Summary of Risk Assessment Conducted Pursuant to subsection 83(1) of the *Canadian Environmental Protection Act, 1999*

New Substances Notification 20757: Cyclohexane, 1,1'-methylenebis[4-isocyanato-, homopolymer, 2-butoxyethanol- and polyethylene glycol mono-Me ether blocked (Chemical Abstracts Service Registry Number 1415043-98-9)

Regulatory decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA), and pursuant to section 83 of the Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance and have determined that it is not anticipated to enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long term harmful effect on the environment or its biological diversity, constitute or may constitute a danger to the environment on which life depends, or constitute or may constitute a danger in Canada to human life or health.

Substance identity

The notified polymer is cyclohexane, 1,1'-methylenebis[4-isocyanato-, homopolymer, 2-butoxyethanol- and polyethylene glycol mono-Me ether blocked (Chemical Abstracts Service Registry Number[1] 1415043-98-9). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains carbodiimide groups.

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in industrial coatings. Potential uses may include consumer adhesives and coatings.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to soil, water and sediment. The substance is expected to be persistent in these compartments based on its very long hydrolysis half-life (> 180 days) and very low biodegradability (≤ 10% over 28 days). The substance is not expected to bioaccumulate based on its high molecular weight, which will limit its ability to cross biological membranes.

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Environmental risk assessment

Based on the available hazard information, the substance has low acute toxicity to fish and aquatic invertebrates (median lethal loading rate > 100 mg/L) and low chronic toxicity to algae (no-observed-effect loading rate > 10 mg/L). A predicted no-effect concentration was not calculated given the low potential for harm to the environment.

The notified activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activity is expected to be mainly from formulation and cleaning of transportation vessels by release of the substance to water at low rates. No potential activities that could significantly increase environmental risks compared to those notified were identified. A predicted environmental concentration was not calculated due to the low potential for ecotoxicity.

Based on the low potential for exposure and ecotoxicity, the substance is unlikely to cause harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance is expected to have a low acute toxicity by the oral route (median lethal dose 300-2000 mg/kg body weight, with no toxicity observed at the highest dose when corrected for purity) and inhalation route (median lethal concentration > 1 mg/L/4 hr, both when corrected for purity). It is not a dermal sensitizer (> 10% estimated concentration required to produce a stimulation index of 3 (local lymph node assay)). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in industrial coatings, direct exposure of the general population is not expected due to the industrial nature of the use. Consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be chemically reacted into a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media is not expected given the specialized industrial use of the substance, which results in little or no release to the environment. Potential uses of the substance include consumer adhesives and coatings, where direct exposure of the general population is expected to be mainly by contact with the skin at low levels. Exposure will be low given its high molecular weight, which will limit its ability to cross biological membranes.

Based on the low toxicity and low potential for exposure, the substance is not likely to pose a significant health risk to the general population, and is therefore unlikely to be harmful to human health.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

Assessment conclusion

When the substance is used as notified, it is not expected to be harmful to human health or the environment according to the criteria under section 64 of the Act.

A conclusion under CEPA, on this substance, is not relevant to, nor does it preclude an assessment against the hazard criteria for Workplace Hazardous Materials Information System that are specified in the *Controlled Products Regulations* or the *Hazardous Products Regulations* for products intended for the workplace.