ECHA
EUROPEAN CHEMICALS AGENCY

How to undertake a qualitative human health assessment and document it in a chemical safety report

Practical Guide 15

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The purpose and nature of practical guides

Practical guides aim to help stakeholders interact with the European Chemicals Agency (ECHA). They provide practical tips and advice and explain the Agency's processes and scientific approaches. Practical guides are produced by ECHA, under its sole responsibility. They do not replace the formal Guidance (which is established under the formal guidance consultation process involving stakeholders) that provides the principles and interpretations needed for a thorough understanding of the requirements of REACH. However, they communicate and explain the Guidance in a practical way for a specific issue.

This practical guide aims to assist registrants to comply with their obligations in relation to the assessment of exposure and the characterisation of risk for substances for which a threshold cannot be established. It reflects current thinking in this area. Good practices in this area are emerging, improving as the implementation of REACH develops, and experience grows. The practical guide has been developed with input from industry representatives and Member State competent authorities, whose assistance is gratefully acknowledged.

Table of Contents

1. INTRODUCTION

1.1 What is this document about?

Registrants of substances have duties under REACH which may include performing a chemical safety assessment. A qualitative assessment is required for substances for which a threshold cannot be established. This often applies to irritants/corrosives, sensitisers, carcinogens, mutagens and reproductive toxicants.

This practical guide aims to support registrants in undertaking a qualitative assessment that:

- is based on solid and well-justified reasoning
- uses consistent and transparent decision-making on appropriate risk management measures
- is clearly documented in the chemical safety report (CSR).

1.2 What is the scope of this document?

This document aims to support registrants in undertaking a qualitative assessment and risk characterisation with respect to human health, and reporting it in the chemical safety report (CSR).

It describes the key steps in the process, the methodologies and tools available and illustrates how to document it in a CSR. It includes worked examples to illustrate how these elements can be applied.

Qualitative assessment of environmental exposure and physico-chemical properties are outside the scope of this document. The preparation of exposure scenarios for communication down the supply chain is also outside the scope.

This document is addressed to manufacturers and importers of chemical substances who are required to perform a chemical safety assessment under REACH. It is also addressed to downstream users of substances who intend to perform their own chemical safety assessment.

It is assumed that the reader is familiar with the REACH Regulation and their duties under it, and has a general understanding of exposure assessment and risk assessment.

1.3 What is the legal background?

The main legal obligations regarding chemical safety assessments are described in Title II of the REACH Regulation (Article 14), and Annexes I and XII of the Regulation.

A chemical safety assessment must be performed for all substances registered in quantities of 10 tonnes or more per year per registrant, and if the criteria listed in Article 14 of REACH apply. Annex I of REACH sets out the steps in a REACH chemical safety assessment. A preliminary step is a human health hazard assessment for specified health effects. The principal outputs from this assessment are often Derived No Effect Levels (DNELs).

When a DNEL cannot be determined but hazards are identified, a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario must be carried out (REACH Annex I, section 6.5).

1.4 Where can I get more information?

The European Chemicals Agency (ECHA) website contains a wide range of supporting information at all levels. The main access point for the support material is: http://echa.europa.eu/support.

More detailed guidance on performing a chemical safety assessment is provided in the ECHA Guidance on Information Requirements and Chemical Safety Assessment (IR & CSA). The pathfinder for this guidance is at: http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment. The section most relevant to qualitative assessment is Part E: Risk Characterisation, where the principles of qualitative risk characterisation and endpoint related guidance are given. Table E.3-1 and related sections of Part E indicate which risk management measures are appropriate. This practical guide develops this advice, to help identify measures that are proportionate to the risk.

An "Illustrative example of a chemical safety report" is available at: http://echa.europa.eu/documents/10162/13634/csr_illustrative+example_en.pdf. Part 1 includes practical advice regarding chemical safety reports. Part 2 presents a complete chemical safety report for an imaginary substance, for which a combination of quantitative and qualitative assessment is carried out.

ECHA's chemical safety assessment and reporting tool, Chesar, is an application developed by ECHA to help registrants carry out chemical safety assessments (CSAs) and prepare chemical safety reports (CSRs) and exposure scenarios for communication in the supply chain. See http://chesar.echa.europa.eu/ for further details and to download the software.

Among the practical approaches to performing the qualitative assessment, use of control banding tools is mentioned. A selection of them is presented, with links to the sources, in Appendix 1 of this guide.

This document follows on from Practical Guide 14 on "How to prepare toxicological summaries and how to derive DNELs". All ECHA practical guides are published on the ECHA website. To find them, from the "support" section (via the link above), select "guidance on REACH and CLP" and "practical guides".

A glossary of terms used in this document is provided in Appendix 4 of this guide.

2. CHEMICAL SAFETY ASSESSMENT

2.1 Overview of chemical safety assessments

A chemical safety assessment fulfils several purposes.

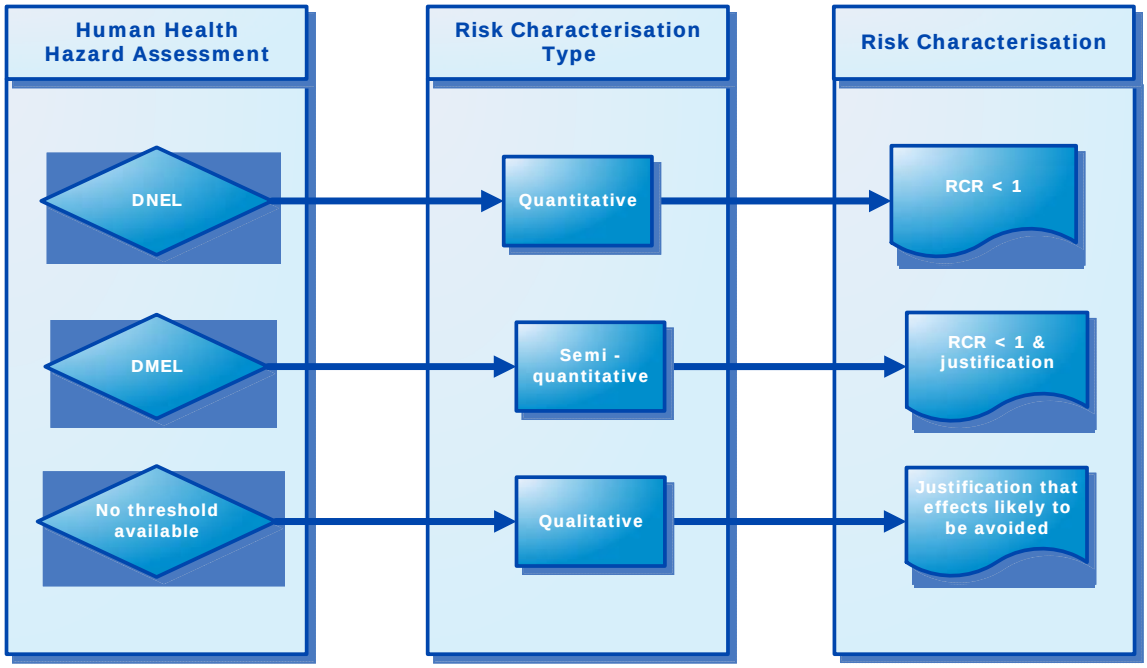
1. It enables a registrant to establish and document the conditions of manufacture and use which are needed to control risks to human health and the environment throughout the life cycle of the substance.

2. It establishes conditions of safe use that are then communicated through the supply chain via the extended safety data sheet (extended SDS).

3. It provides information that supports the work of Member States and ECHA in implementing a number of the regulatory processes in the REACH Regulation. This includes substance evaluation, authorisation and restriction.

An overview of the principle types of chemical safety assessment is presented in Figure 2.1.

Figure 2.1: Overview of principle types of chemical safety assessment



When Derived No Effect Levels (DNELs) can be established, a quantitative risk characterisation is undertaken. Control of risk is demonstrated if the risk characterisation ratio (RCR) is below 1.

When a DNEL cannot be derived, a qualitative risk characterisation is undertaken. A qualitative assessment differs from a quantitative assessment in that you cannot quantify the risk in the form of an RCR. Therefore, you must provide solid and consistent justification to support the conclusion that the operational conditions and risk management measures described in the exposure scenario are sufficient to avoid the likelihood of adverse health effects.

A possible output of the health assessment is a Derived Minimal Effect Level (DMEL), derived for non-threshold mutagens and non-threshold carcinogens. When a DMEL has been established, the risk characterisation is referred to as "semi-quantitative", and is a combination of a quantitative and qualitative assessment approach. Control of risk is demonstrated if the risk characterisation ratio (RCR) is below 1 and additional justification is provided to demonstrate that the control measures described in the exposure scenarios are suitable to minimise exposure.

In practice, chemical safety assessments often require a combination of types of risk characterisation, and not simply one approach. For example, a quantitative risk characterisation may be required for systemic toxicity and a qualitative risk characterisation for respiratory irritation.

In such a case, a suitable approach is to initially undertake a quantitative risk characterisation for those effects with DNELs established, namely systemic toxicity. Then, qualitatively evaluate if the operational conditions and risk management measures (OC/RMMs) provide adequate control with respect to respiratory irritation.

An alternative approach might be preferable for other situations. Consider an example where the substance is a carcinogen, with no threshold value, and also hepatotoxic, with a DNEL for liver toxicity. In this case, the approach could be firstly to generate exposure scenarios with OC/RMMs to provide adequate control for carcinogenicity. The next step is to check if exposure to toxic hazards is adequately controlled by this set of OC/RMMs.

When a substance has more than one health effect, such as in the example above, the leading health effect will affect the selection of the OC/RMMs. Guidance on identification of the leading health effects can be found in the Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.8: Characterisation of dose [concentration]-response for human health (R.8.7).

Four chemical safety assessments are illustrated in Section 5. Example 1 is based on a combined quantitative and qualitative risk characterisation, Example 2 is a semi-quantitative risk characterisation, Examples 3 and 4 are qualitative risk characterisations.

2.2 Key steps in a qualitative assessment

The process steps for a qualitative assessment are very similar to those of a quantitative assessment. The main differences are that the hazard assessment conclusions are based on hazard qualitative description and potency considerations rather than DNELs (there is no 'threshold' level), and the risk characterisation is developed by justification rather than calculation of a risk characterisation ratio. A semi-quantitative assessment is a combination of both, where a quantitative assessment, based on the DMEL is supplemented by qualitative assessment.

The main steps are described below. They are illustrated in Figure 2.2, and the elements specific to qualitative assessments are highlighted.

Further details are provided in the Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA) - Part E, Section 3.4 and Annex I of REACH.

1. Assess the human health hazards
    - As there is no DNEL or DMEL, use Table E3-1 in Guidance on IR&CSA - Part E, or control banding tools (Appendix 1) to assign the substance to a hazard band (such as low, moderate or high hazard).

2. Generate exposure scenarios[1]
    - Generate exposure scenarios for all identified uses in a similar manner to quantitative assessments. Specify the operational conditions and risk management measures that are appropriate to the hazard band. This is discussed further in section 4.

