

Novolab NV		Date: 23-09-2021
Diebeke 7 (IZ) 9500 Geraardsbergen Belgium		Version: 1.5
	User Information Sheet	Documentn°: C4-2



ROLL-O-GLOVE® Nitri - Extra Sensitive for single use - latex free

Powder Free Ambidextrous Non-Sterile 24cm nitrile gloves with textured fingertips.

ROLL-O-GLOVE® Nitri - Extra Sensitive are PPE Category III (Complex Design) gloves according to Council Directive 89/686/EEC. (see SPC0234760/1520/EN, SPC0234760/1520, SPC0268083/1809, CHM0268022/1809/CL/A - B - C).

Certificate number: 2777/13038-02/E00-00

Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Authorized representative(EU): Novolab NV Diebeke 7(IZ) 9500 Geraardsbergen Belgium info@novolab.be +3254421580		References & size: A29557 (XS-6) A29558 (S-7) A29559 (M-8) A29560 (L- 9) A29561 (XL-10)
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PRODUCT CHARACTERISTICS AND CLASSIFICATION

- The gloves are made of powder free & latex free chlorinated nitrile (acrylonitrile butadiene).
- Gloves that offer an excellent sensitivity and strength at a low cost while they show full compliance with the latest regulations. Contains no natural rubber (latex).
- The soft blue color makes them useful in different industries such as: Food Industry, Medical institutions or PPE environments.
- Secure grip in both wet and dry conditions duo to the textured finger tips
- Disposable gloves are intended for splash protection (Not suitable for long duration chemical exposure – use heavy duty gloves instead-see intended use)
- R-DON Technology for enhanced donning with damp hands.

Classification: PPE CAT III (complex design)

Applicable norms: EN ISO 21420: 2020 – EN ISO 374 – EN455 – MDR (EU) 2017/745

R-DON Technology Patent pending US 16/464,914 and PCT/MY2019/050033

*Notified body: SATRA TECHNOLOGY EUROPE LTD, Bracetown Business Park, Clonee, Dublin D15 YN2P, Ireland (N.B. 2777).

Design: Ambidextrous – textured fingers – beaded cuff – blue color

Packaging: 100 gloves per dispenser, 10 dispensers per case.

Quality regulation in conformity with 21CFR820 and sampling procedure according to ISO2859

Product conformity in compliance with ASTM D 6319-00a

PHYSICAL PROPERTIES & EXPLANATION OF PROTECTION LEVELS

EN ISO 21420: 2020			
Meets or exceeds EN455-1:2000, EN455-2:2009+A1:20011, EN455-3:2006 and EN455-4:2009 relating to MDR (EU) 2017/745 for medical devices. Suitable for food contact: Tested in accordance with BS EN 1186-9/2002. (In application EC 1935/2004)			
Tested in accordance with EN ISO 374-5:2016   VIRUS	Tested against viruses The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.		
EN ISO 374-1/Type B   KPT	Tested in accordance with EN ISO 374-1:2016* (EN ISO 374-1:2016 replaces & exceeds EN374-1:2003)		
		EN16523:2015 Permeation Level	EN ISO 374-4:2019 Degradation
	K = 40% Sodium Hydroxide	6	13.9%
	P = 30% Hydrogen Peroxide	4	27.0%
T = 37% Formaldehyde	5	36.4%	

EN ISO 374-1:2016 Permeation levels are based on breakthrough times as follows:

Performance level (EN 16523:2015)	1	2	3	4	5	6
Minimum breakthrough times (mins)	10	30	60	120	240	480

The gloves have passed the permeation test for at least 3 chemicals from the defined list of 18 chemicals.

The gloves obtained a breakthrough time of at least 30 minutes for these chemicals. By this result Level B was obtained.

TYPE A: 6 chemicals - TYPE B: 3 chemicals – TYPE C: 1 chemical

EN ISO 374-4:2019 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical

"This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals."

"The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400 mm - where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture."

"It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation."

"When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves"

"Before usage, inspect the gloves for any defect or imperfections.

