

# Manufacturer's Information

pursuant to PPE Regulation (EU) 2016/425, Appendix II, Section 1.4. (Published in the Official Journal of the European Union)

Please read carefully before using! You are required to enclose this information leaflet when passing on the personal protective equipment, or to present it personally to the recipient. You may therefore reproduce this leaflet at your own discretion.

## Declaration of Conformity

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.

### A. Markings on the gloves:

Trademark, art.-no. of manufacturer, 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 pictogram with expiry date: month/year

- 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
- 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

### B. Explanation and numbers of the standards whose requirements the gloves satisfy:

Standards retrieved from: the Official Journal of the European Union. Available from Beuth Verlag GmbH, 10787 Berlin, www.beuth.de.

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

#### 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 374-1:2016+A1:2018/Typ B



KPT

**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.

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.

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.

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

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 micro-organisms (bacteria, fungi and viruses) according to EN ISO 374-5:2016**

**Marking of gloves that protect against bacteria, fungi and viruses**

EN 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.

**WARNINGS:**  
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

### C. Purpose, applications and risk assessment:

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

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 before use:

When donning the glove, please ensure that both glove and hand are clean, glove size is right, and it is properly fit on the contours and crotches of fingers. In case of contamination / perspiration, take off the glove, allow it to dry before wearing again and/or discard depending on the condition of glove.

When an indication of hand hygiene precedes a contact that also requires glove usage, hand rubbing or hand washing should be performed before donning glove.

#### 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 for heat application are requested, make certain that they satisfy the requirements of EN 407:2020 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.
- Gloves meeting the requirement for resistance to puncture in accordance with EN388:2016+A1:2018 may not be suitable for protection against sharply pointed objects such as hypodermic 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.
- For further information regarding the permissible user exposure, e.g. temperature, duration please contact the manufacturer.

#### Doffing instruction:

Clean off the outside of the gloves at least daily and prior to removing them.

Loosen the gloves on both hands. Hold hands down to prevent the material, product, or contaminated water from dripping onto your skin or clothing.

Keep the gloves down and remove the first glove only to the fingers – the cuff will remain over your palm

Grab the second glove with the first glove and remove it. The first glove should slip off.

Handle gloves by the inside only – the area not contaminated. Avoid touching the outside of the glove.

Wash your hands with soap and water – do not use hand sanitizers.

### D. Cleaning, care and disinfecting:

#### 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.

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.

#### E. Storage and ageing:

Keep in a cool, dry place; do not expose to direct sunlight; keep away from any ignition sources; store in the original packaging if possible. The mechanical properties of the gloves will not change for a period of up to 5 years from the manufacturing date, provided they are stored as recommended. A precise service life cannot be stated, as it depends on the type of use and on whether the user ensures that the gloves are used exclusively for their intended purpose. The manufacturing date (month/year) is stated on the gloves.

#### F. Disposal:

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

#### G. Material composition:

Nitrile, non-powdered

#### H. Packaging:

This item will be delivered in a uniform cardboard box with a content of: 10 box

The smallest sales unit is: 100 piece

#### I. Health risks:

There have been no reported incidents of allergies provoked by use of the gloves for their intended purpose. You should nonetheless consult a doctor or dermatologist if you experience an allergic reaction.

#### Notified body responsible for the EU Type Examination:

SATRA Technology Europe Ltd.

Bracetown Business Park

Clonee, Dublin D15 YN2P

Ireland

Kenn-Nr.: 2777

in accordance with EU PPE Regulation 2016/425.

**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

**Manufacturer's name and address:**

BIG Arbeitsschutz GmbH, Königsberger Str. 6, 21244 Buchholz/Nordheide, Germany

**For the full Declaration of Conformity and additional technical information, please visit:**  
**[www.big-arbeitsschutz.de](http://www.big-arbeitsschutz.de)**



issued on 17.05.2024/Rev.04