

Personal protective equipment INNOCUOUSNESS OF MATERIALS



This document lists the potentially hazardous substances that may be present in textiles used in PPE. This document is applicable to all PPE containing textile. If there are other materials than textile ones involved, the appropriate document (leather, polymers...) may be used to further assess the innocuousness of the PPE.

Column "Chemical": lists the hazardous substances that could be used in the PPE materials or in its usual manufacturing process. It thus enables to check only the hazardous substances that would be used in the material considered and thus better respond to the mandatory assessment of materials innocuousness.

Column "Test method and conditions": quotes the relevant test method which is representative of the risk for the PPE user. Thus, unless otherwise advised, the materials shall be tested after extraction in a sweat simulant (for example as described in ISO 105-E04 standard) or any simulant corresponding to the use of the PPE (eg. oil for PPE in food contact). If there is no standard method, laboratories may suggest to use internal test methods based on the analysis of the extracts in simulants. If it is required to detect an allergenic substance, it shall be done by a relevant analytical method of an extracted solution in water, if there is no other existing test method; the test shall be considered as positive if the result exceeds the detection limit.

Column "Mandatory": The test is noted as mandatory if it is required for the CE certification. In other cases, the SYNAMAP recommends to perform the test in case it is uncertain whether the substances in table 1 are used or may be present, and only at customer request for the substances in table 2.

## Warnings

This document is an indicative guideline only and cannot pretend to guarantee innocuousness. In fact, substances found in PPE materials depend on the origin of the raw materials and processes used. Thus some tests indicated as recommended may have to be done if the processes or the materials used are unknown or in case of a doubt on them.

Some PPE applications may require compliance to specific requirements or regulation (eg. ATEX directive for environments with risk of explosion, food contact etc....). in such case, these specific requirements must be taken into account by using the appropriate documents.



#### Innocuousness

All PPE must comply to the requirements of the European Directive 89/686/CE concerning innocuousness. Thus PPE must be so designed and manufactured as to preclude risks and other nuisance factors under foreseeable conditions of use. Regarding materials, the clause 1.2.1.1 of the directive applies:

1.2.1.1 Suitable constituent materials: PPE materials and parts, including any of their decomposition products, must not adversely affect user hygiene or health.

The compliance must be checked by using the relevant harmonised European standards. Thus the pH (acid, alkaline) requirement quoted in numerous standards such as EN340 (protective clothing) or EN 420 (protective gloves) must be ascertained.

# Where to find the reference documents:

European Directives : www.eur-lex.eu

EN, ISO standards: National Standard Organisation . For France :www.afnor.org

Ecolabel: www.eco-label.com Ecolabel for textiles: Decision 2009/567/CE Ecolabel for shoes: Decision 2009/563/CE

Oekotex 100 and 200 : www.oeko-tex.com

### Contact

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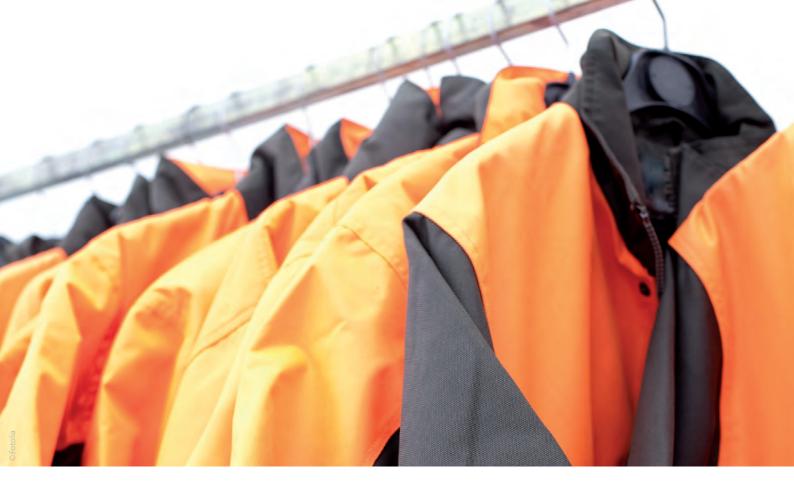


Table 1: "List of substances that may be present in textiles"

