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

New Substances Notification No. 18805: 2,4,8,10-Tetraoxa-3,9-diphosphaspiro[5,5]undecane, 3,9-bis[2,6(1,1-demethylethyl)-4-methylphenoxy]-

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 chemical, 2,4,8,10-tetraoxa-3,9-diphosphaspiro[5,5]undecane, 3,9-bis[2,6(1,1-demethylethyl)-4-methylphenoxy]- (Chemical Abstracts Service Registry No. 80693-00-1), can be classified as a phosphite ester.

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 an antioxidant additive to plastics. 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 and sediment. The substance is expected to be persistent in soil and sediment based on its very low biodegradability (<10%) and very low water solubility (≤0.01 mg/L) which will limit its susceptibility to hydrolysis. The substance is not expected to bioaccumulate based on its low estimated bioconcentration factor (<250 L/kg), its highly hydrophobic nature which limits uptake, and the low bioaccumulation factors of its biotransformation products.

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 significant adverse effects observed in saturated solutions). A predicted no-effect concentration was not calculated due to the low ecotoxicity.

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 not expected. The substance is to be transported in closed paper bags, and is expected to be encapsulated in the polymer matrix of end-use products and unavailable for further exposure. A predicted environmental concentration for notified activities was not estimated given the low ecotoxicity of the substance. No other potential activities have been identified.

Based on the low potential for environmental release 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 a 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 *in vitro* or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an antioxidant additive to plastics, direct exposure of the general population is not expected. The substance will be present in end-use products at low concentrations (0.01-1%), and is expected to be encapsulated in the polymer matrix of plastics and unavailable for release. Indirect exposure of the general population from environmental media such as drinking water is expected to be low.

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

When the substance is used as notified or for other identified potential uses, 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.