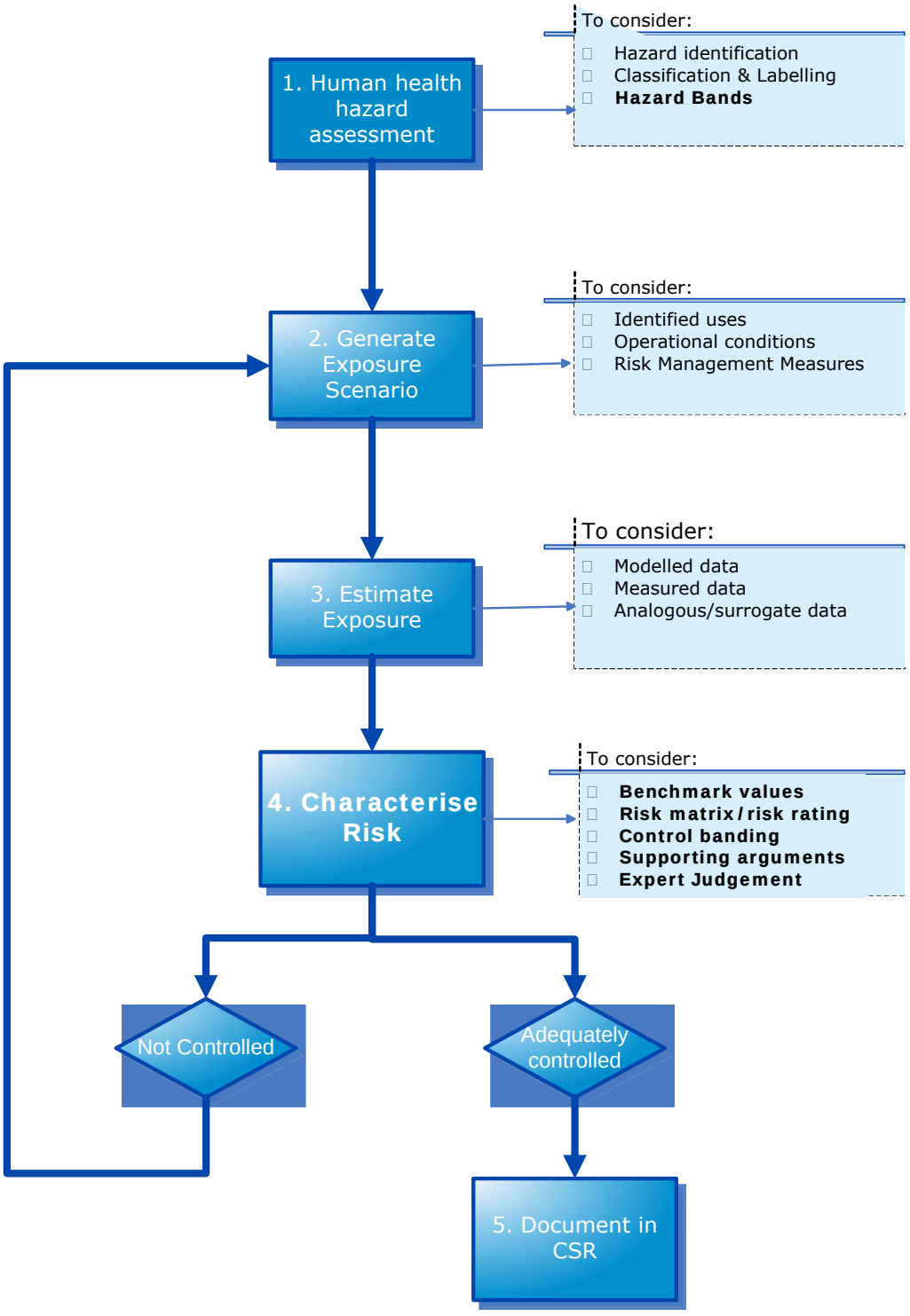
3. Estimate the exposure
    - In qualitative assessments, exposure estimation provides a firm basis on which to demonstrate that exposure is adequately controlled. Estimate the potential for exposure based on modelling, measurement data, or appropriate analogous/surrogate data, in the same way as with quantitative assessments. This is detailed in Part D of the Guidance on IR&CSA.

4. Characterise the risk
    - This is the step that differs most from quantitative assessments. Base the qualitative risk characterisation on a systematic, documented approach. Possibilities include reference to benchmark values, using risk matrices and/or risk rating, control banding and supporting arguments. This is described further in section 3. If the initial conditions of use indicate the risk is not controlled, amend the exposure scenario to establish conditions of use that adequately control the risk. This is an iterative process.

5. Document the qualitative assessment in the chemical safety report
    - Ensure that the qualitative assessment, together with the basis for conclusions, is presented in the CSR. See section 6 for further discussion and an example.

[1] More information can be found in the Guidance on Information Requirements and Chemical Safety Assessment: Exposure Scenario Format in Part D Chesar generates the exposure scenarios for the CSR in a simplified format, which can be viewed within Chesar Manual 4, Annex 2
http://chesar.echa.europa.eu/documents/2326902/2424433/chesar2_user_manual_part4_en.pdf

Figure 2.2: Main steps in preparing a qualitative assessment. The aspects that are most relevant to a qualitative assessment are highlighted in bold



3. QUALITATIVE ASSESSMENT METHODOLOGIES

There is no single, standardised methodology for performing a qualitative assessment. The approach you select depends on aspects such as the inherent hazards of the substance and the potential for exposure during use. It also depends on practical aspects such as the availability of reference information, preferred in-house methodology and methodologies widely used in your industry sector.

Common methodologies that are suitable for qualitative assessment are outlined here. Other approaches, if they are well founded and transparent, may be equally valid.

Regardless of the methodology applied, the conclusion of the risk characterisation must be justified.

3.1 Comparison of exposure estimate with benchmark values

In a quantitative assessment, the risk is characterised by comparing the estimated exposure with a DNEL. This approach is not available in a qualitative assessment, as a DNEL has not been derived. Nevertheless, it may be possible to compare the estimated exposure with a benchmark value to get an indication of whether the exposure is likely to be controlled. Examples of benchmark values include:

1. A Derived Minimal Effect Level (DMEL), if one has been derived. (This is termed a "semi-quantitative" assessment in this practical guide)
2. An exposure benchmark range (EBR) that may have been derived for other purposes (such as from COSHH Essentials, or EKMG. See Appendix 1)
3. Databases on exposure to hazardous substances (such as MEGA data compiled by IFA (Institut fur Arbeitsschutz, http://www.dguv.de/ifa/en/index.jsp)
4. Sector, company or professional experience of the exposure levels under known conditions for a given activity.

When comparing the exposure estimate to the benchmark value, the estimate may simply be described as being above or below the benchmark value. Descriptor terms such as "high"," moderate" and "low" may also be used, based on categories defined by the registrant.

3.2 Risk matrix

A risk matrix is a development of the comparison approach above. It is based on the definition of risk as the probability that exposure to a hazardous substance will result in an adverse effect.

The two main factors that determine the level of risk in chemical exposure can be presented as (i) the likelihood that exposure will occur and (ii) the substance hazard band. Each parameter is typically categorised into three or more bands. Descriptor terms such as "high"," moderate" and "low" are used. A risk matrix is constructed by describing the resultant risk for each combination of the likelihood of exposure and the substance hazard band.

A simple risk matrix is presented in Table 3.1. High potential risk is shown in red, moderate risk in yellow, and low risk in white. From this, we see that if there is a "high" likelihood of exposure to a substance of "high" hazard, the resultant risk is "high". Conversely, if there is a "low" likelihood of exposure to a substance of "low" hazard, the conclusion is "low risk".

Table 3.1: Example of a risk matrix

Likelihood of exposure	Substance Hazard Band		
	Low	Moderate	High
High	Moderate Risk	High Risk	High Risk
Moderate	Low Risk	Moderate Risk	High Risk
Low	Low Risk	Low Risk	Moderate Risk

Note: This risk matrix is for illustration purposes only. The risk matrix used in an assessment will depend on the application.

The main steps in a qualitative assessment using a risk matrix approach are as follows:

1. Select or construct a risk matrix
   There is no standardised risk matrix. Select or construct a risk matrix that suits the assessment needs of the substance.

2. Assign the substance to a hazard band
   The substance hazard band is assigned based on the substance classification and hazard statements. There are a number of accepted systems for hazard categorisation, such as presented in ECHA Guidance on IR&CSA Part E, Table E.3-1, or in the control banding tools described in Appendix 1.

3. Evaluate the likelihood of exposure
   The likelihood of exposure can be established by estimating the exposure and, if possible, comparing with benchmark values such as described in section 3.1. The method selected will depend on the assessment and the information available.

4. Establish the risk
   From the substance hazard band and the likelihood of exposure, use the risk matrix to establish the resultant risk.

The use of a risk matrix in a qualitative assessment is illustrated in section 5, example 3.

3.3 Risk rating

The risk matrix approach can be expanded to include numeric values. This is termed 'risk rating'. A number is assigned to the likelihood of exposure and to the hazard band. The risk is then expressed as the product of these values. From this, a relative risk ranking can be generated. Risk rating and risk ranking facilitates comparison between different exposure scenarios. This can help to ensure consistency between the risk management measures applied.

An example of a risk rating table is presented in Table 3.2. This is adapted from the methodology for chemical risk assessment developed by INRS (Institut National de Recherche et de Sécurité, France). In this matrix, the numbers 1, 3, 10, 30 and 100 are assigned to the five exposure classes, reflecting likelihood of exposure. The numbers 1 to 10 000 are assigned to the five hazard bands. The risk rating is obtained by multiplying these numbers. The scores with high potential risk are shown in red, moderate risk in yellow, and low risk in white.

Table 3.2: Example of a risk rating matrix

Likelihood of exposure	Substance Hazard Band				
	1	2	3	4	5
5	100	1 000	10 000	100 000	1 000 000
4	30	300	3 000	30 000	300 000
3	10	100	1000	10 000	100 000
2	3	30	300	3 000	30 000
1	1	10	100	1 000	10 000

Note: This risk rating matrix is for illustration purposes only. It is adapted from the methodology for chemical risk assessment developed by INRS (See Appendix A.1)

3.4 Control banding

Control banding is a generic risk assessment methodology applied to chemical handling. An example of a control banding approach is COSHH Essentials, developed by the HSE (Health and Safety Executive, UK). A description of this and other control banding methods available is presented in Appendix 1.

In control banding, the substance is initially assigned to a hazard band, using the hazard classification of the substance. Then, based on the occupational activity, the substance properties and potential for exposure, a control band is derived.

Each occupational activity within a given control band is provided with a range of risk management measures, often described in detail in a control sheet. The activities included in control banding tools cover most occupational tasks, for example weighing, machining and cleaning.

Control banding is designed to provide guidance on how to achieve safe conditions of use of chemical substances in occupational scenarios. The list of control measures provided for a given use in a given control band can be extensive and it may not be necessary to use all of the measures available. When generating an exposure scenario based on a control band approach, it may be necessary to select applicable risk management measures from all the measures recommended for that use/control band. The hierarchy of control (presented in section 4.1 below) should be kept in mind when selecting the RMMs most appropriate for the exposure scenario.

3.5 Supporting argumentation and expert judgement

Qualitative assessments are often highly dependent on supporting argumentation and expert judgement. Statements should be corroborated as much as possible by specific reference to relevant supporting material. The relevance of any referenced material to the assessment in question should be clearly established.

Reference sources can include sector information, guidance from ECHA and national authorities, published research or studies. The *Exposure Factors Handbook* published by the US EPA provides information on various physiological and behavioural factors commonly used in assessing exposure to environmental chemicals: http://www.epa.gov/ncea/efh/report.html.

Reference to measured data and to relevant site-specific performance indicators provides strong support for statements that risks are adequately controlled.

Expert and competent intervention may be required, particularly in relation to the handling of high hazard substances, or moderate hazard substances in high quantities.

Risk management measures (RMMS)

The identification of risk management measures within exposure scenarios is an important step of the risk characterisation process. Risk management measures leading to control of risk are described in the exposure scenario for each identified use of the substance and for specified sets of operational conditions. Information on these measures is then communicated through the supply chain via the extended safety data sheet.

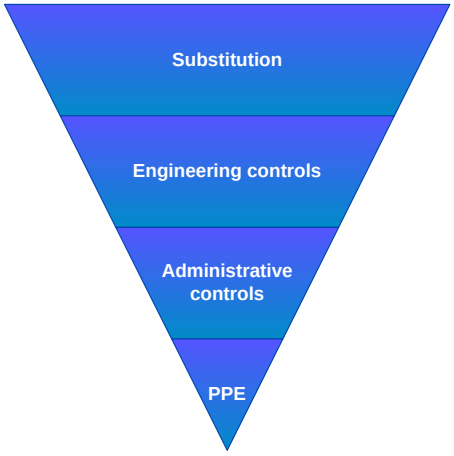
The assessment of risks and documentation that the risks are controlled are more challenging in a qualitative assessment. There is higher uncertainty compared with a quantitative assessment, and there is limited opportunity to base the risk characterisation on numeric values.

The risk management measures that are appropriate depend on the physico-chemical (e.g. dustiness, vapour pressure) and the toxicological properties and operational conditions. Substances leading to serious health effects arising from exposure will require the use of more stringent risk management measures than those typically associated with substances giving rise to moderate or mild adverse health effects.

3.6 The control hierarchy

To achieve effective control in the workplace, the "hierarchy of control" is an established concept and is referred to in the Chemical Agents Directive (Directive 98/24/EC). This concept can be applied to the selection of RMMs in human health assessments for REACH. The elements of the hierarchy are usually presented as an inverted pyramid, where the most effective and strongly recommended RMMs are on the top.

Figure 4.1. Diagram of the RMMs from the hierarchy of control perspective:



- **Substitution / Elimination**

Substitution or elimination is not an option for a registrant CSR, and consequently is not considered further here.

- **Engineering controls**

Control through engineering refers to the design of process plant and equipment to isolate emission sources, maximise containment, ensure enclosure and prevent contact between workers and the hazardous substance. Ventilation systems designed to control emissions at source are included as engineering controls.

