

of this review, EPA has decided to retain its classification of each of the cresol isomers (m-, o-, and p-cresol) in weight-of-evidence Group C, possible human carcinogen. The deficiencies noted by the commenter regarding the in vitro and in vivo studies relied on by the Agency are reasons for the Agency's decision not to classify the evidence of carcinogenicity as "sufficient."¹⁹ Reviewed together, however, these studies do provide limited evidence of animal carcinogenicity and, thus, justify classification of the cresol isomers in weight-of-evidence Group C. The Agency, therefore, will retain its original decision to adjust the RQ for cresols from 1,000 to 100 pounds, and to establish final RQs of 100 pounds for each of the cresol isomers.²⁰

d. *Diethanolamine*. Three commenters opposed the 100-pound proposed RQ for diethanolamine based on the chronic toxicity criterion. The commenters asserted that a primary criteria RQ of 1,000 pounds is more appropriate for this substance, and that application of the secondary RQ adjustment criterion of biodegradation should be applied to raise the final RQ to 5,000 pounds.

Under the methodology for developing primary criterion RQs based on chronic toxicity, a substance is first assigned two rating values, one based on the dose that causes a particular effect, and one based on the severity of the effect. The dose rating value (RV_d) ranges from one to 10, with 10 representing the most toxic substances. The effect rating value (RV_e) also ranges from one to 10, with 10 representing the most severe effect. The product of the RV_d and RV_e for a substance yields a composite score between one and 100. Tentative chronic toxicity RQs are then assigned on the basis of the composite score.²¹

¹⁹ For further information on the data and findings of the in vitro and in vivo studies, see Section 3 of the Technical Background Document to Support Rulemaking Pursuant to CERCLA Section 102, Volume 7, available for inspection as part of the public docket for this rulemaking at the CERCLA Docket Office, Crystal Gateway #1, 12th Floor, 1235 Jefferson Davis Highway, Arlington, VA 22202.

²⁰ For detailed responses to the comments on the carcinogenicity of cresols, see Response Numbers II.B.10 and II.B.11 in Section II of the responses to comments document for this rulemaking, available for inspection at the CERCLA Docket Office, Crystal Gateway #1, 12th Floor, 1235 Jefferson Davis Highway, Arlington, VA 22202.

²¹ For further information on the relationship of composite scores to tentative chronic toxicity RQs, see the Technical Background Document to Support Rulemaking Pursuant to CERCLA Section 102, Volume 2, available for inspection as part of the public docket for this rulemaking at the CERCLA Docket Office, Crystal Gateway #1, 12th Floor, 1235 Jefferson Davis Highway, Arlington, VA 22202.

Because no chronic toxicity studies have been reported for diethanolamine, both EPA and the commenters used data from a 13-week subchronic study (Melnick (1992)²² to develop their respective conclusions. Based on a different interpretation of these same data, the commenters supported use of an RV_e of 5, rather than the RV_e of 7 used by EPA to assign a 100-pound primary criterion RQ for diethanolamine. The commenters generally agreed with the Agency on an RV_d of 3.8 for the substance.

In supporting an RV_e of 5 for diethanolamine, one of the commenters asserted that increased blood urea nitrogen (BUN) is incorrectly listed as an effect and that reported kidney changes do not identify impairment of kidney function. EPA disagrees; upward trends in relative kidney weight and BUN have been observed together, suggesting that kidney function (i.e., removal of excess urea) in the exposed animals is impaired, resulting in increased kidney weight. The Agency, therefore, considers it appropriate to place diethanolamine in RV_e category 7 because of the observed "necrosis * * * with a detectable decrement of organ function." This results in a composite score of 26.6 (i.e., $3.8 RV_d \times 7 RV_e$) and a corresponding chronic toxicity primary criterion RQ of 100 pounds.

This commenter also supported raising the primary criterion RQ for diethanolamine one level, based on the secondary criterion of biodegradation. Two (Bridie et al. (1979) and Gannon et al. (1978))²³ of the eight studies submitted by the commenter on the biodegradation of diethanolamine reported BOD₅ values equal to or greater than the standard for upward RQ adjustment on the basis of biodegradation. These experiments, however, were conducted using "adapted" sewage sludge (see previous discussion on biphenyl), rather than under conditions normally found in the environment. One (Bridie et al. (1979)) of these two studies also evaluated diethanolamine using unadapted sewage sludge, but the result was a BOD₅ of only two percent.

Because the data provided by the commenter do not justify application of the secondary RQ adjustment criterion

²² Melnick, R.L., 1992. NTP Technical Report on the Toxicity Studies of Diethanolamine (CAS No. 111-42-2) Administered Topically and in Drinking Water to F344/N Rats and B6C3F1 Mice. National Toxicology Program. NIH Publication No. 92-3343.

²³ Bridie, A.L. et al., 1979. Biochemical Oxygen Demand and Chemical Oxygen Demand of Some Petrochemicals. *Water Research* 13:627-30; and Gannon, J.E. et al., 1978. Microbial Degradation of Diethanolamine and Related Compounds. *Microbios*. 23:7-18.

of biodegradation to diethanolamine, the Agency has promulgated a final RQ of 100 pounds (as proposed) based on chronic toxicity.

e. *Ethylene Glycol*. One commenter stated that, based on the incidence of pet and wildlife poisonings due to ingestion of ethylene glycol antifreeze, the 5,000-pound proposed RQ for ethylene glycol is inappropriate. The commenter asserted that, by raising the RQ to 5,000 pounds, EPA would be sending the false message that ethylene glycol is not dangerous. According to the commenter, such a message would result in reduced attention to all but the largest releases of this substance. For this reason, the commenter urges EPA to retain a one-pound RQ for ethylene glycol.

While EPA shares the concerns expressed by the commenter regarding acute exposures to ethylene glycol, the Agency believes that a lower RQ for ethylene glycol would not necessarily prevent accidental poisonings to humans, pets, and wildlife. RQs under CERCLA serve only to notify the Federal, State, and local governments of the release so that authorities can determine whether a response is necessary under the particular circumstances of the release.

In addition, the technical data supplied by the commenter do not support assignment of an RQ for ethylene glycol below 5,000 pounds. Under EPA's RQ adjustment methodology, an acute mammalian toxicity RQ for oral exposure to a hazardous substance (e.g., ethylene glycol) is determined based on the dose that is lethal to 50 percent of the animal population tested (known as the LD₅₀ value). For the oral exposure route, LD₅₀s of between 100 and 499 milligrams per kilogram (mg/kg) define the range that results in a 5,000-pound RQ based on acute mammalian toxicity. LD₅₀ values above 499 mg/kg also result in RQs at the maximum 5,000-pound level; LD₅₀s below 100 mg/kg result in RQs between one and 1,000 pounds.

The commenter supplied several pieces of information to support the position that ethylene glycol should be assigned a one-pound RQ. This information included studies on the toxicity of ethylene glycol, a table showing regulation of ethylene glycol under Federal environmental statutes (e.g., the CAA and CERCLA), and newspaper articles describing accidental poisonings. EPA has carefully reviewed these materials. None of the data submitted by the commenter support an RQ of one-pound; in fact, all of these data are well above the upper bound of the range of acute mammalian toxicity