Supporting Materials for a Safe Use Determination for Exposures to Bisphenol A (BPA) from Certain Polycarbonate Eyewear Products Manufactured, Distributed, or Sold by the Vision Council Member Companies

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Summary

This document presents an evaluation of a Safe Use Determination (SUD) request from The Vision Council (TVC) for exposures to bisphenol A (BPA) from certain polycarbonate eyewear products manufactured, distributed or sold by TVC member companies[1]. The request covers prescription glasses and sunglasses, over-the-counter (OTC) reading glasses, non-prescription sunglasses, and safety glasses. According to the request, polycarbonate plastic is used in various components of eyewear, such as frames, nose pads, and lenses. The polycarbonate plastic may contain unreacted BPA, and may release additional free BPA under use conditions that degrade the polycarbonate.

The evaluation is specific to the information provided to the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) and is not necessarily applicable to any other product or exposure scenario.

OEHHA utilized a screening-level approach to evaluate this request. In this approach, an upper-end estimate of the level of dermal exposure to BPA from wearing eyewear products manufactured, distributed, or sold by TVC member companies was determined. The estimate was based on data submitted by TVC on migration of BPA from specific polycarbonate eyewear components into a solution mimicking human perspiration, as determined by liquid chromatography tandem mass spectrometry (LC/MS/MS), as well as additional product information and several assumptions. In addition, TVC submitted data from acetonitrile extraction studies on the maximum BPA content in specific components of polycarbonate eyewear products covered by this request. These data indicated that the maximum BPA concentrations in the eyewear product components are as follows:

- Temple: 25 micrograms per gram (µg/g)

[1] Member companies are listed in Appendix 1 of the SUD request and are available from the TVC website at https://www.thevisioncouncil.org/member-companies.

- Nose pad: 68 µg/g
- Frame: 120 µg/g
- Lens: 302 µg/g

No BPA was detected in the migration studies with any of the 128 polycarbonate eyewear components tested in incubations with artificial perspiration at physiologic temperatures over 24 hours. OEHHA therefore based the upper bound estimate of exposure on the assumption that BPA was present in the artificial perspiration at the Limit of Detection (LOD), 15 nanograms per gram (ng/g), in these studies.

OEHHA estimated the upper bound for dermal exposure to BPA for users of these polycarbonate eyewear products is 0.53 µg per day. This upper-end estimate of BPA exposure is lower than the "Maximum Allowable Dose Level (MADL)" of 3 µg per day (dermal exposure from solid materials) (Cal. Code of Reg. Title 27, section 25805(b)(1)). Thus, OEHHA determined that a warning would not be required for exposures to BPA from polycarbonate eyewear products, namely prescription glasses and sunglasses, OTC reading glasses, non-prescription sunglasses, and safety glasses manufactured, distributed or sold by TVC member companies with acetonitrile extractable concentrations of BPA (as determined by LC/MS/MS) in the temple, nose pad, frame and lens at or below 25 µg/g, 68 µg/g, 120 µg/g, and 302 µg/g, respectively.

A number of factors may tend to increase or decrease estimates of exposure to BPA relative to the approach used to develop the dermal exposure in this document. The assumptions made have likely resulted in an overestimate of dermal exposure from the average use of these eyewear products.

This SUD evaluation was limited to exposure to BPA resulting from use of certain polycarbonate eyewear products (prescription glasses and sunglasses, OTC reading glasses, non-prescription sunglasses, and safety glasses) manufactured, distributed or sold by TVC member companies, with acetonitrile extractable concentrations of BPA as specified above. Exposures to other substances on the Proposition 65 list, if any, that may result from the use of these eyewear products were not reviewed by OEHHA in the context of this request.

1. Introduction

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency for the implementation of Proposition 65[2]. On March 8, 2019, OEHHA announced that it had received a request from The Vision Council (TVC) for a Safe Use Determination (SUD) for exposures to bisphenol A (BPA) from certain polycarbonate eyewear products manufactured, distributed, or sold by TVC member companies. The SUD request was made by TVC, on behalf of its member companies, pursuant to Title 27 of the California Code of Regulations, section 25204[3]. OEHHA provided a public comment period on this SUD request from March 8 to April 8, 2019. No public hearing was requested and no public comments were received.

BPA is on the Proposition 65 list of chemicals known to the state to cause reproductive toxicity, specifically for the female reproductive toxicity endpoint. For chemicals that are listed as causing reproductive toxicity, the "Maximum Allowable Dose Level (MADL)" is defined as the level of exposure that corresponds to the "no observed effect level" divided by 1000. The MADL for BPA (dermal exposure from solid materials) is 3 micrograms per day (µg/day)[4].

