**Messages to communicate in the supply chain on extended SDS for substances II**

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*Although the below communication aims to answer the majority of questions from customers, Cefic or any of the above organisations are aware that it may not address all questions as many different situations may arise in supply chains. The arrangements between individual suppliers and individual customers may also be either more complex than supposed in the questions considered in this paper or may differ from these. Should you have a specific issue that is not covered below please discuss it with your supplier. Companies are also advised to check individual cases with their company lawyers.*

*The recommendations below are focusing on supply chain communication on substances. There is still limited experience on mixtures at the moment and they are therefore out of scope for this communication.*

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## 1. What is an Exposure Scenario (ES)[1]?

An 'Exposure Scenario' describes how a substance can be safely handled to control exposures to both human health and the environment for the uses of the substance. ESs include the operational conditions (OCs) and risk management measures (RMMs), identified as necessary for controlling exposures for the relevant uses.

The full REACH definition for an Exposure Scenario is as follows:

*An Exposure Scenario is a set of conditions that describe how a substance (as such, in a mixture or in an article) is manufactured or used during its life-cycle and how the manufacturer or importer or downstream user controls or recommends controlling exposure of humans and the environment[2] .*

ESs are required to be developed as part of the registration process for the identified uses[3] of substances that are put on the market in amounts of >10 tonnes per year and legal entity and are classified as hazardous or are assessed to be PBT or vPvB[4]. If safe use can be demonstrated, the associated ESs will be annexed to the Safety Data Sheet. Those uses for which safe use cannot be demonstrated will be identified as 'uses advised against' and also reported in the SDS.

It should be noted that one identified use can be linked to more than one ES and one ES can cover several identified uses as long as the associated activities, described as Contributing Scenarios (CS) (including their OCs and RMMs) are applicable to those uses. Uses and their associated CS may in turn be consolidated under a particular application area as is the case with the Cefic Generic Exposure Scenario[5] approach, e.g. Uses in Coatings, Uses in Cleaning Agents.

[1] See ECHA guidance on ES for more information: http://guidance.echa.europa.eu/exposure_scenarios_en.htm

[2] See definition of 'exposure scenario' in article 3.37 of the REACH Regulation

[3] See definition of 'use' in article 3.24 of the REACH Regulation

[4] ES must be provided for substances meets the criteria for classification as dangerous in accordance with the CLP Regulation 1272/2008 or is assessed to be a PBT or vPv, see article 14.4 of the REACH Regulation

[5] More information on Generic Exposure Scenarios can be found on the Cefic website: http://www.cefic.org/Documents/IndustrySupport/Cefic-GES-under-REACH.pdf

The uses that are covered in the ES can be defined in a standardised way using the so-called 'use descriptor'[6] system provided in ECHA guidance. However, in many cases listing a series of use descriptors alone in the extended SDS is insufficient to describe the use that the ES covers and it might be difficult for the downstream user to decide whether his particular use is covered or not.

*Note that REACH only addresses the concept of 'Use' in general terms. The Use Descriptor system is intended to support consistency of communication of uses up and down the supply chain. However, different suppliers may describe a use in different ways.*

When checking whether a use is covered, it is important to check how the use is described including the associated use conditions and whether it matches your knowledge of how you handle the substance. For formulators this should also include the downstream uses of their formulated products that contain the substance for which the ES has been received.

Section 1 of the ES often includes a short title plus summary scope statement describing the activities covered by the ES and is included alongside the Use Descriptor codes. It is recommended to review the title and scope statement in the first instance to see if the details described are typical of your own activities. The activities are usually broken down into Contributing Scenarios, e.g. bulk transfers, sampling, filling of equipment and containers, with associated OCs and RMMs required for safe handling.

## 2. What is an extended SDS and what information does it contain?

An extended SDS for a substance is an SDS with at least one exposure scenario (ES) included in the annex. The term 'extended' is not meant to indicate only that the content of the main body of the SDS (sections 1 through 16) has been updated.

The main body of an SDS has a well defined format and content prescribed by the Regulation (EU) No. 453/2010. Comprehensive guidance on what information should be included in the respective sections will be available from ECHA shortly[7]. The REACH text, however, does not define the format/layout or the content of the ES attached to the SDS.

An extended SDS for a substance should describe all the different uses that have been assessed by the supplier (or someone further up his supply chain) and are relevant for the recipient (see advice below). It should contain specific operational conditions (OCs) and risk management measures (RMMs) that are considered necessary to adequately control the risks associated with how the substance is used further down the supply chain. The extended SDS will only consider uses that the substance manufacturer/importer already knows or has been made aware of and has decided to include in his chemical safety assessment.

It is recommended that a supplier should only provide an extended SDS when both the registration number and the relevant exposure scenarios are ready (if ESs are needed,

[6] More information on the Use Descriptor system can be found here: http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf

[7] Draft Guidance on SDS can be found here: http://guidance.echa.europa.eu/guidance4_en.htm

please see question 7 below). In case suppliers do not have the ES for communication ready, and the registration number/s is/are included, it is proposed to include a phrase in section 15 that the ESs are under development. This solution is of course temporary until ESs are available.

Including the registration number for a substance in the SDS without attaching the ES is not recommended because downstream users will inevitably query where the ES is if an ES is needed. If you choose to do it anyway, it is proposed to indicate that the ES are under development (see above). Additionally, the SDS will have to be updated again when the ES does become available causing further administrative burden on the downstream users. The deadlines from article 39 for downstream users start from the date you receive an extended SDS with both a registration number and an ES[8].

However it should be noted that an ES only needs to be provided for a substance classified as hazardous or assessed to be a PBT or vPvB. If an SDS is provided for a substance that is not classified as hazardous or is neither a PBT nor a vPvB then it will usually not contain an ES. Other valid reasons for a supplier not including an ES with the SDS are listed in section 7.

**It is proposed that a supplier should only provide an extended SDS when both the registration number and the relevant exposure scenarios are ready (if ES are needed, please see above).**

### 3. Where can I find more information about Exposure Scenarios?

Examples of Exposure Scenarios can be found in Part II of the Practical Guide on Exposure Assessment and Communications in the Supply Chains, Annexes A2.11, A2.14 – A2.17. Further explanations to exposure scenarios are given in chapters 3.2 and 9[9] of the Practical Guide.