Chemical	Test method and conditions	Requirements	Mandatory	Concerns	Notes
рН (acid/alkaline)	EN ISO 3071 - EN 1413	Clothing, gloves 3.5 ≤ pH ≤ 9.5 EN 420, EN 340 Shoes >3.2 Difference index ≤0.7 EN ISO 20346/20347	YES	All textiles	
Aromatic amines, arylamines	EN ISO 14362-1/2 if 4-aminoazobenzene is detected : prEN ISO 14362-2	≤30 mg/kg Directive 2003/3/CE ≤ 20 mg/kg Oekotex cat II/III	YES	All pigmented textiles and sewing yarns	
Cadmium	EN 1122	≤ <b>0.01%</b> Directive 91/338/CE	NO	Plastics	
Chlorophenols (PCP, TeCP)	XPG 08-015 Ecolabel for textile FD CEN/TR 14823	< 0.05 mg/kg Ecolabel for textile <0.5 mg/kg Oekotex cat II	NO	Textiles made of natural fibres	Mandatory in Germany
Dimethylfumarate CAS 624-49-7	No standard method	≤0.1 mg/kg Decision 2009/251/EC	YES	Textiles in combination with leather	
Dimethylformamide CAS 68-12-2	No standard method	No requirement ≤ 10 mg/kg (Germany)	NO	Polyurethane	See the specific document from SYNAMAP on www.synamap.fr
Formaldehyde CAS 50-00-0	EN ISO 14184-1	≤ 30 mg/kg Ecolabel for textile Skin contact ≤ 75 mg/kg Ecolabel for textile Other cases ≤ 20 mg/kg Ecolabel for shoes	NO	All textiles Textiles for shoes	May be required by notified bodies, especially in case of direct skin contact
Extractable Nickel	See "Other Materials"			Presence of metal parts	
Organostannic compounds (TBT, TPT, DBT, DOT)	No standard method Oekotex 200	≤ <b>0.1% stain</b> Decision 2009/425/CE ≤ <b>0.05 mg/kg</b> Ecolabel for textile	NO	All textiles	Substances progressively banned: TBT,TPT: 1/07/2010 DBT, DOT: 1/07/2012
Perfluoroctanes : PFOS PFOA – CAS 3825-26-1	No standard method	≤ <b>0.1% (PFOS)</b> Directive 2006/122/CE	YES	Textiles treated for flame retardancy / water resistance	
Phthalates (DINP, DNOP, DEHP, DIDP, BBP, DBP)	See "Polymer" document			Polymer coated textiles	
Flame retardants (PBB, TRIS, TEPA, PBDE, OBDE)	No standard method	≤ <b>0.1%</b> (PBDE,OBDE) Directive 2003/11/CE	YES	Textiles treated for flame retardancy	

Table 2: "List of substances that may be marginally used in textiles" – without mandatory testing for CE certification

Chemical	Test methods and conditions	Requirements	Concerns	Notes
Acrylonitrile monomer	No standard method	≤ <b>1,5 mg/kg</b> Ecolabel for textiles	Acrylic	
Chloroalkanes (short chlorinated paraffinic compounds)	No standard method	≤ <b>1%</b> Directive 2002/45/CE	Textiles for shoes	
Vinyl chloride monomer	ISO 6401		PVC coated textiles	
Organo-halogenated compounds	No standard method Total content Oekotex 200	≤ <b>250 mg/kg</b> Ecolabel for textiles	Artificial cellulosic fibres	
Nonylphenol CAS 104-40-5 Nonylphenol ethoxylate CAS 9016-45-9	No standard method	≤ <b>0.1%</b> Directive 2003/53/CE	All textiles	
Orthophenylphenol (OPP) CAS 90-43-7	No standard method Total content Oekotex 200	≤ 100,0 mg/kg Oekotex cat II/III	All textiles	
Paraphenylene diamine (PPD) – CAS 106-50-3	No standard method	Detection limit	Dark pigmented textiles	The manufacturer must inform the user that this allergen is used.
<b>Pesticides</b> (Fungicides, Biocides, Herbicides, Insecticides)	No standard method Total content Oekotex 200	≤ 0,05 mg/kg For each substance Ecolabel for textiles ≤ 1,0 mg/kg Oekotex cat II/III	Textiles made of natural fibres	
Polychlorobiphenyls Polychloroterphenyls (PCB, PCT)	EN ISO 17070	≤ <b>0,1 mg/kg</b> Directive 76/769/CE ≤ <b>0,05 mg/kg</b> Ecolabel for textiles	All textiles	
<b>Total heavy metals</b> (As, Pb, Cd)	prEN ISO 17072-2	≤ 100 mg/kg For each part Ecolabel for shoes	Textiles for shoes	
Extractible Antimony (Sb)	prEN ISO 17072-1	≤ <b>30 mg/kg</b> Oekotex cat II/III	All textiles	
Extractible Arsenic (As)	prEN ISO 17072-1	≤ <b>1,0 mg/kg</b> Oekotex cat II/III	All textiles	
Extractible Lead (Pb)	prEN ISO 17072-1	≤ <b>1,0 mg/kg</b> Oekotex cat II/III	All textiles	
Extractible Chromium (Cr)	prEN ISO 17072-1	≤ <b>2,0 mg/kg</b> Oekotex cat II/III	All textiles	
Extractible Cobalt (Co)	prEN ISO 17072-1	≤ <b>4,0 mg/kg</b> Oekotex cat II/III	All textiles	
Extractible Copper (Cu) extractible	prEN ISO 17072-1	≤ <b>50,0 mg/kg</b> Oekotex cat II/III	All textiles	
Extractible Nickel (Ni)	prEN ISO 17072-1	≤ <b>4,0 mg/kg</b> Oekotex cat II/III	All textiles	
Extractible Mercury (Hg)	prEN ISO 17072-1	≤ <b>0,02 mg/kg</b> Oekotex cat II/III	All textiles	

### **SYNAMAP**

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