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

New Substances Notification 20102: 2-Propenoic acid, 2-methyl-, C_{12-15} alkyl esters, polymers with cetyl methacrylate, 2-(dialkylamino)ethyl methacrylate and stearyl methacrylate, *tert*-Bu 2-ethylhexaneperoxoate-initiated (Confidential Accession No. 19421-9)

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 2-propenoic acid, 2-methyl-, C_{12-15} alkyl esters, polymers with cetyl methacrylate, 2-(dialkylamino)ethyl methacrylate and stearyl methacrylate, *tert*-Bu 2-ethylhexaneperoxoate-initiated (Confidential Accession No. 19421-9). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains potentially cationic amines.

Notified and potential uses

The substance is proposed to be imported into Canada in quantities less than 10 000 kg/yr for the notified use in automotive lubricants and fluids. No other uses are anticipated in Canada.

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 soil and sediment. The substance is expected to be persistent in these compartments because the functional groups susceptible to degradation are embedded within the large polymer matrix. The substance is not expected to bioaccumulate based on its high molecular weight which will limit its ability to cross biological membranes.

Ecological assessment

Based on the available hazard information, the substance has low acute toxicity in algae (median effective loading rate >100 mg/L). Given the low water extractability (<2%), it is not expected to have adverse effects in aquatic organisms at saturation. A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

The notified activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified uses is expected to be mainly by release of the substance to water at low rates. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and ecotoxicity. No potential

activities which could significantly increase environmental risks compared to those notified were identified.

Based on the low potential for ecotoxicity and environmental exposure, 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). It is not expected to be mutagenic *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 automotive lubricants and fluids, direct exposure of the general population is expected to be mainly by contact with the skin at low levels. Exposure to the substance would be infrequent, of short-duration, and limited by the low concentration of the substance in these products. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels given the low water availability of the substance. No potential uses which could significantly increase human health risks compared to the notified uses were identified.

Based on the low toxicity and low potential for 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

The substance 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.