

Ground Water Quality Standard for Chloroperfluoropolyether Carboxylates (CIPFPECAs)

CASRN#: 220182-27-4, 220207-15-8, 330809-92-2, and 329238-24-6

JANUARY 2022

Summary of Decision: In accordance with the New Jersey Ground Water Quality Standards rules 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 0.002 µg/L (ppb) (rounded from 0.0019 µg/L (ppb) in accordance with N.J.A.C. 7:9C-1.7(c)4iii) for chloroperfluoropolyether carboxylates (CIPFPECAs). The basis for this criterion 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. At this time, it is not possible for the Department to derive a PQL for CIPFPECAs because there have been no analytical reference standards validated by an independent third party. When an appropriate analytical method is available, the Department will update 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> to include a PQL. Therefore, the applicable enforceable standard is 0.002 µg/L. This standard applies to the total concentration of CIPFPECAs detected in ground water. The Department will replace the ISGWQC with a specific criterion as soon as reasonably possible by rule.

Chloroperfluoropolyether Carboxylates (CIPFPECAs)

General Molecular Formula:

Chemical Abstracts System Registration Number (CASRN) for CIPFPECAs are:

- 220182-27-4 - Ethyl ester, hydrolyzed
- 220207-15-8 - Ethyl ester, hydrolyzed, sodium salt
- 330809-92-2 - Hydrolyzed, ammonium salts
- 329238-24-6 - Free anion

The substances designated by all of the CASRN shown above exist as the free anion in the environment and in the body.

Each CASRN refers to multiple congeners (also called oligomers) of different chain length, represented by the following general formula based on the nomenclature used by Washington et al. (2020):



Where e and p designate the number of ethyl and propyl groups, respectively, and e and/or p must be >0.

The positions of the e and p groups can be either as shown or reversed within the molecule.

Background: An interim specific ground water quality criterion was developed for chloroperfluoropolyether carboxylates (CIPFPECAs), which are per- and polyfluoroalkyl substances (PFAS). The CIPFPECAs have been used as processing aids and discharged to the environment by Solvay Specialty Polymers U.S.A. (referred to as Solvay), an industrial facility in West Deptford, NJ. CIPFPECAs occur as mixtures of congeners of different carbon and oxygen chain lengths. They are reported to be bioaccumulative in humans with a half-life of 2.5-3 years. EFSA (2010) indicates that Solvay’s CIPFPECA products are used as processing aids in the production of fluoropolymers used in food processing equipment, food contact articles, and antistick coatings on cooking utensils. No information on the annual amounts of CIPFPECAs produced or used worldwide has been identified. Information on the environmental occurrence of CIPFPECAs outside of New Jersey is very limited.

CIPFPECAs are associated with numerous health endpoints in occupationally exposed workers, including increased serum lipids and liver enzymes, decreased immunoglobulins, changes in endocrine parameters, and others. Potential sources of human exposure to CIPFPECAs have not yet been fully characterized. CIPFPECAs were detected in private wells in the vicinity of Solvay’s West Deptford facility, and levels in some of these wells are estimated to be several hundred parts per trillion (ng/L) (McCord et al., 2020). CIPFPECAs have been detected in soil (Washington et al., 2020), vegetation and sediment (unpublished data from NJDEP/EPA study) in Sol-



vay's vicinity. They have also been discharged to air and to water. Direct and/or indirect potential human exposure is possible from all these media.

Reference Dose (RfD): No information is available regarding the carcinogenic potential of CIPFPECA as relevant human epidemiological studies or chronic carcinogenicity bioassays in laboratory animals have not been conducted.

The most sensitive toxicological effects (i.e., effects that occurred at the lowest dose) in the available toxicology studies were observed in male rats in a 13-week study of a mixture of CIPFPECA congeners of different chain lengths (RTC, 2016). Increased relative liver weight, decreases in red blood cell parameters, and hepatocellular micro- and macrovesicular vacu-

olation likely due to steatosis were identified as endpoints that are sensitive, adverse or precursor to adverse, and relevant to humans. These three endpoints were considered for RfD development.

The RfD of 0.28 ng/kg/day for increased relative liver weight, which incorporates a total uncertainty factor (UF) of 3000, was selected as the basis for the interim specific criterion. This RfD is based on a Benchmark Dose Lower Confidence Limit (BMDL) for this sensitive and well-established effect of CIPFPECA and other PFAS, which has been determined to be indicative of adversity and relevant to humans (DWQI, 2015; DWQI, 2017). The RfDs for decreases in red blood cell parameters and hepatocellular macro- and microvesicular vacuolation were not supportable because the total UF exceeded the maximum recommended UF of 3000.

