Product Data Sheet

Product:	GentleSafe® EXTRA	
Trademark:	SAFE®	
REF:	879	
Manufacturer:	DACH Schutzbekleidung GmbH & Co. KG	

Classification:	CAT III according to Regulation (EU) 2016/425 for personal protective equipment (PPE). Class I according to Regulation (EU) 2017/745 for medical devices; UMDNS code: 11-882.
Materials:	Carboxylated nitrile butadiene rubber
Product description:	The nitrile glove is powder-free, latex-free and impervious to liquids. It offers excellent dexterity with high comfort and maximum dexterity (level 5/5). High elasticity with low effort. No hand fatigue. Ambidextrous wear, rolled edge, non-sterile, excellent tactile sensation. Textured surface all around the glove. Excellent grip, even when handling wet or moist objects. Excellent performance against chemicals, especially cytostatics and solvents, acids and bases, oxidizing agents, viruses, bacteria and fungi. Suitable for contact with foodstuff. EXTRA longer glove for even more safety against chemicals and EXTRA wearing comfort.
Pictograms and standards:	

Product performance:	*Testing against chemicals*		
	EN ISO 374-1:2016+A1:2018 and EN 16523-1:2015+A1:2018		
	Chemical	Level	EN ISO 374-4:2019 Degradation %

40% Sodium Hydroxide (K)	6	-3.9
30% Hydrogen Peroxide (P)	1	8.1
40% Acrylamide	6	NT
1% Ethidium Bromide	6	NT
NT = not tested		
Testing against infective agents accordingly EN ISO 374-5:2016 and ISO 16604:2004		
Protection against bacteria and fungi	Pass	
Protection against viruses	Pass	
Determination of resistance to penetration accordingly EN 374-2:2014		
Air leak test	Pass	
Water leak test	Pass	
Testing against the permeation of cytostatic drugs		
ASTM D6978-05(2019)		
Chemical	Minimum breakthrough detection time (Specimen 1/2/3) (Minutes)	Average steady state permeation rate (Specimen 1/2/3) (µg/cm²/Minute)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	14.9 (16.9, 14.9, 14.3)	0.5 (0.6, 0.5, 0.5)
Cisplatin, 1 mg/ml (1,000 ppm)	>240	N/A
Cylophosphamid (Cytoxan) 20.0 mg/ml (20,000 ppm)	>240	N/A
Dacarbazine 10.0 mg/ml (10,000 ppm)	>240	N/A
Doxorubicin HCl 2 mg/ml (2,000 ppm)	>240	N/A
Etoposide 20.0 mg/ml (20,000 ppm)	>240	N/A

	Fluorouracil 50.0 mg/ml (50,000 ppm)	>240	N/A
	Paclitaxel 6.0 mg/ml (6,000 ppm)	>240	N/A
	ThioTepa 10.0 mg/ml (10,000 ppm)	17.1 (17.2, 17.1, 18.5)	0.9 (0.9, 0.9, 0.8)
	Dexterity and innocousness of material testing		
	EN ISO 21420:2020		
	Dexterity		Level 5
	pH Level		Pass
	Polycyclic Aromatic Hydrocarbons Content		Not detected - Pass
	Food safety testing		
	Resolution ResAP (2004) 4 and Regulation (EG)1935/2004		
	Overall migration		Pass
	Specific migration of primary aromatic amine		Pass
	Specific migration of nitrosamine and nitrosatable substances		Pass
	Medical examination gloves testing		
	Standard	Test	Result
	EN 455-1:2000	Freedom from holes	Pass
	EN 455-2:2015	Physical properties:	Pass
	Partial tests	Length: ≥ 240 mm	304 mm
		Width S: 80±10 mm	84 mm
		Width M: 95±10 mm	94 mm
		Width L: 110±10 mm	104 mm
		Width XL: ≥ 110 mm	113 mm
		Force at break: ≥ 6.0 N	9,25 N

		Force at break after challenge testing: ≥ 6.0 N	9,1 N
	EN 455-3:2015	Labelling	Pass
	Partial tests	Gloves shall not be dressed with talcum powder (magnesium silicate)	Pass
		Powder residues < 2mg	0,23 mg
	EN 455-4	Shelf life	Pass
Thickness:	Cuff: 0.09 mm; Palm: 0.1 mm; Finger: 0.14 mm (± 0.02 mm)		
Weight:	S: 5,5g, M: 6,0g, L: 6,8g, XL: 7,6g (± 0,4g)		
Other features:	 No intolerance reactions: This product does not contain natural latex.  Virus-tight according to ASTM 1671: Determination of the resistance of materials to the penetration of viral pathogens.  Non sterile.		
Color:	White		

Packaging and variants:	**Packaging**	**Quantity**
	Dispenser box	100 pcs.
	Shipping carton	1000 pcs.
GTIN:	879/W/S	4049825006688
	879/W/M	4049825006695
	879/W/L	4049825006701
	879/W/XL	4049825006718

Limitation:	The gloves are designed for single use. The duration of protection in working use may differ from the breakthrough time determined according to EN 374, as it depends on the working conditions.
Storage:	Store in a dry place without direct sunlight in the original packaging (see packaging). If the storage conditions are observed, the product has a storage life of 3 years (see labeling on the product).
Environmental sustainability and disposal:	In the case of contaminated products, the type and extent of contamination determines the disposal, and the applicable laws and regulations of the relevant country must be followed. A non-contaminated product can be thermally recycled or disposed of in landfills without releasing toxic substances.