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

New Substances Notification 19663: 1,2-Ethanediamine, *N*-(2-aminoethyl)-, reaction products with glycidyl *p*-tolyl ether (Chemical Abstracts Service Registry Number 68411-70-1)

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 determined that the substance is 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, and 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 import is authorized subject to conditions as described in Ministerial Condition No. 19663 published in the *Canada Gazette* Part I, Vol. 152, No. 47 on November 24, 2018.

Substance identity

The notified chemical is 1,2-ethanediamine, *N*-(2-aminoethyl)-, reaction products with glycidyl *p*-tolyl ether (Chemical Abstracts Service Registry Number[1] 68411-70-1), and is a considered a substance of 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 in industrial coatings. Potential uses may include commercial and consumer coatings.

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 water, soil and sediment. The substance is expected to be persistent in these compartments based on its very low biodegradability (≤10% over 28 days). The substance is not expected to bioaccumulate based on low to moderate octanol-water partitioning coefficient (log K_{ow} <5) of most components.

Ecological assessment

Based on the available hazard information, the substance has low acute toxicity in fish (no adverse effects observed in saturated solutions), moderate acute toxicity in aquatic invertebrates (median effective concentration (EC_{50}) 1-100 mg/L) and high acute toxicity in algae (EC_{50} <1 mg/L). The substance

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has high chronic toxicity in algae (10% effective concentration (EC_{10}) <0.1 mg/L). The toxicity of the substance may be mitigated through the binding of its amine groups with negatively charged organic matter (i.e., suspended sediment or soil). Using the EC_{50} from the most sensitive organism (algae) and by applying an assessment factor of 5 to account for species sensitivity variation, the acute predicted no-effect concentration (PNEC) was calculated to be in the range of 10-100 µg/L. Using the EC_{10} from the most sensitive organism (algae) and by applying an assessment factor of 5 to account for species sensitivity variation, the chronic PNEC was calculated to be in the range of 1-10 µg/L. These were used to estimate the ecological risk.

The notified and 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 by release of the substance to water from cleaning of transportation vessels resulting in an acute predicted environmental concentration (PEC) in the range of 10-100 µg/L and from formulation and use in industrial coatings resulting in chronic PECs in the range of 1-10 µg/L. For potential activities such as manufacturing, environmental exposure is expected to be mainly by release of the substance to water resulting in a chronic PEC in the range of 10-100 µg/L.

Comparing the PEC with the acute and chronic PNECs for notified activities, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard and exposure, indicated that the substance is unlikely to cause ecological harm in Canada when used as notified.

However, based on an increased PEC combined with the high chronic toxicity in algae, the substance is anticipated to cause ecological harm in Canada. The risks have been identified with release of the substance to water associated with potential manufacturing activities.

Human health assessment

Based on the available hazard information on structurally related chemicals, the substance is expected to have a moderate acute toxicity by the oral route (median lethal dose (LD_{50}) 300-2000 mg/kg body weight) and low acute toxicity by the dermal route (LD_{50} >2000 mg/kg body weight). The notified substance is expected to have moderate subchronic toxicity following repeat oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) 30-300 mg/kg-bw/day). It is expected to be a strong dermal sensitizer (0.1-1% estimated concentration required to produce a stimulation index of 3 (EC3) in the local lymph node 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 100 to 1000 µg/kg-bw/day based on the NOAEL of the oral subchronic toxicity study in mammalian test animals. The PTDI is the estimated level of long-term exposure without risk of adverse health effects. The acceptable exposure limit (AEL) was calculated to be in the range of 1 to 10 µg/cm^2 based on the EC3 range of the local lymph node assay in mammalian test animals. The AEL is the level of exposure below which no skin sensitization induction is expected in exposed individuals.

When the notified substance is used in industrial coating applications, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be chemically reacted into a stable matrix once the product is cured and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 1 to 10 µg/kg-bw/day and 0.1 to 1 µg/kg-bw/day for children and adults, respectively. Potential uses of the substance include

consumer coatings, where direct exposure of the general population is expected to be mainly by contact with the skin at conservatively estimated levels in the range of 100 to 1000 µg/cm^2. Indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 1 to 10 µg/kg bw/day 0.1 to 1 µg/kg-bw/day for children and adults, respectively.

Because all estimated human exposures resulting from the notified use are less than the PTDI and AEL, meaning at levels that do not pose a concern, 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 when used as notified.

However, based on the increased potential for dermal exposure if used in consumer coating applications combined with the substance being a dermal sensitizer, the substance is anticipated to be harmful to human health when used for this potential use.

Assessment conclusion

The substance is suspected to be harmful to the environment according to the criteria under paragraph 64 (*a*) but not (*b*) of the Act and to human health according to the criteria under paragraph 64 (*c*).

Due to the identified risk to human health and the environment related to the dermal sensitization and chronic aquatic toxicity, a ministerial condition was issued to restrict the manner in which the notifier may import the substance with conditions on its use and handling in order to mitigate these potential risks. Ministerial Condition No. 19663 was published in the *Canada Gazette* Part I, Vol. 152, No. 47 on November 24, 2018.

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.