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

New Substances Notification 20430: 1,2,4,5,7,8-Hexoxonane, 3,6,9-trimethyl-, 3,6,9-tris(Et and Pr) derivs. (Chemical Abstracts Service registry number 1613243-54-1)

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 substance is 1,2,4,5,7,8-hexoxonane, 3,6,9-trimethyl-, 3,6,9-tris(Et and Pr) derivs. (Chemical Abstracts Service registry number[1] 1613243-54-1) and is considered a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCBs).

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 an additive in polymerization. Following listing on the Domestic Substances List, the substance can be manufactured in Canada, but no other uses are anticipated.

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 air and soil. The substance is expected to be persistent in air based on its estimated long half-life (1-10 days). The substance is not expected to be persistent in soil based on its potential for hydrolysis in soil pore water. The substance is expected to bioaccumulate to some degree based on its high predicted bioaccumulation factor (<5000 L/kg) and moderate bioconcentration factor (<1000 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance is expected to have low acute toxicity to fish, aquatic invertebrates and algae (median lethal loading rate and median effective loading rate >100 mg/L), low chronic toxicity to algae (10% effective concentration >10 mg/L) and moderate chronic toxicity to aquatic invertebrates (no-observed-effect-concentration (NOEC) 0.1-10 mg/L). Using the NOEC from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of

4 to account for species sensitivity variation and mode of action, the predicted no-effect concentration was calculated to be in the range of 100-1000 µg/L, which was used to estimate the ecological risk.

The notified and 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 are expected to be minimal, as no significant releases are expected and the substance is expected to be effectively removed during wastewater treatment. A predicted environmental concentration (PEC) was not calculated due to the low potential for environmental exposure. 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 1-10 µg/L.

Based on the low potential for environmental exposure, the substance is unlikely to cause ecological harm 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 (LD_{50}) >2000 mg/kg body weight) and it is expected to have low acute toxicity by the dermal route (LD_{50} > 2000 mg/kg body weight). The substance has a moderate subchronic toxicity following repeated oral doses in mammalian test animals (28-day lowest-observed-adverse-effect level 30-300 mg/kg-bw/day; 90-day no-observed-effect level (NOEL) 10-100 mg/kg-bw/day). The substance has a moderate reproductive/developmental toxicity following repeated oral doses in mammalian test animals (no-observed-adverse-effect level 30-300 mg/kg-bw/day). It is expected to be a moderate dermal sensitizer (29-64 % response (guinea pig maximization test)). It is not mutagenic *in vitro* and is not expected to be clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be in the range of 0.1-1 mg/kg-bw/day based on the NOEL of the oral subchronic toxicity study in mammalian test animals. The PTDI is the estimated level of long-term exposure without risk of adverse health effects.

When the notified substance is used as an additive in polymerization, direct exposure of the general population is not expected due to the industrial nature of the use. 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 activities include the manufacture of the substance in Canada, where indirect exposure of the general population from environmental media such as drinking water is expected to be at levels in the range of 10^{-4} to 10^{-3} mg/kg bw/day for children and 10^{-5} to 10^{-4} mg/kg bw/day for adults. Consumers are not exposed to the substance in end-products as it is consumed during polymerization.

Because the estimated human exposure is less than the PTDI, meaning at levels that do not pose a concern, 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.