

Ground Water Quality Standard for Caprolactam

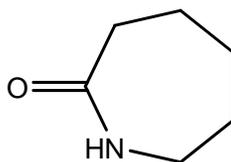
CASRN# 105-60-2

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 3000 µg/L and PQL of 5000 µg/L (ppb) for caprolactam. 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 5000 µg/L.**

Caprolactam

Molecular Formula: C₆H₁₁NO

Molecular Structure:



Background: Caprolactam is utilized as starting material for the production of Nylon-6. It is produced by polycondensation and the seven membered ring monomer is present in unwashed nylon-6 in relatively large amounts. Its presence has also been detected in water that has been in contact with polyolefin bottles at ambient temperatures. Caprolactam has been evaluated by the U.S. Environmental Protection Agency (USEPA) and a Reference Dose is available on the [USEPA IRIS database](#). IRIS does not provide a carcinogenicity assessment, but caprolactam was negative for carcinogenicity in a chronic dietary bioassay in male and female F344 rats and B6C3F1 mice (NTP, 1982), and was evaluated as "probably not carcinogenic to humans" by the International Agency for Research on Cancer (IARC, 1999). Therefore, caprolactam is considered to be a non-carcinogen in the development of a human health-based ground water criterion.

Reference Dose: The IRIS Reference Dose for caprolactam is 0.5 mg/kg/day and was developed in 1988 based on a dietary three generation reproduction study in rats (Serotta et al., 1984). In this study, the No Observed Adverse Effect Level (NOAEL) was 1000 ppm in the diet, equivalent to a dose of 50 mg/kg/day. At higher doses, (5000 and 10,000 ppm) reduced body weight of offspring was seen, as well as reduced body weight and food consumption of the parental generation. At the highest dose (10,000 ppm), a slight increase in the severity of nephropathy was seen in males of the first parental generation. An uncertainty factor of 100, appropriate for a NOAEL in a chronic study, was used to derive the Reference Dose of 0.5 mg/kg/day.

Derivation of Ground Water Quality Criterion: The interim specific ground water quality criterion was derived pursuant to the formula established at N.J.A.C. 7:9C-1.7 (c)4, using 0.5 mg/kg/day as the Reference Dose (as explained above) and standard

default assumptions:

$$\frac{0.5 \text{ mg/kg/day} \times 70 \text{ kg} \times 0.2}{2 \text{ L/day}} = 3.5 \text{ mg/L or } 3500 \text{ ug/L}$$

Where:

0.5 mg/kg/day = Reference Dose

70 kg = assumed body weight of average person

0.2 = Relative Source Contribution from drinking water

2 L/day = assumed daily drinking water intake

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 analytic 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). No published method was listed in the National Environmental Methods Index (NEMI) database for this chemical. A Dialog search located a peer reviewed journal article that contained sufficient performance information to generate a PQL. The article reported a quantitation concentration of 69 ppb in water from 72-hour bottle exposure studies using an analytical method that consisted of conventional Solid Phase Extraction (SPE) techniques to isolate the Caprolactam from water followed by GC/MS with occasional use of HPLC to confirm the quantitation (Skjevraak, et al, 2005). Other articles contained similar analytical approaches but did not report any method performance information. Therefore, by rounding to one significant figure, the Department has established a PQL of 70 ppb for Caprolactam.

Conclusion: Based on the information provided above (and cited below), the Department has established an interim specific ground water quality criterion of 3500 µg/L and a PQL of 5000 µg/L (ppb) for caprolactam. Pursuant to N.J.A.C. 7:9C-1.9(c), since the PQL is higher than the criterion for this constituent, the applicable constituent standard is 5000 µg/L.

Technical Support Documents: *Interim Specific Ground Water Quality Criterion Recommendation Report for Caprolactam*, Dr. Gloria Post, NJDEP, September 7, 2006; *Procedure for Describing Process for Development of Analytical Practical Quantitation Levels (PQLs) for Caprolactam*, R. Lee Lippincott, Ph.D, NJDEP, September 14, 2006.

References:

IARC (1999). International Agency for Research on Cancer. Summaries and Evaluations. Volume 71, p. 383. Caprolactam.

NTP (1982). National Toxicology Program. Technical Report No. 214 on the Carcinogenesis Bioassay of Caprolactam. National Institutes of Health Pub. No. 81-1770.

Serota, D.G., A.M. Hoberman, M.A. Friedman, and S.C. Gad. 1988. Three-generation reproduction study with caprolactam in rats. *J. Appl. Toxicol.* 8(4): 285-293. (Cited in USEPA IRIS database.)

Skjevraak, Ingun; et. al. 2005. Non-targeted multi-component analytical surveillance of plastic food contact materials: Identification of substances not included in EU positive

lists and their risk assessment. J. Food Additives and Contaminants. October 2005. 22 (10): 1012-1022.

USEPA (2002). Integrated Risk Information System. Caprolactam (CASRN 105-60-2). Last modified, 12/3/2002.



New Jersey Department of Environmental Protection
Water Monitoring and Standards
Bureau of Water Quality Standards and Assessment
www.state.nj.us/dep/wms/bwqsa/
(609) 777-1753

