Ground Water Quality Standard for Perfluorononanoic acid

CASRN# 375-95-1

October 2015 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 (ppb) and a practical quantitation level (PQL) of 0.003 µg/L (ppb) for perfluorononanoic acid (PFNA). 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**.

Perfluorononanoic acid (PFNA)
Molecular Formula:
$C_9HF_{17}O_2$
Molecular Structure:

Background: PFNA is a fully fluorinated carboxylic acid**.** PFNA was historically used primarily as a processing aid in the emulsion process used to make fluoropolymers, mainly polyvinylidene fluoride (Prevedouros et al., 2006). Like other perfluorinated chemicals (PFCs), PFNA is extremely persistent in the environment and is soluble in water (Post et al., 2013). The manufacture and use of PFNA and other long-chain perfluorinated carboxylates is currently being phased out by eight major manufacturers through a voluntary stewardship agreement with the U.S. Environmental Protection Agency (USEPA), with the ultimate goal of eliminating emissions and product content by 2015 (USEPA, 2010, 2012). Most of the participating companies are currently operating at or near this goal (see USEPA's Web site at http://www.epa.gov/oppt/pfoa/pubs/stewardship/). Notwithstanding this progress, environmental contamination caused by PFNA is anticipated to continue for the foreseeable future due to its persistence in the environment, formation from precursor compounds (discussed below), and the potential for continued production by other manufacturers in the U.S. and/or overseas (USEPA, 2009; Lindstrom, et al., 2011).

Reference Dose: The Reference Dose is based on increased liver weight in pregnant mice observed in a developmental study conducted by USEPA (Das et al., 2014). Of the numerous effects observed in this study, increased maternal liver weight was selected as the critical endpoint for quantitative risk assessment because serum levels and liver weights were both measured at the same time point (gestational day (GD) 17), one day after the last dose. Liver weight increased in a dose-related manner, with a Lowest Observed Adverse Effect Level (LOAEL) of 1 mg/kg/day and a serum level BMDL (lower confidence limit on the benchmark dose) of 4,900 ng/ml (4.9 µg/ml) for increased liver weight (Das et al., 2015; numerical data and statistical parameters obtained from C. Lau, USEPA). A No Observed Effect Level (NOAEL) was not identified. An uncertainty factor of 1000 was applied to the BMDL to derive a target human serum level (i.e., Reference Dose in terms of serum level) of

4.9 ng/ml (4.9 µg/L). This includes uncertainty factors of 10 for intraspecies variability, 3 for interspecies variability, 10 to account for less-than-chronic study duration in Das et al. (2015), and 3 for gaps in the toxicological database.

A chemical specific Relative Source Contribution factor (RSC) of 0.5, based on the 95th percentile of serum PFNA in the U.S. general population from the most recent (2011-12) NHANES (CDC, 2015), is applied to the target human serum level of 4.9 ng/ml to derive the target human serum level from drinking water exposure only:

4.9 ng/ml x 0.5 = 2.45 ng/ml which rounds to 2.5 ng/ml (2.5 µg/L)

Pharmacokinetic data support a factor of 0.08 (ng/kg/day)/(ng/ml) relating PFNA intake and increase in PFNA serum level. This factor is used to derive the daily PFNA intake from drinking water (ng/kg/day) which will result in an increase in the serum level of 2.5 ng/ml (4.9 µg/L) as follows.

$$\frac{0.08 \text{ ng/kg/day}}{\text{Ng/ml}} \times 2.5 \text{ ng/ml} = 0.2 \text{ ng/kg/day}$$

Based on the average daily water consumption value recommended by USEPA (2011) of 16 ml/kg/day (0.016 L/kg/day), the drinking water concentration that will result in exposure to 0.2 ng/kg/day is:

$$\frac{0.2 \text{ ng/kg/day}}{0.016 \text{ L/kg/day}} = 13 \text{ ng/L}$$

Using the chemical specific RSC of 0.5 and default assumptions for drinking water consumption and body weight, the Reference Dose that supports the derivation of a criterion of 13 ng/L is 0.74 ng/kg/day, as follows:

$$\frac{13 \text{ ng/L} \times 2 \text{ L/day}}{70 \text{ kg} \times 0.5} = 0.74 \text{ ng/kg/day}$$

