Bundesinstitut für Risikobewertung

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Skin creams, make-up and shampoos should be free from *Pluralibacter*

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The Federal Institute for Risk Assessment (BfR) has assessed the health risks associated with cosmetic products contaminated with *P. gergoviae*. Only externally applied products - such as skin creams, make-up or shampoos - were considered.

Since its introduction in 2005, an increasing number of products posing a microbiological risk have been notified via the European rapid alert system for consumer products "Safety Gate" (formerly RAPEX). Ten cosmetic products listed in the RAPEX database were affected by confirmed contamination with *P. gergoviae*.

If products contaminated with *P. gergoviae* are used, the bacterium can enter the body via open wounds or the mucous membranes. Severe infections may develop in people with pre-existing conditions.

In the opinion of the BfR, externally applied cosmetic products should be free of *P. gergoviae* in order to avoid a health risk for humans. The health risks associated with the use of such cosmetic products cannot currently be quantified due to the lack of reliable data.

1 Subject of the assessment

In this opinion the Federal Institute for Risk Assessment (BfR) assesses the potential health risks of topically (externally) applied cosmetic products contaminated with *Pluralibacter* (*P.*) *gergoviae*.

2 Results

Cosmetic products contaminated with *P. gergoviae* may pose a health risk to consumers. Cosmetic products should therefore not be contaminated with facultatively pathogenic *P. gergoviae* in order to avoid a health risk, especially for sensitive risk groups.

P. gergoviae is a facultative pathogenic bacterium that can cause severe infections. Even though the BfR is not aware of any infections caused by the use of cosmetic products, a health risk to humans from products contaminated with *P. gergoviae* cannot be excluded. When using cosmetic products which remain on the skin, such as skin care products or make-up, prolonged skin contact with or persistence of *P. gergoviae* on the skin cannot be excluded. For so-called rinse-off products such as shower gels and hair shampoos it has to be expected that the bacteria are largely rinsed off the body during the washing process. However, contact with mucous membranes and open wounds may lead to a transfer into the bloodstream, both with leave-on and rinse-off products.

The probability of adverse health effects due to the use of such products cannot at present be estimated due to the lack of data, including the infectious dose and the infection risk of various risk groups.

[1] The statement replaces BfR Statement 014/2017 of 18 July 2017

3 Rationale

3.1 Risk assessment

3.1.1 Hazard identification

Bacteria of the genera *Enterobacter* and *Pluralibacter* belong to the family *Enterobacteriacae*. It is a group of gram-negative, facultatively anaerobic, rod-shaped bacteria. They belong to the normal intestinal flora, but are ubiquitously distributed and have been found in stool or faeces samples of humans and animals, in plants and plant material, in water, in insects and in dairy products.

P. gergoviae are facultatively pathogenic. Especially persons with weakened immune system, people suffering from a chronic illnesses, surgical patients or other sensitive groups are at risk.

It is known that *P. gergoviae* bacteria are equipped with efflux pumps that transport parabens (esters of 4-hydroxybenzoic acid, which are preservatives used in cosmetics) from the cell interior to the outside (Davin-Regli et al., 2006). They cause a natural resistance against parabens and other biocides. *P. gergoviae* may show decreased susceptibility to preservatives so that survival or growth in cosmetic products is possible (Periame et al., 2014, 2015).

3.1.2 Hazard characterisation

Infections with *P. gergoviae* have been described in connection with respiratory diseases, urinary tract infections, endophthalmitis (an infection of the inside of the eye) and blood poisoning (Chen et al., 2009, Sánchez et al., 2005, Satlin et al., 2013). Very rarely infection occurred in otherwise healthy individuals. Occasionally, clinical outbreaks have been reported (Freire et al., 2016, Boban et al., 2011). During an outbreak in a neonatal intensive care unit in Malaysia, 11 infants developed sepsis caused by *P. gergoviae* and the bacterium was detected both in saline/sugar solution used to dissolve parenterally administered drugs and on the hands of the nursing staff (Ganeswire et al., 2003).
Infections can lead to serious clinical pictures as a result of an inflammatory reaction of various tissues and organs, in which septic processes with fatal consequences are possible. Many strains of *P. gergoviae* are multiresistant to antibiotics, which makes treatment more difficult and delays the success of therapy.

3.1.3 Exposure assessment

Altogether there are only few publications which make statements about microbial contamination of cosmetics. Lundov and Zachariae (2008) as well as the BfR (Vincze et al., 2019) evaluated data on cosmetic product recalls from Safety Gate (formerly RAPEX, Rapid Alert System for Non-Food Consumer Products) of the European Union. Contaminations with *Pseudomonas aeruginosa* were reported most frequently, but other opportunistic germs such as *Candida albicans*, *Klebsiella oxytoca*, *Burkholderia cepacia*, *Staphylococcus aureus* and *Enterobacter cloacae* were also found. A wide range of products was affected by contamination, e.g. baby shampoo, baby cream, make-up, washing gel, mascara, toothpaste, face milk and shower gel. Due to a proven contamination with *P. gergoviae* (formerly *E. gergoviae*), ten cosmetic products containing between $3x10^3$ and $1.9x10^7$ CFU/g have been notified through Safety Gate (formerly RAPEX) to date. The abbreviation CFU stands for colony-forming unit and refers to microorganisms producing a single colony.

Depending on the type of use, cosmetic products can be differentiated between so-called rinse-off and leave-on products. Rinse-off products like shower gels are spread on the body surface, remain there in diluted form only for a relatively short time and are rinsed off again. It can be assumed that the rinsing process also removes the majority of bacteria. Leave-on cosmetics remain on the skin or the mucous membranes for a longer period of time. For both product types contact with the outer skin as well as contact with mucous membranes or possible existing wounds cannot be excluded.
For example, in the eighties a baby shampoo contaminated with Pseudomonas aeruginosa led to ear infections in small children. The products were contaminated with up to 10^6 CFU/g. Very likely, also persons with a special risk, such as immunocompromised persons, use cosmetic products. However, infection rates with *P. gergoviae* due to the use of cosmetic products cannot at present be derived due to the lack of epidemiological data.

3.1.4 Risk characterisation

The "Notes of Guidance" of the Scientific Committee on Consumer Safety (SCCS) recommend for cosmetic products for general use (category 1) a microbial count limit for mesophilic aerobic microorganisms of 10^3 CFU/g. DIN EN ISO 17516, "Cosmetic products - Microbiology - Microbiological limits", also provides a value of less than or equal to 1×10^3 CFU/g or 1×10^3 CFU/ml aerobic mesophilic microorganisms for a externally applied products. For cosmetics intended for use on children under 3 years of age, around the eyes or on mucous membranes, a limit of ≤ 100 CFU/g or ml applies. The application of this standard is not mandatory by law, but it is used as an international standard by large parts of the industry. *Pluralibacter* belong to the group of mesophilic, aerobic microorganisms. From the point of view of the BfR, dose-dependent health risks are possible by using products containing *P. gergoviae*. As there is only little data so far on the occurrence of the bacteria in cosmetics the risk cannot be quantified. The probability of health risks when using such products cannot at present be assessed. However, in the case of infection there is a serious health risk with the clinical symptoms and mortality rates described.

Further information on the topic of cosmetics is available from the BfR website:

Summary page for all publications on health assessment of cosmetics:
https://www.bfr.bund.de/en/health_assessment_of_cosmetics-570.html

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About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It advises the German federal government and German federal states ("Laender") on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

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