



CALIFORNIA PROPOSITION 65

The Safe Drinking Water and Toxic Enforcement Act of 1986
Guide for Optical Laboratories

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The Vision Council
225 Reinekers Lane #700
Alexandria, VA 22314
703-548-4560
www.thevisioncouncil.org

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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 lawsuits 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. Eyewear cases, chains, plano sunglasses and over-the-counter reading glasses have been targeted. In addition, other segments of the ophthalmic optics industry could be targeted as new substances get added to the substance list. For example, Bisphenol A (BPA) was added to the list, creating concern in the ophthalmic community given that BPA is an ingredient used in the manufacture of polycarbonate plastic. In turn, this led to The Vision Council’s successful effort to secure a Safe Use Determination covering BPA in polycarbonate used in the production of optical devices from the state of California in April 2020.

This Prop 65 guidance document is tailored to the needs of the Optical Laboratories Division, especially those labs physically located California. The Vision Council has prepared a similar guidance document on Prop 65 compliance exists for members involved in manufacturing and distributing eyewear and sunwear products in California. This guide, however, includes content germane to optical laboratories.

QUESTIONS AND ANSWERS

- WHO** Companies with 10 or more employees that are physically present in California or, which sell, distribute, or store goods in California, including sales to California placed via the internet or catalogs.
- 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 determined to cause cancer, birth defects or other reproductive harm. Also, it covers exposures to such substances in the workplace or in the environment.
- WHERE** Unless adequately labeled with the proper warning language, 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 lists are updated periodically.
- WHY** Many chemicals and other substances have been determined to 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.
- 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 must be provided that the lenses contains a substance(s) determined by California to be carcinogenic and/or teratogenic. Also, labs must ensure that if their work environments expose employees to materials containing Prop 65 substances, then that appropriate warning signage be posted to inform employees and visitors of the presence of listed substances.

TESTING REQUIREMENTS & 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, and specialty chemicals used in industrial applications. Those substances may be naturally occurring or synthetic.

The Prop 65 substance list is very long (containing over 1000 substances) and is constantly changing. To ensure that your compliance efforts reflect the current inventory of listed substances, you should consult the following link, which is the up-to-date list of substances being regulated by California: <https://oehha.ca.gov/proposition-65/proposition-65-list> 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 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 identifying the only substances members must concern themselves with for compliance purposes. Members should identify and vet substances in their products against the master Prop 65 list. The abridged list, however, represents a good faith attempt to identify some of the substances that might be found in ophthalmic products and thus of interest to members of The Vision Council.

Chemical	Type of Toxicity	Listing Mechanism	CAS No.	Date Listed	NSRL or MADL (µg/day)*	Classification
Disodium cyanodithioimido-carbonate	developmental	AB	138-93-2	30-Mar-99	<u>56 (oral)</u> <u>170 (oral) as 32% pesticidal formu- lation</u>	Fire Retardant
Polybrominated biphenyls	cancer	SQE	---	1-Jan-88	0.02	Fire Retardant
Polybrominated biphenyls	developmental	AB	---	1-Oct-94		Fire Retardant
Polychlorinated biphenyls	cancer	LC	---	1-Oct-89	0.09	Fire Retardant
Polychlorinated biphenyls	developmental	SQE	---	1-Jan-91		Fire Retardant
Polychlorinated biphenyls (containing 60 or more percent percent chlorine by molecular weight)	cancer	SQE	---	1-Jan-88		Fire Retardant
Benzyl chloride	cancer	AB	100-44-7	1-Jan-90	4	Halogenated Solvents
2,2-Bis(bromomethyl)-1,3-propanediol	cancer	AB	3296-90-0	1-May-96		Halogenated Solvents
Bis(2-chloroethyl)ether	cancer	SQE	111-44-4	1-Apr-88	0.3	Halogenated Solvents
Bis(chloromethyl)ether	cancer	LC	542-88-1	27-Feb-87	0.02	Halogenated Solvents
Bisphenol A (BPA)	female	SQE	80-05-7	11-May-15	<u>3 mcg/day</u> <u>(dermal expo- sure from solid materials)</u>	Halogenated Solvents
Bromoethane	cancer	AB	74-96-4	22-Dec-00		
2-Bromopropane	female, male	AB	75-26-3	31-May-05		
Carbon tetrachloride	cancer	SQE	56-23-5	1-Oct-87	5	Halogenated Solvents
Chlorinated paraffins (Average chain length, C12; approximately 60 percent chlorine by weight)	cancer	SQE	108171-26-2	1-Jul-89	<u>8</u>	Halogenated Solvents
Chloroethane (Ethyl chloride)	cancer	AB	75-00-3	1-Jul-90	<u>150</u>	Halogenated Solvents
Chloromethyl methyl ether (technical grade)	cancer	LC	107-30-2	27-Feb-87	<u>0.3</u>	Halogenated Solvents
2-Chloropropionic acid	male	LC	598-78-7	7-Aug-09		Halogenated Solvents
1,2-Dibromo-3-chloropropane (DBCP)	cancer	FR	96-12-8	1-Jul-87	0.1	Halogenated Solvents
1,2-Dibromo-3-chloropropane (DBCP)	male	LC	96-12-8	27-Feb-87	<u>3.1 (oral)</u> <u>4.3 (inhalation)</u>	Halogenated Solvents

