

PROPOSITION 65 SAFE HARBOR LEVELS:

No Significant Risk Levels for
Carcinogens and Maximum
Allowable Dose Levels for
Chemicals Causing Reproductive
Toxicity

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Reproductive and Cancer Hazard
Assessment Branch
Office of Environmental Health Hazard
Assessment
California Environmental Protection
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Proposition 65 Safe Harbor Levels Development

The Office of Environmental Health Hazard Assessment (OEHHA) of the California Environmental Protection Agency is the lead agency for the implementation of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65 or the Act). In that role, OEHHA has developed Proposition 65 safe harbor levels -- no significant risk levels (NSRLs) for carcinogens and maximum allowable dose levels (MADLs) for chemicals that cause reproductive toxicity. The NSRL is the daily intake level calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime (70-year) exposure at the level in question. The MADL is the level at which chemicals listed for reproductive toxicity would have no observable effect assuming exposure at 1,000 times that level. The NSRLs and MADLs are promulgated in Title 22, California Code of Regulations*, sections 12705 and 12805 respectively to assist interested parties in determining whether warnings are required for exposures to listed chemicals, and whether discharges to sources of drinking water are prohibited.

Safe harbor levels may be based on risk assessments conducted outside OEHHA, as provided for in Sections 12705(b), 12705(c), and 12805. In some cases, this can expedite safe harbor development. However, it should be noted that the process of review and consideration of existing risk assessments can be a lengthy one, and will depend on the complexity of the scientific information underlying the assessment, as well as on available resources.

This document provides the status of the development and adoption of intake levels calculated for all chemicals on the Proposition 65 list. In units of micrograms per day ($\mu\text{g}/\text{day}$), Part A reports NSRLs adopted in regulation for carcinogens and Part B reports MADLs adopted in regulation for chemicals that cause reproductive toxicity.

Parts C and D of this document give priority levels for development of dose response assessments for chemicals that cause cancer and reproductive toxicity, respectively. OEHHA assigns priority levels based on the availability and quality of scientific data for dose-response assessments, potential for exposure, resources available to perform the assessment, needs expressed by interested parties and input from the public and the Attorney General's office. Priority assignments change as assessments are completed or the basis for the priority changes. Interested parties are invited to recommend changes in priority levels. In general, OEHHA will give priority to chemicals that are newly added to the Proposition 65 list and propose safe harbor levels for them within one year of their addition to the list.

Parts C and D include safe harbor levels that have been proposed for adoption in regulation.

This report will be updated on a regular basis.

* All further section references are to Title 22 of the California Code of Regulations unless otherwise indicated.

A. No Significant Risk Levels (NSRLs) Adopted in Regulation for Carcinogens

The table below lists NSRLs for Proposition 65 carcinogens in regulation (Sections 12705 and 12709). These levels are intended to provide “safe harbors” for persons subject to the Act, and do not preclude the use of alternative levels that can be demonstrated by their users as being scientifically valid.

A three-tiered procedure for development of NSRLs is currently in place. NSRLs may be based on a *de novo* dose response assessment conducted or reviewed by OEHHA (Section 12705(b)), an assessment conducted by another state or federal agency (Section 12705(c)), or an expedited process conducted by OEHHA (Section 12705(d)). The last column of the table below indicates which of these processes was used to develop the NSRL for each chemical. NSRLs represent the daily intake level calculated to result in a cancer risk of one excess case of cancer in 100,000 individuals exposed over a 70-year lifetime.

NSRLs for chemicals in bold have been adopted since the last report. As chemicals are removed from the Proposition 65 list, the regulatory process to remove the safe harbor level from regulation will be initiated.

Carcinogen	Level (µg/day)	Section
A-alpha-C (2-Amino-9H-pyrido[2,3-b]indole)	2	12705(d)
Acetaldehyde	90 (inhalation)	12705(c)
Acetamide	10	12705(d)
2-Acetylaminofluorene	0.2	12705(d)
Acrylamide	0.2	12705(c)
Acrylonitrile	0.7	12705(b)
Actinomycin D	0.00008	12705(d)
AF-2; [2-(2-furyl)-3(5-nitro-2-furyl)acrylamide]	3	12705(d)
Aldrin	0.04	12705(b)
2-Aminoanthraquinone	20	12705(d)
<i>o</i> -Aminoazotoluene	0.2	12705(d)
4-Aminobiphenyl	0.03	12705(d)
3-Amino-9-ethylcarbazole hydrochloride	9	12705(d)
1-Amino-2-methylantraquinone	5	12705(d)
2-Amino-5-(5-nitro-2-furyl)-1,3,4-thiadiazole	0.04	12705(d)
Amitrole	0.7	12705(d)
Aniline	100	12705(c)
<i>o</i> -Anisidine	5	12705(d)
<i>o</i> -Anisidine hydrochloride	7	12705(d)
Aramite	20	12705(d)
Arsenic	0.06 (inhalation)	12705(b)
	10 (except inhalation)	12709
Asbestos	100 fibers/day (inhalation)	12705(b)
	NSRL for fibers \geq 5 micrometers (mm) long and 0.3 wide, with a length/width ratio \geq 3:1 as measured by phase contrast microscopy.	
Auramine	0.8	12705(d)
Azaserine	0.06	12705(d)
Azathioprine	0.4	12705(d)
Azobenzene	6	12705(c)

