Preservatives in cosmetics technology

ABSTRACT

Preservatives are chemical compounds that, when added to a product, protect it from the growth of microorganisms. However, to fulfil this basic function, preservatives should be appropriately selected for a given cosmetic formulation.

The article aimed to present the key concepts regarding the preservation of cosmetics and legal regulations in this area. Moreover, cosmetics of low microbiological risk were characterised and the studies verifying the effectiveness of preserving cosmetic products were presented.

The key to reduce the likelihood of microbial infections is to identify their origin. Therefore, in order to limit potential primary and secondary contamination in cosmetic products, it is necessary to determine and find a solution to reduce the sources of these infections.

Keywords: preservatives in cosmetics, microbiological safety, microbiological purity, cosmetics of low microbiological risk

STRESZCZENIE

Środki konserujące to związki chemiczne, które dodane do produktu chronią go przed rozwojem drobnoustrojów. Jednak, aby konserwant mógł spełnić tę podstawową funkcję, powinien być odpowiednio dobrany do danej formułacji kosmetycznej.

Celem pracy było przedstawienie kluczowych pojęć dotyczących konserwowania kosmetyków oraz regulacji prawnych w tym zakresie. Przedmiotem pracy była również charakterystyka kosmetyków niskiego ryzyka mikrobiologicznego oraz przedstawienie istoty badań mających na celu weryfikację skuteczności zakonserwowania produktów kosmetycznych.

Kluczem do zmniejszenia prawdopodobieństwa powstania zakażeń mikrobiologicznych jest charakterystyka ich pochodzenia. Dlatego, aby ograniczyć potencjalne zakażenia pierwotne i wtórne w produktach kosmetycznych, należy zidentyfikować oraz znaleźć rozwiązanie na ograniczenie źródeł powstania tych zakażeń.

Słowa kluczowe: konserwanty w kosmetykach, bezpieczeństwo mikrobiologiczne, czystość mikrobiologiczna, kosmetyki niskiego ryzyka mikrobiologicznego
INTRODUCTION
The name „preservative” is derived from Latin, where „conservo” means „to preserve”. According to the meaning of the term „preservative”, its function is to ensure the microbiological safety of the product during its use. At the same time, each preservative used in the formulations of cosmetic products must be safe for human health [1-3]. There are two types of microbiological contamination of the manufactured product: primary and secondary. The primary contamination is a result of impurities from the production process, while the second type is a result of the use of the product by the consumer [1, 4]. The human body is an ideal habitat for various microorganisms, and thus can be a source of microbial contamination. It directly affects the safety of the product when, for example, a cosmetic is applied to the skin with inadequately washed hands [5]. A preservative in a cosmetic product is used to neutralize secondary contamination, while the correction of production contamination with a preservative is an unacceptable practice. A factory quality management system should be developed that includes cleaning, disinfection, and occupational hygiene procedures to ensure the absence of primary contamination during production. Secondary pollution also includes contamination of raw materials used in the production of the product. This type of threat can also be eliminated by designing an appropriate quality management system in the production factory, taking into account strict quality control of raw materials before their use in the production process, as well as by creating a list of qualified suppliers [5-7].

THE ROLE OF PRESERVATIVES IN THE COSMETIC FORMULATION
Preservatives are ingredients of cosmetics that ensure the safety of their use within the shelf life declared by the manufacturer on the packaging. This is directly related to the microbiological safety of a given cosmetic preparation and its impact on consumer health [3, 5, 6, 8]. Preservatives effectively protect cosmetics against contamination with microorganisms, including pathogenic microorganisms, i.e. Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans or Escherichia coli. The presence of these pathogens in cosmetic products is unacceptable [1, 9, 10] and may affect their quality, causing a noticeable change in their properties, such as smell (e.g. the characteristic smell of ammonia), consistency, or color. Sometimes sediment, stratification, or change in pH may appear in the product [3, 11]. Particularly dangerous are infections with Gram-negative bacteria, which have a high ability to adapt to changing environmental conditions. A cosmetic contaminated with microorganisms undoubtedly threatens human health, and the residues of toxins released by microorganisms can cause skin irritation, allergies, infections, and other adverse reactions [5, 6, 12].

