

ECARF Seal of Quality



Criteria for allergy-friendly wet wipes

BACKGROUND

Wet wipes, in rare cases, provoke allergic reactions due to the ingredients they contain, such as preservatives or fragrances. The ECARF Seal of Quality certifies wet wipes as allergy friendly if the manufacturer of the products is able to provide evidence of efficient quality management. This must include an analysis of the raw materials, the product composition, a product test on human subjects, and an effective complaint management system.

ECARF-certified wet wipes have demonstrated in scientific tests that they do not to cause side effects and there is no expected risk that a new allergy will develop through their use. However, despite meticulous product formulation and testing, allergic reactions cannot be completely ruled out in individual cases.

1. CRITERIA

1.1. Ingredients

Allergy-friendly wet wipes must not contain irritating ingredients in amounts that exceed their respective threshold values. This property must be confirmed through the tests indicated below. As a rule, wet wipes of all categories may not contain ingredients with known allergic potential.

Furthermore, they must comply with additional standards, depending on the product category:

- Fragrances
 In 1999, SCCNFP (Scientific Committee on Cosmetic and Non-Food Products intended for Consumers) identified 26
 fragrances with a higher allergenic potential than other fragrances. These 26 substances may not be included in ECARF-certified products.
- Preservatives
 They should be used in moderate amounts and at the lowest possible effective concentrations. Methylisothiazolinone,
 Kathon CG (MCI/MI) and/or iodopropynyl butylcarbamate cannot be used.
- Benzyl Alcohol
 An exception is made for benzyl alcohol, which acts as both a fragrance and a preservative. Since the allergenic potential of benzyl alcohol is considered very low, this ingredient may be used at a concentration of less than 1%.



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Banned ingredients:

- Fragrances subject to individual labelling
- Type I allergens: Allergy-friendly wet wipes may not contain food allergens (such as wheat protein, walnut protein, peanut protein, almond protein, macadamia nut protein). Specifically, if a product contains ingredients such as walnut oil, evidence must be provided that the substance does not contain any protein, since the protein is a type I allergy trigger.

The concentrations of the following categories of substances are the deciding factor. This is individually evaluated by dermatologists:

Dyes

ECARF dermatologists and allergologists evaluate the formula and ingredients of each product for quality and safety based on the above criteria and international standards.

1.2. Subject testing

The product's tolerability in persons with sensitive, eczema-prone skin is proven in clinical tests involving human subjects. Tolerability is demonstrated in a usage test corresponding to the product application. 20 subjects of the designated user group with sensitive skin and medically diagnosed atopic dermatitis are included in the test, during which the wet wipes are used. The application period may vary depending on the product type. Allergy friendliness will be considered clinically proven if none of the subjects experience significant worsening of their condition within this period, apart from typical variations in skin condition due to atopic dermatitis.

2. QUALITY CONTROL AND COMPLAINT MANAGEMENT

The manufacturer has a functioning, quality-assured system that effectively handles any consumer complaints. Compliance with the following is ensured:

- The manufacturer's contact details, such as telephone number or email address, are clearly visible on the product packaging;
- Complaints are followed up in an appropriate manner by experienced personnel of the manufacturer;
- An efficient organisational structure is in place to systematically record complaints, evaluate them and integrate them
 into product safety. The manufacturer agrees to make this data available to ECARF on an ongoing basis and to suggest
 improvements in the event of unexpected problems;
- An efficient system to provide ECARF dermatologists with test solutions for the patch test if contact allergy caused by the product is suspected.