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

New Substances Notification 20916: 2-Pentene, 1,1,1,2,3,4,5,5,5-nonafluoro-4-(trifluoromethyl)-, (2*E*)- (Chemical Abstracts Service Registry Number 3709-71-5)

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 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 2-pentene, 1,1,1,2,3,4,5,5,5-nonafluoro-4-(trifluoromethyl)-, (2*E*)-(Chemical Abstracts Service Registry Number[1] 3709-71-5).

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 in polyurethane manufacturing applications. Potential uses may include various industrial and commercial applications such as in lubricating oils, in protective coating materials, and as a solvent and cleaning agent.

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 long atmospheric half-life (> 2 days). The substance is not expected to bioaccumulate in aquatic organisms as its physico-chemical properties indicate it will not partition to aquatic media.

Environmental risk assessment

Based on the available hazard information, the substance has low acute toxicity to fish (no adverse effects observed in saturated solutions), high acute toxicity to aquatic invertebrates

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(median effective concentration (EC_{50}) < 1 mg/L) and high chronic toxicity to algae (10% effective concentration < 0.1 mg/L). Using the EC_{50} from the most sensitive organism (aquatic invertebrates) and by applying an assessment factor of 10 to account for species sensitivity variation and extrapolation from acute severe effects to acute no-effects, the predicted no-effect concentration (PNEC) was calculated to be in the range of 1-10 µg/L, which was used to estimate the risk to the environment.

The notified substance is highly volatile and, as such, its abiotic effects were also assessed. The photochemical ozone creation potential of the substance is considered to be low. The ozone depletion potential of the substance is considered to be negligible given that the fluorine-carbon bonds are relatively stable under environmental conditions. The global warming potential of the substance is considered to be low.

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 activity is expected to be mainly from cleaning of transportation vessels by release of the substance to water resulting in a predicted environmental concentration (PEC) in the range of 0.01-0.1 µg/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 0.1-1 µg/L.

Comparing the PEC 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 harm to the environment in Canada.

Human health risk assessment

Based on the available hazard information, the substance has a low acute toxicity by the inhalation route (median lethal concentration > 20 mg/L/4hr) and a moderate acute toxicity by the oral route (median lethal dose 300-1000 mg/kg body weight). It has low subchronic toxicity following repeated oral and inhalation doses in mammalian test animals (28-day oral no-observed-adverse-effect level > 300 mg/kg-bw/day; 28-day inhalation no-observed-adverse-effect concentration (NOAEC) > 3.0 mg/L/6 hour). The substance has a low reproductive/developmental toxicity following repeated inhalation doses in mammalian test animals (NOAEC > 3.0 mg/L/6 hour). It is not a dermal sensitizer (stimulation index < 3 in a local lymph node assay). It is not mutagenic or clastogenic *in vitro* and is not expected to be clastogenic *in vivo*. Therefore, the substance is unlikely to cause genetic damage.

When the notified substance is used in polyurethane manufacturing applications, consumers may come into contact with end-use products containing the substance; however, direct exposure is not expected because the substance will be encapsulated within a stable matrix once the product is cured and the release of the substance from the matrix is expected to be very slow. Indirect exposure of the general population from environmental media such as drinking water and air is expected to be at low levels given the low potential for environmental release. Potential uses of the substance include a variety of commercial and industrial uses,

where direct and indirect exposure of the general population is expected to be at levels that do not pose a concern, similar to that of the notified use.

Based on the available toxicity information and the low potential for exposure, 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.

The assumptions made in the assessment 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

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 the *Hazardous Products Regulations* for products intended for the workplace.