

PRODUCT SPECIFICATION

ENSURE 70X SERIES

HEAVY DUTY Nitrile Exam Gloves

with Low Dermatitis Potential



7.0 Mil Thickness

- Full-Textured Surface
- Ergonomically Designed
- Anti-Slip Grip
- Enhanced Strength
- Chemotherapy Drug and Fentanyl Permeation Tested**
- Black Color
- Ambidextrous
- Powder-Free
- No Sulfur Added
- Non-Sterile
- Beaded Cuff



Patented Technology*



*No dithiocarbamates, thiurams or mercaptobenzothiazoles (MBT)
Patent www.lowderma.com/patents
** Fentanyl Citrate >240 Minutes;
FDA 510(k) Cleared for medical use

QUALITY & CONFORMITY

- Manufactured under ISO 13485, ISO 9001, and US FDA QSR Quality Management System
- Conforms to ASTM D6319
- Complies with PPE Regulation MDR(EU) 2017/745, Cat III and MDD 93/42/EEC
- Complies with US FDA 21 CFR 177.2600 for food handling
- Meets ASTM D6978 and USP 800 PPE requirement for use of chemotherapy gloves when handling hazardous drugs
- Conforms to the following additional test standards:

ASTM D412	Tensile Properties of Vulcanized Rubbers
ASTM D5151	Standard Test Method for Detection of Holes in Medical Gloves
ASTM D573	Accelerated Aging for Rubber (at 70° C for 166hr)
ASTM D6124	Test Method for Residual Powder on Medical Gloves
ASTM D6978	Tested for use with Chemotherapy Drugs and Fentanyl Citrate
ISO 16604	Viral Penetration Test

CHEMICAL RESISTANCE

CHEMICAL NAME	ASTM F739 (Minutes)	EN16523-1*	CHEMICAL NAME	ASTM F739 (Minutes)	EN16523-1*
Acetic Acid, 10%	> 480		Hydrogen Peroxide, 30%	17.8	Level 2
Acetone, 80%	0		Isopropyl Alcohol, 70%	49.5	Level 2
Ammonium Hydroxide	55.7		Isopropyl Alcohol, 99.5%	45.2	
Butanol	27.8		Methanol in water, 1.5%		Level 6
Cidex OPA	28.9		n-Heptane		Level 3
Citric Acid, 30%	> 480		n-Hexane, 96%	70.3	
Chlorhexidine Gluconate, 4%	> 480		Nitric Acid, 10%	> 480	
Ethanol, 70%	25.2		Phenol, 10%	5	
Ethanol, 99%	9.6		Phenol, 0.1%		Level 6
Ethidium Bromide, 5%		Level 6	Potassium Hydroxide, Saturated	> 480	
Formaldehyde, 37%	> 480	Level 6	Povidone Iodine, 10%	> 480	
Formalin, 10% T	> 480		1-Propanol	24.3	
Glutaraldehyde, 50%	> 480	Level 6	Sodium Hydroxide, 40% K	> 480	Level 6
Hydrochloric Acid, 10%	> 480		Sodium Hypochlorite, 10-13%	> 480	Level 6
Hydrochloric Acid, 37%	166.9		Sulphuric Acid, 50%	> 480	Level 6

* with measured breakthrough time of >480 minutes for level 6, >60 minutes for level 3, and >30 minutes for level 2

PHYSICAL SPECS & PROPERTIES

Size	XS (5/6)	Small (6/7)	Medium (7/8)	Large (8/9)	XL (9/10)	XXL (10/11)
Palm Width ± 5 mm	75	85	95	106	116	125
Glove Length (mm)	Typical Value 245-250 (240 Minimum)					
Thickness (mm mils)	Typical Values Cuff 0.10 mm 4.0 mils Palm 0.13 - 0.14 mm 5.1 - 5.5 mils Finger 0.18 - 0.20 mm 7.0 - 7.9 mils					
Test	Before Aging		After Aging			
	Minimum	Typical Value	Minimum	Typical Value		
Tensile Strength (MPa)	18	25 - 31	14	27 - 33		
Ultimate Elongation	500%	550-600%	400%	540 - 588%		
Force at Break (Newton)	6.0	7.3 - 8.2	6.0	7.5 - 8.2		

PERFORMANCE REQUIREMENTS

Characteristic	Inspection Level	AQL
Freedom from Holes	G1	1.5
Visual Defects (Major)	G1	2.5
Visual Defects (Minor)	G1	4.0
Physical Properties	S2	4.0
Physical Dimensions	S2	4.0
Powder Residue	-	1.5mg/ glove (Max)

CHEMOTHERAPY DRUGS & FENTANYL

No breakthrough after 240 minutes: Cisplatin, Cyclophosphamide (Cytoxan,) Cytarabine, Dacarbazine, Doxorubicin Hydrochloride, Etoposide, Fluorouracil, Ifosfamide, Methotrexate, Mitomycin C, Mitoxantrone, Paclitaxel (Taxol,) Vincristine Sulfate. **Warning, do not use for:** Thiotepa, Carmustine. **No breakthrough after 240 minutes:** Fentanyl Citrate

PRODUCT NUMBERS

Size	Item #	Case Quantity
X-Small	N/A	N/A
Small	ESN701	1000
Medium	ESN702	1000
Large	ESN703	1000
X-Large	ESN704	1000
XX-Large	ESN705	1000

PACKAGING/DIMENSION

100 gloves / box (S - XXL)
10 boxes / case

420mm(L) X 254mm(W) X 265mm(H)

SHELF LIFE & STORAGE

Five years from date of manufacture. Store in a cool, dry place away from direct sunlight or fluorescent lighting.

Manufactured in Malaysia for Essential Distribution, Inc.

The information on this document is a guideline of typical values and characteristics of the product.

Caution: Other components used in making gloves may cause allergic reactions in some users.