CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
PROPOSITION 65

NOTICE OF PROPOSED RULEMAKING
TITLE 27, CALIFORNIA CODE OF REGULATIONS

AMENDMENT TO SECTION 25805
SPECIFIC REGULATORY LEVELS:
CHEMICALS CAUSING REPRODUCTIVE TOXICITY

ETHYLENE GLYCOL (INGESTED)

April 8, 2016

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment (OEHHA) proposes to establish a Proposition 65[1] Maximum Allowable Dose Level (MADL) for oral exposure to ethylene glycol of 8,700 micrograms per day by amending Section 25805(b) of Title 27 of the California Code of Regulations[2].

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 **May 23, 2016**, 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 "ETHYLENE GLYCOL MADL" in the subject line. Hard-copy comments may be mailed, faxed, or delivered in person to the appropriate address below.

Mailing Address: Ms. Monet Vela
Office of Environmental Health Hazard Assessment
P.O. Box 4010, MS-23B
Sacramento, California 95812-4010
Fax: (916) 323-2517
Street Address: 1001 I Street
Sacramento, California 95814

[1] The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq., referred to herein as "Proposition 65" or "The Act."
[2] All further references are to sections of Title 27, Cal. Code of Regs., unless otherwise indicated.

Please be aware that OEHHA is subject to the California Public Records Act and other laws that require the release of certain information upon request. Comments on all regulatory and other actions are routinely posted on our website. By sending us your comments you are waiving any right to privacy you may have in the information you provide. Individual commenters should advise OEHHA when submitting documents to request redaction of home address or personal telephone numbers. Names of commenters will not be redacted.

A public hearing on this proposed regulatory amendment will be scheduled on request. To request a hearing send an e-mail to Monet Vela at monet.vela@oehha.ca.gov or to the address listed above by no later than **May 9, 2016**, which is 15 days before the close of the comment period. 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 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 proposed regulatory action described in this notice to Monet Vela, in writing at the address given above, via e-mail to monet.vela@oehha.ca.gov or (916) 323-2517. Fran Kammerer will be a back-up contact. She can be contacted at (916) 445-4693 or fran.kammerer@oehha.ca.gov.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Proposition 65 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[3]. 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[4]. Warnings are not required and the discharge prohibition does not apply when exposures are insignificant.[5] The MADL safe harbors provide guidance for determining when this is the case.[6]

[3] Health and Safety Code section 25249.6.
[4] Health and Safety Code section 25249.5.
[5] Health and Safety Code sections 25249.9 and 25249.10
[6] See Sections 25801 to 25805

Details on the basis for the proposed MADL for oral exposure to ethylene glycol are provided in the Initial Statement of Reasons for this regulatory amendment, which is available on request from Monet Vela and is posted on the OEHHA web site at www.oehha.ca.gov.

This proposed regulation sets forth a MADL for adoption into Section 25805 that was derived using scientific methods outlined in Section 25803.

The proposed regulation would adopt the following MADL for oral exposure to ethylene glycol, by amending Section 25805 as follows (addition in underline):

(b) Chemical Name	Level (Micrograms/day)
Ethylene Glycol (ingested)	8,700 (oral)

OEHHA reviewed the studies identified in the NTP-CERHR Monograph[7] that provide the basis for the listing, and conducted a literature search for any other relevant studies or reports published after the NTP-CERHR review was completed. Additional relevant studies were identified and reviewed by OEHHA. This is discussed in more detail in the initial statement of reasons for this proposed regulatory amendment.

Anticipated Benefits of the Proposed Regulation: Some businesses may not be able to afford the expenses of establishing a MADL 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 a MADL, this regulatory proposal may encourage businesses to lower the amount of the listed chemical in their products to a level that does not require a warning. This in turn may reduce exposures to ethylene glycol and reduce resident, worker and environmental exposures to chemicals that cause reproductive toxicity.

No Inconsistency or Incompatibility with Existing Regulations

OEHHA has conducted an evaluation for whether there are any other regulations on this matter and has found that these are the only regulations dealing with ethylene glycol. Therefore, OEHHA has determined that the proposed regulation is neither inconsistent nor incompatible with existing state regulations because it provides compliance assistance to businesses subject to the Act, but does not impose any mandatory requirements on those businesses, state or local agencies and does not address compliance with any other law or regulation.

[7] NTP-CERHR (2004). NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Ethylene Glycol. Research Triangle Park, NC, National Toxicology Program, Center for the Evaluation of Risks to Human Reproduction: NIH Publication No. 04 – 4481. Available online at http://ntp.niehs.nih.gov/?objectid=4980AA81-E919-4E85-60B789CA36E59FA5

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

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 harm. The law also prohibits the discharge of listed chemicals into sources of drinking water.

Because the proposed MADL 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.

Benefits of this regulation include, sparing businesses the expense of calculating their own MADL and possibly enable them to reduce or avoid litigation costs. By providing a MADL, it 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. This in turn may reduce exposure to ethylene glycol and reduce resident, worker and environmental exposures to chemicals that cause reproductive harm.

PEER REVIEW

This notice and the Initial Statement of Reasons will be provided to the Developmental and Reproductive Toxicant 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.

IMPACT ON LOCAL AGENCIES OR SCHOOL DISTRICTS

Because Proposition 65 expressly[8] 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.

COSTS OR SAVINGS TO STATE AGENCIES

Because Proposition 65 expressly[9] 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 expressly[10] 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 regulatory level 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

The proposed MADL was developed to provide compliance assistance for these businesses in determining whether a warning is required or a discharge is prohibited. The MADL provides a level of exposure at or below which a warning is not required and

[8] See Health and Safety Code section 25249.11(b)
[9] See Health and Safety Code section 25249.11(b)
[10] See Health and Safety Code section 25249.11(b)

a discharge is not prohibited. Use of the MADL is not mandatory. The implementing regulations allow a business to calculate its own level and provide guidance in order to assist businesses in doing so.[11] However, conducting such a process can be expensive and time consuming, and the resulting levels may not be defensible in an enforcement action. 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 MADL will not impose any mandatory requirements on small business. Rather, the proposed MADL 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

Government Code section 11346.5(a)(13) requires that 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 be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, 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, which contains the text of the regulation and the information upon which the regulation is based. A copy of the Initial Statement of Reasons, the text of the regulation and documents used by OEHHA to develop the proposed regulation are available upon request from OEHHA at the address, e-mail 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, if held, or whose comments were received by OEHHA during the public comment period, and anyone who requests notification from

[11] Title 27, Cal. Code of Regs., section 25801 et seq.

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, e-mail 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: April 8, 2016