[redacted]

CJ 12/01/23
DSB 12/1/23
GH 12/4/23
RJA 12/4/23

United States
Environmental Protection Agency

Office of Chemical Safety and
Pollution Prevention

November 30, 2023

MEMORANDUM

SUBJECT: Risk Assessment of the Per- and Polyfluoroalkyl Substances (PFAS) in SN-23-0002-0006 and SN-23-0008-0011

FROM: Risk Assessment Branches/Industrial Chemistry Branch
New Chemicals Division
Office of Pollution Prevention and Toxics

TO: Geraldine Hilton
Risk Management Branch 1
New Chemicals Division
Office of Pollution Prevention and Toxics

This memo presents the New Chemicals Program's risk assessment [1] of the per- and polyfluoroalkyl substances (PFAS) in SN-23-0002 through 0006 and SN-23-0008 through 0011. This assessment considers the persistence, bioaccumulation and toxicity (PBT); expected degradation, hydrolysis and incineration products; and exposure pathways resulting in potential or expected[2] exposure to workers, environmental receptors, consumers and the general population for the nine substances in the Significant New Use Notices (SNUNs).

The New Chemicals Program's conclusions regarding the risks posed by the per- and polyfluoroalkyl substances (PFAS) in SN-23-0002-0006 and SN-23-0008-0011 are based on an evaluation of these substances under the New Chemical Program's *Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances* (hereafter referred to as the *PBT policy* (US EPA, 1999) and the *Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use*

[1] Determination of risk is a function of hazard and exposure. Generally, numerical values are assigned to the hazard and exposure components of the risk equation to arrive at a numeric risk value. This quantitative method is used by the New Chemicals Program whenever possible. As explained throughout this document, the inability to precisely quantify hazard and exposure for the class of substances known as PFAS (per- and polyfluoroalkyl substances) requires the New Chemicals Program to qualitatively assess risk. In this case, we document the existence of a hazard concern that will increase over time due to sustained and widespread exposures, leading to a buildup (bioaccumulation) of the SNUN substances in people and the environment leading to risks of concern.

[2] Throughout this document, the terms "potential" or "expected," when referring to exposure, mean that, depending on the individual SNUN substance, life cycle stage (manufacture, distribution, use and disposal), exposure pathway, or receptor (humans or environmental organisms) there is either more or less uncertainty about exposure. Importantly, the use of either term means there is exposure, but it is a matter of the level of uncertainty in that finding. Details for each exposure scenario are in separate reports (See Section 4 for additional details).

[redacted]

Notices (SNUNs) (hereafter referred to as the *PFAS Framework;* US EPA, 2023a). The New Chemicals Program's conclusions further take into consideration the risk assessments (and other information) submitted by Inhance Technologies, LLC (hereafter referred to as Inhance) for SN-23-0002-0006 and SN-23-0008-0011, the *PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024* (US EPA, 2021a) with commitments to action on PFAS in the environment, and the *National PFAS Testing Strategy: Identification of Per- and Polyfluoroalkyl Substances (PFAS) for Testing* (US EPA, 2021b), to collect data/information on the many PFAS that are in US commerce and have been detected in the environment.

The New Chemicals Program concludes that each of the nine Significant New Use Notice (SNUN) substances in the two Inhance consolidated submissions are persistent, bioaccumulative, and toxic chemicals (PBTs). Three of the SNUN substances (SN-23-0002 [PFOA], SN-23-0004 [PFNA], and SN-23-0005 [PFDA]) are well studied PFAS that are known to be extremely toxic. PFOA and PFDA have EPA-reviewed toxicity assessments that have been made public. PFNA has been reviewed by the Agency for Toxic Disease Registry (ATSDR), the EPA Office of Water has a proposed Maximum Contaminant Level (MCL) that addresses PFNA, made public in a March 2023 proposed rule, and EPA is currently developing a draft Integrated Risk Information System (IRIS) toxicity assessment scheduled to be released for public comment and peer review in the first quarter of 2024 [3]. The toxicity of the other six SNUN substances do not yet have EPA-developed, public toxicity assessments. In addition, there are potential or expected environmental releases of the nine SNUN substances and these releases are expected to result in human exposures and exposures to aquatic life, based on the manufacture, processing, distribution, use and disposal associated with the significant new use of these nine SNUN substances. Further, as described more fully in Section 1.2.2, data already show the presence of seven of the nine SNUN substances in the human body (exceptions are SN-23-0010 [PFHxDA] and SN-23-0011 [PFODA]) widespread across the U.S. population. In fact, nearly 100% of people sampled in the U.S. have been exposed to at least one PFAS (NAS, 2022). Thus, the New Chemicals Program concludes there is risk of concern from the manufacture, distribution, use, and disposal of the nine SNUN substances for the significant new use identified in Inhance's Significant New Use Notices. Finally, data gaps are identified, where appropriate, for the SNUN substances.

1 Background

1.1 Significant New Use Notices (SNUN) Submissions from Inhance

Inhance submitted two consolidated SNUNs for a total of nine substances (see Table 1). The nine substances are formed as byproducts during the surface coating (via fluorination) of high density polyethylene (HDPE) fuel and non-fuel storage containers, and remain in or on the walls of the container and migrate into any liquid subsequently stored in the container (see Section 2.1). Seven of the nine substances are existing chemicals and are included on the TSCA Inventory; the exceptions are SN-23-0006 [PFuDA] and SN-23-0009 [PFTrDA].

[3] The ATSDR Minimum Risk Level (MRL) for PFNA was used by Inhance in their risk assessment. The proposed EPA's Office of Water proposed PFAS National Primary Drinking Water Regulation rulemaking incorporating final MCLs for several PFAS is scheduled to be finalized in 2024 (88 FR 18638; March 29, 2023).

[redacted]

EPA has determined that the nine substances are PFAS (per- and polyfluoroalkyl substances), as defined in the *PFAS Framework*, containing the structure R-(CF_2)-CF(R')R", where both the CF_2 and CF moieties are saturated carbons (US EPA, 2023a). Specifically, the nine substances are perfluorocarboxylic acids containing fluorinated carbon chain lengths of 8-18 carbons.

The Inhance submission included 83 attachments with the first consolidated submission (SN-23-0002-0006) and 70 attachments with the second consolidated submission (SN-23-0008-0011). Two risk assessments were submitted by Inhance. Both state that they consider risks associated with all nine PFAS substances covered by the SNUNs. The first risk assessment ("Attachment 003" in the first consolidated SNUN set) states that it considers the hazard, exposure and risk to workers, consumers, the general population and environmental organisms from fluorinated fuel storage containers of various sizes. The second risk assessment ("Attachment 12" in the second consolidated SNUN set) states that it considers the hazard, exposure, and risk to workers, consumers, the general population and environmental organisms from fluorinated containers to be used in a variety of consumer products [redacted] and a variety of pesticide container products). Many exposure scenarios and pathways were evaluated in both risk assessments submitted by Inhance.

In addition, EPA acknowledges receipt and review of the following information on September 29, 2023, discussed further throughout this document:

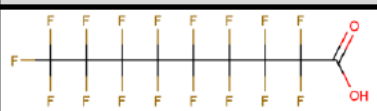
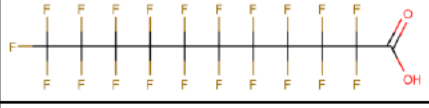
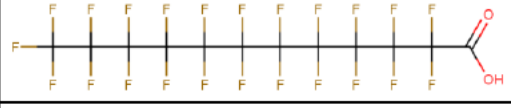
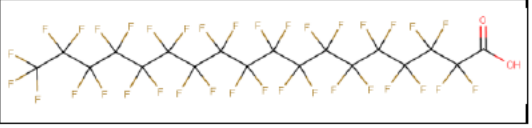
- Cover letter
- Report entitled – "Use of Drinking Water Standards"
- PDF of a 25-slide presentation summarizing the newly submitted information
- Results of sampling fuel containers for the nine SNUN substances (collected from October, 2022 to May, 2023)
- Results of sampling packaging containers for the nine SNUN substances (collected from October, 2022 to May, 2023)
- The analytical method used to measure the nine SNUN substances in the containers
- Customer/sector information for fuel containers
- Customer/sector information for packaging containers
- An economic impact assessment on the loss of the Inhance fluorination technology on the fuel/packaging systems

Finally, EPA acknowledges receipt and review of a document entitled *Combined LC/MS/MS Procedure for Measurement and Analysis of PFAS in HDPE* on November 1, 2023.

Table 1: Substances in the Two Consolidated SNUNs

Chemical Substance (Abbrev., No. of Carbons)	CASRN	SNUN Number	PV[1](kg/yr)	Structure
Perfluorooctanoic acid (PFOA, 8)	335-67-1	SN-23-0002	0.337	

[redacted]

Chemical Substance (Abbrev., No. of Carbons)	CASRN	SNUN Number	PV[1](kg/yr)	Structure
Perfluorononanoic acid (PFNA, 9)	375-95-1	SN-23-0004	0.212	
Perfluorodecanoic acid (PFDA, 10)	335-76-2	SN-23-0005	0.213	
Perfluoroundecanoic acid (PFuDA, 11)	2058-94-8	SN-23-0006*	0.223	
Perfluorododecanoic acid (PFDoA, 12)	307-55-1	SN-23-0003	0.202	
Perfluorotridecanoic acid (PFTrDA, 13)	72629-94-8	SN-23-0009*	0.21	
Perfluorotetradecanoic acid (PFTeDA, 14)	376-06-7	SN-23-0008	0.211	
Perfluorohexadecanoic acid (PFHxDA, 16)	67905-19-5	SN-23-0010	0.371	
Perfluorostearic acid (PFODA, 18)	16517-11-6	SN-23-0011	0.233	

*Not on TSCA inventory

[1] Taken from the SNUN submissions, representing the maximum estimated annual production volume (PV) by Inhance for each SNUN substance formed as a byproduct from the fluorination process and represents both fuel and non-fuel container production

1.2 Review Process for PFAS in the New Chemicals Program

1.2.1 Background

Harmful per-and poly-fluoroalkyl substances (PFAS) are an urgent public health and environmental issue facing communities across the United States. PFAS have been manufactured and used in a variety of industries in the United States and around the globe since the 1940s, and they are still being used today. Because of the duration and breadth of use, PFAS can be found in surface water, groundwater, soil, and air – from remote rural areas to densely-populated urban centers. A growing body of scientific evidence shows that exposure at certain levels to specific PFAS can adversely impact human health and other living things. Despite these concerns, PFAS are still used in a wide range of consumer products and industrial applications.[4]

[4] EPA's *PFAS Strategic Roadmap* (p. 5).

[redacted]

In October of 2021, EPA released both the *PFAS Strategic Roadmap* (US EPA, 2021a) with commitments to a broad range of actions on PFAS in the environment and a *National PFAS Testing Strategy* (US EPA, 2021b) to collect data/information on the many PFAS that are in US commerce and have been detected in the environment. One of the key actions in the *PFAS Strategic Roadmap* includes ensuring a robust review process for new PFAS in the TSCA New Chemicals Program. As a result of the need for a robust review process as identified in the *PFAS Strategic Roadmap* and the challenges associated with precisely quantifying the exposures and risks associated with PBTs, as reflected in the New Chemicals Program PBT policy, especially PBT PFAS (see section 1.2.2), the New Chemicals Program recently released the *PFAS Framework*, which describes the approach and methodology the New Chemicals Program uses to evaluate PFAS new chemical notices (US EPA, 2023a), described in section 1.2.3.

1.2.2 Challenges to Precisely Quantifying Risk for PBT PFAS Including the Nine SNUN Substances

Precisely quantifying the risk posed by PBT PFAS, including the nine SNUN substances, is complicated by: (1) the lack of robust toxicity information on most of the thousands of PFAS (exceptions include some of the SNUN substances, for example, PFOA, PFNA and PFDA, and other PFAS not covered by the 9 SNUNs – e.g., PFOS, PFHxA, PFBS, GenX); (2) the exceptionally high toxicity of the well-studied PFAS; (3) the likely additive impacts of exposure to multiple PFAS; (4) the persistence of PFAS; (5) the bioaccumulative properties of PFAS; (6) the widespread occurrence of PFAS in the environment; and (7) the apparent widespread existing exposures and body burdens of PFAS in humans. These factors can lead to risks to human health and the environment being underestimated by conventional, quantitative risk assessment methods. Each of these seven complicating factors is further explained in this section.

First, only one (PFOA) of the nine SNUN substances has robust toxicity information *for <u>both</u>* human health and environmental organisms. Thus, for the other eight SNUN substances, information is lacking (for either human health or environmental organisms, or both) which does not allow for the completion of precise estimates of the risk posed by the SNUN substance of interest. In order to precisely quantify risk[5], an accurate hazard identification value that reflects some level of certainty needs to be identified for the substance of interest. Use of a close analogue is often used in place of hazard information for a given chemical, but this does introduce uncertainty.[6] Thus, hazard information on the substance of interest should be used whenever possible. This leads to the second complicating factor: the available information on a limited number of more well-studied PFAS (such as PFOA, PFNA and PFDA) indicates that they are extremely toxic, and understanding the toxicity of each of the nine SNUN substances would

[5] In this risk assessment, the New Chemicals Program did not quantify risk. Thus, for 8 of 9 SNUN substances available human health hazard information was sufficient to identify hazard concerns for PBT classification purposes (the exception was PFTrDA). For the environmental organisms, PFOA was used as an analogue for the eight other SNUN substances.

[6] For example, lack of toxicity information led both EPA and Inhance (in the Inhance-submitted risk assessment) to use analogues for either or both human health and environmental organisms where there was no available hazard information for certain of the SNUN substances.

[redacted]

be necessary to precisely understand the hazard of all of the SNUN substances. Due to the uncertainty with the use of analogues and the possible spectrum of toxicity among PFAS, some PFAS may be more or less toxic than expected or predicted by use of an analogue.

Third, the nine SNUN substances co-exist as byproducts from the fluorination process and so to properly quantify risk, their additive effects need to be considered. However, conducting a risk assessment to quantify the additive effects poses a challenge. EPA is working to develop methodologies to evaluate mixtures and risk in other contexts and programs[7] but a standard, widely accepted method and approach for PFAS is not yet available. Fourth, it has been established that the carbon-fluorine bond is extremely stable and persists in the environment. When a chemical substance is both present and persistent in the environment, it is difficult to quantify exposure using traditional methods that only capture exposures associated with a release at a particular point in time.

Fifth, PFAS have been shown to bioaccumulate in the environment, humans and environmental organisms. Importantly, bioaccumulation of PFAS can be significantly higher in humans compared to rodents, which are typically used to determine the points of departure for use in quantitative human health risk assessment (ITRC, 2023). PFOA has a reported half-life in humans of 2.3-3.8 years (as reviewed in Seals et al. (2011) and recently confirmed in Li et al. [2018]. This means it would take the body more than a decade[8] to rid itself of PFOA residing in the body assuming there is no further exposure. Any new or additional exposure would result in an increase in the time it would take for the body to rid itself of PFOA. Sixth, due to their persistence and bioaccumulative nature, PFAS have been widely detected in the environment around the globe, thus showing widespread exposures. Small releases to the environment can have a significant long-term contribution to exposure and risk. Current risk assessment methods used in the two Inhance risk assessments do not account for chemical substance accumulation over time in environmental media, environmental organisms and humans.[9]

And finally, the persistence, bioaccumulation and toxicity of many PFAS has resulted in an existing burden in humans, environmental organisms, and the environment that is not accounted for in the New Chemicals Program's traditional quantitative methodologies or in Inhance's risk assessments. The National Academy of Sciences recently provided an overview of the extent and magnitude of PFAS contamination, stating "(D)ata from the National Health and Nutrition Examination survey [NHANES] show that nearly 100 percent of people in the United States are exposed to at least one PFAS…" (as cited in NAS, 2022, p. xi; also referred to as NHANES data). These data showing PFAS in human serum include the presence of five of the SNUN substances (PFOA, PFNA, PFDA, PFuDA and PFDoA), but the incidence and concentrations are highest for PFOA and PFDA. There are other biomonitoring data showing the presence of

[7] For example, see risk assessment for mixtures guidance at the Office of Research and Development (epa.gov/ and search for 1986 Guidelines for the Health Risk Assessment of Chemical Mixtures).

[8] On average, it takes 5-7 half-lives to eliminate a chemical from the body. For example, if the half-life is 3 years, at the end of 3 years, half (i.e., 50%) of the chemical is still present. After the "second half-life", there would be 25% of the original concentration. At the end of 5 half-lives, approximately 3% would still be present (15 years later). See National Institute of Health, National Library of Medicine (www.ncbi.nom.nih.gov)

[9] The two Inhance risk assessments use conventional methods for quantifying risk that do not account for bioaccumulation. See Sections 2 and 3 for details and more discussion.

[redacted]

two of the other SNUN substances in human serum in US samples (PFTeDA and PFTrDA).[10] This existing body burden of PFAS in humans is constantly changing as a result of exposures by people to PFAS already in the environment –this makes it extremely difficult to accurately and precisely quantify the risk from additional, incremental exposures to the nine SNUN substances.

Notably, many of the SNUN substances have been shown to be widespread in fish tissue in U.S. waters (Table 2). Fish are time-integrating indicators of persistent pollutants, and contaminant bioaccumulation in fish tissue has important human health implications (EPA 2020a). EPA's National Aquatic Resource Surveys are statistical surveys designed to assess the status of the condition of waterbodies in U.S. and to evaluate changes affecting the quality of these waters over time. The 2013-2014 National Rivers and Streams Assessment (NRSA) and the 2015 National Coastal Condition Assessment (NCCA) demonstrate widespread PFAS contamination in freshwater fish in U.S. rivers and the Great Lakes, respectively (USEPA 2020a, 2020b). Specifically, EPA has detected several of the SNUN substances (SN-23-0003, -0004, -0005, -0006) at high frequencies of detection in its statistical surveys of the nation's rivers and the Great Lakes (shown in Table 2).

Table 2: Detection Frequency of SNUN Substances in Freshwater Fish Tissue (2013-2014 NRSA and 2015 NCCA)

SNUN Substance	Detection Frequency 2013-14 NRSA[1] (in percent)	Detection Frequency 2015 NCCA: Great Lakes[2] (in percent)
SN-23-0003 (PFDoA)	70	81
SN-23-0004 (PFNA)	39	78
SN-23-0005 (PFDA)	84	88
SN-23-0006 (PFuDA)	88	91

[1] Total of 349 fish samples collected at river sites were analyzed for 13 per- and polyfluoroalkyl substances (PFAS)
[2] Total of 152 fish samples collected at Great Lakes nearshore sites were analyzed for 13 per- and polyfluoroalkyl substances (PFAS)

In addition to the seven complicating factors described, there is uncertainty in determining the amount of the nine SNUN substances that are actually manufactured as byproducts during the fluorination process. This uncertainty makes it difficult to accurately quantify exposures (see section 2.2 for discussion of potential underestimation of production volume in the risk assessment submitted by Inhance). Available data also show that other PFAS (not covered by the Long Chain PFAS Significant New Use Rule [SNUR]), in addition to the nine SNUN substances, are also byproducts from fluorinating containers. The possible contribution of these other PFAS to the bioaccumulation and toxicity potential of the nine SNUN substances is unknown at this time.

