

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

New Substances Notification 21337: Oxirane, 2-methyl-, polymer with oxirane, carboxymethyl nonyl ether, branched (Chemical Abstracts Service Registry Number 125304-09-8)

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 based on the available information, that when used as notified, the substance 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 oxirane, 2-methyl-, polymer with oxirane, carboxymethyl nonyl ether, branched (Chemical Abstracts Service Registry Number¹ 125304-09-8). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because its number average molecular weight is less than 1000 daltons and it contains a high percentage of low molecular weight components.

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 an industrial surfactant. Potential uses may include cosmetics, consumer cleaning applications, paints and coatings, adhesives, and lubricants.

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 water. As a surfactant, some of the substance will also be present at the surface of the water or suspended organic matter. The substance is not expected to be persistent in water based on its high biodegradability (> 60% over 28 days). The substance is not

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expected to bioaccumulate based on its expected low to moderate bioconcentration factor (< 1000 L/kg) and biotransformation potential.

Environmental risk assessment

Based on the available hazard information, the substance is expected to have low to moderate acute toxicity towards fish (median effective concentration (EC_{50}) > 1 mg/L), moderate acute toxicity towards aquatic invertebrates (EC_{50} 1-100 mg/L) and high chronic toxicity to algae and aquatic invertebrates (lowest-observed-effect-concentration and no-observed-effect-concentration (NOEC) < 0.1 mg/L). Using the NOEC from the most sensitive organism (aquatic invertebrates), the predicted no-effect concentration (PNEC) was calculated to be in the range of 10-100 µg/L, which was used to estimate the risk to the environment.

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 activity 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 0.1-1 µg/L, and from disposal by release of the substance to water resulting in a PEC in the range of 10-100 µg/L, with the exact value being below the PNEC value. For potential activities such as manufacturing and other industrial uses, environmental exposure is expected to be mainly by release of the substance to water resulting in PECs in the range of 10-100 µg/L, also below the PNEC. For potential activities such as use in personal care or cleaning products, environmental exposure is expected to be mainly by release of the substance to water resulting in a PEC in the range of 1-100 µg/L, also expected to be below PNEC.

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 harm to the environment in Canada.

Human health risk 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). The substance is not expected to be mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. There are no structural alerts for adverse human health effects and the weight of evidence indicates the substance has low acute oral toxicity, and low potential for skin sensitization.

When the notified substance is used as an industrial surfactant, 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 low potential for release to the environment and high biodegradation potential of the substance. However, if the substance is used in cosmetics or consumer cleaning products, an increased direct exposure may exist, and is expected to be mainly by contact with the skin at levels that are significantly

higher than that of the notified use. Indirect exposure of the general population to the substance due to potential uses is expected to be similar to that of the notified use.

Based on the low toxicity and low potential for exposure from the intended use, 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 potential activities, it is not suspected 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.