EN ISO 374-5: 2016 Protection against bacteria, fungi and viruses

Protection against Bacteria & Fungi:

EN ISO 374-2:2019	Resistance to penetration (Freedom from holes)	Level
	Air leakage (passed)	AQL <1.5 (level 2)
	Water leakage (passed)	AQL <1.5 (level 2)

Determination of resistance to penetration (Freedom from holes). The gloves have passed air leak & water leak test as stated in the standard. A glove which resists penetration and passes both air leak and water leak test to Performance level 2 is deemed to be an effective barrier to bacteria and fungi. The performance levels are ascertained from the Acceptance Quality Level(AQL) set in manufacturing and defined in EN 374-2 as shown in the table A below.

Table A: (Acceptance Quality levels (AQL) and inspection levels from ISO 2859)

Performance level	Acceptance quality level	Inspection levels
Level 3	<0.65	G1
Level 2	<1.5	G1
Level 1	<4.0	S4

Protection against Viruses

Testing in accordance with ISO 16604:2004 for resistance to penetration by blood-borne pathogens. Test method using Phi-X174 bacteriophage. The gloves have passed the test successfully and are deemed to be an effective barrier against viruses.

Size & dexterity EN ISO 21420: 2020					
ASTM D3767					
SIZE	Length	Width	THICKNESS		
	mm	mm	cuff (mm)	palm (mm)	finger (mm)
Extra small	240±5	75±5	0,05-0,08	0,06-0,09	0,08-0,14
Small	240±5	85±5	0,05-0,08	0,06-0,09	0,08-0,14
Medium	240±5	95±5	0,05-0,08	0,06-0,09	0,08-0,14
Large	240±5	106±5	0,05-0,08	0,06-0,09	0,08-0,14
Extra large	240±5	115±5	0,05-0,08	0,06-0,09	0,08-0,14
Dexterity: level 5					

PRECAUTIONS FOR USE

- Some gloves might contain ingredients which are known to be a possible cause of allergies in sensitized persons, who may develop irritant in/or allergic reactions. If allergic reactions should occur, obtain medical advice immediately. For more information, please contact your distributor.
- Before use, inspect the gloves for any defects or visual imperfections. If in doubt, do not use the gloves, change them for new ones.
- Correct use of PPE is essential to prevent infection or avoid risk of exposure to harmful chemical substances.
- Keep all chemicals from your skin prior to the use of the gloves, even if considered to be harmless.
- Ensure no chemicals can enter by the cuff.

INTENDED USE

- Nitrile disposable gloves are not intended for applications involving direct exposure to harsh chemicals, use heavy duty protective gloves instead. Disposable gloves should only be used for brief contact or splash protection and are intended for single use only. Nitrile disposable gloves are not suitable for thermal, cryo or mechanical protection. Immediately discontinue use if damaged.
- The gloves prevent hand contamination with biological and chemical liquids, but not prevent punctures and injuries caused by needles and other sharp objects.
- Gloves should not be reused. If the gloves have been in contact with body fluid or harmful chemicals remove them carefully and dispose per facility policy. Gloves are not designed to be laundered.
- To prevent transmission of infection to patients the following treatment must be followed:
 1. Gloves must be changed before next patient is examined or next lot of chemical handled.
 2. During donning do not touch finger of gloves with bare hands.
- The information given in the pictograms or data provided on chemical resistant breakthrough times is based on laboratory tests and is therefore advisory only, since it does not necessarily reflect the actual duration of use in the workplace.

For any additional information please contact the distributor.

PACKAGING, STORAGE & DISPOSAL

- Gloves are packed in closed dispenser boxes of 100 pcs.
- Store the gloves in a cool and dry place for maintaining the best quality. Do not store above 40°C. Gloves should be protected in any case from direct sunlight, UV light exposure, X-ray devices or other ozone sources during storage. Disposal of the gloves should be in accordance with local authority regulations and with industry best practices. Chloroprene gloves are not biodegradable and thus should be disposed properly.