

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

New Substances Notification 21631: 1,4-Cyclohexanedicarboxylic acid, 1,4-dinonyl ester, branched and linear (Chemical Abstracts Service Registry Number 2449089-78-3)

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 notified chemical is 1,4-cyclohexanedicarboxylic acid, 1,4-dinonyl ester, branched and linear (Chemical Abstracts Service Registry Number¹ 2449089-78-3), and is considered a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as an additive in plastics. Potential uses may include coatings, sealants, adhesives and paints.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition primarily to soil and sediment. The substance is not expected to be persistent in these compartments based on high biodegradability (> 60% in 28 days). The substance is not expected to bioaccumulate based on its low predicted bioaccumulation and bioconcentration factors (< 250 L/kg).

Environmental risk assessment

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Based on the available hazard information, the substance is expected to have low acute and chronic toxicity to fish, aquatic and terrestrial invertebrates, and algae (no adverse effects were observed in saturated solutions). The notified substance was found to have low toxic effects on the growth of several plant species. A predicted no-effect concentration was not calculated given the low potential for hazard to the environment.

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 use as an additive in plastics which would result in negligible concentrations in water. A predicted environmental concentration was not calculated given that there is low hazard potential. No potential activities which could significantly increase environmental risks compared to those notified were identified.

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

Human health risk assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral and dermal routes (median lethal dose > 2000 mg/kg body weight) and low subchronic toxicity following repeated oral doses in mammalian test animals (90-day no-observed-adverse-effect level [NOAEL] > 300 mg/kg-bw/day). The substance is expected to have a low reproductive toxicity following repeated oral doses in mammalian test animals (NOAEL > 300 mg/kg-bw/day); however, signs of developmental toxicity were observed following repeated oral doses in mammalian test animals (NOAEL 30-300 mg/kg-bw/day). It is not a dermal sensitizer (estimated concentration required to produce a stimulation index of 3 > 10% in a local lymph node assay). It is not mutagenic or clastogenic *in vitro* and is not expected to be genotoxic *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an additive in plastics, direct and indirect exposure can occur through multiple routes (oral, dermal, inhalation) and sources may include drinking water, food and beverages, air, soil, and dust. The total direct and indirect exposures are estimated to be at levels in the range of 0.01-0.1 mg/kg-bw/day for adults and 0.1-1 mg/kg-bw/day for infants. These estimates include the notified use as well as any potential uses for the substance.

The target margin of exposure (MOE_T) was calculated to be 1000 based on the available information. The MOE_T is the level of exposure at or above which there is no expected risk to the exposed population. The derived margin of exposure (MOE_D) is the ratio of the point of departure value to the estimated exposure and is compared to the MOE_T. As the MOE_D for the combined direct and indirect exposure is higher than the MOE_T for all estimated human exposures (> 2000), 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.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

Assessment conclusion

When the substance is used as notified or for other identified potential activities, it is not expected to be harmful to human health or the environment according to the criteria under section 64 of the Act.

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 the workplace.