Derivation of Interim Specific Ground Water Quality Criterion: The interim specific ground water quality criterion for PFNA was derived pursuant to the formula established at N.J.A.C. 7:9C-1.7(c)4, using 0.74 ng/kg/day as the Reference Dose (as explained above), and standard default assumptions:

$$\frac{0.74 \text{ ng/kg/day} \times 70 \text{ kg} \times 0.5}{2 \text{ L/day}} = 13 \text{ ng/L} = 0.013 \text{ ug/L}$$

(which rounds to 0.01 ug/L)

Where: 13 ng/L = Interim specific ground water criterion
70 kg = Average adult body weight
2 L/day = Assumed daily water consumption
0.5 = Relative Source Contribution factor

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 De-

partment uses a value of five times the median as an upper boundary of the interlaboratory 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. The Department's Office of Quality Assurance currently certifies three commercial laboratories for PFNA analysis. The three certified laboratories had similar performance values for PFNA analysis using USEPA Method 537 and/or proprietary methods. The statistical technique that was used is called the "Bootstrap Estimate of a confidence interval of the mean" and was calculated using the statistical package "R". This process was used because sufficient interlaboratory data (from a minimum of five laboratories) were not available to follow the Department's usual PQL calculation procedures. 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 2.5 ng/L (rounded to 3 ng/l). **Therefore, the Department has established a PQL of 0.003 ppb or 0.003 ug/L for PFNA.**

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 0.003 µg/L (ppb) for PFNA. 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 PFNA is 0.01 µg/L**.

Technical Support Documents:

Interim Specific Ground Water Criterion For Perfluorononanoic Acid (PFNA, C9) NJDEP Office of Science Web site at http://nj.gov/dep/dsr/pfna/index-April2015.htm;

Practical Quantitation Level (PQL) determination to support Interim Specific Ground Water Quality Criterion development for Perfluorononanoic Acid(PFNA), R. Lee Lippincott, Ph.D., NJDEP, March 6, 2014

References:

CDC (2015). Centers for Disease Control and Prevention. NHANES 2011-2012. http://wwwn.cdc.gov/nchs/nhanes/search/nhanes11_12.aspx Accessed January 22, 2015.

Das, K.P., Grey, B.E., Rosen, M.B., Wood, C.R., Tatum-Gibbs, K.R., Zehr, R.D., Strynar, M.J., Lindstrom, A.B., Lau, C. (2015). Developmental toxicity of perfluorononanoic acid in mice. Reproductive Toxicology 51:133-144.

Lindstrom, A.B., Strynar, M.J., Libelo, E.L. (2011a). Polyfluorinated compounds: Past, present, and future. Environ. Sci. Technol. 45: 7954–7961.

Post, G.B., Louis, J.B., Lippincott, R.L., and Procopio, N.A. (2013). Occurrence of perfluorinated chemicals in raw water from New Jersey public drinking water systems. Env. Sci. Technol. 47:13266-75.

Prevedouros, K., Cousins, I.T., Buck, R.C., Korzeniowski, S.H. (2006). Sources, fate and transport of perfluorocarboxylates. Environ. Sci. Technol. 40: 32–44.

USEPA. 2009. United States Environmental Protection Agency. Existing Chemical Action Plans. Office of Pollution Prevention and Toxics. Long-Chain Perfluorinated Chemicals (PFCs) Action Plan. 12/30/09

USEPA. (2010). United States Environmental Protection Agency. Office of Pollution Prevention and Toxics. 2010/2015 PFOA Stewardship Program.

USEPA. (2011). Exposure Factors Handbook 2011 Edition (Final). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-09/052F. http://www.epa.gov/ncea/efh/pdfs/efh-complete.pdf

USEPA. (2012). United States Environmental Protection Agency. Perfluorooctanoic Acid (PFOA) and Fluorinated Telomers 2011 Annual Progress Reports.

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.