- **Administrative controls**

Administrative controls are management tools that include modification of operational conditions. They seek to reduce exposure opportunity, control the way the work is carried out, limit exposure duration, and ensure that the work activity is carried out in a pre-determined way. They support engineering controls in reducing the potential for exposure.

- **Personal protective equipment (PPE)**

Personal protective equipment includes clothing, gloves, respirators and eye protection. PPE is the lowest ranked option because the effectiveness of personal protective equipment depends to a large extent on its appropriate selection, use and maintenance. It protects only the individual wearer and does not prevent exposure or contamination of the wider working environment. Nevertheless, it may be the best available option for infrequent tasks of short duration and for maintenance tasks or emergency situations. PPE may also be used to complement implemented engineering controls.

3.7 How to select, specify and evaluate the effectiveness of the control measures

The challenge for the registrant is to select the appropriate risk management measures from the available options to include in the exposure scenario. There are a number of sources of advice regarding control measures:

- Recommended risk management measures for substances of low, moderate and high hazard are presented in the Guidance on IR&CSA Part E in Table E.3-1. These are summarised in Table 4.1. The complete Table E.3-1 is presented in Appendix 3.

- Supporting guidance on risk management measures and operational conditions is contained in Chapter R.13 of the IR&CSA guidance. It describes the use conditions that have an impact on exposure, available risk management measures for workers and consumers. It also provides guidance on how to evaluate the effectiveness of the proposed OCs and RMMs and how to use the RMM library. (http://echa.europa.eu/documents/10162/13632/information_requirements_r13_en.pdf)

- The Cefic website includes libraries of RMMs for use in developing exposure scenarios: (www.cefic.org/Industry-support/Implementing-reach/Libraries).

- Some control banding tools, such as COSHH Essentials (see Appendix 1), include control sheets. These control sheets describe operational conditions and risk management measures for specified tasks that provide safe conditions of use for workplace scenarios (Appendix 1).

Such information sources present an extensive list of measures. It is not feasible, necessary or appropriate to include all of these in every exposure scenario. Judgement is required to select risk management measures appropriate to the use presented in the exposure scenario. A number of aspects to consider are summarised below. Some of these points are illustrated in the examples in section 5.

1. Select the appropriate risk management measures in accordance with the principles of the control hierarchy (Figure 4.1).

2. Be clear about whether the potential for exposure needs to be highly controlled, well controlled or controlled at a basic level, depending on the hazard band and operational conditions. Specify an occupational health and safety management system that corresponds with the hazard.

3. Take particular care when the substance is of high hazard. The registrant may need to recommend that the downstream user consults an expert for competent, site-specific advice, to check that the RMMs proposed in the CSR and exposure scenario are suitable for their situation and that adequate control will be achieved in practice. This will help to ensure that critical site-specific risk management solutions deliver adequate control.

4. Provide specific advice when possible. For example, when respiratory protection is required, specify the type of respirator (from half-face for low risk to air-fed hood or powered respirator for the high hazard band) as well as the type of filter (specific to the substance). This can require more detailed consideration in qualitative assessments.

5. Ensure the specified OC/RMMs are proportionate. In qualitative assessments, the "easiest" approach for a registrant can be to be overly precautionary. Keep downstream users in mind, to ensure their exposure is adequately controlled, but that excessive and unnecessary RMMs are not required. This avoids potentially time-consuming communication about the appropriateness of the measures later on.

6. Distinguish between additional OC/RMMs that are good practice but not essential to control the risk, and therefore not mandatory. This is illustrated in example 1 in section 5 on spray painting. A specific type of spray gun, generating less aerosol, and therefore reducing exposure, is recommended as a 'good practice'.

7. Be aware that the hazard band may vary depending on the concentration of the substance in a product. For example, a substance may be classified as an irritant, but may not have irritant properties when diluted to below 10% (substance – specific 'cut-off point'). Consequently, the appropriate control measures will also vary.

8. Similarly, the hazard band may vary depending on the combination of hazards. For example, a substance that presents a low hazard with respect to each inhalation, skin and eye irritation separately, is categorised as a moderate hazard substance, if all of these effects could occur, as the health impact is significantly increased.

Table 4.1 Options for control (adapted from ECHA Guidance on IR&CSA Part E: Risk Characterisation, included in Appendix 3)

Hazard Band: LOW	Hazard Band: MODERATE	Hazard Band: HIGH
Select the appropriate RMM/OC from the following: • Minimisation of manual tasks; • Minimisation of splashes and spills; • Avoid contact with contaminated tools, objects and equipment; • Regular cleaning of the work area; • Management measures to ensure RMMs are used correctly and remain effective (consider performance indicators[2] to use); • Training for staff on good practice; • Good standard of personal hygiene.	**As for LOW hazard but also consider:** • Containment as appropriate; • Segregation of emitting processes; • Minimise number of staff exposed; • Effective extraction of contaminants at source; • Provision of a good standard of general ventilation.	**As for MODERATE hazard but also consider:** • Very high level of containment[3] and closed systems that prevent release and allow easy safe maintenance; • Equipment under negative pressure, if possible; • Controlled access to work areas; • Planned maintenance programmes; • Permit to work systems for maintenance activities; • Regular cleaning of equipment and work area; • Management/supervision to check RMMs in place are used correctly and OCs followed; • Training for staff on good practice; • Emergency planning and response; • Procedures for removal and decontamination of waste; • Enhanced occupational hygiene practices; • Recording of incidents and near misses. • For sensitisers: Without prejudice to relevant national legislation pre-employment screening and appropriate health surveillance.
Select appropriate PPE[4] from the following: • Substance/task appropriate respirator; • Chemical goggles; • Face shield; • Substance/task appropriate gloves; • Full skin coverage with appropriate light weight barrier material.	**PPE: As for LOW hazard but also consider:** • skin coverage with appropriate barrier material based on potential for contact with chemicals.	**PPE: As for MODERATE hazard but also consider for sensitisers:** • all skin and mucous membranes with potential exposure protected with appropriate PPE; • appropriate respirator mandatory unless complete containment is verified for all phases of the operation.

[2] Performance indicators include workplace monitoring, biomonitoring, measurements against original specifications for engineering solutions or anything that can readily act as a proxy for the performance of the RMMs and indicates conditions of safe use are present and remain effective.
[3] Exceptions relate to short term tasks causing breaches of containment, e.g. taking samples.
[4] PPE should be appropriate to the hazard, the likelihood of exposure and the demands of the task.

4. EXAMPLES OF QUALITATIVE ASSESSMENTS

Four examples of how qualitative assessments can be handled in a chemical safety report are presented here.

Example 1: Professional spray painting with a substance for which DNELs are established for long-term systemic exposure by inhalation and skin. It is also an irritant by inhalation and dermal contact, but with no DNEL established for these effects. The example illustrates a risk characterisation that is quantitative for some health effects and qualitative for others, for a substance of moderate hazard.

Example 2: Fine chemical manufacturing using a carcinogenic substance with a DMEL established for inhalation and dermal exposure. The example is an illustration of a semi-quantitative risk characterisation, for a substance of high hazard.

Example 3: Machining metal parts that contain a substance that is a respiratory irritant, but with no DNEL established. The example illustrates a risk characterisation that is qualitative only, for a substance of moderate hazard.

Example 4: Widespread use of a chemicals in the mining industry that contains a substance that is skin defatting and eye irritant, with no DNEL established. The example illustrates a risk characterisation that is qualitative only, for a substance of low hazard.

These examples are simplified to illustrate key points. They illustrate the use of a range of methodologies. However, these methodologies may not be applicable to all assessments. It is the registrant's responsibility to undertake an appropriate chemical safety assessment for their uses.

An example of how to document the assessment in a CSR is presented in section 6. It is based on example 2.

4.1 Example 1: Combined quantitative and qualitative risk characterisation – Spray painting with substance with toxic and irritant properties

SUBSTANCE: Substance A is a constituent of coatings.
SCENARIO: Spray application by workers in a non-industrial environment.
HAZARDS: The substance is classified as a respiratory/skin/eye irritant H315/H335/H319 and toxic by inhalation H331. It has a DNEL for systemic toxicity, but not for irritation. The registrant assigns it to the **moderate hazard band**.
PHYSICAL PROPERTIES: Non volatile liquid (10Pa at 25°C).

METHODOLOGY: **Quantitative and qualitative risk characterisation**

1. The exposure estimates are compared with the DNEL that is determined for systemic toxicity.
2. The conditions of use that give RCR<1 with respect to the toxic effects are established.
3. These conditions of use are evaluated to see if they are adequate with regard to dermal and respiratory tract irritation.
4. Supporting arguments are based on ECHA guidance and sector based information sources.

EXPOSURE ESTIMATE: Stoffenmanager was used for inhalation exposure estimation, as it is suitable for aerosols. The exposure through the skin was estimated using Ecetoc TRA v3.

Step 1 - Human health hazard assessment

The hazard conclusion (for workers) and classification of Substance A is summarised in Table 5.1. Based on the hazard statements, the registrant categorises Substance A as a "moderate hazard", following ECHA Guidance on IR&CSA, Part E, Table E.3-1[5] (included in Appendix 3).

[5] When a substance is simultaneously irritant to the respiratory system, skin and eyes (individually low hazard) the overall hazard band is "moderate"

Table 5.1: Conclusions of human health hazard assessment for Substance A in example 1 (workers)

Route	Type of effect	Most sensitive end-point	Hazard conclusion	Scope of assessment
Inhalation	Systemic/Long-term	Repeated dose toxicity	DNEL = 25mg/m^3	Quantitative
	Systemic/Acute		No hazard identified	Not needed
	Local/Long-term	Irritation/resp tract	Low hazard	Qualitative
	Local/Acute	Irritation/resp tract	Low hazard	Qualitative
Dermal	Systemic/Long-term toxicity	Repeated dose toxicity	DNEL = 10 mg/kg bw /day	Quantitative
	Systemic/Acute		No hazard identified	Not needed
	Local/Long-term	Skin irritation/corrosion	Low hazard	Qualitative
	Local/Acute	Skin irritation/corrosion	Low hazard	Qualitative
Eyes		Eye irritant	Low hazard	Qualitative

Step 2 - Generate exposure scenario for paint spray in workshops (Example 1)

In example 1, an exposure scenario is generated for spray painting in car repair/body shops, where car body painting is undertaken.

The initial exposure scenario is shown in Table 5.2. It covers workshops where spray booths are available. Use of respiratory protective equipment (RPE), gloves, eye protection and chemical protective clothing is standard practice in workshops of this type. These measures were included as RMM's.

Table 5.2: Initial exposure scenario / professional paint spray – example 1

Professional paint spraying [PROC 11]
Product (article) characteristics
• Concentration of substance in mixture: 15%
Amount used (or contained in articles), frequency and duration of use/exposure
• Duration of activity: 4-8 hours
Technical and organisational conditions and measures
• General ventilation: Spray booth
• Occupational Health and Safety Management System: Daily cleaning and inspection/maintenance at least monthly
• Other: Restrict access to spray painting area
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment: Yes. [Effectiveness Inhalation: 90%]. Powered respirator (TH2), with combined AP filter
• Dermal protection: Yes. [Effectiveness Dermal: 90%] Butyl rubber, breakthrough time>480 mins.
• Eye/face protection: Chemically resistant face shield and/or goggles
• Chemical Protective Clothing (CPC): overall and boots to prevent skin contact.
Other conditions affecting workers exposure
• Distance to the task: within breathing zone
• Volume of working room: < 100 m^3.
• Body surface potentially exposed: Two hands and upper wrists (1500 cm^2).
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply
• High volume low pressure (HVLP) spray gun if feasible, due to higher transfer efficiencies

Note: This exposure scenario is simplified to highlight aspects relevant to this example. The determinants are a combination of those required for Stoffenmanager (for inhalation) and Ecetoc TRA (for dermal) exposure modelling.

Step 3 - Estimate exposures

The estimated exposure and risk characterisation are presented in Table 5.3. Stoffenmanager and Ecetoc TRA were used for inhalation and dermal exposure modelling respectively. The risk characterisation is the ratio of the exposure estimate to the DNEL for long term systemic effects, as given in Table 5.1

Table 5.3: Exposure estimate for initial exposure scenario

Route of exposure	Exposure estimate	Risk Characterisation
Inhalation (long term, systemic)	0.1 mg/m^3 (90th percentile)	0.004
Dermal (long term, systemic)	6.4 mg/kg/day	0.64
Combined routes		0.64

Step 4 - Characterise risk

The risk characterisation ratios with respect to long-term systemic exposure by inhalation and dermal routes are both below 1. The combined RCR is 0.64. Adverse systemic health effects are likely to be avoided if the operational conditions and risk management measures specified in the exposure scenario are implemented.

