

THE EVER CHANGING FACE OF SAFETY REGULATIONS IN AMERICA

PROPOSITION 65

California's Proposition 65 (Prop65) and the Federal Government's Consumer Products Safety Improvement Act (CPSIA) are two legislative regulations that have begun to affect the optical industry in the United States. In this article, we will discuss primarily Prop65 with some sprinkling of CPSIA and how they are impacting the distribution of ophthalmic products from the manufacturing/importing side, through laboratory processing and onto the ECP dispensary.

By Steven E. Ross

However, before we begin this legislative journey as it relates to our beloved industry – I must do this – the legal disclaimer. This writing is intended as an informative overview for the ophthalmic business reader. It is pertinent for those who distribute optical products and also those who are involved with processing or dispensing in the United States and particularly in the State of California. What is written, including any action items, by no means ensures that all hazards, liabilities or current laws will be mitigated.

There may in fact be practices, standards and/or regulatory requirements applicable to your company or professional office that exceed these written recommendations. Further, because federal and state regulations are not aligned, and are subject to change, consulting all sources of information from federal, state, regional and city authorities is recommended. And finally, please consult your legal counsels at every turn.

So now I am off the hook, right?

PROP65

The State of California is one of the largest economies in the world.¹ Even with their recent economic woes, they probably still rank in the top ten worldwide, all by themselves as a single state economy. Consequently, we pay close attention – it is big market. We also view California as a trendsetter; and Prop65 is one of those legislative actions that is being offered for trendsetting consideration.

Prop65 was originally designated as the 'safe drinking water and toxic enforcement act of 1986'.² As such, it was intended by its authors to protect California citizens and the State's drinking water sources from chemicals known to cause cancer, birth defects or other reproductive harm; and to inform citizens about exposures to such chemicals. Prop65 had broad appeal because after all, who doesn't want clean drinking water? The current concern is that Prop65 has evolved to include virtually all products sold in the State. The primary questions are:

- | What companies are subject to Prop65?
- | Why is this important?

Prop65 applies to products sold at retail, along with all mail order and internet sales of products in California. Because you sell frames, lenses, contact lenses, processing equipment and supplies and/or optical accessories in the State of California, you are subject to this law, as long as you have ten or more employees.³ That should answer the first question for all of us. Secondly, it is most important because you do not want to find yourself on the wrong end of a lawsuit. More on that later...

SAFETY CONCERNS

Ingestion, absorption and inhalation are the three major concerns with California's Prop65; and when it comes to their safe harbor levels^{3a}, the measurements must be in micrograms per day ($\mu\text{g}/\text{d}$). Now patients don't normally eat their glasses; yet many adults chew on their temple tips, or for whatever reason find the occasional need to make some direct contact between eyewear and the oral cavity.

Nose pads rest on the nose, temples are secured in place by the ears and both metals and plastics often rest along the brow line. Likewise, lenses frequently come into contact with the face. Corneal contact with RGP's or soft lenses is most obvious. So we can see how ingestion and absorption might have some potential with eyewear; or at least a reasonable person might come to that conclusion. Inhalation on the other hand, is not such an obvious factor until you consider lens processing. Anyone that has edged high-index lenses has noticed the odor. Even though the laboratory optician is not a retail consumer, his/her lab probably ordered the lenses electronically; and not to say that the odor from high-index products is hazardous. We will not have that answer until someone does the due diligence. Just take notice of how Prop65 may apply.

The point to be made is that there are compounds, chemicals and the like that are present in ophthalmic eyewear 'known to the State of California' to cause cancer and/or birth defects. Phthalates (Thal'-ates) are a primary example of such chemicals. All of them are oily, colorless liquids that, 'have been used for about 50 years to make hard plastics softer and more flexible in such products as vinyl flooring and seat coverings, raincoats, shower curtains, garden hoses and even toys.'⁴ We can add eyeglasses to that list. The difficulty is that there are good phthalates and there are bad phthalates. Seven of them are 'known to the State of California' to cause cancer and/or birth defects; and all too frequently, those 'bad' phthalates keep showing up in eyewear.

Lead (Pb) is a naturally occurring element that we find in virtually everything. We've all heard of lead-based paints and lead found in toys. Well it's in eyewear too; and as you have undoubtedly surmised, lead in quantities above the designated safe harbor level⁵ is 'known to the State of California' to cause cancer and/or birth defects.

Another example is Bisphenol A (BPA) – an organic compound used as a primary ingredient in the production of polycarbonate. During substrate processing, there is a change in the molecular structure; so testing may prove that it is impossible to 'wring out' any BPA from finished lenses. Nevertheless, BPA is a concern because it is currently under review by the State of California and will probably wind up on the list.

THE LIST

Frequently, the California state government publishes a list of chemicals that are 'known to the State of California' to cause cancer and/or birth defects.⁶ Legislation demands at least an annual publication, but the list is most often revised/published on a quarterly basis. Chemicals are added and occasionally removed; but the list (as of February 8, 2013) is 22 pages long and includes nearly 1,000 chemicals! Of those, there are nearly 150 chemicals known to scientists (members of The Vision Council) to be used in polymer production. Once again, if a chemical is on the list and in your product, it is thereby 'known to the State of California' to cause cancer and/or birth defects and must carry a warning label!

