



Nitrile

## Strong disposable gloves that offer a higher level of protection against harmful exposures.

- Ultimate barrier significantly reduces risk of harmful exposures and rip-tear
- 2X more chemical splash protection than leading brands<sup>†</sup> due to breakthrough polymer bonding technique\*
- Highest known standard for barrier quality and consistency (Low 0.40 AQL)<sup>‡</sup>
- Made with TNT™ Chemical Splash Resistance Technology, for soft durable protection against a wide range of chemicals
- Silicone free design is paint and finish process friendly



### Industries

- Life Sciences
- Chemical
- Automotive
- Automotive Aftermarket
- Food Processing
- Machinery and Equipment
- Maintenance

### Recommended For

- Laboratory analysis
- Sample taking and processing
- Transferring liquids and solids
- Light assembly tasks
- Paint shop
- Blending, compounding materials
- Light chemical handling
- Filtration Process
- Cleaning of equipment, tables and floors
- Light duty maintenance
- Pharmaceutical manufacturing



## TECHNICAL DATA SHEET

### PRODUCT INFORMATION

	<b>93-850</b>
<b>Material</b>	Nitrile
<b>Color</b>	Green
<b>Glove Design</b>	Powder-Free, Chlorinated, Silicone Free, Textured Fingers
<b>Cuff</b>	Beaded
<b>Manufacturing/QMS Audit Standards</b>	ISO 9001
<b>Regulatory</b>	ASTM D6319, Category III, EN ISO 374-5:2016, EN ISO 374-1:2016, EN 420:2003 + A1:2009, EN 421:2010, FDA21 CFR 177-2600-US Food Contact Approved, Food Type: Rubber, ISO 9001
<b>Packaging</b>	100 gloves per dispenser; 10 dispensers per case; 1000 gloves per case; *90 gloves per dispenser (Size XXL); *900 gloves per case (Size XXL)
<b>Storage</b>	Keep out of direct sunlight; store in a cool and dry place. Keep away from sources of ozone or ignition.
<b>Country of Origin</b>	Malaysia
<b>User Needs Segment</b>	Robust
<b>Available sizes</b>	XS (5.5 - 6), S (6.5 - 7), M (7.5 - 8), L (8.5 - 9), XL (9.5 - 10), XXL (10.5 - 11)
<b>Anti-static</b>	Yes
<b>Vulcanization Chemical Accelerators</b>	<ul style="list-style-type: none"> <li>Zinc Dibutyldithiocarbamate (ZDBC)</li> </ul> <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)	240 / 9.5		ASTM D3767, EN 420
Freedom from Holes (Inspection level I)	0.40 AQL		ASTM D5151, EN 455-1
Palm Thickness (mm/mils)	0.12 / 4.7		ASTM D3767, EN 420
Finger Thickness (mm/mils)	0.19 / 7.5		ASTM D3767, EN 420
	<b>BEFORE AGING</b>	<b>AFTER AGING</b>	
Ultimate Tensile Strength (MPa)	27	27	ASTM D412 & D573
Elongation at Break (%)	620	550	ASTM D412
Force at break (N)	12	12	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)	XXL (10.5 - 11)
<b>Product Code</b>	93850060	93850070	93850080	93850090	93850100	93850110

#### Technology



#### Performance Standards and Regulatory Compliance



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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.



**Guido Van Duren**

Director – Global Regulatory Affairs  
PPE Products  
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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:

**MicroFlex<sup>®</sup> 93-850**

**PPE to be used against category III risks**

EN ISO 374-5



VIRUS

EN ISO 374-1:2016  
Type B



JKOPT

EN 421



is in conformity with the provisions of Regulation (EU) 2016/425 and with the standards EN ISO 374-5:2016, EN ISO 374-1:2016, EN 420:2003 + A1:2009, EN 421:2010 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2018/1558, 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)**  
**TECHNOLOGIEPARK 70**  
**B-9052 ZWIJNAARDE**  
**BELGIUM**

Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 2018/09/18

# 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:

**MICROFLEX® 93-850**

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  <i>Simulant used: Distilled Water</i>	Alcoholic food  <i>Simulant used: Ethanol 10%</i>	Acidic food  <i>Simulant used: Acetic acid 3%</i>	Fatty food correction factor 1  <i>Simulant used: Ethanol 95%/Isooctane</i>	Fatty food correction factor 2  <i>Simulant used: Ethanol 95%/Isooctane</i>	Fatty food correction factor 3  <i>Simulant used: Ethanol 95%/Isooctane</i>	Fatty food correction factor 4  <i>Simulant used: Ethanol 95%/Isooctane</i>	Fatty food correction factor 5  <i>Simulant used: Ethanol 95%/Isooctane</i>
2 hours/temp. 40°C	< 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>
10min/40°C	< 10 mg/dm <sup>2</sup>	< 10 mg/dm <sup>2</sup>	< 50 mg/dm <sup>2</sup>					

Analytical tolerance for aqueous, alcoholic and acidic food simulant is 1mg/dm<sup>2</sup> and for fatty food simulant is 3mg/dm<sup>2</sup> 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.



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Date 18/01/2022

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