ECHA
EUROPEAN CHEMICALS AGENCY

An Illustrative Example of a CSR

Part 1 – Introductory Note with advice on preparing your chemical safety report

June 2017

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An Illustrative Example of a CSR. Part 1: Introductory Note with advice on preparing your chemical safety report

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Table of Contents

List of acronyms

AC	Article category
CLP	Classification, Labelling and Packaging
Chesar	Chemical Safety Assessment and Reporting
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DMEL	Derived minimum effect level
DNEL	Derived no-effect level
ECHA	European Chemicals Agency
ERC	Environmental release category
ES	Exposure Scenario
IUCLID	International Uniform Chemical Information Database
LEV	Local Exhaust Ventilation
OC	Operational Conditions
PBT	Persistent, Bioaccumulative, Toxic substances
PC	Chemical product category
PNEC	Predicted no-effect concentration
PPE	Personal Protective Equipment
PROC	Process category
RCR	Risk characterisation ratio
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk management measure
SDS	Safety Data Sheet
SPERC	Specific Environmental Release Category
vPvB	very Persistent and very Bioaccumulative substances

1. INTRODUCTION

The Chemical Safety Report (CSR) is a central element of the REACH process and is essential for compliance with registration requirements. It is the key source of information for extended Safety Data Sheets. It also forms a basis for many regulatory activities including substance evaluation, authorisation and restriction.

This publication gives tips and advice to registrants on how to avoid common deficiencies and improve the accuracy and clarity of information in a Chemical Safety Reports. It addresses shortcomings commonly identified by ECHA when working with CSRs submitted to the Agency.

It is published in four parts:

- **Part 1:** *An Introductory Note*, which gives general hints and tips to consider when preparing a Chemical Safety Report
- **Part 2:** *An Illustrative Example of a CSR* for a hypothetical substance. It exemplifies how to describe uses for a substance, assess the hazards, to estimate exposure to the environment and human using a range of estimation methods and build exposure scenarios for manufacture and industrial, professional and consumer uses. Comments are included which explain the reasoning for the approach taken, and which clarify how critical factors could be resolved.
- **Part 3**: *IUCLID 6.1 substance data set* from which the Chemical Safety Report (sections 1 to 8) has been generated.
- **Part 4**: *Chesar 3.2 substance file* from which the Chemical Safety Report (sections 9 and 10) has been generated

The advice provided here is intended for submitters of new registration dossiers and for registrants updating CSRs already submitted to the Agency. It may also be of assistance to downstream users who prepare their own CSR.

2. CHEMICAL SAFETY ASSESSMENTS AND REPORTS

The scope of a CSA is described in Annex I of the REACH Regulation as follows:
"The chemical safety assessment (CSA) of a manufacturer shall address the manufacture of a substance and all the identified uses. The chemical safety assessment of an importer shall address all identified uses. The chemical safety assessment shall consider the use of the substance on its own (including any major impurities and additives) and in mixtures. The assessment shall consider all stages of the life cycle of the substance resulting from the manufacture and identified uses, including the service life of the substance in articles and the waste life stage. The chemical safety assessment shall be based on a comparison of the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance taking into account implemented and recommended risk management measures and operational conditions."

The chemical safety report (CSR) documents the chemical safety assessment. The main headings for the CSR are listed in Annex 1 to the REACH Regulation. The CSR is submitted to ECHA in a registration dossier (in accordance with Article 10 and 14 of the REACH Regulation).

The information contained in the CSR fulfils several purposes:

1. For the registrant, the CSR is used to document:
   - the intrinsic properties and hazards of a chemical substance;
   - the conditions of manufacture and use which are needed to control the risks to human health and the environment throughout the life cycle of the substance;
   - the expected emissions and exposure to humans and environment resulting from manufacture and uses, throughout the life cycle of the substance;
   - the characterisation of risks following such emissions and exposures;

2. For Member States and ECHA, the CSR provides information that supports their work on a number of the regulatory processes contained in the REACH Regulation. This includes dossier and substance evaluation, authorisation and restriction.

