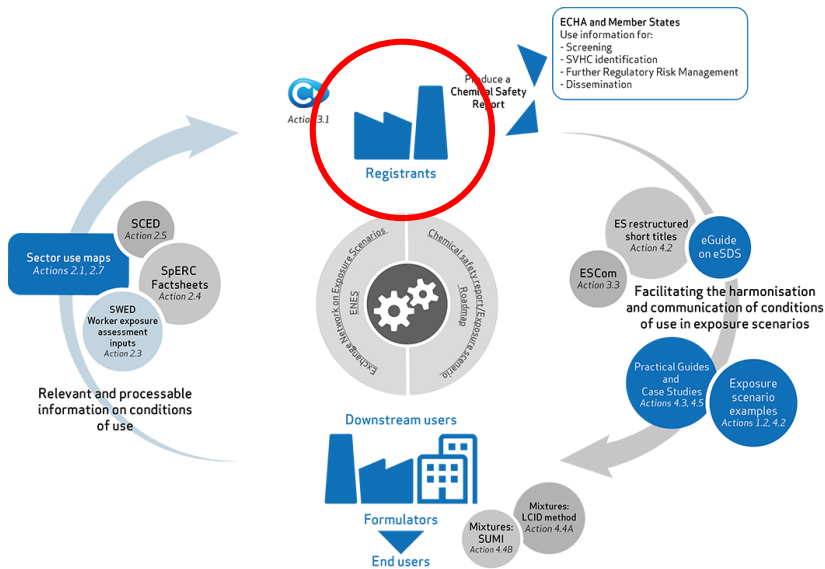


# Carry out Chemical Safety Assessment (CSA) Generate ES for communication

Gerald Bachler

1



2

## 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 recourses 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, SWEDs and SCEDs 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

3

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

|  | Environment   | Workers  | Consumers  |
|--|---|--|--|
| Part D – Framework for exposure assessment<br>Part E – Risk Characterisation | R.16 – Environmental exposure assessment  | R.14 – Occupational exposure assessment  | R.15 – Consumer exposure assessment  |
| <b>Phys-chem hazards</b>   | n.a.  | Flammability, Explosivity, Oxidising potential   | Flammability, Explosivity, Oxidising potential   |
| <b>Qualitative hazards</b>   | Remote marine areas, Ozone depleting, Absence of short-term toxicity for low water solubility and/or high hydrophobicity substances,... | Aspiration, Skin/Respiratory Sensitizer, Eye/Skin/Lung Irritants, Eye damaging, Skin corrosion, Drowsiness/Dizziness, Skin Sensitizer... | Aspiration, Skin/Respiratory Sensitizer, Eye/Skin/Lung Irritants, Eye damaging, Skin corrosion, Drowsiness/Dizziness, Skin Sensitizer... |
| <b>Semi-quantitative hazards</b>   | PBT, vPvB   | CM, Respiratory Sensitizer   | (CM), Respiratory Sensitizer   |
| <b>Quantitative hazards</b>  | Acute toxicity, Chronic toxicity  | Reprotoxicity, Specific organ tox, Acute toxicity,...  | (Reprotoxicity), Specific organ tox, Acute toxicity,...  |

Some endpoints may fall into different hazard categories, depending on the available tox information. E.g. threshold carcinogens, acute toxicity, lung irritation

