

Update to Title 27, California Code of Regulations, Section 27000

Chemicals Required by State or Federal Law to be Tested for Carcinogenicity and Reproductive Toxicity That Have Not Been Adequately Tested according to the California Department of Pesticide Regulation or the US Environmental Protection Agency

Staff Report for Consent Item

September 2022



Office of Environmental Health Hazard Assessment
California Environmental Protection Agency

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Acronyms used

US EPA	US Environmental Protection Agency
CalEPA	California Environmental Protection Agency
OEHHA	Office of Environmental Health Hazard Assessment, CalEPA
DPR	Department of Pesticide Regulation, CalEPA
OPPT	Office of Pollution Prevention and Toxics, US EPA
OPP	Office of Pesticide Programs, US EPA
CIC	Carcinogen Identification Committee
DARTIC	Developmental and Reproductive Toxicity Identification Committee

I. Introduction

Background

Proposition 65 requires the state to publish a list of chemicals that are required to be tested under federal or state law for carcinogenicity or reproductive toxicity that have not yet been adequately tested (Health and Safety Code section 25249.8(c)). The law states:

c) On or before January 1, 1989, and at least once per year thereafter, the Governor shall cause to be published a *separate list* of those chemicals that at the time of publication are required by state or federal law to have been tested for potential to cause cancer or reproductive toxicity but that the state's qualified experts have not found to have been adequately tested as required. (emphasis added)

The list of chemicals that need further testing can be found in Title 27, Cal. Code of Regs., section 27000. A copy of the list, including the change the Office of Environmental Health Hazard Assessment (OEHHA) is recommending, is included in Section II of this report. This list is separate and distinct from the "Proposition 65 List," that is, the list of chemicals known to cause cancer or reproductive toxicity.

The Section 27000 list has no regulatory impact. It does not require that any testing be done; it is simply a source of information concerning chemicals that need further testing pursuant to state or federal law.

Each year, OEHHA requests information from the California Department of Pesticide Regulation (DPR) and the US Environmental Protection Agency's (US EPA) Office of Pollution Prevention and Toxics (OPPT) and Office of Pesticide Programs (OPP) to update the Section 27000 list. Since the statute and the regulation require that the "state's qualified experts" find that the chemicals on this list have not been adequately tested, updates to the list are reviewed by the Carcinogen Identification Committee (CIC) and the Developmental and Reproductive Toxicity Identification Committee (DARTIC) in public meetings of these committees. The committee members are asked to ratify the information in this report so OEHHA can update the list. The committees' task is ministerial in that they are relying on the information provided to OEHHA by DPR and US EPA in order to identify the chemicals that need to be added to or removed from the Section 27000 list and are not making any independent judgment concerning the information provided.

Update to Section 27000

In response to requests for information, OEHHA received letters regarding required testing from:

- Department of Pesticide Regulation
- US Environmental Protection Agency, Office of Pollution Prevention and Toxics
- US Environmental Protection Agency, Office of Pesticide Programs

OEHHA staff reviewed these responses and identified one recommended change to the Section 27000 list – removal of bromadiolone from the list. Based on information received from DPR, data requirements for this compound have been fulfilled, and further carcinogenicity (oncogenicity) and reproductive toxicity (teratogenicity) testing are not required. This is shown in the response letter and attachment to it, excerpted below. These are included for reference in Section III:

Response Letter:

DPR reviewed and updated the attached table (DPR Proposition 65 Chemical Review List) to reflect current toxicology summary information including studies received ... or under evaluation, by our Human Health Assessment Branch. For clarity, all changes are highlighted.

Attachment:

DPR Proposition 65 Chemical Review Updated July 14, 2022

Following is a listing of SB 950 (Birth Defect Prevention Act of 1984) data gaps for oncogenicity, reproduction, and teratology studies for the non-200 pesticidal active ingredients. This list changes as data gaps are filled by additional data or replacement studies. Highlighting indicates a change from the previous year for the associated active ingredient.

