

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

New Substances Notification 20187: 5,8,11,14,17-Eicosapentaenoic acid, ethyl ester, (5Z,8Z,11Z,14Z,17Z)- (Chemical Abstracts Service registry number 86227-47-6)

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 5,8,11,14,17-eicosapentaenoic acid, ethyl ester, (5Z,8Z,11Z,14Z,17Z)- (Chemical Abstracts Service registry number¹ 86227-47-6).

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 prescription drugs. Potential uses may include being an ingredient in a natural health product or in a personal care product.

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 very high biodegradation. The substance is not expected to bioaccumulate based on metabolism in biota.

Ecological assessment

Based on the available hazard information, the substance is expected to have low acute toxicity to fish, aquatic invertebrates, and algae. A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

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 activity is expected to be mainly from use and disposal by release of the substance to water at low rates. For potential activities such as manufacturing and formulation, environmental exposure is expected to

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be mainly from release of the substance to water at very low rates. A predicted environmental concentration was not calculated due to the low potential for environmental exposure.

Based on the low potential for ecotoxicity and environmental exposure, the substance is unlikely to cause ecological harm in Canada.

Human health assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral, intraperitoneal, and subcutaneous routes (median lethal dose >2000 mg/kg body weight). The substance has low subchronic toxicity following repeated oral doses in mammalian test animals (12-month no-observed-adverse-effect level (NOAEL) >100 mg/kg-bw/day). The substance is expected to have low to moderate reproductive/developmental toxicity following repeated oral doses in mammalian test animals (no-observed-adverse-effect level (NOAEL) >30 mg/kg-bw/day). The substance may be dermally irritating, while it is not expected to be a strong dermal sensitizer. It is not mutagenic *in vitro* or clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in prescription drugs, direct exposure of the general population is assessed by the Therapeutics Products Directorate of Health Canada. Potential uses of the substance include being an ingredient in a natural health product or in a personal care product, where assessment of the direct exposure of the general population is the responsibility of the appropriate Health Canada directorate. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels given the low potential for environmental release.

Based on the low toxicity and low potential for exposure, 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 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 *Hazardous Products Regulations* for products intended for the workplace.