

**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 25705
SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT RISK:**

DICHLOROACETIC ACID

May 22, 2020

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment (OEHHA) proposes to adopt a Proposition 65¹ No Significant Risk Level (NSRL) of 17 micrograms per day for dichloroacetic acid, by amending Title 27, California Code of Regulations, section 25705(b)².

PUBLIC PROCEEDINGS

Any written comments concerning this proposed action must be received by OEHHA by **July 7, 2020**, 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.

Because of limited in-office staffing during the COVID-19 emergency, OEHHA strongly recommends that comments be submitted electronically through our website at <https://oehha.ca.gov/comments>. Comments submitted in paper form may still be mailed or faxed, but delays may occur if staff are unable to timely access them.

Mailing Address: Ms. Esther Barajas-Ochoa
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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

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

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 Esther Barajas-Ochoa at esther.barajas-ochoa@oehha.ca.gov or to the address listed above by no later than **June 22, 2020**, which is 15 days before the close of the comment period. OEHHA will provide 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 website at least ten days before the public hearing date. The notice will provide the date, time, and location of the hearing.

CONTACT

Please direct inquiries concerning the proposed regulatory action described in this notice to Esther Barajas-Ochoa at esther.barajas-ochoa@oehha.ca.gov or by telephone at (916) 322-2068. Mario Fernandez is a back-up contact person for inquiries concerning processing of this action and is available at mario.fernandez@oehha.ca.gov or (916) 323-2635.

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 individual³. 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 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 when 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 regulations adopted by OEHHA (Sections 25701-25721). Section 25701 describes alternative methods for making such a determination. Section 25703 sets forth the process for determining “no significant risk” levels for purposes of Proposition 65 and Section 25705 establishes those levels for certain listed chemicals.

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.

Details on the basis for the proposed NSRL for dichloroacetic acid are provided in the Initial Statement of Reasons for this regulatory amendment, which is available on request from Esther Barajas-Ochoa and is posted on the OEHHA website at www.oehha.ca.gov.

This proposed amendment to Section 25705 would add an NSRL for dichloroacetic acid by amending Section 25705(b) as follows (addition in underline):

Chemical	NSRL, in micrograms per day
<u>Dichloroacetic acid</u>	<u>17</u>

To develop the proposed NSRL for dichloroacetic acid, OEHHA relied on a study by DeAngelo *et al.* (1999)^{6,7}, a study by Bull *et al.* (2002)⁸, Volume 106 in the series of International Agency for Research on Cancer (IARC) Monographs on the Evaluation of Carcinogenic Risks to Humans, entitled “Trichloroethylene, Tetrachloroethylene, and Some Other Chlorinated Agents”⁹, the National Toxicology Program (NTP) report entitled “Toxicology Studies of Bromodichloroacetic Acid (CAS No. 71133-14-7) in F344/N Rats and B6C3F₁/N Mice and Toxicology and Carcinogenesis Studies of Bromodichloroacetic Acid in F344/NTac Rats and B6C3F₁/N Mice (Drinking Water

⁶ DeAngelo AB, George MH, House DE (1999). Hepatocarcinogenicity in the male B6C3F₁ mouse following a lifetime exposure to dichloroacetic acid in the drinking water: Dose-response determination and modes of action. *J Toxicol Environ Health A* 58(8):485-507.

⁷ Individual animal survival and tumor data provided by Dr. DeAngelo, December 2007.

⁸ Bull RJ, Orner GA, Cheng RS, Stillwell L, Stauber AJ, Sasser LB, Lingohr MK, Thrall BD (2002). Contribution of dichloroacetate and trichloroacetate to liver tumor induction in mice by trichloroethylene. *Toxicol Appl Pharmacol* 182(1):55-65.

⁹ International Agency for Research on Cancer (IARC 2014). IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 106, **Trichloroethylene, Tetrachloroethylene, and Some Other Chlorinated Agents**. IARC, World Health Organization, Lyon, France. Available from: <http://monographs.iarc.fr/ENG/Monographs/vol106/index.php>.

Studies)¹⁰, and additional genotoxicity studies^{11,12,13,14,15,16,17}. The 2014 IARC Monograph summarizes the available data from rodent carcinogenicity studies, as well as other information relevant to the carcinogenic activity of dichloroacetic acid. The 2015 NTP report primarily discusses toxicological effects of bromodichloroacetic acid, but also summarizes genotoxic information on dichloroacetic acid, a metabolite of bromodichloroacetic acid. Zhang et al. (2016), Hu et al. (2017), Varshney et al. (2013), Hassoun et al. (2014), Ono et al. (1991), Stalter et al. (2016), and Hassoun and Dey (2008) provide additional information on genotoxicity. The NSRL for dichloroacetic acid is based upon the results of the most sensitive scientific study deemed to be of sufficient quality¹⁸.

Anticipated Benefits of the Proposed Regulation

Some businesses may not be able to afford the expense of establishing an NSRL may be vulnerable to litigation for a failure to warn or for a prohibited discharge of the listed chemical. By providing an NSRL, this regulatory proposal spares businesses the expense of calculating their own NSRL and may enable them to 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. This in turn may reduce exposure to dichloroacetic acid and reduce resident, worker and environmental exposures to chemicals that cause cancer.

