Technical Data Sheet

Article: 2215 teXXor

Model: Nitril-Disposable Gloves, powder-free

Size: S (6-7), M (7-8), L (8-9), XL (9-10)

For details on product dimensions and weights see below (table).

Colour: lavender

Material: Nitrile, non-powdered

Mat. thickness: 0,12 mm (approx.) double measured

Packaging: 10 box / carton

quantity per box: 100 pieces

Details of packaging are below mentioned (table)

Care instructions:

PPE-category: **Categroy III - includes risks that may lead to serious consequences such as death or irreversible damage to health, in accordance with PPE Regulation (EU) 2016/425, Annex I**
(published in the Official Journal of the European Union)

MD class: **Medical device class I - includes low risks, according to MDR regulation (EU) 2017/745 (reference in the Official Journal of the European Union)**

Standardize:

EN ISO 21420:2020 - Protective gloves - General requirements and test methods

EN ISO 374-1:2016+A1:2018 - Protective gloves against dangerous chemicals and micro-organisms (Part 1: Terminology and performance requirements for chemical risks)

Typ B:	Chemicals:	EN 374-4:2013	Class
	40% Sodium hydroxide (K)	-4,3%	6
	30% Hydrogen peroxide (P)	18%	6
	37% Formaldehyde(T)	28%	6

EN ISO 374-5:2016 - Protective gloves against dangerous chemicals and micro-organisms (Part 5: Terminology and performance requirements for micro-organisms risks)

Resistance to bacteria and fungi: passed
Resistance to virus: passed

EN 455 - Medical gloves for single use

EN 455-1:2020+A1:2022 - Medical gloves for single use - Part 1: Requirements and testing for freedom from holes - passed
EN 455-2:2015 - Medical gloves for single use - Part 2: Requirements and testing for physical properties - passed
EN 455-3:2015 - Medical gloves for single use - Part 3: Requirements and testing for biological evaluation - passed
EN 455-4:2009 - Medical gloves for single use - Part 4: Requirements and testing for shelf life determination - passed

EGV 1935:2004 - Regulation (EC) of the European Parliament and of the Council dated 27 October 2004 on materials and objects intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, Official Journal of the European Union L 388/4 dated 13.11.2004 (and their changes)

Explanation: The gloves can therefore be used safely in the food industry for the preparation and handling of foodstuffs. Their unprinted surfaces may come into direct contact with dry, watery, acidic and alcoholic foodstuffs and dairy products for short periods of time.

(X = not tested)

More detailed information on the standards can be found on the following pages.

Fittings:

Nitrile (lavender), non-powdered, textured surface, AQL 1.5, rolled cuff, can be worn left and right, tested for use with foodstuffs according to regulation (EG) 1935:2004, material thickness: palm = approx. 0.12 mm/finger = approx. 0.14 mm
dispenser box with 100 gloves

Characteristics:

The gloves provide a good fingertip feel and sense of touch due to the low material thickness and are therefore comfortable to wear. They have a low AQL value, thus ensuring a high level of safety for the wearer. They are also certified for handling food.

Application:

Applicable for many hygiene tasks and/or to protect the wearer, such as in the food processing industry, building cleaning and cleaning in general, warehousing and logistics, sorting and packaging work

Additional information regarding purpose, applications and risk assessment:

These gloves satisfy the requirements of the quoted standards. Please note that the actual conditions of use cannot be simulated and that the decision on the glove's suitability for its intended purpose therefore lies exclusively with the user. The manufacturer is not responsible for improper use. Hence, an assessment of the residual risk should be performed before use in order to determine whether this glove is suitable for its intended purpose.

Kindly note the printed pictograms and performance levels.

Precautionary measures during use:

- Only use gloves with a printed chemical pictogram when handling chemicals.
- Make certain that the selected glove is resistant to the chemicals being used.
- Do not use these gloves to protect against serrated edges or blades, etc.
- If gloves must be used in a hot environment, make certain that they satisfy the requirements of EN 407 and that they were tested as specified therein.
- Do not use the gloves close to moving machine parts.
- Check the gloves carefully before use to make certain there are no defects or imperfections.
- Take note that the gloves do not protect against sharp objects such as injection needles.
- Discard damaged, worn, dirty or soiled gloves, irrespective of the substance (including on the inside), as they may lead to skin irritation and rashes. Consult a doctor or dermatologist should such cases arise.