<i>Chemical</i>	<i>Testing Needed</i>
...	
Bromadiolone*	Data requirements fulfilled; concurrence received from OEHHA
...	

Section II shows the change to the 27000 list. The proposed deletion is marked in **highlight** and ~~strikethrough~~.

OEHHA's review of information received in the US EPA letters, also provided in Section III below, did not require any additional changes to the list.

The proposed change to the list will be presented to the DARTIC and the CIC at their October and December 2022 meetings as a “consent” item, which means the item will simply be voted on as a “yes” or “no”. A “yes” vote means the committee member is authorizing OEHHA to make the change to the list proposed in this report. A “no” vote means the committee member opposes the proposed change. To authorize OEHHA to update the list as proposed, a majority of members from each committee must vote in favor of the change.

Staff recommendation

Staff recommends a “Yes” vote, which would authorize OEHHA to delete bromadiolone from the Section 27000 list, based on the information provided by DPR.

Any committee member who has clarifying questions or wishes to make a statement concerning this report may do so at the meeting.

II. Section 27000 List with Proposed Change

STATE OF CALIFORNIA
ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

DIVISION 4, TITLE 27 CALIFORNIA CODE OF REGULATIONS

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

§27000. CHEMICALS REQUIRED BY STATE OR FEDERAL LAW TO HAVE BEEN TESTED FOR POTENTIAL TO CAUSE CANCER OR REPRODUCTIVE TOXICITY, BUT WHICH HAVE NOT BEEN ADEQUATELY TESTED AS REQUIRED.

(a) The Safe Drinking Water and Toxic Enforcement Act of 1986 requires the Governor to publish a list of chemicals formally required by state or federal agencies to have testing for carcinogenicity or reproductive toxicity, but that the state's qualified experts have not found to have been adequately tested as required [Health and Safety Code Section 25249.8(c)].

(b) Chemicals required to be tested by the California Department of Pesticide Regulation.

- (1) The Birth Defect Prevention Act of 1984 (SB 950) mandates that the California Department of Pesticide Regulation (CDPR) review chronic toxicology studies supporting the registration of pesticidal active ingredients. Missing or unacceptable studies are identified as data gaps.
- (2) The studies are conducted to fulfill generic data requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which is administered by the United States Environmental Protection Agency (U.S. EPA).
- (3) The studies are reviewed by CDPR according to guidelines and standards promulgated under FIFRA. Older studies may not meet current guidelines.
- (4) The existence of a data gap for a compound does not indicate a total lack of information on the carcinogenicity or reproductive toxicity of the compound. In some cases, information exists in the open scientific literature, but SB 950 requires specific additional information.
- (5) A data gap does not necessarily indicate that an oncogenic or reproductive hazard exists. For the purposes of this list, a data gap is still considered to be present until the study is reviewed and found to be acceptable.
- (6) Following is a listing of SB 950 data gaps for oncogenicity, reproduction, and teratology studies for pesticidal active ingredients. This list changes as data gaps are filled by additional data or replacement studies.

(7) For purposes of this section, "onc mouse" means oncogenicity in mice, "onc rat" means oncogenicity in rats, "repro" means reproduction, "tera rat" means teratogenicity in rats, "tera rabbit" means teratogenicity in rabbits.

<i>Chemical</i>	<i>Testing Needed</i>
Acid Blue 9*	onc rat, onc mouse, repro, tera rat, tera rabbit
Acid Yellow 23*	onc rat, onc mouse, repro, tera rat, tera rabbit
Bromadiolone*	Data requirements fulfilled; concurrence received from OEHHA
Butoxy polypropylene glycol*	onc rat, onc mouse, repro, tera rat, tera rabbit
Butoxy polypropoxy polyethoxy ethanol – iodine complex*	onc rat, onc mouse, repro, tera rat, tera rabbit
Castor oil*	onc rat, onc mouse, repro, tera rat, tera rabbit
Chlorophacinone*	onc rat, onc mouse, repro
Chromic acid*	onc rat, onc mouse, repro, tera rabbit
Menthol*	onc rat, onc mouse, repro, tera rat, tera rabbit
Meta-cresol*	tera rat, onc rat, onc mouse, repro, tera rabbit
Sodium chlorate*	onc rat, onc mouse, repro, tera rat, tera rabbit
Sodium phenate*	onc rat, onc mouse, repro, tera rat, tera rabbit
Tetraglycine hydroperiodide*	onc rat, onc mouse, repro, tera rat, tera rabbit
2,4-Xylenol*	onc rat, onc mouse, repro, tera rat, tera rabbit

* Claims are pending review that data should not be required.

