ECHA
EUROPEAN CHEMICALS AGENCY

CHEMICAL SAFETY REPORT

An illustrative example

Part 1 - Introductory note &
Part 2 - Illustrative CSR

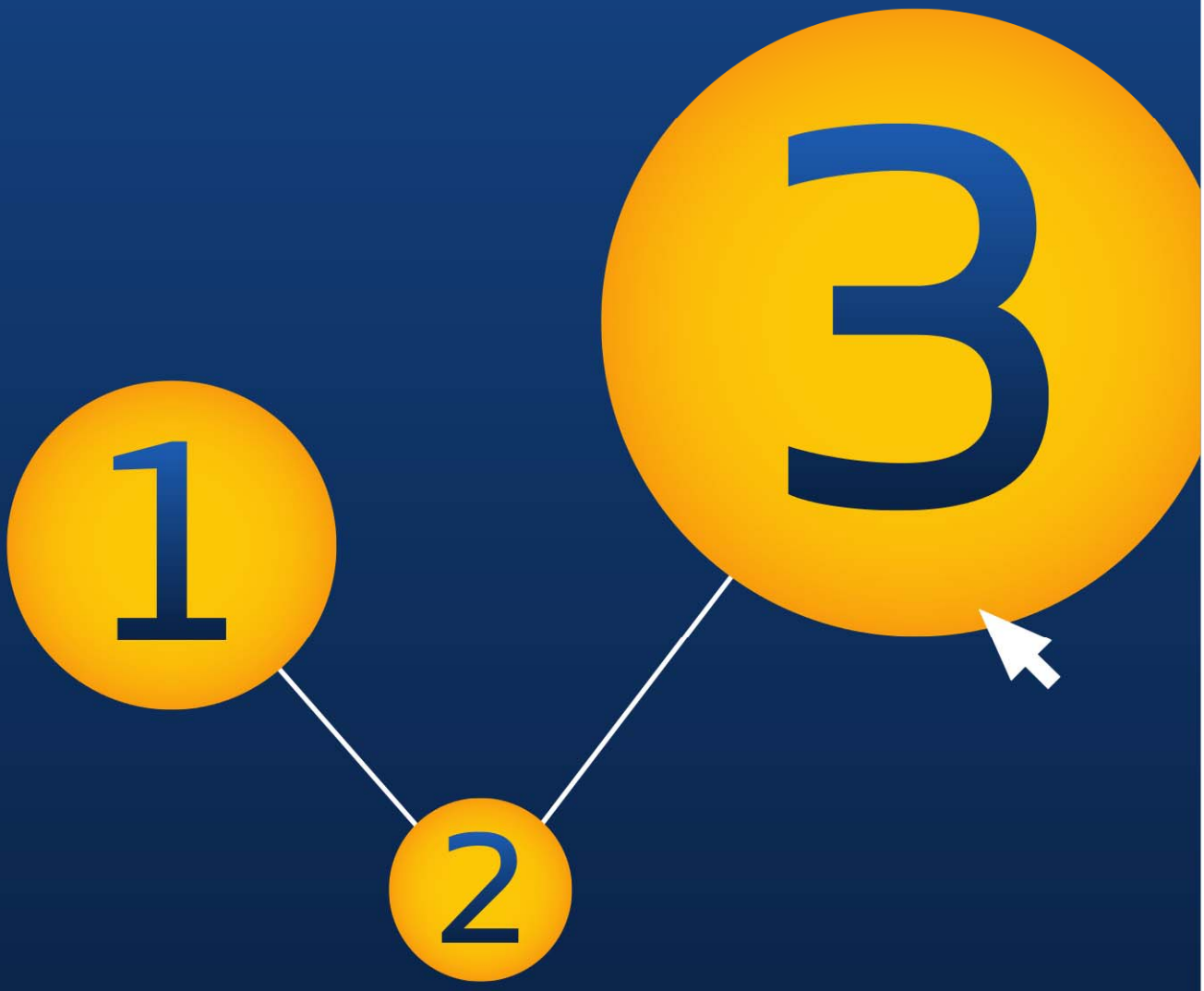

Table of Contents

Index of Tables

Disclaimer
This document contains general recommendations assisting registrants in complying with their obligations under the REACH Regulation. However, users are reminded that the text of the REACH regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

Chemical Safety Report - an illustrative example

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PART 1 - INTRODUCTORY NOTE

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 characterization 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 from which information is provided to all users of chemicals, from large industrial users to consumers. It also forms a basis for many regulatory activities including substance evaluation, authorisation and restriction.
This publication provides practical advice on aspects to consider when undertaking a chemical safety assessment (CSA) for environmental and human exposure. It has two sections. Part 1, this introductory note, and Part 2, which is an illustrative example of a Chemical Safety Report for a hypothetical substance.

The introductory note and illustrative example address shortcomings commonly identified by ECHA when working with CSRs submitted to the Agency. This introductory note contains general advice to consider when preparing a chemical safety report and outlines the scope of the example CSR, including the software tools used and the properties of the substance. The example CSR shows what an actual CSR looks like, and includes explanatory comments which expand on the reasoning and approach taken.

This advice is intended for registrants 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 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 of 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 emission/exposure of man and environment resulting from manufacture and uses throughout the life cycle of the substance;
- the risks following such emission/exposure;

2. For the downstream users, the safety data sheet is based on the relevant parts of the CSR, which may be extended to include exposure scenarios for their identified uses.

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

The CSA conducted as part of the REACH process is substance based, and applies to all stages of the life cycle. 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 of all chemicals used on site, based on actual operational conditions and the known effectiveness of risk management measures. Information from the registrant's CSR can be used to support the local assessments and compliance with the requirements set out in other relevant legislation.

2.1 Objectives of this document

ECHA aims to support industry in improving the quality of the information provided in the chemical safety report. This applies both to updates of existing CSRs in registered dossiers and to CSRs being prepared for the future registration deadlines of 1 June 2013 and 1 June 2018 or for new registrations.

The objective of this introductory note and CSR example is to illustrate:

- The nature and content of the information required in a CSR, in accordance with the Chemical Safety Report Format (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 CSRs that have been submitted;
- The format of the report generated when using ECHA's Chemical Safety Assessment and Reporting Tool, Chesar.

Although this document is aimed at registrants, downstream users who prepare a downstream user CSR in accordance with Article 37 and Annex XII of the Regulations may 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, they need only undertake the exposure assessment and risk characterisation (Sections 9 and 10 of the CSR). This is undertaken only for the use(s) not covered in the registrant's CSR.

3. GENERAL ADVICE WHEN PREPARING A CHEMICAL SAFETY REPORT

Practical advice on aspects to consider when preparing a chemical safety report is provided below. It addresses 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/web/guest/guidance-documents/.

3.1 Hazard Assessment

1. Pay attention to the classification and labelling and the PBT assessment, as those are critical elements for establishing the hazards of the substance and the principal need for assessing the risks. Make sure that you include the comparison of the data with the criteria provided in CLP Regulation and Annex XIII of 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

3. Provide sources, 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

4. Treat a substance as PBT if all available information is inconclusive for ruling out PBT properties for at least one criterion.

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

3.2 Building Exposure Scenarios

6. Identify all uses, covering the entire life cycle of the substance. Where appropriate, communicate with Downstream Users to ensure that all uses are covered and that the assumptions regarding operational conditions and risk management conditions reflect the range of actual situations

7. Build exposure scenarios and contributing scenarios carefully, to ensure that all identified uses are appropriately assessed. Nevertheless, avoid unnecessary duplication.

8. Keep in mind that the exposure scenarios will be annexed to the SDS and constitute an essential element for supporting safe use. Make sure the important information can be easily identified by downstream users.

9. Title the scenarios carefully, to give a clear and easily understandable description of which activities are covered in the ES. Provide a brief process description of each exposure scenario

10. Describe the uses clearly and concisely. Use harmonised terminology of the sector in which the use occurs whenever possible. Ensure you assign the PROC/ERC/PC/AC descriptor consistent with the use you want to assess

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 your CSR, ensure all potential uses are covered and clearly described. They should incorporate assumptions regarding volumes, concentrations, other operational conditions and risk management measures which are realistic, which ensure safe use and which are not overly precautionary

12. Implement a system so 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. A mechanism for updates is particularly important when external expertise is employed to develop the CSR

3.3 Exposure Estimation and Risk Characterisation

13. Select the most appropriate method for exposure estimation, which is generally measurement data or an exposure modelling tool. Robust measurement data, if available, is a valuable source of information. Exposure estimation tools are widely used and a range of tools are available which cover a range of situations. Select the most suitable tool with care, and understand the strengths and the limitations of the tool

14. For threshold substances, where DNEL and PNEC values are established, undertake a quantitative risk characterisation. The assessment is referred to as semi-quantitative when a DMEL is established for non-threshold substances. Otherwise the assessment is qualitative

15. Where a quantitative risk assessment is undertaken, establish the conditions of use such that the exposure is below the DNEL or PNEC (that is, the Risk Characterisation Ratio is less than 1).

16. Where a qualitative or semi-quantitative risk assessment is undertaken, provide a clear description of the operational conditions and associated risk management measures that are necessary to minimise and control the emissions and exposures.

17. Assess the combined risk as well as the individual risks in Risk Characterisation (section 10). For example, assess combined oral, dermal and inhalation for human health or assess combined exposure from wide dispersive use at local scale for the environment

3.3.1 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

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 environment using literature sources, sector specific ERCs (termed SpERCs) or site-based information as appropriate

21. If you use literature sources such as OECD Emission Scenario Documents (ESD) to refine the releases, ensure that both the documented and the actual conditions of use are well defined and are equivalent. Report the condition of use associated to 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 (see SPERC fact sheet). Go back to the SpERC owner if you are uncertain

23. When using a SpERC for release estimation, report in the 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

24. When using site based information (such as measured emission values and information on process conditions) to refine the releases, clearly justify that assumption, especially when null release to a particular environmental compartment (air, water, soil) is assumed. Report the relevant OC/RMM ensuring such non-release or controlled release in ES

25. Report appropriate information on waste, such as fraction of substance per exposure scenario "released" to waste treatment and types of waste treatment (if needed)

26. Make sure that the safety assessment is realistic. Base your assessment on OCs/RMMs that 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 ES

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

3.3.2 Human Health Assessment

28. Carry out a risk assessment for all routes and adverse health effects for which a hazard is identified (that is inhalation, dermal, or oral; acute or chronic, local or systemic) and for all relevant populations

29. Exposure estimates can be obtained using an appropriate model. Generally a screening tool (termed Tier I) is selected initially. 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 in the CSR. Use supporting evidence where this is helpful (for example, from another tool or from measured data)

30. When using Ecetoc TRA estimation tools, take care to select the most appropriate description or process category (PROC). This affects the assumptions regarding the effectiveness of engineering controls.

31. Exposure estimates can be based on measured data. Provide sufficient details on the measurement results. As a guideline, if there are a small number of data points, provide individual results. For a larger data set, provide statistical data (typically the number of samples, arithmetic mean, geometric standard deviation, 90th or 95th percentile). Clearly identify measurement time or reference period. Measurements should reflect OC/RMM described in the ES. More limited measurement data and detail may be sufficient when it is provided for supporting evidence only. Measured data should be from personal sampling, unless area samples can be justified

32. 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 version 3 is "no LEV". This is applicable for most situations and should be changed with caution. Justification is required if the LEV option is selected where the dermal route is potentially

significant

33. Do not apply precautionary OC/RMMs which are not essential to control the substance specific risk. It can create problems later on for downstream users whose use may not be covered. (For example, they may implement excellent containment measures and as a result the specified personal protective equipment (PPE) is not required). It is the role of the local risk assessment to identify specific RMM's to control the overall risk to their workers

34. When a RMM is required, engineering controls such as process design measures to prevent or reduce personal exposure, including LEV, are preferred to PPE, in accordance with good occupational hygiene practice

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

36. If a RMM such as LEV or PPE is not likely to be available to downstream users (including professional end-users) and consumers, do not include it as a RMM. Adequate control of exposure to dangerous substance should be achieved by other means, such as product design or concentration limits

37. When PPE is required, be as detailed as possible. For example, specify the filter type necessary in respiratory protective equipment (RPE), the material of construction for gloves etc. Again, be realistic about the efficiency achieved, particularly if used by professional end users and consumers. It should be recognised that the specified materials are suited to the substance under assessment, but may not be appropriate for the range of substances that may be present on site. The local site should consider if alternative specifications are required for combined exposure. Furthermore, PPE is only effective when used as part of a comprehensive PPE programme

38. If applicable, provide a "lower level" of substance concentration below which no PPE or other RMM is required. Also, if appropriate, provide the maximum allowed levels for a given type of PPE/RMM. Again, this is to reduce future communication with downstream users whose use may not be covered

3.4 Considerations relating to Joint Registration

39. If you are part of a joint registration, the CSR can be submitted jointly (by the lead), individually or a combination.

40. Clear confirmation is needed in each registrant's dossier

a. which of his uses are covered in the joint CSR and which are covered in an individual CSR

b. that the exposure scenarios related to the member's own activities are implemented

c. that the relevant exposure scenarios are communicated to the customers

41. Member registrants relying on the lead registrant's CSR should ensure they are familiar with and support the lead registrant's joint CSR.

4. ILLUSTRATIVE EXAMPLE CSR

The Illustrative Example CSR is presented in Annex 1. It is based on an imaginary substance, termed "ECHA substance", which is an additive for inks, coatings, lubricants and polishes.

4.1 Scope of Illustrative Example CSR

The Illustrative Example 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 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 form part of a CSR. Topics which are not illustrated here, due in part to the substance properties, include:

- Part A, requiring a summary of the risk management measures (this section is obligatory in all CSR's)
- Semi quantitative assessment (non threshold substances such as carcinogens, but where a DMEL has been established)
- Physico-chemical hazards (where hazard is significant)
- PBT or vPvB substances
- Substances with low systemic DNEL or low PNEC
- Substances with moderate or high qualitative hazards
- Assessments based on measured data
- Article service life

4.2 Software Tools

The Illustrative Example Chemical Safety Report was generated using IUCLID, (ECHA's IUCLID CSR plug-in (sections 1 to 8)) and Chesar (ECHA's Chemical Safety Assessment and Reporting Tool, (sections 9 and 10)).

New versions of both of these software tools were in development during the preparation of this document, namely IUCLID development from version 5.3 to 5.4 and Chesar development from version 1.2 to 2.

The Illustrative Example CSR was based on IUCLID 5.4 and Chesar 2, which are under development. As the software was not finalised at the time of preparation, the format of the CSR presented in Annex 1 may not exactly match the report generated by the final

versions of IUCLID 5.4 and Chesar 2.

Chesar incorporates two screening exposure estimation tools, namely Ecetoc TRA and EUSES. Exposure estimates using Ecetoc TRA were determined using version 3, released in April 2012. Ecetoc TRA v3 is to be incorporated in Chesar v2.

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 was used in one exposure scenario as supportive data (section 9.3) and the Stoffenmanager exposure estimation tool was used in another exposure scenario (Section 9.4), while Consexpo 4.1 was used to assess the exposure for consumers (Section 9.5).

A registrant or downstream user may generate an assessment and report using their preferred approach. It should, however, fulfil the provisions of Annex 1 or Annex XII of the REACH regulations respectively.

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). 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", there was sufficient 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.

A DNEL for long term systemic effects via the inhalation, dermal and oral routes has been derived from repeated oral dose toxicity tests. The inhalation and dermal DNEL for workers is 24,7 mg/m3 and 7mg/kg bw/day respectively. Exposure for workers is not expected to occur via the oral route. 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/m3 and 3.5mg/kg bw/day respectively. A quantitative assessment of exposure to consumers was conducted for the inhalation, dermal and oral routes.

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

PART 2 – ILLUSTRATIVE CSR

DISCLAIMER

This illustrative CSR is based on an imaginary substance. It reflects the preliminary outcome of an ECHA internal project. The European Chemicals Agency does not accept any liability as to the completeness of this illustrative example and its compliance with the obligations imposed on registrants under the REACH Regulation. It thus cannot be used as a justification for compliance of a CSR with the legal requirements. Users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice.

Please note: This example does not represent ECHA guidance agreed by all stakeholders.

EDITORIAL NOTE

For understanding the scope and the purpose of this document (CSR example Part 2), please read also the Introductory Note (CSR example Part 1).

The present document includes *Notes and Comments*. These provide explanation to the reader of the example but they are not meant to be part of the CSR itself.

ECHA invites interested parties to submit comments on this document which may incorporated in future updates. These can be submitted via the Contact ECHA page at: http://echa.europa.eu/about/contact_en.asp

Please note: The current format of the example will be updated in Q3 2012, in order to fully align with IUCLID 5.4 and Chesar 2.0.

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

The substance **ECHA Substance** is a monoconstituent substance (origin: organic) having the following characteristics and physicochemical properties.

The following public name is used: ECHA Substance.

Table 1.1 Substance identity

CAS number:	####-##-#
CAS name:	ECHA Substance
IUPAC name:	ECHA Substance
Molecular formula:	CxHyOz
Molecular weight range:	300

Structural formula:
CxHyOz

1.2 Composition of the substance

Name: ECHA Substance

Description: Monoconstituent substance

Degree of purity: 88.0 — 94.0 % (w/w)

Table 1.2 Constituents

Constituent	Typical concentration	Concentration range	Remarks
ECHA Substance	90.0 % (w/w)	88.0 — 94.0 % (w/w)	Main constituent
Impurity 1	7.0 % (w/w)	5.0 — 8.0 % (w/w)	Impurity
Impurity 2	3.0 % (w/w)	1 — 4.0 % (w/w)	Impurity

1.3. Physicochemical properties

Table 1.3 Overview of physicochemical properties

Property	Results	Value used for CSA / Discussion
Physical state at 20°C and 1013 hPa	The substance is a liquid.	**Value used for CSA:** liquid The substance is a liquid.
Melting / freezing point	EEC guideline A1 was followed for melting point determination. Thermal analysis (Differential scanning calorimetry (DSC).	**Value used for CSA:** -54°C at 1013 hPa No endothermal melting peak or exothermal freezing peak was

Property	Results	Value used for CSA / Discussion
		observed. The test item has no melting or freezing point down to a temperature of -54ºC (319ºK)
Boiling point	ECC guideline 92/69/ECC A.2 boiling temperature, thermal analysis, DSC. Two samples were tested.	**Value used for CSA:** 304°C at 1013 hPa
Relative density	Oscillating densimeter following EEC guideline A.3 (EC, 1992).	**Value used for CSA:** 0.981 at 20°C
Vapour pressure	Consolidated version of Council Directive 67/548/EEC Annex V, part A: A.4 and OECD guidelines 104 (1995) and 113 (1981). Preliminary test on thermal stability was performed. Dynamic method and Vapour pressure balance (effusion method) was used. Temperature range of 151ºC to 286ºC for dynamic method and 25ºC to 51ºC for effusion method. T (ºC) P (Pa) 20 7.8 25 34 50 220	**Value used for CSA:** 7.8 Pa at 20 °C
Surface tension	EEC guideline A.5, by ring method Because of poor solubility of 149+-8 mg/L at 20°C, a 90 % solution had to be used.	**Value used for CSA:** 37 mN/m at 20°C and 139 mg/L
Water solubility	Determination of water solubility was performed in accordance with EEC guideline A.6 by flask method.	**Value used for CSA:** 149 mg/L at 20 °C Determination of water solubility was performed in accordance with EEC guideline A.6 by flask method. Water solubility was determined to be 149 ± 8 mg/L at 20ºC.
Partition coefficient n-octanol/water (log value)	EEC guideline A.8. using shake flask method.	**Value used for CSA:** Log Kow (Pow): 4.7 at 20 °C
Flash point	EEC guideline A.9, method. Closed crucible according to DIN ISO 2719.	**Value used for CSA:** 142°C at 1013 hPa
Self-ignition temperature	EEC guideline A.15 (EC, 1992), and DIN 51 794	The test item showed an auto-ignition temperature of 300ºC.
Viscosity	OECD Guideline 114 "Viscosity of Liquids".	**Value used for CSA:** 0.085 Pa s (dynamic) at 20°C

Data waiving

Information requirement: Flammability

Reason: other justification

Justification: There are no functional groups within the test item molecule that could cause pyrophoricity or flammability in contact with water. Basis: "Guidance on information requirements and chemical safety assessment", Chapter R.7a: Endpoint specific guidance, R.7.1.10.3 and table R.7.1-27 (ECHA, May 2008).

Information requirement: Explosive properties

Reason: other justification

Justification: The test item molecule contains hydroxyl- and ether-groups that are able to contribute to the explosive property. Therefore, according to "Guidance on information requirements and chemical safety assessment", Chapter R.7a: Endpoint specific guidance, R.7.1.11.3 (ECHA, May 2008) the oxygen balance (OB) for the test item molecule (CxHyOz) was calculated with the result OB = -260. Since the oxygen balance is less than -200, the substance should not have explosive properties. This result was confirmed by differential scanning calorimetry (DSC) that showed no exothermic reactions up to 250°C.

Information requirement: Oxidising properties

Reason: other justification

Justification: According to "Guidance on information requirements and chemical safety assessment", Chapter R.7a: Endpoint specific guidance, R.7.1.13.3 (ECHA, May 2008) oxidising properties can be excluded because the oxygen in the substance is chemically bonded only to carbon.

Information requirement: Granulometry

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, granulometry (required in section 7.14) does not need to be conducted because the substance is marketed or used in a non solid or granular form. The submitted substance is liquid.

Information requirement: Stability in organic solvents and identity of relevant degradation products

Reason: other justification

Justification: In accordance with column 1 of REACH Annex IX, the study does not need to be conducted since stability of the substance is not considered to be critical.

Information requirement: Dissociation constant

Reason: other justification

Justification: The substance can be regarded as a hydrocarbon with two ether and one alcohol functional groups (neither of these are typical acid / base moiety). Therefore, a dissociation constant study is not required.

2. MANUFACTURE AND USES

Quantities

Table 2.1 Overview of quantities (in tonnes/year)

Year	Total tonnage	Uses exempted from CSR	Article
2010	Manufactured: 150 Imported: - Directly exported:	Used as intermediate under strictly controlled conditions (on-site): - Used as intermediate under strictly controlled conditions (transported): - Used for research purposes: -	Imported in articles: - Produced articles: -
2011	Manufactured: 220 Imported: - Directly exported: -	Used as intermediate under strictly controlled conditions (on-site): - Used as intermediate under strictly controlled conditions (transported): - Used for research purposes: -	Imported in articles: - Produced articles: -
2012	Manufactured: 320 Imported: - Directly exported: -	Used as intermediate under strictly controlled conditions (on-site): - Used as intermediate under strictly controlled conditions (transported): - Used for research purposes: -	Imported in articles: - Produced articles: -

2.1 Manufacture

Table 2.2 Manufacture

Identifiers	Use descriptors	Other information
(Confidential) 1. Manufacture of the substance	• PROC 1/ PROC 8a • ERC 1	Tonnage of substance for that use (tonnes): 320 Number of sites: 1 Remarks:

Notes and comments

Re Manufacture Information

A description of the technological process is not included in this illustrative example of a CSR. However the type of information which should be provided in this section includes:

a. Type of chemical reaction

b. Type of processes and activities (e.g. batch or continuous process, if batch: Multipurpose or dedicated equipment, closed or open process, etc.)

c. Pressure and temperature of the processes

d. Physical state of the substance in the different process steps

e. Cleaning processes related to the isolated raw product

f. Steps where use of water is involved.

Some information on the manufacturing conditions (operational conditions and risk management measures directly impacting on release and exposure estimates) is reported in chapter 9.1 (exposure scenarios). Duplication of information should be avoided.

2.2 Identified uses

Table 2.3 Formulation

Identifiers	Use descriptors	Other information
2. Formulation of liquid mixtures	**Process category (PROC):** PROC 3/ PROC5/PROC8a/PROC 8b/ PROC 9 **Product category formulated:** PC 9a **Environmental release category (ERC):** ERC 2 **Technical function of the substance during formulation:** Other: co-emulsifier, antifoamer, wetting agent	Tonnage of substance for that use (tonnes): 320 Number of sites: 10-100 Substance supplied to that use: as such (substance itself) Remarks:

Table 2.4 Uses at industrial sites

Identifiers	Use descriptors	Other information
3. General Industrial use of coating and inks	**Process category (PROC):** PROC 2/ PROC5 / PROC 7 / PROC 8a / PROC 8b / PROC 10 / PROC 13 **Environmental release category (ERC):** ERC 5 **Product category used:** PC 9a **Sector of end use:** **Technical function of the substance:** Other: co-emulsifier, antifoamer, wetting agent	Tonnage of substance for that use (tonnes): 100 Number of sites: >100 Substance supplied to that use: in a mixture Subsequent service life relevant for that use?: Yes Link to the subsequent service life Remarks:

Table 2.5 Uses by professional workers

Identifiers	Use descriptors	Other information
4. Professional painting	**Process category (PROC):** PROC 8a / PROC 10/ PROC 11 **Product category used:** PC 9a **Environmental release category (ERC):** ERC 8c/ ERC 8f **Sector of end use:** **Technical function of the substance:** Other: co-emulsifier, antifoamer, wetting agent	Tonnage of substance for that use (tonnes): 50 Substance supplied to that use: in a mixture Subsequent service life relevant for that use?: Yes Link to the subsequent service life: Remarks:

Table 2.6 Consumer uses

Identifiers	Use descriptors	Other information
5. Consumer painting indoor/outdoor	**Product category used:** PC 9a **Environmental release category (ERC):** ERC 8c/ ERC 8f **Technical function of the substance:** Other: co-emulsifier, antifoamer, wetting agent	Tonnage of substance for that use (tonnes): Substance supplied to that use: in a mixture Subsequent service life relevant for that use?: Yes Link to the subsequent service life: Remarks:

Notes and Comments

Re Identified uses

Please note: Section 2.2 and 9.1 do not cover all life-cycle stages and uses of the ECHA Substance. Specifically: the service life in articles resulting from use in coatings and inks is not addressed, and uses in lubricants are not included.

Also, the industrial use of coatings and inks refers to industrial sites operating various coating and printing operations in parallel with each other. In order to ensure appropriate advice to more specialised downstream users, a registrant may wish to provide more differentiation in the exposure scenarios and hence in the use description. The same may apply for a substance with a different hazard profile, where the registrant may see the need to explain the use in more detail to be able to demonstrate control of risk in his CSR.

2.3 Uses advised against

None

3. CLASSIFICATION AND LABELLING

3.1 Classification and labelling according to CLP / GHS

Name: **ECHA Substance**

Implementation: EU

State/form of the substance: liquid

Remarks: Self-classification. The impurities in the ECHA Substance have no hazardous effects and thus do not affect the classification of the ECHA Substance.