Based on information provided in the SUD request and in additional materials[5], OEHHA has identified BPA exposures for analysis to be the exposures of users of polycarbonate eyewear products, including those intended for vision-correction (e.g., prescription glasses and sunglasses, over-the-counter (OTC) reading glasses) as well as those used for eye protection (e.g., non-prescription sunglasses, safety glasses).

This document first provides a brief description of TVC member companies' polycarbonate eyewear products that are the subject of this request, including how BPA is used in the manufacture of these products. This is followed by a brief summary of the empirical data and exposure analysis that accompanied the SUD request. The next section presents OEHHA's analysis and estimate of an upper-bound dermal BPA exposure level from use of TVC member companies' polycarbonate eyewear products that are the subject of this request, and comparison of this exposure level to the dermal MADL of 3 µg/day.

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[2] The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 *et seq*, is commonly known as Proposition 65 and is hereafter referred to as Proposition 65.

[3] All further references are to sections of Title 27 of the Cal. Code of Regulations.

[4] The dermal MADL for BPA was adopted October 1, 2016 in section 25805(b)(1).

[5] In addition to information provided in the initial request, The Vision Council submitted data and information to support their request for a SUD on BPA in polycarbonate eyewear in communications dated 6/28/2016, 12/2/2016, and 7/16/2018.

1.1 Product Description and Use

The following is based on information provided in the SUD request and additional communications with TVC.

The SUD request covers a range of eyewear products with at least one component (e.g., lenses, frames[6], temples[7], and/or nose pads) made of polycarbonate plastic. Categories of eyewear products within the scope of the request are vision correction glasses (prescription glasses and sunglasses, OTC reading glasses) and eye protection glasses (nonprescription sunglasses, and safety glasses).

According to TVC, polycarbonate plastic is used in many eyewear lenses and other components (e.g., frames, temples, and nose pads). TVC estimates that over 19 million glasses with polycarbonate plastic are manufactured, distributed, and sold annually in California.

Polycarbonate plastic is created by chemical reaction of BPA monomer to form a polymer. Residual BPA may be present in polycarbonate due to incomplete polymerization. This residual BPA can diffuse to the surface of the polycarbonate plastic (Hoekstra and Simoneau, 2013; Mercea, 2008), where it comes into contact with the skin when the eyeglasses are worn. Polycarbonate also degrades under conditions such as ultraviolet (UV) light exposure and increased humidity (Danish Ministry of Environment, 2015). As this degradation occurs, additional BPA may also become available for dermal contact over the lifespan of a product. Thus, some amount of BPA is reasonably anticipated to be present in polycarbonate eyewear products.

Eyewear products are typically worn for either vision correction or protection of the eyes from external factors (e.g., sunlight). TVC estimates that approximately 32.6 million Californians use at least one type of eyewear, between vision-correcting eyewear (e.g., prescription glasses, OTC reading glasses) and eye-protection glasses (e.g., non-prescription sunglasses, safety glasses).

1.2 Exposure Analysis Provided by The Vision Council

In the analysis provided by TVC, “average” and “worst-case” BPA exposure estimates were determined for users of polycarbonate eyewear. Dermal contact was the sole exposure pathway included in the exposure estimate; potential ingestion exposure via

[6] Note that, per TVC, for the purposes of evaluation of components of eyewear in the context of this SUD, the “bridge” of an eyewear product is considered part of the frame component.
[7] Note that, per TVC, for the purposes of evaluation of components of eyewear in the context of this SUD, the “earpiece” of an eyewear product is considered part of the temple component.

hand-to-mouth transfer was estimated to be less than a picogram per day, which was described as “insignificant”.

TVC submitted empirical data for extractable BPA in 128 samples covering a variety of eyewear products from two types of extraction studies, i.e., extraction with acetonitrile, and extraction with a solution mimicking human perspiration (artificial perspiration). Samples of eyewear product components (including prescription lenses, non-prescription sunglass lenses, frames, temple arms, and/or nose pads containing polycarbonate) were provided by eight TVC member companies that represent a “large percent(age) of the eyewear market share in California”. Specifically, data were submitted on the following:

- 24 samples from prescription lenses[8]
- 25 samples from sunglasses lenses
- 33 samples from assorted frames
- 27 samples from the temple region of assorted frames
- 15 nose pads[9]
- 4 samples from safety glasses