The CSA conducted as part of the REACH process addresses all stages of life cycle of an individual substance. It supports, but does not replace, the site-based risk assessments undertaken in accordance with national environmental and health and safety regulations.

These local risk assessments address the overall risk resulting from all chemicals used on site, based on actual operational conditions and the known effectiveness of risk management measures in place. Information from the registrant's CSR can be used to support the local assessments and compliance with the requirements set out in other relevant legislations.

2.1 Objectives of the Illustrative Example of a CSR

ECHA aims to support industry in improving the accuracy and clarity of the information provided in the chemical safety report. This applies to both updates of existing CSRs in dossiers of already registered substances and to CSRs being prepared for the future registrations. The objective of this CSR example is to illustrate:

- The nature and content of the information required in a CSR (Annex 1, Section 7 of REACH);
- How to improve the quality and consistency of CSRs and to resolve common shortcomings identified by ECHA when working with the existing CSRs;

- The information in a IUCLID file that is integrated in a chemical safety report;
- The export files and the documents generated when using ECHA's Chemical Safety Assessment and Reporting Tool, Chesar.

Although this publication is aimed at registrants, downstream users who prepare a downstream user CSR in accordance with Article 37 and Annex XII to the REACH Regulation may also find it of benefit. If a downstream user is satisfied with the outcome of the hazard assessment of the registrant, as presented in the Safety Data Sheet, he needs only to undertake the exposure assessment and risk characterisation (Sections 9 and 10 of the CSR), and address those uses not covered in the registrant's extended Safety Data Sheet. The information presented – especially related to the Sections 9 and 10 - may also be useful for those preparing a CSR for the purposes of the authorisation process.

3. GENERAL ADVICE WHEN PREPARING A CHEMICAL SAFETY REPORT

3.1 SAFETY REPORT

Tips and advice on aspects to consider when preparing a chemical safety report are provided below. They address both general issues and specific points with regard to risk assessment for environmental and human exposure.
Comprehensive guidance on how to prepare a CSR, "Guidance on information requirements and chemical safety assessment" is available on the ECHA website.
http://www.echa.europa.eu/guidance-documents. Practical guides are also available on topics such as deriving DNELs and reporting a qualitative assessment. See
http://www.echa.europa.eu/practical-guides

3.2 Hazard Assessment

1. Pay attention to the classification and labelling and to the PBT assessment, as those are critical elements for establishing the hazards of the substance and assessing the exposure and the risks. Make sure that you include the comparison of the data with the criteria provided in the CLP Regulation and Annex XIII to REACH, and take into consideration the data gaps and waiving proposals.

2. Derive the DNEL and PNEC values with care, as these are critical parameters in the assessment. Justify the derivation, including the assessment factors used, particularly if you deviate from the guidance (Chapter R.8 and R.10 of ECHA Guidance on IR&CSA[1]).

3. Where the required and/or existing test data do not support the derivation of a no-effect level, you may derive a minimum effect level (DMEL) indicating the likelihood of an adverse effect at a certain dose-level (semi-quantitative assessment) or any other more qualitative measure of the potency of the substance. For irritation and corrosion to skin and eyes (and under certain conditions also to the respiratory tract) you may assume that no-effects are to be expected if the concentration in a mixture is below the classification threshold for these effects.

4. Provide information sources, reference to test methods and justifications as appropriate in the hazard assessment. If you deviate from the standard method, provide information that can be understood by an independent reviewer.

5. Systematically fill the endpoint summaries in IUCLID to establish a consistent starting point for the exposure assessment and risk characterisation.

[1] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

3.3 Building Exposure Scenarios

6. Identify all uses occurring during the entire life cycle of the substance. Where appropriate, communicate with downstream users to ensure that all uses are included and that your assumptions regarding the operational conditions and risk management conditions reflect the range of actual situations. Utilise the information provided by downstream sector organisations, describing the uses and the actual conditions of use in the sector (*sector use maps*). Such *use map* information can be downloaded from a dedicated page on the ECHA website[2] and directly fed into the registrant's chemical safety assessment.

