

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

New Substances Notification No. 18562: 2-Imidazolidinone, 1-(2-hydroxyethyl)-

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, 2-Imidazolidinone, 1-(2-hydroxyethyl)-, (Chemical Abstracts Service Registry No. 3699-54-5), can be classified as a urea, imidazolidinone.

Notified and Potential Activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for use as an industrial solvent. Other potential uses may include numerous potential applications such as use in 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 its expected half-life in water (<182 days). The substance is not expected to bioaccumulate based on its very low octanol-water partition coefficient ($\log K_{ow} \leq 0$) and low predicted bioconcentration and bioaccumulation factors (<250 L/kg).

Ecological Assessment

Based on the available hazard information on the substance and surrogate data 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) and is expected to have low subchronic toxicity in aquatic organisms. A predicted no-effect concentration was not calculated given the low potential for ecological risk.

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 expected to be negligible. Given the low potential for ecotoxicity, the

predicted environmental concentration for notified activities was not estimated. There are numerous potential applications of the substance, but due to the low ecotoxicity of the substance, environmental release from any potential use would also be of low concern for ecological health.

Based on its low ecotoxicity, and low potential for persistence and bioaccumulation, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information, the substance has a low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg body weight) and a low potential for subchronic toxicity and reproductive/developmental toxicity following repeat oral doses in mammalian test animals (28-day no-observed-effect level >1000 mg/kg-bw/d). It is a non-sensitizer. It is not mutagenic or clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an industrial additive, direct exposure of the general population is not expected. Consumers may come into direct dermal contact with end-use products containing the substance; however, given the very low octanol-water partition coefficient ($\log K_{ow} \leq 0$) and very low expected concentration in end-use products, dermal absorption and systemic exposure is expected to be very limited. Indirect exposure of the general population from environmental media such as drinking water is expected to be negligible.

Based on its structure, the substance could potentially be used in personal care products. Although there is an increased exposure potential via direct dermal exposure of the general population from these potential applications, given the very low octanol-water partition coefficient of the substance, dermal absorption and systemic exposure is not expected.

Based on the low potential for dermal uptake, negligible indirect exposure and 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.

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.