

# Ongoing developments on Bisphenol A

## Bisphenol A Settlement - California Proposition 65

TÜV Rheinland LGA Products - Information

June 2022

The US based NGO, Center for Environmental Health (CEH) has recently tested socks for children, babies and adults from several brands for the substance Bisphenol A (BPA). *Please see also Customer information "Ongoing developments on Bisphenol A" from November 2021.*

The substance is listed under California Proposition 65, also known as the Safe Drinking Water and Toxic Enforcement Act of 1986 of the State of California, for its developmental toxicity as well as female reproductive toxicity.

Under California Proposition 65, the Maximum Allowable Dose Level (MADL) for dermal absorption of BPA is 3 µg/day.

CEH claims to have found concentrations of Bisphenol A exceeding the CalProp65 MADL and has sent legal notices (60-Day Notices) to companies selling contaminated socks in California without a Proposition 65 warning label for the presence of Bisphenol A.

### CURRENT DEVELOPMENTS (60-DAY NOTICE)

In April 2022, several footwear manufacturers were served with a 60-Day Notice due to presence of Bisphenol A in their women's shoes. Unfortunately, based on a 60-Day Notice, no indication of the affected materials or content can be made.

Based on experience, it can be assumed that leather or polyurethane are the subject of the investigation, both materials may contain Bisphenol A.

### CURRENT SETTLEMENT(S) FOR BISPHENOL A IN SOCKS

There is now a first settlement regarding Bisphenol A in socks.

[Settlement - CGC-22-598022 - CEH v. Easy Spirit dated May 15, 2022](#)

Like all other settlements, it is only legally binding for the named manufacturer, however it is also a guide for the industry selling similar products. It also gives a clear indication regarding the applied analytical method.

The content of Bisphenol A (and other Bisphenols such as Bisphenol S or F) in socks is specified in the above mentioned settlement as  $\leq 1$  ppm (mg/kg, part per million). If the manufacturer cannot comply with these requirements, the article must be labelled according to the regulations.

In addition, further information on the analytical method (LC-MS/MS, acetonitrile extraction) is also provided.

CALIFORNIA PROPOSITION 65

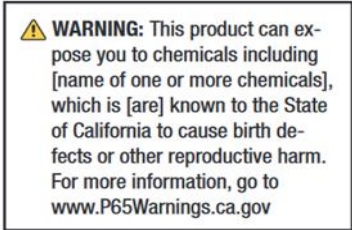
The Safe Drinking Water and Toxic Enforcement Act of 1986, also known as California Proposition 65, requires businesses to inform Californians of exposures to chemicals known to cause cancer, birth defects or other reproductive harm. It does not limit or prohibit substances, it is a right-to-know law for the public. The list of chemicals is updated at least annually. If a company is using one of the substances in their products sold in California, it is required to label the product with a warning.

The warning is not required if there is proof that the concentration of the substance is low enough to pose a health risk, the exposure is below the respective MADL “Safe harbor level”, or the consumer is not exposed to the substance.

In cases where higher concentrations of a listed substance are found by external parties like CEH, the legal notices are usually followed by a consent between the involved parties.

LABELLING UNDER CALIFORNIA PROPOSITION 65

If a business is not sure if their product contains a certain chemical on the Prop65 list or suspects it and it may expose consumers to it, it is required to carry a label with a warning. The warning includes the name of the substance from the list as well as the potential hazard, e.g. “reproductive harm” as well as an equilateral triangle with an exclamation mark. This symbol is followed by the word WARNING.



MATERIALS THAT MAY CONTAIN BISPHENOLS

CEH has mainly tested socks made from Polyester and Elasthane (Spandex) mixtures, where concentrations of up to 10 mg/kg can be found. This is a first in the textile/fashion industry, as BPA has been mainly associated with Polycarbonates as well as Thermal Receipt Paper.

The appearance of harmful concentrations of the substance in Apparel and textile products have not been on the radar of brands and labs. Bisphenol S and F are known to appear in high concentrations in Nylon, Polyamide and chrome-free tanned leathers.

Substance	Polyester and blends	Elasthan and Polyurethane	Nylon	Polyamide	Chrome free (re)tanned leather
Bisphenol A	•	•			
Bisphenol S			•	•	•
Bisphenol F			•	•	•

Please keep in mind that this is not limited to socks as BPA may be introduced in different textile processes as an impurity and it is not clear yet, if Polyester/Elasthane mixtures are the only source of BPA. Most likely also other fibers and fiber mixtures are concerned, e.g. Cotton and Cotton/Elasthane. Polyester and mixtures with Elasthane or other fibers should be in the focus of any testing/evaluation activities.

## RECOMMENDATION

As a precautionary measure, many companies selling socks in the U.S. have begun to label products with a warning if the concentration of Bisphenol A is above the method detection limit or unknown.

In light of the first initial settlement, it is recommended that the Bisphenol A concentration be determined using an appropriate analytical test method (extraction with THF or acetonitrile followed by LC-MS/MS) that has at least a limit of quantitation of 1 ppm (mg/kg).

Companies who decide to not react to the recent developments, should at least prepare a process enabling them to respond in a timely manner to any legal notices and avoid the payment of high fines.

Further information on current legal changes can also be found on our homepage at [www.tuv.com](http://www.tuv.com) or <https://www.tuv.com/regulations-and-standards/en/>.

Further technical information can be obtained from:

**TÜV Rheinland LGA Products GmbH**

Technical Competence Center Softlines

Kathrin Endress

[Kathrin.Endress@de.tuv.com](mailto:Kathrin.Endress@de.tuv.com)

Am Grauen Stein

51105 Cologne

Germany

Steffen Tuemptner

[Steffen.Tuemptner@de.tuv.com](mailto:Steffen.Tuemptner@de.tuv.com)

Alboinstr. 56

12103 Berlin

Germany

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