

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

New Substances Notification No. 18073: Phosphorodithioic acid, O,O-bis(2-methylpropyl) ester, trialkylamine salt

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

Phosphorodithioic acid, O,O-bis(2-methylpropyl) ester, trialkylamine salt (Confidential Accession No. 18679-4) is a chemical that can be classified as a dithiophosphate.

Notified and Potential Activities

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for use in the mining industry. Potential uses may include automotive lubricants.

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 because it has an estimated half-life of <180 days. The substance is not expected to bioaccumulate based on its predicted bioaccumulation factor of <5000 L/kg.

Ecological Assessment

Based on the available hazard information on the substance, the substance has low acute toxicity in aquatic organisms (median effective concentration >100 mg/L). A predicted no-effect concentration was not calculated for this substance given its low potential for ecological hazard.

No significant releases are expected from the notified uses of the substance, and given the low potential hazard associated with the substance, calculation of a predicted environmental concentration was deemed unnecessary.

Based on the low potential for ecological hazard and notified uses of the substance, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has a moderate potential for acute toxicity by the oral route of exposure (median lethal dose (LD₅₀) 300-2000 mg/kg bw), a low acute toxicity by the dermal route of exposure (LD₅₀ >2000 mg/kg bw), and moderate potential for subchronic toxicity (28-day no-observed-adverse-effect level = 30-300 mg/kg bw/day) following repeat oral doses in mammalian test animals (for neurotoxicity). It is a severe eye irritant (maximum average score = 25-50), a moderate skin irritant (primary irritation index = 3.1 to 5), and is likely a moderate to weak dermal sensitizer in laboratory animals. It is not mutagenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When used in the mining industry, direct exposure of the general population is not expected. Indirect exposure of the general population from environmental media such as drinking water due to an unforeseen environmental release is estimated to be at levels of 1.71×10^{-6} to 3.59×10^{-6} mg/kg bw/day for adults and children, respectively.

When used for potential uses such as automotive lubricants, direct exposure to the general population is expected to be mainly by contact with the skin at an estimated level of 0.123 mg/kg bw per event. Indirect exposure of the general population from environmental media such as drinking water due to potential increases in import volumes and additional uses is estimated to be at levels of 1.71×10^{-5} to 3.59×10^{-5} mg/kg bw/day for adults and children, respectively.

Based on the estimated direct exposure of the general population to the substance resulting from its potential use as an automotive lubricant for acute exposures (e.g., 4 times a year) in conjunction with the lack of adverse effects observed in the acute dermal toxicity test, 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. Based on the estimated indirect exposure of adults or children through drinking water, the substance is not likely to pose a significant health risk to the general population when used as notified, and taking into account potential increases in import volumes and additional uses, and is therefore unlikely to be harmful to human health.

Assessment Conclusion

When used as notified or for 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.