EN ISO 21420:2020 - Protective gloves - General requirements and test methods:

This standard specifies the relevant test methods to be used for all protective gloves and the general requirements for design principles, glove assembly, resistance of the glove material to water penetration, harmlessness, comfort and performance as well as the labeling to be carried out by the manufacturer and the information to be provided by the manufacturer.

Protective gloves against dangerous chemicals and micro-organisms:

EN ISO 374-1:2016+A1:2018, Part 1:	**Terminology and performance requirements for chemical risks**
EN ISO 374-2:2019, Part 2:	**Determination of resistance to penetration**
EN ISO 374-4:2019, Part 4:	**Determination of resistance to degradation by chemicals**
EN ISO 374-5:2016, Part 5:	**Terminology and performance requirements for risks by micro-organisms**
EN 16523-1:2015+A1:2018, Part 1:	**Determination of material resistance to permeation by chemicals – Part 1 Permeation by liquid chemicals under conditions of continuous contact**

Definition of terms:

Degradation:	An adverse change in one or more properties of a material used in a protective glove due to contact with a chemical. NB: Examples of degradation include flaking, swelling, disintegration, embrittlement, discolouration, a change in appearance, hardening or softening etc.
Penetration:	Movement of a chemical through materials, seams, pinholes or other imperfections in the protective glove material at a non-molecular level.
Permeation:	Movement process of a chemical through the material of the protective glove material at a molecular level. NB: Permeation includes the following: Absorption of molecules of the chemical into the contacted (outside) surface of a material; Diffusion of the absorbed molecules in the material; Desorption of the molecules from the opposite (inside) surface of the material.

Terminology and performance requirements for micro-organisms risks EN ISO 374-5:2016:

Article	Result article 2215
Resistance to Bacteria & Fungi	passed
Resistance to Virus	passed

Resistance to penetration EN ISO 374-2:2019 - Acceptable quality limit (AQL):

Performance level	Acceptable quality limit (AQL)	Inspection level	Article 2215
3	< 0,65	G1	
2	< 1,50	G1	AQL = 1,50
1	< 4,00	S4	

Determination of resistance to degradation EN 374-4:2019:

Code letter	Test chemical	CAS-RN	Class	Article 2215
K	40% Sodium hydroxide	1310-73-2	Inorganic alkali	-4,3%
P	30% Hydrogen peroxide	7722-84-1	Peroxide	18%
T	37% Formaldehyde	500-00-0	Aldehyde	28%

Material resistance to permeation by chemicals EN ISO 374-1:2016+A1:2018:

Breakthrough time (min.)	Performance level for permeation
> 10	1
> 30	2
> 60	3
> 120	4
> 240	5
> 480	6

Protective gloves against chemicals are classified in three types, based on their permeation performance:

- Type A: The permeation performance must satisfy at least Level 2 for no less than six test chemicals according to the following table:
- Type B: The permeation performance must satisfy at least Level 2 for no less than three test chemicals according to the following table:
- Type C: The permeation performance must satisfy at least Level 1 for no less than one test chemical according to the following table:

List of test chemicals:

Code letter	Test chemical	CAS-RN	Class	Breakthrough time (min.) art. 2215	Level art. 2215
A	Methanol	67-56-1	Primary alcohol		
B	Acetone	67-64-1	Ketone		
C	Acetonitril	75-05-8	Nitrile		
D	Dichloromethane	75-09-2	Chlorinated hydrocarbon		
E	Carbon sulphide	75-15-0	Sulphur-containing organic compound		
F	Toluene	108-88-3	Aromatic hydrocarbon		
G	Diethylamine	109-89-7	Amine		
H	Tetrahydrofuran	109-99-9	Heterocyclic and ether compounds		
I	Ethyl acetate	141-78-6	Ester		
J	n-heptane	142-82-5	Aliphatic hydrocarbons		
K	Sodium hydroxide 40%	1310-73-2	Inorganic alkali	> 480	6
L	Sulphuric acid 96%	7664-93-9	Inorganic acid, oxidizing		
M	Nitric acid 65%	7697-37-2	Inorganic acid, oxidizing		
N	Acetic acid 99%	64-19-7	Organic acid		
O	Ammonia water 25%	1336-21-6	Organic alkali		
P	Hydrogen peroxide 30%	7722-84-1	Peroxide	> 480	6
S	Hydrofluoric acid 40%	7664-39-3	Inorganic acid		
T	Formaldehyde 37%	50-00-0	Aldehyde	> 480	6

Type B:

The three tested chemicals must be identified by their code letter, positioned below the pictogram as shown below. If chemicals not included in the list are also tested, information on the performance levels must be made available in the user instructions.