Classification

The substance is classified as follows:

Table 3.1 For physicochemical properties

Endpoints	Classification	Reason for no classification	Justification for (non) classification can be found in section
Explosives		conclusive but not sufficient for classification	1.3, 6.1
Flammable gases		data lacking (not relevant for the substance)	
Flammable aerosols		data lacking	
Oxidising gases		data lacking (not relevant for the substance)	
Gases under pressure		data lacking (not relevant for the substance)	
Flammable liquids		conclusive but not sufficient for classification	1.3, 6.2
Flammable solids		data lacking (not relevant for the substance)	
Self-reacting substances and mixtures		conclusive but not sufficient for classification	1.3, 6.2
Pyrophoric liquids		conclusive but not sufficient for classification	1.3, 6.2
Pyrophoric solids		data lacking (not relevant for the substance)	

Endpoints	Classification	Reason for no classification	Justification for (non) classification can be found in section
Self-heating substances and mixtures		conclusive but not sufficient for classification	1.3, 6.2
Substances and mixtures which in contact with water emits flammable gases		conclusive but not sufficient for classification	1.3, 6.2
Oxidising liquids		conclusive but not sufficient for classification	1.3, 6.3
Oxidising solids		data lacking (not relevant for the substance)	
Organic peroxides		data lacking (not relevant for the substance)	
Corrosive to metals:		data lacking	

Table 3.2 For health hazards

Endpoints	Classification	Reason for no classification	Justification for (non) classification can be found in section
Acute toxicity - oral		conclusive but not sufficient for classification	5.2
Acute toxicity - dermal		conclusive but not sufficient for classification	5.2
Acute toxicity - inhalation		conclusive but not sufficient for classification	
Skin corrosion/irritation	Skin Irritant, Category 2 (Hazard statement: H315: Causes skin irritation.)		5.3.4 and 5.4.3
Serious damage/eye irritation	Eye Irritant, 2 (Hazard statement: H319: Causes serious eye irritation.)		5.3.4 and 5.4.3
Respiration sensitisation		data lacking	5.5.3
Skin sensitisation		conclusive but not sufficient for classification	5.5.3
Aspiration hazard		data lacking	
Reproductive toxicity-		conclusive but not sufficient for classification	5.9.3

Endpoints	Classification	Reason for no classification	Justification for (non) classification can be found in section
fertility			
Reproductive toxicity-developmental toxicity		data lacking	5.9.3
Reproductive toxicity: Effects on or via lactation:		data lacking	5.9.3
Germ cell mutagenicity		conclusive but not sufficient for classification	5.7.3
Carcinogenicity		data lacking	5.8
Specific target organ toxicity - single		conclusive but not sufficient for classification	5.2.3
Specific target organ toxicity - repeated		conclusive but not sufficient for classification	5.6.3

Table 3.3 For environmental hazards

Endpoints	Classification	Reason for no classification	Justification for (non) classification can be found in section
Hazards to the aquatic environment	Aquatic Chronic 3 (Hazard statement: H412: Harmful to aquatic life with long lasting effects.)		7.6
Hazardous to the atmospheric environment		data lacking	7.3

Labelling

Signal word: Warning

Hazard pictogram:

GHS07: exclamation mark

Hazard statements:

H315: Causes skin irritation.

H319: Causes serious eye irritation.

H412: Harmful to aquatic life with long lasting effects.

Precautionary statements:

P273: Avoid release to the environment.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313: If eye irritation persists: Get medical advice/attention.

P273: Avoid release to the environment.

P501:Dispose of contents/containers in accordance with (specify local/regional/national/international regulation here)

3.2 Classification and labelling according to DSD / DPD

3.2.1 Classification and labelling in Annex I of Directive 67/548/EEC

3.2.2 Self classification(s)

Chemical name: **ECHA Substance**

Table 3.4 Classification according to Directive 67/548/EEC criteria

Endpoints	Classification	Reason for no classification	Justification for (non) classification can be found in section
Explosiveness		conclusive but not sufficient for classification	1.3, 6.1
Oxidising properties		conclusive but not sufficient for classification	1.3, 6.3
Flammability		conclusive but not sufficient for classification	1.3, 6.2
Thermal stability		conclusive but not sufficient for classification	
Acute toxicity		conclusive but not sufficient for classification	5.2
Acute toxicity-irreversible damage after single exposure		conclusive but not sufficient for classification	5.2
Repeated dose toxicity		conclusive but not sufficient for classification	5.6
Irritation / Corrosion	Xi; R38 Irritant; Irritating to skin		5.3.4 and 5.4.3
Sensitisation		conclusive but not sufficient for classification	5.5.3
Carcinogenicity		data lacking	5.8
Mutagenicity - Genetic Toxicity		conclusive but not sufficient for classification	5.7.3
Toxicity to reproduction- fertility		conclusive but not sufficient for classification	5.9.3
Toxicity to reproduction-development		data lacking	5.9.3
Toxicity to reproduction - breastfed babies		data lacking	5.9.3
Environment	R52/53 Harmful to aquatic organisms may cause long-term adverse effects in the aquatic environment.		7.6

Labelling

Xi; Irritant

R-phrases:

R38; Irritating to skin.

R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment

S-phrases:

S61 - Avoid release to the environment. Refer to special instructions/safety data sheets

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3.2.3 Other classification(s)

Classification for mixtures

Notes and Comments

Re Classification for Mixtures

To assess the use of the substance in mixtures (CLP 2012/2008, generic concentration limit):

Mixtures containing ≥10 w-% ECHA Substance are classified as skin irritant.

Mixtures containing ≥10 w-% ECHA Substance are classified as eye irritant.

4. ENVIRONMENTAL FATE PROPERTIES

4.1 Degradation

4.1.1 Abiotic degradation

4.1.1.1 Hydrolysis

The studies on hydrolysis are summarised in the following table:

Table 4.1 Overview of studies on hydrolysis

Method	Results	Remarks	Reference
OECD Guideline 111 (Hydrolysis as a Function of pH)	Recovery (in %): pH 4: 100 at 50 °C after 120 h pH 7: 98 at 50 °C after 120 h pH 9: 100 at 50 °C after 120 h Transformation products: no	1 (reliable without restriction) key study experimental result **Test material: ECHA Substance**	Ref 4.1.1.1 (2007)

Discussion

In the preliminary test, the test item was found to be stable at pH 4, 7 and 9, respectively. No further testing was deemed necessary as less than 10% has been hydrolysed after 120 hours at each of the three pH values.

The following information is taken into account for any hazard / risk / persistency assessment:

Stable to hydrolysis at pH 4, 7 and 9.

4.1.1.2 Phototransformation/photolysis

4.1.1.2.1 Phototransformation in air

Discussion

No experimental data available. As this study is not a standard information requirement in REACH and there is no indication from the CSA on the need to investigate further the fate and behaviour of the substance (Annex X requirement), no further testing is considered necessary.

4.1.1.2.2 Phototransformation in water

Discussion

No experimental data available. As this study is not a standard information requirement in REACH and there is no indication from the CSA on the need to investigate further the fate and behaviour of the substance (Annex X requirement), no further testing is considered necessary.

4.1.1.2.3 Phototransformation in soil

Discussion

No experimental data available. As this study is not a standard information requirement in REACH and there is no indication from the CSA on the need to investigate further the fate and behaviour of the substance (Annex X requirement), no further testing is considered necessary.

4.1.2 Biodegradation

4.1.2.1 Biodegradation in water

4.1.2.1.1 Estimated data

4.1.2.1.2 Screening tests

The test results are summarised in the following table:

Table 4.2 Overview of screening tests for biodegradation in water

Method	Results	Remarks	Reference
Test type: ready biodegradability activated sludge, non-adapted OECD Guideline 301 B (Ready Biodegradability: CO2 Evolution Test)	Inherently biodegradable % Degradation of test substance: 56after 28 d (CO2 evolution) 29 after 21 d (CO2 evolution) 11 after 14 d (CO2 evolution) 1 after 6 d (CO2 evolution)	1 (reliable without restriction) key study experimental result **Test material: ECHA Substance**	Ref 4.1.2.1.2.a (2006)
Test type: ready biodegradability activated sludge, domestic, non-adapted OECD Guideline 301 A (new version) (Ready Biodegradability: DOC Die Away Test)	The test item must be regarded as not readily biodegradable in the 10 day window and after 28 days. % Degradation of test substance: 54 after 42 d (DOC removal)	1 (reliable without restriction) key study experimental result **Test material: ECHA Substance**	Ref 4.1.2.1.2.b (2009)

4.1.2.1.3 Simulation tests (water and sediments)

The test results are summarized in the following table:

Table 4.3 Overview of simulation tests for biodegradation in water

Method	Results	Remarks	Reference
Natural water / sediment OECD Guideline 308 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems)	% Degradation of test substance: 50 after 36 days at the temperature of 11ºC (Radio chem. measured)) (marine water without sediment) 50 after 52 days at the temperature of 11ºC (Radio chem. measured)(marine water/sediment) 50 after 81 days at the temperature of 11ºC (Radio chem. measured) (marine sediment) Transformation products: no	2 (reliable with restrictions) key study experimental result **Test material: ECHA Substance**	Ref 4.2.1.3, (1993)

4.1.2.1.4 Summary and discussion of biodegradation in water and sediment

Discussion (screening testing)

The test item must be regarded as not readily biodegradable. However, as the substance still degraded between 40-60% in CO2 Evolution test, it is a clear indication that extensive primary biodegradation has occurred. The REACH Guidance on Information Requirements R.7b states 'When results of ready biodegradability tests indicate that the pass level criterion is almost fulfilled (i.e. ThOD slightly below 60%) such results can be used to prove inherent biodegradability.', Therefore the ECHA Substance is considered to be inherently biodegradable.

The following information is taken into account for any hazard / risk / persistency assessment:

The substance is considered to be inherently biodegradable.

Value used for CSA:

Biodegradation in water: Inherently biodegradable

Discussion (simulation testing)

Biodegradation of ^{14}C-labelled ECHA Substance in marine water alone, water/sediment system and sediment was estimated by collection and quantification of the formed radio-labelled CO_2.

A study was conducted to determine the biodegradation of ECHA Substance in a marine water/sediment simulation test. 50% of the substance was found to be degraded under aerobic conditions after 36 days and 81 days as measured by ^{14}C determination in CO_2 fraction in water and sediment compartments, respectively.

The following information is taken into account for any hazard / risk / persistency assessment:

Half lives used for persistency assessment are 36 days for marine water and 81 days for

marine sediments.

Value used for CSA:

Half-life in marine water: 36 days at the temperature of 11ºC

Half-life in marine sediment: 81 days at the temperature of 11ºC

4.1.2.2 Biodegradation in soil

The test results are summarized in the following table:

Table 4.4 Overview of simulation tests for biodegradation in soil

Method	Results	Remarks	Reference
Test type: laboratory Soil type: Reconstituted soil system (compost + sandstone) (#1) OECD Guideline 307 (Aerobic and Anaerobic Transformation in Soil)	% Degradation of test substance: 50 after 36 d (Test mat. analysis (at 1000 ppm concentration)) (#1) Transformation products: no	3 (reliable with restrictions) supporting study experimental result **Test material: ECHA Substance**	Ref 4.1.2.2 (1988)

Discussion

ECHA Substance was incubated with a reconstituted soil system (compost + sandstone) in darkness for 40 d. The samples were analyzed for residual ECHA Substance at various intervals during this period. Volatilisation of the substance was also studied concurrently indicating insignificant volatilisation with only 0.22% of the substance volatilised over 40d at 1000ppm. The substance was degraded microbiologically after adaptation of microorganisms. Biodegradation was evident through the presence of a lag phase. Disappearance due to other factors via volatilization, physicochemical transformations, photodecomposition and leaching was considered insignificant based on choice of experimental conditions and stability of compound.
Consistent with results obtained in screening biodegradation and water / sediment simulation studies ECHA Substance was degraded in soil to an extent of 50% after 36 days of incubation at concentrations of 1000 ppm.

The following information is taken into account for any hazard / risk / persistency assessment:

The results from the soil simulation test were not used for exposure assessment, as the study has a reliability score of 3 However, this information is used as supporting evidence in PBT assessment. The value used for this purpose is 36 days at 20 ^{o}C, equivalent to 68 days at 12 ^{o}C.

Value used for CSA:

4.1.3 Summary and discussion of degradation

Abiotic degradation

Based on available data from fate studies abiotic degradation (i.e hydrolysis study) is only expected to make a minor contribution to the overall environmental fate of the substance. The substance is considered to be stable to hydrolysis at pH 4, 7 and 9.

Biotic degradation

Results from OECD screening studies as well as results from marine water/sediment and soil simulation studies on the substance, indicate that ECHA Substance can expected to biodegrade under aerobic conditions in the aquatic and terrestrial environment where upon a significant portion of the parent compound is mineralized.

4.2 Environmental distribution

4.2.1 Adsorption / desorption

The studies on adsorption/desorption are summarised in the following table:

Table 4.5 Overview of studies on adsorption / desorption

	Results	Remarks	Reference
Study type: adsorption/desorption (soil) Batch equilibrium method OECD Guideline 106 (Adsorption - Desorption Using a Batch Equilibrium Method) EU Method C.18 (Adsorption / Desorption Using a Batch Equilibrium Method	Mass balance (in %) at end of adsorption phase: 96.7 after 48 h (#1) 92.2 after 48 h (#2) 85.9 after 48 h (#3) 72.7 after 48 h (#4) 95.7 after 48 h (#5) Mass balance (in %) at end of desorption phase: 20 after 48 h (#1) 45 after 48 h (#2) 84 after 48 h (#3) 77 after 48 h (#4) 53 after 48 h (#5) Koc = 818-942 cm3/g Kd = 3-31 cm3/g Mean Koc at 20°C: 776, log Koc 2.89	1 (reliable without restriction) key study experimental result **Test material: ECHA Substance** **Soil characteristics:** soil 1: clay (pH 5.6, % OC 3.29) soil 2: silt loam (pH 7.7, % OC 2.39) soil 3: loam (pH5.4, % OC 3.32) soil 4: silt (pH6.7, % OC 1.36) soil 5: loamy sand (pH 3.5, % OC 4.43)	Ref 4.2.1 (2007)

Discussion:
The test item can be considered to have a medium to low mobility in soil (according to MCCALL classification scheme, a substance with Koc 150 - 500 can be classified to have a medium mobility and with Koc 500 - 2000 to have a low mobility). Adsorption of the test substance is not completely reversible, as % desorption was 20 - 84 % in the desorption kinetics and ≤ 24 % (overall mean for each soil) for desorption isotherms.

No further study on adsorption/desorption is being proposed as according to Annex IX to REACH Regulation the study does not need to be conducted if based on the substance physicochemical properties the substance can be expected to have a low potential for adsorption.

Value used for CSA:

Koc at 20°C: 776, log Koc: 2.89

4.2.2 Volatilisation

4.2.3 Distribution modelling

4.2.4 Summary and discussion of environmental distribution

Based on the test results the substance is not highly adsorptive that indicates that soil and sediment are not expected to be the main target compartments for exposure assessment. The assessment of those compartments is further exemplified in Section 9.

In addition, no further distribution modelling was considered necessary as this study is not a standard information requirement in REACH and the exposure assessment indicating the concentrations in all the environmental compartments is performed in Section 9 of the CSA.

4.3 Bioaccumulation

4.3.1 Aquatic bioaccumulation

The studies on aquatic bioaccumulation are summarised in the following table:

Table 4.6 Overview of studies on aquatic bioaccumulation

Method	Results	Remarks	Reference
Brachydanio rerio (new name: Danio rerio) Aqueous (freshwater) flow-through Total uptake duration: 5 wk Total depuration duration: 2 wk Details of method: Bioaccumulation of ECHA Substance (radiolabelled, specific activity 0.480 MBq/mg) was investigated in a flow-through system set up according to OECD guideline 305 C. Zebra fish were exposed for five weeks to a concentration of 3 and 30 µg/l respectively followed by depuration period of two weeks. OECD Guideline 305 C (Bioconcentration: flow-through fish test)	BCF: 4055 dimensionless (whole body w.w.) (kinetic) (Exposure concentration 3 µg/L) BCF: 2530 dimensionless (whole body w.w.) (kinetic) (Exposure concentration 30 µg/L) Elimination: yes; 98-99 % of loss at the end of the depuration period.: 2 wk Lipid content: 5 % Transformation products: no	2 (reliable with restrictions) key study experimental result **Test material: ECHA Substance**	Ref 4.3.1 (1991)

4.3.2 Terrestrial bioaccumulation

4.3.3 Summary and discussion of bioaccumulation

Aquatic bioaccumulation

Aquatic bioaccumulation of ECHA Substance was investigated in a flow-through system set up according to OECD guideline 305 C. A BCF of 4055 (whole fish) at a concentration of 3µg/l was detected whereas at a concentration of 30 µg/l the BCF was 2530. After the depuration period a loss of 98 - 99 % (not known if due to metabolism, elimination or both) was demonstrated (Ref 4.3.1 1991). Therefore it can be considered that ECHA

Substance bioaccumulates in organisms in a short time period. However the observed loss during depuration was still comparably fast and high.

The following information is taken into account for any hazard / risk / bioaccumulation assessment:

Bioaccumulates in aquatic organisms, BCF = 4055.

Value used for CSA:

BCF: 4055 dimensionless

Terrestrial bioaccumulation

No experimental data available. Based on the study on aquatic bioaccumulation, relatively high log Kow (log Kow 4.7) and biodegradation test, it can be assumed that the substance is potentially bioaccumulative also in terrestrial ecosystem. As this study is not a standard information requirement in REACH and there is no indication from the CSA on the need to investigate further the fate and behaviour of the substance (Annex X requirement), no further testing is considered necessary.

4.4 Secondary poisoning

No potential to cause toxic effects if accumulated (in higher organisms) via the food chain (see CSR chapter 7.5.3 "Calculation of PNECoral (secondary poisoning)"

Interpretation of the available data with regard to the potential to bio-accumulate in the food chain:

The potential for bio-accumulation in the food chain is expected to be high based on the available data. Nevertheless, the substance is not considered to cause toxic effects if bioaccumulated because is not classified for repeated dose toxicity or reproductive toxicity (see section 5).

Notes and Comments

General considerations

a. The purity of the substance in all experimental studies is the same as described in Section 1.2. The impurities are considered not to be relevant for the assessment of any experimental studies.

b. For tests that are not standard information requirements in REACH, no test results or further testing has been proposed because the CSA indicates the need to further investigate the fate and behaviour of the substance (Annex X requirement).

5. HUMAN HEALTH HAZARD ASSESSMENT

5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

5.1.1 Non-human information

No data available.

5.1.2 Human information

No data available.

5.1.3 Summary and discussion of toxicokinetics

Assessment of oral toxicokinetics based on the physicochemical properties of ECHA Substance:-

Molecular weight 300

Water solubility 149 mg/L

Partition coefficient log Kow = 4.7

The following remarks on the toxicokinetics of ECHA Substance are based on the available studies. Experimental toxicokinetic studies were not available.

ABSORPTION

The physicochemical characteristics of ECHA Substance (log Pow 4.7) and the molecular mass are in a range suggestive of absorption from the gastro-intestinal tract subsequent to oral ingestion. This assumption of an oral absorption is confirmed by the data subchronic oral toxicity.

N-octanol/water partition coefficient and molecular weight of ECHA Substance are in ranges which favour dermal absorption.

DISTRIBUTION and METABOLISM

As a small molecule a wide distribution is expected. This assumption is confirmed by the changes shown in the repeated dose toxicity studies following oral application. The structure of ECHA Substance suggests that it will preferably be either directly conjugated in a phase-II reaction or undergoes further oxidation in the alcohol moieties of the molecule.

ELIMINATION

The n-Octanol/water partition coefficient (log Pow of 4.7) is suggestive of accumulation of unchanged ECHA Substance in fatty tissues subsequent to absorption from gastro-intestinal tract or from lungs. However, on the basis of the molecular structure excretion into urine as glucuronide is assumed to be a preferred route of elimination. Elimination is assumed to be rapid. Therefore, no potential for bioaccumulation is to be expected.

Notes and Comments

General considerations

a. The information in the hazard assessment part of the CSR is to be interpreted in conjunction with the robust study summaries reported in IUCLID. Please note: A CSR as such would not be considered compliant without the relevant IUCLID dossier where the study details are to be reported in the form of RSS.

b. The ECHA Practical Guide 3: How to Report Robust Study Summaries (ECHA, 2010) provides guidance on what needs to be reported for the hazard assessment which is then transferred to the CSR.

c. An Information Toolkit is available which provides a roadmap with practical information and tools to help in using existing information and non-test methods (i.e. predictions). The toolkit directs the registrant to Practical Guides on how to report read-across and categories in IUCLID.

http://echa.europa.eu/documents/10162/17235/pg_report_robust_study_summaries_en.pdf

http://echa.europa.eu/web/guest/support/information-toolkit

5.2 Acute toxicity

5.2.1 Non-human information

5.2.1.1 Acute toxicity: oral

The results of experimental studies are summarised in the following table:

Table 5.1 Overview of experimental studies on acute toxicity after oral administration

Method	Results	Remarks	Reference
rat (Sprague-Dawley) female oral: gavage OECD Guideline 423 (Acute Oral toxicity - Acute Toxic Class Method) EU Method B.1 tris (Acute Oral Toxicity - Acute Toxic Class Method)	LD50: > 2000 mg/kg bw (female)	1 (reliable without restriction) key study experimental result **Test material (IUPAC name): ECHA Substance**	Ref. 5.2.1.1 (2005)

5.2.1.2 Acute toxicity: inhalation

Table 5.2 Overview of experimental studies on acute inhalation toxicity

Method	Results	Remarks	Reference
rat (Sprague-Dawley) male inhalation: vapour (whole body) equivalent or similar to OECD Guideline 403 (Acute Inhalation Toxicity)	LC50 (24 h): > 5000 ppm (male) . No animals died and no clinical signs were observed.	1 (reliable without restrictions) key study experimental result **Test material (IUPAC name): ECHA Substance**	Ref. 5.2.1.2 (2004)

5.2.1.3 Acute toxicity: dermal

The results of experimental studies are summarised in the following table:

Table 5.3Overview of experimental studies on acute toxicity after dermal administration

Method	Results	Remarks	Reference
rat (Sprague-Dawley) male/female Coverage: semiocclusive OECD Guideline 402 (Acute Dermal Toxicity) EU Method B.3 (Acute Toxicity (Dermal))	LD50: > 2000 mg/kg bw (male/female) LD50: > 2000 mg/kg bw (female) LD50: > 2000 mg/kg bw (male)	1 (reliable without restriction) key study experimental result **Test material (IUPAC name):** **ECHA Substance**	Ref. 5.2.1.3 (2005)

5.2.1.4 Acute toxicity: other routes

No data available for ECHA Substance.

5.2.2 Human information

No data available for ECHA Substance.

5.2.3 Summary and discussion of acute toxicity

Acute oral toxicity: LD50 > 2000 mg/kg bw

Acute dermal toxicity: LD50 > 2000 mg/kg bw

The following information is taken into account for any hazard / risk assessment:

Acute oral toxicity: OECD Guideline 423, GLP compliant. No adverse effects were observed. Therefore, the acute oral toxicity of ECHA Substance is low.

Acute dermal toxicity: OECD Guideline 402, GLP compliant. No adverse effects were observed. Therefore, the acute oral toxicity of ECHA Substance is low.

Acute inhalation toxicity: OECD Guideline 402, GLP compliant. No adverse effects were observed. Therefore, the acute oral toxicity of ECHA Substance is low.

Justification for classification or non classification

Based on the available data, the substance is not classified.

5.3 Irritation

5.3.1 Skin

5.3.1.1 Non-human information

The results of experimental studies on skin irritation are summarised in the following table:

Table 5.4 Overview of experimental studies on skin irritation

Method	Results	Remarks	Reference
rabbit (New Zealand White) Coverage: semiocclusive (shaved) OECD Guideline 404 (Acute Dermal Irritation / Corrosion) EU Method B.4 (Acute Toxicity: Dermal Irritation / Corrosion)	Irritating Erythema score: 3 of max. 4 (animal #1) (Mean of 24, 48 and 72 h) (not fully reversible within: 72 hours) 2.3 of max. 4 (animal #2) (Mean of 24, 48 and 72 h) (not fully reversible within: 72 hours) 1.6 of max. 4 (animal #3) (Mean of 24, 48 and 72 h) (not fully reversible within: 72 h) Edema score: 0 of max. 4 (mean) (Mean of 24, 48 and 72 h) (no effects)	1 (reliable without restriction) key study experimental result **Test material (IUPAC name):** **ECHA Substance** (amount applied 0.5 ml)	Ref. 5.3.1.1 (2000)

5.3.1.2 Human information

No data available for ECHA Substance.

5.3.2 Eye

5.3.2.1 Non-human information

The results of experimental studies on eye irritation are summarised in the following table:

Table 5.5 Overview of experimental studies on eye irritation

Method	Results	Remarks	Reference
rabbit (New Zealand White) OECD Guideline 405 (Acute Eye Irritation / Corrosion) EU Method B.5 (Acute Toxicity: Eye Irritation / Corrosion)	The substance is not irritating according to Directive 67/548/EEC but it is classified as Eye irritant Category 2 according to the CLP Regulation. Cornea score: 1.7 of max. 3 (animal #1) (Time point: 24, 48, 72 h) (fully reversible 7 days after dosing)) 1.7 of max. 3 (animal #2) (Time point: 24, 48, 72 h) (fully reversible 7 days after dosing)) 2 of max. 3 (animal #3) (Time point: 24, 48, 72 h) (fully reversible 7 days after dosing)) Iris score: 0.7 of max. 1 (animal #1) (Time point: 24, 48 h) (fully reversible 7 days after dosing)) (mean, observed values) 0.3 of max. 1 (animal #2) (Time point: 24, 48 h) (fully reversible 7 days after dosing)) (mean, observed values) 0.3 of max. 1 (animal #3) (Time point: 24, 48 h) (fully reversible 7 days after dosing)) (mean, observed values) Conjunctivae score: 1.3 of max. 2 (animal #1) (Time point: 24, 48, 72 h) (fully reversible 7 days after dosing)) (mean, observed values) 1.3 of max. 2 (animal #2)) (Time point: 24, 48, 72 h) (fully reversible 7 days after dosing)) (mean, observed values) 1.3 of max. 2 (animal #3) (Time point: 24, 48, 72 h) (fully reversible 7 days after dosing)) (mean, observed values) Chemosis score: 1.3 of max. 2 (animal #1) (Time point: 24, 48, 72 h) (fully reversible 7 days after dosing)) (mean, observed values) 1 of max. 2 (animal #2) (Time point: 24, 48, 72 h) (fully reversible 7 days after dosing)) (mean, observed values) 1 of max. 2 (animal #3) (Time point: 24, 48, 72 h) (fully reversible 7 days after dosing)) (mean, observed values)	1 (reliable without restriction) key study experimental result **Test material (IUPAC name):** **ECHA Substance**	Ref. 5.3.2.1 (1995)

5.3.2.2 Human information

No data available for ECHA Substance.

5.3.3 Respiratory tract

5.3.3.1 Non-human information

No data available for ECHA Substance.

