



Nitrile

Affordable protection and comfort

- Manufactured with a thinner nitrile formulation that increases comfort and improves flexibility without compromising protection
- Offers textured fingertips to provide an improved grip for a variety of applications
- Packed 300 gloves per dispenser box to provide additional value and convenience
 - *250 pieces/dispenser for Size XL



Industries

- Food Processing
- Automotive
- Life Sciences

Recommended For

- Catering/Meal preparation
- Food processing and handling
- Inspection of parts, equipment
- Assembly and inspection of components
- Equipment repair and maintenance
- Picking and fastening components
- Adjusting parts and systems
- Handling of paint/glue guns and sprayers
- Transferring liquids and solids
- Sample taking and processing



TECHNICAL DATA SHEET

PRODUCT INFORMATION

	82-133
Material	Nitrile
Color	Cobalt
Glove Design	Chlorinated, Silicone Free, Textured Fingers
Cuff	Beaded
Manufacturing/QMS Audit Standards	ISO 13485, ISO 9001
Regulatory	Category III, EAC TP TC 019:2011, EC 1935/2004, EC 2002/72, EC 2023/2006, EN ISO 374-1:2016, EN 374:2003, EN 420:2003 + A1:2009, EN ISO 374-5:2016, FDA21 CFR 177-2600-US Food Contact Approved, ISO 9001, ISO 13485
Packaging	300 gloves per dispenser, 10 dispensers per shipper, 3000 gloves per shipper **Size XL 250 pieces/dispenser, 2500 pieces/shipper
Storage	Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.
Country of Origin	China
User Needs Segment	High Touch
Available sizes	XS (5.5 - 6), S (6.5 - 7), M (7.5 - 8), L (8.5 - 9), XL (9.5 - 10)
Anti-static	Not Tested
Vulcanization Chemical Accelerators	<ul style="list-style-type: none"> Zinc Dibutyldithiocarbamate (ZDBC) Zinc Diethyldithiocarbamate (ZDEC) <p><i>Only a very small number of users may be sensitive to this ingredient(s) and hence may develop irritant and/or allergic contact reactions.</i></p>

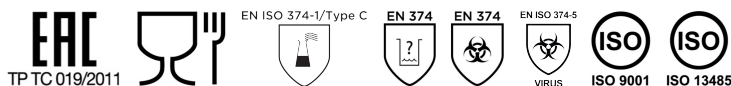
PHYSICAL PROPERTIES

	Typical Values		Testing Method
Length (mm/inches)	230 / 9.1		ASTM D3767, EN 420
Freedom from Holes (Inspection level I)	1.5 AQL		ASTM D6319-10, ASTM D5151-06 (2011)
Palm Thickness (mm/mils)	0.06 / 2.4		ASTM D3767, EN 420
Finger Thickness (mm/mils)	0.08 / 3.1		ASTM D3767, EN 420
	BEFORE AGING	AFTER AGING	
Ultimate Tensile Strength (MPa)	≥ 14	≥ 14	ASTM D6319-10
Elongation at Break (%)	≥ 500	≥ 400	ASTM D6319-10
Force at break (N)	3	3	EN 455-2

ORDERING INFORMATION

Size	XS (5.5 - 6)	S (6.5 - 7)	M (7.5 - 8)	L (8.5 - 9)	XL (9.5 - 10)
Product Code	82133060	82133070	82133080	82133090	82133100

Performance Standards and Regulatory Compliance



For additional information visit us at www.ansell.com, or call us at

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EU DECLARATION OF CONFORMITY

The Manufacturer
ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM

declares under his sole responsibility, that the PPE described hereafter:

EDGE[®] 82-133

Products manufactured as of: [2018/04/21]

PPE to be used against category III risks

EN ISO 374-1/Type C



EN ISO 374-5



VIRUS

is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-1:2016, EN 420:2003 + A1:2009, EN ISO 374-5:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2018/0249, issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of the Notified Body:

CENTEXBEL (0493)
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A handwritten signature in black ink, appearing to read 'Guido Van Duren'.

Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2018/02/08

EU DECLARATION OF CONFORMITY

The Manufacturer
ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS
BELGIUM

declares under his sole responsibility, that the PPE described hereafter:

EDGE[®] 82-133

Products manufactured till: [2018/04/20]

PPE to be used against category III risks

EN 374



EN 374



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN 374:2003, , EN 420:2003 + A1:2009 and is identical to the PPE which is subject to the EC Type examination; under certificate number 032/2015/0339 issued by the Notified Body:

CENTEXBEL (0493)
TECHNOLOGIEPARK 70
B-9052 ZWIJNAARDE
BELGIUM

and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of the Notified Body:

CENTEXBEL (0493)
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B-9052 ZWIJNAARDE
BELGIUM



Guido Van Duren
Director - Regulatory affairs
Ansell

Place: Brussels
Date: 2015/03/18

FOOD DECLARATION OF PRODUCT COMPLIANCE

The Business Operator, established in the European Community:

**ANSELL HEALTHCARE EUROPE N.V.
RIVERSIDE BUSINESS PARK, BLOCK J
BOULEVARD INTERNATIONAL 55
B-1070 BRUSSELS**

declares that the glove described hereafter:

EDGE® 82-133

belonging to the "Elastomers & Rubber" category

is in conformity with the following provisions:

the EC-regulation 1935/2004 and the EC-regulation 2023/2006 related to Good Manufacturing Practices (GMP) for Materials and Articles intended to come in contact with Foodstuffs (for more detailed information please also consult Ansell GMP Food Declaration).

