

Due to the wide range of potential applications for examination gloves, Sempermed recommends the following Sempercare® products in the defined segments in accordance with the demands on their use.

	LATEX EXAM GLOVES				NITRILE EXAM GLOVES								VINYL EXAM GLOVES			STERILE EXAM GLOVES			
	Sempercare® premium	Sempercare® edition IC	Sempercare® edition	Sempercare® latex pp	Sempercare® nitrile	Sempercare® safe+	Sempercare® shine+	Sempercare® soft	Sempercare® silk	Sempercare® aloe	Sempercare® skin²	Sempercare® velvet	Sempercare® syntretch	Sempercare® vinyl pf	Sempercare® vinyl pp	Sempercare® premium sterile	Sempercare® nitrile pf sterile	Sempercare® latex pp sterile	
PRODUCT FEATURES	Higher wall thickness	x	x		x	x							x			x	x		
	Tactile sensitivity	x	x	x	x		x	x	x	x	x	x				x		x	
	Higher grip and dexterity		x	x	x	x											x	x	
	Innercoating	x	x						x	x			x	x		x			
	High wearing comfort	x	x	x	x			x	x	x	x	x				x		x	
	Extended cuff protection						x	x											
	Suitable for Type-I allergy sufferers					x	x	x	x	x	x	x	x	x	x			x	
Suitable for Type-IV allergy sufferers													x	x	x				
APPLICATIONS	minimal risk	Patient mobilisation	x	x	x	x			x	x		x	x	x	x	x		x	
		Medication dispensing	x	x	x	x			x	x		x	x	x	x	x		x	
		Food preparation	x	x	x	x			x	x		x	x				x		
		Non-invasive physical examinations	x	x	x	x	x		x	x		x	x	x	x	x	x	x	
		Operation theater cleaning	x	x	x		x	x	x	x		x	x		x		x	x	
	complex risk	Instrument handling	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
		Dental procedures	x	x	x				x	x	x	x	x					x	
		IV injection / insertion	x	x	x		x		x	x		x	x	x	x		x	x	
		Staple removal	x	x	x		x		x	x		x	x				x	x	
		Patient wound dressing	x	x	x		x		x	x		x	x	x			x	x	
		Desinfection of instruments					x	x		x	x							x	
		Handling cytotoxics*					x	x										x	
		Catheterization															x	x	
RECOMMENDED SEGMENTS	Hospital	Ⓢ	Ⓢ	Ⓢ	Ⓢ	Ⓢ	Ⓢ	Ⓢ	Ⓢ	Ⓢ	Ⓢ	Ⓢ	Ⓢ	Ⓢ	Ⓢ	Ⓢ	Ⓢ		
	Dental		Ⓢ	Ⓢ				Ⓢ	Ⓢ	Ⓢ	Ⓢ	Ⓢ							
	Primary care	Ⓢ	Ⓢ	Ⓢ	Ⓢ								Ⓢ	Ⓢ	Ⓢ	Ⓢ	Ⓢ		
	Longterm care	Ⓢ		Ⓢ										Ⓢ	Ⓢ				
	Animal health	Ⓢ	Ⓢ	Ⓢ	Ⓢ									Ⓢ	Ⓢ				

\* For detailed information please consult the Cytotoxics List available at [www.sempermed.com/en/sempermed-informs/chemical-resistance](http://www.sempermed.com/en/sempermed-informs/chemical-resistance)

pf = powderfree pp = powdered

Version 11 06/2017 DM1500202



## EXAMINATION GLOVES FROM SEMPERMED – WE PROTECT YOUR HANDS

As one of the world's leading manufacturers of medical gloves, with more than 95 years of experience in research, development and production, it is important for us to give our clients and users recommendations for the optimal use of our extended range of Sempercare® products.

### 2-Times Certified Protection

Because selecting the right glove can have an impact on the health of the user as well as the patient, the high requirements of the European standards and guidelines are controlled: All Sempercare® products are certified as medical devices in accordance with the Medical Devices Regulation guideline 93/42 EWG, and fulfill all parts of standard EN455. Moreover, they are also certified as Personal Protective Equipment in accordance with Directive 89/686 EEC. This advanced purpose enables the use of Sempercare® gloves in many applications.

