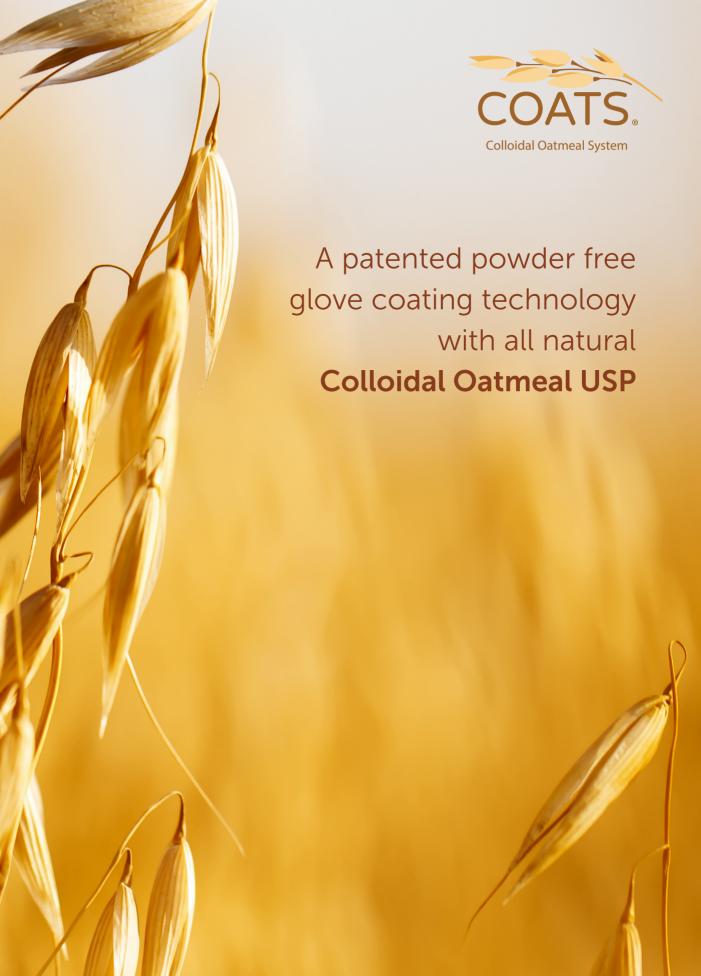






Nitrile & Latex Powder Free Colloidal Oatmeal Coated Gloves



### WHAT IS COATS®

COATS is an acronym for Colloidal Oatmeal System. It is a patented glove coating technology which contains a clinically proven skin protectant.

# Colloidal Oatmeal System



### **BEYOND PROTECTION**

Oatmeal has been used for centuries as a soothing agent to relieve itch and irritation associated with various dry skin conditions. In June 2003, colloidal oatmeal gained the FDA approval to be used as a skin protectant.

Realising the unique benefits of colloidal oatmeal, we at Mun, combined this knowledge with our innovative glove-making technology to offer you GloveOn COATS—the revolutionary glove that goes beyond protection.

# DERMATOLOGICAL BENEFITS OF COLLOIDAL OATMEAL



#### **MOISTURISING**

Hold moisture in the outermost layer of the skin through occlusive and water-binding properties



#### **PROTECTING**

Forms a viscous occlusive barrier to protect from external irritants



#### **SOOTHING**

Relieves inflammation, irritation and itch, which facilitates skin recovery



#### ANTI-OXIDANT

Protects the skin from oxidative damages



#### pH BUFFERING

Preserves the skin's protective barrier function by restoring pH balance



#### **CLEANSING**

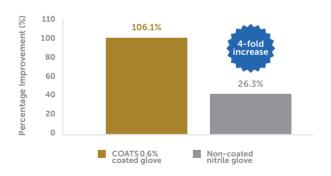
Acts as a natural cleanser by removing dead skin cells



## **EFFICACY OF GLOVEON COATS GLOVES**

#### Improvement in Skin Hydration

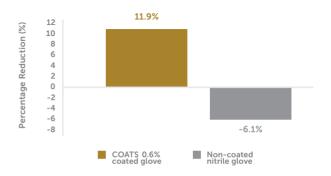
• GloveOn COATS gloves demonstrated a 4-fold increase in skin hydration improvement compared to non-coated nitrile gloves, with a remarkable 106.1% improvement from baseline.<sup>[1]</sup>



### **Reduction in Water Evaporation**

 GloveOn COATS gloves showed a 11.9% reduction in water evaporation as opposed to 6.1% increase in water evaporation observed in non-coated nitrile gloves.<sup>[1]</sup>

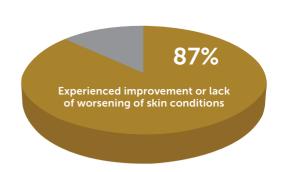
The higher the water loss, the greater the likelihood for skin damage.



