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

New Substances Notification 20010: Pentane, 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoromethyl)- (Chemical Abstracts Service registry number 132182-92-4)

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 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. Order 2020-87-04-01 amending the Domestic Substances List outlines information requirements for those activities and was published in the *Canada Gazette* Part II, Vol. 154, No. 6 on March 18, 2020. 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 pentane, 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-(trifluoromethyl)- (Chemical Abstracts Service registry number[1] 132182-92-4).

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 solvent used by professionals for cleaning and degreasing. Potential uses may include consumer 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 air. The substance is expected to be persistent in air based on its free radical reaction rate coefficient resulting in an expected half-life >2 days. Volatility will prevent the aquatic exposure necessary to accumulate in aquatic organisms in the environment.

[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.

The photochemical ozone creation potential of the substance is considered to be low and the ozone depletion potential of the substance is considered to be negligible given that the substance is resistant to oxidation. The global warming potential is considered low.

Ecological assessment

No releases to the aquatic environment are expected and any amount released to water would rapidly volatize given the high vapour pressure of the substance (133 - 13 332 Pa). As such, exposure of aquatic life (such as fish, aquatic invertebrates and algae) to the substance is not expected. Based on the available hazard information, the substance has low acute and chronic toxicity to fish, aquatic invertebrates, and algae (no adverse effects observed in saturated solutions). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

As the substance will reside in the atmosphere, the concentration in the aquatic compartment was not predicted. However, assessments of photochemical ozone creation potential, ozone depletion potential and global warming potential were conducted. In each case, the impact is considered low. No release to water is expected. No potential activities were identified which would pose an environmental risk.

Based on the low potential for ecotoxicity and the lack of abiotic impacts, the substance is unlikely to cause ecological harm in Canada.

Human health assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral and dermal routes (median lethal dose >2000 mg/kg body weight) and moderate subchronic toxicity following repeated oral doses in mammalian test animals (28-day no-observed-adverse-effect level (NOAEL) 30-300 mg/kg-bw/day). It is not a dermal sensitizer (stimulation index < 3 (local lymph node assay)). It is not expected to be mutagenic *in vitro* and is not 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 0.1-1.0 mg/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.

When the notified substance is used as a solvent used by professionals for cleaning and degreasing, 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 is not expected given the specialized industrial use of the substance which would limit public exposure. However, if the substance is used in consumer products that release or spray the substance as a vapour, mist or aerosol, an increased level of direct exposure may exist, and is expected to be via inhalation route.

Based on the low potential for exposure when used as notified, 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.

However, based on the potential for inhalation exposure combined with indications that the substance has toxicity similar to long chain perfluoroalkyl substances (PFAS), the potential use of the substance in consumer products that release or spray the substance as a vapour, mist or aerosol could significantly alter the exposure and/or conditions of use resulting in the substance becoming harmful to human

health. Consequently, more information is necessary to better characterize potential health risks associated with these activities.

Other considerations

This substance is controlled in the United States. The United States Environmental Protection Agency issued a Significant New Use Rule (SNUR) for the substance, indicating “no release to water”.

Assessment conclusion

When the substance is used as notified, it is not suspected to be harmful to human health or the environment according the criteria under section 64 of the Act. However, it is suspected that a significant new activity in relation to the substance could result in the substance meeting those criteria.

There is potential risk to human health related to systemic organ toxicity similar to long chain PFAS should the substance be used in a consumer product that releases or sprays the substance as a vapour, mist or aerosol. The SNAc provisions under CEPA were applied to the substance in order to obtain additional information and ensure the substance undergoes further assessment before these potential activities are undertaken. Order 2020-87-04-01 was published in the *Canada Gazette* Part II, Vol. 154, No. 6 on March 18, 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.