
**Footwear — Critical substances
potentially present in footwear and
footwear components**

*Chaussures — Substances critiques potentiellement présentes dans la
chaussure et les composants de chaussures*

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 16178 was prepared by the European Committee for Standardization (CEN) in collaboration with ISO Technical Committee TC 216, *Footwear*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna agreement).

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Footwear — Critical substances potentially present in footwear and footwear components

1 Scope

This Technical Report establishes a list of critical chemical substances potentially present in footwear and footwear components.

This Technical Report describes the critical chemical substances, their potential risks, in which materials they could be found, and which test method(s) can be used to quantify them. It does not include requirements; it is the responsibility of the user of this Technical Report to fix his level of acceptance, e.g. using a defined concentration or detection limit or quantification limit, etc.

The proposed test methods indicate the state of the art. Some substances do not include a test method, as no normative test method is available at the moment of the publication of this Technical Report. If possible, it will be included in a further revision of this Technical Report.

This Technical Report applies to any kind of footwear and footwear material.

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2 Terms and definitions

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

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2.1

allergen

substance that is capable of inducing an allergic reaction

2.2

allergy

immunologically mediated response to certain specific substances (allergens)

NOTE Type-1 allergy is mediated by IgE antibodies, may cause asthma, rhinitis, urticaria. Type-4 allergy is mediated by T-cells, may cause dermatitis.

2.3

detection limit

value from which a substance is considered as detectable

NOTE 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.

2.4

quantification limit

value from which a substance is considered as measurable

NOTE It is the value where the uncertainty of measurement is equal to 50 % of the determined value.

2.5

absence of a chemical

a chemical is absent from a material, when the test method is unable to detect it

NOTE The amount of the chemical is smaller than the detection limit of the test method.

2.6
critical substances

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

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

NOTE 2 Legislations could change; this Technical Report gives the information available at its publication date. It is the responsibility of the user of this Technical Report to ensure that no changes occur.

2.6.1
critical substances category 1

substances with proven dangerous effect on the wearer

NOTE These substances are restricted by regulation at European level.

2.6.2
critical substances category 2

substances with dangerous effect on the wearer

NOTE These substances are restricted by regulation at national level in some countries.

2.6.3
critical substances category 3

substances with environmental impact

NOTE These substances are mentioned in European Ecolabel

2.6.4
critical substances category 4

substances that are highly suspected to have an effect on the wearer

NOTE These substances may not be restricted by regulation at the present time.

2.6.5
critical substances category 5

substances that are suspected to have an effect on the wearer

NOTE These substances may not be restricted by regulation at the present time.

3 Presence of chemicals in footwear materials

A number of chemicals are present in footwear materials. Table 1 gives:

- a) in which materials they are supposed to be, (see Annex A for all information);
- b) the list of the critical chemicals, (see Annex B for all information);
- c) test methods that can be used to provoke and quantify them;
- d) the potential risk associated, assessed by the use of the critical substances category scale (see Clause 3.6).

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.

Table 1 — Critical chemicals potentially present in footwear and footwear components

Substance (see Annex B)	Test method	leather			Synthetic material										Natural material				Miscellaneous			
		Leather	Coated leather	Leather board	PVC	EVA	Rubber	PU - TPU elasthan	PE-T PP	Polyester	Polyamide	Chloride fibre	Polyacrylic	Latex	Cellulosic natural textile	Proteinic natural textile	Wood - cork	Adhesives	Metal hardware	Prints for textile	Cellulose	
Acrylonitrile							5											5				
AZO - arylamines	ISO 17234-1	1	1	1																		
AZO - arylamines When 4- aminoazobenzene is suspected	ISO 17234-2	1	1	1																		
AZO - arylamines	EN 14362-1										1	1	1	1	1	1				1		
AZO - arylamines	EN 14362-2								1											1		
AZO - arylamines When 4- aminoazobenzene is suspected	EN 14362-3								1	1	1	1	1	1	1	1				1		
Cadmium Special requirement for PVC	EN 1122		1		1	1	1	1													1	
Chloroorganic carriers																						
Chromium VI	ISO 17075	2	2	2						3												
Colophony																		5				
Dimethylformamide (DMF)			4																			
Dimethylfumarate (DMFU)		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			1	1	1
Disperses dyes and dyestuffs	DIN 54231:2005										2	2	2	2	2	2						
Flame retardant Only for product claiming FR properties		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1			1	1	1
Formaldehyde	ISO 17226-1 and ISO 17226-2	2	2	2																		
Formaldehyde	EN 120																					2
Formaldehyde	ISO 14184-1								2	2	2	2	2	2	2	2						2