### Sempercare® Product Portfolio

#### 2-Times Certified Protection



### The Optimal Glove Choice

The demands vary greatly. In addition to protecting against chemicals and cleaning products\* our gloves are used to avert the risk of infections, especially blood-transmitted infections, such as Hepatitis B, Hepatitis C, or HIV – as required.

Impermeable to liquids and chemicals, yet elastic, adapting optimally to the hand form and skin, as well as unprecedented dexterity – there is hardly a glove that meets all of these requirements. Therefore is the selection of the most appropriate glove for each application area, of great importance. The protective function in this case is dependent on the glove material to defend against substances as well as the mechanical stresses faced by the glove. The wearing time of the glove also plays an important role.

\* For detailed information please consult the chemical resistance list available at [www.sempermed.com/en/sempermed-informs/chemical-resistance](http://www.sempermed.com/en/sempermed-informs/chemical-resistance)

**IMPORTANT NOTE:** The latest information is available at [www.sempermed.com](http://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 classification correspond to the latest status prior to printing. Technical details are average values from production and may vary in individual cases. Subject to mistakes, printing errors and amendments.  
CAUTION: Natural latex can cause allergic reactions, including anaphylactic shock.

### CONTACT US!

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## DESIGNED AROUND YOUR HANDS

### EXAMINATION GLOVES



The Sempercare® product portfolio, offers the right solution for the most diverse demands. For more information see: [www.sempermed.com](http://www.sempermed.com)



## Formulation of Final Product

In accordance with Regulations (EU) 2017/745 & (EU) 2016/425 and the following standards: EN 455-3 & EN 420.

We,  
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Austria**

authorised EC representative of the manufacturer  
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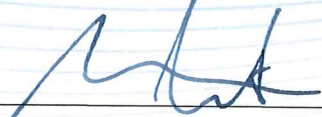
disclose the formulation of the final product identified as

### sempercare nitrile skin<sup>2</sup>

DESCRIPTION	RAW MATERIAL	CAS-NUMBER	COMPOSITION [%]
<b>BASE MATERIAL</b>	Nitrile latex	9010-81-5	90 - 95%
<b>PH ADJUSTER</b>	Potassium hydroxide	1310-58-3	1.0 - 2.0%
<b>CROSSLINKING SYSTEM</b>	Zinc oxide	1314-13-2	1.0 - 4.0%
<b>CROSSLINKING SYSTEM</b>	Sulphur	7704-34-9	1.0 - 3.0%
	Zinc diethyldithiocarbamate	14324-55-1	
	Zinc dibutyldithiocarbamate	136-23-2	
	Zinc 2-mercaptobenzothiazole	155-04-4	
<b>PIGMENT</b>	Titanium dioxide	13463-67-7	1.0 - 4.0%
	C.I. Pigment Blue 15	147-14-8	
	C.I. Pigment Violet 23	6358-30-1	
<b>OUTSIDE</b>	Calcium stearate	1592-23-0	< 0.1%

All data are provided only for the purpose of your orders hereafter. No part of them may be made available to others without prior consent.

Issued: 09 June 2020



Dr. Alexander Weinert  
Head of Technical Product Management




Christoph Hafenscher  
Technical Product Manager

## Recommendation on Chemical Resistance – Cytostatics

Sempermed gloves for single use have been tested in accordance with ASTM D6978 "Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs" by independent accredited test institutes.

<b>Classification:</b>
Not suitable
Suitable if changed before permeation breakthrough
Suitable for longer surgeries*

<b>Permeation Rate:</b>
The tests were performed according to ASTM D6978

**Caution: Damaged or swelling gloves shall be changed immediately!**

\*For reason of precaution it is recommended to change gloves after 2 hours!

