

A practical way to generate and communicate safe use information for cleaning and maintenance products under REACH

Guidance for suppliers, formulators and end-users in the detergents and maintenance products supply chain.

IMPORTANT

The information provided in this Guidance aims at supporting suppliers of ingredients, formulators of detergent products and their end users and Occupational Health managers of institutional cleaning companies to comply with their duties under REACH.

The information provided in this document is intended for information purposes only. It has been gathered to the best of our knowledge and it may be subject to changes.

Compliance with REACH is an individual company responsibility and A.I.S.E. and NVZ assume no liability for any use made by any person or company having access to this information.

In case any user of this Guidance would identify any mistake that should be amended (s)he is invited to inform the A.I.S.E. Secretariat accordingly.

Table of contents

Contents

1. Introduction	2
1.1 Content of this guidance	2
1.2 How to read this Guidance	2
2. Legislative background	2
2.1 REACH	2
2.2 Occupational Health and Safety Legislation.....	3
3. Use Maps	4
3.1 Obligations for suppliers	4
3.2 A.I.S.E. Use Maps	5
3.2.1 Obligations for formulators	7
3.2.2 The bottom-up approach	8
3.2.3 A.I.S.E. SUMIs	9
Obligations for cleaning companies.....	18
Annex 1: Generic approach of Use Maps and uses not covered by A.I.S.E. Use Map using enzyme ingredients as an example	21
Annex 2: Additional background information.....	29
Use descriptor system	29
Phases of professional cleaning process.....	30
Annex 3: PROC's relevant for the Institutional cleaning sector.....	32
Annex 4: PROC Hierarchy	33

1. Introduction

1.1 Content of this guidance

This Guidance contains all necessary information to support, as much as possible, actors involved in the supply chain of detergent and maintenance products in their obligation to comply with REACH requirements and ensure safe use of products. Beyond a general overview of the legal background, the Guidance explains all the tools available to companies to generate and communicate safe use information. In particular, the Guidance describes the concepts and elements of the Use Maps package and its link to the SUMI package (Safe Use of Mixtures Information), with a focus on the practical use of these tools.

1.2 How to read this Guidance

This Guidance includes some introductory generic sections that can be of use to all the readers of this document, followed by more specific ones which are targeted at groups of professionals with specific roles in the supply chain. For more details on the sections included in this Guidance, please refer to the Table of Contents at the beginning of the document.

2. Legislative background

To ensure that detergent and maintenance products placed on the market can be safely manufactured and used, both by professionals and consumers, several pieces of legislation apply. This Guidance will focus on the prescriptions and practical implementation of two of them: the REACH Regulation (EC) No 1907/2006¹ and the Directive on Safety and Health at Work². The objective of both these legislations is to ensure protection of workers and users of cleaning and maintenance products as well as the environment.

In this background section, some basic concepts regarding the above mentioned legislations will be illustrated. Then, the following chapter 'legislation into practice' will provide an outline of the tools available to comply with the legislation, as well as how information generated under REACH can be used to comply with OSH (Occupational Safety & Health) legislation.

2.1 REACH

The REACH Regulation on the Registration, Evaluation, Authorisation and restriction of Chemicals entered into force in June 2007 and the aim is to increase the knowledge of potential risks of new and existing chemicals and manage these appropriately. Companies producing or importing chemical substances have the obligation under REACH to assess if these substances pose any risk to human health or to the environment. This is done via the Chemical Safety Assessment (CSA): a process assessing the conditions where a substance can be used safely throughout all its identified uses along the whole supply chain. This obligation also covers the uses of mixtures in which the substance is present (e.g. cleaning products), if the substance concentration is high enough to contribute to the classification of that mixture. The CSA is normally carried out by suppliers or importers of substances, which are registrants under REACH, but there are cases where formulators can carry out a CSA as Downstream Users.

REACH also regulates how the outcome of the CSA has to be communicated down the supply chain. If any risk is identified, this will have to be communicated along with the necessary measures required to protect human health and the environment. In fact, a supplier has to

¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410>

² <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01989L0391-20081211>

annex so-called Exposure Scenarios (ES) to the Safety Data Sheet. This is a document with information on how a substance can be used safely in all its identified uses and is related to the results of the CSA.

Formulators of mixtures (e.g. detergents, paints) do not have an obligation under REACH to compile an ES to attach to the SDS of their products. They do however have the obligation to evaluate the Exposure Scenarios of the individual substances in the mixture for the safe use of that mixture. The results of this evaluation (e.g. wearing gloves for certain uses of the product) have to be communicated down the supply chain, so that the end-user knows how to safely use the product.

The correct functioning of this process relies a lot also on upstream communication. This enables the registrant of a substance to know how it is used throughout the supply chain and, therefore, consider all the relevant uses in the CSA.

After the third and last REACH registration deadline on May 31st 2018, all substances produced or imported in the EU above 1 ton per year should have been registered and a CSA **including an exposure assessment with risk characterisation** should have been carried out for all those produced or imported above 10 tonnes per year that are classified or PBT/vPvB (*refer to REACH art 14(4)*).

Further details on the REACH process can be found on the ECHA dedicated webpages, which are also translated in several EU languages: [REACH 2018 in your language³](#).

2.2 Occupational Health and Safety Legislation

Although every European Member State has its own national Occupational Health Legislation, the basis is set out in the European Occupational Health & Safety Directives. The main principle of this legislation is that the employer is responsible for creating safe workplaces and making sure employees work safely. To achieve this, the employer has to know all possible risks linked to the work and how to take appropriate risk management measures to minimize these risks. *Note: National occupational health legislations may pose additional obligations than those described below.*

A cleaner/worker can be exposed to several risks during his work. While cleaning in an office building usually the main risk is posed by the cleaning product itself, which may for instance be irritating or corrosive to the skin or the eyes. While cleaning a hospital or slaughterhouse the cleaner is exposed to multiple other risks, mainly from the (usually unknown) substance(s) that need to be cleaned. While window-cleaning the additional risk can be a ladder on which the cleaner has to stand to do his work. Regardless of the type of risks, Risk Management Measures (RMM) need to be implemented to minimize the risks as much as possible.

The risks of working with hazardous substances or mixtures are quantified through the limit value(s) of a substance. A limit value is usually defined as a level to which it is believed a worker can be exposed day after day for a working lifetime without adverse health effects. After assessing how the cleaner/worker is exposed to a cleaning product (and thus to the substances in the mixture) during his/her work, safe use can be determined by comparing the

³ <https://echa.europa.eu/reach-2018/>

exposure to the limit value: when the exposure remains below the limit value, the use is safe and the risks are properly managed.

3. Use Maps

3.1 Obligations for suppliers

As earlier described in the “REACH” chapter, the registrant of the substance has to determine whether all the use scenarios of that substance throughout the supply chain are safe. Gathering such information from customers (often formulators) and the (professional and industrial) end-users has proven to be a difficult task due to the fact that supply chains can be very complex. When precise information on how products are used is missing, the CSA is carried out based on incomplete or unrealistic input and it results in ESs describing conditions that are not representative of the real market. To close this gap and ensure that registrants have this important information available, a network of experts (ENES, the Exchange Network on Exposure Scenarios⁴) has included the sector organisations in this part of the communication chain. In particular, this was done by analysing and standardising the descriptions of all known end-uses in each sector in the so-called **Use Map**⁵.

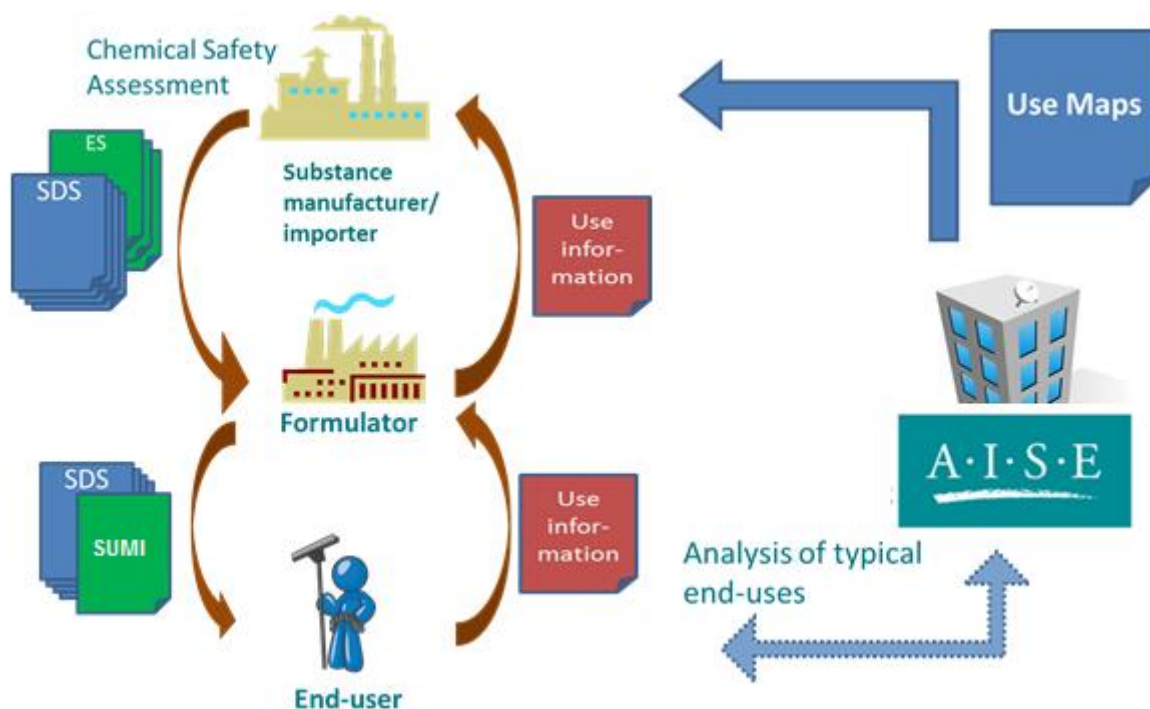


Figure 1: Phases and actors in the creation of Use Maps, SUMIs, ESs and SDSs

The Use Map describes the common uses in a sector, arranged by life cycle stage and in a harmonized language, i.e. using the ECHA use descriptor system (updated in Dec 2015) and, where possible, the ESCom standard phrases. Each use is described by a use name and some market information and it consists of a number of contributing activities which are also listed. The use maps are mainly intended for registrants as input for their CSA. An end-user

⁴ <https://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios>

⁵ https://www.aise.eu/documents/document/20171211163252-aise_letter_to_suppliers_use_maps_package_final.pdf

will probably not work directly with this format, except to verify the adequateness of the information received.

