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JUST THE FACTS

Disposable medical gloves constitute a major advance in the war against infectious diseases by preventing the transmission of infectious agents between the patients and health care workers. The most effective disposable medical gloves are made of natural rubber. These natural rubber gloves provide a combination of unsurpassed barrier protection, in-use strength, comfort and fit – all at a low cost and with minimal impact on the environment.

Natural rubber gloves also contain latex proteins, which can cause sensitivity in some individuals and, in rare instances, serious allergic reactions. For these reasons, there have been some recent efforts to limit the access of health care workers to natural rubber medical gloves.

These fact sheets are designed to present the facts about natural rubber gloves, synthetic substitutes and latex allergies, and to clear up some misconceptions. They also contain information about innovative approaches to manufacturing medical gloves to minimize the likelihood of latex protein allergy while maintaining the unparalleled benefits of natural rubber.

DISPOSABLE MEDICAL GLOVES: THE BASICS

More than 20 billion disposable medical gloves are used in the United States every year. In the health care environment, these gloves are life-saving devices that prevent the transmission of AIDS, hepatitis B, and other infectious diseases that can be contracted through contact with blood and other bodily fluids.

In recent years, the incidence of allergic reactions to latex proteins has raised new questions about glove choices. In the final analysis, health care workers must weigh the importance of barrier protection against the risk of a possible allergic reaction. In addition, because disposable medical gloves are used in such large quantities, both economy and environmental impact must also be taken into account.

Types of Disposable Medical Gloves

Disposable medical gloves are categorized in three ways:

- How they are used – examination gloves or surgical gloves
- The material from which they are made – natural rubber (also called latex) or synthetic rubber; and
- Whether they are powdered or powder free.

Differences between Natural Rubber and Synthetic Disposable Medical Gloves

Material

- Natural rubber gloves are derived from *Hevea* latex, and organic substance extracted from rubber trees.
- Most synthetic medical gloves used today are made from either polyvinyl chloride (also called 'PVC' or 'vinyl'), or nitrile. Other synthetic gloves are made from polyurethane, neoprene, polyethylene and thermoplastic elastomer (also called "TPE").

Plastic Properties

- Natural rubber gloves are well known for their strength, elasticity, high resistance to tearing, excellent comfort and fit, and ease of putting on, or "donning".
- Synthetic gloves – with the exception of those made of polyurethane – generally exhibit tensile strength inferior to that of natural rubber gloves. In fact, no single synthetic substitute equals natural rubber gloves in all relevant physical properties.

Barrier Protection

- This is unquestionably the most critical function of medical gloves. While both natural rubber and synthetic gloves, tested when they are new, exhibit similar barrier protection, differences in their in-use performance can be dramatic. This is particularly true with vinyl gloves. Studies testing gloves after use in various medical procedures have shown that:
 - Natural rubber gloves exhibited a leakage rate of between 0 and 4 percent
 - Vinyl gloves are 13 times more likely to leak than natural rubber gloves, with leakage rates as high as 60 percent. The barrier performance of more costly nitrile gloves is comparable to that of natural rubber.

Cost

- Synthetic gloves are from 2 to 10 times more expensive than natural rubber gloves, with the exception of vinyl gloves, which are comparable in price.

Environmental Impact

- Natural rubber gloves are derived from latex obtained from rubber trees, a renewable resource. In addition, natural rubber gloves are biodegradable. Synthetic gloves are made of materials derived from petroleum. Synthetic gloves are not biodegradable, and disposal by incineration releases dioxin, cyanide, vinyl chlorides, hydrogen chloride, and other harmful substances. The large-scale use and disposal of synthetic gloves would have an adverse environmental impact.

Standards for Disposable Medical Gloves

Several organizations, including the American Society for Testing and Materials (ASTM), whose standards are often adopted by the US Food and Drug Administration (FDA), have established standards for disposable medical gloves. Other groups that have established these standards include the International Organization for Standardization (ISO) and other similar organizations in Europe, Canada, Australia and New Zealand.

