

CALIFORNIA PROPOSITION 65 THE SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986 GUIDE FOR OPTICAL LABORATORIES

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EXECUTIVE SUMMARY

Proposition 65 is a California initiative that became a state law in 1986. Officially it is known as the Safe Drinking Water and Toxic Enforcement Act; however, it is commonly referred to as “Prop 65”. The law seeks to regulate the existence of certain chemical substances found in the environment, the workplace or in consumer products within the state of California.

While some of the Prop 65 controls are intended to protect California’s drinking water sources from contamination by these chemicals, the law also seeks to allow California consumers, residents and workers the opportunity to make informed choices about products and environments that contain potentially hazardous chemicals.

Prop 65 law suits may be brought by an Attorney General or District Attorney in California; however Prop 65 includes a private right of action allowing “any person in the public interest” to bring suit, including consumer advocate groups and private citizens. Most Prop 65 cases are brought forward by “private enforcers.”

These enforcers target certain segments of the California marketplace, and recently eyewear cases, chains, plano sunglasses and over-the-counter reading glasses have been in their sights. In addition, other segments of the ophthalmic optics industry could be target as new substances get added to the substance list. For this reason, as a trade association we believe that this guide can help keep our members informed about Prop 65 so that steps can be taken by the membership to avoid Prop 65 compliance issues.

This version of The Vision Council’s guidance document on Prop 65 is intended for the Optical Laboratories Division, and in particular those labs physically located California. This document is similar to, and incorporates sections of, another guidance document from The Vision Council on Prop 65 compliance written for its members involved in manufacturing and distributing eyewear and sunwear products in and into California. This guide, however, includes content germane to optical laboratories.

QUESTIONS AND ANSWERS

WHO	Those companies that have 10 or more employees and whose businesses: 1.) are physically present in California; or, 2.) whose products are sold, distributed or stored in California, including sales in California placed via the internet or catalogs.	WHY	A great many chemicals and other substances are understood to possibly or definitively cause cancers, birth defects/developmental delays, or other health hazards in humans. In this area California, through Prop 65, is promoting the strictest state requirements in the U.S., requiring that consumers be warned of the presence of such substances in products.
WHAT	Proposition (Prop) 65 (“The Safe Drinking Water and Toxic Enforcement Act”) is a California state law that requires consumers in California be informed when products they seek to purchase contain substances that have been determined to cause cancer, birth defects or other reproductive harm. It also covers exposures to such substances in the workplace or in the environment.	HOW	Optical laboratories should confirm that their processing materials and coatings do not contain chemical substances on the Prop 65 list or, if they do contain such substances, that the amounts are below any relevant de minimis or “safe harbor” level for those substances. If not, then a conspicuous, clear and reasonable warning to the consumer must be provided that the lenses contain a substance(s) determined by California to be carcinogenic and/or teratogenic. California state regulations set out specific language and guidance for these warnings. Also, labs must ensure that if materials that contain Prop 65 substances are used within their work environment that the appropriate warning signage is posted to warn employees and visitors including safety professional such as fire fighters, of the presence of listed substances.
WHERE	All sales in California of products containing substances on the Prop 65 list, or exposures to such substances in the environment or workplace in California, except for those businesses with fewer than 10 employees.		
WHEN	The law has been in place since 1986 and its regulated substance listing is updated periodically. However, tort lawyers and enforcer groups have been suing many businesses, including distributors of optical products, specifically nonprescription sunglasses and over the counter reading glasses, for lack of Prop 65 compliance.		

TESTING REQUIREMENTS AND CHEMICAL LISTINGS

Prop 65 requires the Governor of California to publish a list of chemical substances that are known to the State of California to cause cancer, birth defects or other reproductive harm. The list contains a wide range of chemicals, including dyes, solvents, pesticides, drugs, food additives, byproducts of certain processes, or specialty chemicals used in industrial applications. Those substances may be naturally occurring or synthetic.

