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# A GREATER COMMITMENT TO HEALTH AND SAFETY

The Single European Act does not stop at removing barriers to trade: it also seeks to upgrade social and welfare policy throughout Europe. It includes a specific pledge to improve health and safety at work for all European workers.

The commitment to 'level up' to the best practice currently employed within the Union has been enshrined in a legally binding **Framework Directive (89/391/EEC)**, which not only lays down broad guidelines for health and safety but also places upon the employer an absolute duty "to ensure the safety and health of employees in their workplace". This directive is amplified by five daughter directives, of which one directly governs the use of protective gloves.

## **The Use of Personal Protective Equipment Directive 89/656/EEC**

Four articles of the Directive merit particular attention, as they place substantial responsibilities on employers:

**ARTICLE 3** states that before selecting any PPE a basic assessment must be made to identify and evaluate the risk. Where possible, the risk must be reduced or eliminated by a modification of workplace practice. This option is always to be preferred to the use of PPE.

Under **ARTICLE 4**, the employer must inform his workers of the risks in the workplace, supply appropriate and correctly fitting PPE which complies with EU standards, and give adequate instruction in its use. He should further ensure that the PPE is used only for the purpose intended by the manufacturer, and in accordance with the manufacturer's instructions.

**ARTICLE 5** requires the employer to:

1. Audit workplace hazards and assess the level of risk to employees.
  2. Define the properties necessary in the gloves to protect the employees.
  3. Ensure that all gloves used in the workplace conform to the PPE Directive and relevant EN standards.
  4. Compare the merits of the various types of protection available.
  5. Keep full records of assessments and reasons for selecting a particular type of glove.
- If the risk should alter in any way, for instance by the introduction of a new chemical or industrial process, the assessment must be repeated.

Finally, **ARTICLE 6** requires Member States to introduce written rules for workplace situations in which the use of PPE shall be considered compulsory.

Naturally, employers will have to be aware of and comply with these rules.

To comply with the new regulations, you must select gloves which not only adhere to the above Directive and relevant safety standards, but also are demonstrably of good quality and fittest for the intended task. All Ansell Healthcare industrial products satisfy these requirements, and our experts will be glad to assist you in making the safest choice.

# COMPLYING WITH THE PPE DIRECTIVE: 89/686/EEC

The Directive specifies two classes of glove meeting two levels of risk: 'minimal', and 'mortal' or 'irreversible' risk. A risk which falls between these two levels may be described as 'intermediate'. To comply with the 89/656/EEC. Directive, you must establish the level of risk and select gloves of the appropriate class.

A system of marking has been developed to help you in that selection.

- **Gloves of simple design - for minimal risk only**

For gloves of simple design offering protection from low level risks, e.g. janitorial gloves, manufacturers are permitted to test and certify gloves themselves.

Gloves of this category are CE-marked as follows:



- **Gloves of intermediate design - for intermediate risk**

Gloves designed to protect against intermediate risk, e.g. general handling gloves requiring good cut, puncture and abrasion performance, must be subjected to independent testing and certification by a Notified Body. Only these approved Bodies may issue a CE mark, without which the gloves may not be sold.

Each Notified Body has its own identification number. The name and address of the Notified Body that certifies the product has to appear on the instructions for use that will accompany the gloves.

Gloves of intermediate design are CE-marked as follows:



- **Gloves of complex design - for irreversible or mortal risk**

Gloves designed to protect against the highest levels of risk e.g. chemicals, must also be tested and certified by a Notified Body. In addition, the quality assurance system used by the manufacturer to guarantee homogeneity of production must be independently checked. The Body carrying out this evaluation will be identified by a number which must appear alongside the CE mark (in this case, 0493).

Gloves of complex design are CE-marked as follows:



Please note that the original PPE Directive 89/686/EEC has been amended by both the 93/95/EEC Directive and the CE marking Directives 93/68/EEC and 95/58 EEC.

# RAISING STANDARDS IN EUROPE

The primary aim of the Personal Protective Equipment Directive is to improve safety at work. This is achieved by establishing standards for manufacture and use that will apply throughout the Union; and this is the remit of the Committee for European Normalisation (CEN). The committee is made up of representatives of the national standards organisations in each of the Member States plus EFTA, along with major European PPE manufacturers.

Naturally, Ansell Healthcare has played an active part in drawing up the standards for protective gloves and during the revisions of these standards.

If you would like any further clarification of these Directives, or further information on testing and certification procedures, please contact our Technical Service.

# STANDARDS FOR GLOVES

## STANDARD EN 420: 2003

### GENERAL REQUIREMENTS FOR PROTECTIVE GLOVES

#### **SCOPE**

This standard defines the general requirements for glove design and construction, innocuousness, comfort and efficiency, marking and information applicable to all protective gloves. This standard can also apply to arm guards.

