

CEPE

Chemical Safety Assessment Using Sector Specific "Use Maps"

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About CEPE





+/- 800 companies €13 billion / year 85 printing inks €3 billion / year 20 artist colours €0.3 billion /year 20 National Associations

> 110,000 direct jobs 85% of total market

Millions of users and businesses need our products



Speaker introduction





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Chair of CEPE ESRAG (Exposure Scenario Risk Assessment Group)

Global Manager Product Safety
AkzoNobel

Chemical safety/risk assessment in SSbD





The SSbD assessment composed of four steps:

Step 1 – Hazard assessment of the chemical/material

Step 2 – Human health and safety aspects in the chemical/material production and processing phase

Step 3 – Human health and environmental

aspects in the final application phase

Step 4 – Environmental sustainability

assessment

Chemical Risk Assessment



Risk assessments are used to identify and evaluate the **likelihood** of adverse effects which may arise from exposure to a chemical



 $RISK = HAZARD \times EXPOSURE$

Human health hazard



A health hazard is a potential source of danger to a person's health; a negative health effect











Exposure



Exposure is a way how a person can come into contact with chemicals

Exposed population	Exposure routes
Workers	Dermal & inhalation
General population	Oral, dermal & inhalation



Examples of exposure to paint and coating products



Use maps (1)





Use maps (2)

Use maps – What?

Pre-defined, standardized sets of information containing the relevant Operational Conditions & Risk Management Measures for the majority of uses of the mixtures that are relevant for the sector

Specific Consumer Exposure Determinants ("SCEDS")

Descriptors

Name of the SCEDs Title from each a PC/AC descriptor PC/AC number SCED code <sector><SCED>

mixture (g/g)

transfer factor Numerical - (default

Value and [ESCOM phrase Code

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SWEDs (Specific Worker Exposure Descriptions) **SCEDs** (Specific Consumer Exposure Determinants) **SpERCs** (Specific Environmental Release Categories)





Use maps (3)

Example of a CEPE SWED

Field No	Field name	CEPE SWED 1	
		Field content	
1	SWED identifiers		
1 1	SWED title	Industrial (Spray and non-Spray) Painting,	
1.1		Liquid - Enhanced Room Ventilation	
1.2	SWED code	CEPE_SWED_IS_Pr5_c_liq	
1.3	Short description of process/activity covered	Painting process activities requiring enhanced ventilation, eye and dermal controls	
1.6	Relevant contributing activity		
1.6.1	Contributing activity/name	Preparation of material for application; Cleaning	
1.6.2	Corresponding PROC	PROC 5	
2	Core conditions of use		
2.1	Percentage (w/w) of substance in mixture	<= 100 %	
2.2	Physical form of the used product	Liquid, including paste/slurry/suspension	
2.3	Duration of activity	≤8 h/day	
2.4	Occupational health and safety management system	Advanced	
2.5	Room Ventilation	Enhanced (5 to 10 ACH)	
2.6	Local Exhaust Ventilation (LEV)	No	
2.7	Use of Respiratory Protection Equipment (RPE)	No	
2.8	Use of gloves & other dermal protection	Chemical resistant dermal protection with basic employee training. Effectiveness ≥ 90%.	
2.9	Use of eye/ face protection	Goggles	
2.10	Place of use	Indoors	
2.11	Operating temperature (°C)	40 °C	
2.11.1	Details on operating temperature	Explanation for the CSR:ambient temperature	
3	Description of other conditions of		
	avposure assessment tool		
4	Rigorous containment		
4 1	Rigorously contained system	No	
4.1	Description of non-technical means		
	for rigorous containment and strict		
	control for manual intervention.		
5	Measured data available		
6	Additional good practice advice		
0	Additional good practice advice		



Use maps (4)



Use maps – by whom?

Sector associations \rightarrow have the knowledge on the way their products are used within the sector

Use maps – for whom ?

