

27 June 2017

Updates to the Illustrative example of a CSR

• Purpose and Scope

The Illustrative example of a CSR has been updated (from its 2012 edition). The substance hazard and properties' profile for "ECHA substance" remain the same, however this version captures the lessons learnt over the past 4 years and the further development of good practice in chemical safety assessment under REACH. The main drivers for the update were: i) new Chesar 3.2 functionalities, ii) the need to bring the example in line with the updated ECHA guidance and iii) new elements emerging outside ECHA during last years, such as updates to the ECom Standard Phrase Catalogue.¹

In the paragraphs that follow we provide a brief overview on the main changes. **Note that changes in the CSR** (generated from the Chesar 3.2 file) **will also have a direct impact on the exposure scenario for communication**. Hence, many of the points beneath will be reflected in ECHA's illustrative example of exposure scenarios for communication to be annexed to the safety data sheet.

• Overview on new elements

- To align with ECHA's Guidance on Information Requirements and Chemical Safety Assessment (IR&CSA) Chapters R.12 (use description)² and R.14 (Occupational Exposure Assessment)³, contributing scenarios (CS) covering "maintenance and cleaning" activities have been introduced where relevant and the new PROC 28 has been assigned. As the ECETOC TRA version 3.0 exposure estimation tool for workers does not provide exposure estimates for PROC 28 yet, PROC 8a has been used instead as the input parameter assuming that there are similarities in the exposure, and the assessment tool has been reported as "external" in Chesar 3.2. Moreover, PROC 10 has been assigned to the contributing scenario "industrial printing in closed systems". As PROC 10 in the ECETOC TRA v3.0 for workers does not correspond to a closed system, PROC 2 has been used as the input parameter, assuming that it is more appropriate for estimating the exposures, and reported in Chesar 3.2 as assessment with "external" tool.⁴
- The release estimation for the environmental CS at the Formulation life cycle stage has been reviewed to better reflect the information contained in the OECD Emission Scenario Document (ESD) for coatings (OECD 2009); specifically, the release factor in the CSR example to water has been set equal to 0.05% and the justification has been reviewed.
- The SPERCs used for the environmental release estimation at industrial end use have been reviewed, to better describe the generic situation of "industrial use of coatings". The SPERCs were "invented" for this example. Each contributing activity has an individual and specific SPERC allocated to it e.g. water-based large scale, water-based small scale and water-free process. The source of the information for these SPERCs was the OECD ESD for coatings.

¹ Available on <http://www.cefic.org/Industry-support/Implementing-reach/escom/>

² http://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

³ https://echa.europa.eu/documents/10162/13632/information_requirements_r14_en.pdf

⁴ The same would apply for spraying (PROC 7) and dipping (PROC 13) in closed systems

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- The environmental assessment for the widespread uses (professional, consumers) has been updated to include the updated release factor to water adopted by the Chapter R.16 of ECHA's Guidance on environmental exposure assessment⁵ for ERC 8f and ERC 8c.
- The conditions of use and remarks on the consumer exposure based on the ConsExpo exposure estimation tool have been reviewed, to take into account how ConsExpo assessments can now be more systematically reported in a REACH CSR generated with Chesar 3.2. An automated export of the ConsExpo assessments to Chesar, exemplified already in the exposure scenario for consumers, is expected to become publically available in July 2017.
- The exposure estimates for consumer exposure have been updated to extrapolate from the "event" exposure concentration to the concentration over the whole day; this revision takes into account the provisions of Chapter R.15 of ECHA's Guidance on consumer exposure assessment.⁶
- Standard phrases from the most recent ECom Standard Phrase Catalogue⁷ have been used, whenever possible, for naming of contributing scenarios as well as for describing the conditions of use. Note: We are aware that these phrases are not always ideal, however the emphasis in the illustrative CSR example is on demonstrating the functionality.
- The conditions of use for a *Stoffenmanager*-based exposure assessment (i.e. professional use, spraying) have been consolidated to avoid duplication with the conditions of use linked to the ECETOC TRA v3.0 (workers). For example, only one condition of use to express the concentration of a substance in a mixture for both *Stoffenmanager* and TRA workers has been applied.
- A new ART based exposure assessment has been included for professional uses (i.e. contributing scenarios for roller and brushing). Therefore some new *conditions of use templates* have been defined to report the ART based assessment (chapter 9.4.3 in the example). Some of the ART *conditions of use* have been consolidated with those used in the ECETOC TRA, to avoid duplication in the exposure scenario for communication.
- The qualitative assessment for the inhalation route (long term and short term) has been reviewed and streamlined. The ECHA substance is classified as a skin and eye irritant but no studies on irritancy effects are available for the inhalation route. Nevertheless, the example illustrates how a chemical safety assessment for the inhalation route can be carried out.
- A weight of evidence approach (i.e. supported by measured data) has been added when PROC 1-3 is used as an input to the ECETOC TRA v3.0 (worker) exposure estimation tool for a closed system outside of the chemical production sector. For example, the PROC 2 TRA exposure estimate for (i) tunnel drying after spray coating and (ii) for closed printing processes. This is in line with provisions described in Chapter R.14 of ECHA Guidance on occupational exposure assessment.⁸
- The reference to Classification and labelling in Annex I to Directive 67/548/EEC has been removed since it is no longer applicable. Such classification can no longer be reported in IUCLID 6.

⁵ http://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf

⁶ <http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>,

⁷ <http://www.cefic.org/Industry-support/Implementing-reach/escom/>

⁸ http://echa.europa.eu/documents/10162/13632/information_requirements_r14_en.pdf