The key points are given below. Some gloves designed for very specialist applications, such as electrician's or surgical gloves are governed by other stringent job-specific standards (Details are available on request).

#### **DEFINITION**

A glove is an item of personal protective equipment which protects the hand or any part of the hand from hazards. It may also cover part of the forearm and arm.

A performance level is a number (between 0 and 4) which shows how a glove has performed in a specific test, and by which the results of that testing may be graded. Level 0 indicates that the glove is either untested or falls below the minimum performance level. A performance level X means that the test method is not suitable for the glove sample. Higher numbers indicate higher levels of performance.

#### **REQUIREMENTS**

##### **GLOVE CONSTRUCTION AND DESIGN**

- Gloves have to offer the greatest possible degree of protection in the foreseeable conditions of end use
- When seams are included, the strength of these seams should not reduce the overall performance of the glove

## **INNOCUOUSNESS**

- The gloves themselves shouldn't cause any harm to the user
- pH of the glove should be between 3.5 and 9.5
- Chromium (VI) content should be below detection (< 10 ppm)
- Natural rubber gloves shall be tested on extractable proteins as per EN 455-3.

## **CLEANING INSTRUCTIONS**

- If care instructions are provided, the levels of performance should not be reduced after the maximum recommended number of cleaning cycles.

## **ELECTROSTATIC PROPERTIES**

- Anti-static gloves that are designed to reduce the risk of electrostatic discharges shall be tested as per EN 1149
- Obtained test values are to be reported on the Instructions for Use
- An electrostatic pictogram shall NOT be used

## **SIZING (SEE TABLE BELOW)**

- Gloves that are below the minimum length are to be called 'Fit for Special Purpose'.

## **DEXTERITY**

- If required, performance to be graded as per table below

## **WATER VAPOUR TRANSMISSION AND ABSORPTION**

- If required, gloves shall allow water vapour transmission (5mg/cm<sup>2</sup>.h)
- If gloves exclude water vapour transmission, it should be at least 8 mg/cm<sup>2</sup> for 8 hours.

## **MARKING & INFORMATION**

### **Marking of the glove**

- Each glove should be marked with:
  - Name of manufacturer
  - Glove and size designation
  - CE mark
  - Appropriate pictograms accompanied by the relevant performance levels and the reference of the EN standard.
- The marking should be legible throughout the life of the glove. Where marking of the glove is not possible in view of the characteristics of the glove, it should be mentioned on the first packaging enclosure.

### **Marking of the packaging immediately containing the gloves**

- Name and address of the manufacturer or representative
- Glove and size designation
- CE mark
- Usage info
  - simple design: "for minimal risks only"
  - intermediate design or complex design: relevant pictograms
  - When protection is limited to part of the hand, this shall be mentioned (e.g. "Palm Protection style only")

- Reference to where information can be obtained

## Instructions for Use

**(to be supplied when the glove is placed on the market)**

- Name and address of the manufacturer or representative
- Glove designation
- Size range available
- CE mark
- Care & storage instruction
- Instructions and limitations of use
- A list of substances used in the glove which are known to cause allergies
- A list of all substances in the glove shall be made available upon request
- Name and address of Notified Body that certified the product



## Sizing of gloves

Glove Size	Fits hand Size	Hand Circumference/ length (mm)	Minimum length of the glove (mm)
6	6	152/160	220
7	7	178/171	230
8	8	203/182	240
9	9	229/192	250
10	10	254/204	260
11	11	279/215	270

## Glove dexterity

Performance level	Smallest diameter of pin that can be picked up with gloved hand 3 times / 30 seconds (mm)
1	11.0
2	9.5
3	8.0
4	6.5
5	5.0

# STANDARD EN 374: 2003

## GLOVES GIVING PROTECTION FROM CHEMICALS AND MICRO-ORGANISMS

### SCOPE

This standard specifies the capability of gloves to protect the user against chemicals and/or micro-organisms.

### DEFINITIONS

#### Penetration

Penetration is the movement of a chemical and/or micro-organism through porous materials, seams, pinholes or other imperfections in a protective glove material at a non-molecular level.

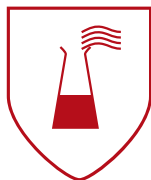
#### Permeation

The rubber and plastic films in gloves do not always act as barriers to liquids. Sometimes they can act as sponges, soaking up the liquids and holding them against the skin. It is therefore necessary to measure breakthrough times, or the time taken for the hazardous liquid to come in contact with the skin.

