Tyre Generic Exposure Scenario

Scaling Equation Guidance

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December 16, 2009

Version 1.0

Introduction

Downstream users (DU) are required to confirm compliance with the exposure scenario forwarded by registrant. Because of the diversity of OCs and RMMs among tyre production facilities, ETRMA expects that the manufacturer/importer will provide scaling rules as described in *Part G: Extending the SDS* in the REACH CSA TGD. This may include the inclusion of a scaling equation in the eSDS annex, identification of valid linear relationships for key determinants of exposure or preparation of a spreadsheet model. The scaling equation allows DUs to combine OCs and RMMs differently than in the ES prepared by the registrant to confirm compliance with the ES at the facility level. The scaling approach allows the DU to make an independent determination of whether a specific facility has achieved control of risk within the boundaries of the ES. The calculation or determination is performed by the DU user after receipt of the eSDS and does not affect the CSA prepared by the supplier. The scaling equation approach is not required when control of risk can be demonstrated for worst case parameter selections, such as the ERC emission factors. There are at least two possible scaling approaches that can be used by the supplier.

Method 1: Linear Scaling Equation

An example the linear scaling equation is provided below in **Figure 1**. In this example, the generic exposure scenario prepared by the supplier establishes a set of default parameters that demonstrates an acceptable RCR less than 1. The registrant has confirmed that each of the parameters in the scaling equation is linearly related to the risk characterization ratio (RCR). If there are bounds to the applicability of scaling (e.g. if water solubility is exceeded), the supplier will provide a range appropriate for scaling. The example calculation shown in Figure 1 would be done at the facility level to document an acceptable RCR at that facility. As an alternative to a formal scaling equation, the supplier could provide the parameters that independently scale linearly with the RCR and the appropriate range for scaling.

Method 2: Spreadsheet

If the RCR cannot be adequately characterized by simple linear factors, the registrant has the option of preparing a tool for the DU user to confirm compliance for with the ES. This approach is required when RCR is not linearly related to key determinants of exposure. For example, the supplier could provide a copy of the ECETOC TRA Tier 1 model preloaded with the default scenario. Guidance would be provided by the supplier indicating the parameter inputs that may be modified. Other tools such as web-based tools or EUSES are also considered to be valid.

Figure 1: Example Scaling Equation

RCR $_{actual, air}$ << 1 for all plausible usage rates (up to 1,000 ton/site/year).

$$RCR_{actual,water} = RCR_{ES} \cdot \left(\frac{M_{actual}}{M_{ES}}\right) \cdot \left(\frac{C_{actual}}{C_{ES}}\right) \cdot \left(\frac{f_{water,actual}}{f_{water,ES}}\right) \cdot \left(\frac{1 - f_{abatement,actual}}{1 - f_{abatement,ES}}\right) \cdot \left(\frac{T_{emission,ES}}{T_{emission,actual}}\right)$$

Exposure scenario assumptions:
RCR_{ES} = 0.91
M_{ES} = Quantity of finished tyre processed = 52,000 ton/yr (about 16,000 tyre/day)
C_{ES} = Fraction of the substance uses in production = 0.0058 % w/w = 0.01 phr
$f_{water, ES}$ = Emission factor: fraction emitted from process prior to abatement = 0.05 % w/w
$f_{abatement}$= Efficiency of abatement or control technology = 0%
$T_{emission}$ = Duration of emissions = 300 days/year

Example calculation completed by downstream user to check whether activity is within boundaries of ES:
M_{actual} = 16,500 ton/year (about 5,000 tyre/day)
C_{actual} = 0.5 phr = 0.25%w/w
$f_{water, actual}$ = 0.001% w/w (based on effluent data for similar chemical)
$f_{abatement}$ = *0%* (no additional treatment technologies required)
$T_{emission}$ = 250 days/year

$$RCR_{actual,water} = 0.91 \cdot \left(\frac{16{,}500\ t/yr}{52{,}000\ t/yr}\right) \cdot \left(\frac{0.25\%}{0.0058\%}\right) \cdot \left(\frac{0.001\%}{0.05\%}\right) \cdot \left(\frac{100\% - 0\%}{100\% - 0\%}\right) \cdot \left(\frac{300\ t/y}{250 t/y}\right) = 0.3$$

Conclude control of aquatic risk is achieved because $RCR_{actual,water} < 1$.

Reference

ECHA, 2008. Guidance on information requirements and chemical safety assessment Part G: Extending the SDS. Guidance for the implementation of REACH. May, 2008.