MATERIAL SAFETY DATA SHEET

POWDER FREE NITRILE EXAMINATION GLOVE – STRIP & PACK

Section 1 - Identification of the substance/preparation and of the company / undertaking

Product Name	**Powder Free Nitrile Examination Glove – Strip & Pack, Non-sterile (Below 7 mils as measured at palm).**	
Product Identification	**A powder free patient examination glove is a disposable device made of synthetic rubber that may bear a trace amount of glove powder and is intended to be worn on the hand / fingers for medical purposes to provide a barrier against potentially infectious materials and other contaminants.**	
Product Code & Classification	**FDA: LZA – 880.6250, Class I**	**MDD: Class I**
Approval Numbers	**FDA 510(K) No K053657**	
Performance Reference Standards	**ASTM D – 6319**	**EN-455-Part 1 and 2**
		EN 1186
Manufacturing Standard	**ISO 9001 / ISO 13485**	**MDD 93/42/EEC**

Section 2 – Composition/Information on ingredients

Base Ingredient (Polymer)	**Acrylonitrile Butadiene Rubber Latex**
Main Ingredients	**Sulphur**
	Zinc Oxide
	Accelerators
	Anti-oxidant (phenolic)
	Whitening Agent

ALL THE ABOVE CHEMICALS USED ARE NON TOXIC OR NON HAZARDOUS

Section 3 - Hazards Identification

Hazard Description	**Similar type of powder free examination gloves have been tested for following study and NO IRRITATION was observed** **Skin irritation study in rabbit** **Sensitization study in guinea pig**

Section 4 – First aid measures

General Information	**Discontinue use immediately if you experience any reddening, burning, or irritation**
After skin contact	**Users who are sensitive to nitrile and/or components used in the manufacture of these gloves should discontinue use immediately and consult a physician.**
Others	**Supply fresh air; consult doctor in case of complaints**

Section 5 – Fire fighting measures

Flammability	**Product burns with excessive smoke**
Extinguishing Media	**Water, dry agent, foam**

Section 6 – Accidental release measures

Personal Protection	**Refer to section 8**

Section 7 – Handling and storage

Handling	**Handle with care**
Storage	**Store gloves in original packing in a cool, dry and well-ventilated area, away from dust, direct sunlight, moisture, X-Ray. Improper storage may reduce shelf life.**

Section 8 – Exposure controls/personal protection

General Information	**Gloves are for SINGLE use only, disposable and NON - STERILE** **Punctures or tears may occur after donning. Frequently inspect each glove after donning for punctures or tears, and immediately discontinue use if damaged.** **These gloves should not be worn by, or exposed to, individuals allergic to nitrile. Other component used in making gloves may also cause allergic reactions in some users.**

Section 9 – Physical and chemical Properties

General Information

Type	**Ambidextrous, Textured surface**
Colour	**Blue, White, Black, Violet**
Size	**X-Small, Small, Medium, Large, X-Large and XX-Large**
Cuff	**Beading**
Width	**X-Small = 70 ± 10 mm** **Small = 80 ± 10 mm** **Medium = 95 ± 10 mm** **Large = 110 ± 10 mm** **X-Large = 120 ± 10 mm** **XX – Large = ≥ 120 mm**
Length	**Minimum 230 mm**
Thickness	**Minimum 0.05 mm**
Donning Lubricant	**Chlorinated**
External Lubricant	**Stearate Polymer**

Section 10 – Stability and reactivity

Conditions to avoid	**Exposure to excess ozone condition and excessive heat (38^{o}C, 100^{o}F)**
Material to avoid	**None known**

Section 11 – Toxicologial information

Toxicity	**Nitrile Examination Gloves are NON-TOXIC and is Biodegradable by a combination of chemical and biological reactions.**

Section 12 – Ecological information

Biocompatibility	**The chemical formulation of the gloves and surface lubricating materials do not contain any substances normally known to be harmful to the user or to any person with whom the gloves contact.**

Section 13 Disposal considerations

Product Recommendation	**Must be dumped or incinerated in accordance to local regulations or authorities.**

Section 14 – Transport information

Transport information **Not dangerous according to the above specifications, No special requirements**

Section 15 – Regulatory information

Labeling
According to EU guidelines **MDD 93/42/EEC**
EU Régulation 1907/2006/EC, Article 31

According to US guidelines **FDA 21 CFR Part 807**

Section 16 – Other information

The information is based on the present state of our knowledge and does not therefore guarantee certain properties. Recipients of our product must take responsibilities for observing existing laws and regulation.