



**M A X T E R**  
GLOVE MANUFACTURING SDN BHD  
(229862-H)

Lot 6070, Jalan Haji Abdul Manan  
6th Miles Off Jalan Meru  
41050 Klang, Selangor, Malaysia  
Tel: 603-33929888 (8 lines) Fax: 603-33923328  
E-MAIL: maxter@tm.net.my  
www.maxter.com.my

# MATERIAL AND SAFETY DATA SHEET

## Powdered Latex Examination Gloves

### Factory:

#### Maxter Glove Manufacturing Sdn Bhd

Lot 6070, Jalan Haji Abdul Manan,

6<sup>th</sup> Miles Off Jalan Meru,

41050 Klang,

Selangor, Malaysia

Tel: (603) 33929888

Fax: (603) 33923328

### SECTION 1 DESCRIPTION OF PRODUCT

- 1.1 Device Family: Powdered Latex Examination Gloves  
Classification : Class I, Non- sterile  
Conformity : Annex VII, self declaration of conformity

Powdered latex examination glove is classified as Class I medical device as per Rule 1, Annex IX of Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC.

- 1.2 Brief Description  
The powdered latex examination glove is made from 100% natural rubber, ambidextrous and non-sterile. It is treated with absorbable modified cornstarch powder (USP) which is to facilitate the user in donning the glove and as well as to prevent the glove surface from sticking to each other.

- 1.3 Intended Use  
The powdered latex examination glove is a medical device, which protects the hand of the user.

The main function of wearing gloves is to protect the wearer against contamination of infectious materials particularly viruses, bacteria, infected blood and body fluids. Thus, the single most important criterion in gloves selection is barrier protection, as defined by all users, including physicians, dentists, medical and non-medical workers and researchers.



The next most important criterion are strength, fit, comfort and dexterity, that is the ability for the glove to stretch, remain soft and comfort to the hand due to the thickness and elastomeric nature of the latex glove.

It is intended for single use only.

The powdered latex examination gloves are usually used for conducting medical examination, dentistry, clinical examination, diagnostic and therapeutic procedures and also for laboratory purposes.

**SECTION 2 PHYSICAL DATA**

Meet with the requirements of ASTM D3578:2005 Standard Specification for Rubber Examination Gloves and EN455-1:2000, EN455-2:2009+A1:2011 and EN455-3:2006 Medical Gloves for Single Use.

|                              |   |
|------------------------------|---|
| Width                        | 95 ± 10 mm (size medium)  |
| Length                       | 240 mm minimum  |
| Thickness                    | 0.08 mm minimum (providing tactile sensitivity)   |
| Tensile Strength (unaged)    | 18.0 MPa minimum (providing superior strength)  |
| Ultimate elongation (unaged) | 650% minimum  |
| Tensile Strength (aged)      | 14.0 MPa minimum  |
| Ultimate elongation (unaged) | 500% minimum  |
| Watertightness               | Substantially impermeable to water vapour and liquid water providing an excellent biological barrier. Double gloving is recommended for reduced risk. |

**SECTION 3 HEALTH HAZARD INFORMATION**

Biocompatibility data  
 Guinea Pig Sensitization (Buehler) -  
 Did not indicate a potential for dermal irritation or allergic contact sensitization.

Repeated Insult Patch Test -  
 Did not indicate a potential for dermal irritation or allergic contact sensitization.

**SECTION 4 FIRST AID MEASURES**

Inhalation/ Eye  
 Dusted with absorbable corn starch powder (USP). Powder may be irritating to the respiratory tract or eye. If symptoms persist, seek medical help.



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Caution: Users should consider the circumstances of use in deciding whether to remove any residual powder on gloves after donning. Powder can be removed by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel or other effective method.

Skin

Warning: Isolated cases of allergic reactions to latex rubber or powder have been reported. If you experience a reaction to this product, discontinue use immediately and seek medical help. This product contains Natural Rubber Latex which may cause allergic reactions in some individuals.

**Note: Pre and post leaching processes during the manufacture of gloves have significantly reduced protein levels in gloves.**

**SECTION 5**

**HANDLING AND STORAGE**

Storage

Store in cool, dry place, avoid excessive heat (40 ° C, 104 ° F). Open box should be shielded from exposure to direct sun or fluorescent lighting.

Disposal

Material may be recycled or disposed of in accordance to local disposal regulations.

Fire Hazard

Flammable. Suitable extinguishing media are: - dry extinguishing media, foam.

**SECTION 6**

**SPECIAL PROTECTION INFORMATION**

In accordance to EN 374-3: 2003 Permeation by Chemicals

|                      |         |
|----------------------|---------|
| 40% Sodium hydroxide | Class 5 |
| 96% Sulphuric acid   | Class 2 |