

SG mark for materials and medical devices tested for harmful substances / Version 2023



Responsibility for Consumer Health

The SG Mark is awarded exclusively by the Test and Research Institute Pirmasens, PFI. The Institute was founded about 65 years ago for product testing, research, and certification for the footwear industry and its suppliers and offers a unique treasure house of industry-specific know-how.

Chemical products are indispensable for the production and processing of materials of all kinds – today and in the future. Of course, chemical substances may only be used in such a way that there are no risks to health and the environment. In order to protect the consumer and the environment, attention must be paid to the proper and careful production of materials and to the use of suitable compounds and low-pollutant materials in production and further processing. This high level of quality should be ensured and certified by independent controls.

SG-Mark Supports Responsible Manufacturers

Producers and retailers should know the value chain of their goods precisely and manage it responsibly. Labelling the products with the SG Mark (where SG stands for “Schadstoff-Geprüft”, meaning “tested for hazardous compounds”) provides ideal support for these aims. The mark testifies to a degree of care exercised during production and distribution which goes beyond legal requirements.

Only those products which satisfy the stringent limit values and pollutant parameters listed in the SG catalogue of test criteria are awarded the SG Mark. The SG limit values generally are far below statutory levels. The mark indicates that according to our present knowledge no health hazards are to be expected. And that gives the consumer – and also the manufacturer – confidence.

Further Informationen

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Testing According to the Strictest Criteria

The SG test criteria catalogue was developed by experts on the basis of the latest scientific findings. Which tests are carried out depends on the materials, the excipients used to manufacture them and the production process. The tests guarantee the reliable detection of relevant pollutants. The SG test criteria catalogue covers all product-relevant requirements from REACH Annex XVII, as well as the most important SVHC candidates. In addition, an analytical screening for expected and unknown substances is carried out. The migration conditions are chosen in such a way as to simulate the worst possible use case. Based on the test results obtained, a possible health risk of Class I medical devices regarding the safety of use can be estimated in a biological risk assessment.

The test results are supplemented by corresponding documentation from the product supplier on the basic materials used and the manufacturing process. The quality control of the product manufacturer then guarantees the consistently high quality of the products.

Finished products and materials awarded the SG mark are checked annually by the PFI in random samples, depending on their relevance.

Requirements

The SG mark can only be awarded to those who are certified according to ISO 9001 or have been audited by our PFI experts. If a product bears the SG mark, this signals to the consumer that they have taken special care in production. Items intended for young children are subject to particularly strict requirements.

Performance:

- the basic materials first undergo the PFI laboratory test
- for additional colors, a color variant test can be selected if necessary
- the results will be made available as SG expertise

On request:

- Biological risk assessment for Class I medical devices based on DIN EN ISO 10993-1, DIN EN ISO 10993-17, DIN EN ISO 10993-18, DIN EN ISO 14971
- SG Label can be applied for, if all conditions are met