In the acetonitrile extraction studies, product component samples were incubated with acetonitrile for 16 hours at 90°C; TVC states that extraction of BPA from polycarbonate with acetonitrile “is nearly 100%”. This was confirmed by additional information from the analytical laboratory used by TVC, which demonstrated a 94.1% extraction efficiency of BPA from a polycarbonate sample using this protocol. In the artificial perspiration extraction studies, intended to simulate migration of BPA to skin, product component samples were incubated with artificial perspiration solution[10] for 24 hours at 37°C. TVC states that extraction of BPA with such artificial perspiration reflects potential migration of BPA under conditions experienced by an “average user”, giving the example of “conditions under which sunglasses in particular are worn (high temperatures and sweaty face at the beach)”. In each of these extraction studies, BPA was quantified in the extractant solution by liquid chromatography tandem mass spectrometry (LC/MS/MS), with a limit of detection (LOD) of 15 nanograms per gram (ng/g).

BPA measurements in the acetonitrile extraction of eyewear component samples ranged from below the LOD to 301.84 microgram per gram (µg/g). No BPA was quantified in the artificial perspiration extraction of eyewear component samples. Because BPA was not detected in the artificial perspiration following incubation, the

[8] One prescription lens sample did not have acetonitrile extraction data available.
[9] Five samples from the temple region of assorted frames did not have artificial perspiration extraction data available.
[10] According to TVC, the artificial perspiration solution, obtained from Pickering Laboratories, is reported to contain “amino acids, minerals, and metabolites”.

LOD was used as an upper-bound value for the amount of BPA extracted from the eyewear samples into the artificial perspiration.

Use patterns for these products, including duration of contact with the eyewear, will differ across product type. However, as specified in the exposure assessment submitted by TVC, prescription vision correction glasses are generally worn more frequently, and for a greater duration than non-prescription eyewear. TVC states that prescription vision correction glasses "are often worn continuously during all waking hours".

Several estimates of the potential exposure to BPA from eyewear are presented in the TVC request. Potential exposure to the "average eyewear user" was calculated from typical use patterns, "exemplar" product dimensions, and the results of the artificial perspiration extraction testing to determine the amount of BPA transferred from the surface of all relevant eyewear components (e.g., lens, frame, nose pad) to the skin. TVC calculated "average" BPA exposures of up to 0.13 µg/d for users of their members' eyewear products.

"Worst-case" BPA exposure was estimated using either the upper-bound BPA concentration from the acetonitrile extraction studies (row G in Table 1 below) or the maximum theoretical surface transfer rate from any sample in the artificial perspiration extraction studies (row H in Table 1 below). In calculating each worst-case BPA exposure estimate, the amount of skin in contact with the eyewear product was estimated from the surface area of a "typical" prescription eyewear product to be 25 square centimeters [cm^2], and the contact duration was taken to be 16 hours, which is the estimated time an adult is awake during a 24-hour period. Table 1 lists the parameters used to derive these two "worst-case" BPA exposure estimates of 0.29 µg/d (row G) and 0.2 µg/d (row H).

Table 1. Estimated "worst-case" BPA exposures submitted by TVC

Parameter	Unit	Value	Basis
A. Maximum surface transfer rate of BPA	$\mu g/cm^2/sec$	2.03×10^{-7}	Maximum calculated from an eyewear component sample from the artificial perspiration study = (15 ng BPA / g artificial perspiration) × (5 mL artificial perspiration) × (1 g/mL density artificial perspiration) × (1 µg / 1000 ng) / [(24 hr) × (60 min / hr) × 60 sec / min) × (4.29 cm^2 product sample)
B. Maximum[a] concentration of BPA in eyewear	$\mu g/cm^3$	30	Maximum concentration measured in an eyewear component sample from the acetonitrile extraction study (25 µg/g) with adjustment for density of polycarbonate (1.2 g/cm^3); = 25 µg/g × 1.2 g/cm^3
C. Surface area of facial skin in contact with eyewear	cm^2	25	Rounded, from calculated total surface area of "typical" prescription eyewear in contact with skin; = frame and bottom of lenses (9.3 cm^2) + temple arms (14.9 cm^2)
D. Facial lipid layer depth	cm	0.0004	Assumed, based on Sheu *et al*. (1999)[b]
E. Volume of the lipid layer with product contact	cm^3	0.01	= **C × D**
F. Contact duration	hr	16	Based on average time sleeping for adults (18-64 yrs old) reported by US EPA (2011) = 24 hrs - 8.3 hrs
G. Daily dermal dose from maximum surface transfer rate of BPA	µg	0.29	= **A x C x [F x (60 min / hr) x (60 sec / min)]**
H. Daily dermal dose from maximum concentration of BPA	µg	0.2	= **B x E x (F / 24)**

[a] Note that TVC subsequently submitted data from samples tested in additional acetonitrile extraction studies in which the maximum concentration of BPA is 302 µg/g × 1.2 g/cm^3 = 362 µg/g.
[b] Note that Sheu *et al*. (1999) state that in sebum rich areas, such as the face, skin surface lipid film (SSLF) thickness was > 4 µm [0.0004 cm].

