CEFIC Guidance
Specific Environmental Release Categories (SPERCs) Chemical Safety Assessments, Supply Chain Communication and Downstream User Compliance

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Preamble

REACH exposure scenarios are a new concept for establishing and communicating conditions of safe use of substances in the supply chain. This is a particular challenge for the environmental aspects. Here, the conditions of safe use encompass amounts handled in an operation, fractions of substance amounts lost from the process to air, water and soil and the efficiency of risk management measures. In the past, such information was not subject to routine risk assessments. However, REACH requires considering these factors in the Chemical Safety Assessment and to establish REACH exposure scenarios which define conditions under which control of risks is warranted.

From the above it is clear that best practice examples are not yet available. As a result, guidance development has to fall back to theoretical considerations. The present document, developed by CEFIC's SPERC Core Team, builds on the following:

1) The quantitative nature of standardized environmental assessments needs to be carried through the supply chain. This facilitates adapting conditions of use, which are defined at a generic level, to the conditions prevailing at specific sites.
2) The conditions of use are developed with the actual use conditions in mind. To that end, this document provides guidance on how to describe these conditions in terms which feed into risk assessments.
3) Redundant communication in the supply chain is to be avoided. To that end, this document attempts to foster standardization of assessments and their communication.

1. General Relevance - Registrants & Downstream Users

1.1 Scope of the Document

Chapter R16 of the REACH Guidance on Information Requirements & Chemical Safety Assessment (IR&CSA guidance) introduces Environmental Release Categories as generic, broadly applicable emission scenarios. They define the fractions of a substance emitted during a process/application, and provide default assumptions for the local environmental properties. An industry evaluation concluded that ERCs provide for standardization while leading to unrealistically conservative emission estimates.

The IR&CSA guidance acknowledges that an "ERC should be used as a starting point for emission estimation" and explicitly encourages the use of more refined or specific information for emissions. This document provides guidance on the development, and use of specific ERCs (SPERCs). It defines SPERCs, and describes how they are developed and how they can be accessed by registrants and downstream users. It provides guidance for registrants to use SPERCs in performing environmental safety assessments, and to communicate the results to the downstream users. In addition it addresses how downstream users check whether their own uses are covered by a SPERC-based Exposure Scenario.

1.2 What are SPERCs and their limitations

SPERCs can be defined by comparison with ERCs. This is done in Table 1.

Table 1. Comparison of SPERCs and ERC.

	ERC	**Specific ERC (SPERC)**
Emission estimate	Standardized	Standardized
Defaults	Worst case	Good practice
RMMs	Not included	Considered
Responsible	ECHA	Trade associations, sector groups of registrants, end users, or formulators

These are the key aspects regarding SPERCs:

- SPERCs are an element of standardized supply chain communication of environmental assessments, e.g. in GES
- SPERCs are developed by industry sector groups, and trade associations
- SPERCs usually refine the ERC-based emission estimation
- SPERCs define realistic default values
- SPERCs are documented in SPERC factsheets, deposited in ES library
- SPERCs can be employed in CHESAR (ECHA's Chemical Safety Assessment tool), ECETOC TRA, and Petrorisk

1.3 Distinguishing industrial and wide dispersive uses

SPERCs can be defined for industrial and wide dispersive uses. The latter are due to use by consumers and professionals. These uses result in more or less evenly distributed substance emissions over time and in the geographical region under assessment. In addition, there are typically no technical measures by which consumers and professionals can control emissions. However, instructions such as 'Do not pour down the drain' serve to control emissions and can be communicated to customers. For the rest, the communication function of SPERCs for wide dispersive uses is restricted to identifying which uses are included in an assessment and have been assessed to be safe.

User group	Emission permit and / or access to general technical emission control	Obligation to take SDS recommendation into account	SPERC Type
Industrial Use	Yes	Yes	Industrial Use
Professional Use*	No**	Yes	Wide dispersive Use
Consumer Use*	No	No	

* Professional and consumer users are in charge of release control by following instructions for equipment cleaning and disposal.

** Specific measures may be encountered in some professional uses.

In contrast, SPERCs for industrial uses define unit point sources for certain applications and processes with regard to the emissions of substances to the environment. This encompasses that assumptions are made on the typical size of an operation, the typical way a process / application is operated and the risk management measures which are typically applied. The aspects that define a SPERC are exemplified in the SPERC factsheets in Appendix 2.

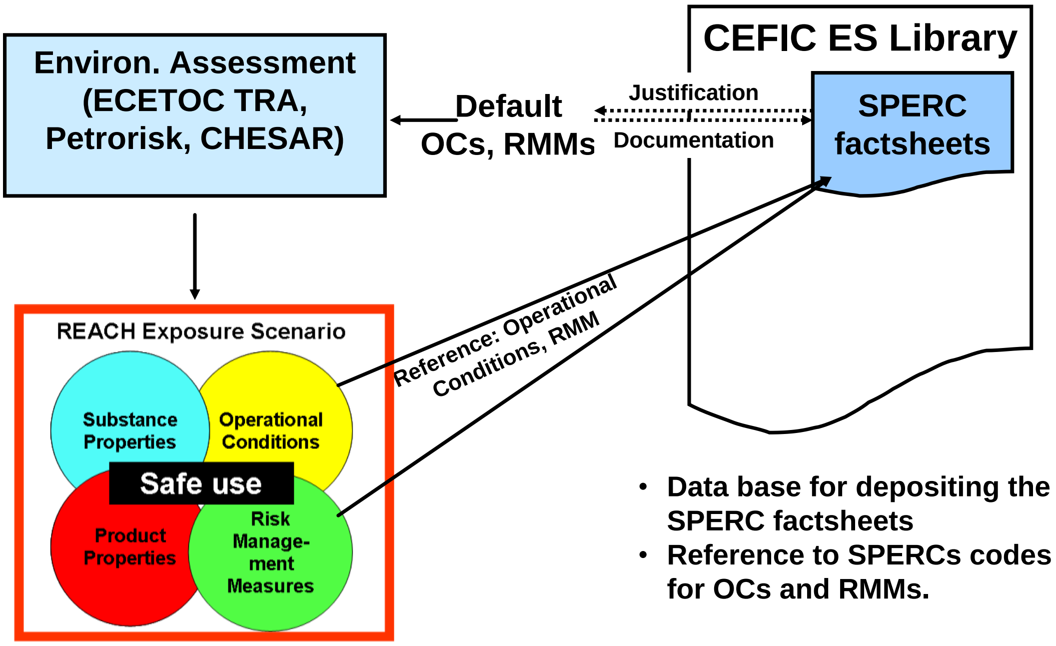
The SPERC factsheet thus defines how much of a substance is typically used per day (and annually, on the basis of emission days per year), which fraction of the substance is released to water, air and soil, and which risk management measures are typically employed to reduce emissions. Each SPERC contains defaults for receiving water dilution and the assumption that municipal wastewater treatment is applicable for local scale calculations.

1.4 SPERC s and Environmental Exposure Scenarios

Figure 1 outlines that environmental exposure assessments are performed using the defaults defined in the SPERC factsheets. These default parameters define the emissions to the environment. When an assessment does not indicate a risk to the environment the default parameters become part of the set of conditions of safe use. This set of conditions is documented in the REACH Exposure Scenarios, which are part of the Chemical Safety Report and are communicated in the supply chain in the annex of the eSDS.

Registrants (and possibly ECHA and national authorities) may deem a detailed documentation of the environmental exposure assessments appropriate for the chemical safety report. At the same time, a simplified, less detailed downstream communication may be desired. A simplified communication of assessment results can be achieved by referring to the SPERC factsheet rather than detailing the set of operational conditions and, if necessary, risk management measures.

Figure 1. Overview of SPERCs and how they are used.



1.5 Publishing, finding, and naming SPERCs

SPERC factsheets can be developed by different actors in the supply chain (see Table in section 1.3). Table 2 provides an overview of the steps involved in providing SPERCs for public use. They encompass publication of the SPERC factsheet on the web-site of the sector group or trade association. In that manner, ownership and responsibility for SPERC content remains with the sector group or the association. The factsheets will become accessible via web-links in the CEFIC Exposure Scenario library.

In addition to publishing the SPERC factsheets, the SPERC default values may also be published on the web-sites in the form of so-called CHESAR templates (xml files). Such xml-files can then be uploaded into the SPERC libraries of the stand alone versions of CHESAR by anyone who wants to perform environmental exposure assessments in conjunction with CHESAR, the chemical safety assessment tool developed by ECHA.

SPERCs will be identified with an unequivocal and systematic name in order to facilitate searching. For instance the SPERC for formulation of detergents and maintenance products is abbreviated as A.I.S.E. 2.1.v1. In this code, the first part (A.I.S.E.) specifies the entity (i.e. A.I.S.E., the European Association for cleaning and maintenance products), which is responsible for the contents of the SPERC. The first number (i.e. 2) specifies the ERC, which is refined by the SPERC. The third part (‘1’) is an index number given by the entity, which is responsible for the contents of the SPERC. One SPERC may contain several sets of default values. These will be indicated by lower case letters, as can be seen in the example SPERC for formulation of detergents and maintenance products. Part four (‘v1’) is the version number.

Table 2. Overview of publishing SPERC related information.

	What	How/Where
Sector Groups / Associations	Publishing SPERC Factsheet	On sector group / association homepage
Sector Groups / Associations	Publishing SPERC Default values, e.g. CHESAR import files	On sector group / association homepage
CEFIC	Publishing web-links to SPERC factsheet	In CEFIC Exposure Scenario Library
	Publishing the SPERC overview	http://cefic.org/templates/shwPublications.asp?HID=750&T=806

In addition to the Factsheets a comprehensive overview of the sets of default values defined for the SPERCs is available in the REACH Tools and Documents Section of the CEFIC homepage. The link is provided in Table 2.

