TECHNICAL REPORT

# ISO/TR 16178

Third edition
2021-09

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

*Chaussures — Substances critiques potentiellement présentes dans la chaussure et les composants de chaussures — Listes des substances chimiques critiques*

Reference number
ISO/TR 16178:2021(E)

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Published in Switzerland

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# Foreword

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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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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/iso/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— withdrawn substances: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.


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# 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.

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**3.4.1**
**critical substances category 1**
substances with proven dangerous effect on the wearer

Note 1 to entry: These substances are widely restricted by national regulation in several countries.

**3.4.2**
**critical substances category 2**
substances with dangerous effect on the wearer

Note 1 to entry: These substances are restricted by national regulation in a limited number of countries.

**3.4.3**
**critical substances category 3**
substances that are highly suspected to have an effect on the wearer

Note 1 to entry: These substances might not be restricted by regulation at the time of publication but they are frequently requested by the market stakeholders.

**3.4.4**
**critical substances category 4**
substances that are suspected to have an effect on the wearer

Note 1 to entry: These substances might not be restricted by regulation. Substances known to have an allergenic effect on the wearer are included in category 4 for reference.

## 4 Presence of chemicals in footwear materials

A number of chemicals are present in footwear materials. Table 1 lists the following:

a) in which materials they are supposed to be. The possible materials potentially used in the footwear industry are given in ISO 21061:2021[67], Annex C.

b) a list of critical chemicals, (see Clause 5 for information);

c) test methods that can be used to quantify them (see Bibliography);

d) the potential risks associated with their use, assessed by the use of the critical substances' category scale

   1) stand for "critical substances category 1";

   2) stand for "critical substances category 2";

   3) stand for "critical substances category 3";

   4) stand for "critical substances category 4".

For composite materials, the tests should be conducted on the entire component.

EXAMPLE 1 Coated textile (cotton + PVC coating). Test on PVC and test on cellulosic natural fibres should be done.

EXAMPLE 2 Mixed textile (PES + cotton). Test on cellulosic natural textile and test on PES textile should be done.


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