**SPERC fact sheet – *Formulation & (re)packing of substances and mixtures – Industrial (Solvent-borne)***

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| **General Information** |
| **Title of Specific ERC** | Formulation & (re)packing of substances and mixtures (industrial): solvent-borne  |
| **Applicable ERC** | 2 – Formulation of preparations |
| **Responsible** | ESIG/ESVOC |
| **Version** | V1 |
| **Code** | ESVOC 2.2.v1 |
| **Scope** | Formulation, packing and re-packing of the substance and its mixtures in batch or continuous operations, including storage, materials transfers, mixing, tabletting, compression, pelletisation, extrusion, large and small scale packing, sampling, maintenance and associated laboratory activities.*Substance Domain*: Applicable to petroleum substances (e.g., aliphatic and aromatic hydrocarbons) and petrochemicals (e.g., ketones, alcohols, acetates, glycols, glycol ethers, and glycol ether acetates).*Size of installation*: Use rate assumed to be 100000 kg/d*Processing conditions:* Dry process |
| **Coverage** | Process Categories: 1 (use in closed process, no likelihood of exposure), 2 (use in closed, continuous process with occasional controlled exposure), 3 (use in closed batch process (synthesis or formulation)), 4 (use in batch and other process (synthesis) where opportunity for exposure arises), 5 (mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)), 8a (transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities), 8b (transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities), 9 (Transfer of substance or preparation into small containers (dedicated filling line, including weighing)), 14 (Production of preparations or articles by tabletting, compression, extrusion, pelletisation),15 (use as laboratory reagent) |

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|  | **Characteristics of specific ERC** | **Type of Input Information** |  |
| **Operational Conditions** | Indoor use. Solvent-based process. Process optimized for highly efficient use of raw materials (very minimal environmental release). Volatile compounds subject to air emission controls. Negligible wastewater emissions as process operates without water contact. Negligible air emissions as process operates in a contained system. Wastewater emissions generated from equipment cleaning with water. |  |  |
| **Obligatory onsite RMMs** | Emission factors to wastewater are based on water solubility. Assumes no free product in wastewater stream; oil-water separation (e.g. *via* oil water separators, oil skimmers, dissolved air floatation) may be required under some circumstances  |  |  |
| **Substance Use Rate** | The substance maximum use rate in a typical operation (MSPERC) is 100000 kg/d | Maximum site tonnage, based on sector knowledge\*. May be overwritten with own use rate. |  |
| **Days Emitting** | 300 days/year  | Default ‘Formulation’ – Tonnage > 2000 tonnes/yearConsider overwriting for own tonnage < 20001 |  |
| **Environmental Parameters for Fate Calculation** | Assumed dilution factor in freshwater is 10. For marine assessments an additional tenfold dilution is assumed, i.e., dilution factor in marine water = 100. | ERC default settings2 |  |

\*A use rate of 100000 kg/d over 300 days is equivalent to 30000 tonnes annually; which is consistent with the maximum capacity for a ‘major’ lubricant producing plant (OECD Lubricants & Lubricant Additives ESD, 2004).

[http://www.oecd.org/document/55/0,3746,en\_2649\_34379\_47582135\_1\_1\_1\_1,00.html](http://www.oecd.org/document/55/0%2C3746%2Cen_2649_34379_47582135_1_1_1_1%2C00.html)

1ECHA Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation, Section R.16.3.2.1

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| 2ECHA Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation, Section R.16.6.3<http://echa.europa.eu/documents/10162/17224/information_requirements_r16_en.pdf>  | **Characteristics of Specific ERC** | **Justification** |
| **Emission Fractions****(from the process)** | ***To Air*** VP > 1000 PaVP 100-1000 PaVP 10-100 PaVP < 10 Pa | **f (vapor pressure)**0.0250.010.0050.0025 | Estimates on the basis of substance vapor pressure taken from EUTGD (2003) Appendix 13. These values are consistent with the range of emissions reported in OECD Coatings ESD4 and consistent with EU Solvent Emissions Directive after typical RMMs as further documented in *Coatings SPERC Factsheet*. |
| ***To Wastewater/Sewer/ Water courses***WS < 1 mg/LWS 1-10 mg/LWS 10-100 mg/LWS 100-1000 mg/LWS >1000 mg/L | ***f* (water solubility)**0.0000050.000020.00020.0020.005 | Emission factors to wastewater are conservatively calculated based on wastewater volume generated from cleaning operations and substance aqueous solubility *Assumption of 5 m3 of wastewater generated per 1 tonne of substance used is relatively conservative.6 Example: 1 mg/L x 5 m3/tonne use x 1000 L/m3 x 1tonne/109mg = 0.000005 tonnes/tonne used. For WS range (e.g., 1-10 mg/L), the geometric mean (i.e., 3.2 mg/L) is used to calculate the fraction released.*OECD Coatings ESD4 reports no releases of volatile substances to water. The values used here are consistent with those reported for dust. |
| ***To Soil*** | 0.0001 | ERC2 default7 |

3European Commission Technical Guidance Document on Risk Assessment (EUTGD) Part 2 – 2nd Edition (2003). Appendix 1 Polymers Industry, Table 2.1 (MC = 3).

