TÜV Rheinland test specification.

2 PfG S 0193/04.20 Community Masks – Essential requirements.

1 PURPOSE

This criteria catalogue specifies the minimum requirements to be met by community masks which are neither respiratory protection within the meaning of the PPE Regulation (Regulation (EU) 2016/425) or DIN EN 149:2009 „Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking" nor medical face masks within the meaning of the Medical Devices Regulation (Regulation (EU) 2017/745) or DIN EN 14683:2019 „Medical face masks – Requirements and test methods".

2 SCOPE OF APPLICATION

The requirements described in this criteria catalogue apply to the abovementioned community masks for private use, which are consumer goods within the meaning of the German Foodstuffs, Consumer Goods and Feedstuffs Code (LFGB) and the German Consumer Goods Ordinance (BedGgstV). CE marking is not permitted. If all requirements of this criteria catalogue are met, a test mark of the TÜV Rheinland brand with the keyword „Tested for Harmful Substances" can be awarded.

3 PRINCIPLES

The requirements specified in this criteria catalogue are subject to the following publications in their most current version (incl. amending regulations). Standards apply in their respective current version.

- German Product Safety Act – ProdSG
- German Foodstuffs, Consumer Goods and Feedstuffs Code – LFGB
- German Consumer Goods Ordinance – BedGgstV
- German Regulation on Prohibited Chemicals – ChemVerbotsV
- Regulation (EC) No 1907/2006 – REACH Regulation
- Regulation (EC) No 2019/1021 (POP-Regulation)
- AfPS GS 2019:01 PAH Testing and evaluation of PAH in awarding the GS mark
- Regulation (EC) No 1007/2011 (European Textile Labelling Act)

TÜV Rheinland LGA Products (TRLP) reserves the right to decide whether to recognise reports from accredited laboratories that have already been submitted. These test reports must not be older than one year from the date the order is placed.

4 REQUIRED SPECIMENS, DOCUMENTS AND EVIDENCE

For the initial assessment, the applicant shall provide representative samples in sufficient number.
The following information and documents concerning the article shall be provided:

- Exact product name and description
- Item number
- Manufacturing company name, as declared on the product or the packaging or the information brochures of the manufacturer
- Address(es) of the manufacturing plant(s) including contact person
- Illustration of the article, packaging, user manual
- Bill of all used materials
- Fibre composition
- REACH certificate of conformity
- Declaration affirming the non-use of flame retardants and biocides
- Care labelling for reusable articles

5 TEST REQUIREMENTS

The choice of which tests need to be conducted is left entirely to the testing institute and is carried out based on many years of testing experience, while taking into account relevant exposure scenarios. The investigations thus focus on productioncontingent and materialsspecific substances.

5.1 BASIC REQUIREMENTS FOR MATERIALS, CONSTRUCTION, DESIGN AND LABELLING

Community masks can consist of one or more layers of densely woven textile fabric or dense nonwoven fabric. Knitted fabrics should not be used because of their open structure. Synthetic fibres such as Polyolefins, polyester, polyamide are particularly suitable as fibres. Cellulosebased fibres such as cotton or regenerated fibres should not be used because of their negatively changing properties when exposed to moisture (exhaled air).
The testing institute reserves the right to check the design

of the product to determine whether it is typical for a mask. Masks with an untypical design are excluded from testing and evaluation according to this criteria catalogue.

a) Multilayer layers shall be firmly bonded together
b) Masks shall not disintegrate, split or tear during intended use
c) Masks shall fit closely over the nose, mouth, chin, and the sides
d) The user must be clearly informed by means of a warning in a suitable form (e.g. on the packaging and by means of a user information leaflet enclosed with the masks) that the masks do not offer any protection like
   - Respiratory protection masks of the categories FFP 2 or FFP 3 as defined in the PPE Ordinance or EN 149:2009 and/or
   - Medical face masks in the sense of the Medical Devices Regulation or EN 14683:2019.
e) Masks must be hygienically perfect and must not have any smell.
f) The masks maybe disposable or reusable articles. The respective use must be clearly identifiable for the user e.g. on the packaging and by means of an information leaflet.
g) Reusable articles must be washable at least at 60 °C and fully functional after 5 washes.
h) Even in moist condition caused by human breath, the user must be able to breathe appropriate through the mask.
i) Coloured masks must be colourfast.