1.6 What to do if a use is not covered by a SPERC?

If an actor in the supply chain decides that a certain use is not covered by a SPERC, there is the possibility to develop a SPERC and publish it according to the mechanism outlined above. The present document provides guidance on developing SPERC factsheets.

2 SPERCs in relation to the Chemicals Safety Assessment

2.1 The SPERC-Based Environmental Safety Assessment Process and the Relevance of MTEU, MSafe and MSPERC

When performing Environmental Safety Assessments as part of the REACH Chemical Safety Assessments, three different amounts need to be distinguished. Their meaning is explained in Table 3 below. Appendix 1 explains how the exposure assessment tool ECETOC TRA (and, in a very similar manner, the other tools referred to in Table 5) handles these amounts.

Table 3. Definition of MT_{EU}, M_{Safe} and M_{SPERC} and their function in SPERC-based Environmental Safety Assessments.

Acronym	Definition	Role in Assessment	How are values obtained?
MT_{EU}	EU amount of a substance registered per legal entity per use.	Tonnage input to the exposure assessment calculations.	Derived based on market intelligence.
M_{SPERC}	Typical amount used in a particular operation – Relevant for industrial uses.	Reference value for assessing SPERCs on a site level	Estimated on sector knowledge.
M_{Safe}	Amount corresponding to PEC = PNEC for a particular use based on the most critical compartment.	Output of the risk assessment; critical for downstream user scaling (further details below).	Calculated as M_{SPERC} /RCR* (per use) * The highest value of RCR identifies the critical compartment and is used to derive M_{Safe}

The assessment processes starts by deriving values of MT_{EU}. Usually MT_{EU} is the EU-amount (in tonnes per annum) registered for a given use for a legal entity. It is entered into the release estimation portion of the assessment tool as an input value to calculate the amounts used in the unit region (defined by the IR CSA guidance). Additional inputs are substance physico-chemical and fate properties. These data feed into the calculation of the Predicted Environmental Concentrations (PECs) for the different compartments (sewage treatment plant, freshwater, marine water, air, soil, and sediment). With the inclusion of Predicted No-Effect Concentrations (PNECs), Risk Characterization Ratios (RCRs) are calculated as the ratio of PEC over PNEC. These RCRs are the outcome of the risk assessment. If the initial assessment results in RCRs > 1 (for local RCRs, regional RCRs, or both) iteration will be required.

2.2 Accounting for Operational Conditions in SPERCs

The Operational Conditions underlying the environmental emission estimation situation defined in a SPERC is addressed in two ways. A set of phrases is employed to give a general indication of the operational conditions. The free text section of the SPERC factsheet provides the details on the operational conditions (OCs) assumed for a process or application. The narrative of SPERC factsheet is intended to be used for identifying the process step(s) which is (are) critical for the emissions to the environment and for rationalizing what fraction of a substance is lost from a process to water, air, and soil. In that manner the narrative explanation of typical sector operational conditions provides justification for the selection of the initial release factors. A registrant may estimate the environmental releases using a SPERC. If he so does, he accepts the description and uses the parameter values defined in the SPERC factsheet to estimate the emission to the environment.

The release factors represent empirical values. They determine which fraction of a substance is emitted from the process or use to water, air, or soil. They may be obtained by professional judgment or, if available from OECD emission scenario documents, which may also provide detailed descriptions of operational conditions and may serve as justification for the release factors. The typical RMMs used in a given application are specified such that the final release factors can be obtained. OCs may be indicated in the Chemical Safety Report by reference to the Factsheet. In contrast, release factors and the required RMM efficiencies need to be made explicit in the Chemical Safety Report.

For example, the narrative for ‘Uses in Coatings – Industrial (Solvent-borne)’ (see Appendix 2) clarifies that substance losses are reduced through use of general and site-specific risk management measures to maintain workplace concentrations of airborne VOCs and particulates below respective OELs; and through use of closed or covered equipment/processes to minimize evaporative losses of VOCs.

The SPERC factsheet – ‘Industrial use in formulation of liquid cleaning and maintenance products’ (also Appendix 2) serves to illustrate the degree of differentiation, which may be necessary. These SPERCs distinguish between the degree of viscosity, the size of the operation and type of product.

Another important distinction is between solvent-based and water-based processes. In solvent-based processes (product formulation or for instance use in coatings), solvent washings are collected and disposed of as waste. As a result, there are no emissions of the formulated substances from formulation processes to water ($f_{Release,water}$ = 0). For solvents, however, it is acknowledged that a fraction of the solvent used may evaporate. Depending on the size of the operation, $f_{Release,air}$ for the formulation of solvent-borne coatings and paints is set to 5% and 3% for volatiles, for smaller and large operations, respectively and to 0.005% for particulates. Due to the overall process design, releases to soil do not occur as part of standard practice. For that reason $f_{Release,soil}$ is set to zero. Please note, that the use of solvent for cleaning may be covered by a SPERC for industrial use of solvents in cleaning operations. In contrast, in the water-borne formulation processes of the detergent and cosmetic industries, the mixing vessels and filling lines are cleaned with water and the washings are disposed of with the wastewater ($f_{Release,water}$ equals 0.5 and 0.25% for small and large operations, respectively). For further detail on default values please refer to the SPERC overview (http://cefic.org/templates/shwPublications.asp?HID=750&T=806).

2.3 Accounting for Risk Management Measures (RMMs) in SPERCs

As part of current practice, emissions are controlled by risk management measures (RMMs), if so required. SPERCs reflect this by including RMMs, where these are applicable for the operations. RMMs impact on the exposure assessment by reducing the emission. To that end, RMMs can be assigned a numerical value for their substance removal efficiency in the release streams, particularly, of air and wastewater. Such efficiency values have been defined in the BAT- BREF-documents. They are available via the CEFIC library of RMMs and are abbreviated as RE_{RMM}. If more refined information is available, it can of course be used in developing a SPERC. Table 4 shows the default efficiencies for those RMMs, which are included in the CEFIC library of RMMs. It is important to note that RMM efficiencies are often dependent upon a number of properties, such as thermomechanical and physical-chemical; thus, default efficiencies may not reflect those that are actually achievable (i.e., actual efficiencies may be less than or greater than the default value). Consequently, it is the assessor's responsibility to decide that the assumptions made regarding RMM efficiencies are appropriate for the process/use and the substances being evaluated.

Table 4. Default RMM efficiencies included in CEFIC RMM library (Status: December 2009).

RMM Air		**RMM Water**	
Type	E_{RMM}	Type	E_{RMM}
Wet scrubber - for dusts	0.5	Sedimentation of solids	0.3
Wet scrubber - for gas removal	0.7	Air flotation	0.8
Waste gas membrane separation	0.9	Filtration	0.5
Separator	0.1	Oil-Water Separation	0.9
Dust collection - air cyclones	0.7	Chemical treatment - Wet Air Oxidation	0.5
Waste gas treatment - thermal oxidation	0.98	Adsorption	0.1
Waste gas treatment - catalytic oxidation	0.9	Ion Exchange	0.8
Waste gas treatment – adsorption	0.8	Thermal Treatment - Distillation / Rectification	0.9
Biological treatment - degradable substances	0.7	Biological treatment Anaerobic	0.75
Waste gas treatment – condensation	0.1	Biological treatment – Aerobic	0.76
		Central Biological Waste Water Treatment	0.97
		Biological treatment - Sludge treatment e.g. thermal sludge reduction	0.6

In the course of the chemical safety assessment, the assessor may start with a certain set of conditions (M_{SPERC}, release factors and SPERC defaults) and come to the conclusion that risks to the environment are not adequately controlled. In that situation, the removal efficiency which is required for demonstrating safe use can be calculated. Based on this required removal efficiency (RRE), suitable RMMs and associated efficiencies (as indicated in the relevant SPERC factsheet) may be selected to refine the assessment. Similarly, it is possible to refine emissions on the basis of the RRE and justify this approach via the assumption that the technologies referenced in the SPERC factsheet can reasonably achieve such an efficiency (either alone or in combination). Alternatively, the assessor may accept this information as an indication of the typical conditions to be assessed and subsequently start the assessment by including the typical RMM straight away.

2.4 Release Factors and RMM Efficiencies in Emission Estimation

The release factors define the primary emissions from a process. The efficiency of a risk management measure defines the degree by which the emissions are reduced. Both are combined to obtain the resulting overall emission factor (Equation 1).

$$F_{\text{Overall, water}} = F_{\text{Release,Water}} \times RE_{\text{Total, RMM-Water}} \qquad \text{Equation 1}$$

In the course of iterating the Exposure Scenarios, the assessor determines which RMM efficiency or removal efficiency is required for demonstrating safe use. In many cases, the required removal efficiency may be met by the RMMs and associated efficiencies (individually or in combination) defined in the SPERC factsheet. In other cases the assessor may have to also consider offsite RMMs (e.g., municipal sewage treatment) in combination with onsite RMMs. If the combined effect of multiple RMMs can be assumed linear (i.e., RMMs in combination are equally as effective as when implemented alone), overall or total removal efficiencies should be calculated according to Equation 2.

$$RE_{\text{Total,RMM}} = 1 - (1 - RE_{\text{RMM, 1}}) \times (1 - RE_{\text{RMM,2}}) \times (1 - RE_{\text{RMM,n}}) \qquad \text{Equation 2}$$

Ultimately, the assessor must conclude whether or not the SPERC-based emission assessment was successful, i.e. safe use was demonstrated, within the appropriate boundaries of typical substance and process/use conditions and that reasonable RMM removal efficiencies have been assumed. When this is not the case, the assessment may need to be refined beyond the boundaries set by the SPERC-based emission assessment.

2.5 SPERCs and assessment tools: EUSES, TRA, CHESAR

Chapter R16 of the REACH Guidance on Information Requirements & Chemical Safety Assessment (IR&CSA guidance) mentions several tools for supporting environmental exposure assessments. These include ECHA's chemicals safety assessment tool CHESAR, ÉUSES, and the TGD Excel Sheet. PETRORISK and ECETOC TRA ENV are additional tools which are based on the TGD Excel Sheet and which offer complementary functionalities. All these tools implement the exposure assessment rules as laid down in Chapter R16 of the IR&CSA guidance.