Preservatives are essential ingredients in many cosmetics. The necessity to preserve a given cosmetic results from the susceptibility of cosmetic raw materials to microbiological infections [2, 8, 12]. A group of cosmetics that require particularly high attention to microbiological quality are natural cosmetics, which contain raw materials that have not been subjected to chemical processing, purification, or sterilization with gamma radiation [2]. For example, treatment with gamma radiation, e.g. corn starch, causes the naturalness index to decrease from 1 to 0, which translates into a reduction in the index of the entire product. However, the naturalness index is known as a particularly important marketing parameter in the segment of natural cosmetics. On the other hand, the use of corn starch not treated with gamma radiation makes it a potential source of microorganisms [13, 14]. Raw materials of natural origin are characterized by a very diverse microflora, which results from the way the plants are grown, as well as high water activity. Therefore, in general terms, plant extracts, oils (especially cold-pressed), and other ingredients of natural origin belong to cosmetic raw materials with a high microbiological risk. They may contain a variety of microorganisms, both beneficial and unfavorable for the human skin microbiome. Manufacturers of these raw materials try to protect them by using preservatives, such as sodium benzoate and potassium sorbate. Both of these substances are approved by Ecocert - an international independent association specializing in the certification of natural and organic cosmetics, as preservatives suitable for use in certified cosmetics. The greater content of cosmetic raw materials in the product formula, the greater its susceptibility to microbial infection. Notably, the growth of microorganisms may increase during transport or may be a result of improper storage. An indispensable element of using cosmetic raw materials in the production of cosmetics is their quality control, including microbiological quality [6, 13, 14]. The water environment is particularly susceptible to the growth of microorganisms [15]. Moreover, the water content in most cosmetic formulas is usually in the highest percentage of the composition. For production purposes, tap water is usually used, previously purified at the production factory or by the supplier. In the case of testing the quality of industrial water, the manufacturer determines the points of the last draw-off point, taking into account the delivery route (hoses, pumps), and then monitors the microbiological purity of this water. There are no legal guidelines regarding the requirements for the quality of water used in the production of cosmetics, but usually, manufacturers test the microbiological purity of water according to the limits of Pharmacopoeia or the requirements of the EN ISO 17516:2014 standard. The water quality assessment criteria do not include the guidelines.
from the Regulation of the Minister of Health of March 29, 2007, as in the case of drinking water [16-18]. The quality of the water determines the final stage of its administration. The recommended requirements for the total number of aerobic microorganisms are less than 100 CFU/ml. Of course, this determination can be extended with information about the absence of microorganisms from a particular group of pathogens, like for instance *Escherichia coli* [9, 19]. The use of production water with extended storage time stored in tanks is not necessarily a good solution. Before purchasing production water from external suppliers, a Certificate of Analysis (COA) for the batch is necessary to accept the delivery. In the other case, the best solution is to independently test the quality parameters specified in the COA, along with verifying its microbiological purity before using it in production. Water suppliers, due to limited awareness, sometimes adopt a water intake point without taking into account the way of its supply (pumps, hoses) and the cleanliness of transport tanks. These may be critical reasons for discrepancies between the results of tests included in the certificate of analysis provided by the supplier, and the results of self-conducted tests of the quality of this water [19, 20]. In order to prevent infections occurring already at the stage of cosmetic mass production, a system of periodic validation of monitoring of cleaning and disinfection procedures used in a given production facility should be implemented. The assessment of the microbiological purity of industrial water should be a permanent element of such a monitoring plan [7,21]. The diagram of factors influencing the microbiological quality of a cosmetic product is shown in Fig. 1.

![Diagram of factors influencing the microbiological quality of a cosmetic product](image)

