

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

New Substances Notification 20699: Octadecene, reaction products with hexadecene, hydrogenated (Chemical Abstracts Service Registry Number 2241366-04-9)

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 octadecene, reaction products with hexadecene, hydrogenated (Chemical Abstracts Service Registry Number¹ 2241366-04-9), and is considered a substance of Unknown or Variable composition, Complex reaction product or Biological material (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 a base oil in lubricant products. Potential uses may include formulation in agrochemicals, water treatment chemicals, coatings, synthetic drilling mud fluids, cleaning agents, personal care products, and as functional fluids.

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 moderate biodegradability (30-60% in 28 days). The substance is not expected to bioaccumulate based on low predicted bioconcentration and bioaccumulation factors (< 250 L/kg).

Environmental risk assessment

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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 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 formulation by release of the substance to water resulting in a predicted environmental concentration in the range of 0.1-1 µg/L. For potential activities such as manufacturing, environmental exposure is expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the low potential for 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 and dermal routes (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 (NOAEL) > 300 mg/kg-bw/day). The substance is expected to have a moderate toxicity following repeated inhalation doses in mammalian test animals (28-day NOAEL 30-300 mg/kg-bw/day). It has low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (NOAEL > 300 mg/kg-bw/day). It is not a dermal sensitizer (local lymph node assay). It is not mutagenic *in vitro* or clastogenic *in vitro* or *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in industrial or commercial lubricants, direct exposure of the general population is not expected due to the industrial and commercial nature of the use. When the notified substance is used as a base oil for formulated automotive lubricant products, Do-It-Yourself consumers may come into contact with products containing the substance; however, direct exposure is expected to be infrequent and mainly by contact with the skin at low levels. 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 that are available for application as a spray, where direct exposure is expected to be mainly by inhalation at levels conservatively estimated to be less than 10^{-3} mg/kg-bw/day. Dermal uptake and subsequent systemic distribution of the substance are expected to be limited by its anticipated high octanol-water partition coefficient. Indirect exposure of the general population from environmental media such as drinking water is expected to be at levels that do not pose a concern, similar to that of the notified use.

The target margin of exposure (MOE_T) was calculated to be 300 based on the available information for a similar substance. The MOE_T is the level of exposure at or above which there is no expected risk in the exposed population. The derived margin of exposure (MOE_D) is the ratio of the point of departure value to the available exposure doses and is compared to the

MOE_T. As the MOE_D is higher than the MOE_T for all estimated human exposures, 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.

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.