

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

New Substances Notification 20831: Metal, bis(2,4-pentanedionato- κO^2 , κO^4)-, (T-4)-
(Confidential Accession Number 19589-7)

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 metal, bis(2,4-pentanedionato- κO^2 , κO^4)-, (T-4)- (Confidential Accession Number 19589-7).

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 in vehicle tires. No other uses are anticipated in Canada.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to water. Although the metal moiety is persistent, the substance is not expected to be persistent based on its very high biodegradability (> 85% over 28 days). The substance is not expected to bioaccumulate because it is highly water soluble and readily biodegradable.

Environmental risk assessment

Based on the available hazard information, the substance has moderate chronic toxicity to algae (median effective concentration (EC_{10}) 0.1-10 mg/L), low acute toxicity to fish (median lethal concentration (LC_{50}) > 100 mg/L), and low acute toxicity to aquatic invertebrates (median effective concentration (EC_{50}) > 100 mg/L). Using the EC_{10} from the most sensitive organism (algae) and by applying an assessment factor of 10 to account for species sensitivity variation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 0.1-1 mg/L.

The notified and other potential 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 not expected. Therefore, a predicted environmental concentration (PEC) was not calculated for its notified use pattern due to the low potential for environmental exposure from these activities. For potential activities such as manufacturing, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 0.001-0.01 mg/L, below the PNEC.

Based on the 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 moderate acute toxicity by the oral route (median lethal dose (LD₅₀) 300-2000 mg/kg body weight), low acute toxicity by the dermal route (LD₅₀ > 2000 mg/kg body weight) and low acute toxicity by the inhalation route (LC₅₀ > 5 mg/L). It has moderate subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) 30-300 mg/kg-bw/day). It is not a dermal sensitizer (Stimulation Index < 3.0 (local lymph node assay)). It is mutagenic *in vitro* (positive in two assays and negative in one assay) and clastogenic *in vitro*. However, it is not clastogenic *in vivo*, and *in vivo* tests for DNA damage in two tissues were negative after multiple endotracheal instillations. Overall, the substance is unlikely to cause genetic damage *in vivo*.

When the notified substance is used in vehicle tires, direct exposure of the general population is not expected due to the industrial nature of the use. Indirect exposure of the general population from environmental media is not expected given the specialized industrial use of the substance, which results in little or no release to the environment. Use of the substance in vehicle tires would be in a part of the tire that is not exposed to road wear and, as such, would not be released to the environment from tire use. No potential uses that could significantly increase human health risks compared to the notified uses were identified.

Based on the low potential for 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.

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 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.