Chemical	Type of Toxicity	Listing Mechanism	CAS No.	Date Listed	NSRL or MADL (µg/day) ^a	Classification
p-Dichlorobenzene	cancer	SQE	106-46-7	1-Jan-89	20	Halogenated Solvents
1,1-Dichloroethane	cancer	AB	75-34-3	1-Jan-90	100	Halogenated Solvents
Dichloromethane (Methylene chloride)	cancer	SQE	75-09-2	1-Apr-88	50 200 (inhalation)	Halogenated Solvents
1,2-Dichloropropane	cancer	AB	78-87-5	1-Jan-90	9.7	Halogenated Solvents
Ethylene dichloride (1,2-Dichloroethane)	cancer	SQE	107-06-2	1-Oct-87	10	Halogenated Solvents
Hexafluoroacetone	male	LC	684-16-2	1-Aug-08		Halogenated Solvents
Methyl chloride	developmental	AB	74-87-3	10-Mar-00		Halogenated Solvents
Methyl chloride	male	LC	74-87-3	7-Aug-09		Halogenated Solvents
4,4'-Methylene bis(2-chloroaniline)	cancer	FR	101-14-4	1-Jul-87	0.5	Halogenated Solvents
Tetrafluoroethylene	cancer	AB	116-14-3	1-May-97		Halogenated Solvents
Vinyl trichloride (1,1,2-Trichloroethane)	cancer	AB	79-00-5	1-Oct-90	10	Halogenated Solvents
Antimony oxide (Antimony trioxide)	cancer	AB	1309-64-4	1-Oct-90		Metals
Arsenic (inorganic arsenic compounds)	cancer	LC	--	27-Feb-87	0.06 (inhalation) 10 (except inhalation)	Metals
Arsenic (inorganic oxides)	developmental	SQE	---	1-May-97		Metals
Beryllium and beryllium compounds	cancer	SQE	---	1-Oct-87		Metals
Beryllium					0.1	Metals
Beryllium oxide					0.1	Metals
Beryllium sulfate					2.00E-04	Metals
Cadmium	developmental, male	SQE	---	1-May-97	4.1 (oral)	Metals
Cadmium and cadmium compounds	cancer	SQE	---	1-Oct-87		Metals
Cadmium					0.05 (inhalation)	Metals
Chromium (hexavalent compounds)	cancer	LC	---	27-Feb-87	0.001 (inhalation)	Metals
Chromium (hexavalent compounds)	developmental, female, male	SQE	---	19-Dec-08		Metals
Cobalt metal powder	cancer	AB	7440-48-4	1-Jul-92		Metals
Cobalt [II] oxide	cancer	AB	1307-96-6	1-Jul-92		Metals
Cobalt sulfate	cancer	LC	10124-43-3	20-May-05		Metals

