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

Ministerial Condition No. 17312: Benzene, 1,1'-(1-methylethylidene)bis[3,5-dibromo-4-(2,3-dibromopropoxy)-, Chemical Abstracts Service Registry Number 21850-44-2

Regulatory Decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999), 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 determined that the substance could 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.

In order to ensure that the substance does not cause harm to the environment or human health in Canada, its manufacture and/or import is authorized subject to conditions on its use, handling, and disposal as described in Ministerial Condition No. 17312, published in the *Canada Gazette*, Part I, Vol. 147, No. 48, November 30, 2013. In addition, to address the uncertainty related to the ecological hazard of the substance, toxicological test data is required to be provided to the Minister of the Environment pursuant to a Notice sent under paragraph 71(1)(c) of CEPA 1999.

Substance Identity

The substance is a chemical that is a brominated flame retardant (BFR).

Notified Activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for use as a flame retardant in automotive airbags, automotive textiles, and flex duct insulation.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the aquatic environment, the substance will partition primarily to sediment. The potential for the substance to migrate from products could also result in its presence in airborne particles, such as dust. The substance is expected to be persistent in the environment, with a half-life greater than 182 days in water and soil and a half-life greater than 365 days in sediment. Laboratory experiments and ecological monitoring data indicate it is bioavailable. The substance may be able to accumulate in organisms, with a predicted bioaccumulation factor BAF > 5000.

Ecological Assessment

The available hazard information for the substance indicates it has low acute toxicity to fish, daphnids, and algae (LL_{50} > 100 mg/L). Surrogate toxicity data for a structurally related chemical indicates the substance has moderate chronic toxicity to pelagic organisms (LC_{50} = 0.1 – 10 mg/L) and low chronic toxicity to benthic organisms (LC_{50} > 100 mg/kg).

Additional experimental evidence considered in the assessment suggests the substance has the potential for endocrine-mediated effects on reproduction and development. However the evidence was not conclusive and so definitive studies addressing these sensitive endpoints would be needed to further assess the ecological hazard of the substance. The predicted no effect concentration (PNEC) for the pelagic and benthic compartments were calculated based on the surrogate toxicity data and were < 10 µg/L and < 100 mg/kg, respectively.

The notified activities and other potential activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure is expected to occur mainly from point source release of the substance to water following cleaning of transportation vessels and manufacturing. The predicted environmental concentrations from these activities are estimated to be < 10 µg/L in water and > 100 mg/kg in sediments. If the substance is used widely as a replacement for other BFRs, an increase in exposure may occur.

Based on the potential for the predicted environmental concentrations of the substance to exceed the predicted no effect concentrations, the substance could cause ecological harm in Canada. The risk has been identified with point source releases from transportation vessels and manufacturing.

Human Health Assessment

Based on the available hazard information on the substance, the substance has a low acute toxicity by the oral, dermal and inhalation routes of exposure (acute oral LD50 >2 000 mg/kg bw, acute dermal LD50 > 2000 mg/kg bw, acute inhalation LC50>20 mg/L) and a low subchronic toxicity following repeat oral doses in mammalian test animals (NOAEL>2 000 mg/kg bw/day). It is a minimal eye and skin irritant (PII ≤ 2.0 and MAS ≤2.3) and a non-sensitizer. It is not mutagenic *in vitro.* Therefore, the substance is unlikely to cause genetic damage.

When used as a flame retardant in airbags, automotive textiles, and flex duct insulation, direct exposure of the general population to the notified substance is expected to be mainly by contact with the skin or by inhalation of dust. The cumulative exposure (direct and indirect together) of the general population is expected to be at levels of 5.0×10^{-5} and 1.4×10^{-4} mg/kg bw/day, for adults and children, respectively. However, if the substance is used as a replacement for other BFRs, (fabrics, textiles, furniture, construction materials), a potential for increased direct exposure (oral and inhalation routes of exposure) and indirect exposure may exist.

Based on the low potential for oral and inhalation exposure in conjunction with the absence of toxicity endpoints in the available studies, the substance is not expected to be harmful to human health.

Other Considerations

This substance is subject to Ministerial Condition 12848a published in the *Canada Gazette* Part I, Vol. 139, No. 18 on April 30, 2005, which restricts the manner in which that notifier may manufacture and/or import the substance, with conditions on its use, handling, and disposal in order to mitigate risks from point source releases such as those from transportation vessels and manufacturing.

Assessment Conclusion

The substance is suspected to be harmful to the environment according to the criteria under paragraph 64(*a*) of CEPA 1999. The substance is not suspected to be harmful to the environment or human health according to the criteria under section 64(*b*) or (*c*) of CEPA 1999.

Due to the identified environmental risk related to aquatic toxicity, a Ministerial Condition No. 17312 was published in the *Canada Gazette* Part I, Vol. 147, No. 48 on November 30, 2013 to restrict the manner in which the notifier may manufacture and/or import the substance, with conditions on its use, handling, and disposal in order to mitigate risks from point source releases.

As the substance was identified as having the potential to cause endocrine-mediated effects on reproduction and development, a Notice was sent under paragraph 71(1)(c) of CEPA 1999. This requires the company to which it is addressed to conduct a multi-generational fish study and an amphibian metamorphosis assay prior to exceeding a specified volume and submit the data to the Minister of the Environment for further assessment.

A conclusion under CEPA 1999 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 workplace use.