

Criteria for allergy-friendly disposable baby nappies

BACKGROUND

Disposable baby nappies can cause allergic reactions due to the ingredients used, such as preservatives. The ECARF Seal of Quality certifies disposable baby nappies as allergy-friendly if the manufacturer is able to provide evidence of efficient quality management. This must include an analysis of the raw materials, the product composition, a clinical test on human subjects, and an effective complaint management system.

ECARF-certified disposable baby nappies have demonstrated in scientific tests that they do not cause side effects and there is no expected risk that a new allergy will develop through their use. Despite meticulous product formulation and testing, allergic reactions or irritations cannot be completely ruled out in individual cases. Furthermore, all types of disposable nappies can cause so-called "nappy dermatitis" with allergy-like symptoms under certain circumstances. Therefore, even with ECARF-certified products, nappy dermatitis cannot be completely ruled out. The manufacturers of allergy-friendly disposable baby nappies must meet the following criteria for their product(s):

1. CRITERIA

1.1. Necessary Product Features

Allergy-friendly disposable baby nappies may not contain any irritating ingredients. This property must be confirmed through the tests indicated below. As a rule, baby nappies of all categories may not contain ingredients with known allergic potential.

The manufacturer shall provide proof (through test results from recognised external and independent testing institutes) on the basis of documents (test protocols, safety data sheets, product information, manufacturer's declarations) with regard to the following parameters:

- The following ingredients are tested (following the standard procedure NWSP 351 of the European Disposables and Nonwovens Association (EDANA)):
 - Fragrances
 - Bleach residue
 - Formaldehyde (in accordance with DIN EN 1541:2001)
 - Softening agents (in accordance with DIN EN 71 Part 9:2007, DIN EN 71 Part 10:2012 and DIN EN 71 Part 11:2006)
 - Dyes
 - Glyoxal (in accordance with DIN 54603:2008)
 - Heavy metals (as cold-water extract in accordance with DIN EN 645:1994 or as hot-water extract in accordance with DIN EN 647:1994 using ICP OES or ICP MS;
 - Metals in plastics after migration in accordance with Regulation 10/2011 (EC) by means of ICP-OES following DIN EN ISO 11885:2009 or ICP-MS following DIN EN ISO 17294-2:2017)

- Adhesives, diffusion-proof plastics in areas in contact with the skin and preservatives should only be used in the lowest possible effective concentrations or not at all.
- All product characteristics must be documented by the manufacturer and verified by ECARF.

1.2. Subject testing

The product's tolerability in babies with sensitive, eczema-prone skin is proven in clinical tests involving human subjects. Tolerability is demonstrated in a corresponding usage test in which the disposable nappy is used on at least 20 babies with sensitive skin in medically diagnosed hypersensitivity or atopic dermatitis. If no deterioration of the skin condition occurs in any of the test subjects within seven days of application, good skin tolerance is considered to have been demonstrated.

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.