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EN421:2010

Colloidal Oatmeal System

Nitrile Exam Gloves Powder Free, Standard Cuff

GloveOn® COATS® (colloidal oatmeal system) is a patented and unique nitrile glove technology, which contains an FDA-recognised skin protectant. These utilise the powerful benefits of all-natural oats as a coating that forms a natural, moisturising barrier between the glove and skin. This acts as a preventative measure against skin irritation and hydration dermatitis. Therefore, users who suffer from dry and itchy skin can now use GloveOn® COATS® to protect their hands while they work.

	VIRUS	\sim		
Physical Dimensions				
Length (mm)	≥ 230			
Palm Thickness (mm)	0.07 ± 0.02			
Finger Thickness (mm)	0.09 <u>+</u> 0.02			
Physical Properties	Before Ageing	After Ageing		
Tensile Strength (MPa)	≥ 18	≥ 16		
Elongation (%)	≥ 500	≥ 400		
Performance Requirements	Increation Lovel	AQL		
renormance Requirements	Inspection Level	AGL		
Watertightness	G1	1.5		
Watertightness	G1	1.5		
Watertightness Physical Dimensions	G1 S2	1.5 4.0		
Watertightness Physical Dimensions Physical Properties	G1 52 52	1.5 4.0 4.0		
Watertightness Physical Dimensions Physical Properties Visual Inspection (Major)	G1 S2 S2 S4	1.5 4.0 4.0 2.5		

EN ISO 374-1:2016/Type C EN ISO 374-5:2016

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Chemotherapy Drugs and Concentration (Tested for Resistance to Permeation by Chemotherapy Drugs as per ASTM D6978-05 Test Report PN 134889A)	Minimum Breakthrough Detection Time (minutes)
Carmustine (BCNU), 3.3mg/ml (3,300 ppm)	21.9 minutes
Cisplatin, 1.0mg/ml (1,000 ppm)	>240 minutes
Cyclophosphamide (Cytoxan), 20.0mg/ml (20,000 ppm)	>240 minutes
Dacarbazine (DTIC), 10.0mg/ml (10,000 ppm)	>240 minutes
Doxorubicin Hydrochloride, 2.0mg/ml (2,000 ppm)	>240 minutes
Etoposide (Toposar), 20.00mg/ml (20,000 ppm)	>240 minutes
Fluorouracil, 50.0mg/ml (50,000 ppm)	>240 minutes
Methotrexate, 25.0mg/ml (25,000 ppm)	>240 minutes
Mitomycin C, 0.5mg/ml (500 ppm)	>240 minutes
Paclitaxel (Taxol), 6.0mg/ml (6,000 ppm)	>240 minutes
Thiotepa, 10.0mg/ml (10,000 ppm)	36.0 minutes
Vincristine Sulfate, 1.0mg/ml (1,000 ppm)	>240 minutes
WARNING: Carmustine and Thiotepa, at the tested concentration, degraded COATS	nitrile glove at 21.9 minutes and

36.0 minutes, respectively. The safe use of gloves in chemotherapy treatment is solely the decision of clinicians authorised to make such decision.

Measured breakthrough time (minutes)	>10	>30	>60	>120	>240	>480
Permeation performance level	1	2	3	4	5	6

REORDER CODE & PACKAGING

Regular Pack:

CTS121XS (XS), CTS121SS (S), CTS121MM (M), CTS121LL (L) & CTS121XL (XL)

- 200 gloves per box (XS to L)
- 180 gloves per box (XL)
- 10 boxes per carton

Handy Pack:

CTS157SS (S), CTS157MM (M) & CTS157LL (L)

- 50 gloves per box
- 40 boxes per carton

FEATURES

- Fingertip textured Powder free
- Not made with natural rubber latex
- Chemo drugs tested
- Lab chemical tested Ambidextrous
- Standard cuff Dawn blue colour

REGULATORY COMPLIANCE

ARTG 164563, FDA 510(k), EU 2016/425, REACH, EU 10/2011, EC 1935/2004, MDR (EU) 2017/745

STANDARDS

ASTM D6319, ASTM D6124, ASTM D5151, ASTM F1671, ASTM D6978, EN 1186, EN 455 part 1, 2, 3 & 4, CEN/TS 14234, EN ISO 374-1 (Type C), EN 16523-1, EN 374 part 2, 4 & 5, EN 13130, EN 420, EN421 (excluding Clause 4.3), HACCP Certified, ISO 10993 part 5 & 10

PATENTS

Patent 7,691,436; Patent 7,718,240; Patent 7,740,622; Patent 8,075,965; Patent 8,458,818

MANUFACTURING ACCREDITATIONS

ISO 9001, ISO 13485, EN ISO 13485

Chemical	EN 16523-1:2015 Permeation Level	EN 374-4:2013 Mean Degradation	
K 40% Sodium Hydroxide	6	-0.7	
T 37% Formaldehyde	4	21.1	



Mun Australia Toll free: 1800 456 837 munglobal.com.au



