

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

New Substances Notification 20257: Amines, polyethylenepoly-, reaction products with maleated alkenealkene polymer (Confidential Accession Number 19480-8)

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, polyethylenepoly-, reaction products with maleated alkenealkene polymer (Confidential Accession No. 19480-8). 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 up to or greater than 10 000 kg/yr for the notified use in automotive lubricants. Potential uses may include do-it-yourself applications.

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 high molecular weight and lack of environmentally hydrolysable groups. The substance is not expected to bioaccumulate based on its high molecular weight which will limit its ability to cross biological membranes.

Ecological assessment

Based on the available hazard information, the substance is not expected to have adverse effects to fish, aquatic invertebrates, and algae. A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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 activities is expected to be mainly from processing and use in lubricants from release of the substance to water at low rates. A predicted environmental concentration was not calculated due to the 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 ecological harm in Canada.

Human health assessment

Based on the available hazard information, the substance has 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 (median lethal concentration >2 mg/L/4 hr with no lethality at the highest concentration tested) and low subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-effect level >1000 mg/kg-bw/day).

When the notified substance is used in industrial or commercial automotive lubricants, direct exposure of the general population is not expected due to the industrial nature of the use. Indirect exposure of the general population from environmental media is not expected given the specialized industrial and commercial use of the substance, which results in little or no release to the environment. Potential uses of the substance include automotive lubricants for do-it-yourself applications, where direct and indirect exposure of the general population is expected to be at levels that do not pose a concern.

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 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 *Hazardous Products Regulations* for products intended for the workplace.