5.2 SPECIFIC REQUIREMENTS FOR USABILITY AND MARKING

PARAMETER	LIMIT VALUE / REQUIREMENT	TEST METHOD
a) Bonding of the layers in case of multilayer masks	Layers firmly bonded	Visual and manual check on 10 masks
b) Durability	No disintegration into individual parts, no tearing of the material or tearing of parts or tearing of joints or seams	Visual and manual check on 10 masks by means of user test carried out by 5 test persons
c) Fit and handling	Fit and handling perfect	Visual and manual check on 10 masks by means of user test carried out by 5 test persons
d) Warning and instructions for use in accordance with the recommendations of the German Federal Institute for Drugs and Medical Devices	Existing and clear information	Visual check
e) Odour	No odour	User test on 10 masks carried out by 5 test persons (2a MS-0030854 TRLP)
f) Marking of disposable/reusable	Existing and clear	Visual check
g) Washable at 60 °C (Reusable items)	Usability perfect (A, B, C, H)	5 home launderings on 10 masks with heavyduty detergent at 60 °C, user test carried out by 5 test persons
h) Appropriate breathability through the mask expressed by the air permeability and the differential pressure after conditioning for 4 hours at a temperature of (20 ± 5) °C and a relative humidity of (85 ± 5)	Air flow rate 8 l/min, pressure difference < 40 Pa/cm²	Test on 5 masks acc. ISO 9237:1995 in conjunction with EN 14683:2019 point 5.2.7 and Annex C (following)
i) Fastness to perspiration Fastness to saliva and perspiration Fastness to washing at 60 °C without steel balls	Grade 5 Fast Grade 4	ISO 105-E04 DIN 53160-1/-2 DIN EN ISO 105-C08

5.3 REQUIREMENTS ON HARMFUL SUBSTANCES

PARAMETER	REQUIREMENT	METHOD
Azo dyes*	20 mg/kg	DIN EN 14362-1/3
APEO (NPEO, OPEO)*	50 mg/kg (sum)	Solvent extraction, GC-MS / LC-MS
AP (Nonylphenol, Octylphenol)*	5 mg/kg (sum)	Solvent extraction, GC-MS / LC-MS
Pentachlorophenol (PCP) Tetrachlorophenoles (TeCP)	0.05 mg/kg 0.05 mg/kg (sum)	DIN EN ISO 17070
Dimethylfumarat	0.1 mg/kg	Solvent extraction, GC-MS
Flame retardants (inlc. Hexabromobiphenyl)*	Not used	n.a.
Biocides	Not used	n.a.
PFOS*	1 µg/m²	Solvent extraction, GC-MS / LC-MS
PFOA* PFOA related substances*	0.025 mg/kg 0.1 mg/kg	Solvent extraction, GC-MS / LC-MS
PAH*	Category 1	AfPS GS 2019:01 PAK
Cadmium	40 mg/kg	Microwave digestion, ICP-OES / ICP-MS
Lead	75 mg/kg	Microwave digestion, ICP-OES / ICP-MS
Short chained paraffins (SCCP)	50 mg/kg (sum)	CADS/ISO/FDIS 18219:2014
Phthalates*	250 mg/kg	Solvent extraction, GC-MS
Formaldehyde	16 mg/kg	DIN EN ISO 14184-1
Allergizing and cancerogenic dyes*	20 mg/kg	DIN 54231
Quinoline	50 mg/kg	DIN 54231
Organotins: TBT, TPhT, DBT, DOT	0.5 mg/kg (per substance)	Solvent extraction, GC-MS, Determination DIN EN ISO 17353
Soluble heavy metals	REACH Annex XVII entry 72	Extraction with artificial acidic sweat solution according to ISO 105-E04 (testing solution II) and ICP-OES / ICP-MS
pH-value Textile	> 4,0 < 7,5	EN ISO 3071
Nickel release	< 0,5 µg/cm2/week	DIN EN 1811 DIN EN 12472

* For information on the detailed scope of each substance class please refer to 2 PfG S 0151

6 TÜV RHEINLAND MARK (TEMPLATE)

If all the requirements of this catalog are fulfilled, a TÜV Rheinland test mark as „tested for harmful substances“ can be awarded. This underlines the quality of the product.

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