

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

New Substances Notifications No. 19885 and 19886: Confidential Accession Numbers 19357-5 and 19358-6

### **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 substances and have determined that they are 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 identities**

The following two substances were submitted as Consolidated New Substances Notifications (NSNs), which take place when the technical information provided for one substance is used to address the technical information requirements for the remaining substance(s). The substances in Consolidated Notifications are very similar, and are expected to have the same exposure and hazard profiles.

The notified polymers are:

- NSN 19885: Oil, polymer with 2,3-dihydroxypropyl stearate and 1,1'-methylenebis[4-isocyanatobenzene] (Confidential Accession No. 19357-5)
- NSN 19886: Oil, polymer with 2,3-dihydroxypropyl stearate and 1,1'-methylenebis[isocyanatobenzene] (Confidential Accession No. 19358-6)

The polymers do not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because they contain terminal isocyanates.

### **Notified and potential activities**

The substances are proposed to be manufactured in and/or imported into Canada each in quantities greater than 10 000 kg/yr for the notified use in industrial adhesives. Potential uses may include commercial adhesives.

### **Environmental fate and behaviour**

Based on their physical and chemical properties, if the substances are released to the environment, they will tend to partition to soil and sediment. The substances are expected to be persistent in soil and sediment because they react with water to form high molecular weight, insoluble complexes that are resistant to degradation. The substances are not expected to bioaccumulate based on their high molecular weight, which will limit their ability to cross biological membranes.

### **Ecological assessment**

Based on the available hazard information on structurally related chemicals, the substances are expected to have low acute toxicity in aquatic organisms (no adverse effects observed in saturated solutions). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

The notified and potential activities in Canada were assessed to estimate the environmental exposure potential of the substances throughout their life cycle. Environmental exposure from the notified activity is expected to be mainly from formulation, cleaning of transportation vessels, and use in industrial adhesives by release of the substances to water at low rates. Releases are expected to be negligible. For potential activities such as use in commercial adhesives, environmental exposure is expected to be negligible, similar to that of the notified use. A predicted environmental concentration was not calculated due to the low hazard profile of the substances and low potential for environmental exposure.

Based on the low potential for ecotoxicity and environmental exposure, the substances are unlikely to cause ecological harm in Canada.

### **Human health assessment**

Based on the available hazard information on structurally related chemicals, the substances are expected to have low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight).

When the notified substances are used in industrial adhesives, direct exposure of the general population is not expected due to the industrial nature of the use. Consumers may come into contact with end-use products containing the substances; however, direct exposure is not expected because the substances will be chemically reacted into a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media is not expected given the specialized industrial use of the substances, which results in little or no release to the environment. No potential uses were identified that would significantly alter the exposure scenarios considered for the notified use of the substances.

Based on the low potential for exposure, the substances are not likely to pose a significant health risk to the general population, and are therefore unlikely to be harmful to human health.

### **Assessment conclusion**

When the substances are used as notified or for other identified potential activities, they are not expected to be harmful to human health or the environment according to the criteria under section 64 of the Act.

A conclusion under CEPA, on these substances, 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 the workplace.