For each contributing activity, a code is provided to ensure a clear link with the corresponding exposure assessment input (SWED, SCED or SPERC). The input includes the conditions of use and risk management measures. The conditions and risk management measures can be shared with registrants directly by the sector association and should include results of a CSA for this contributing activity. See example below:

Use: Generic use within a sector, e.g. 'Widespread use by professional workers'
Contributing Activity: task that is part of that specific use, e.g. 'transfer', 'spraying', ...

USE					CONTRIBUTING ACTIVITY 1 FOR THAT USE			
USE					CONTRIBUTING ACTIVITY 2 FOR THAT USE			
Use identification and general description					Link activities to exposure assessment inputs			
Use code	Link to entry in previous use maps	Life Cycle Stage	Life Cycle Stage code	Use name	Contributing activity (CA) type	CA name	CA descriptor	Exposure assessment input code for this CA
AISE_PW_001_v1		Widespread use by professional workers	PW	Professional uses; Wash cleaning and disinfecting products	Workers	Transfer of professional product to a container (bottle/bucket/machine); medium RMM	PROC8a - Transfer of substance or mixture (charging and discharging) at non-dedicated facilities	AISE_SWED_PW_8a_1
					Workers	Transfer of professional product via a dedicated system (bottle/machine); no RMM	PROC8a - Transfer of substance or mixture (charging and discharging) at non-dedicated facilities	AISE_SWED_PW_8a_2
					Workers	Professional uses; Use in a closed process	PROC1 - Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.	AISE_SWED_PW_1_1

Figure 2: Example of Use and Contributing Activity for that use

Very useful guidance documents on the Use Maps template and concept, as well as for each of its components, have been developed. A.I.S.E. contributed to the preparation of this material together with many other cross-sector experts as the framework is applicable to all types of chemicals:

- Use Maps (Guidance [here](#))
- SCEDs (Guidance [here](#))
 SCEDs inform on conditions of use for substances in consumer products, e.g. the habits and practices of how consumers actually use the products.
- SPERCs (Guidance [here](#))
 SPERCs inform on operational conditions and risk management measures and the corresponding release factors to water, air, soil and waste.
- SWEDs (Guidance [here](#))
 SWEDs inform on operational conditions and risk management measures for activities by workers.

3.2 A.I.S.E. Use Maps

Since 2009, A.I.S.E. has been gathering information within its membership to identify all uses of a substance to ensure that the REACH risk assessment is appropriate and accurate. The analysis of the professional uses has been done through cooperation with an independent research organisation (Netherlands Organisation for Applied Scientific Research, TNO) and experts from several cleaning companies. It resulted initially in more than 150 different uses, which have been aggregated after a grouping exercise.

The improved A.I.S.E. use maps V1.1 were published at the end of 2017 and were incorporated to the template, discussed and agreed on, in the context of the CSR/ES

Roadmap. They cover industrial, professional and consumer (end) uses and are representative of a wide range of applications (> 80%) identified by A.I.S.E. members, regardless of the size of the company and of the specificity of the market. For the same activity, e.g. spraying of a product, the use maps could list the different combinations of Risk Management Measures and Operational Conditions that can occur on the market depending on several factors, e.g. CLP classification of the product. To make an efficient use of such information, registrants are encouraged to base their risk assessment on the less stringent conditions, e.g. in the absence of RMMs if it occurs. If safe use can be demonstrated under these conditions, also more rigorous conditions of use are considered covered. Differently, if safe use cannot be demonstrated, other stricter scenarios should be considered and communicated to the DUs accordingly via the ESs. In general, for the cleaning business it is advised to make use of the developed scenarios, mainly controlling risk by minimizing duration and concentration. Other options, such as including additional Personal Protective Equipment not covered by the received ESs, are not advised.

It is also important to consider that to ensure that the Use Maps are applicable to a vast majority of typical uses, in those cases where Personal Protective Equipment or Local Exhaust Ventilation is indicated, as well as any other RMM and OC, the minimum effectiveness value has been considered. This is to ensure that the conditions assessed by registrants are sufficiently conservative and are carried out in a worst-case approach.

In the case of LEV, the exact value of the effectiveness per PROC is included in the one used by the ECETOC TRA and indicated in the ECHA Excel Template of the Use Maps available in the ECHA Use Maps Library.

In the case of gloves the value of effectiveness considered is of 80%.

In those cases where a higher value of the effectiveness for the LEV or of the PPE is essential to ensure the safety of the cleaner/worker, the registrant shall carry out the CSA deviating from the conditions indicated in the A.I.S.E. Use Maps and shall communicate this clearly to its customer. In other words, if the conditions that shall be implemented to ensure the safe use of a product are more stringent than any of the combinations available in the A.I.S.E. Use Maps, the registrants shall not make reference to the A.I.S.E. SWEDs/SUMIs code in its SDS.

In case a more generic exemplification of assumptions that are made is needed, a description of a professional cleaning process has been included in Annex I.

Through the A.I.S.E. Use Mapping Table for professional uses, the supplier is able to assess how the cleaner/worker is exposed to the substance during the different use processes. He determines whether that use is safe for that substance by comparing the exposure to the defined limit value(s) (when an OEL exists), and establishing below which concentration of the substance a mixture (the cleaning product) is still safe. When the formulator remains below the established concentration of the OEL, and the cleaner/worker remains within the conditions of the SWED, it is proven that the use remains below the limit value(s) and is thus safe for use.

See beneath an overview of the uses covered in the A.I.S.E. Use Maps (**Table 1**) and a summary of the existing contributing activities foreseen for the industrial and professional uses (**Table 2**, included as a worksheet in the A.I.S.E. Use Maps Excel file).

Use code	Life Cycle Stage	Use name	Sectors of use (SU)	Product categories (PC)
AISE_IS_001_v1	Use at industrial sites	Industrial uses; Washing, cleaning and disinfecting products	SU1; SU2a; SU2b; SU4; SU5; SU6a; SU6b; SU7; SU8; SU9; SU11; SU12; SU13; SU14; SU15; SU16; SU17; SU18; SU19; SU20; SU23; SU24;	PC 35; PC8
AISE_IS_002_v1	Use at industrial sites	Industrial uses; Metal surface treatment products	SU17	PC14
AISE_F_001_v1	Formulation or re-packing	Formulation into mixture; Washing, cleaning, maintenance and disinfecting products		PC35; PC8; PC31; PC3
AISE_PW_001_v1	Widespread use by professional workers	Professional uses; Washing, cleaning and disinfecting products	SU1; SU2a; SU2b; SU4; SU5; SU6a; SU6b; SU7; SU8; SU9; SU11; SU12; SU13; SU14; SU15; SU16; SU17; SU18; SU19; SU20; SU23; SU24;	PC35; PC8;
AISE_PW_002_v1	Widespread use by professional workers	Professional uses; Polishes and wax blends	SU5; SU6a; SU18;	PC31
AISE_C_001_v1	Consumer use	Consumer uses; air care products		PC 3
AISE_C_002_v1	Consumer use	Consumer uses; washing and cleaning products		PC 35
AISE_C_003_v1	Consumer use	Consumer uses; polishes and wax blends		PC31
AISE_C_004_v1	Consumer use	Consumer uses; biocidal products		PC8