The Prop 65 substance list is very long (containing over 900 substances) and is constantly changing. To ensure that your compliance efforts reflect the current inventory of listed substances, the following link should be consulted for the up-to-date list of substances being regulated by California: http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html. Labs should confirm that the materials they use do not contain chemical substances on the Prop 65 list or, if they do contain such substances, that the amounts are below any relevant de minimis or “safe harbor” level for those substances. However, only about 1/3rd of the substances set out on the Prop 65 list provide a safe harbor limit.

The Vision Council and NSL have created a smaller version of that list to help members better understand some of the kinds of chemicals which may be more common in ophthalmic products. We are not representing this reduced list as the only substances members must concern themselves with for compliance purposes. Members should identify and vet against the master Prop 65 list the substances in their products. The abridged list, however, represents a good faith attempt to identify some of the substances that NSL feels might be found in ophthalmic products and thus of interest to The Visions Council members.

Chemical	Type of Toxicity	CAS No.	NSRL or MADL ¹ (µg/day)	Classification
Disodium cyanodithioimidocarbonate	developmental	138-93-2	56 (oral) 170 (oral) as 32% pesticidal formulation	Fire Retardant
Polybrominated biphenyls	cancer	---	0.02	Fire Retardant
Polybrominated biphenyls	developmental	---		Fire Retardant
Polychlorinated biphenyls	cancer	---	0.09	Fire Retardant
Polychlorinated biphenyls	developmental	---		Fire Retardant
Polychlorinated biphenyls (containing 60 or more percent percent chlorine by molecular weight)	cancer	---		Fire Retardant
Benzyl chloride	cancer	100-44-7	4	Halogenated Solvents
2,2-Bis(bromomethyl)-1,3-propanediol	cancer	3296-90-0		Halogenated Solvents

Chemical	Type of Toxicity	CAS No.	NSRL or MADL ¹ (µg/day)	Classification
Bis(2-chloroethyl)ether	cancer	111-44-4	0.3	Halogenated Solvents
Bis(chloromethyl)ether	cancer	542-88-1	0.02	Halogenated Solvents
Bisphenol A	Developmental	80-05-7	290	
Bromoethane	cancer	74-96-4		Halogenated Solvents
2-Bromopropane	female, male	75-26-3		Halogenated Solvents
Carbon tetrachloride	cancer	56-23-5	5	Halogenated Solvents
Chlorinated paraffins (Average chain length, C12;approximately 60 percent chlorine by weight)	cancer	108171-26-2	8	Halogenated Solvents
Chloroethane (Ethyl chloride)	cancer	75-00-3	150	Halogenated Solvents
Chloromethyl methyl ether (technical grade)	cancer	107-30-2	0.3	Halogenated Solvents
2-Chloropropionic acid	male	598-78-7		Halogenated Solvents
1,2-Dibromo-3-chloropropane (DBCP)	cancer	96-12-8	0.1	Halogenated Solvents
1,2-Dibromo-3-chloropropane (DBCP)	male	96-12-8	3.1 (oral) 4.3 (inhalation)	Halogenated Solvents
p-Dichlorobenzene	cancer	106-46-7	20	Halogenated Solvents
1,1-Dichloroethane	cancer	75-34-3	100	Halogenated Solvents
Dichloromethane (Methylene chloride)	cancer	75-09-2	50 200 (inhalation)	Halogenated Solvents
1,2-Dichloropropane	cancer	78-87-5	9.7	Halogenated Solvents
Ethylene dichloride (1,2-Dichloroethane)	cancer	107-06-2	10	Halogenated Solvents
Hexafluoroacetone	male	684-16-2		Halogenated Solvents
Methyl chloride	developmental	74-87-3		Halogenated Solvents

