

O-PHENYLEDEDIAMINE

CAS number: 95-54-5

Synonyms: 1,2-Benzenediamine, o-diaminobenzene, diolene, orthamine

Chemical formula: $C_6H_8N_2$

Structural formula: —

Workplace exposure standard (retained)

TWA: 0.1 mg/m³

STEL: —

Peak limitation: —

Notations: Carc 2., DSEN

IDLH: —

Sampling and analysis: The recommended value is quantifiable through available sampling and analysis techniques.

Recommendation and basis for workplace exposure standard

A TWA of 0.1 mg/m³ is recommended to protect for potential eye and skin irritation and blood dyscrasia in exposed workers.

Given the limited data available from the primary sources, it is recommended that a review of additional sources be conducted at the next scheduled review.

Discussion and conclusions

o-Phenylenediamine is used in manufacturing of chemical substances such as dyes and photographic developing agents (as an intermediate that will be consumed during synthesis) and in manufacturing lubricants and corrosion inhibitors.

Critical effects of exposure are eye and skin irritation and possible blood dyscrasia.

Limited toxicological data available with no human data available. Slight irritation of the nose is reported in rats following acute inhalation. Slight skin irritation and moderate eye irritation is reported in rabbits following topical application. A single intraperitoneal injection in rats and oral dosing in cats resulted in methaemoglobin formation. A decrease in the number of erythrocytes and increased serum activities of the alkaline phosphatase (ALP), aldolase and alanine (ALA) and aspartate aminotransferase (AAT) reported in rats following oral dosing at 0.8 mg/kg/day for eight weeks. However, no further details are available (ACGIH, 2018). Carcinogenicity reported in animals by the oral route. However, carcinogenicity is not considered relevant to humans (DFG, 1999).

The available data are limited to derive a standard *de novo*. The SWA TWA of 0.1 mg/m³ by ACGIH (2018) is recommended to be retained to limit any irritant effects and blood dyscrasia.

A review of the additional data sources is recommended at the next scheduled review to attempt to address the data gap.

Recommendation for notations

Classified as a category 2 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.

There are insufficient data to recommend a skin notation.

DRAFT

APPENDIX

Primary sources with reports

Source	Year set	Standard
SWA	1991	TWA: 0.1 mg/m³
TWA adopted from ACGIH.		
ACGIH	2001	TLV-TWA: 0.1 mg/m³
TLV-TWA recommended to minimise the potential for possible blood dyscrasia, e.g., reduction of RBC, and eye and skin irritation		
Summary of data:		
• Toxicity comparable to <i>p</i>-phenylenediamine: ◦ TLV-TWA of 0.1 mg/m³ to minimise potential for respiratory and skin sensitisation ◦ protection from eye and skin irritation, dermatitis and blood dyscrasia • Derivation of TLV-TWA not provided.		
Human data:		
• No human data provided.		
Animal data:		
• LC₅₀ male rats and male mice >56 mg/m³ (1 h), >91 mg/m³ (4 h) • LD₅₀: >5,000 mg/kg (rats and rabbits, dermal) • Acute poisoning symptoms include disturbances in respiration, tremor, convulsions, excess salivation and increased excitability • Slight nose irritation in rats following acute inhalation; no further details • Slight skin irritation and moderate eye irritation in rabbits • Single IP injection (10.814 mg/kg) to male rats induced 10.8% methemoglobin; no further details • In cats, methaemoglobin formation was weak with non-lethal oral doses of 25–50 mg/kg • A decrease in the number of RBC and increased serum activities of the ALP, aldolase and ALA and AAT in rats following 0.8 mg/kg/d for 8 wk; no further details provided • Carcinogenic effects in liver of male rats and mice of both sex noted in limited available studies; unknown relevance to humans.		
Insufficient data to recommend a sensitiser or skin notation or TLV-STEL.		
DFG	1999	Not assigned
MAK not recommended due to evidence of carcinogenicity in the form of liver tumours in rats and mice.		
Summary of additional data:		
• Eye irritation observed in animal experiments • Oral diet studies in rats and mice; significant increase in liver tumours in male rats in the high dose group (5/16, controls: 0/16), in male mice in the low dose group (5/17, controls: 0/14) and in female mice in both dose groups (6/18, 6/15; controls: 1/15).		
SCOEL	NA	NA
No report.		



Source	Year set	Standard
OARS/AIHA	NA	NA
No report.		
HCOTN	NA	NA
No report.		

Secondary source reports relied upon

Source	Year	Additional information
NICNAS	✓ 2013	- Oral LD₅₀ in cats reported as >50 and <250 mg/kg; symptoms including respiratory disturbance, agitation, methaemoglobinaemia, saltatory spasms and mottled livers 4 h LC₅₀: 1,873 mg/m³ in rats; >91 mg/m³ in mice - No reliable carcinogenicity data/studies available.

Carcinogenicity — non-threshold based genotoxic carcinogens

Is the chemical mutagenic? Insufficient data

Is the chemical carcinogenic with a mutagenic mechanism of action? No

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

Notations

Source	Notations
SWA	—
HCIS	Carcinogenicity – category 2, Skin sensitisation – category 1
NICNAS	Carc. Cat. 3
EU Annex	Carcinogenicity – category 2, Skin sensitisation – category 1
ECHA	NA
ACGIH	Carcinogenicity – A3
DFG	Carcinogenicity – 3, Sh (dermal sensitiser)
SCOEL	NA
HCOTN	NA
IARC	Carcinogenicity – Group 2B
US NIOSH	NA

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:	108.14
Conversion factors at 25°C and 101.3 kPa:	1 ppm = Number mg/m ³ ; 1 mg/m ³ = Number ppm
This chemical is used as a pesticide:	☐
This chemical is a biological product:	☐
This chemical is a by-product of a process:	☐
A biological exposure index has been recommended by these agencies:	☐ ACGIH ☐ DFG ☐ SCOEL

Workplace exposure standard history

Year	Standard
Click here to enter year	

References

American Conference of Industrial Hygienists (ACGIH®) (2018) TLVs® and BEIs® with 7th Edition Documentation, CD-ROM, Single User Version. Copyright 2018. Reprinted with permission. See the [TLVs® and BEIs® Guidelines section](#) on the ACGIH website.

Deutsche Forschungsgemeinschaft (DFG) (1999) o-Phenylenediamine – MAK value documentation.

International Agency for Research on Cancer (IARC) (in preparation). IARC Monographs on the evaluation of the carcinogenic risk to humans, Volume 123.

National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (2013) 1,2-Benzenediamine: 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 European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (the CLP Regulation).