ECARF Seal of Quality

Criteria for allergy-friendly face masks

BACKGROUND

Face masks (particle filtering half masks) are worn by adults and children from the age of seven in the context of the current coronavirus pandemic, both in public areas and indoors, voluntarily or according to law.

They protect against the inhalation of viruses and also against the nasal or bronchial inspiration of larger particles, such as airborne allergenic pollen.

According to the international literature (as at 27 February 2022), standardised tests have been conducted on the FFP2 mask and surgical masks in terms of their protective effect in adults with grass pollen allergies.

At high pollen levels, conjunctival, nasal and bronchial symptoms were significantly reduced. Both types of mask have been recommended for prophylactic use in people with pollen allergies.

1. CRITERIA

1.1. Necessary Product Features

The following information must be present on the particle filtering half masks to be tested:

- Name of the **manufacturer**
- **Product name/model** (numbers, e.g. 8822 or combination of letters + numbers, e.g. M9501A)
- **Applied standard** (for EN 149 particle filters)
- **Protection class** (e.g. FFP2)
- **CE marking**
- **Test site number** (four-digit number next to CE marking)
- **Expiry date** of the product (either on the packaging, in the attached information or on the mask)

A declaration of conformity must be available, specifying the creator (manufacturer or importer), the product and the applied standards. The information provided must be consistent in relation to the product offered.

1.2. Subject testing in the exposure chamber

Subjects with a history of allergic rhinoconjunctivitis or rhinitis and who have the condition for at least two years will be **tested in the chamber outside of their clinically relevant pollen season under the following conditions:**

- Without a mask
- With a mask
- Over a period of two hours
- With the same pollen load/m³ air (grass pollen or birch pollen)
- For at least seven days without the use of antihistamines
- Identical humidity and temperature
- Around 24 hours after provocation, a safety telephone call is made in order to check whether any late reactions have occurred and, if so, to document them.
- All provocation tests are conducted only after an ethics committee has voted in their favour.
- Provocation tests are based on the applicable SOPs (Standard Operating Procedures) for the exposure chamber.

Face masks must bring about a reliable decrease in symptoms when tested in persons with confirmed allergic rhinoconjunctivitis or rhinitis and pollen-induced asthma compared to exposure to the same pollen at the same level (same amount of pollen/m³ air) at the same temperature and humidity over a period of two hours.

The ECARF Seal of Quality is granted if, in controlled tests in an exposure chamber, the total symptom score is reduced by at least 60% when using the mask in comparison with no mask.

2. QUALITY CONTROL AND COMPLAINT MANAGEMENT

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

- 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.