[10] Draft ORD report entitled "Report on comparison of cell-based bioactivity concentrations and human population blood concentrations for selected PFAS compounds", which is in the administrative record for this action.

[redacted]

Based on these considerations, and as outlined further in the *PFAS Framework*, EPA generally expects to evaluate risk for PBT PFAS qualitatively. Thus, EPA's risk assessment for these PFAS SNUN substances is qualitative.[11]

1.2.3 Overview of the *PFAS Framework*

The New Chemicals Program generally follows the PBT Policy (US EPA, 1999) in assessing and managing PMNs and SNUNs that involve PBTs. This longstanding policy is used to identify substances that meet the criteria for persistence, bioaccumulation and toxicity and warrant appropriate risk mitigation efforts (see Section 3 for further information).

In 2023, the New Chemicals Program incorporated the 1999 PBT Policy into the *PFAS Framework* for the review of PFAS PMNs and SNUNs. The purpose of the *PFAS Framework* is to provide a clear approach for the New Chemicals Program to review PFAS PMN and SNUN substances in light of significant health and environmental concerns associated with, widespread environmental exposure to, and environmental persistence of PFAS, and to identify any appropriate risk mitigation (including banning manufacture, if warranted) and any appropriate PFAS testing requirements.

When a substance under review is identified as PFAS using the definition outlined in the *PFAS Framework*, including key components of interest such as potential degradants and metabolites, a PBT determination is made by the New Chemicals Program for the submitted PFAS and/or key degradants and metabolites using a weight of evidence approach based on data from the specific new chemical substance or appropriate analogues, as described in section 3.1. Although it is possible to quantify exposure to an immediate release of a specific amount of PFAS, the estimated exposure would not reflect the overall human health and environmental impact posed by the released PBT PFAS as such substances persist and bioaccumulate over time and humans already have a body burden of PFAS. For PBT PFAS chemicals, EPA will generally qualitatively consider the potential or expected extent of exposures to workers, the general population, consumers and the environment throughout the lifecycle of the PFAS, but will not attempt to quantitatively assess exposures or risk due to the limitations outlined in section 1.2.2.

The New Chemicals Program's evaluation of whether the nine SNUN Substances are PBTs under the PBT Policy is consistent with the PFAS Framework. Then, because the New Chemicals

[11] Although EPA has concluded that a quantitative risk assessment is not appropriate to capture the full risk associated with these PFAS for the reasons described in this Section (1.2.2) and elsewhere in this document, EPA did perform a sensitivity analysis that calculates risk for PFOA and PFDA using EPA's human health hazard information and the exposure calculations submitted by Inhance. EPA's human health hazard information (i.e., PODs) for PFOA and PFDA are different from the ones used by Inhance and represent the EPA internal and public review of the available scientific information. Eighty percent of the calculations in the sensitivity analysis showed risk and 20% did not (See "Sensitivity Analysis: Calculating risk using EPA-derived toxicity values with Inhance-derived exposure values" as part of the administrative record for this action). Inhance's risk assessment utilized the ATSDR MRL as the human health hazard POD for PFNA and, using that POD, did not show risk for any scenario in their quantitative assessment. EPA is currently developing a draft Integrated Risk Information System (IRIS) toxicity assessment scheduled to be released for public comment and peer review in the first quarter of 2024. In addition, there were deficiencies, unrelated to the PODs, in Inhance's quantitative risk assessment, discussed further in section 2.6.

[redacted]

Program has determined these substances to be PBTs that are formed during the fluorination process leading to widespread exposure – especially to consumers (as pointed out in Section 4) - and consistent with the PFAS Framework, it has qualitatively assessed the risk of the nine SNUN substances.

The considerations outlined in the *PFAS Framework* are also applied in the review of the risk assessments submitted by Inhance in the next section.

2 Review of the Risk Assessments and Other Information Submitted by Inhance

Two risk assessments were included in the Inhance submissions – one to evaluate the nine SNUN substances formed in fuel storage containers and one to evaluate the nine SNUN substances formed in non-fuel storage containers (see section 1.1). As outlined in the *PFAS Framework* and in section 1.2.2, the persistence and bioaccumulation of these substances, and the existing and widespread environmental occurrence and human body burdens of PFAS were not taken into consideration in the Inhance risk assessments (though bioaccumulation was acknowledged as an uncertainty by Inhance). The following sections present EPA's review of important information in the submitted risk assessments regarding the presence of long-chain PFAS in fluorinated HDPE containers, the uncertainty in the amount of PFAS being produced as byproducts, as well as environmental and human health risk assessment concerns.

Since the submission of the SNUNs on December 30, 2022, EPA has received more detailed information from Inhance regarding the optimization of Inhance's fluorination process, analytical methods used for testing, and detailed sample information (i.e., manufacturing location, customer sector, and the amount of PFAS detected). These data were received on September 29, 2023. While these data do indicate that Inhance has adapted its process with respect to certain types of containers to reduce the amount of long-chain perfluoroalkyl carboxylate (LCPFAC) formed—stating that over 98% of the samples have non-detectable levels for the 9-18 carbon LCPFACs—for the 8-carbon PFOA, the non-detect frequency dropped to 84%. This shows at a minimum that of the nine SNUN substances, the one that is currently known to be the most toxic (i.e., PFOA) is still being produced as a byproduct during Inhance's fluorination process. In addition, the detection limit used in these studies provided by Inhance (~300 ppt in extracts from the plastic container coupons) is much higher than other comparable methods. For example, EPA Office of Pesticide Program's Biological and Economic Analysis Division (BEAD) has validated a method in the laboratory that is much more sensitive than the one employed for these measurements by Inhance. The level of detection is 2 ppt and the level of quantification is 20 ppt for most PFAS tested (see "Summary of EPA Container Coupon Method for PFAS Determination" in the administrative record for this action).

2.1 Presence of Long-Chain PFAS in Fluorinated HDPE Containers

The risk assessments conducted by Inhance did not consider that the nine SNUN substances co-exist when formed as byproducts from the fluorination process. Inhance provided evidence for the existence and migration of long-chain PFAS from the HDPE container walls into the container contents (methanol, CE10 fuel, and water were used as media for extraction) in the original risk

[redacted]

assessments and again provided more evidence in their September 29, 2023 submission of additional information (see Section 1.1). Because the nine SNUN substances co-exist and are chemically similar, they will likely interact with each other. Considering exposure and hazard for each SNUN substance separately does not account for the additive[12] exposure and the likely hazard/toxicity interaction (whether it be additive, greater than additive, or something altogether different), thus leading to an underestimation of the risk to human health and the environment.

In addition, EPA is aware of studies which indicate that other PFAS substances (e.g., PFAS which have fewer than 7 fluorinated carbons) are also expected to leach from fluorinated HDPE containers (US EPA, 2021 and 2022; Whitehead and Peaslee, 2023; Vitale et al., 2022). Thus, these shorter-chain PFAS are likely byproducts of Inhance's fluorination process and co-exist with the LCPFAC. For instance, testing conducted by the BEAD Laboratory within EPA's Office of Pesticide Programs showed that 86% of the mass of PFAS that leached from a fluorinated 55 gallon drum were of the short-chain variety (US EPA, 2021c). Both short- and long-chain PFAS are linked to adverse human health effects, with overlap in toxicities (see section 2.4). The possible contribution of these other PFAS to the exposure, bioaccumulation and toxicity potential of the nine SNUN substances may affect the estimation of risk for the nine SNUN substances.

2.2 Production Volume Uncertainty

In order to accurately and precisely quantify risk, it is important to have confidence in the estimates of the amount of the nine SNUN substances formed from Inhance's fluorination process. For the substances that were considered in the Inhance-submitted risk assessments, Inhance provided estimates of production volume which claim that the nine SNUN substances are produced at levels below 400 grams per year for each one. Estimating the production volumes for these substances is difficult because the volumes can only be determined indirectly, as opposed to using stoichiometric calculations. For example, a PFAS byproduct that is produced upon fluorination may remain entrained within the HDPE matrix, but still have the potential to migrate from the container walls. In this scenario, that PFAS would not be counted in the production volume estimate even though it results from the fluorination process. In order to account for this issue, extraction conditions (e.g., solvent, heat, duration) must be used which are capable of extracting the maximum amount of PFAS possible from the HDPE matrix. Multiple extractions must also be used in order to demonstrate that PFAS is no longer leaching from the container walls and all the PFAS has been extracted. Given the large amount of uncertainty with these production volume estimates, it is impossible to precisely quantify risk using the current information provided by Inhance.

2.3 Dermal Exposure

Inhance developed conceptual exposure models for both the fuel and non-fuel uses of their fluorinated containers. In both models, they recognize that dermal exposure occurs, but they dismiss the possibility of the SNUN substances being absorbed across the skin layer because they

[12] Additivity means that it is likely that the SNUN substances interact so that both hazard and exposure could be additive as they are present as a mixture. This additivity could be either due to dose additivity or response additivity (see epa.gov/risk and search for 1986 *Guidelines for the Health Risk Assessment of Chemical Mixtures*).

[redacted]

believe the SNUN substances are too large. While this may be an uncertainty for most of the SNUN substances, there is information showing dermal exposure/absorption occurs for PFOA (Fasano et al. 2005. Fairley et al., 2007, and Franko et al. 2012). Again, PFOA is recognized as one of the highly toxic PFAS substances. Similar information documenting absorption through the skin layer for the other eight SNUN substances is not readily available and therefore is an uncertainty and may underestimate risk.

2.4 Toxicity to Aquatic Organisms

The aquatic toxicity analysis in the risk assessment performed by Li et al 2021 was referenced and used in the Inhance risk assessments. Li et al. estimated an aquatic life chronic predicted no-effect concentration (PNEC; 0.0067 mg/L) based on a species sensitivity distribution (SSD) approach using test data for PFOA (SN-23-0002). Inhance also applied the estimated PNEC for PFOA using read-across for the remaining eight SNUN substances to evaluate hazards. EPA agrees with this approach to evaluate the environmental hazard of the nine SNUN substances. The actual hazard value used to derive the PNEC was an HC_5[13] value of 0.033 mg/L, which meets the EPA criteria for chronic toxicity concern for aquatic organisms (or, a T score of 2 for the PBT score).[14]

2.5 Toxicity to Human Health

The human health toxicity values proposed in the Inhance-submitted risk assessments are based on hazards that support a human health toxicity score of 2, consistent with EPA's approach (Table 2; section 3.3.2; US EPA, 2023a). EPA has qualitatively evaluated risk for these cases per the *PFAS Framework* and for the reasons explained in section 1.2.2 concluded that it is challenging to quantitatively and precisely assess risk from PBT PFAS, including the nine SNUN substances. Further, EPA identified a number of deficiencies in the Inhance-submitted quantitative risk assessments, with key concerns briefly described in this section.

While EPA is qualitatively evaluating risk for the nine SNUN substances, and therefore not selecting hazard points of departures (PODs) for a quantitative risk assessment, EPA notes that Inhance did not use EPA-developed, publicly available, risk assessments/PODs for PFOA and PFDA, and did not address why they chose the ones they did use. For example, PODs have been used by the EPA in other contexts to develop reference doses for PFOA and PFDA that are substantially different from the values used in the Inhance risk assessments. For PFOA, the interim reference dose published by EPA's Office of Water of 1.5×10^{-9} mg/kg-bw/day (US EPA, 2022), is 2000-fold lower than the Inhance-selected value of 3×10^{-6} mg/kg-bw/day (ATSDR, 2021). For PFDA, EPA's IRIS Program developed a draft reference dose of 4×10^{-10} mg/kg-bw/day (US EPA, 2023b), 37,500-fold lower than Inhance-selected value of 1.5×10^{-5} mg/kg-bw/day (TCEQ, 2016). Use of either of the EPA PFOA or PFDA PODs—or any other PODs for any of the SNUN substances—by Inhance would change the risk results for these two SNUN substances. For example, if Inhance had used EPA's

[13] An HC_5 is the logarithm of the fifth percentile of the distribution of chronic toxicity values for PFOA from 24 species representing eight taxonomic groups.

[14] See Section 3 for the details of scoring attribution for the P, B, and T for a PBT assignation.

[redacted]

PODs for PFOA and PFDA, Inhance would have identified risks of concern for 80% of the scenarios calculated.[15]

In the Inhance risk assessments, the risk for each SNUN substance was considered individually. EPA notes that Inhance provided data that show there is a mixture of PFAS (i.e., the nine SNUN substances) present in the fluorinated containers, indicating a need to carefully consider how the PFAS may act in concert to elicit adverse human health effects. Additionally, as described in section 2.1, present in the fluorinated containers are both the nine SNUN substances—which are all perfluorocarboxylic acids, with variation only in fluorinated carbon chain length, from 8-18 carbons (Table 1)—and the likely existence of other, shorter-chain PFAS formed as byproducts during fluorination (US EPA, 2021 and 2022; Whitehead and Peaslee, 2023; Vitale et al., 2022). Considering the similarity in structure across the PFAS present in the fluorinated containers, along with the known overlap in toxicities of both short- and long-chain PFAS, it is reasonable to expect the potential for additive effects among the PFAS that would likely affect the overall bioaccumulation and risk posed by the nine SNUN substances (US EPA, 2023c, Fenton et al., 2021). There is a growing body of evidence on the dose additive effects for mixtures of PFAS (for example, see Addicks et al., 2023; Dale et al., 2022; Marques et al., 2021) which, if not accounted for, will result in underestimating risk.

As noted in the Inhance risk assessments (Section 6 in both), there is uncertainty associated with not quantifying the bioaccumulative effects that are expected to occur with these PFAS substances which also, if not accounted for, will result in underestimating risk.

Finally, Exhibit 11 in the September 29, 2023 submission by Inhance is a document entitled: *Use of Drinking Water Standards.* This 10-page document points out that, even though the units are the same, concentrations of a substance in a container matrix or fluid is not the same as the concentrations of that same substance in a drinking water standard. EPA agrees and this does not change this assessment as we are not applying drinking water standards – nor are we quantifying risk – in this qualitative risk assessment.

Despite this non-exhaustive list of unaccounted for toxicity considerations, as well as differences in the identification of relevant human health toxicity information in the Inhance risk assessments, the Inhance risk assessments provide toxicity information supporting a human health toxicity score of 2 for each of the SNUN substances (see Table 3).

[15] Although EPA has concluded that a quantitative risk assessment is not appropriate to capture the full risk associated with these PFAS for the reasons described in this Section (1.2.2) and elsewhere in this document, EPA did perform a sensitivity analysis that calculates risk for PFOA and PFDA using EPA's human health hazard information and the exposure calculations submitted by Inhance. Eighty percent of the calculations performed in the sensitivity analysis showed risk and 20% did not (See "Sensitivity Analysis: Calculating risk using EPA-derived toxicity values with Inhance-derived exposure values" as part of the administrative record for this action). Inhance's risk assessment utilized the ATSDR MRL as the human health hazard POD for PFNA and, using that POD, did not show risk for any scenario in their quantitative assessment. EPA is currently developing a draft Integrated Risk Information System (IRIS) toxicity assessment scheduled to be released for public comment and peer review in the first quarter of 2024. In addition, there were deficiencies, unrelated to the PODs, in Inhance's quantitative risk assessment, discussed further in section 2.6.

[redacted]

Table 3. Human Health Toxicity Values Used in the Inhance Risk Assessments

Case Number (Chemical, Abbr., No. of Carbons)	*Toxicity Value*	*Basis*	*Reference*
SN-23-0002 (PFOA, 8)	3×10^{-6} mg/kg-bw/day	Skeletal effects in mice	Koskela et al, 2016 as cited in ATSDR, 2021
SN-23-0004 (PFNA, 9)	3×10^{-6} mg/kg-bw/day	Liver weight increases in pregnant mice in a developmental toxicity study. This was coupled with measured serum and liver PFNA levels in pregnant mice. In addition, offspring showed decreased body weight, developmental delays, increased liver weight, and PFNA in liver and serum up to PND 70	Das et al., 2015, as cited in ATSDR, 2021
SN-23-0005 (PFDA, 10)	1.5×10^{-5} mg/kg-bw/day	Decreases in fetal body weight in a mouse developmental study (LOAEL = 0.1 mg/kg-bw/day)	Harris and Birnbaum 1989 as cited in TCEQ 2016
SN-23-0006 (PFuDA, 11)	PFDoA as analogue		
SN-23-0003 (PFDoA, 12)	1.2×10^{-5} mg/kg-bw/day	Twenty-five percent reduction in body weight in 14-day oral rat study at 5 mg/kg-bw/day; with a NOAEL of 1 mg/kg-bw/day	Shi et al. as cited in TCEQ, 2016
SN-23-0009 (PFTrDA, 13)	PFDoA as analogue		
SN-23-0008 (PFTeDA, 14)			
SN-23-00010 (PFHxDA, 16)	PFOA as analogue		
SN-23-0011 (PFODA, 18)			

2.6 EPA's Summary of the Deficiencies in the Inhance Risk Assessments

EPA does not agree with the Inhance risk assessment conclusion that there are no risks to either human health or environmental organisms from exposure to the nine SNUN substances. Not taken into consideration in the Inhance risk assessments are the: 1) persistence and bioaccumulation of the nine SNUN substances; 2) widespread existing environmental and human body burdens of different PFAS, including the available *National Report on Human Exposure to Environmental Chemicals* using the *National Health and Nutrition Examination Survey,* or NHANES[16] data documenting the presence of five of the SNUN substances (PFuDA, PFDoA and the highly toxic PFOA, PFNA, and PFDA) in human serum, information on the presence of two (PFTeDA and PFTrDA)

[16] As cited in NAS, 2022 but all data are available at – cdc.gov/exposurereport/data_tables.html (and searching for individual chemicals).

[redacted]

of the remaining SNUN substances in US human serum samples[17], and the EPA National Aquatic Resource Survey data supporting widespread presence in freshwater fish tissue in U.S. rivers and Great Lakes for, PFuDA, PFDoA, and the highly toxic PFNA and PFDA, which affects the ability to estimate exposure to, and hazard and risk for, the nine SNUN substances (US EPA 2020a); and 3) the co-existence and likely interaction of the nine SNUN substances with the possible contributions from other PFAS which may affect the hazard/exposure estimates for the nine SNUN substances. Furthermore, although the estimated production volumes provided by Inhance for the nine SNUN substances are uncertain, the exposure calculations and estimates made by Inhance in their risk assessments demonstrate that the nine SNUN substances are formed as byproducts from the fluorination process and would be released to the environment (if use is permitted).

