TSCA Section 5(a)(3) Determination for Significant New Use Notice (SNUN) SN-17-0011

Number: SN-17-0011
TSCA Section 5(a)(3) Determination: The significant new use is not likely to present an unreasonable risk (5(a)(3)(C)).

Chemical Name:
Generic: Polyfluorohydrocarbon.

Significant New Use: Use other than as described in PMN P-15-0326. The significant new use rule (SNUR) at 40 CFR 721.10907 for this chemical substance requires notification to EPA for any use other than as described in PMN P-15-0326 or consumer use.

Conditions of Use (intended, known, or reasonably foreseen)[1]:
Intended conditions of use (generic): Import for use as a foam additive, consistent with the manufacturing, processing, use, distribution, and disposal information described in the SNUN.
Known conditions of use (generic): Applying such factors as described in footnote 1, EPA evaluated whether there are known conditions of use and identified, based on the previous PMN, import for use as a specialty gas, and transfer fluid.
Reasonably foreseen conditions of use: Applying such factors as described in footnote 1, EPA evaluated whether there are reasonably foreseen conditions of use and identified, based on previous TSCA submissions, the following reasonably foreseen uses: use as a refrigerant, fire extinguishant, and cleaning agent.

Summary: The significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, based on the risk assessment presented below.

[1] Under TSCA § 3(4), the term "conditions of use" means "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." In general, EPA considers the intended conditions of use of a new chemical substance to be those identified in the section 5(a) notification. Known conditions of use include activities within the United States that result from manufacture that is exempt from PMN submission requirements. Reasonably foreseen conditions of use are future circumstances, distinct from known or intended conditions of use, under which the Administrator expects the chemical substance to be manufactured, processed, distributed, used, or disposed of. The identification of "reasonably foreseen" conditions of use will necessarily be a case-by-case determination and will be highly fact-specific. Reasonably foreseen conditions of use will not be based on hypotheticals or conjecture. EPA's identification of conditions of use includes the expectation of compliance with federal and state laws, such as worker protection standards or disposal restrictions, unless case-specific facts indicate otherwise. Accordingly, EPA will apply its professional judgment, experience, and discretion when considering such factors as evidence of current use of the new chemical substance outside the United States, evidence that the PMN substance is sufficiently likely to be used for the same purposes as existing chemical substances that are structurally analogous to the new chemical substance, and conditions of use identified in an initial PMN submission that the submitter omits in a revised PMN. The sources EPA uses to identify reasonably foreseen conditions of use include searches of internal confidential EPA PMN databases (containing use information on analogue chemicals), other U.S. government public sources, the National Library of Medicine's Hazardous Substances Data Bank (HSDB), the Chemical Abstract Service STN Platform, REACH Dossiers, technical encyclopedias (e.g., Kirk-Othmer and Ullmann), and Internet searches.

EPA estimated that the chemical substance could have low persistence and a low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms. Based on environmental toxicity and human health test data on the chemical substance, EPA estimates that the chemical substance has moderate environmental hazard and potential for the following human health hazards: neurotoxicity, systemic toxicity, and developmental toxicity. EPA concludes that the significant new use is not likely to present an unreasonable risk under the conditions of use.

Fate: Environmental fate is the determination of which environmental compartment(s) a chemical moves to, the expected residence time in the environmental compartment(s) and removal and degradation processes. Environmental fate is an important factor in determining exposure and thus in determining whether a significant new use of a chemical substance may present an unreasonable risk. EPA estimated physical/chemical and fate properties of the chemical substance using data received for the chemical substance and EPI (Estimation Program Interface) Suite™ (http://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface). In wastewater treatment, the chemical substance is expected to be removed with an efficiency of 99.8% via stripping. Removal of the chemical substance by biodegradation is negligible. Sorption of the chemical substance to sludge is low and to soil and sediment is moderate. Migration of the chemical substance to groundwater is expected to be moderate due to moderate sorption to soil and sediment. Due to high estimated vapor pressure and Henry's law constant, the chemical substance is expected to undergo extensive volatilization to air. Overall, these estimates indicate that the chemical substance has high potential to volatilize to air and has moderate potential to migrate to groundwater.