Chemical	Type of Toxicity	CAS No.	NSRL or MADL ¹ (µg/day)	Classification
Methyl chloride	male	74-87-3		Halogenated Solvents
4,4'-Methylene bis(2-chloroaniline)	cancer	101-14-4	0.5	Halogenated Solvents
Tetrafluoroethylene	cancer	116-14-3		Halogenated Solvents
Vinyl trichloride (1,1,2-Trichloroethane)	cancer	79-00-5	10	Halogenated Solvents
Antimony oxide (Antimony trioxide)	cancer	1309-64-4		Metals
Arsenic (inorganic arsenic compounds)	cancer	--	0.06 (inhalation) 10 (except inhalation)	Metals
Arsenic (inorganic oxides)	developmental	---		Metals
Beryllium and beryllium compounds	cancer	---		Metals
Beryllium			0.1	Metals
Beryllium oxide			0.1	Metals
Beryllium sulfate			2E-04	Metals
Cadmium	developmental, male	---	4.1 (oral)	Metals
Cadmium and cadmium compounds	cancer	---		Metals
Cadmium			0.05 (inhalation)	Metals
Chromium (hexavalent compounds)	cancer	---	0.001 (inhalation)	Metals
Chromium (hexavalent compounds)	developmental, female, male	---		Metals
Cobalt metal powder	cancer	7440-48-4		Metals
Cobalt [II] oxide	cancer	1307-96-6		Metals
Cobalt sulfate	cancer	10124-43-3		Metals
Cobalt sulfate heptahydrate	cancer	10026-24-1		Metals
Gallium arsenide	cancer	1303-00-0		Metals
Iodine-131	developmental	10043-66-0		Metals
Lead	developmental, female, male	---	0.5	Metals
Lead and lead compounds	cancer	---		Metals
Lead			15 (oral)	Metals

Chemical	Type of Toxicity	CAS No.	NSRL or MADL ¹ (µg/day)	Classification
Lead acetate	cancer	301-04-2	23 (oral)	Metals
Lead phosphate	cancer	7446-27-7	58 (oral)	Metals
Lead subacetate	cancer	1335-32-6	41 (oral)	Metals
Lithium carbonate	developmental	554-13-2		Metals
Mercury and mercury compounds	developmental	---		Metals
Methylmercury compounds	cancer	---		Metals
Nickel (Metallic)	cancer	7440-02-0		Metals
Nickel acetate	cancer	373-02-4		Metals
Nickel carbonate	cancer	3333-67-3		Metals
Nickel carbonyl	cancer	13463-39-3		Metals
Nickel carbonyl	developmental	13463-39-3		Metals
Nickel compounds	cancer	---		Metals
Nickel hydroxide	cancer	12054-48-7; 12125-56-3		Metals
Nickelocene	cancer	1271-28-9		Metals
Nickel oxide	cancer	1313-99-1		Metals
Nickel refinery dust from the pyrometallurgical process	cancer	---	0.8	Metals
Nickel subsulfide	cancer	12035-72-2	0.4	Metals
Selenium sulfide	cancer	7446-34-6		Metals
Silica, crystalline (airborne particles of respirable size)	cancer	---		Metals
Thorium dioxide	cancer	1314-20-1		Metals
1,3-Butadiene	cancer	106-99-0	0.4	Monomers
1,3-Butadiene	developmental, female, male	106-99-0		Monomers
Chlorendic acid	cancer	115-28-6	8	Monomers
Chloroprene	cancer	126-99-8		Monomers
p-Cresidine	cancer	120-71-8	5	Monomers
Dimethylvinylchloride	cancer	513-37-1	20	Monomers
Dinitrotoluene (technical grade)	female, male	---		Monomers
Dinitrotoluene mixture, 2,4-/2,6-	cancer	---		Monomers
2,4-Dinitrotoluene	cancer	121-14-2	2	Monomers
2,4-Dinitrotoluene	male	121-14-2		Monomers
2,6-Dinitrotoluene	cancer	606-20-2		Monomers