Chemical	Type of Toxicity	Listing Mechanism	CAS No.	Date Listed	NSRL or MADL (µg/day) ^a	Classification
Cobalt sulfate heptahydrate	cancer	AB	10026-24-1	2-Jun-00		Metals
Gallium arsenide	cancer	LC	1303-00-0	1-Aug-08		Metals
Iodine-131	developmental	SQE	10043-66-0	1-Jan-89		Metals
Lead	developmental, female, male	LC	---	27-Feb-87	0.5	Metals
Lead and lead compounds	cancer	AB	---	1-Oct-92		Metals
Lead					15 (oral)	Metals
Lead acetate	cancer	SQE	301-04-2	1-Jan-88	23 (oral)	Metals
Lead phosphate	cancer	SQE	7446-27-7	1-Apr-88	58 (oral)	Metals
Lead subacetate	cancer	LC	1335-32-6	1-Oct-89	41 (oral)	Metals
Lithium carbonate	developmental	FR	554-13-2	1-Jan-91		Metals
Mercury and mercury compounds	developmental	AB	---	1-Jul-90		Metals
Methylmercury compounds	cancer	AB	---	1-May-96		Metals
Nickel (Metallic)	cancer	LC	7440-02-0	1-Oct-89		Metals
Nickel acetate	cancer	LC	373-02-4	1-Oct-89		Metals
Nickel carbonate	cancer	LC	3333-67-3	1-Oct-89		Metals
Nickel carbonyl	cancer	SQE	13463-39-3	1-Oct-87		Metals
Nickel carbonyl	developmental	AB	13463-39-3	1-Sep-96		Metals
Nickel compounds	cancer	LC	---	7-May-04		Metals
Nickel hydroxide	cancer	LC	12054-48-7; 12125-56-3	1-Oct-89		Metals
Nickelocene	cancer	LC	1271-28-9	1-Oct-89		Metals
Nickel oxide	cancer	LC	1313-99-1	1-Oct-89		Metals
Nickel refinery dust from the pyrometallurgical process	cancer	SQE	---	1-Oct-87	0.8	Metals
Nickel subsulfide	cancer	SQE	12035-72-2	1-Oct-87	0.4	Metals
Selenium sulfide	cancer	LC	7446-34-6	1-Oct-89		Metals
Silica, crystalline (airborne particles of respirable size)	cancer	SQE	---	1-Oct-88		Metals
Thorium dioxide	cancer	LC	1314-20-1	27-Feb-87		Metals
1,3-Butadiene	cancer	SQE	106-99-0	1-Apr-88	0.4	Monomers
1,3-Butadiene	developmental, female, male	AB	106-99-0	16-Apr-04		Monomers
Chlorendic acid	cancer	SQE	115-28-6	1-Jul-89	8	Monomers
Chloroprene	cancer	AB	126-99-8	2-Jun-00		Monomers

Chemical	Type of Toxicity	Listing Mechanism	CAS No.	Date Listed	NSRL or MADL (µg/day) ^a	Classification
p-Cresidine	cancer	SQE	120-71-8	1-Jan-88	<u>5</u>	Monomers
Dimethylvinylchloride	cancer	SQE	513-37-1	1-Jul-89	<u>20</u>	Monomers
Dinitrotoluene (technical grade)	female, male	<u>AB</u>	---	20-Aug-99		Monomers
Dinitrotoluene mixture, 2,4-/2,6-	cancer	AB	---	1-May-96		Monomers
2,4-Dinitrotoluene	cancer	SQE	121-14-2	1-Jul-88	2	Monomers
2,4-Dinitrotoluene	male	<u>AB</u>	121-14-2	20-Aug-99		Monomers
2,6-Dinitrotoluene	cancer	SQE	606-20-2	1-Jul-95		Monomers
2,6-Dinitrotoluene	male	<u>AB</u>	606-20-2	20-Aug-99		Monomers
Ethyl acrylate	cancer	SQE	140-88-5	1-Jul-89		Monomers
Ethylene oxide	cancer	FR	75-21-8	1-Jul-87	2	Monomers
Ethylene oxide	female	LC	75-21-8	27-Feb-87	20	Monomers
Ethylene oxide	developmental, male	<u>LC</u>	75-21-8	7-Aug-09		Monomers
Glycidol	cancer	AB	556-52-5	1-Jul-90		Monomers
Isoprene	cancer	AB	78-79-5			Monomers
4,4'-Methylenedianiline	cancer	SQE	101-77-9	1-Jan-88	<u>0.4</u>	Monomers
Methyl isocyanate (MIC)	developmental, female	<u>SQE</u>	<u>624-83-9</u>	<u>12-Nov-10</u>		Monomers
o-Phenylenediamine and its salts	cancer	<u>AB</u>	95-54-5	15-May-98		Monomers
o-Phenylenediamine					<u>26</u>	Monomers
o-Phenylenediamine dihydrochloride					<u>44</u>	Monomers
Propylene oxide	cancer	SQE	75-56-9	1-Oct-88		Monomers
Toluene diisocyanate	cancer	LC	26471-62-5	1-Oct-89	<u>20</u>	Monomers
Trientine hydrochloride	developmental	<u>FR</u>	38260-01-4	27-Feb-01		Monomers
Trimethyl phosphate	cancer	AB	512-56-1	1-May-96	<u>24</u>	Monomers
Vinyl bromide	cancer	SQE	593-60-2	1-Oct-88		Monomers
Vinyl chloride	cancer	LC	75-01-4	27-Feb-87	3	Monomers
Vinyl fluoride	cancer	<u>AB</u>	75-02-5	1-May-97		Monomers
Naphthalene	cancer	<u>AB</u>	91-20-3	19-Apr-02	<u>5.8</u>	PAH
Butyl benzyl phthalate (BBP)	developmental	<u>AB</u>	85-68-7	2-Dec-05		Phthalates
Di-n-butyl phthalate (DBP)	developmental, female, male	<u>AB</u>	84-74-2	2-Dec-05	<u>8.7</u>	Phthalates
Di(2-ethylhexyl)phthalate (DEHP)	cancer	SQE	117-81-7	1-Jan-88	<u>310</u>	Phthalates