Table 1 (continued)

Substance (see Annex B)	Test method	Leather			Synthetic material								Natural material				Miscellaneous					
		Leather	Coated leather	Leather board	PVC	EVA	Rubber	TPU elasthan	PE-T PP	Polyester	Polyamide	Chloride fibre	Polyacrylic	Latex	Cellulosic natural textile	Proteinic natural textile	Wood - cork	Adhesives	Metal hardware	Prints for textile	Cellulose	
Heavy metals	ISO 17072-1	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4		4	4	4
		4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4		4	4	4
	ISO 17072-2	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4		4	4	4
		4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4		4	4	4
Footwear for children less than 36 months	EN 14602:2004	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3		3	3	3	3
	EN 71-3	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2		2	2	2	2
Mercapto benzothiazole																						
Extractible latex proteins	EN 455-3												4									
N-ethylphenylamine																						
Nickel	EN 1811 CR 12471 (with or without EN 12472)																					1
Nitrosamines	EN 12868																					

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Annex A (informative)

Materials used in the footwear industry

A.1 Leather

A general term for hide or skin with its original fibrous structure more or less intact, tanned to be rotproof. The hair or wool might or might not have been removed. Leather is also made from a hide or skin which has been split into layers, or segmented, either before or after tanning. However, if the tanned hide or skin is disintegrated mechanically and/or chemically into fibrous particles, small pieces or powders and then, with or without the combination of a binding agent, is made into sheets or other forms, such sheets or forms are not leather. If the leather has a surface coating, whatever is applied, or a glued on finish, such surface coating layers should not be thicker than 0,15 mm.

A.2 Coated leather

Leather where the surface coating applied to the leather does not exceed one third of the total thickness of the product, but is in excess of 0,15 mm.

A.3 Leather fibre board

Term for materials where tanned hides or skins are disintegrated, mechanically and/or chemically, into fibrous particles, small pieces or powders and then, are made into sheets or other forms, with or without the combination of a binding agent. A minimum amount of 50% in weigh of dry leather is necessary to use the term leather fibre board.

A.4 PVC

Polymer constituted of polymerised vinyl chloride. In footwear material, PVC is used with plasticizer in order to create flexibility. It can also be used as polymeric coating in a coated fabric or patent leather.

A.5 EVA foam

Polymer composed of ethylene vinyl acetate; it can be expanded to foam. It is used as a lightweight midsole in some trainers and as an outsole in some summer sandals where resistance to abrasion is not required.

A.6 Rubber, synthetic rubber, rubber foam

Rubbers are polymers based on either synthetic or natural materials that are cross-linked to give required physical performance properties and chemical resistance. Extensively used as outsoles in many styles of footwear. (See ISO 1382)

A.7 Thermoplastic polyurethanes (TPU)

Thermoplastic polyurethanes are compounds formed from the condensation of isocyanates and polyols and can be remoulded on the application of heat. They can be in moulded in the compact or cellular forms.