Persistence[2]: Persistence is relevant to whether a significant new use of a chemical substance is likely to present an unreasonable risk because chemicals that are not degraded in the environment at rates that prevent substantial buildup in the environment, and thus increase potential for exposure, may present a risk if the substance presents a hazard to human health or the environment. EPA estimated degradation half-lives of the chemical substance using EPI Suite™. EPA estimated that aerobic and anaerobic biodegradation half-lives of the chemical substance are > 6 months, atmospheric oxidation by hydroxyl radical (OH•) is rapid, and atmospheric oxidation by ozone (O3) is rapid. These estimates indicate that the chemical substance may be very persistent in aerobic environments (e.g., surface water) and anaerobic environments (e.g., sediment). However, due to rapid air oxidation and high volatility, it is not likely that the chemical substance will accumulate in aerobic (e.g. surface water) and anaerobic environments (e.g., sediment).

[2] Persistence: A chemical substance is considered to have limited persistence if it has a half-life in water, soil or sediment of less than 2 months or there are equivalent or analogous data. A chemical substance is considered to be persistent if it has a half-life in water, soil or sediments of greater than 2 months but less than or equal to 6 months or if there are equivalent or analogous data. A chemical substance is considered to be very persistent if it has a half-life in water, soil or sediments of greater than 6 months or there are equivalent or analogous data. (64 FR 60194; November 4, 1999)

Bioaccumulation[3]: Bioaccumulation is relevant to whether a significant new use of a chemical substance is likely to present an unreasonable risk because substances that bioaccumulate in aquatic and/or terrestrial species pose the potential for elevated exposures to humans and other organisms via food chains. EPA estimated the potential for the chemical substance to bioaccumulate using EPI Suite™. EPA estimated that the chemical substance has low bioaccumulation potential based on BCFBAF model result < 1000 (bioconcentration factor = 21 [estimated] and bioaccumulation factor = 33 [estimated]). EPA estimated that the chemical substance could have low persistence and a low potential for bioaccumulation, such that repeated exposures are not expected to cause food-chain effects via accumulation in exposed organisms.

Human Health Hazard[4]: Human health hazard is relevant to whether a significant new use of a chemical substance is likely to present an unreasonable risk because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties, available data on the chemical substance, and by comparing it to structurally analogous chemical substances for which there is information on human health hazard. Absorption of the chemical substance is expected to be good via the lungs based on physical/chemical properties. EPA identified neurotoxicity, systemic toxicity, and developmental toxicity as hazards based on submitted tests for the chemical substance (OECD 413, 414, and 416). EPA identified a NOAEC of 7,500 ppm (50,322 mg/m^3) for systemic, developmental and neurotoxicity, which was used to derive exposure route- and population-specific points of departure for quantitative risk assessment.

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[3] Bioaccumulation: A chemical substance is considered to have a low potential for bioaccumulation if there are bioconcentration factors (BCF) or bioaccumulation factors (BAF) of less than 1,000 or there are equivalent or analogous data. A chemical substance is considered to be bioaccumulative if there are BCFs or BAFs of 1,000 or greater and less than or equal to 5,000 or there are equivalent or analogous data. A chemical substance is considered to be very bioaccumulative if there are BCFs or BAFs of 5,000 or greater or there are equivalent or analogous data. (64 FR 60194; November 4 1999)