For the qualitative risk characterisation with respect to irritant health effects, we assess whether the risk management measures already included in the initial exposure scenario also protect against local effects (respiratory/skin/eye irritation). The RMMs already included are: mechanical ventilation, segregation, PPE for respiratory system, skin and eyes and good occupational hygiene practice. It is assumed that RMMs to control long term exposure are also applicable to controlling acute exposure.

We look at a number of sources of recommended RMMs to evaluate whether the suggested RMMs are appropriate and sufficient. Firstly, we review Table E3-1 of the ECHA Guidance on IR&CSA, Part E. The RMMs already in the exposure scenario are included in the suggested measures for moderate hazard band substances.

We also consult sector specific and national guidance. The European Council of the Paint, Printing Ink and Artists' Colours Industry (CEPE)[6], has identified best practice risk management measures for the manufacture and application of coatings, including spray painting in a professional environment. The CEPE RMMs for typical worst case manufacturing conditions are consistent with those included in the exposure scenario. The recommended RMMs are also consistent with the Safe Work Australia Draft Code of Practice (2011) on Spray Painting and Powder Coating[7].

The RMMs specified in the initial exposure scenario are consistent with the recommendations of the three sources referred to above. This indicates that when the OC/RMM specified to protect against systemic effects are implemented, local effects are likely to be avoided. No additional measures are warranted, and changes to the initial exposure scenario are not required. (Note that for exposure scenarios with high hazard substances and potential for exposure, expert judgement may be required.)

[6] www.cepe.org (see section on REACH)

[7] www.safeworkaustralia.gov.au/sites/SWA/Legislation/model-COP/Documents/Spray_Painting_Powder_Coating-DRAFT.pdf

Step 5 – Document in CSR

An illustration of how to document a qualitative assessment is provided in section 6. It is based on example 2, but the main elements are the same for all assessments.

4.2 Example 2: Semi-quantitative risk characterisation - Manufacture of chemicals using carcinogenic substance

SUBSTANCE: Substance B is used in fine chemical manufacture.
SCENARIO: Batch manufacture of chemicals.
HAZARDS: The substance is classified H350: (may cause cancer, 1B). A DMEL was determined for the inhalation and dermal routes.
The registrant categorised it as a **high hazard.**
PHYSICAL PROPERTIES: Medium volatility liquid. Substance B has vapour pressure of 7kPa at 25°C, and molecular weight of 50.

METHODOLOGY: **Semi-quantitative (inhalation) and qualitative (dermal) risk characterisation**

1. The exposure estimate for inhalation is compared with the DMEL. The conditions of use that give exposure below the DMEL with respect to the carcinogenic effects are established.
2. The customary risk management measures with respect to dermal exposure to carcinogens are established
3. Supporting arguments are made based on uncertainties in the risk characterisation and the sufficiency of the risk management measures.

EXPOSURE ESTIMATE: The results of personal (inhalation) and biological exposure measurements onsite are used to estimate the exposure.

Step 1 - Human health hazard assessment

The hazard conclusion (for workers) and classification of Substance B is summarised in Table 5.4. Based on the classification, Substance B is categorised as a "high hazard", according to ECHA Guidance on IR&CSA, Part E, Table E.3-1.

Table 5.4: Conclusions of human health hazard assessment for Substance B in example 2 (workers)

Route	Type of effect	Most sensitive endpoint	Hazard conclusion	Scope of Assessment
Inhalation	Systemic/Long-term	Carcinogenicity	DMEL = 2 mg/m^3	Semi-quantitative
	Systemic/Acute	Acute toxicity	No hazard identified	Not needed
	Local/Long term		No data available (no further information necessary)	Not needed
	Local/Acute		No data available (no further information necessary)	Not needed
Dermal	Systemic/Long term toxicity	Carcinogenicity	DMEL = 0.6 mg/kg bw/day	Qualitative
	Systemic/Acute	Acute toxicity	No hazard identified	Not needed
	Local/Long term		No hazard identified	Not needed
	Local/Acute		No hazard identified	Not needed
Eyes			No hazard identified	Not needed

Step 2 - Generate exposure scenario for batch manufacturing (example 2)

In example 2, an exposure scenario is generated for the use of Substance B in batch manufacturing of chemicals.

The initial exposure scenario is shown in Table 5.5. Substance B is charged to the reactor vessel directly from storage tanks via closed lines and high integrity valves.

Table 5.5: Initial exposure scenario / batch chemical manufacture – example 2[1]

Closed batch manufacture [PROC 3] Closed transfers and reactor vessel
Product article characteristics
• Concentration of substance in mixture: 100%
Amount used or contained in articles, frequency and duration of use/exposure
• Duration of activity: < 8 hours
Technical and organisational conditions and measures
• Containment: Closed batch process with occasional controlled exposure. *Charging of material is from bulk containers via closed lines and high integrity valves. Reactor is closed during process. Clean in place before opening.*
• General ventilation: Enhanced (5-10 air changes per hour)
• Local Exhaust Ventilation: No
• Occupational Health and Safety Management System: Advanced [1]
Conditions and measures related to personal protection, hygiene and health evaluation

• Respiratory protective equipment: No
• Dermal protection: Yes [Effectiveness Dermal: 95%] Butyl rubber, thickness > 0.7mm, break-through time >480 mins.
• Chemical Protective Clothing (CPC): overall and boots to prevent skin contact.
Other conditions affecting workers exposure
• Process temperature: <40°C
• Place of use: indoor
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply
• Process under negative pressure if possible
• In-line sampling
• No opening of port after addition of Substance B to process

This exposure scenario is simplified to highlight aspects relevant to this example.
[1] Advanced Occupational Health and Safety Management System include:

- Training in normal and emergency operation procedure
- Programme for personal exposure monitoring
- Biological exposure monitoring (if there is a known biomarker)
- Controlled access

Step 3 - Estimate exposures

The estimated exposure by inhalation and risk characterisation is presented in Table 5.6. The exposure estimate was based on personal exposure monitoring undertaken by the registrant over a two year period. The measured data8 on which the estimate is based is summarised in Table 5.7. The 90th percentile was 0.12 mg/m3, which is below the DMEL for inhalation of 2 mg/m3.

There is no exposure estimate provided for dermal exposure. Measurements were not undertaken as monitoring methods are not available. Modelling was not undertaken as a suitable modelling tool for carcinogens was not identified.

Biological exposure monitoring (urine) was undertaken post shift on a quarterly basis for biomarker B for over two years. Biomarker B has not been detected since monitoring commenced. The biological half-life of the substance is three hours. The total number of samples is 32. This indicates that exposure by both the inhalation and dermal routes is controlled.

Table 5.6: Exposure estimate for initial exposure scenarios

Route of Exposure	Exposure Estimate	Risk Characterisation
Inhalation (long term, systemic)	0.12 mg/m^3	Exposure/DMEL = 0.06

[8] See Chapter R14 of ECHA Guidance on IR&CSA for guidance on use of measured data

Table 5.7: Summary of personal exposure measurements to Substance B during batch manufacture

Parameter	Value	Comment
Analyte	Substance B	Sampled and analysed in accordance with MDHS 96
Number of sites	1	Substance B is manufactured at one registrant location, 3-4 campaigns per year
Number of personal samples	12	2011 & 2012. All personal samples over full shift. Exposure assessment in accordance with EN689
Arithmetic mean - 8 hour TWA	0.05 mg/m^3	4 samples below detection limit (DL) of 0.02 mg/m^3 (0.7 x DL was used to calculate mean)
90th percentile 8 hour TWA	0.12 mg/m^3	This is the exposure in the workplace and excludes the protection provided by any RPE worn
Geometric standard deviation	2.4	Indicates data are homogenous

Step 4 - Characterise risk

The risk with respect to long-term systemic exposure is firstly characterised using the ratio of the exposure to the DMEL. For inhalation exposure, the ratio of the estimated exposure to the DMEL is well below 1, at 0.06.

To evaluate if the conditions of use are adequate to avoid the likelihood of effects, uncertainties related to the hazard assessment and the exposure estimate are considered.

In this assessment, the tolerable risk level used in setting the DMEL was 10-6. This is considered to be precautionary, and to provide a good margin of safety. (Note, information regarding the risk level used in setting the DMEL is detailed in section 5 of the chemical safety report)

Regarding uncertainties in the exposure estimate, the measured data (90th percentile) is 6% of the estimated exposure. Biological exposure monitoring detected no evidence of exposure. This indicates that the exposure of workers is controlled, via both inhalation and dermal routes of exposure.

The risk characterisation is further evaluated by considering the conditions of use. The manufacturing process takes place in a closed system, with no opportunity for dermal contact under normal operating conditions.

The conditions of use incorporate many of the recommended measures in ECHA Guidance IR&CSA Part E for substances in a high hazard band. These include high containment, restricted access, implementation of an advanced Occupational Health and Safety Management System, use of dermal protection whenever unintended exposure may occur (line coupling, sampling etc.) and exposure monitoring (personal and biological). The substance is moderately volatile, so surface contamination would be low, in the event of minor leaks or spills.

It is also noted that the Carcinogens Directive (2004/37/EC) requires that workplace exposures are avoided/minimised as far as technically feasible. Compliance with this directive should ensure that the specified conditions of use are effectively implemented.

Consequently, there is confidence in the conclusion that the exposure is below the DMEL. It is likely that effects are avoided when implementing the OC/RMMs of the exposure scenario.

Step 5 – Document in CSR

An illustration of how to document this qualitative risk characterisation is provided in section 6.

4.3 Example 3: Qualitative risk characterisation - Machining of metal with respiratory and eye irritant properties

SUBSTANCE: Substance M is a constituent in a composite metal used in specialised applications.

SCENARIO: Machining of the cast metal for precision parts.

HAZARDS: Substance M is classified as a category 2 respiratory irritant (H335) and eye irritant (H319). It was not possible to determine a DNEL. The registrant categorised it as a **moderate hazard** according to COSHH essentials.

PHYSICAL PROPERTIES: Metal (20%) in alloy; medium dustiness on machining.

METHODOLOGY: **Qualitative risk characterisation**

1. The substance is assigned to a hazard band according to COSHH essentials.
2. The exposure estimate is compared with the exposure benchmark range for the relevant COSHH hazard band.
3. A risk matrix is used to give an overall indication of the risk (high moderate or low risk), based on the hazard band and the likelihood of exposure.
4. The conditions of use are established so that it is likely that adverse effects are avoided.

EXPOSURE ESTIMATE: Ecetoc TRA v3 is used for exposure estimation.

Step 1 - Human health hazard assessment

The hazard conclusion (for workers) and classification of Substance M is summarised in Table 5.8. Based on the classification, Substance M is categorised in Hazard Band C according to COSHH Essentials. This is a "moderate" hazard band.

Table 5.8: Conclusions of human health hazard assessment for Substance M in example 3 (workers)

Route	Type of effect	Most sensitive endpoint	Hazard conclusion	Scope of Assessment
Inhalation	Systemic/Long term	Repeated dose toxicity	No hazard identified	Not needed
	Systemic/Acute		No hazard identified	Not needed
	Local/Long term	Irritation/resp tract	Moderate hazard[1]	Qualitative
	Local/Acute	Irritation/resp tract	Moderate hazard [1]	Qualitative
Dermal	Systemic/Long term toxicity	Repeated dose toxicity	No hazard identified	Not needed
	Systemic/Acute		No hazard identified	Not needed
	Local/Long term		No hazard identified	Not needed
	Local/Acute		No hazard identified	Not needed
Eyes		Eye Irritant	Low hazard	Qualitative[2]

[1] According to COSHH Essentials. The hazard conclusion from ECHA CSA&IR Part E is "low hazard"

[2] See example 4 for a more detailed treatment of eye irritancy

Step 2 - Generate exposure scenario for manual machining (example 3)

In example 3, an exposure scenario is generated for manual machining of metal parts containing 20% of Substance M.

The initial exposure scenario is shown in Table 5.9. The parts are finished by operators on a variety of grinding and polishing machines. Local exhaust ventilation (LEV) and eye protection is widely used throughout the industry, and is included as a risk management measure in the initial exposure scenario.

Table 5.9: Initial exposure scenario / manual machining of metal parts example 3

Manual Grinding and Polishing of Precision Metal Parts [PROC 24]
Product article characteristics
• Concentration of substance in mixture: 20%
Amount used or contained in articles, frequency and duration of use/exposure
• Duration of activity: < 8 hours
Technical and organisational conditions and measures
• Containment: No
• General ventilation: Good general ventilation (3-5 air exchanges per hour)
• Local Exhaust Ventilation: Yes: [Effectiveness Inhalation: 80%].[1]
• Occupational Health and Safety Management System: Basic
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment: No
• Eye/face protection: Yes. Use suitable eye protection
Other conditions affecting workers exposure
• Place of use: indoor

[1] This parameter is modified in the final exposure scenario, as shown in Table 5.13

Step 3 - Estimate exposures

The estimated exposure is presented in Table 5.10, based on Ecetoc TRA. The Exposure Benchmark Range (EBR) for Hazard Band C products according to COSHH Essentials is included in this table for comparison purposes.

