



THE **VISION**COUNCIL

Regulatory Update

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BpA Notice of Violation on Sunglasses Filed. Is this “Optical Product Zero?”



- NOV filed 03/26/2018
- Named Urban Outfitters
- Alleged exposure to BpA
- Start of Industry Problem?
 - No warning present
 - Not a TVC member
 - Many other polycarbonate products in marketplace to go after
- But, Prop 65 bounty hunters are product parochial.



Prop 65 Labeling and Language Changes

- Consumer Product Warning Changes
- Includes symbols and different warning language
- **Must identify listed substance in product**
 - **“WARNING:** *This product can expose you to chemicals including [identify chemical, such as Bisphenol A], which are known to the State of California to cause cancer [or birth defects or reproductive harm]. For more information go to www.P65Warnings.ca.gov”.*
 - Label appropriately.
 - Label comprehensively. Need to know which Prop 65 substances are in your product and why they are listed.
 - Bisphenol A does not cause cancer; it harms female reproduction.
 - 59 BpA notices as of 04/24/18 – thermal paper, water bottles, drinking vessels, and one for **plano sunglasses**
- **No later than August 30, 2018**



Prop 65 Labeling and Language Changes

• Labeling and Language Changes

- “On product” short form warning
- Includes symbols and different warning language
- **Don’t have to identify listed substance in product!**
 - “Cancer – www.P65Warnings.ca.gov
 - “Reproductive Harm – www.P65Warnings.ca.gov
 - “Cancer and Reproductive Harm – www.P65Warnings.ca.gov
- What does “on product” mean?
 - Any “label” affixed to the product
 - Includes hang tags, pressure labels



• Use of Acronyms on Warnings

- Full chemical name must appear at first mention of chemical; acronyms ok for subsequent mentions
- Bisphenol A, then BpA; Diethylhexyl phthalate, then DEHP



Prop 65 Labeling and Language Changes

– Prop 65 Occupational Warning Changes

- More restrictive
- Includes symbols and different warning language
- **Must identify listed substance in product**
 - **“WARNING:** Entering this area can expose you to [*identify chemical, such as Bisphenol A*] from [*name of one or more sources of exposure*]. [*Name of chemical*] is known to the State of California to cause cancer [*or birth defects or reproductive harm*]. For more information go to www.P65Warnings.ca.gov”.
 - Label appropriately. Bisphenol A does not cause cancer; it harms female reproduction.
- Multiple chemicals require multiple references.
- Must be at least 72 point font in English, unless other language used in affected area. Must be conspicuous
- **No later than August 30, 2018**



– Or, comply with info, training and label requirements:

- Federal Hazardous Communication Standard
- California Hazardous Communication Standard, or
- California Pesticides Safety Regulations



UDI and FDA

– UDI Update

- Class I compliance date now 09/24/2020
 - Both labeling and GUDID participation
- Lens manufacturers and optical labs exemption granted
 - Both labeling and GUDID participation
- Request for frames exemption still pending
 - Both labeling and GUDID participation
 - Based on similarity to lens argument and analysis

– FDA Lab Registration Issue

- Recent FDA audit of optical lab
- Concluded US based lab had to register with the FDA
- Contrary to law and agency practice
- Reached out to FDA through Congressional ties
- Ongoing discussions between TVC and FDA
- Registration fee increase in 2018 to \$4,624.00 from \$3,382.00





QUESTIONS?



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