[4] A chemical substance is considered to have low human health hazard if effects are observed in animal studies with a No Observed Adverse Effect Level (NOAEL) equal to or greater than 1,000 mg/kg/day or if there are equivalent data on analogous chemical substances; a chemical substance is considered to have moderate human health hazard if effects are observed in animal studies with a NOAEL less than 1,000 mg/kg/day or if there are equivalent data on analogous chemical substances; a chemical substance is considered to have high human health hazard if there is evidence of adverse effects in humans or conclusive evidence of severe effects in animal studies with a NOAEL of less than or equal to 10 mg/kg/day or if there are equivalent data on analogous chemical substances. EPA may also use Benchmark Dose Levels (BMDL) derived from benchmark dose (BMD) modeling as points of departure for toxic effects. See https://www.epa.gov/bmds/what-benchmark-dose-software-bmds. Using this approach, a BMDL is associated with a benchmark response, for example a 5 or 10 % incidence of effect. The aforementioned characterizations of hazard (low, medium, high) would also apply to BMDLs. In the absence of animal data on a chemical or analogous chemical substance, EPA may use other data or information such as from in vitro assays, chemical categories (e.g., Organization for Economic Co-operation and Development, 2014 Guidance on Grouping of Chemicals, Second Edition. ENV/JM/MONO(2014)4. Series on Testing & Assessment No. 194. Environment Directorate, Organization for Economic Co-operation and Development, Paris, France. (http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)4&doclanguage=en)), structure-activity relationships, and/or structural alerts to support characterizing human health hazards.

Environmental Hazard[5]: Environmental hazard is relevant to whether a significant new use of a chemical substance is likely to present unreasonable risk because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA determined the environmental hazard for this chemical substance based on acute/chronic toxicity data submitted for the substance. Acute toxicity values measured for fish, aquatic invertebrates, and algae are 1.78 mg/L, 92.9 mg/L, and 4.04 mg/L, respectively. Chronic toxicity values measured for fish, aquatic invertebrates, and algae are 0.24 mg/L, 0.22 mg/L, and 1.63 mg/L, respectively. These toxicity values indicate that the chemical substance is expected to have moderate environmental hazard. Application of assessment factors of 5 and 10 to acute and chronic toxicity values, respectively, results in acute and chronic concentrations of concern of 0.356 mg/L (356 ppb) and 0.022 mg/L (22 ppb), respectively.

Exposure: The exposure to a chemical substance is potentially relevant to whether a significant new use of a chemical substance is likely to present unreasonable risks because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance.

EPA estimates occupational exposure and environmental release of the chemical substance under the intended conditions of use described in the SNUN using ChemSTEER (Chemical Screening Tool for Exposures and Environmental Releases; https://www.epa.gov/tsca-screening-tools/chemsteer-chemical-screening-tool-exposures-and-environmental-releases). EPA uses EFAST (the Exposure and Fate Assessment Screening Tool; https://www.epa.gov/tsca-screening-tools/e-fast-exposure-and-fate-assessment-screening-tool-version-2014) to estimate general population, consumer, and environmental exposures.

EPA considers workers to be a potentially exposed or susceptible subpopulation (PESS) on the basis of greater exposure potential compared to the general population. EPA also considers PESS in conducting general population drinking water exposures by evaluating risks associated with water intake rates for multiple age groups, ranging from infants to adults. EPA considers consumers of specific products to be a potentially exposed or susceptible subpopulation on the basis of greater exposure potential compared to the general population who do not use specific products.

For this assessment, EPA assessed worker exposure via inhalation. Dermal exposures to workers are not expected. Releases to air were estimated. No releases to water or landfill are expected. Exposure to the general population was assessed via fugitive air inhalation. Exposure to the

[5] A chemical substance is considered to have low ecotoxicity hazard if the Fish, Daphnid and Algae LC50 values are greater than 100 mg/L, or if the Fish and Daphnid chronic values (ChVs) are greater than 10.0 mg/L, or there are not effects at saturation (occurs when water solubility of a chemical substance is lower than an effect concentration), or the log Kow value exceeds QSAR cut-offs. A chemical substance is considered to have moderate ecotoxicity hazard if the lowest of the Fish, Daphnid or Algae LC50s is greater than 1 mg/L and less than 100 mg/L, or where the Fish or Daphnid ChVs are greater than 0.1 mg/L and less than 10.0 mg/L. A chemical substance is considered to have high ecotoxicity hazard, or if either the Fish, Daphnid or Algae LC50s are less than 1 mg/L, or any Fish or Daphnid ChVs is less than 0.1 mg/L (Sustainable Futures https://www.epa.gov/sustainable-futures/sustainable-futures-p2-framework-manual).