3 Evaluation of the SNUNs for Potential to be Persistent, Bioaccumulative and Toxic (PBT)

3.1 The New Chemicals Program's PBT Policy

In 1999, EPA issued a policy statement identifying PBT chemicals as a category of concern (US EPA, 1999). The 2018 *Points to Consider When Preparing TSCA New Chemical Notifications* (US EPA, 2018) document provides guidance on how EPA implements the PBT policy in reviews. EPA uses this approach to identify substances that meet the criteria for a score of 2 or more for each of the three key parameters (persistence, bioaccumulation, and toxicity); that is "P2B2T2" or higher. Note that a score of unknown (U) in any category is treated as a 2 or 3 for purposes of identifying PBTs. The criteria for determining scores for persistence and bioaccumulation are shown in Table 4 (US EPA, 2018).

Table 4: Persistence and Bioaccumulation Score Criteria

Persistence[1]	**Low Persistence (P1)**	**Persistent (P2)**	**Very Persistent (P3)**
Water, soil, sediment	< 60 days	≥ 60 days	>180 days
Air	<2 days	>2 days	
Bioaccumulation[1]	**Low Bioaccumulation (B1)**	**Bioaccumulative (B2)**	**Very Bioaccumulative (B3)**
Fish BCF or BAF	<1000	≥1000	≥5000
[1] Note, qualitative estimates based on modeling and/or physical-chemical properties are also used to inform the P and B score. BCF = bioconcentration factor, BAF = bioaccumulation factor.			

Traditional metrics like bioconcentration factor (BCF) and bioaccumulation factor (BAF) may not fully characterize the potential for PFAS to accumulate via dietary exposure (Evich et al. 2022). These metrics are most relevant for chemicals that bioaccumulate via lipophilic partitioning, whereas PFAS typically accumulate by proteinophilic partitioning or other mechanisms. There are

17 "Report on comparison of cell-based bioactivity concentrations and human population blood concentrations for selected PFAS compounds" in the administrative record for this action.

[redacted]

also differences in clearance mechanisms and rates between gill- and air-breathing animals, potentially leading to substantially higher bioaccumulation in the latter (De Silva et al. 2021). Food web-based metrics like biomagnification factors and trophic magnification factors are sometimes considered more robust predictors of bioaccumulation in humans, yet even these are subject to significant uncertainty when measured for PFAS (Franklin 2016; Miranda et al. 2022). Apart from these considerations, it is important to note that human exposure to certain PFAS such as PFOA and PFOS (perfluorooctanesulfonic acid) may occur primarily through drinking water, so even an accurate estimate of bioconcentration in fish harvested for food underestimates potential human exposure (McLachlan et al. 2017).

In addition, EPA considers the known presence and persistence of many PFAS in human serum (half-lives ranging from weeks to years) to be direct evidence of their bioaccumulation potential in humans (Fenton et al., 2021; Li et al. 2018). Thus, since 2018, EPA has evaluated most PFAS in the New Chemicals Program by assigning a bioaccumulation potential rating (B) of B*high. Similarly, a persistence (P) rating of P3 is assigned to most PFAS based on their observed persistence in the environment and the stability of the C-F bond. The only exceptions are those PFAS that react to produce fluorinated degradation products. In such cases, the parent compound may be rated P1 or P2, while the degradation products are rated P3.

The scores for toxicity are based on the following criteria (from p. 15 of the *Points to Consider* document) and EPA uses this same approach for PFAS:

> "*The T score (in the overall PBT score) is based on developmental/reproductive and/or chronic hazards to the general population and/or to chronic hazards to aquatic organisms...; it is not designated for acute toxicity (i.e., mammalian or aquatic organisms) and is not typically used for hazards identified by the dermal or inhalation routes of exposure, as these types of toxicity and exposure routes are not typically associated with P and B chemicals*."[18]

3.2 Persistence and Bioaccumulation Scores for the SNUNs

All nine Inhance SNUN substances are Class 1 chemicals (i.e., their compositions can be represented with definite structural diagrams[19]). They are fully fluorinated alkyl carboxylic acids ranging in chain length from 8 (PFOA) to 18 (PFODA) carbon atoms. Such compounds exhibit observable environmental persistence and are known to be resistant to biodegradation and hydrolysis due to their highly stable chemical structures (USEPA 2009; Post et al. 2012; Kwiatkowski et al. 2014; Evich et al. 2022). Thus, EPA does not expect them to degrade in aqueous media. While trifluoroacetic acid (TFA) has been identified as a representative incineration product for all nine SNUN substances to reflect the possibility of incomplete combustion in municipal solid waste incinerators, TFA is not driving the PBT determination for these SNUN substances.

[18] The phrase …"not typically used for hazards identified by the dermal and inhalation routes of exposure…" relates to portal of entry (i.e., site of contact effects such as skin and respiratory irritation) and not systemic effects (i.e., absorbed into the blood and distributed throughout the body). For chemicals that are absorbed via dermal and inhalation exposures, and that are persistent, bioaccumulative and toxic, these exposure pathways are important.

[19] 83 FR 52694.

[redacted]

Persistence: Most PFAS are considered persistent (P3) due to the extreme stability of the C-F bond and the observed, widespread persistence of perfluorinated chemicals (Kwiatkowski et al. 2014 and references therein). The only exceptions are those PFAS that react to produce fluorinated degradation products. In such cases, the parent compound may be rated P1 or P2, while the degradation products are rated P3. Based on their chemical structures, none of the nine SNUN substances is expected to degrade under environmental conditions. Further, each of them contains multiple C-F bonds, so each is anticipated to be extremely persistent and is therefore rated P3.

Bioaccumulation: EPA rates most PFAS as B*high. Exceptions include those PFAS that react to produce fluorinated degradation products. In such cases, the parent compound may be rated B1 or B*low, while the degradation products are rated B*high. This reflects the observed presence of both long- and short-chain perfluorinated compounds in air, water, environmental organisms, plants, food, beverages, drinking water, and human serum, along with their persistence, and the resulting prolonged exposure times (Brendel et al. 2018, Scheurer and Nödler 2021, Evich et al. 2022, etc.). None of the nine SNUN substances is anticipated to degrade under environmental conditions. All are long-chain PFAS, a class of chemicals which extensive data indicate can bioaccumulate in humans. As such, all are expected to bioaccumulate. References to chemical-specific field data are included in Table 5. Based on these considerations, each of the nine SNUN substances is rated B*high.

Table 5 presents the P and B scores for the nine SNUN substances.

Table 5: Persistence and Bioaccumulation Scores for the Nine SNUN Substances

SNUN Substance, Abbrev., No. of Carbons	P Score*	B Score	B Score Basis**
SN-23-0002 (PFOA, 8)	P3	B*high	Dai and Zeng (2019); Furdui et al. (2007); Vierke et al. (2012); analogy to other PFAS
SN-23-0004 (PFNA, 9)	P3	B*high	De Silva et al. (2011); Furdui et al. (2007); Gebbink et al. (2016); analogy to other PFAS
SN-23-0005 (PFDA, 10)	P3	B*high	De Silva et al. (2011); Furdui et al. (2007); Gebbink et al. (2016); analogy to other PFAS
SN-23-0006 (PFuDA, 11)	P3	B*high	De Silva et al. (2011); Gebbink et al. (2016); Khairy et al. (2019); Murakami et al. (2011); analogy to other PFAS
SN-23-0003 (PFDoA, 12)	P3	B*high	Khairy et al. (2019); Lin et al. (2014); analogy to other PFAS
SN-23-0009 (PFTrDA, 13)	P3	B*high	Zhang et al. (2018); Pan et al. (2017); analogy to other PFAS
SN-23-0008 (PFTeDA, 14)	P3	B*high	Pan et al. (2017); analogy to other PFAS
SN-23-00010 (PFHxDA, 16)	P3	B*high	analogy to other PFAS
SN-23-0011 (PFODA, 18)	P3	B*high	analogy to other PFAS

*The basis of the P scores for all nine SNUN substances is the presence of numerous, highly stable C-F bonds combined with the observed environmental persistence of PFAS as a class.

**In addition to the references listed in the table, the observed bioaccumulation of PFAS in humans and other air-breathing animals is used to support the B scores for all nine SNUN substances.

3.3 Other Fate Considerations for the SNUNs

Manufacture, distribution, use and disposal of the nine SNUN substances results in potential or expected releases to the environment. In understanding the environmental fate of the nine SNUN substances throughout this lifecycle, thermal decomposition of PFAS in waste streams (e.g., from manufacture/distribution), through use (e.g., internal combustion engines such as lawn mowers) and from disposal (e.g., spent containers) is an active area of research. There is uncertainty regarding the conditions needed to achieve complete mineralization and the range of possible products of incomplete combustion (PICs) when those conditions are not met. There are indications that temperatures exceeding 1,000–1,100 °C may be sufficient for complete destruction of many PFAS (Shields et al. 2023). However, because the operating parameters of municipal waste incinerators are not standardized and it is not clear these temperatures are consistently achieved, EPA assesses TFA as a representative incineration product for PFAS to account for expected PIC releases.

Temperatures in internal combustion engines may exceed those in municipal waste incineration (Roberts et al., 2014). Thus, it seems likely that destruction of PFAS would occur given efficient engine operation, but this has not been verified experimentally. Since complete efficiency in the operation of combustion engines cannot be assumed, the possibility of incidental releases and/or incomplete combustion cannot be ruled out and therefore represents an expected route of exposure.

Based on their physical-chemical properties, LCPFACs associated with discarded materials in landfills may be expected to desorb and be transported through subsurfaces more slowly than shorter-chain PFAS. The relevant transport times are not well defined, but may be considerable given possible retention of LCPFACs on containers, organic matter, sorbent membranes, etc. Yet, because of the extreme persistence of these compounds, such transport is still possible. In fact, LCPFACs are known to be present in leachate from municipal solid waste landfills; concentrations of PFOA in the parts per billion (ppb) range have been reported in leachates from multiple landfills (Solo-Gabriele et al. 2020). This indicates that, contrary to Inhance's claim that landfill leachate would result in "very small incremental releases, if any," (Attachment 12 at 25), leaching of the nine SNUN substances can occur and they are expected to migrate through soil, and eventually to groundwater[20].

Most wastewater treatment plants are not required to monitor PFAS, so quantitative removal efficiencies are not well characterized. However, conventional wastewater treatment methods may be ineffective at removing perfluoroalkyl acids (Sinclair and Kannan, 2006; Loganath et al., 2007; Leung et al. 2022). Removal by biodegradation is generally not expected, while sorption and stripping are structure-dependent and more difficult to predict. In fact, many treatment plants exhibit higher concentrations of long-chain PFAS in effluent than in influent due to formation from precursors in the treatment train (USEPA 2019). Thus, the nine SNUN substances would be expected to be released to receiving/surface waters used as sources of drinking water and fish as a food source for humans, and as habitat for aquatic organisms.

[20] As pointed out in the next section (Section 4), Inhance produces more than 200 million fluorinated containers a year.

[redacted]

3.4 Toxicity

As noted earlier, the T score in PBT can be based on either chronic toxicity concerns to aquatic organisms or developmental, reproductive or chronic toxicity concerns for human health.

3.4.1 Toxicity to Aquatic Organisms

The EPA New Chemicals Program uses an aquatic toxicity profile to characterize environmental hazards, which consists of three acute (fish, aquatic invertebrates, and algae) and three chronic (fish, aquatic invertebrates, and algae) ecotoxicity endpoint values. The typical aquatic toxicity profile is established for each substance under review (and expected degradation products) using measured test data, data for analogous substances, and/or modeled data. For this assessment, the majority of available PFAS aquatic toxicity test data are only for PFOA (one of the nine SNUN substances), with most of the other SNUN substances lacking experimental test data/information applicable to this assessment. Modeled data are not incorporated into the environmental hazard assessment for the eight SNUN substances without sufficient data because aquatic toxicity models based on lipophilic partitioning (e.g., ECOSAR) are unreliable for PFAS.

There is a lack of information to determine environmental hazards for eight of the nine SNUN substances, the exception being PFOA, for which an HC_5 value of 0.033 mg/L was reported in Li et al. (2021). This value was used by Inhance in their risk assessment and has been accepted by the EPA's New Chemicals Program to represent the hazard concerns for this qualitative assessment of the nine SNUN substances. PFOA (SN-23-0002) is considered a concern for chronic toxicity to aquatic organisms based on the high environmental hazard observed in the submitted data (Table 6); the environmental toxicity "T" score for SN-23-0002 is T2. For the eight other SNUNs, the environmental toxicity score is considered unknown and thus the PFOA data are used as read-across for EPA's assessment.

The EPA Draft Aquatic Life Ambient Water Quality Criteria for PFOA indicates a chronic water column Criterion Continuous Concentration of 0.094 mg/L (US EPA 2022b). Although this value is slightly less conservative than the HC_5 submitted by Inhance (0.033 mg/L), both values indicate a concern for chronic toxicity to aquatic organisms based on the high environmental hazard and result in a toxicity score of T2.

Table 6: Aquatic Toxicity Profile for the Nine SNUN Chemical Substances

SNUN Substance, Abbrev, No. of Carbons	Hazard Value for Chronic Aquatic Toxicity
SN-23-0002 (PFOA, 8)	HC_5 value of 0.033 mg/L from the Species Sensitivity Distribution (SSD) Reported by Li et al. (2021) and used by Inhance

[redacted]

SNUN Substance, Abbrev, No. of Carbons	Hazard Value for Chronic Aquatic Toxicity
SN-23-0004 (PFNA, 9)	Unknown, using HC_5 value of 0.033 mg/L as Read Across
SN-23-0005 (PFDA, 10)	Unknown, using HC_5 value of 0.033 mg/L as Read Across
SN-23-0006 (PFuDA, 11)	Unknown, using HC_5 value of 0.033 mg/L as Read Across
SN-23-0003 (PFDoA, 12)	Unknown, using HC_5 value of 0.033 mg/L as Read Across
SN-23-0009 (PFTrDA, 13)	Unknown, using HC_5 value of 0.033 mg/L as Read Across
SN-23-0008 (PFTeDA, 14)	Unknown, using HC_5 value of 0.033 mg/L as Read Across
SN-23-00010 (PFHxDA, 16)	Unknown, using HC_5 value of 0.033 mg/L as Read Across
SN-23-0011 (PFODA, 18)	Unknown, using HC_5 value of 0.033 mg/L as Read Across

3.4.2 Toxicity to Human Health

PFAS present a significant concern for human health based on growing epidemiological and laboratory animal study evidence, widespread and persisting presence in the environment, and the tendency to bioaccumulate (Brendel et al. 2018, Scheurer and Nödler 2021, Evich et al. 2022). In laboratory animal studies, PFAS have been shown to lead to reproductive, developmental, liver, kidney and immunological toxicity, as well as cancer (ITRC, 2023). Humans can be more sensitive to PFAS compared to rodents as health effects are observed in humans at doses below those eliciting adverse effects in animal toxicology studies (ITRC, 2023). PFAS exposure has been associated with human health outcomes including increased cholesterol levels as well as evidence for decreased infant and fetal growth, decreased immune response, cancer and thyroid hormone disruption (US EPA 2016a; NAS, 2022; US EPA,2016b). In addition, some PFAS have been shown to cause adverse respiratory effects following acute inhalation exposure (PubChem, 2022).

The EPA New Chemicals Program assessed toxicity to human health for the nine SNUN substances based on available toxicological information for eight of the nine SNUN substances and an analogous substance for one of the SNUN substances (PFTrDA). EPA primarily relied on available human health toxicity information from EPA assessments and the ITRC website (ITRC, 2023) for five of the SNUN substances. For three SNUN substances, EPA identified animal studies in the literature (Hirata-Koizumi et al., 2012, 2015) with relevant human health toxicity information. See the following paragraphs and Table 7 for details.

The available data on perfluorocarboxylic acids (PFCAs) are largely limited to PFOA (8 carbons, SN-23-0002), PFNA (9 carbons, SN-23-0004), and PFDA (10 carbons, SN-23-0005). PFOA and PFDA have EPA-reviewed toxicity assessments that have been made public. PFNA has been reviewed by the Agency for Toxic Disease Registry (ATSDR), the EPA Office of Water (publicly in a proposed rule), and is currently under review with the EPA IRIS program.

[redacted]

For PFOA, EPA relied on the extensive review of the data available in the interim drinking water health advisory document from EPA's Office of Water (US EPA, 2022a). PFNA is reviewed extensively in ATSDR, 2021, as well as in a health-based maximum contaminant level support document from the New Jersey Drinking Water Quality Institute (NJ DWQI, 2015). In addition, EPA has issued a preliminary regulatory determination to regulate PFNA as a contaminant under the Safe Drinking Water Act (PFAS National Primary Drinking Water Regulation Rulemaking, 2023), with a health-based water concentration also based on the ATSDR findings (ATSDR, 2021, as cited in US EPA, 2023d). Finally, for PFNA, EPA is currently developing a draft IRIS toxicity assessment scheduled to be released for public comment and peer review in the first quarter of 2024. [21] For PFDA, there is a draft EPA IRIS toxicological review containing an extensive literature review that has been released for public comment (US EPA 2023b).

There are limited data available on PFuDA (11 carbons, SN-23-0006), PFDoA (12 carbons, SN-23-0003), PFTeDA (14 carbons, SN-23-0008), PFHxDA (16 carbons, SN-23-0010) and PFODA (18 carbons, SN-23-0011). There are no data available for PFTrDA (13 carbons, SN-23-0009). For SN-23-0009, EPA selected analogues based on both availability of data and structural similarity. PFDoA (12 carbons) and PFTeDA (14 carbons) represent good, primary analogues as they bracket the carbon chain length of PFTrDA (13 carbons). Also, the available information on the remaining six SNUN substances provides evidence of concerns for developmental, reproductive, and/or chronic toxicity to substantiate a T2 score for PFTrDA.

The criteria for determining a human health T score of 2 is the identification of developmental, reproductive and/or chronic hazards, typically using human data or animal studies, and can be based on the submitted chemical substance and/or analogues. Key hazards identified by the New Chemicals Program as the basis for a T score of 2 for each SNUN substance are listed in Table 7. EPA notes that the evidence provided is sufficient for a T score of 2, however additional hazard evidence for each SNUN substance is available in the cited documents. While EPA performed a qualitative assessment, some POD values identified by EPA are presented in Table 7 to illustrate the potency of the toxicity for the three well-studied SNUN substances (i.e., PFOA, PFNA and PFDA). However, the PODs were not used to determine a T-score nor for quantitative purposes in this assessment

In addition to the hazards identified for each SNUN substance individually, EPA notes the nine SNUN substances are present together (i.e., co-exist) both within the matrix of the HDPE container as well as in the contents of the container as part of a PFAS mixture that also likely includes short-chain PFAS coproducts. As described in section 2.4, some dose additive effects are expected based on similarity in structure and known overlap in toxicities of both short- and long-chain PFAS present in the fluorinated containers (US EPA, 2023c, Fenton et al., 2021; for examples of dose additive effects, see Addicks et al., 2023; Dale et al., 2022; Marques et al.,

[21] The ATSDR Minimum Risk Level (MRL) for PFNA was used by Inhance in their risk assessment. The proposed EPA's Office of Water proposed PFAS National Primary Drinking Water Regulation rulemaking incorporating final MCLs for several PFAS is scheduled to be finalized in 2024 (88 FR 18638; March 29, 2023).

