CEPE/EuPIA GUIDELINE ON Downstream Communication of Safe Use Information for Mixtures

for the Paint, Varnish, Printing Ink and Artists' Colours Industry

2nd Edition

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This Guide was drawn up by a CEPE/EuPIA Committee based on the best knowledge currently available. The information is provided in good faith and neither the Committee nor CEPE/EuPIA can accept any responsibility for consequences arising in certain cases should these recommendations be employed. Users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this Guide cannot serve as a substitute for legal advice and each company must decide the strategy to follow.

Preface

This CEPE/EuPIA guide is one of a number of support and information documents prepared by CEPE/EuPIA's REACH expert groups, which are intended to help CEPE/EuPIA members deal with specific aspects of the REACH Regulation. The guidance draws on the provisions of the Regulation, and takes into account both ECHA and industry interpretations and guidance on this particular issue.
It continues the well-established CEPE/EuPIA initiative on preparation of guidance that deals with issues specifically for coatings and inks manufacturers.

This document is intended to be a practical guide, setting out one of the options to take to fulfil a coatings and inks manufacturer's obligations to pass information contained in received exposure scenarios along the supply chain. The guidance avoids reproducing text from the REACH Regulation, although references are given to the relevant articles and annexes, and associated guidance documents, for users wishing to consult the source information.

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1. Introduction

1.1 General

Coatings and inks manufacturers, as Downstream Users, receive exposure scenarios of substances from suppliers. Relevant information must then be forwarded to customers. This document is intended to be a practical guide to fulfil this obligation. The guidance aims to be practical and avoids reproducing text from the REACH Regulation, although references are given to the relevant articles and annexes, and associated guidance documents, for users wishing to consult the source information.
This document does *not* contain guidance on how downstream customers should use or process the information they receive, e.g. for demonstrating compliance, scaling or changing operational conditions/risk management measures.

The guidance introduces a 'bottom-up' approach to fulfil the requirement to pass safe use information along the supply chain. Other approaches are available and may be more suitable for a company to take. This guide's objectives are:

- To provide safe use information for classified mixtures
- To provide a mechanism linking the health hazard data in substance Exposure Scenarios to the safe use of mixtures
- To cover the majority of uses within a sector

And, additionally,
- To simplify upstream communication with raw material suppliers

Note: this approach does not cover
- Consumer uses (covered by Specific Consumer Exposure Determinants - SCEDs)
- Environment (will be addressed at a later date via Specific Environmental Release Categories - SpERCs)

1.2 The REACH Requirements[1]

The REACH Regulation requires each downstream actor in a substance use chain to take specific action on receipt of an exposure scenario (ES) for a substance, which is used by that actor:

1. to adopt the operational conditions and risk management measures applicable to the actor's own use(s), to ensure the use is safe to man and/or the environment

2. to pass on to the next actor in the use chain all information relevant to the uses of the substance

CEPE/EuPIA coatings and inks manufacturing members are Downstream Users (Formulators) in REACH. Both the requirements in the box above therefore apply to CEPE/EuPIA members.

[1] See Regulation (EC) 1907/2006, REACH Regulation, Articles 31, 37

This document provides guidance on the **second** requirement in the box above. Guidance on the first requirement – compliance with the operational conditions and risk management measures specified by your supplier, is covered by other CEPE/EuPIA documents)[2].

The requirement to communicate an Exposure Scenario (ES) down the supply chain, strictly speaking and as defined in the REACH legal text, applies only to substances and not to mixtures.

In the case of mixtures for which a safety data sheet (SDS) is legally required, i.e. classified mixtures (under the CLP Regulation), and that contain one or more registered substances for which an extended SDS has been received, downstream users (DUs) must provide their customers (professional or industrial end-users) with information on the hazards of their mixtures and conditions of safe use of these, including advice on Risk Management Measures (RMM) and Operational Conditions (OC).

ECHA guidance provides 3 options for formulators to pass on relevant information obtained via exposure scenarios (ESs) for substances which are contained in their formulations.
Option 1: Forward the ES(s) for the relevant substance(s) contained in the mixture, attached to the SDS for the mixture.

Option 2: Consolidate the ESs for the relevant substance(s) contained in the mixture and annex to the mixture SDS.

Option 3: Consolidate the ESs for the relevant substance(s) contained in the mixture and integrate complementary information in the mixture SDS main body.

This approach is one way of implementing either Option 2 or Option 3.

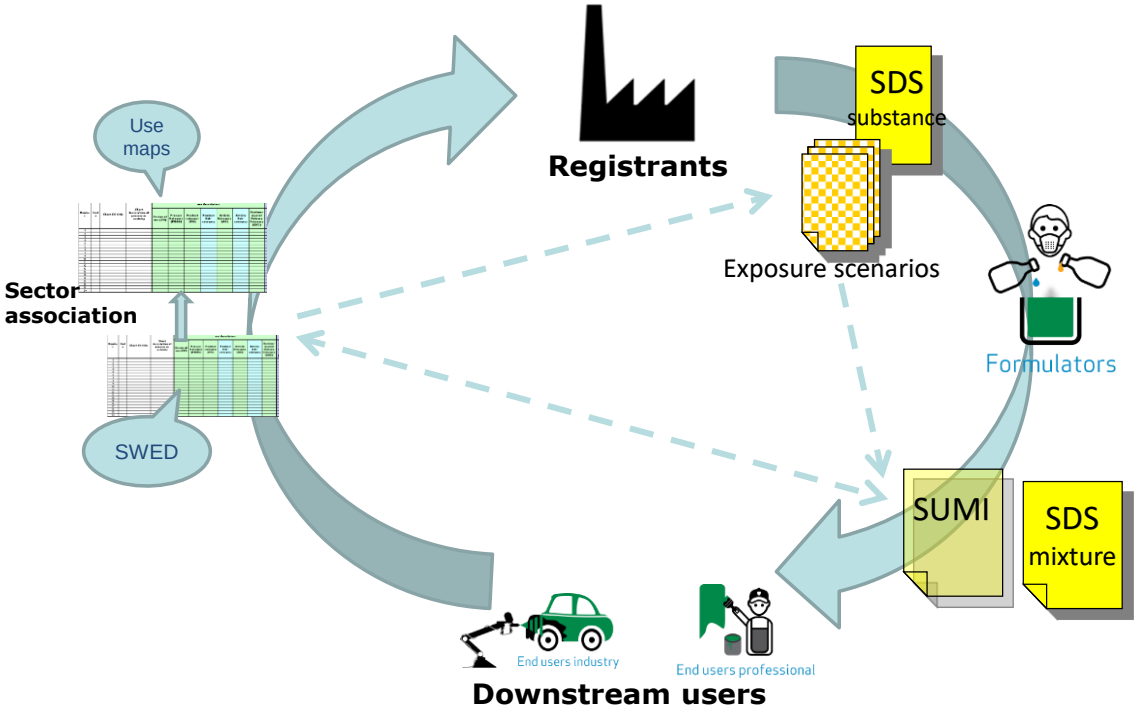
Under certain conditions, particularly if the formulator has prepared a Downstream User Chemical Safety Report – CSR (Art. 37(4)) for a substance in their mixture it might be a requirement to annex to the SDS an Exposure Scenario derived from the CSR.

