

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

New Substances Notification No. 19165: Formaldehyde, homopolymer, reaction products with *N*-propyl-1-propanamine (Chemical Abstracts Service No. 1364859-50-3)

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 formaldehyde, homopolymer, reaction products with *N*-propyl-1-propanamine (Chemical Abstracts Service No. 1364859-50-3).

Notified and potential activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as a hydrogen sulphide scavenger for fuel storage, shipping vessel and pipeline applications. Potential activities may include manufacturing.

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 rapid hydrolysis (half-life ≤ 10 days). The hydrolysis products are not expected to be persistent in water based on their ready biodegradability ($>60\%$ over 28 days). The substance and its hydrolysis products are not expected to bioaccumulate based on the rapid hydrolysis of the substance and the low predicted bioconcentration and bioaccumulation factors of the hydrolysis products (<250 L/kg).

Ecological assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have moderate acute toxicity in fish and aquatic invertebrates (median lethal concentration (LC_{50}) and median effective concentration 1-100 mg/L) and moderate chronic toxicity in algae (10% effective concentration 0.1-10 mg/L). Using the LC_{50} from the most sensitive organism (fish) and by applying an assessment factor of 50 to account for acute to chronic extrapolation and species sensitivity, the predicted no-effect concentration (PNEC) was calculated to be between 0.1 and 1 mg/L, which was used to estimate the ecological risk.

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 activities is expected to be mainly from cleaning of transportation vessels by release of the substance to water at rates of 1 to 10 kg/day. For potential activities such as manufacturing, environmental exposure is expected to be similar to that of the notified use. The predicted environmental concentration (PEC) is estimated to be between 0.001 and 0.01 mg/L for notified and potential activities.

Comparing the PECs for notified and potential activities 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 ecological harm in Canada.

Human health assessment

Based on the available hazard information, the substance has a moderate potential for acute toxicity by the oral route of exposure (median lethal dose (LD₅₀) 50-2000 mg/kg body weight with no signs of systemic toxicity observed) and a moderate to high potential for acute toxicity by the dermal route of exposure (LD₅₀ 200-2000 mg/kg body weight). The substance has high subacute toxicity following repeat dermal doses in mammalian test animals (7-day lowest-observed-adverse-effect level (LOAEL) <60 mg/kg-bw/day). It is a moderate sensitizer (1-10% effective concentration to induce a stimulation index of 3 (local lymph node assay)). It is mutagenic and clastogenic *in vitro*, however it is not clastogenic *in vivo*. Therefore, the substance has potential to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be between 10 and 100 µg/kg-bw/day based on the LOAEL of the dermal subacute toxicity study in mammalian test animals.

When the notified substance is used as a hydrogen sulphide scavenger for fuel storage, shipping vessel and pipeline applications, 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 not expected given the specialized industrial use of the substance, which results in little or no release to the environment. If the substance was manufactured in Canada, direct exposure of the general population is not expected. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels between 0.1 and 1 µg/kg bw/day for children and adults.

Based on a comparison of the PTDI to the estimated human exposure, 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 activities, it is not expected 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 *Hazardous Products Regulations* for products intended for the workplace.