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

New Substances Notification 20919: 1,2,4,5,7,8-Hexoxonane, 3,6,9-triethyl-3,6,9-trimethyl- (Chemical Abstracts Service Registry Number 24748-23-0)

**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 1,2,4,5,7,8-hexoxonane, 3,6,9-triethyl-3,6,9-trimethyl- (Chemical Abstracts Service Registry Number[1] 24748-23-0).

**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 polymerization initiator. Potential uses may include use as an additive in adhesives or in diesel fuel.

**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, soil, sediment and air. The substance is expected to be persistent in air based on its long air-oxidation half-life (1-10 days). The substance is not expected to be persistent in water, soil or sediment based on its moderate hydrolysis half-life (21-60 days). The substance is expected to have a moderate bioconcentration factor (250-1000 L/kg).

**Environmental risk assessment**

1 The Chemical Abstracts Service Registry Number is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

Based on the available hazard information, the substance has low acute toxicity to fish and aquatic invertebrates (no adverse effects observed in saturated solutions), moderate chronic toxicity to aquatic invertebrates (no-observed-effect concentration (NOEC) 0.1-10 mg/L) and low to moderate chronic toxicity to algae (NOEC 0.1-10 mg/L, 10% effective loading rate >10 mg/L). Using the NOEC from the most sensitive organism (algae) and by applying an assessment factor of 4 to account for 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 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 from release of the substance to water at low rates. A predicted environmental concentration (PEC) was not calculated for the notified use 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.

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 risk assessment**

Based on the available hazard information, the substance has a low acute toxicity by the oral route (median lethal dose ($LD_{50}$) > 300 mg/kg body weight with no mortality at the highest dose tested), low acute toxicity by the dermal route ($LD_{50}$ > 200 mg/kg body weight with no mortality at the highest dose tested), and high subchronic oral toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level < 10 mg/kg-bw/day). The substance has low reproductive/developmental toxicity following repeated oral doses in mammalian test animals where developmental effects were noted only in the presence of maternal toxicity. It is expected to be a weak dermal sensitizer as minimal dermal reactions were observed only at the highest concentration tested (29-64% response in a guinea pig maximization test). It is not mutagenic or clastogenic *in vitro.* Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a polymerization initiator, 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 has cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is estimated to be at levels in the range of $10^{-5}$ to $10^{-4}$ mg/kg bw/day and $10^{-6}$ to $10^{-5}$ mg/kg bw/day for children and adults, respectively. Potential uses of the substance include as an additive in adhesives or diesel fuel, where direct exposure of the general population is expected to be negligible. Exposure to the

substance would be infrequent, of short-duration, and is limited by the low concentration of the substance in these products. Indirect exposure of the general population from potential manufacture of the substance in Canada through drinking water is estimated to be at levels in the range of $10^{-4}$ to $10^{-3}$ mg/kg bw/day for children and adults.

The target margin of exposure ($MOE_T$) was calculated to be 100 based on the available information. The $MOE_T$ is the level of exposure at or above which there is no expected risk in the exposed population. The derived margin of exposure ($MOE_D$) is the ratio of the point of departure value to the available exposure doses, and is compared to the $MOE_T$. Given that the $MOE_D$ is higher than the $MOE_T$ for all estimated human exposures, 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.