5.3.3.2 Human information

No data available for ECHA Substance.

5.3.4 Summary and discussion of irritation

Skin irritation:

There is one skin irritation study in rabbits available for ECHA Substance. In a primary skin irritation study ECHA Substance was applied to the intact skin of rabbits for 4 hours. The results of the study indicate that ECHA Substance is moderately irritating to the skin. (two of the test animals had erythrema scores ≥ 2.3). Reversibility was not seen 72 hours after application. No other dermal effects were noted in the study. ECHA Substance is classified as skin irritant, Category 2 a according to the CLP Regulation, the substance is classified as skin irritant, Category 2 and as irritant (Xi) according to Directive 67/548/EEC.

Eye irritation:

There is one eye irritation study in rabbits. Undiluted test material (ECHA Substance) was introduced in the right eye of three animals. The resulting reaction to treatment was assessed 1, 24, 48 and 72 hours and 7 days after treatment. Slight conjunctival redness, chemosis and ocular discharges were observed in the three animals at 1 hour examination.

Moderate conjunctival redness and ocular discharges, well defined chemosis, slight to moderate iris inflammation and moderate corneal opacity were observed in the three animals at 24 hours examination. The scores obtained for the corneal opacity calculated as the mean scores following grading at 24, 48 and 72 h were 1.7, 1.7 and 2 but fully reversed within the 7 day observation period. The medium scores are above the criteria for classification as Eye irritant, Category 2 in the CLP Regulation (mean limit score 1) but below the criteria for 67/548/EEC (≤ 2 mean corneal opacity < 3).

Accordingly, based upon classification criteria of European Directives concerning the classification, packaging and labelling of dangerous substances (67/548/EEC and subsequent revisions), ECHA Substance does not warrant classification as irritating to eyes. However, according to the CLP Regulation, the substance is classified as Eye irritant, Category 2, based on the scores obtained for the corneal opacity (calculated as the mean scores following grading at 24, 48 and 72 h) which are above 1 for the three animals and which fully reverses within the observation period.

<u>The following information is taken into account for any hazard / risk assessment:</u>

Skin irritation: OECD Guideline 404 and EU method B.4. GLP.

Eye irritation: OECD Guideline 405 and EU method B.5. GLP.

Value used for CSA:

Skin irritation / corrosion: skin irritant.

Eye irritation: irritant

Justification for classification or non classification

According to the **CLP Regulation**, the substance is classified as:

Skin Irritant, Category 2, based on slight erythema (grade 1) which were observed in 3 of 6 rabbits.

Eye irritant, Category 2, based on the scores obtained for the corneal opacity (calculated as the mean scores following grading at 24, 48 and 72 h) which are above 1 for the three animals and which fully reverses within the observation period.

According to Annex 1 to **Directive 67/548/EEC,** ECHA Substance is classified as a skin irritant.

Xi, Irritant: R38 Irritating to skin

5.4 Corrosivity

5.4.1 Non-human information

The data in Section 5.3 (Irritation) indicate that ECHA Substance does not have corrosive properties.

5.4.2 Human information

No data available for ECHA Substance.

5.4.3 Summary and discussion of corrosion

The data in Section 5.3 (Irritation) indicate that ECHA Substance does not have corrosive properties.

5.5 Sensitisation

5.5.1 Skin

5.5.1.1 Non-human information

The results of experimental studies on skin sensitisation are summarized in the following table:

Table 5.6 Overview of experimental studies on skin sensitisation

Method	Results	Remarks	Reference
guinea pig (Dunkin-Hartley) female Guinea pig maximisation test Induction: intradermal Challenge: topical OECD Guideline 406 (Skin Sensitisation) EU Method B.6 (Skin	Not sensitising No. with positive reactions: 1st reading: 1 out of 20 (test group); 24 h after chall.; dose: 100 % 2nd reading: 0 out of 20 (test group); 48 h after chall.; dose: 100 % 1st reading: 0 out of 10 (negative control); 24 h after chall.; dose: 0 %	1 (reliable without restriction) key study experimental result **Test material (IUPAC name):**	Ref. 5.5.1.1 (1996)

Method	Results	Remarks	Reference
Sensitisation)	2nd reading: 0 out of 10 (negative control); 48 h after chall.; dose: 0 %	**ECHA Substance**	

5.5.1.2 Human information

No data available for ECHA Substance.

5.5.2 Respiratory system

5.5.2.1 Non-human information

No data available for ECHA Substance

5.5.2.2. Human information

No data available for ECHA Substance.

5.5.3 Summary and discussion of sensitisation

Skin sensitisation

Skin sensitisation: At the challenge with the undiluted test item, a very slight response was apparent in 1 of the 20 animals of the test group (5.3%) at 24 hours examination. No reaction was observed at 48 hours examination. No reaction to the test item was observed in any animal from the control group. No reaction to the vehicle alone was observed in any animal.

The following information is taken into account for any hazard / risk assessment:

OECD guideline 406 and EU method B.6.

Value used for CSA: not sensitising

Justification for classification or non classification

Based on the available data, the substance is not classified.

5.6 Repeated dose toxicity

5.6.1 Non-human information

5.6.1.1 Repeated dose toxicity: oral

The results of experimental studies are summarised in the following table:

Table 5.7 Overview of experimental studies on repeated dose toxicity after oral administration

Method	Results	Remarks	Reference
rat (Sprague-Dawley) male/female subchronic (oral: gavage) 350 mg/kg 700 mg/kg 1000 mg/kg (nominal in corn oil)	NOAEL: 700 mg/kg bw/day (nominal) (male) In the 1000 mg/kg bw./day group in males, absolute and relative liver weights were increased. Among 8/10 of males in	1 (reliable without restriction) key study experimental result	Ref. 5.6.1.1 (2005)

Method	Results	Remarks	Reference
Vehicle: corn oil Exposure: 90 days (13 weeks) (5 days per week) OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents)	the 1000 mg/kg bw./day slight to moderate degeneration of hepatocytes in centrilobular area in liver was present. No effects were seen in females.	**Test material (IUPAC name): ECHA Substance**	
rat (Wistar) male/female subacute (oral: gavage) DRF pre-study: 1000 - 2000 mg/kg bw/day (actual ingested) main study: 200 mg/kg bw/day (actual ingested) main study: 500 mg/kg bw/day (actual ingested) main study: 1000 mg/kg bw/day (actual ingested) Exposure: 28 d; DRF pre-study: 14 d (daily) OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity in Rodents)	NOAEL: >1000 mg/kg bw/day (actual dose received) (male/female)	1 (reliable without restriction) key study experimental result **Test material (IUPAC name):** **ECHA Substance**	Ref. 5.6.1.1 (2002)

5.6.1.2 Repeated dose toxicity: inhalation

No data available for ECHA Substance.

5.6.1.3 Repeated dose toxicity: dermal

No data available for ECHA Substance.

5.6.1.4 Repeated dose toxicity: other routes

No data available for ECHA Substance.

5.6.2 Human information

No data available for ECHA Substance.

5.6.3 Summary and discussion of repeated dose toxicity

Discussion

A daily oral administration of the test item to wistar rats at a dose level of 200, 500 and 1000 mg/kg body mass over a time period of 28 days resulted in no systemic effects in any of the test groups. In the subchronic study (90-day) in Sprague Dawly rats adverse effects were observed in the 1000 mg/kg bw./day group in males. Increased absolute and relative liver weights were increased and among 8/10 of males mg/kg bw./day slight to moderate degeneration of hepatocytes in centrilobular area in liver was present in this group of males. No effects were seen in females.

The following information is taken into account for any hazard / risk assessment:

90-day study: OECD Guideline 408. GLP.

Value used for CSA (route: oral):

NOAEL: **7**00 mg/kg bw/day (subchronic; rat)

Justification for classification or non classification

Based on the available data, the substance is not classified.

5.7 Mutagenicity

5.7.1 Non-human information

5.7.1.1 In vitro data

The results of experimental studies are summarised in the following table:

Table 5.8 Overview of experimental in vitro genotoxicity studies

Method	Results	Remarks	Reference
Bacterial reverse mutation assay (e.g. Ames test) (gene mutation) S. typhimurium TA 98, TA 100, TA 1535, TA 1537, E coli WP2 uvrA (met. act.: with and without) Doses: 0, 312.5, 625, 1250, 2500, 5000 µg/plate OECD Guideline 471 (Bacterial Reverse Mutation Assay)	Test results: Negative for S. typhimurium TA 98, TA 100, TA 1535, TA 1537, E coli WP2 uvrA (all strains/cell types tested); met. act.: with and without; cytotoxicity: no toxicity was observed up to a concentration of 5000 µg/plate with or without metabolic activation.	1 (reliable without restriction) key study experimental result **Test material (EC name):** **ECHA Substance**	Ref. 5.7.1.1.(2007)
Mammalian cell gene mutation assay (gene mutation) Chinese hamster lung fibroblasts (V79) (met. act.: with and without) Doses: Experiment I: with and without S9-mix: 43.8, 87.5, 175, 350 700, 1400 µg/ml Incubation time: 4 hours Experiment II: with S9-mix, incubation time: 4 hours: 43.8, 87.5, 175, 350 700, 1400 µg/ml without S9-mix, incubation time:24 hours: 43.8, 87.5, 175, 350 700, 1400 µg/ml OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation Test)	Test results: Negative for Chinese hamster lung fibroblasts (V79) (strain/cell type: Chinese hamster V79 cells); met. act.: with and without; cytotoxicity: preliminary toxicity tests	1 (reliable without restriction) key study experimental result **Test material (EC name):** **ECHA Substance**	Ref. 5.7.1.1.(2008)
In vitro mammalian chromosome aberration test (chromosome aberration) Chinese Hamster Lung (CHL) cells (met. act.: with and without)	Test results: Negative for Chinese Hamster Lung (CHL) cells (all strains/cell types tested (Chinese Hamster Lung CHL cells)); met.	1 (reliable without restriction) key study experimental	Ref. 5.7.1.1.(2007)

Method	Results	Remarks	Reference
Doses: 0, 0.34, 0.67, 1.34 mg/ml OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test)	act.: with and without; cytotoxicity: no	result **Test material (EC name):** **ECHA Substance**	

5.7.1.2 In vivo data

Data are not available

5.7.2 Human information

Data are not available

5.7.3 Summary and discussion of mutagenicity

Discussion

ECHA Substance was tested using the Ames test according to OECD TG 471 and GLP and showed no mutagenic activity either with or without exogenous metabolic activation up to 5000 µg/plate, but cytotoxicity was not reached (MHLW 1994). This result confirmed the result of an investigation of xxxx, (xxxx, 1989) when ECHA Substance was investigated in the Salmonella/microsome test (Ames test) in doses up to 5000 µg per plate on Salmonella typhimurium strains TA98, TA100, TA1535 and TA 1537: according to Ames et al. Mut Res 31, 347-364 (1975) and GLP. There was no evidence of mutagenic activity of ECHA Substance with and without mutagenic activation.

In addition, a study was performed to investigate the potential of ECHA Substance to induce gene mutations at the HPRT locus in V79 cells of the Chinese hamsters according to OECD TG 476 and GLP in concentrations up to 1400 µg/ml in the presence and in the absence of S9 -mix. Cytotoxicity was determined in preliminary experiments. Under the conditions reported the test item did not induce gene mutations at the HPRT locus in V79 cells. Therefore, ECHA Substance is considered to be non-mutagenic in this HPRT assay (Harlan CCR 2010).

According to OECD TG 473 and GLP ECHA Substance was tested for chromosomal aberration with Chinese Hamster Lung (CHL) cells and concentrations up to 1.34 mg/ml in the presence and in the absence of a metabolic activation system. There was no evidence for clastogenic activity neither with nor without S9 -mix (MHLW 1994).

The following information is taken into account for any hazard / risk assessment:

ECHA Substance revealed no mutagenic activity in the Ames test according to OECD TG 471 and GLP and is considered as non-mutagenic when tested according to OECD TG 476 and GLP (HPRT-test, Chinese Hamster V79 cells).

ECHA Substance revealed no clastogenic activity when tested in Chinese Hamster Lung (CHL) cells according to OECD TG 473 and GLP.

Value used for CSA: Genetic toxicity: negative

Justification for classification or non classification

Directive 67/548/EEC, Annex 1

ECHA Substance is not classified

Directive 67/548/EEC, Annex 1 and Regulation (EC) No. 1272/2008:

Based on the available data, no classification is needed.

5.8 Carcinogenicity

No data available for ECHA Substance.

5.9 Toxicity for reproduction

5.9.1 Effects on fertility

5.9.1.1 Non-human information

The results of experimental studies are summarised in the following table:

Table 5.9 Overview of experimental studies on fertility

Method	Results	Remarks	Reference
rat (Wistar) male/female screening oral: gavage 50, 200, 1000 mg/kg/day (nominal conc.) Exposure: (once daily) OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test)	NOAEL (P and F1): >= 1000 mg/kg bw/day (male/female)	1 (reliable without restriction) key study experimental result **Test material (IUPAC name): ECHA Substance**	Ref 5.9.1.1 (2007)

5.9.1.2 Human information

No data available for ECHA Substance.

5.9.2 Developmental toxicity

5.9.2.1 Non-human information

Testing proposal

Information requirement: Developmental toxicity/teratogenicity

Proposed test guideline: OECD 414 (Prenatal Developmental Toxicity Study)

Planned study period: The results should be available as soon as possible after ECHA's approval.

Details on method intended: route: oral; species: rat

5.9.2.2 Human information

No data available for ECHA Substance.

5.9.3. Summary and discussion of reproductive toxicity

Discussion

Effects on fertility

The following information is taken into account for any hazard / risk assessment:

Under the conditions of the reproduction/developmental toxicity screening test (OECD 421) no adverse effects were observed at limit dose. The no observed adverse effect level (NOAEL) for reproductive performance and fertility in male and female Wistar rats is therefore 1000 mg/kg bw/d.

The NOAEL for general, systemic toxicity of the test substance was also 1000 mg/kg bw/d for the F0 parental animals.

The NOAEL for developmental toxicity was 1000 mg/kg bw/d.

Justification for classification or non classification

There is conclusive but insufficient data for classification of the test substance with regard to fertility. The substance is not classified for this endpoint in accordance to Directive 67/548/EEC or the CLP Regulation (EC) No 1272/2008.

For developmental toxicity the dossier includes a testing proposal for an OECD 414 study. The study shall be performed in 2012, after the decision from ECHA.

5.10 Other effects

No data available for ECHA Substance for other toxicological effects.

5.11 Derivation of DNEL(s) / DMEL(s)

5.11.1 Overview of typical dose descriptors for all endpoints

Table 5.10 Available dose-descriptor(s) per endpoint as a result of its hazard assessment

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type;	Reference to selected study
Acute toxicity	oral	No adverse effect observed	Ref. 5.2.1.1. (2005) Ref. 5.2.1.3. (2005) Ref. 5.2.1.2. (2004)
Acute toxicity	dermal	No adverse effect observed	
Acute toxicity	inhalation	No adverse effect observed	
Irritation / Corrosivity	skin	irritating	Ref. 5.3.1.1. (2000) Ref. 5.3.2.1. (1995)
Irritation / Corrosivity	eye	irritating	
Irritation / Corrosivity	respiratory	No study available	
Sensitisation	skin	No adverse effect observed (not sensitising)	Ref. 5.5.1.1. (1996)
Repeated dose toxicity	Oral	NOAEL: 700 mg/kg bw/day (subacute; rat)	Ref. 5.6.1.1. (2005)
Repeated dose toxicity	dermal	No study available	
Repeated dose toxicity:	inhalation	No study available	
Mutagenicity		No adverse effect observed (negative)	Ref. 5.7.1.1. (2007-2008)

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type;	Reference to selected study
Reproductive toxicity: fertility impairment	Oral	No adverse effect observed	Ref. 5.9.1.1. (2007)

5.11.2 Selection of the critical DNEL(s) / DMEL(s) and / or qualitative / semi-quantitative descriptor for critical health effects

Table 5.11 Hazard conclusions for workers

Route	Type of effect	Hazard conclusion	Most sensitive endpoint (referring to original study)
Inhalation	Systemic effect - Long-term	DNEL = 24.7 mg/m3	Repeated dose toxicity (oral)
	Systemic effects - Acute	No hazard identified	Acute toxicity (inhalation)
	Local effects - Long-term	No data available (no further information necessary)	
	Local effects - Acute	No data available (no further information necessary)	
Dermal	Systemic effect - Long-term	DNEL = 7 mg/kg bw /day	Repeated dose toxicity (oral)
	Systemic effects - Acute	No hazard identified	Acute toxicity (dermal)
	Local effects - Long-term	Low hazard	Skin irritation/corrosion
	Local effects - Acute	Low hazard	Skin irritation/corrosion
Eyes		Low hazard	

Further explanation when no DNEL is derived

Inhalation local Long term: no data available regarding local respiratory effects; the substance is however classified for skin and eye irritation; absence of route specific information is justified, based on conditions of use and qualitative risk characterisation. (See section 9/10)

Inhalation local Acute: no data available regarding local respiratory effects ; the substance is classified for skin and eye irritation; absence of route specific information is justified, based on conditions of use and qualitative risk characterisation. (See section 9/10)

Dermal local Long term: the substance is classified for skin irritation

Dermal local Acute: the substance is classified for skin irritation; low hazard assigned according to ECHA CSA Guidance part E Table E 3-1

Eyes: the substance is classified for eye irritation; low hazard assigned according to ECHA CSA Guidance part E Table E 3-1

Table 5.12 Further explanation on DNEL derivation for workers

		Assessment factors for DNEL derivation
Inhalation (Long-term - systemic effects)	**DNEL derivation method:** ECHA REACh guidance **Dose descriptor starting point** NOAEC = 617 mg/m3	AF for difference in duration of exposure: 2 (*DNEL is based on an oral 90 day study*) AF for interspecies differences: 1 (*AF not used for inhalation route*) AF for other interspecies differences: 2.5 AF for intra species differences:5 (workers) Overall Assessment Factor: 25
Dermal (Long-term - systemic effects)	**DNEL derivation method:** ECHA REACh guidance **Dose descriptor starting point** NOAEL = 700 mg/kg bw/day	AF for difference in duration of exposure: 2 (*based on an oral 90 day study*) AF for interspecies differences: 4 (*experimental animal was rat*) AF for other interspecies differences: 2.5 AF for intra species differences:5 (*this is for workers*) AF for remaining uncertainties: Overall Assessment Factor: 100

Inhalation systemic long term. Route-to-route extrapolation:
$NOAEC_{corr}=NOAEL_{oral}*(1/0.38\ m^3/kg/d)*(ABS_{oral\text{-}rat}/ABS_{inh\text{-}human})*(6.7\ m^3\ (8h)/10\ m^3\ (8h))$ = 700 mg/kg/d*(1/0.38 m^3/kg/d)*(0.5*1)*0.67=617 mg/m^3.

It is assumed that oral absorption rate is 50% of that of inhalation absorption.

$ABS_{oral/rat}$=oral absorption rate in rats, $ABS_{inh./human}$=inhalation absorption rate in humans

Dermal systemic long-term. Route-to-route extrapolation: It is assumed that oral and dermal absorption rates are equal

Table 5.13 Hazard conclusions for general population

Route	Type of effect	Hazard conclusion	Most sensitive endpoint (referring to original study)
Inhalation	Systemic effect Long-term	DNEL = 6.08 mg/m3	Repeated dose toxicity (oral)
	Systemic effects - Acute -	No hazard identified	Acute toxicity (inhalation)
	Local effects - Long-term	No data available (no further information necessary)	
	Local effects Acute	No data available (no further information necessary)	
Dermal	Systemic effect Long-term	DNEL (Derived No Effect Level) = 3.5 mg/kg bw /day	Repeated dose toxicity (oral)
	Systemic effects - Acute -	No hazard identified	Acute toxicity (dermal)
	Local effects - Long-term	Low hazard	Skin irritation/corrosion
	Local effects Acute	Low hazard	Skin irritation/corrosion
Oral	Systemic effect Long-term	DNEL = 3.5 mg/kg bw/day	Repeated dose toxicity (oral)
	Systemic effects - Acute -	No hazard identified	Acute toxicity (oral)
Eyes		Low hazard	

Further explanation when no DNEL is derived

Inhalation local Long term: no data available regarding local respiratory effects; the substance is however classified for skin and eye irritation; absence of route specific information is justified based on conditions of use and qualitative risk characterisation.

Inhalation local Acute: no data available regarding local respiratory effects ; the substance is classified for skin and eye irritation; absence of route specific information is justified based on conditions of use and qualitative risk characterisation.

Dermal local Long term: the substance is classified for skin irritation

Dermal local Acute: the substance is classified for skin irritation; low hazard assigned according to ECHA CSA Guidance part E Table E 3-1

Eyes: the substance is classified for eye irritation; low hazard assigned according to ECHA CSA Guidance part E Table E 3-1

Table 5.14 Further explanation on DNEL derivation for general population

		Assessment factors for DNEL derivation
Inhalation (Long-term - systemic effects)	**DNEL derivation method:** ECHA REACh guidance **Dose descriptor starting point** NOAEC = 304 mg/m3	AF for difference in duration of exposure: 2 (*DNEL is based on an oral 90 day study*) AF for other interspecies differences: 2.5 AF for intra species differences:10 Overall Assessment Factor: 50
Dermal (Long-term - systemic effects)	**DNEL derivation method:** ECHA REACh guidance **Dose descriptor starting point** NOAEL = 700 mg/kg bw/day	AF for difference in duration of exposure: 2 (*based on an oral 90 day study*) AF for interspecies differences: 4 (*experimental animal was rat*) AF for other interspecies differences: 2.5 AF for intra species differences:10 (*this is for general population*) AF for remaining uncertainties: Overall Assessment Factor: 200
Oral (Long-term - systemic effects)	**DNEL derivation method:** ECHA REACh guidance **Dose descriptor starting point** NOAEL = 700 mg/kg bw/day	AF for difference in duration of exposure: 2 (*based on an oral 90 day study*) AF for interspecies differences: 4 (*experimental animal was rat*) AF for other interspecies differences: 2.5 AF for intra species differences:5 (*this is for workers*) AF for remaining uncertainties: Overall Assessment Factor: 200

Inhalation systemic long-term. Route-to-route extrapolation:
$NOAEC_{corr}=NOAEL_{oral}*(1/1.15\ m^3/kg/d)*(ABS_{oral\text{-}rat}/ABS_{inh\text{-}human}) = 700\ mg/kg/d*(1/1.15\ m^3/kg/d)*(0.5*1)=304\ mg/m^3$ It is assumed that oral absorption rate 50% of that of inhalation absorption.

Dermal systemic long-term. Route-to-route extrapolation: It is assumed that oral and dermal absorption rates are equal

6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

6.1 Explosivity

Explosivity is not a hazard associated with ECHA Substance (confirmed by oxygen balance and differential scanning calorimetry), see additional information in:

Data waiving: see CSR section 1.3 Physicochemical properties.

Classification according to GHS

Name: ECHA Substance

State/form of the substance: liquid

Reason for no classification: conclusive but not sufficient for classification

Classification according to DSD / DPD

Classification status: 67/548/EEC self classification (ECHA Substance)

Reason for no classification: conclusive but not sufficient for classification

6.2 Flammability

The available information on flammability is summarised in the following table:

Table 6.1 Overview of information on flammability

<table>
<tr><th>Method</th><th>Results</th><th>Remarks</th><th>Reference</th></tr>
<tr><td>Non-equilibrium method closed cup (closed crucible according to DIN ISO 2719 (Pensky-Martens))

EU Method A.9 (Flash-Point)</td><td>Flash point:
140.0 °C at 101.3 kPa

Remarks:

The results of the preliminary and main tests are summarized in the following table:
<table>
<tr><th>sample n°</th><th>Start temperature (°C)</th><th>Gradient (°C/min)</th><th>Measured Flash point (°C)</th><th>Atmospheric Pressure (kPa)</th><th>Corrected Flash point(°C)</th></tr>
<tr><td>Pre-test</td><td>25</td><td>8.3</td><td>148.3</td><td>102.1</td><td>150.1</td></tr>
<tr><td>1</td><td>132</td><td>1.2</td><td>142.0</td><td>102.0</td><td>143.8</td></tr>
<tr><td>2</td><td>132</td><td>1.2</td><td>144.0</td><td>101.8</td><td>145.9</td></tr>
<tr><td>3</td><td>132</td><td>1.1</td><td>140.0</td><td>101.8</td><td>141.9</td></tr>
</table></td><td>1 (reliable without restriction)

key study

experimental result

Test material: ECHA Substance</td><td>Reference 6.2. (2006)</td></tr>
</table>

Data waiving: see CSR section 1.3 Physicochemical properties.

Flash point

Flash point of ECHA Substance was determined according to EEC-guideline A.9, method closed crucible according to DIN ISO 2719.

The test item was heated up in a closed crucible and at defined temperatures it was tried to ignite the gaseous phase upon the surface of the liquid with the hot surface.

The flash point of the test item: 140ºC / 413.2K (101.3 kPa)

The following information is taken into account for any hazard / risk assessment:

Flash point of ECHA Substance was determined according to EEC-guideline A.9, method closed crucible according to DIN ISO 2719.

Classification according to GHS

Name: ECHA Substance

State/form of the substance: liquid

Reason for no classification (Flammable gases): data lacking, not relevant for ECHA Substance

Reason for no classification (Flammable aerosols): data lacking

Reason for no classification (Flammable liquids): conclusive but not sufficient for classification

Reason for no classification (Flammable solids): data lacking, not relevant for ECHA Substance

Classification according to DSD / DPD

Classification status: 67/548/EEC self classification ECHA Substance

Reason for no classification: conclusive but not sufficient for classification

6.3 Oxidising potential

Oxidising potential is not a hazard associated with ECHA Substance, because the substance does not contain chemical groups associated with oxidizing properties. See additional information;

Data waiving: see CSR section 1.3 Physicochemical properties.