Carcinogen	Level (µg/day)	Section
Benz[a]anthracene	0.033 (oral)	12705(b)
Benzene	6.4 (oral)	12705(b)
	13 (inhalation)	12705(b)
Benzidine	0.001	12705(b)
Benzo[b]fluoranthene	0.096 (oral)	12705(b)
Benzo[j]fluoranthene	0.11 (oral)	12705(b)
Benzofuran	1.1	12705(b)
Benzo[a]pyrene	0.06	12705(c)
Benzyl chloride	4	12705(c)
Benzyl violet 4B	30	12705(d)
Beryllium	0.1	12709
Beryllium oxide	0.1	12705(c)
Beryllium sulfate	0.0002	12705(c)
Bis(2-chloroethyl)ether	0.3	12705(b)
Bis(chloromethyl)ether	0.02	12705(b)
Bromodichloromethane	5	12705(c)
Bromoform	64	12705(b)
1,3-Butadiene	0.4	12705(c)
Butylated hydroxyanisole	4000	12705(b)
beta-Butyrolactone	0.7	12705(d)
Cadmium	0.05 (inhalation)	12705(b)
Captafol	5	12705(d)
Captan	300	12705(d)
Carbazole	4.1	12705(d)
Carbon tetrachloride	5	12705(b)
N-Carboxymethyl-N-nitrosourea	0.70	12705(b)
Chlorambucil	0.002	12705(d)
Chlordane	0.5	12705(c)
Chlordecone (Kepone)	0.04	12705(d)
Chlorendic acid	8	12705(d)
Chlorinated paraffins (Ave. chain length C12; approx. 60% chlorine by weight)	8	12705(d)
Chloroethane (Ethyl chloride)	150	12705(b)
Chloroform	20 (oral)	12705(c)
	40 (inhalation)	12705(c)
Chloromethyl methyl ether (technical grade)	0.3	12705(d)
3-Chloro-2-methylpropene	5	12705(d)
4-Chloro-ortho-phenylenediamine	40	12705(d)
Chlorothalonil	200	12705(d)
<i>p</i> -Chloro-ortho-toluidine	3	12705(d)
<i>p</i> -Chloro- <i>o</i> -toluidine, hydrochloride	3.3	12705(d)
Chlorozotocin	0.003	12705(d)
Chromium (hexavalent)	0.001 (inhalation)	12705(b)
Chrysene	0.35 (oral)	12705(b)
C.I. Basic Red 9 monohydrochloride	3	12705(d)
Cinnamyl anthranilate	200	12705(d)
Coke oven emissions	0.3	12705(c)

Carcinogen	Level (µg/day)	Section
<i>p</i> -Cresidine	5	12705(d)
Cupferron	3	12705(d)
Cyclophosphamide (anhydrous)	1	12705(d)
Cyclophosphamide (hydrated)	1	12705(d)
D&C Red No. 9	100	12705(d)
Dacarbazine	0.01	12705(d)
Daminozide	40	12705(d)
Dantron (Chrysazin; 1,8-Dihydroxyanthraquinone)	9	12705(d)
DDT, DDE, DDD (in combination)	2	12705(b)
DDVP (Dichlorvos)	2	12705(c)
2,4-Diaminoanisole	30	12705(d)
2,4-Diaminoanisole sulfate	50	12705(d)
4,4'-Diaminodiphenyl ether (4,4'-Oxydianiline)	5	12705(d)
2,4-Diaminotoluene	0.2	12705(d)
Dibenz[a,h]anthracene	0.2	12705(d)
7H-Dibenzo[c,g]carbazole	0.0030 (oral)	12705(b)
Dibenzo[a,h]pyrene	0.0054 (oral)	12705(b)
Dibenzo[a,i]pyrene	0.0050 (oral)	12705(b)
1,2-Dibromo-3-chloropropane	0.1	12705(b)
<i>p</i> -Dichlorobenzene	20	12705(b)
3,3'-Dichlorobenzidine	0.6	12705(b)
1,1-Dichloroethane	100	12705(d)
1,2-Dichloroethane (Ethylene dichloride)	10	12705(b)
Dichloromethane (Methylene chloride)	200 (inhalation)	12705(b)
	50	12705(c)
1,2-Dichloropropane	9.7	12705(b)
Dieldrin	0.04	12705(b)
Di(2-ethylhexyl)phthalate (DEHP)	310	12705(b)
Diethylstilbesterol	0.002	12705(d)
Diglycidyl resorcinol ether (DGRE)	0.4	12705(d)
Dihydrosafrole	20	12705(d)
3,3'-Dimethoxybenzidine (<i>o</i> -Dianisidine)	0.15	12705(b)
3,3'-Dimethoxybenzidine dihydrochloride	0.19	12705(b)
4-Dimethylaminoazobenzene	0.2	12705(d)
trans-2-[(Dimethylamino)methylimino]-5-[2-(5-nitro-2-furyl)vinyl]-1,3,4-oxadiazole	2	12705(d)
7,12-Dimethylbenz(a)anthracene	0.003	12705(d)
3,3'-Dimethylbenzidine (<i>o</i> -Tolidine)	0.044	12705(b)
3,3'-Dimethylbenzidine dihydrochloride	0.059	12705(b)
Dimethylcarbamoyl chloride	0.05	12705(d)
1,2-Dimethylhydrazine	0.001	12705(d)
Dimethylvinylchloride	20	12705(d)
2,4-Dinitrotoluene	2	12705(c)
1,4-Dioxane	30	12705(b)
Direct Black 38 (technical grade)	0.09	12705(d)
Direct Blue 6 (technical grade)	0.09	12705(d)
Direct Brown 95 (technical grade)	0.1	12705(d)
Disperse Blue 1	200	12705(d)

