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

New Substances Notification No. 19255: Carbonoperoxoic acid, O,O-(1,1-dimethylpropyl) O-(2-ethylhexyl) ester (Chemical Abstracts Service No. 70833-40-8)

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 carbonoperoxoic acid, O,O-(1,1-dimethylpropyl) O-(2-ethylhexyl) ester (Chemical Abstracts Service Registry Number[1] 70833-40-8).

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 as a polymerization initiator. Potential activities may include manufacturing.

Environmental fate and behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to soil and sediment. The substance is not expected to be persistent in these compartments based on its very short hydrolysis half-life (≤10 days) and high biodegradability (60-85% at 28 days). The products of hydrolysis will tend to partition to water. The main environmental product of hydrolysis is not expected to be persistent in this compartment based on high to very high biodegradability (>60% at 14 days). The substance and its main product of hydrolysis are not expected to bioaccumulate based on the high biotransformation rate of the substance and low bioconcentration factor of the product of hydrolysis (<250 L/kg).

Ecological 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 (median lethal concentration (LC_{50}), median effective concentration (EC_{50}) and median effective loading rate >100 mg/L) and low to moderate chronic toxicity in algae (10% effective concentration (EC_{10}) in the range of

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0.1-1 mg/L; 10% effective loading rate >10 mg/L). The hydrolysis products have low to moderate acute toxicity in fish and aquatic invertebrates (LC_{50} and EC_{50} >1 mg/L) and low to moderate chronic toxicity in algae (EC_{10} >0.1 mg/L). Using the EC_{10} from the most sensitive organism (algae) and by applying an assessment factor of 10 to account for species sensitivity variation, 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 activities is not expected given the specialized conditions for handling the substance, and given that the substance will be consumed during use. 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 by release of the substance to water resulting in a PEC in the range of 1-10 µg/L.

Based on the low potential environmental exposure from notified activities, and comparing the PEC with the PNEC for potential activities resulting in a ratio less than 1, the substance is unlikely to cause ecological harm in Canada.

Human health 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 to moderate subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level >300 mg/kg-bw/day; 28-day no-observed-effect level 30-300 mg/kg-bw/day). It is an extreme skin sensitizer (81-100% response (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, 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. No potential uses which could significantly increase human health risks compared to the notified uses were identified.

Based on the low potential for human 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.