CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

NOTICE OF PROPOSED RULEMAKING
TITLE 27, CALIFORNIA CODE OF REGULATIONS

AMENDMENT TO SECTION 25705
SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT RISK: IMAZALIL

SEPTEMBER 23, 2011

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment (OEHHA) proposes to establish a specific regulatory level posing no significant risk for imazalil and amend Title 27, California Code of Regulations, section 25705.[1]

PUBLIC PROCEEDINGS

Any written statements or arguments concerning this proposed action, regardless of the form or method of transmission, must be received by OEHHA by 5:00 p.m. on **November 7, 2011**, the designated close of the written comment period.

Written comments can be sent by e-mail, mail or fax addressed to:

Monet Vela
Office of Environmental Health Hazard Assessment
Proposition 65 Implementation Program
P. O. Box 4010
Sacramento, California 95812-4010
FAX: (916) 324-1786
Telephone: (916) 323-2517
monet.vela@oehha.ca.gov

Comments sent by courier should be delivered to:

Monet Vela
Office of Environmental Health Hazard Assessment
1001 I Street, 19th Floor
Sacramento, California 95814

It is requested but not required that hard-copy statements or arguments be submitted in triplicate.

[1] All further regulatory references are to Title 27 of the California Code of Regulations unless otherwise indicated.

On request only, OEHHA will schedule a public hearing to present oral comments. The request must be submitted in writing to OEHHA at the address listed above no later than **October 21, 2011**, which is 15 days before the close of the comment period. OEHHA will mail a notice for any scheduled public hearing to interested parties on the Proposition 65 mailing list for regulatory public hearings. The notice will also be posted on the OEHHA web site at least ten days before the public hearing date. The notice will provide the date, time, location and subject matter to be heard.

If a hearing is scheduled and you have special accommodation or language needs, please contact Monet Vela at (916) 323-2517 or monet.vela@oehha.ca.gov at least one week in advance of the hearing. TTY/TDD/Speech-to-Speech users may dial 7-1-1 for the California Relay Service.

CONTACT

Please direct inquiries concerning the substance and processing of the action described in this notice to Monet Vela, in writing at the address given above, or by telephone at (916) 323-2517. Fran Kammerer is a back-up contact person for inquiries concerning processing of this action and is available at (916) 445-4693.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq. and commonly known as Proposition 65 (hereinafter Proposition 65 or the Act), prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the State to cause cancer or reproductive toxicity, without first giving clear and reasonable warning to such individual (Health and Safety Code section 25249.6). The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into any source of drinking water (Health and Safety Code section 25249.5).

For chemicals known to the state to cause cancer, an exemption from the warning requirement is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which the person is responsible produces no significant risk or that a discharge which otherwise complies with all applicable requirements would not cause any significant amount of the discharged or released chemical to enter any source of drinking water (Health and Safety Code sections 25249.9 and 25249.10). A determination that a level of exposure poses no significant risk may be made utilizing regulations that have previously been adopted by OEHHA (sections 25701-25721). Section 25701 describes alternative methods for making such a determination. Section 25705 sets forth the process by which OEHHA may identify specific regulatory levels for determining “no significant risk” for purposes of Proposition 65 and establishes those levels for certain listed chemicals.

Details on the basis for the proposed level are provided in the initial statement of reasons, which is incorporated in the rulemaking record.

This amendment to section 25705(c) would adopt the following No Significant Risk Level (NSRL) for one chemical listed as known to cause cancer:

Chemical	NSRL, in units micrograms per day
Imazalil	11

Under Section 25705(c), an NSRL may be determined by the lead agency based on state or federal risk assessments, unless a specific regulatory level of a chemical listed under Proposition 65 has already been established in Section 25705(b). Here, the NSRL is based upon a federal risk assessment by the U.S. Environmental Protection Agency (U.S. EPA). The cancer unit risk value adopted by U.S. EPA provides the basis for calculating the proposed NSRL, as discussed in more detail in the initial statement of reasons for this regulatory amendment.

This notice and the initial statement of reasons are being provided to the OEHHA Science Advisory Board's Carcinogen Identification Committee (CIC) to review and comment on the proposed NSRL.

AUTHORITY

Health and Safety Code Section 25249.12.

REFERENCE

Health and Safety Code Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11.

IMPACT ON LOCAL AGENCIES OR SCHOOL DISTRICTS

OEHHA has determined the proposed regulatory action would not impose a mandate on local agencies or school districts nor does it require reimbursement by the State pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code. OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

COSTS OR SAVINGS TO STATE AGENCIES

OEHHA has determined that no savings or increased costs to any State agency will result from the proposed regulatory action.

EFFECT ON FEDERAL FUNDING TO THE STATE

OEHHA has determined that no costs or savings in federal funding to the State will result from the proposed regulatory action.