Carcinogen	Level (µg/day)	Section
Epichlorohydrin	9	12705(b)
Estradiol 17b	0.02	12705(d)
Ethyl-4,4'-dichlorobenzilate (Chlorobenzilate)	7	12705(d)
Ethylene dibromide	0.2 (oral)	12705(b)
	3 (inhalation)	12705(b)
Ethylene oxide	2	12705(b)
Ethylene thiourea	20	12705(d)
Ethyleneimine	0.01	12705(d)
Folpet	200	12705(c)
Formaldehyde (gas)	40	12705(c)
2-(2-Formylhydrazino)-4-(5-nitro-2-furyl)thiazole	0.3	12705(d)
Furmecyclox	20	12705(c)
Glu-P-1 (2-Amino-6-methyldipyrido[1,2-a:3',2'-d]imidazole)	0.1	12705(d)
Glu-P-2 (2-Aminodipyrido[1,2-a:3',2'-d]-imidazole)	0.5	12705(d)
Gyromitrin (Acetaldehyde methylformylhydrazone)	0.07	12705(d)
HC Blue 1	10	12705(d)
Heptachlor	0.2	12705(c)
Heptachlor epoxide	0.08	12705(c)
Hexachlorobenzene	0.4	12705(b)
Hexachlorocyclohexane		
alpha isomer	0.3	12705(c)
beta isomer	0.5	12705(c)
gamma isomer	0.6	12705(c)
technical grade	0.2	12705(b)
Hexachlorodibenzodioxin	0.0002	12705(b)
Hexachloroethane	20	12705(d)
Hydrazine	0.04	12705(c)
Hydrazine sulfate	0.2	12705(c)
Hydrazobenzene (1,2-Diphenylhydrazine)	0.8	12705(d)
IQ (2-Amino-3-methylimidazo[4,5-f]quinoline)	0.5	12705(d)
Isobutyl nitrite	7.4	12705(d)
Lasiocarpine	0.09	12705(d)
Lead	15 (oral)	12705(b)
Lead acetate	23 (oral)	12705(b)
Lead phosphate	58 (oral)	12705(b)
Lead subacetate	41 (oral)	12705(b)
Me-A-alpha-C (2-Amino-3-methyl-9H-pyrido[2,3-b]indole)	0.6	12705(d)
MeIQ (2-amino-3,4-dimethylimidazo-[4,5-f]quinoline)	0.46	12705(d)
MeIQx (2-Amino-3,8-dimethylimidazo[4,5-f]quinoxaline)	0.41	12705(d)
Melphalan	0.005	12705(d)
2-Methylaziridine (Propyleneimine)	0.028	12705(b)
Methyl carbamate	160	12705(d)