Table 1: Overview of the uses covered in the A.I.S.E. Use Maps

Relevant use descriptors				Exposure assessment inputs			
SWED	LCS	PROC	Duration per day (min)	Outdoor	LEV ?	Respiratory protection	Protection of hands (gloves)
AISE_SWED_PW_8a_1_L	PW	PROC8a	60	No	No	No	Yes
AISE_SWED_PW_8a_1_S	PW	PROC8a	60	No	No	No	Yes
AISE_SWED_PW_8a_2_L	PW	PROC8a	60	No	No	No	No
AISE_SWED_PW_8a_2_S	PW	PROC8a	60	No	No	No	No
AISE_SWED_PW_8b_1	PW	PROC8b	60	No	No	No	No
AISE_SWED_PW_8b_2	PW	PROC8b	60	No	No	No	Yes
AISE_SWED_PW_1_1	PW	PROC1	480	No	No	No	No
AISE_SWED_PW_3_1	PW	PROC3	480	No	No	No	No
AISE_SWED_PW_4_1	PW	PROC4	480	No	No	No	No
AISE_SWED_PW_11_1	PW	PROC11	60	No	No	No	No
AISE_SWED_PW_11_2	PW	PROC11	60	No	No	No	Yes
AISE_SWED_PW_11_3	PW	PROC11	480	No	No	No	Yes
AISE_SWED_PW_11_4	PW	PROC11	480	No	No	No	No
AISE_SWED_PW_10_1	PW	PROC10	480	No	No	No	No
AISE_SWED_PW_10_2	PW	PROC10	480	No	No	No	Yes
AISE_SWED_PW_19_1	PW	PROC19	480	No	No	No	No
AISE_SWED_PW_19_2	PW	PROC19	480	No	No	No	Yes
AISE_SWED_PW_13_1	PW	PROC13	60	No	No	No	Yes
AISE_SWED_PW_13_2	PW	PROC13	60	No	No	No	No
AISE_SWED_PW_13_3	PW	PROC13	15	No	No	No	Yes
AISE_SWED_IS_8b_1_L	IS	PROC8b	60	No	No	No	Yes
AISE_SWED_IS_8b_1_S	IS	PROC8b	60	No	No	No	Yes
AISE_SWED_IS_8b_2_L	IS	PROC8b	60	No	No	No	No
AISE_SWED_IS_8b_2_S	IS	PROC8b	60	No	No	No	No
AISE_SWED_IS_1_1	IS	PROC1	480	No	No	No	No
AISE_SWED_IS_2_1	IS	PROC2	480	No	No	No	No
AISE_SWED_IS_4_1	IS	PROC4	480	No	No	No	No
AISE_SWED_IS_4_2	IS	PROC4	480	No	No	No	Yes
AISE_SWED_IS_7_1	IS	PROC7	480	No	Yes	No	Yes
AISE_SWED_IS_7_2	IS	PROC7	240	No	No	Yes	Yes
AISE_SWED_IS_7_3	IS	PROC7	60	No	No	No	Yes
AISE_SWED_IS_7_4	IS	PROC7	480	No	No	No	Yes
AISE_SWED_IS_7_5	IS	PROC7	480	No	No	No	No
AISE_SWED_IS_10_1	IS	PROC10	480	No	No	No	Yes
AISE_SWED_IS_10_2	IS	PROC10	480	No	No	No	No
AISE_SWED_IS_13_1	IS	PROC13	480	No	Yes	No	Yes
AISE_SWED_IS_13_2	IS	PROC13	240	No	No	Yes	Yes
AISE_SWED_IS_13_3	IS	PROC13	480	No	No	No	Yes
AISE_SWED_IS_13_4	IS	PROC13	480	No	No	No	No
AISE_SWED_IS_28_1	IS	PROC28	60	No	No	No	Yes

Table 2: Summary of the existing contributing activities foreseen for the industrial and professional uses

3.2.1 Obligations for formulators

When a formulator receives an extended SDS (SDS + ESs) together with a registration number, this triggers new obligations under REACH. Formulators of mixtures have the obligation to analyse the information from the suppliers of their raw materials and adequately communicate them down the supply chain. In order to fulfil this REACH obligation, the formulator first determines which substances in the mixture may be relevant in the determination of what is considered safe use for this product. The CLP classification of the

substances in the mixture is a key aspect to lead this analysis, although other substances, that do not lead to classification of a mixture but still pose a risk, may also be relevant. If these have been incorporated in such a concentration in the mixture that they can be dangerous for a user, then the formulator is under the obligation to communicate the relevant safe use information to customers. Considering the safe use of the final product is responsibility of the formulator, considering all ingredients in the formulation. The same situation occurs when an end-user works with a dilution of a CLP-classified product. The formulator must take the specific conditions of use into considering the dilution proportions.

When it is obligatory for registrants to share the safe use information, this must be done in the form of an Exposure Scenario via an annex to the substance SDS. However REACH does not specify how formulators should communicate the safe use information for mixtures further downstream. This can be very confusing to the end-user, as there are different options available for a formulator to comply with this requirement. In fact, formulators can:

- i) append the ESs only of those substances contributing to the classification, or that may be relevant in the determination of what is considered safe use for this product;
- ii) integrate the ES information resulting from consolidation of various exposure scenarios for substances used in a mixture into the core Sections 1-16 of the SDS or
- iii) append safe use information for the mixture (SUMI) derived from the ES of the relevant component substances.

To ensure a harmonized and standardized way of communicating Safe Use Mixture Information, the Downstream Users of Chemicals Co-ordination Group (DUCC) developed the SUMI mentioned as option iii) above, which is a communication template to facilitate the information-flow downstream to the end-users⁶. Some DUCC sectors have then used this SUMI template to develop a set of SUMIs applicable to the products part of their members' portfolio. See more details on this 'bottom-up approach' in the next chapter.

3.2.2 The bottom-up approach⁷

The 'bottom-up' approach originated by DUCC has as a starting point, the information on the uses of the mixtures and includes two elements to assist formulators with communication: upstream communication of use conditions in the form of the Sector-specific Worker Exposure Descriptions (SWEDs) included in Use Maps, and SUMIs for downstream communication - both within the existing boundaries of REACH. SUMIs are therefore an integral part of this so-called bottom-up approach.

Tools developed by sector organisations, however, are a support to formulators and **do not replace the duty to verify the information received by supplier(s) and select the applicable instructions for safe use towards its end-users**.

In fact, the formulator shall check that all the substances in the product: a) are in such a concentration that they do not pose a risk to the person working with the mixture, or b) the substances can be safely used within the conditions of the relevant SWED. This check is performed for all SWEDs for which the product is suitable. The formulator then mentions all

⁶ http://www.ducc.eu/documents/How%20to%20use%20SUMIs_operational%20framework_18%2007%202017.pdf

⁷ How to use SUMIs – operational framework:

http://www.ducc.eu/documents/How%20to%20use%20SUMIs_operational%20framework_18%2007%202017.pdf

SWED codes for which he has done the assessment and determined that those uses are safe for all relevant dangerous substances in the product. The SUMIs linked to those assessed SWEDs can either be appended or integrated in the core sections of the SDS, with the SUMI codes cited in Section 1.2.

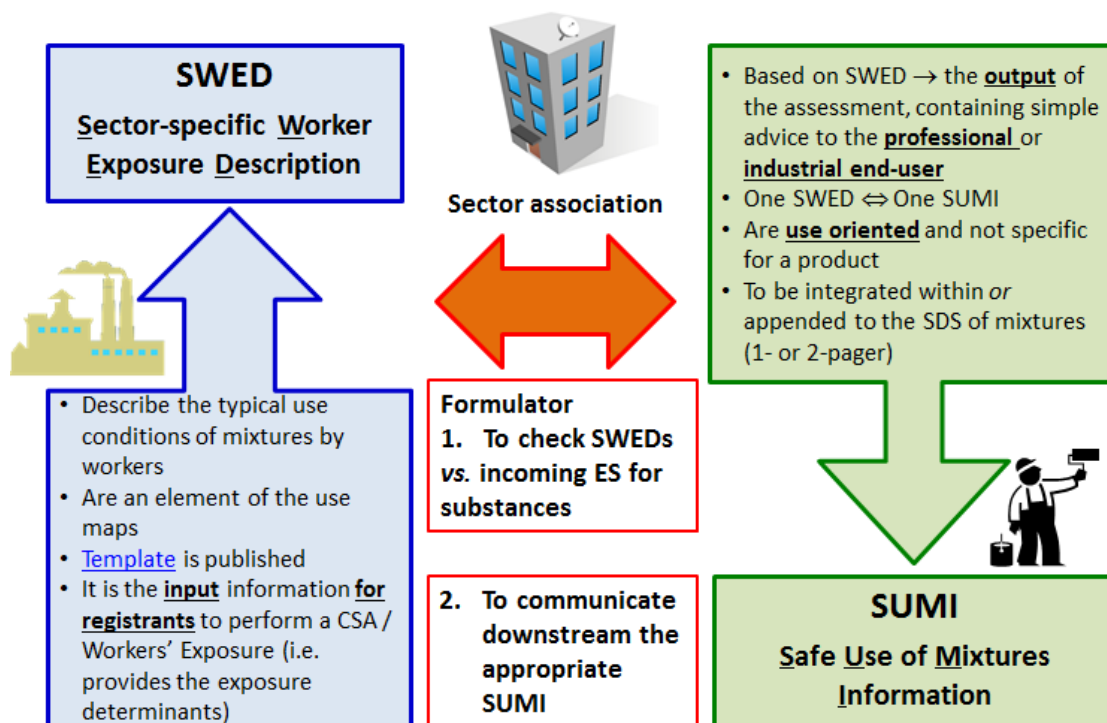


Figure 3: Depiction of the relationship between SUMIs and SWEDs

3.2.3 A.I.S.E. SUMIs

62 SUMI documents for end users have been developed for each standardized use of industrial (32) and professional (30) cleaning and maintenance products.

Although the SUMI cover > 80% of all uses in the institutional detergents industry, it may occur that certain specialized cleaning processes or certain products within an identified application are not covered. In these cases, the information from the SUMI is not sufficient to determine safe use of a cleaning product. This identified use must always be communicated upstream in the supply chain, so that the raw material supplier or the formulator can perform a safety assessment. The cleaning company itself is also allowed to perform a chemical safety assessment themselves. This may however be difficult as the required information to perform a proper assessment is not always available to the end user of a mixture: a formulator does not have the obligation to provide the exact concentration of the substances in the mixture, nor the properties of these ingredients. Additionally, a new obligation from the REACH Regulation will be applicable in most cases: notifying the European Chemicals Agency of the assessment.

Cleaning products which contain enzymes and are used to clean medical devices via ultrasonic baths are an example of such specialized cleaning processes. This is expanded further in Annex I below.

If formulators perform this assessment, they are recommended to clearly and specifically mention that this is a specialized use that does not fall under any of the standardized uses (SUMI), and furthermore communicate the necessary risk management measures that have to be taken to ensure safe use. When national associations or A.I.S.E. ascertain that this use is more widespread throughout the detergents industry, they will consider extending the Use Maps and – consequently – the SUMI, with a new standardized use and communicate this use to raw material suppliers as well.

In the exceptional cases of mixtures with no CLP classification, and therefore no legal obligation to determine safe use, there are several A.I.S.E. SUMIs that have no restrictions of use (i.e. can be applied for 8 hours a day without personal protective equipment or ventilation). These SUMIs can thus also be used in situations where a formulator is not legally required to forward information on safe use.

