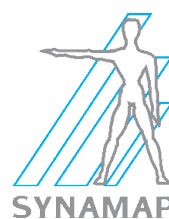


Leather



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Personal protective equipment
INNOCUOUSNESS OF MATERIALS



This document lists the potentially hazardous substances that may be present in leather used in PPE. It is applicable to all PPE containing leather. If there are other materials than leather involved, then the appropriate document (polymer, textile...) may be used to further check 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. Thus it 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 to 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...). 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 leather"

Chemical	Test method and conditions	Requirements	Mandatory	Concerns	Notes
pH (acid/alkaline)	EN ISO 4045	Vêtements, gants 3,5 ≤ pH ≤ 9,5 EN 420, EN 340 Chaussures >3.2 / indice différence ≤0,7 EN ISO 20345/	YES	All leathers	
Aromatic amines, arylamines	EN ISO TS 17234 if 4-aminoazobenzene is detected : prEN ISO 17234-2	≤30 mg/kg Directive 2003/3/CE ≤ 20 mg/kg Oekotex cat II/III	YES	All coloured leathers and sewing yarns	
Cadmium	See "Polymer" document			Polymer coated leather	
Chlorophenols (PCP, TeCP...)	EN ISO 17070	≤ 0.1 mg/kg Ecolabel chaussures <0.5 mg/kg Oekotex cat II	NO	All leathers	Mandatory in Germany
Chromium VI	EN ISO 17075	≤ 3 mg/kg EN420, EN ISO 20344	YES	All chromium tanned or pigmented leathers	
Dimethylfumarate CAS 624-49-7	No standard method	≤0,1 mg/kg Décision 2009/251/EC	YES	All leathers	
Formaldehyde CAS 50-00-0	EN ISO 17226-1 or 2	≤ 150 mg/kg Ecolabel chaussures	NO	All leathers	May be required by notified bodies, especially in case of direct skin contact
Extractable heavy metals	prEN ISO 17072-1	≤ 2,0 mg/kg Oekotex cat II	NO	All leathers	
Organostannic compounds (TBT, TPT, DBT, DOT)	ISO 17353 for analysis	≤ 0,1% étain Décision 2009/425/EC	NO	All leathers	Substances progressively banned : TBT,TPT : 1/07/2010 DBT, DOT : 1/07/2012
Perfluoroctanes : PFOS PFOA – CAS 3825-26-1	No standard method	≤ 0,1% (PFOS) Directive 2006/122/CEE	YES	Leathers treated for flame retardancy / water resistance	
Phthalates (DINP, DNOP, DEHP, DIDP, BBP, DBP...)	See "Polymer" document			Polymer coated leather	
Flame retardants (PBB, TRIS, TEPA, PBDE, OBDE)	No standard method	≤ 0,1% (PBDE,OBDE) Directive 2003/11/CE	YES	Leather treated for flame retardancy	

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

Chemical	Test methods and conditions	Requirements	Concerns	Notes
Chloroalkanes (short chlorinated paraffinic compounds)	No standard method	≤1% - Products from tannery Directive 2002/45/CE	All leathers	
Vinyl chloride monomer	See "Polymer" document		PVC coated leathers	
Polycyclic aromatic hydrocarbons	No standard method Total content Oekotex 200	≤ 0,3 mg/kg Oekotex cat II/III	All leathers	
Total metal content (As, Pb, Cd)	EN 14602 prEN ISO 17072-2	≤ 100 mg/kg For each part Ecolabel for shoes	All leathers	
Nonylphenol CAS 104-40-5 Nonylphenol ethoxylate CAS 9016-45-9	No standard method	≤ 0,1% Directive 2003/53/CE	All leathers	
Orthophenylphenol (OPP) CAS 90-43-7	No standard method Oekotex 200	≤ 100,0 mg/kg Oekotex cat II/III	All leathers	
Paraphenylene diamine (PPD) – CAS 106-50-3	No standard method	Detection limit	Cuir de couleur sombre	The manufacturer must inform the user that this allergen is used.
Pesticides (Fungicides, Biocides, Herbicides, Insecticides)	No standard method Total content Oekotex 200	≤1,0 mg/kg Oekotex cat II/III	All leathers	
Polychlorobiphenyls Polychloroterphenyls (PCB, PCT)	EN ISO 17070	≤ 0,1 mg/kg (Detection limit) Directive 76/769/CE	All leathers	
TCMTB (2-thiocyanomethyl-thiobenzothiazole) CAS 21564-17-0	No standard method	Detection limit	All leathers	
Extractible Antimony (Sb)	prEN ISO 17072-1	≤ 30 mg/kg Oekotex cat II/III	All leathers	
Extractible Arsenic (As)	prEN ISO 17072-1	≤ 1,0 mg/kg Oekotex cat II/III	All leathers	
Extractible Lead (Pb)	prEN ISO 17072-1	≤ 1,0 mg/kg Oekotex cat II/III	All leathers	
Extractible Chromium (Cr)	prEN ISO 17072-1	≤ 2,0 mg/kg Oekotex cat II/III	All leathers	
Extractible Cobalt (Co)	prEN ISO 17072-1	≤ 4,0 mg/kg Oekotex cat II/III	All leathers	
Extractible Copper (Cu) extractible	prEN ISO 17072-1	≤ 50,0 mg/kg Oekotex cat II/III	All leathers	
Extractible Nickel (Ni)	prEN ISO 17072-1	≤ 4,0 mg/kg Oekotex cat II/III	All leathers	
Extractible Mercury (Hg)	prEN ISO 17072-1	≤ 0,02 mg/kg Oekotex cat II/III	All leathers	

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