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

New Substances Notifications 18685, 20381, 20502, 20551, 20654 and 21256: 1-Propanaminium, 3-amino-*N* (carboxymethyl)-*N,N*-dimethyl-, *N*-C_{8-18} acyl derivs., inner salts (Chemical Abstracts Service registry number 97862-59-4)

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 manufacture and import are authorized subject to conditions on as described in the following ministerial conditions:
- Ministerial Condition No. 18685 published in the *Canada Gazette* Part I, Vol. 150, No. 52, December 24, 2016
- Ministerial Condition No. 20381 published in the *Canada Gazette* Part I, Vol. 154, No. 52, September 12, 2020
- Ministerial Condition No. 20502 published in the *Canada Gazette* Part I, Vol. 155, No. 2, January 9, 2021
- Ministerial Condition No. 20551 published in the *Canada Gazette* Part I, Vol. 155, No. 2, January 9, 2021
- Ministerial Condition No. 20654 published in the *Canada Gazette* Part I, Vol. 155, No. 27, July 3, 2021
- Ministerial Condition No. 21256 published in the Canada Gazette Part I, Vol. 156, No. 50, December 10, 2022

Substance identity

The chemical is 1-propanaminium, 3-amino-*N*-(carboxymethyl)-*N,N*-dimethyl-, *N*-C_{8-18} acyl derivs., inner salts (Chemical Abstracts Service registry number[1] 97862-59-4), and is considered a substance of unknown or variable composition, complex reaction products, or biological material (UVCB).

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for use as a surfactant for household cleaners and personal care products. Potential uses are expected to be similar to those notified.

[1] The Chemical Abstracts Service registry number is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

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 not expected to be persistent in water, soil and sediment based on its very high aerobic (>85% over 28 days) and high anaerobic (60-85% over 60 days) biodegradability. The substance is not expected to bioaccumulate based on its low predicted bioconcentration factor (<250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance has moderate acute toxicity in algae and aquatic invertebrates (median effective concentration (EC_{50}) 1-100 mg/L). It has moderate chronic toxicity in fish (no-observed-effect concentration (NOEC) 0.1-10 mg/L) and moderate to high chronic toxicity in aquatic invertebrates (NOEC <10mg/L). Using the EC_{50} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 10 to account for lab to field extrapolation, the predicted no-effect concentration (PNEC) was calculated to be 10-100 µg/L 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 use of rinse-off products by consumers and industrial blending and formulation activities by release of the substance to the aquatic environment via waste water. The predicted environmental concentration (PEC) for notified activities is estimated to be 0.1-10 µg/L for consumer activities and 1-100 µg/L for industrial activities. The substance may potentially be used in other surfactant applications; however, these activities are expected to result in lower environmental exposure than the notified use.

Based on a comparison of the PEC for industrial releases with the PNEC, the substance is anticipated to cause ecological harm in Canada. The risks have been identified with the moderate to high ecotoxicity in conjunction with the potential for increased environmental release resulting from industrial blending and formulation activities.

Human health risk assessment

Based on the available hazard information on the substance, the substance has a low to moderate potential for acute toxicity by the oral route (median lethal dose (LD_{50}) >300 mg/kg body weight) and a moderate potential for acute toxicity by the dermal route (LD_{50} 1000-2000mg/kg body weight). The substance has a moderate potential for subchronic toxicity following repeated oral doses in mammalian test animals (90-day no-observed-adverse-effect level (NOAEL) 10-100 mg/kg-bw/day). It has high developmental toxicity for maternal endpoints (NOAEL 50-250 mg/kg-bw/day), and moderate developmental toxicity for fetal endpoints (NOAEL 250-1000 mg/kg-bw/day) following repeat oral doses in mammalian test animals. It is a weak dermal sensitizer (0-8% response (guinea pig maximization test)). It is not mutagenic *in vitro* or clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage. The provisional daily tolerable intake (PTDI) was determined to be 100-1000 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.

Based on a review of available hazard literature, the substance is unlikely to cause dermal sensitization, but weak to strong sensitization has been linked to two impurities present at varying levels in amidopropyl betaines. A review by the Australian Industrial Chemicals Introduction Scheme for a similar substance and the Cosmetic Ingredient Review concluded that the substance was likely safe to use in cosmetics; however, both cited the presence of impurities that are linked to skin sensitization and that should be limited in products.

When the notified substance is used in household cleaners and personal care products, direct exposure of the general population is expected to be mainly by contact with the skin at low levels. The anticipated concentration of the substance in household cleaner and cosmetics is low (0.1-10%) and dermal absorption is expected to be <10%. The total systemic exposure from direct dermal contact was estimated to be 100-1000 µg/kg-bw/day. Indirect exposure of the general population from environmental media such as drinking water is expected to be at levels of 0.01-1 µg/kg-bw/day mainly by ingestion. Other potential uses as a surfactant are expected to result in lower exposure than notified uses.

Based on sensitization effects associated with impurities present at varying levels, the substance is anticipated to be harmful to human health. The risks have been identified with dermal exposure when used in household cleaners and cosmetics.

Other considerations

A similar substance is risk managed under Ministerial Condition No. 18427 to limit impurities in order to address health concerns regarding dermal sensitization.

Assessment conclusion

The substance is suspected to have a harmful effect on the environment according to the criteria under paragraph 64 (*a*) of the Act and to potentially constitute a danger to human health according to the criteria under paragraph 64 (*c*).

Due to the identified risk to the environment and human health, ministerial conditions were issued to restrict the manner in which the notifier may manufacture or import the substance with conditions on its formulation (concentration of impurities present) in order to mitigate these potential risks.

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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.