SPERC-based emission estimate can be employed with each of these tools. PETRORISK and ECETOC TRA ENV have implemented functionalities which support the automated use of SPERCs. Table 5 specifies how to perform SPERC-based emission assessments in conjunction with these tools.

Table 5. Overview of environmental exposure assessment tools and how they relate to SPERC-based emission estimation.

<table>
<tr><th>Tool</th><th>Use of SPERC-based emission estimation</th></tr>
<tr><td>CHESAR</td><td>- SPERCs will become available as CHESAR templates to be used in CHESAR exposure assessments</td></tr>
<tr><td>EUSES</td><td rowspan="2">- SPERCs not implemented
- SPERC-based emission estimates are derived off-line
- Manual entry of emission estimates</td></tr>
<tr><td>TGD Excel Sheet.</td></tr>
</table>

ECETOC TRA ENV	- SPERCs implemented with selection via pick-list
PETRORISK	- SPERC-based emission automatically feeds into exposure estimation

2.6 Communicating SPERC-based environmental assessments

Wide dispersive uses. SPERC-based environmental assessments are explicit in a large number of parameters. As outlined in section 1.3, consumers and professional users have limited capability of controlling emissions. For that reason, there is no added value in communicating explicit information with respect to SPERCs beyond the minimum requirements. It is sufficient that formulators are provided with the information that wide dispersive uses are safe, including the assumed set of operational conditions and a few key assessment outputs (i.e., the risk-driving compartment, offsite wastewater removal efficiency and M_{Safe}) as outlined in the Exposure Scenario.

Industrial uses. In contrast, industrial downstream users can control their emissions and align the conditions of use at their site with the set of conditions specified to them in the eSDS. This process is referred to as compliance checking. Communicating some parameters to industrial downstream users is indispensable for compliance checking. At the same time communicating all those parameters in the chemical safety report or in the extended safety data sheets runs the risk of diluting the important information items with much redundant information. This section of the guidance provides some thoughts on how to select the appropriate degree of detail.

The parameter sets underlying SPERC-based environmental assessments are defined in the SPERC factsheets. Hence a reference to a SPERC factsheet may be considered sufficient for providing an indication of the relevant operational conditions. In addition, further detail can be provided if deemed necessary. Table 6 shows an example of an environmental assessment in the format of a chemical safety report exposure scenario. In this example a large number of parameters are detailed (the environmental release fractions, the number of emission days, and the risk management measures with their efficiencies). The details are provided as phrases. An example can be found in Section 2.2 under product characteristics. The first phrase used there is ‘Substance is an isomeric mixture’. The phrase has been assigned the code PrC2. For demonstration purposes all phrases contained in Table 6 are given along with their code (i.e. the expressions parentheses).

Table 6. Standardized communication of environmental assessments.

Section 1 Exposure Scenario Title	
Title	
Uses in Coatings – Industrial	
Use Descriptor	
Sector(s) of Use	3
Process Categories	1, 2, 3, 4, 5, 7, 8a, 8b, 10, 13, 15
Environmental Release Categories	4
Specific Environmental Release Category	ESVOC 4.3a.v1
Processes, tasks, activities covered	
Covers the use in coatings (paints, inks, adhesives, etc) including exposures during use (including materials receipt, storage, preparation and transfer from bulk and semi-bulk, application by spray, roller, spreader, dip, flow, fluidised bed on production lines and film formation) and equipment cleaning, maintenance and associated laboratory activities.	
Assessment Method	
See Section 3 [AM1].	
Section 2 Operational conditions and risk management measures	
Section 2.1 Control of worker exposure	
included here	
2.2 Control of environmental exposure	

Product characteristics	
Substance is an isomeric mixture [PrC2]. Predominantly hydrophobic [PrC4a]. Readily biodegradable, failing 10 day window [PrC5c].	
Amounts used	
Fraction of EU tonnage used in region [A1]	1
Regional use tonnage (tonnes/year) [A2]	200
Fraction of Regional tonnage used locally [A3]	1
Annual site tonnage (tones/year) [A5]	200
Maximum daily site tonnage (kg/day) [A4]	10000
Frequency and duration of use	
Continuous release [FD2].	
Emission days (days/year) [FD4]	20
Environmental factors not influenced by risk management	
Local freshwater dilution factor [EF1]	10
Local marine water dilution factor [EF2]	100
Other given operational conditions affecting environmental exposure	
Indoor use [OOC2]. Solvent-based process [OOC13]. Process optimized for efficient use of raw materials [OOC16]. Volatile compounds subject to air emission controls [OOC18]. Negligible wastewater emissions as process operates without water contact [OOC20]. Wastewater emissions generated from equipment cleaning with water [OOC22].	
Release fraction to air from process (initial release prior to RMM) [OOC4]	0.98
Release fraction to wastewater from process (initial release prior to RMM) [OOC5]	0.00007
Release fraction to soil from process (initial release prior to RMM) [OOC6]	0
Technical conditions and measures at process level (source) to prevent release	
Common practices vary across sites thus conservative process release estimates used [TCS1].	
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	
Risk from environmental exposure is driven by freshwater [TCR1a]. Prevent discharge of undissolved substance to or recovery from wastewater [TCR14]. If discharging to domestic sewage treatment plant, no onsite wastewater treatment required [TCR9].	
Treat air emission to provide a typical removal efficiency of (%) [TCR7]	90
Treat onsite wastewater (prior to receiving water discharge) to provide the required removal efficiency ≥ (%) [TCR8]	12.2
If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of ≥ (%) [TCR10]	0
Organizational measures to prevent/limit release from site	
Do not apply industrial sludge to natural soils [OMS2]. Sludge should be incinerated, contained or reclaimed [OMS3].	
Conditions and measures related to municipal sewage treatment plant	
Estimated substance removal from wastewater via domestic sewage treatment (%) [STP3]	84.3
Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%) [STP4]	84.3
Maximum allowable site tonnage (M_{Safe}) based on release following total wastewater treatment removal (kg/d) [STP6]	55820
Assumed domestic sewage treatment plant flow (m^3/d) [STP5]	2000
Conditions and measures related to external treatment of waste for disposal	
External treatment and disposal of waste should comply with applicable regulations [ETW3].	
Conditions and measures related to external recovery of waste	
External recovery and recycling of waste should comply with applicable regulations [ERW1].	
Etc…	

The information provided in Table 6 may be considered appropriate for the Chemical Safety Report. However, depending on their particular situation, customers may need all, little, or none of the detail provided in the CSR. For that reason, the degree of detail by which the relevant results of the SPERC-based assessments are communicated requires consideration of the customers' needs.

2.7 SPERCs and Phrases

The extended safety data sheet is the primary medium foreseen by REACH for conveying the Exposure Scenario information through the supply chains. These may have to be translated into many of the official EU-languages. For that reason, communication of content in a highly standardized manner is preferred. To that end, phrases are currently being developed. The phrases will be deposited into the European Phrase Catalogue (EUPhraC). They address several aspects of the environment section of the Exposure Scenario (Table 7). Some phrases are already included with their codes in Table 6.

Table 7. The phrase types for the environment section of the Exposure Scenario along with the acronym.

Phrase Type	Code
Product characteristics	PrC
Amounts used	A
Frequency and duration of use	FD
Environmental factors not influenced by risk management	EF
Other given operational conditions affecting environmental exposure	OOC
Technical conditions and measures at process level (source) to prevent release	TCS
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil	TCR
Organisation measures to prevent/limit release from site	OMS
Conditions and measures related to municipal sewage treatment plant	STP
Conditions and measures related to external treatment of waste for disposal	ETW
Conditions and measures related to external recovery of waste	ERW

At the same time, the environmental assessment hinges on and produces several quantitative parameters, all of which need to be documented in the Chemical Safety Report. Selected pieces of information may be deemed necessary for supply chain communication.

In order to fulfill both requirements, text fields will be coupled with numerical fields. The text fields contain phrased text pertaining to an environmental assessment and the numerical fields contain the assessment input or output. Table 8 shows an example of the complete Exposure Scenario template, which will be communicated in Chapter 9 of the CSR and subsequently used for communication in the eSDS.

Table 8. Mapping the content of a REACH Exposure Scenario vs the entries of SPERC factsheets and other sources, e.g. Generic Exposure Scenarios.

CSR Exposure Scenario Template		**Origin of 'phrased input'**	
Section 1 Exposure Scenario Title		**From SPERC Factsheet**	**Other Input (e.g. from GES)**
Title			
Short free text title			GES Title – Life Cycle Stage
Use Descriptor			
Sectors(s) of Use Process Categories OR Product Categories Environmental Release Categories Specific Environmental Release Category		 SPERC Code	GES GES GES
Processes, tasks, activities covered			
Detailed description of ES, e.g. derived from GES narrative			GES
Assessment Method			
Assessment tools used			Standard phrase (EUPhraC) or Set by Assessor
Section 2 Operational conditions and risk management measures			
Section 2.2 Control of environmental exposure			
Product characteristics			
Qualitative description of substance/product			Standard phrases (EUPhraC)
Amounts used			
Fraction of EU tonnage used in region [A1] Regional use tonnage (tonnes/year) [A2] Fraction of Regional tonnage used locally [A3] Annual site tonnage (tonnes/year) [A5] Maximum daily site tonnage (kg/day) [A4]		 M_{SPERC} x $T_{Emission}$ SPERC default: M_{SPERC}	Default or User-defined User-defined Default or User-defined User-defined User-defined
Frequency and duration of use			
Description of release			Standard phrases (EUPhraC)
Emission days (days/year) [FD2]		SPERC: $T_{Emission}$	
Environmental factors not influenced by risk management			
Local freshwater dilution factor [EF1] Local marine water dilution factor [EF2]		SPERC default: 10 SPERC default: 100	
Other given operational conditions affecting environmental exposure			
Description of qualitative OCs			Standard phrases (EUPhraC)
Release fraction to air [OOC4 or OOC7] Release fraction to wastewater [OOC5 or OOC8] Release fraction to soil [OOC6 or OOC9]		SPERC: $f_{Release\ Air}$ SPERC: $f_{Release\ Wastewater}$ SPERC: $f_{Release\ Soil}$	