Carcinogen	Level (µg/day)	Section
3-Methylcholanthrene	0.03	12705(d)
5-Methylchrysene	0.0084 (oral)	12705(b)
4,4'-Methylene bis(2-chloroaniline)	0.5	12705(d)
4,4'-Methylene bis(N,N-dimethyl)benzeneamine	20	12705(c)
4,4'-Methylene bis(2-methylaniline)	0.8	12705(d)
4,4'-Methylenedianiline	0.4	12705(d)
4,4'-Methylenedianiline dihydrochloride	0.6	12705(d)
Methylhydrazine	0.058 (oral)	12705(b)
	0.090 (inhalation)	12705(b)
Methylhydrazine sulfate	0.18	12705(b)
Methyl methanesulfonate	7	12705(d)
2-Methyl-1-nitroanthraquinone (of uncertain purity)	0.2	12705(d)
N-Methyl-N'-nitro-N-nitrosoguanidine	0.08	12705(d)
Methylthiouracil	2	12705(d)
Michler's ketone	0.8	12705(d)
Mirex	0.04	12705(d)
Mitomycin C	0.00009	12705(d)
Monocrotaline	0.07	12705(d)
5-(Morpholinomethyl)-3-[(5-nitrofurfurylidene)-amino]-2-oxazolidinone	0.18	12705(b)
MX (3-chloro-4-(dichloromethyl)-5-hydroxy-2(5H)-furanone)	0.11	12705(b)
Nalidixic acid	28	12705(d)
Naphthalene	5.8	12705(b)
2-Naphthylamine	0.4	12705(d)
Nickel refinery dust	0.8	12705(c)
Nickel subsulfide	0.4	12705(c)
Nitrilotriacetic acid	100	12705(d)
Nitrilotriacetic acid, trisodium salt monohydrate	70	12705(d)
5-Nitroacenaphthene	6	12705(d)
Nitrofen (technical grade)	9	12705(d)
Nitrofurazone	0.5	12705(d)
1-[(5-Nitrofurfurylidene)-amino]-2-imidazolidinone	0.4	12705(d)
N-[4-(5-Nitro-2-furyl)-2-thiazolyl]acetamide	0.5	12705(d)
N-Nitrosodi-n-butylamine	0.06	12705(b)
N-Nitrosodiethanolamine	0.3	12705(c)
N-Nitrosodiethylamine	0.02	12705(b)
N-Nitrosodimethylamine	0.04	12705(b)
<i>p</i> -Nitrosodiphenylamine	30	12705(d)
N-Nitrosodiphenylamine	80	12705(b)
N-Nitrosodi-n-propylamine	0.1	12705(b)
N-Nitroso-N-ethylurea	0.03	12705(b)
4-(N-Nitrosomethylamino)-1-(3-pyridyl)-1-butanone	0.014	12705(d)
N-Nitrosomethylethylamine	0.03	12705(c)
N-Nitroso-N-methylurea	0.006	12705(b)
N-Nitroso-N-methylurethane	0.006	12705(d)
N-Nitrosomorpholine	0.1	12705(d)
N-Nitrosornicotine	0.5	12705(d)
N-Nitrosopiperidine	0.07	12705(d)
N-Nitrosopyrrolidine	0.3	12705(c)

Carcinogen	Level (µg/day)	Section
Pentachlorophenol	40	12705(c)
Phenacetin	300	12705(d)
Phenazopyridine	4	12705(d)
Phenazopyridine hydrochloride	5	12705(d)
Phenesterin	0.005	12705(d)
Phenobarbital	2	12705(d)
Phenoxybenzamine	0.2	12705(d)
Phenoxybenzamine hydrochloride	0.3	12705(d)
<i>o</i> -Phenylenediamine	26	12705(d)
<i>o</i> -Phenylenediamine dihydrochloride	44	12705(d)
Phenyl glycidyl ether	5.0	12705(b)
Phenylhydrazine	1.0	12705(b)
Phenylhydrazine hydrochloride	1.4	12705(b)
<i>o</i> -Phenylphenate, sodium	200	12705(d)
Polybrominated biphenyls	0.02	12705(b)
Polychlorinated biphenyls	0.09	12705(c)
Polygeenan	1200	12705(b)
Ponceau MX	200	12705(d)
Ponceau 3R	40	12705(d)
Potassium bromate	1	12705(d)
Procarbazine	0.05	12705(d)
Procarbazine hydrochloride	0.06	12705(d)
1,3-Propane sultone	0.3	12705(d)
beta-Propiolactone	0.05	12705(d)
Propylthiouracil	0.7	12705(d)
Reserpine	0.06	12705(d)
Safrole	3	12705(d)
Sterigmatocystin	0.02	12705(d)
Streptozotocin	0.006	12705(d)
Styrene oxide	4	12705(d)
Sulfallate	4	12705(d)
2,3,7,8-Tetrachlorodibenzo- <i>p</i> -dioxin	0.000005	12705(b)
1,1,2,2-Tetrachloroethane	3	12705(d)
Tetrachloroethylene	14	12705(c)
Tetranitromethane	0.059	12705(b)
Thioacetamide	0.1	12705(d)
4,4'-Thiodianiline	0.05	12705(d)
Thiourea	10	12705(d)
Toluene diisocyanate	20	12705(d)
ortho-Toluidine	4	12705(d)
ortho-Toluidine hydrochloride	5	12705(d)
Toxaphene	0.6	12705(b)
Trichloroethylene	50 (oral)	12705(b)
	80 (inhalation)	12705(b)
2,4,6-Trichlorophenol	10	12705(b)
Trimethyl phosphate	24	12705(d)

Carcinogen	Level (µg/day)	Section
Tris(1-aziridinyl)phosphine sulfide (Thiotepa)	0.06	12705(d)
Tris(2,3-dibromopropyl)phosphate	0.3	12705(d)
Trp-P-1 (Tryptophan-P-1)	0.03	12705(d)
Trp-P-2 (Tryptophan-P-2)	0.2	12705(d)
Urethane (Ethyl carbamate)	0.7	12705(b)
Vinyl chloride	3	12705(b)
Vinyl trichloride (1,1,2-Trichloroethane)	10	12705(d)
2,6-Xylidine	110	12705(b)

B. Maximum Allowable Dose Levels (MADLs) Adopted in Regulation for Chemicals Causing Reproductive Toxicity

The following table is a compilation of MADLs in regulation (Section 12805) for Proposition 65 chemicals that cause reproductive toxicity. These levels represent the no observable effect level (NOEL) for the chemical, divided by 1,000. NOELs are set in accordance with procedures specified in Section 12803. MADLs for chemicals in bold have been adopted since the last report.

