Ground Water Quality Standard for **Dichlormid**

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NIDEP

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 600 μ g/L and PQL of 50 μ g/L (ppb) for Dichlormid. 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 600 \mug/L.**

Dichlormid N, N-diallyl dichloroacetamide Molecular Formula: C₈H₁₁Cl₂NO



Background: Dichlormid is an herbicide "safener" currently approved by the U.S. Environmental Protection Agency (USEPA) for use on corn forage and stover to protect corn from injury when using chloroacetanilide and thiocarbamate herbicides; and to protect rice and wheat from the injury of acetochlor, butachlor, metolachlor, vernolate, Lasso, tri-allate, Ordram, Simagine, etc. Its intended function is to protect the target crops against the unintended effects of herbicides rather than cause an adverse effect itself.

There is a fairly strong toxicological database for Dichlormid; however, all available data was generated by the manufacturers in support of pesticide registration petitions submitted to the USEPA. Some of the available data was provided in summary form in the Federal Register and some of the data was from USEPA's Data Evaluation Records. No data was available from peer-reviewed scientific literature. While it was not possible to evaluate the data as individual, peer-reviewed studies, the data have received extensive internal USEPA review.

In general, Dichlormid appears to exhibit relatively nonspecific systemic toxicity. There is no indication of carcinogenicity or specific developmental or reproductive effects. The critical effects seen in both mice and rats in chronic studies occurs within a consistent and narrow range of No Observed Adverse Effect Levels (NOAEL) and Low Observed Adverse Effect Levels (LOAELs). It is assumed that the primary route of exposure to groundwater contaminated by Dichlormid will be ingestion of water. In the absence of

physical/chemical information, it is not possible to rule out inhalation exposure during showering. However, the single reported inhalation study (14-day, rat) was conducted using an aerosol. This suggests that Dichlormid is not readily volatile. This is consistent with the reported melting point of 5.0-6.5 °C, which suggests that inhalation exposure during showering is not likely to be a significant route of exposure. However, results from a sub-chronic dog study raises the possibility that rodents may not be the most sensitive species. In the dog study, degeneration of voluntary muscle was observed at a dose similar to that producing the critical effects in chronic rodent studies. This raises the possibility that rodents may not be the most sensitive species, although the same effects were not seen in another sub-chronic dog study of similar duration with a higher dose. While this sub-chronic effect is not sufficiently robust either across species or within species to be identified as the critical effect, its occurrence should be accounted for in the derivation of a Reference Dose.

Reference Dose (RfD): The NOAEL for critical effect in chronic studies in rats and mice (changes in liver and kidney histopathology) is 7 mg/kg/day. Based on the uncertainty factor adjustment (described below), the RfD for dichlormid is 0.02 mg/kg/day.

Uncertainty factor (UF) adjustment:

 $\begin{array}{l} UF_{animal-human} = 10 \\ UF_{sensitive\ human} = 10 \\ UF_{modifying\ factor} = 3 \ (based\ on\ observation\ of\ muscle\ degeneration\ in\ single\ sub-chronic\ dog\ study) \end{array}$

 $UF = UF_{total} = 10 \times 10 \times 3 = 300$

RfD = NOAEL/UF = 7 mg/kg/day/300 = 0.02 mg/kg/day

Relative Source Contribution Factor: Data presented by USEPA (Fed. Reg. 67. P. 35996, May 22, 2002) indicates that, for the most highly exposed subgroup (children 1-6 years old), the estimated background exposure to dichlormid (including crop residues, drinking water, and non-dietary sources) would result in a dose of 0.0002 mg/kg/day. This is 1% of the Reference Dose calculated by the Department (see above). Current USEPA guidance for considering non-water sources of exposure when developing water quality criteria recommends using a ceiling of 80% even when data indicates that non-water exposures are less than 20%. Therefore, the Department selected a relative source contribution factor of 0.8 in deriving the ground water quality criterion for dichlormid.

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)4, using 0.02 mg/kg/day as the Reference Dose, a Relative Source Contribution Factor of 0.8 (as explained above), and standard default assumptions:

<u>0.02 mg/kg/day x 70 kg x 0.8</u> = 0.56 mg/L (rounds to 0.6 mg) = 600 μ g/L 2 L/day

Where:

0.02 mg/kg/day = the derived RfD
70 kg = the assumed weight of an adult human
0.8 = the assumed relative source contribution from drinking water
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 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). USEPA recommends that the MDL be multiplied by a factor of five or 10 to account for the variability and uncertainty that can occur at the MDL. The Department uses a value of five as the median upper boundary of the inter-laboratory MDL distribution from the New Jersey certified laboratory community and multiplies the MDL by five to derive the PQL. Establishing the PQL at a level that is five times the MDL provides a reliable quantitation level that most laboratories can be expected to meet during day-to-day operations.

The analytical method was developed by the USEPA ACL (Analytical Chemical Laboratory) using gas chromatography with nitrogen selective thermionic detection. The limit of determination is 10 ppb (see the Federal Register, Vol. 70, No. 35, Wednesday, February 23, 2005, Notices). As explained above, a more conservative detection limit is established using a multiplier of five. 10 ppb x 5 = 50 ppb. Therefore, the Department has established a PQL of 50 ppb for dichlormid.

<u>Conclusion</u>: Based on the information provided above (and cited below), the Department has established an interim specific ground water quality criterion of 600 μ g/L and a PQL of 50 μ g/L (ppb) for dichlormid. 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 dichlormid is 600 \mug/L.**

Technical Support Documents: Interim Specific Ground Water Quality Criterion Recommendation Report for Dichlormid, Dr. Alan Stern, NJDEP, May 24, 2004 (revisions of 6/16/04 incorporated November 27, 2007); Procedure for Describing Process for Development of Analytical Practical Quantitation Levels (PQLs) for Dichlormid, R. Lee Lippincott, Ph.D., NJDEP, [Date].

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