### 4. How are ES communicated along the supply chain?

Exposure Scenarios are communicated to downstream users as attachments to the safety data sheet (so-called extended SDS). The REACH Regulation does not prescribe a fixed format (layout) for this ES annexed to the safety data sheet, The ECHA Guidance on information requirements and chemical safety assessment "Exposure Scenario Format" includes a suggested format for exposure scenarios being part of the CSR or as attachment to the SDS[10]. In addition, ECHA's Chesar system [11]is an example of a tool that can be used to generate an ES format. The use of these formats is not mandatory. However, a

[8] See page 4 of the ECHA fact sheet : http://echa.europa.eu/doc/reach/du_fs/du_fact_sheet_en.pdf

[9]The Practical guide can be found on the Cefic REACH website: http://www.cefic.org/Industry-support/Implementing-reach/Documents-and-Tools1/

[10]http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_ESformat_en.pdf?vers=27_05_10

[11] For more information about ECHA's Chesar tool : http://chesar.echa.europa.eu/

harmonized format supports the consistency and clarity of the of information communicated (also with regard to IT systems – see below).

The communication requirement increases the level of complexity with regards to capturing relevant information into company IT systems (that are invariably different) and further onward communication after assimilating relevant information that has often been received from many different suppliers.

To facilitate the harmonised communication, industry has developed the ESCom Standard, consisting of a standard phrase catalogue (ESCom Phrases) and an IT standard for electronic data transfer (ESCom XML). One aim of the ESCom XML is to define the fields that could be included in the ES in order to provide an electronic system for automatically capturing the information contained in an ES and transferring it between the different computer systems used by the actors in the supply chain thereby enabling them to manage such data, author safety data sheets and make translations possible in other languages by using standard phrase catalogues.

The ESCom Phrases, developed by industry, contains sector specific and generic phrases and can be used to compose a complete ES. Standard phrases may include so called meta data. This is additional information linked to a standard phrase that eases the selection of phrases. The phrase codes assigned to all standard phrases will facilitate the use of phrase catalogues in different languages.

The ESCom Standard is available for free and can be downloaded from the Cefic website:

http://www.cefic.org/Industry-support/Implementing-reach/IT-Tools/

## 5. Where can I find the Exposure Scenario for the substance I buy?

A supplier of a substance is obliged to attach the Exposure Scenario(s) relevant for the uses he has agreed to include in his registration as an annex to the SDS (if one or more ESs are needed)[12].

It might be helpful to the downstream user if the supplier includes in section 16 of the SDS a table of contents or an index table summarising all the ESs contained in the annex (this is in particular recommended for extended SDSs with many ESs). Alternatively, the supplier might provide this information as a cover page after section 16, between the main body of the SDS and the ES annex(es). Examples of how these tables may look can be found in Annex I of this document.

In some cases a substance has a large number of possible different uses in the supply chain (e.g. solvents) and a supplier may end up with many different exposure scenarios being generated for that substance.

[12] According to the first paragraph of Article 31(7) of REACH: *"Any actor in the supply chain who is required to prepare a chemical safety report according to Articles 14 or 37 shall place the relevant exposure scenarios (including use and exposure categories where appropriate)* ***in an annex to the safety data sheet*** *covering identified uses and including specific conditions resulting from the application of Section 3 of Annex XI."*

However, sending all the ESs to customers may create confusion and result in an extended SDS with a large number of pages. As well as potentially causing problems both for the sender and recipient when sending such large documents electronically or in paper format, there are also potential confidentiality issues; for example, if a use described by an ES is confidential for a customer and that ES is also provided to another customer. Suppliers therefore need to decide whether to send only relevant ES to each of their downstream users or to send all ESs associated with that registration to all customers.

It follows, therefore, that not all downstream users need to receive all exposure scenarios that have been generated for a substance, especially where the supplier knows that a particular use is irrelevant for a particular downstream user (or is confidential for some of his customers). Suppliers should also consider whether some ES are only relevant for their own companies and not for the customers e.g. ES for 'manufacturing activities' may only be relevant for a supplier's own activities and not for his customers' activities.

Whilst this approach may be desirable, however, it might not be practical for some suppliers depending on the systems used to author and dispatch safety data sheets.

Finally, if a downstream user has to prepare a CSR for a substance according to article 37 and Annex II of REACH, the resulting relevant ES(s) will need to be attached to the SDS that the downstream user provides to his customers.

## 6. Should all SDS include a registration number? What if the registration number is truncated?

Under certain circumstances, suppliers of substances are allowed to truncate the registration number included on the SDS, specifically by omitting the last 4 digits which are company specific[13].

*Downstream users (DUs) have no obligation to request the full number from their suppliers but enforcement authorities can request full registration numbers*. In this case, DUs will need to contact their supplier(s) preferably using the standard letter provided by Cefic[14]. The supplier should respond by providing the full registration number directly to the enforcement authority within 7 days of the receipt of the request (the response time is increased by an additional 7 days for each subsequent step of the supply chain until the registering manufacturer/importer can be reached). It is recommended that the suppliers keep the initially approached downstream user informed on the actions taken.

In some cases, the SDS of a substance will not contain a registration number. There are a number of valid reasons for this (please see previous Cefic communication: http://www.cefic.org/Documents/IndustrySupport/Communication_January2011_final.pdf)

In these cases, suppliers are advised to consider including an explanation e.g. in section 1.1 "Product Identifier" of the SDS of a substance to avoid uncertainty in the supply chain and to

[13] This provision is specified by Regulation 453/2010

[14] The standard letter is available at : http://www.cefic.org/Industry-support/Implementing-reach/Documents-and-Tools1/ http://www.cefic.org/Industry-support/Implementing-reach/Documents-and-Tools1/

explain the reason for its absence. Examples of phrases that can be used for this purpose are:

*"No registration number is given yet for this phase-in substance since the transition period for its registration according to Article 23 of REACH has not yet expired"*

*"This substance is exempted from Registration according to the provisions of Article 2(7)a and Annex IV of REACH".*

## 7. Why does the Safety Data Sheet of my substance not contain an Exposure Scenario?

There are several valid reasons why an exposure scenario might not be included as an annex to your supplier's safety data sheet.

First of all, not all registrants are obliged to carry out a Chemical Safety Assessment (CSA) and prepare a Chemical Safety report (CSR). For example, substances registered in quantities lower than 10 tonnes/year or substances registered as an onsite isolated or transported isolated intermediate according to article 17 or 18 do not need to include a CSR in the registration dossier.

