

Pilar Orus
Sonia Leranoz*

Colomer Beauty and Professional
Products, Barcelona, Spain

Current trends in cosmetic microbiology

*Corresponding author:

S. Leranoz
Colomer Beauty and Professional Products, SL
Potosí 7, Barcelona, Spain
Tel. 932745600. Fax 932747336
E-mail: sonia.leranoz@thecolomergroup.com

Microorganisms and cosmetics

Microbial contamination of cosmetic products is a matter of great importance to the industry and it can become a major cause of both product and economic losses. Moreover, the contamination of cosmetics can result in their being converted into products hazardous for consumers. The water and nutrients present in cosmetics make them susceptible to microbial growth, although only a few cases of human injury due to contaminated cosmetics have been reported. More often, microorganisms are the cause of organoleptic alterations, such as offensive odors, and changes in viscosity and color.

Methods to detect microbial contamination in cosmetics and their raw materials are usually based on traditional plate counts. However, little is known about the metabolic state of microorganisms residing in cosmetic products or in specific areas of a manufacturing plant. Viable microorganisms are often metabolically injured as a result of adverse physical or chemical conditions (high processing temperatures, cleaning and sanitization agents,

and preservatives). As a result, these microorganisms are in a viable but non-culturable state and thus cannot multiply in a nutritive agar medium. The recovery of stressed microorganisms is a challenge for cosmetic microbiologists, since appropriate diluents, preservatives, neutralizing agents, culture media, etc., are needed. The validation of microbiological detection methods is therefore an indispensable prerequisite for the detection of microorganisms.

A variety of new methods, such as bioluminescence, impedance and cytometry, which are based on the metabolic state of microorganisms, are the most reliable for detecting stressed cells. These "fast" methods allow the detection of microbial contamination, both in the finished product and in raw materials, within 24 h. Fast methods are of great industrial importance, since they facilitate the rapid release of products into the market.

However, despite the advantages offered by fast methods, they are not yet able to detect specific microorganisms, including pathogens. Thus, classical microbiological approaches remain indispensable for the isolation and identification of microorganisms.



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The emergence of cosmetics regulations in Europe

What is a cosmetic product? Historically, this term included products whose purpose was to enhance the appearance or modify the odor of the human body. However, this concept has evolved due to the pressure to continually adapt cosmetics to changing market demands and to fulfill the consumer's needs and expectations. This rapid evolution forced the authorities of different countries, in the middle of the 20th century, to regulate cosmetic products in order to ensure consumer safety. For example, in 1976, the European Community developed its own regulatory framework (Directive 76/768/CEE). Since then, this Cosmetics Directive has been adapted on 29 occasions, taking into account technical progresses. The main features of cosmetics regulations in the European Union (EU) include:

- The definition of a cosmetic product as “any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or keeping them in good condition”.
- A requirement that cosmetic products should be safe for their intended purpose under normal and foreseeable conditions of use.
- The establishment of an inventory of cosmetic ingredients.
- Package labeling that includes a complete listing of ingredients and the expiration date for products with less than a 30-month shelf-life.
- The requirement that manufacturers maintain comprehensive product information, including formal safety assessments.
- Annexes specifying prohibited, restricted, and controlled raw materials, such as coloring agents, preservatives, and UV-filters.

However, with the continuous increase in the variety of raw materials and cosmetic products, it is frequently necessary to rely on pharmaceutical and food regulations and on pharmacopoeias, due to the lack of official cosmetic guidelines. While regulations regarding microbiological content in cosmetic products do not exist, foods are classified according to their nature, and health regulations including microbiological limits are defined. Although some recommendations have been published by governments and cosmetic associations, the only requirement for cosmetics is that they “must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use”.

Differences between cosmetics and food/pharmaceuticals are often a matter of disagreement. Health authorities would like cosmetic companies to achieve the “gold standards” imposed by pharmaceutical regulations and recommendations on areas such as manufacturing, filling, and testing. While the general intention is correct, cosmetics are not meant to be ingested or injected in the human body nor are they to be used for therapeutic purposes.