[redacted]

2021). The T scores for each of the SNUN substances do not account for potential dose additive effects.

Table 7: Basis for Human Health Toxicity Score for PBT Designation

Case Number (Chemical, Abbr., No. of Carbons)	***Primary Basis for Human Health T score*** and associated point of departure	Human Health T Score
SN-23-0002 (PFOA, 8)	***Developmental immune effect*** in children (Grandjean et al., 2012, and Budtz-Jørgensen and Grandjean, 2018, as cited in US EPA, 2022), the basis for Office of Water's interim reference dose (RfD) of 1.5×10^{-9} mg/kg-bw/day	T2
SN-23-0004 (PFNA, 9)	***Decreased body weight and developmental delays*** (Das et al., 2015, as cited in ATSDR, 2021) are the basis for ATSDR's minimal risk level of 3×10^{-6} mg/kg-bw/day (this is the toxicity value used by Inhance, see section 2.5, and used in the EPA Office of Water proposed rule (US EPA, 2023d)).	T2
SN-23-0005 (PFDA, 10)	***Developmental immune effect and decreased birth weight in children*** (Grandjean et al., 2012, Budtz-Jørgensen and Grandjean, 2018, and Wikström et al., 2020, as cited in US EPA 2023b), the basis for the proposed IRIS developmental RfD of 4×10^{-10} mg/kg-bw/day	T2
SN-23-0006 (PFuDA, 11)	***Decrease in neonatal weight and a decrease in postnatal weight gain*** observed in a developmental toxicity study in rats (Takahashi et al., 2014 as cited in ITRC Table 17-8)	T2
SN-23-0003 (PFDoA, 12)	***Full litter resorptions, decreased litter size, decreased number of live pups at birth and other effects*** observed in a rat developmental toxicity study (Kato et al., 2015a in Table 17-8 in ITRC).	T2
SN-23-0009 (PFTrDA, 13)	The New Chemicals Program used ***PFOA*** as an analogue based on structure and substantial availability of data; PFDoA, ***PFTeDA, PFHxDA, PFODA*** are also used as analogues based on closer structural and the availability of some data. Collectively, these data provide evidence for the T2 call.	T2
SN-23-0008 (PFTeDA, 14)	***Liver effects (increased liver weight, centrilobular hepatocyte hypertrophy and microgranulomas), thyroid effects (decreased thyroid weight and follicular cell hypertrophy) and decreased pup weight gain, as well as decreased absolute seminal vesicle weight in males and decreased pituitary gland weight*** observed in a repeated dose reproductive/developmental toxicity study (Hirata-Koizumi et al., 2015).	T2
SN-23-0010 (PFHxDA, 16)	***Liver effects (increased liver weight, centrilobular hepatocyte hypertrophy and fatty change), thyroid effects (increased thyroid weight, decreased T3 and T4), decreased adrenal weight and decreased pup weight gain*** observed in a repeated dose reproductive/developmental toxicity study (Hirata-Koizumi et al., 2015).	T2
SN-23-0011 (PFODA, 18)	***Liver effects (centrilobular hepatocyte hypertrophy and necrosis), reproductive/developmental effects (decrease in number of corpora lutea, implantation, total number of live pups and decreased pup weight)*** observed in a repeated dose reproductive/developmental toxicity study (Hirata-Koizumi et al., 2012).	T2

3.5 Final PBT Score for Each of the Nine SNUN Substances

Based on the analysis presented in Sections 3.1 through 3.4, the New Chemicals Program considers the nine SNUN substances identified in the SNUNs submitted by Inhance to be persistent, bioaccumulative and toxic (PBT) (Table 8).

[redacted]

Table 8: PBT Scores for the Nine SNUN Substances

SNUN Substance, Abbrev., No. of Carbons	Persistence Score	Bioaccumulation Score	Toxicity Score	Total PBT Score
SN-23-0002 (PFOA, 8)	P3	B*-high	T2	P3B*HT2
SN-23-0004 (PFNA, 9)	P3	B*-high	T2	P3B*HT2
SN-23-0005 (PFDA, 10)	P3	B*-high	T2	P3B*HT2
SN-23-0006 (PFuDA, 11)	P3	B*-high	T2	P3B*HT2
SN-23-0003 (PFDoA, 12)	P3	B*-high	T2	P3B*HT2
SN-23-0009 (PFTrDA, 13)	P3	B*-high	T2	P3B*HT2
SN-23-0008 (PFTeDA, 14)	P3	B*-high	T2	P3B*HT2
SN-23-00010 (PFHxDA, 16)	P3	B*-high	T2	P3B*HT2
SN-23-0011 (PFODA, 18)	P3	B*-high	T2	P3B*HT2

4 Environmental Release, Exposure Pathways and Environmental and Human Health Receptors

In the New Chemicals Program, the engineering assessment evaluates industrial/commercial releases to the environment and workplace (occupational) exposures. The exposure assessment covers exposure to the general population, consumers and aquatic species.

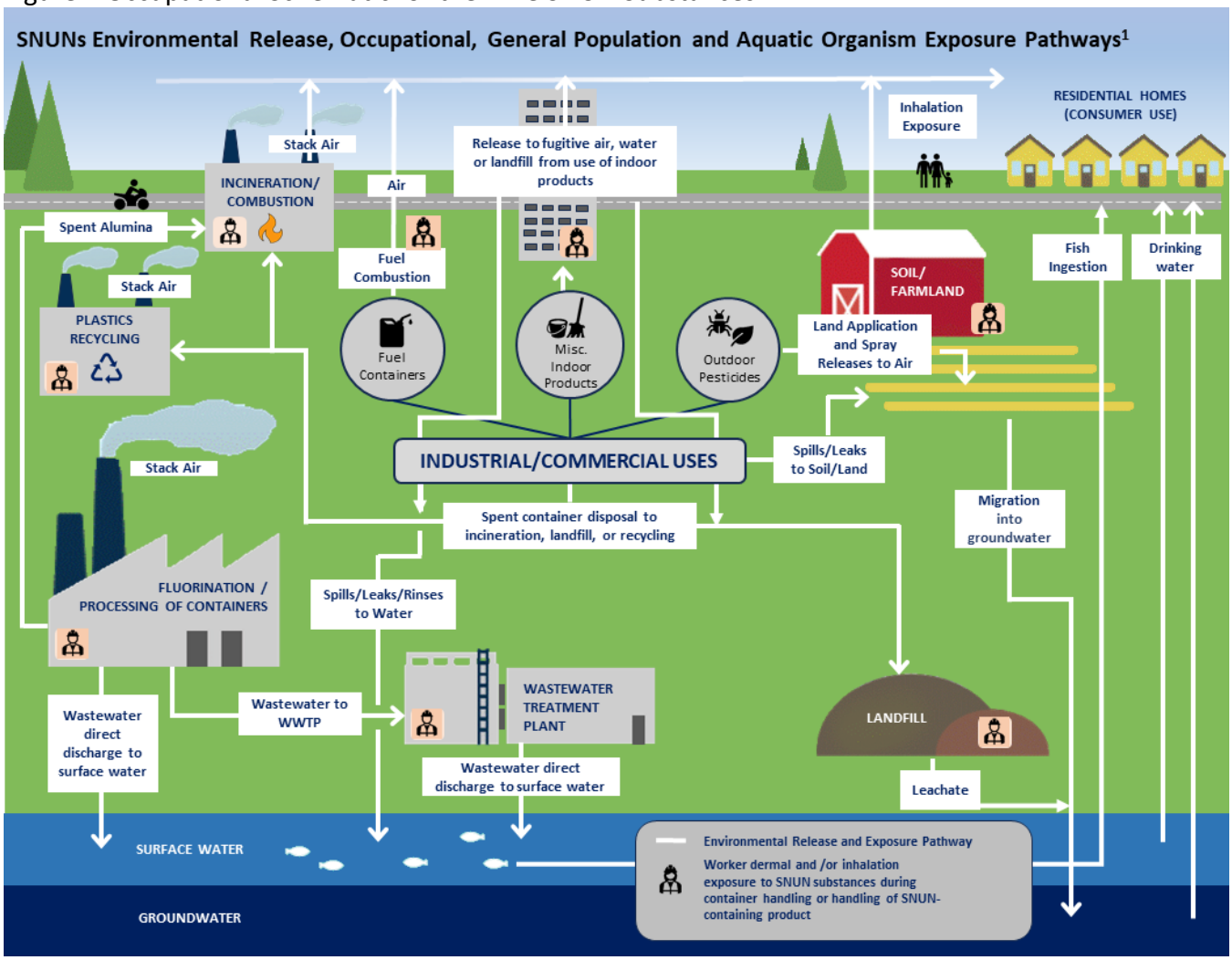
In this summary, as was noted in footnote 2 on page 1 (partially reproduced here[22]), use of "potential or expected" for environmental releases and exposures is a phrase used throughout this risk assessment document. This is to reflect that there is exposure to the nine SNUN substances from the manufacture, processing, use and/or disposal of Inhance fluorinated containers; it is only a matter of degree and level of certainty with respect to each individual SNUN substance, life cycle stage, exposure pathway, and receptor. As was done by Inhance in their risk assessments, there are many exposure scenarios to document and that is done in separate EPA reports (Engineering Reports and Exposure Reports available in the administrative record for this action).

In addition, according to slide #8 in Exhibit 9 submitted by Inhance on September 29, 2023, Inhance fluorinated approximately 121 million containers in 2021. This resulted in an estimated 75 million gallons of container contents and 25 million pounds of plastic. Assuming this is a normal year, it means that over 120 million containers are fluorinated each year and are available for distribution, use and disposal. EPA notes that Inhance's own press release from August 2023 states that it fluorinates over 200 million containers annually (Inhance 2023).

[22] Throughout this document, the terms "potential" or "expected," when referring to exposure, mean that, depending on the individual SNUN substance, life cycle stage (manufacture, distribution, use and disposal), exposure pathway, or receptor (humans or environmental organisms) there is either more or less uncertainty about exposure. Importantly, the use of either term means there is exposure, but it is a matter of the level of uncertainty in that finding. Details for each exposure scenario are in separate reports available in the administrative record for this action.

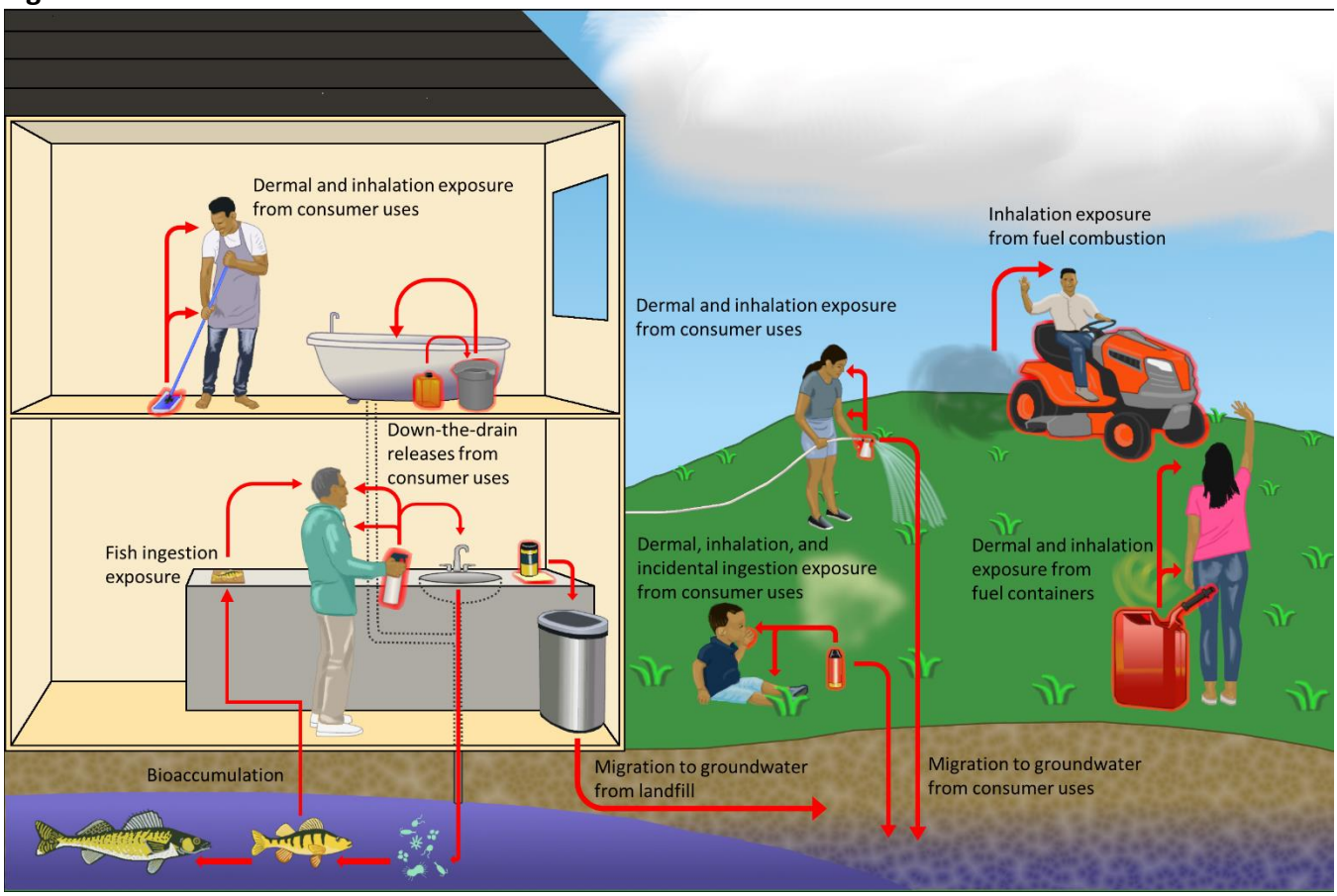
Two conceptual, schematic diagrams are provided in this section; one for environmental releases and occupational, general population, and aquatic organism exposure pathways (Figure 1) and the other for consumer exposures (Figure 2). These figures show many and different releases and exposures for the nine SNUN substances. The fluorinated containers are used in various commercial and consumer applications (fuel and non-fuel). Based on the wide variety of potential uses of the plastic containers fluorinated by Inhance, these schematics do not represent all of the potential or expected releases and exposure pathways from all the applications for the nine SNUN substances.

Figure 1 Occupational Schematic for the Nine SNUN Substances[1]



[1] Not all the release sources and exposure activities from all uses are shown on the diagram. Details of the specific release points and exposure activities are described in the Engineering and Exposure Reports for these chemicals provided under the respective releases and exposures summary table later in this section. Graphics adapted from: PFAS Water Cycle. United States Environmental Protection Agency. October 2022. https://www.epa.gov/system/files/documents/2022-10/pfas-water-cycle-508-friendly_0.pdf

Figure 2 Consumer Schematic for the Nine SNUN Substances



Based on the wide variety of potential uses of the plastic containers fluorinated by Inhance, this schematic does not represent all of the potential exposure pathways for the nine SNUN substances from the containers fluorinated by Inhance.

Consistent with the *PFAS Framework*, the New Chemicals Program will not be quantifying risk (exposure and hazard) for PBT PFAS due to the likelihood that a quantitative risk assessment would underestimate risk and thus not be protective of human health and the environment. A quantitative assessment would provide only a "snapshot" of the exposure at one point in time and would not precisely and accurately reflect the overall environmental and human health risk posed by these chemicals that bioaccumulate over time (see section 1.2.2). This section identifies the environmental media of release and potential or expected exposures to human (workers, the general population and consumers) and ecological receptors of concern.

All of the SNUN substances are PFAS substances that are expected to be formed during the fluorination process of HDPE containers. Potential or expected releases and exposure occur during manufacture, processing, use and disposal (of the containers or its contents). In addition, as pointed out in Sections 2 and 3, EPA also expects other PFAS besides the nine SNUN substances to be formed during the fluorination process. The tables in this section provide an overview of the media of environmental release and exposure (including exposure pathways, and human and environmental receptors) (see Tables 9 and 10 for the fuel storage container use; Tables 11 and 12 for the other (non-fuel) storage container uses).

[redacted]

4.1 Fuel Storage Container Use

Based on a qualitative engineering assessment performed using information provided in the Inhance submission and the physical and chemical properties of the nine SNUN substances, EPA determined that there are potential or expected environmental releases from manufacturing (to air, water, incineration[23]), processing (to air and water), use (to air, water, combustion in engines, land), and end of life disposal (to air, incineration and landfill) of fuel storage containers and tanks where the nine SNUN substances are present as byproducts (Table 9). There is also potential or expected dermal exposure for workers to the nine SNUN substances from fluorinated portable fuel containers, or liquid fuel containing SNUN substances, and for inhalation exposure to workers (Table 9).

Table 9: Environmental Release and Occupational Exposures (Fuel Storage Container Use)[a]

Potential or Expected Environmental Release Media and Occupational Exposure Pathways[b]			
Operation	**Use Description**	**Media of Release (Air, Water, Land, Incineration, Landfill)**	**Worker Exposure Pathway (Inhalation, Dermal)**
Manufacturing (at [redacted] Inhance sites)	The nine SNUN substances are byproducts of the fluorination of fuel storage containers and fuel tanks used in small combustion engines, ground-supported small engines, small motorsport engines, and marine engines.	Air (stack and fugitive), Water from Pressure/Leak testing (via WWTP[c]), Incineration	Inhalation, Dermal
Processing (Unknown Sites, number not specified)		Air (fugitive only), Water (from pressure/leak testing)	
Commercial Use		Air (fugitive), Water (spills and leaks), Incineration (from combustion of fuel), Land/Soil (from spills and leaks)	
End of Life		Air, Incineration, Landfill – all from handling, recycling process and disposal	

[a] Based on the engineering report – see "Engineering Assessment for Fuel Storage Containers and Fuel Tanks Uses" in the administrative record for this action.
[b] For the SNUN substances that are not considered volatile by the EPA, releases to fugitive air and resultant exposure during manufacturing and processing are not expected. See details in the engineering report.
[c] WWTP – wastewater treatment plant.

Based on the qualitative exposure assessment performed using information from the Inhance submission and the physical and chemical properties of the SNUN substances, EPA determined that there is potential or expected human health exposures to the general population via drinking

[23] See Table 9, Media of Release column for a more detailed description of whether a release is from incineration, combustion, or fugitive.

[redacted]

water, fish ingestion, groundwater impacted by landfill leachate, and inhalation of air impacted by fugitive emissions and stack emissions[24], including emissions from incinerators (Table 10). EPA also determined that there are potential or expected exposures to environmental receptors (aquatic organisms) via releases to surface water (Table 10). In addition, there is potential or expected consumer exposures via dermal and inhalation pathways from the use of fluorinated storage containers and fuel tanks where the nine SNUN substances are present (Table 10). Exposure to the general population and aquatic organisms resulting from Down the Drain disposal is not expected related to fuel storage container use.

