

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

New Substances Notification No. 18527: Alcohols, C₂₋₃₃, manufactured of, by-products from, overheads

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, Alcohols, C₂₋₃₃, manufactured of, by-products from, overheads (Chemical Abstracts Service Registry No. 876065-86-0), is of unknown or variable composition, complex reaction products, or biological material (UVCB), can be classified as by-products of alcohol manufacturing.

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 in oil recovery applications and as a solvent in industrial cleaning solutions. Potential uses may include consumer furniture polish products.

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%). Due to its moderate vapour pressure (0.013-133 Pa), the substance has the potential to partition to air; however, it is expected to rapidly oxidize and as such will not remain in this compartment. The substance is not expected to bioaccumulate based on its moderate octanol-water partition coefficient ($\log K_{ow} < 5$).

Ecological Assessment

Based on the available hazard information, the substance has low acute toxicity in fish, aquatic invertebrates and algae (median lethal loading and median effective loading > 100 mg/L). A predicted no-effect concentration was not calculated for the substance given the low potential for ecological risk.

The notified and potential activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified industrial and potential consumer activities is expected to be negligible as the substance will be discarded through industrial organic waste disposal. A predicted environmental concentration was not estimated given the low potential for environmental release and the low expected ecotoxicity.

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

Human Health Assessment

Based on the available hazard information, the substance has a low acute toxicity by oral and dermal routes (median lethal dose >2000 mg/kg body weight). The substance has a low subchronic toxicity (90-day no-observed-adverse-effect level (NOAEL) >100 mg/kg-bw/d) and a moderate reproductive and developmental toxicity (NOAEL 250-1000 mg/kg-bw/d) following repeat oral doses in mammalian test animals. It is not a skin sensitizer (0% response (Buehler scale)). It is not mutagenic *in vitro* and not clastogenic *in vivo*. Therefore the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be 0.1-1 mg/kg-bw/d based on the oral repeat dose reproductive/developmental toxicity study in mammalian test animals of 250-1000 mg/kg-bw/d.

When the notified substance is used as a solvent in industrial cleaning solutions or for oil recovery fluids, direct and indirect exposure of the general population is expected to be negligible given the industrial nature of the use. The substance has potential consumer applications in furniture polish products, resulting in an increased potential for direct dermal and inhalation exposure of the general population. The total dermal and inhalation exposure from furniture polish sprays or wipes was estimated to be 0.1-0.5 mg/kg-bw/d. The potential for indirect exposure from potential use of the substance in furniture polish is considered to be low.

Based on the low potential for significant direct or indirect exposure of the general population from notified use, and based on a comparison of the PTDI to the estimated exposure from potential consumer uses, 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.