## 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

MAXIMUM ALLOWABLE DOSE LEVEL (ORAL EXPOSURE) ATRAZINE, PROPAZINE, SIMAZINE, 2,4-DIAMINO-6-CHLORO-S-TRIAZINE (DACT), DES-ETHYL ATRAZINE (DEA), AND DES-ISOPROPYL ATRAZINE (DIA)

**JUNE 10, 2016** 

NOTICE IS HEREBY GIVEN that the Office of Environmental Health Hazard Assessment (OEHHA) proposes to adopt Proposition 65<sup>1</sup> Maximum Allowable Dose Levels (MADLs) for oral exposure to atrazine, propazine, simazine, 2,4-diamino-6-chloro-s-triazine (DACT)<sup>2</sup>, des-ethyl atrazine (DEA), and des-isopropyl atrazine (DIA) that induce reproductive toxicity by amending Section 25805(b) of Title 27 of the California Code of Regulations<sup>3</sup>.

The proposed oral MADLs are 100 micrograms per day for each of the six chemicals. The MADLs are based on data for atrazine, which is representative of all six of the identified chemicals.

The rulemaking for adoption of these MADLs been delayed because the listing of these chemicals under Proposition 65 was challenged in a legal proceeding<sup>4</sup>. This regulatory action will not be finalized until atrazine, propazine, simazine, DACT, DEA, and DIA are listed under Proposition 65 as known to the state to cause reproductive toxicity (developmental and female reproductive endpoints). The listings are based on formal identification of these chemicals by the US Environmental Protection Agency (US EPA)

<sup>&</sup>lt;sup>1</sup> The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seg., referred to herein as "Proposition 65" or "The Act."

<sup>&</sup>lt;sup>2</sup> DACT was incorrectly identified as 2,3-diamino-6-chloro-s-triazine (instead of 2,4-diamino-6-chloro-striazine) in the Feb. 7, 2014 notice of intent to list the chemical and in the March 24, 2015 notice of listing. All further references are to sections of Title 27, Cal. Code of Regs., unless otherwise indicated.

as causing developmental and female reproductive toxicity. The US EPA is a body recognized as authoritative for the listing of chemicals as known to cause reproductive toxicity under Proposition 65 (Section 25306(I)).

#### PUBLIC PROCEEDINGS

Any written comments concerning these proposed actions, regardless of the form or method of transmission, must be received by OEHHA by 5:00 p.m. on **July 25, 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 <a href="mailto:P65Public.Comments@oehha.ca.gov">P65Public.Comments@oehha.ca.gov</a>. Please include "TRIAZINE MADLs" 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) 323-2610

Street Address: 1001 I Street Sacramento, California 95814

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 these proposed regulatory amendments will be scheduled upon request. To request a hearing, please send an e-mail to Monet Vela at <a href="monet.vela@oehha.ca.gov">monet.vela@oehha.ca.gov</a> or to the address listed above by no later than July 11, 2016. OEHHA will mail a notice of the hearing to the requester and interested parties on the

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<sup>&</sup>lt;sup>4</sup> Syngenta v OEHHA, Sacramento County Superior Court case #34-2014-8000-1809. Judgment was entered in favor of OEHHA on April 8, 2016. Syngenta has appealed the decision and is asking the Third District Court of Appeal for a stay of the listing of these chemicals during the pendency of the appeal. OEHHA is opposing that request. No decision has been issued on that question by the Court of Appeal.

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 by calling (916) 323-2517. Fran Kammerer is a back-up contact person for inquiries concerning processing of these actions and is available at Fran.Kammerer@oehha.ca.gov or by telephone at (916) 445-4693.

#### 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<sup>5</sup>. 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<sup>6</sup>. Warnings are not required and the discharge prohibition does not apply when exposures are insignificant. The proposed MADLs provide guidance for determining when an exposure is insignificant.8

Details on the basis for the proposed MADLs for six chemicals are provided in the Initial Statement of Reasons for these regulatory amendments, which is available on request from Monet Vela and is posted on the OEHHA web site at <a href="www.oehha.ca.gov">www.oehha.ca.gov</a>.

