Exposure Scenario processing for mixtures

Critical Component Approach (CCA)

Brussels, ENES5 meeting 21&22 November 2013: Breakout session G

Jongerius consult BV

Caesar Consult

Onno Jongerius

Joost van Rooij

Agenda

1. **Introduction**

2. Outline Generic Mixture Exposure Scenario Approach (GMES)

3. Critical Component Approach (CCA)
   - *Presentation CCA method -> CCA results for ENES Examples M1 & M2*
   - *Guided discussion CCA*

Coffee break

4. Development "Mixture ES" for the example "Sanitary cleaner"
   - *Presentation GMES method -> Mixture ES for ENES Example "Sanitary Cleaner"*
   - *Guided discussion GMES*

5. Wrap-up

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1. Introduction
Who are we?

Chemical management support (>22 years)

Onno Jongerius

www.jongeriusconsult.com

Industrial Toxicology & Hygiene support (>22 years)

Joost van Rooij

www.caesar-consult.nl

Jongerius Consult supports companies / industry sectors with strategic & practical implementation of REACH & CLP aligned to the business needs
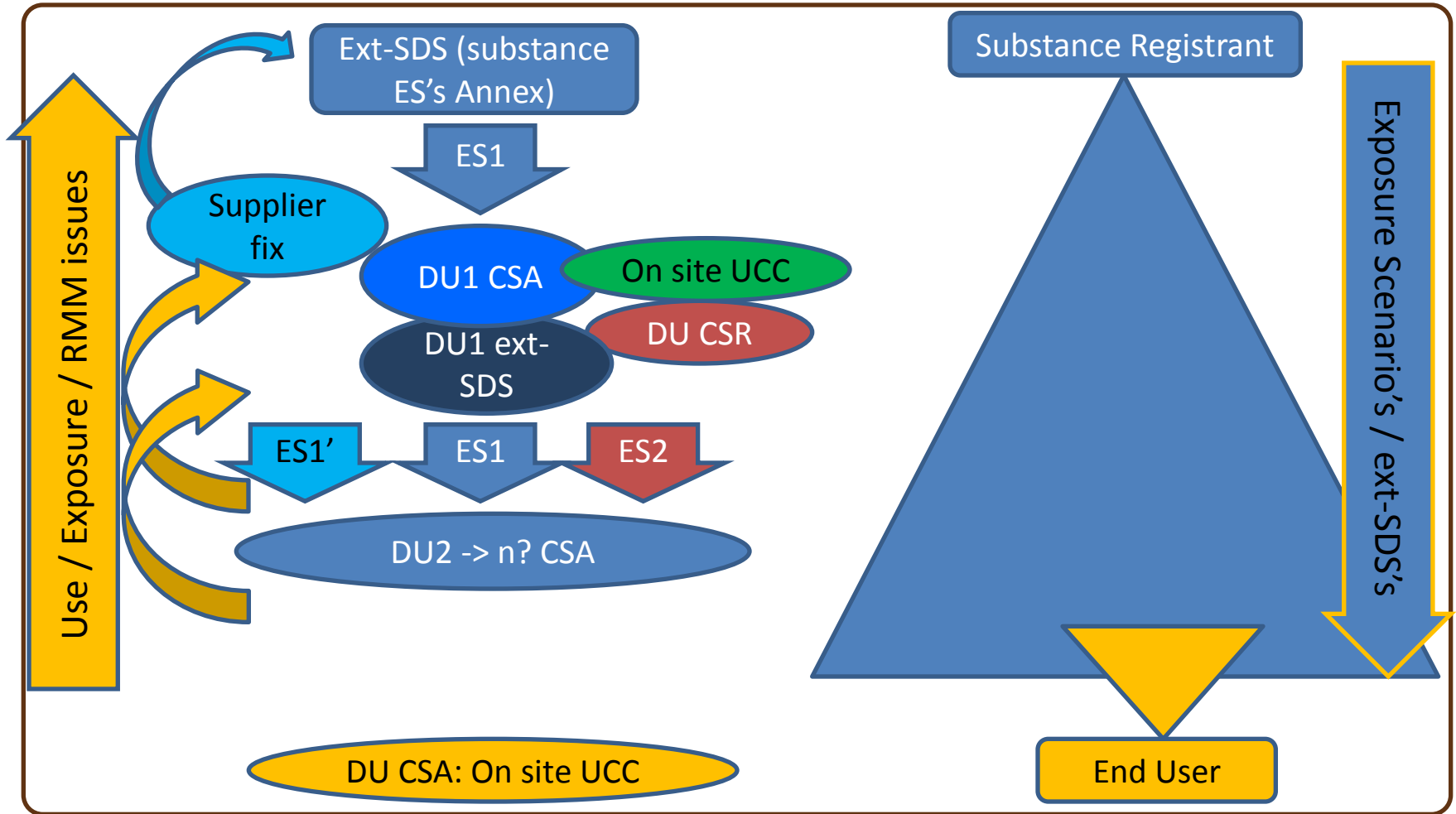
Caesar Consult supports companies / industry sectors / others to reduce or prevent health risks from exposure to hazardous substances at work or at home

Jongerius Consult & Caesar Consult jointly developed a REACH Compliance Training program and various practical tools and solutions. Amongst others, we work on a practical solution to process ES for Mixtures since mid 2011, being further matured by interaction with Industry

We are honoured & thankful sharing / discussing our concepts and ideas on the ENES meeting. We hope it has added value to come to a workable solution for Industry processing ES in Mixtures. We are looking forwards to your input and suggestions
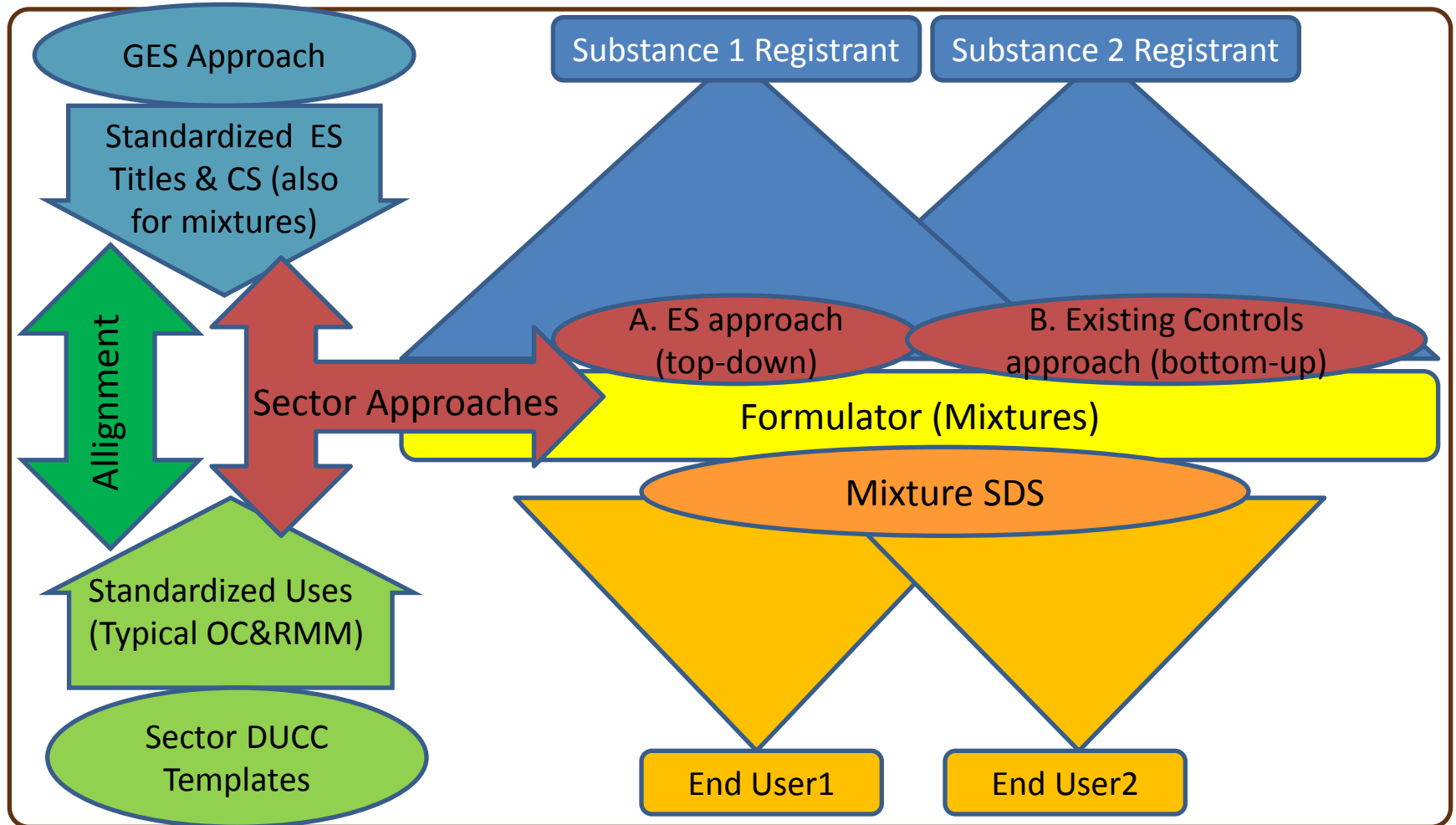
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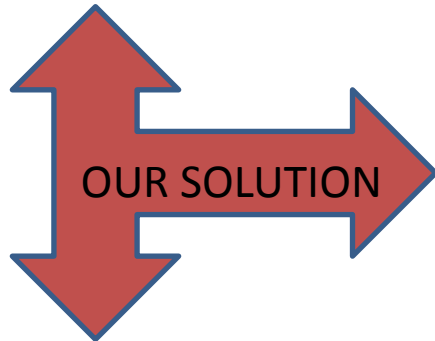
OUR SOLUTION → ***Generic Mixture Exposure Scenario (GMES) approach***