Registrants \rightarrow input for the Chemical Safety Assessment Formulators \rightarrow internal mapping of uses

Use maps (5)



Use maps – Where? https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps- library

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ECHA $>$ Legislation $>$ REACH $>$ Registration $>$ 1	Information requirements > Chemical safety report > C	hemical safety report/Exp	osure scena	rio roadmap > Use maps > U	Jse maps Library
Information requirements	Use maps				
Chemical safety report	Concept Templates and submissi	on Use maps li	orary		
	This library includes the use description and assessment (SWEDs), for consumers expose exposure assessment (SPERCs), made avai The information aims at supporting registra (CSAs). Registrants will find here the use d level, as well as the associated conditions of safety assessment. To stay informed about new submissions to Weekly . The library is structured by sector and prod access to the following information:	I the input parameter ure assessment (SCE lable by sector organi nts in preparing their secription for key typi f use. This provides a the library or update uct. Clicking on a sec	s for work Ds) and fo sations for chemical : cal produc realistic b s, please s tor name b	ers exposure r environmental their typical uses. safety assessments ts, as agreed at sector asis for their chemical ubscribe to ECHA below will give you	See also - Harmonised set of conditions of use [PDF] - Video-tutorial: How to import and use a use map in Chesar 3 - Video-tutorial: How to update a use map in Chesar 3 - Joint statement of
	 Background information on the use ma 	p coverage			Cefic, DUCC and ECHA on use maps
	 Direct access to use map files, includin Industry sector associations and ECHA encor a short questionnaire. The feedback receive gain insight into how the use maps are bein meet your needs. 	g Chesar files when a ourage you to provid ed will be used to imp ng used and how they	vailable. e feedbac rove our u could be f	k! Click here to access se map library and to urther developed to	 Downstream users CSR/ES roadmap How to improve your dossier

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International Association for Soaps, Detergents and Maintenance Products

> CEPE

European Council of the Paint, Printing Ink and Artists' Colours Industry

> CLE CropLife Europe

> Concawe Fuels

> Cosmetics Europe Cosmetics and personal care products

> EFCC

European Federation for Construction Chemicals

> ESIG European Solvents Industry Group

> EuPC **European Plastics Converters**

> FEICA Association of the European Adhesive and Sealant Industry

> Fertilizers Europe Fertilizers Europe

> I&P Europe / I&P Europe Imaging and printing products I&P Europe

> IFRA International Fragrance Association



A CEPE example on SSbD Step 3 assessment

Substance X is an additive a paint product at low levels.

A supplier is offering a new additive (Y) with an improved technical performance and claims that Y has better classifications.

Conducting Step 3 on human health for uses of X and Y in a DIY interior trim paint product

Input information on substances



	Name	X	Y	
		(Harmonised)	(Self-classification)	
		Skin Sens. 1 H317	Skin Irr. H315	
Substance	Classification	STOT SE 1 H370 (inhalation)	Eye Irr. H320	
Substance	Molecular weight (g/mol)	107	96	
	Log Kow	0.7	0.9	
	Vapour Pressure	2.02 kPa	925 Pa	
	Volum registered under REACH	> 1000 tonnes/year	100-1000 tonnes	
Droduct	Name	Interior trim paint	Interior trim paint	
Product	Weight fractionsubstance (%)	0.5%	0.3%	
Donulation	Name	general	general	
Population	Body weight (Kg)	60	60	
	Inhalation - long term DNEL			
	(mg/m3)	83.76	1.42	
Hazard accossment (Conoral		Two-year inhalation study of		
Hazard assessment (General	Available study based on	carcinogenicity and chronic toxicity	Sub-acute toxicity study (dermal)	
Population	Dermal - long term DNEL			
	(mg/kg bw/d)	10.53	8.15	
	Available study based on	Chronic toxicity study (dermal)	Sub-acute toxicity study (dermal)	

Input information on use scenario

CEPE Specific Consumer Exposure Determinants ("SCEDs")

SCEDs have been developed by downstream user sector organisations under Action Area 2.5 of the ECHA CSR/ES Roadmap. They form part of the use maps concept, to facilitate improved communication upstream to registrants about the uses of formulated chemical products (mixtures).