Because of differences in the properties of natural rubber and synthetic gloves, different specifications are often set for each. Physical specifications under the Standard Malaysian Glove (SMG) and the ASTM standards for natural rubber gloves are shown in the following table:

SMG and ASTM Technical Standards for Examination Gloves

Property	Minimum Requirements *				
	SMG Technical	ASTM D3578-00a		ASTM D6319-00	ASTM D5250-00
		Type I **	Type II ***	Nitrile	Vinyl
Tensile Strength (Mpa)	21	18	14	14	9
Elongation at Break (%)	700	650	650	500	300
Tensile Strength (Mpa) (after ageing)	16	14	14	14	-
Elongation at Break (%) (after ageing)	500	500	500	400	-

* Higher numbers denote higher strength and elasticity

** Gloves with maximum stress of 5.5 Mpa at 500% elongation are classified as Type I.

*** Gloves with maximum stress of 2.8 Mpa at 500% elongation are classified as Type II.

SENSITIVITIES TO DISPOSABLE MEDICAL GLOVES

Sensitive users of disposable medical gloves may be subject to any of three types of reactions:

Skin Irritation: A local irritation that is **not** an allergic reaction can occur in connection with the use of any type of medical glove, natural or synthetic.

- **Cause:** Residual soaps, hand cream, powder, disinfectants that remain on hands, temperature and pH extremes and other factors.
- **Symptoms:** Burning sensation, itching, skin rash or flakiness, swelling, fissures, sores and drying.
- **Onset:** Ranges from minutes to hours following contact with irritant(s).

Type IV Allergy of Delayed Hypersensitivity: This allergic reaction is cell-mediated. It is manifested on the skin as contact dermatitis (which can be caused by either natural rubber or synthetic gloves). This is the most common type of allergic reaction to medical gloves.

- **Cause:** Residual chemicals used in the manufacture of both natural rubber and synthetic gloves, particularly thiuram, mercaptobenzothiazoles and carbamates.
- **Symptoms:** Similar to those of irritation. Redness of skin, inflammation or blister formation and eczema.
- **Onset:** Within 1-2 days after contact with allergen(s)

Type I Allergy of Delayed Hypersensitivity: This allergic reaction involves the IgE antibodies in the immune system. This is the least prevalent, and potentially most severe, type of allergic reaction to medical gloves.

- **Causes:** Residual extractable latex proteins found in some natural rubber gloves. The allergic reaction is often termed *latex protein allergy*.
- **Symptoms:** These can vary from mild reactions such as hives, hay fever, allergic conjunctivitis (runny nose, itchy eyes), to asthma and in rare cases, anaphylaxis.
- **Onset:** Within minutes following contact with allergen(s)

Other Causes of Immediate Hypersensitivity (Type I Allergy) to Proteins

Many protein sources can cause Type I allergy. Protein in some foods, such as seafood, peanuts, bananas, watermelons, avocados, pineapples, potatoes and tomatoes may elicit Type I allergic reactions in sensitive individuals, as may plant pollen, insect bites, and a number of drugs including penicillin.

Incidence of Immediate Hypersensitivity (Type I Allergy) to Proteins

Studies have shown that, among the general population in the US, the incidence of allergy to latex proteins is less than 1%. The incidence has been reported to be higher in the health care sector (3% to 16%) as indicated by skin-prick testing. In addition, as many as 50% of *spina bifida* patients and children who have undergone multiple invasive procedures have also been reported as latex protein-sensitive.

It is believed that gloves widely used by health care workers in the 1980s due to concerns about AIDS had high levels of residual extractable latex proteins. There is therefore a great possibility that latex protein sensitivity reported among health care workers today is related, at least in part, to exposure to these high-protein gloves. In recent years, manufacturing methods for natural rubber gloves have substantially improved, and the latex protein content of today's gloves can be much lower than could previously be achieved. Such are the gloves manufactured in Malaysia under the SMG system, which ensures users of not only effective barrier protection, but also of reduced likelihood of allergy.