Moreover, not all registrants who are required to carry out a CSA/CSR are required to prepare an exposure scenario (ES):

- Registrant of a substance that does not meet the criteria in REACH article 14.4
- Other reasons explained by the registrant

Even if he is not obliged to do so, the registrant may choose to provide his downstream users with a safety data sheet on a voluntary basis.

Finally, the substance might belong to one of the categories that are exempt from registration under REACH (e.g. it is a polymer, a substance manufactured/imported below 1 tonne/year, etc.) or the product is a pre-registered substance where the manufacturer/importer has not yet submitted his registration.

Exposure scenarios will therefore normally only be attached to SDSs after the relevant hazardous substance has been registered by the supplier (or someone further up his supply chain). Due to the implementation of several changes in the IT systems and processes of companies, the attachment of the exposure scenario might be temporarily delayed.

If the substance is exempted or has not been registered yet by the supplier, it is proposed that he should include a comment somewhere on the safety data sheet (e.g. section 15.2, or included in the annex if a blank sheet is to be automatically attached) to explain that it will be registered under a later deadline. Suggested phrases are given below[15]:

[15] These phrases are included in the draft ECHA Guidance on SDS: http://guidance.echa.europa.eu/guidance4_en.htm and in the European phrase catalogue EuPhraC (www.euphrac.eu)

*"No registration number is given yet for this preregistered substance since the transition period for its registration according to Article 23 of REACH has not yet expired"*

*"This substance is exempted from Registration according to the provisions of Article 2(7)a and Annex IV of REACH".*

## 8. What should I do when receiving an extended SDS for a substance containing one or more exposure scenarios?

A recipient of an extended SDS is obliged to:

- **assess** whether his own uses (for own activities e.g. mixing) are covered by exposure scenarios and
- **communicate** the information from the extended SDS to his customers down the supply chain. Each level of the supply chain is supposed to forward the information in the most appropriate way to the next level
  and
- **comply** with the RMM/OC's or demonstrate equivalent controls are in place thereby ensuring safe use. The DU should find the most suitable ES for his use. It should be noted that there is no need to have a 100% match of the OCs/RMMs applied by the DU, in these cases, scaling[16] may be possible.

Recipients of an extended SDS are advised to carry out the checks described below to assess whether their own uses are covered. It may be useful to consider the uses that are relevant for the DU further down the supply chain. These actions are detailed in the check-list included in point 10 and summarised in the chart included in Annex III.

## 9. What should a downstream user do if his use is not included on the extended SDS?

If a downstream user has determined that the uses described in the extended SDS do not cover his uses (see Q10 below), then he has several options:

- The downstream user can **contact his supplier** to discuss whether the supplier will assess the missing use and provide a new extended SDS containing the relevant information for the additional use. For practical reasons, before starting the 'formal' request to cover an additional use, it is advised **to have a dialogue with the supplier** in order to analyse the situation as in many cases it may imply an update of the registrant's CSR which requires time.

In some cases, during this informal dialogue, it may turn out that the use was indeed covered, it was just not clear to the Downstream user. Scaling possibilities may be part of this dialogue (see below). The legal text says in Article 37.3 that the CSR needs to be

[16] Scaling means adjusting your operational conditions and Risk Management measures to achieve a similar situation to the one described in the ES. It is a complex process and there are a number of ongoing initiatives to refine this concept. The outcome is expected later in 2011.

updated including the new ES within one month of the request of making a new use known, or at least one month before the next delivery (whichever is the later date).

However, in order to make a use known to a supplier "sufficient information" needs to be provided[17] and so the deadline only begins once both parties are satisfied that "sufficient information" is available. An example of the minimum level of detail is the input to the TRA tool e.g. SES template[18].

o If the use is described, but the conditions are not matched, the downstream user can **apply scaling**. Information required to conduct scaling should be made available in section 4 of the ES. Scaling tools must be specific to the quantitative exposure estimation tool used by the registrant, e.g. ECETOC TRA for worker risk assessment. Scaling tools and related guidance must clearly define the parameters for which scaling is possible and the limitations of scaling (in contrast to conducting a new risk assessment). Guidance on the scope and the limitations of scaling are under development as well as scaling tools for worker (based on the ECETOC TRA) and the environment (based on the e,g, ECETOC TRA and EUSES).

However, this should be assessed case by case as some uses may need a more complex assessment.

o The downstream user can **prepare his own Chemical Safety Report** (including the appropriate exposure scenario) if one is required. This might be a preferable option if the downstream user would like his particular use to remain confidential and scaling turned out to be not appropriate. In this case the DU should notify to ECHA that he has prepared his own CSR for this particular use[19].

o The downstream user can discontinue using the substance for any uses not included in the exposure scenarios attached to the extended SDS.

o The downstream user can implement the RMMs and OCs as described in the ES.

o The downstream user can change his supplier

The DU has to choose and implement one of the options above within 12 months from the receipt of the extended SDS. The 12 months start to count for the DU when the registration number AND the ES are included in the extended SDS.

**It is proposed that a supplier should only provide an extended SDS when both the registration number and the relevant exposure scenarios are ready (if ES are needed, please see above).**

[17] article 37.2 of the REACH Regulation

[18] The Cefic SES template is available here: http://www.cefic.org/Industry-support/Implementing-reach/Documents-and-Tools1/

[19] For more information about how to notify to ECHA : http://echa.europa.eu/reach/du/du_use_reprting_en.asp

## 10. CHECK-LIST FOR RECIPIENT OF AN EXTENDED SDS

✓ **Is the substance registered under REACH?**

- Look for registration number in section 1 of the SDS.
- If there is no registration number, the substance may be exempted or have a later registration deadline. In this case, besides his usual compliance with the information contained in the supplier's SDS there is no further obligation under REACH for the DU to check that his uses are included in an ES,
- Note that even where no registration number is provided there may still be a list of uses in section 1.2 of the SDS; the DU can still use this information to assure himself that his use will be included when the ES is eventually attached or, if his use is not listed, it may provide him with a reminder that he still needs to communicate his use upstream at the relevant time.

