

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

New Substances Notification No. 18827: Ethanol, 2-[[2-(2-hydroxyethoxy)ethyl]methylamino]-

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 chemical, ethanol, 2-[[2-(2-hydroxyethoxy)ethyl]methylamino]- (Chemical Abstracts Service Registry No. 68213-98-9), can be classified as an alkanolamine.

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 as an additive in oil field applications. Based on the functionality of the substance, other potential uses may include consumer products such as cosmetics and personal care products.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water. The substance is not expected to be persistent in water based on experimental biodegradability data of an analogue substance. The notified substance is not expected to bioaccumulate based on its estimated low bioconcentration and bioaccumulation factors (<250 L/kg).

Ecological Assessment

Based on the available hazard information on structurally related chemicals, the substance has low acute toxicity in fish, aquatic invertebrates and algae (median lethal concentration and median effective concentration >100 mg/L). A predicted no-effect concentration was not calculated given the low ecotoxicity.

The notified and 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 not expected. The substance will be used in an enclosed piping system and

wastewater containing the substance is expected to be recycled, or collected for disposal by an approved waste management company. A predicted environmental concentration for notified activities was not estimated given the low potential for ecotoxicity or exposure. The notified substance could have other potential uses; however, given the low ecotoxicity, it is not expected that any other potential activities will result in environmental concentrations high enough to elicit adverse effects to aquatic organisms.

Based on the low potential for environmental release and low ecotoxicity, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on structurally related chemicals, the substance has a low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg), and a low potential for subchronic toxicity following repeat oral (90-day no-observed-adverse-effect level (NOAEL) >100 mg/kg-bw/d) and dermal (90-day NOAEL >200 mg/kg-bw/d) doses in mammalian test animals. The substance has a moderate potential for reproductive/developmental toxicity following repeat oral doses in mammalian test animals (NOAEL 250-1000 mg/kg-bw/d) and a low to moderate potential for reproductive/developmental toxicity following repeat dermal doses in mammalian test animals (NOAEL >500 mg/kg-bw/d). It is not a dermal sensitizer (dermal sensitization not produced in guinea pig maximization test, local lymph node assay or human trials). It is not mutagenic *in vitro* and not clastogenic *in vivo*, and did not induce carcinogenicity by the oral and dermal routes of exposure. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be 1-10 mg/kg-bw/d for local effects (irritation) based on the no-observed-effect level from repeated dermal doses in mammalian test animals of 20-200 mg/kg-bw/d, and 1-10 mg/kg-bw/d for systemic effects based on the NOAEL from repeated dermal doses in mammalian test animals of >200 mg/kg-bw/d.

When the notified substance is used as an industrial chemical additive, the substance is intended for industrial use only and direct exposure of the general population is not expected. 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 potential consumer uses such as cosmetics and personal care products, an increased direct exposure potential may exist. The maximum/overall inhalation dose was estimated to be 0.1-1 mg/kg-bw/d and the maximum/overall dermal dose was estimated to be 1-5 mg/kg-bw/d for potential consumer uses. The use of the notified substance in consumer products may also lead to an increased indirect exposure potential. A worst case scenario arising from exposure through drinking water was calculated to be 10^{-8} - 10^{-7} mg/kg bw/d.

Based on a comparison of the PTDI to the estimated human exposure, and considering other available lines of evidence, 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 uses, it is not suspected to be harmful to human health or the environment according to the criteria under section 64 of CEPA.

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 workplace use.