Advice for Individuals who are Sensitive to Latex Proteins

- Health care workers and others who believe they may have allergies to latex proteins should have themselves diagnosed, preferably using the simple skin-prick test.
- Individuals with food-related protein allergies may have cross-sensitivity to latex proteins.
- Individuals who are sensitive to latex proteins should avoid contact with any products containing them and they should use synthetic substitutes instead of natural rubber gloves.

Note: While synthetic disposable medical gloves are free of latex proteins they are by no means guaranteed to be allergy-free.

- Delayed hypersensitivity (Type IV) reactions have been traced to chemicals often used in processing synthetic gloves.
- Immediate hypersensitivity (Type I) reactions have also been reported by users of vinyl products and nitrile gloves.

Some experts predict that such reactions to synthetic gloves will become more common as users are exposed to synthetics for longer periods.

POWDERED DISPOSABLE MEDICAL GLOVES

Some natural rubber gloves are manufactured with a thin coating of cornstarch powder to facilitate donning of the gloves and to prevent the sides from sticking together. Cornstarch powder is not known to be an allergen.

Powdered Gloves and Allergies to Latex Proteins

During the manufacture of powdered natural rubber gloves, cornstarch may absorb residual extractable latex proteins. Powder particles containing the proteins may remain on the gloves and can act as an aeroallergen when they become airborne. Inhalation of these particles may cause adverse reactions in individuals who are sensitive to latex proteins. However, if natural rubber gloves are treated to reduce their proteins prior to powdering, absorption of these proteins will be minimal. New generation rubber gloves, such as those produced under Malaysia's SMG Program, have a low level of undesirable aeroallergens. This is true for low-powder as well as powder-free gloves.

Removing Residual Latex Proteins

Because residual extractable proteins are water-soluble, they can be easily washed out during the production process. Hence the amount of latex protein in natural rubber gloves is directly related to the amount and conditions of processing, particularly washing. A number of new and improved technologies are now available for effectively reducing the undesirable residual extractable proteins in gloves.

Powdered Gloves and Post-Operative Patients

The presence of foreign bodies has been reported to be a major cause of adverse post-operative reactions such as tissue adhesion, delay in wound healing and cancer-like growths called granulomas. Cornstarch powder particles from surgical gloves may contribute to these reactions. However, studies have indicated that the majority of foreign bodies associated with adverse reactions have been particles other than powder, namely, gauze lint or sutures. Starch particles accounted for only 3% to 5% of the total.

Powder-free Gloves – Minimizing the Impact of Powder

Powder-free latex gloves with little or no powder are also now available in the market place.

Most powder-free gloves have been extensively washed and treated with the chlorine process, which not only removes the tackiness of the gloves without the need for cornstarch powder, but also eliminates most of the extractable latex proteins.

In addition, a newer type of powder-free glove is the polymer-coated glove. Proper processing minimizes the residual latex protein content of these gloves as well.

MEETING THE CHALLENGE OF LATEX PROTEIN SENSITIVITY

As the world largest exporter of natural rubber gloves, Malaysia takes very seriously the problem of latex protein allergy, and the government has committed significant resources to research and development addressing this challenge. Research undertaken jointly by the Rubber Research Institute of Malaysia (RRIM), the Tun Razak Research Centre (TARRC) in the United Kingdom, and the natural rubber glove industry in Malaysia has yielded a much greater understanding of what causes allergic reactions to latex proteins, particularly in natural rubber gloves. As a result, new and improved manufacturing and testing technologies have been developed and are now available to effectively reduce the level of residual extractable latex proteins in natural rubber gloves.

In addition, through joint studies with dermatologists and immunologists overseas, guidelines have been established for manufacturing gloves with low levels of extractable latex proteins, which significantly reduce the risk of allergy to latex proteins. These guidelines are the basis for the Standard Malaysian Glove (SMG) Program, a quality-control program for the manufacture of high quality, low protein, low-powder gloves. The SMG Program provides users with gloves that are not only unequalled in barrier protection, but also present minimum risk of protein allergy,

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