The existing requirements for an SDS to be provided for a hazardous mixture apply regardless of any new REACH requirements relating to ESs.

[2] CEPE GUIDELINE ON Assessing and demonstrating compliance with received ES information for the Paint, Varnish, Printing Ink and Artists' Colours Industry, current version, download from members' area of www.cepe.org

The CEPE/EuPIA recommendation that an SDS is provided for all mixtures, regardless of the mixture classification or the intended use, remains in force and is unaffected by the additional REACH requirements for ESs.

Diagram 1: The information cycle



This guidance complements and inter-links with other CEPE/EuPIA information, in particular the CEPE Guidance on Safety Data Sheets[3]

1.3 The 'Bottom-Up' Approach

The 'Bottom-Up' approach has been developed by CEPE/EuPIA and other downstream associations, to facilitate communication of safe use information for mixtures based on substance ESs. A DUCC explanatory document, giving background information on the 'bottom-up' concept is available[4]. It is envisioned that information will be provided for hazardous mixtures, supplied for occupational uses (i.e. industrial/professional). It is not necessary to use this approach for non-hazardous mixtures, even though you may supply an SDS.

The approach introduces new concepts and terminology:

1.3.1 SWED: Sector-specific Worker Exposure Description

[3] CEPE Guideline on Safety Data Sheets for the Paint, Varnish, Printing Ink and Artists' Colours Industry, current version, download from members' area of www.cepe.org

[4] Sector-specific approaches towards developing and communicating information for the safe use of mixtures

A SWED (also known as a 'generic exposure scenario') is a description of an end-use of a coating or printing ink, including the assumed (or typical) operational conditions and risk management measures used by the actors for the activities covered by the use group, and identifying the potential exposure routes for workers. It is specific to a sector and includes the data required to compare the assumed exposure of a worker to substances in a mixture during all component activities against the limits set for substances contained in the mixture, as determined by the manufacturer/importer of the substance in their Chemical Safety Report (CSR).

CEPE/EuPIA has categorised the various end-use scenarios most used by customers of its members' products into SWEDs. For each SWED, the end-use is divided into the various activities that will be undertaken in the use of the mixture; for example, decanting, mixing, application, film formation (called drying/curing in SUMIs for ease of understanding by end-users), cleaning equipment, waste handling. These are applicable to the majority of the industry's products and are available as an Excel file.

SWEDs:

- are based on the REACH sector use maps
- address workers' exposure
- are not substance-based
- require a validation step by the formulator

For each SWED, the following characteristics have been defined:

- Contributing activities (all process steps included in a complete use)
- Operational Conditions (daily duration and level of ventilation in place for each activity)
- Risk Management Measures (protective equipment normally used for each activity).

CEPE/EuPIA has identified the workers' exposure from various relevant routes. The SWEDs are available both as a simple CEPE/EuPIA table (for use by members) and in the ECHA standard format (to be used by registrants in their Chemical Safety Assessments and to generate exposure scenarios for communication).

The CEPE/EuPIA SWEDs
CEPE/EuPIA has established 17 SWEDs covering the majority of its products' uses.

- 13 for application of **paint**
- 4 for **printing inks**

Paint Application SWEDs

CEPE_IS_01_v2	Industrial spray painting, automated booth
CEPE_IS_02_v2	Industrial spray painting, walk-in booth
CEPE_IS_03_v2	Industrial spray painting, exhaust ventilation
CEPE_IS_04_v2	Industrial non-spray painting, automated booth
CEPE_IS_05_v2	Industrial non-spray painting, exhaust ventilation
CEPE_PW_01_v2	Professional spray painting, near-industrial setting
CEPE_PW_02_v2	Professional non-spray painting, near-industrial setting
CEPE_PW_03a_v2	Professional spray painting, indoor (without respiratory protection)*
CEPE_PW_03b_v2	Professional spray painting, indoor (with respiratory protection)*
CEPE_PW_04_v2	Professional painting, indoor brush/roller
CEPE_PW_05a_v2	Professional spray painting, outdoor (without respiratory protection)
CEPE_PW_05b_v2	Professional spray painting, outdoor (with respiratory protection)
CEPE_PW_06_v2	Professional painting, outdoor brush/roller

** Note: For some uses, different levels of protection may be prescribed, depending on the type of products used e.g. RPE may be required for the outdoor spraying of bridge structures with two-pack or anti-corrosive coatings, but not for outdoor spraying of buildings with decorative coatings. In such cases, two levels of SWEDs with respective SUMIs have been created to differentiate these activities.*

Ink Application SWEDs

EuPIA_IS_01_v2	Printing in an enclosed or extracted process
EuPIA_IS_02_v2	Printing with enhanced (mechanical) room ventilation
EuPIA_IS_03_v2	Printing with good room ventilation
EuPIA_IS_04_v2	Digital printing with good room ventilation

Associated with each of the 17 SWEDs is a SUMI.

1.3.2 SUMI: Safe Use of Mixtures Information

The SUMI is the medium for communicating the conditions for safe use of substances in a mixture, for a particular end-use. It is based on the SWED information and is the output of the approach, tailored to the end user. The SUMI gives the appropriate operating conditions and risk management measures for a range of mixtures in a specified area of use.

The SUMI is not a stand-alone document. For communication down the supply chain, it is supplied either annexed to, or incorporated into the SDS – usually Section 8. Information in the SDS and the associated SUMI must be consistent. It does not replace SDS, as the SDS includes product-specific information (e.g. classification, specifications of personal protective equipment).
A SUMI reflects a use and not a product and more than one SUMI may be needed for each product, depending on its intended uses.

SUMIs:

- have common structural elements
- indicate the Operational Conditions required for safe use for each activity included in the SWED
- indicate the Risk Management Measures required for safe use for each activity included in the SWED
- may contain pictograms depicting the RMMs required

The SWED/SUMI provides a qualitative link between the data provided by suppliers of substances with the assumed exposure to that substance when used in mixtures. It can also form the input information for a Chemical Safety Assessment – Workers' Exposure (providing the exposure determinants). The graphic below shows the information cycle along the supply chain.

The SUMI should be supplied in an official language of the Member State into which the mixture is supplied.

There is one SUMI for each SWED/end use, not one SUMI per SDS. You may need to supply a SUMI for each of your customer's end-uses for any one product e.g. spraying, dipping.

