Microbial contamination

Usual microorganism in cosmetics are filamentous fungi, yeast and bacteria.

How Microorganisms Get into Cosmetics

Cosmetic firms are legally responsible for making sure their products are safe. Some of the ways cosmetics may become contaminated with bacteria or fungi are:

- Contaminated raw materials, water or other ingredients
- Poor manufacturing conditions
- Ingredients that encourage growth of microorganisms, without an effective preservative system
- Packaging that doesn’t protect a product adequately
- Poor shipping or storage conditions
- Consumer use, such as the need to dip fingers into the product


Microbiological control

The different needs for microbiological examinations of cosmetic products are established from the microbiological risk analysis, which are carried out in order to determine the type of cosmetic product (low microbiological risk etc) you have. The microbiological risk analyses include consideration of the type of user, site of application, potential alteration of cosmetic products as well as the pathogenicity of microorganisms. Specified microorganisms are aerobic mesophilic bacteria or yeast undesirable in a cosmetic product and recognised as a skin pathogen species that may be harmful for human health or as an indication of hygienic failure in the manufacturing process. Microorganisms considered as specified microorganisms are Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans and Escherichia coli.

Microbiological control of final product

No limits for microbial contamination of cosmetics are enclosed in the Cosmetics Directive or in the national Danish implementation of this Directive. Recommendations on limits of microbial contamination in cosmetic products can be found in the notes of guidance for the testing of cosmetic ingredients and their safety evaluation prepared by EU’s Scientific Committee of Consumer Products (SCCP) (5). The Danish Environmental Protection Agency recommends the use of these levels. In SCCP’s notes of guidance, two separate categories of cosmetics products are defined, as various skin areas can be differently sensitive.

Category 1: Products specifically intended for children under 3 years, eye areas and mucous membranes, leave-on products.
Category 2: Other products, rinse-off products.

The **quantitative specifications** are – Generally acceptable levels:

Category 1: Total viable count for aerobic mesophilic microorganisms (bacteria, yeast and moulds) not more than 10^2 cfu/g or ml in 0.5g or 0.5 ml of the product

Category 2: Total viable count for aerobic mesophilic microorganisms not more than 10^3 cfu/g or ml in 0.1g or 0.1 ml of the product

It is not acceptable that the following potentially pathogenic microorganisms are present in cosmetic products:

*Staphylococcus aureus*  *Pseudomonas aeruginosa*  *Candida albicans*

The occurrence of indicator bacteria is not mentioned in SCCP’s notes of guidance (5). But it is generally acknowledged that neither the occurrence of E. coli nor other members of Enterobacteriaceae are acceptable in cosmetic products.

**Qualitative limits:**

Category 1: *Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans or E.coli* must not be detectable in 0.5g or 0.5 ml of the product.

Category 2: *Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans or E.coli* must not be detectable in 0.1g or 0.1ml of the product

**Microbial contamination** Microbiological durability depends on product composition, content of preservatives, manufacturing hygiene, packaging, transport and storage. The ability of microorganisms to grow and reproduce in cosmetic products is well known. Water is essential for microbial growth and water-based products often have a limited durability, as they are sensitive to microbial growth. More are cosmetics ideal nutrient media for microorganisms.

**During manufacturing** Contamination during production and filling in cosmetic products may occur. Raw materials can contribute to a significant level of microbial contamination to the finished product. Testing of raw materials before use, especially those of natural origin is important. The specifications of the raw materials must include microbiological purity. Water is a raw material, and the most common ingredient. Water must be tested continuously for microbial growth. It might be necessary to sterilise deionised water to obtain a sufficient purity.

Many other conditions of production may influence the contamination during manufacturing, such as contaminated areas, insufficient manufacturing hygiene, personal hygiene and insufficient preservation. Effective cleaning is very important.
After opening  From the moment of opening the cosmetic product is subject to constant and variable microbial contamination from the domestic environment and the consumer's hands and body (the skin). Since microorganisms are ever present in the home, especially in warm, moist areas, such as bathrooms and kitchens, cosmetics are exposed to contamination with both spoilage and potentially hazardous micro-organisms during use. Purity after opening depends on the preservative ability of the product, suitability of the packaging, storage and application. The following scenarios can contribute to contamination of a cosmetic product, fingers dipped in product, spillage of water into product, shampoo used by several different people


Microbiological quality

The aim of that section of the cosmetic product safety report is to determine the acceptable microbiological specifications of the raw materials (substances or mixtures) and finished product from a microbiological point of view. In accordance with Annex I to Regulation (EC) No 1223/2009, particular attention is to be paid to the microbiological specifications of cosmetic products intended to be used on sensitive body parts and on specific populations. In addition, information regarding microbiological quality is essential in order to justify the effectiveness of the preservation system and justify the indicated minimum durability of the cosmetic product stored under appropriate conditions and period-after-opening (PAO) of the finished product in terms of safety.

The microbiological specifications of the raw materials (substances or mixtures) and cosmetic product are to form part of the safety assessment. Particular attention is to be paid to the microbiological specifications of cosmetic products intended to be used around the eyes, on mucous membranes in general, on damaged skin (e.g. skin care products suitable for atopic or irritated skin), on children under three years of age, on elderly people or on persons with compromised immune responses.

a) Microbiological quality of substances and mixtures

The main parameters for microbiological quality are the original level of contamination and the possibility of microbial growth. Particular attention should be paid to the raw materials (substances and mixtures) most susceptible to microbial growth (e.g. water-based mixtures, protein-rich materials, plant or animal raw
materials). On the other hand, there are raw materials which do not support microbial growth, e.g. organic solvents.

b) Microbiological quality of the finished cosmetic product

Concerning microbiological susceptibility, there is a difference between three product categories:

1. low microbiological risk products (e.g. products with an alcohol content > 20 %, products based on organic solvents, high/low-pH products), for which neither a preservation challenge test nor microbiological quality tests on the finished product are necessary. A scientific justification is to be provided, however;

2. single-use products, and products which cannot be opened (e.g. for which the packaging allows dosing the product without it coming in contact with the air), for which only microbiological quality tests on the finished product are necessary. A scientific justification is to be provided, however;

3. all other products, for which both a preservation challenge test and microbiological quality tests on the finished product are necessary.

Specific ‘Guidelines on Microbiological Quality of the Finished Product’ are provided in the SCCS Notes of Guidance ([1]).

Preservatives:

http://ec.europa.eu/DocsRoom/documents/15281/attachments/1/translations/


Preservatives in the EU

What are preservatives?

A preservative is a natural or synthetic ingredient that is added to products to prevent them from spoiling.

Preservatives ensure that cosmetics and personal care products, as well as pharmaceuticals and foods, remain safe during their period of use by consumers.

Preservatives must undergo rigorous evaluation, including safety assessments and quality testing, to ensure that they are safe for use.

Why do we need them?

Without preservatives, cosmetic products, just like food, can become contaminated, leading to product spoilage.

Microbial contamination of products, especially those used around the eyes and on the skin, can cause irritation or infections. Preservatives help prevent such problems.

What is the European Commission doing about them?

- It ensures an updated list of scientifically evaluated safe preservatives for their use in cosmetic products on the EU market.

- It supports and guides national authorities to monitor products already on the EU market.

- It encourages scientific research and innovation so that new and more efficient preservatives for cosmetic products are discovered.