Table 5.10. Exposure estimate for initial exposure scenarios

Route of Exposure	Exposure Estimate	Exposure Benchmark Range Hazard Band C [1] (for dust)
Inhalation	0.2 mg/m^3	0.01 to 0.1 mg/m^3

[1] From COSHH Essentials. See Appendix 1

Step 4 - Characterise risk

The risk was characterised using the risk matrix approach described in section 3.1. Only the long-term risk is discussed here. It is assumed that if the risk from long-term exposure is controlled, then the risk from acute exposure is also controlled, as exposure throughout the shift is continuous.

The likelihood of exposure was established by comparing the estimated exposure with the exposure benchmark range (EBR). The EBR gives an indication of the range that can be achieved when implementing the control measures associated with each band.

The registrant defines the following criteria to decide the likelihood of exposure:

if the estimated exposure is within or below the range, the likelihood of exposure is low; if over ten times the upper range, the likelihood of exposure is high; otherwise the likelihood of exposure is moderate.

Note that this use of the EBR is beyond the original purpose of COSHH Essentials and it should be applied with care. However, it provides a numeric and transparent basis to an assessment where no DNEL is available.

The estimated exposure is 0.2 mg/m3. The registrant concludes that the likelihood of exposure is "moderate".

The risk matrix in Table 5.11 is used to derive the risk characterisation. The likelihood of exposure is "moderate", the substance hazard band is "moderate", so the resultant risk is "moderate" (highlighted in yellow in Table 5.12).

Table 5.11: Risk matrix Table used to assist in Risk Characterisation for initial exposure scenario

Likelihood of exposure	Substance Hazard Band		
	Low	Moderate	High
High	Moderate Risk	High Risk	High Risk
Moderate	Low Risk	Moderate Risk	High Risk
Low	Low Risk	Low Risk	Moderate Risk

A moderate risk may be acceptable for some situations. However, in this instance, the registrant is aware that best practice in the industry includes improved containment of equipment and efficiency of the extraction systems. Consequently, the registrant decides to modify the exposure scenario to include improved local exhaust ventilation.

Steps 2-4 / Iteration - modified exposure scenario, exposure estimation and Risk Characterisation for manual machining

The modified exposure scenario and exposure estimates are shown in Table 5.12 and 5.13 respectively. After iteration, the exposure estimate is now 0.1mg/m3. This is within the exposure benchmark range for Hazard Band C. From this, it is concluded that the likelihood of exposure is "low".

The risk characterisation is illustrated in Table 5.14. The likelihood of exposure is "low", the substance hazard band is "moderate", so the resultant risk is "low" (highlighted in grey in Table 5.14).

This indicates that the likelihood of adverse effects is avoided and the exposure scenario

is finalised.

Table 5.12: Final exposure scenario / manual machining of metal parts - example 3

Manual Grinding and Polishing of Precision metal parts [PROC 24]
Product article characteristics
• Concentration of substance in mixture: 20%
Amount used or contained in articles, frequency and duration of use/exposure
• Duration of activity: < 8 hours
Technical and organisational conditions and measures
• Containment: No
• General ventilation: Basic general ventilation (3-5 air exchanges per hour)
• Local Exhaust Ventilation: Yes: [Effectiveness Inhalation: 90%].[1]
• Occupational Health and Safety Management System: Basic
Conditions and measures related to personal protection, hygiene and health evaluation
• Respiratory protective equipment: No
• Eye/face protection: Yes. Use suitable eye protection
Other conditions affecting workers exposure
• Place of use; indoor
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply
• Investigate potential for automation with CNC control

[1] This parameters have been modified after the initial risk characterisation.

Table 5.13: Exposure estimate for final exposure scenario, manual machining

Route of exposure	Exposure estimate	Exposure Benchmark Range Hazard Band C [1] (for dust)
Inhalation	0.1 mg/m^3	0.01 to 0.1 mg/m^3

[1] From COSHH Essentials. See Appendix 1.

Table 5.14: Risk matrix Table used to assist in Risk Characterisation for final exposure scenario for manual machining

Likelihood of exposure	Substance Hazard Band		
	Low	Moderate	High
High	Moderate Risk	High Risk	High Risk
Moderate	Low Risk	Moderate Risk	High Risk
Low	Low Risk	Low Risk	Moderate Risk

Step 5 – Document in CSR

An illustration of how to document a chemical safety assessment that includes a qualitative risk characterisation is provided in section 6. It is based on example 2, but the main elements are the same for all assessments.

4.4 Example 4: Qualitative risk characterisation – handling of mining chemical with skin and eye irritant properties

SUBSTANCE: Substance D is used as a solvent component of mining chemicals.
SCENARIO: Widespread use in mining chemicals (industrial).
HAZARDS: It is classified for skin defatting (R66-EUH066) and eye irritation (R36-H319). It was not possible to derive DNELs for dermal routes of exposure. No effects were observed through inhalation. The registrant assigned it to the **low hazard** category.
PHYSICAL PROPERTIES: It is a liquid of low volatility (227 Pa @ 25°C).

METHODOLOGY: Qualitative risk characterisation
Inhalation: Since there is no hazard related to inhalation exposure, no inhalation exposure estimate is required.
Dermal/Eye: There is no DNEL available. No suitable benchmark value such as DMEL/COSHH Essentials/EKMG or other has been identified. Therefore, dermal exposure estimation is not meaningful. The risk is characterised by reference to benchmark measures of control. This methodology is proportionate to the low risk presented by the substance.

Step 1 - Human health hazard assessment

The hazard conclusion (for workers) and classification of Substance D is summarised in Table 5.15. Based on hazard statements, Substance D is categorised as 'low hazard', according to ECHA Guidance on IR & CSA, Part E, Table E.3-1 with respect to eye irritancy.

Table 5.15: Conclusions of human health hazard assessment for Substance D in example 4 (workers)

Route	Type of effect	Most sensitive endpoint	Hazard conclusion	Scope of Assessment
Inhalation	Systemic/Long-term		No hazard identified	Not needed
	Systemic/Acute		No hazard identified	Not needed
	Local/Long-term		No hazard identified	Not needed
	Local/Acute		No hazard identified	Not needed
Dermal	Systemic/Long-term toxicity		No hazard identified	Not needed
	Systemic/Acute		No hazard identified	Not needed
	Local/Long-term	Skin defatting from prolonged or repeated exposures	Low hazard	Qualitative
	Local/Acute		No hazard identified	Not needed
Eyes		Eye irritant	Low hazard	Qualitative

Step 2 - Develop exposure scenario for industrial use in mining chemicals

The industrial use of mining chemicals involves the following contributing scenarios (and process category):

- Bulk transfers (PROC2)
- Drum/batch transfers (PROC8b)
- Pouring from small containers (PROC9)
- Mixing and blending in closed systems (PROC3)
- Equipment operation (closed and open systems) (PROC5)
- Phase separation (closed systems) (PROC4)
- Ion exchange (closed system) (PROC2)
- Sample collection (PROC3)
- Equipment cleaning and maintenance (PROC8a)
- Material storage (PROC1)

The process categories are based on the generic exposure scenario for mining chemicals of the European Solvents Industry Group (ESIG) http://www.esig.org. The risk management measures initially considered to address the dermal defatting and eye irritating properties of Solvent D are based on good practice within the industry. These measures are the same for all contributing scenarios; therefore the RMM advice is grouped in one exposure scenario.

The generic exposure scenario is shown in Table 5.16. This exposure scenario uses standard phrases [with references in block parentheses] developed for inclusion in the European Standard Phrase Catalogue (EuPhraC).

Table 5.16: Generic exposure scenario / Use in mining chemicals - example 4

Section 1	**Exposure Scenario Title**
Title	Mining chemicals GEST22_I Industrial G26
Sector of Use	Industrial (SU3)
Process Category	PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9
Environmental Release Category	ERC4
Processes, tasks, activities covered	Covers the use of the substance in extraction processes at mining operations, including material transfers, winning and separation activities, and substance recovery and disposal. [GES22_I]
Section 2	**Operational conditions and risk management measures**
Section 2.1	**Control of worker exposure**
Product characteristics	
Physical form of product	Liquid, vapour pressure < 0.5 kPa at STP [OC3]
Vapour pressure	227 Pa @ 25°C
Concentration of substance in product	Covers percentage substance in the product up to 100% [G13]
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated differently) [G2]
Human factors not influenced by risk management	Not applicable
Other Operational Conditions affecting worker exposure	Assumes a good basic standard of occupational hygiene is implemented [G1]. Assumes use at not more than 20°C above ambient temperature, unless stated differently [G15].
Operational Conditions	**Risk management measures**
General measures (skin irritants) [G19].	If repeated and/or prolonged skin exposure to the substance is likely, then wear suitable gloves tested to EN374 and provide employee skin care programmes [PPE20]
General measures (eye irritants) [G44].	Use suitable eye protection [PPE26]. Avoid direct eye contact with product, also via contamination on hands [E73].
Bulk transfers [CS14]	No other specific measures identified [EI20]
Drum/batch transfers [CS8]	No other specific measures identified [EI20]
Manual [CS34] Pouring from small containers [CS9]	No other specific measures identified [EI20]
General process exposures from closed processes[CS15]	No other specific measures identified [EI20]
General process exposures from open processes [CS16]	No other specific measures identified [EI20]
phase separation [CS106] (closed systems) [CS107]	No other specific measures identified [EI20]
Ion exchange processes [CS105] (closed systems)[CS107]	No other specific measures identified [EI20]
Sample collection [CS2] – long term exposure	No other specific measures identified [EI20]
Clean down and Maintenance [CS39]	No other specific measures identified [EI20]
Storage [CS67]	No other specific measures identified [EI20]

Note: References in block parentheses refer to ESIG standard phrases

Step 3 - Estimate exposures

Not applicable as no benchmark value as been identified.

Step 4a - Characterise the risk: skin defatting

Substance D does not meet the criteria for H315 (irritating to skin) but causes concern because of skin dryness, flaking or cracking. Consequently, the supplemental hazard information, EUH066 (repeated exposure may cause skin dryness or cracking), is applied.

Substances with this supplemental hazard information are not categorised in ECHA Guidance on IR&CSA, Part E, Table E.3-1. Nevertheless, it is proposed to apply the RMM recommended for skin irritants to Substance D.

The RMM is communicated by use of the following standard phrase:

- PPE20: If repeated and/or prolonged skin exposure to the substance is likely, then wear suitable gloves tested to EN374 and provide employee skin care programmes

This phrase has been included as an RMM for all tasks covered by the exposure scenario. This RMM is widely applied in the mining industry and found to provide adequate control. If the user complies with this generic statement, the likelihood of effects due to skin defatting is avoided.

Step 4b - Characterise the risk: eye irritation

Eye irritation is categorised as 'low hazard', according to ECHA Guidance on IR & CSA, Part E, Table E.3-1. Exposures should be controlled so the likelihood of effects is avoided. It is proposed to apply the RMM for eye irritants indicated in Table E3-1 to Substance D.

Exposure should be controlled primarily by avoidance of contact with the substance. As an added precaution, suitable eye protection should be worn. Generation of aerosols, which would increase the risk, is not expected with any of the identified uses.

These measures are communicated by use of the following standard phrases:

- [G1]: Assumes a good basic standard of occupational hygiene is implemented.

- [G44]: General measures (eye irritants):

- [E73]: Avoid direct eye contact with product, also via contamination on hands.

- [PPE26]: Use suitable eye protection.

These phrases have been included as RMMs for all activities covered by the exposure scenario. These RMMs are widely applied in the mining industry and found to provide adequate control. If the user complies with these generic statements, the likelihood of effects due to eye irritation is avoided.

5. DOCUMENTING A QUALITATIVE ASSESSMENT

Exposure to chemical substances can give rise to a spectrum of effects, from serious irreversible effects, such as cancer, to minor reversible effects, such as mild irritation. The level of detail and justification of an assessment that is provided in a chemical safety report (CSR) should be proportionate to the hazard and the conditions of use.

Software tools have been developed by ECHA to facilitate chemical safety reporting. These are described in section 6.1 below. The sections in a CSR that are most relevant to a qualitative assessment for human health exposure are highlighted in section 6.2. Extracts from a sample CSR are presented in section 6.3, to illustrate how a qualitative exposure assessment and risk characterisation can be documented.