Classification according to GHS

Name: ECHA Substance

State/form of the substance: liquid

Reason for no classification (Oxidising gases): data lacking, not relevant for ECHA Substance

Reason for no classification (Oxidising liquids): conclusive but not sufficient for classification

Reason for no classification (Oxidising solids): data lacking, not relevant for ECHA Substance

Classification according to DSD / DPD

Classification status: 67/548/EEC self classification ECHA Substance

Reason for no classification: conclusive but not sufficient for classification

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1 Aquatic compartment (including sediment)

7.1.1 Toxicity test results

7.1.1.1 Fish

7.1.1.1.1 Short-term toxicity to fish

The results are summarised in the following table:

Table 7.1 Overview of short-term effects on fish

Method	Results	Remarks	Reference
Danio rerio freshwater static EU Method C.1 (Acute Toxicity for Fish) OECD Guideline 203 (Fish, Acute Toxicity Test)	LC50 (96 h): 10.3 mg/L test mat. (95% CL = 8-16 mg/l (meas. (arithm. mean))	1 (reliable without restriction) key study experimental result **Test material: ECHA Substance**	Ref 7.1.1.1.1 (2007)

Discussion

The LC50 (96 hours) was 10.3 mg/l (measured concentration) with 95% confidence limits of 8-16 mg/l. The other results were LC50 (3 h): 21.5 mg/L test mat. (measured), LC50 (24 h): 10.3 mg/L test mat. (measured), LC50 (48 h): 10.3 mg/L test mat. (measured), LC50 (72 h): 10.3 mg/L test mat. (measured).,

The following information is taken into account for acute fish toxicity for the derivation of PNEC:

LC50 (96 hours) for freshwater fish: 10.3 mg/L

Value used for CSA:

LC50 for freshwater fish: 10.3 mg/L

7.1.1.1.2 Long-term toxicity to fish

Data waiving

Reason: other justification

Justification: In accordance with column 2 of REACH Annex IX, the study shall be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The substance has a water solubility of 149 mg/L and has been classified with Aquatic Chronic 3. As the exposure assessment (see chapter 9) does not indicate the need to investigate further the effects on aquatic organisms (as all the RCR's to all the compartments are well below 1 and all

the supported uses are therefore assessed to be safe) no further long-term testing is proposed for aquatic compartments.

7.1.1.2 Aquatic invertebrates

7.1.1.2.1 Short-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 7.2 Overview of short-term effects on aquatic invertebrates

Method	Results	Remarks	Reference
Daphnia magna freshwater static OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)	EC50 (48 h): 22.1 mg/L test mat. (95% CL 18.4 – 24.3 mg/l) (meas. (initial)) based on: mobility	1 (reliable without restriction) key study experimental result **Test material: ECHA Substance**	Ref 7.1.1.2.1 (2006)

Discussion

The test substance was found to be toxic to Daphnia magna after 48 h at a measured concentration of 25.0 mg/L. EC50 (24 h) was 25.8 mg/L test mat. (measured) based on: mobility; EC50 (48 h) was 22.1 mg/L. The LOEC after 48 hours was 25 mg/L (measured concentration).

The following information is taken into account for short-term toxicity to aquatic invertebrates for the derivation of PNEC:

EC50 (48 hours) for freshwater invertebrates: 22.1 mg/L

Value used for CSA:

EC50 for freshwater invertebrates: 22.1 mg/L

7.1.1.2.2 Long-term toxicity to aquatic invertebrates

Data waiving

Reason: other justification

Justification: In accordance with column 2 of REACH Annex IX, the study shall be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The substance has a water solubility of 149 mg/L and has been classified with aquatic chronic 3. As the exposure assessment (see chapter 9) does not indicate the need to investigate further the effects on aquatic organisms (as all the RCR's to all the compartments are well below 1 and all the supported uses are therefore assessed to be safe) no further long-term testing is proposed for aquatic compartments.

7.1.1.3 Algae and aquatic plants

The results are summarised in the following table:

Table 7.3 Overview of effects on algae and aquatic plants

Method	Results	Remarks	Reference
Desmodesmus subspicatus (algae) freshwater static OECD Guideline 201 (Alga, Growth Inhibition Test)	EC50 (72 h): 52.2 mg/L test mat. (meas. (geom. mean)) based on: biomass (/ yield inhibition (95%CL: 48.8-61.7 mg/l)) EC50 (72 h): 80.6 mg/L test mat. (meas. (geom. mean)) based on: growth rate (95%CL: 78.9-82.3 mg/l) EC10 (72 h): 34.8 mg/L test mat. (meas. (geom. mean)) based on: biomass (/ yield inhibition (95%CL: 28.5-43.9 mg/l)) EC10 (72 h): 51.9 mg/L test mat. (meas. (geom. mean)) based on: growth rate (95%CL: 45.2-56.2 mg/l)	1 (reliable without restriction) key study experimental result **Test material: ECHA Substance**	Ref 7.1.1.3 (2007)

Discussion

Effects on algae / cyanobacteria

The EC50 values with 95% confidence intervals for inhibition of biomass (EbC50) and specific growth rate (ErC50) after 72 h were 52.2 (48.8-61.7) and 80.6 (78.9-82.3) mg/l, respectively . The EC10 (72 h) was 34.8 mg/L test mat. (measured) based on: biomass (/ yield inhibition) and EC10 (72 h): 51.9 mg/L test mat. (measured) based on: growth rate.

The following information is taken into account for effects on algae / cyanobacteria for the derivation of PNEC:

ErC50 (72h) for freshwater algae: 80.6 mg/L

ErC10 (72h) for freshwater algae: 51.9 mg/L

Value used for CSA:

EC50 for freshwater algae: 80.6 mg/L

EC10/LC10 or NOEC for freshwater algae: 51.9 mg/L

7.1.1.4 Sediment organisms

Discussion

Toxicity to sediment organisms is not a standard information requirement in Annex IX. Moreover, as the exposure assessment (see chapter 9) does not indicate the need to investigate further the effects on sediment organisms (as all the RCRs to all the compartments are well below 1 and all the supported uses are therefore assessed to be safe) no further long-term testing on sediment is proposed.

7.1.1.5 Other aquatic organisms

Discussion

No further data on other aquatic organisms available

7.1.2 Calculation of Predicted No Effect Concentration (PNEC)

7.1.2.1 PNEC water

Table 7.4 PNEC water

PNEC	Assessment factor	Remarks / Justification
PNEC aqua (freshwater): 0.0103 mg/L	1000	Extrapolation method: assessment factor Since the three taxonomic groups (fish, invertebrates, algae) are covered but only short-term toxicity data are available for fish and invertebrates, an assessment factor of 1000 is applied on the lowest L(E)C50 of the relevant available toxicity data (fish LC50 = 10.3 mg/l).
PNEC aqua (marine water): 0.00103 mg/L	10000	Extrapolation method: assessment factor Since the three taxonomic groups (fish, invertebrates, algae) are covered but only short-term toxicity data are available for fish and invertebrates and there is no additional data on marine taxonomic groups (e.g. echinoderms, molluscs), an assessment factor of 10000 is applied on the lowest L(E)C50 of the relevant available toxicity data (fish LC50 = 10.3 mg/l).
PNEC aqua (intermittent releases): 0.103 mg/L	100	Extrapolation method: assessment factor Since the three taxonomic groups (fish, invertebrates, algae) are covered but only short-term toxicity data are available for fish and invertebrates, an assessment factor of 100 is applied on the lowest L(E)C50 of the relevant available toxicity data (fish LC50 = 10.3 mg/l).

7.1.2.2 PNEC sediment

Table 7.5 PNEC sediment

PNEC	Assessment factor	Remarks / Justification
PNEC sediment (freshwater): 0.837 mg/kg sediment dw		Extrapolation method: partition coefficient Reference to equations in Guidance Part B, Version 2.1 (December 2011), paragraph B.7.2.4 - Derivation of PNEC for sediment and soil where $PNEC_{water}$ [$mg \cdot l^{-1}$]: 0.0103

PNEC	Assessment factor	Remarks / Justification
		Koc [$cm^3 \cdot g^{-1}$]: 776 $PNEC_{sed}$ [$mg \cdot kg^{-1}$ of wet sediment]: 0.182 0.182 mg/kg wet sediment = 0.837 mg/kg sediment dw
PNEC sediment (marine water): 0.0837 mg/kg sediment dw		Extrapolation method: partition coefficient Reference to equations in Guidance Part B, Version 2.1 (December 2011), paragraph B.7.2.4 - Derivation of PNEC for sediment and soil Where: $PNEC_{water}$ [$mg \cdot l^{-1}$]: 0.00103 Koc [$cm^3 \cdot g^{-1}$]: 776 $PNEC_{sed}$ [$mg \cdot kg^{-1}$ of wet sediment]: 0.0182 0.0182 mg/kg wet sediment = 0.0837 mg/kg sediment dw

7.2 Terrestrial compartment

7.2.1 Toxicity test results

7.2.1.1 Toxicity to soil macro-organisms

Data waiving

Information requirement: Toxicity to soil macro-organisms except arthropods

Reason: other justification

Justification: In accordance with column 2 of REACH Annex IX in the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. As the substance does not indicate high adsorption (log Koc <3) and is not persistent nor very persistent; and there is no indication that the substance is very toxic (EC/LC50 <1 mg/L for algae, daphnia or fish), the substance belongs according to REACH Guidance R.7C Table R.7.11-2 to soil hazard category 1. As the exposure assessment (see Chapter 9) based on PNECsoil(screen) does not indicate the risk for terrestrial compartment (all RCRs to all compartments are well below 1 and all the supported uses are therefore assessed to be safe) no further testing is proposed for terrestrial toxicity.

7.2.1.2 Toxicity to terrestrial plants

Data waiving

Reason: other justification

Justification: In accordance with column 2 of REACH Annex IX in the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. As the substance does not indicate high adsorption (log Koc <3) and is not persistent nor very persistent, and there is no indication that the substance is very toxic (EC/LC50 <1 mg/L for algae, daphnia or fish), the substance

belongs according to REACH Guidance R.7C Table R.7.11-2 to soil hazard category 1. As the exposure assessment (see Chapter 9) based on PNECsoil(screen) does not indicate the risk for terrestrial compartment (all RCRs to all compartments are well below 1 and all the supported uses are therefore assessed to be safe) no further testing is proposed for terrestrial toxicity.

7.2.1.3 Toxicity to soil micro-organisms

Data waiving

Reason: other justification

Justification: In accordance with column 2 of REACH Annex IX in the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. As the substance does not indicate high adsorption (log Koc <3) and is not persistent nor very persistent, and there is no indication that the substance is very toxic (EC/LC50 <1 mg/L for algae, daphnia or fish), the substance belongs according to REACH Guidance R.7C Table R.7.11-2 to soil hazard category 1. As the exposure assessment (see Chapter 9) based on PNECsoil(screen) does not indicate the risk for terrestrial compartment (all RCRs to all compartments are well below 1 and all the supported uses are therefore assessed to be safe) no further testing is proposed for terrestrial toxicity.

7.2.1.4 Toxicity to other terrestrial organisms

7.2.2 Calculation of Predicted No Effect Concentration (PNEC soil)

Table 7.6 PNEC soil

PNEC	Assessment factor	Remarks / Justification
PNEC soil: 0.161 mg/kg soil dw		Extrapolation method: partition coefficient Reference to equations in Guidance Part B, Version 2.1 (December 2011), paragraph B.7.2.4 - Derivation of PNEC for sediment and soil * where $PNEC_{water}$ [$mg \cdot l^{-1}$]: 0.0103 Koc [$cm^3 \cdot g^{-1}$]: 776 $PNEC_{soil}$ [$mg \cdot kg^{-1}$ ww]; 0.142 0.142 mg/kg wet weight = 0.161 mg/kg soil dw

7.3 Atmospheric compartment

No experimental data available. As this study is not a standard information requirement in REACH and there is no indication from the CSA on the need to investigate further the atmospheric compartment (Annex X requirement), no further testing is considered necessary.

* The equation in the guidance will be updated to PNECsoil = (0.01176+0.01765*Koc)*PNECwater

7.4 Microbiological activity in sewage treatment systems

7.4.1 Toxicity to aquatic micro-organisms

The results are summarised in the following table

Table 7.7 Overview of effects on micro-organisms

Method	Results	Remarks	Reference
activated sludge of a predominantly domestic sewage freshwater static OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test)	EC50 (3 h): > 149 mg/L test mat. (meas. (geom.. mean)) based on: respiration rate	1 (reliable without restriction) key study experimental result **Test material: ECHA Substance**	Ref 7.4.1 (2007)

Discussion

The inhibition ranged from 12% to 31%. The EC50 for the test substance was determined to be greater than 1000 mg/l. However, as the substance has a water solubility of 149 mg/L, the EC50 for the test substance has been considered to be 149 mg/l.

The following information is taken into account for effects on aquatic micro-organisms for the derivation of PNEC:

EC50 (3 h): > 149 mg/L

Value used for CSA:

EC50/LC50 for aquatic micro-organisms: 149 mg/L

7.4.2 PNEC for sewage treatment plant

Table 7.8 PNEC sewage treatment plant

Value	Assessment factor	Remarks/Justification
PNEC STP: 1.49 mg/L	100	Extrapolation method: assessment factor The EC50 microorganisms was determined to be greater than 1000 mg/l. As the substance has a water solubility of 149 mg/L, the EC50 for the test substance has been considered to be 149 mg/l. Applying an assessment factor of 100, the PNEC STP is greater than 1.49 mg/l.

7.5 Non compartment specific effects relevant for the food chain (secondary poisoning)

7.5.1 Toxicity to birds

No information on toxicity to birds available. Toxicity to birds is not a standard information requirement in Annex IX. Moreover, as the substance is not toxic to mammals (not classified for toxicity) no further toxicity testing on birds is proposed.

7.5.2 Toxicity to mammals

No experimental data in addition to those presented under CSR Chapter 5 is available. This is not a standard information requirement for environment in REACH.

Data from CSR Chapter 5 on Human Health Hazard Assessment shows that ECHA substance is not classified nor for repeated dose toxicity or reproductive toxicity. Substance is only classified as an eye and skin irritant. The dataset is not complete and testing proposals have been presented. The need of secondary poisoning assessment will be re-evaluated based on the outcome of the proposed studies.

7.5.3 Calculation of PNECoral (secondary poisoning)

Table 7.9 PNEC oral

PNEC	Assessment factor	Remarks/Justification
No potential to cause toxic effects if accumulated (in higher organisms) via the food chain		Assessment on secondary poisoning is not mandatory, as the substance does not have any of the classifications for human health mentioned in the Scope of Exposure Assessment Guidance to trigger the detailed assessment on secondary poisoning

7.6 Conclusion on the environmental hazard assessment and on classification and labelling

Environmental classification justification

The results from the aquatic toxicity studies are as follows:

LC50 (96 h) fish = 10.3 mg/l (measured concentration) with 95% confidence limits of 8 - 16 mg/l.

EC50 (48 h) Daphnia = 22.1 mg/l (measured concentration) with 95% confidence limits of 18.4 – 24.3 mg/l.

ErC50 (72 h) algae = 80.6 mg/l (measured concentration) with 95% confidence limits of 78.9-82.3 mg/l.

EC50 microorganisms was determined to be greater than 1000 mg/l.

As the substance is not readily biodegradable and stable to hydrolysis, the substance is considered as not rapidly degradable; in addition the experimentally determined BCF> 500 (log Kow>4), the substance is classified with aquatic chronic 3 and H 412 according to the CLP criteria.

Based on the results from the aquatic toxicity (values in the range 10 -100 mg/l) and since the substance is not readily biodegradable and has a log Pow of > 4, the substance is classified as follows:

- according to Directive 67/548/EEC the substance is classified as R52/53.

Based on the results from the aquatic toxicity (values in the range 10 -100 mg/l) and since the substance is not readily biodegradable and has a log Pow of > 4, the substance is classified as follows:

- according to Directive 67/548/EEC the substance is classified as R52/53.

- according to the CLP Regulation 1272/2008 the substance is classified as Chronic Category 3.

Notes and Comments

a) According to REACH Guidance R.7b the ErC50 should always be used over EbC50 in toxicity to algae studies.

b) Details regarding the derivation methods for PNECs can be found in dedicated sections in REACH Guidance R.8.

c) If phrases for human health listed below are to be assigned, exposure assessment regarding secondary poisoning may be required if the substance has a log Kow ≥ 3 or BCF ≥ 100 and is not readily biodegradable.

a. H373: Causes damage to organs through prolonged or repeated exposure (cat 2)
b. H372: Causes damage to organs through prolonged or repeated exposure (cat 1)
c. H360: May damage fertility or the unborn child (cat 1A or 1B)
d. H361: Suspected of damaging fertility or the unborn child (cat 2)
e. H362: May cause harm to breast-fed child

ECHA substance does not meet the above classification criteria. Hence the assessment of secondary poisoning does not need to be covered.

8. PBT AND vPvB ASSESSMENT

8.1 Assessment of PBT / vPvB Properties

8.1.1 Summary and overall conclusions on PBT or vPvB properties

Overall conclusion: Based on the assessment described in the subsections below the ECHA Substance is not PBT / vPvB

Rationale: The ECHA Substance is not P / vP based on criteria laid down in Annex XIII of REACH

8.1.2 PBT / vPvB criteria and justification

Assessed substance: ECHA Substance itself

Persistence assessment

Screening criteria

The results of the hydrolysis study (According to OECD Guideline 111, see Chapter 4.1.1.1) revealed that the substance is stable under the test conditions.

The Biodegradation DOC Die Away Test (OECD Guideline 301A, see Chapter 4.1.2.1.2) demonstrated that, although ECHA Substance did not reach the threshold of 70% degradation for being considered as "Ready Biodegradable", there was substantial microbial metabolism of ECHA Substance. Moreover, the CO2 Evolution Test (OECD Guideline 301B) confirmed that even though the substance is not readily biodegradable; it can be considered as inherently biodegradable.

Criteria based on Annex XIII of REACH

Simulation studies on water/sediment (OECD Guideline 308, see Chapter 4.1.2.1.3) revealed that ECHA Substance does not meet the 60-days degradation half-life criteria to be identified as a PBT substance in the marine environment.

Half-life times for marine water (36 days at 11°C is below the criteria for the substance to be regarded as persistent or very persistent (T1/2 <= 60 days in marine water). The T1/2 for marine sediment compartment is 81 days at 11°C being well below the criteria for considering the substance as persistent in sediment (T1/2 <= 180 days).

No simulation data is available for fresh water/sediment compartments. However, as the degradation of chemicals in seawater is generally considered to be slower than that in freshwater tests, the available marine water/sediment simulation test is considered to cover fresh surface water and sediment as well. Therefore, based on the marine water/sediment simulation test the degradation half-life for fresh water and fresh water sediment is expected to be lower than the criteria in Annex XIII to REACH Regulation (T1/2 <= 40 days in fresh- or estuarine water, T1/2 <= 120 days in fresh- or estuarine sediment).

Further simulation study on soil (OECD Guideline 307, see Chapter 4.1.2.2) revealed

that ECHA Substance does not meet the 120-days degradation half-life criteria to be identified as a PBT in terrestrial environment as The half-life time for soil (50 % degradation in 68 days at 12 °C) is well below the criteria for the substance to be regarded as persistent or very persistent (T1/2 <= 120 days in soil).

Moreover, the substance is not very adsorptive (log Koc <3) revealing that soil is not the target compartment for ECHA Substance, That is also supported by the exposure assessment that where the RCRs for soil compartment are all below 1 (highest RCR for soil: 0.16)

Conclusion on P / vP properties:

It can therefore be concluded that based on the criteria mentioned above the substance is not persistent (not P) and not very persistent (not vP) in the environment.

Bioaccumulation assessment

As the substance does not meet the criteria for being persistent or very persistent, no further assessment on bioaccumulation and toxicity is needed.

Toxicity assessment

As the substance does not meet the criteria for being persistent or very persistent, no further assessment on bioaccumulation and toxicity is needed.

9. EXPOSURE ASSESSMENT

9.0 Introduction

Testing proposals have been submitted with the IUCLID source dataset. The risk management measures reported in the exposure scenarios are based on the interim hazard assessment. They may need to be reviewed, depending on the outcome of the testing.

9.0.1 Overview of uses and Exposure Scenarios

ECHA Substance is used as an additive for inks and coatings. It functions as a co-emulsifier, antifoamer and wetting agent. Mixtures for industrial and professional applications contain ECHA Substance in concentrations up to 2%. Formulated products for consumer uses contain ECHA Substance up to 1%.

The substance is manufactured in a closed system. It is formulated into coatings and inks in batch processes. It is used in a wide variety of industrial applications, both open and closed, such as component labelling, spraying of larger pieces in spray booths, application by roller//brush or dipping. The substance is also used for painting both by professionals and by consumers.

Tonnage information:

Assessed tonnage: 320 tonnes/year based on:

- 320 tonnes/year manufactured

Tonnage supplied per market sector:

- Market sector: PC9a (Coating and inks): 200 tonnes/year
- Market sector: PC24 (Lubricants): 120 tonnes/year

The following table list all the exposure scenarios (ES) assessed in this CSR.

Notes and Comments

Re: Overview on uses

d) Exposue scenarios for the lubricant products have not been developed in this illustrative example CSR. These would normally be included in the table below and in section

e) Where appropriate, exposure scenarios should address article service life. These are not included in this illustrative example CSR (only mentioned as unidentified Exposure Scenario ESx)

Table 9.1 Overview of exposure scenarios and contributing scenarios

Identifiers	Market Sector	Titles of exposure scenarios and the related contributing scenarios.	Tonnage (tonnes per year)
ES1 - M1	-	Manufacture of the substance - Manufacture in contained systems (ERC1) - Closed manufacturing process (PROC 1) - Maintenance and cleaning operation (PROC 8a)	320.0
ES2- F1	-	Formulation of liquid mixtures - Formulation of mixtures in closed and open systems (ERC2) - Receiving and charging of the substance (PROC 8b) - Mixing, dispersing, completion in closed batch process (PROC 3) - Mixing, dispersing, completion in open multistage batch process (PROC 5) - Transfer in non-dedicated facilities (PROC 8a) - Transfer at dedicated facilities (PROC 8b) - Filling small containers in dedicated lines (PROC 9) - Maintenance and cleaning operation (PROC 8a)	320.0
ES3-IW1	PC 9a	General industrial use of coatings and inks - Industrial use of coatings and inks involving water (low volatiles, low water solubility) (ERC 5) - Industrial use of coatings and inks water free (low volatiles) (ERC5) - Application of coatings and inks in closed systems with occasional exposure (PROC 2) - Raw material receipt and transfers (PROC 8b) - Preparation of coatings and inks for application (PROC 5) - Batch loading of equipment (manual, non-dedicated) (PROC 8a) - Spray coating – any technique (PROC 7) - Brushing, roller, spreader, flow coating or printing – any technique (PROC 10) - Dipping and pouring, - any technique (PROC 13) - Curing and drying processes after application – Elevated temperatures (PROC 2) - Manual cleaning and maintenance of equipment (PROC 8a) ➢ Related Subsequent service life : ESx	100.0
ES4- PW1	PC 9a	Professional painting - Use leading to inclusion into/onto matrix (ERC 8f) - Transfer in non dedicated facilities (PROC 8a) - Roller and brushing (PROC 10) - Professional spraying (PROC 11) ➢ Related Subsequent service life : ESx	50.0
ES5- C1	PC 9a	Consumer painting	50.0

Identifiers	Market Sector	Titles of exposure scenarios and the related contributing scenarios.	Tonnage (tonnes per year)
		- Use leading to inclusion into/onto matrix (ERC 8f) - Use in water-borne wall paints (PC9a) - Use in rich solvent paints (PC9a) ➢ Related Subsequent service life : ESx	
Manufacture: M-#, Formulation: F-#, Industrial end use: IW-#, Professional end use: PW-#, Consumer end use: C-#, Service life (by workers in industrial settings): SL-IW-#, Service life (by professional workers): SL-PW-#, Service life (by consumers): SL-C-#.)			

9.0.2 Assessment of exposure to the environment

9.0.2.1 Scope and type of the assessment

The scope of exposure assessment and type of risk characterisation required for the environment are described in the following table. This is based on the hazard conclusions reported and justified in section 7.

Table 9.2 Type of risk characterisation required for the environment

Protection target	Type of risk characterisation	Hazard conclusion (see section 7)
Fresh water	**Quantitative**	**PNEC =** 0,010 mg/l
Fresh water sediment	**Quantitative**	**PNEC =** 0,84 mg/kg dw
Marine water	**Quantitative**	**PNEC =** 0,0010 mg/l
Marine water sediment	**Quantitative**	**PNEC =** 0,084 mg/kg dw
Sewage treatment plant	**Quantitative**	**PNEC =** 1,5 mg/l
Air	**Not needed**	**No hazards identified related to composition of atmosphere**
Soil	**Quantitative**	**PNEC =** 0,16 mg/kg dw
Predators (food chain)	**Not needed**	**No hazards identified**

9.0.2.2 Comments on assessment approach

A quantitative assessment was carried out for all environmental protection targets except for air and for predators, for which no hazard had been identified.

The release estimation for the industrial scenarios is based on the following methods:

- Site related information (see manufacturing ES);
- Literature sources (OECD Emission Scenario Documents) (see formulation ES);
- Specific Environmental Release Categories (SPERCs) (see general industrial use of coatings and inks ES).

Release estimation for wide dispersive use (namely professional and consumer uses) were based on default ERC release factors.

The regional concentrations are reported in section 10.6 (see Table 10.48). The local Predicted Exposure Concentrations (PECs) reported for each contributing scenario correspond to the sum of the local concentrations (Clocal) and the regional

concentrations (PEC regional).

Potential risks to environmental compartments were evaluated using fate and transport model EUSES 2.1 and release module as implemented in Chesar 1.2.

The relevant OC and RMM (reported in the ES) driving the release factors (reported in corresponding exposure estimation section) reflect typical condition of use applied at manufacturing site or by downstream users.

Notes and Comments

Re Environment risk assessment

a) ECHA Substance is classified for the environment with Aquatic Chronic Category 3 (H412), based on short-term toxicity studies. The hazard identified for aquatic organisms is extrapolated to sediments and soil with the equilibrium portioning method. Exposure assessment as therefore carried out for water, soil and sediments (see also ECHA Guidance on Information Requirements Part B Chapter 8 (Scope of Exposure Assessment, Figure B-8-3).

b) Assessment on secondary poisoning is not mandatory, as the substance does not have any of the classifications for human health mentioned in the Scope of Exposure Assessment Guidance to trigger the detailed assessment on secondary poisoning.

c) The substance is not readily biodegradable and the PNEC is low/medium. Safe use at industrial sites cannot be demonstrated using default ERC factors for release rate estimation, except for wide dispersive uses. Consequently more appropriate release factors were used. It has been assumed that a suitable SpERC may become available in future from the relevant downstream user organisation. For the time being, the emission factors and the related conditions of use reported in this example are based on expert judgement in ECHA and may need to be refined once the corresponding SpERCs become available.

d) The substance is not regarded as PBT nor vPvB. Consequently no emission minimisation is required

e) Regarding waste, the minimum information expected to be reported in the CSR related to waste are special considerations on waste treatment (if any) and the fraction of substance becoming waste.

f) See ECHA Guidance on Information Requirements and CSA Chapter R16 for details on environmental exposure assessment

9.0.2.3 Man via environment

9.0.3 Assessment of exposure to men via environment

9.0.3.1 Scope and type of assessment

The scope of exposure assessment and type of risk characterisation required for man via the environment are described in the following table. This is based on the hazard conclusions reported and justified in section 5.11.

Table 9.3 Type of risk characterisation required for man via environment

Route of exposure and type of effects	Type of risk characterisation	Hazard conclusion (see section 5.11)
Inhalation: Long term, Systemic	**Quantitative**	DNEL = 6.1 mg/m3
Oral: Long term, Systemic	**Quantitative**	DNEL = 3.5 mg/kg bw /day

9.0.4 Assessment of exposure to workers

9.0.4.1 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 reported and justified in section 5.11.

