



BPA and Polycarbonate Plastic: Safety and Proposition 65 Updates

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Polling Question #1

Please indicate your perspectives about polycarbonate?

- ☐ Polycarbonate is safe and I don't have any concerns.
- ☐ I believe polycarbonate is generally safe, although I do have some concerns.
- ☐ I am undecided about the safety of polycarbonate.
- ☐ I don't believe polycarbonate is generally safe.
- ☐ I have serious concerns about the safety of polycarbonate.

Polling Question #2

Which statement best describes your usage of polycarbonate?

- ☐ I use polycarbonate and my customers have not expressed safety concerns.
- ☐ I use polycarbonate, but my customers have concerns.
- ☐ I don't use polycarbonate because of my customers' concerns.
- ☐ I don't use polycarbonate.

PC/BPA Global Group Introduction

- Global coalition of bisphenol A (BPA) and polycarbonate plastic manufacturers
- Focused on health and environmental aspects of BPA and polycarbonate
- Integrated global structure
 - Global Science Team
 - Regional Communications/Advocacy Teams
 - + Korea, China, Europe, Japan, North America

Introduction to BPA

- Essential ingredient to make polycarbonate plastic and epoxy resins
 - Polycarbonate: High clarity, shatter-resistant, light weight
 - Examples: Electronic equipment housing, CDs/DVDs, protective/corrective eyewear, components of medical devices
 - Epoxy: Tough/durable, chemically resistant, good adhesion
 - Examples: Protective paints/coatings, wind turbine blades, aerospace composites, circuit boards, structural adhesives
 - Trace residual levels of BPA (typically < 100 ppm)
- BPA has 50+ year safety track record
 - One of best tested substances in commerce

Is BPA Safe?

- Unequivocal answer from FDA (February 2016)

U.S. Department of Health and Human Services

FDA U.S. Food and Drug Administration
Protecting and Promoting *Your Health*

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Food

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Food Additives & Ingredients

- Overview of Food Ingredients, Additives & Colors
- Consumer Info About Additives & Ingredients
- Determining the Regulatory Status of a Food Ingredient
- Color Additives in Food
- Food & Color Additive Petitions
- Food Additive Status List

Questions & Answers on Bisphenol A (BPA) in Food Containers and Packaging

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Questions & Answers on Bisphenol A (BPA) in Food Containers and Packaging

FDA acknowledges the interest that many consumers have in the use of Bisphenol A (BPA) in food packaging. FDA has performed extensive research on BPA and has reviewed hundreds of studies about BPA's safety. We reassure consumers that current approved uses of BPA in food containers and packaging are safe. Additional research is underway to enhance our understanding of BPA. FDA will take these studies into account as it continues to ensure the safe use of BPA in food packaging. Here, FDA experts answer some key questions about the agency's research on and regulation of BPA.

"Is BPA safe?"

Yes. Based on FDA's ongoing safety review of scientific evidence, the available information continues to support the safety of BPA for the currently approved uses in food containers and packaging. ... Studies pursued by FDA's National Center for Toxicological Research (NCTR) have shown no effects of BPA from low-dose exposure."

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Who Else Has Reviewed BPA Safety?

- Government bodies worldwide reach independent conclusions similar to FDA
 - Four published in recent months
 - Earlier government assessments (e.g., EFSA, Health Canada, Japanese AIST) reach similar conclusions
- South Korea Ministry of Food and Drug Safety (MFDS)
 - Risk assessment published March 2016 in *Environmental Research* journal

“we find that there are no health concerns for the general Korean population from dietary exposure or from aggregated exposure [to BPA]”

- Exposure levels in North America and Europe found to be similar to South Korean exposures

Who Else Has Reviewed BPA Safety?

- Food Safety Authority of Ireland (FSAI)

- Total Diet Study published March 2016

“the results show that the Irish population is generally not at risk from the chemical contaminants analysed in the diet”

and

“exposure to BPA is of low concern”

- Food Standards Australia New Zealand (FSANZ)

- Australian Total Diet Study published January 2016

“public health and safety risk from BPA is considered to be very low”

- Swiss Federal Council

- Evaluation published December 2015

“BPA poses no health risk to consumers, because the exposure of consumers is too low to cause health effects” (translated from German)

FDA Research Overview

- Extensive FDA research program underway
 - Designed to answer key scientific questions and resolve uncertainties about the safety of BPA
- Nineteen papers published to date in peer-reviewed scientific literature, most notably:
 - Comprehensive set of rodent and non-human primate pharmacokinetic studies
 - Subchronic toxicity study in rats
- Results so far provide strong support for safety of BPA
- More research from FDA and NTP underway



What's Next?

- FDA chronic toxicity study (~2-year) in rats likely to be the largest study ever conducted on BPA
 - “In-life” part of study complete since early 2015
 - Now approaching data analysis phase
 - Final report not likely before late-2017/early-2018
- NTP also active with human pharmacokinetic studies
 - Oral exposure study published June 2015
 - Results confirm and extend findings from previous studies
 - BPA rapidly metabolized and eliminated from body
 - Dermal exposure study now underway

Legal Disclaimer

The decision whether to warn consumers about product risks pursuant to Proposition 65 ultimately rests with manufacturers, sellers, and distributors of consumer products and any other persons who, in the course of doing business, knowingly and intentionally expose an individual to a chemical listed under Proposition 65. This presentation is intended to provide technical information to allow companies to comply with Proposition 65 and is not intended as legal advice.

Proposition 65 Background

What is Proposition 65?

- Safe Drinking Water and Toxic Enforcement Act of 1986
 - Enacted into law by California voters as a ballot initiative
 - Intended to protect CA citizens and drinking water sources from chemicals known cause cancer, birth defects, or other reproductive harm
 - Administered by the CA Office of Environmental Health Hazard Assessment (OEHHA)

What Does Proposition 65 Require?

