

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

New Substances Notification 20937: Coconut oil, ethoxylated (Chemical Abstracts Service Registry Number 67762-35-0)

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 polymer is coconut oil, ethoxylated (Chemical Abstracts Service Registry Number¹ 67762-35-0). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because the substance will substantially degrade.

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 as a non-ionic surfactant in automatic dishwashing detergents. Potential uses may include detergents and cleansers, personal care products and as a surfactant in the textile, pulp and paper, ink, and adhesive industries.

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. The substance is not expected to be persistent in this compartment based on its ready biodegradation (> 60% over 28 days). The substance is not expected to bioaccumulate because it will rapidly be metabolized and eliminated based on the bioaccumulation potential for similar alcohol ethoxylates.

Environmental risk assessment

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Based on the available hazard information, the substance is expected to have moderate acute toxicity to aquatic invertebrates (median effective loading rate 1-100 mg/L) and moderate chronic toxicity to algae (10% median effective loading rate (EL₁₀) 0.1-10 mg/L). Using the EL₁₀ from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 50 to account for acute to chronic extrapolation and species sensitivity variation, a predicted no-effect concentration (PNEC) was calculated to be in the range of 100-1000 µg/L. In the estimation of risk to the environment, a more conservative PNEC value of 70 µg/L was used based on the Canadian Federal Environmental Quality Guideline for alcohol ethoxylates.

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 and notified use by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L, and from formulation in consumer dishwashing detergents by release to water resulting in a PEC in the range of 0.01-0.1 µg/L. For potential activities such as manufacturing, environmental exposure is expected to be mainly by release of the substance to water resulting in a PEC in the range of 1-10 µg/L.

Comparing the PEC with the PNEC, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard, and exposure, indicates that the substance is unlikely to cause harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance is expected to have a low acute toxicity by the oral route (median lethal dose > 2000 mg/kg body weight) and low subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) > 300 mg/kg-bw/day). The substance is expected to have a low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (NOAEL > 300 mg/kg-bw/day).

When the notified substance is used as a surfactant in automatic dishwashing detergents, consumers may come into contact with end-use products containing the substance; however, direct exposure is expected to be mainly by incidental contact with the skin at low levels given that exposure to the substance will be mitigated by the large size of the polymer which will limit dermal uptake. Potential uses of the substance include cleaning products and personal care products, where direct exposure of the general population is expected to be mainly by contact with the skin at levels in the range of 0.01-0.1 mg/kg-bw/day. Indirect exposure of the general population from environmental media such as drinking water is not expected given the low potential for environmental release.

The target margin of exposure (MOE_T) was calculated to be 1000 based on the available information. The MOE_T is the level of exposure at or above which there is no expected risk in the exposed population. The derived margin of exposure (MOE_D) is the ratio of the point of

departure value to the available exposure doses and is compared to the MOE_T . As the MOE_D is higher than the MOE_T for all estimated human exposures, 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 identified 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.