The proposed MADLs were derived using scientific methods outlined in Section 25803.

<sup>6</sup> Health and Safety Code section 25249.5

<sup>&</sup>lt;sup>5</sup> Health and Safety Code section 25249.6

<sup>&</sup>lt;sup>7</sup> Health and Safety Code sections 25249.9 and 25249.10 <sup>8</sup> See Sections 25801 through 25805

The proposed regulations would adopt the following MADLs for six chemicals, by amending Section 25805 as follows (addition in underline):

#### PROPOSED REGULATORY AMENDMENTS

The proposed changes to Section 25805(b) are provided below in underline:

Chemical name	Level (micrograms per day)
Atrazine	100 (oral)
Propazine	100 (oral)
Simazine	100 (oral)
2,4-Diamino-6-chloro-s-triazine (DACT)	100 (oral)
Des-ethyl atrazine (DEA)	100 (oral)
Des-isopropyl atrazine (DIA)	100 (oral)

## **Anticipated Benefits of the Proposed Regulation**

Some businesses may not be able to afford the expense of establishing MADLs and therefore may have to defend 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. By providing MADLs, this regulatory proposal does not require but may encourage businesses to lower the amount of the listed chemical in their products to a level that does not cause a significant exposure. This in turn may increase the protection of public health by reducing exposures to chemicals that cause reproductive harm.

### No Inconsistency or Incompatibility with Existing Regulations

After conducting an evaluation on any related regulations in this area, the Office has found that these are the only regulations dealing with Proposition 65 Maximum Allowable Dose Levels for these specific chemicals. Therefore, OEHHA has determined that the proposed regulations are neither inconsistent nor incompatible with existing state regulations. The proposed regulations do not impose any mandatory requirements on businesses, state, or local agencies and do not address compliance with any other law or regulation.

#### RESULTS OF THE ECONOMIC IMPACT ANALYSIS

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 listed under Proposition 65 as known to cause cancer or developmental or reproductive harm. The law also prohibits the discharge of listed chemicals into sources of drinking water.

This regulatory proposal will have no effect on the creation/elimination/expansion of California businesses.

**Benefits:** By providing MADLs, this regulatory proposal spares businesses the expense of calculating their own MADL and may also enable them to reduce or avoid litigation costs. In addition, the MADL 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.

#### **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<sup>9</sup> 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 do they 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.

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<sup>&</sup>lt;sup>9</sup> See Health and Safety Code section 25249.11(b)

#### COSTS OR SAVINGS TO STATE AGENCIES

Because Proposition 65 expressly 10 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 actions.

#### EFFECT ON FEDERAL FUNDING TO THE STATE

Because Proposition 65 expressly<sup>11</sup> 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 actions.

#### **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 MADLs provide compliance assistance to businesses subject to the Act, 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.

#### COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

Because the proposed regulation does not impose any new requirements on 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 actions.

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

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

is not prohibited. Use of the MADLs is not mandatory. The implementing regulations allow a business to calculate its own levels. However, conducting such an analysis can be expensive and time consuming, and the resulting levels may not be defensible in an enforcement action.

#### **EFFECT ON SMALL BUSINESSES**

OEHHA has determined that the proposed regulation will not impose any mandatory requirements on small business. Rather, the proposed regulation will provide compliance assistance for small businesses subject to the Act because the regulation 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. Furthermore, Proposition 65 expressly exempts businesses with less than 10 employees from the warning and discharge requirements of the law.

#### 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, 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 documents used by OEHHA to develop the proposed regulation are available upon request from OEHHA at the address and telephone number indicated above. These documents are also posted on OEHHA's Web site at <a href="https://www.oehha.ca.gov">www.oehha.ca.gov</a>.

#### 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

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<sup>&</sup>lt;sup>12</sup> Section 25801 et seq.

regulation 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 prior 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 <a href="https://www.oehha.ca.gov">www.oehha.ca.gov</a>.

#### 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 <a href="https://www.oehha.ca.gov">www.oehha.ca.gov</a>.

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

Allan Hirsch Chief Deputy Director

Dated: June 10, 2016