

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

New Substances Notification 20169: Alkanes, C₁₁-C₁₆-branched and linear (Chemical Abstracts Service registry number 1809170-78-2)

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 alkanes, C₁₁-C₁₆-branched and linear (Chemical Abstracts Service registry number¹ 1809170-78-2) and is considered a substance of unknown or variable composition, complex reaction products or biological materials (UVCB). The substance is primarily aliphatic and contains very little aromatic content.

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 metal working fluids, rolling oils, lamp fuels, and a chemical intermediate. Potential uses include personal care products.

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 air, soil and sediment. The substance is not expected to be persistent in these compartments based on short atmospheric half-life (<2 days) and high biodegradability (>60% in 28 days). The substance is not expected to bioaccumulate based on bioconcentration factors for analogue substances (<1000 L/kg).

Ecological 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 ecological hazard.

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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 activities is expected to be mainly from cleaning of transportation vessels and disposal of metalworking fluids. Release of the substance to water resulting from these activities is expected to be negligible. A predicted environmental concentration was not calculated due to the low potential for environmental exposure and ecotoxicity. No potential activities which could significantly increase environmental risks compared to those notified were identified.

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

Human health assessment

Based on the available hazard information, the substance is expected to have a low acute toxicity by the oral, dermal and inhalation routes (oral and dermal median lethal dose > 2000 mg/kg body weight; inhalation median lethal concentration >5 mg/L/4hr) and low subchronic toxicity following repeated oral doses in mammalian test animals (90 no-observed-adverse-effect level (NOAEL) >100 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). It is not a dermal sensitizer (Buehler assay). It is not expected to be mutagenic *in vitro* or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage. The provisional tolerable daily intake (PTDI) was calculated to be in the range of 1-10 mg/kg bw/day based on the NOAEL of the oral subchronic/reproductive/developmental toxicity study in mammalian test animals. The PTDI is the estimated level of long-term exposure without risk of adverse health effects.

When the notified substance is used in metal working fluids, in rolling oils and as a chemical intermediate, direct exposure of the general population is not expected due to the industrial nature of the use. When it is used in consumer lamp fuels, exposure may occur by incidental contact with the skin. Potential uses of the substance include 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 0.1-1 mg/kg-bw/day for toddlers and adults. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 10^{-4} - 10^{-3} mg/kg-bw/day for toddlers and 10^{-5} - 10^{-4} mg/kg-bw/day for adults, for both the notified and potential uses.

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.

Other considerations

A group of alkane substances ([Gas Oils and Kerosenes](#)) was prioritized for assessment under phase 2 of the Chemicals Management Plan (CMP) (Environment and Climate Change Canada and Health Canada 2019). The carbon chain lengths of the notified substance are in the range of those substances addressed in the CMP assessment. As of this writing, the Existing Substances draft screening assessment report concludes that only gas oils and kerosenes with aromatic contents of 20% by weight or greater meet the criteria under section 64 of the Act.

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