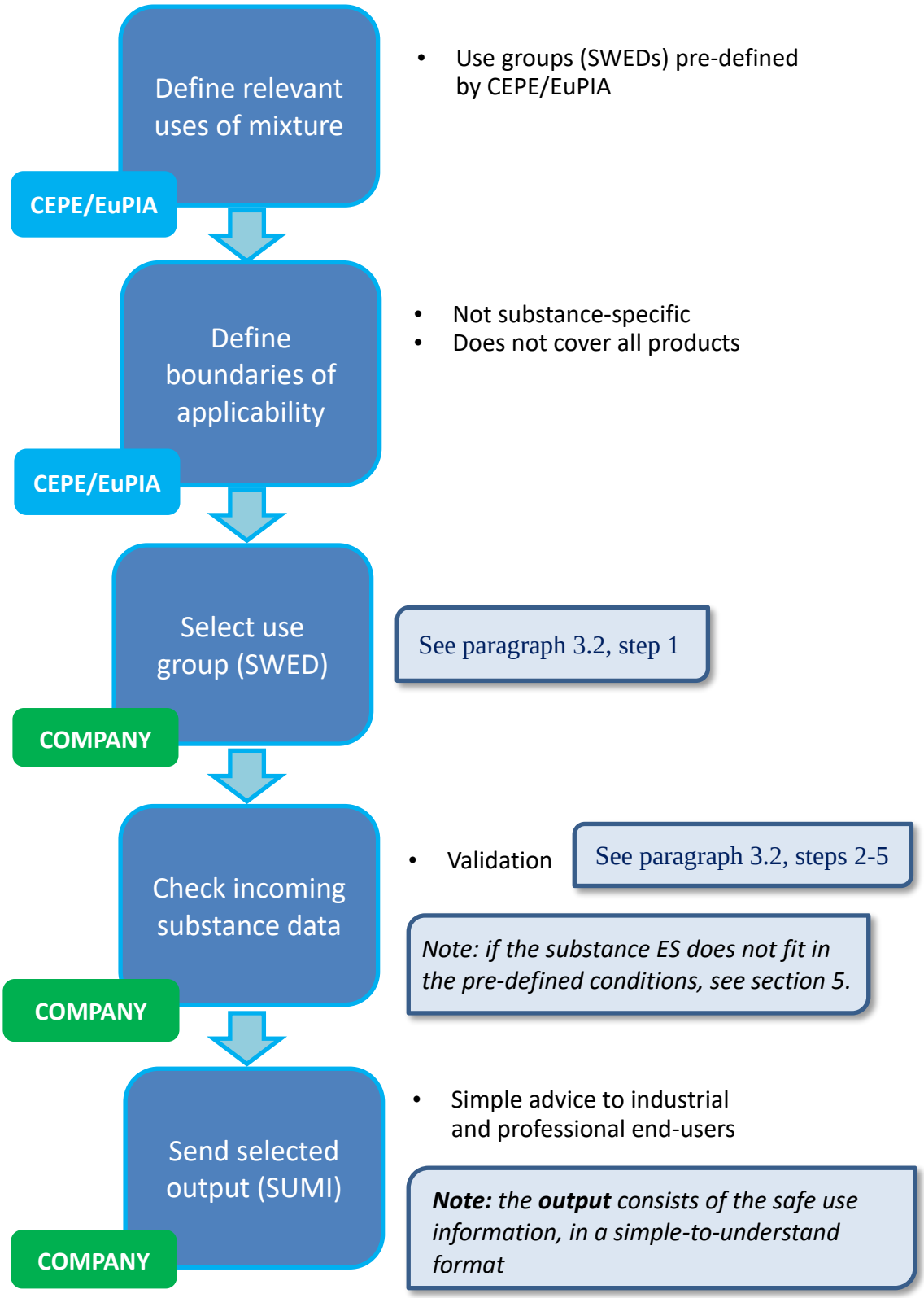
It is not necessary to supply a SUMI for a mixture that is:

- not classified as hazardous (including those not classified but carrying the EUH208 supplementary statement)
- is only classified for physical hazards e.g. flammability, or for environmental hazards.

A SUMI should be provided for a mixture containing a substance for which a CEPE Plug-in Phrase identifying a health effect has been given in Section 16 of the SDS if a relevant DNEL is available.

Diagram 2: The “Bottom-up” approach

The “bottom-up” approach is so-called because it starts by considering the “bottom” of the supply chain: the use by the end-user.



2. The SWED/SUMI approach

2.1 Mechanism of the SWED concept

For each contributing activity estimated exposure levels has been set, using the default exposure estimate values given in the ECETOC Targeted Risk Assessment tool, TRA (v.3)[5]. CEPE/EuPIA have decided to use ECETOC TRA for the exposure assessment, as this tool is used by the majority of registrants.

The Operational Conditions and Risk Management Measures control the exposure to the substances in a mixture. For each OC and RMM, an exposure modifying factor has been assigned (again, from the ECETOC TRA document). By applying these exposure modifiers to the initial exposure estimate, the assumed exposure of a worker can be calculated for each contributing activity of a SWED.

For example:
For an industrial spraying operation, the default exposure estimate for a high fugacity mixture is 500ppm

If local exhaust ventilation with efficiency of 95% is in place, only 5% of the mixture will be available to be exposed to i.e. exposure modifying factor = (100-95)/100 = 0.05

Assumed exposure = 500 X 0.05 = 25ppm

Further details on exposure modifying factors are given in Annex 1.

2.2 The Minimum Tolerable DNEL[6]

These assumed exposure values set the limits on the applicability of the OC/RMMs to protect against substances in any mixture used for each activity.

By comparing all activities in a SWED, the highest estimated exposure can be ascertained. The value of this can be considered to be the 'Minimum Tolerable DNEL' for this use of the mixture. Again, it defines the limit of applicability of the overall SWED.

2.3 Substance DNELs

Under the REACH process, any substance for which a CSR has been produced, and therefore, an Exposure Scenario(s) has been provided, will have also been assigned various DNELs (one per route –inhalation/dermal). You will need to assign the substance a fugacity level - the property of a substance indicating the level of volatility in a gas or vapour, or dustiness in a solid *(see A.1.6)*.
Note: The ECETOC TRA evaluation cannot predict exposures to solids suspended or dissolved in liquids. Therefore CEPE has made the following approximations for solid substances in a liquid mixture:

[5] www.ecetoc.org/tra

[6] CEPE/EuPIA's concept of tolerable DNELs follows the requirements of REACH, Annex I, 6.4. saying that a substance-related risk is sufficiently controlled if the estimated exposures do not exceed the respective substance DNELs i.e. the Risk Characterisation Ratio (RCR) is less than 1 (see paragraph 3.2, Step 4)

- *for spraying, the High dustiness level is assumed*
- *for all other activities, no inhalative exposure to solid substances is foreseen. (Dermal exposure remains relevant however.)*

This has necessitated a separate CEPE Workbook for validating the SWED/SUMI for powders in liquids.

For powder coatings, the fugacity of any solid substance in the powder coating should be taken as High (i.e. high dustiness) due to the final dustiness of the powder coating. CEPE has also developed a separate workbook for powder coatings.

- DNELs will be found in the SDS for the substances used. Note that DNELs may vary between suppliers of the same substance, so the most appropriate one should be used (e.g. from the joint registration dossier)[7]. Individual DNELs for registered substances are available on the ECHA dissemination website[8] (click on 'Eye' symbol  in the last column; select Toxicological Information then Toxicological Summary, however, these may not always be available) if not in the SDS. A list of DNELs for inhalation is available on the GESTIS DNEL database[9].
- Substance DNELs may not always be available: see 2.4 for further information.

