EXECUTIVE SUMMARY

ETHANOLAMINE - Oral Risk Assessment - CAS # 141-43-5			
PARAMETER	**LEVEL**	**UNITS**	**DERIVED**
NOAEL (no-observed-adverse-effect level)	120	mg/kg-day	From a developmental toxicity study in Wistar rats
Oral RfD (oral reference dose)	0.04	mg/kg-day	From a developmental toxicity study in Wistar rats with a 3,000x uncertainty factor.
TAC (total allowable concentration)	0.3	mg/L	For a 70 kg adult drinking 2 L/day with a default 20% Relative Source Contribution for drinking water
SPAC (single product allowable concentration)	0.03	mg/L	For a 70 kg adult drinking 2 L/day assuming the default 10 drinking water sources of ethanolamine
STEL (short term exposure level)	4	mg/L	From a developmental toxicity study in Wistar rats, for a 10 kg child drinking 1L/day

KEY STUDY	Hellwig, J. and A.B. Liberacki. 1997. Evaluation of the Pre-, Peri-, and Postnatal Toxicity of Monoethanolamine in Rats Following Repeated Oral Administration during Organogenesis. Fundamental and Applied Toxicology. 40(1):158-162.
CRITICAL EFFECT	Maternal toxicity, which included reduced maternal food consumption and body weight, observed in pregnant rats that received ethanolamine via gavage and occurred in the absence of developmental toxicity.
UNCERTAINTY FACTORS	• 10x for interspecies extrapolation • 10x for intraspecies extrapolation • 10x for extrapolation from a less-than-lifetime study to a lifetime exposure duration • 1x for extrapolation from a LOAEL to a NOAEL • 3x for database deficiencies. Therefore, the total uncertainty factor is 3,000x.
TOXICITY SUMMARY	Human data were limited to reports on the induction of asthma after exposure to airborne ethanolamine. There were several repeated-dose systemic studies in laboratory animals, although none fully met current regulatory guidelines. Increased liver and kidney weights with associated cloudy swelling were seen when dietary ethanolamine was administered to rats at 640 mg/kg-day and higher for 90 days, with a NOAEL of 320 mg/kg-day. Skin irritation and transient lethargy, but no gross or histopathology were noted in dogs, rats or guinea pigs that inhaled 12 to 26 ppm ethanolamine vapors continuously for 90 days. Reduced body weight, lethargy, reduced prothrombin levels, and increased liver weights were seen in a non-standard early study in which rats received ethanolamine in drinking water for approximately seven months. In a standardized gavage developmental study, maternal toxicity was observed in Wistar rat dams in the absence of developmental toxicity at 450 mg/kg-day. The NOAEL was 120 mg/kg-day. In another developmental study, reduced fetal weight was seen at gavage doses that preceded and included maternal toxicity in pregnant Long Evans rats given ethanolamine beginning at 50 mg/kg-day. However, the latter study in Long Evans rats was possibly compromised since only ten treated dams per dose were studied. Further, more recently conducted standardized developmental studies did not corroborate these reductions in fetal weight at doses that failed to elicit maternal toxicity. Thus, the key study and critical effect were considered the maternal toxicity observed after pregnant Wistar rats received ethanolamine via gavage. A benchmark dose level was not estimated since maternal toxicity is generally characterized by a spectrum of effects, rather than quantitatively modeled based on one effect. Thus, the traditional NOAEL/uncertainty factor approach was used to determine the RfD for ethanolamine. The weight of evidence suggests that ethanolamine has some genotoxic potential *in vitro*, but no *in vivo* data were identified. Based on U.S. EPA (2005) guidelines, there is *inadequate information to assess carcinogenic potential* of exposure to ethanolamine in humans, due to the lack of human epidemiological data and chronic toxicity data in laboratory animals.
CONCLUSIONS	The drinking water levels developed in this assessment are considered protective of public health since they were based on the most sensitive endpoint from standardized studies in laboratory animals, due to lack of human data. Appropriate uncertainty factors to account for data deficiencies were applied to obtain these risk levels.