WARNING LABELS

If a business sells a product in California containing a substance or substances that are on the Prop65 list in excess of the de minimis level (safe harbor) for that substance, then a 'clear and reasonable' warning must be provided to the public. The law allows for the warning to be provided by a variety of means, such as direct labeling of the product, posting signs at the workplace, or publishing notices in a newspaper, depending on the circumstances and provided the warning is clear and reasonable. Unless the ECP/optical retailer elects to put up a warning sign, the obligation

to warn the public rests with the producer or packager – except where the ECP/retailer is responsible for introducing a chemical known to the State to cause cancer or reproductive toxicity into the consumer product in question. If the warning is on a label, it must be conspicuous enough to be read and understood by the consumer.⁷

The most efficient method of warning is when the ECP/retailer elects to place a warning sign in a conspicuous position at their place of business or within the professional office. Clearly distasteful to a professional office or merchant, such warning signs alert consumers to the fact that carcinogens and/or other toxins are present. Therefore, many will elect not to take such action; they will not put up a sign. Hence, the burden for warning the public about carcinogenic/toxic products, most often falls on the producer/packager.

As distasteful as warning signs may be to the ECP/retailer, Prop65 labeling is an even worse marketing concern for any optical company trying to bring safe and viable products to market. In fact, I cannot think of a more negative marketing campaign than one that includes the words, 'my stuff causes cancer and/or birth defects.' Yet that is the law in California; and we may take some solace with the understanding that Prop65 warning labels and signs are everywhere in the State. Everybody, no matter your product or industry, is in the same boat. When traveling the State of California, you will find Prop65 warning signs in restaurants and hospitals; you will find them in apartment complexes, grocery stores and banks. It is literally impossible to move about the state and not encounter Prop65 warning signs at every turn. Consequently, the public is almost numb to the alerts. At this juncture, such a sign in an ECP dispensary (even though conspicuous) may garner little attention from the public. Nevertheless, it is most distasteful for manufacturers and distributors of optical goods; and a significant challenge to limit the labeling to the State of California when your products are shipped nationwide. It is granted that the marketing concerns that surround such labeling are valid on optical products being displayed in Des Moines, Iowa.

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Once again, the most efficient method for warning the public is when the ECP/retailer elects to post a sign. Such signage will not only protect the distribution chain upon which he/she thrives, it will also serve to protect the retail establishment itself.

ENFORCEMENT

Enforcement is carried out through civil lawsuits against Prop65 violators. These lawsuits may be brought by the California Attorney General, any district attorney, or certain city attorneys (those in cities with a population exceeding 750,000). Lawsuits may also be brought by private parties ‘acting in the public interest’, but only after providing notice of the alleged violation to the Attorney General, the appropriate district attorney and city attorney, and the business accused of the violation.⁸

ENFORCEMENT BOILS DOWN TO THIS...

Because the State of California doesn’t have any money, enforcement comes from law firms organized around Prop 65. The lawyers know the ‘ins-and-outs’ of litigation and thereby act (or so they may claim) in the public interest. I personally know of two optical companies that settled out-of-court for \$50,000 each; two more cases where it was cheaper to pay off the whistleblowers than fight the cases in court. Interestingly enough, both lawsuits were centered, not on product content, but on the labeling issue. The whistleblower(s) entered an optical place of business and simply looked

for labeling (the warning signs, package labeling, etc.); finding no such conspicuous signage, the fun began. Enforcement has effectively become a perversion, because those ‘charged with enforcement’ do not appear to care what is actually in your product; they care only about the public warning.

THE 3-LEGGED DEFENSE

The 3-legged defense includes three steps:

- | labeling
- | due diligence
- | testing

There is no way to keep you from being sued. There is however a way of climbing a little higher on the tree; in other words, let us not become the low-hanging-fruit when it comes to Prop65 compliance suits. Let’s put up some speed bumps and/or road blocks to make certain any whistleblower gets the message that there are easier targets than us.

STEP ONE: LABELING

As distasteful as labeling may be, there is little way around it.

“But I test my frames – I test my lenses – I test all the supplies I sell to my laboratory partners – and I do not have phthalates, lead or BPA in my stuff! So why must I be concerned about warning signs or labeling?”

Once again, the list is nearly 1,000 chemicals long and growing. There may well be free radicals from the production process that remain in your product(s) – residual chemicals that are on the list; and it is doubtful that you have tested for all the possibilities. Further,

a reasonable person might very well ask the question: “If you have not tested for it, how can you claim it is not there?” The questions are endless and still, the lawsuits are centered on labeling not content.