Chemical Listed as Causing Reproductive Toxicity	Level ($\mu\text{g}/\text{day}$) ^a
Benzene	24 (oral) 49 (inhalation)
Cadmium	4.1 (oral)
2,4-DB (2,4-dichlorophenoxybutyric acid)	910
1,2-Dibromo-3-chloropropane (DBCP)	3.1 (oral) 4.3 (inhalation)
Di(2-ethylhexyl)phthalate (DEHP), for intravenous exposures only	4200 (adults) 600 (infant boys, age 29 days- 24 months) 210 (neonatal infant boys, age 0-28 days) [Levels for male children and adolescents can be calculated by application of the default bodyweights specified in Section 12703(a)(8) to the procedure specified in Sections 12801 and 12803]
Di(2-ethylhexyl)phthalate (DEHP), for oral exposures only	410 (adults) 58 (infant boys, age 29 days-24 months) 20 (neonatal infant boys, age 0-28 days) [Levels for male children and adolescents can be calculated by application of the default bodyweights specified in Section 12703(a)(8) to the procedure specified in Sections 12801 and 12803]

Chemical Listed as Causing Reproductive Toxicity	Level (µg/day) ^a
<i>m</i> -Dinitrobenzene	38
Disodium cyanodithiomidocarbonate	56 (oral)
Ethyl dipropylthiocarbamate	[170 (oral) for a 32% pesticidal formulation] 700 (oral and inhalation)
Ethylene glycol monoethyl ether (EGEE)	6700 (dermal) 750 (oral)
Ethylene glycol monoethyl ether acetate (EGEEA)	960 (inhalation) 1100 (oral)
Ethylene glycol monomethyl ether	1400 (inhalation) 63 (oral)
Ethylene glycol monomethyl ether acetate	98 (oral)
Ethylene oxide	20
Hydramethylnon	120 (oral)
Lead	0.5
Linuron	460
Methyl bromide as a structural fumigant	810 (inhalation)
N-Methylpyrrolidone	3200 (inhalation) 17000(dermal)
Potassium dimethyldithiocarbamate	720
Quizalofop-ethyl	590
Sodium dimethyldithiocarbamate	23 (oral)
Thiophanate-methyl	[58 (oral) for a 40% pesticidal formulation] 600 (oral)
Toluene	7000 ^b

^a Where a source or product results in exposures by multiple routes, the total exposure must be considered. For example, the MADL for benzene is exceeded when the absorbed dose exceeds 24 µg/day. If only inhalation and oral exposure occurs, the benzene MADL is exceeded when:

$$(\text{oral dose} \div 24 \text{ } \mu\text{g/day}) + (\text{inhalation dose} \div 24 \text{ } \mu\text{g/day}) > 1.0$$

^b Level represents absorbed dose (rounded from 6,525 µg/day). Since 100% of ingested toluene is absorbed, oral dose is equivalent to administered dose. It is assumed that roughly 50% of the dose administered by the inhalation route is absorbed. Therefore the MADL for inhaled toluene is 13,000 µg/day (rounded from 13,050 µg/day), corresponding to an absorbed dose of 6,525 µg/day.

C. Priority List for the Development of NSRLs for Proposition 65 Carcinogens

OEHHA has developed the following priority list, which classifies into four priorities carcinogens for which dose-response assessments have not been completed. OEHHA assigns priority levels based on the availability and quality of scientific data for dose-response assessments, potential for exposure, resources available to perform the assessment, need expressed by interested parties and input from the public and Attorney General's office. OEHHA anticipates proposing NSRLs for the majority of chemicals in the first priority group within the next year, and for second priority chemicals within the next two to five years. It is unlikely that NSRLs for third and fourth priority chemicals would be released within the next five years.

Priority assignments change as assessments are completed or the basis for the priority changes. Any interested party may submit recommendations to OEHHA for revising the priority assignment for any of the chemicals listed, preferably with supporting rationale for the change in priority. In general, OEHHA will give priority to chemicals that are newly added to the Proposition 65 list and propose safe harbor levels for them within one year of their addition to the list.

If a level is currently being proposed for adoption in regulation, it is given below. Chemicals in bold font have been added to the Proposition 65 list or changed in priority status since the last report.