4

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

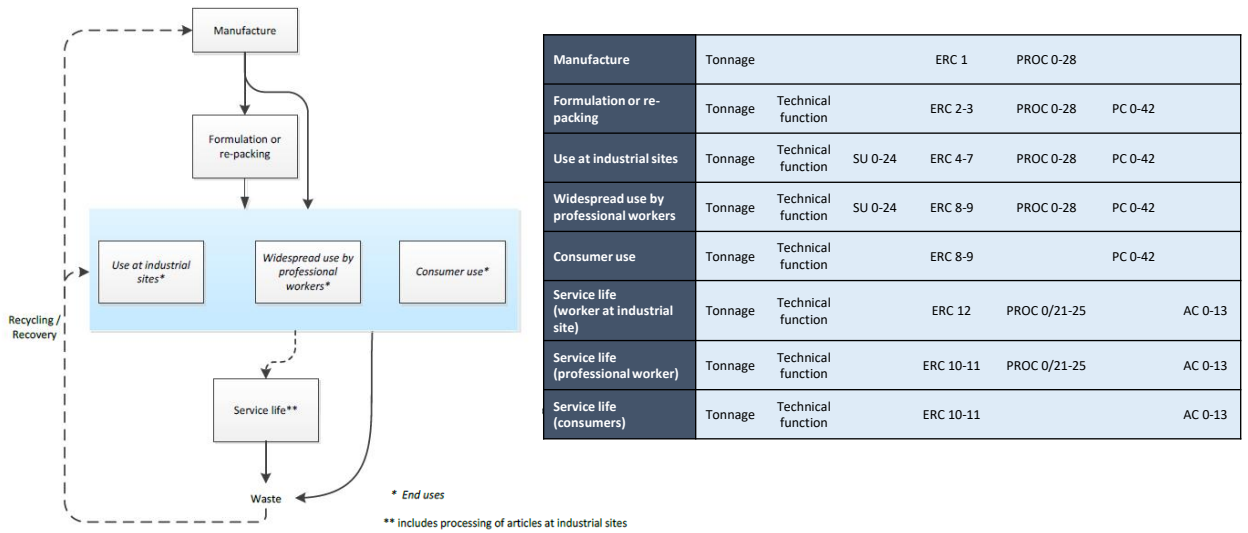


Figure taken from: ECHA (2015) Guidance R.12 – Use description

5

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

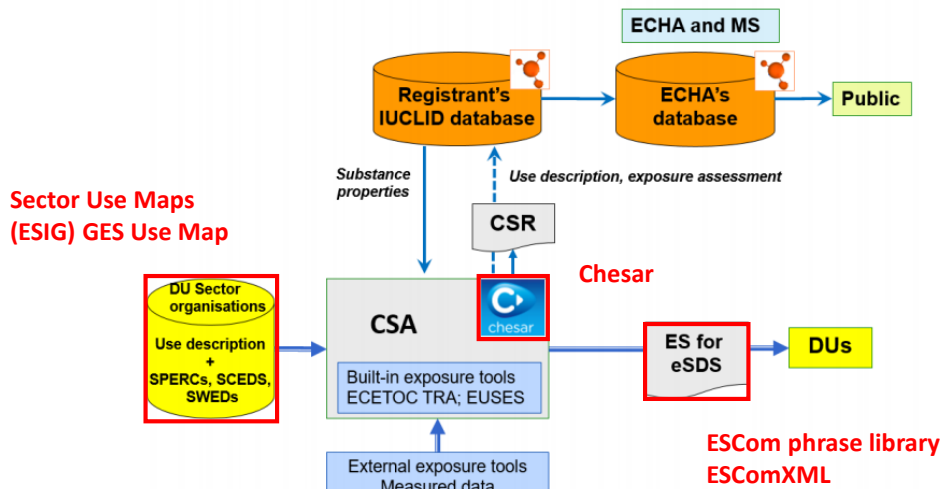


Figure taken from: ECHA (2017) Chesar 3 User manual

6

# Chesar

**Box 1: import phys-chem and hazard data from IUCLID**

Substance management

Import Chesar substance file | Import IUCLID substance dataset via web service

Search Go to advanced search

Total 1 Previous 1 Next

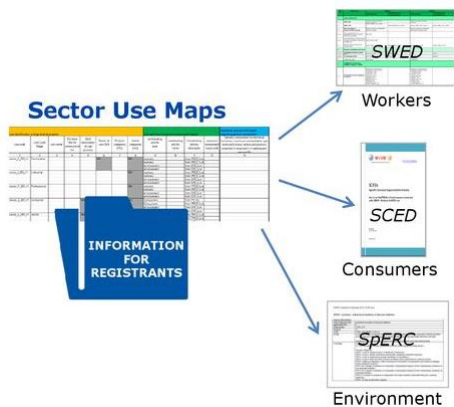
| * Chemical name | Reference substance | EC number | CAS number       | Legal entity | IUCLID UID                               |
|-----------------|---------------------|-----------|------------------|--------------|--|
| ECHA substance  | ECHA Substance      | 11111-1-1 | ECHA CSR Example |              | IUC5-16d2090-fa12-4b08-9387-9afdf35e58bc |

