

Criteria for allergy-friendly toothpaste

BACKGROUND

Toothpastes can in rare cases cause allergic reactions due to the ingredients used, such as preservatives or fragrances. This is because the oral mucosa reacts differently from the skin. Even with an existing contact allergy, for example to nickel, the substance is usually tolerated on the mucous membrane. However, toothpaste also comes into contact with surrounding skin on the lips and around the mouth, so contact allergies may well occur there.

ECARF certified toothpastes have demonstrated in scientific tests that no side effects are to be expected from their use and a risk of developing a new allergy is unlikely. Despite meticulous product formulation and testing, allergic reactions or irritations cannot be completely ruled out in individual cases.

The manufacturers of allergy-friendly toothpastes must meet the following criteria for their product(s):

1. CRITERIA

1.1. Ingredients

Allergy-friendly toothpastes may not contain irritating ingredients at concentrations that exceed their respective threshold values. This must be confirmed through the tests indicated below. Generally, toothpastes may only contain ingredients that have no allergic potential in the concentrations used. ECARF only certifies toothpastes for adults.

Other standards must also be complied with:

- **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. ECARF certified products may not contain any of these 26 fragrances, or may only contain them in trace amounts below the allergenic threshold. Since fragrances can also improve product quality, there is no objection to the use of non-allergenic fragrances or fragrances below the allergenic threshold.
- **Preservatives:** They may be unavoidable for certain products due to the risk of harmful contamination that may occur in their absence. Preservatives should not be used or only be used in the lowest possible concentrations. Methylisothiazolinone and certain derivatives, Kathon CG (MCI/MI) and/or iodopropynyl butylcarbamate cannot be used in any formulations.
- 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 %.

Banned ingredients:

- Fragrances subject to individual labelling
- The proteins lysozyme, lactoferrin and immunoglobulin (constituents of milk and egg).

The concentrations of the following substance class are the deciding factor. This is individually evaluated by dermatologists or allergists:

- Dyes
- Flavourings
- Particles for peeling
- Activated carbon
- Beeswax: For pharmaceutical grade purified wax, proof that it is not contaminated with pollen or propolis is required
- 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 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 mucous membrane with medically diagnosed atopic dermatitis use the toothpaste twice daily 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 mucous membrane condition associated with atopic dermatitis are taken into account.

2. QUALITY CONTROL AND COMPLAINT 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.