# Improvement or Lack of Worsening of Skin Conditions

 87% of healthcare workers who wore COATS gloves experienced improvement or lack of worsening of skin conditions from baseline.

At the beginning of the study, symptoms of mild redness, rash, swelling, an dryness/cracking were reported.









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				
Physical Dimensions					
Length (mm)	ASTM: ≥ 230; EN: Median ≥ 240				
Palm Thickness (mm)	0.07 ± 0.02				
Finger Thickness (mm)	0.09 ±	± 0.02			
Physical Properties	Before Ageing	After Ageing			
Tensile Strength (MPa)	≥ 18	≥ 16			
Median Force at Break (N)	≥ 6	≥ 6			
Elongation (%)	≥ 500	≥ 400			
Performance Requirements	Inspection Level	AQL			
Wetertielet Teet		4.5			
Watertight Test	G1	1.5			
Visual Inspection (Major)	G1 S4	2.5			
Visual Inspection (Major)	\$4	2.5			
Visual Inspection (Major)  Visual Inspection (Minor)	S4 S4	2.5 4.0 ASTM: 4.0;			
Visual Inspection (Major)  Visual Inspection (Minor)  Physical Dimensions	S4 S4 ASTM: S2; EN: N=13	2.5 4.0 ASTM: 4.0; EN: Median value must comply ASTM: 4.0;			

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.

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

#### PACKAGING

200 gloves per box for XXS to L 180 gloves per box for XL 10 boxes per carton

#### REGULATORY COMPLIANCE

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

#### **STANDARDS**

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

#### **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

\*Applicable to HNGC only

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

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





Colloidal Oatmeal System

# Latex Exam Gloves Powder Free, Standard Cuff

GloveOn® COATS® (colloidal oatmeal system) is a patented and unique latex 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.













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Length (mm) ASTM: > 230; EN: Median > 240

Palm Thickness (mm) 0.11 + 0.03

Palm Thickness (mm)	$0.11 \pm 0.03$				
Finger Thickness (mm)	0.13 ± 0.03				
Physical Properties	Before Ageing	After Ageing			
Tensile Strength (MPa)	≥ 18	≥ 16			
Median Force at Break (N)	≥ 6	≥ 6			
Elongation (%)	≥ 650	≥ 500			
Performance Requirements	Inspection Level	AQL			
Watertight Test	G1	1.5			
Visual Inspection (Major)	\$4	2.5			
Visual Inspection (Minor)	\$4	4.0			
Physical Dimensions	ASTM: S2; EN: N=13	ASTM: 4.0; EN: Median value must comply			
Physical Properties	ASTM: S2; EN: N=13	ASTM: 4.0; EN: Median value must comply			
Powder Amount	N = 5	≤ 2 mg/glove			
Protein Content	N = 3	≤ 50µg/g			
Colloidal Oatmeal Content	N = 5	≥ 5mg/glove			

#### **FEATURES**

- Fully textured Powder free
- Made with natural rubber latex
- Lab chemical tested Ambidextrous
- Standard cuff Lime green colour

#### PACKAGING

100 gloves per box for XS to XL 10 boxes per carton

#### REGULATORY COMPLIANCE

FDA 510(k), REACH,

ROHS Directive 2002/95/EC, EU 10/2011, ARTG 127794, EC 1935/2004, MDR 2017/745

#### **STANDARDS**

ASTM D5151, ASTM D6124, ASTM D3578, ASTM D5712, EN ISO 374-1 (Type B), EN 16523-1, EN 374 part 2, 4 & 5, EN 420, EN 455 part 1, 2, 3 & 4, EN 1186, EN 13130, CEN/TS 14234, ISO 10993 part 5 & 10, HACCP Certified\*

