

Criteria for allergy-friendly disposable gloves

BACKGROUND

People with sensitive skin or neurodermatitis depend on protective gloves to protect them from allergic substances or irritants. However, over time, many of these people develop allergic reactions to wearing the gloves or to certain substances in them.

Members of certain professions and occupations who are required to wear such gloves on a regular basis and for long periods of time are particularly at risk. If an allergy develops, those affected are prone to hand eczema and skin rashes in reaction to the protective gloves.

Generally, gloves should be worn as often as necessary and for as short a time as possible. If the gloves must be worn for long periods of time, it is advisable, and not just for people with allergies, to wear seamless, undyed cotton glove liners underneath.

ECARF certifies disposable gloves that do not contain certain allergenic substances (in particular latex, powder).

1. TEST CRITERIA

1.1. Document review (technical data sheet, safety data sheet)

The following parameters must be described in the technical data sheet:

- key properties of the material:
 - material
 - colour
 - fit
 - length
 - width
 - thickness
 - tensile strength
 - elasticity
 - tear resistance
 - quality standard
 - packaging

- permeation levels
- breakthrough time
- storage recommendations

The following parameters must be described in the safety data sheet:

- material/preparation and company name
- composition/information on the ingredients
- potential risks
- first aid measures
- fire control measures
- accidental release measures
- handling and storage
- exposure controls and personal protective equipment
- physical-chemical properties
- stability and reactivity
- toxicological data
- ecological data
- disposal instructions
- transport details
- regulations
- miscellaneous information

The following instructions for correct use should be included with the gloves:

- Use these gloves as often as necessary and for as short a time as possible.
- If used for long periods of time, wear undyed, seamless cotton glove liners underneath.

1.2. Subject testing

The product's tolerability in persons with sensitive, eczema-prone skin must be proven in clinical tests involving human subjects. Tolerability is demonstrated in a usage test corresponding to the product application, in which at least 20 test persons of the respective designated user group with sensitive skin and medically diagnosed atopic dermatitis use the disposable gloves for 30 minutes twice a day over a period of 7 days.

The product is considered allergy-friendly if it is demonstrated that no significant deterioration occurs in any of the subjects within this period; fluctuations in the skin condition associated with atopic dermatitis are taken into account.

2. QUALITY CONTROL AND COMPLAINTS MANAGEMENT

The manufacturer has established a functional system of quality control that responds effectively to consumer complaints.

The following is also ensured:

- The manufacturer's contact details, such as the address, telephone number and/or email address, are clearly visible on the product packaging;
- Consumer complaints are handled and followed up in an appropriate manner by qualified and experienced personnel of the manufacturer;
- The assessment of consumer complaints and, if applicable, any inferred areas of improvement are reapplied to product quality and safety. The manufacturer agrees to make this data available to ECARF on an ongoing basis.