7. Ensure that each identified use of the substance is covered by a single exposure scenario. To keep the information in the CSR concise, avoid multiple reporting of the same use.

8. Each use such as manufacture, formulation and the various uses at industrial sites, by professional workers or by consumers may consist of a number of contributing activities. For example, a manufacturing use could have one contributing activity for the environmental emissions and several contributing activities for worker activities such as material transfer, dis/charging vessels, carrying out chemical reactions and the cleaning and maintenance of equipment.

9. Describe each use clearly and concisely. Use the harmonised terminology of the sector in which the use occurs, whenever possible. This includes a clear and easy to understand name of the use, and intuitive names for the contributing activities. Avoid just paraphrasing the generic descriptor categories (PROC/ERC/PC/AC) when giving the contributing activities a name but ensure that descriptors assigned are consistent with the use you want to assess. Complement the use name and the names of the contributing activities with a *further description of use* in order to facilitate the understanding of the purpose, the technical layout and the coverage of the use process.

10. REACH requires that the description of the uses in the IUCLID dossier and the titles of the corresponding exposure scenarios in the CSR are consistent with each other. Or in other words: it should be transparent which conditions of uses and which exposure estimate corresponds to which use. Therefore, the names of the uses and their contributing activities in IUCLID should be copied as the titles of the exposure scenarios and their contributing scenarios. In this way, it is always clear which exposure scenario covers which use.

11. Keep in mind that downstream users have to assess whether the exposure scenarios drawn from your CSR match their use. To avoid time-consuming communication and updating of your CSR, ensure all potential uses are covered and clearly described so that the relevant information can be easily identified by downstream users. Exposure scenarios should incorporate information regarding volumes, concentrations, other operational conditions and risk management measures which are realistic, which ensure safe use and which are not overly precautionary.

Note: All the information mentioned above may have already been compiled by downstream sector organisations in the form of use maps. Utilise such use maps, and where downstream sectors have not yet published or updated their use maps encourage them to do so.

[2] https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library

3.4 Exposure Estimation and Risk Characterisation

12. Select the most appropriate method for exposure estimation. This is generally the use of measurement data or an exposure modelling tool/s. Robust measurement data, if available, are a valuable source of information. However, when using measured datasets for estimating the emissions or the exposure downstream, make sure that the dataset is sufficiently representative and can be linked to concrete conditions of use, under which such exposure occurs. Exposure estimation tools are widely used and a range of tools is available which cover many situations. Select the most suitable tool with care and understand the strengths and the limitations, including the applicability domain, of the tool. For worker exposure, the brief characterisation of the tools as contained in Chapter R.14 of ECHA Guidance on IR&CSA may help you in this respect.

13. For substances where DNEL and PNEC values are established, undertake a quantitative risk characterisation. Where a DMEL is established, a semi-quantitative assessment is needed, demonstrating the minimisation of exposure. For an endpoint for which a DN(M)EL cannot be established (e.g. eye irritancy), the assessment is referred to as qualitative.

14. Where a quantitative risk assessment is undertaken, establish the conditions of use needed to achieve the exposure below the DNEL or PNEC (that is, the risk characterisation ratio is less than 1), therefore demonstrating safe use.

15. Where a qualitative or semi-quantitative assessment is undertaken, provide a clear description of the operational conditions and associated risk management measures that are necessary to control, and minimise if necessary, the emissions and exposures. See Practical Guide 15[3] "How to undertake a qualitative human health assessment and document it in a Chemical Safety Report" for further information.

16. For human health, assess the combined risk for systemic effects due to exposure via the various exposure routes: dermal, inhalation and oral, where appropriate. In some case, the aggregate exposure (e.g. from different consumer products containing the same substance) might be assessed as well (Part D of ECHA Guidance on IR&CSA).