EN ISO 374-12016+A1:2018/Typ B

KPT

BIG Arbeitsschutz GmbH | Königsberger Str. 6 | 21244 Buchholz | Telefon 04181 9095 0 | Fax 04181 9095 55 | info@big-arbeitsschutz.de | www.big-arbeitsschutz.de

WARNINGS:

- **This information does not provide any details on the actual duration of protection at the workplace; it also does not distinguish between blends and pure chemicals.**
- **Resistance to chemicals was assessed using samples taken only from the palm and tested under laboratory conditions (apart from the glove measures 400 mm or longer, in which case the cuff is also tested); the stated resistance refers only to the tested chemicals. Resistance may differ if the chemical is present in a blend.**
- **Users are recommended to check whether the glove is suitable for its intended application, as the conditions at the workplace may differ from those during type testing, depending on the temperature, abrasion and degradation.**
- **Protective gloves that have already been used may provide less resistance to dangerous chemicals due to changes in their physical properties. The actual service life may be reduced significantly due to degradation, movement, stringing, abrasion and suchlike, caused by contact with chemicals. Degradation may be the most significant factor in regard to aggressive chemicals; this must be duly considered in the selection of protective gloves against chemicals.**
- **The gloves must always be checked for imperfections before use.**
- **The manufacturer must provide decontamination instructions for reusable gloves.**
- **Gloves are for single-use only if they do not include decontamination instructions, and the following warning must be added: To be used only once.**

Protection against microorganisms (bacteria, fungi and viruses) according to EN ISO 374-5:2016

Marking of gloves that protect against viruses, bacteria and fungi

ISO 374-5:2016

VIRUS

The bacteriophage penetration test according to ISO 16604:2004 (method B) must be performed and passed if a protection against viruses be stated.

WARNING:
Resistance to penetration was assessed under laboratory conditions and refers exclusively to the tested samples.

EN 455 - Medical gloves for single use:

	Result article 2215
EN 455-1:2020+A1:2022 - Medical gloves for single use - Part 1: Requirements and testing for freedom from holes	passed
EN 455-2:2015 - Medical gloves for single use - Part 2: Requirements and testing for physical properties	passed
EN 455-3:2015 - Medical gloves for single use - Part 3: Requirements and testing for biological evaluation	passed
EN 455-4:2009 - Medical gloves for single use - Part 4: Requirements and testing for shelf life determination	passed

Materials and articles in contact with foodstuffs:

EN 1186-1:2002, Part 1:	Guide to the selection of conditions and test methods for overall migration
EN 1186-5:2002, Part 5:	Test methods for overall migration into aqueous food simulants by cell
EN 1186-14:2002, Part 14:	Test methods for substitute tests for overall migration from plastics
EN 13130 and CEN/TS 14234	,,Materials and articles in contact with foodstuffs – Plastics”

The gloves have been tested for their migration behaviour in accordance with standards EN 1186, EN 13130 and CEN/TS 14234 ""Materials and objects in contact with foodstuffs - plastics"", in their current form.
They comply with the provisions of:
- Regulation (EC) No. 1935:2004 of the European Parliament and of the Council dated 27 October 2004.
The gloves can therefore be used safely in the food industry for the preparation and handling of foodstuffs. (additional user instructions: further information is available on request.)

The clearance declaration No. ohne from 12.01.2022 was issued by:
Semperit Technische Produkte Ges.m.b.H.
Modecenterstrasse 22
1030 Vienna
Austria

Markings on the gloves:

Trademark, art.-no. of manufacutrer, size, CE-icon, pictograms with the corresponding numbers of the relevant European PPE standards, i-mark, factory icon with date of manufacture: month/year, hourglass pictogramm with expiry date: month/year

teXXor	Brand label of manufacturer
2215	Article no. of the manufacturer
10	Size of gloves (example)
	Pictograms with the corresponding numbers of the relevant European PPE standards (example, detailed pictogram see previous pages).
	The glass and fork symbol testifies that the product complies with the applicable requirements of Regulation (EC) 1935:2004 (and subsequent amendments) and can be used in the preparation and handling of foodstuffs.
	Do not reuse
CE	The CE marking confirms compliance with the requirements of European Regulation 2016/425.
2777	Four-digit number of the testing institute, which monitors the quality assurance of the manufacturer. This will be attached to the CE mark on the product.
	i mark: Reference to the manufacturer's information.
	Date of manufacture month/year: 00/0000
	Expiry date month/year: 00/0000