Secondly, and in consideration of ingestion, absorption and inhalation, the State of California wants producers to measure chemicals in micrograms per day ($\mu\text{g}/\text{d}$). To complicate matters, they list safe harbor levels on some chemicals and compounds (lead is an example) in $\mu\text{g}/\text{d}$. Yet analytical testing laboratories test for content, generally in parts per million (ppm); and there is no correlation between ppm found in the scientific laboratory and $\mu\text{g}/\text{d}$ absorbed through the wearer’s skin. So even if lead is present in very small quantities in your product, a conversion is not possible. There is no effective way to tell if your product ‘contaminated with very small quantities of lead’ is within the safe harbor limit. Although many analytical laboratories use CPSIA tolerances for Prop65 compliance, the concept/the use of those tolerances has not as yet been tested in court. So we really do not know if that practice will pass muster. Hence, step one in the 3-legged defense is labeling.

As a final word on labeling, and as previously noted, labeling is the focus of current litigation; but I remind you only to share this thought. The labeling nightmare might be considered a blessing in the end. Labeling your product(s) actually buys much needed time. It provides the opportunity for due diligence supported by testing.



The sign at left is an actual posted warning at a Los Angeles Times facility⁹; and if you are interested, the signs are also available for purchase in Spanish.¹⁰

STEP 2: DUE DILIGENCE

This is the tedious process of determining product content.

Due diligence begins with MSDS sheets and the comparison between what is provided on the MSDS sheet to the chemicals and compounds on the list. Yet the process will go much deeper because you will undoubtedly stumble upon some rabbit hole(s); and those holes, those trails must be followed to their conclusion. Due diligence demands that one gets to the heart of the matter; so find the chemists and engineers responsible for the manufacture of the product(s) and have them respond to your inquiries. When possible, ask the producers if they can make your product to be lead-free; can they use the phthalates, other materials, other chemicals and solvents that are not found on the list?

In conjunction, my personal hope is the scientific community will soon find a conversion method that allows us to move from ppm to µg/d, because we are not there yet. Labeling is buying all of us much needed time.

Due diligence is a must because we need to know what's in our stuff. Beyond our inherent desire to provide a safe product for consumers, the State of California and the attorneys that feed off Prop65 will eventually find the search for labels and warning signs non-productive. Their opportunity for lawsuits centered on the labeling issue will eventually dry up; so they too may actually become concerned with product content from a litigation standpoint. Consequently, we best be prepared for such forthcoming realities. Now is the time because we have the time; do not squander it.

STEP 3: TESTING

Testing will always be in support of your due diligence efforts. It also serves as an effective quality control mechanism to be certain that your products are as safe and contaminant-free as you originally found them to be.

PERIODIC TESTING

The Federal Government, through the Consumer Product Safety Council (CPSC) is placing an emphasis on testing like never before. This group (outside the scope of Prop 65) is currently focused on children's products:

“Periodic testing means third party testing that must be conducted on the continuing production of children's products. This testing is in addition to the testing that was conducted when a children's product was initially tested for certification or when the product was retested and certified following a material change. Periodic testing must be performed by a CPSC-accepted third party laboratory. The requirement is effective on February 8, 2013.”

“Periodic testing must be conducted at a minimum of 1-, 2-, or 3-year intervals, depending upon whether the manufacturer has a periodic testing plan, a production testing plan, or plans to conduct continued testing using an accredited ISO/IEC 17025:2005 laboratory.”¹⁰

I would encourage you to read the entire CPSC document on-line because it includes a number of frequently asked questions such as, who must comply and how one must comply, etc. The point being of course is to set yourself on a path of preparedness. Because of their Prop65 labeling focus, the State of California is not requiring periodic testing as CPSC now demands; but they will.

At the time of this writing, Prop65 has not yet found its way into other states or countries. Yet we need to take heed because California is a trendsetter; it's quite possible that Prop65 will metastasize and find its way into your house of legislation. I virtually guarantee there has been discussion outside of California because (as we shared at the outset) Prop65 was originally the 'safe drinking water and toxic enforcement act of 1986'² – and everybody wants clean water. Lastly, Prop 65-type legislation offers a lot of money to people that choose to make their living on the enforcement side of the ledger. So now would be the time to recognize Prop65 as the law in California that others may adopt; and then

begin to set up your version of the 3-legged defense to ensure viable ophthalmic products and business opportunities both now and well into the future. For further information, please contact Steve Ross through NSL Analytical or The Vision Council: www.nslanalytical.com www.thevisioncouncil.org



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Employment:

- | June'09 to present: Ophthalmic Mfg Rep; NSL Analytical Services, Inc.; Cleveland, OH
- | April'09 - June'09: Sales Mgmt. Consultant; Nikon Optical USA; S. Windsor, CT
- | September'89 to present: President; OptiGroup, Inc.; Fairborn, OH
- | November'00- June'02: MW Lab President; HOYA Corporation; Dallas, TX
- | September'94- Nov'00: President; Midwest Optical Laboratories, Inc.; Fairborn, OH

Publications:

- | 1984 – 2000: Occasional articles in both regional & national optical trade press
- | 2000 – 2012: The lens book – a lens resource publication for Midwest optical customers & CS

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