## semperguard® (5)

The following table shows an overview of the most commonly used Semperguard® disposable gloves and the most frequently required chemical resistances.

### CHEMICAL RESISTANCE LIST

	Break-through time according to EN 374-3 in minutes					
CHEMICAL (SYNONYMS)	SEMPERGUARD <sup>®</sup> Nitrile Xtension (300)		SEMPERGUARD <sup>®</sup> Nitrile Comfort	SEMPERGUARD <sup>®</sup> Nitrile Xenon	SEMPERGUARD <sup>®</sup> Nitrile Xtra Lite / Style	SEMPERGUARD <sup>®</sup> Latex PF IC
Acetic acid (10%) (methyl carbon acid)	Level 4		Level 5	Level 6	Level 6	Level 2
Acetone (2- propanone, methyl ketone)	Х	Х	Х	Х	Х	Х
Acetonitrile (cyanomethane, ethyl nitrile)	Х	Х	Х	Х	Х	Х
Acryl amide (40%) (acrylic acid amide)	Level 6	Level 6	Level 6	Level 6	Level 6	
Ammoniumhydroxid (25 %)	Level 1		Level 1			А
Benzalconiumchloride liquid (Quats)				Level 6		Level 6
Chloroform (trichloromethane)	Х	Х	Х	Х	Х	Х
Cyclohexanol (Hexalin / at 23°C)	Level 3	Level 4	Level 2			Level 1
Dichloromethane (methylene chloride, Freon 30)	Х	Х	Х	Х	Х	Х
Diethyl amine (DEA)	Х	Х	Х	Х	Х	X
Diethyl ether (diethyloxid, ethoxyethane)	Х	Х	Х	Х	Х	Х
Dimethylsulfoxide DMSO (deltan, demasorb)	Х	Х	Х	Х	Х	Х
Ethanol (20%) (ethyl alcohol)	Level 1	Level 6	А	Level 1	Level 1	А
Ethanol (70%) (ethyl alcohol)	А	Level 1	А	А	А	Х
Ethanol p.a. (ethyl alcohol)	А		А	А	А	Х
Ethidium bromide (1%) (homidium bromide)	Level 6	Level 6	Level 6	Level 6	Level 6	Х
Ethyl acetate (Aceto acid ether)	Х	А	Х	Х	Х	Х
Formaldehyde (37%) with Methanol (10%) (formalin, methyl aldehyde) *	Level 5	Level 6	Level 6	Level 1	Level 1	
Gasoline (heavy, bp 150 – 190°C)	Х	Х	Х	Х	Х	Х
Glutaraldehyde (5%) (1,3- diformylpropane; Glutaral)	Level 6	Level 6	Level 6	Level 6	Level 6	
Heptane – n	Х	А	Х	Х	Х	Х
Hexane – n	Х	А	Х	Х	Х	Х
Hydrofluoric acid (40%)	Х	Level 1	Х			
Isopropyl alcohol (40%) (2- propanol, isopropanol, IPA)	Level 1	Level 1	А	Level 1	Level 1	А
Isopropyl alcohol p.a. (2- propanol, isopropanol, IPA)	Level 1	Level 1	А	А	А	А
Methanol (5%) (methyl alcohol)	Level 6		Level 6			
Methanol p.a. (methyl alcohol)	А	А	А	Х	Х	Х
Ninhydrin (0.2%)		Level 6	Level 6		Level 6	
Nitric acid (10%) (Aqua fortis, spirit of nitre)	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6
Nitric acid (36%) (Aqua fortis, spirit of nitre)	Level 3	Level 4	Level 3	А	А	
Phenol (80%) (carbolic acid, benzenol, hydroxybenzene)	Х	Level 2	Х	Х	Х	
Phosphoric acid (30%) (orthophosphoric acid)	Level 6		Level 6	Level 6	Level 6	
Potassium hydroxide (30%) (caustic potash, lye)	Level 6	Level 6	Level 6	Level 6	Level 6	
Sodium hydroxide (30%)(caustic soda, lye, white caustic)	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6
Sodium hydroxide (40%)(caustic soda, lye, white caustic)	Level 6	Level 6	Level 6	Level 6	Level 6	Level 5
Sulphuric acid (96%) (vitriol)	Level 1	Level 1	А			Level 1
Toluene (methylbenzol, phenylmethan, toluol)	Х	Х	х	Х	Х	X
Trichlorethane (methyltrichloromethane)	Х	х	х	х	Х	Х
Xylene (xylol, dimethylbenzene)	х	x	Х	х	X	X

