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Preservation of Cosmetics against Microbial Contamination

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ABSTRACT

Preservatives are crucial in preserving the integrity and stability of cosmetic products, ensuring consumer safety and extending their shelf-life, as they can be damaged by microorganisms. Cosmetic items can be contaminated in two ways: during manufacturing or during use by the user; as a result, many limitations and legalizations have been implemented to reduce microbiological development. Preservation systems include two phases: primary preservation during production and secondary preservation after manufacture. Cosmetic items have been preserved using three basic strategies: physical, chemical, and physicochemical. Cosmetic preservation faces difficulties such as selecting a suitable preservative based on safety, antibacterial efficacy, compatibility, and other factors. This review aims to discuss cosmetics preservation strategies which are considered an important part of cosmetic microbiology.

Keywords: Cosmetics Preservation, Cosmetic Microbiology, Preservation Strategies, Preservation Legislation.

INTRODUCTION

The US Food and Drug Administration (FDA) defines cosmetics is “substances intended for cleansing, beautifying, promoting, attractiveness, or altering appearance [1,2].

A cosmetic product is a product designed to be used on the outside of the human body, like skin, hair, nails, lips, or genitals. Its main purposes are to clean, add fragrance, change appearance, mask odors, or protect these body parts (European Cosmetics Directive (76/768/EEC). Otherwise cosmetics like foundations, compact powder, lipstick, eye liner, eyeshadow, and brushes can be harmful to skin health due to their potential to harbor bacteria and spread infections [3].

The Scientific Committee on Consumer items (SCCP) has released notes of recommendations regarding cosmetic items that divide them into two categories: (a) items intended for use on the eye region or mucous membranes in children under three years old; and (b) additional cosmetic items [4]. Contamination of cosmetic products poses a serious risk to the industry and could result in losses for both goods and money. Because they have access to nutrients and water, microorganisms may alter the color, viscosity, and smell of an object [5].

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Furthermore, contaminated microbes or their activity may occasionally result in health issues for people, including skin irritation, allergic contact dermatitis, and infections, particularly in the mouth, eyes, and wounds [6].

Cosmetic product contamination is a major industry risk, potentially resulting in product and economic losses. Microorganisms can induce organoleptic changes, such as disagreeable scents, viscosity, and color changes, when water and nutrients are present [7].

Cosmetic items can be polluted in two ways: during manufacturing or by the consumer while in use [8]. Such contaminants can be present on a package surface or in a product prior to filling, causing possible consumer health issues or product damage [9].

Tropical countries' warm, humid climates support microorganism survival and growth in highly contaminated cosmetic products, allowing for rapid growth and reproduction [10].

Cosmetic products serve as substrates for various microorganisms' survival and development due to their nutrient content, including water, lipids, polysaccharides, alcohol, proteins, amino acids, glycosides, peptides, and vitamins [7]: As a result, natural components are more vulnerable to microbial contamination due to their high initial bio load or excellent microbial development platform. Despite the hurdles. Preservative regulations varies by area. The EU Cosmetics Directive 76/768/EEC defines preservatives as substances "for the primary purpose of inhibiting the development of microorganisms" in cosmetic items [11].

Category products must contain no more than 102 CFUs of aerobic mesophilic microorganisms per milliliter or gram, with *Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus,* and *Candida albicans* not detectable within 0.1 or 0.5 g/ml of the product [12].

To prevent microbial growth in cosmetics, use preservatives, GMPs, aseptic preparation, water treatment, raw material control, equipment disinfection, and personnel qualification, along with secondary preservative strategies. Secondary preservative strategies for cosmetics include physicochemical, chemical, and physical methods. Physical preservation involves basic packing with a physical barrier to prevent microbial contamination, but materials may increase contamination [13].

Contamination in cosmetics can be reduced through Physicochemical Secondary Preservation, which focuses on water content, pH, and emulsion form, while Chemical Secondary Preservation targets synthetic or natural antimicrobial ingredients [14].

The aim of the study is to investigate strategies for keeping cosmetic products microbiologically stable from manufacturing processes until the product reaches safe to customer.

PRESERVATION CONCEPT

Preservation involves using natural and synthetic chemical preservatives in cosmetic preparations to prevent spoilage caused by microbial development without altering the product's characteristics [15]. Beside, preservatives are used to maintain the microbiological purity of cosmetics during production, packaging, and storage, particularly during the entire use period [16]. Self-preservation or free preservation is a cosmetic preservation method that doesn't require an additional chemical ingredient, often referred to as a preservative.

Preservation strategies

Manufacturers of cosmetics use different strategies to prevent microbial contamination, the microbial preservation strategies range from the first stages of manufacture to consumption by customer, in order to minimize the risk of microbial contamination.

To achieve a good protection of cosmetic products against microbial contamination, the industry provides two stages of preservation:

- The strategy of primary preservation occurs during manufacturing and is based on the application of GMP.
- The secondary preservation, which takes place after manufacture, uses chemical, physical, or physicochemical methods to attain efficient protection [13].

Primary preservation Strategy: Good manufacturing practice (GMP)

Good manufacturing practices(GMP), utilizing judicious raw materials with anti-microbial properties, can prevent microbial growth and produce cosmetics with weaker preservative concentration [17].

Cosmetic products must adhere to GMP guidelines, ensuring strict sterility and minimizing contamination risk. Positive pressure, water filtration, and microbiological testing can reduce contamination, while rigorous aseptic conditions, especially for self-preserving formulations, are recommended [14].

