

Ground Water Quality Standard for Hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (GenX)

CASRN#: 13252-13-6 and 62037-80-3

JUNE 2023

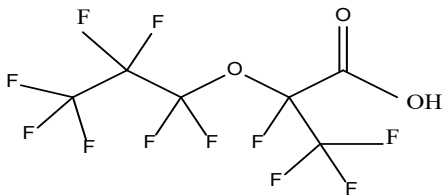
Summary of Decision: In accordance with the New Jersey Ground Water Quality Standards at N.J.A.C. 7:9C-1.7, the Department of Environmental Protection (Department) has established an interim specific ground water quality criterion (ISGWQC) of 0.02 µg/L (ppb) for hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (hereafter referred to as GenX). The basis for this ISGWQC is discussed below. Pursuant to N.J.A.C. 7:9C-1.9(c)1, interim practical quantitation levels (PQLs) are derived for constituents with interim specific criteria as appropriate in accordance with the approaches specified within this section. The Department has established an interim PQL of 0.0075 µg/L (ppb). Pursuant to

N.J.A.C. 7:9C-1.9(c), the higher (less stringent) of the PQL and the criterion is the ground water quality standard. **Therefore, the enforceable standard for GenX is the ISGWQC of 0.02 µg/L.** The ISGWQC, interim PQL and interim standard are posted in the “Table of Interim Specific Ground Water Quality Criteria (ISGWQC) and Interim PQLs for Constituents in Class II-A Ground Water” at <https://nj.gov/dep/wms/bears/gwqs.htm>. This ISGWQC is intended to be protective for chronic (lifetime) exposure to GenX in drinking water. The Department will replace the ISGWQC with a specific criterion as soon as reasonably possible by rule.

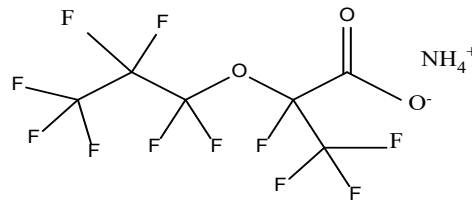
Hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (GenX)

Molecular Formula: C₆H₄F₁₁NO₃

Molecular Structure:



hexafluoropropylene oxide dimer acid (HFPO-DA)



HFPO-DA ammonium salt

Chemical Abstracts System Registration Numbers (CASRN):

- 13252-13-6 HFPO-DA
- 62037-80-3 HFPO-DA ammonium salt

Background: HFPO-DA and HFPO-DA ammonium salt are acid and salt forms of the same substance and are collectively referred to as GenX. They are six-carbon perfluoroether carboxylates that are members of the per- and polyfluoroalkyl substances (PFAS) family. Both the acid and the salt forms dissociate to the anionic form in the environment, including in ground water, and in the body.

HFPO-DA and HFPO-DA ammonium salt are the major components of the GenX processing aid technology developed by DuPont de Nemours, Inc. (DuPont) to replace the use of perfluorooctanoic acid (PFOA) as a processing aid in fluoropolymer production (USEPA, 2021). In 2015, the Chemours Company (Chemours) was created and separated from DuPont, and the GenX technology, including HFPO-DA and its ammonium salt, are now Chemours products (USEPA, 2021).



GenX has been released to the environment from industrial facilities where it is made or used (USEPA, 2021), including Chemours Chambers Works in Deepwater, New Jersey. GenX has been detected in environmental media near these facilities (USEPA, 2021), including in soil and ground water on and near the Chambers Works Site.

Reference Dose (RfD): The USEPA finalized its toxicity assessment of GenX in 2021. The Department reviewed the basis of the USEPA (2021) RfD of 3 ng/kg/day and concluded that it is scientifically justified and health protective. As explained in USEPA (2021), the chronic RfD for GenX is based on histopathological changes in the livers of parental female mice exposed before mating, during gestation, and during lactation, for a total of 53-64 days, in a reproductive/developmental study (DuPont-18405-1037, 2010). USEPA (2021) performed Benchmark Dose (BMD) modeling of the dose-response data for hepatic histopathological changes and identified the point of departure (POD) as a BMDL₁₀ (lower confidence level of the BMD for a 10% change) of 0.09 mg/kg/day.