**Fig. 1 Factors influencing the microbiological quality of a cosmetic product.**

**Source:** Own elaboration based on [7,21].

**CRITERIA FOR SELECTION OF A PRESERVATIVE FOR COSMETICS**

A good preservative should act quickly, reduce microbes even at low concentrations and prevent the formation of resistant forms of microbes. Moreover, the preservative should not be allergenic, irritating, or toxic to humans. The requirements for preservatives also apply to their physicochemical properties, such as lack of color and fragrance. It is also expected that preservatives should show biocidal activity in an environment with different pH and different temperatures. In addition, preservatives must not penetrate the skin and must be stable, i.e. resistant to light and oxygen. Different preservatives show diverse activity and scope of action, which is related to their chemical structure, as well as the mechanism of action on living cells. Individual groups of microorganisms have different properties, which are related to their metabolism and the presence of specific cellular enzymes. These conditions determine the sensitivity of microorganisms to selected chemical compounds (including preservatives). One of the most commonly used preservatives in the cosmetics industry are compounds of phenols, organic acids, alcohols, and quaternary ammonium bases [1, 2, 8, 10]. In addition to a number of expectations placed on preservatives, it should also be remembered that the key to their effectiveness is the right selection in terms of the type of cosmetic mass. An extremely important criterion for the selection of a preservative is the kind of cosmetic base. This is so crucial because some ingredients in the formulation may decrease or increase the antimicrobial activity of a given preservative. Therefore, there is a possibility of an antagonistic or synergistic interaction of a given cosmetic ingredient with a preservative. For example, the addition of sequestrants (e.g. disodium EDTA, sodium gluconate) - increases the permeability of the cell membrane, and then the preservative destroys microorganisms more easily. Another important aspect is the pH environment of the cosmetic - it must be in line with the pH range in which the given preservative shows optimal effectiveness. When selecting a preservative for a given cosmetic mass, it is also necessary to carefully analyze the spectrum of antimicrobial activity of a given preservative. The preservative system should be effective against both Gram-negative and Gram-positive bacteria as well as molds and yeasts. An important aspect to choose preservatives is also the target group for a given cosmetic. In the case of cosmetics for children or people with sensitive skin, preservatives with low allergenic potential should be used. The type and material of the packaging of the designed cosmetic is also significant. Some packaging (i.e. atomizers, packaging with a pump) limits direct contact of the cosmetic mass with the external environment and provides a kind of protection against microorganisms. When introducing a preservative into a cosmetic mass, it should also be remembered that its effectiveness depends on the original microbiological purity of the raw materials used [1,2,5,8,11,12].

**TESTING THE EFFECTIVENESS OF PRESERVATION OF A COSMETIC PRODUCT**

The test of the effectiveness of cosmetic preservation (a challenge test) is aimed to verify whether the preservative ingredients used in a given cosmetic product actually protect
it against the development of secondary infections during use. This test is carried out during research and implementation work on the formulation, as well as before starting the production. The procedure is based on controlled, single or multiple contaminations of the tested cosmetic mass with specific strains of microorganisms. The product inoculated with microorganisms is left in appropriate culture conditions (proper temperature, lack of light) for the time strictly defined in the procedure. Then, the reduction of the microorganisms by the preservative contained in the formulation is observed over time. For this purpose, microbiological cultures of the infected product are seeded, which allows for determining the degree of reduction of microorganisms by the preservatives used in the sample. The result is given in the number of viable microbial cells (CFU/ml - colony forming units). The most commonly used methods for testing the effectiveness of preservation include: the method specified in the PN-EN ISO 11930:2019-03 standard, the Koko Test, and the pharmacopoeial method. The selection of strains used in the preservation efficiency test should cover the full microbiological spectrum. For example, the strains used in PN-EN ISO 11930:2019-03 Gram-negative bacteria (Pseudomonas aeruginosa, Escherichia coli), Gram-positive bacteria (Staphylococcus aureus), yeast (Candida albicans) and molds (Aspergillus brasiliensis). The preservation test finally confirms that the finished product is properly protected against the possible development and multiplication of microorganisms during use. Therefore, it is a kind of simulation of the effectiveness of the preservatives used in the formulation against secondary infections of the product which are a result of consumer use or contact with the environment of use [4, 22-24].