#### Not recommended

A: only recommended for splash protection –

- change gloves immediately after contact
- Level 1: recommended for short contact (up to 10 min)

Level 2: for applications up to 30 min

\*Higher measurement values not available

Level 3: for applications up to 60 min Level 4: for applications up to 120 min Level 5: for applications up to 240 min Level 6: for applications up to 480 min\* Not tested

## semperguard® (§

All protective gloves in the Sempermed product range are of very high quality and have been tested in accordance with the specified standards.

DISPOS	ABLE GLC	VES						
Product name	Semperguard® Nitrile Xtension	Semperguard® Nitrile Xpert	Semperguard® Nitrile Comfort	Semperguard® Nitrile Xenon	Semperguard® Nitrile Xtra Lite	Semperguard® Style	Semperguard® Latex pf IC	Semperguard® Latex pp
			-				Carl I	
Product features	COMFORTABLE NITRILE • Extra length: 300 mm • Drip protection on shaft • Good chemical resistance*	ROBUST NITRILE • Signal colour blue (HACCP standard) • Greater thickness • Greater resilience • Good chemical resistance* • No silicon added	COMFORTABLE NITRILE • Signal colour blue (HACCP standard) • Extremely comfortable to wear • Good chemical resistance*	THE HYGIENE GLOVE • White • Extremely comfortable to wear • Outstanding tactility	LIGHTWEIGHT NITRILE • Lavender blue, offering compliance with HACCP standards • Excellent elasticity • Skin-friendly	BLACK NITRILE • Black • Excellent elasticity • Especially suitable for applications which are visible to the public	THE ALL- ROUNDER • Natural • Inner coating • Highly tear- resistant/excellent elasticity • Good tactility/ very comfortable to wear	THE POWDERED OPTION • Natural • Powdered • Easy fit, even on wet hands • Excellent value for money
Material	Nitrile	Nitrile	Nitrile	Nitrile	Nitrile	Nitrile	Natural latex	Natural latex
Interior	Powder-free	Powder-free	Powder-free	Powder-free	Powder-free	Powder-free	Powder-free	Powdered
Exterior	Textured fingers	Textured	Textured fingers	Textured fingers	Textured fingers	Textured fingers	Textured	Textured fingers
Length	Median 300 mm	Median 240 mm	Median 240 mm	Median 240 mm	Median 240 mm	Median 240 mm	Median 240 mm	Median 240 mm
Thickness (double) typical production value	0.16 mm	0.26 mm	0.20 mm	0.10 mm	0.14 mm	0.14 mm	0.24 mm	0.20 mm
MPG Medical Devices Directive	CE Class I		CE Class I	CE Class I	CE Class I	CE Class I	CE Class I	CE Class I
PPE Personal Protective Equipment Directive	PPE Category III complex risks	PPE Category III complex risks	PPE Category III complex risks	PPE category I Minimal risks	PPE Category III complex risks	PPE category III Complex risks	PPE Category III complex risks	PPE Category III complex risks

\*see chemical resistance list on www.sempermed.com

REUSABLE PROTECTIVE GLOVE				SPECIAL PROTECTIVE GLOVE				
Product name	Semperstar	Sempersoft	Semperplus		Product name	Semperclean MC		
	2							
Product features	SKIN-FRIENDLY • Phthalate-free • Extra thickness for greater safety • Good chemical resistance	COMFORTABLE VINYL • Phthalate-free • Particularly skin-friendly • Extremely comfortable to wear	ROBUST NITRILE • Latex-free • Extra length for greater protection		Product features	THE SPECIALIST • Anatomically shaped • Special surface treatment provides excellent grip safety • Maximum comfort • Available in 6 sizes for guaranteed fit		
Material	Vinyl	Vinyl	Nitrile		Material	Natural latex		
Interior	Flocklined with cotton	Flocklined with cotton	Flocklined with cotton		Interior	Powder-free coated		
Exterior	Structured	Structured	Diamond pattern		Exterior	Micro-rough		
Length	Median 320 mm	Median 320 mm	Median 330 mm		Length	270 – 285 mm		
Thickness	0.6 mm	0.5 mm	0.38 mm		Thickness single	0.22 mm		
PPE Personal Protective Equipment Directive	PPE Category III complex risks	PPE Category III complex risks	PPE Category III complex risks		MD classification Medical Devices Directive	CE Class I		
					PPE Personal Protective Equipment Directive	PPE Category III complex risks		

