

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

Significant New Activity No 17909 9-Decenamamide, *N,N*-dimethyl-, Chemical Abstracts Service Registry No. 1356964-77-6

Regulatory Decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999), and pursuant to section 83 of that Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance. The Ministers have determined that it is not anticipated to enter the environment in a quantity or concentration or under conditions that:

- (a) have or may have an immediate or long term harmful effect on the environment or its biological diversity, or
- (b) constitute or may constitute a danger to the environment on which life depends, or
- (c) constitute or may constitute a danger in Canada to human life or health.

However, a significant new activity (SNAc) notice was adopted based on uncertainties regarding potential human health impacts of the substance in relation to certain new activities. [SNAc Notice No. 17909](#) outlines information requirements for those activities and was published in the *Canada Gazette* Part I, Vol. 149, No. 11 - March 14, 2015. Notification is required prior to commencement of those activities identified as a potential risk to ensure the substance undergoes further assessment and risk management consideration.

Substance Identity

The substance is a chemical that can be classified as an aliphatic amide.

Notified Activities

The substance is proposed to be manufactured in/and or imported into Canada in quantities greater than 10 000 kg for use in industrial and household cleaning products.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition primarily to the aquatic compartment. The substance is not expected to be persistent in water based on its high ready biodegradation (60% to 85%). The substance is not expected to be bioaccumulative based on its moderate octanol-water partition coefficient ($\log K_{ow} = 2.5$ to 3.5).

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance has moderate acute toxicity ($LC_{50} = 1$ to 100 mg/L) in fish, daphnia, and algae and moderate chronic toxicity ($NOEC = 0.1$ to 10 mg/L) in daphnia. The predicted no effect concentration was calculated to be 10 to 100 μ g/L using the 48h EC_{50} from the most sensitive organism (daphnia), which was used to estimate the ecological risk.

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 the release of the substance to surface water from use, formulation, and the cleaning of transportation vessels. The predicted environmental concentration for notified activities is estimated to be greater than 1 μ g/L.

Based on a low to moderate hazard characterization and considering exposure from all potential uses of the notified substance, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information on the substance and surrogate toxicity study data on a structurally related chemical, the substance has a moderate potential for acute toxicity by the oral and inhalation routes of exposure ($LD_{50} = 300$ to 1000 mg/kg bw and $LC_{50} > 3.6$ mg/L/4h, respectively), a high potential for acute toxicity by the dermal route ($LD_{50} = 200$ to 1000 mg/kg bw) and a moderate potential for subchronic toxicity following repeat oral doses in mammalian test animals ($NOAEL = 250$ to 1000 mg/kg bw/day). The notified substance is not considered likely to cause developmental toxicity ($NOAEL > 1000$ mg/kg bw/day). The notified substance is likely to cause severe to very severe irritation to eyes ($MMS = 50$ to 80), and is considered to elicit moderate to severe skin irritation ($PII = 3.1$ to 6.5). The notified substance is not expected to be a sensitizer. Based on negative results following *in vitro* and *in vivo* testing, the substance is not mutagenic or clastogenic. Therefore the substance is considered unlikely to cause genetic damage.

When used in cleaning products, direct exposure of the general population is expected to be mainly by contact with the skin and/or by inhalation at levels less than 0.1 mg/kg bw/day. Indirect exposure of the general population from environmental media such as drinking water is conservatively expected to be less than 5 μ g/kg bw/day and mainly by ingestion. However, if the substance is used in personal care products, that is any cosmetic or drug as defined in section 2 of the *Food and Drugs Act* or in any natural health product as defined in subsection 1(1) of the *Natural Health Products Regulations*, an increased direct exposure potential via frequent and sustained dermal contact may exist.

Based on the estimates of direct and human exposure from use of the substance in cleaning products in conjunction with the moderate subchronic toxicity, 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.

However, based on the potential for increased direct dermal exposure in relation with the moderate subchronic toxicity (toxic effects on the kidneys), the use of the substance in personal care products may significantly alter the exposure of the general population resulting in the substance becoming harmful to human health. Consequently, more information is necessary to better characterize potential health risks.

Assessment Conclusion

When used as notified, the substance is not suspected to be harmful to human health or environment according to the criteria under section 64 of CEPA 1999. However it is suspected that a significant new activity in relation to the substance may result in the substance meeting those criteria.

Due to the potential risk to the general population related to the subchronic toxicity if the substance is used in personal care products, that is any cosmetic or drug as defined in section 2 of the *Food and Drugs Act* or in any natural health product as defined in subsection 1(1) of the *Natural Health Products Regulations*, a SNAc notice was issued to obtain information to ensure that the substance, in relation to these potential activities, undergoes further assessment. [SNAc Notice No. 17909](#) was published in the Canada Gazette Part I, Vol. 149, No. 11 on March 14, 2015.

A conclusion under CEPA 1999, 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 workplace use.