Table 9.4 Type of risk characterisation required for workers

Route	Type of effect	Type of risk characterisation	Hazard conclusion (see section 5.11)
Inhalation	Systemic effect / Long-term	Quantitative	DNEL = 24.7 mg/m3
	Systemic effect / Acute	Not required	No hazard identified
	Local effect / Long-term	Qualitative	No data available (no further information required)
	Local effect / Acute	Qualitative	No data available (no further information required)
Dermal	Systemic effect / Long-term	Quantitative	DNEL = 7 mg/kg bw /day
	Systemic effect / Acute	Not required	No hazard identified
	Local effect / Long-term	Qualitative	Low hazard
	Local effect / Acute	Qualitative	Low hazard
Eyes	Local effect	Qualitative	Low hazard

9.0.4.2 Comments on assessment approach:

A quantitative assessment was carried out for long term systemic hazards via skin and inhalation. The exposure of workers was estimated primarily using the ECETOC TRA (April 2012 version 3) modelling tool. The following approaches were taken:

1. For industrial use of spray coating, measured exposure data was available and was used to support the exposure estimation from ECETOC TRA. The amount of measured data available was insufficient to use as the primary estimate of exposure levels

2. For professional uses of coating by spraying and by roller/brush application Stoffenmanager (Tier II model) was used to demonstrate safe use of the substance

Adverse systemic health effects were not associated with short term inhalation and dermal routes. Consequently, short term and peak exposures were not quantitatively assessed.

A qualitative assessment was carried out with respect to irritation for all routes, based on a categorisation of "low hazard". The "low hazard" is assigned based on the control banding concept as described in ECHA Guidance on IR&CSA, Part E, Table E.3-1. The OC/RMM for safe use based on a quantitative assessment were evaluated as to whether they provide sufficient protection against adverse irritation effects, or whether additional measures are needed.

- For respiratory exposure, the qualitative assessment is limited to aerosol forming conditions and open processes under elevated temperature. This is because the vapour pressure of the substance is relatively low

- For use in mixtures with concentration < 10% (concentration cut off for classification of mixtures), the hazard is considered negligible and thus no risk management of any of exposure routes is needed. This is based on the "low hazard" categorisation for the pure substance (see above) and the assumption that the dermal local irritation hazard further decreases when diluted to below the classification limit.

The criteria for selection of OC/RMM are summarized here below:

1. The minimum RMM necessary was applied to ensure the exposure levels are safe (covering all relevant endpoints, and the combined risk) taking into account for uncertainty of exposure estimation.

2. If technically feasible, engineering controls such as LEV have been recommended as preferred RMM option to reduce risk for industrial workers in accordance with good occupational hygiene practice.

9.0.4.3 Common risk management measures for workers

The main specifications for personal protective equipment (PPE) appropriate for ECHA Substance are as follows:

Respiratory Protective Equipment: Filter type A. To be combined with particulate filter when there is potential for exposure to aerosol, for example, in spraying operations

Gloves: Butyl rubber gloves conforming to EN374, with thickness of > 0.7mm. Breakthrough time to be greater than task duration. Gloves should be worn when there is potential for dermal exposure.

Notes and Comments

Re: Worker Risk Assessment

a) The Ecetoc TRA approach was not considered optimal for assessing the exposure due to aerosol formation, so supporting measurements or alternative tools were used

b) Note that particular caution needs to be applied when estimating dermal exposure. While using TRA workers, the default option is that LEV is not appropriate for control of dermal exposure. The default option should always be applied, unless specific considerations apply.

c) Regarding the qualitative assessment for inhalation irritancy, no exposure scenarios in this example involves aerosol formation or elevated temperature in open system of the concentrated substance. Hence, a detailed qualitative assessment for inhalation irritancy was not required.

d) The advice contained in the introductory note regarding selection of OC/RMM's was followed. Specifying the minimum OC/RMM necessary for safe use avoids creating difficulties for downstream users. It is possible that RPE is not required by these criteria, but a site based risk assessment would find it necessary.

e) Regarding PPE, details regarding effectiveness, filter type, glove material and breakthrough time were provided. Specific advice on usage, exact type, frequency of filter or glove changing etc. was not included as that should be based on the local risk assessment.

f) PPE was used to protect against dermal and eye irritancy when dealing with concentrated substance, whenever there was potential for exposure (based on qualitative assessment). In the formulated product, the substance was diluted to below the cut-off limits for eye and dermal irritancy classification. Consequently PPE was not recommended further down the supply chain except if required to protect against long term systemic health effects.

g) When PPE is recommended in the exposure scenario, it should be worn during the identified tasks when there is potential for exposure. Where there is potential for dermal exposure to areas other than hands (arms/face etc.), additional protective equipment (such as protective clothing, gauntlets, aprons, face shields etc.) should be worn. It is assumed that a comprehensive PPE program is implemented including selection, fit testing, training in use, maintenance and recording, as appropriate.

h) See Chapter R14 of guidance on information requirements and CSA for details on occupational exposure assessment.

9.0.5 Assessment of exposure to consumers

9.0.5.1 Scope and type of assessment

The scope of exposure assessment and type of risk characterisation required for consumers are described in the following table based on the hazard conclusions reported and justified in section 5.11.

Table 9.5 Type of risk characterisation required for consumers

Route	Type of effect	Type of risk characterisation	Hazard conclusion (see section 5.11)
Inhalation	Systemic effect / Long-term	Quantitative	DNEL = 6.08 mg/m3
	Systemic effect / Acute	Not required	No hazard identified
	Local effect / Long-term	Qualitative	No data available (no further information required)
	Local effect / Acute	Qualitative	No data available (no further information required)
Dermal	Systemic effect / Long-term	Quantitative	DNEL = 3.5 mg/kg bw /day
	Systemic effect / Acute	Not required	No hazard identified
	Local effect / Long-term	Qualitative	Low hazard
	Local effect / Acute	Qualitative	Low hazard
Oral	Systemic effect / Long-term	Quantitative	DNEL = 3.5 mg/kg bw/day
	Systemic effect / Acute	Not required	No hazard identified
Eyes	Local effect	Qualitative	Low hazard

9.0.5.2 Comments on assessment approach:

Consumer exposure was assessed using Tier 2 tools (Consexpo 4.1), since Tier 1 (ECETOC TRA, Consumers v.2) tools were not able to demonstrate the safe use of the substance for consumer use of paints. Consexpo 4.1 has been used in connection with relevant RIVM fact sheet to cover consumer use of different products (water borne and solvent rich).

Notes and Comments

Re: Consumer Risk Assessment

a) Consexpo 4.1, a Tier II tool based on an evaporation model, was the exposure estimation tool used for consumer exposure. The RCR determined using ECETOC TRA Consumer v.2 model was > 1. This was considered to be overly conservative. This is mainly due to the fact that, despite the low volatility of ECHA Substance, it falls into one of the upper volatility bands of the TRA tool. Consequently a Tier II tool, Consexpo 4.1, was used to demonstrate safe use of the substance.

b) Tier II tools like Consexpo generally have more input parameters than Ecetoc TRA. All input parameters should be reported, so that the calculation can be reproduced.

c) See Chapter R15 of guidance on information requirements and CSA for details on consumer exposure assessment

9.1 ES1: Manufacture of the substance

The substance is manufactured in closed continuous process (PROC 1).

Releases to environmental compartments are based on both site information and ERC release factor, taking into account the following assumptions:

- No water releases occur since water is not used in the process or for cleaning / maintenance operations; solvents used for such activities are collected and treated as waste.

- Exhausted air from process is collected and send to an onsite incineration unit. An initial release, before RMMs are taken account of, has been estimated using the conservative ERC1 release factor.

- Wastes collected during cleaning and maintenance operation are also incinerated onsite.

The main opportunity for worker exposure is during maintenance and cleaning operations, which involve opening the system for access. This was assessed using PROC 8a use descriptor (transfer of substance from/to vessels at non-dedicated facilities). PROC 8a has been selected because it assumes that there is direct contact with the substance and that there is no particular process design measures to control the exposure.

Regarding the qualitative assessment with respect to irritancy, the following assumptions apply:

- There is negligible potential for exposure during manufacturing tasks, which are closed. Consequently the inhalation risk is low and no additional risk management measures are required.

- There is however potential for contact with the concentrated substance during maintenance and cleaning. The risk management measures required based on the quantitative assessment provide sufficient protection against any irritancy hazard. tasks,

Environment:	
Manufacture in contained systems	ERC 1
Worker	
Closed manufacturing process	PROC 1
Maintenance and cleaning operation	PROC 8a

Notes and Comments

Re: Content of Introductory section to exposure assessments

This section should:

- provide a clear and concise description of the activities/processes covered in the exposure scenario,
- highlight where methodology applied deviates from standard methodology described previously
- identify main events where exposure to humans and environment occurs
- address qualitative assessment if appropriate
- provide any additional information to assist reader in correctly interpreting the exposure scenarios

Re: REACH and site based risk assessments

It is useful to distinguish between REACH CSAs and site-based risk assessments and be aware of how they complement one another. The REACH CSA provides hazard information and conditions for safe use for a given substance. Site based risk assessments are undertaken in accordance with national Environmental Health Safety legislation and should ensure that the RMM's proposed in the REACH exposure scenario are adequate and appropriate. Site based assessments should take into consideration the combined effect of all substances present, and of all activities and waste sources on the site.

9.1.1 ES1: Exposure scenario for Manufacture of the substance

9.1.1.1 ES1: Control of environmental exposure: Manufacture in contained system

Amount used, frequency and duration of use (or from service life)
• Daily use at a site: <= 16 tonnes/day • Annual use at a site: <= 320 tonnes/year • Percentage of tonnage used at regional scale: = 100 %
Technical and organisational conditions and measures
• Water used in process or maintenance (cleaning) operation: No • Exhaust air treatment: Onsite incineration [Effectiveness Air: 99%]
Conditions and measures related to sewage treatment plant
• Municipal STP: No
Conditions and measures related to treatment of waste (including article waste)
• Specific conditions of waste treatment: Required. Waste is incinerated on site by incineration conforming to standard as laid down in 2000/76/EC Directive. When incinerated on site full decomposition is expected and thus releases are negligible
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 1.8E4 m3/d • Effluent discharge rate: <= 2E3 m3/d

9.1.1.2 ES1: Control of workers exposure for "Closed manufacturing process" [PROC 1]

	Method
Product (article) characteristics	
• Concentration of substance in mixture: Substance as such (100%)	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA worker V3
Technical and organisational conditions and measures	
• Containment: Closed system (minimal contact during routine operations)	TRA worker V3
• Occupational Health and Safety Management System: Advanced	TRA worker V3
• Local Exhaust Ventilation: No [Effectiveness inhalation: 0%].	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness inhalation: 0%].	TRA worker V3
• Dermal Protection: No [Effectiveness Dermal: 0%]	TRA worker V3
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 40 C	TRA worker V3
• Place of use: Indoors	TRA worker V3
• Body surface potentially exposed: One hand face only (240 cm2)	TRA worker V3

9.1.1.3 ES1: Control of workers exposure for "Maintenance and cleaning operation" [PROC 8a]

Further specification: it includes manual cleaning of open vessels

	Method
Product (article) characteristics	
• Concentration of substance in mixture: Substance as such (100%)	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 4 hour	TRA worker V3
Technical and organisational conditions and measures	
• Containment: No	TRA worker V3
• Occupational Health and Safety Management System: Advanced	TRA worker V3
• Local Exhaust Ventilation: No [Effectiveness inhalation: 0%]	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: Yes (Respirator with APF of 10) [Effectiveness inhalation: 90%].	TRA worker V3
• Dermal protection: Yes (chemically resistant gloves conforming to EN374 with basic employee training). [Effectiveness Dermal: 90%].	TRA worker V3
• Eye protection: Yes (chemically resistant face shield, goggles or safety glasses with side shields when there is potential for direct contact).	
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 40 C	TRA worker V3
• Place of use: Indoors	TRA worker V3
• Body surface potentially exposed: Two hands & face (960 cm2)	TRA worker V3

9.1.2 ES 1: Exposure estimation for Manufacture of the substance

9.1.2.1 Environmental Exposure for Manufacture in contained system

9.1.2.1.1 Environmental releases

Table 9.6 ES1: Summary of the local releases to the environment

Compartment	Release factor estimation method	Explanation / Justification
Water	Release factor	**Initial release factor (%): 0** **Release factor after onsite risk management (%):**

Compartment	Release factor estimation method	Explanation / Justification
		0 **Local release rate (kg/day):** 0 **Explanation/Justification:** Closed system. No water used in the process or for cleaning equipment/maintenance operation
Air	ERC (ERC 1)	**Initial release factor (%): 5** **Release factor after onsite risk management (%): 0.05** **Explanation/Justification:** Very conservative initial release factor of 5% (ERC 1) was assumed. Exhaust air is then treated in onsite incineration unit with 99% of effectiveness.
Soil	Release Factor	**Initial release factor (%):** 0 **Explanation/Justification:** Closed system. No release to soil

Table 9.7 ES1: Summary of the local releases to the waste

Compartment	Release factor to waste	Explanation / Justification
Waste from the process	6%	Conservative assumption based on ERC release factor to wastewater
Waste from on site treatment of discharges	0%	Waste containing substance is incinerated on site. No waste containing ECHA substance is expected to be generated from incineration process

Summed releases from all life cycle stages: see section 9.0.3.

Notes and Comments

Re: Release Estimation Refinement

Release estimation from the manufacturing stage exemplifies the case where no measured data is available but information on processes and RMM driving release to environment are well known.

- Release to water has been assumed to be 0 since the process is water free (cleaning operation included). For release to air, a conservative assumption for the initial release has been made, using the ERC release factor of 5%.
- Exhaust air is incinerated on-site, which is assumed to reduce the emissions by a factor of 100. Similary, there is no direct release to soil.
- Release to waste from the process has been conservatively set to 6% (assuming that potential release to water, described by ERC release factor, are transferred to waste). This is the minimum information to be reported in the CSR for the waste stage

These OC/RMM for reducing or avoiding releases are reported in the environmental CS, section 9.1.1.

9.1.2.1.2 Environmental exposure

Table 9.8 ES1: Summary of exposure concentrations

Protection target	Exposure concentration	Explanation / Justification
Water: Fresh Water (Pelagic)	**Local PEC:** 2.84E-6 mg/L **Local concentration:** 0 mg/L	
Water: Fresh Water (Sediment)	**Local PEC:** 2.31E-4 mg/kg dw	
Water: Marine Water (Pelagic)	**Local PEC:** 3.36E-7 mg/L **Local concentration:** 0 mg/L	
Water: Marine Water (Sediment)	**Local PEC:** 2.73E-5 mg/kg dw	
Water: Sewage Treatment Plant (Effluent)	**Local PEC:** 0 mg/L	
Air	**Local PEC:** 1.23E-4 mg/m³ **Local concentration:** 1.22E-4 mg/m³	
Soil: Agricultural Soil	**Local PEC:** 1.84E-4 mg/kg dw **Local concentration:** 1.82E-4 mg/kg dw	

For regional PECs see section 10.6

9.1.2.1.3 Indirect exposure of humans via the environment

Exposure via inhalation

The exposure concentrations in air are reported in the Table "Summary of exposure concentrations" of the preceding section 9. 1.2.1.2 "Environmental exposure".

Exposure via food consumption: Total daily intake for humans

Table 9.9 ES1: Summary of estimated daily human doses and concentrations in food

Type of food	Daily human dose through intake		Explanation / Justification
	Total estimated daily intake for humans: 2.635E-4 mg/kg bw/day		
	Estimated daily dose through intake from local exposure	Concentration in food from local exposure	
Drinking water	3.36E-7 mg/kg bw/day	1.18E-5 mg/L	
Fish	1.89E-5 mg/kg bw/day	0.012 mg/kg	
Leaf crops	2.1E-4 mg/kg bw/day	0.012 mg/kg	
Root crops	2.7E-5 mg/kg bw/day	0.005 mg/kg	
Meat	4.56E-6 mg/kg bw/day	0.001 mg/kg	
Milk	2.69E-6 mg/kg bw/day	3.36E-4 mg/kg	
	Dose from regional exposure: see section 10.6		

9.1.2.2 Exposure estimation of Worker for Closed manufacturing process (PROC 1)

Table 9.10 ES1: Summary of exposure concentrations for contributing scenario: Closed manufacturing process

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	0.13 mg/m³	**Method:** TRA workers v.3	
Dermal: Long term, Systemic	0.034 mg/kg bw/day	**Method:** TRA workers v.3	

9.1.2.3 Exposure estimation of Worker for Maintenance and cleaning operation (PROC 8a)

Table 9.11 ES1: Summary of exposure concentrations for contributing scenario: Maintenance and cleaning operation

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	7.5 mg/m³	**Method:** TRA workers v.3	
Dermal: Long term, Systemic	1.4 mg/kg bw/day	**Method:** TRA workers v.3	

9.2 ES2: Formulation of liquid mixtures

Formulation refers to the mixing of raw materials to produce paints, coatings and inks and filling into containers in dedicated facilities.

Formulation processes which require worker intervention include: receiving and charging the substance; use in closed or open batch processes; transfer of the mixtures and filling small to medium sized containers. Maintenance and cleaning operations are also included.

The environmental emission estimates for coatings and inks are based on emission scenarios developed by OECD by UK's Environment Protection Agency (2009).

The main opportunity for worker exposure arises from open process and maintenance cleaning operations.

Regarding the qualitative assessment with respect to irritancy, the following assumptions apply:

- There is no potential for aerosol generation. Consequently the inhalation risk is low and no additional risk management measures are required.
- There is potential for dermal exposure to the pure substance and eye contact during most of the tasks, but particularly during receipt and transfer, during formulation and during maintenance and cleaning of formulation equipment. Consequently, use of appropriate dermal and eye protection is required whenever such exposure could occur.

Environment:	
Formulation of mixtures in closed and open systems	ERC 2
Worker	
Receiving and charging of the substance	PROC 8b
Mixing, dispersing, completion in closed batch process	PROC 3
Mixing, dispersing, completion in open multistage batch process	PROC 5

Transfer in non-dedicated facilities	PROC 8a
Transfer at dedicated facilities	PROC 8b
Filling small containers in dedicated lines	PROC 9
Maintenance and cleaning operation	PROC 8a

9.2.1 ES2: Exposure scenario for Formulation of liquid mixtures

9.2.1.1 ES2: Control of environmental exposure: Formulation of mixtures in closed and open systems

Amount used, frequency and duration of use (or from service life)
• Daily use at a site: <= 0.5 tonnes/day   • Annual use at a site: <= 100 tonnes/year • Percentage of tonnage used at regional scale: = 100 %
Technical and organisational conditions and measures
• Collect water from equipment/drums cleaning as waste: Yes [Effectiveness water: 100%]
Conditions and measures related to municipal sewage treatment plant
• Municipal STP: No
Conditions and measures related to treatment of waste (including article waste)
• Specific conditions of waste treatment: Required. Off site incineration of the waste containing substance as laid down in 2000/76/EC Directive. When disposed of via incineration full decomposition is expected and thus releases are negligible
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 1.8E4 m3/d • Effluent discharge rate: <= 2E3 m3/d

9.2.1.2 ES2:Control of workers exposure for "Receiving and charging the substance" [PROC 8b]

	Method
Product (article) characteristics	
• Concentration of substance in mixture: Substance as such (100%)	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hours	TRA worker V3
Technical and organisational conditions and measures	
• Containment: Semi-closed process with occasional controlled exposure	TRA worker V3
• Occupational Health and Safety Management System: Advanced	TRA worker V3
• Local Exhaust Ventilation: No [Effectiveness Inhalation: 0%]	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA worker V3
• Dermal protection: Yes (chemically resistant gloves conforming to EN374) [Effectiveness Dermal: 80%]	TRA worker V3
• Eye protection: Yes (chemically resistant face shield, goggles or safety glasses with side shields when there is potential for direct contact).	
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 40 C	TRA worker V3
• Place of use: Indoor	TRA worker V3
• Body surface potentially exposed: Two hands (960 cm2)	TRA worker V3

9.2.1.3 ES2: Control of workers exposure for "Mixing, dispersing, completion in closed batch process" [PROC 3]

	Method
Product (article) characteristics	
• Concentration of substance in mixture: Substance as such (100%)	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA worker V3
Technical and organisational conditions and measures	
• Containment: Closed batch process with occasional controlled exposure	TRA worker V3
• Occupational Health and Safety Management System: Advanced	TRA worker V3
• Local Exhaust Ventilation: Yes [Effectiveness Inhalation: 90%]	TRA worker V3
• Local exhaust ventilation (for dermal): No [Effectiveness Dermal: 0%]	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA worker V3
• Dermal protection: Yes (chemically resistant gloves *conforming to EN374) [Effectiveness Dermal: 80%]	TRA worker V3
• Eye protection: Yes (chemically resistant face shield, goggles or safety glasses with side shields when there is potential for direct contact).	
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 40 C	TRA worker V3
• Place of use: Indoor	TRA worker V3
• Body surface potentially exposed: One hand face only (240 cm2)	TRA worker V3

* Dermal protection is required based on a qualitative assessment, and not on the quantitative assessment

9.2.1.4 ES2: Control of workers exposure for "Mixing, dispersing, completion in open multistage batch process" [PROC 5]

	Method
Product (article) characteristics	
• Concentration of substance in mixture: Substance as such (100%)	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA worker V3
Technical and organisational conditions and measures	
• Containment: No	TRA worker V3
• Occupational Health and Safety Management System: Advanced	TRA worker V3
• Local Exhaust Ventilation: Yes [Effectiveness Inhalation: 90%]	TRA worker V3
• Local exhaust ventilation (for dermal): No [Effectiveness Dermal: 0%]	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA worker V3
• Dermal protection: Yes (chemically resistant gloves conforming to EN374) [Effectiveness Dermal: 80%]	TRA worker V3
• Eye protection: Yes (chemically resistant face shield, goggles or safety glasses with side shields when there is potential for direct contact)	
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 40 C	TRA worker V3
• Place of use: Indoor	TRA worker V3
• Body surface potentially exposed: Two hands face (480 cm2)	TRA worker V3

9.2.1.5 ES2: Control of workers exposure for "Transfer in non-dedicated facilities" [PROC 8a]

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1 – 5%	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA worker V3
Technical and organisational conditions and measures	
• Containment: No	TRA worker V3
• Occupational Health and Safety Management System: Advanced	TRA worker V3
• Local Exhaust Ventilation: No [Effectiveness Inhalation: 0%]	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA worker V3
• Dermal protection: No [Effectiveness Dermal: 0%]	TRA worker V3
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 40 C	TRA worker V3
• Place of use: Indoor	TRA worker V3
• Body surface potentially exposed: Two hands (960 cm2)	TRA worker V3

9.2.1.6 ES2: Control of workers exposure for "Transfer at dedicated facilities" [PROC 8b]

Further specification: Covers also transfer of process waste to storage containers

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1 – 5%	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA worker V3
Technical and organisational conditions and measures	
• Containment: Semi-closed process with occasional controlled exposure	TRA worker V3
• Occupational Health and Safety Management System: Advanced	TRA worker V3
• Local Exhaust Ventilation: No [Effectiveness Inhalation: 0%]	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA worker V3
• Dermal protection: No [Effectiveness Dermal: 0%]	TRA worker V3
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 40 C	TRA worker V3
• Place of use: Indoor	TRA worker V3
• Body surface potentially exposed: Two hands (960 cm2)	TRA worker V3

9.2.1.7 ES2: Control of workers exposure for "Filling small containers in dedicated lines" [PROC 9]

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1 – 5%	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hour	TRA worker V3
Technical and organisational conditions and measures	
• Containment: Semi-closed process with occasional controlled exposure	TRA worker V3
• Occupational Health and Safety Management System: Advanced	TRA worker V3
• Local Exhaust Ventilation: No [Effectiveness Inhalation: 0%]	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA worker V3
• Dermal protection: No [Effectiveness Dermal: 0%]	TRA worker V3
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 40 C	TRA worker V3
• Place of use: Indoor	TRA worker V3
• Body surface potentially exposed: Two hands face (480 cm2)	TRA worker V3

9.2.1.8 ES2: Control of workers exposure for "Maintenance and cleaning operation" [PROC 8a]

Further specification: Covers maintenance and cleaning operation of equipment where undiluted substance is used

	Method
Product (article) characteristics	
• Concentration of substance in mixture: Substance as such (100%)	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 4 hour	TRA worker V3
Technical and organisational conditions and measures	
• Containment: No	TRA worker V3
• Occupational Health and Safety Management System: Advanced	TRA worker V3
• Local Exhaust Ventilation: No [Effectiveness Inhalation: 0%]	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: Yes (Respirator with APF of 10) [Effectiveness Inhalation: 90%]	TRA worker V3
• Dermal protection: Yes (chemically resistant gloves conforming to EN374) [Effectiveness Dermal: 80%]	TRA worker V3
• Eye protection: Yes (chemically resistant face shield, goggles or safety glasses with side shields when there is potential for direct contact)	-
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 40 C	TRA worker V3
• Place of use: Indoor	TRA worker V3
• Body surface potentially exposed: Two hands (960 cm2)	TRA worker V3

9.2.2 ES2: Exposure estimation for Formulation of liquid mixtures

9.2.2.1 Exposure estimation for the environment (Formulation of mixtures in closed and open systems)

9.2.2.1.1 Environmental releases

Table 9.12 ES2:Summary of the local releases to the environment

Compartment	Release factor estimation method	Explanation / Justification
Water	Release factor	**Initial release factor (%):** 1 **Release factor after onsite risk management (%):** 0 **Local release rate (kg/day):** 0 **Explanation/Justification:** Adapted from the EMISSION SCENARIO DOCUMENT ON COATINGS INDUSTRY (PAINTS, LACQUERS AND VARNISHES), OECD, July 2009. Release factor for liquid substances to waste or wastewater is possibly only via equipment and/or packaging cleaning, with an expected maximum fraction released to waste or wastewater equal to 1% (OECD 2009). Fluids used for cleaning equipment or packaging containing substance should be collected as waste and sent to external waste treatment, so that release to wastewater has been set equal to 0%.
Air	Release factor	**Initial release factor (%):** 0.6 **Release factor after onsite risk management (%):** 0.6 **Local release rate (kg/day):** 3 **Explanation/Justification:** Taken from the EMISSION SCENARIO DOCUMENT ON COATINGS INDUSTRY (PAINTS, LACQUERS AND VARNISHES), OECD, July 2009. It is based on worst case release factor for low volatility substance (<1000 Pa) and high boiling point (> 120°C)
Soil	Release factor	**Initial release factor (%):** 0 **Explanation/Justification:** No release to soil

Table 9.13 ES2: Summary of the local releases to the waste

Compartment	Release factor to waste	Explanation / Justification
Waste from the process	1%	Substance in waste comes from packaging material and cleaning fluids (ref. OECD, 2009)
Waste from on site treatment of discharges	0%	No RMM assumed

Summed releases from all life cycle stages: see section 9.0.3.