5.1 Software tools for chemical safety report generation

ECHA has developed two software tools to assist registrants in preparing a chemical safety report (CSR), namely Chesar and the CSR plug-in tool.

Chesar (ECHA's Chemical Safety Assessment and Reporting Tool) enables registrants to import substance information from the IUCLID dossier as a basis for the exposure assessment and risk characterisation. ECETOC TRA v.3 is in-built to facilitate exposure modelling.

Users can develop and manage details on the life cycle of the substance, the exposure assessment and the risk characterisation. The information is automatically presented in a report format. The features in Chesar that apply to a qualitative assessment are described in Appendix 2.

The CSR plug-in tool uses information provided in IUCLID to generate sections 1 to 8 of the CSR. If Chesar is used, the CSR plug-in tool can automatically incorporate sections 9 and 10 from Chesar in the CSR. Alternatively, the registrant can prepare the exposure assessment and risk characterisation using their own system and merge it with sections 1 to 8 generated using the CSR plug-in tool.

Both the CSR plug-in tool and Chesar can be downloaded free of charge from the IUCLID and Chesar websites respectively www.iuclid.eu and http://chesar.echa.europa.eu.

5.2 Chemical safety report format

The format for a CSR is outlined in Annex I of the REACH Regulation. For downstream users, reduced requirements are presented in REACH Annex XII. The exposure assessment and risk characterisation are documented in sections 9 and 10 of the CSR.

A brief description of the typical content of these sections relating to human health is presented below. The topics are the same as for a quantitative risk assessment. However, a fuller description of the methodology and references is generally necessary for a qualitative assessment. Justification of the risk characterisation conclusion is required.

CSR Section 9.0 : Introduction

- Overview of uses and list of exposure scenarios.
- The scope of the assessment (based on section 5).
- The methodology used (e.g. modelling tool/s, risk matrix, reference material etc.).
- Factors which influenced the risk assessment (such as assumptions regarding

process and operational conditions, volatility/fugacity, cut-off points for mixtures).

CSR section 9.1 to 9.n : Exposure scenarios 1 to n

- Descriptive introduction to the exposure scenarios.
- Assessment considerations specific to that scenario.
- Exposure scenario, with final operational conditions and risk management measures.
- Exposure estimate with risk characterisation.
- Details on any exposure data used.
- Conclusion on risk characterisation (with justification).

Note: Although section 10 deals with Risk Characterisation, it may aid clarity to include individual risk characterisation and justifications in section 9, together with the exposure scenario and the exposure estimate.

CSR Section 10 : Risk Characterisation

- Risks from combined sources (such as worker and consumer, combination of work tasks, combination of consumer products, environmental plus other sources etc.)

5.3 Example of documenting a qualitative assessment in a CSR

The qualitative assessment should be documented clearly and justified in the CSR. Segments to illustrate the information that could be included under the given sections are presented in the following pages. These extracts of a CSR are based on example 2 in section 5 (closed batch manufacturing process with a carcinogen).

The segments presented here are an indication of the type of discussion and information that can be included, and are not recommended text. It is the registrants' responsibility to document the chemical safety assessment appropriately for their uses.

Extracts of CSR for Example 2: Substance B / Batch Manufacturing of Chemicals using a Carcinogenic Substance

CSR SECTION 9 – EXPOSURE ASSESSMENT

9.0 Introduction

[Note: Section 9.0 typically includes subsections with an overview of the uses and exposure scenarios. Section 9.0.2. details the exposure assessment approach for the environment, workers and consumers. Sample extracts from the subsection on assessment of exposure to workers only are presented here (numbered 9.0.2.3 in this example.)]

9.0.2. Introduction to the assessment

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9.0.2.3. Workers

Scope and type of assessment

The scope of exposure assessment and type of risk characterisation required for workers are described in the following table. This is based on the hazard conclusions presented in section 5.11.

Table 9.1: Type of risk characterisation required for workers

Route	Type of effect	Hazard conclusion (see section 5.11)	Type of risk characterisation
Inhalation	Systemic /Long term	DMEL(Derived Minimum Effect Level) = 2 mg/m^3	Semi-quantitative
	Systemic/Acute	No hazard identified	Not needed
	Local/Long term	No data available (no further information necessary)	Not needed
	Local/Acute	No data available (no further information necessary)	Not needed
Dermal	Systemic/Long term toxicity	DMEL = 0.6 mg/kg bw /day	Qualitative
	Systemic/Acute	No hazard identified	Not needed
	Local/Long term	No hazard identified	Not needed
	Local/Acute	No hazard identified	Not needed
Eyes	Local	No hazard identified	Not needed

CSR Extracts for Example 2 continued:

Comments on assessment approach

A semi-quantitative assessment was undertaken for inhalation exposure to substance B. The exposure level was established using measured data. The conditions of use for which the exposure was below the DMEL (inhalation and dermal) were established.

This risk characterisation was supported by a qualitative risk characterisation. The qualitative element of the risk characterisation included reference to the uncertainties in the hazard assessment and the exposure estimate. The objective was to establish whether additional RMMs are required to minimise the likelihood of adverse health effects occurring. Finally, the conditions of use were reviewed with respect to good practice and regulatory requirements.

There is no exposure estimate provided for dermal exposure. Measurements were not undertaken as monitoring methods are not available. Modelling was not undertaken as a suitable modelling tool for carcinogens was not identified. Consequently, a qualitative assessment was undertaken for dermal exposure to substance B. The conditions of use were reviewed with respect to evidence of exposure from biological exposure monitoring, good practice and regulatory requirements.

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9.1 Exposure scenario 1: Batch Manufacture of Chemicals

[Note: Section 9.1 onwards in a CSR presents the exposure scenarios, from manufacturing through industrial and professional use to consumer use. Extracts from the exposure scenario for batch manufacture using Substance B is presented here, referred to as section 9.1. Only the contributing scenario for workers for the manufacturing process (ES 1.1) is illustrated here]

Environment contributing scenario(s):	
ES1.0 Manufacture in contained system	ERC 1
Worker contributing scenario(s):	
ES1.1 Closed batch manufacturing process	PROC 3

Description of the activities and technical processes covered in the exposure scenario:

Substance B is a reagent in batch manufacturing of chemicals (PROC 3).

The exposure scenario for batch manufacturing is shown in section 9.1.2.1. Substance B is charged to the reactor vessel directly from storage tanks via closed lines and high integrity valves. The process is maintained under negative pressure and closed throughout the process. The sequence of operations is such that the charge port is not opened after addition of Substance B to the process. There is a clean-in-place procedure for the reactor before the port is opened.

CSR Extracts for Example 2 continued:

9.1.2. Worker contributing scenario 1: Closed batch manufacturing process (PROC 3)

9.1.2.1. Conditions of use (contributing scenario)

Closed batch manufacture [PROC 3] Closed transfers and reactor vessel	
Product article characteristics	Method
• Concentration of substance in mixture: 100%	TRA Workers
Amount used or contained in articles, frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA Workers
Technical and organisational conditions and measures	
• Containment: Closed batch process with occasional controlled exposure. *Charging of material is from bulk containers via closed lines and high integrity valves. Reactor is closed during process. Clean in place before opening.*	TRA Workers
• General ventilation: Enhanced (5-10 air changes per hour)	TRA Workers
• Local Exhaust Ventilation: No [Effectiveness Inhalation: 0%].	TRA Workers

• Occupational Health and Safety Management System: Advanced . *This includes*
  • *Training in normal and emergency operation procedure*
  • *Program for personal exposure monitoring*
  • *Biological exposure monitoring (if there is a known biomarker)*
  • *Controlled access*
	TRA Workers

Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment: No [Effectiveness Inhalation: 0%].	TRA Workers
• Dermal protection: Yes. [Effectiveness Dermal: 95%]. *Butyl rubber, thickness > 0.7mm, breakthrough time >120 mins.*	TRA Workers
• Chemical Protective Clothing (CPC): Yes. *Overall and boots to prevent skin contact.*	
Other conditions affecting workers exposure	
• Process temperature: < 40°C	TRA Workers
• Place of use: indoor	TRA Workers
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Process under negative pressure if possible	
• In-line sampling	
• Elimination of port opening after addition of Substance B to process	

CSR Extracts for Example 2 continued:

9.1.2.2. Exposure and risks for workers

The exposure concentrations and risk characterisation are reported in the following table.

Table 9.2: Exposure concentrations and risks for workers

Route of exposure and typed of effects	Exposure concentration	Risk Characterisation
Inhalation (systemic, long term)	0.12 mg/m³ (Measured data : 90th percentile)	Exposure/DMEL =0.06 Semi-quantitative (see below)

Remarks on exposure data

Measured data is available from personal exposure and biological exposure surveys undertaken in the registrant company. The sample size is sufficient to meet the recommendations to ECHA Guidance on IR&CSA Chapter R14, in relation to both the number of measurements and the quality of the methodology used. Consequently, the measured data were used to determine the ratio to the DMEL. *[note to registrant: relevant information on measured data should be provided]*.

An overview of the measured data from one site location is presented in Table 9.3.

Table 9.3: Summary of personal exposure measurements to Substance B during batch manufacture

Parameter	Value	Comment
Analyte	Substance B	Sampled and analysed in accordance with MDHS 96
Number of personal samples	12	2011 & 2012. All personal samples over full shift. Exposure assessment in accordance with EN689
Arithmetic mean - 8 hour TWA	0.05 mg/m^3	4 samples below detection limit (DL) of 0.02 mg/m^3 (0.7 x DL was used to calculate mean)
90th percentile 8 hour TWA	0.12 mg/m^3	This is the exposure in the workplace and excludes the protection provided by any RPE worn
Geometric standard deviation	2.4	Indicates data are homogenous

Biological exposure monitoring (urine) has been undertaken post shift on a quarterly basis for biomarker B for over two years. Biomarker B has not been detected since monitoring commenced. The biological half-life of the substance is three hours. The total number of samples is 32.

Conclusion on risk characterisation

The combined ratio of the measured exposure to the DMEL is below 1, at 0.06. To evaluate if the conditions of use are adequate to avoid adverse effects, uncertainties related to the hazard assessment and in the exposure estimate are considered.

The tolerable risk level used in setting the DMEL was 10^{-6}, as shown in section 5. This is considered to be precautionary, and to provide a good margin of safety.

Furthermore, biological exposure monitoring detected no evidence of exposure. This indicates that the exposure of workers is controlled, via both inhalation and dermal routes of exposure.

The risk characterisation is further evaluated by considering the conditions of use. The manufacturing process takes places in a closed system, with no opportunity for dermal contact under normal operating conditions. The conditions of use incorporate many of the recommended measures in ECHA Guidance IR&CSA Part E for substance in a high hazard band. These include high containment, restricted access, an advanced Occupational Health & Safety Management System, use of dermal protection whenever unintended exposure may occur (line coupling, sampling etc.) and exposure monitoring (personal and biological). The substance is relatively volatile, so surface contamination would be low, in the event of minor leaks or spills

It is also noted that the Carcinogens Directive (2004/37/EC) requires that workplace exposures are avoided/minimised as far as technically feasible. Compliance with this directive should ensure that the specified conditions of use are effectively implemented.

Consequently, there is confidence in the conclusion that the exposure is below the DMEL for inhalation and that the exposure by the dermal route is also low. It is likely that effects are avoided when implementing the OC/RMMs of the exposure scenario.

Appendix 1 – CONTROL BANDING

A 1.1. Limitations of control banding tools

The available control banding tools assist in conducting a qualitative assessment and characterisation that reduces the subjective element. The parameters usually taken into consideration include:

- Properties of the substance – hazard classification, form, volatility, dustiness.
- Quantity of the substance used, frequency and duration of exposure.
- Task for which the substance is used, conditions of use.

However, there are a number of uncertainties that need to be considered when deciding upon the final set of RMMs:

a) While most tools consider the scale of use in daily (continuous) operation/batch, they may not be sensitive to duration and frequency. These factors also affect the level of exposure and the level of risk.

b) The methodology utilised in the tools may not account for working temperature or energy at generating points, dispersion patterns, personal factors, etc.

c) Complex process or exposure patterns require care in matching of risk phrases with the hazard bands and care in selecting and implementing the RMMs.

d) Control banding tools identify control solutions that provide protection for the large majority of the working population. However, for the susceptible groups of individuals such as young and aged workers, as well as child bearing age or pregnant women who may require additional protection when exposed to specific hazardous materials, a more precautionary approach may be prudent and a greater degree of control provided.

