

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
(PROPOSITION 65)**

**REQUEST FOR RELEVANT INFORMATION ON
CHEMICALS BEING CONSIDERED FOR LISTING
BY THE AUTHORITATIVE BODIES MECHANISM:
DDE AND NITROBENZENE**

October 30, 2009

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) is requesting information as to whether 1,1-dichloro-2,2-bis(*p*-chlorophenyl)ethylene (DDE) and nitrobenzene meet the criteria for listing as reproductive toxicants under the Safe Drinking Water and Toxic Enforcement Act of 1986.¹ This action is being proposed under the authoritative bodies listing mechanism.²

Chemical	CAS No.	Endpoint	Reference	Chemical Use
1,1-Dichloro-2,2-bis(<i>p</i> -chlorophenyl)-ethylene (DDE)	72-55-9	Developmental, male reproductive	U.S. EPA (2008)	Environmental degradation product of DDT, an insecticide.
Nitrobenzene	98-95-3	Male reproductive	U.S. EPA (2009)	Used in the synthesis of other industrial chemicals and intermediates. Occurs in shoe and metal polishes and soaps.

Background on listing via the authoritative bodies mechanism: A chemical must be listed under the Proposition 65 regulations when two conditions are met:

- 1) An authoritative body formally identifies the chemical as causing reproductive toxicity (Section 25306(d)³).
- 2) The evidence considered by the authoritative body meets the sufficiency criteria contained in the regulations (Section 25306(g)).

¹ Commonly known as Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986 is codified in Health and Safety Code section 25249.5 *et seq.*

² See Health and Safety Code section 25249.8(b) and Title 27, Cal. Code of Regs., Section 25306.

³ All referenced sections are from Title 27 of the Cal. Code of Regulations.

However, the chemical is not listed if scientifically valid data which were not considered by the authoritative body clearly establish that the sufficiency of evidence criteria were not met (Section 25306 (h)).

The U.S. Environmental Protection Agency (U.S. EPA) is one of several institutions designated as authoritative for the identification of chemicals as causing reproductive toxicity (Section 25306(l)).

OEHHA is the lead agency for Proposition 65 implementation. After an authoritative body has made a determination about a chemical, OEHHA evaluates whether listing under Proposition 65 is required using the criteria contained in the regulations.

DDE

OEHHA's determination: DDE appears to meet the criteria for listing as known to the State to cause reproductive toxicity under Proposition 65, based on findings of the U.S. Environmental Protection Agency (U.S. EPA, 2008).

Formal identification and sufficiency of evidence: In 2008, the U.S. EPA published a report on DDE (U.S. EPA, 2008). This report concludes that the chemical causes developmental and male reproductive toxicity, and appears to satisfy the formal identification and sufficiency of evidence criteria in the Proposition 65 regulations.

OEHHA is relying on the U.S. EPA's conclusions in the report that DDE causes reproductive toxicity. The U.S. EPA report concludes:

“DDE has been found to be an antiandrogenic compound, which may explain a number of reproductive and developmental effects seen in male rats exposed to DDE at various ages.”

“Observed effects in the male animals include reduced anogenital distance and retention of thoracic nipples in pups exposed during gestation and lactation; delayed puberty in rats exposed either during juvenile development or at very high doses during gestation and lactation; and reduced accessory sex organ weights in exposed adult males.”

“[A]nimal studies also reveal susceptibility to DDE during development, particularly in males. In rats, exposure to 100 mg/kg/day during gestation resulted in a significant decrease in ventral prostate weight in males at 15 months of age and a decrease in weights of glans penis, ventral prostate, and epididymis at 10 months old; reduced anogenital distance and increased mean number of retained nipples also were observed in the newborns. Anogenital distance at birth was reduced in male rat pups exposed transplacentally to 100 mg/kg/day during gestational (and also unquantified pup exposure during lactation); the animals also had retained thoracic nipples on postnatal day 13 and a significant delay in the onset of puberty was reported.”

Based on the U.S. EPA report and the references cited in the report, the evidence appears sufficient for listing by the authoritative bodies mechanism.

Nitrobenzene

OEHHA's determination: Nitrobenzene appears to meet the criteria for listing as known to the State to cause reproductive toxicity under Proposition 65, based on findings of the U.S. Environmental Protection Agency (U.S. EPA, 2009).

Formal identification and sufficiency of evidence: In 2009, the U.S. EPA published a report on nitrobenzene (U.S. EPA, 2009). This report concludes that the chemical causes male

reproductive toxicity, which appears to satisfy the formal identification and sufficiency of evidence criteria in the Proposition 65 regulations.

OEHHA is relying on the U.S. EPA's discussion of data and conclusions in the report that nitrobenzene causes reproductive toxicity. The U.S. EPA report concludes:

“In male rats (F344/N and CD) and mice (B6C3F1), nitrobenzene exposure via the inhalation and oral routes has been shown to cause testicular atrophy, including a dramatic decrease in sperm count with ensuing loss of fertility.”

“In rodents... nitrobenzene is a moderately effective male reproductive toxicant.”

There “is strong evidence for nitrobenzene to act as a male reproductive toxicant...”

Thus, the U.S. EPA (2009) has formally identified nitrobenzene as causing male reproductive toxicity in rodents.

Request for relevant information: OEHHA is committed to public participation in its implementation of Proposition 65. OEHHA wants to ensure that its regulatory decisions are based on a thorough consideration of all relevant information. OEHHA is requesting public comment concerning whether these chemicals meet the criteria set forth in the Proposition 65 regulations for authoritative bodies listings.

After reviewing all comments received, OEHHA will determine whether DDE and nitrobenzene meet the regulatory criteria for administrative listing. If listing proceeds, OEHHA will publish a Notice of Intent to List.

In order to be considered, **comments must be received by OEHHA by 5:00 p.m. on Wednesday, January 6, 2010.** We encourage you to submit comments in electronic form, rather than in paper form. Comments transmitted by e-mail should be addressed to coshita@oehha.ca.gov. Comments submitted in paper form may be mailed, faxed, or delivered in person to the addresses below:

Mailing Address: Ms. Cynthia Oshita
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS-19B
Sacramento, California 95812-4010

Fax: (916) 323-8803

Street Address: 1001 I Street
Sacramento, California 95814

Optional public forum: Upon request, OEHHA will schedule a public forum to provide individuals an opportunity to present oral comments on the possible listing of DDE and nitrobenzene. At the forum, the public may discuss the scientific data and other relevant information on whether either chemical meets the criteria for listing in the regulations.

Requests for a public forum must be submitted in writing no later than **December 4, 2009.** The written request must be sent to OEHHA at the mailing address above. If a public forum is requested, a notice will be posted on the OEHHA Web site at least ten days before the forum date. The notice will provide the date, time, location and subject matter to be heard. Notices will also be sent to those individuals requesting such notification.

If you have any questions, please contact Ms. Oshita at coshita@oehha.ca.gov or at (916) 445-6900.

References

U. S. EPA, 2008: Health Effects Support Document for 1,1-Dichloro-2,2-bis(*p*-chlorophenyl)ethylene (DDE). U.S. Environmental Protection Agency Office of Water (4304T) Health and Ecological Criteria Division Washington, DC 20460. EPA Document Number EPA-822-R-08-003, January 2008 (www.epa.gov/safewater/ccl/pdf/DDE.pdf).

U. S. EPA, 2009: Toxicological Review of Nitrobenzene (CAS No. 98-95-3) in Support of Summary Information on the Integrated Risk Information System (IRIS). U.S. Environmental Protection Agency Washington, DC. EPA/635/R-08/004F January 2009 (www.epa.gov/iris).