

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

New Substances Notification No. 17873: Coconut oil, reaction products with boric acid (H_3BO_3), diethanolamine and polyol

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

Coconut oil, reaction products with boric acid (H_3BO_3), diethanolamine and polyol (Confidential Accession Number 18829-1) is a chemical that can be classified as a boron compound. It is a chemical of unknown or variable composition, complex reaction product and biological material (UVCB).

Notified and Potential Activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 1 000 kg/yr for use in engine oil. Potential uses may include a borated lubricant.

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 based on the expected rapid hydrolysis (half-life <1 hour) to form boric acid, fatty alkanolamides and a polyol. The substance is not expected to bioaccumulate based on rapid hydrolysis.

Ecological Assessment

Based on the available hazard information from surrogate data on structurally related chemicals, the substance has low to moderate acute toxicity (median lethal concentration > 1 mg/L) in aquatic organisms (i.e., algae, daphnia and fish) and low to moderate chronic toxicity in aquatic organisms. Since boric acid is known to have a high toxicity for fish and algae, the predicted no effect concentration (PNEC) was calculated to be 10-100 mg/L (using the Canadian Council of Ministers of the Environment long-term exposure Canadian Water Quality Guideline for boron for freshwater organisms of 1.5 mg boron/L, converted based on molecular weights) and was used to estimate the ecological risk.

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 expected to be mainly from transportation, formulation and application by release of the substance to water at very low levels. Environmental exposure from potential activities is expected to be by release of the substance to surface water at levels of 0.03 kg/day. The predicted environmental concentration (PEC) was not calculated for notified activities; however the PEC for potential activities is estimated to be negligible for lubricants and 0.01-0.1 µg/L for metalworking fluids.

Comparing the PEC with the PNEC, the ratio is less than 1, indicating that the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information from surrogate data on structurally related chemicals, the substance has a low potential for acute toxicity by the oral and dermal routes of exposure (median lethal dose >2000 mg/kg) and a low potential for subchronic toxicity following repeat dermal doses in mammalian test animals (28-day no-observed-adverse-effect-level (NOAEL) >600 mg/kg bw/d and 90-day NOAEL >200 mg/kg bw/d). It is not likely to be a sensitizer. It is not mutagenic *in vitro* and therefore the substance is unlikely to cause genetic damage.

When used as notified, direct exposure of the general population is expected to be mainly by contact with the skin at levels of 0.819 mg/kg-bw/d. When used for its potential use as a borated lubricant, direct exposure of the general population is expected to be mainly by contact with the skin at levels of 0.819 mg/kg-bw/d. Indirect exposure of the general population from environmental media such as drinking water is expected to be negligible.

Based on the estimated exposure doses for both its notified use and potential use being below the dermal provisional tolerable daily intake of 1.0 mg/kg/day, in conjunction with the low acute dermal toxicity, 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 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 the workplace use.