2.4 Demonstrating Safe Use

REACH says that a substance risk is sufficiently controlled if the estimated exposures do not exceed the respective substance DNELs
The appropriate DNEL (inhalation/dermal) given for the substance in the eSDS appropriate for this use must be compared against the Minimum Tolerable DNEL for the SWED. This must be done for each substance (using the appropriate fugacity level), for which a DNEL has been received, in the mixture.

The risk from the use of the mixture is sufficiently controlled if the exposure estimation for the SWED does not exceed any of the relevant component substance DNELs for each exposure route (inhalation/dermal) e.g.

Substance DNEL > Minimum Tolerable DNEL ➔ SAFE USE

2.5 Basic considerations for the SWED concept

Only those **substances which contribute to the classification of the mixture** (for relevant exposure routes) need to be considered.
Only the **relevant DNELs** (long-term systemic[10], inhalation and dermal exposure of workers) are used in the calculation. The long-term DNEL is almost always the

[7] If the lowest DNEL for the substance shows safe use, then there is no need to check others.
[8] http://echa.europa.eu/information-on-chemicals/registered-substances
[9] http://www.dguv.de/ifa/GESTIS/GESTIS-DNEL-Datenbank/index-2.jsp
[10] A systemic effect is one affecting the whole body, or at least multiple organ systems often away from the exposure site e.g. acute toxicity, reproductive toxicity. A local effect is one that is observed at the site of first contact e.g. corrosion, sensitisation.

lowest and therefore more conservative figure, but please check before validation of the SWED if a lower local DNEL value per exposure route is provided which should be used instead.

If the long-term systemic DNEL has not been provided for inhalation or dermal exposure, check in SDS section 2 or 3 if the substance causes non-threshold health effect for which no safe exposure limit can be defined. This is typically the case for mutagenic, carcinogenic or reprotoxic substances, which require a qualitative risk assessment and are beyond the scope of the recent CEPE SUMIs. Specific regulations might be applicable here, e.g. the Carcinogens and Mutagens Directive 2004/37/EC.

If the non-threshold health effect is irritation/ corrosion of skin and/ or eyes or skin sensitization, a qualitative risk assessment can reveal that the CEPE SUMI is applicable. OCs/RMMs as provided in the supplier eSDS need to be compared to the SUMI OCs/RMMs, where it is expected that common skin and eye protection plus ventilation for any handling, respiratory protection plus use with highly efficient ventilation for spray operations are identical with the general requirements recommended for safe use of coatings and printing inks. Document your check (see 3.2 Step 5 below).

If the substance causes a local effect such as irritation/ corrosion or skin sensitization (e.g. acetic acid), it is also possible that a threshold effect has been confirmed and you receive local DNELs. You can use these to validate the SWED / SUMI if no lower long-term systemic DNEL is available, and the substance causes no severe health effect (i.e. CMR, see above).

This guidance concentrates on the inhalation, eye and dermal exposure routes (for eye exposure no quantitative assessment is possible so this is addressed qualitatively). Oral exposure is not expected for industrial and professional end-users.

An ES will **not** be received for every substance. The REACH Regulation requires only that your supplier provides you with an ES for a substance that has been registered, is classified as hazardous and is produced or imported in quantities of 10 or more tonnes per annum[11].

Note: For biocidal substances, a DNEL may not have been set. In such case, a qualitative assessment needs to take into account the OCs/RMMs specified in the approval of the active substance/biocidal product. Therefore, check OCs/RMMs in the SUMI are appropriate and document.

If no ES has been received, there is no legal obligation to pass on the information for that substance.
Additionally, substances without any DNEL and no exposure scenarios provide no starting point to derive safe use information, however, a qualitative assessment can be carried out. (check OCs/RMMs are appropriate - see 3.2 Step 5 below).

[11] REACH Article 14

You may receive an ES for a substance before it has been registered (no Registration Number in Section 1 of the SDS in the case of a single substance, or in Section 3 of the SDS in the case of a mixture). In such a case, although not legally required, it is recommended that you review the content of the ES and decide if any information is significant. In which case, relevant information should be included in the SDS for the mixture you supply. If a DNEL is provided, you can still apply the SWED/SUMI approach.

The basic assumption is that the vast majority of substances used in coatings materials are REACH registered and DNELs have been derived for relevant health effects and exposure routes. This means that typically for a coating material DNELs are available for all hazardous substances contributing to the hazard classification. If you are expecting substance DNELs, but these cannot be found in the SDS, it is recommended that, in the first instance, the supplier is contacted.

If you don't have a DNEL, all is not lost. You can still use the SUMI, but need to check that the OCs and RMMs are no less conservative than those specified in the substance SDS.

The standard SWED/SUMI approach is based on an assumption that the mixture consists of >25% of the substance. The CEPE/EuPIA workbook allows you to introduce a reducing factor taking into account the concentration of the substance in the mixture if below 25%. This may be appropriate if the substance DNEL is lower than the Minimum Tolerable DNEL and the SUMI is not, therefore, appropriate for the use (see section 5.2.1).

Multi-component products e.g. where a base coating, thinner, and hardener are sold as individual products and then mixed prior to application, need special treatment. These will be handled individually during the preparation stage, but as the mixed material during application and subsequent activities. It is suggested that, initially, you should check each component separately. If they all pass, then there is no problem.

If one or more component fails the validation, then you can:

- Validate the individual components against the Minimum Tolerable DNELs for the preparation stage in the SWED; and
- Validate the mixed product, for relevant activities i.e. application and activities that take place after mixing. In this case, you may be able to apply a concentration-related modifying factor to the mixed material (see 5.2.1).

The concept of tolerable DNELs may be applicable to substances which are classified as **carcinogenic, mutagenic or reprotoxic (CMR) if DNELs have been assigned for the appropriate exposure routes.**

CEPE/EuPIA's reasoning for the choice of PROC or exposure estimate for each activity in the SWED follows:

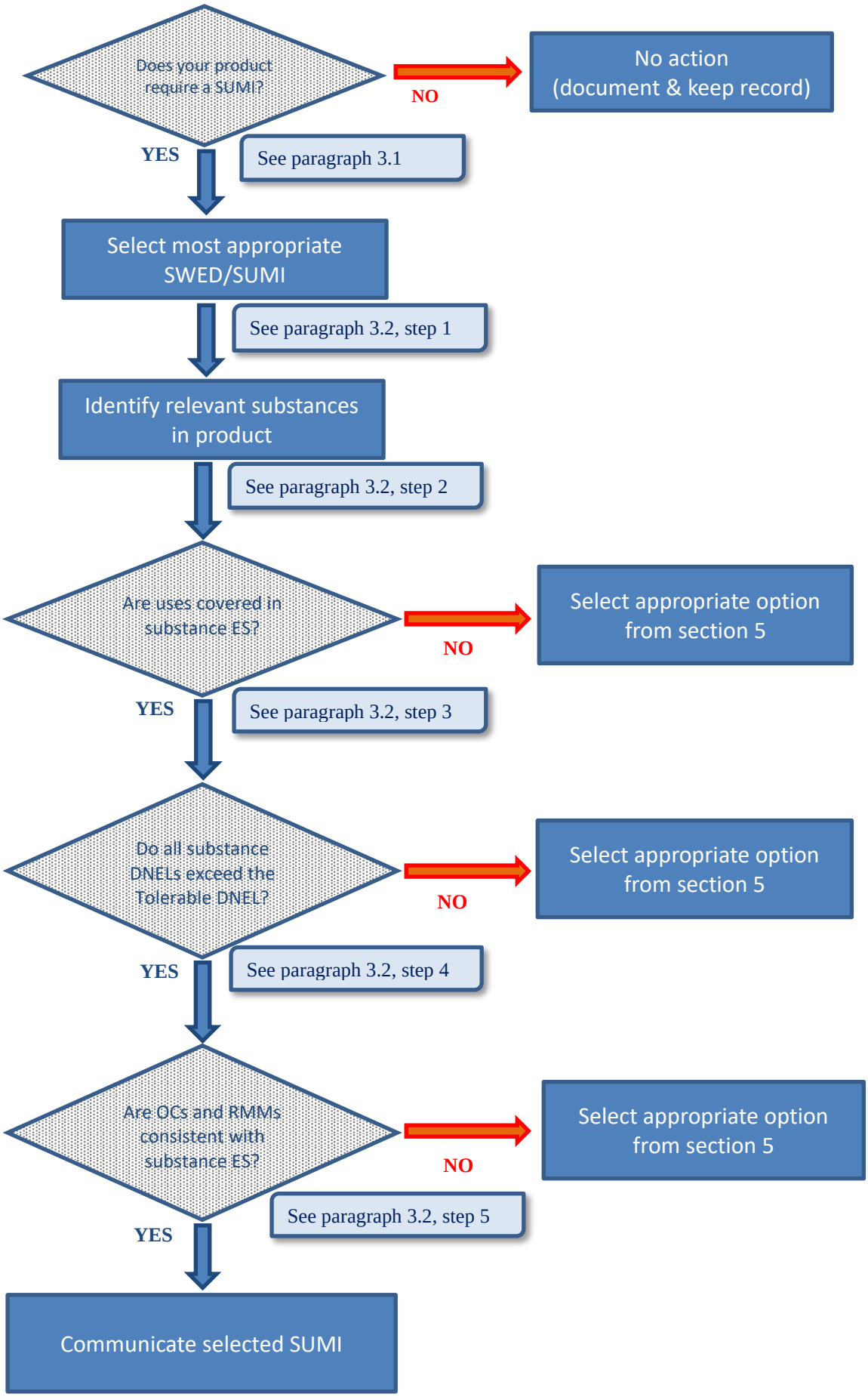
- Delivery/Storage is not included in SWEDs or SUMIs as neither is expected to lead to any routine exposure, hence the use of PROC 3 default values for

the exposure assessment. Any sampling that is undertaken would be covered by the Preparation activity. Any delivery by tanker would be covered by the 'transfer' activity – 'Loading of application equipment and handling of coated parts'.

- No dermal exposure is foreseen during the film formation process as touching the part would damage the film (accidental contact cannot be considered part of the characterization of use [for either painting or printing activities]). Therefore, no exposure calculation is given for this component.
- Handling of painted parts, which could result in some dermal exposure, is included in the 'transfer' activity – 'Loading of application equipment and handling of coated parts'.
- Curing ovens are not currently adequately addressed in the ECETOC TRA tool, therefore options exist. CEPE has assigned PROC 4 to the drying/curing (film formation) stage of all non-enclosed industrial painting SWEDs (CEPE_IS_02_v2, CEPE_IS_03_v2 & CEPE IS_05_v2), as the drying/curing process is likely to be carried out on a batch basis with exposure possible when the oven is opened. Inhalation exposure is modified by the enhanced mechanical ventilation expected for other associated activities.
- In the two enclosed processes (CEPE_IS_01_v2 & CEPE IS_04_v2) the film formation activity is assigned PROC 2 exposure estimate values due to the enclosed nature of the activity. In both, the ventilation is set to 70% as the activity will take place under the normal ventilation level of the facility i.e. enhanced (mechanical) room ventilation.
- The film formation activity of the enclosed printing process (EuPIA_IS_01_v2) is, likewise, assigned PROC 2 exposure estimate values and the ventilation is set to 90% as the activity will take place under the normal ventilation level of the facility i.e. LEV.
- For the non-enclosed printing processes (EuPIA_IS_02_v2, EuPIA_IS_03_v2 & EuPIA_IS_05_v2), the ventilation for the film formation activity is set at the normal ventilation level of the facility.
- For professional non spray painting (CEPE_PW_02_v2, CEPE PW_04_v2 & CEPE_PW_06 v2), although the film formation stage may be concurrent with the application activity, eye and skin protection is not specified as, equally, it may not be concurrent with continued application, hence the worst-case is assumed.
- Dermal exposure is also not expected for 'industrial application, automated booth' activities for painting, e.g. CEPE_SWED_IS_01_v2 & CEPE_SWED_IS_04_v2.
- For digital printing, PROC 2 default exposure estimates are assigned rather than PROC 10 due to the minimal risk of exposure in this activity (backed up by measured exposure data).

3. Using the SWED/SUMI methodology for a product

Diagram 3: Work-flow of the SWED/SUMI



3.1 Which mixtures require a SUMI?

It is not necessary to supply a SUMI for a mixture that is:

- not classified as hazardous (including those not classified but carrying the EUH208 supplementary statement)
- is only classified for physical hazards e.g. flammability, or environmental hazards

Not all hazardous substances need to be considered when validating safe use information on the mixture. You can ignore any substance for which:

- an ES has not been received or no DNEL has been set (but if that substance is classified as a CMR, the mixture will need specific assessment).
- an ES has been received but:
  - the exposure routes covered are not relevant to the uses being considered. For instance: ingestion is unlikely to occur in occupational uses;
  - it is present in the mixture at a concentration below REACH thresholds[12]i.e. you only need to check substances that trigger classification of the mixture - these are listed in Section 3 of the SDS.

3.2 The SWED/SUMI validation process

Step 1 Select the most appropriate SWED and SUMI

Based on your knowledge or assumptions of your customers' use, select the most applicable SWED from the CEPE/EuPIA table and, hence, the most appropriate SUMI. The SWEDs are available here:

CEPE-EuPIA SWEDs January 2017 final.xl

The suite of SUMIs can be found here:
https://members.cepe.org/cepe_v2/Item/NaN/62528

(Note: for best results it is recommended to log into the members' Workplace *before* clicking the link. If it still does not work, the folder can be found via:
CEPE website > Members' Area > Chemicals management & safety > REACH > REACH Implementation Support > Safe Use of Mixtures Information).

Step 2 Identify the substances in the mixture

Obtain data from section 3 of the raw material SDS. Only substances contributing to the health classification of the mixture need to be taken into account.