- Annual publication of a list of chemicals “known to the state to cause cancer or reproductive toxicity”
- “Clear and reasonable” warnings if individuals are exposed

Proposition 65 Background

What is it Not?

- Not a ban or restriction on listed chemicals
- Does not require reformulation
- Does not impose warning/labeling requirements on other states or countries
- Not a safety determination

What's the Current Status?

- Currently ~900 substances on the list; more being added
 - Includes food ingredients, common household products, naturally occurring substances, ethyl alcohol, prescription and non-prescription drugs
 - Recent additions include styrene, ethylene glycol, and DINP

Proposition 65 History for BPA

- 2009: Unanimous vote from DART-IC to not list BPA as a reproductive or developmental toxicant
- 2013: OEHHA proposed to list BPA as a developmental toxicant based on a 2008 NTP report
 - Litigation underway; may conclude in 2016
- 2015: Reconstituted DART-IC voted to list BPA as a female reproductive toxicant
 - BPA formally listed by OEHHA on May 11, 2015
- May 11, 2016: Compliance date for warning requirements

Is BPA a Female Reproductive Toxicant?

- In advance of May 2015 DART-IC meeting, FDA sent letter to OEHHA
 - Signed by Dr. Luciana Borio (FDA Acting Chief Scientist), April 6, 2015
 - Letter briefly highlighted FDA's own research and extensive scientific assessment

“The results from ... the NCTR study do not support BPA as a reproductive toxicant.”

“The findings of our assessment reaffirm FDA's determination that BPA is safe provided it is used in accordance with our regulations.”

Proposition 65 Warning Requirement

- 25249.6. Required Warning Before Exposure To Chemicals Known to Cause Cancer Or Reproductive Toxicity.

No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10.

- 25249.10. Exemptions from Warning Requirement.

Section 25249.6 shall not apply to any of the following:

(c) An exposure for which the person responsible can show that the exposure ... will have no observable effect assuming exposure at one thousand (1000) times the level in question for substances known to the state to cause reproductive toxicity ...

What's the Exposure Threshold for Warnings?

- OEHHA may establish a “safe harbor level” known as a Maximum Allowable Dose Level (MADL)
 - $\text{MADL} = \text{NOEL} \div 1000$
 - NOEL = No Observable Effect Level
 - A MADL can be specific to a single route of exposure (e.g., oral)
 - More than one MADL can be set for different routes of exposure (e.g., oral and dermal)
- OEHHA proposed (March 2016) a MADL for dermal exposure: 3 $\mu\text{g}/\text{day}$

What's the Exposure Threshold for Warnings?

- OEHHA declined to set a MADL now for oral exposure (or any other route)
 - Regulations provide guidance to set an exposure threshold in the absence of a MADL
- Conservative NOEL for oral exposure is 290 mg/day
 - Exposure threshold = $290 \text{ mg/day} \div 1000 = \underline{290 \text{ } \mu\text{g/day}}$
 - Based on two multi-generation reproduction studies in animals
 - Studies previously determined by OEHHA to be of sufficient quality
 - Systemic toxicity NOEL more conservative than reproductive toxicity NOEL
 - Studies used worldwide as basis for safety assessments
 - NOEL used by FDA for its safety assessment

What's the Exposure?

- Total exposure to BPA from a product is the relevant parameter for the warning exemption
 - Not necessary to add exposures from multiple products from same manufacturer or sold by a retailer
 - Not necessary to add exposures from products manufactured by others
 - Exposure by all routes must be considered
 - Presence of BPA in a product is not the same as exposure
- Consumer product exposure is for the average user
 - “For exposures to consumer products, the level of exposure shall be calculated using the reasonably anticipated rate of intake or exposure for average users of the consumer product, and not on a per capita basis for the general population.” Section 25821(c)(2)

Sample Conservative Exposure Estimate – Oral Exposure

- Oral exposure: Food/beverage in contact with PC
 - Based on maximal migration of BPA from polycarbonate
 - 15 µg BPA/kg food (WHO/FAO report)
 - Other migration values available; may be appropriate to refine the exposure estimate with a more realistic value for a specific product
- Exposure = Migration x Food/Beverage Consumption
 - 30 µg/day for 2L water per day
 - 18 µg/day for 1.2 kg food per day
- Need for Proposition 65 warning based on comparison of exposure with applicable oral exposure threshold

Sample Conservative Exposure Estimate – Dermal Exposure

- Dermal exposure: Skin contact with PC product
 - Based on realistic migration of BPA from polycarbonate
 - 0.12 $\mu\text{g/L}$ (24 hours at 40°C; published Health Canada research)
 - Equivalent to 0.00015 $\mu\text{g BPA/cm}^2$ PC (24 hours)
 - Other migration values available for consideration
- Exposure = $A \times B \times C \div 24$
 - A = Time of skin contact with a product per day (hours/day)
 - B = Skin surface area in contact with a product ($\text{cm}^2/\text{product}$)
 - C = Surface area migration per 24 hours ($\mu\text{g/cm}^2$)
 - 0.003 $\mu\text{g/day}$ (2 hours, palm side of one hand)
 - 0.02 $\mu\text{g/day}$ (8 hours, palm side of both hands)
- Need for Proposition 65 warning based on comparison of exposure with applicable dermal exposure threshold

Technical Guidance Document Available

- Guidance document prepared by the Polycarbonate/BPA Global Group
 - Prepared February 2016, updated April 2016
 - Includes discussion on MADL/NOEL and exposure estimates for PC products
 - Does not include all possible product exposure scenarios or occupational exposure
 - Available upon request

For More Information

- Key Contact

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