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

New Substances Notification 20975: Octane, 1,1'-oxybis- (Chemical Abstracts Service Registry Number 629-82-3)

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 octane, 1,1'-oxybis- (Chemical Abstracts Service Registry Number[1] 629-82-3).

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 applications. Potential use may include applications in personal care 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 sediment and soil. The substance is not expected to be persistent in these compartments based on its very high ready biodegradation (> 85% over 28 days). The substance is not expected to bioaccumulate based on its low water solubility and consequent lack of bioavailability.

Environmental risk assessment

Based on the available hazard information, the substance has low acute toxicity to fish (median lethal concentration > 100 mg/L) and aquatic invertebrates (median effective concentration

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[EC_{50}] > 100 mg/L), low chronic toxicity to aquatic plants and invertebrates (no adverse effects observed in saturated solutions; no-observed-effect-concentration [NOEC] > 10 mg/L) and low chronic toxicity to algae (NOEC >10 mg/L; EC_{50} 10-100 mg/L). Using the NOEC from the most sensitive organism (algae) and by applying an assessment factor of 2 to account for species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 1-10 mg/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 activity is expected to be mainly from cleaning of transportation vessels and formulation by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.001-0.01 mg/L. 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 0.001-0.01 mg/L.

Comparing the PECs with the PNEC, the ratios are 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 and is expected to have a low acute toxicity by the dermal route (median lethal dose > 2000 mg/kg body weight). The substance is expected to have a low subchronic toxicity (90-day no-observed-adverse-effect-level [NOAEL] > 100 mg/kg bw/day) and a low reproductive/developmental toxicity (NOAEL > 300 mg/kg bw/day) following repeated oral doses in mammalian test animals. The substance is not expected to be a dermal sensitizer. It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The substance does not contain structural features associated with adverse human health effects.

When the notified substance is used in industrial applications, direct exposure is not expected. Potential uses of the substance include personal care products, where direct exposure of the general population is expected to be high, mainly by contact with the skin, and potentially through incidental ingestion or inhalation depending on the type of product. Indirect exposure of the general population from environmental media is not expected given that the substance is readily biodegradable and is likely to be removed efficiently from wastewater at municipal treatment facilities.

Based on the low potential for toxicity, 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.