¹⁰ National Toxicology Program (NTP 2015). Toxicology Studies of Bromodichloroacetic Acid (CAS No. 71133-14-7) in F344/N Rats and B6C3F₁/N Mice and Toxicology and Carcinogenesis Studies of Bromodichloroacetic Acid in F344/NTac Rats and B6C3F₁/N Mice (Drinking Water Studies). NTP Technical Report Series No. 583. US Department of Health and Human Services, NTP, Research Triangle Park, NC.

¹¹ Zhang SH, Miao DY, Tan L, Liu AL, Lu WQ (2016). Comparative cytotoxic and genotoxic potential of 13 drinking water disinfection by-products using a microplate-based cytotoxicity assay and a developed SOS/umu assay. *Mutagenesis*. 31(1):35-41.

¹² Hu Y, Tan L, Zhang SH, Zuo YT, Han X, Liu N, Lu WQ, Liu AL (2017). Detection of genotoxic effects of drinking water disinfection by-products using *Vicia faba* bioassay. *Environ Sci Pollut Res Int*. 2016 Oct 26. [Epub ahead of print]

¹³ Varshney M, Chandra A, Chauhan LK, Goel SK (2013). Micronucleus induction by oxidative metabolites of trichloroethylene in cultured human peripheral blood lymphocytes: a comparative genotoxicity study. *Environ Sci Pollut Res Int*. 20 (12): 8709-16.

¹⁴ Hassoun E, Cearfoss J, Mamada S, Al-Hassan N, Brown M, Heimberger K, Liu MC (2014). The effects of mixtures of dichloroacetate and trichloroacetate on induction of oxidative stress in livers of mice after subchronic exposure. *J Toxicol Environ Health A*. 77(6):313-23.

¹⁵ Ono Y, Somiya I, Kawamura M (1991). The evaluation of genotoxicity using DNA repairing test for chemicals produced in chlorination and ozonation processes. *Water Science and technology* 23(1-3): 329-338.

¹⁶ Stalter D, O'Malley E, von Gunten U, Escher BI. (2016). Fingerprinting the reactive toxicity pathways of 50 drinking water disinfection by-products. *Water Res* 91: 19-30.

¹⁷ Hassoun EA, Dey S. (2008). Dichloroacetate- and trichloroacetate-induced phagocytic activation and production of oxidative stress in the hepatic tissues of mice after acute exposure. *J Biochem Mol Toxicol* 22(1): 27-34.

¹⁸ Section 25703(a)(4).

No Inconsistency or Incompatibility with Existing Regulations

After conducting an evaluation on any related regulations in this area, OEHHA has found that these are the only regulations dealing with Proposition 65 No Significant Risk Levels for this specific chemical. Therefore, OEHHA has determined that the proposed regulation is neither inconsistent nor incompatible with existing state regulations. The proposed regulation does not impose any mandatory requirements on businesses, state or local agencies and does not address compliance with any other law or regulation.

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. The law also prohibits the discharge of listed chemicals into sources of drinking water. Dichloroacetic acid is listed under Proposition 65; therefore, businesses that manufacture, distribute or sell products with dichloroacetic acid in the state must provide a warning if their product or activity exposes the public or employees to significant amount of this chemical. Businesses are also prohibited from discharging significant amounts of this chemical into sources of drinking water. The regulatory proposal does not create additional compliance requirements, but instead provides a “safe harbor” value that aids businesses in determining whether a warning is required for a given exposure or a discharge is prohibited.

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.

Benefits of this regulation include sparing businesses the expense of calculating their own NSRL and possibly enabling them to reduce or avoid litigation costs. By providing an NSRL, 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 dichloroacetic acid and reduce resident, worker and environmental exposures to chemicals that cause cancer.

PEER REVIEW

This notice and the Initial Statement of Reasons are being provided to the OEHHA Science Advisory Board’s Carcinogen Identification Committee for 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 does not apply to local agencies or school districts¹⁹, 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 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 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 Proposition 65, 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 Proposition 65, but do 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.

¹⁹ See Health and Safety Code section 25249.11(b).

COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

The proposed NSRL was developed to provide compliance assistance for these businesses in determining whether a warning is required or a discharge is prohibited. The NSRL provides a level of exposure at or below which a warning is not required and a discharge is not prohibited. Use of the NSRL is not mandatory. The implementing regulations allow a business to calculate its own level and provide guidance in order to assist businesses in doing so²⁰. 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 regulation will not impose any mandatory requirements on small business. Rather, the proposed NSRL will provide compliance assistance for small businesses subject to Proposition 65 because it will help them determine whether an exposure for which they are responsible is subject to the warning requirement or discharge prohibition of Proposition 65.

CONSIDERATION OF ALTERNATIVES

Government Code section 11346(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, all the information upon which the regulation is based and the text of the regulation. These documents are posted on OEHHA's website at www.oehha.ca.gov. Due to limited in-office staffing during the COVID-19 emergency, OEHHA strongly recommends that interested parties access these documents via its website. A copy of the Initial Statement of Reasons, the text of the regulation and the documents relied on to develop the proposed regulation are also available upon request from OEHHA at the address and telephone number indicated above.

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

²⁰ Title 27, Cal. Code of Regs., section 25701 et seq.

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 website 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: May 22, 2020