

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

New Substances Notification 20927: Fatty acids, plant-based oil, conjugated, maleated
(Confidential Accession Number 19489-7)

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 fatty acids, plant-based oil, conjugated, maleated (Confidential Accession Number 19489-7), 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 up to or greater than 10 000 kg/yr for the notified use as an additive in industrial coatings. No other uses are anticipated in Canada.

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 high biodegradability (> 60% in 28 days). The substance is not expected to bioaccumulate based on its biomagnification factor (< 1).

Environmental risk assessment

Based on the available hazard information, the substance is expected to have low acute and chronic toxicity to fish, aquatic invertebrates and algae (no adverse effects observed in saturated solutions). A predicted no-effect concentration was not calculated given the low potential for hazard to the environment.

The notified activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified

activity is expected to be mainly from cleaning of equipment and transportation vessels which could result in the release of the substance to water at low rates. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and ecotoxicity. No potential activities that could significantly increase environmental risks compared to those notified were identified.

Based on the low potential for environmental exposure and ecotoxicity, 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 (28-day no-observed-adverse-effect level > 300 mg/kg-bw/day). The substance has low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (no-observed-effect level > 300 mg/kg-bw/day). The substance is a mild dermal sensitizer (8-28% response (Buehler test)). It is not mutagenic *in vitro* and is not clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an additive in industrial coatings, 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 will be unavailable for uptake. Indirect exposure of the general population through environmental media such as drinking water or air is expected to be low given the low potential for environmental release. No potential uses that could significantly increase human health risks compared to the notified uses were identified.

Based on the low potential for exposure, the substance is not likely to pose a significant health risk to the general population, and is unlikely to be harmful to human health.

The assumptions made in this 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.