Article 2250 - Chemical-Protective Gloves NATURLATEX, GERAUT - PPE category III: high risk - size(s): S/7-XXL/11

Manufacturer’s Information

pursuant to PPE Regulation (EU) 2016/425, Annex 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

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.

A. 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, hourglass pictogramm with expiry date

teXXor	Brand label of manufacturer
2250	Article no. of the manufacturer
10	Size (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.
CE	The CE marking confirms compliance with the requirements of European Regulation 2016/425.
0598	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 DIN Media GmbH, D-10787 Berlin. www.dinmedia.de

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

EN 388:2016+A1:2018 - Protective gloves against mechanical risks:

Protective gloves against mechanical risks must achieve at least Level 1 for at least one of the properties (abrasion, cut, tear and puncture resistance) or at least Level A of the TDM cut resistance test according to EN ISO 13997:1999.

Abrasion resistance:	The number of abrasion cycles required to rub through the test specimen.
Cut resistance (Coupe-Test):	The number of test cycles in which the test specimen is cut through with constant force and repeated contact.
Tear resistance:	The force needed to continue tearing the cut sample.
Puncture resistance:	The force needed to puncture the sample using a standardized test stylus.
Cut resistance (TDM):	The minimum force that is necessary to cut through the test specimen with a single contact.

EN 388:2016+A1:2018



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Test criteria	Rating	Article 2250
A = Abrasion resistance	0 - 4	2
B = Cut resistance (Coupe test)	0 - 5	1
C = Tear resistance	0 - 4	3
D = Puncture resistance	0 - 4	1
E = Cut resistance (TDM) according to EN ISO 13997:1999	A - F	X
F = Impact protection test according to EN 13594:2015	P	X

Test	1	2	3	4	5
A = Abrasion resistance (number of abrasion cycles)	100	500	2000	8000	-
B = Cut resistance (index) Coupe test	1,2	2,5	5,0	10,0	20,0
C = Tear resistance (N)	10	25	50	75	-
D = Puncture resistance (N)	20	60	100	150	-

The higher the test number, the better the test performance. 0: indicates that the glove falls below minimum performance level for the given individual hazard. X: indicates that the glove has not been tested or the test method appears not to be suitable for the glove design or material. P means ‘passed’.

Test	A	B	C	D	E	F
E = Cut resistance according to EN ISO 13997:1999 (N)	2	5	10	15	22	30
Article 2250						

EN 13594:2015 - Impact protection :

Every area specified as providing protection against impact must be tested. The test method (dimensions of the test sample) does not permit impact testing of the finger protection. Gloves to protect against mechanical risks may be designed and manufactured in such a way that they offer specific impact damping (e.g. impact protection on the knuckles. the back of the hand, the palms). These gloves must satisfy the requirements of Level 1 according to EN 13594:2015 .

The results of the Coupe test must only be taken as indications if blunting occurs during the cut resistance test (B), while the TDM cut resistance test (E) provides reference results in regard to performance.

WARNING:

The overall classification for gloves with two or more layers does not necessarily indicate the performance of the outermost layer.
Gloves with mechanical resistance that achieve and demonstrate Level 1 tear resistance (C) or higher must not be worn if there is a risk of them catching when operating machines with moving parts.
Tests are taken from the palm area of the glove.

Protective gloves against dangerous chemicals and micro-organisms:

EN ISO 374-1:2016, Part 1:	**Terminology and performance requirements for chemical risks**
EN ISO 374-2:2014, 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 2250
Resistance to Bacteria & Fungi	passed
Resistance to Virus	not assessed

Resistance to penetration EN 374-2:2014 Acceptable quality limit (AQL):

Performance level	Acceptable quality limit (AQL)	Inspection level	Article 2250
3	< 0,65	G1	
2	< 1,50	G1	AQL = 1,50
1	< 4,00	S4	

Resistance to degradation EN ISO 374-4:2019:

Code letter	Test chemical	CAS-RN	Class	Article 2250
A	Methanol	67-56-1	Primary alcohol	no change, -13.0%
K	Sodium hydroxide 40%	1310-73-2	Inorganic base	no change, -14.9%
L	Sulphuric acid 96%	7664-93-9	Inorganic mineral acid	discoloration, -37.2%
N	Acetic acid 99%	64-19-7	Organic acid	no change, 5.1%
O	Ammonia 25%	1336-21-6	Organic base	convex, -8.7%
T	Formaldehyde 37%	50-00-0	Aldehyde	no change, 10.9%

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

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. 2250	Level art. 2250
A	Methanol	67-56-1	Primary alcohol	> 60	3
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	> 120	4
M	Nitric acid 65%	7697-37-2	Inorganic acid, oxidizing		
N	Acetic acid 99%	64-19-7	Organic acid	> 120	4
O	Ammonia water 25%	1336-21-6	Organic alkali	> 60	3
P	Hydrogen peroxide 30%	7722-84-1	Peroxide		
S	Hydrofluoric acid 40%	7664-39-3	Inorganic acid		
T	Formaldehyde 37%	50-00-0	Aldehyde	> 480	6

Marking of the glove:

Type A:

The six 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/Type A



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WARNINGS:

This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.
The chemicals 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 400mm – 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.

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 and fungi) according to EN ISO 374-5:2016

Marking of gloves that protect against bacteria and fungi:

EN ISO 374-5:2016



Not tested against viruses. (this warning must be added if a test against viruses was not performed)

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



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
. (Further information is available on request.)
These gloves are not suitable for contact with fatty food.

The clearance declaration no. FUFDCP2022-01068 from 24.04.2022 was issued by:
intertek Consumer Goods GmbH
Würzburger Straße 152
90766 Fürth
Germany

C. Purpose, applications and risk assessment:

Applicable for general work with high risks as well as when handling liquids, foodstuffs and chemicals within the specified classification, e.g. in the craft trade, construction sector, chemical industry, pharmaceutical industry, food industry, fish industry, agricultural sector, facility management

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:



Do not wash and bleach the gloves. Drying in tumbler is not possible. Do not iron. Professional dry and wet cleaning is not allowed.

Both new and used gloves must be checked carefully for any damage before they are worn. Never store dirty gloves if they are intended for reuse. Users are advised to carefully remove the gloves on the right and then the left if it is not possible to remove the soiling or if doing so would present a danger. Here, use the hand wearing the glove in such a way that the other glove can be removed without coming into contact with the soiling.

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 3 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 (year/month/day) 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:

Natural latex
Lining: 100% cotton liner

H. Packaging:

This item will be delivered in a uniform cardboard box with a content of: 120 pair
The smallest sales unit is: 12 pair

I. Health risks:

This product may contain latex obtained from natural rubber that may provoke allergic reactions. If an allergic reaction should occur consult a doctor or dermatologist.

Notified body responsible for the EU Type Examination:

CENTEXBEL Gent
Technologiepark 70
BE 9052 Gent
Belgium
Notified Body No.: 0493

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):

SGS Fimko Oy,
Takomotie 8
FI-00380 Helsinki,
Finland
Notified Body Nr.: 0598

Manufacturer’s name and address:

BIG Arbeitsschutz GmbH, Bundesstraße 17, 21244 Buchholz/Nordheide, Germany

For the full Declaration of Conformity and additional technical information, please visit:

www.big-arbeitsschutz.de/ info@big-arbeitsschutz.de

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