All ingredients, starting monomers, additives used in manufacturing this glove comply with:

- any positive list
- any relevant SML(Specific Migration Limit) or restrictions as specified in the applicable EU food legislations.

France: Arrêté du 5 août 2020, relatif aux matériaux et objets en caoutchouc destinés à entrer en contact avec des denrées alimentaires

Italy: D.M. 21/03/1973 Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale

Germany: BfR Empfehlung XXI (2021) Bedarfsgegenstände auf Basis von Natur- und Synthesekautschuk

Netherlands: Regeling Verpakkingen en Gebruiksartikelen (Warenwet), Hoofdstuk III, Rubberproducten Verpakkingen

Czech Republic: Vyhláška č. 38/2001 Sb. (Consolidated 2009-5-15) Annex 07: Elastomers and rubber products - list of materials

Slovakia: Výnos MPSR a MZSR z 9. júna 2003 č. 1799/2003 - 100, Annex 10

FDA Code of Federal Regulations, Title 21, Part 177, section 2600 (21 CFR 177.2600) - Rubber articles intended for repeated use

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Global migration data:

Type of foodstuffs - Testing conditions	Aqueous food	Alcoholic food	Acidic food	Fatty food correction factor 1	Fatty food correction factor 2	Fatty food correction factor 3	Fatty food correction factor 4	Fatty food correction factor 5
	<i>Simulant used: Distilled Water</i>	<i>Simulant used: Ethanol 10%</i>	<i>Simulant used: Acetic acid 3%</i>	<i>Simulant used: Olive oil</i>	<i>Simulant used: Olive oil</i>	<i>Simulant used: Olive oil</i>	<i>Simulant used: Olive oil</i>	<i>Simulant used: Olive oil</i>
2 hours/temp. 40°C	< 8 mg/dm ²	< 8 mg/dm ²	> 8 mg/dm ²	< 8 mg/dm ²	< 8 mg/dm ²	< 8 mg/dm ²	< 8 mg/dm ²	< 8 mg/dm ²
10min/40°C	< 10 mg/dm ²	< 10 mg/dm ²	< 50 mg/dm ²					

Analytical tolerance for aqueous, alcoholic and acidic food simulant is 1mg/dm² and for fatty food simulant is 3mg/dm² as per EN 1186.

Storage instruction: Keep away from direct sunlight; store in a cool dry place and keep in the original packaging. Keep away from ozone sources. If gloves are properly stored, as indicated above, they won't lose their performances and won't change the glove characteristics significantly. If gloves could be affected by ageing or storage, the expiry date is mentioned on the packaging materials.



Guido Van Duren
Director - Regulatory affairs
Ansell

Date 06/03/2022

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Date:09-09-2019

**Good Manufacturing Practices Declaration for Ansell's materials
and articles intended to come in contact with food**

Herewith, the undersigned declares that all Ansell gloves that are intended for contact with Food products are manufactured in accordance to the following requirements:

Regulation 1935/2004:

- Gloves are sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or deterioration in its organoleptic properties.
- Gloves are made with only legally acceptable Food-contact ingredients and do not exceed any legal migration levels based on the intended use of the product. Raw materials used in the production of the gloves are specified safe for food contact and are procured from an approved supplier.

Regulation 2023/2006:

- Gloves are made as per 'Good manufacturing practice (GMP)' meaning they are produced and controlled to ensure conformity with the applicable rules and applicable quality standards. This applies to all activities; from procurement through approved suppliers of materials and all aspects of manufacturing, processing, handling, storage, transport and distribution of the finished article.
- The manufacturing plant has a documented and effective quality assurance system in place with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use.
- The qualifications and training of personnel at manufacturing is documented. As well, the manufacturing facility and equipment is designed, cleaned, and maintained as necessary to ensure that in process materials and finished glove products comply with their specifications. Inherent in these requirements are personnel hygiene, pest

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ISO 9002 Certificate
Number FM 40130

control, contamination control, prevention of material damage from the environment, etc., etc.

- A formal risk analysis according to an established procedure has been conducted and each proposed change for its impact on risk to the user of the finished article is documented.
- The manufacturing plant has an effective quality control system and a documented system of tests, inspections, document reviews and formal dispositions on raw materials, in process materials and finished articles. This system includes clear decision-making criteria on materials and articles not meeting specifications.
- The manufacturing's quality control system monitors compliance with Good Manufacturing Practices and correct any failure to comply with GMP without delay. Ansell shall ensure adherence to the effective implementation of GMP through review of the supplier's internal audit system as described in the ISO 9001 Quality Management System.
- The manufacturing site maintains documentation on specifications, manufacturing formulae, and processing necessary to achieve regulatory compliance and product safety in electronic or paper (hard-copy) format.
- Finished articles are labelled with a unique control number, which relates to specific records held by the manufacturer.



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