APPENDIX 1: NanoRiskCat●●●|●● Template

Literature methodology/sources of information

The following sources of information were used to fill out the NanoRiskCat●●●|●● for Polytetrafluoroethylene (PTFE):

Source

1. Relevant literature was identified through ICON The Virtual Journal of Nanotechnology Environment, Health and Safety http://www.icon.rice.edu/advancedsearch.cfm searching for articles that use "PTFE" in Keyword(s) or Word(s) in the Abstract.
2. Relevant literature was identified through PubMed (http://www.ncbi.nlm.nih.gov/) using the search terms: "PTFE AND nano AND toxicity" and "PTFE AND particles AND toxicity"
3. No articles were found to evaluate the environmental hazard of PFTE and only a limited number of studies were found to be relevant in regard to evaluate the human hazard of PFTE particles:

    a. Lee KP, Zapp JA Jr, Sarver JW. Ultrastructural alterations of rat lung exposed to pyrolysis products of polytetrafluoroethylene (PTFE, Teflon). Lab Invest. 1976 Aug;35(2):152-60.

    b. Johnston CJ, Finkelstein JN, Mercer P, Corson N, Gelein R, Oberdörster G. Pulmonary effects induced by ultrafine PTFE particles. Toxicol Appl Pharmacol. 2000 Nov 1;168(3):208-15.

    c. Oberdorster G, Finkelstein JN, Johnston C, Gelein R, Cox C, Baggs R, Elder AC. Acute pulmonary effects of ultrafine particles in rats and mice. Res Rep Health Eff Inst. 2000 Aug;(96):5-74; disc. 75-86.

Human hazard profile

1. **HARN: Does the nanomaterial fulfill the HARN paradigm?**

    Answer: No

Arguments and explanation: To the best of our knowledge, PTFE particles do not fulfill HARN

2. **Bulk – "Level A CLP": Is the bulk form of the nanomaterial known to cause or may cause serious damaging effects?**

   Answer: No

   Arguments and explanation: PTFE is not classified in the Annex VI of Regulation (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

3. **Bulk – "Level B CLP": Is the bulk form of the nanomaterial classified for other less adverse effects according to the CLP?**

   Answer: No

   Arguments and explanation: PTFE is not classified in the Annex VI of Regulation (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

4. **Nano – Acute toxicity: Is the specific nanomaterial known to be acute toxic?**

   Answer: Yes

   Arguments and explanation: Oberdörster et al. (2000) have found that ~18 nm Teflon (polytetrafluoroethylene [PTFE]) generated by heating Teflon in a tube furnace to 486°C were extremely toxic to rats at particle concentrations of ~50 µg/m3 when inhaled for only 15 minutes. This value is significantly lower that the acute toxicity cut-off used in NanoRiskCat for dusts and mists (solid particles and liquid droplets in a gas) set to 5 mg/l.

APPENDIX 1: NanoRiskCat●●●|●● Template

5. **Overall evaluation of human hazard**

We conclude that the color-code that best reflects the human hazard profile of polytetrafluoroethylene is ● based on evidence of acute toxicity of the nanomaterial.

Environment hazard profile

1. **Bulk – "Level A CLP": Is the bulk form of the nanomaterial classified as CLP Acute 1 or Chronic 1 or Chronic 2?**

   Answer: No

   Arguments and explanation: PTFE is not classified in the Annex VI of Regulation (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

2. **Nano – LC_{50}<10 mg/l: Is the nanomaterial in question reported to be hazardous to environmental species i.e. LC50 or EC 50 <10 mg/l?**

   Answer: Unknown

   Arguments and explanation: No studies were identified that would enable us to answer this question

3. **Bulk – "Level B CLP": Is the bulk form of the nanomaterial classified as CLP Chonic 3 or Chronic 4 or documented nano-specific effects?**

   Answer: No

   Arguments and explanation: PTFE is not classified in the Annex VI of Regulation (EC) No

1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

4. **Nano – LC50<100 mg/l: Is the nanomaterial in question reported to be hazardous to environmental species i.e. LC50 or EC 50 <100 mg/l?**

   Answer: Unknown

   Arguments and explanation: No studies were identified that would enable us to answer this question

5. **T½>40 days: Is the nanomaterial in question persistent i.e. T½>40 days?**

   Answer: Unknown

   Arguments and explanation: No studies were identified that would enable us to answer this question

6. **BCF>50: Is the nanomaterial in question bioaccumulative i.e. BCF>50?**

   Answer: Unknown

   Arguments and explanation: No studies were identified that would enable us to answer this question

7. **Dispersive or long-range transport, ecosystem effects?**

   Answer: Unknown

   Arguments and explanation: No studies were identified that would enable us to answer

this question

8. **Overall evaluation of environmental hazard**

We conclude that the color-code that best reflects the environmental hazard profile of nanoPTFE is ● as no studies were identified regarding the environmental hazards of nanoPTFE.