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

New Substance Notification 20057: Oxirane, 2-methyl-, polymer with oxirane, alkoxymethyl 3,5,5-trimethylalkyl ether (Confidential Accession No. 19383-1)

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 polymer is oxirane, 2-methyl-, polymer with oxirane, alkoxymethyl 3,5,5-trimethylalkyl ether (Confidential Accession No. 19383-1). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers*) because its number average molecular weight is less than 1000 daltons and it contains a high percentage of low molecular weight components.

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in paints and coatings. Potential uses may include inks, adhesives, personal care products and consumer cleaning products.

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. The substance is not expected to be persistent in water based on its ready biodegradation. The substance is not expected to bioaccumulate based on its expected rapid biotransformation and elimination rates.

Ecological assessment

Based on the available hazard information, the substance has low to moderate acute toxicity to fish and aquatic invertebrates (median lethal concentration (LC_{50}) median effective concentration (EC_{50}) >1 mg/L), moderate acute toxicity to algae (EC_{50} 1-100 mg/L), moderate chronic toxicity to fish and aquatic invertebrates (lowest-observed-effect-concentration (LOEC) 1-10 mg/L), and low chronic toxicity to algae (LOEC >10 mg/L). Using the LC_{50} from the most sensitive organism (fish) and by applying an assessment factor of 40 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 ecological risk.

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 cleaning of transport vessels by release of the substance to water resulting in a predicted environmental concentrations (PEC) in the range of 1-10 µg/L. No potential activities which could significantly increase environmental risks compared to those notified were identified.

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 ecological harm in Canada.

Human health assessment

Based on the available hazard information, the substance has low acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg body weight). It is expected to have low subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level >300 mg/kg-bw/day). The substance is expected to have a low reproductive/developmental toxicity following repeat oral doses in mammalian test animals (no-observed-effect level >300 mg/kg-bw/day). It is not a dermal sensitizer (negative in the local lymph node assay). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in paints and coatings, direct exposure of the general population is expected to be mainly by contact with the skin. However, dermal contact during use would be infrequent, of limited duration, and at low levels. Once the product is cured, the substance will be chemically reacted into a stable matrix and will no longer be available for uptake. Potential uses of the substance include inks, adhesives and cleaning products, where direct exposure of the general population is expected to be mainly by contact with the skin at moderate levels. Indirect exposure of the general population from environmental media such as drinking water from notified or potential activities is not expected given the low potential for environmental release.

Based on available information on toxicity and 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.