**TEST RESULTS by:**

- ARDL Akron Rubber Development Laboratory, Ohio, USA

**Breakthrough Detection Time (BDT) = Minutes (min)\***

Chemotherapy Drug	mg/ml	Sempercare® Green	Sempercare® Shine / Silk	Sempercare® Cobalt Blue	Sempercare® Velvet	Sempercare® Skin?/ Aloe	Sempercare® Shine+	Sempercare® Nitrile	Sempercare® Nitrile sterile	Sempercare® Safe+
		NCF-035GR	NCF-035WH	NOF-030CO	NOF-030VB	NOF-035	NOF-039WH	NOF-047	NOF-047	NOF-065RB
		Nitrile – NBR	Nitrile – NBR	Nitrile – NBR	Nitrile – NBR	Nitrile – NBR	Nitrile – NBR	Nitrile – NBR	Nitrile – NBR	Nitrile – NBR
		BDT	BDT	BDT	BDT	BDT	BDT	BDT	BDT	BDT
5-Fluorouracil	50,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Carmustine (BiCNU)	3,3	22	14	25	13	23	14	46	46	14
Cisplatin	1,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Cyclophosphamide (Cytoxan)	20,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Cytarabine	100,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Dacarbazine (DTIC)	10,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Daurorubicin HCl	5,0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Doxorubicin HCl	2,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Epirubicin	2,0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Etoposide	20,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Ifosamid	50,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Methotrexate (Amethopterin Hydrate)	25,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Mitomycin C	0,5	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Mitoxantrone HCl	2,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	n/a
Oxaliplatin	5,0	n/a	n/a	n/a	n/a	> 240	n/a	> 240	> 240	> 240
Paclitaxel (Taxol)	6,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240
Thio-Tepa	10,0	27	13	37	14	47	13	38	38	58
Vincristine sulfate	1,0	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240	> 240

\*Concentration: according instruction leaflet

n/a ..... not available

**IMPORTANT NOTE:** The latest chemical resistance list can be found at [www.sempermed.com](http://www.sempermed.com). Please note that the product characteristics are directly dependent on the conditions of use and on the purity of the chemical substances concerned. The chemical resistance has been assessed under laboratory conditions and cannot reflect all actual conditions. 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.

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This document was issued electronically and is therefore valid without signature and has a validity of up to one year.

Date of Issue: 07.02.2022

## Recommendation on Chemical Resistance

Below protective gloves have been tested in accordance with EN 374-3:2003 "Determination of resistance to permeation by chemicals" and EN 16523-1:2015 "Determination of material resistance to permeation by chemicals" and achieve following test results.

**Caution: Damaged or swelling gloves shall be changed immediately!**

For reason of precaution it is recommended to change gloves after 2 hours!

