Supplementary Information

Controlling the risks of nano-enabled products through the life cycle: the case of nano copper oxide paint for wood protection and nano-pigments used in the automotive industry

1. Expert Elicitation to derive RC methodology classification profile for Ecological Risk Assessment (ERA)

Ten ERA experts were chosen from our personal networks and contacted by email in December 2015 with a request to participate in SUNDS methodology development. Three responses were received, including two regulators (from EU) and one researcher (from EU). From these responses, one response was complete and used toward SUNDS ERA sub-module classification development. We were notified that the single response represents the view of two regulator respondents. Data collection through the questionnaires was closed in February 2016. Surveymonkey platform was used to implement the online questionnaire. Respondent identity was coded using aliases ERA#1-3. The discussion of the questionnaire results will follow the questionnaire structure: 1) Questions related to aggregation aspects; 2) Questions related to classification aspects; 3) Case studies specific questions and 4) General questions.

<u>Questions related to aggregation aspects</u>

As reported in the questionnaire *Background information on ERA sub-module section,* aggregation takes place when results are requested at a level of assessment higher than the environmental compartment level. In this case, **non-additive aggregation** is involved, because risks cannot be simply added as they are related to different environmental compartments.

Questions posed on the non-additive aggregation include if the respondents agreed on a) approach of selecting the maximum risk for non-additive aggregation (Q.1), and b) presenting the number of environmental compartments where the risk is not acceptable (Q.2). ERA#2 agrees with both proposals and notes that combination of both these proposals allows distinguishing between risks at lifecycle stage and environmental compartment level simultaneously thus providing a more complete assessment. Both these suggestions will be implemented in the ERA sub-module.

<u>Questions related to classification aspects</u>

As reported in the questionnaire explanation part, classification involves the assignment of classes (e.g. high/medium/low or acceptable/quite acceptable/not acceptable) to deterministic or probabilistic risk values estimated for different level of assessment to offer additional guidance to the non-expert user. Questions posed on classification aspects include a) if classification should be based on confidence intervals or risk magnitude (Q.1), b) if suggested percentiles of risk distribution (Table 2, t1 and t2 in Figure 3) were suitable (Q.2), c) in the classification based on risk magnitude, which percentile should be used as representative for the whole probabilistic risk distribution (Q.3), d) in the classification based on confidence intervals, which percentile should be associated with the deterministic risk value (Q.4), and e) if labels associated with percentiles were suitable and communicative (Q.5).

ERA#2 prefers classification based on confidence intervals, which is in agreement with the opinion of human health risk assessment experts and will thus be implemented in both risk assessment sub-modules. ERA#2 does not agree with the proposed percentile classes in Table 2 and proposes a class of 95th -99th percentile as 90th-99th percentile class is a big interval. Since 95th percentile is a typical threshold in ERA it will be provided as a default threshold in the ERA sub-module as well. The user will then be free to modify default thresholds, as in the case of HHRA sub-module.

For the question which percentile should be used as representative for the whole probabilistic risk distribution in the approach on classification based on risk magnitude (Q.3) there were no responses, as no respondents selected the option “classification based on risk magnitude”.

ERA#2 suggests 95th percentile should be associated with the deterministic risk value (Q.4). As in the case of HHRA sub-module, we decided to use the 95th percentile as default value and to leave the user free to modify it.

Finally, the last question of this section asked if labels associated with percentiles were suitable and communicative (Q.5). ERA#2 affirms this, but suggests to change the middle classification label (“quite acceptable”) to 'uncertain area'/'acceptability not clear'/ 'conclusion not possible'. This comment has been addressed in the HHRA sub-module by changing the label “quite acceptable” with the label “needs further consideration”. In order to be consistent with the HHRA sub-module, the ERA sub-module will also use the label “needs further consideration” instead of “quite acceptable”.

Case study specific questions

This section asked respondents for any relevant publications on the case studies to which the SUNDS ERA sub-module would be tested (Q.1 and 2). ERA#2 suggested a 2011 paper by Gottardo et al. titled *Integrated risk assessment for WFD ecological status classification applied to Llobregat river basin (Spain). Part I & Part II* as relevant for the wood preservative case study.

