

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

New Substances Notification 21012: Docosanoic acid, docosyl ester (Chemical Abstracts Service Registry Number 17671-27-1)

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 docosanoic acid, docosyl ester (Chemical Abstracts Service Registry Number¹ 17671-27-1).

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 toners for printers for commercial and consumer use. Potential uses include cosmetics.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released into the environment, it will tend to partition to soil and sediment. The substance is not expected to be persistent in these compartments based on inherent biodegradation (> 60% over 28 days). The substance is not expected to bioaccumulate based on its very high octanol-water partition coefficient ($\log K_{ow} > 8$), which will limit its bioavailability.

Environmental risk assessment

Based on the available hazard information, the substance is not expected to have adverse effects in saturated solutions to fish (no-observed-effect loading rate (NOELR) > 100 mg/L),

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aquatic invertebrates (NOELR > 100 mg/L), and algae (median effective loading rate > 100 mg/L). A predicted no-effect concentration was not calculated given the low potential for hazard to the environment and low potential for bioaccumulation in aquatic species.

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 not expected due to rapid biodegradation in the environment, its high removal from water during wastewater treatment processes, and its low potential for bioaccumulation in aquatic species. For potential activities such as manufacturing, environmental exposure is expected to be quantitatively similar to that of the notified use. 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). The substance is expected to have low subchronic toxicity and low reproductive/developmental toxicity following repeated oral doses in mammalian test animals. It is not expected to be a dermal sensitizer. It is not mutagenic *in vitro* and is not expected to be clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in toners for printers for consumer and commercial use, the general public will come into direct contact with printed materials containing the notified substance; however, direct exposure of the general population is not expected as the notified substance will be melted and fused into a stable matrix on printing materials and unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water or air is expected to be at low levels given the low potential for environmental release.

Potential uses of the substance includes cosmetics, where direct exposure of the general population is expected to be mainly by topical application to skin or by oral ingestion at levels ranging from moderate to high. Dermal and systemic absorption of the substance will be limited by the physical chemical properties of the substance. Indirect exposure of the general population from environmental media is expected to be at levels that do not pose a concern, similar to that for the notified use.

Based on the low toxicity of the 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 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.