

**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: MON 4660, MON 13900, AND PYMETROZINE**

**January 21, 2011**

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) intends to list the chemicals *MON 4660 (dichloroacetyl-1-oxa-4-azaspiro(4.5)decane)*, *MON 13900 (furilazole)*, and *pymetrozine* as known to the State to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986.<sup>1</sup> This action is being taken under the authoritative bodies listing mechanism.<sup>2</sup>

| <b>Chemical</b>  | <b>CAS No.</b> | <b>Endpoint</b> | <b>Reference</b> | <b>Chemical Use</b>   |
|--|----------------|-----------------|------------------|---|
| <i>MON 4660 (dichloroacetyl-1-oxa-4-aza-spiro(4.5)-decane)</i> | 71526-07-3     | Cancer          | U.S. EPA (1999a) | Herbicide safener* used in formulations with acetanilide herbicides (such as alachlor and/or acetochlor). |
| <i>MON 13900 (furilazole)</i>                                  | 121776-33-8    | Cancer          | U.S. EPA (1999b) | Herbicide safener* used in formulations with the acetanilide herbicide acetochlor.                        |
| <i>Pymetrozine</i>   | 123312-89-0    | Cancer          | U.S. EPA (1999c) | Anti-feeding insecticide used on lettuce, broccoli, celery, and other vegetables and fruits               |

\* A safener is an inert ingredient used to protect the desired crop from the effects of the active herbicide.

OEHHA requested information relevant to the possible listing of *MON 4660*, *MON 13900*, and *pymetrozine* in a notice published in the *California Regulatory Notice Register* on October 22, 2010 (Register 2010, No. 43-Z). OEHHA received no public comments.

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

<sup>1</sup> 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.*

<sup>2</sup> See Health and Safety Code section 25249.8(b) and Title 27, Cal. Code of Regs., section 25306.

- 1) An authoritative body formally identifies the chemical as causing cancer (Section 25306(d)<sup>3</sup>).
- 2) The evidence considered by the authoritative body meets the sufficiency criteria contained in the regulations (Section 25306(e)).

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(f)).

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

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.

**OEHHA's determination:** *MON 4660*, *MON 13900*, and *pymetrozine* each meet the criteria for listing as known to the State to cause cancer under Proposition 65, based on findings of the U.S. EPA (U.S. EPA, 1999a; U.S. EPA, 1999b; U.S. EPA, 1999c).

**Formal identification and sufficiency of evidence for MON 4660 (dichloroacetyl-1-oxa-4-azaspiro(4.5)decane):** In 1999, the U.S. EPA published a report on MON 4660, entitled *Cancer Assessment Document, Evaluation of the Carcinogenic Potential of MON 4660*, which concludes that the chemical causes cancer (U.S. EPA, 1999a). This report satisfies 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 MON 4660 causes cancer. The U.S. EPA report concludes that MON 4660 is "likely to be carcinogenic to humans" by the oral route." Evidence described in the report includes studies showing that MON 4660 increased the incidences of tumors as follows:

Male rats:

- Hepatocellular carcinomas and combined hepatocellular adenomas and carcinomas
- Combined squamous cell papillomas and carcinomas of the stomach

Female rats:

- Combined hepatocellular adenomas and carcinomas

Male mice:

- Hepatocellular carcinomas and combined hepatocellular adenomas and carcinomas
- Squamous cell carcinomas and combined squamous cell papillomas and carcinomas of the stomach

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<sup>3</sup> All referenced sections are from Title 27 of the Cal. Code of Regulations.

Female mice:

- Squamous cell carcinomas and combined papillomas and carcinomas of the stomach

Thus, the U.S. EPA (1999a) has found that MON 4660 causes an increased incidence of malignant tumors or combined malignant and benign tumors in male rats and male and female mice, with tumors at multiple sites in male rats and mice.

**Formal identification and sufficiency of evidence for MON 13900 (furilazole):** In 1999, the U.S. EPA published a report on MON 13900 (furilazole), entitled *Cancer Assessment Document, Evaluation of the Carcinogenic Potential of MON 13900*, which concludes that the chemical causes cancer (U.S. EPA, 1999b). This report satisfies 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 MON 13900 causes cancer. The U.S. EPA report concludes that MON 13900 is "likely to be carcinogenic to humans" by the oral route." Evidence described in the report includes studies showing that MON 13900 increased the incidences of tumors as follows:

Male rats:

- Combined hepatocellular adenomas and carcinomas
- Combined squamous cell papillomas and carcinomas of the stomach
- Testicular interstitial cell tumors of the testes

Female rats:

- Hepatocellular carcinomas and combined hepatocellular adenomas and carcinomas

Female mice:

- Hepatocellular carcinomas and combined hepatocellular adenomas and carcinomas
- Bronchio-alveolar carcinomas and combined bronchio-alveolar adenomas and carcinomas

Thus, the U.S. EPA (1999b) has found that MON 13900 causes increased incidences of malignant or combined malignant and benign tumors in male rats, female rats, and female mice, including rare stomach tumors in male rats and an increased incidence of tumors at multiple sites in male rats and female mice.

**Formal identification and sufficiency of evidence for pymetrozine:** In 1999, the U.S. EPA published a report on pymetrozine, entitled *Cancer Assessment Document, Evaluation of the Carcinogenic Potential of Pymetrozine*, which concludes that the chemical causes cancer (U.S. EPA, 1999c). This report satisfies 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 pymetrozine causes cancer. The U.S. EPA report concludes pymetrozine is "likely to be a human carcinogen" by the oral route." Evidence described in the report

includes studies showing that pymetrozine increased the incidences of hepatocellular carcinomas in male mice and combined benign hepatomas and hepatocellular carcinomas in male and female mice.

Thus, the U.S. EPA (1999c) has found that pymetrozine causes increased incidences of malignant liver tumors in male mice, and combined malignant and benign liver tumors in male and female mice.

**Request for comments:** 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 comments as to whether these three chemicals meet the criteria set forth in the Proposition 65 regulations for authoritative bodies listings. In order to be considered, **comments must be received by OEHHA by 5:00 p.m. on Tuesday, February 22, 2011.** 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](mailto:coshita@oehha.ca.gov). Comments submitted in paper form may be mailed or delivered in person in triplicate, or faxed, 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

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

## References

U.S. Environmental Protection Agency (U.S. EPA, 1999a). Cancer Assessment Document, Evaluation of the Carcinogenic Potential of MON 4660. Final Report. Cancer Health Effects Division, Office of Pesticide Programs. December 9, 1999.

U.S. Environmental Protection Agency (U.S. EPA, 1999b). Cancer Assessment Document, Evaluation of the Carcinogenic Potential of MON 13900. Health Effects Division, Office of Pesticides Programs. September 21, 1999.

U.S. Environmental Protection Agency (U.S. EPA, 1999c). Cancer Assessment Document, Evaluation of the Carcinogenic Potential of Pymetrozine. Health Effects Division, Office of Pesticide Programs. August 24, 1999.