

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 25249.8(c)].

Readers should note that a chemical that already has been designated as known to the state to cause cancer or reproductive toxicity is not included in the following listing as requiring additional testing for that particular toxicological endpoint. However, the "data gap" may continue to exist, for purposes of the state or federal agency's requirements. Additional information on the requirements for testing may be obtained from the specific agency identified below.

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

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 datagaps. 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 (USEPA). The studies are reviewed by CDPR according to guidelines and standards promulgated under FIFRA. Thus, older studies may not meet current guidelines.

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. 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.

Following is a listing of SB 950 data gaps for oncogenicity, reproduction, and teratology studies for the non-200 pesticidal active ingredients. This list will change as data gaps are filled by additional data or replacement studies.

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.

Chemical

Testing Needed

Acid Blue 9*

onc rat, onc mouse, repro, tera rat, tera rabbit

Acid Yellow 23*

onc rat, onc mouse, repro

~~Agrobacterium radiobacter*~~

~~onc rat, onc mouse, repro, tera rat, tera rabbit~~

Alkyl-1,3-propylene diamine acetate alkyl
derived from coconut oil fatty acids

tera rat, tera rabbit (only one required)

~~Alkyl amino-3-amino propane hydroxyl acetate alkyl
derived from coconut oil fatty acids~~

~~tera rat, tera rabbit (only one required)~~

Ammonium thiosulfate*

onc rat, onc mouse, repro, tera rat, tera rabbit

Borax*

onc rat, repro

Bromadiolone*

onc rat, onc mouse, repro, tera rabbit

Butoxy polypropylene glycol*

onc rat, onc mouse, repro, tera rat, tera rabbit

Butoxy polypropoxy polyethoxy ethanol – iodine complex*

tera rat

Castor oil*

onc rat, onc mouse, repro, tera rat, tera rabbit

Chlorophacinone*

onc rat, onc mouse, repro

Chromic acid*

onc mouse, repro, tera rabbit

Copper salts of fatty and rosin acids*

onc rat, onc mouse, repro, tera rat, tera rabbit

Disodium octaborate tetrahydrate

onc rat, repro

Menthol*

onc rat, onc mouse, repro, tera rat, tera rabbit

Meta-cresol*

tera rat, onc rat, onc mouse, repro, tera rabbit

Methoprene*

onc mouse, onc rat, repro, tera rat, tera rabbit

Methyl isothiocyanate*

repro

2,2-(Methyl trimethylene dioxy)bis-(4-methyl-1,3,2-dioxaborinane)*	onc rat, onc mouse, repro, tera rabbit
Mineral oil*	onc rat, repro, tera rabbit
Muscalure*	Tera rat, tera rabbit (only one required)
Petroleum distillates*	onc rat, onc mouse, repro, tera rat, tera rabbit
Petroleum distillates, refined*	onc rat, onc mouse, repro, tera rat, tera rabbit
Petroleum oil, paraffin based*	onc rat, onc mouse, repro, tera rat, tera rabbit
Petroleum oil, unclassified*	onc rat, onc mouse, repro, tera rat, tera rabbit
Polyethoxy polypropoxy polyethoxy ethanol – iodine complex*	tera rat
Propylene oxide*	tera rabbit, repro, tera rat
Sabadilla alkaloids*	onc rat, onc mouse, repro, tera rabbit
Sodium chlorate*	onc rat, onc mouse, repro, tera rabbit
Sodium fluoride*	onc rat, onc mouse, repro, tera rat, tera rabbit
Sodium metaborate	onc rat, repro
Sodium phenate*	tera rat
Tetraglycine hydroperiodide*	tera rat, tera rabbit (only one required)
Triethylene glycol*	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.

(c) Chemicals required to be tested by the United States Environmental Protection Agency, Office of Toxic Substances.

Under Section 4(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.

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

<i>Chemical</i>	<i>Testing Needed</i>
Ethylene dichloride	rtox
1,1,2-Trichloroethane	onc, rtox, tera

NOTE: The testing of the above chemicals is being carried out under "Enforceable Consent Agreements" (or ECAs) under Section 4 of TSCA. In addition, there are a number of ongoing TSCA testing action development activities that may be of interest in the context of Proposition 65. When promulgated, these TSCA Section 4 Test Rules and/or ECAs will require industry to conduct reproductive toxicity, developmental toxicity, and/or cancer studies on a number of 1)hazardous air pollutants (or HAPs), 2) chemicals frequently found at Superfund sites, and 3) U.S. high production volume (or HPV) chemicals. As these, and possibly other, TSCA Section 4 Test Rules/ECAs become effective, this table will be revised to reflect those additional chemical substances for which developmental toxicity, reproductive toxicity, and/or oncogenicity testing is currently being required under Section 4 of TSCA.

