

Occurrence and Evaluation of *Burkholderia cepacia* Contamination in Cosmetic Products

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Burkholderia cepacia is a widespread Gram-negative bacterium from the 'non-fermenter' group. It has been identified as a contaminant in pharmaceuticals, medical devices and cosmetics for some time now. *B. cepacia* belongs to a species group known as the "*Burkholderia cepacia* complex" (BCC). When assessing the risk of such contamination, it should be noted that *B. cepacia* has been identified as a human pathogen. Those affected with infections are people with underlying illness and immunocompromised patients, and of special importance are respiratory infections leading to serious lung diseases. Therefore, *B. cepacia* is classified as an opportunistic pathogen. Accordingly, contamination with these bacteria should be avoided in cosmetic products (not detectable in 1 g or ml). Appropriate countermeasures must therefore be taken during the development and manufacture of cosmetic products to sufficiently account for *B. cepacia*. These include effective preservation, extensive hygiene measures (with particular attention to water quality), and comprehensive controls.

Cosmetic products must be manufactured and marketed in a way that ensures their microbio-

logical quality and safety, ruling out any risk to users. This must be confirmed by a professional safety assessment of the product (EC-Cosmetics Regulation¹⁾). The product must meet purity requirements with regard to microbiological quality, including specifications for total bacterial count and exclusion of specified microorganisms. Additionally, microbiological stability must be demonstrated through a challenge test (preservation efficacy test (PET)). The microbiological requirements must also be tailored to the product's intended use and user group. If microbial contaminants are detected, they must be assessed in terms of risk. Classification as a health hazard must not be limited to historically defined specified microorganisms (ISO 17516²⁾). Instead, new findings on product contamination and potential health hazards must also be considered for the product related risk assessment^{3) 4)}. In recent years, for instance, *Pluralibacter gergoviae* and *Burkholderia cepacia* have emerged as potential health risks in cosmetics. Both the BfR⁵⁾ and the DGK⁶⁾ have highlighted the health risks posed by *P. gergoviae* and its relevance to the cosmetics industry. This text aims to provide

an assessment of *B. cepacia* in this context. Additionally, it provides cosmetic manufacturers with advice on preventing product contamination and the associated health risks posed by *B. cepacia*.

1. Description of the bacterium *Burkholderia cepacia*

Burkholderia cepacia is a Gram-negative, rod-shaped, flagellated bacterium that is classified as aerobic, catalase-positive and non-lactose-degrading (non-fermenter) based on its metabolism. The bacterium was originally isolated as a coloniser of plants and assigned to the genus *Pseudomonas* (*Pseudomonas cepacia*). It was not until 1992 that the taxonomic independence of the genus *Burkholderia* was established.

The genus *Burkholderia* is widely found as a coloniser of plants and, accordingly, also in soil and natural waters, but also in seawater. The genus is characterised by an extensive genome and great genetic variance, with non-pathogenic

associated with biofilms. Since *B. cepacia* is classified as an opportunistic human pathogen, is resistant to some antibiotics and to some biocides, the bacterium is of great importance for product safety assessment when detected as a contaminant.

As knowledge about *B. cepacia* grew, it soon became clear that it is actually a group of very similar species, which were then named and described in the literature as the '*Burkholderia cepacia* complex' (BCC). This is a group of more than 20 species with similar biochemical and serological behaviour. Differentiation within the group often cannot be achieved by conventional physical-chemical methods (phenotypic) but can only be carried out at the genome level using appropriately specific methods (e.g. MALDI-TOF, PCR). Precise classification is particularly important for infectious disease and medical diagnostic findings and decisions. The BCC is therefore also referenced in literature dealing with infectious disease connections between the use of contaminated prod-

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