1. First Priority for NSRL Development

Bromate

Bromoethane

C.I. Direct Blue 218

Ethylbenzene

2,4-Hexadienal (89% trans, trans isomer;
11% cis, trans isomer)

N-Methylolacrylamide

Nitromethane

(Proposed: 39 µg/day)

Ochratoxin A

Propylene glycol mono-*t*-butyl ether

Pyridine

1,2,3-Trichloropropane

2. Second Priority for NSRL Development

Alachlor

p-Aminoazobenzene

Aniline hydrochloride

Anthraquinone

Antimony oxide

Benzotrichloride

2,2-Bis(bromomethyl)-1,3-propanediol

Catechol

Ceramic fibers (airborne particles of respirable size)

***p*-Chloroaniline**

***p*-Chloroaniline hydrochloride**

1-Chloro-4-nitrobenzene

Chloroprene

5-Chloro-*o*-toluidine and its strong acid salts

C. I. Acid Red 114

C.I. Direct Blue 15

Cobalt sulfate heptahydrate

D&C Orange No. 17

Diaminotoluene (mixed)

Dichloroacetic acid

3,3'-Dichlorobenzidine dihydrochloride

1,4-Dichloro-2-butene

1,3-Dichloropropene

Diesel engine exhaust

Diethyl sulfate

Dimethyl sulfate

1,1-Dimethylhydrazine (UDMH)

Fumonisin B₁

Furan

Glycidol

Indium phosphide

Isoprene

Methyleugenol

Methyl iodide

1-Naphthylamine

Nitrapyrin

Nitrobenzene

2-Nitropropane

o-Nitrotoluene

***o*-Phenylphenol**

Propylene oxide

Quinoline and its strong acid salts

Tetrafluoroethylene

Tris(2-chloroethyl)phosphate

Vanadium pentoxide (orthorhombic crystalline form)

Vinyl bromide

4-Vinylcyclohexene

3. Third Priority for NSRL Development

Acetochlor

Acifluorfen

Aflatoxins

1-Amino-2,4-dibromoanthraquinone

Areca nut

Azacitidine

Benzidine-based dyes

Benzo[k]fluoranthene

Betel quid without tobacco

N,N-Bis(2-chloroethyl)-2-naphthylamine

Bischloroethyl nitrosourea (BCNU) (Carmustine)

Bis(2-chloro-1-methylethyl)ether, technical grade

1,4-Butanediol dimethanesulfonate (Busulfan)

Cacodylic acid

Carbon black (airborne, unbound particles of respirable size)

Chloramphenicol

Chlordimeform

1-(2-Chloroethyl)-3-cyclohexyl-1-nitrosourea (CCNU)

1-(2-Chloroethyl)-3-(4-methylcyclohexyl)-1-nitrosourea

Chlorotrianisene
 Cyclosporin (Cyclosporin A; Cyclosporine)
 Cidofovir
C.I. Solvent Yellow 14
 Cisplatin
 Clofibrate
Cobalt metal powder
Cobalt [II] oxide
Cobalt sulfate
 Daunomycin
 N,N'-Diacetylbenzidine
Diazoaminobenzene
Dibenz[a,h]acridine
Dibenz[a,j]acridine
Dibenzo[a,e]pyrene
Dibenzo[a,l]pyrene
2,3-Dibromo-1-propanol
 3,3'-Dichloro-4,4'-diaminodiphenyl ether
 Dienestrol
Diepoxybutane
 1,2-Diethylhydrazine
 Diisopropyl sulfate
 3,3'-Dimethoxybenzidine-based dyes metabolized to 3,3'-dimethoxybenzidine
 3,3'-Dimethylbenzidine-based dyes metabolized to 3,3'-dimethylbenzidine
1,6-Dinitropyrene
1,8-Dinitropyrene
2,6-Dinitrotoluene
 2,4-/2,6-Dinitrotoluene mixture
 Diphenylhydantoin (Phenytoin)
 Diphenylhydantoin (Phenytoin), sodium salt
Di-n-propyl isocinchomeronate (MGK Repellent 326)
Diuron
 Doxorubicin hydrochloride (adriamycin)
Estragole
 Estrogens, steroidal
 Estrone
 Estropipate
Ethinylestradiol
Ethoprop
 Ethyl acrylate
Fenoxycarb
 Furazolidone
 Fusarin C
 Ganciclovir sodium
 Gasoline engine exhaust (condensates/extracts)
 Gemfibrozil
 Glasswool fibers (airborne particles of respirable size)
 Glycidaldehyde
Griseofulvin
Hexamethylphosphoramide
1-Hydroxyanthraquinone
Indeno[1,2,3-cd]pyrene
Iprodione
Iprovalicarb

Isoxaflutole
Lactofen
 Mancozeb
 Maneb
 Medroxyprogesterone acetate
 Merphalan
 Mestranol
Metham sodium
Methylmercury compounds
 Metiram
Metronidazole
 Mustard Gas
Nafenopin
Nickel and nickel compounds
Nickel carbonyl
 Niridazole
***o*-Nitroanisole**
4-Nitrobiphenyl
6-Nitrochrysene
2-Nitrofluorene
1-Nitropyrene
4-Nitropyrene
 Nitrogen mustard (Mechlorethamine)
 Nitrogen mustard hydrochloride (Mechlorethamine HCl)
***N*-Nitrosomethylvinylamine**
***N*-Nitrososarcosine**
 Norethisterone (Norethindrone)
Oxadiazon
Oxazepam
Oxythioquinox (Chinomethionat)
 Oxymetholone
 Panfuran S
PhiP
Polychlorinated dibenzo-*p*-dioxins
 Polychlorinated dibenzofurans
Primidone
 Procymidone
Progesterone
Pronamide
Propachlor
 Propargite
Propoxur
Radionuclides
Selenium sulfide
Silica, crystalline (airborne particles of respirable size)
 Spironolactone
 Stanozolol
 Strong inorganic acid mists containing sulfuric acid
Sulfasalazine (salicylazosulfapyridine)
 Tamoxifen and its salts
 Terrazole
Testosterone and its esters
***p*-a,a,a-Tetrachlorotoluene**
 Thiodicarb

