

Ongoing developments on Bisphenol A

*California Proposition 65 – Findings in socks

*Development of BPA Restriction in the EU

TÜV Rheinland LGA Products - Information

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The US based NGO, Center for Environmental Health (CEH) has been recently testing children, baby and adult socks from several brands for the substance Bisphenol A (BPA).

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.

The NGO claims to have found concentrations that are by far exceeding the Prop65 MADL and has sent legal notices (60 Day Notices) to companies selling contaminated socks in California. The aim is, to get brands to reduce the use of BPA in socks as they can be worn for a long time and may harm especially vulnerable groups like babies and children.

WHAT IS BISPHENOL A?

BPA is a man-made substance used in the manufacturing of Polycarbonates as well as Epoxy Resins. It is also used as a developing agent in thermal receipt paper. Other uses are as an additive in polymers or it may be introduced in products through complex chemical mixtures.

BPA is only one compound of a wider range of substances that are of similar concern due to their structural and biological similarity.

This includes, but is not limited to, Bisphenol S, F, B and C. Those substances are known to be used as dye fixing agents or spinning aids. Bisphenol S and F are also used in phenolic based synthetic tannins in chrome-free tanned leathers.

BPA came under the focus of the regulatory radar in the late 2000s, when it became clear, that the high volume substance shows hormone like activity, endocrine disrupting properties, in humans and the environment.

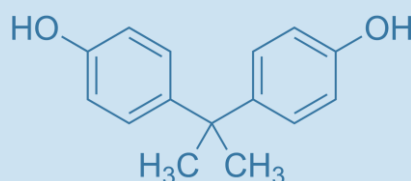
Bisphenol A (BPA)

4,4'-isopropylidenediphenol

EC / List no.: 201-245-8

CAS no.: 80-05-7

Mol. formula: C₁₅H₁₆O₂



CALIFORNIA PROPOSITION 65

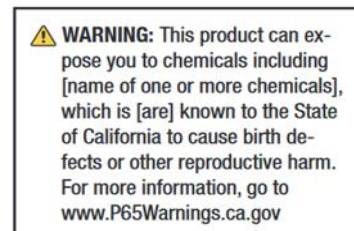
The Safe Drinking Water and Toxic Enforcement Act of 1986, also known as California Proposition 65, requires businesses to inform Californians of exposures to chemicals known to cause cancer, birth defects or other reproductive harm. It does not limit or prohibit substances, it is a right-to-know law 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 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 point. 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	Nylon	Polyamide	Chrome free tanned leather
BPA	•	•			
BPS			•	•	•
BPF			•	•	•

RECOMMENDATION

As a precaution, several companies selling socks in the US consider labelling their products with a warning, if BPA concentrations are not regularly tested or unknown.

In addition to this, it is recommended to determine the BPA concentration in socks with an appropriate analytical test method (Extraction with THF followed by LC-MS/MS) having at least a reporting limit of 0.1 mg/kg.

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 the focus of any testing/evaluation activities.

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.

OTHER REGULATORY ACTIVITIES ON BISPHENOLS

Bisphenol A is restricted in the European Union (EU) for use in thermal paper and toys and is listed as a substance of very high concern (SVHC) due to its endocrine disrupting properties for humans and the environment.

A first restriction proposal was submitted by Germany to avoid possible adverse effects. A second call for comments is currently underway, aiming to extend the initial restrictions in articles.

The German Federal Environment Agency (UBA) and the Federal Institute for Occupational Safety and Health (BAuA), which is responsible for REACH, are identifying updated information on the use of BPA, including quantities, alternatives and switching costs.

Currently, the restriction proposal is to limit the concentration of free BPA and other bisphenols in articles to 10 mg/kg (0.001%). If this level is exceeded, migration can be used to demonstrate that no more than 0.04 mg/l is released from the article into the environment. The proposal covers not only BPA but also structurally related compounds, which include related bisphenols such as Bisphenol S, F and many others.

It should be noted that the limit value of 10 mg/kg is not toxicologically derived and substantiated. The reason for the restriction is, that it is assumed that there are effects for the environment and not so much for humans. It is argued that the value of 10 mg/kg has proven to be target-oriented and practicable for products. A scientifically derived justification is not presented in this context yet.

SOURCES

[Substance Information - ECHA \(europa.eu\)](https://echa.europa.eu)

[Chemicals Considered or Listed Under Proposition 65 | Bisphenol A \(BPA\) \(oehha.ca.org\)](https://oehha.ca.org)

[CEH Finds 84 Sock Brands with High Levels of BPA \(che.org\)](https://che.org)

[Call for evidence on a possible restriction on 4,4'-isopropylidenediphenol \(Bisphenol A\) and structurally related bisphenols of similar concern for the environment \(europa.eu\)](https://europa.eu)

[Survey Powered by Webropol: 2nd Stakeholder Consultation on a Restriction for Bisphenol A and Bisphenols of similar concern \(BPAF, BPB, BPF, BPS\) \(webropolsurveys.com\)](https://webropolsurveys.com)

[Bisphenol A \(BPA\) and Proposition 65: Frequently Asked Questions - Proposition 65 Warnings Website \(ca.gov\)](https://ca.gov)

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

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