A 1.2. Examples of control banding tools

COSHH Essentials

COSHH Essentials is a tool developed in the UK, for workplace scenarios. It is applicable to substances classified under the 2009 Chemicals (Hazard Information and Packaging for Supply) Regulations. It is not applicable to pesticides, pharmaceuticals, process-generated hazards, such as wood particulate and welding fumes. Silica dust is also excluded.

This toolkit is designed for protecting workers from airborne contaminants. It deals with the inhalation route of exposure, but is expanding to include dermal exposure.
The key components are: hazard bands, exposure potential and control methods.
The conclusion is a recommended control sheet that guides users in selecting the most appropriate level of risk management based on:

- Type of task (12 levels).
- The assignment of the chemical hazard to a specific hazard band, based on its properties/hazard
- The volatility (three levels) or potential for generation of airborne particulate (three levels)
- The quantity of the substance used in the task (three levels)

The exposure benchmark ranges, referred to in example 3 are shown in Table A1.1. More information about the tool can be found at:
http://www.hse.gov.uk/coshh/essentials/index.htm

Table A.1.1: Exposure benchmark range in COSHH Essentials

	Exposure benchmark range	
Hazard Band	**Dust / mist (mg / m³)**	**Vapour / gas (ppm)**
A: Unclassified as harmful	1 to 10	50 to 500
B: Harmful	0.1 to 1	5 to 50
C: Toxic, corrosive	0.01 to 0.1	0.5 to 5
D: Very toxic, toxic to reproduction	< 0.01	< 0.5
E: Carcinogen, mutagen, asthmagen	As low as reasonably practicable	

EMKG

In Germany, an easy to use workplace control scheme for hazardous substances (EMKG) was developed. This tool is based on COSHH Essentials but offers more detailed skin exposure assessment. It uses the information obtained from SDSs in conjunction with the workplace conditions, to derive strategies to minimise exposure.

For typical tasks, a guidance is offered on precise RMMs. There are 36 Control Guidance Sheets (CGSs) available. The relationship between the concentration range and the hazard bands is shown in Table A.1.2. More information about the tool can be found at:
http://www.emkg.de/

Table A.1.2: Concentration range in air in EMKG

	Concentration range	
Hazard Band	**Dust / mist (mg / m³)**	**Vapour / gas (ppm)**
A	$1 < c \leq 10$	$50 < c \leq 500$
B	$0.1 < c \leq 1$	$5 < c \leq 50$
C	$0.01 < c \leq 0.1$	$0.5 < c \leq 5$
D	$0.001 < c \leq 0.01$	$0.05 < c \leq 0.5$
E	$c \leq 0.001$	$c \leq 0.05$

INRS

INRS, the French research institute, has developed a control banding system using simple and available information to prioritise risk assessment of chemicals. It takes into consideration the hazard and exposure factors, such as the quantity used, the conditions of use, the properties of the substance, duration of exposure, and means of prevention used. The information sources include SDSs and labels.
More information about the tool can be found at:

http://www.inrs.fr/accueil/produits/mediatheque/doc/publications.html?refINRS=ND%202121

In addition, INRS has published a guide on assessment of risks to human health and the environment (ND 2233-200-05). In this guide, elements such as physico-chemical properties and risks, classification and concentration of the substance are taken into account to determine the level of potential risk, to facilitate decision-making and selection of the most appropriate RMMs.
The description of the methodology is available at:
http://www.inrs.fr/accueil/produits/mediatheque/doc/publications.html?refINRS=ND%202233

Stoffenmanager

Stoffenmanager (the Netherlands) is a tool used to maintain an inventory of hazardous substances, to assess and control the risks within the inventory, to develop a plan for control methods. It also facilitates the development of the qualitative exposure assessment based on a control banding. A series of questions facilitates allocation of a substance into an exposure class. The tool then calculates the risk score. The registrant reviews the selection of various control methods based on the risk score, and chooses the most appropriate and effective for their needs. The tool is generic, but gradually will be adapted to fit various industry sectors.
More information about the tool can be found at: https://www.stoffenmanager.nl/#

Regetox

Regetox is a Belgian two-stage risk assessment strategy that uses the INRS – developed methodology for ranking potential risks on the basis of the R-phrases, annual quantity used and frequency of use. Products receiving the rankings medium and high are then evaluated using the COSHH Essential strategy. More information about the tool can be found following the "demarche" tab) at:
http://www.regetox.med.ulg.ac.be/accueil_fr.htm

The International Chemical Control Toolkit (ICCT)

The International Chemical Control Toolkit (ICCT) developed by the International Labour Organisation ILO, based on COSHH Essentials, is a scheme for protection against harmful and dangerous chemicals in the workplace.

There are a number of relevant instruction guidance sheets developed for the safe handling of a substance under given conditions.

The toolkit can be applied to substances, for example pesticides or common solvents, but also to specific risks – inhalation, skin/eye exposure, environmental risks.

The tool kit is designed in a stepwise approach:
1. Find the hazard classification and match it to a hazard band using the table supplied.
2. Find out how much of the substance you are going to use – scale of use.
3. Find out how much of the substance is going to get into the air – ability to become airborne.
4. Find the control approach, considering:
- hazard level, quantity in use, dustiness/fugacity.
- control options based on specific operations.
- skin and respiratory protection recommended.
5. Find general or task-specific control guidance sheets.

A complete list of guidance sheets and the complete toolkit may be seen at:
http://www.ilo.org/legacy/english/protection/safework/ctrl_banding/index.htm

Appendix 2 – Performing a qualitative assessment with Chesar

This section is intended to direct the user to the features in Chesar that are most relevant for qualitative assessments. Detailed manuals are available for users not already familiar with Chesar.

The Chesar software is structured according to "boxes". A brief overview with particular reference to qualitative assessments is provided here.

Box 1 Substance Management

This box presents the conclusions of the hazard assessment from IUCLID as a "scope of assessment". It describes the type of assessment required (quantitative, qualitative) for each route of exposure (inhalation, dermal and oral) and type of exposure (local, systemic, acute, long-term). Check that any assessment that should be qualitative is correctly assigned. If any changes are required, these are made in section 7 in IUCLID.

Box 2 Report uses

Report all the uses for the full life cycle of the substance.

Box 3 Manage quantitative exposure assessments

Select the appropriate exposure estimation method for each contributing scenario. For those hazards with a DNEL assigned, ensure the conditions of use (operational conditions and risk management measures (OC/RMMs)) result in an RCR below 1. For those hazards without a DNEL, exposure estimates can support arguments to justify adequate control.

Box 4 Build final exposure scenarios and generate the CSR

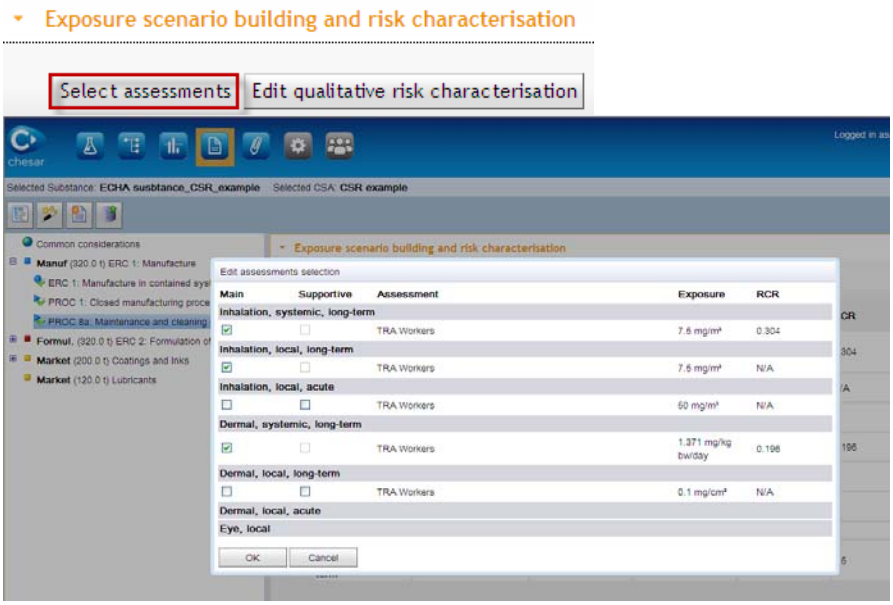
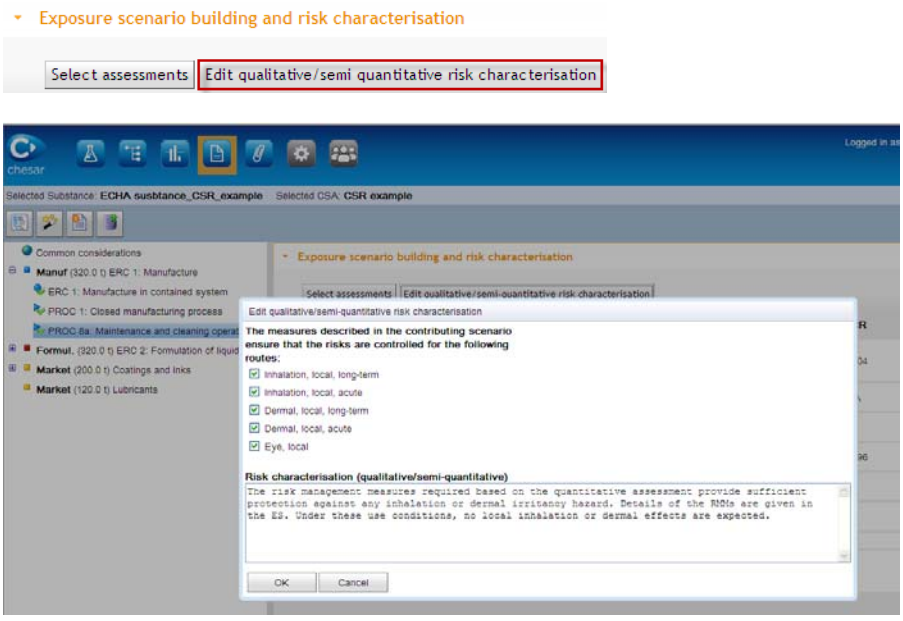
Evaluate whether the OC/RMMs included in the exposure scenario also control risks from the hazards without a DNEL. Add further RMMs if necessary. Any determinants added at this stage do not change the exposure estimation. Justify the conclusion.

The Chesar manual describing the function of box 4 is available at http://chesar.echa.europa.eu/documents/2326902/2424433/chesar2_user_manual_part4_en.pdf. The screens in Chesar that relate specifically to a qualitative assessment are presented in Table A2.1. These are all accessed from Box 4.

The arguments supporting a qualitative assessment can be entered directly in Chesar, and these are included in the CSR that is automatically generated by Chesar. The sections where such text can be entered, and where it is located in the CSR, are presented in Table A2.2. Again, these are all accessed from box 4.

Note that the CSR generated in Chesar differs slightly from the Annex I format of REACH to improve the clarity. The risk characterisation for a given use is presented together with the exposure scenario and the exposure estimation for that use. Consequently, section 10 of the CSR refers to combined risks only.

Table A2.1 Key sections regarding a qualitative assessment in Chesar.

Box 4 Build final exposure scenarios and generate the CSR	
Actions	**Icon / button to be activated**
Specify qualitative assessment In the tab "Exposure scenario building and risk characterisation", click "Select assessments". For qualitative assessments the exposure estimate, if available, is shown. The risk characterisation is based on the qualitative assessment below, not the RCR.	
Confirm risk is controlled For every contributing scenario requiring a qualitative assessment, click the button "Edit qualitative /semi quantitative risk characterisation" in the Exposure scenario building and risk characterisation pane. Add a justification and tick the box to confirm that control of risk is demonstrated.	