<http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides/doc/tgd/tgdpart2_2ed.pdf>

4OECD Series on Emission Scenario Documents, Number 22. July 2009. Emission Scenario Documents on Coating Industry (Paint, Laquers and Varishes).

5OECD Series on Emission Scenario Documents, Number 10. November 2004. Emission Scenario Document on Lubricants and Lubricant Additives.

6Data from OECD Lubricants & Lubricant Additives ESD (2004) suggest a reasonable worst case estimate of wastewater discharge for a blending plant (formulation) is 0.1 m3/tonne lubricant5; thus, assumed value of 5 m3/tonne represents a conservative estimate.

[http://www.oecd.org/document/55/0,3746,en\_2649\_34379\_47582135\_1\_1\_1\_1,00.html](http://www.oecd.org/document/55/0%2C3746%2Cen_2649_34379_47582135_1_1_1_1%2C00.html)

7ECHA Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation, Appendix R.16-1 – Environmental Release Categories

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|  | **Type of RMM** | **Typical Efficiency** |
| **Appropriate Risk Management Measures (RMM) that may be used to achieve required emission reduction** | ***Air*** |
| *On-site Technology*Wet scrubber – gas removalAir filtration – particle removalThermal oxidationVapor recovery – Adsorption*Other* | 70%80 – 99+% (efficiency range; no typical value reported)598%80%Default efficiencies of the RMMs according to CEFIC Risk Management Library and 5*IPPC 2009 draft BREF on Common Waste Water & Waste Gas Treatment/Management Systems in the Chemical Sector*.\*A default value of 0% was selected on the basis that emission fractions obtained from the EUTGD (2003) as presented above already incorporate typical air RMMs. |
| ***Water*** |
| *Offsite Technology*Municipal wastewater treatment plant | The removal efficiency of a sewage treatment plant can be estimated. The standard estimation is via the SimpleTreat module of EUSES or ECETOC TRA.\*Specific substance efficiency calculated via SimpleTreat and is assumed to represent default removal efficiency. |
| *Onsite Technology*Distillation (*of used process solvent; prior to any water contact*)Acclimated biological treatment*Other* | The efficiency of the RMMs varies dependent on the treatment technology and the properties of the substance. The standard RMMs encountered in the processes considered here typically provide removal efficiencies in excess of 80% (according to CEFIC Risk Management Library)For readily and inherently biodegradable substances, the removal efficiency for acclimated biological treatment may be significantly higher than SimpleTreat estimates; thus, SimpleTreat estimates can serve as a conservative lower bound.6Substance-specific efficiencies can be considered. |

5 http://eippcb.jrc.es/reference/

6 http://www.aromaticsonline.net/Downloads/WWTP.doc

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| **Narrative Description of Specific ERC** |
| Formulation of solvent-borne substances encompasses a wide range of activities such as transfers, mixing, tabletting, compression, pelletilisation and sampling. Substance losses are reduced through use of general and site-specific risk management measures to maintain workplace concentrations of airborne VOCs and particulates below respective OELs; and through use of closed or covered equipment/processes to minimize evaporative losses of VOCs. Substance losses to waste water are generally restricted to equipment cleaning as processes operate without contact with water Such uses and substance properties result in limited to no discharge to wastewater or to soil from the industrial site.  |