Thiouracil

Thorium dioxide

Treosulfan

Trichlormethine (Trimustine hydrochloride)

2,4,5-Trimethylaniline and its strong acid salts

Triphenyltin hydroxide

Trypan blue (commercial grade)

Uracil mustard

Vinclozolin

4-Vinyl-1-cyclohexene diepoxide

Vinyl fluoride

Zileuton

4. Fourth Priority for NSRL Development

Alcoholic beverages

2-Aminofluorene

4-Amino-2-nitrophenol

Analgesic mixtures containing phenacetin

Aristolochic acid

Betel quid with tobacco

Bitumens, extracts of steam-refined

Bracken fern

Caffeic acid

Carbon-black extracts

Certain combined chemotherapy for lymphomas

Citrus Red No. 2

Conjugated estrogens

Creosotes

Cycasin

Cytembena

D&C Red No. 8

D&C Red No. 19

3,7-Dinitrofluoranthene

3,9-Dinitrofluoranthene

Erionite

Ethyl methanesulfonate

Herbal remedies containing plant species of the genus Aristolochia

Iron dextran complex

Lynestrenol

8-Methoxypsoralen with ultraviolet A therapy

5-Methoxypsoralen with ultraviolet A therapy

Methylazoxymethanol

Methylazoxymethanol acetate

Nitrogen mustard N-oxide

Nitrogen mustard N-oxide hydrochloride

3-(N-Nitrosomethylamino)propionitrile

Norethynodrel

Oil Orange SS

Oral contraceptives, combined

Oral contraceptives, sequential

Palygorskite fibers

Phenolphthalein

Residual (heavy) fuel oils

Riddelliine
Shale-oils
Soots, tars, and mineral oils
Talc containing asbestiform fibers
Tobacco, oral use of smokeless products
Tobacco smoke
Unleaded gasoline (wholly vaporized)

D. Priority List for the Development of MADLs for Chemicals Causing Reproductive Toxicity

OEHHA has developed the following priority list, which divides into three priorities chemicals causing reproductive toxicity for which dose-response assessments have not been completed. OEHHA assigns priority levels based on the availability and quality of scientific data for dose-response assessments, potential for exposure, resources available to perform the assessment, need expressed by interested parties, and input from the public and the Attorney General's office. OEHHA anticipates proposing MADLs for the majority of chemicals in the first priority group within the next year, and for second priority chemicals within the next two to five years. It is unlikely that MADLs for chemicals in the third priority group would be released within the next five years.

Priority assignments change as assessments are completed or the basis for the priority changes. Any interested party may submit recommendations to OEHHA on revising the priority assignment for any of the chemicals listed, preferably with supporting rationale for the change in priority. In general, OEHHA will give priority to chemicals that are newly added to the Proposition 65 list and propose safe harbor levels for them within one year of their addition to the list.

If a level is currently being proposed for adoption in regulation, it is given below. Chemicals in bold font have been added to the Proposition 65 list or changed in priority status since the last report.

1. First Priority for MADL Development

Amitraz

1-Bromopropane

Bromoxynil octanoate

1,3-Butadiene

Chlorsulfuron

Cycloate

Di-n-butyl phthalate (DBP)

(Proposed: 8.7 µg/day)

Di-n-hexyl phthalate (DnHP)

Metham sodium

Myclobutanil

Vinclozolin

2. Second Priority for MADL Development

Arsenic (inorganic oxides)

Bromacil lithium salt

Bromoxynil

2-Bromopropane

Butyl benzyl phthalate (BBP)

Carbon disulfide

Cocaine

Dichlorophene

Diclofop methyl

Di-isodecyl phthalate (DIDP)

Ethylene thiourea

Fenoxaprop ethyl

Fluazifop butyl

Fluvalinate

Mercury and mercury compounds

Methazole

Methyl mercury

Metiram
Nabam
Nicotine
Nitrapyrin
Oxadiazon
Oxydemeton methyl
Oxythioquinox (Chinomethionat)
Propargite
Resmethrin
Sodium fluoroacetate
Terbacil
2,3,7,8-Tetrachlorodibenzo-para-dioxin (TCDD)
Triadimefon
Tributyltin methacrylate
Triforine
Triphenyl tin hydroxide

3. Third Priority for MADL Development

Acetazolamide
Acetohydroxamic acid
Actinomycin D
All-trans retinoic acid
Alprazolam
Altretamine
Amantadine hydrochloride
Amikacin sulfate
Aminoglutethimide
Aminoglycosides
Aminopterin
Amiodarone hydrochloride
Amoxapine
Anabolic steroids
Angiotensin converting enzyme (ACE) inhibitors
Anisindione
Aspirin
Atenolol
Auranofin
Azathioprine
Barbiturates
Beclomethasone dipropionate
Benomyl
Benzphetamine hydrochloride
Benzodiazepines
Bischloroethyl nitrosourea (BCNU) (Carmustine)
Butabarbital sodium
1,4-Butanediol dimethanesulfonate (Busulfan)
Carbamazepine
Carbon monoxide
Carboplatin
Chenodiol
Chlorambucil
Chlorcyclizine hydrochloride
Chlordecone (Kepone)