Table 1 Cosmetics of low microbiological risk - criteria. Source: [25]

<table>
<thead>
<tr>
<th>Physico-chemical factor</th>
<th>Limits</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>≤ 30</td>
<td>Chemical peels</td>
</tr>
<tr>
<td>pH</td>
<td>≥ 100</td>
<td>Permanent hair waving products</td>
</tr>
<tr>
<td>Content of ethanol or other alcohols</td>
<td>≥ 20%</td>
<td>Perfumes, tonics</td>
</tr>
<tr>
<td>Filling temperature</td>
<td>≥ 65°C</td>
<td>Lipsticks, ointments</td>
</tr>
<tr>
<td>Water activity (aw)</td>
<td>≤ 0.75</td>
<td></td>
</tr>
<tr>
<td>Content of organic solvents (e.g. ethyl acetate, butyl acetate)</td>
<td>&gt; 1000%</td>
<td>Nail polishes</td>
</tr>
<tr>
<td>Hydrogen peroxide content - (oxidizing products)</td>
<td>&gt; 300%</td>
<td>Hair dyes</td>
</tr>
<tr>
<td>Aluminum hydrochloride content</td>
<td>≥ 25%</td>
<td>Antiperspirants</td>
</tr>
</tbody>
</table>

- filling (confection) temperature equal to or higher than 65°C;
- water activity (aw) equal to or less than 0.75.

It is worth explaining that water activity is the ratio of the water vapor pressure above the cosmetic to the water vapor pressure above pure water at the same temperature. Therefore, this parameter determines the water demand of microorganisms. Most bacteria grow in environments in which the water activity is above 0.90. Whereas for the majority of yeasts the value is aw ≥ 0.70 and for most mold fungi it is aw ≥ 0.60. Another group of cosmetic products that qualify for the low microbiological risk group are those that contain more than 25% of aluminum chlorohydrate [25].

LEGAL REGULATIONS FOR THE MAINTENANCE OF COSMETIC PRODUCTS

Preservatives approved for use in cosmetic products placed on the market in the European Union are listed in Annex V to Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of the European Community. It applies throughout the European Union since July 11, 2013, and contains a list of preservatives allowed for use in cosmetics, along with their maximum concentrations in the product and conditions of use. This list was also included in the appendix to the Regulation of the Minister of Health of 30 March 2005. In addition, each ready-made cosmetic undergoes a safety assessment conducted by a qualified Safety Assessor before it hits store shelves. This specialist determines whether the preservative used in a given product meets the conditions of all legal restrictions and whether it has been used in the recipe within the permissible concentration range [26].
The implementing decision of the European Commission of November 25, 2013 on the guidelines for Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (2013/674/EU) indicates that detailed directives on the microbiological quality of the finished product are included in the principles of the Committee Scientific Committee on Consumer Safety (SCCS). In the content of SCCS/1564/15 of April 25, 2016, microbiological limits were set, referring directly to the EN ISO 17516:2014 standard (Table 2). This document combines the previously presented standards for microbiological testing and defines the acceptable content of microorganisms in cosmetic products. According to this standard, cosmetic products are divided into two categories: cosmetics intended for children under three years of age and used around the eyes (category I) and other cosmetics (category II) [9, 26, 27].

<table>
<thead>
<tr>
<th>Type of microbes</th>
<th>Products for special use for children under 3 years of age, around the eyes or on mucous membranes (CATEGORY I)</th>
<th>Other products (CATEGORY II)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aerobic mesophilic microorganisms (bacteria, molds and yeasts)</td>
<td>≤ 1 x 10⁶ CFU/g or ml</td>
<td>≤ 1 x 10⁵ CFU/g or ml**</td>
</tr>
<tr>
<td>Escherichia Coli</td>
<td>Absent in 1 g or 1 ml</td>
<td>Absent in 1 g or 1 ml</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>Absent in 1 g or 1 ml</td>
<td>Absent in 1 g or 1 ml</td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td>Absent in 1 g or 1 ml</td>
<td>Absent in 1 g or 1 ml</td>
</tr>
<tr>
<td>Candida albicans</td>
<td>Absent in 1 g or 1 ml</td>
<td>Absent in 1 g or 1 ml</td>
</tr>
</tbody>
</table>

* The limit is considered exceeded if > 200 CFU or ml
** The limit is considered exceeded if > 2000 CFU or ml

The activities contributing to the contamination of cosmetic products should be limited, such as avoiding storing products in places exposed to solar radiation, elevated temperature, and high humidity. In addition, the cosmetic product should be applied to the skin with clean hands or with a clean applicator. Also, cosmetics should not be left open when they are not in use. Closing the packaging significantly reduces contact with airborne bacteria and fungi. Proper maintenance of the cosmetic is extremely significant because a microbiologically contaminated product can adversely affect the health of consumers.

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LITERATURA / REFERENCES