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

New Substances Notification 16578: Fatty acids, reaction products with alkanolamine and alkyloxide (Confidential Accession No. 18304-7)

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 based on the available information, that when used as notified, the substance 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.

The significant new activity (SNAc) provisions of CEPA were applied to the substance because of potential environmental and human health impacts that could arise as a result of potential new activities. Order 2012-87-09-01 Amending the Domestic Substances List outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 146, No. 24 on November 21, 2012. Notification is required prior to commencement of those activities identified as a potential concern to ensure the substance undergoes further assessment and risk management consideration.

Substance identity

The notified chemical is fatty acids, reaction products with alkanolamine and alkyloxide (Confidential Accession No. 18304-7), and is considered a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

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 gasoline additive. Potential uses may include household cleaners, personal care products, industrial detergents, and a variety of industrial, commercial and consumer applications.

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 and sediment. The substance is not expected to be persistent in these compartments based on its high biodegradability (60-85% over 28 days). The substance is not expected to bioaccumulate based on its low predicted bioconcentration factor (<250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance has moderate acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration and median effective concentration (EC_{50}) 1-100

mg/L). Using the EC_{50} from the most sensitive organism (algae) and by applying an assessment factor of 100 to account for acute to chronic extrapolation and extrapolation from the chronic maximum acceptable toxicant concentration to the predicted no-effect concentration (PNEC), the PNEC was calculated to be in the range of 0.01-0.1 mg/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 to be significant as transportation vessels are not cleaned in Canada, very little loss of the substance is expected during formulation, and any releases from the end use in gasoline will be widely dispersed. For potential activities such as manufacturing and formulation, environmental exposure is expected to be mainly by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.01-0.1 mg/L. For potential activities such as transportation, environmental exposure is expected to be low, similar to the notified use. However, if the substance is used in industrial detergents, an increased exposure potential may exist from release of the substance to water that could result in a PEC in the range of 0.1 to 1 mg/L.

Based on the low potential for environmental exposure when used as notified, the substance is unlikely to cause ecological harm in Canada.

However, the potential use of the substance in industrial detergents or high-volume manufacturing may significantly alter environmental release and exposure resulting in the substance becoming harmful to the environment. Consequently, more information is necessary to better characterize potential environmental risks.

Human health risk assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral and dermal routes (median lethal dose >2000 mg/kg body weight) and low to moderate subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level >30 mg/kg-bw/day). It is a moderate dermal sensitizer (1-10% estimated concentration required to produce a stimulation index of 3 (EC3) (local lymph node assay)). It is not mutagenic *in vitro* and is not expected to be clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage. The acceptable exposure limit (AEL) was calculated to be in the range of 1-10 $\mu g/cm^2$ based on the EC3 of the local lymph node assay sensitization study in mammalian test animals.

When the notified substance is used as a gasoline additive, direct exposure of the general population is expected to be mainly by contact with the skin at very low levels based on the low concentration of the substance in gasoline (<1%) and the anticipated small quantities of gasoline consumers would come into contact with. Indirect exposure of the general population from environmental media such as drinking water or air is expected to be at low levels given the low potential for release to the environment.

Potential uses of the substance include commercial or industrial applications other than those notified, where direct and indirect exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use. However, if the substance is used for household cleaning or personal care products, an increased level of direct exposure may exist. Direct exposure from the use of household cleaning products is expected to be by contact with the skin at levels in the range of 1 to 100 $\mu g/cm^2$. Direct exposure from personal care products is expected to be by contact with the skin at

conservatively estimated levels in the range of 1-1000 μg/cm^2 for adults and 0.01-1000 μg/cm^2 for children.

Based on the low potential for exposure when used as notified, 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.

However, the potential use of the substance in household cleaning or personal care products will increase the potential for dermal exposure, and combined with the dermal sensitization effects of the substance, could result in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with these activities.

Other considerations

This substance is manufactured using the oxirane, methyl as a reactant, which was found to meet the criteria under paragraph 64(c) of the Act and added to the List of Toxic Substances in Schedule 1 of the Act.

Assessment conclusion

When the substance is used as notified, it is not suspected to be harmful to human health or the environment within the meaning of the criteria under section 64 of the Act. However, it is suspected that a significant new activity in relation to the substance could result in the substance meeting those criteria.

Due to the potential risk to human health and the environment related to dermal sensitization and aquatic toxicity if the substance were to be used in household cleaners, personal care products, industrial detergents or high-volume manufacturing, the SNAc provisions under CEPA were applied to the substance in order to obtain information to ensure that the substance undergoes further assessment before these potential activities are undertaken. Order No. 2012-87-09-01 was published in the *Canada Gazette* Part II, Vol. 146, No. 24 on November 21, 2012.

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.