2. OEHHA Analysis of BPA Exposure from Certain TVC Polycarbonate Eyewear Products

OEHHA conducted a screening-level exposure analysis to derive an upper-end estimate of dermal BPA exposure to users of certain polycarbonate eyewear products manufactured, distributed or sold by TVC member companies, as described in Section 1.1. OEHHA's upper-end estimate of BPA exposure to eyewear users is 0.53 µg/day. The parameters used are shown in Table 2, and a discussion of the assumptions used follows the table.

OEHHA utilized a conservative exposure scenario for users of prescription glasses with a "worst-case" exposure duration. In the identified scenario, vision-correction eyewear is worn throughout the day, as by a professional working a 24-hour shift, allowing for continuous dermal contact with BPA present on the surface of the polycarbonate eyewear. Uses of other eyewear products (e.g., OTC reading glasses, non-prescription sunglasses, safety glasses) are expected to be less frequent and of shorter duration.

Table 2. Parameters used in and results of the OEHHA screening-level analysis of BPA exposure resulting from use of certain TVC polycarbonate eyewear products

Parameter	Unit	Value	Basis
A. Maximum amount of BPA extracted per surface area	µg/cm^2	0.0175	Calculated using the mass of BPA at the LOD and surface area for samples from the artificial perspiration study data. Sample "frame #1" from the TVC dataset provided the maximum value = 0.075 µg / 4.286 cm^2
B. Maximum dermal transfer rate of BPA	µg/cm^2/hr	0.000729	= **A** / 24 hrs
C. Maximum surface area of facial skin in contact with eyewear	cm^2	30	Considered to be a reasonable upper-bound value that accounts for variability not captured by OEHHA's empirical measurements of 8 eyewear users (maximum contact surface area measured as 21.6 cm^2).
D. Dermal absorption	unitless	100%	Assumption
E. Contact duration	hr	24	Based on 24-hour shift workers.
F. Daily dermal dose	µg	0.53	= **B** × **C** × **D** × **E**

OEHHA's screening-level (i.e., upper-end) estimate of a daily dermal dose of BPA for users of certain polycarbonate eyewear of 0.53 µg/day (Line E, Table 2) is based on the assumptions described below:

1. Only exposure via the dermal route is included in this assessment. Other routes, such as inhalation or oral ingestion (either by hand-to-mouth or direct mouthing) were assumed negligible, given that no BPA was detected in the artificial perspiration extraction studies.

2. The LOD (15 ng/g) from the artificial perspiration migration studies can be used to estimate the maximum amount of BPA that would be released per surface area in a 24-hour period. No BPA was detected for any of the polycarbonate eyewear components following incubation with artificial perspiration at physiologic temperature (37°C) for 24 hours. The maximum calculated concentration, 0.0175 μg/cm^2, was based on a frame sample (sample #1) with a surface area of 4.286 cm^2. OEHHA assumes that this maximum amount of BPA released per surface area in a 24-hour period applies to all polycarbonate components (temple, nose pad, frame, lens) of a given eyewear product, and that this amount of BPA is available for dermal contact at a constant rate of 0.729 nanograms per square centimeter per hour (ng/cm^2/hr).

3. All BPA in contact with the skin is absorbed.

4. An exposure time of 24 hours, as a "worst-case" scenario, for dermal exposure of users of eyewear products.

5. The use of prescription, vision-correction eyewear would be associated with the greatest duration of wear, compared with the use of sunglasses or safety glasses.

The calculated upper-end dermal exposure estimate for consumers, 0.53 μg/day, falls below the dermal MADL for BPA of 3 μg/day. Therefore, consumer exposure to BPA from these TVC eyewear products is not significant for the purposes of Proposition 65, and does not require warning.

2.1 Uncertainties Associated with the Eyewear User Exposure Estimate

There are uncertainties associated with the models and parameters utilized in the BPA exposure assessment for users of certain TVC polycarbonate eyewear products. Overall, the assumptions utilized in this assessment to address the uncertainties likely result in an overestimate of exposure:

- OEHHA assumes that the empirical data submitted by TVC reflect the BPA content of all eyewear products within the scope of the SUD request. However, the relative amount of residual BPA present in a polycarbonate plastic depends on a number of factors, including the polymerization method used, processing conditions (e.g., high thermal stress during injection molding process), and

additives used (Danish Ministry of Environment, 2015). OEHHA does not have information on these factors for the various eyewear products included within the scope of this SUD; thus there is some uncertainty in OEHHA's assumption that the data on residual BPA content submitted by TVC is truly representative of all the eyewear products included in the SUD.