EFFECT ON HOUSING COSTS

The OEHHA has determined that the proposed regulatory action will have no effect on housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

OEHHA has made an initial determination that the adoption of the regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

IMPACT ON THE CREATION, ELIMINATION, OR EXPANSION OF JOBS/BUSINESSES

OEHHA has determined that the proposed regulatory action will not have any impact on the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

The OEHHA is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

EFFECT ON SMALL BUSINESSES

OEHHA has determined that the proposed regulation will not impose any requirements on small business. Rather, the proposed regulation will assist small businesses subject to the Act in determining whether or not an exposure for which they are responsible is subject to the warning requirement or discharge prohibition.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code Section 11346.5(a)(13), OEHHA must determine that no reasonable alternative considered by OEHHA or that has otherwise been identified and brought to the attention of OEHHA would be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons than the proposed action.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATIONS

OEHHA has prepared and has available for public review an Initial Statement of Reasons for the regulation, all the critical information upon which the regulation is based

and the text of the regulation. A copy of the Initial Statement of Reasons, a copy of the text of the regulation and a copy of the risk assessment which was used by OEHHA to determine the proposed NSRL are available upon request from OEHHA's Proposition 65 Implementation Program at the address and telephone number indicated above. These documents are also posted on OEHHA's Web site at www.oehha.ca.gov.

AVAILABILITY OF CHANGED OR MODIFIED TEXT: The full text of any regulation which is changed or modified from the express terms of this proposed action will be made available at least 15 days prior to the date on which OEHHA adopts the resulting regulation. Notice of the comment period on changed regulations and the full text will be mailed to individuals who testified or submitted written comments at the public hearing, whose comments were received by OEHHA during the public comment period, and who request notification from OEHHA of availability of such changes. Copies of the notice and the changed regulation will also be available at the OEHHA's Web site.

FINAL STATEMENT OF REASONS

A copy of the Final Statement of Reasons may be obtained, when it becomes available, from OEHHA's Proposition 65 Implementation Program at the address and telephone number indicated above. The Final Statement of Reasons will also be available at the OEHHA's Web site at www.oehha.ca.gov.

OFFICE OF ENVIRONMENTAL
HEALTH HAZARD ASSESSMENT

Allan Hirsch
Chief Deputy Director

Dated: September 23, 2011

INITIAL STATEMENT OF REASONS
TITLE 27, CALIFORNIA CODE OF REGULATIONS

PROPOSED AMENDMENT TO

SECTION 25705(c), SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT RISK: IMAZALIL

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
PROPOSITION 65

PURPOSE AND BACKGROUND OF PROPOSED AMENDMENTS OF REGULATION

This proposed regulatory amendment is to provide a no significant risk level (NSRL) for imazalil exposure under Proposition 65[1] in Section 25705(c)(2). The proposed level of 11 micrograms per day is based on findings by the U.S. Environmental Protection Agency (U.S. EPA) regarding the cancer potency of the chemical.

Proposition 65 was enacted as a voters' initiative on November 4, 1986. The Office of Environmental Health Hazard Assessment (OEHHA) is the lead state entity responsible for the implementation of Proposition 65.[2] OEHHA has the authority to promulgate and amend regulations to further the purposes of the Act.[3] The Act requires businesses to provide a warning when they cause an exposure to a chemical listed as known to cause cancer or reproductive toxicity. The Act also prohibits the discharge of listed chemicals to sources of drinking water.

On May 20, 2011, imazalil was listed as a carcinogen, based on findings of carcinogenicity by the U.S. EPA[4,5,6,7], a Proposition 65 authoritative body. The U.S. EPA has developed a cancer slope factor for the chemical, and has used it in its 2003 Reregistration Eligibility Decision (RED).[6] U.S. EPA described its findings in the RED as follows:

---

[1] The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et. seq., hereafter referred to as "Proposition 65" or "The Act".
[2] Title 27, California Code of Regulations, section 25102(o).
[3] Health and Safety Code, section 25249.12(a).
[4] U.S. EPA, 1999. Cancer Assessment Document. Evaluation of the Carcinogenic Potential of Imazalil (Third Review). Cancer Assessment Review Committee. Health Effects Division. Office of Pesticide Programs. December 7, 1999.
[5] U.S. EPA, 2002. Imazalil: The Revised HED Toxicology Chapter for the Reregistration Eligibility Decision Document (RED). PC Code 111901, Case 816389. HED Document No. 0050434. U.S. EPA, Office of Pesticide Programs, Washington DC, 20460, January 31, 2002
[6] U.S. EPA. 2003. Reregistration Eligibility Decision for Imazalil. Chemical List B. Case No. 2325. Office of Prevention, Pesticides and Toxic Substances, U.S. EPA, Washington DC.
[7] U.S. EPA. 2005. R.E.D. Facts. Imazalil. EPA-738-F-04-011. Office of Prevention, Pesticides and Toxic Substances, U.S. EPA, Washington DC.

> "Carcinogenicity studies in rodents indicate imazalil is carcinogenic to male Swiss albino mice and Wistar rats based on a significant increase in liver adenomas and combined adenomas/carcinomas. In rats, there was also an increased incidence of combined thyroid follicular cell adenomas/carcinomas.
>
> Based on current science policy and absent information supporting a mode of action in test animals, EPA quantified the human cancer risk by a linear low-dose (Q_1*) extrapolation. The most potent unit risk, Q_1* $(mg/kg/day)^{-1}$ for imazalil based on male mouse liver adenoma and/or carcinoma combined tumor rates, is 6.1×10^{-2} $(mg/kg/day)^{-1}$ in human equivalents."

