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

New Substances Notification 21182: Hexane, 1,6-diisocyanato-, homopolymer, 2-hydroxyethyl acrylate- and propylene glycol monoacrylate-blocked (Chemical Abstracts Service Registry Number 1392411-89-0)

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 hexane, 1,6-diisocyanato-, homopolymer, 2-hydroxyethyl acrylate- and propylene glycol monoacrylate-blocked (Chemical Abstracts Service Registry Number[1] 1392411-89-0). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains pendant acrylates and a high percentage of low molecular weight components less than 1000 daltons.

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 as a coating resin. Potential uses include manufacturing.

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 water, sediments, and soil. The substance is expected to be persistent in these compartments based on low expected hydrolysis and low biodegradation potential. The substance is not expected to bioaccumulate based on its low predicted bioaccumulation factor (< 250 L/kg) and high molecular weight, which will limit its ability to cross biological membranes.

[1] The Chemical Abstracts Service Registry Number is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

Environmental risk assessment

Based on the available hazard information, the substance has moderate acute toxicity to fish and aquatic invertebrates (median lethal concentration [LC_{50}] and median effective concentration 1-100 mg/L) and moderate chronic toxicity to algae (lowest-observed-effect-concentration and 10% effective concentration > 0.1 mg/L). Using the LC_{50} from the most sensitive organism (fish) and by applying an assessment factor of 100 to account for acute to chronic extrapolation, species sensitivity variation, and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 10-100 µg/L, which was used to estimate the risk to the environment.

The notified and other potential activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activities is expected to be mainly from formulation by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L, and from cleaning of transportation vessels by release of the substance to water resulting in a PEC in the range of 10-100 µg/L, with the exact value being below the PNEC value. For potential activities such as manufacturing, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 10-100 µg/L, also below the PNEC.

Comparing the PEC with the PNEC, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard, and exposure, indicates that the substance is unlikely to cause harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral route (median lethal dose > 2000 mg/kg body weight) and low subchronic and reproductive/developmental toxicity following repeated oral doses in mammalian test animals (29-day no-observed-adverse-effect level > 300 mg/kg-bw/day). The substance is expected to be a dermal sensitizer because it contains structural features associated with sensitization and because it demonstrated increased enzyme activity in the *in vitro* luciferase activation assay. It is not mutagenic *in vitro*; therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used industrially in ultraviolet or electron beam curable coating resins, 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, such as drinking water or air, is expected to be at low levels given the low potential for environmental release. No potential uses that could significantly increase human health risks compared to the notified uses were identified.

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 or for other identified potential activities, 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.