SUPERMAX
GLOVE MANUFACTURING SDN BHD
(218698-T)
since 1989

Lot 38, Putra Industrial Park, Bukit Rahman Putra
40160 Sungai Buloh, Selangor Darul Ehsan, Malaysia
Tel: 603-61452328 (30 lines) Fax: 603-61562191 / 67307883
E-MAIL: smax@po.jaring.my
http://www.supergloves.com

MATERIAL AND SAFETY DATA SHEET

Powder Free Nitrile Examination Gloves

Factory:
Supermax Glove Manufacturing Sdn Bhd
Lot 38, Putra Industrial Park,
Bukit Rahman Putra,
40160 Sungai Buloh,
Selangor, Malaysia
Tel: (603) 61452328
Fax: (603) 61562191

SECTION 1 DESCRIPTION OF PRODUCT

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

Powder free nitrile 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 powder free nitrile examination glove is made from 100% nitrile synthetic rubber (NBR Protein Free), ambidextrous and non-sterile. It is treated with Chlorine 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 powder free nitrile examination glove is a medical device, which protects the hand of the user.

SUPERMAX
GLOVE MANUFACTURING SDN BHD
(218698-T)
since 1969

Lot 38, Putra Industrial Park, Bukit Rahman Putra
40160 Sungai Buloh, Selangor Darul Ehsan, Malaysia
Tel: 603-61452328 (30 lines) Fax: 603-61562191 / 67307883
E-MAIL: smax@po.jaring.my
http://www.supergloves.com

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 nitrile glove.

It is intended for single use only.

The powder free nitrile 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 D 6319-10 Standard Specification for Nitrile Examination Gloves for Medical Application and EN455-1:2000, EN455-2:2009+A2:2013 and EN455-3:2006 Medical Gloves For Single Use.

Width	95 $\pm$ 10 mm (size medium)
Length	240 mm minimum
Thickness	0.05 mm minimum (providing tactile sensitivity)
Tensile Strength (unaged)	14 MPa minimum (providing superior strength)
Ultimate elongation (unaged)	500% minimum
Tensile Strength (aged)	14 MPa minimum
Ultimate elongation (unaged)	400% 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

SUPERMAX GLOVE MANUFACTURING SDN BHD 218698-T

SUPERMAX
GLOVE MANUFACTURING SDN BHD
(218698-T)
since 1989

Lot 38, Putra Industrial Park, Bukit Rahman Putra
40160 Sungai Buloh, Selangor Darul Ehsan, Malaysia
Tel: 603-61452328 (30 lines) Fax: 603-61562191 / 67307883
E-MAIL: smax@po.jaring.my
http://www.supergloves.com

contact sensitization.

SECTION 4	**FIRST AID MEASURES**
Skin	Other components used in making gloves may also cause allergic reactions in some users. **Note: Leaching and washing processes undertaken during the manufacture of powder free gloves have significantly reduced residual chemical 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	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	Level 6
n-Heptane	Level 5

SUPERMAX GLOVE MANUFACTURING SDN BHD 218698-T