

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

New Substances Notification 21574: 1-Octanesulfonic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro- (Chemical Abstracts Service Registry Number 27619-97-2)

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. 21551](#) published in the *Canada Gazette* Part I, Vol. 157, No. 31 on August 5, 2023.

Substance identity

The notified chemical is 1-octanesulfonic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro- (Chemical Abstracts Service Registry Number¹ 27619-97-2).

Notified uses

The substance is proposed to be imported into Canada in quantities less than 10 000 kg/yr for the notified use as an industrial surfactant.

Environmental fate and behaviour

The notified substance is a member of the per- and polyfluoroalkyl substances (PFAS) class. Globally, PFAS can be found in virtually all environmental compartments, including air, surface and groundwater, oceans and soils as well as in wastewater influent and effluent, landfill leachate, sewage sludge, and contaminated sites. While the highest reported concentrations are typically in proximity to known sources of release, PFAS are also routinely reported in locations far removed from these sources.

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Broadly speaking, PFAS are extremely persistent in the environment (i.e., long half-lives) as fluorocarbon moieties (fundamentally -CF₂-) are very stable, resisting biodegradation, hydrolysis, photolysis, and thermolysis. The vast majority of these substances are non-degradable or, in cases where these transformation mechanisms may act upon other parts of more complex PFAS molecules, the stable PFAS transformation products are environmentally persistent.

Some PFAS have been demonstrated to have the potential to bioaccumulate and biomagnify in food webs to a degree that could allow them to reach levels that can cause adverse effects in organisms. Ultimately, bioaccumulation could result in an increased potential for toxicity in organisms.

Environmental risk assessment

Although direct and indirect releases of the substance to the environment are expected to be low in the near term when used as intended, the use of the notified substance is expected to contribute to increased environmental releases and overall (cumulative) environmental exposure to PFAS.

Owing to the source resulting primarily from human activity and the high persistence of PFAS, impacts on the environment such as bioconcentration and biomagnification, long-range transport and ecotoxicity are expected to increase if their entry to the environment continues. Based on what is known about well-studied PFAS and the potential for other PFAS to behave similarly, the substance is anticipated to cause harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance has a moderate acute toxicity by the oral route (median lethal dose (LD₅₀) 300-2000 mg/kg body weight), a low acute toxicity by the dermal route (LD₅₀ > 2000 mg/kg body weight) and high subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level ≤ 30 mg/kg-bw/day). The substance is not expected to be a reproductive/developmental toxicant following repeated oral doses in mammalian test animals. It is not a skin sensitizer in a local lymph node assay. It is not mutagenic *in vitro* and is not clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used as an industrial surfactant, indirect and direct exposure of the general population is not expected. However, use of the notified substance is expected to contribute to increased environmental releases and overall (cumulative) human exposure to PFAS.

Owing to the widespread use of PFAS combined with their ubiquitous presence in the environment, humans are continuously exposed to multiple PFAS, which have the potential to cause adverse effects. Based on what is known about well-studied PFAS and the potential for other PFAS to behave similarly, combined exposures to multiple PFAS may increase the

likelihood of detrimental impacts to human health. Therefore, the notified substance, similar to the class of PFAS, is anticipated to be harmful to human health.

Assessment conclusion

The notified substance is a member of the PFAS class of substances. A [draft State of PFAS Report](#) was published on May 20, 2023 for a 60-day public comment period ending on July 19, 2023. The draft State of PFAS Report proposes that PFAS as a class are harmful to human health and the environment due to their extreme persistence, what is known about well-studied PFAS, as well as the potential for other PFAS to behave similarly, and concern that the potential for combined exposures to multiple PFAS may increase the risk of harm to human health and the environment.

Since the use of the notified substance is expected to contribute to increased environmental releases and overall cumulative exposure to PFAS, 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). This conclusion is consistent with the information and the proposed conclusion in the draft State of PFAS Report. Due to the identified risk to human health and the environment, Ministerial Condition No. 21574 was published in the *Canada Gazette* Part I, Vol. 157, No. 31 on August 5, 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.