

INITIAL STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS

SECTIONS 12705(b) and 12705(d). SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT RISK

SECTION 12805. SPECIFIC REGULATORY LEVELS: REPRODUCTIVE TOXICANTS

The Safe Drinking Water and Toxic Enforcement Act of 1986 commonly known as Proposition 65 (hereinafter the Act) 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 (Health and Safety Code Section 25249.6). 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 a source of drinking water (Health and Safety Code Section 25249.5).

For chemicals known to the state to cause cancer, an exemption from the above requirements is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which he or she is responsible poses no significant risk, or that 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 water (Health and Safety Code Sections 25249.9 and 25249.10). A determination that a level of exposure poses no significant risk may be made utilizing regulations that have previously been adopted by the Office of Environmental Health Hazard Assessment (OEHHA) (Sections 12701 to 12721, Title 22, California Code of Regulations) (unless otherwise specified, all section references are to Title 22, California Code of Regulations). Section 12701 describes alternative methods for making such a determination. One such method is through the application of the specific regulatory level established for the chemical in question in Section 12705. Section 12705(b) supersedes Section 12709 (Exposure to Trace Elements) and Section 12711 (Levels Based on State or Federal Standards).

For chemicals known to the state to cause reproductive toxicity, an exemption from the warning requirement and discharge prohibition discussed above is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which he or she is responsible produces no observable effect, assuming exposure at 1,000 times the level in question, or a discharge which complies with all applicable requirements would not cause any significant amount of the discharged or released chemical to enter any source of drinking water (Health and Safety Code Sections 25249.9 and 25249.10). The maximum dose level at which a chemical has no observable reproductive effect is referred to as the no observable effect level (NOEL). Thus, the exemption applies when the exposure or a discharge in question is at a level that does not exceed the NOEL divided by 1,000.

Regulations previously adopted by OEHHA provide guidance for determining whether an exposure to, or a discharge of, a chemical known to cause reproductive toxicity meets the statutory exemption from the warning requirement or discharge prohibition (Title 22, California Code of Regulations (22 CCR), Sections 12801-12821). These regulations provide two ways by which a person in the course of doing business may make such a determination: (1) by

conducting a risk assessment in accordance with the principles described in Section 12803 to derive a no observable effect level (NOEL), and dividing the NOEL by 1,000; or (2) by application of the specific regulatory level adopted for the chemical in Section 12805 or, in the absence of such a level, by using a risk assessment conducted by a state or federal agency, provided that such assessment is the substantial equivalent of the assessment described in Section 12803, and the maximum allowable daily level (MADL) is one one-thousandth of the NOEL. The specific regulatory levels in Section 12805 represent one one-thousandth of the NOEL.

This proposed regulation sets forth No Significant Risk Levels (NSRLs) for chemicals for adoption in Section 12705(b) using a non-expedited approach, and for adoption in Section 12705(d) using an expedited approach. Both methods are consistent with procedures specified in Section 12703. This proposed regulation also sets forth MADLs using methods specified in Section 12803. Details on the basis for the proposed numbers are provided in the references cited, which are also included in the rulemaking record. The references are risk assessment documents describing and summarizing the derivation of the regulatory levels listed below.

The proposed NSRLs represent the level of exposure to the chemical which is calculated to result in no more than one excess case of cancer in an exposed population of 100,000, assuming exposure over a 70-year lifetime (10^{-5} lifetime risk of cancer), and is based on the risk assessment document prepared or reviewed by OEHHA, Reproductive and Cancer Hazard Assessment Section, in accordance with the principles set forth in Section 12703.

This proposed regulation adopts the following NSRLs for chemicals known to cause cancer in Section 12705(b), in accordance with the methods specified in Section 12703:

Chemical	NSRL, in units micrograms per day	Reference
Chloroethane	150	OEHHA (2000a)
Di(2-ethylhexyl)phthalate (DEHP)	300	OEHHA (2000b)
Lead	15 (oral)	OEHHA (2000c)
Lead acetate	23 (oral)	OEHHA (2000c)
Lead phosphate	58 (oral)	OEHHA (2000c)
Lead subacetate	41 (oral)	OEHHA (2000c)
Methylhydrazine	0.058 (oral) 0.090 (inhalation)	OEHHA (2000d)
Methylhydrazine sulfate	0.18	OEHHA (2000d)
5-Morpholinomethyl-3-[(5-nitrofurfurylidene)-amino]-2-oxazolidinone	0.18	OEHHA (2000e)
MX (3-chloro-4-(dichloromethyl)-5-hydroxy-2(5H)-furanone)	0.11	OEHHA (2000f)
Phenylhydrazine	1.0	OEHHA (2000g)
Phenylhydrazine hydrochloride	1.4	OEHHA (2000g)
Polygeenan	1200	OEHHA (2000h)