✓ **Is the substance classified as hazardous?**

- Look for classification in section 2 of the SDS. If registered and classified for human health and/or environment it is likely that there are ES annexed. There are, however, valid situations where an ES is not available for a hazardous substance (e.g. the substance is due for registration in the scope below 10 tonnes/year or was registered as an intermediate under strictly controlled conditions). In this case, the supplier may have indicated the reason for the absence of ESs e.g. in section 15.2 of the SDS

✓ **Have Sections of the main part of the SDS been modified? Look for the changes**

Changes may occur particularly in sections 8, 9, 11 and 12 of the main part of the SDS. These sections may also include relevant information that can support the implementation of the ES.

You should check that you don't have any relevant information that contradicts the changes made in the SDS and that could impact the classification of the substance or the DNELs/PNECs. If you already possess such information or new information arises during the use of the substance this new information must be communicated to your supplier.

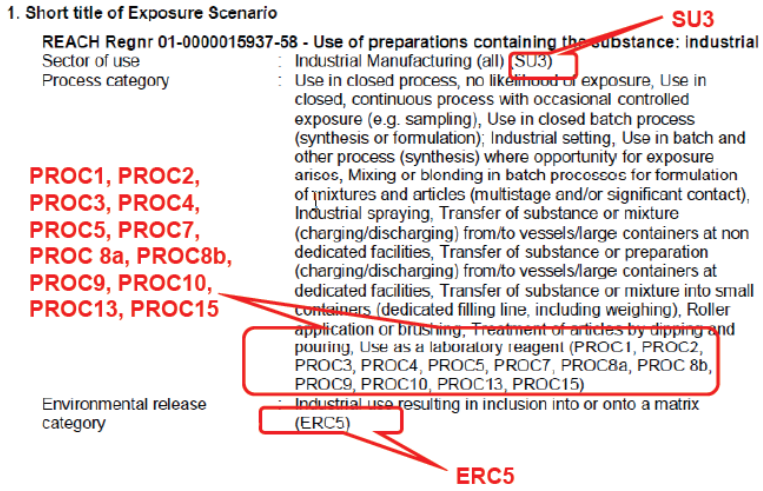
✓ **Is your use covered? First screening based on ES title and Use description**

- Unless you have already done so, translate your uses into a set of use descriptors[20]. When doing so it is advisable to consider whether you can use the use mappings that have already been made available by various sector associations to avoid 'reinventing the wheel' for your use[21].
- Look for the ES title and associated combinations of use descriptors that reflect your uses e.g. initially review the index table (if available) or titles of ES in order to check which may be the most suitable ES for your use
- As mentioned under Q1, describing a Use is not just about the Use Descriptor system. It is important to check how the use is described including the associated

[20] More information on the Use Descriptor system can be found here: http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf

[21] Available use mappings can be found on the Cefic website: http://www.cefic.org/Industry-support/Implementing-reach/Libraries/

use conditions (OCs and RMMs) and whether it matches your knowledge of how you handle the substance. The Use Descriptors and short titles may appear as follows:




At this stage, you should be able to identify any 'obvious mismatch' such as where the main Sector of Use (SU) for your product is not included (e.g. you need an ES that includes consumer use and only industrial/professional uses are included). If this is the case, please refer to Q9 above to see what options are available.
One way to do this it is to check the main Sectors of use: SU3, 21, 22[22]. The other SU are sectors of end-use and are not mandatory.
The ECHA guidance on use descriptors section R.12.2.2 explains which UD are relevant for tier 1 exposure estimation tools and therefore need to be considered more attentively than other UD which are only applicable to support supply chain communication.

It is also important to understand that omission of a particular PROC from the use descriptors provided by your supplier does not automatically mean that your use is not covered because some PROCs may encompass others. This may be confirmed in dialogue with your supplier (see Q9 above). Annex II provides some additional information on the fact that some PROCs may be covered by other PROCs. Please note that this is not a straight-forward process and this Annex is just meant as an illustration of this concept. The interpretation of the PROC inclusion hierarchy may need expert knowledge.

**Whilst there is no legal obligation to use the Use Descriptor system, the UD system is strongly supported by Cefic and has become common practice in industry.**

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SU 3: Industrial uses: Uses of substances as such or in preparations* at industrial sites
SU 21: Consumer uses: Private households (= general public = consumers)
SU 22: Professional uses: Public domain (administration, education, entertainment, services, craftsmen)

Some suppliers may prefer to describe the different uses covered in the Exposure Scenarios by a combination of a short ES title and more detailed descriptions of the tasks included within the ES (known as contributing scenarios). In this case, you need to review the ES to identify the most appropriate description of your use.

✓ **Is your use covered → are OCs and RMMs appropriate?**

Check the relevant sections of the ES for information about conditions of use including Operational Conditions (OCs) and Risk Management Measures (RMMs) for both human health and environment and verify whether they correspond to your use and the controls in place at all the EU facilities where this substance is handled.

The following paragraphs give some indications of the elements that may need to be looked at when assessing the OCs and RMMs for both human health and environment. They do not include an exhaustive list of checks.

**To check OCs/RMMs for the environment:**

Information on safe use regarding the environment should contain a use tonnage either as a typical site tonnage assessed (Msite or MspERC) or the maximum daily site tonnage (Msafe) [all typically in kg/day] and OC and RMMs in place to ensure safe use. (You may also receive an annual tonnage (usually tonnes/year) together with a number of emission days and can calculate the daily use tonnage by dividing annual tonnage by the no. of days – do not forget to check the units!).

Check that your amounts used are lower than the limits provided in the ES and that the OCs and RMMs that are assumed in the ES are in place (Note: spERCs [23] may also refer to the SpERC fact sheet; references to section 8 of main body of the eSDS may also be included). OC may also include dilution factors of the effluent of the sewage treatment plant (STP) your sewer is connected to and when released to the receiving river.