1. **Ready to use, standardized "Mixture ES format" as base**

   - *Aligned to the sector specific use Information (DUCC Templates)*

2. **Stepwise process to complete the Mixture ES(s) for a specific mixture**

   - *Reliable determination of the mixture OC & RMM for the product uses, taking into consideration the Mixture Label & relevant Risk Determining Substances in the Mixture identified via the Critical Component Approach (CCA)*

   - *Can be organized "top-down" or "bottom-up" (sector specific GMES)*

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MIXTURE EXPOSURE SCENARIO FORMAT (WORKER)

Name of mixture	<Product specific mixture name>			

Section 1 – Title of Exposure Scenario (ES)

				Sector code (ES)
Title	<DUCC Template: "Short ES Title">			<DUCC Template: "Code (DU)">
Processes and activities covered	Contributing Scenario (CS)		Sector code - CS	Use descriptor code
	<DUCC Template: "Short description of process or activity 1">		<DUCC Template: "Number 1">	<DUCC Template: "PROC at No 1">
	<DUCC Template: "Short description of process or activity 2">		<DUCC Template: "Number 2">	<DUCC Template: "PROC at No 2">
	<DUCC Template: "Short description of process or activity 3"> -> Etc.		<DUCC Template: "Number 3">	<DUCC Template: "PROC at No 3">
Sector of use	<DUCC Template: "Full description of the SU">		-	<DUCC Template: "SU">
Environmental release category	<DUCC Template: "Full description of the ERC / SPERC">		<DUCC Template: "SPERC">	<DUCC Template: "ERC">

Section 2 - Conditions of use affecting exposure

Characteristics of mixture - general		Qualitative endpoints relevant for chemical safety assessment			
		Irritation / corrosion	Sensitization	Acute toxicity	Carcinogenicity / mutagenicity
Physical state of mixture (at 20°C and 101.3 kPa)	liquid	No	No	No	No
Classification of undiluted mixture: R-Phrases	<R-Phrases of Mixture>				
Classification of undiluted mixture: H-Phrases	<H-Phrases of Mixture>				

2.1 Control of workers exposure

Operational conditions

Temperature of process	Ambient (unless stated differently)
Frequency/duration of use	8-hours/day - 5 workdays/week (unless stated differently)
Indoor or outdoor	indoor (unless stated differently)

Contributing Scenario (task / activity)	% of mixture in handled product?	Risk Management Measures (RMM)
<DUCC Template: "Short description of process or activity 1">	<Mixture %>	<RMMs determined for the specific CS as compilation of the RMMs processed for each relevant health endpoint (qualitative via mixture label and quantitative per RDS)>
<DUCC Template: "Short description of process or activity 2">	<Mixture %>	<RMMs determined for the specific CS as compilation of the RMMs processed for each relevant health endpoint (qualitative via mixture label and quantitative per RDS)>
<DUCC Template: "Short description of process or activity 3"> -> Etc.	<Mixture %>	<RMMs determined for the specific CS as compilation of the RMMs processed for each relevant health endpoint (qualitative via mixture label and quantitative per RDS)>

2.2 Control of environmental exposure

Environmental release category	typical (sp)ERC value		Environmental control measures
<DUCC Template: "Full description of the ERC / SPERC">	Fraction used at main source	<(sp)ERC: "Fraction used at main source">	<RMMs determined for the (sp)ERC based on the quantitative endpoint(s) per RDS>
	Emission days per year	<(sp)ERC: "Emission days per year">	
	Municipal STP	<(sp)ERC: "Municipal STP">	
	Release fraction to air	<(sp)ERC: "Release fraction to air">	
	Release fraction to waste water	<(sp)ERC: "Release fraction to waste water">	
	Release fraction to soil	<(sp)ERC: "Release fraction to soil">	
	River flow rate for dilution	flow rate for ___ m³/day	
	Type of on site Risk Management measures	<(sp)ERC: "Type of on site Risk Management measures">	
	Efficiency of on site Risk Management Measures	<(sp)ERC: "Efficiency of on site Risk Management Measures">	

Section 3 - Exposure estimation and reference to its source

Quantitative endpoints relevant for chemical safety assessment - Risk Determining Substances (RDS) via Critical Component Approach (CCA)

Endpoint			Risk Determining Substance	EC number	% in mixture	Limit value (DNEL-worker / PNEC)		Physical / chemical factors relevant for RDS selection / chemical safety assessment		
Inhalation	short term	local	<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>	ppm	Vapour pressure (hPa)	<RDS-value>	Fugacity category: ? (no vap. pressure)
		systemic	<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>	ppm	Vapour pressure (hPa)	<RDS-value>	Fugacity category: ? (no vap. pressure)
	long term	local	<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>	ppm	Vapour pressure (hPa)	<RDS-value>	Fugacity category: ? (no vap. pressure)
		systemic	<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>	ppm	Vapour pressure (hPa)	<RDS-value>	Fugacity category: ? (no vap. pressure)
Dermal	short term	local	<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>	mg/cm²	Not applicable		
		systemic	<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>	mg/kg bw			
	long term	local	<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>	mg/cm²			
		systemic	<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>	mg/kg bw			
Environment	aquatic	fresh water	<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>	mg/L	Vapour pressure (hPa)	<RDS-value>	
			<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>		Degradability		No

3.1 Worker - Chemical Safety Assessment based on the characteristics of mixture and the risk determining substance(s)

[general statement referring to the Chemical Safety Assessment method used and explaining that when RMMs/OCs instructions are implemented all qualitative and quantitative health hazards are controlled (Risk Characterization Ratios (RCRs) are below 1)].

3.2 Environment - Chemical Safety Assessment based on risk determining substance in mixture

[general statement referring to the Chemical Safety Assessment method and explaining that when RMMs/OCs instructions are implemented all environmental hazards are controlled (RCRs are below 1)]

Section 4 - Guidance to Downstream User to evaluate if he works inside boundaries set by the ES

Further information on the assumptions contained in this Exposure Scenario can be found/obtained from: <www.company.com> and/or <www.sector.org>. Scaling can be done using the exposure estimation tool originally used. Expert advice may be needed.