Notes and Comments

Re: Release Estimation Refinement

a) The default release factors overestimate the releases. In practice, releases to water are possible only via the cleaning operation. OECD ESD (Emission Scenario Documents) on Coating Industry (Paints, Lacquers and Varnishes) 2009, was used as supportive source to refine the release estimation for water. The same source was used to establish the release factor to air, according to vapour pressure and boiling point.

b)There is no potential for direct release to soil, based on both the OECD ESD, and from knowledge of the process.

c) Justification and explanation on the release factors are reported in the exposure table above, while conditions of use driving release factor (e.g. collecting water for equipment or packaging cleaning as waste) are clearly reported Contributing Scenarios for environment.

9.2.2.1.2 Environmental exposure

Table 9.14 ES2:Summary of exposure concentrations (Formulation of mixtures in closed and open systems)

Protection target	Exposure concentration	Explanation / Justification
Water: Fresh Water (Pelagic)	**Local PEC:** 2.84E-6 mg/L **Local concentration:** 0 mg/L	
Water: Fresh Water (Sediment)	**Local PEC:** 2.31E-4 mg/kg dw	
Water: Marine Water (Pelagic)	**Local PEC:** 3.36E-7 mg/L **Local concentration:** 0 mg/L	
Water: Marine Water (Sediment)	**Local PEC:** 2.73E-5 mg/kg dw	
Water: Sewage Treatment Plant (Effluent)	**Local PEC:** 0 mg/L	
Air	**Local PEC:** 4.58E-4 mg/m³ **Local concentration:** 4.57E-4	

Protection target	Exposure concentration	Explanation / Justification
	mg/m³	
Soil: Agricultural Soil	**Local PEC:** 6.86E-4 mg/kg dw **Local concentration:** 6.84E-4 mg/kg dw	

For regional PECs see section 10.6

9.2.2.1.3 Indirect exposure of humans via the environment

Exposure via inhalation

The exposure concentrations in air are reported in the Table "Summary of exposure concentrations" of the preceding section 9.2.2.1.2 "Environmental exposure".

Exposure via food consumption: Total daily intake for humans

Table 9.15 ES2: Summary of estimated daily human doses and concentrations in food

Type of food	Daily human dose through intake		Explanation / Justification
	Total estimated daily intake for humans: 9.302E-4 mg/kg bw/day		
	Estimated daily dose through intake from local exposure	Concentration in food from local exposure	
Drinking water	1.25E-6 mg/kg bw/day	4.38E-5 mg/L	
Fish	1.89E-5 mg/kg bw/day	0.012 mg/kg	
Leaf crops	7.83E-4 mg/kg bw/day	0.046 mg/kg	
Root crops	1E-4 mg/kg bw/day	0.018 mg/kg	
Meat	1.7E-5 mg/kg bw/day	0.004 mg/kg	
Milk	1E-5 mg/kg bw/day	0.001 mg/kg	
	Dose from regional exposure: see section 10.6		

9.2.2.2 Exposure estimation for Worker for Receiving and charging of the substance (PROC 8b)

Table 9.16 ES2: Summary of exposure concentrations for contributing scenario: Receiving and charging of the substance

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	12.5 mg/m³	**Method:** TRA workers v.3	
Dermal: Long term, Systemic	2.7 mg/kg bw/day	**Method:** TRA workers v.3	

9.2.2.3 Exposure estimation for Worker for Mixing, dispersing, completion in closed batch process (PROC 3)

Table 9.17 ES2: Summary of exposure concentrations for contributing scenario: Mixing, dispersing, completion in closed batch process

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	3.8 mg/m³	**Method:** TRA workers v.3	
Dermal: Long term, Systemic	0.14 mg/kg bw/day	**Method:** TRA workers v.3	

9.2.2.4 Exposure estimation for Worker for Mixing, dispersing, completion in open multistage batch process (PROC 5)

Table 9.18 ES2: Summary of exposure concentrations for contributing scenario: Mixing, dispersing, completion in open multistage batch process

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	6.25 mg/m³	**Method:** TRA workers v.3	
Dermal: Long term, Systemic	2.74 mg/kg bw/day	**Method:** TRA workers v.3	

9.2.2.5 Exposure estimation for Worker for Transfer in non dedicated facilities (PROC 8a)

Table 9.19 ES2: Summary of exposure concentrations for contributing scenario: Transfer in non- dedicated facilities

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation:	5 mg/m³	**Method:** TRA workers	

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Long term, Systemic		v.3	
Dermal: Long term, Systemic	2.74 mg/kg bw/day	**Method:** TRA workers v.3	

9.2.2.6 Exposure estimation for Worker for Transfer at dedicated facilities (PROC 8b)

Table 9.20 ES2: Summary of exposure concentrations for contributing scenario: Transfer at dedicated facilities

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	2.5 mg/m³	**Method:** TRA workers v.3	
Dermal: Long term, Systemic	2.74 mg/kg bw/day	**Method:** TRA workers v.3	

9.2.2.7 Exposure estimation for Worker Filling small containers in dedicated lines (PROC9)

Table 9.21 ES2: Summary of exposure concentrations for contributing scenario: Filling small containers in dedicated lines

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	12.5 mg/m³	**Method:** TRA workers v.3	
Dermal: Long term, Systemic	1.37 mg/kg bw/day	**Method:** TRA workers v.3	

9.2.2.8 Exposure estimation for Worker for Maintenance and cleaning operation (PROC 8a)

Table 9.22 ES2: Summary of exposure concentrations for contributing scenario: Maintenance and cleaning operation

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	7.5 mg/m³	**Method:** TRA workers v.3	
Dermal: Long term, Systemic	2.74 mg/kg bw/day	**Method:** TRA workers v.3	

9.3 ES3: General Industrial use of coatings and inks

This scenario covers the industrial use of coatings and inks in a range of processes. This includes closed processes like marking of electronic components, pharmaceutical products and medical devices and.. open application to larger surface areas by spraying, dipping and roller/brush methods. Also auxiliary activities are covered such as: raw material receipt and transfer; preparation of coatings, including mixing; loading of application devices; and tasks following application activities (curing/drying and cleaning/maintenance of equipment).

Two environmental contributing scenarios have been built, one for operations involving water and one for water-free processes. Since the vapour pressure of the substance is low, low potential for release to air is expected

- The processes where water is involved cover wet scrubbing of overspray in spray-painting, electro-deposition coating and equipment cleaning when using waterborne coatings. Wet scrubbing has been identified as the process with the highest expected release rate to water.

- One contributing scenario covers all processes where no water is involved. .

Releases to the environment have been calculated using SPERC XXX 5.1 v1 developed by xyz (Source: xyz) and the setting for low volatile substances with low water solubility have been selected. . Operational conditions leading to release estimation are reported in the SPERC factsheet, as well as the release factors to water and air, with justifications and reference to supportive documentation.

With respect to worker exposure, the contributing scenarios which pose the greatest potential for exposure are coating tasks and maintenance and cleaning.

Regarding the qualitative assessment with respect to irritancy, the following assumptions apply:

- The substance is diluted to a concentration below that level where dermal, eye and inhalation irritancy is likely to occur. Consequently the risk for all routes is low and no additional risk management measures are required.

Notes and Comments

Re:Risk Management Measures

PPE such as respirator and gloves are often worn during coating tasks, due to the many components in the coating. It is worn especially during tasks involving high chemical emissions such as spraying. If the quantitative and qualitative risk assessment has not identified that PPE is essential to ensure safe use, consider including it as recommended good practice measures measure beyond the scope of REACH rather than as a required measure. Local risk assessments should address the overall risk of all chemicals used on site, based on actual operational conditions and the known effectiveness of risk management measures. Engineering measures to prevent exposure are preferred to PPE.

Re: SPERC

The hypothetical SPERC used in this example was built on an existing SPERC, under development by industry association, to give a better estimate of the release to water and to provide relevant OC. If you apply a SPERC for your assessment the scope and the boundaries of such SpERC should be reported in the CSR. If the SpERC factsheet does not contain sufficient information , contact the developer of the SPERC (usually industry associations)

Market sector:	
PC 9a - Coatings and Paints, Thinners, paint removers	
Environment:	
Industrial use of coatings and inks involving water (low volatiles, low water solubility)	ERC 5
Industrial use of coatings and inks water-free (low volatiles)	ERC5
Worker	
Application of coatings and inks in closed systems with occasional exposure	PROC 2
Raw material receipt and transfers	PROC 8b
Preparation of coatings and inks for application	PROC 5
Batch loading of equipment (manual, non-dedicated)	PROC 8a
Spray coating – any technique	PROC 7
Brushing, roller, spreader, flow coating or printing – any technique	PROC 10
Dipping and pouring, - any technique	PROC 13
Curing and drying processes after application – Elevated temperatures	PROC 2
Manual cleaning and maintenance of equipment	PROC 8a

9.3.1 ES3: Exposure scenario for General Industrial use of coatings and inks

9.3.1.1 ES3: Control of environmental exposure: Industrial use of coatings and inks with water involved (low volatiles, low water solubility)

Further specification: covers wet scrubbers for overspray collections and cleaning of equipment where water based coatings are applied

Amount used, frequency and duration of use (or from service life)
• Daily use at a site: <= 0.02 tonnes/day. Results from maximum daily use suggested in SpERC XXX 5.1 v1 (1 ton/day of coating) and substance concentration in product up to 2% • Annual use at a site: <= 4 tonnes/year • Percentage of tonnage used at regional scale: = 100 %
Technical and organisational conditions and measures
• Material use efficiency: > 30% • Overspray management if relevant: wet scrubber with large reservoir (100 mc) exchanged up to 2 times/year and continuous removal of paint-sludge (to be treated as waste) • Equalizing of waste water from maintenance of wet scrubber (if relevant): Dilution over > 200 emission days. • Collection of water from cleaning of equipment and removal of paint sludge (to be treated as waste) before release: Yes
Conditions and measures related to municipal sewage treatment plant
• Municipal STP: Yes [Effectiveness Water: 22%] • Discharge rate of STP: < 2E3 m3/d • Application of the STP sludge on agricultural soil: Yes
Conditions and measures related to treatment of waste (including article waste)
• Specific conditions of waste treatment: Not needed. Concentration in waste of ECHA Substance is expected to be low.
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 1.8E4 m3/d

9.3.1.2 ES3: Control of environmental exposure: Industrial use of coatings and inks water-free (low volatiles)

Further specification: covers all dry processes where water is not used neither in the product nor after application nor for cleaning purposes

Amount used, frequency and duration of use (or from service life)
• Daily use at a site: <= 0.02 tonnes/day. Results from maximum daily use suggested by CEPE (1 ton/day of coating) and substance concentration in product up to 2% • Annual use at a site: <= 4 tonnes/year • Percentage of tonnage used at regional scale: = 100 %
Technical and organisational conditions and measures
• Material use efficiency : > 30%
Conditions and measures related to municipal sewage treatment plant
• Municipal STP: No
Conditions and measures related to treatment of waste (including article waste)
• Specific conditions of waste treatment: Not needed Concentration in waste of ECHA Substance is expected to be low; if disposed of via incineration according to in 2000/76/EC Directive full decomposition is expected and thus releases are negligible.
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 1.8E4 m3/d
• Effluent discharge rate: < 2E3 m3/d

9.3.1.3 ES3: Control of workers exposure for "Application of coatings and inks in closed systems with occasional exposure" [PROC 2]

Further specification: including raw material feeding and cleaning of equipment

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1 – 5%	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA worker V3
Technical and organisational conditions and measures	
• Containment: Closed continuous process with occasional controlled exposure	TRA worker V3
• Occupational Health and Safety Management System: Advanced	TRA worker V3
• Local Exhaust Ventilation: No [Effectiveness Inhalation: 0%]	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA worker V3
• Dermal protection: No [Effectiveness Dermal: 0%]	TRA worker V3
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 40 C	TRA worker V3
• Place of use: Indoor	TRA worker V3
• Body surface potentially exposed: One hand face only (240 cm2)	TRA worker V3

9.3.1.4 ES3: Control of workers exposure for "Raw material receipt and transfers" [PROC 8b]

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1 – 5%	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA worker V3
Technical and organisational conditions and measures	
• Containment: Semi-closed process with occasional controlled exposure	TRA worker V3
• Occupational Health and Safety Management System: Advanced	TRA worker V3
• Local Exhaust Ventilation: No [Effectiveness Inhalation: 0%]	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA worker V3
• Dermal protection: No [Effectiveness Dermal: 0%]	TRA worker V3
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 40 C	TRA worker V3
• Place of use: Indoor	TRA worker V3
• Body surface potentially exposed: Two hands face (480 cm2)	TRA worker V3

9.3.1.5 ES3: Control of workers exposure for "Preparation of coatings and inks for application" [PROC 5]

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1 – 5%	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA worker V3
Technical and organisational conditions and measures	
• Containment: No	TRA worker V3
• Occupational Health and Safety Management System: Advanced	TRA worker V3
• Local Exhaust Ventilation: No [Effectiveness Inhalation: 0%]	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA worker V3
• Dermal protection: No [Effectiveness Dermal: 0%]	TRA worker V3
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 40 C	TRA worker V3
• Place of use: Indoor	TRA worker V3
• Body surface potentially exposed: Two hands face (480 cm2)	TRA worker V3

9.3.1.6 ES3: Control of workers exposure for " Batch loading of equipment (manual, non-dedicated)" [PROC 8a]

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1 – 5%	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 1 hour	TRA worker V3
Technical and organisational conditions and measures	
• Containment: No	TRA worker V3
• Occupational Health and Safety Management System: Advanced	TRA worker V3
• Local Exhaust Ventilation: No [Effectiveness Inhalation: 0%]	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA worker V3
• Dermal protection: No [Effectiveness Dermal: 0%]	TRA worker V3
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 40 C	TRA worker V3
• Place of use: Indoor	TRA worker V3
• Body surface potentially exposed: Two hands (960 cm2)	TRA worker V3

9.3.1.7 ES3: Control of workers exposure for "Spray coating – any technique" [PROC 7]

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1 – 5%	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA worker V3
Technical and organisational conditions and measures	
• Containment: No	TRA worker V3
• Occupational Health and Safety Management System: Advanced	TRA worker V3
• Local Exhaust Ventilation: Yes [Effectiveness Inhalation: 95%]*	TRA worker V3
• Local exhaust ventilation (for dermal): No [Effectiveness Dermal: 0%]	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA worker V3
• Dermal protection: Yes (chemically resistant gloves conforming to EN374) [Effectiveness Dermal: 80%]	TRA worker V3
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 40 C	TRA worker V3
• Place of use: Indoor	TRA worker V3
• Body surface potentially exposed: Two hands and upper wrists (1500 cm2)	TRA worker V3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Eye/face protection: Chemically resistant face shield and/or goggles, if contact may occur during application	
• Respiratory protection: Yes if exposure to aerosol may occur. Use combined filter	
• Chemical Protective Clothing (CPC): overall and boots recommended to prevent skin contact.	
• High volume low pressure (HVLP) spray gun has higher transfer efficiencies (60-70%) than conventional spray guns (30-40%) with reduced potential for exposure	

* The default LEV effectiveness for industrial spraying in TRA v.3 is 95%, and has been used here. This is appropriate for well designed coating lines and spray booths. If the LEV is likely to be poorer, consider using another method

9.3.1.8 ES3: Control of workers exposure for "Brushing, roller, spreader, flow coating or printing – any technique" [PROC 10]

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1 – 5%	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA worker V3
Technical and organisational conditions and measures	
• Containment: No	TRA worker V3
• Occupational Health and Safety Management System: Advanced	TRA worker V3
• Local Exhaust Ventilation: Yes [Effectiveness Inhalation: 90%]	TRA worker V3
• Local exhaust ventilation (for dermal): No [Effectiveness Dermal: 0%]	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA worker V3
• Dermal protection: No [Effectiveness Dermal: 0%]	TRA worker V3
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 40 C	TRA worker V3
• Place of use: Indoor	TRA worker V3
• Body surface potentially exposed: Two hands (960 cm2)	TRA worker V3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Eye/face protection: Chemically resistant face shield and/or goggles, if contact may occur during application	
• Dermal protection: Chemically resistant gloves when there is potential for dermal exposure	

9.3.1.9 ES3: Control of workers exposure for "Dipping and pouring, - any technique" [PROC 13]

Further specification: covers also after drying of the coating

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1 – 5%	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA worker V3
Technical and organisational conditions and measures	
• Containment: No	TRA worker V3
• Occupational Health and Safety Management System: Advanced	TRA worker V3
• Local Exhaust Ventilation: Yes [Effectiveness Inhalation: 90%]	TRA worker V3
• Local exhaust ventilation (for dermal): No [Effectiveness Dermal: 0%]	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA worker V3
• Dermal protection: No [Effectiveness Dermal: 0%]	TRA worker V3
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 40 C	TRA worker V3
• Place of use: Indoor	TRA worker V3
• Body surface potentially exposed: Two hands face (480 cm2)	TRA worker V3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Eye/face protection: Chemically resistant face shield and/or goggles, if contact may occur during application	
• Dermal protection: Chemically resistant gloves when there is potential for dermal exposure	

9.3.1.10 ES3: Control of workers exposure for "Curing and drying processes after application – Elevated temperatures " [PROC 2]

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1 – 5%	TRA worker V3
• Vapour pressure at elevated temperature: = 300 Pa	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA worker V3
Technical and organisational conditions and measures	
• Containment: Closed continuous process with occasional controlled exposure	TRA worker V3
• Occupational Health and Safety Management System: Advanced	TRA worker V3
• Local Exhaust Ventilation: No [Effectiveness Inhalation: 0%]	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA worker V3
• Dermal protection: No [Effectiveness Dermal: 0%]	TRA worker V3
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 70 C	TRA worker V3
• Place of use: Indoor	TRA worker V3
• Body surface potentially exposed: One hand face only (240 cm2)	TRA worker V3

9.3.1.11 ES3: Control of workers exposure for "Manual cleaning and maintenance of equipment" [PROC 8a]

Further specification: covers also waste collection and transfers

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1 – 5%	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 4 hour	TRA worker V3
Technical and organisational conditions and measures	
• Containment: No	TRA worker V3
• Occupational Health and Safety Management System: Advanced	TRA worker V3
• Local Exhaust Ventilation: No [Effectiveness Inhalation: 0%]	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA worker V3
• Dermal protection: Yes (chemically resistant gloves conforming to EN374) [Effectiveness Dermal: 80%]	TRA worker V3
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 40 C	TRA worker V3
• Place of use: Indoor	TRA worker V3
• Body surface potentially exposed: Two hands (960 cm2)	TRA worker V3

9.3.2 ES3: Exposure estimation for General Industrial use in coatings and inks

9.3.2.1 Exposure estimation for the environment (Industrial use of coatings and inks with water involved (low volatiles, low water solubility))

9.3.2.1.1 Environmental releases

Table 9.23 ES3: Summary of the local releases to the environment: Industrial use of coatings and inks with water involved (low volatiles, low water solubility)

Compartment	Release factor estimation method	Explanation / Justification
Water	SPERC (XXX 5.1a.v1)	**Initial release factor (%):** 0,5 **Release factor after onsite risk management (%):** 0,5 **Local release rate (kg/day):** 0.1 **Explanation/Justification:** Based on measured data from an automotive spray coating process. 4 data points obtained for a substance with comparable technical function and physicochemical properties (source: xyz).
Air	SPERC (XXX 5.1a.v1)	**Initial release factor (%):** 2 **Release factor after onsite risk management (%):** 2 **Explanation/Justification:** Releases to air before RMM based worst case for substance meant to become part of an article. From OECD Coatings ESD July 2009 A proportion of solid phase contained in overspray and emitted as such to air
Soil	SPERC (XXX 5.1a.v1)	**Release factor after onsite risk management (%):** 0 **Explanation/Justification:** No direct releases to soil

Table 9.24 ES3: Summary of the local releases to the waste: Industrial use of coatings and inks with water involved (low volatiles, low water solubility)

Compartment	Release factor to waste	Explanation / Justification
Waste from the process	50%	50% release to waste as overspray or from other sources has been assumed
Waste from on site treatment of discharges	0%	No RMM assumed

Summed releases from all life cycle stages: see section 9.0.3.

Notes and Comments

Re: Release Estimation Refinement / wet scrubber

a) The subSPERC used covers the worst case (for release to water) illustrated by collection of overspray in a wet scrubber of coating intended to become part of an article.

b) Release factor to water assumed by the subSPERC is based on measured data and assumes the following OC (reported in the related Contributing Scenario):

- Low efficiency spraying method
- Collection of the overspray in wet scrubber with large reservoir
- Continuous removal in wet scrubber of sludge containing coating
- Equalizer to dilute the discharge of the reservoir over the year
- Collection of water used for cleaning purposes and removal of paint sludge

c) Release factor to air and water are based on OECD Coatings ESD July 2009 and does not include any RMM or particular OC.

d) Release factor to waste based on conservative assumptions.

9.3.2.1.2 Environmental exposure

Table 9.25 ES3: Summary of exposure concentrations: Industrial use of coatings and inks with water involved (low volatiles, low water solubility)

Protection target	Exposure concentration	Explanation / Justification
Water: Fresh Water (Pelagic)	**Local PEC:** 0.004 mg/L **Local concentration:** 0.004 mg/L	
Water: Fresh Water (Sediment)	**Local PEC:** 0.316 mg/kg dw	
Water: Marine Water (Pelagic)	**Local PEC:** 3.9E-4 mg/L **Local concentration:** 3.89E-4 mg/L	
Water: Marine Water (Sediment)	**Local PEC:** 0.032 mg/kg dw	
Water: Sewage Treatment Plant (Effluent)	**Local PEC:** 0.039 mg/L	
Air	**Local PEC:** 6.16E-5 mg/m³ **Local concentration:** 6.09E-5 mg/m³	
Soil: Agricultural Soil	**Local PEC:** 0.025 mg/kg dw **Local concentration:** 0.025 mg/kg dw	

For regional PECs see section 10.6

9.3.2.1.3 Indirect exposure of humans via the environment

Exposure via inhalation

The exposure concentrations in air are reported in the Table "Summary of exposure concentrations" of the preceding section 9.3.2.1.2 "Environmental exposure".

Table 9.26 ES3: Summary of estimated daily human doses and concentrations in food: Industrial use of coatings and inks with water involved (low volatiles, low water solubility)

Type of food	Daily human dose through intake		Explanation / Justification
	Total estimated daily intake for humans: 0.017 mg/kg bw/day		
	Estimated daily dose through intake from local exposure	Concentration in food from local exposure	
Drinking water	3.63E-5 mg/kg bw/day	0.001 mg/L	
Fish	0.014 mg/kg bw/day	8.66 mg/kg	
Leaf crops	1.06E-4 mg/kg bw/day	0.006 mg/kg	
Root crops	0.003 mg/kg bw/day	0.53 mg/kg	
Meat	2.69E-6 mg/kg bw/day	6.25E-4 mg/kg	
Milk	1.58E-6 mg/kg bw/day	1.98E-4 mg/kg	
	Dose from regional exposure: see section 10.6		

9.3.2.2 Exposure estimation for the environment (Industrial use of coatings and inks water free (low volatiles))

9.3.2.2.1 Environmental releases

Table 9.27 ES3: Summary of the local releases to the environment: Industrial use of coatings and inks water free (low volatiles)

Compartment	Release factor estimation method	Explanation / Justification
Water	SPERC (XXX 5.1b.v1)	**Initial release factor (%):** 0 **Release factor after onsite risk management (%):** 0 **Local release rate (kg/day):** 0 **Explanation/Justification:** Release factor to water assumes water free processes and dry collection of the overspray.
Air	SPERC	**Initial release factor (%):** 2

Compartment	Release factor estimation method	Explanation / Justification
	(XXX 5.1b.v1)	**Release factor after onsite risk management (%):** 2 **Explanation / Justification:** Releases to air before RMM based worst case for substance meant to become part of an article. From OECD Coatings ESD July 2009 A proportion of solid phase contained in overspray and emitted as such to air
Soil	SPERC (XXX 5.1b.v1)	**Release factor after onsite risk management (%):** 0 **Explanation / Justification:** No direct releases to soil

Table 9.28 ES3: Summary of the local releases to the waste: Industrial use of coatings and inks water free (low volatiles)

Compartment	Release factor to waste	Explanation / Justification
Waste from the process	50%	50% release to waste as overspray or from other sources has been assumed
Waste from on site treatment of discharges	0%	No RMM assumed

Summed releases from all life cycle stages: see section 10.6.

Notes and Comments

Re: Release Estimation Refinement / water free process

a) The subSPERC used covers water free coating process

b) Release factor to water assumed by the subSPERC is then equal to 0

c) Release factor to air and water are based on OECD Coatings ESD July 2009 and does not include any RMM or particular OC.

d) Release factor to waste based on conservative assumptions.

9.3.2.2.2 Environmental exposure

Table 9.29 ES3: Summary of exposure concentrations: Industrial use of coatings and inks water free (low volatiles)

Protection target	Exposure concentration	Explanation / Justification
Water: Fresh Water (Pelagic)	**Local PEC:** 5.95E-7 mg/L **Local concentration:** 0 mg/L	
Water: Fresh Water (Sediment)	**Local PEC:** 4.83E-5 mg/kg dw	
Water: Marine Water (Pelagic)	**Local PEC:** 1.4E-7 mg/L **Local concentration:** 0 mg/L	
Water: Marine Water (Sediment)	**Local PEC:** 1.14E-5 mg/kg dw	
Water: Sewage Treatment Plant (Effluent)	**Local PEC:** 0 mg/L	
Air	**Local PEC:** 6.16E-5 mg/m³ **Local concentration:** 6.09E-5 mg/m³	
Soil: Agricultural Soil	**Local PEC:** 9.31E-5 mg/kg dw **Local concentration:** 9.11E-5 mg/kg dw	

For regional PECs see section 10.6

9.3.2.2.3 Indirect exposure of humans via the environment

Exposure via inhalation

The exposure concentrations in air are reported in the Table "Summary of exposure concentrations" of the preceding section 9.3.2.2.2 "Environmental exposure".

