

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

New Substances Notification No. 18629: Dioxadithiatetradecandioic acid, 4,11-dimethyl-1,14-bis(2-ethylhexyl) 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 chemical, dioxadithiatetradecandioic acid, 4,11-dimethyl-1,14-bis(2-ethylhexyl) ester (Confidential Accession No. 19004-5), can be classified as an organosulphide ester.

Notified and Potential Activities

The substance is proposed to be imported into Canada in quantities up to 10 000 kg/yr for use as a heat stabilizer in polyvinyl chloride (PVC) products. 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 soil and sediment. The substance is not expected to be persistent in soil and sediment based on its moderate biodegradability (30-60%). The substance is not expected to bioaccumulate based on its estimated low bioconcentration and bioaccumulation factors (<250 L/kg).

Ecological Assessment

Based on the available hazard information on the notified substance and surrogate data on structurally related chemicals, the substance has low acute toxicity in fish, aquatic invertebrates and algae (no adverse effects observed in saturated solutions). A predicted no-effect concentration was not calculated given the low ecotoxicity.

The notified activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Significant environmental exposure from the notified activity is not expected. The substance is not manufactured in Canada and therefore any releases

associated with manufacture will not enter the Canadian environment. A predicted environmental concentration was not calculated due to the low potential for ecotoxicity. No other potential activities have been identified.

Based on the low potential for ecotoxicity or environmental exposure, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information, the substance has a low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg body weight) and a low potential for subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) >300 mg/kg-bw/d). The substance has a low potential for reproductive/developmental toxicity following repeat oral doses in mammalian test animals (NOAEL >1000 mg/kg-bw/d). It does not cause skin sensitization (stimulation index less than 3 using local lymph node assay). It is not mutagenic or clastogenic *in vitro*. Therefore the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be 0.1 to 1 mg/kg-bw/d based on the NOAEL of the oral subchronic toxicity study in mammalian test animals.

When the notified substance is used as a heat stabilizer in PVC products, direct exposure of the general population is expected to be mainly by contact with the skin at low levels as the substance is not expected to be released from within the plastic matrix. Indirect exposure of the general population from environmental media such as drinking water is expected to be at levels of 0.001-0.01 mg/kg-bw/d for children and adults. No other potential uses for the notified substance were identified.

Based on the low toxicity and low potential for direct exposure, and based on a comparison of the PTDI to the estimated indirect 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 the substance is used as notified, 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.