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Test Criteria for the SG-Mark for Components made of	Leather, Felt and Leather fibre (Lefa)	Textiles	Plastic/Rubber Coatings	cardboard, paper, wood, Cellulose, cork	Adhesives / Chemicals	Test Methods
Odour ^[4]	max. 3	max. 3	max. 3	max. 3	-	SNR 195651-2015
Solvents VOC	5 mg/kg Benzene 50 mg/kg	5 mg/kg Benzene 50 mg/kg	5 mg/kg Benzene 50 mg/kg	5 mg/kg Benzene 50 mg/kg	1000 mg/kg ^[7]	Headspace GC/MS ^[30]
2-Phenyl-2-propanol Acetophenone	-	-	10 mg/kg	-	-	Headspace GC-MS ^[30]
Colour Fastness: Rubbing ^{[2] [5]} - Staining Colour Fastness to Perspiration ^{[2] [5]} - Staining	min. Level 3 of the gray scale	min. Level 4 of the gray scale	min. Level 4 of the gray scale	min. Level 3 of the gray scale	-	Leather, lefa: DIN EN ISO 11640:2018 100 cycles dry rubbing, as well as 50 cycles rubbing with sweat solution (according to DIN EN ISO 11641:2013) Textile / other materials: DIN EN ISO105-X12:2016 dry rubbing and rubbing with acidic and alkaline sweat solution: 10 cycles each according to DIN EN ISO 105-E04:2013
pH-Value	3.5 – 7.0 ^[6]	4.5 – 7.5	-	4.5 – 7.5	-	Leather, Lefa: ISO 4045:2018 Textil / Materials: ISO 3071:2020-05
Formaldehyde (free and released by partial hydrolysis)	75 mg/kg 20 mg/kg Infant ^[3]	75 mg/kg 20 mg/kg Infant ^[3]	-	75 mg/kg 20 mg/kg Infant ^[3]	75 mg/kg	Leather, Lefa: ISO 17226-1:2021 Textil / Materials: ISO 14184-1:2011 Wood: EN 717-3:2005
Chlorinated Phenoles ^[25]	0.5 mg/kg je	0.5 mg/kg je	-	0.5 mg/kg each	0.5 mg/kg each ^[9]	ISO 17070:2015, prEN 17134-2:2022
Tin Organic Compounds ^[26]	-	1 mg/kg je	1 mg/kg each	1 mg/kg each	1 mg/kg jeach ^[9]	DIN CEN ISO/TS 16179; DIN SPEC 91179:2012 ISO 22744-1:2020
Azo Dyes, forbidden including Aniline free	20 mg/kg	20 mg/kg	20 mg/kg	20 mg/kg	20 mg/kg	Leather, Lefa: ISO 17234-1:2020, ISO 17234-2:2011 Textil: ISO 14362-1:2017, ISO 14362-3:2017
Carcinogenic and allergenic Dyes ^[12]	-	20 mg/kg	-	-	-	DIN 54231:2022
Quinoline	-	50 mg/kg	-	-	-	DIN 54231:2022
Chlorinated Benzenes and Toluenes ^[23]	-	1 mg/kg	-	-	-	EN 17137: 2018
Polycyclic Aromatic Hydrocarbons, PAH ^{[13] [14]}	∑ 10 mg/kg 0.5 mg/kg each PAH EU	∑ 10 mg/kg 0.5 mg/kg each PAH EU	∑ 10 mg/kg 0.5 mg/kg each PAH EU	∑ 10 mg/kg 0.5 mg/kg each PAH EU	∑ 10 mg/kg ^[9] 0.5 mg/kg each PAH EU	ISO 16190:2021 EN 17131:2019
Phthalate ^[18]	-	-	∑ 500 mg/kg	-	∑ 500 mg/kg	ISO 16181-1:2021; ISO 14389:2022
Chlorinated Paraffines (SCCP, MCCP) ^[16]	∑ 500 mg/kg	-	∑ 500 mg/kg	∑ 500 mg/kg	-	ISO 18219-1/2:2019, ISO 22818:2021

