

## BISPHENOL-A

**CAS number:** 80-05-7

**Synonyms:** 4,4'-(propane-2,2-diyl)diphenol, BPA,  
p,p'-Isopropylidenebisphenol

**Chemical formula:** C<sub>15</sub>H<sub>16</sub>O<sub>2</sub>

### Workplace exposure standard (new)

**TWA:** 2 mg/m<sup>3</sup> (inhalable dust)

**STEL:** —

**Peak limitation:** —

**Notations:** DSEN

**IDLH:** —

**Sampling and analysis:** There is uncertainty regarding quantification of the recommended value with currently available sampling and/or analysis techniques

### Recommendation and basis for workplace exposure standard

A TWA of 2 mg/m<sup>3</sup> is recommended to protect for irritation of the respiratory tract in exposed workers.

### Discussion and conclusions

Bisphenol A (BPA) is widely used in the manufacture of polycarbonate plastics and epoxy resins.

There are limited data available in humans other than reports of contact allergic reactions and local effects on mucous membranes of nose and eyes in occupational settings. A NOAEC of 10 mg/m<sup>3</sup> is reported in rats exposed to airborne BPA daily for 13 weeks (DFG, 2011). Mild irritation of upper respiratory tract was observed at 50 mg/m<sup>3</sup>. Dermal absorption is not considered significant (DFG, 2011; HCOTN, 2019; SCOEL, 2014).

A TWA of 2 mg/m<sup>3</sup> is recommended to protect workers based on the reported NOAEC of 10 mg/m<sup>3</sup> for respiratory effects in rats and allowing for interspecies extrapolation and rounding (SCOEL, 2014).

### Recommendation for notations

Not classified as a carcinogen according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

Classified as a skin sensitiser and not a respiratory sensitiser according to the GHS. While, sensitisation data is conflicting, there is evidence that BPA results in contact allergic reactions. In combination with the GHS classification, a DSEN notation is recommended.

There are insufficient data to recommend a skin notation.

# APPENDIX

## Primary sources with reports

Source	Year set	Standard
<b>SWA</b>	<b>NA</b>	<b>NA</b>
No report.		
<b>ACGIH</b>	<b>NA</b>	<b>NA</b>
No report.		
<b>DFG</b>	<b>2011</b>	<b>MAK: 5 mg/m<sup>3</sup></b>
<p>MAK recommended to protect for local effects on the respiratory tract in exposed workers.</p> <p>Summary of data:</p> <p>Human data:</p> <ul style="list-style-type: none"> <li>• Case reports of contact allergic reactions in occupational settings</li> <li>• Reported local effects on mucous membranes of nose and eyes at 15 mg/m<sup>3</sup> (1969); and irritation of the eyes, nose and throat at 5 mg/m<sup>3</sup>. Concluded that this data was inadequate and not included in evaluation.</li> </ul> <p>Animal data:</p> <ul style="list-style-type: none"> <li>• NOAEC: 10 mg/m<sup>3</sup> for respiratory effects in rats, 13-wk inhalation study:               <ul style="list-style-type: none"> <li>○ 50 and 150 mg/m<sup>3</sup> caused inflammatory hyperplastic changes in the anterior nasal regions</li> <li>○ these effects were reversible</li> </ul> </li> <li>• No reactions observed in appropriately conducted skin patch tests on three rabbits exposed to 500 mg</li> <li>• Irritation of the eye in rabbits after application of 100 mg that persisted for 9, 11 and 28 d</li> <li>• Did not lead to sensitisation effects on the skin in various studies</li> <li>• Reported weak oestrogenic activity and reduced body weights in offspring at high oral doses observed <i>in vivo</i> in oral mouse and rat studies only; estimated at concentrations 20 times higher than the corresponding MAK value</li> <li>• Dermal LD<sub>50</sub>: &gt;3,000 mg/kg (no further information); <i>in vivo</i> studies reported 0.02%, 0.1% and 0.7% absorption</li> <li>• No carcinogenic effects identified.</li> </ul>		
<b>SCOEL</b>	<b>2014</b>	<b>TWA: 2 mg/m<sup>3</sup></b>
<p>TWA recommended to protect for local effects on the respiratory tract in exposed workers.</p> <p>Summary of additional data:</p> <ul style="list-style-type: none"> <li>• Oral NOAEL of 5 mg/kg/d for liver effects in rats and mice (F0 and F1 of 2-gen studies)</li> <li>• Starting point for TWA is NOAEC of 10 mg/m<sup>3</sup> for respiratory effects (rats) divided by an assessment factor of 3 (interspecies extrapolation), then rounded down to 2 mg/m<sup>3</sup> (as per stated SCOEL methodology).</li> </ul>		
<b>OARS/AIHA</b>	<b>NA</b>	<b>NA</b>
No report.		

