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

New Substances Notification No. 18441: Phosphorous acid, triphenyl ester, polymer with α-hydro-ω-hydroxypoly [oxy(methyl-1,2-ethanediyl)], $C_{10-16}$-alkyl esters

**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 polymer, phosphorous acid, triphenyl ester, polymer with α-hydro-ω-hydroxypoly [oxy(methyl-1,2-ethanediyl)], $C_{10-16}$-alkyl esters (Chemical Abstracts Service Registry No. 1227937-46-3), can be classified as a poly(ether) phosphite ester. The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations* because it contains phosphorus above 0.2% by weight.

## Notified and Potential Activities

The substance is proposed to be manufactured and/or imported into Canada in quantities greater than 10 000 kg/yr for use as an additive in food contact plastics. Potential uses are expected to be similar use in other plastics.

## 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 expected to be persistent in soil and sediment based on its very low ready biodegradation (≤10%). The substance is not expected to bioaccumulate based on its high molecular weight making it unable to cross biological membranes, and its low bioconcentration and bioaccumulation factors (<250 L/kg).

## Ecological Assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have low acute toxicity in fish and aquatic invertebrates (median lethal concentration and median effective concentration >100 mg/L). A predicted no-effect concentration was not calculated given the low potential for ecological effects.

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 activity is expected to be low given that the substance is expected to be immobile in the polymer matrix following curing and cross-linking reactions. Any potential unforeseen environmental releases from spills or drum cleaning are expected to be contained because residues and leftover solvents containing the substance will be recycled or disposed of by incineration or by landfill. A predicted environmental concentration for notified activities was not estimated due to the low ecotoxicity and low potential for exposure.

Based on the low ecotoxicity, low release, and the insoluble nature of the substance which will limit its bioavailability and dispersal in the environment, 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 oral route (median lethal dose >2000 mg/kg body weight) and a moderate subchronic toxicity following repeat oral doses in mammalian test animals (90-day no-observed-adverse-effect level of 10-100 mg/kg-bw/d). It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an additive in food contact plastics, direct exposure of the general population is expected to be mainly by skin contact at very low levels. Direct exposure from ingestion of food in contact with plastics containing the notified substance is expected to be negligible. The concentration of the substance in end-use products will be very low (≤1%) and leaching of the substance from end-use products is not expected as the substance will be chemically reacted into a stable polymer matrix once cured. Indirect exposure of the general population from environmental media such as drinking water is not expected based on its low water extractability. The potential for exposure of the general population from potential uses in other plastics for commercial and consumer applications is expected to be similar to the notified use.

Based on the 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**

When the substance is used as notified, it 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.