

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

New Substances Notification 19516: Oxo-heteropolycyclic, polymer with alkyl-alkoxy-alkanediol
(Confidential Accession No. 19345-3)

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 oxo-heteropolycyclic, polymer with alkyl-alkoxy-alkanediol (Confidential Accession No. 19345-3). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because of the high percentage of low molecular weight components.

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use in industrial coatings. Potential uses may include use in consumer printing inks, paints and coatings.

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 soil and sediment. The substance is expected to be persistent in these compartments based on its low biodegradability (10-30% over 28 days). The substance is not expected to bioaccumulate based on its predicted low bioconcentration and bioaccumulation factors (<250 L/kg) due to its susceptibility to metabolic degradation.

Ecological assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have low acute toxicity in fish and algae (median lethal loading rate and median effective concentration (EC_{50}) >100 mg/L) and moderate acute toxicity in aquatic invertebrates (EC_{50} 1-100 mg/L). Using the EC_{50} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 40 to account for acute to chronic extrapolation, species sensitivity variation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 100-1000 µg/L, which was used to estimate the ecological hazard.

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 activities is expected to be mainly from cleaning of transportation vessels by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L, and from formulation and use in industrial coatings by release of the substance to water resulting in a PEC in the range of 0.1-1 µg/L. For potential activities such as manufacturing, environmental exposure is expected to be mainly by release of the substance to water resulting in a PEC similar to that of the notified transportation activities.

Comparing the PEC with the PNEC, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard, and exposure, indicates that 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). It is not mutagenic *in vitro*; therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in industrial coatings, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be chemically reacted into a stable matrix once the products are cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is expected to be at very low levels given the low potential for environmental release.

Potential uses of the substance include consumer paints and coatings, where direct exposure of the general population is expected to be mainly by contact with the skin. Uptake of the substance will be limited given low-moderate concentration of the substance in the products, by the high molecular weight of the majority of the polymer molecules and by the low rate diffusion of the substance through paints and coatings. Potential uses of the substance include in consumer inks, where direct exposure of the general population is expected to be negligible given the very small quantity used at a time. Once paints, coatings and inks are dried, the substance will be chemically reacted into a stable matrix and will be unavailable for uptake. Indirect exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the lack of structure features associated with adverse human health effects, the anticipated low toxicity and the limited 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.