Technical conditions and measures at process level (source) to prevent release			
Description of site-specific process level measures, if applicable			Standard phrases (EUPhraC)
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil			
Identification of risk-driving compartment *Additional phrase describing wastewater controls (contingent on RRE)*			Assessment-defined Standard phrases (EUPhraC)
Treat air emissions to provide a typical removal efficiency of (%) [TCR7] Treat onsite wastewater (prior to receiving water discharge) to provide the required removal efficiency ≥ (%) [TCR8] If discharging to domestic sewage treatment plant, provide the required onsite wastewater removal efficiency of ≥ (%) [TCR10]		SPERC: $RE_{Onsite\ Air}$ SPERC: $RE_{Onsite\ Wastewater}$	Assessment-defined RRE
Organizational measures to prevent/limit release from site			
Description of qualitative RMMs			Standard phrases (EUPhraC)
Conditions and measures related to municipal sewage treatment plant			
Estimated substance removal from wastewater via domestic sewage treatment (%) [STP3] Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%) [STP4] Maximum allowable site tonnage (M_{Safe}) based on release following total wastewater treatment removal (kg/d) [STP6] Assumed domestic sewage treatment plant flow (m^3/d) [STP5]		SPERC default: 2000	Assessment-defined, RE_{STP} $RE_{Total\ Wastewater}$ M_{Safe}
Conditions and measures related to external treatment of waste for disposal			
Description of external treatment of waste			Standard phrases (EUPhraC)
Conditions and measures related to external recovery of waste			
Description of external recovery of waste			Standard phrases (EUPhraC)
Etc…			

2.8 How to refine SPERC-based assessments (registrants)

As indicated in Figure 2, SPERCs are a lower tier element of environmental exposure assessment. That means that assessments employing SPERC- based emission estimates may indicate a possible risk. In such cases refinement is needed. Figure 2 shows that beyond ERC- and SPERC-based assessments there are higher tier environmental exposure estimation options as well as the option to obtain measured environmental concentrations.

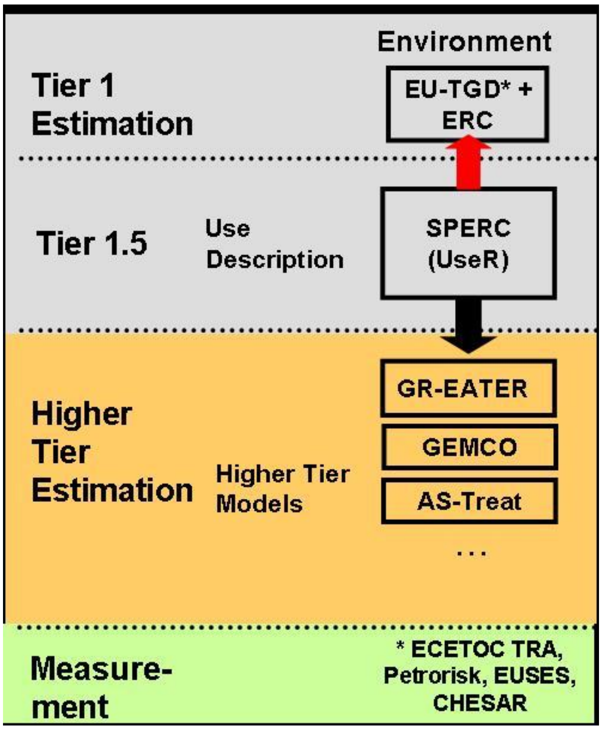


Figure 2: Tiered environmental exposure assessment.

Refinement Options

In addition to and/or in conjunction with the use of refined exposure assessment approaches, there is also the possibility to employ refined substance property data or to refine the emission estimation beyond the estimates provided by a SPERC (Table 9).

As is obvious from the above, there are a variety of refinement options. In view of these options a refinement strategy may be needed. When developing such a strategy, the options for refinement need to be identified and compared with each other with regard to the ease of data availability, the cost of obtaining the data/information, and the likelihood of success with additional data. Once all this information is collected, the most appropriate option can be chosen and a refined assessment can be performed. For more detailed information on refining environmental exposure assessment, please refer to Appendix H of ECETOC Technical Report 107.

Table 9. Overview of the refinement options in environmental exposure assessment.

Refinement Options	
Substance Data	**Emission Estimation**
Refined PNECs based on - higher tier studies - advanced data extrapolation techniques - micro-/mesocosm studies Refined substance property data (e.g): - measured sorption coefficients - improved environmental half-lives - improved (e.g., measured) bioconcentration and/or bioaccumulation factors.	Use of SPERC Use of alternative emission estimation approaches - A/B Tables (ex EU TGD 2003)* - OECD Emission Scenario Documents***** - Proprietary emission estimation. Use of measured emission data*

3 SPERCs and Checking Downstream User Compliance

3.1 Downstream users obligations

According to Art. 31 the extended safety data sheet (eSDS) will provide information on the conditions under which a substance can be safely used. This information is termed Exposure Scenario and encompasses information relating to environmental safety. According to Art. 37.5, the recipient of the information has to check that his operations conform to the conditions outlined in the eSDS and that, if necessary, he applies appropriate risk management measures.

3.2 Downstream User Compliance Check

As outlined in 2.3, a downstream user may receive Exposure Scenario information on different degrees of detail. According to REACH Article 37.5 downstream users are obliged to comply with the Exposure Scenario of substances laid down in the eSDS communicated to them. In the first step, the downstream user may want to make a qualitative assessment of the degree of detail required to perform a compliance check for their operation. This requires knowledge of the SPERC(s) relevant to the operation(s). Typically, smaller businesses operate one or a few similar processes and the number of relevant SPERCs is small. Hence, a downstream user may have to familiarize himself with a limited number of SPERCs and evaluate how their own operations relate to the assumptions made in the SPERC factsheet.

Figure 3 gives a schematic representation of how a downstream user may proceed in checking whether their use is covered by the information provided in the eSDS. The first step is to tabulate the parameter values in the Exposure Scenario and the respective values for a site. These values can then be compared parameter by parameter and assessed whether or not – and if so, to which extent – they deviate. Ratios can be used for each parameter to assign 'safe use' assessment factors. For example, a ratio of site tonnage over ES tonnage less than 1 would represent a criterion of safe use, i.e., PECs at the site would be driven by a smaller site tonnage. Similarly, a ratio of ES dilution over site dilution less than 1 would also represent a criterion of safe use, i.e., there would be more dilution at the site, thus, aquatic PECs would be less. Of course, it is possible and acceptable that some assessment factors may be greater than 1. The final distinction of safe use at a site would be determined by the product of all 'safe use' assessment factors; that is, a product less than 1 would indicate overall safe use at the site.

In the example given in Figure 3 two parameters (release fraction and WWTP) have the same value. Hence, their 'safe use' assessment factors would be 1, respectively. The amount of substance used at the site is 10000 kg/d versus the ES M_{Safe} of 366000 kg/d. This translates into a 'safe use' assessment factor of 0.027. Finally, the dilution rate at the site is five times lower than the default rate; thus, resulting in a 'safe use' assessment factor of 5. Multiplying the individual assessment factors yields a product of 0.14. Consequently, since this value is less than 1, the comparison indicates use at the site to be safe.

Figure 3: Compliance checking through parameter-by-parameter comparison of Exposure Scenario information vs site-specific information.

Information	eSDS	DU		eSDS vs DU
Maximum allowable site tonnage (M_{Safe}) based on release following total wastewater treatment removal (kg/d)	m_{Safe}: 366000 kg/d	m_{Site}: 10000kg/d	➜	0.027
Local freshwater dilution factor	q_{SPERC}:10	q_{Site}: 2	➜	5
Estimated substance removal from wastewater via domestic sewage treatment (%)	$RE_{Overall}$: 63%	RE_{Site}: 63%	➜	1

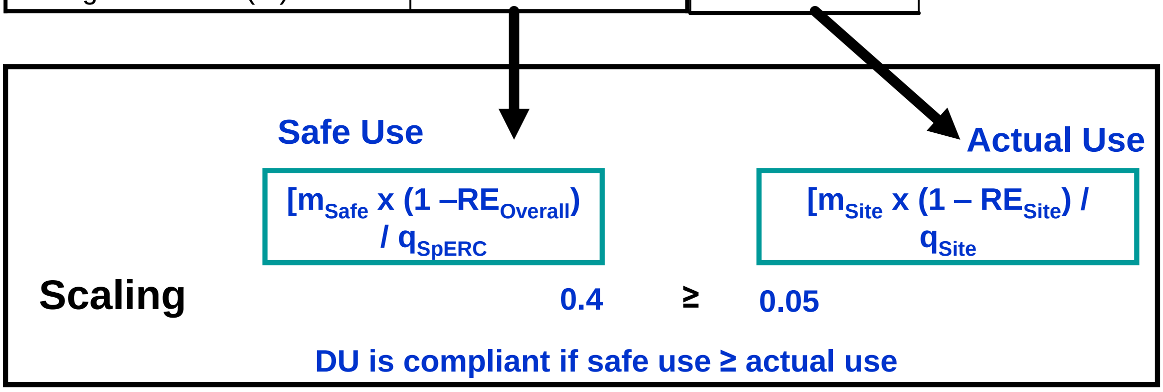
Summary:	Evaluation	Result
- Estimated substance removal from wastewater via domestic sewage treatment is identical in eSDS and at DU.	➜ 1 × 1	
- The substance amount used at the site is lower than M_{Safe} - In favour of safe use by 36.6.	➜ × 0.027	➜ 0.14 < 1 **SAFE USE**
- The site dilution rate is 5 times lower than the SPERC default	–	

3.3 Scaling

As outlined above, the environmental part of the Exposure Scenario constitutes an extended set of parameters, which defines the conditions of safe use. In a SPERC factsheet a unit site is defined by assigning default values for this set of parameters. However, many of these parameters assume site-specific values at an actual site. These parameters are the substance amount used at a site, the size of the river and the efficiency of the risk management measure implemented at a site.