Chemicals (synonyms)	Brand Name	Sempercure® Green	Sempercure® Velvet	Sempercure® Skin? / Aloe	Sempercure® Shine / Silk	Sempercure® Soft	Sempercure® Shine+	Sempercure® Nitrile	Sempercure® Safe+
	Cas-No. / Spec Code	NCF-035GR	NOF-030VB	NOF-035VB	NOF-035WH	NOF-037PK	NOF-039WH	NOF-047OB	NOF-065RB
Acetic acid (10%)	64-19-7	Level 3	Level 3	Level 3	Level 3	Level 6	Level 3	Level 5	Level 5
Acetone (2-propanone, methyl ketone)	67-64-1	X	X	X	X	X	X	X	X
Acetonitrile (cyanomethane, ethyl nitrile)	75-05-8	X	X	X	X	X	X	X	X
Acryl amide (40%)	79-06-1	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6
Ammonium hydroxide (25 %)	1336-21-6	n/a	A	Level 1	Level 1	Level 1	Level 1	Level 1	Level 1
Benzalconiumchloride liquid (Quats)	63449-41-2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Chlorhexidindigluconat (0,5 %)	18472-51-0	n/a	n/a	Level 6	Level 6	Level 6	Level 6	n/a	n/a
Chloroform (trichlormethan)	67-66-3	X	X	X	X	X	X	X	X
Dichlormethan (Methyldichlorid, Freon 30)	75-09-2	X	X	X	X	X	X	X	X
Diethyl amine (DEA)	109-89-7	X	X	X	X	X	X	X	X
Diethyl ether (diethyloxid, ethoxyethane)	60-29-7	X	X	X	X	X	X	X	X
Dimethylsulfoxid DMSO (deltan, demasorb)	67-68-5	X	X	X	X	X	X	X	X
Ethanol (10%) (ethyl alcohol)	64-17-5	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Ethanol (20%) (ethyl alcohol)	64-17-5	Level 1	Level 1	Level 1	Level 1	Level 6	Level 1	Level 6	Level 6
Ethanol (70%) (ethyl alcohol)	64-17-5	n/a	n/a	X	X	A	A	A	A
Ethidium bromide (1%) (homidium bromide)	1239-45-8	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6
Ethyl acetate (Aceto acid ether)	141-78-6	n/a	n/a	X	X	X	X	X	X
Fentanyl Citrate Inj. (100µg/2ml)		n/a	n/a	Level 5	Level 5	Level 5	Level 5	n/a	n/a
Formaldehyd (37%) with Methanol (10% )	50-00-0	Level 6	Level 4	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6
Gasoline (Petrol, heavy, 150 - 190°C)	8032-32-4	X	X	X	X	X	X	X	X
Glutaraldehyde (5%) (Pentan-1,5- dial, Glutaral)	111-30-8	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6
Heptane - n	142-82-5	n/a	n/a	X	X	X	X	X	X
Hexane - n	110-54-3	n/a	n/a	X	X	X	X	A	A
Hydrochloric acid (10%) (muriatic acid, chlorhydric acid)	7647-01-0	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	n/a	n/a
Hydrochloric acid (36%) (muriatic acid, chlorhydric acid)	7647-01-0	n/a	n/a	Level 2	Level 2	Level 2	Level 2	n/a	n/a
Hydrofluoric acid (40%)	7664-39-3	n/a	n/a	n/a	n/a	n/a	n/a	A	A
Hydrogen peroxide (30 %)	7722-84-1	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6
Isopropyl alcohol (70%) (2-propanol, IPA)	67-63-0	Level 1	n/a	Level 2	Level 2	Level 2	Level 2	Level 3	Level 3
Methanol (5%) (methyl alcohol)	67-56-1	n/a	n/a	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6
Methanol p.a. (methyl alcohol)	67-56-1	n/a	n/a	X	X	X	X	X	X
Methylmethacrylate (MMA)	80-62-6	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Ninhydrin (0,2%)	485-47-2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Nitric acid (10%)	7697-37-2	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6
Nitric acid (36%)	7697-37-2	n/a	n/a	n/a	n/a	Level 2	n/a	Level 3	Level 3
Octenidin (0,1%)	71251-02-0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

Chemicals (synonyms)	Brand Name	Sempercure® Green	Sempercure® Velvet	Sempercure® Skin?/ Aloe	Sempercure® Shine / Silk	Sempercure® Soft	Sempercure® Shine+	Sempercure® Nitrile	Sempercure® Safe+
	Cas-No. / Spec Code	NCF-035GR	NOF-030VB	NOF-035VB	NOF-035WH	NOF-037PK	NOF-039WH	NOF-047OB	NOF-065RB
Phenol (10%)	108-95-2	n/a	X	Level 1	Level 1	Level 1	Level 1	X	X
Phosphoric acid (85%) (orthophosphoric acid)	7664-38-2	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Potassium hydroxide (50%) (caustic potash, lye)	1310-58-3	n/a	n/a	Level 6	Level 6	Level 6	Level 6	n/a	n/a
Povidone iodine (10%)	25655-41-8	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Sodium hydroxide (40%) (caustic soda, lye, white caustic)	1310-73-2	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6	Level 6
Sodium hypochlorite (10%)	7681-52-9	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Sulfuric acid (30%) (vitriol)	7664-93-9	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Sulfuric acid (96%) (vitriol)	7664-93-9	A	A	A	A	A	A	A	Level 1
Toluene (methylbenzol, phenylmethan, toluol)	108-88-3	X	X	X	X	X	X	X	X
Trichlorethane (methyltrichloromethane)	71-55-6	X	X	X	X	X	X	X	X
Xylene (xyloi, dimethylbenzene)	95-47-6	X	X	X	X	X	X	X	X

X	Not Recommended	Level 3	> 60min
A	Splash Protection - change glove immediately after contact!	Level 4	> 120min
Level 1	> 10min	Level 5	> 240min
Level 2	> 30min	Level 6	> 480min

n/a ..... not available

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Date: 25.10.2018 / Q4 2018

**Sempermed** *Always keeping you up to date.*

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## Technical product specification

