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

New Substances Notification 19573: 1,6-Hexanediol, reaction products with alkyldiisocyanate and 4-(ethenyloxy)-1-butanol (Confidential Accession No. 19316-4)

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 chemical is 1,6-hexanediol, reaction products with alkyldiisocyanate and 4-(ethenyloxy)-1-butanol (Confidential Accession No. 19316-4), and is considered a substance of unknown or variable composition, complex reaction products or biological materials (UVCB).

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 crosslinker in spray coatings. Potential activities may include formulation and manufacturing. No other uses are anticipated in Canada.

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 and sediment. The substance is expected to be persistent in these compartments based on its very low biodegradability (≤10% over 28 days). The substance is not expected to bioaccumulate based on its low predicted bioconcentration and bioaccumulation factors (<250 L/kg), and the moderate octanol-water partitioning coefficient (log K_{ow} <5) of most components of the substance.

Ecological assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have low acute and chronic toxicity in fish, aquatic invertebrates and algae (no adverse effects observed in saturated solutions; bioavailability expected to be low). The substance has low acute toxicity in soil invertebrates (median lethal concentration (LC_{50}) >100 mg/kg dry soil). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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 activity is expected to be mainly from use in industrial coatings by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L. For potential activities such as formulation and manufacturing, environmental exposure is expected to be mainly by release of the substance to water resulting in a PEC in the range of 10-100 µg/L.

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

Human health assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral, dermal and inhalation routes (oral and dermal median lethal dose >2000 mg/kg body weight; inhalation LC_{50} >1 mg/L/4hr with no significant effects at the highest dose tested) and low subchronic toxicity following repeat oral doses in mammalian test animals (90-day no-observed-adverse-effect level >100 mg/kg-bw/day). The substance has a low reproductive/developmental toxicity following repeat oral doses in mammalian test animals (no-observed-effect level >1000 mg/kg-bw/day). 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* or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a crosslinker in spray coatings, 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 is expected to be at low levels given that significant environmental releases of the substance are not anticipated. No potential uses which 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.

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 *Hazardous Products Regulations* for products intended for the workplace.