The purpose of SCEDs is to provide more realistic information on the uses of mixtures by **consumers** and the resulting exposures, which can be used in Chemical Safety Assessments for substances either by registrants or by downstream users. SCEDs can be used as input information for Tier 1 models, such as ECETOC TRA, or for higher-tier models as appropriate (e.g. ConsExpo).

CEPE SCEDs for DIY painting

CEPE has developed a set of SCED factsheets for do-it-yourself painting and related tasks. The data in these factsheets, where they deviate from standard default values, are based on the results of a study of consumer painting habits and practices commissioned by CEPE. This survey was conducted between March and May 2015 and included 7542 respondents in 15 EU Member States (selected to represent 92% of the EU population). An independent statistical analysis of the survey data was commissioned to derive robust percentile values for use in the SCEDs. The survey results are not published openly, but CEPE remains at the disposal of authorities for dialogue about the basis for these SCEDs.

The full set currently comprises the following SCED factsheets (see individual SCEDs for version details):

CEPE SCED 9a 01	Interior wall paints – roller/brush	
CEPE_SCED_9a_02	Exterior wall paints – roller/brush	
CEPE SCED 9a 03	Interior trim paints – roller/brush	
CEPE SCED 9a 04	Exterior trim paints – roller/brush	
CEPE SCED 9a 05	Interior spray paints – aerosol	
CEPE SCED 9a 06	Exterior spray paints – aerosol	
CEPE SCED 9a 07	Interior removers – roller/brush	
CEPE SCED 9a 08	Exterior removers – roller/brush	
CEPE SCED 9b 09	Fillers and putties (indoor)	
CEPE SCED 9b 10	Plasters and floor equalisers (indoor)	

https://echa.europa.eu/csr-es-roadmap/usemaps/use-maps-library

<u>CEPE Specific Consumer Exposure Determinants ("SCEDs")</u>

Products/activities covered by the SCED:

Trim paints (water-based/solvent-based/high solids) – indoor application by roller or brush (doors, window frames etc.).

Applicability of the SCED (depending on substances properties):

All substances used in consumer paints marketed for the above purpose.

Exposure Determinants or	Value ⁵ and [ESCOM phrase Code] ⁶	
Descriptors		
SCED characteristics		
Name of the SCEDs	Interior trim paints – roller/brush	
PC/AC descriptor	PC9a	
SCED code	CEPE_SCED_9a_03_v1	
Code of other related SCED	1.a.	
Author	CEPE	
Source of SCED	www.cepe.org	
Physical form of the products	Liquids	
User characteristics		
Adult/child assumed	Product used by adult (defaults based upon adult exposure factors)	
Common Determinants		
Concentration of substance in	0.5 (solvent/carrier)	
mixture (g/g)	0.3 (other substances)	
Explanations	CEPE suggested defaults, to be used only in absence of more specific	
	information about substance concentration in product.	
Frequency of use over a day	Once per day	
(event/day)		
Rationale	Unchanged from ECETOC TRA default value	
Frequency of use over a year	7	
(days/year)		
Rationale	CEPE consumer painting survey 2015; 90th percentile for relevant job	
	type. ECHA Guidance on Information Requirements and Chemical Safety	
	Assessment Chapter R.15: Consumer Exposure Assessment defines	
	infrequent use as <15 days per year.	
Dermal Specific Determinants		
Exposure via dermal route	Yes	
Rationale	Unchanged from ECETOC TRA default value	
Skin Contact Area	Inside of 2 hands/ palm of 2 hands / One hand	