Exposure via food consumption: Total daily intake for humans

Table 9.30 ES3:Summary of estimated daily human doses and concentrations in food: Industrial use of coatings and inks water free (low volatiles)

Type of food	Daily human dose through intake		Explanation / Justification
	Total estimated daily intake for humans: 1.264E-4 mg/kg bw/day		
	Estimated daily dose through intake from local exposure	Concentration in food from local exposure	
Drinking water	1.7E-7 mg/kg bw/day	5.95E-6 mg/L	
Fish	3.97E-6 mg/kg bw/day	0.002 mg/kg	
Leaf crops	1.05E-4 mg/kg bw/day	0.006 mg/kg	
Root crops	1.36E-5 mg/kg bw/day	0.002 mg/kg	
Meat	2.29E-6 mg/kg bw/day	5.33E-4 mg/kg	
Milk	1.35E-6 mg/kg bw/day	1.69E-4 mg/kg	
	Dose from regional exposure: see section 10.6		

9.3.2.3 Exposure estimation for Worker for Application of coatings and inks in closed systems with occasional exposure (PROC 2)

Table 9.31 ES3: Summary of exposure concentrations for contributing scenario: Application of coatings and inks in closed systems with occasional exposure

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	2.5 mg/m³	**Method:** TRA workers v.3	
Dermal: Long term, Systemic	0.27 mg/kg bw/day	**Method:** TRA workers v.3	

9.3.2.4 ES3: Exposure estimation for Worker for Raw material receipt and transfers (PROC 8b)

Table 9.32 ES3: Summary of exposure concentrations for contributing scenario: Raw material receipt and transfers

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	2.5 mg/m³	**Method:** TRA workers v.3	
Dermal: Long term, Systemic	2.7 mg/kg bw/day	**Method:** TRA workers v.3	

9.3.2.5 Exposure estimation for Worker for Preparation of coatings and inks for application (PROC 5)

Table 9.33 ES3: Summary of exposure concentrations for contributing scenario: Preparation of coatings and inks for application

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	2.5 mg/m³	**Method:** TRA workers v.3	
Dermal: Long term, Systemic	2.7 mg/kg bw/day	**Method:** TRA workers v.3	

9.3.2.6 Exposure estimation for Worker for Batch loading of equipment (manual, non-dedicated) (PROC 8a)

Table 9.34 ES3: Summary of exposure concentrations for contributing scenario: Batch loading of equipment (manual, non-dedicated)

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	5 mg/m³	**Method:** TRA workers v.3	
Dermal: Long term, Systemic	2.7 mg/kg bw/day	**Method:** TRA workers v.3	

9.3.2.7 Exposure estimation for Worker for Spray coating – any technique (PROC 7)

Table 9.35 ES3: Summary of exposure concentrations for contributing scenario: Spray coating – any technique

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	12,5 mg/m³	**Method:** TRA workers v.3	
Inhalation: Long term, Systemic (not used for RC)	7 mg/m³	**Method:** Measured data*	Personal exposure measurements, 2011 (Internal report ref 12345). Spraying with conventional spray guns in dedicated paint booth. n=9 (3 operators on 3 days); mean = 2.4mg/m3, GSD = 2.2 95th percentile – 6.9 mg/m3. Average measurement duration 160 mins. The 95 percentile with LEV is 6.9 mg/m^3
Dermal: Long term, Systemic	1.7 mg/kg bw/day	**Method:** TRA workers v.3	

9.3.2.8 Exposure estimation for Worker for Brushing, roller, spreader, flow coating or printing – any technique (PROC 10)

Table 9.36 ES3: Summary of exposure concentrations for contributing scenario: Brushing, roller, spreader, flow coating or printing – any technique

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	2.5 mg/m³	**Method:** TRA workers v.3	
Dermal: Long term, Systemic	5.5 mg/kg bw/day	**Method:** TRA workers v.3	

* In industrial spraying, personal exposure sampling results were available and were used as supportive evidence. The number of samples was low and not robust enough as direct evidence. This data is not used for risk characterisation

9.3.2.9 Exposure estimation for Worker for Dipping and pouring – any technique (PROC 13)

Table 9.37 ES3: Summary of exposure concentrations for contributing scenario: Dipping and pouring – any technique

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	2.5 mg/m³	**Method:** TRA workers v.3	
Dermal: Long term, Systemic	2.7 mg/kg bw/day	**Method:** TRA workers v.3	

9.3.2.10 Exposure estimation for Worker for Curing and drying processes after application – Elevated temperatures (PROC 2)

Table 9.38 ES3: Summary of exposure concentrations for contributing scenario: Curing and drying processes after application – Elevated temperatures

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	2.5 mg/m³	**Method:** TRA workers v.3	
Dermal: Long term, Systemic	0.27 mg/kg bw/day	**Method:** TRA workers v.3	

9.3.2.11 Exposure estimation for Worker for Manual cleaning and maintenance of equipment (PROC 8a)

Table 9.39 ES3: Summary of exposure concentrations for contributing scenario: Manual cleaning and maintenance of equipment

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	15 mg/m³	**Method:** TRA workers v.3	
Dermal: Long term, Systemic	0.55 mg/kg bw/day	**Method:** TRA workers v.3	

9.4 ES4: Professional painting

This scenario covers the use of paints/decorative coatings by professional painters. This activity may be performed by brush/roller or by spraying. Concentration of the substance in the product has been set to up to 5% for assessment purposes.

Environmental exposure assessment is based on a ERC 8f release factor (outdoor use leading to inclusion into matrix), covering also ERC 8c (indoor use leading to inclusion

into matrix)

Regarding worker exposure, Stoffenmanager 4.5 was used to derive inhalation exposure estimates for both spraying and brushing operations, since Tier I model (TRA) did not indicate safe use under realistic OC/RMM. In the modelling tool, spraying (PROC 11) was described as "handling of liquids at high pressure resulting in substantial generation of mist or spray/haze" in Stoffenmanager, while roller and brushing (PROC 10) was described as "handling of liquids on large surfaces or workpieces".

Indoor use has been assumed for assessment purposes as the worst case scenario. Outdoor use is also covered by this assessment.

Regarding the qualitative assessment with respect to irritancy, the following assumptions apply:

- The substance is diluted to a concentration below that where dermal, eye and inhalation irritancy is likely to occur. Consequently the risk for all routes is low and no additional risk management measures are required.

Market sector:	
PC 9a - Coatings and Paints, Thinners, paint removers	
Environment:	
Use leading to inclusion into/onto matrix	ERC 8f, ERC 8c
Worker	
Transfer in non-dedicated facilities	PROC 8a
Roller and brushing	PROC 10
Professional spraying	PROC 11

Notes and Comments

Re: Merging Exposure Scenarios

Although painting occurs both indoors and outdoors, only one ES was used. The assessment assumed the worst case for environment (namely outdoor painting) and the worst case for human health (namely indoor painting). This reduces the number of scenarios needed without influencing the outcome. While this approach has the advantaging of reducing the number of scenarios, care should be taken to ensure that it is technically valid to do so and that the assumptions are clear to readers

Re:Risk Management Measures

The comments regarding the role of local risk assessments in determining the most appropriate PPE in Section 9.3 also apply here

9.4.1 ES4: Exposure scenario for Professional painting

9.4.1.1 ES4: Control of environmental exposure: Use leading to inclusion into/onto matrix

Further specification: Covers also ERC 8c (indoor application)

Amount used, frequency and duration of use (or from service life)
• Daily wide dispersive use: = 2.75E-5 tonnes/day
Conditions and measures related to municipal sewage treatment plant
• Municipal STP: Yes [Effectiveness Water: 22 %] • Discharge rate of STP: < 2E3 m3/d • Application of the STP sludge on agricultural soil: Yes
Conditions and measures related to treatment of waste (including article waste)
• Specific conditions of waste treatment: Not required
Other conditions affecting environmental exposure
• Receiving surface water flow rate: >= 1.8E4 m3/d

9.4.1.2 ES4: Control of workers exposure for "Transfer in non-dedicated facilities" [PROC 8a]

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1 – 5%	TRA worker V3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 15 min	TRA worker V3
Technical and organisational conditions and measures	
• Containment: No	TRA worker V3
• Occupational Health and Safety Management System: Basic	TRA worker V3
• Local Exhaust Ventilation: No [Effectiveness Inhalation: 0%]	TRA worker V3
• General ventilation: Basic general ventilation (1-3 air exchange(s) per hour)	TRA worker V3
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protection: No [Effectiveness Inhalation: 0%]	TRA worker V3
• Dermal protection: No [Effectiveness Dermal: 0%]	TRA worker V3
Other conditions affecting workers exposure	
• Process temperature (for liquids): < 40 C	TRA worker V3
• Place of use: Indoor	TRA worker V3
• Body surface potentially exposed: Two hands (960 cm2)	TRA worker V3

9.4.1.3 ES4: Control of workers exposure for "Roller and brushing" [PROC 10]

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1 – 5%	TRA worker V3
• Concentration in product: ≤ 5 %.	Stoffenmanager 4.5
• Dilution of the product with water: No	Stoffenmanager 4.5
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA worker V3
Technical and organisational conditions and measures	
• Containment: No	TRA worker V3
• Occupational Health and Safety Management System: Basic	TRA worker V3
• Engineering controls or containment: No [Effectiveness Inhalation: 0%]	Stoffenmanager 4.5
• General ventilation: No [Effectiveness Inhalation: 0%]	Stoffenmanager 4.5
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment: No [Effectiveness Inhalation: 0%]	Stoffenmanager 4.5
• Dermal protection: Yes (chemically resistant gloves conforming to EN374) [Effectiveness Dermal: 80%]	TRA worker V3
Other conditions affecting workers exposure	
• Distance to the task: within breathing zone	Stoffenmanager 4.5
• Volume of working room: < 100 m^3.	Stoffenmanager 4.5
• Body surface potentially exposed: Two hands (960 cm2)	TRA worker V3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Eye/face protection: Chemically resistant face shield and/or goggles, if contact may occur during application	

9.4.1.4 ES4: Control of workers exposure for "Professional spraying" [PROC 11]

	Method
Product (article) characteristics	
• Concentration of substance in mixture: 1 – 5%	TRA worker V3
• Concentration in product: ≤ 5 %.	Stoffenmanager 4.5
• Dilution of the product with water: No	Stoffenmanager 4.5
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 8 hours	TRA worker V3
Technical and organisational conditions and measures	
• Containment: No	TRA worker V3
• Occupational Health and Safety Management System: Basic	TRA worker V3
• Engineering controls or containment: No [Effectiveness Inhalation: 0%]	Stoffenmanager 4.5
• General ventilation: No [Effectiveness Inhalation: 0%]	Stoffenmanager 4.5
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory protective equipment: Half mask respirator with filter/cartridge (gascartridge) [Effectiveness Inhalation: 60%].	Stoffenmanager 4.5
• Dermal protection: Yes (chemically resistant gloves conforming to EN374) [Effectiveness Dermal: 80%]	TRA worker V3
Other conditions affecting workers exposure	
• Distance to the task: within breathing zone	Stoffenmanager 4.5
• Volume of working room: < 100 m^3.	Stoffenmanager 4.5
• Body surface potentially exposed: Two hands and upper wrists (1500 cm2).	TRA worker V3
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	
• Eye/face protection: Chemically resistant face shield and/or goggles, if contact may occur during application	
• Chemical Protective Clothing (CPC): overall and boots recommended to prevent skin contact.	
• High volume low pressure (HVLP) spray gun has higher transfer efficiencies (60-70%) than conventional spray guns (30-40%) with reduced potential for exposure	

9.4.2 ES4: Exposure estimation for Professional painting indoor/outdoor

9.4.2.1 Exposure estimation for the environment (Use leading to inclusion into/onto matrix)

9.4.2.1.1 Environmental releases

Table 9.40 ES4: Summary of the local releases to the environment

Compartment	Release factor estimation method	Explanation / Justification
Water	ERC (ERC 8f)	**Initial release factor (%):** 1 **Release factor after on site risk management (%):** 1 **Local release rate (kg/day):** 2.75E-4
Air	ERC (ERC 8f)	**Initial release factor (%):** 15 **Release factor after on site risk management (%):** 15
Soil	ERC (ERC 8f)	**Initial release factor (%):** 0.5 **Release factor after on site risk management (%):** 0.5

Summed releases from all life cycle stages: see section 9.0.3.

9.4.2.1.2 Environmental exposure

Table 9.41 ES4: Summary of exposure concentrations

Protection target	Exposure concentration	Explanation / Justification
Water: Fresh Water (Pelagic)	**Local PEC:** 1.35E-5 mg/L **Local concentration:** 1.07E-5 mg/L	
Water: Fresh Water (Sediment)	**Local PEC:** 0.001 mg/kg dw	
Water: Marine Water (Pelagic)	**Local PEC:** 1.41E-6 mg/L **Local concentration:** 1.07E-6 mg/L	
Water: Marine Water (Sediment)	**Local PEC:** 1.14E-4 mg/kg dw	
Water: Sewage Treatment Plant (Effluent)	**Local PEC:** 1.07E-4 mg/L	
Air	**Local PEC:** 6.94E-7 mg/m³ **Local concentration:** 1.03E-8 mg/m³	
Soil: Agricultural Soil	**Local PEC:** 7.03E-5 mg/kg dw **Local concentration:** 6.83E-5 mg/kg dw	

For regional PECs see section 10.6.

9.4.2.1.3 Indirect exposure of humans via the environment

Exposure via inhalation

The exposure concentrations in air are reported in the Table "Summary of exposure concentrations" of the preceding section 9.4.2.1.2 "Environmental exposure".

Exposure via food consumption: Total daily intake for humans

Table 9.42 ES4: Summary of estimated daily human doses and concentrations in food

Type of food	Daily human dose through intake		Explanation / Justification
	Total estimated daily intake for humans: 9.999E-5 mg/kg bw/day		
	Estimated daily dose through intake from local exposure	Concentration in food from local exposure	
Drinking water	1.94E-7 mg/kg bw/day	6.77E-6 mg/L	
Fish	9.03E-5 mg/kg bw/day	0.055 mg/kg	
Leaf crops	1.19E-6 mg/kg bw/day	6.93E-5 mg/kg	
Root crops	8.26E-6 mg/kg bw/day	0.002 mg/kg	
Meat	2.79E-8 mg/kg bw/day	6.48E-6 mg/kg	
Milk	1.64E-8 mg/kg bw/day	2.05E-6 mg/kg	
	Dose from regional exposure: see section 10.6		

9.4.2.2 Exposure estimation for Transfer in non dedicated facilities (PROC 8a)

Table 9.43 ES4: Summary of exposure concentrations for contributing scenario: Transfer in non dedicated facilities

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	6.3 mg/m³	**Method:** TRA workers v.3	
Dermal: Long term, Systemic	2.7 mg/kg bw/day	**Method:** TRA workers v.3	

9.4.2.3 Exposure estimation for Worker for Roller and brushing (PROC 10)

Table 9.44 ES4: Summary of exposure concentrations for contributing scenario: Roller and brushing (PROC 10)

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	6.7 mg/m³	**Method:** Stoffenmanager 4.5	90th percentile has been taken as reference value for exposure estimation
Dermal: Long term, Systemic	1.1 mg/kg bw/day	**Method:** TRA workers v.3	

9.4.2.4 Exposure estimation for Worker for Professional spraying (PROC 11)

Table 9.45 ES4: Summary of exposure concentrations for contributing scenario: Professional spraying

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	5.9 mg/m³	**Method:** Stoffenmanager 4.5	90th percentile has been taken as reference value for exposure estimation
Dermal: Long term, Systemic	4.3 mg/kg bw/day	**Method:** TRA workers v.3	

9.5 ES5: Consumer painting

This scenario covers general exposures of consumers arising from the use of ECHA Substance in household products sold as paints/decorative coatings (PC 9a). Activities covered in this scenario are roller application and brushing. The paints may be water-borne or solvent-borne.

Environmental releases are estimated according to ERC 8f (outdoor wide-spread use leading to inclusion into matrix) release factor. This covers also the indoor use of coatings (ERC 8c)

Inhalation and dermal consumer exposure were assessed using Consexpo 4.1. Input parameters (as related to habits and practice for consumers and documented in the RIVM factsheets, Dutch National Institute for Public Health and the Environment (RIVM) Paint Products Fact Sheet (http://www.rivm.nl/bibliotheek/rapporten/320104008.pdf)) are reported as determinants in the ES or referenced in the exposure table. Two contributing scenarios are assessed:

- Water-based wall paint (RIVM report 320104008/2007, paragraph 2.6)

- Rich solvent paint (RIVM report 320104008/2007, paragraph 2.3)

Parameters that can be regarded as conditions of use (amounts, concentration, consumer habits) are reported in the ES while the model assumptions are reported in the exposure tables.

An evaporation model has been used for inhalation exposure, while a constant rate model has been used for dermal exposure, as suggested in RIVM factsheet.

Regarding the qualitative assessment with respect to irritancy, the following assumptions apply:

- The substance is diluted to a concentration below that where dermal, eye and inhalation irritancy is likely to occur. Consequently the risk for all routes is low and no additional risk management measures are required.

Market sector:	
PC 9a – Coatings and Paints, Thinners, paint removers	
Environment:	
Use leading to inclusion into/onto matrix	ERC 8f, ERC 8c
Consumer	
Use in water-borne wall paints, roller and brush application	PC9a
Use in rich solvent paints, roller and brush application	

9.5.1 ES5: Exposure scenario for Consumer painting

9.5.1.1 ES5: Control of environmental exposure: Use leading to inclusion into/onto matrix

Further specification: Covers both indoor/outdoor (ERC 8c and ERC 8f)

Amount used, frequency and duration of use (or from service life)
• Daily wide dispersive use: = 2.75E-5 tonnes/day
Other conditions affecting environmental exposure
• Municipal STP: Yes [Effectiveness Water: 22%] • Discharge rate of STP: < 2E3 m3/d • Application of the STP sludge on agricultural soil: Yes • Receiving surface water flow rate: >= 1.8E4 m3/d

9.5.1.2 ES5: Control of consumers exposure for "Use in water-borne wall paints, roller and brush application" [PC 9a]

Further specification: Covers both indoor and outdoor use

	Method
Product (article) characteristics	
• Concentration of the substance in the product: < 1%	Consexpo 4.1
Amount used, frequency and duration of use/exposure	
• Product amount per task: = 3750 grams.	Consexpo 4.1
• Frequency: = 2 times/year.	Consexpo 4.1
• Duration of application: = 120 minutes.	Consexpo 4.1
• Duration of exposure: = 132 minutes.	Consexpo 4.1
Other conditions affecting consumers exposure	
• Contact rate = 30 mg/min.	Consexpo 4.1
• Room where tasks take place: Generic room (Volume: 20 m3; ventilation rate: 0,6 exchange/h).	Consexpo 4.1
• Release area: = 15 m2.	Consexpo 4.1

9.5.1.3 ES5: Control of consumers exposure for "Use in rich solvent paints, roller and brush application" [PC 9a]

Further specification: Covers both indoor and outdoor use

	Method
Product (article) characteristics	
• Concentration of the substance in the product: < 1%	Consexpo 4.1
Amount used, frequency and duration of use/exposure	
• Product amount per task: = 1000 grams.	Consexpo 4.1
• Frequency: = 1 time/year.	Consexpo 4.1
• Duration of application: = 120 minutes.	Consexpo 4.1
• Duration of exposure: = 132 minutes.	Consexpo 4.1
Other conditions affecting consumers exposure	
• Contact rate = 30 mg/min.	Consexpo 4.1
• Room where tasks take place: Generic room (Volume: 20 m3; ventilation rate: 0,6 exchange/h).	Consexpo 4.1
• Release area: = 10 m2.	Consexpo 4.1

9.5.2 ES5: Exposure estimation for Consumer painting

9.5.2.1 Exposure estimation for the environment (Use leading to inclusion into/onto matrix)

9.5.2.1.1 Environmental releases

Table 9.46 ES5: Summary of the local releases to the environment

Compartment	Release factor estimation method	Explanation / Justification
Water	ERC (ERC 8f)	**Initial release factor (%):** 1 **Release factor after on site risk management (%):** 1 **Local release rate (kg/day):** 2.75E-4
Air	ERC (ERC 8f)	**Initial release factor (%):** 15 **Release factor after on site risk management (%):** 15
Soil	ERC (ERC 8f)	**Initial release factor (%):** 0.5 **Release factor after on site risk management (%):** 0.5

Summed releases from all life cycle stages: see section 9.0.3.

9.5.2.1.2 Environmental exposure

Table 9.47 ES5: Summary of exposure concentrations

Protection target	Exposure concentration	Explanation / Justification
Water: Fresh Water (Pelagic)	**Local PEC:** 1.35E-5 mg/L **Local concentration:** 1.07E-5 mg/L	
Water: Fresh Water (Sediment)	**Local PEC:** 0.001 mg/kg dw	
Water: Marine Water (Pelagic)	**Local PEC:** 1.41E-6 mg/L **Local concentration:** 1.07E-6 mg/L	
Water: Marine Water (Sediment)	**Local PEC:** 1.14E-4 mg/kg dw	
Water: Sewage Treatment Plant (Effluent)	**Local PEC:** 1.07E-4 mg/L	
Air	**Local PEC:** 6.94E-7 mg/m³ **Local concentration:** 1.03E-8 mg/m³	
Soil: Agricultural Soil	**Local PEC:** 7.03E-5 mg/kg dw **Local concentration:** 6.83E-5 mg/kg dw	

For regional PECs see section 10.6

9.5.2.1.3 Indirect exposure of humans via the environment

Exposure via inhalation

The exposure concentrations in air are reported in the Table "Summary of exposure concentrations" of the preceding section 9.5.2.1.2 "Environmental exposure".

Exposure via food consumption: Total daily intake for humans

Table 9.48 ES5: Summary of estimated daily human doses and concentrations in food

Type of food	Daily human dose through intake	Explanation / Justification
	Total estimated daily intake for humans: 9.999E-5 mg/kg bw/day	
	Estimated daily dose through intake from local exposure / Concentration in food from local exposure	
Drinking water	1.94E-7 mg/kg bw/day / 6.77E-6 mg/L	
Fish	9.03E-5 mg/kg bw/day / 0.055 mg/kg	
Leaf crops	1.19E-6 mg/kg bw/day / 6.93E-5 mg/kg	
Root crops	8.26E-6 mg/kg bw/day / 0.002 mg/kg	
Meat	2.79E-8 mg/kg bw/day / 6.48E-6 mg/kg	
Milk	1.64E-8 mg/kg bw/day / 2.05E-6 mg/kg	
	Dose from regional exposure: see section 10.6	

9.5.2.2 Exposure estimation for Consumer for Use in water-borne wall paints, roller and brush application (PC9a)

Table 9.49 ES5: Summary of exposure concentrations for contributing scenario: Use in water-borne wall paints, roller and brush application

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	0,3 mg/m³	**Method:** Consexpo 4.1	**Representativity and reliability:** ConsExpo 4.1: evaporation model **Remark on exposure value:** Concentration averaged over a day of exposure, assuming maximum one event per day. The most conservative Languimir

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
			equation has been used for the calculation of the mass transfer rate Assumptions (Default ConsExpo 4.1): - 34,7 m3/day of inhalation rate – light exercise - Molecular weight matrix equal 120 g/mol. Consexpo default for wall paint, water-based
Dermal: Long term, Systemic	0,6 mg/kg bw/day	**Method:** Consexpo 4.1	**Representativity and reliability:** ConsExpo 4.1: Constant rate model **Remark on exposure value:** Dose over the day
Oral: Long term, Systemic	0 mg/kg bw/day	**Method:** Consexpo 4.1	**Remark on exposure value:** Oral exposure not relevant for this task

9.5.2.3 Exposure estimation for Consumer for Use in rich solvent paints, roller and brush application (PC9a)

Table 9.50 ES5: Summary of exposure concentrations for contributing scenario: Use in rich solvent paints, roller and brush application

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Inhalation: Long term, Systemic	0,78 mg/m³	**Method:** Consexpo 4.1	**Representativity and reliability:** ConsExpo 4.1: Evaporation model **Remark on exposure value:** Concentration averaged over a day of exposure, assuming maximum one event per day. The most conservative Languimir equation has been used for the calculation of the mass transfer rate Assumptions (Default ConsExpo 4.1): - 34,7 m3/day of inhalation rate – light exercise - Molecular weight matrix equal 300 g/mol. Default ConsExpo for solvent-rich (45%) paint
Dermal: Long term,	0,55 mg/kg bw/day	**Method:** Consexpo 4.1	**Representativity and reliability:** ConsExpo 4.1: Constant rate model

Route of exposure and type of effects	Exposure concentration	Method / name of exposure assessment	Explanation / Justification
Systemic			**Remark on exposure value:** Dose over the day
Oral: Long term, Systemic	0 mg/kg bw/day	**Method:** Consexpo 4.1	**Remark on exposure value:** Oral exposure not relevant for this task

10. RISK CHARACTERISATION

Overview tables of the quantitative risk assessment for workers and environmental exposure are presented in **Appendix 1**.

10.1 ES1: Manufacture of the substance

10.1.1 Human health

10.1.1.1 Workers

Table 10.1 ES1: Risk characterisation: Control of workers exposure for "Closed manufacturing process" [PROC 1]

Route of exposure and type of effects	**Risk characterisation**
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = <0.01**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = <0.01**
Combined routes: Long term, Systemic	**RCR = 0.01**
Justification for qualitative risk characterisation	
Substance vapour pressure is low and formation of aerosol is unlikely. The manufacturing process is a closed system. Under these conditions no local effects on respiratory tract are expected. No contact to skin or eyes is expected (local dermal effects), as the manufacturing process is a closed system.	

Table 10.2 ES1: Risk characterisation: Control of workers exposure for "Maintenance and cleaning operation" [PROC 8a]

Route of exposure and type of effects	**Risk characterisation**
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.30**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.20**
Combined routes: Long term, Systemic	**RCR = 0.50**
Justification for qualitative risk characterisation	
The risk management measures required based on the quantitative assessment provide	

sufficient protection against any inhalation or dermal irritancy hazard. Details of the RMMs are given in the ES. Under these use conditions, no local inhalation or dermal effects are expected.

10.1.1.2 Indirect exposure of humans via the environment

Table 10.3 ES1: Risk characterisation for humans exposed via the environment

Route of exposure and type of effects	Risk characterisation ratio	Justification for risk characterization
Inhalation: Long term, Systemic	**RCR <0.01**	
Oral: Long term, Systemic	**RCR <0.01**	

10.1.2 Environment

10.1.2.1 Aquatic compartment (incl. sediment)

Table 10.4 ES1: Risk characterisation for the aquatic compartment (incl. sediment and secondary poisoning)

Protection target	Risk characterisation ratio	Justification for risk characterization
Fresh Water (Pelagic)	**RCR <0.01**	
Fresh Water (Sediment)	**RCR <0.01**	
Marine Water (Pelagic)	**RCR <0.01**	
Marine Water (Sediment)	**RCR <0.01**	

10.1.2.2 Terrestrial compartment

Table 10.5 ES1: Risk characterisation for the terrestrial compartment (incl. secondary poisoning)

Protection target	Risk characterisation ratio	Justification for risk characterization
Agricultural Soil	**RCR <0.01**	

10.1.2.3 Microbiological activity in sewage treatment systems

Table 10.6 ES1: Risk characterisation for the microbiological activity in sewage treatment systems

Protection target	Risk characterisation ratio	Justification for risk characterization
Sewage Treatment Plant (Effluent)	**RCR = 0**	

10.2 ES2: Formulation of liquid mixtures

10.2.1 Human health

10.2.1.1 Workers

Table 10.7 ES2: Risk characterisation: Control of workers exposure for "Receiving and charging the substance" [PROC 8b]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.51**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.39**
Combined routes: Long term, Systemic	**RCR = 0.90**
Justification for qualitative risk characterisation	
Substance vapour pressure is low and formation of aerosol is unlikely. Under these conditions no local effects on respiratory tract are expected. Dermal and eye irritancy controlled by the use of protective gloves (with 80 % efficacy) and face shield or goggles. Details of the RMMs are given in the ES. Under these use conditions no local dermal effects are expected.	

