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

New Substances Notification No. 18326: Oxirane, 2,2'-[(1-methylethyldiene)bis(4,1-phenyleneoxy methylene)]bis-homopolymer, ester with α-[3-carboxy-1-oxo-(tetrapropenyl)propyl)-ω-[3-carboxy-1-oxo-(tetra propenyl) propoxy]poly(oxy-1,2-ethanediyl)

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

Oxirane, 2,2'-[(1-methylethyldiene)bis(4,1-phenyleneoxy methylene)]bis-homopolymer, ester with α -[3-carboxy-1-oxo-(tetrapropenyl)propyl)- ω -[3-carboxy-1-oxo-(tetra propenyl) propoxy]poly(oxy-1,2-ethanediyl), Chemical Abstracts Service Registry No. 444796-55-8) is a polymer that can be classified as a poly(arylether-ester-ether). The substance does not meet the Reduced Regulatory Requirements criteria according to the New Substances Notification Regulations due to the presence of terminal epoxides and 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 as a surfactant for waterborne epoxy dispersions for commercial uses. Other potential uses may include a variety of industrial applications, such as adhesives, potting and encapsulating media, and coatings.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water. The substance is not expected to bioaccumulate based on its very high molecular weight making it unable to cross biological membranes and its low predicted bioconcentration and bioaccumulation factors (<250 L/kg).

Ecological Assessment

Based on the available hazard information, the substance has moderate acute toxicity in fish (median lethal concentration 1-100 mg/L). The predicted no-effect concentration (PNEC) was calculated to be 0.1-1.0 mg/L, which was used to estimate the ecological risk.

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 and other potential activities is expected to be mainly from transportation, formulation, manufacturing, and commercial use in coatings by release of the substance to water. The predicted environmental concentration (PEC) for notified and other potential activities is estimated to be 0.0001-0.01 mg/L.

Comparing the PEC with the PNEC, the ratio is less than 1, indicating that 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 route of exposure (median lethal dose >2000 mg/kg body weight).

When the notified substance is used as a surfactant for waterborne epoxy dispersions for commercial uses, direct exposure of the general population is only expected to be from contact with a chemically reacted cured coating matrix, and the notified substance will not be available for uptake. When used in do-it-yourself applications, direct exposure of the general population is expected to be mainly by contact with the skin or by inhalation, but the large molecular weight of the substance renders it biologically unavailable and the concentration of the notified substance in the end-use product is low. Indirect exposure of the general population from environmental media such as drinking water is expected to be minimal. For potential uses such as adhesives, potting and encapsulating media, coatings, and various other industrial applications, direct and indirect exposure would be similar to that of the notified use of the substance, and the substance would not be available for uptake due to the reasons noted above.

Based on the 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 <i>Controlled Products Regulations</i> or the <i>Hazardous Products Regulations</i> for products intended for workplace use.