



Nitril-Handschuhe BioClean Biotac

pure¹¹-Nr.: 05030, Hersteller: BioClean

Zusammenfassung

- Neue pure11-Artikelnummer (ab 01.07.2023): 1105030
- Material: Nitril
- Beidhändig tragbar
- Puderfrei
- Latexfrei
- AQL-Wert (Acceptable Quality Level): 1.5
- Texturierte Fingerspitzen
- Strukturierte Oberfläche
- Doppelt unterverpackt

Empfohlene Reinraumklassen

ISO 3 4 5 6 7 8 9

GMP C D

Produktvarianten

pure¹¹-Nr.: 05030XS

Farbe: Weiß / Größe: XS / Herst.-Nr.: BIOTAC-XS / VE: 1.000 Stück

pure¹¹-Nr.: 05030S

Farbe: Weiß / Größe: S / Herst.-Nr.: BIOTAC-S / VE: 1.000 Stück

pure¹¹-Nr.: 05030M

Farbe: Weiß / Größe: M / Herst.-Nr.: BIOTAC-M / VE: 1.000 Stück

pure¹¹-Nr.: 05030L

Farbe: Weiß / Größe: L / Herst.-Nr.: BIOTAC-L / VE: 1.000 Stück

pure¹¹-Nr.: 05030XL

Farbe: Weiß / Größe: XL / Herst.-Nr.: BIOTAC-XL / VE: 1.000 Stück

pure¹¹-Nr.: 05030XXL

Farbe: Weiß / Größe: XXL / Herst.-Nr.: BIOTAC-XXL / VE: 1.000 Stück

Quelle: <https://www.pure11.de/nitril-handschuhe-bioclean-biotac>

BIOCLEAN BIOTAC

Non-sterile Nitrile Gloves

BIOTAC

About

BioClean Biotac Nitrile Gloves are latex-free, powder-free and resistant to a range of chemicals*. The ambidextrous, white 300mm (12") long cleanroom gloves are flexible and comfortable offering the wearer good dexterity for prolonged use.

Specifications

COMPATIBILITY:

ISO Class 5

LENGTH:

300mm (12")

MATERIAL:

Nitrile

PROTEIN LEVEL:

Nitrile contains no natural latex proteins

SURFACE:

Finger-textured

SHAPE:

Ambidextrous

COLOUR:

White

FLEXIBLE & COMFORTABLE

CHEMICAL RESISTANT*

LATEX-FREE

Features

- Resistant to a range of chemicals*
- Latex & powder-free
- Non-particulating EasyTear packaging

EN 421:2010 ISO 374-5:2016



EN ISO 374
Type C



Ansell

Quality Standards

- Manufactured in a facility holding ISO 9001:2015 and (EU)2016/425 Module D certifications
- Conforms to Category 3 - Complex Design Personal Protective Equipment PPE Regulation (EU)2016/425
- Processed in an NEBB certified ISO Class 5 environment
- Complies with the requirements of European Glove Standards EN420:2003 +A1:2009, EN374-1:2016, EN374-5:2016 and EN421:2010
- Physical properties comply with European Medical Glove Standard EN455-2:2015
- Suitable for contact with all foodstuffs. Regulation (EC)1935/2004 and (EC) 2023/2006.

Physical Properties

CHARACTERISTICS	VALUE	TEST METHOD
Freedom From Holes	1.5 AQL Performance Level 2	EN 374-2:2015
Glove Length +/-10mm (mm/inches)	290/11.4	EN 420:2003 + A1:2009
Single Wall Thickness Minimum (mils/mm)	Cuff: 3.15/0.08 Palm: 4.33/0.11 Finger Tip: 6.69/0.17	EN 455-2:2015
Force At Break During Shelf Life	≥6 N	EN 455-2:2015

PALM WIDTHS (mm) ± 5mm							
SIZE	XS	S	M	L	XL	XXL	XXXL*
mm	75	85	95	105	115	119	122
TEST METHOD	EN 420:2003 + A1:2009						

Shelf Life & Storage

Five (5) years from date of manufacture.
Store in a dry, cool place (<40°C) away from direct sunlight and fluorescent light.