DISCLAIMER. The Mixture ES Format and the ENES 5 example data processed via the GMES / SMES approach into a concrete Mixture ES to be attached to the mixture SDS, is prepared by Jongerius Consult BV & Caesar Consult. It aims to provide Industry with a complete and workable solution for inclusion of component ES information in the Mixture SDS in line with the legal obligations under REACH. It is provided as input for the ENES meeting 5 (21&22 November 2013) in good faith and has been based on the best of our current knowledge and expertise. Copying of this material is authorised provided that the source is clearly mentioned and acknowledged.
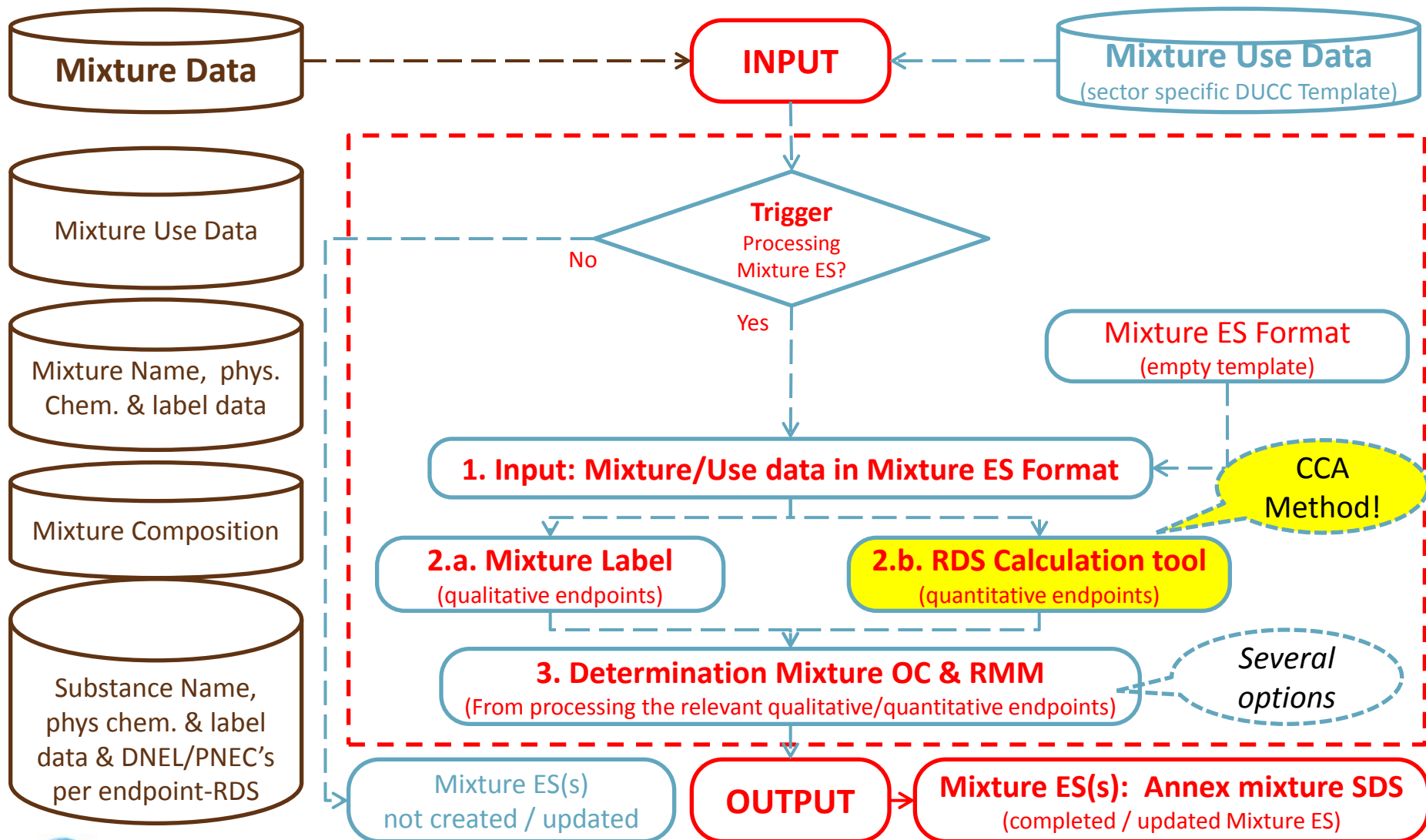
Mixture and composition information

Use information (from DUCC template, if available)

Mixture OC(s) & RMM (determined by GMES approach; several options)

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2. Outline Generic Mixture Exposure Scenario approach (GMES)
Stepwise process to complete the Mixture ES format *"top-down"*

Mixture Data

INPUT

Mixture Use Data
(sector specific DUCC Template)

Mixture Use Data

Mixture Name, phys. Chem. & label data

Mixture Composition

Substance Name, phys chem. & label data & DNEL/PNEC's per endpoint-RDS

Trigger
Processing Mixture ES?

No

Yes

Mixture ES Format
(empty template)

1. Input: Mixture/Use data in Mixture ES Format

CCA Method!

2.a. Mixture Label
(qualitative endpoints)

2.b. RDS Calculation tool
(quantitative endpoints)

3. Determination Mixture OC & RMM
(From processing the relevant qualitative/quantitative endpoints)

Several options

Mixture ES(s) not created / updated

OUTPUT

Mixture ES(s): Annex mixture SDS
(completed / updated Mixture ES)

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Coffee break

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3. Critical Component Approach (CCA)
Purpose and other methods

Determination of Risk Determining Substances (RDS) is important to make the processing of ES for Mixtures practical

1. **DPD+ method** (Cefic)

   Identification of Lead substance based on R-phrases

2. **CCA method** (ECHA)

   Assessment of Critical Components based on DNELs or PNECs

3. **Hybrid methods** (Sectors & Companies)

Note:
- DPD - Dangerous Preparations Directive (1999/45/EC)
- CCA – Critical Component Approach (ECHA Guidance Part G & for downstream users)

➢ The **DPD+ method** determines the so-called **lead substances.**

➢ Possible **Lead substances** are identified based on R-phrases for the following pathways:
- Inhalation
- Dermal
- Oral
- Eyes
- Aquatic environment

➢ For each pathway a **Lead Substance Indicator (LSI)** is calculated. The highest LSI value determines the Lead substance per pathway.

$$\text{LSI}_{inhalation} = Vp * C_i / C_L$$
$$\text{LSI}_{dermal,\ oral,\ eyes,\ or\ aquat.} = C_i / C_L$$

Vp = Vapour Pressure (hPa, at 25ºC) C_i = Concentration of substance (i) in mixture (%)

C_L = Concentration Limit for R-Phrase (%)

➢ Cefic Guidance (2009) & Cefic calculation tool available.

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3. Critical Component Approach (CCA)
The main principles of the CCA method (1)

➢ The **CCA method,** as proposed by Jongerius Consult & Caesar Consult, determines the so-called **critical components**

➢ Possible **critical components** are identified based on DNEL-/PNEC-values for the following endpoints:
- Inhalation: short / long term & local / systemic
- Dermal: short / long term & local / systemic
- Oral: short / long term - systemic
- Aquatic environment

➢ For each endpoint a **Risk Determining Substance (RDS) score** is calculated. The highest RDS score determines the critical component per endpoint.

$$\text{RDS-score}_{\text{inhalation endpoints}} = Vp * C_i / DNEL_i$$

$$\text{RDS-score}_{\text{other health endpoints}} = C_i / DNEL_i$$

$$\text{RDS-score}_{\text{environmental endpoints}} = C_i / PNEC_i$$

Vp = Vapour Pressure (hPa, at 20/25°C) C_i = Concentration of substance (i) in mixture (%)

DNEL or $PNEC_i$ = relevant DNEL or PNEC of substance (i)

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➢ The **<u>CCA method</u>** will not process all substances with a DNEL/PNEC

1. For reasons of proportionality and workability and in line with REACH Art 14(2), the same cut-off values are included as defined in Art 11.2 and section 1.1.2.2. of Annex I of the CLP Regulation.

2. Non-hazardous substances (no label) with a DNEL/PNEC value will not be processed in the CCA method. Non hazardous substance do not have a substance ES that can be processed for a mixture.

> The CCA method will determine the RDS(s) for a mixture, processing all hazardous substances with a DNEL/PNEC value and present in the mixture in a concentration above the most stringent cut-off limit based on the CLP label of the substance

CCA Method -
Cut-off limit values

CCA Method -
Background

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ENES5: Test Mixture M1 - industrial use in rigid foams
Determination RDS via CCA Calculation Tool

ENES5: Test Mixture M1 - industrial use in rigid foams

Mixture classification DPD+	Component	Conc in mixture (%)	REACH registered substance	VP (Pa) 20C	Worker DNEL, inhal, syst, longterm (mg/m^3)	Worker DNEL, dermal, syst, longterm (mg/kg/day)	PNEC (mg/l)	Classification DSD	Classification CLP	SDS available
not classified	A	60,00	yes	< 0,01	98	13,9	0,2	not classified	not classified	SDS
	B	16,00	yes	1,00E-06	3,9	7	0,02	not classified	Eye.Corr/Irr.2 H319	Ext-SDS
	C	10,00	no	< 0,01	---	---	---	R22	Acut.Tox.4 H302	SDS
	water	11,50	no	2,30E+03	---	---	---	not classified	not classified	no
	D	1,20	yes	4,00E+02	35	EBW	0,002	R10, R22, R23, R24, R34	H226, Acut.Tox.3 H301, Acut.Tox.3 H311, Skin.Corr.1B H314, Acut.Tox.3 H331	Ext-SDS
	E	0,70	yes	3,00E+01	0,529	0,15	0,0549	R22, R24, R34	Acut.Tox.4 H302, Acut.Tox.3 H311, Skin.Corr.1B H314	Ext-SDS
	F	0,57	yes	7,50E-02	0,31	0,2	0,084	R34, R52/53	Acut.Tox.5 H303, Acut.Tox.5 H313, Skin.Corr.1B H314, Skin.Sens.1B H317, Aquat.Chron.3 H412	no
	G	0,03	yes	9,10E+01	14,6 (local)	---	4,40E-04	Rep.Cat3 R62, R53	H226, Rep.Tox.Cat2 H361, Aquat.Chron.4 H413	no

CCA Tool - ENES5 M1

CCA Calculation tool - Demo
(draft beta version)

