**CARRYING OUT CHEMICAL SAFETY ASSESSMENTS (CSA) USING THE ENES TOOL SET**

Gerard Bachler

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**Step 1: Determine all hazards that require an exposure and/or risk assessment**

<table>
<thead>
<tr>
<th>Environment</th>
<th>Workers</th>
<th>Consumers</th>
</tr>
</thead>
</table>
| Phys-chem hazards | Environmental exposure scenarios | Tonnage ERC 13 | Exposure Scenario
| Qualitative hazards | | | |
| Semi-quantitative hazards | | | |
| Quantitative hazards | | | |

**Step 2: Create the Life Cycle and determine the respective Use Descriptors**

**Step 3: Carry out the exposure and/or risk assessment for all identified hazards**

- **Phys-chem, Qualitative and Semi-quantitative Hazards**
- **Semi-quantitative and Quantitative Hazards**

**Applicability of the ENES tools**

<table>
<thead>
<tr>
<th>Tool</th>
<th>Chesar</th>
<th>ESCom</th>
<th>ESComXML</th>
<th>IUCLID</th>
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<tbody>
<tr>
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**Additional considerations**

- **Sector Use Maps** do not consistently apply ESCom phrases
  - Electronic communication along the supply chain is not possible
- **Service Life** is currently not covered by any Use Map
- **Screening** of the LCID method is hazard driven
- Substances that do not contribute to the classification of the mixture are not considered by the formulators, but may be the constituent with the highest risk (e.g. enzymes, alkoxysilanes)

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**How do develop a Chemical Safety Assessment (CSA)?**

**Step 1:** Determine all hazards that require an exposure and/or risk assessment

**Step 2:** Create the Life Cycle and determine the respective Use Descriptors

**Step 3:** Carry out the exposure and/or risk assessment for all identified hazards

**Apply ENES tools and other resources to determine the exposure and/or risk of all identified hazards and for all Life Cycle stages.**

**Available ENES tools for Registrants include:**

- **Chesar:** Database which can be used to organise CSA, to communicate CSA to ECHA and to share safe use information with downstream Users
- **Use Maps:** Contain SPERCs, SVEDs and SEEDs that define the typical Conditions of Use (CoU) for the environment, workers and consumers, respectively
- **ESCom phrase library:** Standardised set of phrases that can be used to communicate safe use (the intention is also that in the future this library is available in all official EU languages)
- **ESComXML:** Enables the electronic communication of Exposure Scenarios that contain safe use information

**Indicative boundaries quantitative risk assessment using ECETOC TRA**

**Indicative boundaries quantitative risk assessment using ECETOC TRA when also considering combined exposures**

**Figure taken from:** ECHA (2015) Guidance R.12 – Use description

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**Pharmacokinetics:**

**Dermal route:** mg/kg/day

**Inhalation:**

- **V P @ 30° C**
  - AISE – Ind AISE – Pr of EFCC – Pr of FEICA – Ind FEICA – Pr of
  - High > 10 kPa 1970 660 250/2300/66 1400 ...
- **Indoors**
  - 100 g/mol
  - Does not consider exposure via aerosols

**Risk Management:**

Information
Risk Communication
ESCom
ESComXML
IUCLID
Reach-IT
Sector specific phrases
REACH ...
Semi-quantitative and Quantitative Hazards
*only HH linked with Chesar

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**Environment:**

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**Sector specific guidance documents**

- **Chesar Sector**
  - Use Map
  - EFCC
  - Use Map
  - ESIG GES
  - Use Map
  - ESCom
  - ESComXML
  - PHYS-chem hazards
  - Aspiration hazard
  - Skin irritation/Corrosion
  - Other HH qualitative hazards
  - HH: TRA based assessments
  - Respiratory sensitisation

**Measured data**

- **Env:** EU SES based assessments
- **UV CB**
- **MV E** must be based on EUSES in Chesar

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**Step 2: Create the Life Cycle and determine the respective Use Descriptors**

**Step 3: Carry out the exposure and/or risk assessment for all identified hazards**

- **Phys-chem:** Qualitative and Semi-quantitative Hazards
- **Semi-quantitative and Quantitative Hazards**

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**Additional considerations**

- **Sector Use Maps** do not consistently apply ESCom phrases
  - Electronic communication along the supply chain is not possible
- **Service Life** is currently not covered by any Use Map
  - e.g. substances that may remain in dried coatings, adhesives or comparable mixtures after application in/on the article or substances incorporated in buildings, constructions and parts of them
- **Screening** of the LCID method is hazard driven
  - Substances that do not contribute to the classification of the mixture are not considered by the formulators, but may be the constituent with the highest risk (e.g. enzymes, alkoxysilanes)