### REQUIREMENTS

- The minimum liquid proof section of the glove shall be at least equal to the minimum length of the gloves specified in EN 420.
- **Penetration:** A glove shall not leak when tested to an air and/or water leak test, and shall be tested and inspected in compliance with the Acceptable Quality Level

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



ABC

The 'Chemical resistant' glove pictogram must be accompanied by a 3-digit code. This code refers to the code letters of 3 chemicals (from a list of 12 standard defined chemicals), for which a breakthrough time of at least 30 minutes has been obtained.

CODE LETTER	CHEMICAL	CAS NUMBER	CLASS
A	Methanol	67-56-1	Primary alcohol
B	Acetone	67-64-1	Ketone
C	Acetonitrile	75-05-8	Nitrile Compound
D	Dichloromethane	75-09-2	Chlorinated paraffin
E	Carbone disulphide	75-15-0	Sulphur containing organic compound
F	Toluene	108-88-3	Aromatic hydrocarbon
G	Diethylamine	109-89-7	Amine
H	Tetrahydrofurane	109-99-9	Heterocyclic and ether compound
I	Ethyl acetate	141-78-6	Ester
J	n-Heptane	142-85-5	Saturated hydrocarbon
K	Sodium hydroxide 40%	1310-73-2	Inorganic base
L	Sulphuric acid 96%	7664-93-9	Inorganic mineral acid

- **Permeation:** Each chemical tested is classified in terms of breakthrough time (performance level 0 to 6)

Measured breakthrough time	Protection Index	Measured breakthrough time	Protection Index
> 10 minutes	class 1	> 120 minutes	class 4
> 30 minutes	class 2	> 240 minutes	class 5
> 60 minutes	class 3	> 480 minutes	class 6



The 'Low Chemical resistant' or 'Waterproof' glove pictogram is to be used for those gloves that do not achieve a breakthrough time of at least 30 minutes against at least three chemicals from the defined list, but which comply with the Penetration test.



The 'Micro-organism' pictogram is to be used when the glove conforms to at least a performance level 2 for the Penetration test.

**Warning :** The chemical data information does not necessarily reflect the actual duration in the workplace.

# STANDARD EN 388: 2003

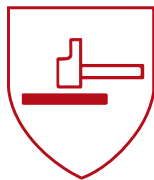
## GLOVES GIVING PROTECTION FROM MECHANICAL RISKS

### SCOPE

This standard applies to all kinds of protective gloves in respect of physical and mechanical aggressions caused by abrasion, blade cut, puncture and tearing.

### DEFINITION AND REQUIREMENTS

Protection against mechanical hazards is expressed by a pictogram followed by four numbers (performance levels), each representing test performance against a specific hazard.



a b c d

The 'Mechanical Risks' pictogram is accompanied by a 4-digit code:

#### **a. resistance to abrasion**

based on the number of cycles required to abrade through the sample glove.

#### **b. blade cut resistance**

based on the number of cycles required to cut through the sample at a constant speed.

#### **c. tear resistance**

based on the amount of force required to tear the sample.

#### **d. puncture resistance**

based on the amount of force required to pierce the sample with a standard sized point.

In all cases, [o] indicates the lowest level of performance, as follows:

Test	Performance Level Rating					
	0	1	2	3	4	5
a. Abrasion resistance (cycles)	<100	100	500	2000	8000	
b. Blade cut resistance (factor)	<1.2	1.2	2.5	5.0	10.0	20.0
c. Tear resistance (newton)	<10	10	25	50	75	
d. Puncture resistance (newton)	<20	20	60	100	150	

These performance levels must be prominently displayed alongside the pictogram on the packaging which immediately contains the gloves.

# STANDARD EN 407: 2004

## GLOVES GIVING PROTECTION FROM THERMAL HAZARDS

### SCOPE

This standard specifies thermal performance for protective gloves against heat and/or fire.

### DEFINITION AND REQUIREMENTS

The nature and degree of protection is shown by a pictogram followed by a series of six performance levels, relating to specific protective qualities.



abcdef

The 'heat and flame' pictogram is accompanied by a 6-digit number:

- **a. Resistance to flammability** (performance level 0 - 4)
- **b. Contact heat resistance** (performance level 0 - 4)
- **c. Convective heat resistance** (performance level 0 - 4)
- **d. Radiant heat resistance** (performance level 0 - 4)
- **e. Resistance to small splashes of molten metal** (performance level 0 - 4)
- **f. Resistance to large splashes of molten metal** (performance level 0 - 4)

Gloves must achieve at least Performance level 1 for abrasion and tear.