Calculation RDS-Score - ENES 5: Test Mixture M1 - industrial use in rigid foams

Mixture	Breakdown	Substance details					DNEL Worker				PNEC	
Product	Substance name	Substance Hazard Statements	Substance in product (%)	Cut-off value %	Vapour presure (hPa)	VP temp (°C)	4. INHALATION - Long term - Systemic		8. DERMAL- long term - Systemic		I. ENVIRONMENT - Aquatic - Fresh water	
							DNEL	RDS-Score	DNEL	RDS-Score	PNEC	RDS-score
							mg/m3		mg/kg bw/d		mg/l	
Test Mixture M1	A		60,00%		1,00E-04	20	98	non hazardous	13,9	non hazardous	0,2	non hazardous
	B	H319	16,00%	1,0%	1,00E-08	20	3,9	0,000	7,0	0,023	0,02	8,0
	C	H302	10,00%	1,0%	1,00E-04	20		no DNEL		no DNEL		no PNEC
	water		11,50%		2,30E+01	20		non hazardous		non hazardous		non hazardous
	D	H226, H301, H311, H314, H331	1,20%	0,1%	4,00E+00	20	35	0,001		no DNEL	0,002	6,0
	E	H302, H311, H314	0,70%	0,1%	3,00E-01	20	0,529	0,004	0,2	0,047	0,0549	0,13
	F	H303, H313, H314, H317, H412	0,57%	1,0%	7,50E-04	20	0,31	below cut off	0,2	below cut off	0,084	below cut off
	G	H226, H361, H413	0,03%	1,0%	9,10E-01	20		below cut off		below cut off	4,40E-04	below cut off

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ENES5: Test Mixture M2- industrial use functional fluids/solvents
Determination RDS via CCA Calculation Tool

ENES5: Test Mixture M2 - industrial use functional fluids / solvents										
Mixture classification DPD+	Component	Conc in mixture (%)	REACH registered substance	VP (Pa) 25C	Worker DNEL, inhal, syst, longterm (mg/m^3)	Worker DNEL, dermal, syst, longterm (mg/kg/day)	PNEC (mg/l)	Classification DSD	Classification CLP	SDS available
R18, R52/53 F+ in use	A	90,00	yes	3,00E+04	2000	2750	0,05	R52/53	H412: Harmful to aquatic life with long lasting effects.	Ext-SDS
	B	10,00	yes	4,00E+03	500	900	150	R11, R36, R67	H225: Highly flammable liquid and vapour; H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness.	Ext-SDS

CCA Calculation tool
(draft beta version)

Calculation RDS-Score - ENES 5: Test Mixture M2 - Industrial use functional fluids / solvents

Mixture	Breakdown	Substance details							RDS - WORKER				RDS - ENVIRONMENT	
Product	Substance name	CAS#	EC#	Substance Hazard Statements	Substance in product (%)	Cut-off value %	Vapour presure (hPa)	VP temp (°C)	4. INHALATION - Long term - Systemic		8. DERMAL- long term - Systemic		I. ENVIRONMENT - Aquatic - Fresh water	
									DNEL	RDS-Score	DNEL	RDS-Score	PNEC	RDS-score
									mg/m3		mg/kg bw/d		mg/l	
Test Mixture M2	A			H412	90,0%	1,0%	300	25	2000	0,135	2750	0,0003	0,05	18,0
	B			H225, H319, H336	10,0%	1,0%	40	25	500	0,008	900	0,0001	150	0,0007

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3. Critical Component Approach (CCA)
Pro's, con's and issues

Pro's

+ Like any RDS method, the CCA method reduces the number of substance ES's to process for the mixture

+ Similar process steps as DPD+

+ Easy to understand and implement / fully automatable

+ The CCA method builds on DNEL /PNEC values as hazard identifiers; empowers the use of these important REACH building blocks

Con's

+/- DNEL / PNEC values are not yet available for all components of a mixture. If and how this may affect the safe use of a mixture depends on how the CCA is embedded in the total process.

Issues

1) Are the proposed filter rules in the CCA method (concentration above the CLP cut-off values & being hazardous) appropriate to identify the RDS(s)?

2) DNEL/PNEC values should be listed in the SDS(08). In reality, DNEL/PNEC values are sometimes lacking /different from the ECHA website.

Possible solutions / suggestions

1) Ideas & feedback from the audience?

2) Normal procedure to check with the Supplier. Is it a general rule to adopt that the DNEL/PNEC values from the Joint Submission dossier on the ECHA website prevail?

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1. What are the general pro's / con's?

2. What is the applicability domain? Any limitations?

3. Any practical issue in the application (issues to solve)?

4. Required actions to make the CCA method operational?

5. General conclusions / recommendation from the group

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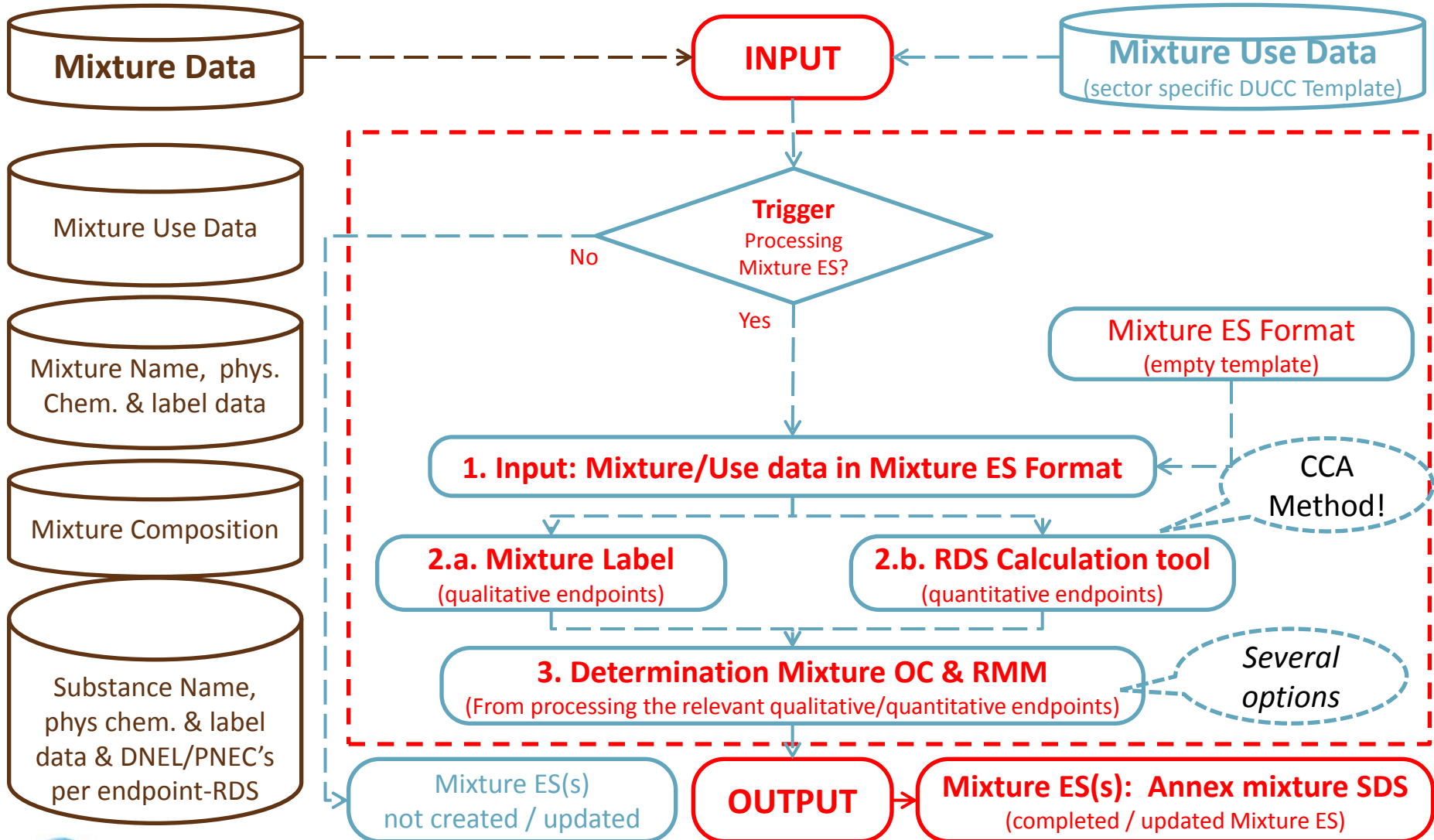CHEMICAL SUBSTANCES RISK ASSESSMENT

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Coffee break

4. Development "Mixture ES" for the example "Sanitary cleaner"

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   - *Guided discussion GMES*

5. Wrap-up

ENES5 Example "Sanitary Cleaner" (AISE)
Stepwise process to complete the Mixture ES format "top-down" (1)

Mixture Data

Mixture Use Data (sector specific DUCC Template)

INPUT

Mixture Use Data

Mixture Name, phys. Chem. & label data

Mixture Composition

Substance Name, phys chem. & label data & DNEL/PNEC's per endpoint-RDS

Trigger
Processing Mixture ES?