These parameters are linearly related. In SPERC factsheets these relationships are documented in so-called scaling equations, which may be provided in the eSDS. Figure 4 shows how scaling can be applied. The starting point is again a compilation of the relevant parameters for the SPERC-based assessments as provided by the eSDS and the corresponding site-specific values. Both sets of values are inserted into the scaling equations. If the numerical value of the SPERC expression is greater than that of the site expression, then the site-specific conditions are within the boundaries of the SPERC-based assessment and the use at the site can be considered safe. Please note, that scaling represents an equivalent approach to the parameter-by-parameter comparison outlined above. Another example of scaling can be found in Part G – Extension of the SDS of the REACH Guidance (Examples 3 & 4).

Information	eSDS	DU
Maximum allowable site ton-nage (M_{Safe}) based on release following total wastewater treatment removal (kg/d)	m_{Safe}: 366000 kg/d	m_{Site}: 10000kg/d
Local freshwater dilution factor	q_{SPERC}:10	q_{Site}: 2
Estimated substance removal from wastewater via domestic sewage treatment (%)	$RE_{Overall}$: 63%	RE_{Site}: 63%



3.4. Boundary of SPERC / Scaling vs DU chemical safety assessment

Figure 4 shows a sub-set of the adjustable parameters for emission assessment, which include, local amount used, emission days per year, receiving water flow rate (or dilution factor), sewage treatment plant effluent flow rate, and risk management measure removal efficiency. These parameters can be refined using site-specific information, which often is obtainable with limited effort and expertise. Adjusting the assessment by refining these parameters is referred to as scaling.

The release factors are an additional set of adjustable parameters; however, refining the default values requires significant justification and, thus, is beyond the boundary conditions defined in the SPERC Factsheet. For that reason, release factor refinements do not constitute a SPERC-based assessment and must be considered an element of downstream user chemical safety assessment.

3.5. Compliance Checking - Outlook

At present, best practice examples for compliance checking of the environmental part of Exposure Scenarios do not exist. For that reason, it is difficult to develop guidance. It appears clear however, that both registrants and downstream users need to prepare for a new task. The biggest challenge is to avoid redundant communication in the supply chain. To that end, downstream users may want to familiarize themselves with the parameters that are relevant for checking compliance with the Exposure Scenarios detailed to them based on the registrants' chemical safety assessment. Those downstream users, which, via their associations/sector groups have developed SPERCs, clearly enjoy the advantage of having the opportunity of access to the scaling equations and knowledge of the relevant parameters.

Registrants who use SPERCs make the best use of available information to obtain assessments which are close to reflecting the situation of the downstream users. As a result of a limited/focused set of parameter values the compliance check may be easier, be it performed via scaling or via a parameter-by-parameter comparison. Consequently, a greater number of customers will abstain from contacting their suppliers regarding compliance checking because of increased simplicity and/or a greater understanding of the environmental Exposure Assessment.

Appendices

Appendix 1 - Substance amounts in Environmental Assessments according to EU TGD and REACH Guidance

Substance Use Rates

REACH requires substance registrations based on the amount produced by the registrant at the European scale (MT_{Total}), expressed as tonnes per year (t/a). The life cycle of a substance may include a variety of uses (Figure A1). In order to assess environmental exposure under REACH, the substance amounts going into these individual uses (MT_{EU} in t/a) must be defined. Subsequently, Regional and Local scale tonnages, or estimates of these amounts, are required in order to perform the assessments.

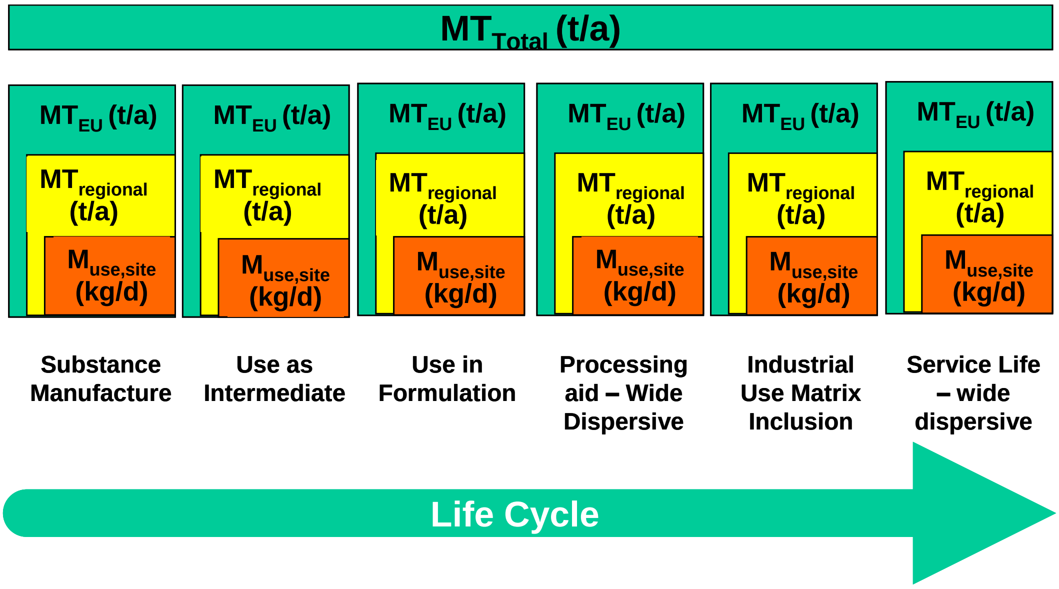
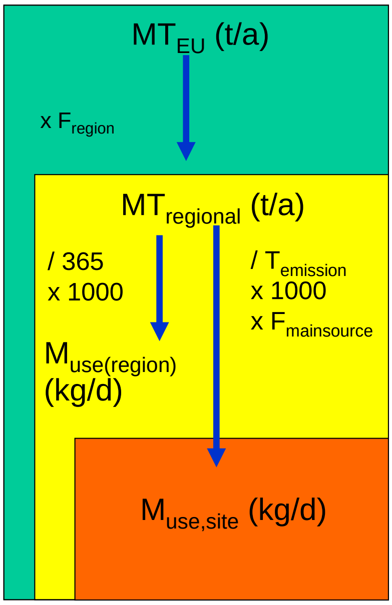


Figure A1. Example illustration of relevant tonnages over the life cycle of a hypothetical substance, required for registration.

The REACH environmental exposure assessment defines the amount of substance emitted to each of air, water and soil, per use. Release to soil is only defined at the regional scale, along with that for air and water. Release at the local scale is defined for air and water for industrial uses, and to water alone for wide dispersive uses. These releases represent the amounts used per time (in kg x d^{-1}) at both the regional ($M_{use,(region)}$) and local ($M_{use,(site)}$) levels. This appendix serves to clarify the relationships between these use rates and the tonnage ($MT_{regional}$ [t/a]) that a registrant assigns to a use.

Figure A.2. summarises the various amount terms and how they are linked and used in the environmental risk assessment under ERC or SPERC type approaches. In principle, they also apply to TIER II assessments where the same parameters can be set manually.



ERC		SPERC	
Point source	Wide dispersive	Point source	Wide dispersive
F_{region}		F_{region}	
1	0.1	1	0.1
100% to region	10% to region	100% to region*	10% to region*
$M_{use(region)}$: - release air - release ww - release soil	$M_{use(region)}$: - release air - release ww - release soil	$M_{use(region)}$: - release air - release ww - release soil	$M_{use(region)}$: - release air - release ww - release soil
$F_{mainsource}$		$F_{mainsource}$	
1	0.002 (refinement possible)	M_{SPERC} /(($MT_{Regional}$ x 1000 / $T_{Emission,local}$) (maximum = 1)	≥0.0005
$M_{use(site)}$: - release air - release wastewater	$M_{use(site)}$: - release wastewater	M_{SPERC} : - release air - release wastewater	$M_{use(site)}$: - release wastewater
Safe use: if $M_{safe}* \geq M_{use(site)}$	Safe use: If RCR ≤1	Safe use: if $M_{safe}* \geq M_{SPERC}$	Safe use: If RCR ≤1
* $M_{safe} = M_{use(site)}$/RCR** ** RCR of the risk driving compartment		* $M_{safe} = M_{SPERC}$ /RCR** ** RCR of the risk driving compartment	

Figure A2. Illustration of the linkage and use of tonnage terms in environmental risk assessments utilizing ERCs or SPERCs.

$M_{use(region)}$ - Regional Use Volumes for SPERC and ERC

The ERC use descriptor triggers which default fraction of MT_{EU} is assigned to the "standard region", which is F_{Region} = 1 for point sources (ERC 1-7 and 12a, 12b) and 0.1 for wide dispersive uses (ERC8a to 11b). Consequently, as SPERCs are in many cases the refinement of ERCs, default F_{region} for SPERC s can be assigned using the same approach. The resulting regional tonnage ($MT_{regional}$ [t/a]) is converted into the regional use volume by dividing with 365 days/year and expressed in kg/day ($M_{use(region)}$ [kg/d]).

Equation (A1): $MT_{regional} = MT_{EU} \times F_{region}$ [t/a]

Equation (A2): $M_{use(region)} = MT_{regional} * 1000 / 365$ [kg/d]

$M_{use(Site)}$ - Use amounts as site/local level

For SPERCs, the use amounts on a site/local level are defined as M_{SPERC} and can be found in the SPERC Factsheets.

