

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

New Substances Notification 16946: 2-Propenoic acid, 2-methyl-, alkyl ester, polymer with butyl 2-propenoate, ethenylbenzene, 2-hydroxyethyl 2-propenoate, 2-oxiranylmethyl 2-methyl-2-propenoate and *rel*-(1*R*,2*R*,4*R*)-1,7,7-trimethylbicyclo[2,2,1]hept-2-yl 2-propenoate, bis(1,1-dimethylpropyl)peroxide- and 1,1-dimethylpropyl 2-ethylhexaneperoxoate-initiated (Confidential Accession No. 18485-8)

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.

The significant new activity (SNAc) provisions of CEPA were applied to the substance because of potential human health impacts that could arise as a result of potential new activities. [Order 2012-87-11-01 Amending the Domestic Substances List](#) outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 147, No. 3 on January 30, 2013. Notification is required prior to commencement of those activities identified as a potential concern to ensure the substance undergoes further assessment and risk management consideration.

Substance identity

The notified polymer is 2-propenoic acid, 2-methyl-, alkyl ester, polymer with butyl 2-propenoate, ethenylbenzene, 2-hydroxyethyl 2-propenoate, 2-oxiranylmethyl 2-methyl-2-propenoate and *rel*-(1*R*,2*R*,4*R*)-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl 2-propenoate, bis(1,1-dimethylpropyl)peroxide- and 1,1-dimethylpropyl 2-ethylhexaneperoxoate-initiated (Confidential Accession No. 18485-8). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains epoxides.

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 in industrial coatings. Potential uses may include consumer paints, coatings and adhesives, and industrial applications other than those notified.

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 water extractability (<2%), which will limit hydrolysis and

biodegradation. The substance is not expected to bioaccumulate based on its high molecular weight, which will limit its ability to cross biological membranes, and its low water extractability (<2%), which will limit bioavailability.

Environmental risk assessment

Based on the low water extractability (<2%), the substance is expected have low bioavailability. Therefore, 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 negligible based on the low water extractability and high rate of removal during wastewater treatment. 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 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) and is expected to have moderate acute toxicity by the inhalation route (no mortality or significant toxicity observed at highest dose tested). The substance is expected to have moderate to high toxicity following repeated inhalation doses in mammalian test animals (91-day no-observed-adverse-effect level (NOAEL) 0.02-0.2 mg/L/6 hour; 14-day NOAEL <0.06 mg/L/6 hour). It is expected to be weakly mutagenic and clastogenic *in vitro*, but is not expected to be clastogenic *in vivo*. Therefore, more information is needed to determine whether the substance causes 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 product is cured and any residual unreacted substance is expected to be encapsulated within the matrix and not readily released. Indirect exposure of the general population from environmental media such as drinking water is not expected given the low potential for release to the environment. If the substance is used in industrial adhesives, direct and indirect exposure of the general population is not expected, similar to the notified use. However, potential uses of the substance include consumer paints, coatings and adhesives, where an increased level of direct dermal exposure may exist.

Based on the low potential for exposure 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 the potential for increased dermal exposure combined with indications that the substance may be mutagenic and genotoxic, the potential use of the substance in consumer paints, coatings and adhesives could significantly alter the exposure and/or conditions of use resulting in the

substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks associated with these activities.

Assessment conclusion

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

Due to the potential risk to human health related to suspected mutagenicity and genotoxicity if the substance were to be used in consumer paints, coatings and adhesives, the SNAC provisions under CEPA were applied to the substance in order to obtain information to ensure that the substance undergoes further assessment before these potential activities are undertaken. Order 2012-87-11-01 was published in the *Canada Gazette* Part II, Vol. 147, No. 3 on January 30, 2013.

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.