

**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:**

TRIS(1,3-DICHLORO-2-PROPYL) PHOSPHATE (TDCPP)

June 1, 2012

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment (OEHHA) proposes to adopt a No Significant Risk Level (NSRL) for tris(1,3-dichloro-2-propyl) phosphate (TDCPP) and amend Title 27, California Code of Regulations, Section 25705.¹ The proposed NSRL of 5.4 micrograms per day ($\mu\text{g}/\text{day}$) is based on a carcinogenicity study in rodents and was derived using the methods described in Section 25703.

PUBLIC PROCEEDINGS

Any written comments concerning this proposed action, regardless of the form or method of transmission, must be received by OEHHA by 5:00 p.m. on **July 16, 2012**, the designated close of the written comment period. All comments received will be posted on the OEHHA website at the close of the public comment period.

The public is encouraged to submit written information via e-mail, rather than in paper form. Send e-mail comments to P65Public.Comments@oehha.ca.gov. Please include "TDCPP Safe Harbor" in the subject line. Hard-copy comments may be mailed, faxed, or delivered in person to the appropriate address below.

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

Mailing Address: Ms. Susan Luong
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

A public hearing on this proposed regulatory amendment will be scheduled on request. To request a hearing send an e-mail to Susan Luong at susan.luong@oehha.ca.gov or to the address listed above by no later than **July 2, 2012**. OEHHA will mail a notice of the hearing to the requester and 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, and location of the hearing.

If a hearing is scheduled and you have special accommodation or language needs, please contact Susan Luong at (916) 327-3015 or susan.luong@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 proposed regulatory action described in this notice to Susan Luong, in writing at the address given above, or by telephone at (916) 327-3015. Monet Vela is a back-up contact person for inquiries concerning processing of this action and is available at monet.vela@oehha.ca.gov or (916) 323-2517.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Proposition 65² 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 individual³. The Act also prohibits a business from knowingly

² The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq., commonly known as Proposition 65 and referred to herein as "Proposition 65" or "The Act."

³ Health and Safety Code section 25249.6.

discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into any source of drinking water⁴.

For carcinogens, an exemption from the warning requirement is provided by the Act when the exposure for which the person is responsible can be demonstrated to produce 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 water⁵. A determination that a level of exposure poses no significant risk may be made utilizing OEHHA regulations (Sections 25701-25721). Section 25701 describes alternative methods for making such a determination. Section 25705 sets forth the process for determining “no significant risk” levels 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 for this regulatory amendment, which is available upon request from Susan Luong and is posted on the OEHHA web site at www.oehha.ca.gov.

This proposed amendment to section 25705(b) would adopt the NSRL for TDCPP as follows:

Chemical	NSRL, in units micrograms per day
Tris(1,3-dichloro-2-propyl) phosphate (TDCPP)	5.4

To develop the proposed NSRL for TDCPP, OEHHA relied on a 2011 OEHHA document entitled, “Evidence on the Carcinogenicity of Tris(1,3-dichloro-2-propyl) phosphate,⁶ which summarizes the available data from rodent carcinogenicity studies of TDCPP, as well as other information relevant to the carcinogenic activity of the chemical. The NSRL is based upon the results of the most sensitive scientific study deemed to be of sufficient quality.⁷ OEHHA determined that this criterion was met by a two-year diet study conducted in male Sprague-Dawley CD rats by Bio/dynamics⁸ and

⁴ Health and Safety Code section 25249.5.

⁵ Health and Safety Code section 25249.9 and 25249.10.

⁶ Office of Environmental Health Hazard Assessment (OEHHA), 2011. Evidence on the Carcinogenicity of Tris(1,3-dichloro-2-propyl) phosphate. California Environmental Protection Agency, OEHHA, Reproductive and Cancer Hazard Assessment Branch, July 2011, available at: http://oehha.ca.gov/prop65/hazard_ident/pdf_zip/TDCPP070811.pdf.

⁷ Section 25703(a)(4).

⁸ Bio/dynamics, Inc., 1981. A Two Year Oral Toxicity/Carcinogenicity Study on Fyrol FR-2 in Rats (Final Report). Volume V. Submitted to Stauffer Chemical Co. by Bio/dynamics, Inc. Project No. 77-2016. Sept. 21, 1981.

reported in the published scientific literature by Freudenthal and Henrich⁹. The study and the derivation of the NSRL are discussed in more detail in the Initial Statement of Reasons for this proposed regulatory amendment.