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| **Safe Use** |
| **Communication in SDS**The REACH registrant establishes a set of standard conditions of safe use for a substance (for industrial use of a solvent-borne processing aid) by adopting the conditions specified in this SPERC and recommending a Required Removal Efficiency (RRE) for adequate risk reduction. If RRE = 0, wastewater emission controls (beyond those specified by the operational conditions) are not required to ensure safe use of the substance. If > 0, the RRE may be achieved via offsite municipal sewage treatment (providing substance removal efficiency, REOffsite) and/or onsite emission controls (providing substance removal efficiency, REOnsite). Multiple onsite emission reduction technologies can also be considered, if necessary and applicable (e.g., REOnsite = 1 – [(1 – REOnsite, 1) x (1 – REOnsite, 2) x etc.], where REOnsite, *n* represents the substance removal efficiency for each onsite emission reduction technology). For direct comparison to the RRE, a total substance emission reduction efficiency (RETotal) is calculated (RETotal = 1 – [(1 – REOnsite) x (1 – REOffsite)]. An RETotal < RRE is indicative of the safe use of a substance. Removal efficiency requirements, as dictated by the assumed operating conditions, are documented in the Chemical Safety Report and communicated in the Safety Data Sheet. All other parameters underlying a substance exposure scenario based on the SPERC ‘Formulation & re(packing) of substances and mixtures – industrial (solvent-borne)’ are implicitly referred to via the reference to this SPERC.**Scaling***Wastewater*The users of solvent-borne processing aids are responsible for evaluating the compliance of their specific situations with the registrant’s information. To that end, the users need to know their site-specific substance use rate (MSite) and days emitting (TEmission, Site), onsite and offsite emission controls and subsequent total substance emission reduction efficiency (RETotal, Site = 1 – [(1 – REOnsite, Site) x (1 – REOffsite, Site)]), sewage treatment plant effluent flow rate (GEffluent, Site) and receiving water dilution factor (qSite). Adequate control of risk exists if the following relevant expression holds true:*for risk driven by wastewater treatment plant microbes*[MSPERC x (1 – RETotal, SPERC)] / GEffluent, SPERC ≥ [MSite x (1 – RETotal, Site)] / GEffluent, Site *for risk driven by freshwater/freshwater sediments, marine water/marine water sediments*[MSPERC x (1 – RETotal, SPERC)] / (GEffluent, SPERC x qSPERC) ≥ [MSite x (1 – RETotal, Site)] / (GEffluent, Site x qSite)*for risk driven by secondary poisoning (freshwater fish/marine top predator) or indirect exposure to humans (oral)* [MSPERC x TEmission, SPERC x (1 – RETotal, SPERC)] / (GEffluent, SPERC x qSPERC) ≥ [MSite x TEmission, Site x (1 – RETotal, Site)] / (GEffluent, SpERC x qSite)It is simpler and thus may be preferable to some users to compare MSite with MSafe (*the maximum tonnage that can be safely used, within the prescribed operating conditions, OCSpERC and RMM, RETotal, SpERC*). Adequate control of risk exists if the following conditions are met [RETotal, Site ≥ RETotal, SPERC, GEffluent, Site ≥ GEffluent, SPERC, and qSite ≥ qSPERC] and MSafe ≥ MSite. Local amount used, emission days per year, receiving water flow rate (or dilution factor), sewage treatment plant effluent flow rate, and risk management measure removal efficiency are the adjustable parameters for emission assessment. These parameters can be refined using site-specific information, which often is obtainable with limited effort and expertise. Adjusting the assessment by refining these parameters is referred to as scaling. Scaling is applied to evaluate compliance of a specific use with a generic Exposure Scenario. For that reason, site parameter values which deviate from the default values need to reflect the actual situation. The release factors are an additional set of adjustable parameters; however, refining the default values requires significant justification and, thus, is beyond the boundary conditions defined in the SPERC Factsheet. For that reason, release factor refinements do not constitute a SPERC-based assessment and must be considered an element of downstream user chemical safety assessment. |

### ESVOC 2.2.v1

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| **Determinant Label** | **Quali-/ Quanti-tative** | **Value** | **Description of Value** | **Effectiveness in % (default, min-max) for water and/or air** | **Exposure route** | **Use conditions worker** | **Use condition consumer** | **Standard Phrase** |
| Indoor/Outdoor use | Qual | Indoor use |   |  | Air/ water/ soil | e-w-3 | e-c-4 | Indoor |
| Process efficiency | Qual | Process optimized for highly efficient use of raw materials (very minimal environmental release) | - |  | Water | e-w-3 | e-c-4 | Same as “value” |
| Equipment cleaning | Qual | No release to wastewater from process as such, wastewater emissions limited to release generated from final equipment cleaning step using water | - |  | Water | e-w-3 | e-c-4 | Same as “value’ |
| On-site treatment of off-air | Qual | Typical measures to maintain workplace concentrations of airborne VOCs and particulates below respective OELs: e.g. Thermal wet scrubber – gas removal and/or air filtration – particle removal and/or thermal oxidation and/or vapour recovery – adsorption | - |  | Air | e-w-3 |  | Same as “value” |
| On site treatment of wastewater | RMM | Acclimated biological treatment | For readily and inherently biodegradable substances, the removal efficiency for acclimated biological treatment may be significantly higher than SimpleTreat estimates; thus, SimpleTreat estimates can serve as a conservative lower bound.Substance-specific efficiencies can be considered and can be used to overwrite the arbitrary default of this determinant value, which is set to 70% | Water 70% | Water | e-w-3 |  | Same as “ value “ |
| Further onsite technology | RMM | Distillation of used process solvent | The efficiency of the RMMs varies dependent on the treatment technology and the properties of the substance. The standard RMMs encountered in the processes considered here typically provide removal efficiencies in excess of 80% (according to CEFIC Risk Management Library) | Waste 80 % | Waste | e-w-3 |  | Same as “value” |
| On-site treatment of off-air | RMM | Upgrade of the system in place or additional air treatment measures, such as wet scrubber and/or air filtration and/or thermal oxidation and/or vapor recovery systems, in order to achieve a reduction of the air emissions | Arbitrary default of this determinant value, which is set to 50%, to be overwritten by the assessor according to the required removal efficiency (assessment outcome) | Air 50% | Air | e-w-3 |  | Same as “value” |
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