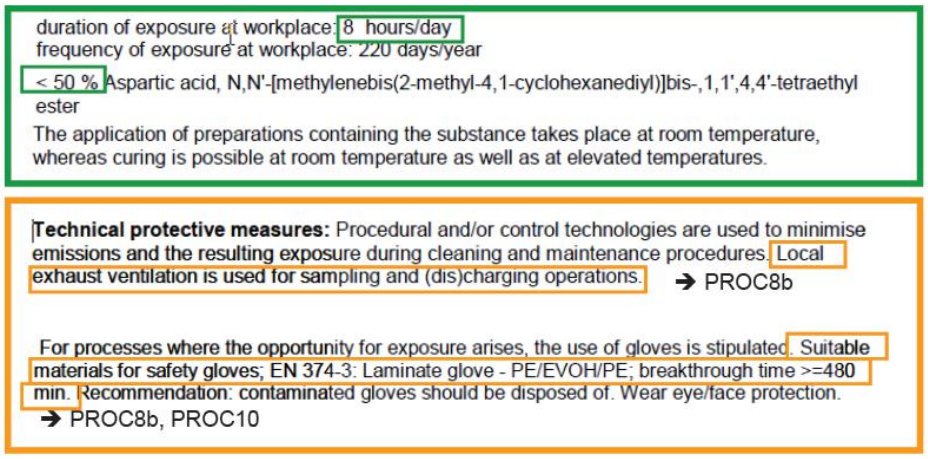
If you do not comply with the limitation of the amounts for use or OCs/RMMs provided, identify the risk driving compartment. This may be communicated in the ES, or if not, , it can be determined from RCRs which may be provided in section 3. The risk driving compartment is the one with the highest RCR. This will help you to identify options for scaling. Risk driving compartments such as soil, indirect human exposure via the environment (inhalation) and terrestrial secondary poisoning are primarily driven by releases to “air”. On the other hand, the risk driving compartments freshwater, marine water, effluent, freshwater sediment, marine water sediment, indirect human exposure via the environment (oral), freshwater/marine secondary poisoning are primarily driven by releases to “water”.

Using the RCR of the “risk driving compartment”, you can adjust the amount used and/or RMMs (or their effectiveness) to reduce release to air or water (depending on

[23] spERCs are specific Environmental Release Categories developed by industry. More information about spERCs is available on : http://www.cefic.org/Industry-support/Implementing-reach/Libraries/

the “risk driving compartment”) to achieve a RCR < 1 for the combination of parameters that reflect your site conditions. This calculation can be done manually or supported by a TIER 1 scaling tool under development (to be published).

**To check OCs/RMMs for human health:**
See example below of what kind of information may be included (please note that the information may be included in different ways, this is just one of the possible options):




It should be noted that a certain level of effectiveness of the control measures listed in the ES are assumed when some PROCs/SpERCs(ERCs) or other types of control measure are chosen. Such effectiveness values may be communicated by the supplier e.g. in the electronic format of the ES (ESComXML) in addition to the extended SDS.

The outcome of the checks on use descriptors and OC/RMM could be described using the following matrix:

| | **Use is described by use descriptors or short title of contributing scenario** | **Use is NOT described by use descriptors or short title of contributing scenario** |
|---|---|---|
| **Use WITHIN operational conditions and RMMs are in place** | RESULT 1:<br>- Use is covered | RESULT 2:<br>- Use may be covered, but needs more detailed analysis/contact with supplier |
| **Use OUTSIDE operational conditions or RMMs are NOT in place** | RESULT 3: Use is not covered<br>Possible options:<br>- Implement OC/RMM (12months)<br>or<br>- Scaling (12months)<br>Or | RESULT 4: Use is not covered<br>Possible options:<br>- Make use known to supplier to assess (DU: 12months, M/I: 1month)<br>Or |

| | | |
|---|---|---|
| | - Carry out DU Chemical Safety Assessment (12 months) & notify ECHA (6months)<br>- Discuss OC/RMM with supplier to re-assess (12months) | - Carry out DU Chemical Safety Assessment (12 months) & notify ECHA (6months)[24]<br>or<br>- Look for an alternative supplier |

**RESULT 1:** the use is described by use descriptors (or covered by PROC inclusion hierarchy) and/or a short title and the OCs/RMMs described in that contributing scenario are sufficiently similar to those you already use in your facilities – the use is safe and covered by the ES and you can continue with this use with no further action

**RESULT 2:** the use is not described by use descriptors or a short title, but the OCs/RMMs of another contributing scenario or part of the exposure scenario are sufficiently similar to those you already use in your facilities and there is no significant mismatch. For example, you may have identified PROC4 (Use in batch and other process) as describing your activities, but PROC5 (Mixing or blending in batch processes) is provided. In this case the different PROCs cannot be considered as an obvious mismatch and then the OCs/RMMs need to be checked.
In absence of a significant mismatch and if similar OCs/RMMs exist in your facilities, the use may be safe and covered by the ES and you can continue with this use with no further action. However, before this conclusion is reached, a more detailed analysis is necessary. The supplier can be contacted at any time if there are questions.

**RESULT 3**: the use is covered by use descriptors or short title, but the OCs/RMMs you currently use in your facilities differ significantly from the OCs/RMMs described in the ES. If you want to continue to use the substance in the same way as you have in the past then within 12 months of receiving the ES you will have to choose one of the following actions:

- adjust the OCs/RMMs of your operations to reflect the conditions in the ES (e.g. reducing the amount of the substance to a level at which it no longer requires the specific controls described in the supplier's ES). This adjustment could include implementing in your own facilities appropriate OCs/RMMs that offer an equivalent level of control to those included in the ES. This can be an option for formulators or end users. Guidance on how to scale may also be found in section 4 of the ES.
- perform your own CSA (e.g. for confidential or critical uses). If this option is chosen you should review carefully article 37.4 which includes exemptions for

[24] The CSA is a complex process that requires expertise. It is strongly recommended to start the assessment before notifying to ECHA, in order avoid identifying potential problems that may arise too late.

which there is no need for further action at this stage. If, however, you still need to perform a CSA, you must notify ECHA within 6 months.

- contact your supplier and request that he revises the OCs/RMMs detailed in his ES in order to include the controls you use. Note that the supplier is not obliged to do this.

The most appropriate way forward will differ on a case by case basis.

