CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 (PROPOSITION 65)

NOTICE TO INTERESTED PARTIES March 7, 2003

Decision Not to Proceed With the Listing of Diethanolamine Via the Authoritative Bodies Listing Mechanism

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65 or the Act) requires the Governor to publish, and update at least annually, a list of chemicals known to the State to cause cancer or reproductive toxicity. The Act provides for administratively listing chemicals as known to the State to cause cancer or reproductive toxicity (Health and Safety Code Section 25249.8(b)) when a body considered to be authoritative by the state's qualified experts has formally identified it as causing cancer or reproductive toxicity. The National Toxicology Program, in addition to other bodies, has been identified as an authoritative body for purposes of the Act. The criteria for listing chemicals through the "authoritative bodies" mechanism are set forth in Title 22, California Code of Regulations (22 CCR) Section 12306.

As the lead agency for the implementation of Proposition 65, the Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency examines documents released by authoritative bodies to identify chemicals for possible listing under Proposition 65. OEHHA identified documents produced by the National Toxicology Program (NTP, 1997a and b) supporting the possible listing of diethanolamine via the authoritative bodies mechanism. On February 5, 1999, OEHHA issued a "Request for Relevant Information" in the California Regulatory Notice Register (Register 99, No. 6) concerning the possible listing of diethanolamine as "known to cause cancer." As part of its commitment to public participation and external scientific peer review in its implementation of Proposition 65, OEHHA solicited, via that notice, information relevant to the evaluation of diethanolamine in the context of the Proposition 65 administrative listing regulatory criteria (22 CCR Section 12306). The notice announced the beginning of the public comment period for receiving written comments and a public forum (held March 2, 1999) for interested parties to present oral comments and to discuss the scientific data and other information relevant to a determination as to whether diethanolamine and other chemicals identified in the notice met the criteria for listing set forth in 22 CCR Section 12306.

OEHHA heard and received in writing substantive public comment on the possible listing of diethanolamine. Considerable scientific information has been released subsequent to the release of the National Toxicology Program report on diethanolamine (NTP, 1997a). This new information has been considered by OEHHA in light of 22 CCR Section 12306(f). Because it is not clear that the scientific criteria for listing under the authoritative bodies

mechanism have been met, OEHHA has decided not to proceed with the administrative listing of diethanolamine under Proposition 65.

References:

National Toxicology Program (NTP, 1997a). *Toxicology and Carcinogenesis Studies of Diethanolamine (CAS No. 111-42-2) in F344/N Rats and B6C3F*₁ *Mice (Dermal Studies)*. Board Draft. NTP Technical Report Series No. 478 NTIS Publication No. 97-3968. US Department of Health and Human Services, NTP, Research Triangle Park, NC.

National Toxicology Program (NTP, 1997b). Summary Minutes from Peer Review of Draft Technical Reports of Long-Term Toxicology and Carcinogenesis Studies by the Technical Reports Review Subcommittee on December 9-10, 1997. NTP, Research Triangle Park, NC.