Interim Specific Ground Water Quality Standard for Perfluorooctanoic Acid (PFOA)

March 2019 *CASRN# 335-67-1* NJDEP

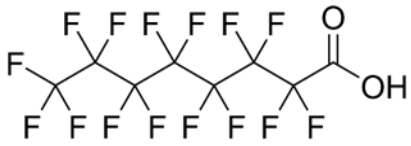
Summary of Decision: In accordance with the New Jersey Ground Water Quality Standards rules at N.J.A.C. 7:9C-1.7, the Department of Environmental Protection (Department) has developed an interim specific ground water quality criterion of 0.01 µg/L and a practical quantitation level (PQL) of 0.006 µg/L (ppb) for perfluorooctanoic acid (PFOA). The basis for this criterion and PQL are discussed below. Pursuant to N.J.A.C. 7:9C-1.9(c), **the applicable constituent standard is 0.01 µg/L**.

Perfluorooctanoic Acid (PFOA)

Molecular Formula:

$CF_3(CF_2)_6COOH$

Molecular Structure:



Background: Perfluorooctanoic acid (PFOA) is part of a larger group of chemicals called poly- and perfluoroalkyl substances (PFAS). PFOA was produced in the U.S. for use in commercial products and industrial processes for over 60 years. Large amounts of PFOA were used as a processing aid in the production of fluoropolymers (e.g. polytetrafluoroethylene) used as non-stick coatings on cookware. Other uses include water, soil, and stain resistant coatings; aqueous film forming foams used in firefighting; and industrial applications. PFOA is soluble in water and is extremely persistent in the environment. The manufacture and use of PFOA was phased out by eight major manufacturers through a voluntary stewardship agreement with the U.S. Environmental Protection Agency (USEPA), with the goal of eliminating emissions and product content by 2015 (USEPA, 2010). Notwithstanding this progress, environmental contamination caused by PFOA is anticipated to continue for the foreseeable future due to its persistence in the environment, formation from precursor compounds, and the potential for continued production by other manufacturers in the U.S. and/or overseas (USEPA, 2009; Lindstrom, et al., 2011).

Reference Dose: PFOA caused numerous toxicological effects in animal studies. Of these, delayed mammary gland development and increased liver weight were the most sensitive non-carcinogenic endpoints with the serum PFOA data needed for dose-response analysis. The Reference Dose (RfD) used to develop the criterion is based on increased liver weight in a 14-day study of male mice (Loveless et al., 2006). A Reference Dose for delayed mammary gland development in prenatally exposed mice (Macon et al., 2011) was also developed. Although it was more sensitive than the RfD based on increased liver weight and was considered scientifically valid, delayed mammary gland development was not used as the basis for the criterion because of lack of precedent for its use as the primary basis for risk assessment. Benchmark Dose (BMD) modeling of the serum PFOA data for increased liver weight from Loveless et al. (2006) determined a serum level BMDL (lower confidence limit on the benchmark dose) for a 10% increase in relative liver weight of 4350 ng/ml. A total uncertainty

factor (UF) of 300 was applied to the serum level BMDL of 4350 ng/ml to derive a Target Human Serum Level (i.e. RfD in terms of serum level) of 14.5 ng/ml. This UF includes UFs of 10 for intra-human variability, 3 for animal-to-human toxicodynamic differences, and 10 to protect against more sensitive toxicological effects, including delayed mammary gland development and hepatic toxicity after developmental exposures, that occurred at doses 100-fold lower than those causing increased liver weight. The RfD of 2 ng/kg/day (2 x 10^{-6} mg/kg/day) is calculated from the Target Human Serum Level (ng/ml) using the chemical-specific clearance factor (CL) of 1.4 x 10^{-4} L/kg/day (1.4 x 10^{-1} ml/kg/day) developed by the USEPA (2016a, 2016b) as follows:

14.5 ng/ml x 0.14 ml/kg/day = 2 ng/kg/day = 2 x 10^{-6} mg/kg/day

PFOA was classified by the Department as having "suggestive evidence of carcinogenic potential" based on testicular, pancreatic, and liver tumors in chronic rat studies. A slope factor of 0.021 $(mg/kg/day)^{-1}$ based on the incidence of testicular tumors was developed. The criterion based on this slope factor at the one in one million cancer risk level (0.014 µg/L, which rounds to 0.01 µg/L) is identical to the criterion based on the RfD.

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, using 2 x 10^{-6} mg/kg/day as the Reference Dose (as explained above), and standard default assumptions:

$$\frac{2 \times 10^{-6} \text{ mg/kg/day} \times 70 \text{ kg} \times 0.2}{2 \text{ L/day}} = 1.4 \times 10^{-5} \text{ mg/L} = 0.014 \text{ µg/L}$$

(which rounds to 0.01 µg/L)

Where:
2 x 10^{-6} mg/kg/day = the derived RfD
70 kg = the assumed weight of an adult human
0.2 = the assumed relative source contribution (20%)
2 L/day = the assumed daily volume of water consumed

Derivation of PQL: The method detection limit (MDL) and the practical quantitation level (PQL) are performance measures used to estimate the limits of performance of analytical chemistry methods for measuring contaminants. The MDL is defined as "the minimum concentration of a substance that can be measured and reported with 99 percent confidence that the analyte concentration is greater than zero" (40 CFR Part 136 Appendix B). The Department uses a value of five times the median as an upper boundary of the inter-laboratory MDL distribution and PQL. Establishing the PQL at a level that is five times the interlaboratory MDL provides a reliable quantitation level that most laboratories can be expected to meet during day-to-day operations.

Sufficient interlaboratory performance data was collected from thirteen (13) laboratories certified for PFOA analysis. The laboratories had similar performance values for PFOA analysis using USEPA Method 537 and/or proprietary methods. A statistical technique called the "Bootstrap estimate of a confidence interval of the mean" was calculated using the statistical package "R". USEPA also uses this method when a limited set of performance data is available (Winslow, 2004). Using this approach, the upper 95% confidence interval (UCL) of the concentration level that would encompass

the certified laboratory community quantification capability value was 0.006 µg/L. **Therefore, the Department has established a PQL of 0.006 ppb or 0.006 ug/L for PFOA.**

Conclusion: Based on the information provided above (and cited below), the Department has established an interim specific ground water quality criterion of 0.01 µg/L and a PQL of 0.006 µg/L (ppb) for PFOA. Since the ground water quality criterion is higher than the PQL for this constituent, pursuant to N.J.A.C. 7:9C-1.9(c), **the applicable constituent standard for PFOA is 0.01 µg/L**.

Technical Support Documents:

Technical Support Document: Interim Specific Ground Water Criterion for Perfluorooctanoic Acid (PFOA). Gloria B. Post, Ph.D., NJDEP; Jessie A. Gleason, M.S.P.H., NJ Dept. of Health. March 2019.

Interim Practical Quantitation Level (PQL) determination to support Interim Specific Ground Water Quality Standard development for Perfluorooctanoic Acid (PFOA). R. Lee Lippincott, Ph.D., NJDEP. March 2019.

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USEPA (2016b). United States Environmental Protection Agency. Health Effects Support Document for Perfluorooctanoic Acid (PFOA). Office of Water. EPA 822-R-16-003. May 2016.

Winslow, S.D., Pepich, B.V., Martin, J.J., Hallberg, G.R., Munch, D.J., Frebis, C.P., Hedrick, E.J., Krop, R.A. (2004). Statistical Procedures for determination and verification of minimum reporting levels for drinking water methods." Environ. Sci. Technol. 40: 281-288.