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

New Substances Notification No. 18152: Dodecanedioic acid, 1,12-bis[2-[4-(4,6-diphenyl-1,3,5-triazin-2-yl)-3-hydroxyphenoxy]ethyl]ester

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

Dodecanedioic acid, 1,12-bis[2-[4-(4,6-diphenyl-1,3,5-triazin-2-yl)-3-hydroxyphenoxy]ethyl]ester (Chemical Abstracts Service Registry No.1482217-03-7) is a chemical that can be classified as a substituted triazine.

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 additive in plastics. Potential uses may include cosmetics.

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 these compartments based on high stability and low potential for biotic or abiotic degradation. The substance is not expected to bioaccumulate based on its large molecular size and limited water solubility.

Ecological Assessment

Based on the available hazard information, the substance has low (median effective level >100 mg/L) acute toxicity in aquatic and sediment organisms. The predicted no-effect concentration was not calculated, as only no-effect levels were observed in toxicity tests.

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 blending into plastics while the potential activity is by release of the substance from manufacturing to sewage treatment plants. Given the low

hazard profile of the notified substance, a predicted environmental concentration for notified activities was not calculated.

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 (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 expected to be a weak sensitizer. It is not mutagenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When used as an additive in plastics, direct exposure of the general population is expected to be mainly by contact with the skin at minimal levels. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels. If the substance is used as an additive in cosmetics, an increased direct exposure potential by dermal contact may exist. However, dermal uptake is expected to be limited based on its high molecular weight, negligible water solubility and very high octanol-water partition coefficient.

Based on low potential for direct and indirect exposure in conjunction with the low oral and dermal acute toxicity, 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 and 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.