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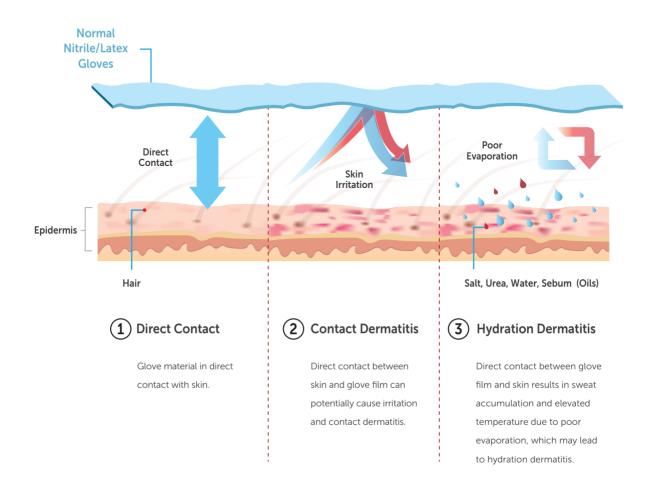
MANUFACTURING ACCREDITATIONS ISO 9001, ISO 13485, EN ISO 13485

\*Applicable to HNGC only

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

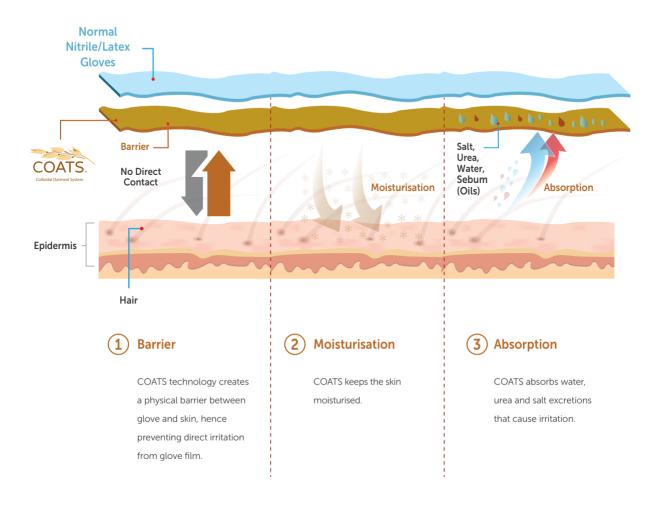
Chemical	EN 16523-1:2015 Permeation Level	EN 374-4:2013 Mean Degradation (%)
K 40% Sodium Hydroxide	3	-15.8
P Hydrogen Peroxide	2	0.0
T 37% Formaldehyde	3	42.5

# TYPICAL CONDITIONS WHEN WEARING A NORMAL GLOVE





## **HOW GLOVEON COATS GLOVE WORKS**



# FEEL THE DIFFERENCE WITH GLOVEON COATS







#### 1 What are Oats?

The oat (avena sativa) is a cereal grain grown and harvested for its seeds, which are used in a wide variety of products, including food, agriculture, health and skincare products.

#### 2. What is Colloidal Oatmeal?

Colloidal oatmeal, the compound utilised in GloveOn COATS gloves, is made by milling the oat seeds into a fine powder. Colloidal oatmeal is recognised by the FDA as a skin protectant. GloveOn COATS gloves utilise the unique benefits of colloidal oatmeal by including a coating of colloidal oatmeal inside the glove. GloveOn COATS gloves moisturise your hands while you wear them, replacing moisture stripped from the skin, removing dead skin cells, relieving itch and irritation, repairing damages from other chemicals and calming the skin.

#### 3. What is Gluten?

Gluten is a mixture of proteins that occur naturally in wheat, rye, barley and crossbreeds of these grains.<sup>3</sup> Gluten can be found in foods containing these ingredients, including bread, pasta, cakes, cereal and various sauces and dressings.<sup>4</sup> For most people, gluten is entirely safe to eat, and is a healthy source of protein and fibre. However, for people who suffer from coeliac disease, gluten can cause serious medical problems.<sup>4</sup>

#### 4. What is Coeliac Disease?

Coeliac is a medical disease in which the immune system reacts abnormally to gluten, causing small bowel damage. Coeliac disease is a genetic predisposition, meaning people who suffer from the disease are born with genes that may result in the development of gluten intolerance. Coeliac disease is estimated to affect 1% - 2% of the population.<sup>5</sup> If undiagnosed, coeliac disease can lead to chronic system inflammation, poor nutrition and malabsorption of nutrients. Coeliac disease cannot be cured, thus people who suffer from this disease must maintain a lifelong gluten–free diet.<sup>6</sup>

#### 5. Do Oats contain Gluten?

Oats do not naturally contain gluten. However, due to the demands of the modern agricultural market, oat crops are often grown in close proximity to, or on plots of land previously used to grow, wheat, barley and rye crops, which may lead to cross-contamination.



