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

New Substances Notification No. 17898: Hexanedioic acid, polymer with 1,3-isobenzofurandione and 1,2-propanediol, diisodecyl 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

Hexanedioic acid, polymer with 1,3-isobenzofurandione and 1,2-propanediol, diisodecyl ester (Chemical Abstracts Service Registry No. 68511-08-0) is a polymer that can be classified as a poly (arylester, ester, ether). The substance does not meet the Reduced Regulatory Requirements criteria according to the New Substances Notification Regulations because of a high percentage of low molecular weight components.

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 in automotive original equipment manufacturer (OEM) adhesives and sealants. Potential uses may include as a plasticizer in consumer applications such as fabric/furniture upholstery or flexible polyvinyl chloride (PVC).

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to sediment and soil. The substance is not expected to be persistent in these compartments because the substance is expected to degrade over time. The substance is not expected to bioaccumulate based on its low bioaccumulation and bioconcentration factors.

Ecological Assessment

Based on the available hazard information on the substance from modelled data, the substance has low acute toxicity in aquatic organisms due to the predicted effect concentrations being higher than the solubility of the substance (2.27×10^{-8} mg/L). Calculation of the predicted no-effect concentration was not considered necessary given the low potential for ecological risk.

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 as the substance is not anticipated to leach from the cured matrix and enter the environment in significant amounts. The predicted environmental concentration for notified activities was not calculated as no exposure is expected.

Based on the predicted low toxicity to aquatic organisms and the 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 and surrogate data on structurally related chemicals, the substance has a low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg) and a low potential for subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect-level >1000 mg/kg-bw/d). It is not considered a sensitizer. It is not mutagenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When used as an adhesive/sealant in automotive OEM vehicle production, direct exposure of the general population is expected to be mainly by contact with the skin at very low levels because the substance is expected to migrate slowly out of the adhesive/sealant after curing and contact with cured sealants/adhesives is expected to be infrequent. Indirect exposure of the general population from environmental media is not expected as the substance will not be released to municipal waste water systems or surface waters when used as intended. In the unlikely event of an environmental release, exposure to environmental media such as drinking water is expected to be at low levels and mainly by ingestion. The substance may potentially be used as a plasticizer in consumer applications such as fabric/furniture upholstery or flexible PVC, which may increase exposure, and there may be exposure to children by ingestion related to mouthing of toys containing the substance.

Based on the low oral acute toxicity in mammalian test animals, 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.