

Office of Environmental Health Hazard Assessment



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Arnold Schwarzenegger
Governor

MEMORANDUM

TO: Christopher Reardon, Chief Deputy Director
Department of Pesticide Regulation

FROM: Allan Hirsch *Allan Hirsch*
Chief Deputy Director

DATE: March 28, 2008

SUBJECT: CHEMICALS REQUIRING TESTING (SECTION 14000, TITLE 22,
CALIFORNIA CODE OF REGULATIONS)

Under the California Safe Drinking Water and Toxic Enforcement Act of 1986 (commonly known as Proposition 65), the Office of Environmental Health Hazard Assessment (OEHHA) is required to update the list of chemicals, which have not been adequately tested as required by state or federal law, for their potential to cause cancer or reproductive toxicity. This list of chemicals is published in Title 22, California Code of Regulations, Section 14000. OEHHA has relied upon information provided by your department to identify the chemicals for which testing is required to fill data gaps for the endpoints of carcinogenicity and reproductive toxicity. Over the years, Dr. Jay Schreider of your staff has provided our office with the updated information and we are most appreciative of his efforts.

OEHHA is in the process of updating the list of chemicals described above; and therefore, we are requesting that your department review the attached list (Subsection (b) of Section 14000, of Title 22 of the California Code of Regulations, copy attached) last provided by your department and provide us with any additions, deletions, or other changes to reflect the current status of the chemicals. A response by June 30, 2008 would be appreciated.

Thank you for your continued cooperation and assistance. In the meantime, if you have any questions, please contact Ms. Cynthia Oshita of my staff at (916) 322-2068.

Attachment

cc: Jay Schreider, Ph.D.
Medical Toxicology Branch
Department of Pesticide Regulation

Cynthia M. Oshita
Proposition 65 Implementation
Office of Environmental Health Hazard Assessment

California Environmental Protection Agency

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EXCERPT FROM TITLE 22, CALIFORNIA CODE OF REGULATIONS

§ 14000. 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)].

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 data gaps. 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). 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 hydroxy 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-dioxaborinate)*	onc rat, onc mouse, repro, tera rabbit
Mineral oil*	onc rat, repro, tera rabbit
Muscalure*	tera rat, tera rabbit (only one is 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,

Polyethoxy polypropoxy polyethoxy ethanol-iodine complex*	tera rabbit 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 U.S. EPA, 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 U.S. EPA, Office of Pesticide Programs.

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.

In 1988, FIFRA was amended to strengthen U.S. EPA'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. U.S. EPA 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 U.S. EPA. These amendments are requiring a substantial number of new studies to be conducted and old studies to be reformatted for U.S. EPA review to ensure they are adequate. U.S. EPA 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.

<i>Chemical</i>	<i>Data Requirements</i>
Acrolein	onc, tera
Alkyl imidazolines	tera
Ametryn	repro, tera
4-Aminopyridine	onc, repro, tera
4-T-Amylphenol	onc, repro
Aquashade	onc, repro, tera
Benzisothiazolin-3-one	onc, repro, tera
Bromonitrostyrene	tera
Busan 77	repro
Chlorflurenol methyl	tera
Chromated arsenicals	tera
Cypermethrin	onc

DCNA	repro
Diclofop-methyl	onc, tera
Dicrotophos	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	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	tera
Iprodione	tera
Irgasan	onc, repro, tera
Lamprecide	onc
Magnesium phosphide	onc
Malathion	onc
Maneb	onc, tera
Mepiquat chloride	tera
Metaldehyde	onc
Methoxychlor	onc, repro, tera
Methyl isothiocyante	tera
Napthaleneacetic acid	onc, repro
Naphthenate salts	tera
Napropamide	repro
Niclosamide	onc, tera
Nicotine and derivatives	onc, tera
Nitrapyrin	onc, tera
Othilinone	tera
Oil of Pennyroyal	tera
Omadine salts	onc, repro, tera
Oxyfluorfen	onc

Pebulate	tera
Perfluidone	tera
Phenmedipham	onc
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	onc
Propylene oxide	tera
Pyrazon	onc, repro
Sethoxydim	onc
Siduron	onc, repro, tera
Sodium fluoride	tera
Sulfometuron-methyl	onc, tera
TBT-containing compounds	onc, tera
TCMB	onc, repro, tera
Temephos	onc, tera
Tetrachlorovinphos	onc
Tetramethrin	onc
Thiabendazole and salts	onc, repro, tera
Thidiazuron	onc, repro, tera
Thiodicarb	tera
Thiophanate-methyl	onc, tera
Triadimefon	onc
Vernolate	onc, repro

Revised: January 1, 2006