RfD for increased relative liver weight

Human Equivalent Dose (HED) = 833 ng/kg/day (BMDL)

- $UF_{intraspecies} = 10$ The default value of 10 was used to account for potentially more sensitive human sub-populations.
- $UF_{interspecies} = 3$ To account for interspecies toxicodynamic differences.
- $UF_{subchronic} = 10$ The study was subchronic, and no chronic studies are available. The magnitude of this effect at a given dose increased with exposure duration in a series of three studies with different durations (7-day, 4-week, 13-week). Additionally, other endpoints for hepatic toxicity occurred at a given dose in studies of longer duration but not at the same dose in shorter duration studies.
- $UF_{LOAEL} = 1$ No adjustment was made because a BMDL is used.
- $UF_{database} = 10$ There are no data on reproductive, developmental, or immunotoxic effects, either for standard endpoints or for specific effects identified as sensitive endpoints for other PFAS (e.g., effects on mammary gland development). Additionally, more sensitive effects, including adverse histopathological changes in the liver and decreases in hematological parameters related to erythrocytes have been identified for CIPFPECA.
- $UF_{Total} = 3000$
Reference Dose = 833 ng/kg/day / 3000 = 0.28 ng/kg/day (2.8×10^{-7} mg/kg/day)

Derivation of Ground Water Quality Criterion: The ground water quality criterion was derived pursuant to the formula established at N.J.A.C. 7:9C-1.7(c)4ii and rounded to one significant digit in accordance with N.J.A.C. 7:9C-1.7(c)4iii, using 0.28 ng/kg/day as the Reference Dose (as explained above) and current USE-PA (2015) assumptions for adult body weight and daily drinking water consumption.

The default equation in the New Jersey 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:



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

$$\text{Criterion for CIPFPECAs } (\mu\text{g/L}) = \frac{2.8 \times 10^{-7} \text{ mg/kg/day} \times 80.0 \text{ kg} \times 1000 \mu\text{g/mg} \times 0.2}{2.4 \text{ L/day} \times 1} = 0.0019 \mu\text{g/L}$$

which is rounded to 2 ng/L (0.002 μg/L)

Where:

- Average Adult Weight = 80.0 kg
- Relative Source Contribution = 20 percent (0.2)
- Assumed Daily Water Consumption = 2.4 liters per day (L/day)
- Conversion factor = 1000 μg/mg
- Reference Dose = 2.8 x 10⁻⁷ mg/kg/day (0.28 ng/kg/day)
- Uncertainty Factor to account for potentially more sensitive carcinogenic effects = 1

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 a 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 (USEPA, 2015). The default RfD specified in the Ground Water Quality Standards is a chemical-specific RfD from the USEPA IRIS database. An RfD for CIPFPECAs is not available in the USEPA IRIS database, hence NJDEP derived an RfD of 2.8 x 10⁻⁷ mg/kg/day (0.28 ng/kg/day) based on health effects data for CIPFPECAs and risk assessment methodology as recommended by USEPA.

A UF of 10 for carcinogens for which no carcinogenic slope factor is available or 1 for non-carcinogens is included in the default assumptions listed in the Ground Water Quality Standards (N.J.A.C. 7:9C-1.7(c)4iv). A UF of 1 is used for the ISGWQC for CIPFPECAs be-

cause CIPFPECAs are classified as non-carcinogens. It should be noted that other uncertainty factors (e.g., a total of 3000 for the RfD for CIPFPECAs) are incorporated into the RfD.

Derivation of PQL: A practical quantitation level (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 NJDOH laboratory multiplied by 5 or derived from laboratory performance data that has been evaluated in accordance with 7:9C-1.9.

An analytical reference standard that has been validated by an independent third party is needed to develop a PQL based on the NJDOH laboratory MDL or from laboratory performance data. However, this validation has not been performed for CIPFPECAs to date. Therefore, it is not possible for the Department to derive a PQL for CIPFPECAs at this time. Pursuant to N.J.A.C. 7:9C-1.9(c)1, interim PQLs are derived for constituents with interim specific criteria as appropriate. At such time when either an MDL from the NJDOH laboratory or a multi-laboratory validated analytical method has been developed using a third-party verified analytical standard, the Department will update the “Table of Interim Specific Ground Water Quality Criteria (ISGWQC) and Interim PQLs for Constituents in Class II-A Ground Water” to include an interim PQL.

Solvay has submitted information to NJDEP on an analytical method for CIPFPECAs from a commercial laboratory to which Solvay provided analytical standards of CIPFPECAs. Information provided by Solvay to the



Department about the analytical method developed by this commercial laboratory, as well as data from research studies conducted by the Department and USEPA, indicate that individual CIPFPECA congeners may be quantitated to 1 ng/L in ground water. Based upon this information, it is anticipated that laboratories will be able to quantitate CIPFPECAs to below the ISGWQS of 2 ng/L.

Conclusion:

Based on the information provided above (and cited below), the Department has established an interim specific ground water quality criterion of 0.002 µg/L without a PQL. The applicable enforceable standard for CIPFPECAs is 0.002 µg/L. This criterion and standard apply to the total concentration of CIPFPECAs detected in ground water.

Technical Support Documents:

Technical Support Document: Interim Specific Ground Water Quality Criterion for Chloroperfluoropolyether Carboxylates. Gloria B. Post, Ph.D., D.A.B.T., NJDEP. 2021.

References:

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NJDEP (2021). New Jersey Department of Environmental Protection. Technical Support Document: Interim Specific Ground Water Quality Criterion for Chloroperfluoropolyether Carboxylates (CAS Numbers 220182-27-4, 220207-15-8, 330809-92-2, and 329238-24-6). Public Version. 2021.

McCord, J. P., Strynar, M. J., Washington, J. W., Bergman, E. L., & Goodrow, S. M. (2020). Emerging Chlorinated Polyfluorinated Polyether Compounds Impacting the Waters of Southwestern New Jersey Identified by Use of Nontargeted Analysis. *Environmental science & technology letters*, 7(12), 903–908.

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