For ERCs, the use amounts on a site/local level are derived via the fraction of local main source ($F_{mainsource}$) which is unitless and by default 1 for point sources and 0.002 for wide dispersive uses (Equation A3). $T_{emission,\ local}$ represents the number of days per year that the substance is emitted to the local environment. The numbers are assigned according to the rules laid out in the REACH Guidance R16.

Equation (A3): $M_{use(site)} = MT_{regional} * 1000 / T_{emission,\ local} \times F_{mainsource}$

Handling wide dispersive uses

For wide dispersive uses $F_{mainsource}$ is equivalent to the quotient of the number of inhabitants in the standard town (10^4) divided by that in the region (2×10^7) multiplied by a safety factor of 4. Hence the default value of $F_{mainsource}$ is 0.002. The safety factor of 4 accounts for temporal and spatial differences in the use pattern. With suitable supporting data, the safety factor may be refined within the range of 1 to 4 (i.e. $0.002 \geq F_{mainsource} \geq 0.0005$).

SPERC s and M_{SPERC}

In the SPERC factsheet for an industrial use, M_{SPERC} is defined as the typical amount (kg/d) used in that process at the local scale. Subsequently, $M_{use(site)}$ can be defined as the M_{SPERC}, under the condition that $M_{SPERC} \times (T_{emission,\ local} / 1000) < MT_{regional}$. For the TRA, M_{SPERC} is substituted into equation (A3) to derive $F_{mainsource}$, rather than use the more conservative default value of 1 (as in the ERC approach).

Equation (A3a): $F_{mainsource} = M_{SPERC} / (MT_{regional} * 1000 / T_{emission,\ local})$

Remark: $F_{Mainsource}$ is limited to a maximum of 1 in case of $M_{SPERC} > (T_{Region} * 1000 / T_{Emission})$

If $M_{SPERC} \times (T_{emission,\ local} / 1000) \geq MT_{regional}$, $M_{use(site)}$ should be defined assuming $F_{mainsource} = 1$, i.e., it would violate mass balance for a local annual tonnage to exceed the regional annual tonnage. Consequently, this portion of the SPERC assessment would then be identical to the ERC approach.

Please note that SPERC s for wide dispersive uses do not include the definition of M_{SPERC}. However, $F_{mainsource}$ may be refined if supporting information is available (as described above). In that manner, the estimate of $M_{use(site)}$ can be refined under the SPERC -based assessment.

Consistency of the approach for ERCs and SPERCs is important for the assessment on the regional and local level. Release fractions to different compartments are used together with the $M_{use(region)}$ to calculate the contribution of each use (represented by an ERC or SPERC in

TIER 1) at the regional scale and together with $M_{use(site)}$ or M_{SPERC} to calculate the local releases.

Release estimation
Based on the tonnage assignments to the region, the regional releases are calculated for air, waste water and soil.

Equation (A4): $Release_{regional(compartment)} = M_{use(region)} \times FR_{compartment}$ [kg/d]

The regional releases to each compartment are added for all uses to calculate the regional background concentrations, which are added to the C_{local} values in order to calculate the PEC_{local} values.

Similarly, local releases are calculated for air, and waste water in the case of point sources and for waste water only in the case of wide dispersive uses.

Equation (A5): $Release_{local(compartment)} = M_{use(site)} \times FR_{compartment}$ [kg/d]
with $M_{use(site)} = M_{SPERC}$ for SPERCs (assuming M_{SPERC} is applicable following the guidance from above)

For wide dispersive uses, the local releases to wastewater are summed and this overall release is used in the EUTGD model and reported. The result is a set of PECs and RCRs that are applicable for all wide dispersive uses.

Evaluation of the assessment

Evaluation for Point Sources
The evaluation for point sources can be summarised as follows:

ERC based assessment
$M_{safe} > M_{use(site)}$
=> safe use of entire M/I tonnage for a particular use at a single site

SPERC-based assessment
$M_{safe} > M_{SPERC}$ (i.e. RCR < 1 – directly from TRA)
=> safe use of typical/maximum volume at site considering the regional background based on $MT_{regional}$

in both cases refinement is necessary if $M_{safe} < M_{SPERC}$ (i.e. RCR > 1)

Example for refinement
E.g. Consider the scenario where M_{SPERC} = 50 kg/d, STP removal efficiency is 0.87 and the calculated RCR = 1.1; thus, M_{safe} = 45 kg/d
To refine, the user must calculate an additional or 'onsite' Removal Efficiency (RE) that ensures safe use; $RE_{onsite} = 1 - M_{safe}/M_{SPERC} = 0.091$ (9.1%)
The Required Removal Efficiency (RRE), equivalent to the Total RE, can then be expressed as: $RRE = RE_{Total} = 1 - (1 - RE_{STP}) * (1 - RE_{onsite}) = 0.88$.
The advantage of defining the RRE, RE_{STP} and RE_{onsite} is that it identifies the overall removal that is required for safe use (RRE), which can be achieved entirely by onsite RMM technology, or if an offsite STP is applicable, via a combination of onsite and offsite technologies. It is primarily for the Risk Assessor to determine the feasibility of RMMs to demonstrate safe use.

Communication of the assessment outcome:

Point Sources
ERC: M_{safe}, STP and removal efficiency (if STP is used),

SPERC: M_{safe}, STP and removal efficiency (if STP is used), RRE, RE_{onsite} (if applicable; i.e., assumed default in assessment and/or necessity of refinement), access to a list of suitable/typical RMMs for industry sector / group of substances with associated efficiencies (via SPERC factsheet) => scaling possible

Wide Dispersive Emissions
ERC: Wide dispersive uses are safe as assessed. A detailed communication is not required as no measures can be taken to ensure safe use.

SPERC: Wide dispersive uses are safe as assessed. A detailed communication is not required as no measures can be taken to ensure safe use (*there may be some exceptions for Professional uses).

Appendix 2 –SPERC Factsheet Examples

SPERC factsheet – Uses in Coatings – Industrial (Solvent-borne)

General Information	
Title of Specific ERC	Uses in Coatings (industrial): solvent-borne
Applicable ERC	4 – Industrial use of processing aids
Responsible	ESIG/ESVOC
Version	V1
Code	ESVOC 4.3a.v1
Scope	Covers the use in coatings (paints, inks, adhesives, etc.) including exposures during use (including materials receipt, storage, preparation and transfer from bulk and semi-bulk, application by spray, roller, spreader, dip, flow, fluidized bed on production lines and film formation) and equipment cleaning, maintenance and associated laboratory activities. *Substance Domain*: Applicable to petroleum substances (e.g., aliphatic and aromatic hydrocarbons) and petrochemicals (e.g., ketones, alcohols, acetates, glycols, glycol ethers, and glycol ether acetates).
Coverage	Process Categories: 1 (use in closed process, no likelihood of exposure), 2 (use in closed, continuous process with occasional controlled exposure), 3 (use in closed batch process (synthesis or formulation)), 4 (use in batch and other process (synthesis) where opportunity for exposure arises), 5 (mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)), 7 (industrial spraying), 8a (transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities), 8b (transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities), 10 (roller application or brushing), 13 (treatment of articles by dipping and pouring), 15 (use as laboratory reagent)

	Characteristics of specific ERC	Type of Input Information	Processing of Input Information
Operational Conditions	Indoor use. Solvent-based process. Process optimized for efficient use of raw materials. Volatile compounds subject to air emission controls. Negligible wastewater emissions as process operates without water contact. Wastewater emissions generated from equipment cleaning with water.		
Substance Use Rate	The substance maximum use rate in a typical operation (M_{SPERC}) is 50000 kg/d	Typical maximum site tonnage, based on sector knowledge*	None
Days Emitting	300 days/year	Default 'Industrial end use' – Tonnage > 5000 tonnes/year[1]	None
Environmental Parameters for Fate Calculation	Assumed dilution factor in freshwater is 10. For marine assessments an additional tenfold dilution is assumed, i.e., dilution factor in marine water = 100.	ERC default settings[2]	None

*Maximum amount of substance that is delivered to a site in one day based on typical site capacity (e.g., two trucks, each with a volume of 25 tonnes)

[1]ECHA Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation, Section R.16.3.2.1

[2]ECHA Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation, Section R.16.6.3

	Characteristics of Specific ERC		Justification
Emission Fractions (from the process)	***To Air***	0.98	OECD Coatings ESD[3]
	To Wastewater/Sewer/ Water courses WS < 1 mg/L WS 1-10 mg/L WS 10-100 mg/L WS 100-1000 mg/L WS >1000 mg/L	***f* (water solubility)** 0.00002 0.00007 0.0007 0.007 0.02	Emission factors to wastewater are conservatively calculated based on wastewater volume generated from blanket wash and cleaning of printing machines and substance aqueous solubility (*assuming no free product in wastewater stream; oil-water separation may be required under some circumstances*). *Assumption of 20 m^3 of wastewater generated per 1 tonne of substance used is relatively conservative.*[4] *Example: 1 mg/L x 20 m^3/tonne use x 1000 L/m^3 x 1tonne/10^9mg = 0.00002 tonnes/tonne used. For WS range (e.g., 1-10 mg/L), the geometric mean (i.e., 3.2 mg/L) is used to calculate the fraction released.*
	To Soil	0	OECD Coatings ESD[3]

[3]OECD Series on Emission Scenario Documents, Number 22. July 2009. Emission Scenario Documents on Coating Industry (Paint, Laquers and Varishes).

[4]Data from Ecoinvent 2.0 database suggest water use for offset printing and gravure printing are 1.14 and 3.54 m^3/tonne solvent, respectively (original reference: *Hischier R. 2007. Life cycle inventories of packaging and graphical paper. Final report ecoinvent data v2.0. Volume 11. Swiss Centre for LCI, Empa – TSL. Dubendorf, CH.*); thus, assumed value of 20 m^3/tonne represents a conservative estimate.

	Type of RMM	Typical Efficiency
Appropriate Risk Management Measures (RMM) that may be used to achieve required emission reduction	***Air***	
	On-site Technology Wet scrubber – gas removal Air filtration – particle removal Thermal oxidation Vapor recovery – Adsorption *Other*	 70% 80 – 99+% (efficiency range; no typical value reported)[5] 98% 80% Default efficiencies of the RMMs according to CEFIC Risk Management Library and [5]*IPPC 2009 draft BREF on Common Waste Water & Waste Gas Treatment/Management Systems in the Chemical Sector*. *A default value of 90% was selected on the basis of expected RMM efficiency consistent with typical site use (i.e., 50 t/d).
	Water	
	Offsite Technology Municipal wastewater treatment plant	The removal efficiency of a sewage treatment plant can be estimated. The standard estimation is via the SimpleTreat module of EUSES or ECETOC TRA. *Specific substance efficiency calculated via SimpleTreat and is assumed to represent default removal efficiency.
	Onsite Technology Air flotation Distillation (*of used process solvent; prior to any water contact*) Acclimated biological treatment *Other*	The efficiency of the RMMs varies dependent on the treatment technology and the properties of the substance. The standard RMMs encountered in the processes considered here typically provide removal efficiencies in excess of 80% (according to CEFIC Risk Management Library) For readily and inherently biodegradable substances, the removal efficiency for acclimated biological treatment may be significantly higher than SimpleTreat estimates; thus, SimpleTreat estimates can serve as a conservative lower bound. Substance-specific efficiencies can be considered.

Narrative Description of / Justification for specific ERC
Description: Industrial use of solvent-borne coatings encompasses a wide range of activities such as spraying, brushing, cleaning, etc. Substance losses are reduced through use of general and site-specific risk management measures to maintain workplace concentrations of airborne VOCs and particulates below respective OELs; and through use of closed or covered equipment/processes to minimize evaporative losses of VOCs. Substance properties and uses result in limited to no discharge to wastewater or to soil from the industrial site. Justification: The overall high efficiency of solvent use in industrial coating processes accounts for the low emission factors to wastewater and air (in combination with on-site RMMs) as identified in the OECD Coatings ESD (2009).

Safe Use

Communication in SDS

The REACH registrant establishes a set of standard conditions of safe use for a substance (for industrial use of a solvent-borne processing aid) by adopting the conditions specified in this SPERC and recommending a Required Removal Efficiency (RRE) for adequate risk reduction. If RRE = 0, wastewater emission controls (beyond those specified by the operational conditions) are not required to ensure safe use of the substance. If > 0, the RRE may be achieved via offsite municipal sewage treatment (providing substance removal efficiency, $RE_{Offsite}$) and/or onsite emission controls (providing substance removal efficiency, RE_{Onsite}). Multiple onsite emission reduction technologies can also be considered, if necessary and applicable (e.g., $RE_{Onsite} = 1 – [(1 – RE_{Onsite, 1}) \times (1 – RE_{Onsite, 2}) \times$ etc.], where $RE_{Onsite, n}$ represents the substance removal efficiency for each onsite emission reduction technology). For direct comparison to the RRE, a total substance emission reduction efficiency (RE_{Total}) is calculated ($RE_{Total} = 1 – [(1 – RE_{Onsite}) \times (1 – RE_{Offsite})]$). An RE_{Total} < RRE is indicative of the safe use of a substance.

Removal efficiency requirements, as dictated by the assumed operating conditions, are documented in the Chemical Safety Report and communicated in the Safety Data Sheet. All other parameters underlying a substance exposure scenario based on the SPERC 'Uses in coatings – industrial (solvent-borne)' are implicitly referred to via the reference to this SPERC.

Scaling

Wastewater

The users of solvent-borne processing aids are responsible for evaluating the compliance of their specific situations with the registrant's information. To that end, the users need to know their site-specific substance use rate (M_{Site}) and days emitting ($T_{Emission, Site}$), onsite and offsite emission controls and subsequent total substance emission reduction efficiency ($RE_{Total, Site} = 1 – [(1 – RE_{Onsite, Site}) \times (1 – RE_{Offsite, Site})]$), sewage treatment plant effluent flow rate ($G_{Effluent, Site}$) and receiving water dilution factor (q_{Site}). Adequate control of risk exists if the following relevant expression holds true:

for risk driven by wastewater treatment plant microbes

$$[M_{SPERC} \times (1 – RE_{Total, SPERC})] / G_{Effluent, SPERC} \geq [M_{Site} \times (1 – RE_{Total, Site})] / G_{Effluent, Site}$$

for risk driven by freshwater/freshwater sediments, marine water/marine water sediments

$$[M_{SPERC} \times (1 – RE_{Total, SPERC})] / (G_{Effluent, SPERC} \times q_{SPERC}) \geq [M_{Site} \times (1 – RE_{Total, Site})] / (G_{Effluent, Site} \times q_{Site})$$

for risk driven by secondary poisoning (freshwater fish/marine top predator) or indirect exposure to humans (oral)

$$[M_{SPERC} \times T_{Emission, SPERC} \times (1 – RE_{Total, SPERC})] / (G_{Effluent, SPERC} \times q_{SPERC}) \geq [M_{Site} \times T_{Emission, Site} \times (1 – RE_{Total, Site})] / (G_{Effluent, SPERC} \times q_{Site})$$

It is simpler and thus may be preferable to some users to compare M_{Site} with M_{Safe} (*the maximum tonnage that can be safely used, within the prescribed operating conditions, OC_{SPERC} and RMM, $RE_{Total, SPERC}$*). Adequate control of risk exists if the following conditions are met [$RE_{Total, Site} \geq RE_{Total, SPERC}$, $G_{Effluent, Site} \geq G_{Effluent, SPERC}$, and $q_{Site} \geq q_{SPERC}$] and $M_{Safe} \geq M_{Site}$.

Local amount used, emission days per year, receiving water flow rate (or dilution factor), sewage treatment plant effluent flow rate, and risk management measure removal efficiency are the adjustable parameters for emission assessment. These parameters can be refined using site-specific information, which often is obtainable with limited effort and expertise. Adjusting the assessment by refining these parameters is referred to as scaling. Scaling is applied to evaluate compliance of a specific use with a generic Exposure Scenario. For that reason, site parameter values which deviate from the default values need to reflect the actual situation. This may have to be justified on demand.

The release factors are an additional set of adjustable parameters; however, refining the default values requires significant justification and, thus, is beyond the boundary conditions defined in the SPERC Factsheet. For that reason, release factor refinements do not constitute a SPERC-based assessment and must be considered an element of downstream user chemical safety assessment.

SPERC factsheet – *Industrial use in formulation of liquid cleaning and maintenance products*

General Information	
Title of Specific ERC	Industrial use in formulation of liquid cleaning and maintenance products
Applicable ERC	2 – Formulation of preparations
Responsible	AISE
Version	V1
Code	AISE SPERC 2.1.g.v1 AISE - Formulation of liquid Detergents/Maintenance Products: Low Viscosity (large scale) AISE SPERC 2.1.h.v1 AISE - Formulation of liquid Detergents/Maintenance Products: Low Viscosity (medium scale) AISE SPERC 2.1.i.v1 AISE - Formulation of liquid Detergents/Maintenance Products: Low Viscosity (small scale) AISE SPERC 2.1.j.v1 AISE - Formulation of liquid Detergents/Maintenance Products: High Viscosity (large scale) AISE SPERC 2.1.k.v1 AISE - Formulation of liquid Detergents/Maintenance Products: High Viscosity (medium scale) AISE SPERC 2.1.l.v1 AISE - Formulation of liquid Detergents/Maintenance Products: High Viscosity (small scale)
Scope	Covers the whole process of formulation as it occurs in the manufacturing of liquid cleaning and maintenance products. This includes storing, mixing, packaging of substances (as part of preparations) and equipment cleaning, maintenance and associated laboratory activities. *Substance Domain:* All (see Narrative Description)
Coverage	Process Categories: 1 (use in closed process, no likelihood of exposure), 2 (use in closed, continuous process with occasional controlled exposure), 3 (use in closed batch process (synthesis or formulation)), 4 (use in batch and other process (synthesis) where opportunity for exposure arises), 5 (mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)), 8a (transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities), 8b (transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities), 13 (treatment of articles by dipping and pouring), 15 (use as laboratory reagent)

	Characteristics of specific ERC			Type of Input Information	Processing of Input Information
Operational Conditions	AISE 2.1.g.v1	Process optimized for highly efficient use of raw materials.		Sector specific classification of detergent formulation sites.	No processing required
	AISE 2.1.h.v1	Process optimized for efficient use of raw materials.			
	AISE 2.1.i.v1	Process with efficient use of raw materials.			
	AISE 2.1.j.v1	Process optimized for highly efficient use of raw materials.			
	AISE 2.1.k.v1	Process optimized for efficient use of raw materials.			
	AISE 2.1.l.v1	Process with efficient use of raw materials.			
Substance Use Rate	AISE 2.1.g.v1	The substance maximum use rate in a typical operation (M_{SPERC} in kg/d)	16700.	Typical maximum site tonnage, based on sector knowledge*	See below*
	AISE 2.1.h.v1		4500		
	AISE 2.1.i.v1		10		
	AISE 2.1.j.v1		16700.		
	AISE 2.1.k.v1		4500		
	AISE 2.1.l.v1		10		
Days Emitting	AISE 2.1.g.v1	Number of days/ year during which emissions take place	300	Equivalent to number of working days, based on sector knowledge	None
	AISE 2.1.h.v1		220		
	AISE 2.1.i.v1		20		
	AISE 2.1.j.v1		300		
	AISE 2.1.k.v1		220		
	AISE 2.1.l.v1		20		
Environmental Parameters for Fate Calculation	AISE 2.1.g.v1	Assumed dilution factor in freshwater is 10. For marine assessments an additional tenfold dilution is assumed, i.e., dilution factor in marine water = 100.		Dilution factors taken from REACH Guidance Document	No processing required
	AISE 2.1.h.v1				
	AISE 2.1.i.v1				
	AISE 2.1.j.v1				
	AISE 2.1.k.v1				
	AISE 2.1.l.v1				

*M_{SPERC} is calculated according to: $\mathbf{M_{SPERC} = M_{Site} \times C_{SP} \times T_{Emission,SPERC}^{-1}}$ with C_{SP} = Concentration of substance in product, M_{Site} = the amount of product manufactured, $T_{Emission,SPERC}$ = number of days emitting. Typical parameters values are given in Table 1.