Table 10: General Population, Consumer, and Environmental Exposures (Fuel Storage Container Use)

Potential or Expected General Population, Consumer and Environmental Exposure Pathways[a]				
Operation	**Use Description**	**Exposure Group**	**Media of Release (Air, Water, Land, Incineration, Landfill)**	**Exposure Pathway (Inhalation, Ingestion, Dermal) and Environmental Receptors (Aquatic Organisms)**
Manufacturing	The nine SNUN substances are byproducts of the fluorination of fuel storage containers and fuel tanks used in small combustion engines, ground-supported small engines, small motorsport engines, and marine engines.	General Population, Environmental Receptors	Air (stack and fugitive*), Water, Incineration	Inhalation*, Ingestion, Aquatic Organisms
Processing (On others site)		General Population, Environmental Receptors	Air (fugitive*), Water	Inhalation*, Ingestion, Aquatic Organisms
Commercial Use 1a		General Population, Environmental Receptors	Air (fugitive), Water, Incineration (from fuel combustion), Land	Inhalation, Ingestion, Aquatic Organisms
End of Life		General Population	Air (fugitive), Incineration, Landfill	Inhalation, Ingestion
Consumer Use		Consumer	Air, Incineration (from fuel combustion)	Inhalation, Dermal

[a] Based on the exposure report – see "Exposure Assessment for Fuel Storage Containers and Fuel Tank Uses" in the administrative record for this action.
*For the SNUN substances that are not considered volatile by the EPA, fugitive air emissions and resultant inhalation exposures are not expected during Manufacturing or Processing. See the engineering and exposure assessments for more detail.

[24] Stack air emissions are point source or directed air streams (i.e., coming out of a stack). Fugitive emissions are non-directed air streams (such as valve leaks, evaporation loss from tanks, etc.).

[redacted]

4.2 Non-Fuel Storage Container Use

Based on a qualitative engineering assessment performed using information provided in the Inhance submission and the physical and chemical properties of the nine SNUN substances, EPA determined that there are potential or expected environmental releases from manufacturing (to air and incineration), from processing (to air), from commercial use (to air, water, land and landfill) and from end of life disposal (to air, incineration and landfill) of storage containers used in miscellaneous applications where the nine SNUN substances are present as byproducts (Table 11). Depending on the process/lifecycle stage and physicochemical properties, there is potential or expected worker exposure to the nine SNUN substances, via dermal pathways from fluorinated product containers, or from liquid products containing SNUN substances, and via inhalation pathways as vapor and mist (Table 11).

Table 11: Environmental Release and Occupational Exposures (Non-Fuel Storage Container Use)[a]

Potential or Expected Environmental Release Media and Occupational Exposure[b,c]			
Operation	**Use Description**	**Media of Release (Air, Water, Land, Incineration, Landfill)**	**Worker Exposure Pathway (Inhalation, Dermal)**
Manufacturing (at [redacted] Inhance sites, [redacted] specifically identified)	The nine SNUN substances are byproducts of the fluorination of storage containers used in various applications: household [redacted], trigger-spray pesticides and [redacted], commercial pesticides, and [redacted].	Air (stack and fugitive), Incineration	Inhalation, Dermal
Processing (no details on the operations of Inhance customers)		Air (fugitive only)	
Commercial Use 1A, Indoor		Air, Water, Landfill	
Commercial Use 1B, Outdoor		Air, Land	
End of Life		Air, Incineration, Landfill – all from handling, recycling process and disposal	

[a] There was no information in the submission for industrial chemical storage application.
[b] Based on the engineering report – see "Engineering Assessment for Containers Used in Various Commercial-Industrial Applications" in the administrative record for this action.
[c] For the SNUN substances that are not considered volatile by the EPA, releases to fugitive air and resultant exposure during manufacturing and processing are not expected. See the detail in the engineering report.

Based on the qualitative exposure assessment performed using information from the Inhance submission and the physical and chemical properties of the SNUN substances, EPA determined that there is potential or expected exposure to the general population via drinking water, fish ingestion, groundwater impacted by land/landfill leachate, and via inhalation from air impacted by fugitive emissions and stack emissions, including emissions from incinerators. In addition, exposure to the

[redacted]

general population is expected via indirect dermal contact and incidental ingestion from pesticide spray applications (Table 12). EPA also determined that there are potential or expected exposures to environmental receptors (aquatic organisms) via releases to surface water and as a result of pesticide spray drift and runoff (Table 12). In addition, there is potential or expected consumer exposure via dermal and inhalation pathways from container handling and using various household products contained in the non-fuel storage containers where the nine SNUN substances are present (Table 12). Releases to water from Down the Drain disposal of consumer products (e.g., [redacted], etc.) into household wastewater are expected, which is in alignment with the conceptual exposure model provided by the submitter (Figure 3, page 39, Attachment 012). Therefore, the general population is expected to be exposed via drinking water and fish ingestion, and environmental exposure to aquatic organisms is expected.

Table 12: General Population, Consumer, and Environmental Exposures (Non-Fuel Storage Container Use)

Potential or Expected General Population, Consumer, and Environmental Exposure Pathways[a]				
Operation	**Use Description**	**Exposure Group**	**Media of Release (Air, Water, Land, Incineration, Landfill)**	**Exposure Pathway (Inhalation, Ingestion, Dermal) and Environmental Receptors (Aquatic Organisms)**
Manufacturing (at [redacted] Inhance sites, [redacted] specifically identified)	The nine SNUN substances are byproducts of the fluorination of storage containers used in various applications, household [redacted], trigger-spray pesticides and [redacted], commercial pesticides, and [redacted]	General Population	Air (stack and fugitive*), Incineration	Inhalation*
Processing (no details on the operations of Inhance customers)		General Population	Air (fugitive*)	Inhalation*
Commercial USE 1A, Indoor		General Population, Environmental Receptors	Air (fugitive*), Water, Landfill	Inhalation*, Ingestion, Aquatic Organisms
Commercial USE 1B, Outdoor		General Population, Environmental Receptors	Air (fugitive/spray drift), Land, Water (spray drift and runoff)	Inhalation, Dermal, Ingestion, Aquatic Organisms
End of Life		General Population	Air (fugitive), Incineration, Landfill	Inhalation, Ingestion
Consumer Use		Consumer, General Population, Environmental Receptors	Air, Land, Water	Inhalation, Dermal, Ingestion, Aquatic Organisms

[redacted]

Potential or Expected General Population, Consumer, and Environmental Exposure Pathways[a]				
Down the Drain		General Population, Environmental Receptors	Water	Ingestion, Aquatic Organisms

[a] Based on the exposure report – see "Exposure Assessment for Containers Used in Various Commercial/Industrial and Consumer Applications" in the administrative record for this action.
*For the SNUN substances that are not considered volatile by the EPA, fugitive air emissions and resultant inhalation exposures are not expected during Manufacturing, Processing, or Commercial Use1A. See the engineering and exposure assessments for more detail.

5 Conclusions

Inhance submitted two consolidated SNUNs for a total of nine chemical substances formed as byproducts from the fluorination of plastic containers (fuel and non-fuel containers). Seven of the nine substances are existing chemicals included on the TSCA Inventory (the exceptions are SN-23-0006 and SN-23-0009). All of the nine SNUN substances are long-chain perfluoroalkyl carboxylic acids ranging from 8-18 carbons long. The nine SNUN substances co-exist on the surface of the container walls, embedded within the container wall, and (via leaching or migration) in the liquid contents of the fluorinated container.

In their submitted risk assessments, Inhance claims - using conventional risk assessment methods – that there are no risks to workers, the general population, or environmental organisms from the fluorination of their HDPE containers. This is based on Inhance identifying hazard values from various sources as points of departure (PODs) and providing estimates (with some measured data) for exposure values for a number of scenarios. There are different interpretations regarding the most appropriate PODs to be used to develop hazard values/reference doses for certain PFAS—for example, in other contexts, EPA has identified PODs for PFOA and PFDA that are 2,000- and 37,500-fold lower, respectively, than the PODs used in Inhance's risk assessments. Inhance's risk assessments did not address why its chosen PODs are the most appropriate. Use of EPA's PODs for PFOA and PFDA in Inhance's risk assessment methodology rather than those used by Inhance results in 80% of evaluated scenarios for the SNUN substances showing risks of concern (see narrative and footnotes in Sections 1.2.2 and 2.5).

Irrespective of the hazard values used, the fact remains that exposures will occur and be widespread due to the extremely large number of containers that Inhance fluorinates annually (i.e., approximately 121 million containers that Inhance fluorinated in 2021 (Exhibit 9, Inhance submission on 9/29/23) up to "more than 200 million plastic articles annually" (as described in Inhance August 2023 press release)) and which were distributed, used and disposed of. Although there is uncertainty in the amount of the nine SNUN substances that are manufactured as byproducts during the fluorination process, the fact is that they are formed and do exist. Such exposures, due to the persistent, bioaccumulative and toxic (PBT) nature of the nine SNUN substances, will contribute to the burden of

[redacted]

PFAS that currently exist in people and the environment and will continue to accumulate over time. There is ample evidence for this accumulation in the existence of seven of the SNUN substances (especially the highly toxic PFOA, PFNA, and PFDA) in human serum (see NHANES and other data, Sections 1.2.2 and 2.6) and for several of the SNUN substances in fish tissue (see fish tissue data, Section 1.2.2).

The available evidence shows that all nine SNUN substances are persistent, bioaccumulative, and toxic (PBT) using the scoring system explained in Section 3 (see section 3.5 for scores). Each of the nine SNUN substances contains multiple C-F bonds, which are extremely stable, and each is anticipated to be extremely persistent and rated P3 (see Section 3.1). Because all nine SNUN substances are long-chain PFAS, a class of chemicals with extensive data indicating they bioaccumulate in humans and fish tissue, all are expected to bioaccumulate and are rated B*high (Section 3.2). Based on their chemical structures, none of the nine SNUN substances are expected to degrade under normal environmental conditions.

Ecological hazards were identified in a species sensitivity distribution (SSD) analysis for chronic effects from PFOA exposure to 24 species from 8 taxonomic groups, including primary producers, fishes, amphibians, crustaceans, rotifers, mollusks, insects, and other invertebrates. The SSD was submitted by Inhance and EPA accepted it. Both Inhance and EPA found the PFOA data would be an acceptable analogue for the other eight SNUN substances and all of the SNUN substances are considered toxic to aquatic life. Based on the EPA criteria for chronic toxicity concern for aquatic organisms, all nine are rated T2 for ecological hazard (see Section 3.4.1). However, the appropriate and available environmental organism toxicity data are on only one of the nine SNUN substances (PFOA); showing a lack of robust environmental toxicity information for the other eight SNUN substances.

Identified human health hazards include systemic, reproductive, developmental and carcinogenic effects. Based on the best available information, including information submitted by Inhance, toxicity information supports a human health toxicity score of T2 for each of the nine SNUN substances (see Section 3.4.2). In fact, one of the SNUN substances (PFOA) has long been the focus of studies related to PFAS and is extremely toxic and persistent, with a half-life in humans of approximately 2-3 years. The other two SNUN substances with substantial available data (PFNA and PFDA) are also highly toxic. Although some toxicity data are available for five of the other SNUN substances (PFTrDA lacks toxicity data), collectively there is a lack of the appropriate toxicity information for this group of PFAS to inform hazard and possible dose-response/bioaccumulation information in humans. This overall lack of sufficient information – coupled with the available information on some PFAS - is indicative of the general concern for PFAS and their unique toxicity characteristics in terms of potency, persistence and bioaccumulation.

In line with the EPA New Chemicals Program PBT Policy (US EPA, 1999) and consistent with the recently released US EPA PFAS Framework (US EPA, 2023a), the New Chemicals program concludes that each of the nine SNUN substances are PBT substances, which means they are expected to accumulate over time in the environment, humans and environmental organisms.

The nine SNUN substances leach or are released into the contents of the fluorinated containers over time through regular use of the containers, including use of the containers for storage. The existence of

these nine SNUN substances on and/or in the fluorinated plastic containers – and the eventual leaching into the contents of the fluorinated containers – results in releases and exposures. Exposure to the nine SNUN substances is expected during the manufacture, processing, distribution, use and disposal of the fluorinated containers that contain these nine SNUN substances. Based on the current fluorination process and the diverse uses of the millions of fluorinated containers, and consistent with the PFAS Framework, releases to the environment of the SNUN substances produced as byproducts during Inhance's fluorination process are expected to be unavoidable and, because of the numerous and diverse pathways for exposure to these SNUN substances – especially to consumers - exposure will occur to these persistent, bioaccumulative and toxic chemicals.

There is also expected to be an additive hazard and exposure concern because the nine SNUN substances co-exist. Additionally, though the SNUNs and this analysis are limited to the nine SNUN substances, there is evidence that other potentially hazardous PFAS are formed during the fluorination process (see Section 1.2.2.). Due to the additive and compounding exposures, there is added concern for this type of byproduct formation and the release and potential exposure of PFAS to human health and the environment.

Consistent with the recently released PFAS Framework, the New Chemicals Program concludes there is risk from the manufacture, distribution, use, and disposal of the nine SNUN substances based on the PBT nature of the nine SNUN substances and the potential or expected exposures to workers, the general population, consumers and environmental organisms. Because these nine SNUN substances are PBTs, they are expected to accumulate over time. Three of the SNUN substances, PFOA, PFNA and PFDA, are extremely toxic. Seven of the SNUNs have been detected in US human serum samples (PFOA, PFNA, PFDA, PFuDA, PFDoA, PFTrDA, and PFTeDA). There are substantial scientific limitations on quantifying risk for bioaccumulative substances. Current quantitative risk assessments for such substances consider risk at only a single point in time; as was done in the risk assessments submitted by Inhance. Thus, Inhance's quantitative risk assessment underestimates the risk due to the unquantified buildup of the nine SNUN substances (for both toxicity and exposure) over time. In addition, as noted in Section 2.4 of this document, additional risks may be associated with existing levels of PFAS in both the environment and human serum (i.e., background levels of PFAS) and possible additive effects from exposures to the nine SNUN substances together.

6 Potentially Useful Information

"Potentially useful information" is a term used to describe those data gaps that, if filled with case-specific information, may reduce uncertainty and provide a more accurate PBT assessment for a premanufacture notice or significant new use notice. The case-specific information refers to information on both compound and components of interest considered in an assessment, which may include expected degradation, hydrolysis and incineration products. The goal of testing requirements for the New Chemical Program is to obtain empirical data with case-specific information, which can be used to remove uncertainties in the risk assessment and better inform the risk management approach.

A tiered testing approach is used to facilitate evaluation of PFAS substances in the New Chemicals Program, in alignment with the PFAS Framework (US EPA, 2023a) and the National PFAS Testing Strategy (US EPA, 2021b). There are two tiers - with Tier 1 testing aimed at collecting information on

[redacted]

physical chemical properties, genetic toxicity and toxicokinetics; and in some cases in vitro dermal absorption studies. Tier 2 includes testing to provide additional information on bioaccumulation potential and repeat dose testing. Tier 1 physical chemical properties and toxicokinetics testing will also inform the choice and design of toxicity studies. The potentially useful information for SN -23-0002-0006 and SN-23-0008-0011, based on this risk assessment, is outlined in Table 13 in this section, based on the tiered testing approach.

In Appendix A, the purpose of each study is identified to guide higher tier testing and to inform the risk management approach. Where sufficient information are available, including where information submitted by Inhance was sufficient, testing is noted as *not applicable* in these appendix tables.

[redacted]

Table 13: Summary of Potentially Useful Information for Each SNUN Substance (a full outline of Potentially Useful Information, including descriptions of dependencies and the purpose of each study is provided in Appendix A)

Case Number (Chemical Name, Chemical Abstracts Service Registry Number)	Tier 1 Studies (Test Guideline)	Tier 2 Studies (Test Guideline)
SN-23-0002 perfluorooctanoic acid (PFOA) CASRN 335-67-1	• Hydrolysis (OECD TG 111; including at pH 2) • K_{oc} (OECD TG 106 or OECD TG 121) • Surface tension of aqueous solution (OECD 115) • Micelle assembly (CMC; Hafta JJH et al 2016; ISO 4311)	• Avian reproduction (OCSPP 850.2300)

SN-23-0004
perfluorononanoic acid (PFNA)
CASRN 375-95-1
	• Water solubility (OECD TG 105)
	• K_{ow} (OECD TG 107)
	• Boiling Point (OECD 103)
	• Hydrolysis (OECD TG 111;including at pH 2))
	• K_{oc} (OECD TG 106 or OECD TG 121)
	• Surface tension of aqueous solution (OECD 115)
	• Micelle assembly (CMC; Hafta JJH et al 2016; ISO 4311)
	• Henry's Law Constant (Ji C, et al. 2007, and Sander R, et al. 2022)
	• Bacterial Reverse Mutation Test (OECD TG 471)
	• One of the following genetic toxicity tests:
	  ○ In Vitro Mammalian Chromosomal Aberration Test (OECD 473)
	  ○ In Vitro Mammalian Cell Micronucleus Test (OECD 487)
	  ○ In Vitro Mammalian Cell Gene Mutation Test (OECD 490)
	• Dermal absorption (in vitro) (OECD TG 428)
		• Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422) ((using mice)
		• Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Chronic study for sediment dwelling organisms (OECD 233) (Dependent on OECD TG 105)
		• Avian reproduction (OCSPP 850.2300)

SN-23-0005 perfluorodecanoic acid (PFDA) CASRN 335-76-2	• Kow (OECD TG 107) • Hydrolysis (OECD TG 111; including at pH 2) • K_{oc} (OECD TG 106 or OECD TG 121) • Surface tension of aqueous solution (OECD 115) • Micelle assembly (CMC; Hafta JJH et al 2016; ISO 4311) • Dermal absorption (in vitro) (OECD TG 428)	• Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) • Chronic study for sediment dwelling organisms (OECD 233) • Avian reproduction (OCSPP 850.2300)
SN-23-0006 perfluoroundecanoic acid (PFuDA)	• K_{ow} (OECD TG 107) • Boiling Point (OECD 103) • Melting Point (OECD TG 102)	• Combined repeated dose toxicity study with reproduction/developmental toxicity screening

Case Number (Chemical Name, Chemical Abstracts Service Registry Number)	Tier 1 Studies (Test Guideline)	Tier 2 Studies (Test Guideline)