** No product containing this active ingredient is registered with CDPR.

(c) Chemicals required to be tested by the U.S. EPA, Office of Pollution Prevention and Toxics

(1) Under 15 U.S.C.A. § 2603(a) of the Toxic Substances Control Act, testing of a chemical is required when that chemical may present an unreasonable risk, or is produced in substantial quantities and enters the environment in substantial quantities, or may have significant or substantial human exposure.

(2) For purposes of this section, "tera" means teratogenicity, "rtox" means reproductive toxicity, "onc" means oncogenicity.

Chemical

Testing Needed

Hydrocarbons, C>4

rtox

(d) Chemicals required to be tested by the U.S. EPA, Office of Pesticide Programs.

(1) The U.S. EPA is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA requires U.S. EPA to register pesticides based on data adequate to demonstrate that they will not result in unreasonable adverse effects to people or the environment when used in accordance with their U.S. EPA-approved labels.

(2) The chemicals listed below are those for which data are unavailable or inadequate to characterize oncogenicity, teratogenicity, or reproductive effects potential. For purposes of this section, "onc" means oncogenicity, "tera" means teratogenicity, and "repro" means reproductive toxicity.

Note: There are no chemicals currently listed under section 27000(d).

III. Responses to Requests for Section 27000 Information from DPR, US EPA OPPT, and US EPA OPP




Julie Henderson
Director

MEMORANDUM

Jared Blumenfeld
Secretary for
Environmental Protection

TO: David Edwards, PhD
Chief Deputy Director
Office of Environmental Health Hazard Assessment

FROM: Karen Morrison, PhD 
Acting Chief Deputy Director
916-445-4000

DATE: July 28, 2022

SUBJECT: RESPONSE TO CHEMICALS REQUIRING TESTING (TITLE 27, CALIFORNIA
CODE OF REGULATIONS)

This memorandum is in response to your recent request that the Department of Pesticide Regulation (DPR) review and provide additions, deletions, or other changes on the status of the chemicals listed under Title 27, California Code of Regulation section 27000.

DPR reviewed and updated the attached table (DPR Proposition 65 Chemical Review) to reflect current toxicology summary information including studies received and evaluated, or under evaluation, by our Human Health Assessment Branch. For clarity, all changes are highlighted.

If you have any questions, please contact me at <Karen.Morrison@cdpr.ca.gov> or 916-445-4000.

Attachment

cc: Amy Gilson, PhD, OEHHA Deputy Director (w/Attachment)
Tyler Saechao, OEHHA Environmental Scientist (w/Attachment)
Tulio Macedo, PhD, DPR Pesticide Registration Branch Chief (w/Attachment)
Shelley DuTeaux, PhD MPH, DPR Human Health Assessment Branch Chief (w/Attachment)

ATTACHMENT

DPR Proposition 65 Chemical Review

Updated July 14, 2022

Following is a listing of SB 950 (Birth Defect Prevention Act of 1984) data gaps for oncogenicity, reproduction, and teratology studies for the non-200 pesticidal active ingredients. This list changes as data gaps are filled by additional data or replacement studies. Highlighting indicates a change from the previous year for the associated active ingredient.