No

Yes

Mixture ES Format (empty template)

1. Input: Mixture/Use data in Mixture ES Format

CCA Method!

2.a. Mixture Label (qualitative endpoints)

2.b. RDS Calculation tool (quantitative endpoints)

3. Determination Mixture OC & RMM
(From processing the relevant qualitative/quantitative endpoints)

Several options

Mixture ES(s) not created / updated

OUTPUT

Mixture ES(s): Annex mixture SDS
(completed / updated Mixture ES)

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ENES5 Example "Sanitary Cleaner" (AISE)

Stepwise process to complete the Mixture ES format *"top-down"(2)*

Mixture Use Data

MIXTURE EXPOSURE SCENARIO FORMAT (WORKER)

Mixture name

1. Input: Mixture/Use data in Mixture ES Format

Name of mixture	<Product specific mixture name>		

Section 1 – Title of Exposure Scenario (ES)

Sector code (ES)

Title	<DUCC Template: "Short ES Title">		<DUCC Template: "Code (DU)">
Processes and activities covered	Contributing Scenario (CS)	Sector code	
	<DUCC Template: "Short description of process or activity 1">	<DUCC Templ...	
	<DUCC Template: "Short description of process or activity 2">	<DUCC Templa...	
	<DUCC Template: "Short description of process or activity 3"> -> Etc.	<DUCC Template: ...	<DUCC Template: "Title at N...
Sector of use	<DUCC Template: "Full description of the SU">	-	<DUCC Template: "SU">
Environmental release category	<DUCC Template: "Full description of the ERC / SPERC">	<DUCC Template: "SPERC">	<DUCC Template: "ERC">

ES Title & mixture use

Section 2 - Conditions of use affecting exposure

Mixture label

Qualitative Endpoints

2.a. Mixture Label (qualitative endpoints)

Characteristics of mixture - general		Qualitative endpoints relevant for chemical safety assessment		
		Irritation / corrosion	Sensitization	Acute toxicity	Carcinogenicity / mutagenicity
Physical state of mixture (at 20°C and 101.3 kPa)	liquid				
Classification of undiluted mixture: R-Phrases	<R-Phrases of Mixture>		No	No	No
Classification of undiluted mixture: H-Phrases	<H-Phrases of Mixture>				

2.1 Control of workers exposure

Operational conditions

Temperature of process	Ambient (unless stated differently)
Frequency/duration of use	8-hours/day - 5 workdays/week (unless stated differently)
Indoor or outdoor	indoor (unless stated differently)

Contributing Scenario (task / activity)	% of mixture in handled product?	Risk Management Measures (RMM)	
<DUCC Template: "Short description of process or activity 1">		RMMs processed for each relevant health endpoint (qualitative via mixture label a...	
<DUCC Template: "Short description of process or activity 2">		RMMs processed for each relevant health endpoint (qualitative via mixture label and quan...	
<DUCC Template: "Short description of process or activity 3"> -> Etc.	<Mixture %>	<RMMs determined for the specific CS as compilation of the RMMs processed for each relevant health endpoint (qualitative via mixture label and quantitative... RDS)>	

Mixture uses: contributing scenarios (CS)

Mixture OC /RMM per CS

3. Determination Mixture OC & RMM (From processing the relevant qualitative/ quantitative endpoints)

2.2 Control of environmental exposure

Environmental release category	typical (sp)ERC value		Environmental control measures
<DUCC Template: "Full description of the ERC / SPERC">	Fraction used at main source	<(sp)ERC: "Fraction used at main source">	<RMMs determined for the (spe)ERC based... the quantitative endpoint(s) per RDS>
		<(sp)ERC: "Emission days per year">	
		...ncipal STP">	
		...ase fraction to air">	
		...ase fraction to waste water">	
	Release fraction to soil	<(sp)ERC: "Release fraction to soil">	
	River flow rate for dilution	flow rate for m³/day	
	Type of on site Risk Management measures	<(sp)ERC: "Type of on site Risk Management Measures">	
	Efficiency of on site Risk Management Measures	<(sp)ERC: "Efficiency of on site Risk Management Measures">	

Mixture uses: ERC / SPERC

Mixture OC /RMM Env.

Section 3 - Exposure estimation and reference to its source

Quantitative endpoints relevant for chemical safety assessment - Risk Determining Substances (RDS) via Critical Component Approach (CCA)

Endpoint			Risk Determining Substance	EC number	% in mixture	Limit value (DNEL-worker / PNEC)		Physical / chemical factors relevant for RDS selection / chemical ... assessment		
Inhalation	short term	local	<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>	ppm	Vapour pressure (hPa)	<RDS-value>	Fugacity
		systemic	<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>	ppm	Vapour pressure (hPa)	<RDS-value>	Fuga...
	long term	local	<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>	ppm	Vapour pressure (hPa)	<RDS-value>	
		systemic	<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>	ppm	Vapour pressure (hPa)	<RDS-value>	
Dermal	short term	local	<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>	mg/cm²	Not applicable		
		systemic	<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>	mg/kg bw			
	long term	local	<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>	mg/cm²			
		systemic	<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>	mg/kg bw			
Environment	aquatic	fresh water	<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>	mg/L	Vapour pressure (hPa)	<RDS-value>	
			<RDS name from CCA Calculation>	< See CCA>	< See CCA>	<RDS-value>		Degradability		N...

Result CCA Method RDS per Quant. Endp.

2.b. RDS Calculation tool (quantitative endpoints)

3.1 Worker - Chemical Safety Assessment based on the characteristics of mixture and the risk determining substance(s)

[general statement referring to the Chemical Safety Assessment method used and explaining that when RMMs/OCs instructions are implemented all qualitative and quantitative health hazards are controlled (Risk Characterization Ratios (RCRs) are below 1)].

3.2 Environment - Chemical Safety Assessment based on risk determining substance in mixture

[general statement referring to the Chemical Safety Assessment method and explaining that when RMMs/OCs instructions are implemented all environmental hazards are controlled (RCRs are below 1]

Section 4 - Guidance to Downstream User to evaluate if he works inside boundaries set by the ES

Further information on the assumptions contained in this Exposure Scenario can be found/obtained from: <www.company.com> and/or <www.sector.org>. Scaling can be done using the exposure estimation tool originally used. Expert advice may be needed.

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ENES5 Example "Sanitary Cleaner" (AISE)
Data provided

	TEST MIXTURE ENES 5: Sanitary Cleaner (AISE)						
Mixture classification CLP	**Component**	**CASn°**	**type of ingredient**	**Conc in mixture (%)**	**Classification DSD**	**Classification CLP**	**SDS available?**
GHS05; Danger H314: Causes severe skin burns and eye damage	Sulphamidic acid	5329-14-6	acid	4,00	R36/38 - R52/53	Skin irrit. 2 H315; Eye irrit. 2 H319; Aquat. chron. 3 H412	Ext-SDS
	Phosphoric acid	7664-38-2	acid	9,80	R34	Met. corr. 1 H290; Skin corr. 1B H314	Ext-SDS
	Alkyl(C10-13) benzenesulfonic acid (ABS) (linear)	85536-14-7	surfactant	6,01	R22-34	Skin corr. 1A H314; Eye dam.1 H318; Acute tox. 4 (Oral) H302	Ext-SDS
	Perfume X	(mixture) **	perfume	0,05	?	Eye irrit. 2 H319; Skin sens. 1B H317; Aquatic chron. 2 H411	No
	disodium 5-amino-4-hydroxy-3-(phenylazo) naphthalene-2,7-di-sulphonate	3567-66-6	Additive/Color	0,004	?	Eye irrit. 2 H319; Skin sens. 1B H317 Aquatic chron. 2 H411	No
	water		solvent	80,14			
	**Contains no sensitizing ingredients <0,01%						

TEST MIXTURE ENES 5: Sanitary Cleaner (AISE)						
Mixture Use	**SU**	**PC**	**PROC**	**ERC**	**Max. Duration**	**Typical RMM**
Brushing undiluted product on surfaces	22	35	10	8a	120 min	Good general ventilation but no LEV; gloves and goggles possible; no resp. protection
Diluting product*	22	35	8a	8a	50 min	Good general ventilation but no LEV; gloves and goggles possible; no resp. protection
Brushing diluted product on surfaces	22	35	10	8a	480 min	Good general ventilation but no LEV; No PPE

*Product instructions prescribes at least 1:10 dilution with water

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AISE Inst. Use map (19-06-2012)

1. Input: Mixture/Use data in Mixture ES Format

Name of mixture	Sanitary Cleaner (test formulation ENES5)		