17. For the environment, assess combined exposure and risks from all wide dispersive uses at the local scale.

3.4.1 Environmental Assessment

18. Undertake an environmental risk assessment for all exposure scenarios identified. Always include a regional assessment. Include the impact on humans via the environment, if required (see Chapter R.16 of ECHA Guidance on IR&CSA).

19. Exposure estimates can be obtained using an appropriate model, such as EUSES, or measured data. Use supporting evidence where this is helpful (for example, from another tool or from measured data).

20. Environmental Release Categories (ERCs) incorporated in modelling tools may overestimate the exposure from industrial sources. If so, refine the releases to the environment using literature sources, sector specific ERCs (also known as SPERCs) or site

[3] https://echa.europa.eu/documents/10162/13655/pg_15_qualitative-human_health_assessment_documenting_en.pdf/26a645d4-a81e-4223-8ca9-20162ae74e72

based information (mainly for a registrant's own use) as appropriate.

21. If you use literature sources such as OECD Emission Scenario Documents (ESD) to refine the releases, ensure that the emission factors (and the related use conditions) from the ESD indeed address the use you intend to assess. Report the condition of use associated with these release factors in the exposure scenario.

22. If you use industry Specific Environmental Release Categories (SPERCs) to refine release factors, ensure that the release factor is in line with the use you want to cover (consult the SPERC fact sheet). When using a SPERC for release estimation, report in the exposure scenario (ES) the conditions of use associated with the release factor described in the SPERC. Do not use SPERCs without supporting information or where clear OC/RMM driving release factors are not reported. Go back to the SPERC owner if you are uncertain.

23. When using site based information (such as measured emission values and information on process conditions) to refine the releases, clearly justify any assumption.
Report the relevant OC/RMM ensuring such controlled release in ES.

24. Report appropriate information on waste, such as the fraction of substance "released" to waste treatment and the specific consideration for waste treatment (if needed) for each exposure scenario.

25. Make sure that the assessment is realistic. Base your assessment on OCs/RMMs that reflect commonly applied good practice for the sector of use. The application of unrealistic OC/RMMs to achieve very low RCRs can create problems for downstream users, whose conditions of use do not match those assumed/advised by the supplier's ES.

26. When risk management measures are required, engineering controls to reduce the release at the source are preferred to end-of-pipe control measures.

3.4.2 PBT Assessment

27. If the PBT assessment is inconclusive, you have the following options: a) treat the substance as if it is a PBT/vPvB substance or b) generate the data necessary to establish whether it is a PBT/vPvB substance.

28. If you conclude that the substance fulfils the PBT/vPvB criteria, or it is considered as such, conduct an emission characterisation. Also, ensure the RMMs minimise emissions to the environment throughout the life cycle of the substance.

3.4.3 Human Health Assessment

29. Carry out a risk assessment for all adverse health effects for which a hazard is identified (considering all relevant routes - inhalation, dermal, and oral – and type of effects - acute and/or chronic, local and/or systemic) and for all relevant populations. Identified hazards also include those not leading to classification. Consult Part D of ECHA Guidance on IR&CSA for criteria for hazard identification.

30. Exposure estimates can be obtained using an appropriate model (taking into account its scope of applicability) or measured data.
Often the initial exposure estimate is calculated with a screening tool (termed Tier I). Use a more advanced model to refine the result, if the initial screening assessment does not demonstrate that the risk is controlled, or if the tool does not accurately reflect the real life situation. Include only the final iterations of the assessment in the CSR. Add supporting evidence if this is helpful (for example, exposure estimations from another tool or from

measured data).

31. When using the ECETOC TRA estimation tools, take care that the PROC selected for the use description corresponds to the actual activity. The PROC affects the underlying assumptions regarding the potential emissions, the effectiveness of the engineering controls and the resulting exposure estimate.