IMPORTANT NOTE: At the time of printing, all of the listed Semperguard<sup>®</sup> protective gloves comply with the specified standards and EU directives. The latest product brochures can be found at www.sempermed.com. Failure to observe this information, in particular with regard to (chemical) resistance, frequency of use and tolerability of the gloves, can result in personal injury and/or material damage. Semperit does not accept any liability for incorrect use of the gloves. In case of doubt, obtain expert advice before use. The information and cl latest status prior to printing. Subject to mistakes, printing errors and amendments. CAUTION: Natural latex can cause allergic reactions, including anaphylactic shock.

PLEASE CONTACT US.

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chemical substances concerned. When working with materials that are harmful to the skin, please always inspect the glove for any holes or tears prior to use. In principle, tests and certificates may only be regarded as general indications and do not exempt the user from the responsibility of making sure that the glove affords the protection requirements for the intended purpose prior to use The chemical resistance recommendations do not form part of the specifications. In case of doubt, obtain expert advice before use.

IMPORTANT NOTE: The latest chemical lists can be found at www.sempermed.com. Please note that the product characteristics are directly dependent on the conditions of use and on the purity of the

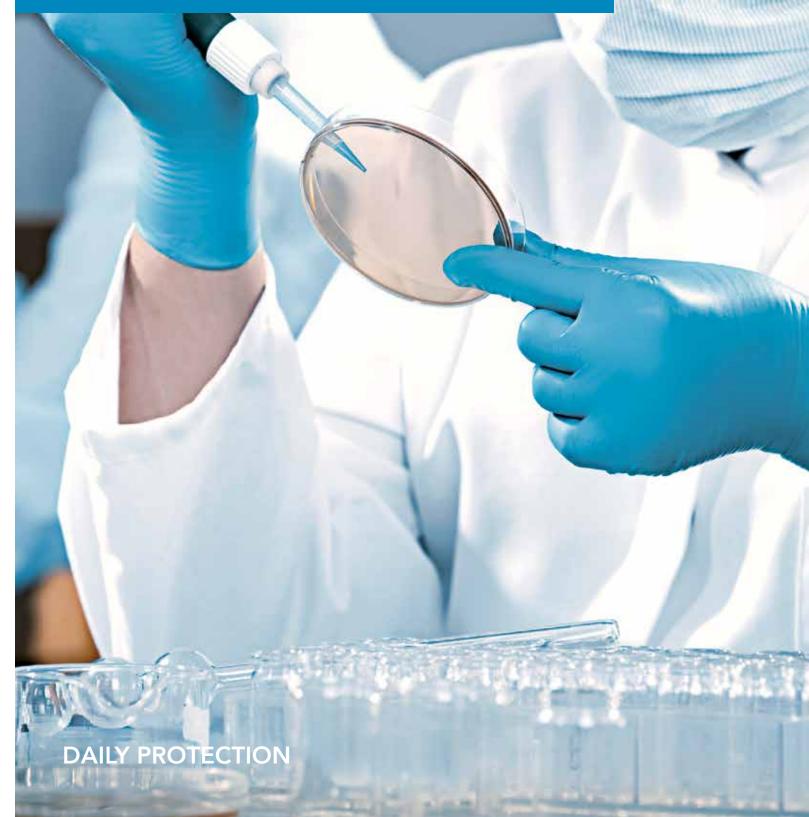
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## semperguard<sup>®</sup> ()

# **PROTECTIVE GLOVES** FOR PHARMACEUTICAL AND LABORATORY APPLICATIONS





# THE OPTIMUM PROTECTIVE GLOVE FOR YOUR AREA OF APPLICATION

In the **pharmaceutical sector**, dual-labelled Semperguard<sup>®</sup> disposable gloves rank high with their certification as medical products according to 93/42/EEC and as personal protective equipment according to 89/686/EEC (dual labelling). This dual labelling offers additional protection to users.