Section 1 – Title of Exposure Scenario (ES)			Sector code - ES
Title	Professional Use of General surface cleaning products		AISE-P305
Processes and activities covered	Contributing Scenario (CS)	Sector code - CS	Use descriptor code
	Transfer of professional cleaning or maintenance product (charging/discharging) to a cleaning equipment (machine/vessel/bucket)	AISE_CSP01	PROC8a
	Brushing a diluted professional cleaning solution, desinfectant or maintenance product	AISE_CSP08	PROC10
	Brushing a concentrated professional cleaning or maintenance product.	AISE_CSP10	PROC10
Sector of use	Professional uses: Public domain (administration, education, entertainment, services, craftsmen)	-	SU22
Environmental release category	AISE 16 - Wide Dispersive Use in 'Down the Drain' cleaning and maintenance products (Consumers and Professionals)	AISE SPERC 8a.1.a.v1	ERC8a

Section 2 - Conditions of use affecting exposure

Characteristics of mixture - general		**Qualitative endpoints relevant for chemical safety assessment**			
		Irritation / corrosion	**Sensitization**	**Acute toxicity**	**Carcinogenicity / mutagenicity**
Physical state of mixture (at 20°C and 101.3 kPa)	liquid	Skin and eye corrosive	No	No	No
Classification of undiluted mixture: R-Phrases	R34				
Classification of undiluted mixture: H-Phrases	H314				

2.1 Control of workers exposure

Operational conditions

Temperature of process	Ambient (unless stated differently)
Frequency/duration of use	8-hours/day - 5 workdays/week (unless stated differently)
Indoor or outdoor	indoor (unless stated differently)

Contributing Scenario (task / activity)	**% of mixture in handled product?**	**Risk Management Measures (RMM)**
Transfer of professional cleaning or maintenance product (charging/discharging) to a cleaning equipment (machine/vessel/bucket)	100%	<RMMs determined for the specific CS as compilation of the RMMs processed for each relevant health endpoint (qualitative via mixture label and quantitative per RDS)>
Brushing a diluted professional cleaning solution, desinfectant or maintenance product	<10%	<RMMs determined for the specific CS as compilation of the RMMs processed for each relevant health endpoint (qualitative via mixture label and quantitative per RDS)>
Brushing a concentrated professional cleaning or maintenance product.	100%	<RMMs determined for the specific CS as compilation of the RMMs processed for each relevant health endpoint (qualitative via mixture label and quantitative per RDS)>

2.2 Control of environmental exposure

Environmental release category	**typical (sp)ERC value**		**Environmental control measures**
AISE 16 - Wide Dispersive Use in 'Down the Drain' cleaning and maintenance products (Consumers and Professionals)	Fraction used at main source	0,00075	<RMMs determined for the (spe)ERC based on the quantitative endpoint(s) per RDS>
	Emission days per year	365	

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2.b. RDS Calculation tool
(quantitative endpoints)

CCA Method!

Calculation RDS-Score - example Sanitary Cleaner

Mixture	Breakdown			Substance details					DNEL Worker									PNEC	
Product	Substance name	CAS#	EC#	Substance Hazard Statements	Substance in product (%)	Cut-off value %	Vapour presure (hPa)	VP temp (°C)	1. INHALATION - Short term - Local effects		3. INHALATION - Long term - Local effects		4. INHALATION - Long term - Systemic		8. DERMAL- long term - Systemic		I. ENVIRONMENT - Aquatic - Fresh water	
									DNEL mg/m3	RDS-score	DNEL mg/m3	RDS-score	DNEL mg/m3	RDS-Score	DNEL mg/kg bw/d	RDS-Score	PNEC mg/l	RDS-score
Sanitary Cleaner	Water	7732-18-5			80,1%			-	non hazardous		non hazardous		non hazardous		non hazardous		non hazardous	
	Phosphoric Acid	7664-38-2	231-633-2	H290, H314	9,8%	1,0%	0,038000	20	2	0,002	1	0,004	no DNEL		no DNEL		no PNEC	
	Sulphamidic Acid	5329-14-6	226-218-8	H319, H315, H412	4,0%	1,0%	0,007800	20	no DNEL		no DNEL		no DNEL		10,0	0,0040	0,048	0,83
	Alkyl(C10-13) benzenesulfonic acid (ABS) (linear)	85536-14-7	287-494-3	H314,H318, H302	6,0%	1,0%	1,00E-10	?	no DNEL		12	0,0000000000005	12	0,000000000001	170,0	0,0	0,287	0,21
	Perfume X	(mixture)	(mixture)	H317, H319, H411	0,05%	1,0%			below cut off		below cut off		below cut off		below cut off		below cut off	
	disodium 5-amino-4-hydroxy-3-(phenylazo) naphthalene-2,7-di-sulphonate	3567-66-6			0,0035%	0,1%			below cut off		below cut off		below cut off		below cut off		below cut off	

Output in Mixture ES Format

Section 3 - Exposure estimation and reference to its source

Quantitative endpoints relevant for chemical safety assessment - Risk Determining Substances (RDS) via Critical Component Approach (CCA)

Endpoint			Risk Determining Substance	EC number	% in mixture	Limit value (DNEL-worker / PNEC)		Physical / chemical factors relevant for RDS selection / chemical safety assessment		
Inhalation	short term	local	Phosphoric Acid	231-633-2	9,8%	2	mg/m3	Vapour pressure (hPa)	0,038	Fugacity category: low (0,01-500 Pa)
		systemic	-	-	-	-		Vapour pressure (hPa)	-	Fugacity category: ? (no vap. pressure)
	long term	local	Phosphoric Acid	231-633-2	9,8%	1	mg/m3	Vapour pressure (hPa)	0,038	Fugacity category: low (0,01-500 Pa)
		systemic	Alkyl(C10-13) benzenesulfonic acid (ABS)	287-494-3	6,0%	12	mg/m3	Vapour pressure (hPa)	1E-10	Fugacity category: negligible (< 0,01 Pa)
Dermal	short term	local	-	-	-	-				
		systemic	-	-	-	-			Not applicable	
	long term	local	-	-	-	-				
		systemic	Sulphamidic acid	226-218-8	4%	10	mg/kg bw			
Environment	aquatic	fresh water	Sulphamidic acid	226-218-8	4%	0,048	mg/L	Vapour pressure (hPa)	0,0078	
								Degradability		Unknown

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ENES5 Example "Sanitary Cleaner" (AISE)
Step 2 identification qualitative/quantitative end-points (2)

1. Input: Mixture/Use data in Mixture ES Format

2.a. Mixture Label (qualitative endpoints)

Section 2 - Conditions of use affecting exposure

Characteristics of mixture - general			Qualitative endpoints relevant for chemical safety assessment			
			Irritation / corrosion	Sensitization	Acute toxicity	Carcinogenicity / mutagenicity
Physical state of mixture (at 20°C and 101.3 kPa)	liquid					
Classification of undiluted mixture: R-Phrases	R34	1	Skin and eye corrosive	No	No	No
Classification of undiluted mixture: H-Phrases	H314					

2.1 Control of workers exposure

2.b. RDS Calculation tool (quantitative endpoints)

CCA Method!

Section 3 - Exposure estimation and reference to its source

Quantitative endpoints relevant for chemical safety assessment - Risk Determining Substances (RDS) via Critical Component Approach (CCA)								Physical / chemical factors relevant for RDS selection / chemical safety assessment		
Endpoint			Risk Determining Substance	EC number	% in mixture	Limit value (DNEL-worker / PNEC)				
Inhalation	short term	local	Phosphoric Acid	231-633-2	9,8%	2	mg/m3	Vapour pressure (hPa)	0,038	Fugacity category: low (0,01-500 Pa)
		systemic						Vapour pressure (hPa)	-	Fugacity category: ? (no vap. pressure)
	long term	local	Phosphoric Acid	231-633-2	9.8%	1	mg/m3	Vapour pressure (hPa)	0,038	Fugacity category: low (0,01-500 Pa)
		systemic	Alkyl(C10-13) benzenesulfonic acid (ABS)	287-494-3	6,0%	12	mg/m3	Vapour pressure (hPa)	1E-10	Fugacity category: negligible (< 0,01 Pa)
Dermal	short term	local	-	-	-	-		Not applicable		
		systemic	-	-	-	-				
	long term	local								
		systemic	Sulphamidic acid	226-218-8	4%	10	mg/kg bw			
Environment	aquatic	fresh water	Sulphamidic acid	226-218-8	4%	0,048	mg/L	Vapour pressure (hPa)	0,0078	
								Degradability		Unknown

3. Determination Mixture OC & RMM
(From processing the relevant quantitative/qualitative endpoints)

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ENES5 Example "Sanitary Cleaner" (AISE)
Step 3 determination Mixture OC & RMM "top-down" (1)

1. Skin and eye corrosive

2. RDS (inhal-ST-local): phosphoric acid

3. RDS (inhal-LT-local): phosphoric acid

No.	Short title	Main User Group (SU)	Sector of Use (SU)	Product Category (PC)	Process Category (PROC)	Environmental Release Category (ERC)	Article Category (AC)	Specification
1	Manufacture of substance	3	8, 9	NA	1, 2, 3, 4, 8b, 9, 15	1	NA	ES1433
2	Industrial use	3	8, 9, 10, 15, 16, 17	0, 1, 7, 9a, 9b, 13, 14, 19, 20, 21, 23, 24, 25, 26, 32, 34, 35, 37, 39	1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 15, 19, 22, 23	2, 3, 4, 6a, 6b, 6d	NA	ES1460
3	Professional use	22	1, 19	9a, 9b, 12, 14, 15, 31, 35, 37, 38	5, 8a, 8b, 9, 10, 11, 13, 19, 25	8a, 8b, 8c, 8e	NA	ES1470
4	Use in Cleaning Agents	21	NA	0, 12, 28, 31, 35, 38, 39	NA	8a, 8e, 11		

Frequency and duration of use	Frequency of use	220 days/year
	The maximum duration considered for this exposure scenario is a working shift of above 4h/day (worst case assumption)	
	Frequency of use	8 hours/day

Organisational measures to prevent /limit releases, dispersion and exposure	Because the substance is corrosive, the risk management measures for human health should focus on the prevention of direct contact with the substance
Conditions and measures related to personal protection, hygiene and health evaluation	Use suitable eye protection and gloves. Wear suitable coveralls to prevent exposure to the skin.

