



Standards and Regulatory Update

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Standards Update ANSI

- ANSI ASC/Z80 - 28 Active standards
 - ANSI Z80.3-2018 – Nonprescription Sunglasses and Fashion Eyewear
 - Updated clarifies testing of photosensitive lenses, making requirements in this standard consistent with international standards
 - PINs has been issued for the 2020 revision
 - ANSI Z80.31 – Specifications for Ready-to-Wear Near Vision Spectacles
 - Released late 2017
 - PINs issued
 - Z80.1 – Recommendations for Prescription Lenses
 - 2020 Revision dates
 - Z80.24 – Information Interchange (Paul Wade)
- ANSI Z87.1
 - ANSI Z87.1-2015-Personal Eye and Face Protection Devices
 - Currently working on 2020 revision
 - Working on “Bio Hazard Protection” (Z87.62)



Standards Update ISO

- ISO/TC172/SC7 – Ophthalmic Optics and Instruments
 - 97 Publications
 - 15 Publications over the last 12 months
 - 20 Standards under Systematic Review
 - 23 Active standards
 - 18 Active work items & 5 Preliminary Work Items
 - 19 Revision or Amendments & 4 New Projects
 - 21 Participating Members (Countries)
 - 12 Observing Members (Countries)
- International Survey on Power and Prism
- US / TVC to host the Fall 2019 ISO Plenary Meeting (Dallas?)
- ISO/TC94 – Sunglasses and Safety Eyewear
 - 15 Publications
 - 13 Standards under Systematic Review
 - 21 Participating Members (Countries)
 - 14 Observing Members (Countries)



California Prop 65 SUD Efforts

- December 2, 2016, TVC submitted an SUD application to OEHHA for BpA in our members products
- Testing occurred on 129 eyewear samples across a variety of eyewear categories
 - Prescription and Sunglass lenses,
 - Ophthalmic and Sunglass frames,
 - temples,
 - safety eyewear
 - nose pads



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California Prop 65 SUD Efforts

- Results showed total BPA content in these samples ranged from not detected (“ND”) 15 parts per billion (“ppb”) to only 302 parts per million (“ppm”), with a vast majority below 10 ppm
- When tested using an artificial perspiration extraction method, not one of the 129 eyewear samples showed any migration of BPA from the samples (>15ppb)
- Toxicology testing reported;
 - If BPA migrated into the artificial perspiration at the detection limit, the theoretical estimated exposure posed by the BPA is significantly less than the Maximum Allowable Dose Level (“MADL”) of 3 micrograms per day (“ $\mu\text{g}/\text{day}$ ”) and a BPA concentration of 302 ppm in eyewear does not result in a detectable exposure to BPA



California Prop 65 SUD Efforts

- Asked OEHHA to issue a completeness determination of our SUD application in early 2017
- Once an SUD application is deemed complete then no NOVs can be filed against the product category in question
- OEHHA issued follow up questions in May of 2017
- TVC staff and counsel met with OEHHA on August 1st, 2017 to discuss their follow up questions
- The issues are largely around the presentation of the data from ATS Testing Facility
- Concerns regarding the “broad” scope of the SUD request was also raised
- Legal counsel is working with the test lab to provide the information requested



California Prop 65 SUD Efforts

- **Next Steps**
 - Provide answers to OEHHA on their latest question and request a notice of completion
 - Once notice of completion has been issued, it may be up to a year before we have the final determination

In the mean time, continue to label!!!



QUESTIONS?



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