Chemical	Type of Toxicity	CAS No.	NSRL or MADL ¹ (µg/day)	Classification
2,6-Dinitrotoluene	male	606-20-2		Monomers
Ethyl acrylate	cancer	140-88-5		Monomers
Ethylene oxide	cancer	75-21-8	2	Monomers
Ethylene oxide	female	75-21-8	20	Monomers
Ethylene oxide	developmental, male	75-21-8		Monomers
Glycidol	cancer	556-52-5		Monomers
Isoprene	cancer	78-79-5		Monomers
4,4'-Methylenedianiline	cancer	101-77-9	0.4	Monomers
Methyl isocyanate (MIC)	developmental, female	624-83-9		Monomers
o-Phenylenediamine and its salts	cancer	95-54-5		Monomers
o-Phenylenediamine			26	Monomers
o-Phenylenediamine dihydrochloride			44	Monomers
Propylene oxide	cancer	75-56-9		Monomers
Toluene diisocyanate	cancer	26471-62-5	20	Monomers
Trientine hydrochloride	developmental	38260-01-4		Monomers
Trimethyl phosphate	cancer	512-56-1	24	Monomers
Vinyl bromide	cancer	593-60-2		Monomers
Vinyl chloride	cancer	75-01-4	3	Monomers
Vinyl fluoride	cancer	75-02-5		Monomers
Naphthalene	cancer	91-20-3	5.8	PAH
Butyl benzyl phthalate (BBP)	developmental	85-68-7		Phthalates
Di- <i>n</i> -butyl phthalate (DBP)	developmental, female, male	84-74-2	8.7	Phthalates
Di(2-ethylhexyl)phthalate (DEHP)	cancer	117-81-7	310	Phthalates
Di(2-ethylhexyl)phthalate (DEHP)	developmental, male	117-81-7	For intravenous exposure: 4200 (adults) 600 (infant boys, age 29 days- 24 mos.) 210 (neonatal infant boys, age 0-28 days).	Phthalates
Di- <i>n</i> -hexyl phthalate (DnHP)	female, male	84-75-3	2200 (oral)	Phthalates

Chemical	Type of Toxicity	CAS No.	NSRL or MADL ¹ (µg/day)	Classification
Di-isodecyl phthalate (DIDP)	developmental	68515-49-1/ 26761-40-0	2200	Phthalates
Diisononyl phthalate (DINP)	cancer	---		Phthalates
Acetaldehyde	cancer	75-07-0	90 (inhalation)	Solvents
Acetamide	cancer	60-35-5	10	Solvents
Acrylonitrile	cancer	107-13-1	0.7	Solvents
4-Aminobiphenyl (4-amino-diphenyl)	cancer	92-67-1	0.03	Solvents
Aniline	cancer	62-53-3	100	Solvents
Aniline hydrochloride	cancer	142-04-1		Solvents
Benzene	cancer	71-43-2	6.4 (oral) 13 (inhalation)	Solvents
Benzene	developmental, male	71-43-2	24 (oral) 49 (inhalation)	Solvents
Butylated hydroxyanisole	cancer	25013-16-5	4000	Solvents
4,4'-Diaminodiphenyl ether (4,4'-Oxydianiline)	cancer	101-80-4	5	Solvents
N,N-Dimethylacetamide	developmental	127-19-5		Solvents
3,3'-Dimethylbenzidine (ortho-Tolidine)	cancer	119-93-7	0.044	Solvents
Ethylbenzene	cancer	100-41-4	54 (inhalation) 41 (oral)	Solvents
2-Ethylhexanoic acid	developmental	149-57-5		Solvents
Hexamethylphosphoramide	cancer	680-31-9		Solvents
Hexamethylphosphoramide	male	680-31-9		Solvents
Hydrazine	cancer	302-01-2	0.04	Solvents
Hydrazobenzene (1,2-Diphenylhydrazine)	cancer	122-66-7	0.8	Solvents
Methylhydrazine and its salts	cancer	---		Solvents
Methylhydrazine			0.058 (oral) 0.090 (inhalation)	Solvents
Methylhydrazine sulfate			0.18	Solvents
N-Methylpyrrolidone	developmental	872-50-4	3200 (inhalation) 17000 (dermal)	Solvents
Nitrobenzene	cancer	98-95-3		Solvents
Nitrobenzene	male	98-95-3		Solvents
2-Nitropropane	cancer	79-46-9		Solvents
N-Nitrosodiphenylamine	cancer	86-30-6	80	Solvents