2.1 Control of workers exposure

Operational conditions

Temperature of process	Ambient (unless stated differently)
Frequency/duration of use	8-hours/day - 5 workdays/week (unless stated differently)
Indoor or outdoor	indoor (unless stated differently)

Contributing Scenario (task / activity)	% of mixture in handled product?	Risk Management Measures (RMM)
Transfer of professional cleaning or maintenance product (charging/discharging) to a cleaning equipment (machine/vessel/bucket)	100%	Use suitable eye protection and gloves.
Brushing a diluted professional cleaning solution, desinfectant or maintenance product	<10%	If diluted less then 100 times (% of mixture > 1%): use suitable eye protection and gloves.
Brushing a concentrated professional cleaning or maintenance product.	100%	Use suitable eye protection and gloves.

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1. Skin and eye corrosive

2. RDS (inhal-ST-local): phosphoric acid

3. RDS (inhal-LT-local): phosphoric acid

4. **RDS (inhal-LT-system): ABS**   6%

Exposure Scenario 11a: Use in Washing and Cleaning Products (liquids) - Professional use

Use descriptors:	Sectors of use:
	SU22: Professional uses: Public domain (administration, education, entertainment, services, craftsmen).
	Process categories:

Non-dedicated facility [PROC8a]	Handle all packages and containers carefully to minimise spills.
Dedicated facility [PROC8b]	Handle all packages and containers carefully to minimise spills.
Transfer from/pouring from containers [PROC9]	Handle all packages and containers carefully to minimise spills..
Rolling, Brushing [PROC10]	Clear spills immediately.]
Securing [PROC11]	Clear spills immediately

2.1 Control of workers exposure

Operational conditions

Temperature of process	Ambient (unless stated differently)
Frequency/duration of use	8-hours/day - 5 workdays/week (unless stated differently)
Indoor or outdoor	indoor (unless stated differently)

Contributing Scenario (task / activity)	% of mixture in handled product?	Risk Management Measures (RMM)	
Transfer of professional cleaning or maintenance product (charging/discharging) to a cleaning equipment (machine/vessel/bucket)	100%	Use suitable eye protection and gloves. [Handle all packages and containers carefully to minimise spills.]	6%
Brushing a diluted professional cleaning solution, desinfectant or maintenance product	<10%	If diluted less then 100 times (% of mixture > 1%): use suitable eye protectio [Clear spills immediately]	<0,6%
Brushing a concentrated professional cleaning or maintenance product.	100%	Use suitable eye protection and gloves. [Clear spills immediately]	6%

1. Skin and eye corrosive

2. RDS (inhal-ST-local): phosphoric acid

3. RDS (inhal-LT-local): phosphoric acid

4. RDS (inhal-LT-system): ABS

5. RDS (dermal-LT-system): sulphamidic acid   4%

N°.	Korte titel	Hoofdg ebruike rsgroep (SU)	Gebruik ssector	Productca tegorie (PC)	Procesate gorie (PROC)	Milieu- emissieca tegorie (ERC)	Voorwerp categorie (AC)	Specificatie
6	Toepassing in reinigingsmiddelen	22	2b	3, 8, 13, 15, 31, 35	1, 2, 4, 5, 8a, 8b, 9, 10, 11, 13, 16, 17, 19, 20	8a, 8b, 8d, 9a, 9b	NA	ES11041
7	Toepassing in reinigingsmiddelen	3	5, 6b, 8, 15	8, 14, 20, 23, 26, 35,	2, 3, 4, 5			

Productkarakteristieken	Concentratie van de stof in het mengsel/artikel	Stofconcentratie: 3% - 15%
	Fysische vorm (tijdens gebruik)	vloeibaar
	Verwerkingstemperatuur	< 60 °C
Gebruikte hoeveelheid	Hoeveelheid gebruikt op werkplek	7 - 1000 ton(nen)/jaar
Frequentie en duur van het gebruik	Blootstellingsduur per dag	15 - 60 min

Organisatorische maatregelen om vrijkomen, dispersie en blootstelling te voorkomen/beperken	Begrijp de gevaarlijke eigenschappen van de stof. Waarborg dat de controlemaatregelen regelmatig worden geïnspecteerd en onderhouden. Alleen behoorlijk opgeleid en erkend personeel zal de stof hanteren
Voorwaarden en maatregelen met betrekking tot persoonlijke bescherming, hygiëne en gezondheidsevaluatie	Beschermende handschoenen dragen. Gebruik geschikte oogbescherming. → Use suitable eye protection and gloves — Indien nodig: Draag geschikte beschermende kleding. Gas/damp/spuitnevel niet inademen. ademhalingsbescherming → If necessary, wear suitable working clothes

2.1 Control of workers exposure

Operational conditions

Temperature of process	Ambient
Frequency/duration of use	8-hours/
Indoor or outdoor	indoor (u

Contributing Scenario (task / activity)	% of mixture in handled product?	Risk Management Measures (RMM)
Transfer of professional cleaning or maintenance product (charging/discharging) to a cleaning equip (machine/vessel/bucket)	4% 100%	**Use suitable eye protection and gloves. [If necessary, wear suitable working clothes]** [Handle all packages and containers carefully to minimise spills.]
Brushing a diluted professional cleaning solution, desinfectant or maintenance pr	> 60 min <0,4% <10%	**If diluted less then 100 times (% of mixture >1%): use suitable eye protection and gloves.** [Clear spills immediately] **[If necessary, wear suitable working clothes]**
Brushing a concentrated professional cleaning or maintenance product.	> 60 min 4% 100%	**Use suitable eye protection and gloves. [If necessary, wear suitable working clothes]** [Clear spills immediately]

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ENES5 Example "Sanitary Cleaner" (AISE)
Step 3 determination Mixture OC & RMM "top-down" (4)

N°.	Korte titel	Hoofdg ebruike rsgroep (SU)	Gebruik ssector	Productca tegorie (PC)	Procesate gorie (PROC)	Milieu-emissieca tegorie (ERC)	Voorwerp categorie (AC)	Specificatie
	Toepassing in reinigingsmiddelen	22	2b	3, 8, 13, 15, 31, 35	1, 2, 4, 5, 8a, 8b, 9, 10, 11, 13, 16, 17, 19, 20	8a, 8b, 8d, 9a, 9b	NA	ES11041
7	Toepassing in reinigingsmiddelen	3	5, 6b, 8, 15	8, 14, 20, 23, 26, 35, 38	2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 15, 16,	4, 6b	NA	ES11043

5. RDS (environment –aquatic – fresh water): sulphamidic acid   4%

2.1 bijdragescenario dat de milieublootstelling beheerst voor: ERC8a, ERC8b, ERC8d, ERC9a, ERC9b

technische voorwaarden en maatregelen op procesniveau (bron) ter verhindering van	Water	Afval niet in de gootsteen werpen., Geen afvalwater rechstreeks in het milieu afscheiden.
Voorwaarden en maatregelen met betrekking tot externe behandeling van afval voor verwerking	Afvalverwerking	Afval zal teruggewonnen of gerecycleerd worden indien mogelijk, Externe behandeling en verwijdering van afval met inachtneming van de desbetreffende plaatselijke en/of nationale voorschriften.
	Verwijderingsmethoden	Verpakkingen die niet meer gereinigd kunnen worden, moeten zoals de stof zelf verwijderd worden

---

2.2 Control of environmental exposure

Environmental release category	typical (sp)ERC value		Environmental control measures
AISE 16 - Wide Dispersive Use in 'Down the Drain' cleaning and maintenance products (Consumers and Professionals)	Fraction used at main source	0,00075	**[Do not dispose waste into drains]**
	Emission days per year	365	**[Dispose of waste product or used containers according to local regulations.]**
	Municipal STP	yes	
	Release fraction to air	0	
	Release fraction to waste water	1	
	Release fraction to soil	0	
	River flow rate for dilution	18000 m^3/day	<0,4% - 4%
	Type of *on site* Risk Management measures	-	
	Efficiency of *on site* Risk Management Measures	-	