<i>Chemical</i>	<i>Testing Needed</i>
Acid Blue 9*	onc rat, onc mouse, repro, tera rat, tera rabbit
Acid Yellow 23*	onc rat, onc mouse, repro, tera rat, tera rabbit
Bromadiolone	Data requirements fulfilled; concurrence received from OEHHA
Butoxy polypropylene glycol*	onc rat, onc mouse, repro, tera rat, tera rabbit
Butoxy polypropoxy polyethoxy ethanol – iodine complex*	onc rat, onc mouse, repro, tera rat, tera rabbit
Castor oil*	onc rat, onc mouse, repro, tera rat, tera rabbit
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Chromic acid*	onc rat, onc mouse, repro, tera rabbit
Menthol*	onc rat, onc mouse, repro, tera rat, tera rabbit
Meta-cresol*	onc rat, onc mouse, repro, tera rat, tera rabbit
Sodium chlorate*	onc rat, onc mouse, repro, tera rat, tera rabbit
Sodium phenate*	onc rat, onc mouse, repro, tera rat, tera rabbit
Tetraglycine hydroperiodide*	onc rat, onc mouse, repro, tera rat, tera rabbit
2,4-Xylenol*	onc rat, onc mouse, repro, tera rat, tera rabbit

**Claims that data should not be required are pending review.*



July 22, 2022

Mr. David Edwards, Ph.D.
Chief Deputy Director
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
1001 I Street, P.O. Box 4010
Sacramento, California 95812-4010

Dear Mr. Edwards:

Thank you for your June 16, 2022, letter that asks the Office of Pollution Prevention and Toxics (OPPT) for assistance in updating the list of chemicals that have not yet been adequately tested as required under Title 27, California Code of Regulations, Section 27000. More specifically, your letter asks OPPT to identify chemical substances for which developmental toxicity, reproductive toxicity, and/or carcinogenicity testing is currently being required under Section 4 of the Toxic Substances Control Act (TSCA).

Enclosed is a list of the chemicals for which reproductive toxicity testing is currently required. There is no developmental or carcinogenicity testing required under TSCA section 4 for these chemicals at this time. For future reference, this information can be determined from publicly available sources. For example, OPPT's Sunset Table, (available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/sunset-dates-chemicals-subject-final-tsca-section-4-test>) lists the chemicals for which testing is, or has been, required under section 4 of TSCA, the date upon which the testing requirements will, or have, expired, and the Federal Register notice that states what tests are, or were, required.

Should you have any questions, please contact David Turk of my staff by email at Turk.David@epa.gov or by telephone at 202-566-1527.

Sincerely,

Denise Keehner
Director
Office of Pollution Prevention & Toxics

Enclosure

**Chemicals for which reproductive toxicity testing,
or an exemption from testing, is currently
required via section 4 of the Toxic Substances Control Act (TSCA)**

July 2022

Chemical Name	CASRN	A reproductive toxicity final study has been received by EPA (yes/no)
76 FR 1067, Jan. 7, 2011		
Hydrocarbons, C>4	68647-60-9	no (no test sponsor to date)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 25, 2022

David Edwards, Ph.D.
Chief Deputy Director
Office of External & Legislative Affairs
California Environmental Protection Agency
P.O. Box 4010
Sacramento, California 95812-4010

Dear Dr. Edwards,

This is a response on behalf of Dana Vogel, Health Effects Division Director, to your letter dated June 16, 2022, asking the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs to update the list of chemicals which require testing under 15 U.S.C.A., Section 2603(a), (formerly Section 4(a)), of the Toxic Substances Control Act, or any other relevant federal law, to characterize potential oncogenicity, teratogenicity or reproductive effects. This request is part of an annual update of the list of chemicals not adequately tested as required under Title 27, California Code of Regulations, Section 27000.

There have been no updates or changes to the information that you requested on the enclosed list of chemicals. For additional information on a particular chemical and/or for future inquiries, this information is contained in the documents found on the EPA's Pesticide website: <https://www.regulations.gov>. For information on data requirements for chemicals undergoing Registration Review, this link should be helpful to you: <https://www.epa.gov/pesticide-reevaluation/registration-review-schedules>.

Sincerely,

A handwritten signature in blue ink, appearing to read "R Fehir".

Rick Fehir, Ph.D., Chief
Science Information Management Branch
Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency