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

New Substances Notifications 19624 and 20696: Hexamethylene diisocyanate, oligomers, reaction products with 3-methoxypropylamine (Chemical Abstracts Service Registry Number 162492-07-1)

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 hexamethylene diisocyanate, oligomers, reaction products with 3-methoxypropylamine (Chemical Abstracts Service Registry Number[1] 162492-07-1), 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 in industrial coatings. Potential uses may include use in commercial 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 and sediment. The substance is expected to be persistent in these compartments based on its very low biodegradability (≤ 10% over 28 days) and resistance to hydrolysis. The substance is not expected to bioaccumulate based on its low octanol-water partitioning coefficient (log K_{ow} 0-3) and estimated low bioconcentration and bioaccumulation factors (< 250 L/kg).

Environmental risk 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 toxicity in fish and aquatic invertebrates and low chronic toxicity in algae (no effects observed in saturated solutions). A predicted no-effect concentration was not calculated given the low potential for 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

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activities such as transportation, formulation and use is expected to be negligible given the methods used for cleaning transport and formulation vessels, and the substance will be encapsulated in a stable matrix in end use products and unavailable for release. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and ecotoxicity. No potential activities which could significantly increase environmental risks compared to those notified were identified.

Based on the low potential for ecotoxicity and environmental exposure, 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 repeat oral doses in mammalian test animals (no-observed-adverse-effect level > 1000 mg/kg-bw/day). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in industrial coatings, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be encapsulated within 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 use of the substance in commercial coatings is expected to lead to direct and indirect exposure of the general population that do not pose a concern, similar to that of the notified use.

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