

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

New Substances Notification No. 18101: Alcohols, C₁₂₋₂₂, distillation residues

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

Alcohols, C₁₂₋₂₂, distillation residues (Chemical Abstracts Service Registry No. 1476777-83-9) are a class of chemicals that can be classified as long chain alkyl esters and alcohols.

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 as a defoamer in paper manufacturing. Potential uses may include consumer products, such as shampoos, soaps, household cleaners and dish detergents.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to sediment and soil. The substance is not expected to be persistent in these compartments because it is expected to undergo biodegradation. The substance is not expected to bioaccumulate based on low estimated bioconcentration factors for the breakdown products.

Ecological Assessment

Based on the available surrogate data on structurally related chemicals, 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.

Given the low potential hazard associated with the substance, calculation of a predicted environmental concentration for notified or potential uses was not required.

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 surrogate data on structurally related chemicals, the substance has a low (median lethal dose >2000 mg/kg body weight) potential for acute toxicity by the oral and dermal routes of exposure and a moderate potential for subchronic toxicity following repeat oral doses in mammalian test animals (no-observed-adverse-effect level 30-300 mg/kg bw/day). The substance has a low potential for developmental toxicity following repeat oral doses in mammalian test animals (no-observed-effect level >1000 mg/kg bw/day). It is a minimal to moderate (primary irritation index = 0-5) skin irritant and a mild/weak sensitizer in animal studies but not a sensitizer in a human study (8-28% response (Buehler scale); effective concentration >10% (local lymph node assay scale)). It is not mutagenic *in vitro* and not clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When used as a defoamer in paper manufacturing, direct exposure of the general population is expected to be mainly by contact with the skin with end-use paper products at low levels. Indirect exposure of the general population from environmental media such as drinking water is expected to be low. When potentially used in consumer products, direct exposure by the general population expected to be high through contact with the skin, however dermal absorption is expected to be low. Indirect exposure from environmental media such as drinking water resulting from potential uses is expected to remain low.

Based on the low likelihood of exposure for notified uses and low dermal absorption for potential uses in conjunction with the low health hazard, 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 used as notified and other 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.