Every SUMI contains:

- A. A title explaining the type of use;
- B. Operational conditions, including maximum duration of the use;
- C. Risk management measures, including whether gloves and goggles have to be worn during use;
- D. Environmental measures;
- E. Good practice advice;
- F. The SWED code that the formulator used to check whether the SUMI covered in an Exposure Scenario of a substance;
- G. Properties of product composition; and
- H. Disclaimer

An example of a SUMI is provided in Figure 4 below.

SUMI

Safe Use of Mixtures Information



AISE_SUMI_PW_13_1_G

Version 1.1, August 2018

A. Professional uses - Treatment of articles by dipping, soaking or pouring

This document is intended to communicate the conditions of safe use for the product and should always be read in combination with the product's Safety Data Sheet and labels.



General description of the process covered

This SUMI applies to professional uses where articles are treated by dipping or pouring. This Safe Use Information is based on the AISE_SWED_PW_13_1. **F.**



B. Operational Conditions

Maximum duration	60 minutes per day.
Range of application / Process conditions	Indoor Use. Process carried out at room temperature. In case of dilution, tap water at a maximum temperature of 45°C is used.
Air exchange rate	Provide a basic standard of general ventilation (1 to 3 air changes per hour). No LEV required.

C. Risk Management Measures

Measures related to personal protective equipment (PPE), hygiene and health evaluation	Wear suitable gloves and eye protection. See section 8 of the SDS of this product for specifications.
	  Training of workers in relation to proper use and maintenance of PPEs must be ensured.
Environmental measures	Prevent that undiluted product reaches surface waters.
	If appropriate AISE SPERC 8a.1.a.v2 may apply: wide dispersive use resulting in release to municipal sewage treatment plant.

E. Additional good practice advice

<p>Don't eat or drink. Don't smoke. Don't use in proximity of open flame.</p>	
<p>Wash hands after use. Avoid contact with damaged skin. Do not mix with other products.</p>	
<p>Spillage instructions</p>	<p>Dilute with fresh water and mop up.</p>
<p>Hygiene practices</p>	<p>Follow the product instructions as specified on the label or in the product information sheet and use good occupational hygiene practices as specified in Section 7 of the product SDS.</p>

G. Additional information depending on product composition

The label and (when required) the Safety Data Sheet contain additional, product specific information crucial for working safely with mixtures. Please refer to the product label and SDS for information including, but not limited to: product hazard classification, potentially allergenic fragrances, notable ingredients and threshold limit values (when available).

H. Disclaimer

This is a document for communicating generic conditions of safe use of a product. It is the responsibility of the formulator to link this SUMI to the SDS of a specific product that he is selling.

If a SUMI (or associated SWED) code is mentioned in the SDS of a product, the formulator of that product declares that all substances in the mixture are present in such concentration, that the use of the product within the conditions of the SUMI is safe. When available, this safe use is ensured by evaluating the results of the chemical safety assessments as performed by the raw material suppliers. When no chemical safety assessment has been carried out by the supplier for an ingredient that contributes to the classification of the mixture, the formulator has performed a safety assessment himself.

Following Occupational Health legislation, the employer of workers that use products that are assessed as safe following SUMI conditions remains responsible for communicating relevant use information to employees. When developing workplace instructions for employees, SUMI Sheets should always be considered in combination with the SDS and the label of the product.

This document is provided by A.I.S.E. for general information purposes only. The formulator uses the content of this document at its sole risk.

A.I.S.E. disclaims any liability to any person or entity for any loss, damage no matter of what kind (actual, consequential, punitive or otherwise), injury, claim, liability or other cause of any kind or character based upon or resulting from the use (even partly) of the content of this document.

Figure 4: An example of a SUMI

As can be seen, a SUMI also contains information that can be found in all Safety Data Sheets of professional cleaning products. Where necessary a reference is made to the SDS of the product which has to be considered when creating workplace instructions.

Table 3 contains an overview of the 62 standard SUMIs stating its code, the title of use, an explanation on the type of exposure during that use and some examples of uses which are covered by that SUMI. Most important for end-users is the title, which states the type of use covered. It has to be noted that many SUMIs are grouped and their code is differentiated by a _G in the case the same activity is carried out with eye protection, i.e. Goggles. The detail on the eye protections required will be indicated in Section 8 of the SDS.

The uses with and without eye protection have not been differentiated, differently than those with protection of hands, because it is a qualitative element of the CSA and it cannot be used as input in a CSA carried out with TRA.

In addition, A.I.S.E. recommends for RPE efficiency to be declared as % efficiency. In the process of standardisation of the SWEDs, the value in the A.I.S.E. Use Maps is now communicated as (APF ≥ 10) where relevant. We recommend converting this to % efficiency to facilitate end users.

In case a more generic exemplification of how a professional cleaning process can be described using the R12 PROC system is needed, before looking at the detailed list of existing processes covered by the A.I.S.E. Use Maps & SUMI, please refer to Annex II.

Overview of the A.I.S.E. SUMI.

SWED code	SUMI code	Title	Explanation	Examples
AISE_SWED_PW_8a_1_L	AISE_SUMI_PW_8a_1	Transfer of product to a container (bottle/bucket/machine); Level II	The product is filled from large containers into a bottle, a bucket or a machine, without dedicated equipment and containment techniques in place. It is a short process. Protection of hands is in place.	Transferring a concentrated product to a bucket, flask or machine, whether or not in combination with diluting the product with water.
AISE_SWED_PW_8a_1_S				
AISE_SWED_PW_8a_2_L	AISE_SUMI_PW_8a_2	Transfer of product to a container (bottle/machine); Level I	The product is filled from large containers into a bottle, a bucket or a machine, without dedicated equipment and containment techniques in place. It is a short process. Protection of hands is NOT in place.	
AISE_SWED_PW_8a_2_S				
AISE_SWED_PW_8b_1	AISE_SUMI_PW_8b_1	Transfer of product via a dedicated system (bottle/bucket/machine); Level II	The product is filled from large containers into a bottle, a bucket or a machine, with dedicated equipment and containment techniques in place.	Automated dosing system for example for applications needing to avoid aerosolization of dust
AISE_SWED_PW_8b_2	AISE_SUMI_PW_8b_2	Transfer of product via a dedicated system (bottle/machine); Level I		
AISE_SWED_PW_1_1	AISE_SUMI_PW_1_1	Professional uses; use in closed process	Application of the product is highly automated. Cleaning in place	Washing machine (dish, laundry, other)

			within highly enclosed production equipment.	
AISE_SWED_PW_3_1	AISE_SUMI_PW_3_1	Professional uses; use in closed process;	Automated or semi-automated application of products in a closed process with occasional exposure. The cleaner may be exposed to vapors of the product.	Dishwasher (institutional are tunnels, non closed systems)
AISE_SWED_PW_4_1	AISE_SUMI_PW_4_1	Professional uses; Semi-closed system	Automated or semi-automated application of products in a semiclosed process.	Automatic all-surface cleaners
AISE_SWED_PW_11_1	AISE_SUMI_PW_11_1	Professional uses; (Trigger) spraying; Level I	Spraying application of product. A product is sprayed on a surface or cloth with low to medium pressure. Protection of hands is NOT in place.	Window cleaner
AISE_SWED_PW_11_2	AISE_SUMI_PW_11_2	Professional uses; (Trigger) spraying; Level II	Spraying application of product. A product is sprayed on a surface or cloth with low to medium pressure. Protection of hands is in place.	Window cleaner
AISE_SWED_PW_11_3	AISE_SUMI_PW_11_3	Professional uses; Spraying; Level II	Spraying application of product. Protection of hands is in place.	Window cleaner
AISE_SWED_PW_11_4	AISE_SUMI_PW_11_4	Professional uses; Spraying; Level I	Spraying application of product. Protection of hands is NOT in place.	Window cleaner
AISE_SWED_PW_10_1	AISE_SUMI_PW_10_1	Professional uses; Brushing after trigger spraying or brushing with tools; Level I	Brushing after trigger spraying or brushing with tools. Protection of hands is NOT in place.	All purpose cleaners Sanitary cleaners Floor stripper
AISE_SWED_PW_10_2	AISE_SUMI_PW_10_2	Professional uses; Brushing after trigger spraying or brushing with tools; Level II	Brushing after trigger spraying or brushing with tools. Protection of hands is in place.	
AISE_SWED_PW_19_1	AISE_SUMI_PW_19_1	Professional uses; Manual application; Level I	Manual application of product. Protection of hands is NOT in place.	All purpose cleaners

AISE_SWED_PW_19_2	AISE_SUMI_PW_19_2	Professional uses; Manual application; Level II	Manual application of product. Protection of hands is in place.	All purpose cleaners
AISE_SWED_PW_13_1	AISE_SUMI_PW_13_1	Professional uses; Treatment of articles by dipping, soaking or pouring; Level II	Treatment of articles by dipping or pouring.	- Toilet cleaners Bleaches
AISE_SWED_PW_13_2	AISE_SUMI_PW_13_2	Professional uses; Treatment of articles by dipping, soaking or pouring; Level I	Treatment of articles by dipping or pouring.	- Toilet cleaners Bleaches
AISE_SWED_PW_13_3	AISE_SUMI_PW_13_3	Professional uses; Treatment of articles by dipping, soaking or pouring; short-term; Level II	Treatment of articles by dipping or pouring.	Drain unblockers
AISE_SWED_IS_8b_1_L	AISE_SUMI_IS_8b_1	Transfer and dilution of concentrated product by using dedicated dosing system; Level II	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.	
AISE_SWED_IS_8b_1_S				
AISE_SWED_IS_8b_2_L	AISE_SUMI_IS_8b_2	Transfer and dilution of concentrated product by using dedicated dosing system; Level I	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.	
AISE_SWED_IS_8b_2_S				
AISE_SWED_IS_1_1	AISE_SUMI_IS_1_1	Industrial uses; use in closed process	Application of the product is highly automated.	Examples are process where strong hygiene requirements apply such as cleaning and disinfecting in food, beverage and pharmacos industries. Application of product in a closed continuous process.
AISE_SWED_IS_2_1	AISE_SUMI_IS_2_1	Industrial uses; use in closed process	Application of the product is highly automated in a closed continuous process.	
AISE_SWED_IS_4_1	AISE_SUMI_IS_4_1	Industrial uses; Automated task; Semi-automated task; Dedicated equipment; Level I	Automated or semi-automated application of products in a semiclosed process. Protection of hands is NOT in place.	Examples are the steps of product rinse in washing and disinfecting applications.
AISE_SWED_IS_4_2	AISE_SUMI_IS_4_2	Industrial uses; Automated task; Semi-automated task; Dedicated equipment; Level II	Automated or semi-automated application of products in a	Examples are the steps of product rinse in washing and disinfecting applications.

			semiclosed process. Protection of hands is in place.	
AISE_SWED_IS_7_1	AISE_SUMI_IS_7_1	Industrial spraying; Automated task; Open systems; Long term; Level IV (LEV)	The product is pumped and sprayed under low pressure with lances onto the surface. The spray application can be followed by a brushing wiping operation, where the residual dirt is removed with a brush or towel or similar tool. The application takes place in a dedicated area, e.g. spraying cabinet.	
AISE_SWED_IS_7_2	AISE_SUMI_IS_7_2	Industrial spraying; Automated task; Open system; Long term; Level III	The product is pumped and sprayed under low pressure with lances onto the surface. The spray application can be followed by a brushing wiping operation, where the residual dirt is removed with a brush or towel or similar tool.	
AISE_SWED_IS_7_3	AISE_SUMI_IS_7_3	Industrial spraying; Automated task; Open system; Short term; Level II	The product is pumped and sprayed under low pressure with lances onto the surface. The spray application can be followed by a brushing wiping operation, where the residual dirt is removed with a brush or towel or similar tool.	
AISE_SWED_IS_7_4	AISE_SUMI_IS_7_4	Industrial spraying; Automated task; Open system; Long term; Level II	The product is pumped and sprayed under low pressure with lances onto the surface. The spray application can be followed by a brushing wiping operation, where the residual dirt is removed with a brush or towel or similar tool.	
AISE_SWED_IS_7_5	AISE_SUMI_IS_7_5	Industrial spraying; Automated task; Open system; Long term; Level I	The product is pumped and sprayed under low pressure with	

			lances onto the surface. The spray application can be followed by a brushing wiping operation, where the residual dirt is removed with a brush or towel or similar tool.	
AISE_SWED_IS_10_1	AISE_SUMI_IS_10_1	Brushing; Automated task; Level II	The product is brushed on and wiped off surfaces in a defined open processes. Protection of hands is in place.	
AISE_SWED_IS_10_2	AISE_SUMI_IS_10_2	Brushing; Automated task; Level I	The product is brushed on and wiped off surfaces in a defined open processes. Protection of hands is NOT in place.	
AISE_SWED_IS_13_1	AISE_SUMI_IS_13_1	Industrial uses; Treatment of articles by dipping or pouring; Level IV (LEV)	Treatment of articles by dipping or pouring. The application takes place in a dedicated area.	
AISE_SWED_IS_13_2	AISE_SUMI_IS_13_2	Industrial uses; Treatment of articles by dipping or pouring; Level III	Treatment of articles by dipping or pouring. The product is used in a defined open processes.	
AISE_SWED_IS_13_3	AISE_SUMI_IS_13_3	Industrial uses; Treatment of articles by dipping or pouring; Level II	Treatment of articles by dipping or pouring. The product is used in a defined open processes.	
AISE_SWED_IS_13_4	AISE_SUMI_IS_13_4	Industrial uses; Treatment of articles by dipping or pouring; Level I	Treatment of articles by dipping or pouring. The product is used in a defined open processes.	
AISE_SWED_IS_28_1	AISE_SUMI_IS_28_1	Equipment maintenance;	Semi-automatic or manual maintenance of equipment. Application of product in a defined process.	

Table 3: Overview of the A.I.S.E. SUMI

A formulator may choose to append the SUMI for each code mentioned in the SDS of the product. Since all SUMIs are generic and standardized, it is also valid to send all SUMIs once to all customers. It is recommended to complement this information, ideally in table format, with the relevant assessment descriptors for that SUMI (i.e. SUMI code, PROC, duration, ventilation, RMM). The formulator has to ensure that the customers know what to do when

SUMI-codes are stated in the SDS. All English SUMIs and the user Guidance are available free of charge on the A.I.S.E. website: www.aise.eu. Translations of the SUMI documentation in the relevant languages of Member States can be found on the website of the local national association for detergents, if and when that association has translated the documentation. The following languages are provided as of the publishing of this guidance, although some national associations have only provided this for their members: Dutch, Finnish, French, German, Italian, Spanish, Swedish, Portuguese.

Regardless of the method of communicating this information, SUMI provides a standardized and simplified way of providing the conditions of safe use of a product. When a cleaning company adheres to these conditions, they can be assured that the cleaner/worker safely uses the product.

Obligations for cleaning companies

As indicated in Chapter 2.2, an employer has to ensure that the employees are not exposed to risks. To do so, the information made available to the employer as the result of the REACH process can be used.

Step-by-step: From SUMI & SDS to workplace instructions

NOTE: This stepwise approach is based on the Dutch Occupational Health Legislation. The Occupational Health Legislations of other EU Member States may pose additional obligations that influence this stepwise approach.

Step 1: Catalogue the possible exposures due to use methods and workplace setting

Before an employer can ask an employee to work with a chemical product, the risks of the use process and the workplace need to be assessed. This assessment will determine how the employee will be exposed to the product. With regards to the use processes, it is important to determine how the work will be carried out: by hand, using a machine, by spraying or brushing, etc.

The workplace also needs to be defined: is the work performed outdoors or indoors? If indoors, are there any possibilities for ventilation of the room? Are there any special facilities present, for instance an emergency shower or local exhaust ventilation?

In case of professional cleaning products it is also necessary to assess the risks of the workplace: does the cleaner need special equipment (e.g. a ladder)? Are there any risks related to the surrounding objects or that which has to be cleaned?

Step 2: Determine if the product should be used for the intended application

After mapping the potential exposures through the use process and the workplace, you need to determine whether the product can be used safely in the desired application. To determine this, you need the SDS of the product. In Section 1.2 of the SDS the supplier has provided a list of recommended or advised against uses.

If your use is advised against, the product cannot be used for the intended application, and you have to search for a different product or use the product in a different way. In cases when

the formulator has mentioned SUMI codes under 'recommended uses' Table 3, this guidance can be used to check whether the intended application falls within a SUMI.

Step 3: Collect product- and use information

For each of the SUMI-codes mentioned in Section 1.2 that are suitable for the intended application, collect the relevant SUMI documents. If the documents are not attached to the SDS of the product, you can find them on the website of your national association.

The following use conditions are unique to each SUMI code:

- The type of use (see Table 3)
- The duration of use
- The use of gloves and goggles

In addition, the following use conditions are common for all existing SUMI⁸:

- Process is carried out at room temperature.
- In case of dilution, tap water at a maximum temperature of 45 degrees Celsius is used.
- When PPE are prescribed: training of the worker in relation to proper use and maintenance of the PPE must be ensured.
- Follow general good practice advice.
- Prevent that the undiluted product reaches surface waters.

The information in a SUMI is specific for the use process, but not the product. You will therefore need the following information from the SDS of the product:

- From Section 2 or the label of the product: the hazard classification of the (undiluted product)
- From Section 7: Additional good practice advice, if not included in the SUMI
- From Section 8: the type of gloves and goggles (if prescribed by the SUMI)
- From Section 15: whether the product contains sensitizing ingredients that may cause an allergic reaction. It should be noted that the information on sensitizing ingredients is sometimes found in other sections of the SDS⁹).

Step 4 Transport and storage of the product

Information on the safe transport and storage of the product can also be found in the SDS. As this information is only applicable when handling large amounts of chemicals, it has to be determined if and when this applies.

In Section 7 of the product, advice is given on safe storage conditions. This includes information on which products or substance may not be stored together, or necessary technical measures for the storage room.

⁸ As mentioned above, specialized cleaning procedures might require a specific SUMI that deviate from these generic conditions.

⁹ Information on sensitizing ingredients are sometimes found in sections 2 or 3 of a MSDS. REACH regulation requires mentioning only if specific concentration thresholds are exceeded. However, for products that are covered by the Detergent regulation, a selection of ingredients prone to sensitizing properties has to be mentioned regardless of their concentration, i.e. enzymes and preservatives.

In Section 14 of the SDS essential information can be found on the classification of the product for any type of transport. When no information is available, or when this information is not relevant, this will be mentioned here.

Step 5 Information on what to do in cases of emergencies or accidents

Section 4 of the SDS contains information on what to do when the product is inhaled, ingested, or comes into contact with skin or eyes. If special facilities are needed in these cases, like eyewash or emergency showers, these need to be available close to the workplace. If applicable, emergency telephone numbers need to be known to the employees.

Section 5 of the SDS contains information on what to do if the product catches fire or when the product is close to a fire. This is only applicable for situations with large amounts of products. Information on suitable and unsuitable extinguishing agents is included in this section. Where large amounts of product are stored, suitable extinguishing agents need to be present.

Section 6 of the SDS contains information on what to do when the product is accidentally released, including personal and environmental precautions, protective equipment, emergency procedures and methods and materials for containment and clean-up.

Step 6 Create workplace instructions for the product

In the previous 5 steps all risks of the product and the workplace have been collected, and management measures and procedures have been determined to be able to work safely. Conditions to work safely with the product are found in the SUMI for each individual use process. Additional risks and mitigation measures of the workplace need to be determined by the employer.

It is important to verify that employees are well informed and understand the appropriate procedures and use conditions. An appropriate way of communicating this information is through a Workplace Instruction Card (WIC). When creating a WIC, make sure the employee can answer the following questions on basis of the information in the WIC:

1. What is the product name of the product I will be using?
2. What are the risks of the product?
3. How can I prevent or minimize the exposure to these risks?
4. Which personal protection equipment do I need?
5. What should I do in cases of emergency? Who is the First Aid contact person?
6. What should I do when the product is accidentally spilled?
7. How should I store the product?
8. What should I do in case of a fire? Is there an emergency procedure I need to follow?
If I work with a machine, how do I handle it in cases of emergency?
9. Who should I call in cases of accidents, emergencies or a fire?
10. Do I have a recent version of this WIC?
11. Where can I find additional information?

Annex I: Generic approach of Use Maps and uses not covered by A.I.S.E. Use Map using enzyme ingredients as an example

As delineated in section 3.2.3, although the A.I.S.E. SUMIs cover > 80% of all uses in the institutional and industrial detergents industry, it may occur that certain specialized cleaning processes or certain products are not covered. In these cases, the information from the existing set of A.I.S.E. SUMIs may not sufficient to determine safe use of a cleaning product.

Cleaning products which contain enzymes and are used to clean medical devices via ultrasonic baths are an example of such specialized cleaning processes. The example below outlines the information to go through the supply chain, using the information from the use maps, by taking enzymes as an example.

REGISTRANT TO FORMULATOR

The use maps act as information for a registrant on the practical application of an ingredient on the market. To use the A.I.S.E. Use Maps a registrant would need for each PROC to find the highest concentration at which the OC/RMMs mentioned in the SWED are still safe.

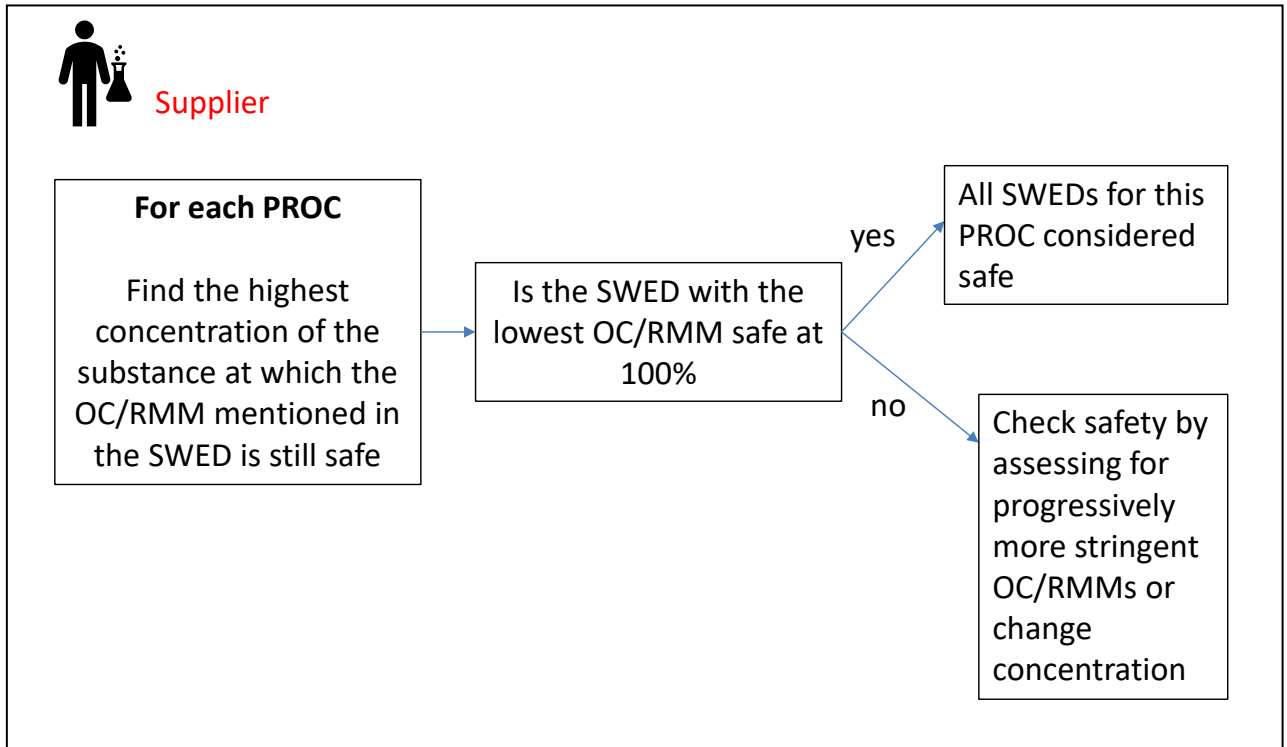


Figure 5: Registrant Use of the A.I.S.E. Use Maps

A formulator can expect results to be cited in a similar way to the information in Table 1: e.g. for AISE_SWED_XX with PROC XX and RMM conditions XX and XX the substance is safe below X%.

Additional notes:

- If the SWED is not safe, then it would preferably communicated as not safe. It helps formulators to be able to distinguish if a SWED was not assessed, versus cases where it was assessed and considered not to be safe.
- Also, registrants do not need to go to 100%. If the substance is not safe for 100% then the value at which it is safe should be cited.
- Finally, citing ranges such as 0.25-1% is strange, as in this case anything <1% will also be safe. Citing data as such make more sense: <X% (e.g. <25%).

Example of the presentation of data in the figures below:

SWED_PW11 Professional uses; (Trigger) spraying: Not advised uses need to be submitted outside the CSA in the REACH submission and these not advised uses need to be listed in section 1 of the SDS.

SWED 8a_PW_1 in Exposure Scenario

Title: Transfer of product to a container
Control of workers exposure for PROC 8a
Safe use concentration of the substance: < X%
Duration and use of exposure Operation carried our for 60 min/day
Other operational conditions affecting worker exposure Good general ventilation at workplace assumed. Indoor use assumed
Conditions and measures related to personal protection, hygiene and health evaluation Wear nitrile rubber, chloroprene rubber, butyl rubber or other suitable gloves, complying Appendix 2 44 with requirements of the EN 374 with the breakthrough time of 480 min. Effectiveness ≥ 90% Training in relation to use and maintenance of the PPE must be provided to ensure required effectiveness of protection.
Additional good practice advice beyond the REACH CSA Use good occupational hygiene practices

Based on the information received the formulator would be able to understand the rapport between the concentration of the ingredient and the risk management measures that need to be applied.

It is the responsibility of the formulator to remain below the concentrations mentioned in the ES and forward relevant information by attaching or referring to the relevant SUMIs.

PROFESSIONAL USER TASKS

An employer has to ensure that the employees are not exposed to risks. To do so, the information made available to the employer as the result of the REACH process can be used.

The employer will receive SUMI documents with accompanying SDS and must use the information to create workplace instructions.

For each application to be following by the employee, the person writing the workplace instructions must assess the data and carry out a risk assessment.

If for example:

The employer is writing workplace instructions for a professional cleaner using a dishwashing product.

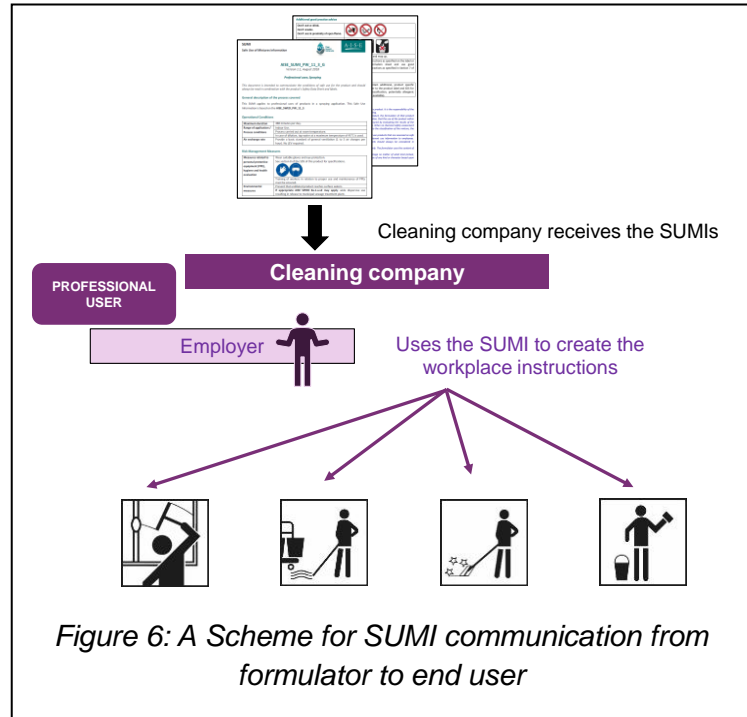


Figure 6: A Scheme for SUMI communication from formulator to end user

- Assess which uses the manufacturer of the cleaning product has foreseen (see Section 1.2 of the SDS) and determine which of these will be applied by the worker.

E.g.

Transfer of substance or mixture, charging and discharging at dedicated facilities PW_8b_2

Title: Transfer of substance or mixture, charging and discharging at dedicated facilities
Control of workers exposure for PROC 8b
Safe use concentration of the substance: < X%
Duration and use of exposure Operation carried out for 60 min/day
Other operational conditions affecting worker exposure Good general ventilation at workplace assumed. Indoor use assumed
Conditions and measures related to personal protection, hygiene and health evaluation
Additional good practice advice beyond the REACH CSA Use good occupational hygiene practices

Professional uses; Closed system PW_3_1

Title: Professional uses; use in closed process
Control of workers exposure for PROC 3
Safe use concentration of the substance: < X%
Duration and use of exposure Operation carried out for 480 min/day
Other operational conditions affecting worker exposure Good general ventilation at workplace assumed. Indoor use assumed
Conditions and measures related to personal protection, hygiene and health evaluation
Additional good practice advice beyond the REACH CSA Use good occupational hygiene practices

- For each use application relevant for the worker, collect the related SUMI documents

E.g.

