

English Version

Footwear - Critical substances potentially present in footwear and footwear components - Lists of critical chemical substances (ISO/TR 16178:2021)

Chaussures - Substances critiques potentiellement présentes dans la chaussure et les composants de chaussures - Listes des substances chimiques critiques (ISO/TR 16178:2021)

Schuhe - Möglicherweise in Schuhen und Schuhbestandteilen vorhandene kritische Substanzen (ISO/TR 16178:2021)

This Technical Report was approved by CEN on 26 July 2021. It has been drawn up by the Technical Committee CEN/TC 309.

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COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (CEN ISO/TR 16178:2021) has been prepared by Technical Committee ISO/TC 216 "Footwear" in collaboration with Technical Committee CEN/TC 309 "Footwear" the secretariat of which is held by UNE.

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This document supersedes CEN ISO/TR 16178:2012.

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Endorsement notice

The text of ISO/TR 16178:2021 has been approved by CEN as CEN ISO/TR 16178:2021 without any modification.

Contents

	Page
Foreword	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Presence of chemicals in footwear materials	2
5 Critical substances potentially present in footwear and footwear components	8
5.1 Acrylonitrile	8
5.1.1 General	8
5.1.2 Potential risks	8
5.1.3 Test methods	8
5.2 Alkylphenols and Alkylphenol ethoxylates (NP, OP, NPEO, OPEO)	8
5.2.1 General	8
5.2.2 Potential risks	9
5.2.3 Test methods	9
5.3 Aromatic amines	10
5.3.1 General	10
5.3.2 Potential risks	11
5.3.3 Test methods	11
5.4 Benzene	11
5.4.1 General	11
5.4.2 Potential risks	11
5.4.3 Test methods	11
5.5 Biocides	12
5.5.1 Orthophenylphenol	12
5.5.2 2-(thiocyanatomethylthio)-1,3-benzothiazole (TCMTB)	12
5.5.3 2-octylisothiazol-3(2H)-one (OIT)	13
5.5.4 4-Chloro-3-methylphenol (CMK)	13
5.5.5 Triclosan	14
5.6 Bisphenol	15
5.6.1 General	15
5.6.2 Potential risks	15
5.6.3 Test methods	15
5.7 Cadmium – Cd	15
5.8 Chlorinated paraffins	15
5.8.1 General	15
5.8.2 Potential risks	16
5.8.3 Test methods	16
5.9 Chlorobenzenes and chlorotoluenes	16
5.9.1 General	16
5.9.2 Potential risks	17
5.9.3 Test methods	17
5.10 Chromium and Chromium VI	17
5.11 Colophony	18
5.11.1 General	18
5.11.2 Potential risks	18
5.11.3 Test methods	18
5.12 Dimethylformamide	18
5.12.1 General	18
5.12.2 Potential risks	19
5.12.3 Test methods	19
5.13 Dimethylfumarate (DMFu)	19
5.13.1 General	19
5.13.2 Potential risks	19

5.13.3	Test methods	20
5.14	Disperses dyes	20
5.14.1	General	20
5.14.2	Potential risks	21
5.14.3	Test methods	21
5.15	Flame retardants	21
5.15.1	General	21
5.15.2	Potential risks	22
5.15.3	Test methods	22
5.16	Formaldehyde	22
5.16.1	General	22
5.16.2	Potential risks	22
5.16.3	Test methods	23
5.17	Heavy metals	23
5.17.1	General	23
5.17.2	List of heavy metals	23
5.17.3	Potential risks	23
5.17.4	Test methods	25
5.17.5	Special cases	25
5.18	Mercaptobenzothiazole	26
5.18.1	General	26
5.18.2	Potential risks	27
5.18.3	Test methods	27
5.19	N-ethylphenylamine	27
5.19.1	General	27
5.19.2	Potential risks	27
5.19.3	Test methods	27
5.20	N methyl-2-pyrrolidone (NMP)	27
5.20.1	General	27
5.20.2	Potential risks	28
5.20.3	Test methods	28
5.21	N,N-dimethylacetamide	28
5.21.1	General	28
5.21.2	Potential risks	28
5.21.3	Test methods	28
5.22	Nickel – Ni	28
5.23	Nitrosamines	28
5.23.1	General	28
5.23.2	Potential risks	29
5.23.3	Test methods	29
5.24	Organotins compounds	29
5.24.1	General	29
5.24.2	Potential risks	30
5.24.3	Test methods	30
5.25	PAHs (Polycyclic aromatic hydrocarbons)	31
5.25.1	General	31
5.25.2	Potential risks	31
5.25.3	Test methods	32
5.26	Paraphenylene diamine	32
5.26.1	General	32
5.26.2	Potential risks	32
5.26.3	Test methods	32
5.27	Pesticides	32
5.27.1	General	32
5.27.2	Potential risks	32
5.27.3	Test methods	33
5.28	Perfluorinated and polyfluorinated chemicals-PFC	33
5.28.1	Different substances	33