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Chromium VI (soluble) With and Without Aging	3 mg/kg	-	-	-	-	ISO 17075:2017 Aging ISO 10195:2021
Soluble mineral Tanning Agents: Aluminium Chromium Titanium Zirkonium	∑ 200 mg/kg ∑ 50 mg/kg Infant ^[3]	-	-	-	-	DIN EN ISO 17072-1:2019
Heavy Metals (soluble): Antimony Arsenic Cadmium Chromium, total (incl. Chromium VI) Cobalt Copper Lead Mercury Nickel Barium Selenium Silver	5.0 mg/kg 0.2 mg/kg 0.1 mg/kg - 1.0 mg/kg 50 mg/kg 0.8 mg/kg 0.02 mg/kg 4.0 mg/kg 100 mg/kg 100 mg/kg 1 mg/kg	5.0 mg/kg 0.2 mg/kg 0.1 mg/kg 1.0 mg/kg 1.0 mg/kg 50 mg/kg 0.8 mg/kg 0.02 mg/kg 4.0 mg/kg 100 mg/kg 100 mg/kg 1 mg/kg	-	5.0 mg/kg 0.2 mg/kg 0.1 mg/kg 1.0 mg/kg 1.0 mg/kg 50 mg/kg 0.8 mg/kg 0.02 mg/kg 4.0 mg/kg 100 mg/kg 100 mg/kg 1 mg/kg	-	Leather, Lefa: ISO 17072-1:2019 Textil: DIN EN 16711-2:2016 Chromium VI: ISO 17075:2017
Heavy Metals Total Content Lead Cadmium Arsenic Mercury	-	-	10 mg/kg each	-	-	DIN EN 16711-1:2016
Preservatives ^[15]	300 mg/kg TCMTB 300 mg/kg CMK 750 mg/kg OPP 100 mg/kg OIT 100 mg/kg Phenol 50 mg/kg Triclosan	100 mg/kg OPP 50 mg/kg Triclosan	-	-	-	based on pr EN ISO 13365-1:2019 and Suppliers Declaration ^[15]
Alkylphenoles (NP, OP) Heptyl- (HpP), pPentylphenol (PeP)	-	-	30 mg/kg each 100 mg/kg each	30 mg/kg each 100 mg/kg each	30 mg/kg each 100 mg/kg each	EN ISO 21084:2019
Alkylphenoethoxylates (NPEO, OPEO)	100 mg/kg each	100 mg/kg each	-	100 mg/kg each	100 mg/kg each	Leather, Lefa: ISO 18218:2015 Textil: ISO 18254:2016
PFAS ^[17] For water, oil and dirt repellent	25 µg/kg	1 µg/m ²	-	1 µg/m ²	-	Leather ISO 23702-1:2021 Textil: EN 17681-1/2: 2022

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Isothiazolines / Isothiazolinones ^[24]	5 mg/kg	-	5 mg/kg	-	5 mg/kg	According EN ISO 13365-1:2020
Glutaraldehyds ^[28]	500 mg/kg	-	-	-	-	DIN EN ISO 17226-1:2019
Bisphenoles A, F, S ^[28]	500 mg/kg	500 mg/kg	500 mg/kg	500 mg/kg	500 mg/kg	E DIN EN ISO 11936:2022-06
Melamins ^[28]	500 mg/kg	-	500 mg/kg	-	500 mg/kg	Migration / HPLC
Migration/Soluble Substances ^[2] worst use case Gebrauchsbedingungen (NIAS) ^[27]	nn	nn	nn 10 mg/dm ²	nn	-	EN 1186 ff. 2002 Migration Screening according ISO 10993-18
Colophonium	-	-	-	-	nn	Extraction / GC/MS
2-Mercaptobenzothiazol (2-MBT) in Rubber, Latex ^[2]	-	-	10 mg/kg	-	-	According EN ISO 13365-1:2020
Nitrosamines in Rubber, Latex ^{[2][3]}	-	-	1.0 µg/dm ² Infant ^[3]	-	-	According DIN EN 12868:1999 (Migration 24 h, 40 °C, without Boiling)
DMFA Dimethylformamide DMAC Dimethylacetate	-	-	100 mg/kg	-	-	Leather EN ISO 16189: 2021 Textil EN ISO 17131:2019
Formamide in EVA	-	-	100 mg/kg	-	-	According EN ISO 16189: 2021
Softener TCEP, TCPP, TDCP ^{[3][8]}	-	-	5mg/kg Infant ^[3]	-	-	EN ISO 17881-2:2016
Cyclic Siloxanes D4, D5, D6 ^[29] In Silicon, Silicon Coatings	-	-	500 mg/kg	-	-	Solvent extraction, GC/MS
Dimethylfumarate	0,1 mg/kg	0,1 mg/kg	-	0,1 mg/kg	0,1 mg/kg	EN ISO 16186:2021, EN 17130:2029
Flame retardant finish	nv	nv	nv	nv	-	Suppliers Declaration; RFA-Screening
Pesticides (Sum) ^[10]	1 mg/kg	1 mg/kg	-	-	-	Suppliers Declaration;
Wood preservative (Sum) ^[11]	-	-	-	1 mg/kg	-	If necessary, examination based on DFG S19

