

# TECHNICAL INFORMATION BULLETIN

## – LATEX AND SYNTHETIC SENSITIVITIES –



In recent years healthcare professionals and the general public have become increasingly concerned with the hazards of blood-borne pathogens and their mode of transmission. Latex gloves provide a primary form of protection. Many latex gloves for medical and laboratory use are made of natural rubber latex (NRL). NRL is a highly durable and flexible material that provides a high measure of protection against pathogens and environmental contaminants.

Although NRL gloves have become the material of choice for hand protection in many industries, some people have reported certain irritations and/or adverse reactions associated with the use of these gloves. These adverse reactions typically manifest themselves in the form of irritation, or delayed hypersensitivity (Type IV), or immediate hypersensitivity (Type I).

### Irritation

#### – Irritant contact dermatitis

**Description:** A non-allergic response usually due to insufficient rinsing of hands or body area in contact with an NRL product. Irritation can also be caused by residual processing chemicals used in manufacturing NRL products. It is important to note that this condition can be confused with a condition caused by a variety of other chemicals often found in other products and is not exclusive to NRL products. Examples of agents that may cause irritation are skin cleansing agents, disinfecting agents, and preservatives.

**Symptoms:** Typically, reddening of the skin, or a rash on the skin that tends to be dry and itchy. The onset of this response typically occurs within minutes to hours of coming into contact with an NRL product.

**Areas of body affected:** Typically affects the areas of the body coming into direct contact with the NRL product. There is no evidence of a potential for systemic involvement.

**What should be done:** If you have experienced symptoms associated with an irritation, you should consider using powder-free gloves which may help reduce your irritation. Consult with your physician if symptoms persist.

### Delayed Hypersensitivity (Type IV)

#### – Allergic contact dermatitis & chemical allergy

**Description:** A cell-mediated allergic response to residual accelerating and/or processing agents used in the manufacturing process of latex products. This type of allergy is similar to that of poison oak.

**Symptoms:** The severity of this type of response is extremely varied. Reactions normally affect the skin and can cause a red rash, small blisters, dry thickened (leathery) skin, crusting, scabbing sores, and peeling. The onset of this response is delayed, typically occurring between 6 to 48 hours after contact.

**Areas of body affected:** Typically undefined, resulting in the condition not being limited to the areas coming into direct contact with the NRL product.

**What should be done:** If you suspect you may have an allergy to the agents used to manufacture natural latex gloves, consult with your physician prior to continuing the use of latex products. Ask your physician for advice regarding the use of alternative gloves, such as powder-free natural latex or synthetic gloves.

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## – LATEX AND SYNTHETIC SENSITIVITIES – [CONTINUED]

### Immediate Hypersensitivity (Type I)

– Protein allergy, Immunoglobulin E (IgE) mediated response

**Description:** An allergic response to the residual water extractable proteins found on finished natural latex devices made of NRL. These proteins originate from the rubber tree (*Hevea brasiliensis*).

**Symptoms:** The severity of this type of response is extremely varied, and can be potentially serious. Symptoms include local or generalized urticaria, rhinitis, conjunctivitis, asthma, or anaphylaxis. The onset of this response is immediate, typically occurring within minutes after contact, but may also occur hours later. Studies indicate that there is a potential risk for systemic involvement.

**Areas of body affected:** Typically undefined, resulting in the condition not being limited to the areas coming into direct contact with the NRL product.

**What should be done:** Studies have shown that users of NRL products who suffer from immediate onset hypersensitivity (Type I) are generally atopic, and typically already exhibit allergies to a number of other substances. If you have experienced any of the reactions listed above or suspect that you may be susceptible to latex allergy, immediately discontinue the use of natural latex products, and notify your supervisor. You must also consult with your physician to determine your risk and the potential severity of the condition. Only your physician/allergist can determine if you are latex sensitive.

### Regulatory Information

The Food and Drug Administration (FDA) has recognized the issues concerning sensitivities surrounding natural rubber latex and have taken certain actions to help reduce the risk for those who currently are sensitive to NRL or may develop an immediate hypersensitivity to NRL. To this end certain regulations have been put in place to warn the public of these risks. Specifically for any medical glove placed on the market in the United States the

following caution is required per 21 Code of Federal Regulations Part 801.437(d):

**“Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.”**

The FDA also gives the following recommendation on its website regarding personal protective equipment (medical gloves):

- *Some people are allergic to the natural rubber latex used in some medical gloves. FDA requires manufacturers to identify on the package labeling the materials used to make the gloves. If you are allergic to natural rubber latex, you should choose gloves made from other synthetic materials (such as polyvinyl chloride (PVC), nitrile, or polyurethane).<sup>1</sup>*

Microflex is fully aware of the concerns its clients have with regard to latex sensitivity and is committed to providing its clients with superior NRL gloves. Microflex is determined to apply the latest information and technologies to the development of its NRL gloves and seeks new methods of lowering the protein levels of all latex gloves. In addition, Microflex has expanded its product line to include gloves made of synthetic materials, which do not contain NRL. For more information about latex sensitivity or the new synthetic gloves available at Microflex, please call 1-800-876-6866.

1. **FDA guidance on Personal Protective Equipment.**  
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/PersonalProtectiveEquipment/ucm056077.htm>