[12] Article 14 (2)

You will need to identify the following data for any relevant substances in the mixture:

- molecular weight to convert DNELs in mg/m^3 to ppm (*Note: if this is not present, and you cannot find it elsewhere, you cannot complete the validation and must do a qualitative assessment)*
- Relevant DNELs (see 2.5)

Step 3 Check received ES information for these substances

For each substance highlighted in Step 2 above, check that the uses highlighted in the SWED /SUMI are accounted for in the exposure scenario of your supplier. You are advised to interpret uses pragmatically and, where necessary, to identify the closest fit.

In addition, check whether any of your customer's uses are listed in the "uses advised against" subsection in Section 1.2 of the substance SDS. If the use is not covered, or is advised against, it is recommended that you check the advice in the CEPE/EuPIA guidance on assessing and demonstrating compliance with received ES information[13]

Step 4 Check the applicability of the SWED

Check the substance DNELs against the Minimum Tolerable DNEL in the SWED, for the appropriate fugacity of the substance, for both inhalative and dermal exposure (see note to paragraph 2.4). The selected SWED provides a list of assumed exposure values and their respective Minimum Tolerable DNELs.

The calculations of exposure estimates for each activity and the overall Minimum Tolerable DNELs for each SWED are given in the following workbooks:


Min tol DNELs liquid


Min tol DNELs solids in liquid


Min tol DNELs powder coatings

Note that DNELs for liquids are often given in mg/m^3, but the SWED calculation needs them to be in ppm. A conversion calculator is included in the CEPE/EuPIA workbook. The figure of 24.07 used corresponds to a temperature of 20^{0}C for the conversion from mg/m^3 to ppm.

The workbook takes the basic data for a substance and applies the exposure modifying factors relevant for the activity, giving the calculated exposure estimates, and therefore tolerable DNELs, for each contributing activity in each SWED. A resulting summary of all CEPE/EuPIA SWEDs is given in the overview table on the data entry page, showing which have

[13] CEPE GUIDELINE ON Assessing and demonstrating compliance with received ES information for the Paint, Varnish, Printing Ink and Artists' Colours Industry, current version, download from members' area of www.cepe.org

been validated. Calculations are also given for scaling due to concentration of the substance in the mixture (see 5.2.1)

The Minimum Tolerable DNELs for the SWED are highlighted in red in the individual calculation sheets per SWED, showing where the problems arise. If substances are used in your mixture with a DNEL lower than the Minimum Tolerable DNEL, they should be replaced or an alternative approach taken (see section 5).

Note, People may be concurrently exposed to a specific substance via different routes of exposure, contributing to the total internal body burden. Thus, concurrent exposure via various routes of exposure needs to be accounted for when characterising overall systemic health risks. Accordingly, the combined systemic effect via both the inhalative and the dermal exposure routes is calculated by the workbook. It should not be considered as safe if the combined Risk Characterisation Ratio (RCR) is above 1. Although this approach does not affect all substances (for example, if each exposure route affects different organs), it is nevertheless included in the Tolerable DNEL calculation in the workbook by default. If a substance fails the validation, where one of the exposure route is not experienced or if systemic effects are not relevant for the substance, it is possible to compare the RCRs for each route separately.

$$RCR = \frac{\text{Min. Tol. DNEL(inhalation)}}{DNEL_{substance}} + \frac{\text{Min. Tol DNEL (dermal)}}{DNEL_{substance}}$$

Safe use is proved if RCR<1

Validation is done per substance. It is not currently possible to calculate a combined exposure to different substances in a mixture. If any substance DNEL is lower than the Minimum Tolerable DNEL, the SWED/SUMI is not valid. In this case, you have a number of options, see section 5.

Step 5 Check Operational Conditions (OCs) and Risk Management Measures (RMMs)

Check whether the OCs and RMMs specified in the SUMI are consistent with the use conditions in the supplier's relevant ES. It is possible you are aware of differences between the actual conditions of use and those which are contained in the ES. You can use expert judgement to show that the individual conditions of use are covered. In such a situation, the use can continue.

If the OCs or RMMs are not consistent, see section 5 for your options.

4. Communication to customers

The information in a SUMI can be forwarded to customers either as an addition to the SDS or by inclusion within the body of the SDS. In the latter

case, the following identifies which Section is most appropriate for the SUMI information:

SUMI content	SDS Section
Ventilation	8.2 (1)
RPE, eye protection, gloves	8.2 (2)

For multi-component products e.g. 2-pack epoxies, the SUMI should be supplied with the SDSs for all components.

5. What to do if the SWED/SUMI is not appropriate

5.1 What to do if the SWED uses are not covered by any of the suppliers ESs, or OC/RMMs in the SUMI are not consistent with substance eSDS

You can:

- contact the supplier for the use to be included in his CSA, and ask for an additional ES to be provided;
  Note: you may have to provide the SWED to the manufacturer/importer to enable them to decide if that use can be included in their ES;
- change supplier to one that has covered the SWED/SUMI requirements in their Registration dossier;
- prepare your own CSA and the consequent ES (if required);
- change the conditions of use in your technical literature and SDS to reflect those covered in the supplier's ES and inform the customer;
- substitute the substance.

*Note: advice on the above aspects of REACH are **not** covered in this guide[14].*

5.2 What do I do if the mixture contains a substance with a DNEL lower than the Minimum Tolerable DNEL for the respective use?

5.2.1 Concentration of substance in mixture

Check if a concentration-related modifying factor can be applied.

The concentration of a substance in a mixture will affect the overall hazard of the mixture. This is taken into account in the ECETOC TRA, which provides reduction factors for substances in mixtures (which are independent of the PROC). The minimum tolerable DNEL for the SWED is multiplied by the relevant modifying factor:

Substance in mixture	Modifying factor
> 25%	1
5 – 25%	0.6
1 – 5%	0.2
< 1%	0.1

[14] For further information and guidance on these options, see ECHA Practical Guide 13: http://echa.europa.eu/documents/10162/13655/du_practical_guide_13_en.pdf, or DUCC/Cefic documents available via https://members.cepe.org/cepe_v2/Item/NaN/3039

These scaling factors are included in the CEPE workbook. Select the appropriate one for the substance concentration in your mixture.

Note: calculate *total* substance concentration if present in different raw materials in the mixture.

- If the above steps do not bring the Minimum Tolerable DNEL below the substance DNEL, the substance(s) must be replaced or an alternative approach is required, such as the CEFIC/VCI 'Lead Component Identification' (LCID) methodology. More information on this is available from the Cefic website.
- Carry out a Downstream User CSA (based on the SWED if possible) etc. For this purpose a guidance document was developed "CEPE Guideline for using ECETOC TRA v3.1 with CEPE SWEDs". The purpose of the guideline is to explain how ECETOC TRA v3.1 can be used to refine the risk assessment for industrial and professional workers based on the paint SWEDs when the SWED/SUMI approach failed. The guidance document as well as the ECETOC TRA files can be found on the CEPE workplace.
  https://members.cepe.org/cepe_v2/Item/NaN/62089
  https://members.cepe.org/cepe_v2/Item/-92/51253

- Inform CEPE if you experience problems applying SWEDs to families of mixtures. It may be possible to find an industry solution i.e. a new SWED/SUMI.
- You may wish to create your own SWED/SUMI. In this case please contact CEPE for advice.