General Questions

This section asked for feedback on the ERA sub-module graphical outputs and any other feedback on the ERA methodology within the SEA module. ERA#2 agreed that graphical output provided was a suitable representation for the ERA sub-module (Q.1). No additional feedback was provided on linking the ERA sub-module to the SEA module.

2. HHRA for n-CB

In the case of n-CB, no toxicological or exposure assessment experiments were conducted in the SUN project. A literature review was used to collect hazard and exposure information, and derive risks. Exposure was calculated in two ways: a) an exposure estimate was available in the literature for production of n-CB (Kuhlbusch et al.,2006)[1] and the highest particle measurement there was used; b) exposure measurements and estimates derived in the SUN project for n-OP were extrapolated to n-CB by considering their relative concentration in the plastic matrix (i.e. 1% wt).

Toxicological data in Elder et al. (2005)[2] was used to derive a DNEL distribution. The NOAEL for inhalation by rats is 1 mg/m3 which determines a DNEL described by a low confidence interval (LCL) equal to 9.71E-03 mg/m3 and an upper confidence interval (UCL) equal to 2.47E+00 mg/m3 .

The assessed exposure scenarios are reported in Table SI.1

Table SI.1. Exposure scenarios for n-CB pigment

[1] Kuhlbusch, T. A. J. and Fissan, H. (2006). Particle characteristics in the reactor and pelletizing areas of carbon black production. Journal of occupational and environmental hygiene,3: 558-567.

[2] Elder, A., Gelein, R., Finkelstein, J. N., Driscoll, K. E., Harkema, J. andOberdörster, G. (2005) Effects of subchronically inhaled carbon black in three species. I. Retention kinetics, lung inflammation, and histopathology.Toxicological Sciences,88: 614-629.

Exposure scenario (ES)	LC stage	Target	Exposure route	Exposure concentration	Additional information
ES1: Production of n-CB	SYN	Worker	Inhalation	5E-02 mg/m3	(Kuhlbusch et al., 2006)
		Worker	Dermal	negligible	
ES2: Manufacture of Master-batch containing 1 wt.% n-CB	FOR	Worker	Inhalation	negligible	
		Worker	Dermal	negligible	
ES3: Consumers and workers handling and working with PP-CB performing operations such as sawing, sanding or drilling that might lead to release of airborne particles.	USE	Worker	Inhalation	3E-06 mg/m3	Adaptation from Pizzol et al. (2019), Table 3 ES4: Cutting studies have been performed in a 20 m3 ventilated chamber (λ=0.5 1/h) using a jig saw. According to the gravimetric analysis of collected airborne respirable particles from 30 to 100 cm from the jig saw the respirable mass concentration was 0.3 µg/m3 where 1 % is CB
		Worker	Dermal	negligible	
		Consumer	Inhalation	3E-06 mg/m3	Adaptation from Pizzol et al. (2019), Table 3 ES4: Cutting studies have been performed in a 20 m3 ventilated chamber (λ=0.5 1/h) using a jig saw. According to the gravimetric analysis of collected airborne respirable particles from 30 to 100 cm from the jig saw the respirable mass concentration was 0.3 µg/m3 where 1 % is CB
		Consumer	Dermal	negligible	
ES4: Shredding	EoL	Worker	Inhalation	3E-9 mg/m3	Adaptation from Pizzol et al. (2019), Table 3, ES5. At the end-of-use the PP is shredded before incineration, landfill or down-use. Shredding studies have been performed in a 20 m3 ventilated chamber (λ=0.5 1/h) using a down scaled industrial shredder. According to the gravimetric samples measured from shredder extract and feed inlet, where the concentrations were assumed to be highest and assuming fully mixed concentrations in the room, the respirable mass release was up to 0.3 µg/(kg of PP). Assuming 100*100*20-meter shredding plant ventilated at rate of 5 1/h and shredding 1000 kg/h PP bumpers the mass concentration would be 0.3 ng/m3 in steady state where 1% is CB
		Worker	Dermal	negligible	