CASRN 2058-94-8	• Hydrolysis (OECD TG 111; including at pH 2)
	• K_{oc} (OECD TG 106 or OECD TG 121)
	• Surface tension of aqueous solution (OECD 115)
	• Micelle assembly (CMC; Hafta JJH et al 2016; ISO 4311)
	• Henry's Law Constant (Ji C, et al. 2007, and Sander R, et al. 2022)
	• Dermal absorption (in vitro) (OECD TG 428)
	• Bacterial Reverse Mutation Test (OECD TG 471)
	• One of the following genetic toxicity tests:
	  ○ In Vitro Mammalian Chromosomal Aberration Test (OECD 473)
	  ○ In Vitro Mammalian Cell Micronucleus Test (OECD 487)
	  ○ In Vitro Mammalian Cell Gene Mutation Test (OECD 490)
	• Toxicokinetics in rats and mice (OECD TG 417)
		test (OECD TG 422) (Dependent on OECD TG 417 study)
		• Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201)
		• Chronic study for sediment dwelling organisms (OECD 233)
		• Avian reproduction (OCSPP 850.2300)

SN-23-0003
perfluorododecanoic acid (PFDoA)
CASRN 307-55-1
	• Water solubility (OECD 105)
	• K_{ow} (OECD TG 107)
	• Hydrolysis (OECD TG 111; including at pH 2))
	• K_{oc} (OECD TG 106 or OECD TG 121)
	• Surface tension of aqueous solution (OECD 115)
	• Micelle assembly (CMC; Hafta JJH et al 2016; ISO 4311)
	• Dermal absorption (in vitro) (OECD TG 428)
	• Bacterial Reverse Mutation Test (OECD TG 471)
	• One of the following genetic toxicity tests:
	  ○ In Vitro Mammalian Chromosomal Aberration Test (OECD 473)
	  ○ In Vitro Mammalian Cell Micronucleus Test (OECD 487)
	  ○ In Vitro Mammalian Cell Gene Mutation Test (OECD 490)
	• Toxicokinetics in rats and mice (OECD TG 417)
		• Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422) (Dependent on OECD TG 417 study and existing information with rats)
		• Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Chronic study for sediment dwelling organisms (OECD 233) (Dependent on OECD TG 105)
		• Avian reproduction (OCSPP 850.2300)

SN-23-0009 perfluorotridecanoic acid (PFTrDA) CASRN 72629-94-8	• Water solubility (OECD 105) • K_{ow} (OECD TG 107) • Vapor Pressure (OECD TG 104) • Boiling Point (OECD 103)	• Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)

Case Number (Chemical Name, Chemical Abstracts Service Registry Number)	Tier 1 Studies (Test Guideline)	Tier 2 Studies (Test Guideline)

	• Hydrolysis (OECD TG 111; including at pH 2)
	• K_{oc} (OECD TG 106 or OECD TG 121)
	• Surface tension of aqueous solution (OECD 115)
	• Micelle assembly (CMC; Hafta JJH et al 2016; ISO 4311)
	• Henry's Law Constant (Ji C, et al. 2007, and Sander R, et al. 2022)
	• Dermal absorption (in vitro) (OECD TG 428)
	• Bacterial Reverse Mutation Test (OECD TG 471)
	• One of the following genetic toxicity tests:
	  ○ In Vitro Mammalian Chromosomal Aberration Test (OECD 473)
	  ○ In Vitro Mammalian Cell Micronucleus Test (OECD 487)
	  ○ In Vitro Mammalian Cell Gene Mutation Test (OECD 490)
	• Toxicokinetics in rats and mice (OECD TG 417)
		• Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Chronic study for sediment dwelling organisms (OECD 233) (Dependent on OECD TG 105)
		• Avian reproduction (OCSPP 850.2300)

SN-23-0008
perfluorotetradecanoic acid (PFTeDA)
CASRN 376-06-7
	• Water Solubility (OECD TG 105)
	• K_{ow} (OECD TG 107)
	• Vapor Pressure (OECD TG 104)
	• Hydrolysis (OECD TG 111; including at pH 2)
	• K_{oc} (OECD TG 106 or OECD TG 121)
	• Surface tension of aqueous solution (OECD 115)
	• Micelle assembly (CMC; Hafta JJH et al 2016; ISO 4311)
	• Dermal absorption (in vitro) (OECD TG 428)
	• Bacterial Reverse Mutation Test (OECD TG 471)
	• One of the following genetic toxicity tests:
	  ○ In Vitro Mammalian Chromosomal Aberration Test (OECD 473)
	  ○ In Vitro Mammalian Cell Micronucleus Test (OECD 487)
	  ○ In Vitro Mammalian Cell Gene Mutation Test (OECD 490)
	• Toxicokinetics in rats and mice (OECD TG 417)
		• Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422) (Dependent on OECD TG 417 study)
		• Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Chronic study for sediment dwelling organisms (OECD 233) (Dependent on OECD TG 105)
		• Avian reproduction (OCSPP 850.2300)

SN-23-0010 perfluorohexadecanoic acid (PFHxDA)	• Water solubility (OECD 105) • K_{ow} (OECD TG 107) • Vapor Pressure (OECD TG 104)	• Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422) (Applicable if in the OECD TG

[redacted]

Case Number (Chemical Name, Chemical Abstracts Service Registry Number)	Tier 1 Studies (Test Guideline)	Tier 2 Studies (Test Guideline)

CASRN 67905-19-5	• Hydrolysis (OECD TG 111; including at pH 2)
	• K_{oc} (OECD TG 106 or OECD TG 121)
	• Surface tension of aqueous solution (OECD 115)
	• Micelle assembly (CMC; Hafta JJH et al 2016; ISO 4311)
	• Dermal absorption (in vitro) (OECD TG 428)
	• Bacterial Reverse Mutation Test (OECD TG 471)
	• One of the following genetic toxicity tests:
	  ○ In Vitro Mammalian Chromosomal Aberration Test (OECD 473)
	  ○ In Vitro Mammalian Cell Micronucleus Test (OECD 487)
	  ○ In Vitro Mammalian Cell Gene Mutation Test (OECD 490)
	• Toxicokinetics in rats and mice (OECD TG 417)
		417, mice are determined to be the species with the longer half-life)
		• Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Chronic study for sediment dwelling organisms (OECD 233) (Dependent on OECD TG 105)
		• Avian reproduction (OCSPP 850.2300)

SN-23-0011
perfluorostearic acid (PFODA)
CASRN 16517-11-6)
	• Water solubility (OECD 105)
	• K_{ow} (OECD TG 107)
	• Vapor Pressure (OECD TG 104)
	• Hydrolysis (OECD TG 111; including at pH 2)
	• K_{oc} (OECD TG 106 or OECD TG 121)
	• Surface tension of aqueous solution (OECD 115)
	• Micelle assembly (CMC; Hafta JJH et al 2016; ISO 4311)
	• Dermal absorption (in vitro) (OECD TG 428)
	• Bacterial Reverse Mutation Test (OECD TG 471)
	• One of the following genetic toxicity tests:
	  ○ In Vitro Mammalian Chromosomal Aberration Test (OECD 473)
	  ○ In Vitro Mammalian Cell Micronucleus Test (OECD 487)
	  ○ In Vitro Mammalian Cell Gene Mutation Test (OECD 490)
	• Toxicokinetics in rats and mice (OECD TG 417)
		• Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422) (Applicable if in the OECD TG 417, mice are determined to be the species with the longer half-life)
		• Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Chronic study for sediment dwelling organisms (OECD 233) (Dependent on OECD TG 105)
		• Avian reproduction (OCSPP 850.2300)

7 REFERENCES

Addicks, G. C., Rowan-Carroll, A., Reardon, A. J. F., Leingartner, K., Williams, A., Meier, M. J., Moffat, I., Carrier, R., Lorusso, L., Wetmore, B. A., Yauk, C. L., & Atlas, E. (2023). Per- and polyfluoroalkyl substances (PFAS) in mixtures show additive effects on transcriptomic points of departure in human liver spheroids. *Toxicological sciences: an official journal of the Society of Toxicology*, 194(1), 38–52. https://doi.org/10.1093/toxsci/kfad044

ATSDR. (2021). Toxicological Profile for Perfluoroalkyls. U.S. Department of Health and Human Services. Public Health Service, Agency for Toxic Substances and Disease Registry, Atlanta, GA. https://www.atsdr.cdc.gov/toxprofiles/tp200.pdfBren del, S., Fetter, É., Staude, C., Vierke, L., & Biegel-Engler, A. (2018). Short-chain perfluoroalkyl acids: environmental concerns and a regulatory strategy under REACH. Environmental Sciences Europe, 30(1), 1-11.

Budtz-Jørgensen, E, Grandjean, P. (2018). Application of benchmark analysis for mixed contaminant exposures: Mutual adjustment of perfluoroalkylate substances associated with immunotoxicity. PLoS ONE 13: e0205388.

Dai, Z. & Zeng, F. (2019). Distribution and bioaccumulation of perfluoroalkyl acids in Xiamen coastal waters. *Journal of Chemistry*, 2019.

Dale, K., Yadetie, F., Horvli, T., Zhang, X., Frøysa, H. G., Karlsen, O. A., & Goksøyr, A. (2022). Single PFAS and PFAS mixtures affect nuclear receptor- and oxidative stress-related pathways in precision-cut liver slices of Atlantic cod (Gadus morhua). *The Science of the total environment*, 814, 152732. https://doi.org/10.1016/j.scitotenv.2021.152732

Das, K. P. , B. E. Grey, M. B. Rosen, C. R. Wood, K. R. Tatum-Gibbs, R. D. Zehr, M. J. Strynar, A. B. Lindstrom, and C. Lau. (2015). "Developmental toxicity of perfluorononanoic acid in mice." Reprod Toxicol 51:133-44. doi: 10.1016/j.reprotox.2014.12.012.

De Silva, A. O., Spencer, C., Scott, B. F., Backus, S., & Muir, D. C. (2011). Detection of a cyclic perfluorinated acid, perfluoroethylcyclohexane sulfonate, in the Great Lakes of North America. *Environmental Science & Technology*, *45*(19), 8060-8066.De Silva, A.O., Armitage, J.M., Bruton, T.A., Dassuncao, C., Heiger-Bernays, W., Hu, X.C., ... & Sunderland, E.M. (2021). PFAS exposure pathways for humans and wildlife: A synthesis of Current knowledge and key gaps in understanding. *Environmental Toxicology and Chemistry*, 40(3), 631-657.

Evich, M. G., Davis, M. J., McCord, J. P., Acrey, B., Awkerman, J. A., Knappe, D. R., ... & Washington, J. W. (2022). Per-and polyfluoroalkyl substances in the environment. Science, 375(6580), eabg9065.

Fairly, KJ, Purdy, R, Kearns, S, Anderson, SE and Meade, B (2007). Exposure to the immunosuppressant Perfluorooctanoic acid, enhances the murine IgE and airway hyperreactiity response to ovalbumin. Toxicological Sciences, 97(2) 375-383.

Fasano, WJ, Kennedy, GL, Szostek, B, Farrar, DG, Ward, RJ, Haroun, L and Hinderliter, PM (2005). Penetration of ammonium perfluorooctanoate through rat and human skin in vitro. Drug and chemical toxicology, 28(1): 79-90.

Feng, Y., Shi, Z., Fang, X., Xu, M., Dai, J. (2009). Perfluorononanoic acid induces apoptosis involving the Fas death receptor signaling pathway in rat testis. Toxicol. Lett. 190, 224-30.

Feng, Y., Fang, X., Shi, Z., Xu, M., Dai, J. (2010). Effects of PFNA exposure on expression of junction-associated molecules and secretory function in rat Sertoli cells. Reprod. Toxicol. 30, 429-37.

Fenton, S. E., Ducatman, A., Boobis, A., DeWitt, J. C., Lau, C., Ng, C., Smith, J. S., & Roberts, S. M. (2021). Per- and Polyfluoroalkyl Substance Toxicity and Human Health Review: Current State of Knowledge and Strategies for Informing Future Research. Environmental toxicology and chemistry, 40(3), 606–630. https://doi.org/10.1002/etc.4890.

Franklin, J. (2016). How reliable are field-derived biomagnification factors and trophic magnification factors as indicators of bioaccumulation potential? Conclusions from a case study on per- and polyfluoroalkyl substances. *Integrated Environmental Assessment and Management*, 12(1), 6-20.

Franko, J, Meade, BJ, Frasch, HF, Barbero, AM and Anderson, SE (2012). Dermal penetration potential of Perfluorooctanoic acid (PFOA) in human and mouse skin. Journal of toxicology and environmental health, Part A, 75(1) 50-62.Furdui, V. I., Stock, N. L., Ellis, D. A., Butt, C. M., Whittle, D. M., Crozier, P. W., ... & Mabury, S. A. (2007). Spatial distribution of perfluoroalkyl contaminants in lake trout from the Great Lakes. *Environmental science & technology*, *41*(5), 1554-1559.

Gebbink, W. A., Bignert, A., & Berger, U. (2016). Perfluoroalkyl acids (PFAAs) and selected precursors in the Baltic Sea environment: do precursors play a role in food web accumulation of PFAAs?. *Environmental science & technology*, *50*(12), 6354-6362.

Grandjean, P., E.W. Andersen, E. Budtz-Jørgensen, F. Nielsen, K. Mølbak, P. Weihe, and C. Heilmann. (2012). Serum vaccine antibody concentrations in children exposed to perfluorinated compounds. JAMA 307:391–397.

Harris, M. W., & Birnbaum, L. S. (1989). Developmental toxicity of perfluorodecanoic acid in C57BL/6N mice. Toxicological Sciences, 12(3), 442-448.
Hirata-Koizumi, M., Fujii, S., Furukawa, M., Ono, A., & Hirose, A. (2012). Repeated dose and reproductive/developmental toxicity of perfluorooctadecanoic acid in rats. The Journal of toxicological sciences, 37(1), 63–79. https://doi.org/10.2131/jts.37.63

Hirata-Koizumi, M., Fujii, S., Hina, K., Matsumoto, M., Takahashi, M., Ono, A., & Hirose, A. (2015). Repeated dose and reproductive/developmental toxicity of long-chain perfluoroalkyl carboxylic acids in rats: perfluorohexadecanoic acid and perfluorotetradecanoic acid. Fundamental Toxicological Sciences, 2(4), 177-190.

Inhance. 2023. Press Release titled: A Proposed Ban by EPA of Inhance Technologies' Fluorination Technology is a Decision with Far Reaching Impacts that Must be Immediately Paused. Dated August 1, 2023.

ITRC (Interstate Technology and Regulatory Council). (2023). PFAS — Per- and polyfluoroalkyl substances. Available at: https://pfas-1.itrcweb

Kato, H., S. Fujii, M. Takahashi, M. Matsumoto, M. Hirata-Koizumi, A. Ono, and A. Hirose. (2015). "Repeated dose and reproductive/developmental toxicity of perfluorododecanoic acid in rats." Environ Toxicol 30 (11):1244-63. doi: 10.1002/tox.21996.

Khairy, M. A., Noonan, G. O., & Lohmann, R. (2019). Uptake of hydrophobic organic compounds, including organochlorine pesticides, polybrominated diphenyl ethers, and perfluoroalkyl acids in fish and blue crabs of the lower Passaic River, New Jersey, USA. *Environmental toxicology and chemistry*, *38*(4), 872-882.

Koskela A, Finnila MA, Korkalainen M, et al. (2016). Effects of developmental exposure to perfluorooctanoic acid (PFOA) on long bone morphology and bone cell differentiation. Toxicol Appl Pharmacol 301:14-21. doi:10.1016/j.taap.2016.04.002

Kwiatkowski CF, Andrews DQ, Birnbaum LS, Bruton TA, DeWitt JC, Knappe DR, Maffini MV, Miller MF, Pelch KE, Reade A and Soehl A. 2020. Scientific basis for managing PFAS as a chemical class. Environmental Science and Technology Letters, 7(8), pp. 532-543.

Leung, S.C.E., Shukla, P., Chen, D., Eftekhari, E., An, H., Zare, F., ... & Li, Q. (2022). Emerging technologies for PFOS/PFOA degradation and removal: A review. *Science of the Total Environment, 827*, 153669.

Li, Y., Fletcher, T., Mucs, D., Scott, K., Lindh, C. H., Tallving, P., & Jakobsson, K. (2018). Half-lives of PFOS, PFHxS and PFOA after end of exposure to contaminated drinking water. Occupational and environmental medicine, 75(1), 46-51.

Li, Q., Wang, P., Hu, B., Wang, C., & Li, D. (2021). Perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) in surface water of China: National exposure distributions and probabilistic risk assessment. Archives of Environmental Contamination and Toxicology, 81, 470-481.

Lin, A. Y. C., Panchangam, S. C., Tsai, Y. T., & Yu, T. H. (2014). Occurrence of perfluorinated compounds in the aquatic environment as found in science park effluent, river water, rainwater, sediments, and biotissues. *Environmental monitoring and assessment*, *186*, 3265-3275.
Marques, E. S., Agudelo, J., Kaye, E. M., Modaresi, S. M. S., Pfohl, M., Bečanová, J., Wei, W., Polunas, M., Goedken, M., & Slitt, A. L. (2021). The role of maternal high fat diet on mouse pup metabolic endpoints following perinatal PFAS and PFAS mixture exposure. *Toxicology*, 462, 152921. https://doi.org/10.1016/j.tox.2021.152921

Loganathan, B.G., Sajwan, K.S., Sinclair, E., Kumar, K.S., and Kannan, K. (2007). Perfluoroalkyl sulfonates and perfluorocarboxylates in two wastewater treatment facilities in Kentucky and Georgia. Water Research. 41(20):4611–4620.

McLachlan, M. S., Zou, H., & Gouin, T. (2017). Using benchmarking to strengthen the assessment of persistence. *Env Sci Tech*, 51(1), pp 4-11.

Miranda, D.D.A., Peaslee, G.F., Zachritz, A.M., & Lamberti, G.A. (2022). A worldwide evaluation of trophic magnification of per- and polyfluoroalkyl substance sin aquatic ecosystems. *Integrated Environmental Assessment and Management*, 18(6), 1500-1512.

Murakami, M., Adachi, N., Saha, M., Morita, C., & Takada, H. (2011). Levels, temporal trends, and tissue distribution of perfluorinated surfactants in freshwater fish from Asian countries. *Archives of environmental contamination and toxicology*, *61*, 631-641.

NAS (2022). National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Division on Earth and Life Studies; Board on Population Health and Public Health Practice; Board on Environmental Studies and Toxicology; Committee on the Guidance on PFAS Testing and Health Outcomes. Guidance on PFAS Exposure, Testing, and Clinical Follow-Up. Washington (DC): National Academies Press (US); (2022) Jul 28. PMID: 35939564

New Jersey Drinking Water Quality Institute. (2015). Health-based Maximum Contaminant Level Support Document: Perfluorononanoic acid (PFNA). New Jersey Drinking Water Quality Institute Health Effects Subcommittee. 191 pp. https://www.nj.gov/dep/watersupply/pdf/pfna-health-effects.pdf

Ohmori, K, Kudo, N, Katayama, K, Kawashima, Y. (2003) Comparison of the toxicokinetics between perfluorocarboxylic acids with different carbon chain length. Toxicology (184): 135-140.