This proposed regulation adopts the following No Significant Risk Levels for chemicals known to cause cancer in Section 12705(d):

Chemical	NSRL, in units micrograms per day	Reference
Carbazole	4.1	OEHHA (2000i)
MeIQ (2-Amino-3,4-dimethylimidazo[4,5-f] quinoline)	0.46	OEHHA (2000i)
MeIQx (2-Amino-3,8 - dimethylimidazo[4,5-f] quinoxaline)	0.41	OEHHA (2000i)
Methyl carbamate	160	OEHHA (2000i)
4-(N-Nitrosomethylamino)-1-(3-pyridyl)-1-butanone	0.014	OEHHA (2000i)
Trimethyl phosphate	24	OEHHA (2000i)

Levels established for carcinogens in Section 12705(b) supersede any existing levels for these carcinogens in Section 12705 (c) and Section 12705 (d). Specific regulatory levels currently exist for di(2-ethylhexyl)phthalate in Section 12705(c), and for lead acetate and lead subacetate in Section 12705(d). In order to minimize potential confusion, this proposed rulemaking action seeks to add the new levels for di(2- ethylhexyl)phthalate, lead acetate and lead subacetate in Section 12705(b), while simultaneously deleting the level for di(2- ethylhexyl)phthalate from Section 12705(c) and the levels for lead acetate and lead subacetate from Section 12705(d).

The proposed regulation adopts the following regulatory levels for chemicals known to cause reproductive toxicity in Section 12805:

Chemical	MADL, in units micrograms per day	Reference
Arsenic (inorganic oxides)	220	OEHHA (2000j)
Benzene	24 (oral) 49 (inhalation)	OEHHA (2000k)
Cadmium	4.1	OEHHA (2000l)
Quizalofop ethyl	590	OEHHA (2000m)

References

Office of Environmental Health Hazard Assessment (OEHHA, 2000a). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen Chloroethane. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, May 2001.

Office of Environmental Health Hazard Assessment (OEHHA, 2000b). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen Di(2-ethylhexyl)phthalate (DEHP). OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, May 2001.

Office of Environmental Health Hazard Assessment (OEHHA, 2000c). No Significant Risk Level (NSRLs) for the Proposition 65 Carcinogens Lead and Lead Compounds (Oral). OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, May 2001.

Office of Environmental Health Hazard Assessment (OEHHA, 2000d). No Significant Risk Level (NSRLs) for the Proposition 65 Carcinogens Methylhydrazine and Methylhydrazine Sulfate. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, May 2001.

Office of Environmental Health Hazard Assessment (OEHHA, 2000e). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen 5-Morpholinomethyl-3-[(5-nitrofurfurylidene)-amino]-2-oxazolidinone. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, May 2001.

Office of Environmental Health Hazard Assessment (OEHHA, 2000f). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen MX (3-chloro-4-(dichloromethyl)-5-hydroxy-2(5*H*)-furanone). OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, May 2001.

Office of Environmental Health Hazard Assessment (OEHHA, 2000g). No Significant Risk Levels (NSRLs) for the Proposition 65 Carcinogens Phenylhydrazine and Phenylhydrazine Hydrochloride. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, May 2001.

Office of Environmental Health Hazard Assessment (OEHHA, 2000h). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen Polygeenan, OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, May 2001.

Office of Environmental Health Hazard Assessment (OEHHA, 2000i) Expedited Cancer Potency Values and No Significant Risk Levels (NSRLs) for Six Proposition 65 Carcinogens: Carbazole, MeIQ, MeIQx, Methylcarbamate, 4-Nitrosomethylamino-1-(3-pyridyl)-1-butanone, and Trimethyl phosphate. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, May 2001.

Office of Environmental Health Hazard Assessment (OEHHA, 2000j). Proposition 65 Maximum Allowable Daily Level (MADL) for Reproductive Toxicity for Arsenic (inorganic oxides). OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Sacramento, May 2001.

Office of Environmental Health Hazard Assessment (OEHHA, 2000k). Proposition 65 Maximum Allowable Daily Level (MADL) for Reproductive Toxicity for Benzene. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Sacramento, May 2001.

Office of Environmental Health Hazard Assessment (OEHHA, 2000l) Proposition 65 Maximum Allowable Daily Level (MADL) for Reproductive Toxicity for Cadmium, OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Sacramento, May 2001.

Office of Environmental Health Hazard Assessment (OEHHA, 2000m). Proposition 65 Maximum Allowable Daily Level (MADL) for Reproductive Toxicity for Quizalofop Ethyl. OEHHA Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Sacramento, May 2001.