6. Record keeping

It is very important that members set up an internal system to record the receipt of substance ESs, the methodology taken for selecting the appropriate SWED/SUMI and to document their validation of the SWED/SUMI against the substances used. This should include procedures to record any updates.

7. Maintenance and updating of the SWED/SUMI

As for any other safety information, a SWED/SUMI must be maintained and updated as necessary when there are changes to the information it contains. This will be done by CEPE/EuPIA and will be communicated to members in the usual ways.

CEPE/EuPIA may add new SWEDs and SUMIs, as identified by members (see 5.2.1).

Members must keep themselves updated if new information becomes available on substance hazards, or which may affect the risk management measures. In particular, any changes to DNELs that might affect the Risk Characterisation Ratio for the substance in a mixture and therefore the acceptability of a SWED/SUMI for a product use must be monitored. You therefore need to repeat or check the substance validation whenever you receive an updated SDS for a raw material.

It is likely that new/additional exposure scenario information will continue to become available progressively for a number of years.

It is suggested that the same timescales as used for SDS changes are adopted for SWED/SUMIs. Recommendations on timeframes for incorporation of major and minor changes can be found in the DUCC document “Revision management of safety data sheets for mixtures complying with REACH and CLP Regulations”[15]. The time periods suggested are for guidance only and are non-binding.

Updating Uses

A realistic and relevant basis for chemical safety assessments is crucial for registrants and downstream users. Industry has developed a mechanism for providing information on uses and conditions of use to registrants. This is called the Sector Use Maps Package.

Templates for developing use maps and the exposure assessment inputs for workers and consumers (called SWEDs and SCEDs respectively) are ready to use. Templates for the environment are also being finalised (SPERCs).

The next step is for downstream user sector organisations to use these templates to generate or update use maps for their most common uses and to make their use maps available to registrants. Registrants can then use them when preparing Chemical Safety Assessments (CSAs).

[15] Available on CEPE Workplace at http://www.cepe.org/efede/main.htm#!FOLDER/3339

Annex 1 – Additional Information

A1.1 Inhalation Exposure Assessment

The inhalation exposure assessment is of primary importance due to the fact that many coatings materials contain volatile substances and are used by application methods which may lead to exposure to these. The CEPE/EuPIA inhalation exposure assessment is based on ECETOC estimates arising from different application and associated activity scenarios e.g. industrial spray application of a substance with medium volatility (fugacity) has an exposure estimate of 500 ppm.

These initial inhalation exposure estimates (ECETOC TR114, Appendix A) have been reduced by using specific modifying factors:

a) Full containment/extraction 95%
b) LEV (ECETOC TR114, Table A-1)
   - industrial use: usually 90%
   - professional: 80%,
c) room ventilation (ECETOC TR114, 2.2.3)
   - technical (enhanced) room ventilation: 70%
   - general room ventilation: 30%
d) the use of respiratory protection
   - compressed air breathing apparatus: 95%
   - appropriate cartridge mask: 90%

According to the fugacity/volatility concept of ECETOC TRA, exposure estimates have been calculated for substances of various fugacities (for very low, low, medium and highly volatile liquid substances). Accordingly, the outcome of CEPE/EuPIA's exposure assessment is – per SWED – a set of 4 exposure estimates per relevant exposure route.
The SWED for a coatings material consists of several steps/activities. For each use group, the highest exposure estimation of the activities covered determines the Minimum Tolerable DNEL:

Example: **EuPIA_SWED_IS_03_v1** Printing with general room ventilation, **medium volatility liquid substances**

Activity	Default exposure estimate (ppm)	Ventilation efficiency	Vent. Factor	RPE	Assumed exposure (ppm)	Minimum tolerable DNEL
Preparation	50	30%	0.7	No	**35**	**35ppm**
Loading	25	30%	0.7	No	17.5	
Application	50	30%	0.7	No	**35**	
Film formation	20	30%	0.7	No	14	
Cleaning	50	30%	0.7	No	**35**	
Waste mgt	25	0%	1	No	25	

A1.2 Ventilation

The ECETOC TRA gives exposure modifying factors for ventilation depending on its efficiency. In the CEPE/EuPIA SWEDs, these are translated into the number of air-changes per hour.

Ventilation Type	Efficiency	Air-changes/hour	Exposure Modifying Factor
Basic natural ventilation	0%	1-3	1
Good general room ventilation (e.g. open windows) OR outdoors	30%	3-5	0.7
Enhanced (mechanical) room ventilation	70%	5-10	0.3
Local exhaust ventilation (for professional workers)	80%	Refer to relevant technical standards	0.2
Local exhaust ventilation (in industrial setting eg spray booth)	90%	Refer to relevant technical standards	0.1
Full containment/extraction	95%	100 or equivalent	0.05

A1.3 Respiratory Protective Equipment

The ECETOC TRA gives exposure modifying factors for respiratory protective equipment according to its efficiency:

RPE Type	Efficiency	Assigned Protection Factor	Exposure Modifying Factor
No RPE	0%	-	1
RPE (respirator with appropriate filter)	90%	10	0.1
RPE (compressed-air breathing apparatus)	95%	20	0.05

A1.4 Dermal exposure

A similar approach can be taken for dermal exposure. Initial exposure estimates are given in the ECETOC TRA and exposure modifying factors can be applied to give a Tolerable DNEL (dermal). Gloves specified to EN374 should be resistant to the solvent (or powder) in use. The efficiency assigned to dermal protection depends on different protection strategies employed. These can be seen in the table below.

Dermal Protection Characteristics	Efficiency	Exposure Modifying Factor	Affected User Groups
Any glove/gauntlet without permeation data and without employee training	0%	1	Applies to both industrial and professional users
Gloves with available permeation data indicating that the material of construction offers good protection for the substance	80%	0.2	
Chemically resistant gloves (i.e. as above) with 'basic' employee training	90%	0.1	
Chemically resistant gloves in combination with specific activity training (e.g. procedures for glove removal and disposal) for tasks where dermal exposure can be expected to occur	95%	0.05	Industrial users only

Note that exposure estimates based on ECETOC TRA may be misleading. Dermal exposure to substances contained in mixtures may be affected by other substances in the mixture. Co-substances may lead to a forced dermal uptake, i.e. neutralisation of acids and bases must be considered.

Also, combined inhalation and dermal effects need to be considered in cases where safe use can be demonstrated for the routes independently, but the combined RCR is greater than 1 (see note to Step 4, paragraph 3.2).

In addition, the risk determining factor is typically related to the type (material, thickness) of the gloves used. The appropriate glove material is typically not mentioned in the ES.
Therefore, for these reasons, a qualitative approach may be more appropriate. CEPE/EuPIA members have long experience in specifying gloves (respective CEPE/EuPIA guidance is already available; see SDS Guidance[16]).

A1.5 Eye Protection

A quantitative assessment for eye protection is not appropriate. Safety glasses or goggles selected in accordance with EN 166 should be specified to protect against liquid splashes, spray mists or dusts as appropriate.