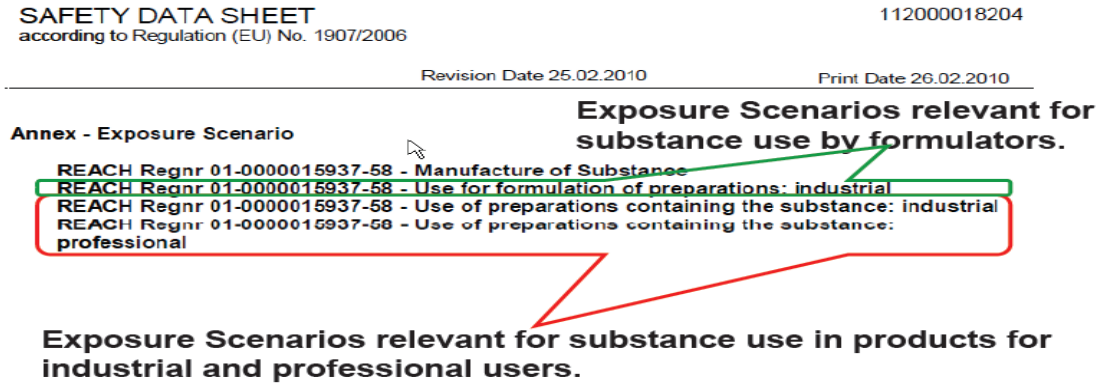
**RESULT 4:** the use is not covered by use descriptors and the OCs/RMMs you currently use in your facilities differ significantly from the OC/RMMs in the ES. If you want to continue to use the substance in the same way as you have in the past then within 12 months of receiving the ES you will have to choose one of the following actions:

- make the use known to the supplier according to Art 37.3 and persuading him to include this use in his ES or
- develop a CSR according to article 37 (in this case you must notify ECHA within 6 months)

For more information on what to do if uses are not covered, see Directors Contact Group paper published by Fecc:
http://www.fecc.org/fecc/images/stories/downloads/SHE/2011/dcg_agreed_proposals.pdf

## 11. ANNEX I: EXAMPLES OF TABLES OF CONTENT / INDEX FOR ES ANNEX[25]

**Example 1:**

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**Example 2:**

**Uses - Worker**

Title : - Industrial

Manufacture of substance

Distribution of substance

Formulation & (re)packing of substances and mixtures

Uses in Coatings

Use in Cleaning Agents

Use in Oil and Gas field drilling and production operations

Lubricants

Metal working fluids / rolling oils

Use as binders and release agents

Use as a fuel

Functional Fluids

Use in laboratories

Water treatment chemicals

Mining chemicals

**Uses - Worker**

Title - Professional

[25] The following examples include in some cases the ES for manufacturing activities. As mentioned above, manufacturing activities may not always be relevant for the downstream users. If this is the case it is recommended to take them out of the annex (and therefore should not appear on the table of content).

Uses in Coatings

Use in Cleaning Agents

Lubricants

Metal working fluids / rolling oils

Use as binders and release agents

Use as a fuel

Functional Fluids

Road and construction applications

Use in laboratories

Water treatment chemicals

**Uses - Consumer**

Title : - Consumer

Uses in Coatings

Use in Cleaning Agents

Lubricants

Use as a fuel

Functional Fluids

Other Consumer Uses

**Example 3**

| ES no | ES Short title / Identified use | Main user group | Supple-mentary | Product Category | Process category | Environ mental category | Article category |
|---|---|---|---|---|---|---|---|
| 1 | Manufacture | SU3 | SU8, SU9 | | PROC1, 2, 3, 4, 8a, 8b, 15 | ERC1 | - |
| 2 | Distribution | SU3 | SU10 | | PROC1, 2, 3, 4, 5, 8a, 8b, 9, 15 | ERC2 | - |
| 3 | Formulation | SU3 | SU10 | | PROC1, 2, 3, 4, 5, 8a, 8b, 9, 14, 15 | ERC2 | - |
| 4 | Coatings | SU3 | - | PC9a | PROC1, 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 15 | ERC5 | - |
| 5 | Coatings | SU22 | - | PC9a | PROC1, 2, 3, 4, 5, 8a, 8b, 10, 11, 13, 15, 19 | ERC8c, 8f | - |
| 6 | Coatings | SU21 | - | PC9a | - | ERC8c, 8f | - |
| 8 | Cleaning agent | SU22 | - | PC35 | PROC1, 2, 3, 4, 8a, 8b, 10, 11, 13 | ERC8a, 8d | - |
| 9 | Cleaning agent | SU21 | - | PC35 | - | ERC8a, 8d | - |
| n | …… | …… | …… | …… | …… | …… | …… |
| nn | Isolation articles | SU21 | - | - | - | ERC11b | AC4 |

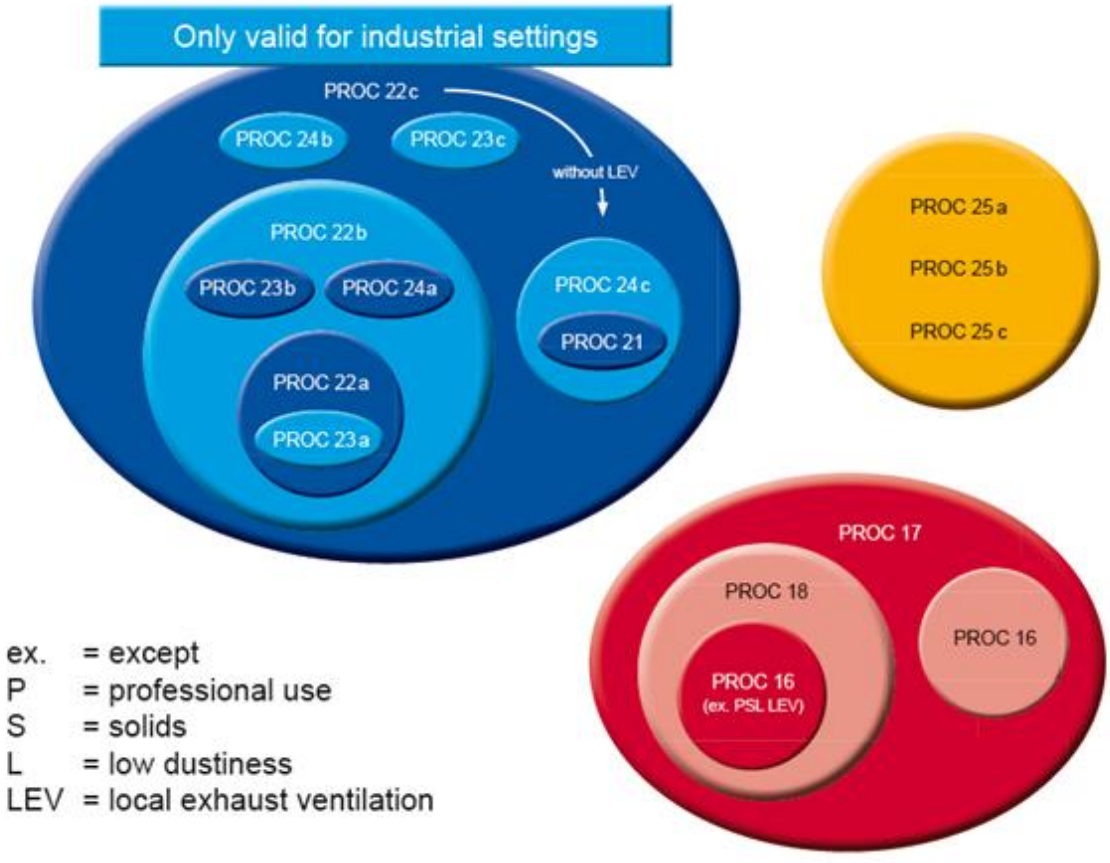
## 12. ANNEX II: PROC INCLUSION HIERARCHY