- **Resistance to flammability:** based on the length of time the material continues to burn and glow after the source of ignition is removed. The seams of the glove shall not come apart after an ignition time of 15 seconds.
- **Contact heat resistance:** based on the temperature range (100-500 °C) at which the user will feel no pain for at least 15 seconds. If an EN level 3 or higher is obtained, the product shall record at least EN level 3 in the flammability test. Otherwise, the maximum Contact heat level shall be reported as level 2.
- **Convective heat resistance:** based on the length of time the glove is able to delay the transfer of heat from a flame. A level of performance shall only be mentioned if a performance level 3 or 4 is obtained in the flammability test.
- **Radiant heat resistance:** based on the length of time the glove is able to delay the transfer of heat when exposed to a radiant heat source. A performance level shall only be mentioned if a performance level 3 or 4 is obtained in the flammability test.
- **Resistance to small splashes of molten metal:** the number of molten metal drops required to heat the glove sample to a given level. A performance level shall only be mentioned if a performance level 3 or 4 is obtained in the flammability test.
- **Resistance to large splashes of molten metal:** the weight of molten metal required to cause smoothing or pinholing across a simulated skin placed directly behind the glove sample. The test is failed if metal droplets remain stuck to the glove material or if the specimen ignites.

# STANDARD EN 511: 1994

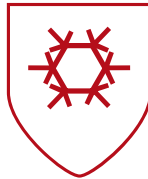
## GLOVES GIVING PROTECTION FROM COLD

### SCOPE

This standard applies to any gloves to protect the hands against convective and contact cold down to  $-50^{\circ}\text{C}$ .

### DEFINITION AND REQUIREMENTS

Protection against cold is expressed by a pictogram followed by a series of 3 performance levels, relating to specific protective qualities.



abc

The 'cold hazard' pictogram is accompanied by a 3-digit number :

- **a. Resistance to convective cold** (performance level 0 - 4)
- **b. Resistance to contact cold** (performance level 0 - 4)
- **c. Permeability by water** (0 or 1)

All gloves must achieve at least Performance level 1 for abrasion and tear.

- **Convective cold resistance:** based on the thermal insulation properties of the glove which are obtained by measuring the transfer of cold via convection.
- **Contact cold resistance:** based on the thermal resistance of the glove material when exposed to contact with a cold object.
- **Water impermeability:** 0 = water penetration after 30 minutes of exposure 1 = no water penetration.

# STANDARD EN 421: 1994

## GLOVES GIVING PROTECTION FROM RADIO-ACTIVE CONTAMINATION AND IONISING RADIATION

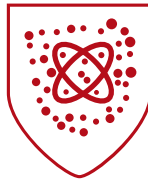
### SCOPE

This standard applies to gloves to protect from Ionising Radiation and Radioactive Contamination

### DEFINITION AND REQUIREMENTS

The nature of protection is shown by a pictogram relating to the specific protective qualities.

- To protect from **radioactive contamination**, the glove has to be **liquid proof** and needs to pass the penetration test defined in EN 374.



- For gloves used in containment enclosures, the glove shall offer high resistance to permeability of water vapour.
- To protect from **ionising radiation**, the glove has to contain a certain **amount of lead**, quoted as lead equivalence. This Lead Equivalence must be marked on each glove.
- Materials exposed to **ionising radiation** may be modelled by their behaviour to ozone cracking. This test is optional and can be used as an aid to selecting gloves which require resistance to ionising radiation.



# ALL THE SUPPORT YOU NEED TO MAKE THE SAFEST CHOICE

Ansell Healthcare have not only adopted all the above procedures, but frequently operate quality controls more stringent than those required by law (In particular, each step of the manufacturing process is carefully monitored to produce the most consistent quality of production in the industry.).

Our documentation contains a more detailed description of each glove, together with recommendations for use, but if you feel you would like any further help in making your choice, we will be glad to send an expert adviser to observe your gloves in action, and recommend the optimum specification.

Remember, under Article 5 of the PPE Directive, you will be required to prove that you are providing your workforce with the safest and fittest protection available: so if you do have any special needs, we strongly recommend that you take advantage of Ansell's unique "hands-on" advisory service.

# THE ANSELL HEALTHCARE GUARANTEE

Any glove you buy from us has been certified as per the PPE 89/686/EEC Directive and relevant EN standards, and is CE marked.

You may be confident that any safety product you buy from Ansell will be manufactured, tested, packaged and documented strictly in accordance with current European legislation.

No one knows more about protective gloves than Ansell.

By choosing protective products you know to be of the highest quality, you will not only be making the best decision for your workforce, but will clearly be fulfilling your obligation under the law.

Ansell Limited is a global leader in barrier protective products. With operations in the Americas, Europe and Asia, Ansell employs more than 11 000 people worldwide and holds leading positions in the natural latex and synthetic polymer glove and condom markets. Ansell operates in three main business segments: Occupational Healthcare,

supplying hand protection to the industrial market; Professional Healthcare, supplying surgical and examination gloves to healthcare professionals; and Consumer Healthcare, supplying sexual health products and consumer hand protection. Information on Ansell and its products can be found at <http://www.ansell.eu>

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