Table 10.8 ES2: Risk characterisation: Control of workers exposure for "Mixing, dispersing, completion in closed batch process" [PROC 3]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.15**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.02**
Combined routes: Long term, Systemic	**RCR = 0.17**
Justification for qualitative risk characterisation	
Substance vapour pressure is low and formation of aerosol is unlikely. Formulation takes place in closed batch system. Under these conditions no local effects on respiratory tract are expected. Eye and dermal irritancy takes place in closed batch system with limited opportunity for exposure. Eye and dermal irritancy controlled by the use of protective gloves (with 80 % efficacy) and face shield or goggles when exposure could occur. Details of the RMMs are	

Route of exposure and type of effects	Risk characterisation
given in the ES. Under these use conditions no local dermal effects are expected.	

Table 10.9 ES2: Risk characterisation: Control of workers exposure for "Mixing, dispersing, completion in open multistage batch process" [PROC 5]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.25**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.39**
Combined routes: Long term, Systemic	**RCR = 0.64**
Justification for qualitative risk characterisation	
Substance vapour pressure is low and formation of aerosol is unlikely. Under these conditions no local effects on respiratory tract are expected. Eye and dermal irritancy controlled by the use of protective gloves (with 80 % efficacy) and face shield or goggles. Details of the RMMs are given in the ES. Under these use conditions no local dermal effects are expected.	

Table 10.10 ES2: Risk characterisation: Control of workers exposure for "Transfer in non-dedicated facilities" [PROC 8a]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.20**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.39**
Combined routes: Long term, Systemic	**RCR = 0.59**
Justification for qualitative risk characterisation	
Adverse irritancy effects are controlled by substance concentration (< 10 %) in mixture, and no local effects are expected.	

Table 10.11 ES2: Risk characterisation: Control of workers exposure for "Transfer at dedicated facilities" [PROC 8b]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.10**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.39**
Combined routes: Long term, Systemic	**RCR = 0.49**
Justification for qualitative risk characterisation	
Adverse irritancy effects are controlled by substance concentration (< 10 %) in mixture, and no local effects are expected.	

Table 10.12 ES2: Risk characterisation: Control of workers exposure for "Filling small containers in dedicated lines" [PROC 9]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.51**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.20**
Combined routes: Long term, Systemic	**RCR = 0.71**
Justification for qualitative risk characterisation	
Adverse irritancy effects are controlled by substance concentration (< 10 %) in product, and no local effects are expected.	

Table 10.13 ES2: Risk characterisation: Control of workers exposure for "Maintenance and cleaning operation" [PROC 8a]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.30**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.39**
Combined routes: Long term,	**RCR = 0.69**

Route of exposure and type of effects	Risk characterisation
Systemic	
Justification for qualitative risk characterisation	
Substance vapour pressure is low and formation of aerosol is unlikely. Under these conditions no local effects on respiratory tract are expected. Eye and dermal irritancy controlled by the use of protective gloves (with 80 % efficacy) and face shield or goggles. Details of the RMMs are given in the ES. Under these use conditions no local dermal effects are expected.	

10.2.1.2 Consumers

This exposure scenario does not address consumers.

10.2.1.3 Indirect exposure of humans via the environment

Table 10.14 ES2: Risk characterisation for humans exposed via the environment

Route of exposure and type of effects	Risk characterisation ratio	Justification for risk characterization
Inhalation: Long term, Systemic	**RCR <0.01**	
Oral: Long term, Systemic	**RCR <0.01**	

10.2.2 Environment

10.2.2.1 Aquatic compartment (incl. sediment)

Table 10.15 ES2: Risk characterisation for the aquatic compartment (incl. sediment and secondary poisoning)

Protection target	Risk characterisation ratio	Justification for risk characterisation
Fresh Water (Pelagic)	**RCR <0.01**	
Fresh Water (Sediment)	**RCR <0.01**	
Marine Water (Pelagic)	**RCR <0.01**	
Marine Water (Sediment)	**RCR <0.01**	

10.2.2.2 Terrestrial compartment

Table 10.16 ES2: Risk characterisation for the terrestrial compartment (incl. secondary poisoning)

Protection target	Risk characterisation ratio	Justification for risk characterisation
Agricultural Soil	**RCR <0.01**	

10.2.2.3 Atmospheric compartment

10.2.2.4 Microbiological activity in sewage treatment systems

Table 10.17 ES2: Risk characterisation for the microbiological activity in sewage treatment systems

Protection target	Risk characterisation ratio	Justification for risk characterisation
Sewage Treatment Plant (Effluent)	**RCR = 0**	

10.3 ES3: General Industrial use of coatings and Inks

10.3.1 Human health

10.3.1.1 Workers

Table 10.18 ES3: Risk characterisation: Control of workers exposure for "Application of coatings and inks in closed systems with occasional exposure" [PROC 2]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.10**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.04**
Combined routes: Long term, Systemic	**RCR = 0.14**
Justification for qualitative risk characterisation	
Adverse irritancy effects are controlled by substance concentration (< 10 %) in product, and no local effects are expected.	

Table 10.19 ES3: Risk characterisation: Control of workers exposure for "Raw material receipt and transfers" [PROC 8b]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.10**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.39**
Combined routes: Long term, Systemic	**RCR = 0.49**

Route of exposure and type of effects	Risk characterisation
Justification for qualitative risk characterisation	
Adverse irritancy effects are controlled by substance concentration (< 10 %) in product, and no local effects are expected.	

Table 10.20 ES3: Risk characterisation: Control of workers exposure for "Preparation of coatings and inks for application" [PROC 5]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.10**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.39**
Combined routes: Long term, Systemic	**RCR = 0.49**
Justification for qualitative risk characterisation	
Adverse irritancy effects are controlled by substance concentration (< 10 %) in product, and no local effects are expected.	

Table 10.21ES3: Risk characterisation: Control of workers exposure for "Batch loading of equipment (manual, non-dedicated)" [PROC 8a]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.20**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.39**
Combined routes: Long term, Systemic	**RCR = 0.59**
Justification for qualitative risk characterisation	
Adverse irritancy effects are controlled by substance concentration (< 10 %) in product, and no local effects are expected.	

Table 10.22 ES3: Risk characterisation: Control of workers exposure for "Spray coating – any technique" [PROC 7]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.51**

Route of exposure and type of effects	Risk characterisation
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.24**
Combined routes: Long term, Systemic	**RCR = 0.75**
Justification for qualitative risk characterisation	
Adverse irritancy effects are controlled by substance concentration (< 10 %) in product, and no local effects are expected.	

Table 10.23 ES3: Risk characterisation: Control of workers exposure for "Brushing, roller, spreader, flow coating or printing – any technique" [PROC 10]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.10**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.79**
Combined routes: Long term, Systemic	**RCR = 0.89**
Justification for qualitative risk characterisation	
Adverse irritancy effects are controlled by substance concentration (< 10 %) in product, and no local effects are expected.	

Table 10.24 ES3: Risk characterisation: Control of workers exposure for "Dipping and pouring, - any technique" [PROC 13]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.10**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.39**
Combined routes: Long term, Systemic	**RCR = 0.49**
Justification for qualitative risk characterisation	
Adverse irritancy effects are controlled by substance concentration (< 10 %) in product, and no local effects are expected.	

Table 10.25 ES3: Risk characterisation: Control of workers exposure for "Curing and drying processes after application – Elevated temperatures" [PROC 2]

Route of exposure and type of effects	**Risk characterisation**
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.10**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.04**
Combined routes: Long term, Systemic	**RCR = 0.14**
Justification for qualitative risk characterisation	
Adverse irritancy effects are controlled by substance concentration (< 10 %) in product, and no local effects are expected.	

Table 10.26 ES3: Risk characterisation: Control of workers exposure for "Manual cleaning and maintenance of equipment" [PROC 8a]

Route of exposure and type of effects	**Risk characterisation**
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.61**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.08**
Combined routes: Long term, Systemic	**RCR = 0.69**
Justification for qualitative risk characterisation	
Adverse irritancy effects are controlled by substance concentration (< 10 %) in product, and no local effects are expected.	

10.3.1.2 Consumers

This exposure scenario does not address consumers.

10.3.1.3 Indirect exposure of humans via the environment

Table 10.27 ES3: Risk characterisation for humans exposed via the environment

Route of exposure and type of effects	**Risk characterisation ratio**	**Justification for risk characterization**
Inhalation: Long term, Systemic	**RCR <0.01**	
Oral: Long term, Systemic	**RCR <0.01**	

10.3.2 Environment

10.3.2.1 Aquatic compartment (incl. sediment)

Table 10.28 ES3: Risk characterisation for the aquatic compartment (incl. sediment and secondary poisoning) – Industrial use of coatings and inks with water involved (low volatiles, low water solubility)

Protection target	Risk characterisation ratio	Justification for risk characterization
Fresh Water (Pelagic)	**RCR = 0.38**	
Fresh Water (Sediment)	**RCR = 0.38**	
Marine Water (Pelagic)	**RCR = 0.38**	
Marine Water (Sediment)	**RCR = 0.38**	

Table 10.29 ES3: Risk characterisation for the aquatic compartment (incl. sediment and secondary poisoning) – Industrial use of coatings and inks water free (low volatiles)

Protection target	Risk characterisation ratio	Justification for risk characterization
Fresh Water (Pelagic)	**RCR <0.01**	
Fresh Water (Sediment)	**RCR <0.01**	
Marine Water (Pelagic)	**RCR <0.01**	
Marine Water (Sediment)	**RCR <0.01**	

10.3.2.2 Terrestrial compartment

Table 10.30 ES3: Risk characterisation for the terrestrial compartment (incl. secondary poisoning) - – Industrial use of coatings and inks with water involved (low volatiles, low water solubility)

Protection target	Risk characterisation ratio	Justification for risk characterization
Agricultural Soil	**RCR = 0.16**	

Table 10.31 ES3: Risk characterisation for the terrestrial compartment (incl. secondary poisoning) - – Industrial use of coatings and inks water free (low volatiles)

Protection target	Risk characterisation ratio	Justification for risk characterization
Agricultural Soil	**RCR <0.01**	

10.3.2.3 Atmospheric compartment

10.3.2.4 Microbiological activity in sewage treatment systems

Table 10.32 ES3: Risk characterisation for the microbiological activity in sewage treatment systems – Industrial use of coatings and inks with water involved (low volatiles, low water solubility)

Protection target	Risk characterisation ratio	Justification for risk characterization
Sewage Treatment Plant (Effluent)	**RCR = 0.03**	

Table 10.33 ES3: Risk characterisation for the microbiological activity in sewage

treatment systems – Industrial use of coatings and inks water free (low volatiles)

Protection target	Risk characterisation ratio	Justification for risk characterization
Sewage Treatment Plant (Effluent)	**RCR = 0**	

10.4 ES4: Professional painting

10.4.1 Human health

10.4.1.1 Workers

Table 10.34 ES4: Risk characterisation: Control of workers exposure for "Transfer in non-dedicated facilities" [PROC 8a]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.25**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.39**
Combined routes: Long term, Systemic	**RCR = 0.64**
Justification for qualitative risk characterisation	
Adverse irritancy effects are controlled by substance concentration (< 10 %) in product, and no local effects are expected.	

Table 10.35 ES4: Risk characterisation: Control of workers exposure for "Roller and brushing" [PROC 10]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.27**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.16**
Combined routes: Long term, Systemic	**RCR = 0.43**
Justification for qualitative risk characterisation	
Adverse irritancy effects are controlled by substance concentration (< 10 %) in product, and no local effects are expected.	

Table 10.36 ES4: Risk characterisation: Control of workers exposure for "Professional spraying" [PROC 11]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.24**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.61**
Combined routes: Long term, Systemic	**RCR = 0.85**
Justification for qualitative risk characterisation	
Adverse irritancy effects are controlled by substance concentration (< 10 %) in product, and no local effects are expected.	

10.4.1.2 Consumers

This exposure scenario does not address consumers.

10.4.1.3 Indirect exposure of humans via the environment

Table 10.37 ES4: Risk characterisation for humans exposed via the environment

Route of exposure and type of effects	Risk characterisation ratio	Justification for risk characterization
Inhalation: Long term, Systemic	**RCR <0.01**	
Oral: Long term, Systemic	**RCR <0.01**	

10.4.2 Environment

10.4.2.1 Aquatic compartment (incl. sediment)

Table 10.38 ES4: Risk characterisation for the aquatic compartment (incl. sediment and secondary poisoning)

Protection target	Risk characterisation ratio	Justification for risk characterization
Fresh Water (Pelagic)	**RCR <0.01**	
Fresh Water (Sediment)	**RCR <0.01**	
Marine Water (Pelagic)	**RCR <0.01**	
Marine Water (Sediment)	**RCR <0.01**	

10.4.2.2 Terrestrial compartment

Table 10.39 ES4: Risk characterisation for the terrestrial compartment (incl. secondary poisoning)

Protection target	Risk characterisation ratio	Justification for risk characterization
Agricultural Soil	**RCR <0.01**	

10.4.2.3 Atmospheric compartment

10.4.2.4 Microbiological activity in sewage treatment systems

Table 10.40 ES4: Risk characterisation for the microbiological activity in sewage treatment systems

Protection target	Risk characterisation ratio	Justification for risk characterization
Sewage Treatment Plant (Effluent)	**RCR <0.01**	

10.5 ES5: Consumer painting

10.5.1 Human health

10.5.1.1 Workers

This exposure scenario does not address workers

10.5.1.2 Consumers

Table 10.41 ES5: Risk characterisation: Consumer use of water borne wall paints, roller and brush applications [PC9a]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.06**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.16**
Oral: Long term, Systemic	**RCR = 0**
Combined routes: Long term, Systemic	**RCR = 0.22**
Justification for qualitative risk characterisation	
Adverse irritancy effects are controlled by substance concentration (< 10 %) in product, and no local effects are expected.	

Table 10.42 ES5: Risk characterisation: Consumer use of solvent rich paints, roller and brush applications [PC9a]

Route of exposure and type of effects	Risk characterisation
Inhalation: Acute, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Local	**Qualitative risk characterisation: risk controlled**
Inhalation: Long term, Systemic	**RCR = 0.13**
Dermal: Acute, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Local	**Qualitative risk characterisation: risk controlled**
Dermal: Long term, Systemic	**RCR = 0.16**
Oral: Long term, Systemic	**RCR = 0**
Combined routes: Long term, Systemic	**RCR = 0.29**
Justification for qualitative risk characterisation	
Adverse irritancy effects are controlled by substance concentration (< 10 %) in product, and no local effects are expected.	

10.5.1.3 Indirect exposure of humans via the environment

Table 10.43 ES5: Risk characterisation for humans exposed via the environment

Route of exposure and type of effects	Risk characterisation ratio	Justification for risk characterization
Inhalation: Long term, Systemic	**RCR <0.01**	
Oral: Long term, Systemic	**RCR <0.01**	

10.5.2 Environment

10.5.2.1 Aquatic compartment (incl. sediment)

Table 10.44 ES5: Risk characterisation for the aquatic compartment (incl. sediment and secondary poisoning)

Protection target	Risk characterisation ratio	Justification for risk characterization
Fresh Water (Pelagic)	**RCR <0.01**	
Fresh Water (Sediment)	**RCR <0.01**	
Marine Water (Pelagic)	**RCR <0.01**	
Marine Water (Sediment)	**RCR <0.01**	

10.5.2.2 Terrestrial compartment

Table 10.45 ES5: Risk characterisation for the terrestrial compartment (incl. secondary poisoning)

Protection target	Risk characterisation ratio	Justification for risk characterization
Agricultural Soil	**RCR <0.01**	

10.5.2.3 Atmospheric compartment

10.5.2.4 Microbiological activity in sewage treatment systems

Table 10.46 ES5: Risk characterisation for the microbiological activity in sewage treatment systems

Protection target	Risk characterisation ratio	Justification for risk characterization
Sewage Treatment Plant (Effluent)	**RCR <0.01**	

10.6 Overall exposure (combined for all relevant emission / release sources)

10.6.1 Human health

Notes and Comments

Re: Combined Risk to Human Health

When relevant, select the combinations of exposure scenarios which could result in simultaneous exposure of humans and report the outcome of the assessment here. This may occur for example, when it is foreseeable that a worker may undertake a combination of tasks in a shift, or that a person could be exposed both from work and via the environment. Combined exposure could also occur for consumers via different product containing the same substance.

10.6.2 Environment (combined for all emission sources)

10.6.2.1 Total releases

The total releases to the environment are presented in the table below. This is the sum of the releases to the environment from all exposure scenarios addressed.

When an exposure scenario has more than one contributing scenario for the environment, the contributing scenario with the greatest release is used to derive the total release. This may lead to an overestimation of the total release

Table 10.47 Total releases to the environment per year from all life cycle stages

Release route	Total releases per year
Water	1.5 tonnes/year
Air	19.08 tonnes/year
Soil	0.5 tonnes/year

10.6.2.2 Regional exposure

Environment

The regional predicted environmental concentration (PEC regional) and the related risk characterisation ratios when a PNEC is available are presented in the table below. The PEC regional has been estimated with EUSES.

When an exposure scenario has more than one contributing scenario for the environment, the contributing scenario with the greatest release is used to derive the PEC regional. This may lead to an overestimation of the PEC regional.

Table 10.48 Summary of predicted regional exposure concentrations (Regional PEC)

Protection target	Regional PEC	RCR
Fresh water	Estimated by EUSES: 2.84E-6 mg/L	<0.01
Fresh water sediment	Estimated by EUSES: 2.73E-4 mg/kg dw	<0.01
Marine water	Estimated by EUSES: 3.36E-7 mg/L	<0.01
Marine water sediment	Estimated by EUSES: 2.64E-5 mg/kg dw	<0.01
Air	Estimated by EUSES: 6.84E-7 mg/m³	<0.01
Agricultural soil	Estimated by EUSES: 1.99E-6 mg/kg dw	<0.01

Man via environment

RCR for oral <0.01 (based on regional total estimated daily intake for humans: 2.1E-5 mg/kg bw/day)

RCR for inhalation = <0.01 (based on PEC regional for air: 6.84E-7 mg/m^3)

10.6.2.3 Local exposure due to all wide dispersive uses

The predicted local environmental concentrations (PEC local) based on the releases from all widespread uses at the local scale are reported in the table below. The risk characterisation ratio is included when a PNEC is available. Those exposure estimates have been obtained with EUSES.

When an exposure scenario has more than one contributing scenario for the environment, the contributing scenario with the greatest release is used to derive the PEC local. This may lead to an overestimation of the PEC local.

Table 10.49 Predicted environmental concentration and risk characterisation ratio for the exposure due to all wide dispersive uses

Protection target	PEC local due to all wide dispersive uses	RCR
Fresh water	2.43E-5 mg/L	<0.01
Fresh water (sediment)	0.002 mg/kg dw	<0.01
Marine water	2.48E-6 mg/L	<0.01
Marine water (sediment)	2E-4 mg/kg dw	<0.01
Sewage treatment plant (effluent)	2.14E-4 mg/L	<0.01
Agricultural soil	1.39E-4 mg/kg dw	<0.01

10.6.2.4 Local exposure due to combined uses at a site

Notes and Comments

Re: Environmental Risk for combined uses at site

When relevant, select the combinations of exposure scenarios which could result in simultaneous environmental exposure at site and report the outcome of the assessment here. This may occur for example, when manufacturing and formulation takes place at the same site.

11. APPENDIX 1

Chemical Safety Report (CSR) for ECHA SUBSTANCE - OVERVIEW TABLES

The overview of the quantitative risk assessment for exposure to workers is presented in Table 1. This table presents the key operational conditions, risk management measures and risk characterisation ratios (RCRs) for all exposure scenarios, both the inhalation and dermal routes. It also includes the method used for deriving the exposure estimate.

The overview of the quantitative risk assessment for environmental exposure assessment is presented in Table 2. This table presents the key operational conditions, release factors, risk management measures and RCRs for all exposure scenarios.

Notes and Comments

Re: Overview Tables

Overview tables can help the person developing the Chemical Safety Report (CSR) to ensure consistency and accuracy. They also provide company managers, ECHA and other reviewers of the CSR with a convenient summary of the key elements of an assessment.

Chemical safety assessments vary in their complexity and length, depending on the key hazards, exposure routes, exposure assessment methodology applied and other factors. Consequently a standardised table will not meet all needs. The tables presented here were developed manually and are considered appropriate to the assessment for the illustrative CSR. They are not intended to provide a fixed template but serve to illustrate how "an overview table" can be helpful in a CSR. Overview tables, when included, should be tailored to the specific assessment.

Overview tables cannot be automatically generated by Chesar 2.0.

Table 1: Overview of the Quantitative Risk Assessment for Exposure to Workers

ES Ref	Stage	Process	PROC	Subst. Conc	Duration exp hrs	Engineering Controls		Personal Protective Equipment		Estimation Method Inhalation	Risk Charaterisation Ratio (RCR)		
						LEV	Other	RPE	Gloves		Inhal.	Dermal	Total
ES1	Manufacture	Closed process	PROC 1	100	>4	no	> 3 ach[1]	no	no	Ecetoc	0.005	0.005	0.01
ES1	Manufacture	Maintenance /clean	PROC 8a	100	1-4	no		90%	90%	Ecetoc	0.30	0.20	0.50
ES2	Formulation	Delivery/charge	PROC 8b	100	0.25-1	no		no	80%	Ecetoc	0.51	0.39	0.90
ES2	Formulation	closed batch	PROC 3	100	>4	90%		no	80%	Ecetoc	0.15	0.02	0.17
ES2	Formulation	Batch mix	PROC 5	100	>4	90%		no	80%	Ecetoc	0.25	0.39	0.64
ES2	Formulation	Transfer/non dedicated	PROC 8a	1-5	0.25-1	no		no	no	Ecetoc	0.20	0.39	0.59
ES2	Formulation	Transfer /dedicated	PROC 8b	1-5	0.25-1	no		no	no	Ecetoc	0.10	0.39	0.49
ES2	Formulation	Small scale fill	PROC 9	1-5	>4	no		no	no	Ecetoc	0.51	0.20	0.71
ES2	Formulation	Maintenance /clean	PROC 8a	100	1-4	no		90%	80%	Ecetoc	0.30	0.39	0.69
ES3	Coating/inks	Application-closed	PROC 2	1-5	>4	no		no	no	Ecetoc	0.10	0.04	0.14
ES3	Coating/inks	Deliver/charge	PROC 8b	1-5	0.25-1	no		no	no	Ecetoc	0.10	0.39	0.49
ES3	Coating/inks	Coating prep	PROC 5	1-5	0.25-1	no		no	no	Ecetoc	0.10	0.39	0.49
ES3	Coating/inks	Batch loading	PROC 8a	1-5	0.25-1	no		no	no	Ecetoc	0.20	0.39	0.59
ES3	Coating/inks	Industrial spraying	PROC 7	1-5	>4	95%	Low pres. gun	no	80%	Ecetoc & meas'd	0.51	0.24	0.75
ES3	Coating/inks	Roller / brush	PROC 10	1-5	>4	90%		no	no	Ecetoc	0.10	0.79	0.89
ES3	Coating/inks	Dip /pour	PROC 13	1-5	>4	90%		No	no	Ecetoc	0.10	0.39	0.49
ES3	Coating/inks	Curing/Drying	PROC 2	1-5	>4	no		no	no	Ecetoc	0.10	0.04	0.14
ES3	Coating/inks	Maintenance /clean	PROC 8a	1-5	1-4	no		no	80%	Ecetoc	0.61	0.08	0.69
ES4	Prof Painting	Transfer	PROC 8a	1-5	<0.25	no		no	no	Ecetoc	0.25	0.39	0.64
ES4	Prof Painting	Roller / brush	PROC 10	1-5	>4	no		no	80%	Stoffen-M	0.27	0.16	0.43
ES4	Prof Painting	Spray	PROC 11	1-5	>4	no		60%	80%	Stoffen-M	0.24	0.61	0.85

[1] ach = air changes per hour

Table 2: Overview of the Quantitative Risk Assessment for Environmental Exposure

ES ref	Use name Site/wide dispersive (WDU)	Amounts	STP and effluent OC	Initial release to water	Initial release to air	On site OC/RMM water [effectiveness]	On site OC/RMM air [effectiveness]	Critical target	RCR
ES1	Site: Manufacture in contained systems	Daily: 16.000 kg/d Annual: 320 t/y Regional tonnage: 100%	STP: No Effluent flow rate: 2000 mc/d River flow rate: 18000 mc/d	0% (Release factor)	5% (ERC1)	No water used in process and maintenance (cleaning)	On site incineration [99%]	Agricultural soil	0.001
ES2	Site: Formulation of mixtures in closed and open systems	Daily: 500 kg/d Annual: 100 t/y Regional tonnage: 100%	STP: No Effluent flow rate: 2000 mc/d River flow rate: 18000 mc/d	1% (release factor)	0,6% (release factor)	Water for equipment/tank cleaning collected as waste [100%]	None	Agricultural soil	0.004
ES3	Site: Industrial use of coating involving water	Daily: 20 kg/d Annual: 4 t/y Regional tonnage: 100%	STP: Yes STP flow rate: 2000 mc/d STP sludge to soil: Yes River flow rate: 18000 mc/d	0,5% (xxx SPERC 5.1a v.1)	2% (xxx SPERC 5.1a v.1)	Low spray efficiency Wet scrubber with large reservoir with continuous removal of sludge Equalizer for continuous release to water over > 200 days Collection of water/sludge before release	None	Freshwater	0.38
ES3	Site: Industrial use of coating water free	Daily: 20 kg/d Annual: 4 t/y Regional tonnage: 100%	STP: No Effluent flow rate: 2000 mc/d River flow rate: 18000 mc/d	0 % (xxx SPERC 5.1b v.1)	2 % (xxx SPERC 5.1b v.1)	Low spray efficiency	None	Agricultural soil	0.0006
ES4	WDU: Use leading to inclusion into/onto matrix	Daily: 0,03 kg/d Regional tonnage: 10%	STP: Yes STP flow rate: 2000 mc/d STP sludge to soil: Yes River flow rate: 18000 mc/d	1% (ERC 8f)	15% (ERC 8f)	None	None	Freshwater	0.001
ES5	WDU: Use leading to inclusion into/onto matrix	Daily: 0,03 kg/d Regional tonnage: 10%	STP: Yes STP flow rate: 2000 mc/d STP sludge to soil: Yes River flow rate: 18000 mc/d	1% (ERC 8f)	15% (ERC 8f)	None	None	Freshwater	0.001

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