

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

New Substances Notification No. 18021: Formaldehyde, reaction products with 1,3-benzenedimethanamine and p-tert-butyl phenol

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 that 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

Formaldehyde, reaction products with 1,3-benzenedimethanamine and p-tert-butyl phenol (Chemical Abstracts Service Registry No. 158800-93-2) is a chemical of unknown or variable composition, complex reaction products, or biological material (UVCB) that can be classified as an aliphatic amine and hindered phenol.

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 industrial and commercial curing agent for epoxy coatings. No other activities are anticipated in Canada.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water, sediment and soil. The substance is not expected to be persistent in sediment and soil because biodegradation is likely to occur. The substance is not expected to bioaccumulate based on its low octanol-water partition coefficient ($\log K_{ow}$ 0-3), and estimates of its bioaccumulation and bioconcentration potential, both of which are expected to be low (<250 L/kg).

Ecological Assessment

Based on the available hazard information on the substance, the substance has moderate acute toxicity in aquatic organisms (median effective concentration (EC_{50}) and median lethal concentration (LC_{50}) of 1-100 mg/L). Acute toxicity data for one of the impurities of the notified substance is moderate (LC_{50} and EC_{50} of 1-100 mg/L). The predicted no-effect concentration

(PNEC) was calculated to be 10-100 µg/L using the EC₅₀ for the notified substance from the most sensitive organism (algae), 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 transportation, formulation, and use by release of the substance to water. The predicted environmental concentration (PEC) for notified activities is estimated to be 0.1-10 µg/L. Environmental exposure from the other potential activities is expected to be mainly from manufacture by release of the substance to water. The PEC for other potential activities is estimated to be 1-10 µg/L.

Comparing the PEC with the PNEC, the ratio is less than 1, indicating that the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on the substance, the substance has a moderate potential for subchronic toxicity by the oral route of exposure (no-observed-adverse-effect level 30-300 mg/kg body weight/day). It is a severe skin irritant (primary irritation index could not be calculated). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When used as an industrial and commercial curing agent for epoxy coatings, direct exposure of the general population through skin contact is expected to be negligible. Indirect exposure of the general population from environmental media such as drinking water and surface water is expected to be negligible.

Based on the low likelihood of 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 used as notified or for other identified potential uses, the substance 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.