Chemical	Type of Toxicity	Listing Mechanism	CAS No.	Date Listed	NSRL or MADL (µg/day)*	Classification
Di(2-ethylhexyl)phthalate (DEHP)	developmental, male	AB	117-81-7	24-Oct-03	For intravenous exposure: 4200 (adults) 600 (infant boys, age 29 days- 24 mos.) 210 (neonatal infant boys, age 0-28 days).	Phthalates
Di-n-hexyl phthalate (DnHP)	female, male	AB	84-75-3	2-Dec-05	2200 (oral)	Phthalates
Di-isodecyl phthalate (DIDP)	developmental	AB	68515-49-1/ 26761-40-0	20-Apr-07	2200	Phthalates
Acetaldehyde	cancer	SQE	75-07-0	1-Apr-88	90 (inhalation)	Solvents
Acetamide	cancer	AB	60-35-5	1-Jan-90	10	Solvents
Acrylonitrile	cancer	FR	107-13-1	1-Jul-87	0.7	Solvents
4-Aminobiphenyl (4-amino-diphenyl)	cancer	LC	92-67-1	27-Feb-87	0.03	Solvents
Aniline	cancer	AB	62-53-3	1-Jan-90	100	Solvents
Aniline hydrochloride	cancer	AB	142-04-1	15-May-98		Solvents
Benzene	cancer	LC	71-43-2	27-Feb-87	6.4 (oral) 13 (inhalation)	Solvents
Benzene	developmental, male	SQE	71-43-2	26-Dec-97	24 (oral) 49 (inhalation)	Solvents
Butylated hydroxyanisole	cancer	AB	25013-16-5	1-Jan-90	4000	Solvents
4,4'-Diaminodiphenyl ether (4,4'-Oxydianiline)	cancer	SQE	101-80-4	1-Jan-88	5	Solvents
N,N-Dimethylacetamide	developmental	LC	127-19-5	21-May-10		Solvents
3,3'-Dimethylbenzidine (ortho-Tolidine)	cancer	SQE	119-93-7	1-Jan-88	0.044	Solvents
Ethylbenzene	cancer	AB	100-41-4	11-Jun-04	54 (inhalation) 41 (oral)	Solvents
2-Ethylhexanoic acid	developmental	LC	149-57-5	7-Aug-09		Solvents
Hexamethylphosphoramide	cancer	SQE	680-31-9	1-Jan-88		Solvents
Hexamethylphosphoramide	male	AB	680-31-9	1-Oct-94		Solvents
Hydrazine	cancer	SQE	302-01-2	1-Jan-88	0.04	Solvents
Hydrazobenzene (1,2-Diphenylhydrazine)	cancer	SQE	122-66-7	1-Jan-88	0.8	Solvents
Methylhydrazine and its salts	cancer	AB	---	1-Jul-92		Solvents
Methylhydrazine					0.058 (oral) 0.090 (inhalation)	Solvents
Methylhydrazine sulfate					0.18	Solvents
N-Methylpyrrolidone	developmental	AB	872-50-4	15-Jun-01	3200 (inhalation) 17000 (dermal)	Solvents
Nitrobenzene	cancer	AB	98-95-3	26-Aug-97		Solvents

