

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

New Substance Notification No. 15870: Acetic acid, 1,1-dimethylethyl ester

### **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**

Acetic acid, 1,1-dimethylethyl ester (Chemical Abstracts Service No. 540-88-5) is a chemical that can be classified as an aliphatic ester.

### **Notified and Potential Activities**

The substance is proposed to be manufactured in/imported to Canada in quantities greater than 10 000 kg/yr for use as a solvent in industrial, commercial and consumer coatings and adhesives. Potential uses may include nail polish remover.

### **Environmental Fate and Behaviour**

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to water and air. The substance is not expected to be persistent in water (half-life  $\leq 182$  days in water) but is expected to be persistent in air (half-life  $> 2$  days in air). The substance is not expected to bioaccumulate based on its low bioconcentration factor ( $< 250$  L/kg).

### **Ecological Assessment**

Based on the available hazard information on the substance in water, the substance has low to moderate (median lethal concentration ( $LC_{50}$ ) and median effective concentration ( $EC_{50}$ )  $> 1$  mg/L) acute toxicity in fish, aquatic invertebrates and algae and moderate (no-observed-effect concentration 0.1-10 mg/L) chronic toxicity in algae and plants. Using the  $EC_{50}$  from the most sensitive organism (green algae) and by applying an appropriate assessment factor, the predicted no-effect concentration (PNEC) was calculated to be 100-1000  $\mu\text{g/L}$ , 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 and potential activities is expected to be mainly from manufacturing, formulation and end-use, through the release of the substance to water at levels of 10-1000 kg/day per site. The predicted environmental concentration (PEC) for notified and potential activities is estimated to be 10-100 µg/L in water. The substance may also be released to air at predicted levels of 1-10 x 10<sup>6</sup> kg/year. The PEC for notified and potential activities is estimated to be 100-10 000 µg/m<sup>3</sup> in air near the point of release, and disperse to 0.001-0.01 µg/m<sup>3</sup> regionally. However, as ecotoxicity of the substance in this compartment is unknown, no PNEC could be calculated nor comparisons made.

Comparing the PEC with the PNEC in water, 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, it has a low potential for acute toxicity by the oral, dermal and inhalation routes of exposure (oral and dermal median lethal dose >2000 mg/kg bw, inhalation LC<sub>50</sub> > 10 mg/L). It has a low to moderate potential for subchronic toxicity following repeat inhalation doses in mice (90-day no-observed-adverse-effect level (NOAEL) >300 mg/kg-bw/d with transitional clinical changes). It has a low potential for reproductive toxicity following inhalation doses in mice (90-day NOAEL >20 mg/kg-bw/d). It is a mild eye and skin irritant and a non-sensitizer. It is not mutagenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be 0.1-1 mg/kg-bw/d based on the NOAEL of the 90-day subchronic toxicity following repeat inhalation doses in mice.

The substance was not tested for carcinogenicity. However, one of the three known major metabolites is t-butyl alcohol (TBA) which has been tested for carcinogenicity. In a 2-year drinking water study, there were some evidence of carcinogenic activity in both male rats and female mice. However, the relevance of the carcinogenicity test to humans is questionable based on the lack of clear dose response in the rodent cancer study, the known species metabolism differences, and no free TBA was detected *in vivo* after exposure to TBAC.

When the notified substance is used in consumer products subject to volatile organic compounds (VOC) regulations such as paint formulations and floor varnish products, direct exposure of the general population is expected to be mainly by inhalation at levels of 10-100 mg/kg/event as a worst case estimate. Indirect exposure of the general population from environmental media such as air is expected to be at levels of 0.001-0.01 mg/kg/day as a worst case estimate. However, if the substance is used in nail polish removers, an increased direct exposure potential by dermal contact and inhalation may exist at levels of 1-10 mg/kg/day. While this conservative worst case chronic estimate exceeds the PTDI, the substance is volatile and 100% dermal absorption is unlikely. Therefore, the substance is not expected to cause a health risk.

Based on a comparison of the PTDI to the direct and indirect exposure estimates for the notified and potential uses, 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 *Hazardous Products Regulations* for products intended for the workplace.