Pan, Y., Zhang, H., Cui, Q., Sheng, N., Yeung, L. W., Guo, Y., ... & Dai, J. (2017). First report on the occurrence and bioaccumulation of hexafluoropropylene oxide trimer acid: an emerging concern. *Environmental science & technology*, *51*(17), 9553-9560.

PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18638 (March 29, 2023) (40 CFR Parts 141 and 142).

Post, G.B., Cohn, P.D., Cooper, K.R. (2012). Perfluorooctanoic acid (PFOA), an emerging drinking water contaminant: A critical review of recent literature. *Environmental Research* 116:93–117.

PubChem. (2022). PubChem: Hexafluoropropylene oxide (CAS No. 428-59-1). https://pubchem.ncbi.nlm.nih.gov/compound/Hexafluoropropylene-oxide

Roberts, A., Brooks, R., and Shipway, P. (2014). Internal combustion engine cold-start efficiency: A review of the problem, causes and potential solutions. Energy Convers. Manag. 82:327–350.

Scheurer, M., & Nödler, K. (2021). Ultrashort-chain perfluoroalkyl substance trifluoroacetate (TFA) in beer and tea–An unintended aqueous extraction. Food Chemistry, 351, 129304.

Seals, R, Bartell, SM, Steenland, K. (2011). Accumulation and clearance of Perfluorooctanoic acid (PFOA) in current and former residents of an exposed community. Environmental Health Perspectives (119)(1): 119-124.

Shi Z, Zhang H, Liu Y, et al. (2007). Alterations in gene expression and testosterone synthesis in the testes of male rats exposed to perfluorododecanoic acid. Toxicol Sci 98(1):206-215. doi: 10.1093/toxsci/kfm070.

Shields, E.P., Krug, J.D., Roberson, W.R., Jackson, S.R., Smeltz, M.G., Allen, M.R., ... & Linak, W.P. (2023). Pilot-scale thermal destruction of per- and polyfluoroalkyl substances in a legacy aqueous film forming foam. *ACS ES&T Engineering*.

Sinclair, E., and Kannan, K. (2006). Mass loading and fate of perfluoroalkyl surfactants in wastewater treatment plants. Environ. Sci. Technol. 40(5):1408–1414.
Solo-Gabriele, H.M., Jones, A.S., Lindstrom, A.B., & Lang, J.R. (2020). Waste type, incineration, and aeration are associated with per- and polyfluoroalkyl levels in landfill leachates. *Waste management*, 107, 191-200.

Takahashi, M., S. Ishida, M. Hirata-Koizumi, A. Ono, and A. Hirose. (2014). "Repeated dose and reproductive/developmental toxicity of perfluoroundecanoic acid in rats." J Toxicol Sci 39 (1):97-108.

Tatum-Gibbs, K, Wambaugh, JF, Das, KP, Zehr, RD, Strynar, MJ, Lindstrom, AB, Delinsky, A and Lau, C. (2011) Comparative pharmacokinetics of perfluorononanoic acid in rat and mouse. Toxicology (281)(1-3): 48-55.

TCEQ (Texas Commission on Environmental Quality) (2016). Texas Risk Reduction Program (TRRP) protective concentration levels. Available at: https://www.tceq.texas.gov/remediation/trrp/trrppcls.html

US EPA, (1999). Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances (also referred to as the NCD PBT Policy). Available at: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/policy-statement-new-chemicals

US EPA, (2009). Long-chain perfluorinated chemicals (PFCs) Action Plan. Available at: assessing-and-managing-chemicals-under-tsca/long-chain-perfluorinated-chemicals-pfcs-action-plan

US EPA. (2016a). Health effects support document for perfluorooctane sulfonate (PFOS) [EPA Report]. (EPA 822-R-16-002). Washington, DC: U.S. Environmental Protection Agency, Office of Water, Health and Ecological Criteria Division. https://www.epa.gov/sites/production/files/201605/documents/pfos_hesd_final_508.pdf

US EPA. (2016b). Health effects support document for perfluorooctanoic acid (PFOA) [EPA Report]. (EPA 822-R-16-003). Washington, DC: U.S. Environmental Protection Agency, Office of Water, Health and Ecological Criteria Division. https://www.epa.gov/sites/production/files/201605/documents/pfoa_hesd_final-plain.pdf

US EPA, (2018). Points to Consider When Preparing TSCA New Chemical Notifications (https://www.epa.gov/sites/default/files/2018-06/documents/points_to_consider_document_2018-06-19_resp_to_omb.pdf)

US EPA. (2019). The EPA's Review of Per- and Polyfluoroalkyl Substances (PFAS) in Industrial Wastewater Discharge. (EPA 821-R-19-006). Washington, DC: U.S. Environmental Protection Agency, Office of Water, Health and Ecological Criteria Division. https://downloads.regulations.gov/EPA-HQ-OW-2021-0547-0359/content.pdf

US EPA. 2020a. National rivers and streams assessment 2013–2014: Technical support document. EPA 843-R-19-001. U.S. Environmental Protection Agency, Office of Water, Washington, D.C.

US EPA. 2020b. National Coastal Condition Assessment 2015 Technical support document. EPA 841-R-20-002. U.S. Environmental Protection Agency, Office of Water and Office of Research and Development, Washington, D.C.

US EPA. (2021a). PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024. epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024

US EPA. (2021b). National PFAS Testing Strategy: Identification of Per- and Polyfluoroalkyl Substances (PFAS) for Testing. epa.gov/assessing-and-managing-chemicals-under-tsca/national-pfas-testing-strategy

US EPA. (2021c). MEMORANDUM: EPA's Analytical Chemistry Branch PFAS Testing Rinses from Selected Fluorinated and Non-Fluorinated HDPE Containers. epa.gov/pesticides/rinses-selected-fluorinated-and-non-fluorinated-hdpe-containers

US EPA. (2022a). INTERIM Drinking Water Health Advisory: Perfluorooctanoic Acid (PFOA) CASRN 335-67-1. U.S. Environmental Protection Agency, Washington, DC. EPA/822/R-22/003. https://www.epa.gov/system/files/documents/2022-06/interim-pfoa-2022.pdf.

USEPA. (2022b). DRAFT Aquatic Life Ambient Water Quality Criteria for Perfluorooctanoic acid (PFOA) (EPA 842-D-22-001). Washington, DC: U.S. Environmental Protection Agency, Office of Water, Health and Ecological Criteria Division. https://www.epa.gov/wqc/aquatic-life-criteria-perfluorooctanoic-acid-pfoa#2022

US EPA. (2023a). Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs). https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/framework-addressing-new-pfas-and

US EPA. (2023b). IRIS Toxicological Review of Perfluorodecanoic Acid (PFDA) and Related Salts (Public Comment and External Review Draft). U.S. Environmental Protection Agency, Washington, DC, EPA/635/R-23/056a. https://cfpub.epa.gov/ncea/iris_drafts

US EPA. (2023c). Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS) (Public Review Draft). Office of Water and Office of Research and Development. EPA Document Number: EPA-822-P-23-003.

US EPA. (2023d). Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): HFPO-DA and its Ammonium Salt (also known as GenX Chemicals), PFBS, PFNA, and PFHxS (draft for public review). Office of Water. EPA Document Number: EPA-822-P-23-004.

Vierke, L., Staude, C., Biegel-Engler, A., Drost, W., & Schulte, C. (2012). Perfluorooctanoic acid (PFOA)—main concerns and regulatory developments in Europe from an environmental point of view. *Environmental Sciences Europe*, *24*, 1-11.

Vitale, R.J., Acker, J.K., Somerville, S.E. (2022). An assessment of the potential for leaching of per- and polyfluoroalkyl substances from fluorinated and non-fluorinated high-density polyethylene containers. *Environmental Advances*, 9(100309). https://doi.org/10.1016/j.envadv.2022.100309.

Whitehead HD and GF Peaslee. 2023. Directly fluorinated containers as a source of perfluoroalkyl carboxylic acids. Environmental Science and Technology Letters, 10(4)), pp. 350-355.

Wikström, S, Lin, PI, Lindh, CH, Shu, H, Bornehag, CG. (2020). Maternal serum levels of perfluoroalkyl substances in early pregnancy and offspring birth weight. Pediatr Res 87: 34 1093-1099. http://dx.doi.org/10.1038/s41390-019-0720-1.

Zhang, X., Hu, T., Yang, L., & Guo, Z. (2018). The investigation of perfluoroalkyl substances in seasonal freeze–thaw rivers during spring flood period: a case study in Songhua River and Yalu River, China. *Bulletin of environmental contamination and toxicology*, *101*, 166-172.

8 Appendix A

Table A1. Tier 1 Potentially Useful Information for SN-23-0002 (perfluorooctanoic acid (PFOA), CASRN 335-67-1)

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
Water Solubility (OECD TG 105)	Measured (4.34 g/L)	• *Not applicable, sufficient test data available*
K_{ow} (OECD TG 107)	Measured (3.15)	
Vapor Pressure (OECD TG 104)	Measured (0.0316 Torr)	
Boiling Point (OECD 103)	Measured (189°C)	
Melting Point (OECD TG 102)	Measured (55°C)	
Hydrolysis (OECD TG 111; including pH 2)	Predicted to be stable	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{oc} (OECD TG 106 or OECD TG 121)	None	
Surface tension of aqueous solution (if structural alerts for surfactants/detergents) (OECD 115)	Chemical structure	• Anionic surfactant properties are expected based on structure • Prerequisite to inform Tier 2 testing
Micelle assembly (if surface tension ≤ 45 mN/m at conc. 0.5 wt% in water and 20°C) (CMC; Hafta JJH et al 2016; ISO 4311)	None	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Henry's Law Constant (if BP < 25°C and WS ≥ 0.5 mg/L) (Ji C, et al. 2007, and Sander R, et al. 2022)	None	• *Not applicable, BP > 25°C*
Bacterial Reverse Mutation Test (OECD TG 471)	ATSDR, 2021	• *Not applicable, sufficient test data available*
One of the following genetic toxicity tests: In Vitro Mammalian Chromosomal Aberration Test (OECD 473) In Vitro Mammalian Cell Micronucleus Test (OECD 487) In Vitro Mammalian Cell Gene Mutation Test (OECD 490)		
Toxicokinetics in rats and mice (OECD TG 417)	ATSDR, 2021	

[redacted]

Table A2. Tier 2 Potentially Useful Information for SN-23-0002 (perfluorooctanoic acid (PFOA), CASRN 335-67-1)

Tier 2 Studies (Test Guideline)	Data used in assessment	Purpose
Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)	ATSDR, 2021	• *Not applicable, sufficient data available*
Other bioaccumulation studies	Dai and Zeng (2019); Furdui et al. (2007); Vierke et al. (2012); analogy to other PFAS	
Water soluble: Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201)	HC5 value of 0.033 mg/L from the Species Sensitivity Distribution (SSD) for PFOA Reported by Li et al. (2021) and used by Inhance	
Avian reproduction (OCSPP 850.2300)	None	• To address lack of substance-specific bioaccumulation potential in the environment/food chain • Reduce uncertainty in B score

[redacted]

Table A3. Tier 1 Potentially Useful Information for SN-23-0004 (perfluorononanoic acid (PFNA), CASRN 375-95-1)

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
Water Solubility (OECD TG 105)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{ow} (OECD TG 107)	Estimation	
Vapor Pressure (OECD TG 104)	Measured (0.00977 Torr)	• *Not applicable, sufficient test data available*
Boiling Point (OECD 103)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Melting Point (OECD TG 102)	Measured (69-71°C)	• *Not applicable, sufficient test data available*
Hydrolysis (OECD TG 111; including pH 2)	Predicted to be stable	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{oc} (OECD TG 106 or OECD TG 121)	None	
Surface tension of aqueous solution (if structural alerts for surfactants/detergents) (OECD 115)	Chemical structure	• Anionic surfactant properties are expected based on structure • Prerequisite to inform Tier 2 testing
Micelle assembly (if surface tension ≤ 45 mN/m at conc. 0.5 wt% in water and 20°C) (CMC; Hafta JJH et al 2016; ISO 4311)	None	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Henry's Law Constant (if BP < 25°C and WS ≥ 0.5 mg/L) (Ji C, et al. 2007, and Sander R, et al. 2022)	None	
Bacterial Reverse Mutation Test (OECD TG 471)	None	• To address lack of substance-specific genetic toxicity information
One of the following genetic toxicity tests: In Vitro Mammalian Chromosomal Aberration Test (OECD 473) In Vitro Mammalian Cell Micronucleus Test (OECD 487) In Vitro Mammalian Cell Gene Mutation Test (OECD 490)	None	
Dermal absorption (in vitro) (OECD TG 428)	Predicted to be absorbed	• To determine whether dermal absorption may occur
Toxicokinetics in rats and mice (OECD TG 417)	Tatum-Gibbs et al (2011) and Ohmori et al. (2003)	• *Not applicable, sufficient test data available information suggests PFNA has a longer half-life in mice*

[redacted]

Table A4. Tier 2 Potentially Useful Information for SN-23-0004 (perfluorononanoic acid (PFNA), CASRN 375-95-1)

Tier 2 Studies (Test Guideline)	Data used in assessment	Purpose
Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)	Das et al., 2015 2015; Feng et al., 2009; and Feng et al., 2010 as cited in NJ DWQI	• To address lack of substance-specific in vivo mammalian guideline hazard data to better inform the human health T score, and therefore risk to workers the general population, and consumers and to account for different lifestages for susceptible populations (i.e., pregnant women, developing fetus and juveniles). • Mice should be used (based on Tier 1 toxicokinetics study)
Other bioaccumulation studies	De Silva et al. (2011); Furdui et al. (2007); Gebbink et al. (2016); analogy to other PFAS	• *Not applicable, sufficient data available*
Water soluble: Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Insoluble in water: Chronic study for sediment dwelling organisms (OECD 233)	Analogue	• The analogue, PFOA, is considered a sufficiently similar analogue for PFNA, differing in structure by a single fully fluorinated carbon; • Substance-specific data would be prioritized for identifying chronic environmental hazards for the aquatic toxicity "T" score and therefore, risk to the environment
Avian reproduction (OCSPP 850.2300)	None	• To address lack of substance-specific bioaccumulation potential in the environment/food chain • Reduce uncertainty in B score

[redacted]

Table A5. Tier 1 Potentially Useful Information for SN-23-0005 (perfluorodecanoic acid (PFDA), CASRN 335-76-2)

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
Water Solubility (OECD TG 105)	Measured (5.13E-6 g/L)	• *Not applicable, sufficient test data available*
K_{ow} (OECD TG 107)	Estimated	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Vapor Pressure (OECD TG 104)	Measured (0.00174 Torr)	• *Not applicable, sufficient test data available*
Boiling Point (OECD 103)	Measured (218°C),	
Melting Point (OECD TG 102)	Measured (77.2-78.9°C)	
Hydrolysis (OECD TG 111; including pH2)	Predicted to be stable	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{oc} (OECD TG 106 or OECD TG 121)	None	
Surface tension of aqueous solution (if structural alerts for surfactants/detergents) (OECD 115)	Chemical structure	• Anionic surfactant properties are expected based on structure • Prerequisite to inform Tier 2 testing
Micelle assembly (if surface tension ≤ 45 mN/m at conc. 0.5 wt% in water and 20°C) (CMC; Hafta JJH et al 2016; ISO 4311)	None	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Henry's Law Constant (if BP < 25°C and WS ≥ 0.5 mg/L) (Ji C, et al. 2007, and Sander R, et al. 2022)	None	• *Not applicable, BP > 25*°C and WS < 0.5 mg/L
Dermal absorption (in vitro) (OECD TG 428)	Predicted to be absorbed	• To determine whether dermal absorption may occur
Bacterial Reverse Mutation Test (OECD TG 471)	US EPA, 2023b	• *Not applicable, sufficient test data available*
One of the following genetic toxicity tests: In Vitro Mammalian Chromosomal Aberration Test (OECD 473) In Vitro Mammalian Cell Micronucleus Test (OECD 487) In Vitro Mammalian Cell Gene Mutation Test (OECD 490)		
Toxicokinetics in rats and mice (OECD TG 417)	US EPA, 2023b	• *Not applicable, sufficient test data available*

[redacted]

Table A6. Tier 2 Potentially Useful Information for SN-23-0005 (perfluorodecanoic acid (PFDA), CASRN 335-76-2)

Tier 2 Studies (Test Guideline) for	Data used in assessment	Purpose
Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)	US EPA, 2023b	• *Not applicable, sufficient data available*
Other bioaccumulation studies	De Silva et al. (2011); Furdui et al. (2007); Gebbink et al. (2016); analogy to other PFAS	
Water soluble: Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND Insoluble in water: Chronic study for sediment dwelling organisms (OECD 233)	Analogue	• The analogue used in this assessment, PFOA, is considered sufficiently similar to PFDA, differing in structure by two fewer fully fluorinated carbons • Substance-specific data would be prioritized for identifying chronic environmental hazards for the aquatic toxicity T score and therefore, risk to the environment
Avian reproduction (OCSPP 850.2300)	None	• To address lack of substance-specific bioaccumulation potential in the environment/food chain • Reduce uncertainty in B score

[redacted]

Table A7. Tier 1 Potentially Useful Information for SN-23-0006 (perfluoroundecanoic acid (PFuDA) CASRN 2058-94-8)

Tier 1 Studies (Test Guideline) for	Data used in assessment	Purpose
Water Solubility (OECD TG 105)	Measured (0.056 g/L)	• *Not applicable, sufficient test data available*
K_{ow} (OECD TG 107)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Vapor Pressure (OECD TG 104)	Measured (7.41E-4 Torr)	• *Not applicable, sufficient test data available*
Boiling Point (OECD 103)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Melting Point (OECD TG 102)	None	
Hydrolysis (OECD TG 111; including pH2)	Predicted to be stable	
K_{oc} (OECD TG 106 or OECD TG 121)	None	
Surface tension of aqueous solution (if structural alerts for surfactants/detergents) (OECD 115)	Chemical structure	• Anionic surfactant properties are expected based on structure • Prerequisite to inform Tier 2 testing
Micelle assembly (if surface tension ≤ 45 mN/m at conc. 0.5 wt% in water and 20°C) (CMC; Hafta JJH et al 2016; ISO 4311)	None	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Henry's Law Constant (if BP < 25°C and WS ≥ 0.5 mg/L) (Ji C, et al. 2007, and Sander R, et al. 2022)	None	
Dermal absorption (in vitro) (OECD TG 428)	Predicted to be absorbed	• To determine whether dermal absorption may occur
Bacterial Reverse Mutation Test (OECD TG 471)	None	• To address lack of substance-specific genetic toxicity information
One of the following genetic toxicity tests: In Vitro Mammalian Chromosomal Aberration Test (OECD 473) In Vitro Mammalian Cell Micronucleus Test (OECD 487) In Vitro Mammalian Cell Gene Mutation Test (OECD 490)		
Toxicokinetics in rats and mice (OECD TG 417)	None	• To address lack of substance-specific bioaccumulation information • Prerequisite for in vivo mammalian toxicity testing (see purpose for OECD 422) • To better inform risk to workers, the general population and consumers