Where to find Use Chesar: [chesar.echa.europa.eu](https://chesar.echa.europa.eu)

How to import Use Maps into Chesar: [youtube.com/watch?v=L15qtgpXUDA](https://youtube.com/watch?v=L15qtgpXUDA)

7

## Use Maps



Exposure Risk characterization exposure estimates information

SWED

Show less

SWED title Transfer and dilution of concentrated product by using dedicated dosing system; Level II

SWED code AISE\_SWED\_RS\_1\_1

Description of the applicability domain (in terms of substance properties)

Advice to assessor

Description of activities/processes The product is filled from large containers into a machine or a vessel. Filling means to link and delink a tube with the container. It is a short process.

W1 Product (article) characteristics

Percentage (w/w) of substance in mixture/article 1 %

Physical form of the used product Liquid

W2 Amount used (or contained in articles), frequency and duration of co-exposure

Duration of activity 1 h/day

W3 Technical and organisational conditions and measures

Occupational Health and Safety Management System Basic

General ventilation Basic general ventilation (1-3 air changes per hour) Inh. effect: 0 % Der. effect: 0 %

Local exhaust ventilation No Inh. effect: 0 % Der. effect: 0 %

W4 Conditions and measures related to personal protection, hygiene and health evaluation

Respiratory protection No Inh. effect: 0 % Der. effect: 0 %

Dermal protection Yes (Chemically resistant gloves conforming to EN3) Der. effect: 80 %

Use of eye protection No

W5 Other conditions affecting workers exposure

Place of use Indoor

Operating temperature 25 °C

Where to find Use Maps: [echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library](https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library)

How to import Use Maps into Chesar: [youtube.com/watch?v=ePRzoYC7fxc](https://youtube.com/watch?v=ePRzoYC7fxc)

8

# ESCom phrase library

Library of standard phrases to communicate ES along the supply chain:

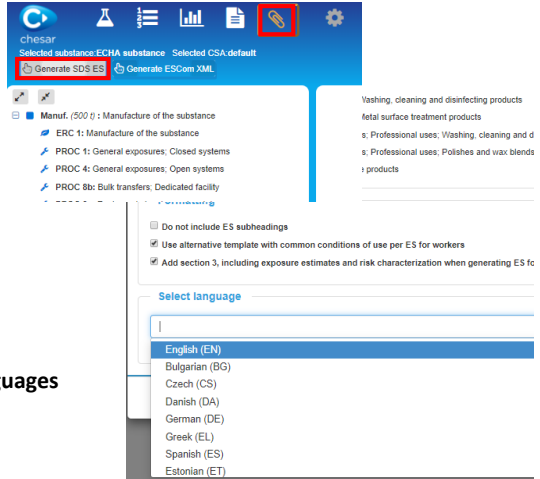
- ES and CS title
- Use Map Codes
- Use descriptors
- Operational conditions (OCs)
- Risk management measures (RMMs)

Current version (4.1) contains 1744 active phrases

**Aim** is to make the phrases available in all official EU languages

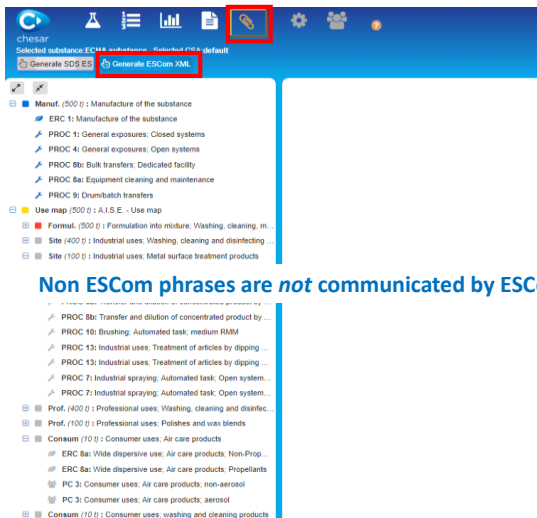
How to submit phrases to ESCom: [draft.euphrac.eu](http://draft.euphrac.eu)

