

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

New Substances Notification No. 18197: 1,4-Cyclohexanedicarboxamide, *N1,N1,N4,N4*-tetrakis (2-hydroxyethyl)-, trans-

### 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

1,4-Cyclohexanedicarboxamide, *N1,N1,N4,N4*-tetrakis (2-hydroxyethyl)-, trans- (Chemical Abstracts Service Registry No. 1215841-86-3) is a chemical that can be classified as an alkanolamide.

### 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 in powder coatings. Potential uses may include consumer applications such as stain-resistant fabrics and flame-resistant foams.

### 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 moderate potential for biodegradation. The substance is not expected to bioaccumulate based on a very low octanol-water partition coefficient and low bioconcentration and bioaccumulation factors.

### 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 aquatic organisms (median effective concentration (EC<sub>50</sub>) >100 mg/L). Using the EC<sub>50</sub> from the most sensitive organism (green algae) and by applying an appropriate assessment factor, the predicted no effect concentration (PNEC) was calculated to be 1-10 mg/L, which was used to estimate the ecological risk.

The notified 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 production and application of the powder coating by release of the substance to water at levels of 1-10 kg/d-site. The predicted environmental concentration (PEC) for notified 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 low potential for acute toxicity by the oral and inhalation routes of exposure (median lethal dose >2000 mg/kg-bw and median lethal concentration >5 mg/L/4 hours) and a low potential for subchronic toxicity following repeat oral and inhalation doses in mammalian test animals (28-day no-observed-adverse-effect level >300 mg/kg-bw/d; no-observed-effect level >0.6 mg/L). It is not expected to be a sensitizer. It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When used in powder coatings, direct exposure of the general population is not expected because the substance is expected to chemically react into a stable polymer matrix once applied and cured. Indirect exposure of the general population from environmental media such as drinking water is expected to be at levels of 0.1-1 µg/kg-bw/d and mainly by ingestion, which is not a concern because of low oral toxicity. The substance may potentially be used in some consumer applications such as stain-resistant fabrics and flame-resistant foams. However, direct and indirect exposure of the general population is expected to be low, similar to that estimated for the notified use.

Based on the low potential for direct and indirect exposure in conjunction with the low oral and inhalation acute toxicity in mammalian test animals, 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 and 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.