Product name	sempercure nitrile skin <sup>2</sup>	Version / Index no:
Spec code	NOF/NCF-035VB-N-3CZ	sempercure nitrile skin <sup>2</sup> _Version
Date of issue	28/02/2019	D_February 2019_EN

### General information

Type	single use examination and disposable protective glove, non sterile
Labelling	information printed on dispenser box
Shape	ambidextrous - straight fingers
Material	Nitrile Butadiene Rubber (NBR) [not made with natural rubber latex]
Colour	violet blue
Inside	powder free
Outside	no treatment
Cuff / surface	rolled cuff / finger textured
Shelf life	3 years
Available sizes	XS (5-6) S (6-7) M (7-8) L (8-9) XL (9-10)

### Dimensions, physical properties and biocompatibility

Glove length	median $\geq$ 240 mm (according to EN 455-2)
Minimum wall thickness	<i>at finger</i> 0.14 mm (double measured) / 0.07 mm (single measured)
	<i>at palm</i> 0.12 mm (double measured) / 0.06 mm (single measured)
	<i>at cuff</i> 0.08 mm (double measured) / 0.04 mm (single measured)
Glove width	according to EN 455-2: median XS $\leq$ 80 mm, S $80 \pm 10$ mm, M $95 \pm 10$ mm, L $110 \pm 10$ mm, XL $\geq 110$ mm
Force at Break	median $\geq$ 6 N (during shelf life according to EN 455-2)
Tensile Strength	min. 14 MPa after aging (according to ASTM D6319)
Elongation at Break	min. 400% after aging (according to ASTM D6319)
Residual powder / Powder content	$\leq$ 2 mg (according to EN 455-3)

### Performance requirements and inspection levels

Freedom from holes (Barrier)	AQL $\leq$ 1.5 (as per EN 455-1, sampling in accordance with ISO 2859-1, G-1 )
Dimensions and physical properties	AQL 4.0 (as per ASTM D6319, sampling in accordance with ISO 2859-1, S-2 )

### Standards, guidelines & quality certificates

Quality certification	ISO 9001, ISO 13485, ISO 14001
Conformity to directives and regulations	<ul style="list-style-type: none"> <li>- Medical Device Directive 93/42/EEC: Class I</li> <li>- PPE Regulation (EU) 2016/425: Category III</li> <li>- Food Contact Materials Regulation (EC) 1935/2004</li> </ul>
Conformity to standards	EN 420, EN ISO 374-1, EN 374-2, EN 16523-1, EN 374-4, EN ISO 374-5, EN 455 1-4, ASTM D6319, ASTM F1671

## Technical product specification

Product name	sempercure nitrile skin <sup>2</sup>	Version / Index no:
Spec code	NOF/NCF-035VB-N-3CZ	sempercure nitrile skin <sup>2</sup> _Version
Date of issue	28/02/2019	D_February 2019_EN

### Instructions and additional statements

<b>Storage instruction</b>	Store in original packaging in a dry and dark place at 10 °C to 30 °C. Refer to guidelines of storage of rubber products as described in ISO 2230:2002. Ensure that storage area is kept cool, dry and dust free, avoid ventilation and storage close to photocopy equipment. Copper-ions discolour the glove. Protect gloves against ultraviolet light sources, as sunlight and oxidizing agents. Storage above 30 °C will lead to accelerated aging and should be avoided.
<b>Cautionary statement and ingredient information</b>	This product contains accelerators (Dithiocarbamate type, Zinc-mercaptobenzothiazol) not to be used in a hypersensitivity of these substances. For further information, a list of substances contained in the glove is available upon request.

### Reporting system

<b>Medical device vigilance and reporting system</b>	According to the official reporting criteria of the Medical Device directive, incidents caused by examination gloves must be reported immediately to our Medical Device reporting officer. E-Mail: <a href="mailto:sempermed.complaints@semperitgroup.com">sempermed.complaints@semperitgroup.com</a> or Tel.: +43 2630 310 0
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 A. Wöss Director	 J. Glantschnig Regulatory Affairs Manager Sempermed	 L. Rieger Head of Product Management
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<b>Remark</b>	Replaces all previous versions. All standards references refer to the date of document issue.
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