Where to find the ESCom library: [cfcic.org/guidance/reach-implementation/escom-guidance](http://cfcic.org/guidance/reach-implementation/escom-guidance)



9

## ESComXML



Non ESCom phrases are *not* communicated by ESComXML

### 7. ES 7: Consumer use; Air care products

#### 7.1. Title section

ES name: Consumer uses; Air care products  
Product category: Air care products (PC 3)

| Environment   |        | SPERC  |
|---|--------|--|
| 1. <del>Wide dispersive use: Air care products: Non-Propellants</del> | ERC 8a | <del>Wide dispersive use: Air care products: Non-Propellants</del> |
| 2. <del>Wide dispersive use: Air care products: Propellants</del>     | ERC 8a | <del>Wide dispersive use: Air care products: Propellants</del>     |
| Consumer  |        | SCED   |
| 3. <del>Consumer uses: Air care products: non-aerosol</del>           | PC 3   | <del>Consumer uses: Air care products: non-aerosol</del>           |
| 4. <del>Consumer uses: Air care products: aerosol</del>               | PC 3   | <del>Consumer uses: Air care products: aerosol</del>               |

#### 7.2. Conditions of use affecting exposure

##### 7.2.1. Control of environmental exposure: ~~Wide dispersive use: Air care products: Non-Propellants (ERC 8a)~~

| Other conditions affecting environmental exposure                            |
|--|
| Municipal sewage treatment plant is assumed.                                 |
| Spraying of insoluble solids, which finally are disposed off via wastewater. |
| Indoor or outdoor use  |

##### 7.2.2. Control of environmental exposure: ~~Wide dispersive use: Air care products: Propellants (ERC 8a)~~

| Other conditions affecting environmental exposure                   |
|---|
| Municipal sewage treatment plant is assumed.                        |
| <del>Spray applications with complete vaporization of product</del> |
| Indoor or outdoor use   |

##### 7.2.3. Control of consumer exposure: ~~Consumer uses, Air care products; non-aerosol (PC 3)~~

| Product (article) characteristics  |
|--|
| Covers concentrations up to 10 %   |
| Oral exposure is considered to be not relevant.                                |
| No spraying  |
| Amount used (or contained in articles), frequency and duration of use/exposure |
| For each use event, covers use amounts up to 2.5 g/event                       |
| Exposure duration = 8 h/event  |
| Covers use up to 1 events per day  |
| Other conditions affecting consumers exposure                                  |
| <del>Consumer uses: Air care products: non-aerosol</del>                       |

##### 7.2.4. Control of consumer exposure: ~~Consumer uses, Air care products; aerosol (PC 3)~~

Where to information on ESCom XML: [cfcic.org/guidance/reach-implementation/escom-guidance](http://cfcic.org/guidance/reach-implementation/escom-guidance)

10

## Applicability of the ENES tools

### Chesar

- ✓ In general, applicable for all substances

### Sector Use Maps

- ✓ Applicable for “simple” substances that can be assessed with the ECETOC TRA
- ✗ Currently Sector Use Maps do not address the Service Life
- ✗ Currently typically not capable to address:
  - Qualitative hazards (except eye irritation/damage)
  - Semi-quantitative hazards (CMR, PBT/vPvB, respiratory sensitizer)
  - Substance that require higher tier models (except the EFCC Use Map) and/or measured data
  - UVCBs
  - Low volatile substances (VP <500 Pa) with the potential for aerosol generation
  - Solids in liquids
- Currently limitations for carrying out combined (aggregated) exposures

### ESCom phrase library/ESComXML

- ✓ In principle, applicable for all substances
- ✗ Currently Sector Use Maps do not consistently utilise the ESCom package
- ✗ Limitations may apply to sector specific phrases (which also prevent the utilisation of ESComXML)

**Thank you very much for your attention**