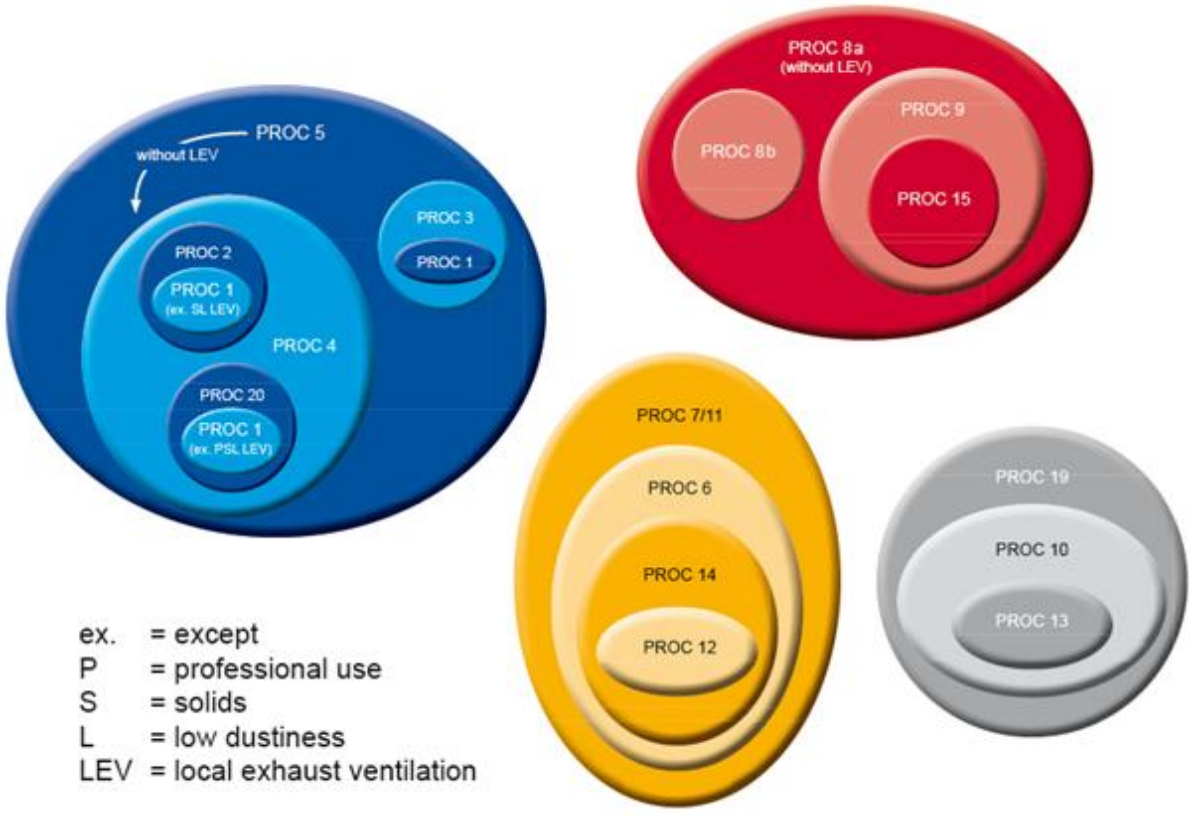
*The PROC inclusion hierarchy concept has been developed by a VCI project group and is described below*.

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 and to define a sequence of PROCs in which one PROC covers the next.

The following considerations should be noted regarding the development and application of this PROC inclusion hierarchy:

- 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)
- This schema may be used by DU as an indication of which PROCs may be covered by other PROCs.
- It only refers to inhalation exposure estimates derived from the ECETOC TRA worker model and is therefore not applicable if a modified TRA or any other exposure model has been applied. The utility of the approach for activities where significant dermal exposures may occur has not been validated.
- The exposure estimates associated with each PROC will change with the conditions of use (e.g. concentration, duration, LEV, industrial/professional setting etc). It follows therefore that applying a hierarchy of PROCs that does not account for the associated conditions of use is likely to lead to mistakes.






**Example 1:**

– If PROC 19 is safe for the industrial use of a medium volatile liquid for 1-4 hours as pure substance with no Respiratory Protective Equipment but with LEV then PROC 10 and PROC 13 are also safe for exactly the same set of conditions:.

| PROC | Type of setting | Duration of activity per day | Use of ventilation ? | Efficiency of respiratory protection (%) | Total Exposure (mg/kg/day) |
|---|---|---|---|---|---|
| PROC 19 | industrial | 1 - 4 hours | Indoors with LEV | 90% | **14,32** |
| PROC 10 | industrial | 1 - 4 hours | Indoors with LEV | 90% | 1,55 |
| PROC 13 | industrial | 1 - 4 hours | Indoors with LEV | 90% | 0,86 |
| PROC 19 | industrial | 1 - 4 hours | Indoors with LEV | 90% | 14,32 |
| PROC 10 | industrial | 1 - 4 hours | Indoors with LEV | 90% | 1,55 |
| PROC 13 | industrial | 1 - 4 hours | Indoors without LEV | 90% | **15,50** |

*assumed vapour pressure of liquid: 5000 Pa*

**Example 2:**

– If PROC 6 is safe for a given set of conditions then PROC 14 and PROC 12 are also safe for the same set of conditions.

