

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

New Substances Notification No. 19916: Amines, C₃₆-alkylenedi- (Chemical Abstracts Service No. 68955-56-6)

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 the substance is anticipated to enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

In order to ensure that the substance does not cause harm to the Canadian environment or human health, its manufacture and import are authorized subject to conditions as described in [Ministerial Condition No. 19916](#) published in the *Canada Gazette* Part I, Vol. 153, No. 33 on August 17, 2019.

Substance identity

The notified chemical is amines, C₃₆-alkylenedi- (Chemical Abstracts Service Registry Number¹ 68955-56-6), and is a substance referred to as Unknown or Variable composition, Complex reaction products or Biological materials (UVCB).

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 an additive in industrial and commercial coatings, adhesives and sealants, and in the manufacture of soles for footwear. Potential uses may include use as an additive in consumer coatings, adhesives and sealants.

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 ready biodegradation of analogue substances (30-60% over 28 days). The substance is expected to bioaccumulate based on its high bioaccumulation and bioconcentration factors (> 5000 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance has low acute toxicity in fish (no adverse effects observed in saturated solutions) and high chronic toxicity in aquatic invertebrates and algae (no-

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observed-effect-concentration < 0.1 mg/L and 10% effective concentration (EC₁₀) < 0.1 mg/L, respectively). Using the EC₁₀ from the most sensitive organism (algae) and by applying an assessment factor of 10 to account for species sensitivity variation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 0.1-1 µg/L, which was used to estimate the risk 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 and use in industrial coatings by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.01-0.1 µg/L, and from cleaning of transportation vessels by release of the substance to water resulting in a PEC in the range of 0.1-1 µg/L, with the exact value being below the PNEC value. For potential activities such as manufacturing, environmental exposure is expected to be mainly by release of the substance to water resulting in a PEC in the range of 0.1-1 µg/L, with the exact value also below the PNEC.

Comparing the PEC with the PNEC, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard, and exposure, indicates that 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 low acute toxicity by the oral route (median lethal dose > 1000 mg/kg body weight). It has moderate subchronic toxicity following repeated oral doses in mammalian test animals (no-observable-adverse-effect level (NOAEL) 30-300 mg/kg-bw/day). The substance is expected to have low reproductive/developmental toxicity (NOAEL > 500 mg/kg-bw/day). It is not expected to be mutagenic *in vitro*, and is unlikely to cause genetic damage. The substance does, however, cause severe and irreversible damage to the skin and eyes.

When the notified substance is used as an additive in industrial and commercial coatings, adhesives and sealants, and in the manufacturing of soles for the footwear industry, consumers may come into contact with end-use products containing the substance; however, direct exposure to the substance is not expected because the substance will be chemically reacted into a stable matrix and will be unavailable for direct dermal exposure and uptake. Indirect exposure of the general population from environmental media such as drinking water are expected to be at levels that do not pose a concern. Potential uses of the substance include in products available to consumers such as coatings, adhesives and sealants, where direct exposure of the general population is expected to be mainly by contact with the skin. Inadvertent exposure of the eyes is also possible. Indirect exposure from any potential use is expected to be at levels that do not pose a concern, similar to that from the notified uses.

When the substance is used as notified, it is not suspected to be harmful to human health as the general public will be exposed only to finished products in which the substance is cured. However, based on the potential use of the uncured substance in coating, adhesive and sealant products available to consumers, the substance could cause irreversible effects on the skin and eyes and potentially some systemic toxicity. The substance is anticipated to be harmful to human health when the substance is used in consumer coating, adhesive and sealant applications.

The assumptions made in the assessment and the risk management measures applied 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

The substance is not suspected to have a harmful effect on the environment according to the criteria under paragraph 64(a) or (b) of the Act, but is suspected to constitute a danger to human health according to the criteria under paragraph 64 (c).

Due to the potential risk to human health related to the severe and irreversible skin and eye damage if the substance is used in coatings, adhesives and sealants available to consumers, a ministerial condition was issued to restrict the manner in which the notifier may manufacture or import the substance with conditions on its use in order to mitigate these potential risks. Ministerial Condition No. 19916 was published in the *Canada Gazette* Part I, Vol. 153, No. 33 on August 17, 2019.

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.