Exposure Determinants or	Value ⁵ and [ESCOM phrase Code] ⁶	
Descriptors		
Rationale	Unchanged from ECETOC TRA default value	
Dermal transfer factor	1	
Rationale	Unchanged from ECETOC TRA default value	
Inhalation Specific Determinants		
Exposure via inhalation route	Yes	
Rationale	Unchanged from ECETOC TRA default value	
Spray application?	No	
Amount of Product used per	1300g	
application (g/event)		
Rationale	Unchanged from ECETOC TRA default value	
Exposure Time per event (h)	7	
Rationale	CEPE consumer painting survey 2015 (90th percentile); includes exposure	
	time whilst not actually painting	
Inhalation transfer factor	1	
Rationale	Unchanged from ECETOC TRA default value	
Place of use	Indoor	
Oral Specific Determinants		
Exposure via oral route	Oral exposure not foreseen	
Rationale	Negligible hand-to-mouth transfer can be assumed for adult users - hand	
	washing is normal before eating, smoking etc.	
Volume swallowed (cm ³)	Not applicable	
Rationale	Not applicable	
Oral transfer Factor	Not applicable	
Rationale	Not applicable	

Exposure estimation in ConsExpo



Substance X

Results ? Gr	aphs ?	Sensitivity anal	ysis ? Exposure	fractions
nhalation				
Exposure model Exp	osure to vapour	- Evaporation		
Mean event concentration	6.0>	< 10 ¹ mg/r	m ³	
Peak concentration (TWA 15 mi	n) 8.6 >	< 10 ¹ mg/r	m ³	_
Mean concentration on day of e	xposure 5.5	mg/r	m ³	1
Year average concentration	1.0>	< 10-1 mg/r	m³	•
External event dose	3.0	mg/ł	kg bw	
External dose on day of exposur	e 3.0	mg/ł	kg bw	
Dermal				
Exposure model Dire	ect product conta	ict - Constant rat	te	
Dermal load	4.2 >	< 10 ⁻² mg/d	cm²	
External event dose	3.0>	< 10 ⁻¹ mg/ł	kg bw	
External dose on day of exposur	e 3.0>	< 10 ⁻¹ mg/ł	kg bw	7

Substance Y

Output scenario Application			
Results ? Graphs	? Sensitivit	y analysis ?	Exposure fractions ?
Inhalation Exposure model Exposure to v	apour - Evaporat	ion	
Mean event concentration	$2.3 imes 10^{1}$	mg/m³	
Peak concentration (TWA 15 min)	$3.3 imes10^1$	mg/m³	
Mean concentration on day of exposure	2.1	mg/m³	
Year average concentration	4.0 × 10-2	mg/m³	
External event dose	1.1	mg/kg bw	
External dose on day of exposure	1.1	mg/kg bw	
Dermal Exposure model Direct produce	t contact - Consta	ant rate	
Dermal load	$2.5 imes 10^{-2}$	mg/cm²	
External event dose	1.8 × 10 ⁻¹	mg/kg bw	
External dose on day of exposure	1.8 × 10 ⁻¹	mg/kg bw	

Assessment results



Substance Y fails SSbD step 3 assessment

	X	Y
Inhalation exposure		
(mg/m3)	5.5	2.1
Inhalation DNEL		
(mg/m3)	83.76	1.42
Inhalation RCR	0.07	1.5
Dermal exposure (mg/kg		
bw/d)	0.3	0.18
Dermal DNEL (mg/kg		
bw/d)	10.53	8.15
Dermal RCR	0.03	0.02
Total RCR	0.1	1.52

RCR	SSbD Step 3	Criteria evaluation
> 1.5	0	Fail the
1 - 1.5	1	criteria
0.75 - 1	2	Pass the
< 0.5	3	criteria

RCR (Risk Characterization Ratio) = Exposure/safe limit; RCR < 1 is safe; RCR ≥ 1 is unsafe

Lessons learnt from the example



For downstream users, SSbD is mainly applied on (alternative) materials in re-design phase → don't generate data on material and depending on information from suppliers (also downstream users) for hazard assessment.

Most of materials for paints and coatings are mixtures and not pure substance vs. chemical safety assessment is on substance \rightarrow extra complicated to apply SSbD assessment

Inconsistent conclusions on chemical safety/risk assessment under different frameworks and methodologies \rightarrow What does it mean for SSbD assessment?

Reactive chemistry required for functions (e.g. product durability) vs. Non-hazardous materials

Intensive expertise and resource is needed

Questions?