The cancer unit risk value used by U.S. EPA provides the basis for establishing a no significant risk level (NSRL). As stated in Section 25705(c), unless a specific regulatory level of a chemical listed under Proposition 65 has been established in Section 25705(b), an NSRL may be determined by the lead agency based on state or federal risk assessments.

The U.S. EPA assessment underwent a public process before adoption. U.S. EPA issued its preliminary human health risk assessment for imazalil on February 7, 2002. After review of public comments, the Agency has determined that the risk assessment did not need to be updated for the RED.

The NSRL is frequently expressed as the daily intake level posing no significant risk of cancer, in units of micrograms per day. In general, daily intake levels associated with lifetime cancer risks above one per one-hundred thousand (which can be expressed in scientific terms as10^{-5}) exceed the NSRL for cancer under Proposition 65 (Section 25703(b)).

The NSRL can be calculated as follows. The risk level of 10^{-5} is divided by the U.S. EPA unit risk value, a measure of the carcinogenic activity of the chemical. When unit risk is expressed in units of one divided by milligram (mg) per kilogram (kg) bodyweight per day ($(mg/kg\text{-}day)^{-1}$), the result of this calculation is a dose associated with a 10^{-5} risk in units of mg/kg-day. This dose then can be converted to an intake amount in units of milligrams per day by multiplying by the bodyweight for humans. When the calculation is for the general population the bodyweight is assumed to be 70 kg in NSRL calculations (Section 25703(a)(8)). The intake can be converted to a micrograms–per-day amount by multiplying by 1000. This sequence of calculations can be expressed mathematically as:

$$\text{NSRL} = \frac{10^{-5} \times 70\ \text{kg}}{\text{unit risk}} \times 1000\ \mu\text{g/mg}.$$

The unit risk value for imazalil derived in the U.S. EPA documents is 0.061 $(mg/kg\text{-}day)^{-1}$. Inserting this number into the equation above results in an NSRL of 11 micrograms (µg)/day.

PROPOSED REGULATORY AMENDMENT

The proposed change to Section 25705(c)(2) is provided below in underline:

(2) The following levels based on state or federal risk assessments shall be deemed to pose no significant risk:

Chemical name	Level (micrograms per day)
Acetaldehyde	90 (inhalation)
…	
Imazalil	11
…	

NECESSITY

This proposed regulatory amendment would adopt an NSRL that conforms with the Proposition 65 implementing regulations and reflects the currently available scientific knowledge about this chemical. The NSRL, as a "safe harbor number," provides assurance to the regulated community that exposures or discharges below it are considered not to pose a significant risk of cancer. Exposures below the NSRL are exempt from the warning and discharge requirements of Proposition 65.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDIES, REPORTS, OR DOCUMENTS

The 2003 U.S. EPA Reregistration Eligibility Decision was relied upon for the proposed amendment to Section 25705(c). The document provides the basis for calculating the NSRL for the chemical. A copy will be included in the regulatory file for this action.

REASONABLE ALTERNATIVES TO THE REGULATION AND THE AGENCY'S REASONS FOR REJECTING THOSE ALTERNATIVES

The alternative to the amendment to Section 25705(c) would be to not promulgate an NSRL for the chemical or to promulgate it in a different subsection of Section 25705. Failure to promulgate an NSRL would leave the business community without a safe harbor to assist them in determining compliance with Proposition 65. Development of a safe harbor based on a new OEHHA risk assessment pursuant to Section 25705(b) would be unnecessary and an imprudent use of limited state resources. The data set serving as the basis for

the assessment would be the same selected by OEHHA, and the derivation would use the same methods as used by U.S. EPA in establishing the unit risk value for use in its 2003 RED.[8] This value serves as the basis for U.S. EPA regulations of imazalil, addressing risks from food and occupational exposures. Publication of an expedited safe harbor pursuant to Section 25705(d) would not be appropriate since a reliable value from an intensive scientific process is available.

REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESSES

OEHHA is not aware of any cost impacts that small businesses would incur in reasonable compliance with the proposed action. In addition, Proposition 65 is limited by its terms to businesses with 10 or more employees (Health and Safety Code, section 25249.11(b)), so it has no effect on very small businesses.

EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON BUSINESS

OEHHA does not anticipate that the regulation will have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states

DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS CONTAINED IN THE CODE OF FEDERAL REGULATIONS

Proposition 65 is a California law that has no federal counterpart. There are no federal regulations addressing the same issues and, thus, there is no duplication or conflict with federal regulations.

[8] U.S. EPA. 2003. Reregistration Eligibility Decision for Imazalil. Chemical List B. Case No. 2325. Office of Prevention, Pesticides and Toxic Substances, U.S. EPA, Washington DC.