

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

New Substances Notification 20432: 1-Butanaminium, 4-amino-*N*-(2-hydroxy-3-sulfopropyl)-*N,N*-dimethyl-4-oxo-, *N*-coco alkyl derivs., inner salts (Chemical Abstracts Service registry number 2041102-83-2)

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 as described in [Ministerial Condition No. 20432](#) published in the *Canada Gazette* Part I, Vol. 154, No. 47, November 21, 2020.

Substance identity

The notified chemical is 1-butanaminium, 4-amino-*N*-(2-hydroxy-3-sulfopropyl)-*N,N*-dimethyl-4-oxo-, *N*-coco alkyl derivs., inner salts (Chemical Abstracts Service registry number¹ 2041102-83-2), and is 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 as a surfactant in liquid laundry and dish soaps (home and commercial), shampoos, cleansers and industrial hand wash products. Potential uses may include pesticide and fertilizer formulants, fire-fighting agents, oil drilling, electroplating baths, fracking and petroleum manufacture and the full spectrum of personal and home care products.

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. As a surfactant, some of the substance will also be present at the surface of the water or suspended organic matter. The substance is not expected to be persistent in these compartments based on moderate and inherent biodegradation (>30% over 28 days). The substance is not expected to bioaccumulate based on the substance's very high water solubility (>10 000 mg/L) and low predicted bioconcentration factor (<250 L/kg).

Environmental risk assessment

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.

Based on the available hazard information, the substance has high acute toxicity to fish (median lethal concentration (LC₅₀) <1 mg/L), moderate toxicity to aquatic invertebrates (median effective concentration (EC₅₀) 1 – 100 mg/L), and moderate toxicity to algae (72 hour median effect concentration [growth rate] (E_rC₅₀) 1 – 100 mg/L). Using the LC₅₀ from the most sensitive organism (fish) and by applying an assessment factor of 100 to account for acute to chronic extrapolation and species sensitivity variation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 1 – 10 µg/L, which was used to estimate the ecological risk.

The notified 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 consumer use and industrial processing by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 1-10 µg/L for consumer use and 100-1000 µg/L for industrial processing.

Based on a comparison of the PEC with the PNEC resulting in a ratio greater than 1, the substance is anticipated to cause ecological harm in Canada. The risks have been identified with release of the substance to water when used in industrial processing and formulation activities.

Human health risk assessment

Based on the available hazard information, the substance is expected to have a low acute toxicity by the oral and dermal routes (median lethal dose >2000 mg/kg body weight), low subchronic toxicity following repeated oral doses (90-day no-observed-adverse-effect level (NOAEL) >100 mg/kg bw/day; 28-day NOAEL >300 mg/kg bw/d for systemic effects), and high subchronic toxicity following repeated inhalation doses in mammalian test animals (lowest-observed-adverse-effect concentration <0.06 mg/L/6 hour). The substance is expected to have low developmental toxicity following repeated oral doses in mammalian test animals (NOAEL 30-300 mg/kg bw/day for embryotoxicity secondary to maternal toxicity). It is not expected to be a skin sensitizer, although impurities in the substance are expected to cause dermal sensitization. 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 as a surfactant in liquid laundry and dish soaps, shampoos, and cleansers, direct exposure of the general population is expected to be mainly by contact with the skin. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels. Potential consumer uses of the substance include personal care products and home care products, where direct exposure of the general population is expected to be mainly by contact with the skin or at very low levels by inhalation. Potential industrial uses of the substance include pesticide and fertilizer formulants, fire-fighting agents, oil drilling, electroplating baths, fracking and petroleum manufacture, where direct exposure of the general population is not expected due to the industrial nature of the use. 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.

Based on sensitization effects associated with impurities present at certain levels, the substance is anticipated to be harmful to human health. The risks have been identified with dermal exposure when used in personal care and home care products.

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.

Other considerations

Similar substances are risk managed under Ministerial Conditions No. 18427, No. 18685 and No. 20381 to limit impurities in order to address health concerns regarding dermal sensitization. Additionally, to limit the potential for ecological risk, the Ministerial Condition No. 18685 specified procedures for the handling and disposal of the substance.

Assessment conclusion

The substance is suspected to be harmful to the environment according to the criteria under paragraph 64 (a) 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 potential of impurities and to aquatic toxicity, a ministerial condition was issued to restrict the manner in which the notifier may manufacture or import the substance with conditions on its formulation (concentration of impurities), handling and disposal in order to mitigate these potential risks. Ministerial Condition No. 20432 was published in the *Canada Gazette* Part I, Vol. 154, No. 47 on November 21, 2020.

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.