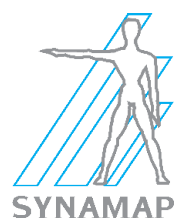


Polymers



Personal protective equipment
INNOCUOUSNESS OF MATERIALS



This document lists the potentially hazardous substances that may be present in polymers (plastics and rubbers) used in PPE. Synthetic polymeric fibres are included in the "textile" document. This document is applicable to all PPE containing a polymer. If there are materials than polymers involved, the appropriate document (leather, textile...) 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 polymers"

Substance chimique	Méthode d'essai et conditions	Exigence	Obligation	Concerne	Remarques
pH (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 polymers	
Cadmium	EN 1122	≤ 0,01% Directive 91/338/CE	NO	Plastics	
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	≤ 3 mg/kg French Arrêté 9.11.1994 food contact (rubbers)	NO	All polymers	Mandatory in case of food contact
Extractable Nickel		See "Other Materials"		Presence of metal parts	
N- Nitrosamines (including N-ethylphenyl amine)	EN 12868 or EN 14602	≤ 1 µg/dm² French Arrêté 9.11.1994 food contact ≤ 0.1 mg/kg Ecolabel for shoes	NO	Elastomers	Mandatory in case of food contact
Nitrosable substances	No standard method	< 10µg/dm² French Arrêté 9.11.1994 food contact	NO	Elastomers	Mandatory in case of food contact
Phthalates (DINP, DNOP, DEHP, DIDP, BBP, DBP...)	ISO 18856	Not detectable Directive 2007/19/CE food contact	NO	Plasticized soft plastics	This test may be used to check the absence of given phthalates. Ex : DEHP, DBP et BBP forbidden for plastics in food contact (Directive 2007/19/CE)
Soluble proteins of natural rubber latex	EN 455-3	No legal limit Germany : 200 mg/kg	YES	Natural latex	Mandatory for gloves (EN 420). Recommended for all PPE containing natural rubber latex.
Flame retardant (PBB, TRIS, TEPA, PBDE, OBDE)	No standard method	≤ 0,1% (PBDE,OBDE) Directive 2003/11/CE	YES	Polymers treated for flame retardancy	
Dithiocarbamates salts (ZDEC,...)	No standard method	Detection limit	NO	Elastomers	The manufacturer must inform the user that this allergen is used.
Salts of Mercaptobenzothiazole (ZnMBT, NaMBT)	No standard method	Detection limit	NO	Elastomers	The manufacturer must inform the user that this allergen is used.
Thiurams (TMTD...)	No standard method	Detection limit	NO	Elastomers	The manufacturer must inform the user that this allergen is used.

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
Acrylonitrile monomer	No standard method	≤ 1,5 mg/kg Ecolabel for textile	Nitrile elastomer	
Vinyl chloride monomer	ISO 6401	≤ 1 mg/kg Directive 80/766/CE	PVC	Mandatory in case of food contact
Organostannic compounds (TBT, MBT)	No standard method Oekotex 200	≤ 0,1 mg/kg Oekotex catII/III	All polymers	
Nonylphenol CAS 104-40-5 Nonylphenol ethoxylate CAS 9016-45-9	No standard method	≤ 0.1% Directive 2003/53/CE	All polymers	
Orthophenylphenol (OPP) CAS 90-43-7	No standard method Oekotex 200	≤ 100,0 mg/kg Oekotex cat II/III	Elastomers	
Paraphenylene diamine (PPD) – CAS 106-50-3	No standard method	Limite de détection	Black elastomers	
Chloroalkanes (short chlorinated paraffinic compounds)	No standard method	≤ 1% Directive 2002/45/CE	Elastomers	The manufacturer must inform the user that this allergen is used.
Total heavy metals (As, Pb, Cd)	prEN ISO 17072-2	≤ 100 mg/kg for each part Ecolabel for shoes	Polymers for shoes	
Peroxydes	No standard method	< 0,08% French arrêté 9.11.1994	Elastomers	Mandatory in case of food contact
Volatile organic compounds	No standard method	< 0,5% French arrêté 9.11.1994	Elastomers	Mandatory in case of food contact
Aromatic amines	EN ISO 14362-1/2	≤ 1 mg/kg	Elastomers	Mandatory in case of food contact

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