#### 6. I have Coeliac Disease. Can I wear GloveOn COATS gloves?

Yes. While minute traces of gluten due to cross-contamination may be in the colloidal oatmeal coating of GloveOn COATS gloves, topical exposure to gluten is completely safe for coeliac sufferers. According to the Centre for Coeliac Research, "...it is the oral ingestion of gluten that activates the immunological cascades leading to the autoimmune process typical of coeliac disease". That is, the adverse symptoms associated with coeliac disease occur only when gluten is ingested orally. The presence of gluten in products designed for external use, in particular the application of gluten products to the skin has been deemed safe by the Centre for Coeliac Research

"If you have coeliac disease, then the application of gluten containing products to the skin should not be a problem, unless you have skin lesions that allow gluten to be absorbed systematically in great quantities"

— Dr Alessio Fasano, Medical Director of the Centre for Coeliac Research.<sup>7</sup>

In fact, it is generally agreed that gluten molecules are too large to be absorbed through the skin<sup>8</sup>. As always, you should practice appropriate hand washing techniques as part of routine hygiene practices when you anticipate contact with potentially infectious people or substances.

#### 7. Will my patients be exposed to Gluten if I use GloveOn COATS gloves?

No. The colloidal oatmeal coating is present only inside GloveOn COATS gloves, meaning the patient does not come into contact at all with this coating. If donned and doffed correctly, the inside of the glove should not be exposed to the patient.

If, through circumstance, the patient was to come into contact with the inside of the glove, this would cause no adverse harm to the patient, as topical exposure to gluten is completely safe for coeliac sufferers. Further, GloveOn COATS gloves require only a minimal coating of colloidal oatmeal to achieve the unique skin benefits. Thus, the traces of gluten (if any) in the colloidal oatmeal coating would be extremely small.

Clinical studies that have examined the benefits of colloidal oatmeal on the skin have found that it is a safe and effective treatment for a wide range of skin conditions.<sup>9</sup>

- 1 Aspen Clinical Research Report OATCLI4C. A Clinical Study to Measure the Effects of COATS 0.6% Coating Concentration Blend on the Skin vs 'Non-Coated Nitrile Glove (Control): To Demonstrate the Benefits of this Coating as a Protectant; and the Reparative Role on Damaged Skin. (2014).
- Drower, E., Reyna, R., Wilson, K., Fercho, D., & Schmidt, T. (2016). Evaluation of Colloidal Oatmeal-Coated Exam Gloves on Skin of Healthcare Workers. American Journal of Infection Control, 44.
- 3 US Food and Drug Administration (2014). 'Gluten-Free' now means what is says. Consumer Health Information, August 2014 Bulletin.
- 4 State Government of Victoria (2015). Gluten-free diet. Retrieved from https://www.betterhealth.vic.gov.au/health/HealthyLiving/gluten-free-diet
- BioMed Central Ltd. (2013). A novel serogenetic approach determines the community prevalence of celiac disease and informs improved diagnostic pathways. Retrieved from http://bmcmedicine.biomedcentral.com/articles/10.1186/1741-7015-11-188.
- 6 Coeliac Australia (2015). Coeliac Disease. Retrieved from http://www.coeliac.org.au/coeliac-disease/.
- 7 Gluten Free Dietitian (2015). Personal Care Products: Do you need to worry about gluten? Retrieved from http://www.glutenfreedietitian.com/personal-care-products-do-you-need-to-worry-about-gluten/.
- Howard, D. (2015). A Glutton for Gluten: Should Skin Care be Gluten-Free? Retrieved from https://education.dermalogica.com.au/Content/docs/AGluttonforGluten.pdf
- 9 European Medicines Agency (2008). Assessment Report on Avena Sativs L., Herba and Avena Sativa L., Fructus.





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