32. When using measured data for exposure estimation, provide sufficient details on the measurement results. For a large data set, provide statistical data (typically the number of samples, arithmetic mean/geometric mean, geometric standard deviation, 90th percentile, LoD or LoQ of the method/s used). Clearly identify measurement duration or reference period, date and year. Measurements should reflect the tasks, OC and RMM described in the workers' CS / consumer CS. More limited number of measurement data may be sufficient when it is provided as a supporting evidence only. Measured data from personal sampling is preferred but data from static sampling may also be used if it reflects the workers' exposure.

33. The ECETOC TRA exposure estimation tool gives an option for using local exhaust ventilation (LEV) to reduce exposures by the dermal route. The default setting in TRA version 3 is "no LEV". This is applicable for most situations and should only be changed with caution. Justification is required when the LEV option is selected to control dermal exposure.

34. Ensure the OC/RMMs are appropriate to control the substance specific risk. They should reflect widely applied good practice for the sector of use. The application of unrealistic OC/RMMs to achieve very low RCRs can create problems for downstream users, whose conditions of use do not match those assumed/advised by the supplier's ES.

35. When a RMM is required, engineering controls such as process design measures to prevent or reduce emissions at source, including LEV, are generally preferred to PPE, in accordance with good occupational hygiene practice. Although this hierarchy of control measures is not built into the available exposure estimation tools, the principle should be considered in the CSA under REACH. Nevertheless, there may be uses and operational conditions under which PPE may be the only risk management measure to apply (e.g. very short tasks or task where LEV is not practicable).

36. Be realistic about the effectiveness achievable by the RMMs. In the estimation tools, apply performance effectiveness values that are reasonable for the operational conditions likely to be encountered.

37. If a RMM is not likely to be available to downstream users, do not include it in the exposure scenarios. For example, for widespread professional cleaning activities it is not likely that LEV is available. Achieve adequate control of exposure to dangerous substance by other means, such as product design or concentration limits.

38. When PPE is required, be as detailed as possible. For example, specify the respirator and filter type necessary in respiratory protective equipment (RPE), the material and break through time for chemical resistant gloves etc. Again, be realistic about the effectiveness possible to be achieved, particularly if used outside industrial work places. The effectiveness of PPE is highly dependent on how it is used. Thus proper instruction, training and supervision is crucial. It should be recognised that the specified filter and glove material are appropriate for the substance under assessment but may not be appropriate when various substances are used together (at a particular workplace or in a mixtures). The local site assessment should consider if alternative specifications are required for simultaneous use of different substances.

3.5 General Considerations and Joint Registration

39. Ensure that the CSR can be readily updated in the future. Updates may be required, for example, on request by a downstream user whose use is not covered. It is particularly important to plan a mechanism for updates if you use external expertise to develop the CSR.

40. If you are part of a joint registration, the CSR can be submitted jointly (by the lead), or individually by some or all registrants, or as a joint core part with individual additions or deletions.

41. Each registrant's dossier should clearly:
    a. Identify the uses covered in the joint CSR and those which are covered in an individual CSR;
    b. Confirm that the exposure scenarios related to the member's own activities are implemented;
    c. Confirm that the relevant exposure scenarios are communicated to the customers.

42. Member registrants who rely on the lead registrant's CSR should ensure they are familiar with and support the lead registrant's joint CSR.

4. ILLUSTRATIVE EXAMPLE OF A CSR

The Illustrative Example of a CSR is based on an imaginary substance, called "ECHA Substance", which is an additive for inks, coatings, lubricants and polishes.

4.1 Scope of the Illustrative Example of a CSR

The Illustrative Example of a CSR includes exposure scenarios and risk characterisations for the following life cycle stages:

- manufacture of ECHA Substance
- formulation of inks and coatings using ECHA Substance as an additive
- industrial use of coatings (printing, dipping, spray and brush/roller application)
- professional use of coatings (spray and brush/roller application)
- consumer uses of coatings (brush/roller application)

The Illustrative Example of a CSR is a complete CSR for those stages assessed, from section 1 to 10 inclusive. Explanatory comments are included in the CSR in the form of comment boxes and call-outs, to expand on the reasoning and approach taken. *It is not intended that they would be in a real CSR submitted to ECHA as part of the registration dossier*.
The Illustrative Example includes a detailed treatment of most, but not all, topics which may relevant to a CSR. Topics that are not illustrated here, due to, in part, the substance properties, include:

- Part A, requiring a summary of the risk management measures (this section is obligatory in all CSRs)
- Semi-quantitative assessment (this applies to substances such as carcinogens, where a DMEL has been established)
- Assessment for physico-chemical hazards like flammability
- PBT or vPvB substances
- Complex (multiconstituent, UVCB, reacting on use) substance
- Substances with low systemic DNEL or very low PNEC
- Substances with moderate or high hazards
- Assessments based on measured data
- Article service life
- Waste stage

4.2 Software Tools

The Illustrative Example of a CSR was generated from IUCLID 6.1[4] and Chesar 3.2.[5] The files used to generate the report are provided on the ECHA website[6]. The Chesar 3.2 file is also a useful to learn how to use the Chesar software.

Please note that the IUCLID 6.1 substance dataset contains only the information that is to be reported in the CSR (chapters 1 to 8). It is therefore not an example for a complete and

[4] https://iuclid6.echa.europa.eu/
[5] https://chesar.echa.europa.eu/
[6] https://echa.europa.eu/support/practical-examples-of-chemical-safety-reports

REACH compliant technical dossier. In fact, REACH also requires that the robust test summaries that form the basis for the hazard assessment part of the CSR are included in the IUCLID technical dossier. The details that are necessary to make the robust study summaries complete and thereby a compliant REACH technical dossier are not reported in the dataset, as these details are not meant to be transferred to the CSR.
The IUCLID 6.1 substance dataset is limited to data needed to the development of a CSR only.

Chesar incorporates screening exposure estimation tools, namely ECETOC TRA v3 for workers and consumers, EUSES for the fate and transport pathways of the substance and a dedicated model to calculate the releases to the environment. These estimation tools are not applicable to all assessment cases, Chesar therefore includes the possibility to use exposure estimates from other sources, such as measured data or alternative tools, and these should be used when appropriate.

In the Illustrative Example, measured data were used in some contributing scenarios as supportive data (Section 9.3) in conjunction with ECETOC TRA. Stoffenmanager and ART exposure estimation tools were used in another exposure scenario (Section 9.4), while ConsExpo Web was used to assess the exposure for consumers (Section 9.5).

4.3 Overview of Substance Properties and Hazard Classification

ECHA Substance is a monoconstituent substance, liquid at room temperature and with a relatively low vapour pressure (< 10 Pa) at ambient temperature. It has a water solubility of around 150 mg/l and a Log Kow of 4.7.

The substance is classified as harmful to the environment with a PNEC freshwater of 10 µg/l. Although the substance did not reach the threshold to be considered "readily biodegradable", in the test there was sufficient microbiological activity for it to be considered "inherently biodegradable". The substance is not regarded as PBT or vPvB.

A quantitative environmental assessment was carried out for the relevant compartment (soil or water, including sediments and sewage treatment plan (STP) for each exposure scenario, for the regional impact and for the impact on man via the environment.

The substance is classified as irritant to skin and eyes. DNELs for long-term systemic effects via the inhalation, dermal and oral routes have been derived from repeated oral dose toxicity test. The inhalation and dermal DNEL for workers is 24.7 mg/m^3 and 7 mg/kg bw/day, respectively. Exposure for workers is not expected to occur via the oral route. Therefore, a quantitative assessment of exposure to workers was conducted for the inhalation and dermal routes.

The inhalation and dermal DNEL for consumers is 6.1 mg/m^3 and 3.5 mg/kg bw/day, respectively. A quantitative assessment of exposure to consumers was conducted for the inhalation, dermal and oral route.

The substance is considered to be of "low hazard" regarding eye/dermal irritation, and the local effects were assessed qualitatively. No information was available on respiratory tract irritation. However, due to the established eye/dermal irritancy, also a qualitative exposure assessment for irritation on the inhalation route was carried out.

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