

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

Significant New Activity No. 18911: Heteromonocycle, 2-methyl-, polymer with oxirane, carboxymethyl hexadecyl ether

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.

However, a significant new activity (SNAc) notice was adopted based on uncertainties regarding potential human health impacts of the substance in relation to certain new activities. SNAc No. 18911 outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 151, No. 17, August 23, 2017. Notification is required prior to commencement of those activities identified as a potential risk to ensure the substance undergoes further assessment and risk management consideration.

Substance Identity

Heteromonocycle, 2-methyl-, polymer with oxirane, carboxymethyl hexadecyl ether (Confidential Accession No. 19101-3) is a polymer that can be classified as an alkyl polyglycol ether carboxylic acid. The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations* because it substantially degrades and contains 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 in metalworking fluids. The potential use of the substance in consumer products, such as personal care products, cosmetics and household cleaners/detergents, has also been assessed and the available information was determined to be inadequate to assess activities under the conditions of potential use.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water and soil. The substance is not expected to be persistent in water or soil based on its high biodegradability (60-85% over 28 days). 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 on the substance, the substance has low acute toxicity (median lethal concentration and median effective concentration >100 mg/L) in fish, algae and aquatic invertebrates. The substance has low chronic toxicity (no-observed-effect concentration (NOEC) >10 mg/L) in fish and moderate chronic toxicity (NOEC and lowest-observed-effect concentration 0.1-10 mg/L) in aquatic invertebrates. A predicted no-effect concentration was not considered necessary as the ecological risk, when combined with the low potential for environmental exposure, is not expected to be significant.

The notified and other potential activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental release from the notified activity is expected to be mainly to wastewater at low levels from cleaning of transport vessels and equipment, formulation activities and use. Significant environmental exposure is not expected as the substance will be efficiently removed by waste water treatment processes due to its high biodegradability. The notified substance could potentially be used in personal care products, cosmetics and household detergents. Environmental exposure resulting from these potential uses is expected to be low, similar to that of the notified activities. A predicted environmental concentration for notified or potential activities was not estimated due to the low potential for environmental release.

Based on the low potential for significant environmental exposure and the limited ecological risk, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on the substance and 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) and is expected to have a moderate potential for subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level 250-1000 mg/kg-bw/d). It is an extreme skin sensitizer (64-80% response (guinea pig maximization test)). It is not mutagenic *in vitro* or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in metalworking fluids, direct exposure of the general population is not expected as the nature of the use is solely industrial. Indirect exposure of the general population from environmental media such as drinking water is expected to be low. However, if the substance is used in personal care products, cosmetics or household cleaners/detergents, an increased direct exposure potential via the dermal and oral routes of exposure may exist. Indirect exposure due to these potential uses is expected to be low.

Based on the low potential for direct or indirect exposure of the general population when used as notified, 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.

However, based on its extreme skin sensitization properties in conjunction with the increased potential for direct exposure, the potential use of the substance in personal care products and household cleaners may result in the substance becoming harmful to human health. More information is necessary to better characterize potential health risks.

Other Considerations

Similar substances were found that have been subject to risk management measures due to concerns for skin sensitization, repeated dose toxicity and/or significant public exposure from potential uses in consumer applications.

Assessment Conclusion

When the substance is used as notified, it is not suspected to be harmful to human health or environment according to the criteria under section 64 of CEPA. However it is suspected that a significant new activity in relation to the substance may result in the substance meeting those criteria.

Due to the potential risk to the general population related to the extreme skin sensitization properties of the substance if used in personal care products or household cleaners, a SNAc notice was issued to obtain information to ensure that the substance, in relation to these potential activities, undergoes further assessment before such activities can be undertaken. SNAc Order No. 18911 was published in the *Canada Gazette* Part II, Vol. 151, No. 17, August 23, 2017.

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.