Not only do defined Semperguard<sup>®</sup> products satisfy ASTM F1671 viral resistance standards, they also passed the European medical quality standards. Ideally balanced tactile properties and wearability over long periods provide a high level of protection for the pharmaceutical sector.

Various chemical substances that can permanently damage the skin are used in the **laboratory sector**. Wearing protective gloves is essential when working with such substances as gloves protect against injury upon skin contact.

Our Semperguard® product portfolio allows for safe handling when working with sensitive substances and articles. Excellent tactile and grip safety, even after longer periods of use, provide extended comfort without hand fatigue.

## **PROTECTIVE GLOVES FOR PHARMACEUTICAL** AND LABORATORY APPLICATIONS

THE TWO TOP PRIORITIES REGARDING THE USE OF PROTECTIVE GLOVES ARE THE SAFETY AND PROTECTION OF THE WEARER AND THE PURITY AND PROTECTION OF THE ARTICLES USED.

Our many years of experience in the production of high-quality protective gloves according to medical standards and to the EU Directive for Personal Protective Equipment (PPE) allow us to respond to the various needs of the user and optimize the glove properties accordingly.

Semperguard<sup>®</sup> products are subject to strict testing standards, and here our position as a fully integrated supplier proves itself of value as it allows us to provide our customers with consistently high quality from the manufacturing to sales.





Manufacturers of protective gloves are able to label their products as a medical product and as personal protective equipment (PPE).

The **advantage** of dual labelling for the user is in the expanded specific functions. The basis for this is that the products satisfy the requirements of the Medical Devices Directive 93/42/EEC and those of the Personal Protective Equipment Directive 89/686/EEC and, therefore, pass both conformity assessment procedures.

Questions? Contact us!

# **OVERVIEW OF THE MOST IMPORTANT REQUIREMENTS FOR EACH SECTOR**

### PHARMACEUTICAL APPLICATIONS

- ASTM F1671-compliant viral resistance.
- Dual labelling as medical product and PPE.
- Excellent grip safety.
- Maximum comfort and extremely easy to put on.
- Particularly skin-friendly.





#### LABORATORY APPLICATIONS

• ASTM F1671-compliant viral resistance.

- Chemical resistance to select chemical substances.
- Maximum comfort, even after long periods of use.
- "Fit & Feel" comfort and gripping properties.
- Compliance with medical AQL.

# **STANDARDS AND PICTOGRAMS**

In the EU, there are a large number of standards for gloves which are labelled as PPE. The basis is EN 420, which defines the general requirements for protective gloves, e.g. the contents of the information for users, the safety of the glove material, as well as the characteristics of the product (e.g.: length, size, etc.). In combination with EN 420, standard EN 374 also applies.



PERMEATION: The pictogram with a beaker stands for waterproof gloves and slight protection against chemical hazards. It confirms that the glove has been tested for the penetration of certain chemicals.



PENETRATION: The pictogram for protection against bacteriological contamination states whether the glove is free of holes and is, therefore, impermeable to micro-organisms according to the definition in the standard. It is tested at AQL level during production.



CE MARK: Products with the CE mark comply with the currently valid EU safety regulations, which in this case means compliance with the PPE Directive, which in turn is mandatory for this labelling.



PPE Cat. I-III – The requirements for Personal Protective Equipment are regulated by EU Directive 89/686/EEC, in order to guarantee the health and safety of the user.



MDD: EU Directive 93/42/EEC forms a legal basis for the marketing and use of medical devices and their accessories. Medical devices are classified according to their risk potential, whereas examination gloves fall under Class I and must comply with European standard EN 455.

- ASTM VIRAL RESISTANCE: Medical gloves are tested for viral resistance in a standard testing procedure according to the ASTM F1671 standard. During the procedure, gloves are tested for impermeability by means of penetration of the tiny Phi-X 174 bacteriophage.
- AQL 1.5 AQL is a statistical measure of quality assurance, which determines how many defective units are allowed in a randomly drawn sample. The European standard for medical gloves (EN 455) prescribes an AQL of 1.5 for holes, which has to be determined according to tightened inspection requirements.