

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 the viruses as well as airborne allergens; this includes house dust mite allergens.

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. However, given the properties of the two masks, it can be inferred that they are also suitable for protection against house dust mite allergens, with the FFP2 mask being preferred.

1. Test criteria

1.1 Required 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 due to house dust mites and who have had the condition for at least two years will be tested in the exposure chamber under the following conditions:

- Without mask
- With mask
- Over a period of two hours
- With the same amount of allergen/m³ air

- 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 rhinitis or rhinoconjunctivitis and asthma due to house dust mite allergens compared to exposure to the mite allergens at the same level without a mask (same amount of allergen/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 50 % 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.