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

New Substances Notification 19622: Ethane, 1,1,2,2-tetrafluoro-1-(2,2,2-trifluoroethoxy)- (Chemical Abstracts Service registry number 406-78-0)

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 that it 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.

Substance identity

The notified chemical is ethane, 1,1,2,2-tetrafluoro-1-(2,2,2-trifluoroethoxy)- (Chemical Abstracts Service registry number[1] 406-78-0).

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 an industrial solvent. No other uses are anticipated in Canada.

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 this compartment based on its half-life >2 days in air. The substance is not expected to bioaccumulate based on its low octanol-water partitioning coefficient (low K_{ow} 0-3), estimated low bioconcentration and bioaccumulation factors (<250 L/kg) and very high volatility (vapour pressure >13 332 Pa).

The ground-level ozone creation potential of the substance is considered to be low. The ozone depletion potential of the substance is considered to be low. The global warming potential is considered low.

Ecological assessment

Based on the available hazard information, the substance has low acute toxicity in fish, aquatic invertebrates and algae (30% effective concentration (EC_{30}) 1-100 mg/L; no adverse effects observed in saturated solutions). Using the EC_{30} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 50 to account for acute to chronic extrapolation and species sensitivity

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variation, the predicted no-effect concentration (PNEC) was calculated to be in the range of 1-10 mg/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 cleaning of transportation vessels from release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.001-0.01 mg/L. For potential activities such as manufacturing, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 0.01-0.1 mg/L.

Comparing the PECs with the PNEC, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard, and exposure, indicates that 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 dermal and inhalation routes (dermal median lethal dose >2000 mg/kg body weight; inhalation median lethal concentration >2500 ppm) and moderate subchronic toxicity following repeat inhalation doses in mammalian test animals (28 and 90-day no-observed-adverse-effect level (NOAEL) ≥1000 ppm with no treatment-related effects or neurotoxicity). It is not a dermal sensitizer (>10% estimated concentration required to produce a stimulation index of 3 (local lymph node assay)). It is not mutagenic *in vitro* or 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 1-10 mg/kg bw/day based on the NOAEL of the inhalation 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 an industrial solvent, 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 conservatively estimated to be at levels in the range of 10^{-6}-10^{-5} mg/kg-bw/day for adults and 10^{-5}-10^{-4} µg/kg-bw/day for children. Indirect exposure of the general population from environmental media such as air is expected to be negligible as significant atmospheric release is not anticipated. Potential activities include manufacturing, where indirect exposure of the general population from environmental media such as drinking water is conservatively estimated to be at levels in the range of 10^{-5}-10^{-4} µg/kg-bw/day for adults and children. No direct exposure from this activity is expected. Indirect exposure via inhalation is expected to be negligible, similar to that of the notified use.

Because all estimated human exposures are less than the PTDI, meaning at levels that do not pose a concern, 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.

Assessment conclusion

When the substance is used as notified or for other identified potential activities, it is not expected to be harmful to human health or the environment according to the criteria under section 64 of the Act.

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.