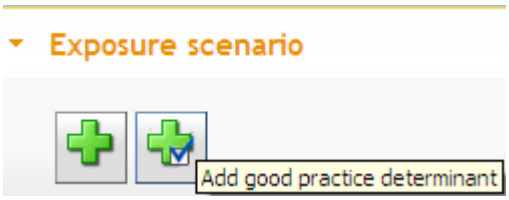
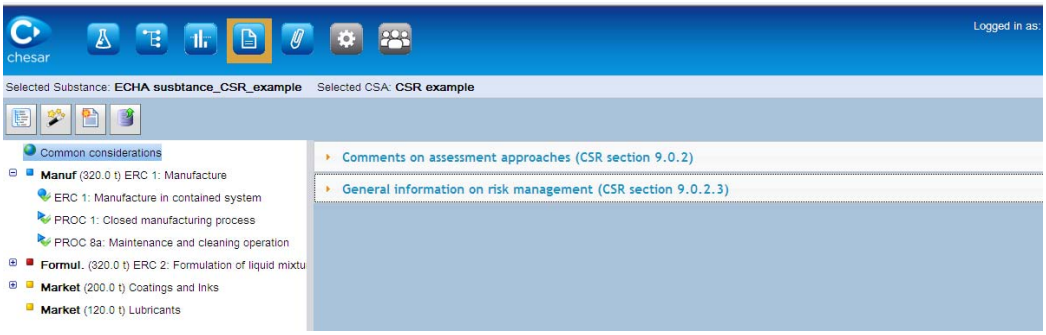
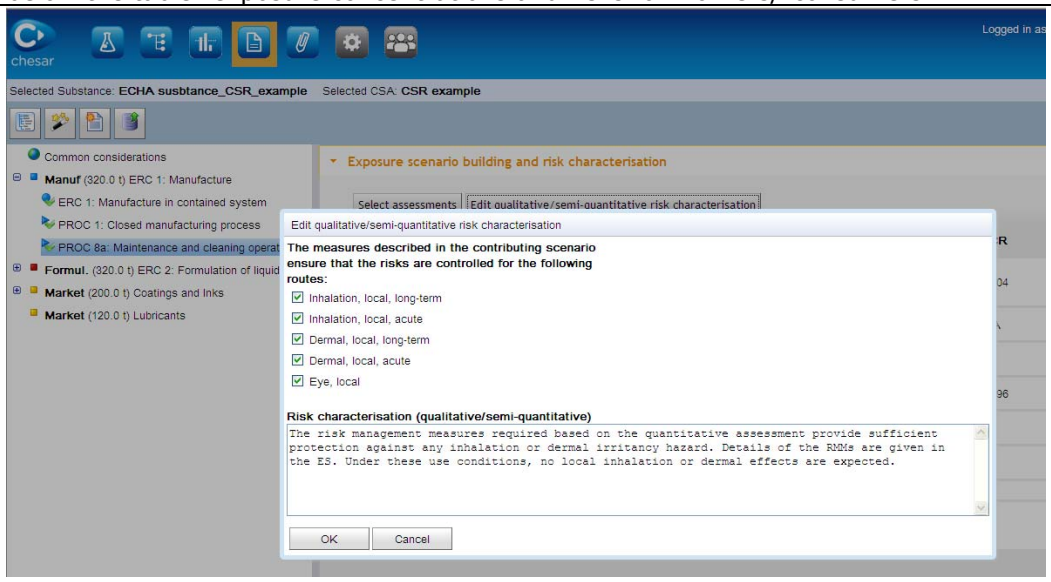
Add determinants In the tab "Exposure scenario" (scroll down), add additional determinants necessary to ensure control of risks and/or "good practice determinant" if relevant. These are presented in the ES but do not have any impact on the exposure estimation.	

Table A2.2 Documenting a qualitative assessment in Chesar

Box 4 Build final exposure scenarios and generate the CSR	
Text to include in CSR	**9.0.2** Discussion on the qualitative assessment methodology, scope of assessment etc **9.0.2.3** General information on risk management measures for workers/consumers
Where to enter it in Chesar	
Text to include in CSR	**9.1 to 9.n** Discussion on introduction to ES regarding qualitative assessment considerations for that specific ES
Where to enter it in Chesar	
Text to include in CSR	**9.n.x.2** Conclusion on the risk characterisation for each contributing scenario. This is printed below the table "exposure concentrations and risks for workers/-consumers"
Where to enter it in Chesar	

Appendix 3 – Hazard Categories and suggested OC/RMM's from Table E3-1

Category of danger/Type of effect/risk phrase (DSD)	R phrase code	Type of effect/hazard statement (CLP)	Hazard statement code	Exposure route	Risk Management Measures and Operational Conditions	
					General	PPE
HIGH HAZARD						
Carcinogens Category 1 and 2		**Carcinogenicity Category 1A and Category 1B**			- Any measure to eliminate exposure should be considered; - Very high level of containment required, except for short term exposures e.g. taking samples; - Design closed system to allow for easy maintenance; - If possible keep equipment under negative pressure; - Control staff entry to work area; - Ensure all equipment well maintained; - Permit to work for maintenance work; - Regular cleaning of equipment and work area;	- Substance/task appropriate respirator; - Substance/task appropriate gloves; - Full skin coverage with appropriate barrier material; - Chemical goggles.
May cause cancer	R45	May cause cancer	H350	Inhalation, oral, dermal		
May cause cancer by inhalation	R49	May cause cancer by inhalation	H350i	Inhalation		
Mutagens Category 1 and 2		**Germ cell mutagenicity Category 1A and 1B**				
May cause heritable genetic damage	R46	May cause genetic defects	H340	Inhalation, oral, dermal		
Mutagens Category. 3*		**Germ cell mutagenicity Category 2***				
Possible risk of irreversible effects	R68	Suspected of causing genetic defects	H341	Inhalation, dermal, oral		
Strong corrosive		**Skin corrosion Category 1A**				- Face shield; - Substance/task appropriate gloves; - Full skin coverage with appropriate barrier material; - Chemical goggles.
Causes severe burns	R35	Causes severe skin burns and eye damage	H314	Inhalation, dermal, oral		

Acute toxicity		**Acute toxicity Category1 and Category 2**			- Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice; - Procedures and training for emergency decontamination and disposal; - Good standard of personal hygiene; - Recording of any 'near miss' situations; - Sensitisers - Without prejudice to relevant national legislation, pre-em.ployment screening and appropriate health surveillance	- Substance/task appropriate respirator; - Substance/task appropriate gloves; - Full skin coverage with appropriate barrier material; - Chemical goggles.
Very toxic	R26	Fatal if inhaled	H330	Inhalation		
Very toxic	R27	Fatal in contact with skin	H310	Dermal		
Very toxic	R28	Fatal if swallowed	H300	Oral		
Extreme/strong skin sensitiser***		**Skin sensitisation Category 1 or 1A*****				- All skin and mucous membranes with potential exposure protected with appropriate PPE
May cause sensitisation by skin contact	R43	May cause an allergic skin reaction	H317	Dermal		
Respiratory sensitiser		**Respiratory sensitisation Category 1, 1A or 1B**				- Appropriate respirator mandatory unless complete containment is verified for all phases of the operation;
May cause sensitisation by inhalation	R42	May cause allergy or asthma symptoms or breathing difficulties if inhaled	H334	Inhalation		
Very serious irreversible effects-single exposure		**Specific Target Organ Toxicity-Single Exposure Category 1**				- Substance/task appropriate respirator; - Substance/task appropriate gloves; - Full skin coverage with appropriate barrier material; - Chemical goggles
Very toxic: danger of very serious irreversible effects through inhalation	R39/26	Causes damage to organs	H370	Inhalation		
Very toxic: danger of very serious irreversible effects in contact with skin	R39/27	Causes damage to organs	H370	Dermal		

Very toxic: danger of very serious irreversible effects if swallowed	R39/28	Causes damage to organs	H370	Oral		
Toxic: danger of very serious irreversible effects through inhalation	R39/23	Causes damage to organs	H370	Inhalation		
Toxic: danger of very serious irreversible effects in contact with skin	R39/24	Causes damage to organs	H370	Dermal		
Toxic danger of very serious irreversible effects if swallowed	R39/25	Causes damage to organs	H370	Oral		
MODERATE HAZARD						
Carcinogens Category3**		**Carcinogenicity Category 2****			- Containment as appropriate; - Minimise number of staff exposed; - Segregation of the emitting process; - Effective contaminant extraction; - Good standard of general ventilation; - Minimisation of manual phases; - Avoidance of contact with contaminated tools and objects; - Regular cleaning of equip-	- Substance/task appropriate gloves; - Skin coverage with appropriate barrier material based on potential for contact with the chemicals; - Substance/task appropriate respirator; - Optional face shield; - Eye protection.
Limited evidence of carcinogenicity	R40	Suspected of causing cancer	H351	Inhalation, dermal, oral		
Corrosive		**Corrosivity Category 1B and Category 1C**				
Causes burns	R34	Causes severe skin burns and eye damage	H314	Inhalation, dermal, oral		
Acute toxicity		**Acute toxicity Category 3**				
Toxic	R23	Toxic if inhaled	H331	Inhalation		
Toxic	R24	Toxic in contact with skin	H311	dermal		
Toxic	R25	Toxic if swallowed	H301	oral		

Possible risk of irreversible effects-single exposure		**Specific Target Organ Toxicity-Single Exposure Category 2**			ment and work area; - Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice; - Good standard of personal hygiene.	
Harmful: possible risk of irreversible effects through inhalation	R68/20	May cause damage to organs	H371	Inhalation		
Harmful: possible risk of irreversible effects in contact with skin	R68/21	May cause damage to organs	H371	dermal		
Harmful: possible risk of irreversible effects if swallowed	R68/22	May cause damage to organs	H371	Oral		
Irritants		**Eye and skin irritation Category 2 and Specific Target Organ Toxicity-Single Exposure Category 3 (respiratory irritation)******				
To the eyes, skin and respiratory system simultaneously	R36/37/38	Causes serious eye irritation	H319	Eyes, inhalation, dermal		
		May cause respiratory irritation	H335 and			
		Causes skin irritation	H315			
Moderate skin sensitiser***		**Skin sensitisation category 1B*****				
May cause sensitisation by skin contact	R43	May cause an allergic skin reaction	H317	Dermal		
Eye damage		**Eye damage Category**				- Chemical goggles.

		1				
Risk of serious damage to eyes	R41	Causes serious eye damage	H318	Eyes		
LOW HAZARD						
Eye Irritant		**Eye irritation Category 2**			- Minimisation of manual phases/work tasks; - Work procedures minimising of splashes and spills; - Avoidance of contact with contaminated tools and objects; - Regular cleaning of equipment and work area; - Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed; - Training for staff on good practice; - Good standard of personal hygiene.	- Chemical goggles. - Face shield; - Substance/task appropriate gloves; - Full skin coverage with appropriate light-weight barrier material. - Substance/task appropriate respirator.
Irritating to the eyes	R36	Causes serious eye irritation	H319	Eyes		
Skin Irritant		**Skin irritation Category 2**				
Irritating to skin	R38	Causes skin irritation	H315	Dermal		
Irritant to the respiratory system		**STOT SE 3**				
Irritating to the respiratory system	R37	May cause respiratory irritation	H335	Inhalation		

Source: Guidance on information requirements and chemical safety assessment, Part E

Appendix 4 - KEY TERMS and ABBREVIATIONS

Exposure Scenario (ES)
An "exposure scenario" (ES) is a set of information describing the conditions at manufacturing or use of a substance that may give rise to exposure to humans and/or to the environment. A final ES describes the conditions under which the risk is considered adequately controlled.

Operational Conditions (OC)
The "operational conditions" (OCs) are the set of information on the use of a substance. They describe the types of activities to which the exposure scenario relates, how frequently, how often and for how long a substance is used and in which type of process, at which temperatures etc. Only parameters influencing the exposure level are included in the exposure scenario.

Risk Management Measures (RMM)
The term "risk management measure" (RMM) means an activity or device that reduces or avoids the direct and indirect exposure of humans (including workers and consumers) and the different environment compartments to a substance during its use. Risk management measures applied in industrial uses include local exhaust ventilation (LEV), waste gas incinerators or on-site and municipal waste water treatment and personal protective equipment (PPE).

Conditions of use
The "conditions of use" include the operational conditions and risk management measures (if required).

Risk Characterisation Ratio (RCR)
The risk characterisation ratio is the ratio of the exposure to the predicted no-effect concentrations (PNEC) or derived no-effect levels (DNEL), for environmental and human exposure respectively. When the RCR is less than 1, the risk is considered to be controlled for the conditions of use for which the exposure was determined.

Derived No Effect Level (DNEL)
Levels of exposure to a substance above which humans should not be exposed.

Derived Minimal Effect Level (DMEL)
A reference risk level which should be used to better target risk management measures for substances for which no DNEL can be derived, such as non-threshold mutagens/-carcinogens. Exposure levels below a DMEL are judged to be of very low concern, due to a high likelihood that effects are avoided for the Exposure Scenario under consideration.

Exposure Estimation Tools
Ecetoc TRA – workers, consumers and environmental exposure modelling
- *European Centre for Ecotoxicology and Toxicology of Chemicals, Targeted Risk Assessment*

Stoffenmanager – workers exposure modelling
- *Consortium sponsored by Dutch Ministry of Social Affairs and Employment*

Advanced Reach Tool (ART) - workers exposure modelling
- *international consortium of industry and member states*

ConsExpo - consumers exposure modelling
- *RIVM, Dutch National Institute for Public Health and the Environment*

EUSES - environmental exposure modelling

- *EU System for Evaluation of Substance*

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