Specific Benefits Anticipated by the Regulation: Some businesses may not be able to afford the expense of establishing an NSRL and therefore may face litigation for a failure to warn or for a prohibited discharge of the listed chemical. Adopting this regulation will save these businesses those expenses and may reduce litigation costs. In addition, by providing an NSRL, this regulatory proposal may encourage businesses to reduce the amount of the listed chemical in their products to a level that does not cause a significant exposure. This may reduce exposures to TDCPP and reduce state's residents, worker and environmental exposures to chemicals that cause cancer.

PEER REVIEW

This notice and the initial statement of reasons are being provided to members of the Carcinogen Identification Committee for scientific peer review and comment.

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.

RESULTS OF ECONOMIC IMPACT ANALYSIS (Gov. Code section 11346.3(b))

By providing an NSRL, this regulatory proposal spares businesses the expense of calculating their own NSRL and may also enable them to reduce or avoid litigation costs. In addition, the NSRL does not require, but may encourage, businesses to lower the amount of the listed chemical in their product to a level that does not cause a significant exposure, thereby providing a public health benefit to Californians.

⁹ Freudenthal RI and Henrich RT, 2000. Chronic toxicity and carcinogenic potential of tris(1,3-dichloro-2-propyl) phosphate in Sprague-Dawley rat. *International Journal of Toxicology* **19**(2):119-25.

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

This regulatory proposal will not affect the creation or elimination of jobs within the State of California. Proposition 65 requires businesses with ten or more employees to provide warnings when they expose people to chemicals that are known to cause cancer or reproductive toxicity. The law also prohibits the discharge of listed chemicals into sources of drinking water. TDCPP is listed under Proposition 65 as causing cancer, and therefore businesses that knowingly expose employees or members of the public to TDCPP through their products or operations must provide a warning.

Because the proposed NSRL provides compliance assistance to businesses subject to the Act, but does not impose any mandatory requirements on those 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.

NO INCONSISTENCY OR INCOMPATIBILITY WITH EXISTING REGULATIONS

OEHHA has determined that the proposed regulation is neither inconsistent nor incompatible with existing state regulations because it does not impose any mandatory requirements on businesses, state or local agencies and does not address compliance with any other law or regulation.

IMPACT ON LOCAL AGENCIES OR SCHOOL DISTRICTS

Because Proposition 65 expressly¹⁰ does not apply to 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.

¹⁰ See Health and Safety Code section 25249.11 (b)

COSTS OR SAVINGS TO STATE AGENCIES

Because Proposition 65 expressly¹¹ does not apply to any State agency, 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

Because Proposition 65 expressly¹² does not apply to any federal agency, 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

OEHHA has determined that the proposed regulatory action will have no effect on housing costs because it provides compliance assistance to businesses subject to the Act, but does not impose any mandatory requirements on those businesses.

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

Because the proposed NSRL provides compliance assistance to businesses subject to the Act, but does not impose any mandatory requirements on those businesses, 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.

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

Since the proposed NSRL provides compliance assistance to businesses subject to the Act, but does not impose any mandatory requirements on those businesses, the Office of Environmental Health Hazard Assessment is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

¹¹ See Health and Safety Code section 25249.11(b)

¹² See Health and Safety Code section 25249.11(b)

EFFECT ON SMALL BUSINESSES

OEHHA has determined that the proposed NSRL will not impose any mandatory requirements on small business. Rather, the proposed NSRL will provide compliance assistance for small businesses subject to the Act because it will help them determine whether or not an exposure for which they are responsible is subject to the warning requirement or discharge prohibition of the Act.

CONSIDERATION OF ALTERNATIVES

The OEHHA must determine that no reasonable alternative considered by the OEHHA or that has otherwise been identified and brought to the attention of the OEHHA would either 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 or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposal described in this Notice.

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 information upon which the regulation is based and the text of the regulation. A copy of the Initial Statement of Reasons, the text of the regulation and the risk assessment which was used by OEHHA to develop the proposed regulation are available upon request from OEHHA at the address and telephone number indicated above. This document is 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, if held, or whose comments were received by OEHHA during the public comment period, and anyone who requests notification from OEHHA of the availability of such changes. Copies of the notice and the changed regulation will also be available on the OEHHA Web site at www.oehha.ca.gov.

FINAL STATEMENT OF REASONS

A copy of the Final Statement of Reasons for this regulatory action may be obtained, when it becomes available, from OEHHA at the address and telephone number indicated above, and on the OEHHA website at www.oehha.ca.gov.

OFFICE OF ENVIRONMENTAL
HEALTH HAZARD ASSESSMENT

Allan Hirsch
Chief Deputy Director

Dated: June 1, 2012