Test Criteria for the SG-Mark for Components made of	Metallic accessories	Test Method
Nickel Release ^[2]	Negative	Rubbing test CR 12471:2002 oder 13093:2017-09 EN 1811:2021; EN 12474:2009
Cadmium, Lead ^[2]	50 mg/kg per Metal	DIN EN 16711-1:2016 (ASTM E 1645)

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Erläuterungen

- [1] for materials that do not come into direct contact with the skin
 - [2] in case of expected direct skin contact
 - [3] Children under 36 months, usually up to shoe size 27
 - [4] 1= odorless; 2= weak; 3= distinct, tolerable; 4= highly harassing; 5= unbearable
 - [5] Level 1 of the grey scale = very strong staining, level 5 of the grey scale = no staining
 - [6] a maximum pH value of 8.0 is permitted for chamois leather
 - [7] Benzene, Trichlorbenzene, Dichlorbenzene, Toluene, Xylene, Tetrachlormethane, Trichlormethan e, Trichlormethane , Pentachlorethane, Dichlorethene , Trichlorethen, Cyclohexan, Methanol, Dimethylformamid, Dimethylacetamid, 1-Methyl-2-pyrrolidon (NMP)
 - [8] Tris(2-chlorethyl)phosphat (TCEP), Tris[2-chlor-1-(chlormethyl)ethyl]phosphat (TDCEP), Tris(2-chlor-1-methylethyl)phosphat (TCPP)
 - [9] in the cured film
 - [10] for Felt and Wool: DDT, Lindan, Aldrin, Dieldrin, Methoxychlor, DDD, DDE, Heptachlor, Heptachlorepoxyd, HCH (a,b,d,e), Malathion, Mirex, Parathion(-ethyl), Permethrin
 - [11] Lindan, Dichlofluuanid, Pentachloranisol, Endosulfan, Permethrin, Chlorthalonil, Tolyfluuanid
 - [12] Carcinogenic dyes: Acid red 26, Basic red 9, Basic violet 14, Direct black 38, Direct blue 6, Direct red 28, Disperse blue 1, Disperse orange 11, Disperse yellow 3, Basic Violet 3
Allergenic dyes: Disperse blue 1, Disperse blue 3, Disperse blue 7, Disperse blue 26, Disperse blue 35, Disperse blue 102, Disperse blue 106, Disperse blue 124, Disperse brown 1, Disperse orange 1, Disperse orange 3, Disperse orange 37/76, Disperse Orange 149, Disperse red 1, Disperse red 11, Disperse red 17, Disperse yellow 1, Disperse yellow 3, Disperse yellow 9, Disperse Yellow 23, Disperse yellow 39, Disperse yellow 49
 - [13] U.S. EPA listed 16 PAH: naphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, dibenzo[a,h]anthracene, benzo[g,h,i]perylene, indeno[1,2,3-cd]pyrene and 8 EU PAHs according to Directive 2005/69/EC: benzo[a]pyrene, benzo[e]pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[j]fluoranthene, Benzo[k]fluoranthene, dibenzo[a, h]anthracene
 - [14] PAH levels below 0.2 mg/kg are not taken into account for the sum
 - [15] additional manufacturer's declaration on the preservative process and the preservatives used required
 - [16] short-chain chlorinated paraffins C10-C13 and medium-chain chlorinated paraffins C14-C17