The BMDL₁₀ of 0.09 mg/kg/day was converted to a Human Equivalent Dose (HED) POD (POD_{HED}) of 0.01 mg/kg/day (10,000 ng/kg/day) with a dosimetric adjustment factor (DAF) of 0.14 (based on animal-to-human body weight scaling) as follows:

$$\text{Dose to animals (ng/kg/day)} \times \text{DAF (unitless)} = \text{HED (ng/kg/day)}$$

$$0.09 \text{ mg/kg/day} \times 0.14 = 0.01 \text{ mg/kg/day}$$

A total uncertainty factor (UF) of 3000 (10 for intraspecies variability, 3 for interspecies extrapolation, 10 for subchronic-to-chronic exposure duration, and 10 for database uncertainties [for potentially more sensitive effects]) was applied to the POD_{HED} of 0.01 mg/kg/day to derive the chronic RfD of 3×10^{-6} mg/kg/day (3 ng/kg/day), as follows:

$$\text{POD (mg/kg/day)} / \text{UF} = \text{RfD (mg/kg/day)}$$

$$0.01 \text{ mg/kg/day} / 3000 = 3 \times 10^{-6} \text{ mg/kg/day (3 ng/kg/day)}$$

The critical study for the RfD was of subchronic duration (total exposure of 53-64 days). In addition to the chronic RfD mentioned above, USEPA (2021) also developed a subchronic RfD of 30 ng/kg/day for GenX. The USEPA (2021) subchronic RfD of 30 ng/kg/day was derived by applying a total UF of 300 (10 for intraspecies variability, 3 for interspecies extrapolation, and 10 for database uncertainties; no duration adjustment needed) to a POD_{HED} of 0.01 mg/kg/day. The same POD_{HED} of 0.01 mg/kg/day that was used to derive the subchronic RfD of 30 ng/kg/day was also used to derive the chronic RfD of 3 ng/kg/day which is the basis of the ISGWQC

GenX was classified by the Department and USEPA (2021) as having “suggestive evidence of carcinogenic potential” based on an increased incidence of liver tumors in females, and an increased incidence of pancreatic and a possible increase in testicular Leydig cell, tumors in males, in a chronic rat study. Although it was concluded that the cancer risk assessment is too uncertain for use as the basis of the interim specific ground water criterion, the estimated cancer risk at the criterion of 0.02 µg/L is far below the Department’s cancer risk goal for ground water quality criteria of one in one million.

Derivation of Ground Water Quality Criterion: The ISGWQC was derived pursuant to the equation established at N.J.A.C. 7:9C-1.7(c)4ii using 3 ng/kg/day as the Reference Dose (as explained above) and current USEPA (2015) assumptions for adult body weight and daily drinking water consumption. The RfD of 3 ng/kg/day for GenX provided by USEPA (2021) has one significant figure. The Department determined that a two significant figure RfD could not be derived for GenX because the POD of 0.09 mg/kg/day used to calculate the RfD has only one significant figure (USEPA, 2021; Table 13 - BMDL₁₀ for parental female mice from DuPont 18405-1037, 2010).

The default equation in the Ground Water Quality Standards (N.J.A.C. 7:9C-1.7(c)4ii) for derivation of an ISGWQC for non-carcinogens, and for carcinogens for which a cancer slope factor is not available, is:



$$\text{Criterion } (\mu\text{g/L}) = \frac{\text{Reference Dose} \times \text{Average Adult Weight} \times \text{Conversion Factor} \times \text{Relative Source Contribution}}{\text{Assumed Daily Water Consumption} \times \text{Uncertainty Factor}}$$

$$\text{Criterion for GenX } (\mu\text{g/L}) = \frac{3 \text{ ng/kg/day} \times 80.0 \text{ kg} \times 1000 \mu\text{g/mg} \times 0.2}{2.4 \text{ L/day} \times 1} = 0.02 \mu\text{g/L}$$