Source	Year set	Standard
<b>HCOTN</b>	<b>2019</b>	<b>TWA: 3.3 mg/m<sup>3</sup></b>
TLV-TWA is recommended to protect for local effects on the respiratory tract in exposed workers. Summary of additional data:		
<ul style="list-style-type: none"> <li>Concluded available human data not suitable with quantitative assessment based on animal data</li> <li>Recommended TWA is derived from NOAEC of 10 mg/m<sup>3</sup> for respiratory effects (rats), divided by an assessment factor of 3 (interspecies extrapolation)</li> <li>No skin notation warranted based on estimated Critical Absorption Value</li> <li>Some animal data suggests developmental effects but not robust enough for assessment; however, pregnant women and their offspring represent groups at increased risk.</li> </ul>		

## Secondary source reports relied upon

Source	Year	Additional information
NICNAS	✓ 2014	<ul style="list-style-type: none"> <li>Critical health effects include systemic long-term effects of reproductive toxicity and general toxicity (liver and kidney effects) and local effects of skin sensitisation and eye and respiratory irritation</li> <li>Hazard classification in the HCIS (Safe Work Australia) is considered appropriate.</li> </ul>

## Carcinogenicity — non-threshold based genotoxic carcinogens

Is the chemical mutagenic?

No

**The chemical is not a non-threshold based genotoxic carcinogen.**

## Notations

Source	Notations
SWA	NA
HCIS	Skin sensitisation – category 1
NICNAS	—
EU Annex	Skin sensitisation – category 1
ECHA	NA
ACGIH	NA
DFG	—
SCOEL	—
HCOTN	NA
IARC	NA
US NIOSH	SK:SEN

NA = not applicable (a recommendation has not been made by this Agency); — = the Agency has assessed available data for this chemical but has not recommended any notations

## Skin notation assessment

### Calculation

Insufficient data to assign a skin notation.

## IDLH

Is there a suitable IDLH value available? No

## Additional information

Molecular weight:	228.29
Conversion factors at 25°C and 101.3 kPa:	1 ppm = Number mg/m <sup>3</sup> ; 1 mg/m <sup>3</sup> = Number ppm
This chemical is used as a pesticide:	<input type="checkbox"/>
This chemical is a biological product:	<input type="checkbox"/>
This chemical is a by-product of a process:	<input type="checkbox"/>
A biological exposure index has been recommended by these agencies:	<input type="checkbox"/> ACGIH <input type="checkbox"/> DFG <input type="checkbox"/> SCOEL

## Workplace exposure standard history

Year	Standard
<a href="#">Click here to enter year</a>	

## References

Deutsche Forschungsgemeinschaft (DFG) (1999) Bisphenol A – MAK value documentation.

Deutsche Forschungsgemeinschaft (DFG) (2011) Bisphenol A – MAK value documentation.

EU Scientific Committee on Occupational Exposure Limits (SCOEL) (2014) Recommendation from the Scientific Committee on Occupational Exposure Limits for Bisphenol-A. SCOEL/SUM/113.

Health Council of the Netherlands (HCOTN) (2019) Bisphenol-A. Health-based calculated occupational cancer risk values. The Hague: Health Council of the Netherlands; publication no. 2019/32.

National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (2016) Bisphenol-A. Human health tier II assessment – IMAP report.

Tenth Adaptation to Technical Progress Commission Regulation (EU) No 2017/776 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the

US National Institute for Occupational Safety and Health (NIOSH) (2011) Skin Notation Profiles: Bisphenol A (BPA)