 - [17] PFAS compounds according to REACH Annex XII and POP Regulation in their latest version in addition to the analysis: Manufacturer's declaration on the non-use of perfluorinated alkyl substances (PFAS)
 - [18] Diisononylphthalat (DINP), Di-n-octylphthalat (DNOP), Diethylhexylphthalat (DEHP), Diisodecylphthalat (DIDP), Benzylbutylphthalat (BBP), Di-n-butylphthalat (DBP), Diisobutylphthalat (DIBP), Di-(2-methoxyethyl)-phthalat (DMEP), Di-n-hexylphthalat (DHP), 1,2-Benzoldicarbonsäureester, di-C7-11-verzweigte und lineare Alkylester (DHNU), 1,2-Benzoldicarbonsäureester di-C6-8-verzweigte Alkylester, C7-reich (DIHP), Di-n-pentylphthalat (DPP), Diisopentylphthalat (DIPP), n-Pentyl-isopentylphthalat (PIPP), Di-cyclo-hexylphthalat (DcHP), 1,2-Benzodicarbonic acid dipentylester branched and linear, 1,2-Benzodicarbonic acid, Di-C6-10-alkylester; 1,2-Benzodicarbonic acid, mixed Decyl-, Hexyl- and Octyldiester with $\geq 0.3\%$ Dihexylphthalate, 1,2-Benzodicarbonic acid, Dihexylester, branched and linear (DHxP), 1,2-Benzodicarbonic acid, Dipentylester, branched and linear, Diisohexylphthalate (DIHxP)
 - [23] 2-Chlortoluene, 3-Chlortoluene, 4-Chlortoluene, 2,3-Dichlortoluene, 2,4-Dichlortoluene, 2,5-Dichlortoluene, 2,6-Dichlortoluene, 3,4-Dichlortoluene, 2,3,6-Trichlortoluene, 2,4,5-Trichlortoluene, 2,3,4,5-Tetrachlortoluene, 2,3,4,6-Tetrachlortoluene, Pentachlortoluene, 4-Chlorbenzotrichloride / aaa4-Tetrachlortoluene, 1,3-Dichlorbenzene, 1,4-Dichlorbenzene, 1,2,3-Trichlorbenzene, 1,2,4-Trichlorbenzene, 1,3,5-Trichlorbenzene, 1,2,3,4-Tetrachlorbenzene, 1,2,3,5-Tetrachlorbenzene, 1,2,4,5-Tetrachlorbenzene, Pentachlorbenzene, Hexachlorbenzene, 1,2-Dichlorbenzene
 - [24] 1,2-Benzisothiazol-3-one (BIT), 2-Methyl-4-isothiazolin-3-one (MIT), 5-Chlor-2-methyl-4-isothiazolin-3-one (CIT)
 - [25] Pentachlorphenol (PCP), Tetrachlorphenole (TeCP) (each Isomer), Trichlorphenole (TriCP) (each Isomer), Dichlorphenole (DiCP) (each Isomer), Monochlorphenole (MCP) (each Isomer)
 - [26] Tributyl tin compounds (TBT/TBTO), Dibutyl tin compounds (DBT), Monobutyl tin compounds (MBT), Triphenyl tin compounds (TPT), Dioctyl tin compounds (DOT)
 - [27] NIAS = non intentional added substances
 - [28] If it is exceeded, the E content of the migration limit according to [27] can be checked.
 - [29] Octamethylcyclotetrasiloxane (D4), Decamethylcyclopentasiloxane (D5), Dodecamethylcyclohexasiloxane (D6)
 - [30] 120°C / 45min
- AET analytical assessment threshold (AET) of detected substances after extraction with acidic synthetic welding solution. Limit value for the specific migration of materials and articles from Plastics intended to come into contact with food (according to REGULATION (EU) No. 1012011)
- BG Detection Limits
- nn not detected (<BG)
- nv no use (Supplier Conformation)
- no Test