Glove Cleanliness Characteristics

PARTICLES				TYPICAL PARTICLE COUNT				TEST METHOD
$\geq 0.5\mu\text{m}(\text{counts}/\text{cm}^2)$				< 1500				IEST-RP-CC005.4
TYPICAL EXTRACTABLE IONS								TEST METHOD
ANIONS	Fluoride	Chloride	Nitrite	Bromide	Nitrate	Phosphate	Sulphate	IEST-RP-CC005.4
$(\mu\text{g}/\text{cm}^2)$	ND	0.11	ND	ND	0.26	ND	0.017	
CATIONS	Lithium	Sodium	Ammonium	Potassium	Calcium	Magnesium	Zinc	
$(\mu\text{g}/\text{cm}^2)$	ND	0.029	0.011	0.03	0.31	0.002	ND	
ND = Not Detected, NT = Not Tested								

TO ORDER

Re-order code

BIOTAC-XS
BIOTAC-S
BIOTAC-M
BIOTAC-L
BIOTAC-XL
BIOTAC-XXL
BIOTAC-XXXL

Size

XS
S
M
L
XL
XXL
XXXL*

Packing

100 pieces per sealed inner PE bag; one inner PE bag per sealed outer PE bag; 10 outer bags per lined carton (1000 pieces).

*Size subject to minimum order quantity and lead time.

For additional information visit us at www.bioclean.com, or contact us at;

Nitritex Ltd

Minton Enterprise Park
Oaks Drive
Newmarket, Suffolk
CB8 7YY
United Kingdom
Tel: +44 1638 663338

Ansell US

111 Wood Avenue South
Suite 210
Iselin, NJ 08830
USA
Tel: +1 800 800 0444

Nitritex (M) Sdn.Bhd

2 Jalan Jurunilai U1/20
Seksyen U1, Hicom Glenmarie Industrial Park
40150 Shah Alam, Selangor
Malaysia
Tel: +603 5569 3857/3859

BIOTAC/1904/PDS18



Neither this document nor any other statement made herein by or on behalf of Ansell should be construed as a warranty of merchantability or that any Ansell product is fit for a particular purpose. Ansell assumes no responsibility for the suitability or adequacy of an end user's selection of gloves for a specific application.

*Warning: No glove provides complete protection against all chemicals. Users must test the gloves against the particular chemicals and environment in which they will be used.

**Please see product validation pack or contact Ansell customer service for specific data on use of gloves with cytotoxic drugs. Gloves used for protection against such drugs must be selected specifically for the type of chemicals used.

Ansell, ® and TM are trademarks owned by Ansell Limited or one of its affiliates. © 2012 – 2019 Ansell Limited. All Rights Reserved.

European Standard EN374-3:2003

Protective gloves against chemicals and micro-organisms

Determination of resistance to permeation by chemicals
Permeation time in minutes

Tested Chemical	Breakthrough Time	Permeation Performance Level
Ammonium fluoride 40%	>480	6
Hydroxylamine 10%	>480	6
Phosphoric Acid 85%	>480	6
Tetramethylammonium hydroxide 3%	>480	6
Trichloroacetic acid 100%	32	2
Acetone	2	0
Acetonitrile	2	0
Formaldehyde 30%	>480	6
Hexane	26	1
Hydrochloric Acid 32%	>480	6
Sodium Hypochlorite 12%	>480	6
Hydrogen Peroxide 5%	>480	6
Sodium Hydroxide 1%	355	5
Sulphuric Acid 20%	>480	6

MASTER CODE

SPECIFICATIONS

PACKAGING

PRODUCT CERTIFICATIONS

BIOTAC

300mm (12")
Nitrile
ISO Class 5 Compatible
Category 3

100 pieces double bagged
Free of Amines & Amides
Recyclable Components



GB10/81851

GB04/61092

UK e-mail: info@nitritex.com
Tel: +44 (0) 1638 663338
Fax: +44 (0) 1638 668890
Nitritex Ltd, CB8 7YU, United Kingdom