Section 1 – Title of Exposure Scenario (ES)			Sector code - ES
Title	Professional Use of General surface cleaning products		AISE-P305
Processes and activities covered	Contributing Scenario (CS)	Sector code - CS	Use descriptor code
	Transfer of professional cleaning or maintenance product (charging/discharging) to a cleaning equipment (machine/vessel/bucket)	AISE_CSP01	PROC8a
	Brushing a diluted professional cleaning solution, desinfectant or maintenance product	AISE_CSP08	PROC10
	Brushing a concentrated professional cleaning or maintenance product.	AISE_CSP10	PROC10
Sector of use	Professional uses: Public domain (administration, education, entertainment, services, craftsmen)	-	SU22
Environmental release category	AISE 16 - Wide Dispersive Use in 'Down the Drain' cleaning and maintenance products (Consumers and Professionals)	AISE SPERC 8a.1.a.v1	ERC8a

Section 2 - Conditions of use affecting exposure

Characteristics of mixture - general		Qualitative endpoints relevant for chemical safety assessment			
		Irritation / corrosion	Sensitization	Acute toxicity	Carcinogenicity / mutagenicity
Physical state of mixture (at 20°C and 101.3 kPa)	liquid	Skin and eye corrosive	No	No	No
Classification of undiluted mixture: R-Phrases	R34				
Classification of undiluted mixture: H-Phrases	H314				

2.1 Control of workers exposure

Operational conditions

Temperature of process	Ambient (unless stated differently)
Frequency/duration of use	8-hours/day - 5 workdays/week (unless stated differently)
Indoor or outdoor	indoor (unless stated differently)

Contributing Scenario (task / activity)	% of mixture in handled product?	Risk Management Measures (RMM)
Transfer of professional cleaning or maintenance product (charging/discharging) to a cleaning equipment (machine/vessel/bucket)	100%	Use suitable eye protection and gloves. [If necessary, wear suitable working closthes]. [Handle all packages and containers carefully to minimise spills].
Brushing a diluted professional cleaning solution, desinfectant or maintenance product	<10%	If diluted less then 100 times (% of mixture >1%): use suitable eye protection and gloves. [f necessary, wear suitable working closthes]. [Clear spills immediately.]
Brushing a concentrated professional cleaning or maintenance product.	100%	Use suitable eye protection and gloves. [Clear spills immediately.]

2.2 Control of environmental exposure

Environmental release category	typical (sp)ERC value		Environmental control measures
AISE 16 - Wide Dispersive Use in 'Down the Drain' cleaning and maintenance products (Consumers and Professionals)	Fraction used at main source	0,00075	[Do not dispose waste into drains]. [Dispose of waste product or used containers according to local regulations.]
	Emission days per year	365	
	Municipal STP	yes	
	Release fraction to air	0	
	Release fraction to waste water	1	
	Release fraction to soil	0	
	River flow rate for dilution	18000 m^3/day	
	Type of *on site* Risk Management measures	-	
	Efficiency of *on site* Risk Management Measures	-	

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Generic Mixture Exposure Scenario (GMES) approach - example
Pro's, con's and issues (1)

Pro's	Con's
+ "Mixture ES format" enables alignment with mixture use data from any Sector specific DUCC Template + The stepwise GMES approach addresses not only the quantitative endpoints, but also the qualitative endpoints of the mixture. + "Mixture ES format" with step 1 & 2a & 2b are easy to understand, relatively simple to complete and automatable + The GMES approach provides a "ready to use" solution for a formulator with simple mixtures, clear mixture uses from one or more sectors and clear substance ES's	- The "top down" processing of substance ES's in step 3 may have many pitfalls and problems to solve. It requires good quality substance ES(s) and expertise to recognize that it are indeed good ES(s) to use. Not always clear! Issues that may pop-up are: a) RDS-ES is not covering the Mixture use; b) RDS-ES is not meeting the Mixture OC's (scaling required); c) RDS-ES may also contain good practice advice rather than risk based RMM's; d) More…? - Not all environmental endpoints / compartments are yet addressed (only aquatic fresh water).

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Generic Mixture Exposure Scenario (GMES) approach & example
Pro's, con's and issues (2)

Issues	Possible solutions / suggestions
1) The "top-down" processing of substance ES's for each RDS (RDS-ES) in order to identify the required mixture OC & RMM's might be problematic and is time consuming.	1) An alternative approach is to conduct a CSA (e.g. with a tier 1 tool) for each RDS. See follow-up slide
2) Is the proposed GMES approach automatable?	2) The GMES approach based on "top-down" processing of RDS-ES's is hard to automate. A GMES approach using RDS-CSA processing in alignment with the sector mixture uses ("bottom-up"), has a much higher potential to be automated.
3) When the development of the Mixture ES is determining the Mixture OC&RMM reliably on risk based principles (e.g. via RDS-CSA process), how to deal with the DU requirements to complete a use compliance check on the substance ES's?	3) When the Mixture ES is based on a risk based determination of the Mixture uses rather than on processing substance ES(s), a use compliance check to cover the mixture uses has no purpose. Can it be replaced by the risk based Mixture ES processing like suggested in REACH Art 31 (2)?

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Name of mixture	Sanitary Cleaner (test formulation ENES5)		
Section 1 – Title of Exposure Scenario (ES)			Sector code - ES
Title	Professional Use of General surface cleaning products		AISE-P305
Processes and activities covered	Contributing Scenario (CS)	Sector code - CS	Use descriptor code
	Transfer of professional cleaning or maintenance product (charging/discharging) to a cleaning equipment (machine/vessel/bucket)	AISE_CSP01	PROC8a
	Brushing a diluted professional cleaning solution, desinfectant or maintenance product	AISE_CSP08	PROC10
	Brushing a concentrated professional cleaning or maintenance product.	AISE_CSP10	PROC10
Sector of use	Professional uses: Public domain (administration, education, entertainment, services, craftsmen)	-	SU22
Environmental release category	AISE 16 - Wide Dispersive Use in 'Down the Drain' cleaning and maintenance products (Consumers and Professionals)	AISE SPERC 8a.1.a.v1	ERC8a

Section 2 - Conditions of use affecting exposure

Characteristics of mixture - general		Qualitative endpoints relevant for chemical safety assessment			
		Irritation / corrosion	**Sensitization**	**Acute toxicity**	**Carcinogenicity / mutagenicity**
Physical state of mixture (at 20°C and 101.3 kPa)	liquid	Skin and eye corrosive	No	No	No
Classification of undiluted mixture: R-Phrases	R34				
Classification of undiluted mixture: H-Phrases	H314				

2.1 Control of workers exposure

Operational conditions

Temperature of process	Ambient (unless stated differently)
Frequency/duration of use	8-hours/day - 5 workdays/week (unless stated differently)
Indoor or outdoor	indoor (unless stated differently)

Contributing Scenario (task / activity)	% of mixture in handled product?	Risk Management Measures (RMM)
Transfer of professional cleaning or maintenance product (charging/discharging) to a cleaning equipment (machine/vessel/bucket)	100%	Use suitable eye protection and gloves.
Brushing a diluted professional cleaning solution, desinfectant or maintenance product	<10%	If diluted less then 100 times (% of mixture >1%): use suitable eye protection and gloves.
Brushing a concentrated professional cleaning or maintenance product.	100%	Use suitable eye protection and gloves.

2.2 Control of environmental exposure

Environmental release category	typical (sp)ERC value		Environmental control measures
AISE 16 - Wide Dispersive Use in 'Down the Drain' cleaning and maintenance products (Consumers and Professionals)	Fraction used at main source	0,00075	[Prevent leaks and prevent soil / water pollution caused by leaks. Dispose of waste product or used containers according to local regulations.]
	Emission days per year	365	
	Municipal STP	yes	
	Release fraction to air	0	
	Release fraction to waste water	1	
	Release fraction to soil	0	
	River flow rate for dilution	18000 m^3/day	
	Type of *on site* Risk Management measures	-	
	Efficiency of on site Risk Management Measures	-	

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1. What are the general pro's / con's?

2. What is the applicability domain? Any limitations?

3. Any practical issue in the application (issues to solve)?

4. Required actions to make the GMES approach operational?

5. General conclusions / recommendation from the group

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Agenda

1. Introduction

2. Outline Generic Mixture Exposure Scenario Approach (GMES)

3. Critical Component Approach (CCA)
   – *Presentation CCA method -> CCA results for ENES Examples M1 & M2*
   – *Guided discussion CCA*

Coffee break

4. Development "Mixture ES" for the example "Sanitary cleaner"
   – *Presentation GMES method -> Mixture ES for ENES Example "Sanitary Cleaner"*
   – *Guided discussion GMES*

5. Wrap-up

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