

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

New Substances Notification 21045: Waxes and waxy substances, rice bran, oxidized (Chemical Abstracts Service Registry Number 1883583-80-9)

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 waxes and waxy substances, rice bran, oxidized (Chemical Abstracts Service Registry Number¹ 1883583-80-9), and is considered a substance of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

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 industrial, commercial and consumer applications as a component in polishes, coatings, inks and plastics, and in plastic manufacturing. Potential uses may include personal care products, household cleaning products and food packaging materials.

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 soil and sediment. The substance is not expected to be persistent in these compartments based on its expected inherent biodegradation (10-30% over 28 days). The substance is not expected to bioaccumulate based on its limited bioavailability and susceptibility to biotransformation.

Environmental risk assessment

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Based on the available hazard information, the substance has low acute toxicity to fish and aquatic invertebrates (median lethal loading rate > 100 mg/L, median effective loading rate > 100 mg/L) and low chronic toxicity to algae (10% effective loading rate > 10 mg/L). A predicted no-effect concentration was not calculated given the low potential for hazard to the environment.

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 use in industrial, commercial or consumer applications from release of the substance to water at low rates. For potential activities such as manufacturing or use in various other applications, environmental exposure is expected to be at levels that do not pose a concern, similar to that of the notified activities. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and ecotoxicity.

Based on the low potential for ecotoxicity and 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 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 (90-day no-observed-adverse-effect level > 1000 mg/kg-bw/day). It is not a dermal sensitizer. It is not mutagenic or clastogenic *in vitro*, and is not genotoxic *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as a component in coatings, plastics, and as a plastic mold releasing agent consumers may come into contact with end-use products containing the substance, however, direct exposure is not expected because the substance will be encapsulated within a stable matrix once the product is cured and would be unavailable for uptake. When the notified substance is used as a component in various types of polish, including for shoes, cars and floors, direct exposure of the general population is expected to be mainly by contact with the skin. Systemic exposure will be limited by the high molecular weight and very high octanol-water partition coefficient ($\log K_{ow} > 8$) of most components of the notified substance, which will limit systemic uptake. Indirect exposure of the general population from environmental media such as drinking water is not expected given the low potential for environmental release. Potential uses of the substance include personal care products, household cleaning products and food packaging materials, where direct and indirect exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the low toxicity profile of this substance, it 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 used 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.