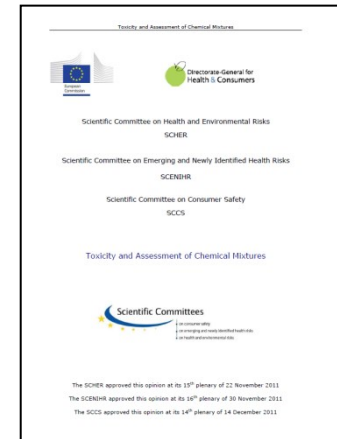
The Basic Premise



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

One Major Scientific Resource

- **Scientific Committee on Health and Environmental Risks (SCHER)**
- **Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)**
- **Scientific Committee on Consumer Safety (SCCS)**



Relied upon the findings of three scientific EU bodies

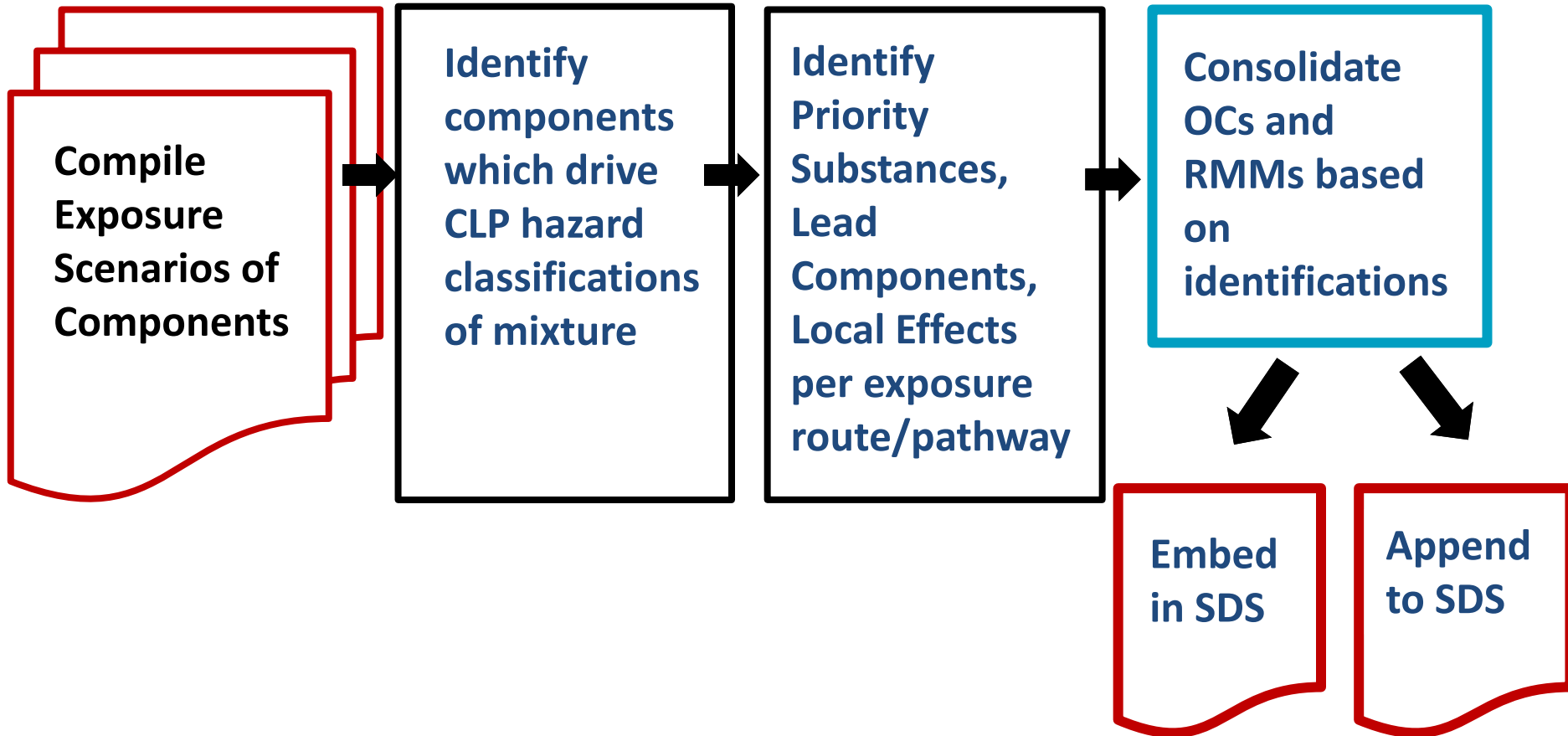
Practical Considerations

LCID methodology may be applied:

When the identity of the Lead Component(s) is less obvious

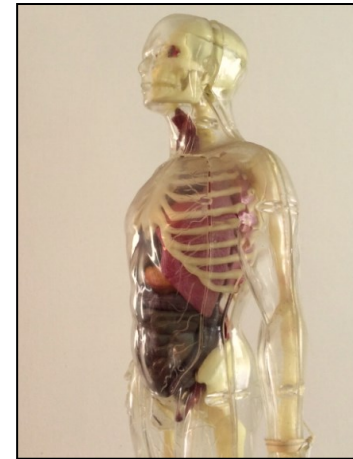
To support your intuitive conclusions

LCID Methodology High Level Workflow



Exposures

- Exposure Route
 - Inhalation
 - Dermal
 - Oral (Consumer only)