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

The USEPA is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA requires USEPA 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 USEPA-approved labels.

In 1988, FIFRA was amended to strengthen USEPA's pesticide regulatory authority and responsibilities to reregister pesticides registered prior to 1984 to ensure they meet today's stringent scientific and regulatory standards. Reregistration requires registrants to develop up-to-date data bases for each pesticide active ingredient. As part of the reregistration process, modifications may be made to registrations, labels or tolerances to ensure they are protective of human health and the environment. Also, reregistration reviews will identify any pesticides where regulatory action may be necessary to deal with unreasonable risks. USEPA has been directed to accelerate the reregistration process so that the entire process is completed by 1997. The 1988 amendments set out a five-phase schedule to accomplish this task with deadlines applying to both pesticide registrants and the USEPA. These amendments are requiring a substantial number of new studies to be conducted and old studies to be reformatted for USEPA review to ensure they are adequate. USEPA may, in the future, request additional data or information to further evaluate any concerns over the safety of pesticide products.

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.

Chemical

Data Requirements

Aerolein	onc, tera
Alkyl imidazolines	tera
Ametryn	repro, tera
4-Aminopyridine	onc, repro, tera
4-T-Amylphenol	onc, repro, tera
Aquashade	onc, repro, tera
Benzisothiazolin-3-one	onc, repro, tera
<u>Benzisothiostyrene</u>	onc
Bromonitrostyrene	tera
Busan 77	repro
Chlorflurenol methyl	repro tera
<u>alpha-Chlorohydrin</u>	tera
Chromated arsenicals	tera
Cypermethrin	onc
<u>Dithianon</u>	tera
DCNA	repro
Diclofop methyl	onc, tera
Dierotophos	onc, repro
Dihalodialkylhydantoins	onc, repro, tera
Dimethepin	onc, repro, tera
Dimethyldithiocarbamate	onc, repro, tera
Dinocab and its compounds	tera
Dipropyl isocinchomeronate	repro
Dodine	onc, tera
Endothall and salts	onc, repro, tera
Ethofumesate	onc
Ethoxyquin	onc, repro, tera
Fenthion	tera
Fenvalerate	onc, repro, tera
Fluvalinate	repro, tera
Hydroxy-methyldithiocarbamate	tera
Imazalil	onc
Inorganic chlorates	onc, repro, tera
Inorganic sulfites	onc, repro, tera
Iodine-potassium iodide	onc, repro, tera
Iprodione	tera

Irgasan	onc, repro, tera
Lamprecide	one
Magnesium phosphide	onc
Malathion	one
Maneb with ETU	tera, one
Mepiquat chloride	tera
Metalddehyde	one
Methoxychlor	onc, repro, tera
Methyl isothiocyanate	<u>onc, repro, tera</u>
Naphthaleneacetic acid	onc, repro
Naphthenate salts	tera
Napropamide	repro
Niclosamide	one, tera
Nicotine and derivatives	onc, repro, tera
Nitrapyrin	one, tera
Oethilinone	tera
Oil of Pennyroyal	tera
Omadine salts	onc, repro, tera
Oxyfluorfen	one
Pebulate	tera
Perfluidone	tera
Phenmedipham	one
Phenol and salts	tera
2-Phenylphenol and salts	onc, tera
Pine oils	tera
Poly (hexamethylene biguanide)	onc, repro
Polyethoxylated aliphatic alcohols	onc, repro, tera
Prometon	tera
Propanil	onc, repro
Propetamphos	tera
Propiconazole	one
Propylene oxide	tera
Pyrazon	onc, repro
Sethoxydim	one
Siduron	onc, repro, tera
Sodium fluoride	tera
Spinetoram	<u>onc</u>
Sulfometuron-methyl	one, tera

TBT-containing compounds	one, tera
TCMB	one, repro, tera
Temephos	one, tera
Tetrachlorovinphos	one
Tetramethrin	one <u>tera</u>
Thiabendazole and salts	one, repro, tera
Thidiazuron	one, repro, tera
Thiodicarb	tera
Thiophanate methyl	one, tera
Triadimefon	one
Vernolate	one, repro

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