	Emission Fractions (from the process)		Justification
To air ***(*** f_{Air}***)***	AISE 2.1.g.v1	0	EU TGD 2003 Technical Guidance Document on Risk Assessment. Part II, Appendix1 A Table A2 (p 226) EU TGD 2008 Guidance on information requirements and chemical safety assessment. Chapter R.16: Environmental Exposure Estimation, Guidance on the implementation of REACH, European Chemicals Agency, May 2008. Franke et al., 1995 Ökobilanzierung- Sachbilanz für die Waschmittel-Konfektionierung Tenside Surf. Det, 32:(508-514 Royal Haskoning 2009 Review and evaluation of environmental emission scenarios for fragrance materials during compounding of perfume oils and formulation of consumer products (Research Institute for Fragrance Materials Ref.:9S3975.01/R0007/Nijm, 2009).
	AISE 2.1.h.v1	0	
	AISE 2.1.i.v1	0	
	AISE 2.1.j.v1	0	
	AISE 2.1.k.v1	0	
	AISE 2.1.l.v1	0	
To water (f_{Water}***)***	AISE 2.1.g.v1	0.0001	
	AISE 2.1.h.v1	0.001	
	AISE 2.1.i.v1	0.002	
	AISE 2.1.j.v1	0.001	
	AISE 2.1.k.v1	0.002	
	AISE 2.1.l.v1	0.004	

	Type of RMM	Typical Efficiency
Appropriate Risk management measures (RMM) that may be used to achieve required emission reduction	***Air:***	None
	Water:	Typical emission reducing equipment/procedures in the detergent/cleaner plants may comprise: 1. Spill protected areas 2. (Dry) cleaning procedures with maximization of waste reuse in the process 3. Collection of spills and handling by an external third party (typically via incineration) 4. On-site physico-chemical pre-treatment of the waste water (e.g. via pH adjustment, flocculation/precipitation, sedimentation) 5. Handling of the physico-chemical sludge by an external third party (typically via incineration)
	Waste water treatment plant (WWTP)	Waste waters from detergent/cleaner manufacturing will normally be treated additionally by on-site or/and off-site biological WWTP. The removal efficiency of detergent ingredients in a biological WWTP can be estimated via models such as SimpleTreat or obtained from monitoring programmes. In some instances, WWTPs may be equipped with additional steps such as sand filtration, activated carbon treatment or ultrafiltration of the effluent. These will lead to further increased removal of individual chemicals and total BOD/COD.
	Selection of typical RMM technologies applied in on-site treatment of wastewaters.	Default RMM efficiencies[1] according to Risk Management Library - pH adjustment / flocculation coagulation: 30% - (ultra-) filtration, membrane filtration: 50% - on-site biological treatment : > 75% if substances are soluble and biodegradable

[1] The efficiency of the RMMs varies dependent on the treatment technology and the properties of the substance. Specific efficiencies for specific substances can be considered in the assessment.

Narrative Description of / Justification for specific ERC

Industrial use in formulation of cleaning and maintenance products

For economic reasons, formulation of preparations requires optimized use of raw materials for inclusion into products. Losses of raw materials via volatilization are negligible. Significant losses to the environment can be the result of cleaning of mixing vessels, tubings, production/packaging lines. High viscosity products adhere more strongly to the walls of mixing vessels, tubings, production/packaging lines. They are less efficiently transferred into the packaging. Hence, emissions caused by equipment cleaning are higher and lower for high and low viscosity products, respectively. These losses occur irrespective of the physical-chemical properties of the detergent ingredient substances. For that reason, this SPERC pertains to all substances.

Technical comments

- Before treatment means: emissions as entering an on-site biological WWTP, or if absent, as leaving the site towards a municipal WWTP.
- It is assumed for simplicity that 1 kg detergent or cleaner (excl. water) represents ~ 1 kg COD. Actual average value for the chemical ingredients may range from 1-2.
- Emissions to soil or solid waste are not discussed here, as justified in IFRA (2009), these are considered negligible. Emissions to air are discussed below.

M_{SPERC} is calculated according to Expression 1:

$$M_{SPERC} = C_{SP} \times M_{Site} \times T_{Emission,SPERC}^{-1}$$

A realistic high-end value of a substance concentration in a liquid product amounts to 20%.

The numbers that are presented in this SPERC are consistent with the emissions used as default in published Life Cycle Inventories (LCI) for the manufacturing of detergents and cleaners. These data were the basis for the A/B Tables of the EU Technical Guidance Document have been adopted as defaults in this SPERC. In addition, more recent information was included in this factsheet (See ‘Emission Fractions’).

Safe Use

Communication in SDS

The REACH registrant establishes a set of standard conditions of safe use for a substance for formulation of cleaning and maintenance products by adopting the conditions specified in this SPERC and eventually recommending a certain efficiency required for an adequate risk reduction. This may include the removal efficiency of municipal sewage treatment plant ($RE_{STP,SPERC}$), and the efficiency of an on-site emission reduction ($RE_{ER,SPERC}$). This information is documented in the Chemical Safety Report and communicated in the Safety Data Sheet. All other parameters underlying a substance exposure scenario based on the SPERC 'Industrial Use in Formulation of Cleaning and Maintenance Products' are implicitly referred to via the reference to the SPERC.

Scaling

Wastewater

The formulators of detergent products are responsible for evaluating the compliance of their specific situations with the registrant's information. To that end, they need to decide which of the SPERCs applies to their operation. In addition, they need to know their site-specific substance use rate (M_{Site}), onsite and offsite emission controls and subsequent total substance emission reduction efficiency ($RE_{Total,\ Site} = 1 – [(1 – RE_{Onsite,\ Site}) \times (1 – RE_{Offsite,\ Site})]$), sewage treatment plant effluent flow rate ($G_{Effluent,\ Site}$) and receiving water dilution factor (q_{Site}). Adequate control of risk exists if the following relevant expression holds true:

for risk driven by wastewater treatment plant microbes

$[M_{SPERC} \times (1 – RE_{Total,\ SPERC})] / G_{Effluent,\ SPERC} \geq [M_{Site} \times (1 – RE_{Total,\ Site})] / G_{Effluent,\ Site}$

for risk driven by freshwater/freshwater sediments, marine water/marine water sediments

$[M_{SPERC} \times (1 – RE_{Total,\ SPERC})] / (G_{Effluent,\ SPERC} \times q_{SPERC}) \geq [M_{Site} \times (1 – RE_{Total,\ Site})] / (G_{Effluent,\ Site} \times q_{Site})$

for risk driven by secondary poisoning (freshwater fish/marine top predator) or indirect exposure to humans (oral)

$[M_{SPERC} \times T_{Emission,\ SPERC} \times (1 – RE_{Total,\ SPERC})] / (G_{Effluent,\ SPERC} \times q_{SPERC}) \geq [M_{Site} \times T_{Emission,\ Site} \times (1 – RE_{Total,\ Site})] / (G_{Effluent,\ SPERC} \times q_{Site})$

It is simpler and thus may be preferable to some users to compare M_{Site} with M_{Safe} (*the maximum tonnage that can be safely used, within the prescribed operating conditions, OC_{SPERC} and RMM, $RE_{Total,\ SPERC}$*). Adequate control of risk exists if the following conditions are met [$RE_{Total,\ Site} \geq RE_{Total,\ SPERC}$, $G_{Effluent,\ Site} \geq G_{Effluent,\ SPERC}$, and $q_{Site} \geq q_{SPERC}$] and $M_{Safe} \geq M_{Site}$.

Local amount used, emission days per year, receiving water flow rate (or dilution factor), sewage treatment plant effluent flow rate, and risk management measure removal efficiency are the adjustable parameters for emission assessment. These parameters can be refined using site-specific information, which often is obtainable with limited effort and expertise. Adjusting the assessment by refining these parameters is referred to as scaling. Scaling is applied to evaluate compliance of a specific use with a generic Exposure

Scenario. For that reason, site parameter values which deviate from the default values need to reflect the actual situation. This may have to be justified on demand.

The release factors are an additional set of adjustable parameters; however, refining the default values requires significant justification and, thus, is beyond the boundary conditions defined in the SPERC Factsheet. For that reason, release factor refinements do not constitute a SPERC-based assessment and must be considered an element of downstream user chemical safety assessment.

Table 1: Derivation of the default substance use rate M_{SPERC} for *Industrial use in formulation of liquid cleaning and maintenance products*. The derivation is based on typical values of the operational conditions for the various applications covered by this SPERC[2].

SPERC	**Other Operational Conditions – Phrase**	**Operational Conditions – Values for selected parameters expressing the operational conditions for the SPERC 'industrial use – formulation of liquid cleaning and maintenance products.**			
	Phrase	Substance Use Rate (M_{SPERC}) in kg/d[3]	Days emitting (days per year	Annual production (t/y)	Substance concentration in product
AISE 2.1.g.v1 AISE 2.1.j.v1	Process optimized for highly efficient use of raw materials.	16700	300	25000	20%
AISE 2.1.h.v1 AISE 2.1.k.v1	Process optimized for efficient use of raw materials.	4500	220	5000	20%
AISE 2.1.i.v1 AISE 2.1.l.v1	Process with efficient use of raw materials.	10	20	1	20%

[2] Numerical values need to be confirmed based on association input.
[3] Refers to the substance, not the product.

Typical parameter combinations are given in Table 1 below

[1]ECHA Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation, Section R.16.3.2.1

[2]ECHA Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation, Section R.16.6.3

Appendix 3 – Members of the SPERC Core Team

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