Chemical	Type of Toxicity	CAS No.	NSRL or MADL ¹ (µg/day)	Classification
p,p'-Oxybis(benzenesulfonyl hydrazide)	developmental	80-51-3		Solvents
Thiourea	cancer	62-56-6	10	Solvents
Toluene	developmental	108-88-3	7000b	Solvents
Toluene	female	108-88-3		Solvents
1. NSRL: No Significant Risk Level MADL: Maximum Allowable Dose Level				

LABELING AND WARNING SIGNAGE

Occupational Exposure

Prop 65 substance exposures to lab workers or other individuals in an occupational setting should be a concern for Optical Lab members. Prop 65 substances might be found in any number of items found at a lab, from coating and finishing materials to lens blanks and substances found in lens shavings. Regular office materials such as toner cartridges and some cleaning supplies can also contain Prop 65 chemicals.

The easiest way to achieve Prop 65 compliance in the work place is to post warning signs alerting your employees and visitors that certain substances or products containing those substances that California has included on its Prop 65 list are present. This warning can take different forms. For example, a warning on the label or labeling of a product containing a listed substance can suffice as long as the warning language is appropriate and conspicuous.

An alternative way to warn is by using signage in the workplace. The signage needs to be conspicuous, and posted where it would be seen before an individual possibly is exposed to a Prop 65 substance.

Another alternative available to the labs is to provide a warning that complies with all information, training and labeling as required by the: 1.) federal Hazard Communication Standard (29 C.F.R. § 1910.1200); 2.) the California Hazard Communication Standard (California Code Regulations, title 8, section 5194) or for pesticides; 3.) the Pesticides and Worker Safety requirements (California Code Regulations, title 3, § 6700, et seq.) Typically, compliance

with these federal and state laws also requires the posting of a conspicuous sign in the workplace. In other words, you may already be Prop 65 compliant because you are complying with these other laws.

For a warning to be compliant with Prop 65 it shall clearly communicate to the reader that he or she is being exposed to a Prop 65 substance. The California regulations have authorized the following as compliant language:

1. For exposure to a substance that is known by California to cause cancer:
 - a. *“WARNING: This area contains a chemical known to the State of California to cause cancer.”*
2. For exposure to a substance that is known by California to cause birth defects or reproductive toxicity:
 - a. *“WARNING: This area contains a chemical known to the State of California to cause birth defects or reproductive harm.”*

It is recommended that you do not deviate from the exact warning language set out in the regulation. Instances of similar language, often “watered down” to only suggest that a Prop 65 substance “might be” present, have been found to be noncompliant in law suits brought by citizens enforcers groups.

Consumer Products

Consumer products can be labeled in a number of ways to achieve Prop 65 compliance. For example, a warning, typically on a label, or in certain circumstances in the retail setting renders your product Prop 65 compliant as long as the warning is conspicuous, clear and reasonable, and it alerts the consumer to the fact that the product contains a substance(s) determined by California to be carcinogenic and/or teratogenic. Thus, direct labeling of the product or posting signs at the point of sale, depending on the circumstances and provided the warning is clear and reasonable, will achieve compliance.

