

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

New Substances Notification 20676: Formaldehyde, reaction products with alkylene glycol
(Confidential Accession No. 19535-3)

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, reaction products with alkylene glycol (Confidential Accession No. 19535-3), and is considered a substance of Unknown or Variable composition, Complex reaction product or Biological material (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 gas scavenger in industrial settings. No other uses are anticipated in Canada.

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 air and water. The substance is not expected to be persistent in these compartments because it will be subject to rapid photooxidation, hydrolysis and biodegradation. The substance is not expected to bioaccumulate based on low predicted bioconcentration and bioaccumulation factors (<250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance has moderate acute toxicity to fish and aquatic invertebrates (median lethal concentration 1-100 mg/L), moderate chronic toxicity to algae (10% effective concentration (EC₁₀) 0.1-10 mg/L), and low chronic toxicity to aquatic invertebrates (EC₁₀ >10 mg/L). Using the EC₁₀ from the most sensitive organism (algae) and by applying an assessment factor of 10 to account for acute to chronic extrapolation, species sensitivity variation and mode of action, the predicted no effect concentration (PNEC) was

calculated to be in the range of 100-1000 µg/L, which was used to estimate the risk to the environment.

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 activity is expected to be mainly from cleaning of transportation vessels from release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L. For potential activities such as manufacturing and formulation, environmental exposure is expected to be quantitatively similar to that of the notified use.

Comparing the PEC 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 harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance has a moderate acute toxicity by the oral route (median lethal dose (LD₅₀) 300-2000 mg/kg body weight) and low acute toxicity by the dermal route (LD₅₀ >2000 mg/kg body weight). It has moderate subchronic toxicity following repeated oral doses in mammalian test animals (90-day no-observed-adverse-effect level 10-100 mg/kg-bw/day). It is not expected to be a dermal sensitizer (0% response (Buehler test)). It is mutagenic and clastogenic *in vitro*, but it is not clastogenic *in vivo*. Therefore, the substance has the potential to cause genetic damage.

Based on the toxicity information on the hydrolysis products, the substance is expected to be carcinogenic and have reproductive and developmental toxicity upon repeated exposure at high doses.

When the notified substance is used as a gas scavenger, 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 conservatively estimated to be at levels in the range of 10⁻⁴ to 10⁻³ mg/kg bw/day for adults and toddlers. No potential uses that could significantly increase human health risks compared to the notified uses were identified. For potential activities such as manufacturing, indirect exposure of the general population from environmental media such as drinking water is expected to be at levels similar to that of the notified use.

The target margin of exposure (MOE_T) was calculated to be 1000 based on the local effects observed. The MOE_T is the minimal margin of exposure required for no expected risk in the exposed population. The derived margin of exposure (MOE_D) is the ratio of the point of departure value to the available exposure doses. The MOE_D was calculated to be > 10 000, which is higher than the MOE_T of 1000 for all estimated human exposures. Therefore, the substance is not likely to pose a significant health risk to the general population and is considered 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 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 the *Hazardous Products Regulations* for products intended for the workplace.