Product Specification

Product Name:	BioClean Biotac™
Product Description:	Non-Sterile, Powder Free Cleanroom Gloves
Product Code:	BIOTAC XS, S, M, L, XL, XXL

Glove Design:

Material	Nitrile	Shape	Ambidextrous	Colour	Natural
-----------------	---------	--------------	--------------	---------------	---------

Classification and Approval

Type definition (89/686/EEC, PPE Directive)	Complex design (Cat 3)	EC Certificate of Conformity Number	04408351
Notified Body Number Article 10	0493	Notified Body Number Article 11b	0120

Properties:

Spec	Size	XS	S	M	L	XL	XXL
Total length, mm (min)		290	290	290	290	290	290
Palm width, mm (± 5 mm)		75	85	95	105	115	119

Single wall Thickness, mm (min)	Cuff	Palm	Finger Tip
	0.08	0.11	0.17

Natural Latex Protein Content (µg/g)	Zero
--------------------------------------	------

Physical Properties	
During Shelf Life	After Challenge Testing
Force at Break (N)	Force at Break (N)
≥ 9	≥ 6

Typical Liquid Particle Count ≥0.5µm (Counts /cm ²)	<1500
---	-------

Typical Extractable Ions				
Anions	Fluoride	Chloride	Nitrate	Sulphate
(µg/cm ²)	ND	0.11	0.26	0.017
Cations	Sodium	Potassium	Magnesium	Calcium
(µg/cm ²)	0.029	0.03	0.002	0.31

Protection:

Resistance Against Permeation by Chemicals		
Test chemical	Breakthrough time	Performance level
Hydrochloric Acid 32%	>480	6
Sodium Hypochlorite 12 %	>480	6
Formaldehyde 30%	>480	6

Resistance to Penetration		
Characteristic	Water Leak Test	Air Leak Test
AQL	1.5	1.5
Performance Level	2	2

Packaging: (Amine & Amide free)

- 100 pieces per sealed inner bag
- 1 sealed inner bag per sealed outer bag
- 10 sealed outer bags per carton liner
- 1 carton liner per outer carton (1000 pieces)

Product Specification

Referenced Standards:

Attribute	Standard	Title
Physical Properties	EN 420: 2003	Protective gloves – General requirements and test methods
Physical Properties	EN 374-1: 2003	Protective gloves against chemicals and micro-organisms – Part 1: Terminology and performance requirements
Physical Properties	EN 374-2: 2003	Protective gloves against chemicals and micro-organisms – Part 2: Determination of resistance to penetration
Physical Properties	EN 374-3: 2003	Protective gloves against chemicals and micro-organisms – Part 3: Determination of resistance to permeation by chemicals
Physical Properties	EN 455-2: 2009	Medical gloves for single use – Requirements and testing for physical properties
Protein Content	EN 455-3: 2006	Medical gloves for single use – Requirements and testing for biological evaluation
Powder Content	EN 455-3: 2006	Medical gloves for single use – Requirements and testing for biological evaluation
pH Level	EN ISO 3071:2006	Textiles. Determination of pH of aqueous extract
Particulates and Extractables	IEST-RP-CC-005.3	IEST-RP-CC005.3 Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments
Sampling	ISO 2859-1:1999	Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
Sterilization	ISO 11137-1:2006	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
Sterilization	ISO 11137-2:2006	Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose



Contact Details:

United Kingdom	Canada	Singapore	Malaysia	China
<p>NITRITEX LTD Minton Enterprise Park, Oaks Drive, Newmarket, Suffolk, CB8 7YY United Kingdom Tel: +44 (0) 1638 663338 Fax: +44 (0) 1638 668890 Email: info@nitritex.com</p>	<p>NITRITEX CANADA LTD 7030 Woodbine Avenue, Suite 500, Markham, Ontario L3R 6G2 Canada Tel: +1 (905) 946 9539 Fax: +1 (905) 946 8584 Email: info@nitritexcanada.com</p>	<p>NITRITEX ASIA PTE LTD Technopark@Chai Chee Blk 750C Chai Chee Road Unit #03-05 Singapore 469003 Tel: +65 6536 9123 Fax: +65 6438 5159 Email: info@nitritex.com.sg</p>	<p>NITRITEX MALAYSIA SDN BHD No.2, Jalan Jurnilai U1/20, Seksyen U1, Hicom Glenmarie Industrial Park, 40150 Shah Alam, Selangor, Malaysia Tel: +603 (5569) 3857 Fax: +603 (5569) 3862 Email: info@nitritex.com.my</p>	<p>NITRITEX CHINA Room 304, Sunny Plaza Jing'an, No. 351 Anyuan Road, Shanghai 200040, PR China Tel: +86-21-5252 0157 Fax: +86-21-6266 0431 Email: info@nitritex.cn</p>