A.8 Thermoplastic elastomers or thermoplastic rubbers (TPE-TPR)

Thermoplastic elastomers or thermoplastic rubbers (not vulcanized) (TPE or TPR) combine the processability of plastics with the flexibility and durability of rubbers, while more light weight and formable. These properties provide favourable conditions for the production of thermoplastic materials, due to a structure consisting of block copolymers that combine elastic chain segments with rubbery properties, and very rigid segments (at room temperature). They play the same role as the sulphur bonds formed during vulcanisation process, i.e. to prevent the chain displacement against stress. However, due to the absence of a cross-linked structure, cohesion is lost when exceeding the glass transition temperature and the hot material can flow and is suitable for injection moulding.

A.9 Latex

Rubber latex is a water-based colloidal solution that includes spherical rubber particles with a diameter smaller than 1 µm, dispersed in an aqueous continuous phase and relatively stable. Due to its hydrophobic nature, it is non-miscible with water, and the suspension is stabilised due to the fact that every rubber particle is coated with a layer of natural or synthetic emulsifiers (see ISO 1382).

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A.10 Blown material, foam (standards.iteh.ai)

Synthetic expanded polymer with a closed-cell or open-cell structure, which may be flexible or rigid, used for a variety of products.

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A.11 Composite materials

Composites, also known as composite materials or reinforced plastics, consist of a polymeric matrix or continuous phase and a discrete phase, made up of one or more loads or reinforcements in the form of mineral and/or synthetic fibres. As a result, a structural material is obtained, whose mechanical properties are, at least, higher than the values obtained from the lineal combination of the individual properties of both constituents. For instance, carbon or glass fibres are commonly used as reinforcing materials.

A.12 Polyurethane (PU)

The polyurethane includes those polymers with urethane groups in the molecular backbone, regardless of the chemical composition of the rest of the chain. Urethane groups (see Figure A.1) are produced through a chemical reaction between a diisocyanate and a polyol. Thus, typical polyurethane may contain, in addition to the urethane linkages, aliphatic and aromatic hydrocarbons, esters, ethers, amides, urea and isocyanurates groups. A wide range of properties can be obtained depending on chemical composition used: thermoplastic, thermoset, rigid or flexible, cellular or compact polyurethanes, etc. Polyurethanes are used as structural materials, coatings, adhesives and sealants.

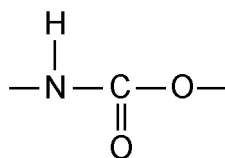


Figure A.1 — Urethane groups

A.13 Textile

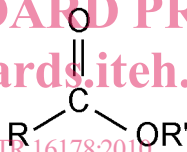
Originally used to describe a woven fabric the term now is applied to fibres, filaments, or yarns, natural or man-made, and products obtained from them.

NOTE For example, threads, cords, ropes, braids, lace, embroidery, nets and fabrics made by weaving, knitting, felting, bonding, and tufting are textiles.

A.14 Polyester

Polymer with ester bonds in its main string (See Figure A.2). Today, the definition of polyester includes the big family of synthetic polymer, with the most used polycarbonate and most of all poly(ethylene terephthalate) (PET).

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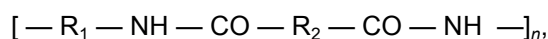
Figure A.2 — Ester bond

A.15 Polyester fibre

Fibres composed of synthetic linear macromolecules having in the chain at least 85 % (by mass) of an ester of a diol and benzene — 1,4 — dicarboxylic acid (terephthalic acid).

A.16 Polyamides

A synthetic linear polymer in which the linkage of the simple chemical compound or compounds used in its production takes place through the formation of amide groups, e.g.,



Where R, R₁, and R₂ are generally, but not necessarily, linear divalent hydrocarbon chains (—CH₂—)_m.

Polyamides are distinguished from one another by quoting the number of carbon atoms in the repeating unit, or units for polyamides made from two reactants. In the latter case, the number of carbon atoms in the diamine is given first, this being followed by the number in the dicarboxylic acid, e.g.,

- hexanolactam (E – caprolactam)