SUMI_PW_8b_2

SUMI_PW_3_1

- Check which operational conditions and risk management measures are relevant for safe use of the product (type of use, duration, ventilation, use of personal protective equipment, etc.)

USE	Duration per day (min)	Outdoor	LEV?	Respiratory Protection	Protection of hands (gloves)	Goggles
Transfer of substance or mixture, charging and discharging at dedicated facilities	60	No	No	No	No	No
Professional uses; Closed system	480	No	No	No	No	No

Table 4: Summary for OC and RMMs for identified uses

- Ensure that the operational conditions are applicable for the location where the product will be used (e.g. an office building).
- Ensure that the correct personal protective equipment is given to the worker (see section 8 of the SDS for specifications (e.g. material) of personal protective equipment).
- Check which other information is relevant for the worker, e.g. on transport and storage (Section 7 and 14 of the SDS) and regarding first aid/accidents (Sections 4, 5 and 6 of the SDS)
- Consider which other workplace instructions following OSH legislation are relevant for the worker

FORMULATOR TASKS

Based on the information received from registrants of the ingredients, a formulator can determine the SUMIs that are applicable for the specific product. Firstly, they determine the foreseen activities (PROCs) with the product by the end user. The Exposure Scenarios of the relevant substances (see chapter x.x.x.) should be checked for the safety assessment results for each of these foreseen activities. The formulator can now identify the Risk Management Measures required. With this information the specific SWED of the relevant PROCs can be determined, since each contributing activity mapped out in the SWEDs, the SWED codes will have different levels. The levels are associated to different RMMs.

After the relevant SWEDs have been determined for each relevant ingredient in the mixture, the formulator can identify the SWEDs for the full formulation – i.e. the most conservative SWED to ensure safe use considering the information of all the ingredients in the formulation.

Finally, the formulator can determine which SUMIs are relevant for the final product. To achieve this, the formulator needs the list of relevant SWEDs determined in the previous step, as well as the CLP classification regarding eye damage of the mixture (and, where relevant, the CLP classification of a dilution of the mixture). The latter is necessary to determine whether goggles are required for the relevant uses of the product. When the relevant SUMIs have been determined, the formulator can now forward the relevant SUMIs to his customers via the SDS.

If there's additional information relevant for the end user that is not mentioned in the SUMI, this information could be included in the SDS or in the product information sheet (e.g. do not aerosolise/spray the product). Product specific elements should be mentioned in product specific documentation (SDS/label/other product information), not in generic documentation such as the SUMI.

APPLICATION NOT COVERED BY THE STANDARD SUMI – ENZYME INGREDIENT FOR MEDICAL DEVICE CLEANING AS EXAMPLE

Although the SUMI cover > 80% of all uses in the institutional detergents industry, it may occur that certain specialized cleaning processes or certain products within an identified application are not covered. An example is the cleaning of medical devices using an ultrasonic bath. These are applications can result in aerosolization of enzymes due to ultrasonic bath if the system is left open. This may lead to additional RMMs and stricter OC as compared to the the existing set of SUMIs. In this case the generic SUMI approach will not be sufficient to forward relevant safe use information to the end user. To be more precise, for use of enzyme products in application of ultrasonic cleaning, the device must be closed during operation. It is e.g. also required to insert a lag time after cessation of the ultrasonic treatment (approx. 5 min.) before opening the device.

For such specific uses specified OC or RMM need to be recommended. This should be either based on the specific information from the Exposure Scenarios from the enzyme manufacturer, or (if the manufacturer did not include the foreseen use in his assessment) the formulator can decide to do his own assessment (DU CSA).

The final set of OC/RMM for this specialized product can then be conveyed via a company specific SUMI that can be made product specific and thus be edited to contain any extra information. In Figure 7, the example of such a specific SUMI for medical device cleaning is presented.

SUMI

Safe Use of Mixtures Information

COMPANY

LOGO

Professional use; Cleaning of medical devices

This document is intended to communicate the conditions of safe use for the product and should always be read in combination with the product’s Safety Data Sheet and labels.

General description of the process covered


This SUMI applies to professional uses where enzyme containing detergents are used in medical device cleaning. Covers the transfer of product, cleaning by hand, and cleaning in an ultrasonic bath.

Operational Conditions

Maximum duration	480 minutes per day.
Physical form	Liquid or encapsulated low dust granules.
Range of application / Process conditions	Indoor Use. Process carried out elevated temperatures (60°C-70°C)
Air exchange rate	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

Risk Management Measures

Technical and organisational conditions and measures	Supervision in place to check that the risk management measures in place are being used correctly and operation conditions followed.
	Clear spills immediately: Clean with a vacuum cleaner equipped with a HEPA filter or Flush carefully with plenty of water. Avoid splashing.
	In an ultra-sonic bath: Process contained with a loose lid or cover, not airtight. The enclosure is not opened during the activity. The lid must be kept on for additional 5 minutes after the ultra-sonic treatment is completed.
	Ensure staff are informed of and trained on the nature of exposure and basic actions to minimise exposure.
	Ensure regular inspection, cleaning and maintenance of equipment and machines.
	Ensure daily cleaning of the equipment.
Conditions and measures related to	Wear suitable gloves tested to EN374. For further specification, refer to section 8 of the SDS.

personal protection, hygiene and health evaluation	
	Wash off any skin contamination immediately. If irritation develops and persists, get medical attention.
	Consider the need for risk based health surveillance.
Environmental measures	Prevent that undiluted product reaches surface waters.
	If appropriate AISE SPERC 8a.1.a.v3 may apply: wide dispersive use resulting in release to municipal sewage treatment plant.

Additional good practice advice

<p>Don't eat or drink. Don't smoke. Don't use in proximity of open flame. Don't spray product.</p>	
<p>Wash hands after use. Avoid contact with damaged skin. Do not mix with other products.</p>	
Hygiene practices	Follow the product instructions as specified on the label or in the product information sheet and use good occupational hygiene practices as specified in Section 7 of the product SDS.

Additional information depending on product composition

For more information visit: https://amfep.org/_library/_files/amfep-guidance-safety-in-the-use-of-enzyme-containing-reagents-for-medical-device-cleaning.pdf
The label and (when required) the Safety Data Sheet contain additional, product specific information crucial for working safely with mixtures. Please refer to the product label and SDS for information including, but not limited to: product hazard classification, potentially allergenic fragrances, notable ingredients and threshold limit values (when available).

Figure 7: Example of a Company Specific SUMI for a product which is not covered by A.I.S.E. SUMI

Please note that the SUMI is focusing on the enzyme component. A company must also consider if any other ingredient requires other additional OC/RMM. In this example, gloves have been included as a requirement, this may be due to other ingredients in the formulation or may be dependent on the enzyme class being used.

Annex 2: Additional background information

Use descriptor system

A very important aspect of communicating uses in the supply chain is the mapping of uses of products within a market sector. To support this mapping procedure, the European Chemicals Agency (ECHA) has developed the use descriptor system¹⁰. The use descriptor system is based on five separate descriptor-lists which combined, form a brief description of use:

- The sector of use category (SU) describes in which sector the substance is used. This includes mixing or re-packing of substances at formulator's level as well as industrial, professional and consumer end-uses.
- The chemical product category (PC) describes in which types of chemical products the substance (found as a substance or in a mixture) is finally contained when it is supplied to end-uses (by industrial, professional or consumer users).
- The process category (PROC) describes the application techniques or process types defined from the occupational perspective (see Annex II for an overview of relevant PROCs).
- The environmental release category (ERC) describes the broad conditions of use from the environmental perspective.
- The article category (AC) describes the type of article into which the substance has eventually been processed. This also includes mixtures in their dried or cured form (e.g. dried printing ink in newspapers; dried coatings on various surfaces).

For the detergents and maintenance products industry, the European association of this sector (A.I.S.E.) has further elaborated this system. All industrial, professional and consumer uses of products in the detergents sector were analysed and evaluated following the use descriptors as mentioned above. More specific ERCs (SpERCs) were formulated to better suit the environmental release situation for these products.

¹⁰ Guidance on information requirements and chemical safety assessment. Chapter R.12: Use descriptor system (Version 3.0, December 2015)

Phases of professional cleaning process

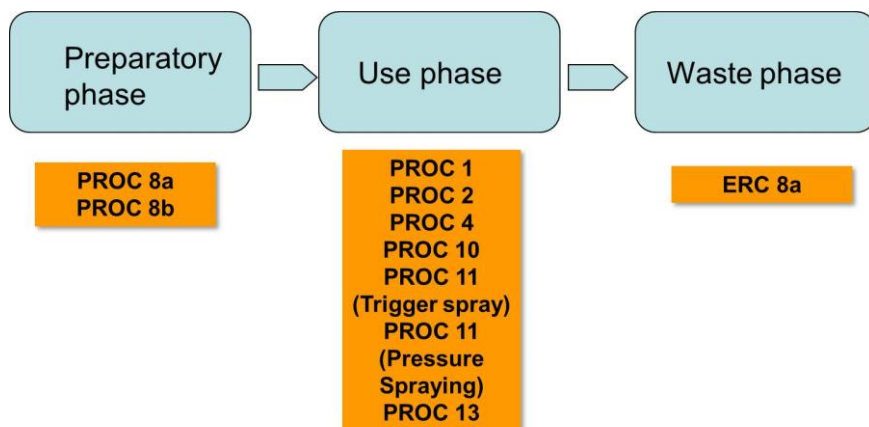


Figure 8: phases of a typical professional cleaning process

Figure 8 shows the three phases for a typical cleaning process. First there is the preparatory phase in which the product is transferred in for instance a machine, bucket, or cleaning equipment. In this phase it is important to note that the undiluted product is used. Process categories of this phase include PROC 8a and 8b. Often, the product is strongly diluted during the preparatory phase for the use phase.

