

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

New Substances Notification No. 18319: 1,2,3,4-Butanetetracarboxylic acid, polymer with 2,2-bis(hydroxymethyl)-1,3-propanediol and 3-hydroxy-2,2-dimethylpropanal, 1,2,2,6,6-pentamethyl-4-piperidinyl 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 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 polymer, 1,2,3,4-Butanetetracarboxylic acid, polymer with 2,2-bis(hydroxymethyl)-1,3-propanediol and 3-hydroxy-2,2-dimethylpropanal, 1,2,2,6,6-pentamethyl-4-piperidinyl ester (Chemical Abstracts Service Registry No. 101357-36-2), can be classified as a poly(cycloether-ester). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations* because it contains tertiary amines and a high percentage of low molecular weight components.

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 a Hindered Amine Light Stabilizer (HALS) in the production of plastic. Potential uses may include as a HALS in other materials.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to soil and sediment. The substance is not expected to be persistent in soil and sediment based on hydrolytic instability under typical environmental conditions. The substance is not expected to bioaccumulate based on its high molecular weight which will limit its ability to cross biological membranes.

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, aquatic invertebrates and algae (median lethal concentration (LC₅₀) and median effective concentration

1-100 mg/L). Using the LC₅₀ from the most sensitive organism (aquatic invertebrates) and by applying an appropriate assessment factor, the predicted no-effect concentration (PNEC) was calculated to be 10-100 µg/L, which was used to estimate the ecological risk.

The notified activity in Canada was 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 accidental spills or cleaning of equipment by release of the substance to water at low levels. Transportation materials will be incinerated after use. The concentration of the notified substance in released waste is expected to be low ($\leq 1\%$) because its water extractability will limit its availability in the aquatic environment. The predicted environmental concentration (PEC) for notified activities is estimated to be 1-10 µg/L. No other activities were identified.

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 ecological harm in Canada.

Human Health Assessment

Based on the available hazard information, the substance has a moderate acute toxicity by the oral route (median lethal dose 300-2000 mg/kg body weight). It is not mutagenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a HALS for plastics production, the potential for direct exposure of the general population is expected to be low given that the substance will be present in plastics at low concentrations ($<1\%$) and is unlikely to readily migrate out of end use products. The potential for indirect exposure of the general population from environmental media such as drinking water is expected to be low. It is expected that products containing the substance will be disposed via landfill or incineration at end of life. Release of the substance to the environment from products disposed of in landfills is unlikely because of its low solubility in water and due to the encapsulating polymer. Unforeseen environmental releases during transportation and storage are expected to be minimal. The substance could potentially be applied in the production of engineering resins and olefin films, although these potential uses are similar to those of the notified use in plastics. Exposure of the general population from these potential uses is expected to be similar to the potential for exposure from the notified use.

Based on the low potential for direct or indirect exposure of the general population, 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 the *Hazardous Products Regulations* for products intended for workplace use.