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

New Substances Notification No. 18171: Alkenes, $C_{11}$-$C_{13}$, $C_{12}$ rich, reaction products with alkene carbonate, phenol and sulfur, calcium salts

**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 that 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

Alkenes, $C_{11}$-$C_{13}$, $C_{12}$ rich, reaction products with alkene carbonate, phenol and sulfur, calcium salts (Confidential Accession No. 19210-8) is a chemical of unknown or variable composition, complex reaction products, or biological material (UVCB) that can be classified as phenate sulphide calcium salts.

## Notified and Potential Activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for use as a lubricant additive in marine diesel oils. Potential uses are expected to be similar to those notified.

## Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to soil or sediment. The substance is only expected to be persistent in sediment based on results of inherent biodegradation tests. The substance is not expected to bioaccumulate based on its predicted bioconcentration factor (<5000 L/kg).

## Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has low acute toxicity in fish, aquatic invertebrates, algae and bacteria (median lethal concentration and median effective concentration ($EC_{50}$) >100 mg/L), and low acute toxicity in plants ($EC_{50}$ >100 mg/kg). The substance has low chronic toxicity in fish, aquatic invertebrates and algae (no-observed-effect level >10 mg/L), and soil organisms (no-observed-effect concentration >10 mg/kg). Calculation of the predicted no-effect concentration was not considered necessary given the low ecotoxicity.

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 expected to be mainly from cleaning of transportation vessels, blending of the notified substance and end-use in marine diesel oils by release of the substance to water at low to negligible levels. The predicted environmental concentration for notified activities was not calculated.

Based on the low toxicity to aquatic organisms and low potential for environmental exposure, the substance is unlikely to cause ecological harm in Canada.

**Human Health Assessment**

Based on the available hazard information on the substance, the substance has a low (median lethal dose >2000 mg/kg-bw) potential for acute toxicity by the oral and dermal routes of exposure and a low (28-day no-observed-adverse-effect level >300 mg/kg-bw/d) potential for subchronic toxicity following repeat oral doses in mammalian test animals. It is a weak (effective concentration ($EC_3$) >10%) sensitizer. It is not mutagenic *in vitro* and not clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage. The acceptable exposure level (AEL) was calculated to be 100-1000 µg/cm$^2$ based on the $EC_3$ level of >10% in the sensitization study.

When used for industrial marine diesel oil applications, direct exposure of the general population is expected to be negligible. Indirect exposure of the general population from environmental media such as drinking water is expected to be low given its low water solubility and tendency to adsorb to sediment. When potentially used in consumer motor oil formulations, direct exposure of the general public is expected to be mainly by contact with the skin at levels of 100-1000 µg/cm$^2$.

Based on the low potential for exposure for the notified use and based on a comparison of the AEL to the estimated exposure for potential uses, 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 used as notified or for other identified potential uses, the substance is not suspected to be harmful to human health or the environment according to the criteria under section 64 of CEPA.

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 workplace use.