

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

New Substances Notification 21179: Amines, polyalkylenepoly-, reaction products with substituted heteromonocycle and succinic anhydride polyisobutenyl derivs (Confidential Accession Number 19701-9)

### **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 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**

The notified polymer is amines, polyalkylenepoly-, reaction products with substituted heteromonocycle and succinic anhydride polyisobutenyl derivs (Confidential Accession Number 19701-9). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains potentially cationic amines.

### **Notified and potential uses**

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as lubricant additive. No other uses are anticipated in Canada.

### **Environmental fate and behaviour**

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to soils and sediments. The substance is expected to be persistent in these compartments based on its low bioavailability and lack of environmentally hydrolyzable groups. The substance is not expected to bioaccumulate based on its high molecular weight, which will limit its ability to cross biological membranes.

### **Environmental risk assessment**

Based on low water extractability (< 2%), this substance is predicted to have low bioavailability and is expected to have low aquatic hazard. A predicted no-effect concentration was not calculated given that there is low potential for hazard to the environment.

The notified activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. A predicted environmental concentration was not calculated given that there is low potential for environmental exposure and ecotoxicity. No potential activities which could significantly increase environmental risks compared to those notified were identified.

Based on the low potential for ecotoxicity and environmental exposure, the substance is unlikely to cause harm to the environment in Canada.

### **Human health risk assessment**

Based on the available hazard information, the substance is expected to have a low acute toxicity by the oral route (median lethal dose > 2000 mg/kg body weight), a low to moderate acute toxicity by the inhalation route (> 2 mg/L/4 hours with no lethality at the highest concentration tested) and low subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level > 1000 mg/kg-bw/day).

When the notified substance is used as a lubricant additive in industrial applications, direct exposure of the general population is not expected due to the industrial nature of the use. When the substance is used as an additive in lubricants available to consumers, consumers using the products may come into contact with the notified substance, mainly by incidental contact with the skin; direct exposure is expected to be limited, however, by the low frequency of use, the low concentration of the substance in the product, and by the large molecular size of the substance which will limit its ability to cross the skin barrier. Indirect exposure of the general population from environmental media such as drinking water and air is expected to be at low levels given that there is low potential for environmental release. No potential uses that could significantly increase human health risks compared to the notified uses were identified.

Based on the low toxicity and 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.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

### **Assessment conclusion**

When the substance is used as notified or for other identified potential activities, it is 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 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 the workplace.