Chemical	Type of Toxicity	Listing Mechanism	CAS No.	Date Listed	NSRL or MADL ($\mu\text{g}/\text{day}$) ^a	Classification
Nitrobenzene	male	AB	98-95-3	30-Mar-10		Solvents
2-Nitropropane	cancer	SQE	79-46-9	1-Jan-88		Solvents
N-Nitrosodiphenylamine	cancer	SQE	86-30-6	1-Apr-88	80	Solvents
p,p'-Oxybis(benzenesulfonyl hydrazide)	developmental	LC	80-51-3	7-Aug-09		Solvents
Thiourea	cancer	SQE	62-56-6	1-Jan-88	10	Solvents
Toluene	developmental	SQE	108-88-3	1-Jan-91	7000b	Solvents
Toluene	female	LC	108-88-3	7-Aug-09		Solvents

LABELING AND WARNING SIGNAGE

Occupational Exposure

Prop 65 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 workplace is to post a warning sign 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 so long as the warning language is appropriate and conspicuous

An alternative way to warn is by using signage in the workplace. The signs need 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 (Cal. Code Regs., title 8, section 5194) or for pesticides, 3) the Pesticides and Worker Safety requirements (Cal Code Regs, title 3, § 6700, et seq. Typically, compliance with these federal and state laws also require 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. Specifically, the warning signage must comply with the following:

- A. Contain the warning symbol, which consists of a yellow equilateral triangle with a bold black outline, containing a black exclamation point.



- B. The word "**WARNING**" in all capital letters, in bold print.
- C. And the appropriate warning based on the substance in the product:

- a. For single carcinogens: "Entering this area can expose you to [name of the chemical] from [name of one or more sources of exposure]. [Name of chemical] is known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov.
 - b. For multiple carcinogens: "Entering this area can expose you to chemicals known to the State of California to cause cancer, including [name of the chemicals], from [name of one or more sources of exposure]. For more information, go to www.P65Warnings.ca.gov.
 - c. For single reproductive toxicants: "Entering this area can expose you to [name of chemical] from [name of one or more sources of exposure]. [Name of chemical] is known to the State of California to cause birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.
 - d. For multiple reproductive toxicants: "Entering this area can expose you to chemicals known to the State of California to cause birth defects or other reproductive harm, including [name of one or more chemicals], from [name of one or more sources of exposure]. For more information, go to www.P65Warnings.ca.gov.
 - e. For exposure to both listed carcinogens and reproductive toxicants: "Entering this area can expose you to chemicals known to the State of California to cause cancer and birth defects or other reproductive harm, including [name of one or more chemicals known to cause cancer and name of one or more chemicals known to cause birth defects or other reproductive harm, from [name of one or more sources of exposure]. For more information, go to www.P65Warnings.ca.gov.
 - f. For exposure to a single chemical that is listed both as a carcinogen and as a reproductive toxicant: "Entering this area can expose you to [name of chemical] from [name of one or more sources of exposure]. [Name of chemical] is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.
- D. The warning sign must be posted at all public entrances to the affected area.
 - E. Must use at least 72-point font.
 - F. Sign must be in English, unless other languages are used on other signage in the affected area, in which case it must be in that language too.
 - G. Must be conspicuous, likely to be read, and call out the source of exposure.

Consumer Products

Consumer products can be labeled in different 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.

That warning must incorporate the following information:

- A. Warning Image -- a yellow equilateral triangle with a bold black outline, containing a black exclamation point.



- B. The symbol can be in black and white if the sign, label or hang tag it is placed on does not incorporate yellow already.
- C. The symbol **must** be put to the left of the warning text, in a font size no smaller than the height of the word "**WARNING**", and then the rest of the warning language.
- D. Must Identify the Chemicals in the Product. **You must identify by name one or more of the Prop 65 chemical substances found in your consumer product.**
 - a. The new language for product exposure where the Prop 65 substance is a **carcinogen** is as follows: "**WARNING:** This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov."
 - b. The new language for product exposure where the Prop 65 substance is a **reproductive/ birth defect toxicant** is as follows: "**WARNING:** This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov."
 - c. The Prop 65 list is broken out into two "pathways." One for substances that cause cancer, and other for substances that cause birth defects or reproductive harm. If the product contains **at least one substance that causes cancer, and at least one other substance that causes reproductive harm/ birth defects** then the warning **must read:** "**WARNING:** This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer, and [name of one or more chemicals], which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov."
 - d. Vision Council members **must test their products comprehensively** and warn appropriately, as different pathways may be implicated.
 - e. Historical substances of concern for members of The Vision Council include (*please test on your own for all potential concerns*):
 - i. Bisphenol A – found in polycarbonate; birth defect/reproductive harm pathway.