Dimensions/weights article:

Size	Length in mm	Width in mm	Height in mm double measured
S (6-7)	≤ 240	80 ± 10	0,12
M (7-8)	≤ 240	95 ± 10	0,12
L (8-9)	≤ 240	110 ± 10	0,12
XL (9-10)	≤ 240	115 ± 10	0,12

Details of packaging unit (Box):

Größe	kg gross	kg net	Length in cm	Width in cm	Height in cm
S (6-7)			22,00	11,00	6,80
M (7-8)			22,00	11,00	6,80
L (8-9)			22,00	11,00	6,80
XL (9-10)			22,00	11,00	6,80

Details of packaging unit (VE):

Size	kg gross	kg net	Length in cm	Width in cm	Height in cm
S (6-7)	4,10	3,10	36	26	25
M (7-8)	5,10	4,10	36	26	25
L (8-9)	5,80	4,80	36	26	25
XL (9-10)	6,20	5,20	36	26	25

Hazardous ingredients - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals):

The product is manufactured in compliance with Annex XVII of the European REACH regulation 1907/2006 and contains no hazardous substances in concentrations requiring declaration.

Declaration of Conformity

CE These gloves are classified as personal protective equipment (PPE). The CE mark confirms that the product satisfies the applicable requirements of Regulation (EU) 2016/425.

Identification and selection:

Selection of gloves must be made according to workplace requirements, type of hazard and relevant environmental conditions. The employer is responsible for choosing the right PSA. Therefore, it is necessary to check the suitability of the gloves for the needs needed before use.

Regulation for use:
The gloves fulfil the safety requirements only if they are worn in an entirely correct manner and in their best condition. Check the gloves for defects or flaws before use. If any tears or holes appear during use of the gloves, they must be disposed of immediately. Make sure that the gloves are not too large or too small and fit exactly. Modifications to this PPE are not permitted. Follow the instructions provided in the manufacturer's information and keep this information in a safe place during the entire service life of the PPE. We assume no responsibility for any damages and/or consequences resulting from improper use.

Care instructions:

This product is a disposable single use product and therefore should not be washed, bleached, tumble-dried, ironed, professionally dry cleaned or wet cleaned.

Cleaning, care and disinfecting:
The gloves must be carefully examined before they are worn to ensure that there is no damage. These gloves are single-use, disposable products; used gloves must be properly disposed of after use. If the gloves are contaminated with impurities that could pose a hazard, we recommend that the gloves be carefully wiped down alternating right and left. Use the gloved hand in such a way that the gloves can be removed without unprotected hands coming into contact with the impurities.

Storage and aging:
The gloves should be stored in their original packaging in a dark, cool and dry place, away from direct sunlight and away from any sources of heat. Prolonged contact with direct sunlight or excessive heat will shorten the service life. Avoid any contact of the product with solvents which could result in changes to the product or its properties. The service life is generally up to 5 years when used and stored properly (see also expiry date on the packaging). The dispenser boxes are also marked with the production date (month/year).

Disposal:
Used gloves may be contaminated with environmentally harmful or hazardous substances. Dispose of the gloves in accordance with applicable local laws.

Health risks:
Allergies, caused by the proper use of the gloves, are not yet known. If an allergic reaction still occurs, consult a doctor or dermatologist.

First Aid:
Remove the gloves if they are contaminated with hazardous materials.
In case of contact with skin: immediately consult a doctor if an allergic reaction occurs.
In case of eye contact: wash out the affected eye with water. Consult a doctor immediately.

The notified body responsible for the EU Type Examination:
SATRA Technology Europe Ltd.
Bracetown Business Park
Clonee, Dublin D15 YN2P
Ireland
Kenn-Nr.: 2777

Notified body that monitors the manufacturer’s quality assurance based on the production process (module D, in accordance with Annex VIII of PPE regulation (EU) 2016/425):
SATRA Technology Europe Ltd.
Bracetown Business Park
Clonee, Dublin D15 YN2P
Ireland
Kenn-Nr.: 2777

For the full Declaration of Conformity and manufacturer's information, please visit:
www.big-arbeitsschutz.de

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