As is the situation discussed above relative to warnings of occupational exposure, the California state regulations set out specific language for warnings to be used for consumer products: *“WARNING: The following products contain a chemical known to the State of California to cause cancer [OR to cause birth defects or other reproductive harm].”* You should not deviate from this language for the reasons states above in our discussion of workplace exposure. If you elect to label your product with the warning, then the obligation to do so is on the producer or packager rather than on the retail vendor (except where the retail seller itself is responsible for introducing a chemical known to the state to cause cancer or reproductive toxicity into the consumer product in question). As mentioned above, if the warning is on a label, it must be conspicuous enough to be read and understood by the consumer, and convey the information set out above. Signs at the product’s point of sale display can also satisfy Prop 65, as long as the signage makes it clear that the warning covers the products in the display. For example, a retail outlet or eye care professional can provide warning signs throughout its store in lieu of the producer placing a warning on the label, but the retailer or ECP has to implement that signage correctly. We discussed this issue with the California Attorney General’s (AG) office and were advised that such a sign needs to be in close proximity to the identified product(s), applying a reasonableness standard, in order for it to satisfy the law as it relates to those product(s). The representative from the AG’s office said that the sign has to be close enough that it would be reasonable to expect the consumer to see it when making a decision whether to purchase the product. Thus the retailer or ECP might post

signage to the effect that: *“WARNING: The following products contain a chemical known to the State of California to cause cancer [OR to cause birth defects or other reproductive harm]: Product X, Product Y, and Product Z.”*

Any member of The Vision Council who elects to rely on retail store signage in lieu of actually labeling their products must be mindful that they will be ultimately responsible if the retailer’s signage falls short of any Prop 65 requirements or is not conspicuous enough. For more information on the labeling regulations please refer to http://www.oehha.org/prop65/law/pdf_zip/RegsArt6.pdf.

Prop 65 covers sales of goods to customers in California; however it also covers sales into California over the internet. If you are selling product over the internet, and that product contains listed substances so that a warning label would be required on the product if it physically were sold in California, then that warning must be associated with the product’s internet presence.

PENALTIES AND ACCOUNTABILITY

The penalties for violations of Prop 65 are not insignificant: any business that violates or threatens to violate Prop 65 is liable for a civil penalty not to exceed \$2,500 per day for each violation.

Under Prop 65, if the enforcer prevails at trial or by forcing a settlement that benefits the public then the defendant can be ordered to pay all the legal fees. In other words, you would be liable not just for your fees but also the fees for the attorney representing the person or company suing you. We have heard member reports of having to pay such fees ranging up to tens of thousands of dollars as conditions of settling law suits, and then having to pay civil penalties on top of this.

This means that defending each small product complaint can easily exceed \$50,000 when you add your company costs (your time, your legal team, etc.) to the costs and penalties assessed against you. In addition to direct financial cost, your company, brand licensor and/or distributor could likely suffer damage to the brand because of negative press arising from being a defendant in a Prop 65 action.

LEGAL DISCLAIMER

This document has been prepared by The Vision Council for its members for informational purposes only, and does not constitute legal advice. This information is not intended to create, and receipt of it does not constitute, a lawyer-client relationship, and you must not rely on this information as an alternative to legal advice from your attorney or other professional legal services provider. Consult with your attorney if you have specific questions about any legal matter, including questions involving Proposition 65.

RESOURCES

Online at www.thevisioncouncil.org (Recordings, Links, Ongoing Documents) or <http://oehha.ca.gov/prop65.html>

Legal Questions: Rick VanArnam, The Vision Council's Regulatory Affairs Counsel, at rvanarnam@barnesrichardson.com or (212) 725-0200, ext. 126.

Technical & Testing Questions: Jeff Endres, Senior Technical Director, at jendres@thevisioncouncil.org or (703)740-2245.

Regulatory & Legislative Questions: Jason McElvaney, Government and Regulatory Affairs Liaison, at Jason@mcelvaneypublicaffairs.com or (512) 751-5555.

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