

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

New Substances Notification 21335: Eicosanol, manuf. of, distn., residues (Chemical Abstracts Service Registry Number 2682937-26-2)

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 chemical is eicosanol, manuf. of, distn., residues (Chemical Abstracts Service Registry Number¹ 2682937-26-2), and is considered a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

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 a component of a fuel additive. Potential uses may include personal care products, finger paints, fragrances and air fresheners, consumer coatings, lubricants and greases, automotive care products, machine wash liquids and detergents.

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 not expected to be persistent in these compartments based on very high ready biodegradation (> 85% over 28 days). The substance is expected to have a moderate potential to bioaccumulate based on its low predicted bioconcentration factor (< 250 L/kg) and moderate predicted bioaccumulation factor (250-1000 L/kg).

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Environmental risk assessment

Based on the available hazard information, the substance has low toxicity to fish, aquatic invertebrates, and algae (no adverse effects observed in saturated solutions). A predicted no-effect concentration was not calculated given the low potential for hazard to the environment.

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 low. A predicted environmental concentration was not calculated due to the low potential for ecotoxicity or exposure. No potential activities which could significantly increase environmental risks compared to those notified were identified.

Based on the low potential for ecotoxicity, the substance is unlikely to cause harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance is expected to have a low acute toxicity by the oral and dermal routes (median lethal dose > 2000 mg/kg body weight) and is expected to have low subchronic toxicity following repeated oral doses in mammalian test animals (90-day no-observed-adverse-effect level > 100 mg/kg-bw/day). It is not expected to be a dermal sensitizer (0 % response (guinea pig maximization test)). It is not expected to be mutagenic *in vitro* or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage. In addition, the substance does not contain structural features associated with adverse human health effects.

When the notified substance is used as a component of a fuel additive, 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 such as drinking water is estimated to be at levels in the range of 1×10^{-5} - 1×10^{-4} mg/kg bw/day for adults and children. Potential uses of the substance may include a variety of consumer products including personal care products, fragrances and air fresheners, and finger paints, where direct exposure of the general population is expected to be at levels that do not pose a concern. Indirect exposure of the general population from environmental media such as drinking water is expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the low toxicity, 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 identified 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.