general population via drinking water and fish ingestion was not assessed because no releases to water were expected. Exposure to the general population via groundwater impacted by landfill leachate and stack air was not assessed because releases to landfill and stack air are expected to be negligible. Consumer exposures were not assessed because consumer uses were not identified as conditions of use.

Risk Characterization: EPA applies a margin of exposure approach to calculate potential human health risks of significant new uses of chemicals. A benchmark (acceptable) margin of exposure is derived by applying uncertainty factors for the following types of extrapolations: intra-species extrapolation (UF_H = 10 to account for variation in sensitivity among the human population), inter-species extrapolation (UF_A = 10 to account for extrapolating from experimental animals to humans) and LOAEL-to-NOAEL extrapolation (UF_L = 10 to account for using a LOAEL when a NOAEL is not available). Hence, in the New Chemicals Program, a benchmark MOE is typically 100 and 1,000 when NOAELs and LOAELs, respectively, are used to identify hazard. When allometric scaling or pharmacokinetic modeling is used to derive an effect level, the UF_H may be reduced to 3, for a benchmark MOE of 30. The benchmark MOE is used to compare to the MOE calculated by comparing the toxicity NOAEL or LOAEL to the estimated exposure concentrations. When the calculated MOE is equal to or exceeds the benchmark MOE, the significant new use of a chemical substance is not likely to present an unreasonable risk. EPA assesses risks to workers considering engineering controls described in the SNUN but in the absence of personal protective equipment (PPE) such as gloves and respirators. If risks are preliminarily identified, EPA then considers whether the risks would be mitigated by the use of PPE (e.g., impervious gloves, respirator).

Risks to human health for the significant new use of the chemical substance were evaluated using the route-specific effect levels (i.e. NOAEC) described above. Risks were identified for workers for neurotoxicity, systemic, and developmental toxicity (MOE = 20; Benchmark MOE = 100) via inhalation exposure based on quantitative hazard data for the chemical substance. Risks were not evaluated for workers via dermal exposures, because dermal exposures are not expected. Risks will be mitigated if exposures are controlled by the use of appropriate PPE, including a NIOSH certified respirator with an APF of 10. EPA expects that employers will require and workers will use appropriate PPE (i.e. a NIOSH certified respirator with an APF of 10), consistent with the Safety Data Sheet prepared by the SNUN submitter, in a manner adequate to protect them.

Risks were not identified for the general population via inhalation exposure based on quantitative data for the chemical substance (MOE = 12,581; Benchmark MOE = 100). Risks were not evaluated for the general population via drinking water and fish ingestion, because exposures are expected to be negligible.

Risks to the environment were evaluated by comparing estimated surface water concentrations with the estimated acute and chronic COCs. Risks to the environment were not identified due to no releases to water.

It is reasonably foreseen, based previous TSCA submissions that this chemical could be used other than as described in the SNUN and previously submitted PMN. However, the existing SNUR for this chemical substance defines certain conditions of use as significant new uses. Conditions of use that fall under the restrictions of the SNUR are not likely to present

unreasonable risk of injury to health or the environment because those conditions of use would be prohibited unless and until EPA makes an affirmative determination that the significant new use is not likely to present an unreasonable risk or takes appropriate action under section 5(e) or 5(f). EPA previously assessed the known use and did not identify unreasonable risk to human health or the environment.

Because worker exposures can be controlled by PPE, no unreasonable risks to the general population or environment were identified, and there are no expected consumer exposures, EPA has determined that the significant new use is not likely to present unreasonable risk to human health or the environment under the conditions of use.

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