[16] CEPE Guideline on Safety Data Sheets for the Paint, Varnish, Printing Ink and Artists' Colours Industry, current version, download from members' area of www.cepe.org

A1.6 Fugacity Ranges

Substances fall into different fugacity levels - the property of a substance indicating the level of volatility in a gas or vapour, or dustiness in a solid. The appropriate Minimum Tolerable DNEL must be selected for the fugacity of the substance being validated.

Note that the dustiness of a solid substance is not relevant in either a liquid or powder coating. The ECETOC TRA evaluation cannot predict exposures to solids suspended or dissolved in liquids or in a powder matrix. Therefore, for any solids dispersed in liquid mixtures, it is recommended to use the high fugacity (dustiness) figure for spraying only; for other activities the user will have no inhalative exposure to the solid substance. For solids in powder coatings, you should take the high fugacity figure as exposure will be to the powder coating, which is assumed to be very dusty.

The fugacity bands for volatility and dustiness are given below.

Liquid Vapour pressure at 20°C			
Very Low	**Low**	**Medium**	**High**
< 0,01 Pa	0,01-500 Pa	500-10.000 Pa	>10.000 Pa

Solid Dustiness		
Low	**Medium**	**High**
Non or slightly dusty e.g. granules, sugar	Dusty e.g. talc	Very dusty e.g. milled powder, flour, fume

Annex 2. References/sources of information

A2.1. CEPE/EuPIA

A2.1.1. CEPE/EuPIA Guideline on Safety Data Sheets, Part 1 (latest edition)
http://www.cepe.org/efede/main.htm#!FOLDER/3336
https://members.cepe.org/cepe_v2/Item/-100/3336

A2.1.2. CEPE/EuPIA REACH webpage (including SpERCs etc.)
http://www.cepe.org/efede/public.htm#!HTML/6790

A2.1.3 CEPE/EuPIA GUIDELINE on downstream communication of raw material ES information for the Paint, Varnish, Printing Ink and Artists' Colours Industry
http://www.cepe.org/efede/main.htm#!FOLDER/3336http://www.cepe.org/efede/main.htm#!FOLDER/3336http://www.cepe.org/efede/main.htm#!FOLDER/3039

(Note: if clicking links does not work, copy and paste link into your browser address bar after logging into the members' Workplace.)

A2.2 ECHA

A2.2.1 Guidance on information requirements and chemical safety assessment
http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
Part D: Framework for exposure assessment; Chapter R.13: Risk management measures and operational conditions; Chapter R.14: Occupational exposure assessment

A2.2.2 Practical examples of exposure scenarios
https://echa.europa.eu/support/practical-examples-of-exposure-scenarios

A2.2.3 Guidance for downstream users
http://echa.europa.eu/regulations/reach/downstream-users

A2.2.3 Guidance on the compilation of Safety Data Sheets
https://echa.europa.eu/documents/10162/23036412/sds_en.pdf/

A2.2.4 Safety data sheets and exposure scenarios guide (interactive)
https://echa.europa.eu/safety-data-sheets-and-exposure-scenarios-guide

A2.2.4 ECHA Directors' Contact Group summary paper on unsupported uses (see issue no. 22)
http://echa.europa.eu/documents/10162/13559/echa_dcg_solutions_summary_en.pdf

A2.2.5 Practical Guide 13: How Downstream Users can handle Exposure Scenarios

http://echa.europa.eu/documents/10162/13655/du_practical_guide_13_en.pdf
https://echa.europa.eu/practical-guides

A2.3. European Union

A2.3.1 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
http://ec.europa.eu/environment/chemicals/reach/reach_en.htm
https://echa.europa.eu/regulations/reach/legislation

A2.3.2 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures,
http://ec.europa.eu/growth/sectors/chemicals/classification-labelling_en
http://echa.europa.eu/regulations/clp/legislation

A2.4 Other industry

A2.4.1 CEFIC guidance documents on REACH implementation – ES-CSA-CSR guidance
https://cefic.org/guidance/reach-implementation/es-csr-csr-guidance/

A2.4.2 DUCC Report on experience gained with performing a Downstream User Chemical Safety Assessment (DU CSA) and developing a Downstream User Chemical Safety Report (DU CSR)
www.ducc.eu/Publications.aspx (Guidance & Tools)

A2.4.3 Explanatory document on "Sector Specific approaches towards developing and communicating information for the safe use of mixtures" which includes also a template for the SUMI – the Safe Use of Mixtures Information.
www.ducc.eu/Publications.aspx (Guidance & Tools)

A2.4.4 ECETOC Targeted Risk Assessment (TRA) tool**.**
http://www.ecetoc.org/tools/targeted-risk-assessment-tra/

Annex 3. Glossary of terms and acronyms

Term	Explanation
CLP	Regulation on classification, labelling and packaging of substances and mixtures, Regulation (EC) No. 1272/2008
CMR	Carcinogen, mutagen or reproductive toxicant
Conditions of use	Conditions of use are operational conditions (OC, e.g. duration of activity) and risk management measures (RMMs, e.g. local exhaust ventilation)
CSA	Chemical safety assessment
CSR	Chemical safety report
DNEL	Derived No-Effect Level
DU	Downstream user
DUCC	Downstream Users of Chemicals Co-ordination Group
ECETOC TRA	European Centre for Ecotoxicology and Toxicology of Chemicals Targeted Risk Assessment
ECHA	European Chemicals Agency
EMF	Exposure Modifying Factor
EN	European Norm
ERC	Environmental Release Category. Categories for release of substances into the environment.
ES	Exposure Scenario
ESDS	Extended Safety Data Sheet
H statement	CLP hazard statement
hPa	hectoPascal
kg	Kilogram
L phrase	CEPE/EuPIA health or safety phrase
LEV	Local Exhaust Ventilation
M/I	Manufacturer or importer (of a substance)
OC	Operational condition (of use) such as duration and frequency of substance use, application temperature or state of aggregation of the substance
OEL	Occupational Exposure Limit
PBT	A substance meeting the criteria as persistent, bioaccumulative and toxic in the aquatic environment
PC	Product category
PPE	Personal protective equipment
PNEC	Predicted no-effect concentration
PROC	Process category
RCR	Risk Characterisation Ratio
REACH	Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk management measure (e.g. gloves of a certain specification, instructions).
RPE	Respiratory Protective Equipment
Scaling	Use of simple arithmetic operations to determine if one's actual conditions of use are covered by the ES. It is limited to linear relationships (for example: with a doubling of the receiving water volume, the calculated concentration of a substance which can be expected there is halved, if the other input parameters remain equal).
SCED	Specific Consumer Exposure Determinant
SDS	Safety data sheet
SpERC	Specific environmental release category (industry or sector-specific ERC)

Term	Explanation
SU	Sector of use
SUMI	Safe Use of Mixtures Information
SWED	Sector-specific Worker Exposure Description
Use	In the context of REACH, the categorisation of activities and processes by the REACH Use Descriptor System (e.g. SU, PROC, PC, ERC)
vPvB	A substance meeting the criteria as very persistent and very bioaccumulative in the aquatic environment