Material Safety Data Sheet

Product Identification

Product Name:	BioClean 100
Product Description:	Nitrile Cleanroom Glove, ISO Class 5 compatible
Product Code:	BIOTAC

Composition/Information on Ingredients:

Ingredient	Symbol	CAS No	Purpose
Carboxylated Butadiene Acrylonitrile Polymer Latex			Base rubber material
Zinc Oxide	ZnO	8051-03-4	Activator
Sulphur	S	81032-32-8	Curative
Zinc Dibutyldithiocarbamate	ZDBC	20609-60	Accelerator
Nitric Acid	HNO ₃	78989-43-2	Processing chemical
Titanium Dioxide	TiO ₂	98084-96-9	Colorant
Modified Corn Starch		977050513	Stripping aid
Potassium Hydroxide	KOH	1310-58-3	Stabiliser
Calcium Carbonate	CaCO ₃	1317-65-3	Stripping Aid
Calcium Nitrate	CaN ₂ O ₆	95680-75-4	Coagulant

All chemicals are non-toxic/non-hazardous

Hazards Identification

BioClean 100 gloves are non-toxic/non-hazardous

First Aid Measures

Not applicable

Fire Fighting Measures

Fire prevention: Keep away from open flames and sparks. No smoking
Fire Fighting: Extinguish using powder, water spray, foam or carbon dioxide

Accidental Release Measures

Not applicable

Handling and Storage

No special handling required
Store in a cool dry place away from direct sunlight and heat (5°C to 35°C)

Exposure Controls and Personal Protection

Not applicable

Physical and Chemical Properties

Highly stable



Material Safety Data Sheet

Stability and Reactivity

Highly stable

Toxological Information

BioClean 100 gloves are non-toxic/non-hazardous

Ecological Information

There are no ecological implications associated with the use of BioClean 100, however see Disposal Considerations, below

Disposal Considerations

The method of glove disposal depends on how the glove was used. **If the glove is contaminated with a toxic compound or biological material that is covered by any disposal regulations, the gloves must be handled in the same way as the toxic material itself.** If gloves are not contaminated or have been properly decontaminated, either landfill or incineration is a satisfactory means of disposal (see below). Since ordinary aerobic or anaerobic decomposition processes in gloves will not form any toxic products, gloves may be disposed of in any landfill. Breakdown in landfill will be very slow except for products made of cotton or natural rubber. Incineration is an optimum choice, but glove disposal by incineration can lead to pollution by the release of toxins. A good incinerator unit will completely burn all types of gloves as well as any intermediate decomposition products formed during the process.

Transport Considerations

No special transport considerations. Non-hazardous cargo.

Regulatory Information

None

Other Information

None

Contact Details:

Europe	North America	Asia
<p>NITRITEX LTD Minton Enterprise Park, Oaks Drive, Newmarket, Suffolk, CB8 7YY United Kingdom Tel: +44 (0) 1638 663338 Fax: +44 (0) 1638 668890 Email: info@nitritex.com</p>	<p>NITRITEX CANADA LTD 7030 Woodbine Avenue, Suite 500, Markham, Ontario L3R 6G2 Canada Tel: +1 (905) 946 9539 Fax: +1 (905) 946 8584 Email: nitritex@cs.com</p>	<p>NITRITEX ASIA PTE LTD 11 Keng Cheow Street, #03-09 Riverside Piazza, Singapore 059608, Republic of Singapore Tel: +65 6536 9123 Fax: +65 6438 5159 Email: nitritex@pacific.net.sg</p>