Exposure Pathway

- Air
- Water
- Soil

Priority Substances



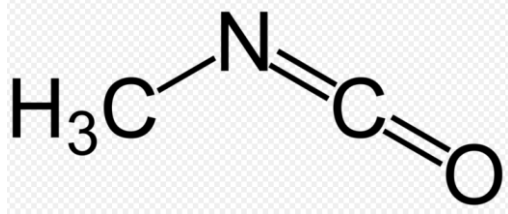
Health: Carcinogens, Mutagens*; these usually do not have DNELs which is not necessarily the same for reproductive toxicants

Environment: Persistent, Bioaccumulative Toxic substances (PBTs) or very Persistent and very Bioaccumulative substances (vPvBs)

***Carcinogens, Categories 1A, 1B or 2**
Mutagens, Categories 1A, 1B or 2

These substances are generally assumed to have the most stringent Risk Management Measures

Grouping



Grouping may be considered if there are components in the mixture of similar structure and are known to have similar toxicological effects via similar modes of action, for example, isocyanates or acid anhydrides.

At present, the LCID methodology does follow the hazard additivity principles utilized for CLP classifications (ECHA, 2013)*

* ECHA, Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures, 2013

Local Effects

- Eye, skin, or respiratory tract irritation/corrosivity
- Skin or respiratory sensitization
- Dryness and cracking of the skin



Ozone Layer Hazard



Very specific environmental effect in comparison with the other toxic endpoints related to the environment.

Must limit their release as much as possible.

Deliverables

Practical Guide (with step-by step instructions)	Health Hazards: Table 1 Environmental Hazards: Table 2
Detailed workflows	Human Health: Figures 5a and 5b Environmental Figures 6a and 6b
Examples	Annex III
Technical Documentation	Annex IV

Test Examples

Test Example 4	Test Example 6			Comments
CLP Hazard Classification of mixture	Ac. Tox. 4 (oral, dermal, inhal), STOT RE 1, STOT RE 3 (inac.), Eye Irrit. 2			
Relevant components	Component 1	Component 2	Component 3	
Relevant CAS No. (if available)				
Concentration of component	70	20	10	
Health Hazard CLP classification of relevant component	STOT RE 3 (inac.)	Ac. Tox. 3 (oral)	Ac. Tox. 4 (dermal)	
	Eye Irrit. 2	Ac. Tox. 3 (dermal)	STOT RE 3 (inac.)	
		Ac. Tox. 3 (dermal)	STOT RE 3 (inac.)	
		STOT RE 1	Eye Irrit. 2	
Relevant local effects	Eye Irrit. 2		Eye Irrit. 2 STOT RE 3 (inac.)	Components 1 and 3 contribute to the local effects CLP hazard classification of the mixture.
Health Hazard Priority Substance (acute)	No	No	No	
DNEL inh (mg/m ³)	305	50	Not available	
DNEL derm (mg/kg bw day)	44	40	Not available	
DNEL oral (mg/kg bw day) (if available, e.g., consumer)	Not available	Not available	Not available	
Vapor Pressure @ 20°C (kPa)				For this example, the vapor pressure is not relevant due to low PPs of all components and thus no local exposure to expect.
LCI DNEL - inh	70/305 = 0.23	20/50 = 0.4	Not available	LCI + DNEL
LCI DNEL - derm	70/44 = 1.6	20/40 = 0.5	Not available	LCI + DNEL
LCI DNEL - oral	Not available	Not available	Not available	
Grouping - by route of exposure				
LC ₅₀ DNEL - by route of exposure				
C ₅₀ - by route of exposure (%)				
Are there DNELs available for all the relevant components? (yes/no)	No, only for components 1 and 2			Component 3 does not have a DNEL available, but does have both an LC50 dermal value and oral LC50 available.
MOEC inh (mg/m ³)	Not available	Not available	Not available	
MOEL derm (mg/kg bw day)	Not available	Not available	Not available	
MOEL oral (mg/kg bw day)	Not available	Not available	Not available	
LC50 MOEC - inh				
LC50 MOEL - derm				
LC50 MOEL - oral				

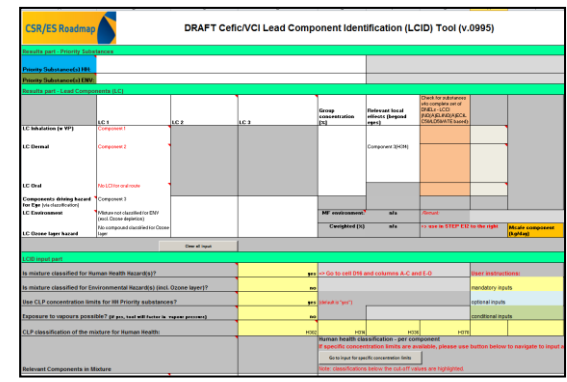
Examples include applying LCID methodology:

- With presence of priority substances
- Use of DNEL or PNEC values
- Application of grouping
- Use of back-up approach

Purpose is to explain in a practical way, the methodology and/or to verify user's understanding of the LCID methodology

LCID Excel-Based Tool

- Cells are pre-programmed for ease of calculations
- Short instructions
- Colour-coded for ease of data entry
- Includes examples from the Practical Guide to demonstrate use
- Can be saved for record-keeping or provide to authorities
- To be published shortly



Automation

Primary focus was developing an approach based on science and logical assumptions

Now available to IT system developers to create algorithms/rules sets