

ECARF Seal Of Quality

Criteria for allergy-friendly wet wipes

Basic situation

In rare cases, wet wipes can cause allergic reactions due to the ingredients they contain, such as preservatives or perfumes. The ECARF Seal of Quality designates wipes as allergy friendly if the manufacturer is able to provide evidence of efficient quality management, which includes the assessment of the raw materials, the product formulation, a product test involving subjects and a working complaint management system.

ECARF-certified wet wipes have been proven in scientific tests that their use will not cause side effects, and there is no expected risk that a new allergy will develop. Despite the most careful product formulation and product testing, an allergic reaction in individual cases cannot be completely ruled out.

1. Formulation and ingredients

Allergy-friendly wet wipes products must not contain irritating ingredients beyond the irritation threshold. This property needs to be confirmed by use tests as described below. It is paramount for all wet wipes, that the products do not contain any ingredient with a well-recognized allergenic potential.

Furthermore, depending on the product category, additional standards are required:

- **Fragrances:** In 1999, the SCCNFP identified a set of 26 fragrance allergens with a higher potential to cause allergies in comparison to other fragrances. These 26 Fragrances must not be contained in ECARF certified products.
- **Preservatives:** Preservatives should be used with utmost modesty and at the lowest possible effective concentrations. Methylisothiazolinone, Kathon CG (MCI/MI) and/or Iodopropynylbutylcarbamate cannot be contained in any formulations.

ECARF dermatologists and allergists evaluate the formulation and ingredients of wet wipes for quality and safety, based on the criteria listed above as well as on the basis of international standards.

2. User tests

Through user tests, the product is shown to be acceptable for persons with highly sensitive, eczematous skin. This is tested according to normal product use by at least 20 patients of the respective user group with medically diagnosed atopic dermatitis demonstrating sensitive skin. The period of use for the test varies according to product type. If over the course of seven days no deterioration of skin condition is noted in any of the subjects, the product is generally considered acceptable for sensitive skin.

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3. Quality Control and Complaint Management

The manufacturer has established a functional system of quality control that responds effectively to consumer complaints. The following components are in place:

- contact information such as manufacturer telephone number or e-mail address are easy to find on the packaging of the product;
- a personal response by experienced personnel is guaranteed in the case of any complaint;
- an efficient structure is in place through which complaints are systematically catalogued, assessed and used to improve product security. The producer agrees to make these data constantly available to ECARF and to present a suggestion for improvement in the case of unexpected problems;
- an efficient system for providing ECARF dermatologists with test materials for a patch test, in case suspicion of a contact allergy triggered by the product should arise.