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WHAT TO DO IN THE CASE OF MICROBIOLOGICAL FINDINGS

Contamination | Microbiological quality plays an essential role in cosmetics to ensure a good product and to protect consumers. Dr Bernhard Fellenberg explains what to do if microorganisms are detected and how to classify a possible finding.

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Cosmetic products must be microbiologically safe and harmless for the consumer in compliance with EU Regulation 1223/2009[1]. These requirements must be met throughout the entire shelf life of a product or until it is used up. In addition to product preservation, other parameters such as compliance with cosmetic GMP (ISO 22716)[2], the quality of raw materials used, type and frequency of application and packaging material used play an important role regarding microbiology.

What does 'positive finding' mean?

A positive result means any detection of microorganisms in an examined cosmetic product. It is of importance that the examination was carried out correctly, e.g., that false results due to contamination in the laboratory are excluded[3]. The detection of microorganisms can be carried out by a quantitative test method (e.g., determination of the total bacterial count) or by a qualitative method (detection of a specific microorganism in a quantity of, for example, 1g of product).

Microbiological limits

ISO 17516[4] specifies international limit values regarding the microbiological quality of cosmetics. This standard reflects the state of the art and is used for assessment. The specifications differ depending on the product category:

- Product category 1: Products for children under three years of age, products for use in the eye area or in the mucous membrane area.
- Product category 2: All other products (products for general use).

The limit values are described as follows:

- Total number of aerobic mesophilic microorganisms:
  Product category 1: ≤ 100 CFU/g
  Product category 2: ≤ 1,000 CFU/g
- Absence of the following specified microorganisms in 1g of product: Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans.

If these criteria are not met, a cosmetic product is considered unsatisfactory in terms of microbiological

photo: Dr Bernhard Fellenberg, BAV

quality. ISO 17516 provides for an exceedance in the quantitative determination (total number of aerobic mesophilic microorganisms) only from a value of ≤ 200 CFU/g or ≤ 2.000 CFU/g (considering the measurement uncertainty).
In addition, reference should be made to a current BfR statement from 2020 on Pluralibacter gergoviae[5]. Here, the absence of Pluralibacter gergoviae in cosmetics is required to avoid a health risk for humans. Cosmetics containing this microorganism are also to be classified as microbiologically unsatisfactory.
Further comprehensive explanations on the statement of the BfR can be found on the website of the DGK[6].

Sell products despite a finding?

The decisive factor here is whether the criteria of ISO 17516 are met. If the criteria are not met, it must be assumed that the product may generally not be resold or placed on the market. In individual cases, higher values may be acceptable if it can be shown that

- the number of microorganisms in the product remains stable or decreases over the life cycle of the product
- the microorganism is harmless to health
- there is no adverse effect on the product or on consumer health.

In these individual cases, a comprehensive risk assessment with corresponding microbiological know-how involving all specialist departments is always necessary. An example of this is findings with Bacillus spp. (spore formers). These microorganisms usually represent a low risk potential[7].
In the case of detection of microorganisms in smaller quantities (e.g., 50 CFU/g with a limit value of 2.000 CFU/g), a decision must also be made on a case-by-case basis. The fact that the specifications of ISO 17516 are met (in the case of a positive result) does not automatically mean that the product is microbiologically safe.
When assessing a possible risk, the following must be considered, among other things:

- type and number of microorganisms
- type of product
- possibility of growth over time (re-testing)
- contamination over individual or several batches, other products, etc.

Here, too, microbiological know-how and an established MQM system play the decisive role.

Positive result: Test frequency

In the case of a positive result, it is important to secure and verify this by further testing of samples from the same batch. Furthermore, batches that were produced before or after the positive result should be tested more frequently. In addition, retesting of the affected product or batch after longer periods of time (e.g., after one, two and four weeks) should clarify whether the bacterial count is increasing or not.

Identification of microorganisms

In the case of a finding in the quantitative microbial count or in the case of qualitative detection of a so-called non-specified microorganism, identification is always indicated. This applies regardless of whether the requirements of ISO 17516 are met or not – identification must therefore also be carried out in the case of low microbial counts.
Only in this way can a possible risk potential be determined and possible sources of entry be identified at an early stage. Appropriate measures can thus usually be taken more quickly and in a more targeted manner.

MORE INFORMATION ONLINE

Information on the most important microorganisms in cosmetics can be found online with webcode 100686
www.cossma.com

Sources of an entry

The main sources of microorganisms are:

- raw materials and starting materials used, including the production water
- premises, especially in production rooms: entry via surfaces and air
- technical equipment
- handling of products and staff hygiene
- packaging materials

In general, bacteria play a much more important role than yeasts and moulds. Among the bacteria themselves, gram-negative germs play a more important role than gram-positive germs. Representatives of these are, for example: Pseudomonas aeruginosa, Burkholderia cepacia, Pluralibacter gergoviae, etc. As a frequent source of entry for these gram-negative microorganisms, the raw material water (possible danger of biofilm formation) plays the most important role.
In contrast, mostly gram-positive microorganisms (mostly spore-formers such as Bacillus spp.) enter the products via the raw materials (especially powders, vegetable raw materials). □

GLOSSARY

CFU: Colony forming unit

BfR: German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung)

DGK: German Society for Scientific and Applied Cosmetics (Deutsche Gesellschaft für wissenschaftliche und angewandte Kosmetik)

MQM system: Microbiological Quality Management system

References:

1 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, as amended

2 ISO 22716: 2008-12, Cosmetics - Good manufacturing practice (GMP) - Guide to good manufacturing practice.

3 Microbiological testing of cosmetics – frequent errors, Fellenberg, Euro Cosmetics, 4/5-2022

4 ISO 17516: 2014-10, Cosmetic products - Microbiology - Microbiological limits

5 Skin creams, make-up and shampoos should be free of Pluralibacter gergoviae, updated statement No. 038/2020 of 7 September 2020, BfR

6 Recommendation of the DGK specialist group "Microbiology and Industrial Hygiene" on dealing with risks from Pluralibacter gergoviae in cosmetic products, Eigener/Keck-Wilhelm/Nussbaum/Simmering/Staub, statement November 2020, www.dgk-ev.de

7 Aerobic spore formers (Bacillus spp.) as contaminants of cosmetic products, Eigener/Nussbaum, sofwjournal, 7/8-2022