- ii. Various phthalates – used as plastic softeners; birth defect/reproductive harm pathway. *(Although historically we have seen NOV's for DEHP, there are other phthalates on the Prop 65 list and you must label if your product contains any of them.)*
- iii. Nickel found in metal components, like hinges and screws; cancer pathway.

D. If the product contains one substance that is identified on the Prop 65 list as **both a carcinogen and a reproductive toxicant** then the warning language must read: **“WARNING:** This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the State of California to cause cancer, and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.”

E. You must proactively analyze your products, and its components, for Prop 65 substances, and be mindful of the different pathway warning requirements. Bisphenol A and phthalates have been substances of concern historically for members of The Vision Council. However, stainless steel hinges and hardware could be nickel coated or otherwise contain nickel as an alloying element; memory metals could contain nickel; other substances could be present.

a. The Vision Council has confirmed with the California Office of Environmental Health Hazard Assessment (“OEHHA”) that while nickel alloys are not listed, *per se*, on the Prop 65 list (certain nickel compounds are), nickel alloys contain metallic nickel. Metallic nickel is listed on the Prop 65 list and has no published safe harbor. Therefore, products containing nickel alloys trigger the metallic nickel warning requirement unless you possess toxicological testing establishing no significant risk of exposure.

a. Remember, Prop 65 safe harbor levels are based on exposure testing. A parts-per-million (PPM) based test can confirm the presence or absence of a listed substance but does not establish compliance with a Prop 65 safe harbor level for that substance.

F. Changes to the Warning if you put the Warning Directly on the Product

You will now have the option to use an abbreviated warning if the warning is affixed directly on the product. An on-product warning requires the following elements:

A. The warning symbol.



B. The word **“WARNING”** in all capital letters, in bold print.

C. And the appropriate warning based on the substance in the product:

a. “Cancer – www.P65Warnings.ca.gov”

b. “Reproductive Harm – www.P65Warnings.ca.gov”

c. “Cancer and Reproductive Harm – www.P65Warnings.ca.gov”

D. The font size can be no smaller than 6-point font but must be no smaller than the largest typeface used on the product for other consumer information.

E. If you place the warning directly on the product you are excused from having to identify the actual

chemical substance(s) found in the product.

- F. Affixed to product includes any label on, attached to or enclosing, the product.
 - a. Hangtags, pressure labels, packaging that encloses the product.

A. Other Requirements for Consumer Products

- A. The manufacturer, producer, packager, importer or distributor is the party responsible for Prop 65 warning compliance, except in certain circumstances discussed below.
- B. The warning label can be affixed to the product or to its immediate container or wrapper.
- C. Full chemical name must appear at first mention of chemical; acronyms ok for subsequent mentions.
- D. A product specific warning can also be on a posted sign, shelf tag or shelf sign.
 - a. But must be at each point of display of the product.
 - b. Cannot use the abbreviated warning language in these cases.
- E. For internet purchases, the warning language goes on the actual page where the consumer product is displayed or is accessed via a hyperlink on the product-display page, or on any other page "prominently displaying" the warning prior to completing the purchase.
 - a. The word "WARNING" must be associated with the hyperlink.
 - b. Shopping cart placement available.
- F. For catalog purchases, the warning must be clearly associated with the item being purchased.
- G. When a sign, label or shelf tag used with a consumer product to provide the warning includes consumer information in a language other than English, then the warning must also be provided in that additional language.

B. Shifting the Responsibility to the Retailer

A manufacturer, producer, packager, importer, supplier or distributor of a consumer product subject to Prop 65 can push the compliance responsibility to the retailer by doing the following:

- A. Provide written notice directly to a retail seller's authorized agent.
- B. State that the product may result in the exposure to one or more chemicals on the Prop 65 list.
- C. Provide the exact name or description of the product, or specific identifying information such as the UPC.
- D. Include all necessary warning materials, such as labels, shelf signs, or tags.
- E. Obtain confirmation either electronically or in writing of the retailer's receipt of the notice.
- F. You must renew this notice within 6 months of the first time it is served, and then annually thereafter.
- G. An additional notice is required within 90 days when a new chemical(s) or end point(s) is included in the warning.

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 lawsuits, 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 [Proposition 65 Website](#)

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

Technical & Testing Questions: Michael C. Vitale, Senior Technical Director, at mvitale@thevisioncouncil.org or (703)548-2684.