

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

New Substances Notification 21436: *Pseudomonas putida*-fermented, from D-glucose, potassium salts (Chemical Abstracts Service Registry Number 2122153-41-5)

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 based on the available information, that when used as notified, the substance is not 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, constitute or may constitute a danger to the environment on which life depends, or constitute or may constitute a danger in Canada to human life or health.

The significant new activity (SNAc) provisions of CEPA were applied to the substance because of potential human health impacts that could arise as a result of potential new activities.

[Significant New Activity Notice No. 21436](#) outlines information requirements for those activities and was published in the *Canada Gazette* Part I, Vol. 157, No. 15 on April 15, 2023. Notification is required prior to commencement of those activities identified as a potential concern to ensure the substance undergoes further assessment and risk management consideration.

Substance identity

The notified chemical is *Pseudomonas putida*-fermented, from D-glucose, potassium salts (Chemical Abstracts Service Registry Number¹ 2122153-41-5), 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 up to 1000 kg/yr for the notified use in personal cleaning formulations, manual dish detergents, laundry detergents and hard surface cleaners. Potential uses may include the full spectrum of cosmetics and home care products.

Environmental fate and behaviour

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Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to water. As a surfactant, some of the substance will also be present at the surface of the water or to suspended organic matter. The substance is not expected to be persistent in water based on its high ready biodegradation (60-85% over 28 days under aerobic conditions; > 85% over 42 days under anaerobic conditions). The substance is not expected to bioaccumulate based on its expected biotransformation and low predicted bioconcentration factor (< 250 L/kg).

Environmental risk assessment

Based on the available hazard information, the substance has low acute toxicity to aquatic invertebrates (median effective concentration (EC_{50}) > 100 mg/L) and algae (EC_{50} > 100 mg/L), moderate acute toxicity to fish (median lethal concentration 10-100 mg/L), and low chronic toxicity to aquatic invertebrates (10th percentile lethal concentration > 10 mg/L). A predicted no-effect concentration was not calculated given the low potential for hazard to the environment.

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 processing, use and disposal of consumer products by release of the substance to water at low rates. A predicted environmental concentration was not calculated due to the low potential for environmental exposure.

Based on the low potential for ecotoxicity and environmental exposure, 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 (LD_{50}) > 2000 mg/kg body weight) and is expected to have low acute toxicity by the dermal route (LD_{50} > 2000 mg/kg body weight). The substance has low subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) > 300 mg/kg-bw/day). The substance has low reproductive/developmental toxicity following repeated oral doses in mammalian test animals (NOAEL > 300 mg/kg-bw/day). It is not expected to be a dermal sensitizer (negative results *in chemico* and *in vitro*). It is not mutagenic *in vitro* and is not expected to be clastogenic *in vitro*. Therefore, the substance is unlikely to cause genetic damage. However, based on the available information, the substance may cause significant, irreversible eye damage at concentrations higher than those outlined in Significant New Activity (SNAc) Notice No. 21436, when used in certain applications.

For all notified and potential uses, exposure of the general population by inhalation is expected at very low levels. When the notified substance is used in personal cleaning formulations,

manual dish detergents and laundry detergents, direct exposure of the general population is expected to be mainly by contact with the skin and incidental contact with the eyes. When the notified substance is used in hard surface cleaners, direct exposure of the general population is expected to be mainly by contact with the skin. Potential uses of the substance include the full spectrum of cosmetics, where direct exposure of the general population is expected to be mainly by contact with the skin and eyes. Potential uses of the substance also include the full spectrum of home care products, where 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 for the notified and potential uses is expected to be at low levels given the low potential for release to the environment.

Based on the potential for ocular exposure combined with indications that the substance may cause irreversible ocular damage at certain levels of exposure, the use of the substance at concentrations higher than those outlined in SNAC Notice No. 21436 in cosmetics, manual dish detergents and laundry detergents available to consumers is anticipated to be harmful to human health. Consequently, SNAC Notice No. 21436 requires additional information prior to use at concentrations higher than those outlined in said notice to better characterize potential health risks associated with these activities.

The assumptions made in the assessment and the risk management measures applied (see below) 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 suspected to constitute a danger to human health according to the criteria under paragraph 64 (c), but is not suspected to have a harmful effect on the environment according to the criteria under paragraph 64 (a) or (b) of the Act.

Due to the potential risk to human health related to irreversible ocular damage when the substance is used in personal cleaning formulations, manual dish detergents and laundry detergents and if the substance were to be used in the full spectrum of cosmetics, the SNAC provisions under CEPA were applied to the substance in order to obtain information to ensure that the substance undergoes further assessment before these potential activities are undertaken. SNAC Notice No. 21436 was published in the *Canada Gazette* Part I, Vol. 157, No. 15 on April 15, 2023.

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.