- BPA was not detected in the migration studies of polycarbonate eyewear components conducted with artificial perspiration as an extractant at physiologic temperature (37°C) over 24 hours. The use of artificial perspiration to simulate potential dermal contact with consumer products and articles is well established. OEHHA assumes that this approach reflects actual-use conditions of products within the scope of the request. The use of the LOD in the absence of detected levels of BPA in the artificial perspiration studies is a conservative assumption. Moreover, this study immersed eyewear samples in artificial perspiration, a scenario unlikely to occur continuously for 24 hours, if at all, which also indicates that the use of the LOD from these studies is a conservative assumption. On the other hand, the condition and age of a given eyewear product may affect the migration of BPA. In addition, more BPA may migrate from eyewear to the skin surface under certain conditions than is predicted by artificial perspiration such as when the level of sebum (oil) content present on the skin surface is higher than that used in the artificial perspiration studies. Overall, uncertainties associated with the use of the LOD from the 24-hour migration studies conducted with artificial perspiration as an extractant are expected to result in an overestimate of dermal BPA exposure.

- Due to data limitations, OEHHA uses a constant dermal transfer rate to estimate dermal exposure, assuming there is continuous dermal contact with the eyewear product.

- Skin surface area in contact with these eyewear products has not been measured and reported in the literature. Relevant dimensions of the face and head are subject to greater variation than those of eight eyewear users included in a skin contact survey conducted by OEHHA (see Table 2, row C). A 2010 study of facial anthropometric differences relevant to respirator fittings from the National Institute of Occupational Safety and Health found statistically significant differences in facial anthropometric dimensions by gender, ethnicity, and age (Zhuang *et al.,* 2010). Variation in the dimensions of the various eyewear products included within the scope of the SUD request also contributes to uncertainty in estimates of facial skin surface area in contact with eyewear. Given this, OEHHA considered 30 cm^2 to be a reasonable upper-bound value for contact surface area (the maximum measured value among the eight eyewear

users surveyed by OEHHA was 21.6 cm^2). Use of this upper-bound value is expected to result in an overestimate of dermal BPA exposure for the average user of eyewear products.

- OEHHA assumes that all BPA in contact with the skin is absorbed. Of the multiple studies conducted with human skin samples, the percent of BPA absorbed within 24 hours was reported to be as high as 59% (Demierre *et al*., 2013; Liu and Martin, 2019; Marquet *et al*., 2011; Mørck *et al*., 2010; Toner *et al*., 2018; Zalko *et al*., 2010). However, no data are specifically available regarding absorption of BPA by facial skin, which is expected to be more permeable than skin from other regions of the body (OEHHA, 2012). An expectation that facial skin is likely to be more permeable than skin from other parts of the body is supported by measurements of stratum corneum depth and trans epidermal water loss (Bohling *et al*., 2014; Gorcea *et al*., 2019).

- OEHHA assumes that a prescription eyewear product is used for a duration of 24 hours per day, as a worst-case estimate. Indeed, there are populations (e.g., firefighters, nurses, physicians, security guards) for whom 24-hour work shifts are not uncommon, and who may wear either vision-correction or vision-protection eyewear during such a shift. There are no empirical data providing information on the use patterns (e.g., frequency and duration of use) for each type of eyewear product within the scope of the SUD request.

Conclusions

This screening-level analysis, which relied on relatively conservative assumptions, only applies to the BPA exposure scenarios discussed in this document. OEHHA is not drawing conclusions for other chemicals, other exposure scenarios, or other products.

Based on this screening level analysis and utilizing experimental data provided by TVC, the upper-end estimate of BPA dermal exposure for users of certain TVC polycarbonate eyewear products, as specified further below, is 0.53 µg/day. This exposure falls below the dermal MADL for BPA of 3 µg/day. Thus, exposures to BPA from use of such eyewear products, under the conditions described in this assessment, would not require a Proposition 65 warning.

This determination is specific to exposures to BPA from polycarbonate eyewear products, namely prescription glasses and sunglasses, OTC reading glasses, non-prescription sunglasses, and safety glasses manufactured, distributed or sold by TVC member companies with acetonitrile extractable concentrations of BPA (as determined

by LC/MS/MS) in the temple, nose pad, frame, and lens at or below 25 µg/g, 68 µg/g, 120 µg/g, and 302 µg/g, respectively.

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