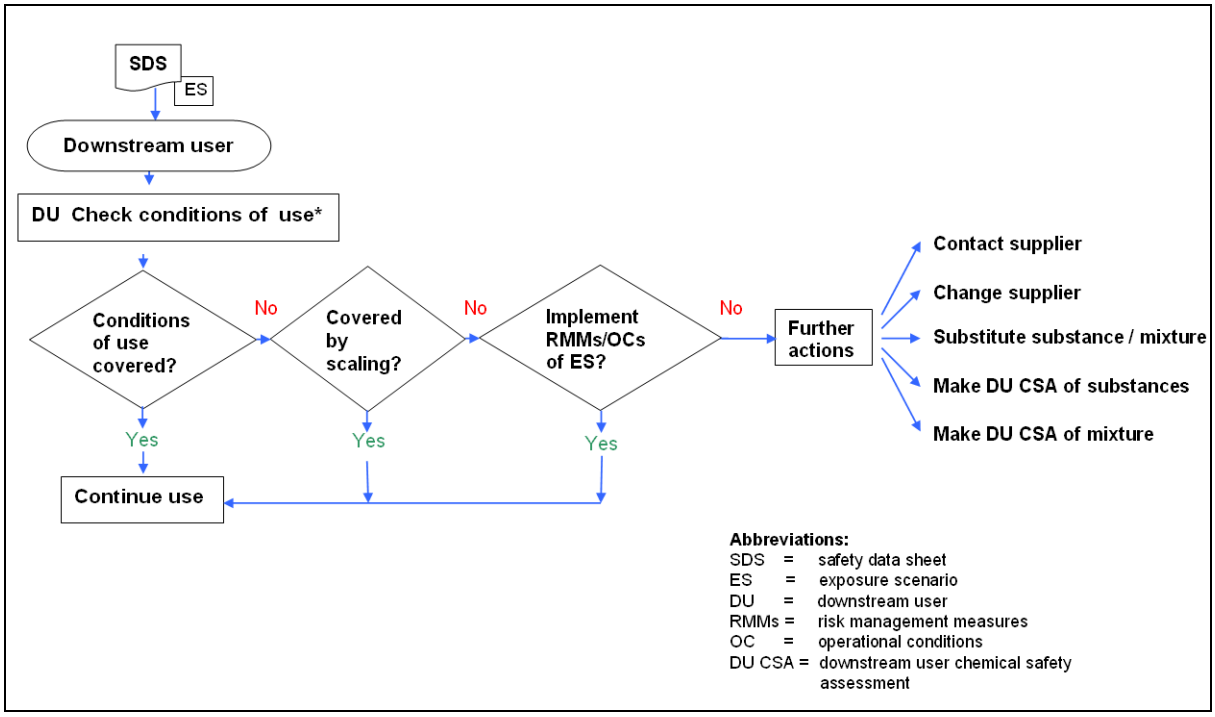
| PROC | Type of setting | Duration of activity per day | Use of ventilation ? | Efficiency of respiratory protection (%) | Total Exposure (mg/kg/day) |
|---|---|---|---|---|---|
| PROC 6 | industrial | 1 - 4 hours | Indoors with LEV | 90% | **1,55** |
| PROC 14 | industrial | 1 - 4 hours | Indoors with LEV | 90% | 0,52 |
| PROC 12 | industrial | 1 - 4 hours | Indoors with LEV | 90% | 0,18 |
| PROC 6 | industrial | 1 - 4 hours | Indoors with LEV | 90% | 1,55 |
| PROC 14 | industrial | 1 - 4 hours | Indoors without LEV | 90% | **5,21** |
| PROC 12 | industrial | 1 - 4 hours | Indoors with LEV | 90% | 0,18 |

*assumed vapour pressure of liquid: 5000 Pa*

Another example: PROC 23a is covered by 22a and 22b and 22c, but not by 24a or 23b. PROC 22b covers 23b and 24a and 22a and 23a (for the same set of conditions).

Please note that in some cases, the hierarchy will not work for certain specific combinations of conditions. Some of these cases are explicitly in the illustration above.

## 13. ANNEX III: MAIN TASKS FOR A DOWNSTREAM USER ON RECEIPT OF AN EXTENDED SDS[26]




*: "use" includes the supplier's own use(s) and identified use(s) of customers if applicable (e.g. in case of formulators).

"Further actions" describe different options available to the downstream user, each of which can be chosen as the path forward at this stage. Alternatively several of these options can be considered in parallel until a suitable resolution becomes apparent.

With regard to the option 'Make DU CSA of mixture', it should be noted that at present there is no guidance available on how to carry out such a CSA. Such a CSA for a mixture is foreseen by Article 31(2) of REACH for the purposes of generating consolidated information for an SDS. Neither Article 14 nor Article 37 of REACH generate a requirement for such a CSA to be prepared as part of a registration

[26] Extracted from Cefic/VCI REACH Practical Guide on Exposure Assessment and Communication in the Supply Chain, Part 1

## 14. ANNEX IV: GLOSSARY:

| | |
|---|---|
| BDI: | Federation of German Industries |
| Cefic: | European Chemical Industry Council |
| Concawe: | oil companies' European association for environment, health and safety in refining and distribution |
| CS: | Contributing Scenario |
| CSA: | Chemical Safety Assessment |
| CSR: | Chemical Safety Report |
| DNEL: | Derived No Effect Level |
| DU: | Downstream User |
| DUCC: | Downstream User of Chemicals Co-ordination group |
| ES: | Exposure Scenario |
| ESComXML: | Exposure Scenario for Communication XML standard |
| EuPhraC: | European Phrase Catalogue |
| FECC: | European Chemical Distributors Association |
| GES: | Generic Exposure Scenario |
| LEV: | Local Exhaust Ventilation |
| Msafe : | maximum daily site tonnage |
| Msite or MspERC: | typical site tonnage assessed |
| OC: | Operational Conditions |
| PBT: | Persistent, bio-accumulative and/or toxic chemicals |
| PNEC: | Predicted No Effect Concentration |
| PROC: | Process Category |
| RCR: | Risk Characterisation Ratio |
| RMM: | Risk Management Measures |
| SDS: | Safety Data Sheet |
| spERC: | Specific Environmental Release Classes |
| STP: | Sewage Treatment Plant |
| SU: | Sector of Use |
| vPvB: | very Persistent and very Bioaccumulative |
| UD: | Use Descriptor |