CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

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

NOTICE OF INTENT TO LIST CHEMICALS June 25, 1999

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) provides two mechanisms for administratively listing chemicals which are known to the State to cause cancer or reproductive toxicity (Health and Safety Code Section 25249.8(b)). One such mechanism by which a chemical may be listed is if a body considered to be authoritative by the state's qualified experts has formally identified it as causing cancer or reproductive toxicity. The following are identified as authoritative bodies for purposes of Proposition 65 as it pertains to chemicals known to cause reproductive toxicity: the US Environmental Protection Agency (US EPA), the International Agency for Research on Cancer (for transplacental carcinogenicity only), the US Food and Drug Administration, and the National Institute for Occupational Safety and Health. 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 intends to list the chemical, N-methylpyrrolidone, as known to the State to cause reproductive toxicity, pursuant to this administrative mechanism as provided in Health and Safety Code Section 25249.8(b) and 22 CCR, Section 12306.

N-methylpyrrolidone was the subject of a notice of intent to list published in the *California* Regulatory Notice Register (CRNR) on April 23, 1999. Relevant information on N-methylpyrrolidone was requested in a notice published in the CRNR on October 30, 1998 and a public forum was held on December 18, 1998. In the October 30, 1998 notice as well as in the supporting documents released on October 30 and April 23, 1999, OEHHA clearly stated that N-methylpyrrolidone was under consideration for listing as known to cause developmental toxicity, male reproductive toxicity and female reproductive toxicity. However due to a typographical omission in the notice of intent to list published on April 23, 1999, only developmental toxicity was listed as a toxicological endpoint under consideration. In order to clarify the record that N-methylpyrrolidone is in fact under consideration for all three toxicological endpoints, OEHHA hereby re-publishes the notice of intent to list for N-methylpyrrolidone. The document providing more detail on the basis for the listing can be obtained from OEHHA's Proposition 65 Implementation Office at the address and telephone number indicated below, or from the OEHHA Home Page at: http://www.oehha.ca.gov/. Anyone objecting to the listing of N-methylpyrrolidone as causing reproductive toxicity (which includes developmental toxicity) on the basis that there is no substantial evidence that the criteria of sufficiency of evidence of reproductive toxicity identified in 22 CCR, Section 12306 have been

satisfied should provide written comments in <u>triplicate</u>, along with supporting documentation, by mail or by fax to:

Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment
301 Capitol Mall, 2nd Floor, Room 205
Sacramento, California 95814
Fax No.: (916) 327-1097
Telephone: (916) 445-6900

Comments may also be hand-delivered to Ms. Oshita at the Office of Environmental Health Hazard Assessment at the same address.

In order to be considered, comments must be postmarked (if sent by mail) or received at OEHHA (if delivered in person or sent by FAX) by 5:00 p.m. on Monday, July 26, 1999.

The following chemical has been determined by OEHHA to meet the criteria set forth in 22 CCR, Section 12306 for listing as causing reproductive toxicity under the authoritative bodies mechanism:

Chemical	CAS No.	Toxicological Endpoint	Reference ^a
N-Methylpyrrolidone	872-50-4	developmental toxicity	US EPA (1994a,b)
		male reproductive toxicity	
		female reproductive toxicity	

Formal identification by US EPA of chemicals causing reproductive toxicity is provided in US EPA (1994b) below, while additional information on the basis for such identification is provided in US EPA (1994a).

References

US Environmental Protection Agency (US EPA, 1994a) Proposed Rule: Addition of Certain Chemicals; Toxic Chemical Release Reporting; Community Right to Know. *Federal Register* (**59** FR 1788).

US Environmental Protection Agency (US EPA, 1994b). Final Rule: Addition of Certain Chemicals; Toxic Chemical Release Reporting; Community Right to Know. *Federal Register* (**59** FR 61432).