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 KRESOXIM-METHYL AND TETRACONAZOLE

December 2, 2011

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) intends to list the chemicals *kresoxim-methyl* and *tetraconazole* as known to the State to cause cancer 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**	**Occurrence**
Kresoxim-methyl (143390-89-0)	Cancer	U.S. EPA (1999)	Fungicide used on apples, cherries, grapes, pears, pome fruits and pecans
Tetraconazole (112281-77-3)	Cancer	U.S. EPA (2000)	Triazole fungicide used to control leafspot and powdery mildew on sugar beets

OEHHA requested information relevant to the possible listing of *kresoxim-methyl* and *tetraconazole* in a notice published in the *California Regulatory Notice Register* on October 22, 2010 (Register 2010, Vol. No. 43-Z). OEHHA received public comments on both chemicals.

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 cancer (Section 25306(d)[3]).
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)).

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[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.

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: *Kresoxim-methyl* and *tetraconazole* 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, 1999; U.S. EPA, 2000).

Formal identification and sufficiency of evidence for kresoxim-methyl: In 1999, the U.S. EPA published a report on kresoxim-methyl entitled *Cancer Assessment Document, Evaluation of the Carcinogenic Potential of Kresoxim-Methyl* that concludes that the chemical causes cancer (U.S. EPA, 1999). 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 kresoxim-methyl causes cancer. The U.S. EPA report concludes that kresoxim-methyl is "'likely to be carcinogenic to humans' by the oral route." Evidence described in the report includes studies showing that kresoxim-methyl increased the incidences of hepatocellular carcinoma in male and female rats in two experiments in each sex.

Thus, the U.S. EPA (1999) has found that kresoxim-methyl causes increased incidence of malignant liver tumors in two experiments in male rats and in two experiments in female rats.

Formal identification and sufficiency of evidence for tetraconazole: In 2000, the U.S. EPA published a report on tetraconazole, entitled *Cancer Assessment Document, Evaluation of the Carcinogenic Potential of Tetraconazole* that concludes that the chemical causes cancer (U.S. EPA, 2000). 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 tetraconazole causes cancer. The U.S. EPA report concludes tetraconazole is "'likely to be carcinogenic to humans' by the oral route." Evidence described in the report includes studies showing that tetraconazole causes increases in the incidences of hepatocellular carcinomas and combined hepatocellular carcinomas and adenomas in male and female mice.

Thus, the U.S. EPA (2000) has found that tetraconazole causes increased incidences of malignant 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 chemicals meet the criteria set forth in the Proposition 65 regulations for authoritative bodies listings. In order to be considered, **OEHHA must receive comments by 5:00 p.m. on Tuesday, January 17, 2012.** We encourage you to submit comments in electronic form, rather than in paper form. Comments transmitted by e-mail should be addressed to

P65Public.Comments@oehha.ca.gov. Comments submitted in paper form may be mailed, faxed, or delivered in person to the addresses below:

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

References

U.S. Environmental Protection Agency (U.S. EPA, 1999). Cancer Assessment Document, Evaluation of the Carcinogenic Potential of Kresoxim-methyl. Final Report. Health Effects Division, Office of Pesticide Programs. August 19, 1999.

U.S. Environmental Protection Agency (U.S. EPA, 2000). Cancer Assessment Document, Evaluation of the Carcinogenic Potential of Tetraconazole. Final Report. Health Effects Division, Office of Pesticide Programs. January 11, 2000.