5.28.2	Potential risks	36
5.29	pH	36
5.29.1	General	36
5.29.2	Potential risks	37
5.29.3	Test methods	37
5.30	Phenol	37
5.30.1	General	37
5.30.2	Potential risks	37
5.30.3	Test methods	37
5.31	Phenyl mercury	37
5.31.1	General	37
5.31.2	Potential risks	38
5.31.3	Test methods	38
5.32	Phthalates	38
5.32.1	General	38
5.32.2	Potential risks	40
5.32.3	Test methods	40
5.33	Polychlorophenols	40
5.33.1	General	40
5.33.2	Potential risks	42
5.33.3	Test methods	42
5.34	Paratertiary butyl phenol formaldehyde (PTBF)	42
5.34.1	General	42
5.34.2	Potential risks	42
5.34.3	Test methods	42
5.35	Quinoline	42
5.35.1	General	42
5.35.2	Potential risks	43
5.35.3	Test methods	43
5.36	Thiuram and thiocarbamate	43
5.36.1	General	43
5.36.2	Potential risks	43
5.36.3	Test methods	43
5.37	Volatile organic compounds (VOC)	44
5.37.1	General	44
5.37.2	Potential risks	44
5.37.3	Test methods	44
Bibliography		46

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/foreword.html.

This document was prepared by Technical Committee ISO/TC 216, *Footwear*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 309, *Footwear*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO/TR 16178:2012), which has been technically revised.

The main changes compared to the previous edition are as follows:

- new [Table 1](#) including a new system of grading;
- withdrawn substances:
proteins in latex, substances destroying ozone layer, polychlorobiphenyls, polychloroprene, vinyl chloride;
- added substances:
benzene, bisphenol, NMP, DMAC, phenyl mercury, quinoline, VOC;
- biocides are grouped together (CMK, OIT, OPP, TCMTB);
- Annex A is now in ISO 21061^[67];
- Annex B is now [Clause 5](#);
- bibliography, updated.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Footwear — Critical substances potentially present in footwear and footwear components — Lists of critical chemical substances

1 Scope

This document defines lists of critical chemical substances potentially present in footwear and footwear components.

This document describes the critical chemical substances, their potential risks of nocuousness, in which materials they could be found, and which test method(s) can be used to quantify them.

The test methods listed indicate the state of the art. For some substances, a test method is not available.

This document is applicable to any kind of footwear and footwear components.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

allergen

substance that is capable of inducing an allergic reaction

3.2

allergy

immunologically mediated response to certain specific substances (allergens)

Note 1 to entry: Type-1 allergy (respiratory allergy) is mediated by IgE antibodies, can cause asthma, rhinitis, urticaria. Type-4 allergy (dermal allergy) is mediated by T-cells, can cause dermatitis.

3.3

limit of detection

value from which a substance is considered as detectable

Note 1 to entry: This means that the signal associated to the substance is three times bigger than the background noise signal. The limit of detection is determined experimentally by the laboratory for each substance.

3.4

critical substances

chemical substance that can be found in footwear or footwear components and can have an effect on the wearer and/or environmental impact due to its chemical reactivity

Note 1 to entry: The effects caused by critical substances vary. It can be carcinogenic or mutagenic effects, allergy, reaction to toxics, etc.