In the use phase the (mostly diluted) products are used to clean; for instance to spray the product on a surface and brushing it with a cloth. During the use phase, several PROCs can be applicable (for more details regarding the PROC definition see Annex I). Since the product in this phase is often strongly diluted, the risk management measures as communicated in the SDS of the product have changed. A mixture that is classified as irritant will generally lose that classification once it is diluted. Personal Protection Equipment (PPE) prescribed in the SDS for the undiluted product can thus be irrelevant for the use phase.

When a cleaner/worker is at work, he is not constantly performing the same operation during the workday. The maximum duration of a PROC per phase, during a full 8 hour shift is described in the overview Table 2 of A.I.S.E. SWEDs. Preparing the product for the use phase, like dilution, usually takes only a few minutes – not longer than a total of 50 minutes per day. The actual spraying in PROC 11 (Trigger or high pressure spraying) of a cleaning product only takes up to 50 minutes per day as well; other processes, i.e. PROCs may be performed up to 8 hours.

Cleaning is usually performed indoors. Often, no active ventilation (Local Exhaust Ventilation, LEV) is present where the cleaning operations are performed (buildings, public places, etc). Ventilation as may be prescribed in the SDS of a cleaning product may include opening a door or window, which leads to a natural renewal of the air (in general 50%). This ventilation of the work space is a way to reduce the cleaning product exposure for the cleaner. Other exposure-reducing methods can be found in personal protection equipment, for instance: gloves, safety goggles or respiratory masks. These methods are generally only used in the preparation phase or PROCs in which the undiluted product is used. The possible RMMs per phase are shown in Figure 6.

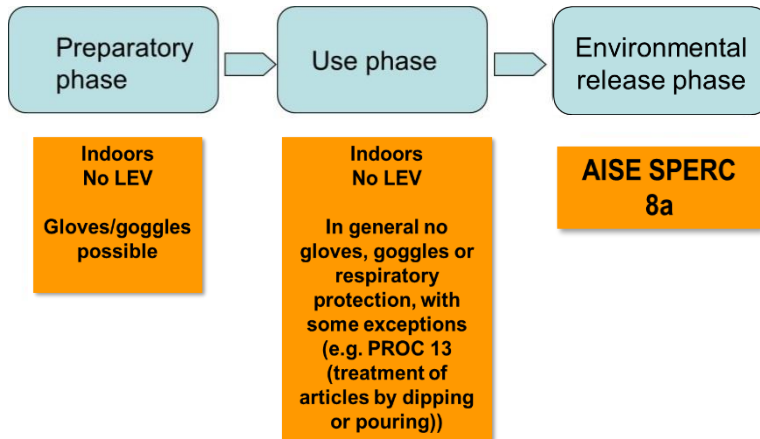


Figure 9: Possible Risk Management Measures in each phase.

The SWEDs for professional (institutional) uses are the result of combining carefully assessed operational conditions.

To determine daily exposure of cleaners/workers to cleaning products, it is important to know how long they generally perform these scenarios in a normal working day and which RMMs are taken. The general conditions in each scenario were carefully assessed by the A.I.S.E. expert team.

The combination of this data forms the foundation of the A.I.S.E. Use Mapping Table for professional use¹¹.

<https://echa.europa.eu/fr/csr-es-roadmap/use-maps/use-maps-library>

Annex 3: PROC's relevant for the Institutional cleaning sector

The following PROCs from the full list indicated in the [ECHA R12 Guidance](#) is of relevance:

	Process category	Examples and explanations
PROC 1	Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions	Use of the substances in high integrity contained system where little potential exists for exposures, e.g. any sampling via closed loop systems.
PROC 2	Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions. It is not high integrity and occasional exposure will arise e.g. through maintenance, sampling and equipment breakages.
PROC 3	Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition	
PROC 4	Chemical production where opportunity for exposure arises	Use in batch manufacture of a chemical where significant opportunity for exposure arises, e.g. during charging, sampling or discharge of material, and when the nature of the design is likely to result in exposure.
PROC 7	Industrial spraying	
PROC 8a	Transfer of substance or mixture (charging and discharging) at nondedicated facilities	Sampling, loading, filling, transfer, dumping, bagging in non- dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.
PROC 8b	Transfer of substance or mixture (charging and discharging) at dedicated facilities	Sampling, loading, filling, transfer, dumping, bagging in dedicated facilities. Exposure related to dust, vapour, aerosols or spillage, and cleaning of equipment to be expected.
PROC 10	Roller application or brushing	Low energy spreading of e.g. coatings. Including cleaning of surfaces. Substance can be inhaled as vapours, skin contact can occur through droplets, splashes, working with wipes and handling of treated surfaces.
PROC 11	Non industrial spraying	Air dispersive techniques. Spraying for surface coating, adhesives, polishes/cleaners, air care products, sandblasting. Substances can be inhaled as aerosols. The energy of the aerosol particles may require advanced exposure controls.
PROC 13	Treatment of articles by dipping and pouring	Immersion operations. Treatment of articles by dipping, pouring, immersing, soaking, washing out or washing

		in substances; including cold formation or resin type matrix. Includes handling of treated objects (e.g. after dyeing, plating,). Substance is applied to a surface by low energy techniques such as dipping the article into a bath or pouring a preparation onto a surface.
PROC19	Manual activities involving hand contact	
PROC28	Manual maintenance (cleaning and repair) of machinery	

Table 5: PROCs from the full list indicated in the ECHA R12 Guidance

Annex 4: PROC Hierarchy

When ECETOC TRA is used, the PROC hierarchy system can be applied. Since TRA contains specific exposure defaults for each PROC, a hierarchical system of sets of PROCs in which the exposure is similar was defined. The European Chemical Federation (Cefic) has further explained this hierarchy approach in a guidance on communication with extended SDSs¹².

The idea of the PROC hierarchy is to show that if a given PROC is safe for a given set of conditions another PROC is also safe for the same set of conditions. The hierarchical relationship between PROCs is only valid where the same set of conditions apply (e.g. industrial/professional setting, duration of activity, type of ventilation, concentration in mixture, fugacity/dustiness, whether respiratory protective equipment is required or not etc.). The PROC hierarchy is a tool to help downstream users verify their uses are covered in the substance Exposure Scenario (ES), even though a specific PROC may not be listed in the ES.

The figure below schematically shows three groups of PROCs with similar exposure.

¹² Cefic-DUCC-FECC-Concawe: Messages to communicate in the supply chain on extended SDS for substances II (Final version 13 July 2011) Available at: http://www.cefic.org/Documents/IndustrySupport/Cefic%20communication%20on%20extSDS_130711.pdf (Accessed 30-04-2014)

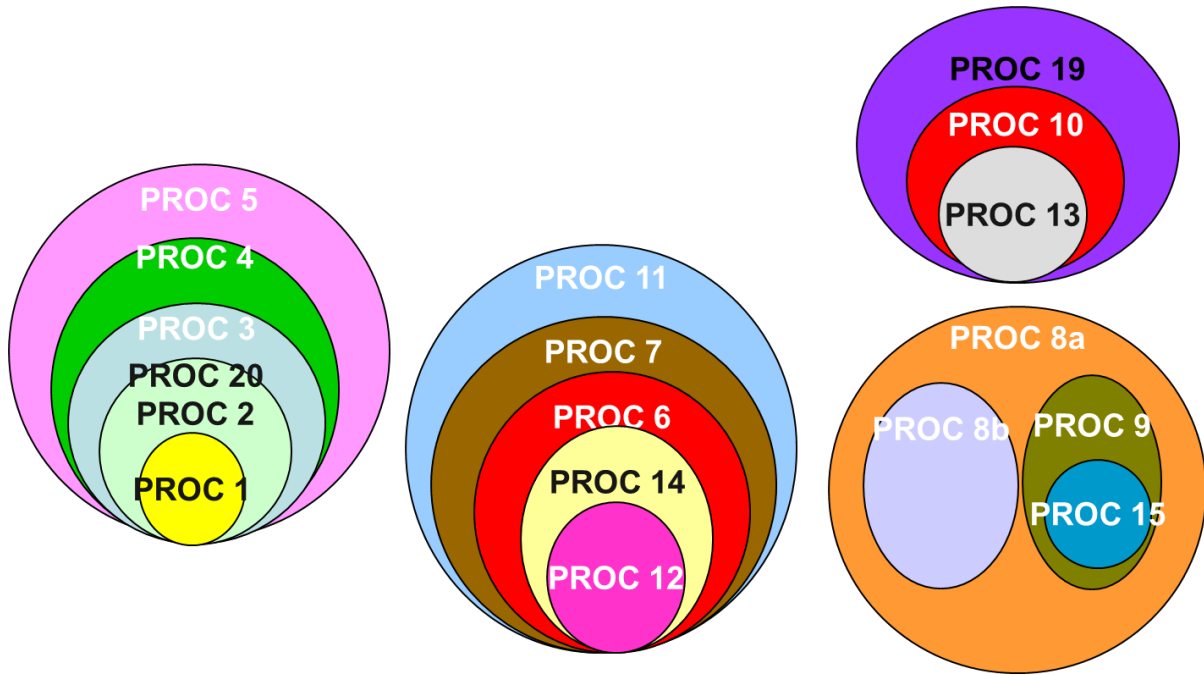


Figure 10: PROC hierarchy for institutional uses assessed with ECETOC TRA⁴.

Following Figure 10, it can be assumed for instance that:

- If in an exposure scenario PROC 19 is covered, PROC 10 and PROC 13 are also safe within the same conditions
- If in an exposure scenario PROC 8a is covered, PROC 8b, PROC 9 and PROC 15 are also safe within the same conditions
- If in an exposure scenario PROC 3 is covered, PROC 20, PROC 2 and PROC 1 are also safe within the same conditions.

More information on the PROC hierarchy system can be found in the Cefic-DUCC-FECC-Concawe guidance.