The seventh amendment to the Cosmetic Directive (Directive 2003/15/EC, effective in March 2005) was approved recently and it incorporated a new concept based on microbiological criteria: the PAO (period after opening). The PAO is an indication of the period of time since the product was first opened and used, and specifies how long the cosmetic product can be used without any deterioration linked to microbial contamination that could harm the consumer's health. The PAO requirement is not relevant when there is no risk of microbial deterioration (i.e. in the case of sealed pressurized containers or single-use products). The PAO is indicated by an open-jar symbol accompanied by the recommended number of months within which the product should be used, followed by the abbreviation “M”, standing for “menses” (months in Latin); e.g. 12 months is indicated by 12M. PAO information is printed on both the primary and secondary packaging of the cosmetic product (the container and its carton, if any) and should not be confused with the expiration date. In fact, for cosmetic products with a minimum durability of more than 30 months, it is not mandatory to print the expiration date whereas the PAO must be printed, where applicable. In the case of products sensitive to deterioration by microorganisms, measures to avoid opening of the product before it reaches the final consumer should be considered.

Cosmetics preservatives and microbial resistance

Microbiologists working in the field of cosmetics are frequently required to design preservative systems that provide good protection of cosmetic products against microbial contamination. However, scientific information on this issue is scarce, since most biocide studies deal with antibiotics for human treatment. Microbiologists must therefore work within a narrow range of preservative concentrations in order to achieve effectiveness against microorganisms while avoiding toxicity for consumers. For this reason, regulations in the EU and in other countries have specified preservatives allowed, their maximum concentrations, and other directions specifically related to the kind of cosmetic product.

In the search for an effective preservative system, it is necessary to consider not only its efficacy against microorganisms, but also the compatibility of the component preservatives with other raw materials of the frequently intricate formulas for cosmetics, their antagonism or synergism with other ingredients, the product manufacturing process, and the associated costs. Cosmetic preservatives are molecules that are toxic for the consumer as well as potential sources of allergies and skin disorders. Virtually all cosmetic preservatives, including disinfectants, are effective against both prokaryotic and eukaryotic cells, as, unlike antibiotics, they do not act against a defined target cell.

In order to evaluate the biocide effectiveness of a new cosmetic product, various tests are carried out to demonstrate that the product will not be contaminated during its shelf-life, especially by the consumer's use. The assay advised by different pharmacopoeias and by cosmetic organizations, such as the Cosmetic, Toiletries and Fragrance Association (CTFA), is the challenge test, in which the product is artificially and heavily contaminated by representative microorganisms. After defined periods of time, a specifically defined reduction in the microbial populations must take place. Some laboratories carry out other, usually more sensitive tests, such as determination of minimal inhibitory concentrations (MIC) of the preservatives alone and determination of decimal reduction times (D-values). Furthermore, it is advisable to perform challenge tests using adapted strains isolated from contaminated products or from the production plant (*house* organisms) in addition to those obtained from culture collections, as required in pharmacopoeias.

Preservative systems usually consist of two or more molecules with different modes of action against microorganisms. The challenge is to extend biocide action to all kinds of microorganisms while avoiding the promotion of microbial resistance. In cosmetics microbiology, the use of preservatives could reproduce the experience of clinical microbiology after the emergence of antibiotics. After years of overuse and misuse of these drugs, bacteria developed antibiotic resistance, which has become a global health crisis. Antibacterial substances added to diverse cosmetic products are similar to antibiotics in many ways. When used

correctly, they inhibit bacterial growth—although their purpose is not to cure disease but to prevent the transmission of disease-causing organisms to non-infected persons. Like antibiotics, preservatives can select for resistant strains. Thus, it is not unconceivable that these strains could undergo cross-resistance to antimicrobial agents used to treat humans. This scenario is unlikely to originate at the consumer's home, because preservative concentrations in products are usually high enough to prevent the development of adapted strains. However, resistance could develop at manufacturing plants with low standards of hygiene or if the microbiological control of raw materials (especially water) is not adequate. The growth of microbial biofilms resistant to several preservatives and disinfectants is favored by the dilution of cosmetic products in different areas of the production plant. Biofilms result in intermittent and erratic contaminations by bacteria resistant to preservatives commonly used in cosmetics. The addition of higher concentrations of preservatives to products (always according to regulations) in order to avoid this kind of contamination could solve the problem in some instances, but this approach is not practical since it could generate toxicity for the consumer. Preservatives should never be used to mask poor manufacturing practices.

Current trends

Cosmetics microbiologists face new challenges, such as the need to develop formulations that are less aggressive to consumers but also well-protected against microbial contamination. Current trends in the field include research on new molecules with biocide power and good toxicological compatibility, analysis of the synergisms and antagonisms of preservative blends, and the search for fast, reliable methods to detect microbial contamination and to test preservative efficiency in each formulation. There is a need for specialists in cosmetics development, preservation, plant hygiene and sanitation, good manufacturing practices, toxicology, etc., to solve problems involving cosmetics contamination and to ensure consumer safety.