Where:

Reference Dose	=	3 ng/kg/day
Average Adult Weight	=	80.0 kg
Conversion Factor	=	1000 μg/mg
Relative Source Contribution	=	0.2
Assumed Daily Water Consumption	=	2.4 L/day
Uncertainty Factor	=	1

(It was determined that an additional uncertainty factor of 10 for carcinogens for which no carcinogenic slope factor is applicable was not necessary because the Reference Dose based on non-carcinogenic effects is protective for potential carcinogenic effects. Therefore, no adjustment [i.e., an uncertainty factor of 1] was made.)

The Ground Water Quality Standards (N.J.A.C. 7:9C-1.7(c)4iv) state that alternative values may be used instead of the default values shown in the rule “if the Department determines, based on constituent-specific factors and/or data, as well as applicable USEPA guidance, generally accepted scientific evidence and methodologies, and/or peer-reviewed sources of information, that use of an alternative value(s) is more suitable than a default value in the equation at (c)4...ii...for the derivation of a particular specific or interim specific criterion.” The body weight of 80.0 kg and daily water consumption of 2.4 L/day were used instead of the default values of 70 kg and 2 L/day specified in the Ground Water Quality Standards because these values (80.0 kg and 2.4 L/day) are the latest recommendations by USEPA (2015).

Derivation of Practical Quantitation Level (PQL): A PQL is the lowest concentration of a constituent that can be reliably achieved among laboratories within specified limits of precision and accuracy and is used to estimate the limits of performance of analytical chemistry methods for measuring contaminants during day-to-day operations. The Ground Water Quality

Standards (N.J.A.C. 7:9C-1.9(c)3ii) state that a PQL for a ground water contaminant can be based on either a Method Detection Limit (MDL) from the NJ Department of Health (NJDOH) laboratory multiplied by five or derived from laboratory performance data that has been evaluated in accordance with N.J.A.C. 7:9C-1.9.

Presently, the NJDOH laboratory is not certified under the Department’s Regulations Governing Certification of Laboratories and Environmental Measurements at N.J.A.C. 7:18 to perform analysis for GenX using EPA Method 533. Thus, the Department collected sufficient interlaboratory performance data from six Office of Quality Assurance (OQA) certified laboratories to recommend an interim PQL of 0.0075 μg/L (median interlaboratory MDL*5) for GenX in ground water using EPA Method 533.

Conclusion: Based on the information provided above (and cited below), the Department has established an ISGWQC of 0.02 μg/L and an interim PQL of 0.0075 μg/L. Since the ISGWQC is higher than the interim PQL for this constituent, the applicable enforceable standard is the ISGWQC of 0.02 μg/L.



Technical Support Documents:

Interim Specific Ground Water Quality Criterion for hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (GenX). Gloria B. Post, Ph.D., D.A.B.T., NJDEP. 2022.

<https://dep.nj.gov/dsr/igwqc-technical-support-documents/>

Interim Practical Quantitation Level for hexafluoropropylene oxide dimer acid (CAS # 13252-13-6) and its ammonium salt (CAS# 62037-80-3) (GenX). R. Lee Lippincott, Ph.D., NJDEP. 2022.

<https://dep.nj.gov/dsr/igwqc-technical-support-documents/>

References:

DuPont-18405-1037. (2010). An Oral (Gavage) Reproduction/Developmental Toxicity Screening Study of H-28548 in Mice. U.S. EPA OPPTS 870.3550; OECD Test Guideline 421. E.I. du Pont de Nemours and Company. Study conducted by WIL Research Laboratories, LLC (Study Completed: December 29, 2010), Ashland, OH.

USEPA (2015). United States Environmental Protection Agency. Human Health Ambient Water Quality Criteria: 2015 Update. Office of Water. EPA 820-F-15-00. June 2015.

USEPA (2021). United States Environmental Protection Agency. Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3). Office of Research and Development. EPA/600/R-20/345F.