[redacted]

Table A8. Tier 2 Potentially Useful Information for SN-23-0006 (perfluoroundecanoic acid (PFuDA) CASRN 2058-94-8)

Tier 2 Studies (Test Guideline)	Data used in assessment	Purpose
Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)	Takahashi et al., 2014 (rats)	• In Takahashi et al, rats were tested; however, if in the OECD TG 417 study listed previously, mice are determined to be the species with the longer half-life, the OECD TG 422 study should be performed in mice to better inform the human health T score, and therefore risk to workers, the general population and consumer and to account for different lifestages for susceptible populations (i.e., pregnant women, developing fetus and juveniles). •
Other bioaccumulation studies	De Silva et al. (2011); Gebbink et al. (2016); Khairy et al. (2019); Murakami et al. (2011); analogy to other PFAS	• *Not applicable, sufficient data available*
Water soluble: Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND Insoluble in water: Chronic study for sediment dwelling organisms (OECD 233)	Analogue	• The analogue used in the assessment, PFOA, is considered a sufficiently similar analogue for PFuDA, PFOA contains seven fully fluorinated carbons compared to the ten for PFuDA. • Substance-specific data would be prioritized for identifying chronic environmental hazards for the aquatic toxicity T score and therefore, risk to the environment.
Avian reproduction (OCSPP 850.2300)	None	• To address lack of substance-specific bioaccumulation potential in the environment/food chain • Reduce uncertainty in B score

[redacted]

Table A9. Tier 1 Potentially Useful Information for SN-23-0003 (perfluorododecanoic acid (PFDoA), CASRN 307-55-1)

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
Water Solubility (OECD TG 105)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{ow} (OECD TG 107)	Estimation	
Vapor Pressure (OECD TG 104)	Measured (6.17E-5 Torr)	• *Not applicable, sufficient test data available*
Boiling Point (OECD 103)	Measured (249°C)	
Melting Point (OECD TG 102)	Measured (112-114 °C)	
Hydrolysis (OECD TG 111; including pH2)	Predicted to be stable	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{oc} (OECD TG 106 or OECD TG 121)	None	
Surface tension of aqueous solution (if structural alerts for surfactants/detergents) (OECD 115)	Chemical structure	• Anionic surfactant properties are expected based on structure • Prerequisite to inform Tier 2 testing
Micelle assembly (if surface tension ≤ 45 mN/m at conc. 0.5 wt% in water and 20°C) (CMC; Hafta JJH et al 2016; ISO 4311)	None	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Henry's Law Constant (if BP < 25°C and WS ≥ 0.5 mg/L) (Ji C, et al. 2007, and Sander R, et al. 2022)	None	• *Not applicable, BP > 25°C*
Dermal absorption (in vitro) (OECD TG 428)	Predicted to be absorbed	• To determine whether dermal absorption may occur
Bacterial Reverse Mutation Test (OECD TG 471)	None	• To address lack of substance-specific genetic toxicity information
One of the following genetic toxicity tests: In Vitro Mammalian Chromosomal Aberration Test (OECD 473) In Vitro Mammalian Cell Micronucleus Test (OECD 487) In Vitro Mammalian Cell Gene Mutation Test (OECD 490)		
Toxicokinetics in rats and mice (OECD TG 417)	None	• To address lack of substance-specific bioaccumulation information • Prerequisite for in vivo mammalian toxicity testing (see purpose for OECD 422) • To better inform risk to workers, the general population, and consumers

[redacted]

Table A10. Tier 2 Potentially Useful Information for SN-23-0003 (perfluorododecanoic acid (PFDoA), CASRN 307-55-1)

Tier 2 Studies (Test Guideline)	Data used in assessment	Purpose
Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)	Kato et al., 2015a (rats)	• In the Kato et al. study, rats were tested; however, if in the OECD TG 417 study listed previously, mice are determined to be the species with the longer half-life, the OECD 422 study should be performed in mice to better inform the human health T score, and therefore risk to workers, the general population, and consumers and to account for different lifestages for susceptible populations (i.e., pregnant women, developing fetus and juveniles). • Mice should be used (based on Tier 1 toxicokinetics study).
Other bioaccumulation studies	Khairy et al. (2019); Lin et al. (2014); analogy to other PFAS	• *Not applicable, sufficient data available*
Water soluble: Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Insoluble in water: Chronic study for sediment dwelling organisms (OECD 233)	Analogue	• The analogue used in this assessment, PFOA, is considered a sufficiently similar analogue to PFDoA; PFOA contains seven fully fluorinated carbons compared to the eleven in PFDoA. • Substance-specific data would be prioritized for identifying chronic environmental hazards for the aquatic toxicity T score and therefore, risk to the environment.
Avian reproduction (OCSPP 850.2300)	None	• To address lack of substance-specific bioaccumulation potential in the environment/food chain • Reduce uncertainty in B score

[redacted]

Table A11. Tier 1 Potentially Useful Information for SN-23-0009 (perfluorotridecanoic acid (PFTrDA), CASRN 72629-94-8)

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
Water Solubility (OECD TG 105)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{ow} (OECD TG 107)	None	
Vapor Pressure (OECD TG 104)	Estimation	• To address lack of substance-specific data • To understand if engineering controls are sufficient to prevent worker inhalation exposure • Prerequisite to inform Tier 2 testing
Boiling Point (OECD 103)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Melting Point (OECD TG 102)	Measured (112-123 °C)	• *Not applicable, sufficient test data available*
Hydrolysis (OECD TG 111; including pH 2)	Predicted to be stable	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{oc} (OECD TG 106 or OECD TG 121)	None	
Surface tension of aqueous solution (if structural alerts for surfactants/detergents) (OECD 115)	Chemical structure	• Anionic surfactant properties are expected based on structure • Prerequisite to inform Tier 2 testing
Micelle assembly (if surface tension ≤ 45 mN/m at conc. 0.5 wt% in water and 20°C) (CMC; Hafta JJH et al 2016; ISO 4311)	None	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Henry's Law Constant (if BP < 25°C and WS ≥ 0.5 mg/L) (Ji C, et al. 2007, and Sander R, et al. 2022)	None	
Dermal absorption (in vitro) (OECD TG 428)	Predicted to be absorbed	• To determine whether dermal absorption may occur
Bacterial Reverse Mutation Test (OECD TG 471)	None	• To address lack of substance-specific genetic toxicity information
One of the following genetic toxicity tests: In Vitro Mammalian Chromosomal Aberration Test (OECD 473) In Vitro Mammalian Cell Micronucleus Test (OECD 487) In Vitro Mammalian Cell Gene Mutation Test (OECD 490)		
Toxicokinetics in rats and mice (OECD TG 417)	None	• To address lack of substance-specific bioaccumulation information • Prerequisite for in vivo mammalian toxicity testing (see purpose for OECD 422)

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
		• To better inform risk to workers, the general population and consumers

Table A12. Tier 2 Potentially Useful Information for SN-23-0009 (perfluorotridecanoic acid (PFTrDA), CASRN 72629-94-8)

Tier 2 Studies (Test Guideline)	Data used in assessment	Purpose
Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)	Analogue (PFOA, PFDoA, PFTeDA, PFHxDA, PFODA (see Table 6))	• To address lack of substance-specific in vivo mammalian hazard data to better inform the human health T score, and therefore risk to workers the general population, and consumers and to account for different lifestages for susceptible populations (i.e., pregnant women, developing fetus and juveniles). • Mice should be used (based on Tier 1 toxicokinetics study). • PFOA was used as an analogue based on structure and substantial availability of data; PFDoA, PFTeDA, PFHxDA, PFODA were also used as analogues based on closer structural similarity and the availability of some data; substance-specific data in the species with the longer half-life (identified in the toxicokinetics study previously) would be prioritized for identifying hazards
Other bioaccumulation studies	Zhang et al. (2018); Pan et al. (2017); analogy to other PFAS	• *Not applicable, sufficient data available*
Water soluble: Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Insoluble in water: Chronic study for sediment dwelling organisms (OECD 233)	Analogue	• The analogue used in this assessment, PFOA, is considered a sufficiently similar analogue for PFTrDA; PFOA differs in structure by five fewer fully fluorinated carbons; • Substance-specific data would be prioritized for identifying chronic environmental hazards for the aquatic toxicity T score and therefore, risk to the environment.
Avian reproduction (OCSPP 850.2300)	None	• To address lack of substance-specific bioaccumulation potential in the environment/food chain • Reduce uncertainty in B score

[redacted]

Table A13. Tier 1 Potentially Useful Information for SN-23-0008 (perfluorotetradecanoic acid (PFTeDA), CASRN 376-06-7)

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
Water Solubility (OECD TG 105)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{ow} (OECD TG 107)	None	
Vapor Pressure (OECD TG 104)	Estimation	• To address lack of substance-specific data • To understand if engineering controls are sufficient to prevent worker inhalation exposure • Prerequisite to inform Tier 2 testing
Boiling Point (OECD 103)	Measured (270°C)	• *Not applicable, sufficient test data available*
Melting Point (OECD TG 102)	Measured (130-135°C)	
Hydrolysis (OECD TG 111; including pH 2)	Predicted to be stable	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{oc} (OECD TG 106 or OECD TG 121)	None	
Surface tension of aqueous solution (if structural alerts for surfactants/detergents) (OECD 115)	Chemical structure	• Anionic surfactant properties are expected based on structure • Prerequisite to inform Tier 2 testing
Micelle assembly (if surface tension ≤ 45 mN/m at conc. 0.5 wt% in water and 20°C) (CMC; Hafta JJH et al 2016; ISO 4311)	None	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Henry's Law Constant (if BP < 25°C and WS ≥ 0.5 mg/L) (Ji C, et al. 2007, and Sander R, et al. 2022)	None	• *Not applicable, BP > 25°C* • To address lack of substance-specific data
Dermal absorption (in vitro) (OECD TG 428)	Predicted to be absorbed	• To determine whether dermal absorption may occur
Bacterial Reverse Mutation Test (OECD TG 471)	None	• To address lack of substance-specific genetic toxicity information
One of the following genetic toxicity tests: In Vitro Mammalian Chromosomal Aberration Test (OECD 473) In Vitro Mammalian Cell Micronucleus Test (OECD 487) In Vitro Mammalian Cell Gene Mutation Test (OECD 490)		
Toxicokinetics in rats and mice (OECD TG 417)	None	• To address lack of substance-specific bioaccumulation information

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
		• Prerequisite for in vivo mammalian toxicity testing (see purpose for OECD 422) • To better inform risk to workers, the general population, and consumers

Table A14. Tier 2 Potentially Useful Information for SN-23-0008 (perfluorotetradecanoic acid (PFTeDA), CASRN 376-06-7)

Tier 2 Studies (Test Guideline)	Data used in assessment	Purpose
Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)	Hirata-Koizumi et al., 2015 (rats)	• In the Hirata-Koizumi et al., study, rats were tested; however if in the OECD TG 417 study listed previously, mice are determined to be the species with the longer half-life, the OECD 422 study should be performed in mice to better inform the human health T score, and therefore risk to workers, the general population, and consumers and to account for different lifestages for susceptible populations (i.e., pregnant women, developing fetus and juveniles). •
Other bioaccumulation studies	Pan et al. (2017); analogy to other PFAS	• *Not applicable, sufficient data available*
Water soluble: Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Insoluble in water: Chronic study for sediment dwelling organisms (OECD 233)	Analogue	• The analogue used in this assessment, PFOA, is considered a sufficiently similar analogue for PFTeDA; PFOA differs in structure by six fewer fully fluorinated carbons; • Substance-specific data would be prioritized for identifying chronic environmental hazards for the aquatic toxicity T score and therefore, risk to the environment.
Avian reproduction (OCSPP 850.2300)	None	• To address lack of substance-specific bioaccumulation potential in the environment/food chain • Reduce uncertainty in B score

[redacted]

Table A15. Tier 1 Potentially Useful Information for SN-23-0010 (perfluorohexadecanoic acid (PFHxDA), CASRN 67905-19-5)

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
Water Solubility (OECD TG 105)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{ow} (OECD TG 107)	None	
Vapor Pressure (OECD TG 104)	Estimation	• To address lack of substance-specific data • To understand if engineering controls are sufficient to prevent worker inhalation exposure • Prerequisite to inform Tier 2 testing
Boiling Point (OECD 103)	Measured (211°C)	• *Not applicable, sufficient test data available*
Melting Point (OECD TG 102)	Measured (153-155°C)	
Hydrolysis (OECD TG 111; including pH 2)	Predicted to be stable	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{oc} (OECD TG 106 or OECD TG 121)	None	
Surface tension of aqueous solution (if structural alerts for surfactants/detergents) (OECD 115)	Chemical structure	• Anionic surfactant properties are expected based on structure • Prerequisite to inform Tier 2 testing
Micelle assembly (if surface tension ≤ 45 mN/m at conc. 0.5 wt% in water and 20°C) (CMC; Hafta JJH et al 2016; ISO 4311)	None	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Henry's Law Constant (if BP < 25°C and WS ≥ 0.5 mg/L) (Ji C, et al. 2007, and Sander R, et al. 2022)	None	• *Not applicable, BP* > 25°C
Dermal absorption (in vitro) (OECD TG 428)	Predicted to be absorbed	• To determine whether dermal absorption may occur
Bacterial Reverse Mutation Test (OECD TG 471)	None	• To address lack of substance-specific genetic toxicity information
One of the following genetic toxicity tests: In Vitro Mammalian Chromosomal Aberration Test (OECD 473) In Vitro Mammalian Cell Micronucleus Test (OECD 487) In Vitro Mammalian Cell Gene Mutation Test (OECD 490)		
Toxicokinetics in rats and mice (OECD TG 417)	None	• To address lack of substance-specific bioaccumulation information • Prerequisite for in vivo mammalian toxicity testing (see purpose for OECD 422) • To better inform risk to workers, the general population, and consumers

[redacted]

Table A16. Tier 2 Potentially Useful Information for SN-23-0010 (perfluorohexadecanoic acid (PFHxDA), CASRN 67905-19-5)

Tier 2 Studies (Test Guideline)	Data used in assessment	Purpose
Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)	Hirata-Koizumi et al., 2015 (rats)	• In the Hirata-Koizumi et al., study, rats were tested; however if in the OECD TG 417 study listed previously, mice are determined to be the species with the longer half-life, the OECD should be performed in mice to better inform the human health T score, and therefore risk to workers, the general population and consumers and to account for different lifestages for susceptible populations (i.e., pregnant women, developing fetus and juveniles). •
Other bioaccumulation studies	analogy to other PFAS	• *Not applicable, sufficient data available*
Water soluble: Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Insoluble in water: Chronic study for sediment dwelling organisms (OECD 233)	Analogue	• The analogue used in this assessment, PFOA, is considered a sufficiently similar analogue for PHHxDA; PFOA differs in structure by eight fewer fully fluorinated carbons; • Substance-specific data would be prioritized for identifying chronic environmental hazards for the aquatic toxicity T score and therefore, risk to the environment.
If there is concern for bioaccumulation: Avian reproduction (OCSPP 850.2300)	None	• To address lack of substance-specific bioaccumulation potential in the environment/food chain • Reduce uncertainty in B score

[redacted]

Table A17. Tier 1 Potentially Useful Information for SN-23-0011 (perfluorostearic acid (PFODA), CASRN 16517-11-6)

Tier 1 Studies (Test Guideline)	Data used in assessment	Purpose
Water Solubility (OECD TG 105)	Estimation	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{ow} (OECD TG 107)	None	
Vapor Pressure (OECD TG 104)	Estimation	• To address lack of substance-specific data • To understand if engineering controls are sufficient to prevent worker inhalation exposure • Prerequisite to inform Tier 2 testing
Boiling Point (OECD 103)	Measured (235°C)	• *Not applicable, sufficient test data available*
Melting Point (OECD TG 102)	Measured (162-172°C)	
Hydrolysis (OECD TG 111; including pH2)	Predicted to be stable	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
K_{oc} (OECD TG 106 or OECD TG 121)	None	
Surface tension of aqueous solution (if structural alerts for surfactants/detergents) (OECD 115)	Chemical structure	• Anionic surfactant properties are expected based on structure • Prerequisite to inform Tier 2 testing
Micelle assembly (if surface tension ≤ 45 mN/m at conc. 0.5 wt% in water and 20°C) (CMC; Hafta JJH et al 2016; ISO 4311)	None	• To address lack of substance-specific data • Prerequisite to inform Tier 2 testing
Henry's Law Constant (if BP < 25°C and WS ≥ 0.5 mg/L) (Ji C, et al. 2007, and Sander R, et al. 2022)	None	• *Not applicable, BP > 25°C*
Dermal absorption (in vitro) (OECD TG 428)	Predicted to be absorbed	• To determine whether dermal absorption may occur
Bacterial Reverse Mutation Test (OECD TG 471)	None	• to address lack of substance-specific genetic toxicity information
One of the following genetic toxicity tests: In Vitro Mammalian Chromosomal Aberration Test (OECD 473) In Vitro Mammalian Cell Micronucleus Test (OECD 487) In Vitro Mammalian Cell Gene Mutation Test (OECD 490)		
Toxicokinetics in rats and mice (OECD TG 417)	None	• To address lack of substance-specific bioaccumulation information • Prerequisite for in vivo mammalian toxicity testing (see purpose for OECD 422) • To better inform risk to workers, the general population and consumers

[redacted]

Table A18. Tier 2 Potentially Useful Information for SN-23-0011 (perfluorostearic acid (PFODA), CASRN 16517-11-6)

Tier 2 Studies (Test Guideline)	Data used in assessment	Purpose
Combined repeated dose toxicity study with reproduction/developmental toxicity screening test (OECD TG 422)	Hirata-Koizumi et al., 2012	• In the Hirata-Koizumi et al. study, rats were tested, however, if in the OECD TG 417 study listed previously mice are determined to be the species with the longer half-life, the OECD TG 422 study should be performed in mice to better inform the human health T score, and therefore risk to workers, the general population, and consumers and to account for different lifestages for susceptible populations (i.e., pregnant women, developing fetus and juveniles). •
Other bioaccumulation studies	Analogy to other PFAS	• *Not applicable, sufficient data available*
Water soluble: Chronic study for aquatic organisms (OECD 210, OECD 211, and OECD 201) AND/OR Insoluble in water: Chronic study for sediment dwelling organisms (OECD 233)	Analogue	• The analogue used in this assessment, PFOA, is considered a sufficiently similar analogue to PFODA; PFOA differs in structure by ten fewer fully fluorinated carbons; • Substance-specific data would be prioritized for identifying chronic environmental hazards for the aquatic toxicity T score and therefore, risk to the environment.
If there is concern for bioaccumulation: Avian reproduction (OCSPP 850.2300)	None	• To address lack of substance-specific bioaccumulation potential in the environment/food chain • Reduce uncertainty in B score