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

New Substances Notification No. 18375: Phenol, 2-(1,1-dimethylethyl)-6-methyl-4-[3-[[2,4,8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]dioxaphosphepin-6-yl]oxy]propyl]-

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 phenol, 2-(1,1-dimethylethyl)-6-methyl-4-[3-[[2,4,8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]dioxaphosphepin-6-yl]oxy]propyl]- (Chemical Abstracts Service No. 203255-81-6).

Notified and Potential Activities

The substance is proposed to be manufactured in and/or imported Canada in quantities greater than 10 000 kg/yr for use in food contact plastics. No other activities are anticipated in Canada.

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 biodegradation potential (≤10%). The substance is not expected to bioaccumulate based on its low predicted bioconcentration factor (<250 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 and algae (no adverse effects observed in saturated solution). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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 low as the substance is imported at a low concentration in end-use products, and no major releases are expected. A predicted environmental concentration

for notified activities was not estimated given the low potential for ecological release. No other potential activities have been identified.

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

Human Health Assessment

Based on the available hazard information, the substance has low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg body weight) and a low potential for subchronic toxicity following repeat oral doses in mammalian test animals (90-day no-observed-adverse-effect level >100 mg/kg-bw/d). It is not a dermal sensitizer (0-8% 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 in food contact plastics, consumers are expected to come into direct dermal contact with end-use products containing the substance; however, exposure is expected to be low as the notified substance will be present at very low concentrations and will be incorporated into the polymer matrix of the plastic products. Oral exposure following migration of the substance from plastic films is estimated to be <0.1 mg/kg bw-day, which is considered low. Indirect exposure of the general population from environmental media such as drinking water is expected to be low. No other potential uses were identified for the notified substance.

Based on the low toxicity and the low potential for exposure of the general population, 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 *Hazardous Products Regulations* for products intended for the workplace.