Chlordiazepoxide
Chlordiazepoxide hydrochloride
1-(2-Chloroethyl)-3-cyclohexyl-1-nitrosourea (CCNU) (Lomustine)
Cidofovir
Cladribine
Clarithromycin
Clobetasol propionate
Clomiphene citrate
Clorazepate dipotassium
Codeine phosphate
Colchicine
Conjugated estrogens
Cyanazine
Cycloheximide
Cyclophosphamide (anhydrous)
Cyclophosphamide (hydrated)
Cyhexatin
Cytarabine
Dacarbazine
Danazol
Daunorubicin hydrochloride
o,p'-DDT
p,p'-DDT
Demeclocycline hydrochloride (internal use)
Diazepam
Diazoxide
Dichlophenamide
Dicumarol
Diethylstilbestrol (DES)
Diflunisal
Dihydroergotamine mesylate
Diltiazem hydrochloride
o-Dinitrobenzene
p-Dinitrobenzene
2,4-Dinitrotoluene
2,6-Dinitrotoluene
Dinitrotoluene (technical grade)
Dinocap
Dinoseb
Diphenylhydantoin (Phenytoin)
Doxorubicin hydrochloride (adriamycin)
Doxycycline (internal use)
Doxycycline calcium (internal use)
Doxycycline hyclate (internal use)
Doxycycline monohydrate (internal use)
Endrin
Environmental tobacco smoke (ETS)
Epichlorohydrin
Ergotamine tartrate
Estropipate
Ethionamide
Ethyl alcohol in alcoholic beverages
Ethylene dibromide
Etodolac

Etoposide
Etretinate
Filgrastim
Flunisolide
Fluorouracil
Fluoxymesterone
Flurazepam hydrochloride
Flurbiprofen
Flutamide
Fluticasone propionate
Ganciclovir sodium
Gemfibrozil
Goserelin acetate
Halazepam
Halobetasol propionate
Haloperidol
Halothane
Heptachlor
Hexachlorobenzene
Hexamethylphosphoramide
Histrelin acetate
Hydroxyurea
Idarubicin hydrochloride
Ifosfamide
Iodine-131
Isotretinoin
Leuprolide acetate
Levodopa
Levonorgestrel implants
Lithium carbonate
Lithium citrate
Lorazepam
Lovastatin
Mebendazole
Medroxyprogesterone acetate
Megestrol acetate
Melphalan
Menotropins
Meproamate
Mercaptopurine
Methacycline hydrochloride
Methimazole
Methotrexate
Methotrexate sodium
Methyl chloride
Methyltestosterone
Midazolam hydrochloride
Minocycline hydrochloride (internal use)
Misoprostol
Mitoxantrone hydrochloride
Nafarelin acetate
Neomycin sulfate (internal use)
Netilmicin sulfate
Nickel carbonyl

Nifedipine
Nimodipine
Nitrofurantoin
Nitrogen mustard (Mechlorethamine)
Nitrogen mustard hydrochloride (Mechlorethamine hydrochloride)
Norethisterone (Norethindrone)
Norethisterone acetate (Norethindrone acetate)
Norethisterone (Norethindrone)/Ethinyl estradiol
Norethisterone (Norethindrone)/Mestranol
Norgestrel
Oxazepam
Oxymetholone
Oxytetracycline (internal use)
Oxytetracycline hydrochloride (internal use)
Paclitaxel
Paramethadione
Penicillamine
Pentobarbital sodium
Pentostatin
Phenacemide
Phenprocoumon
Pimozide
Pipobroman
Plicamycin
Polybrominated biphenyls
Polychlorinated biphenyls
Pravastatin sodium
Prednisolone sodium phosphate
Procarbazine hydrochloride
Propylthiouracil
Pyrimethamine
Quazepam
Retinol/retinyl esters, when in daily dosages in
 excess of 10,000 IU, or 3,000 retinol equivalents.
Ribavirin
Rifampin
Secobarbital sodium
Sermorelin acetate
Streptomycin sulfate
Streptozocin (streptozotocin)
Sulfasalazine (salicylazosulfapyridine)
Sulindac
Tamoxifen citrate
Temazepam
Teniposide
Testosterone cypionate
Testosterone enanthate
Tetracycline (internal use)
Tetracyclines (internal use)
Tetracycline hydrochloride (internal use)
Thalidomide
Thioguanine
Tobacco smoke (primary)
Tobramycin sulfate

Triazolam
Trientine hydrochloride
Trilostane
Trimethadione
Trimetrexate glucuronate
Uracil mustard
Urethane
Urofollitropin
Valproate (Valproic acid)
Vinblastine sulfate
Vincristine sulfate
Warfarin
Zileuton