Contamination in manufacturing is primarily caused by raw materials, including water, and the manufacturing process itself, with water quality influencing product contamination, including species like *Pseudomonas*, *Achromobacter, Aeromonas, Flavobacterium, Xanthomonas, Actinobacter,* and *Aerobacter* spp [18].

The existence of *E. coli* could indicate recent wastewater contamination. Water that has been softened or deionized frequently has its microbiological quality altered. Water continues to be one of the main causes of product contamination. From natural waters, species including *Pseudomonas*, *Achromobacter, Aeromonas, Flavobacterium, Xanthomonas, Actinobacter,* and *Aerobacter* spp. were found [19].

Water treatment can alter its microbiological quality, with UV and bacterial filtration ensuring optimum quality. Animal or vegetable raw materials can be highly contaminated by coliforms, while synthetic materials are relatively free of contamination. Manufacturing processes can also be contaminated by human microorganisms, such as *fecal streptococci, staphylococci, enterobacteria, and Pseudomonas.* Maintenance materials, poor cleaning, and product change can also contribute to contamination. Air quality in manufacturing chambers is crucial, with workers and movement size contributing to 80% and 15% respectively [20].

Secondary Preservation Strategy

Preservatives are used to keep cosmetics microbiologically pure during production, packaging, and storage, but especially over the entire usage period. Preservatives are commonly employed in tiny amounts [16]. Cosmetic items have been preserved using three basic tactics during storage and transportation. Also, use: Preservation of physical, chemical, and physicochemical properties [13].

Physical Secondary Preservation

Main packaging that has a physical barrier to prevent microbiological contamination is used in this preservation technique. Proper packaging Airless packaging is a popular method of shielding goods from environmental damage. The purpose of bottles and containers is to keep microorganisms out of the items. Wide-neck jars with shives are not quite as good as tubes, which are frequently used in the pharmaceutical industry.

The nozzle provides contamination with a more discrete and smaller surface. Certain tubes feature non-return valves, which prevent the tube from relaxing to allow air to enter once they are squeezed. The blister pack, sachet, single-application pack, and single-shot capsule are the safest types of packaging [14].

A microbiological danger may exist in the packaging before the cosmetic product's contents are added. These days, wide-open bottles of cosmetics offer one of the largest obstacles to any preservation system because of their vast surface area exposed to a moist, polluted environment [21].

PHYSICOCHEMICAL PRESERVATION

pH control

The pH, or hydrogen ion concentration, is essential to the survival of microorganisms. Every organism has a pH where it grows best. When the pH moves away from neutrality, microorganisms often grow more slowly [14].

pH values affect microorganism development, with yeasts able to withstand acidic conditions. However, bacteria can experience stress at higher values, making products with low or high pH less susceptible to contamination [13].

Temperature

Maintaining products at a temperature that promotes the growth of microorganisms is one of the incorrect preservation techniques. Twenty to twenty-five degrees Celsius are ideal for the growth of microorganisms and their potential interactions with the active components in preservatives [22].

The water activity (aw)

A decrease in water activity reduces the growth of microorganisms. Indeed, in order to survive and flourish, microorganisms must maintain a turgescent condition in cells by osmosis with external media. Loss of turgescence causes an increase in latency, a decrease in growth, and a drop in the total number of microbial cells [17].

Emulsion Form

Water-in-oil emulsions reduce microbiological contamination risk, enhance cosmetic efficiency, and enhance antibacterial action, but their efficacy depends on oil phase composition, phenolic compounds, and structure [23].

CHEMICAL SECONDARY PRESERVATION

Synthetic Chemical Preservatives

Cosmetic product contamination is a major industry risk, with the potential to cause both product and economic losses. In the presence of water and nutrients, microorganisms can generate organoleptic changes such as disagreeable odors, viscosity, and color changes.

Preservative selection in cosmetics is based on antimicrobial efficacy, non-toxicity, and compatibility with other ingredients. Interest in less-toxic preservatives and potential alternatives like plant extracts and preservative-free products is growing due to the lack of less-toxic options in the industry [24].

The most commonly used antibacterial preservatives are shown in Figure 1. These are classified based on their chemical composition: organic acids, alcohols, and phenols, aldehydes and formaldehyde releasers, isothiazolinones, biguanides, quaternary ammonium compounds (QAC), nitrogen compounds, heavy metal derivatives, and inorganic compounds. Detailed information about the mechanism of action of these antimicrobial preservatives is given below:

Natural Chemical Preservatives

Nature offers a broad spectrum of defense mechanisms against microbiological contamination [14]. Plant extracts and essential oils are commonly used in cosmetic preparations due to their well-known properties, which include antioxidants, anti-inflammatory and antimicrobial agents, emollients, dyes, humectants, wound healing, anti-mutagens, anti-aging, UV-B protection, and skin discoloration reduction. Several studies have proven that natural ingredients are effective as preservatives in cosmetic goods [13].

Multifunctional Ingredients:

According to European regulations, the only authorized preservatives are those mentioned in the Cosmetic Directive. However, many cosmetic components, including alcohols, essential oils, extracts, and surfactants, are antibacterial. These materials are not mentioned as preservatives because they are employed for their positive effect on the skin and may also contribute to the preservation of the formulation [25].

Listed of some alternative preservative: according to Dao et al. [8].

1. **Paraben:** Provides broad antimicrobial activity, potent within pH 4–8 range. Interference with cytoplasmic membrane causes inactivation.
2. **Caprylyl glycol:** Exhibits viscosity modulating properties, supporting chemical preservative activity.
3. **Medium chain saturated fatty acids:** such as hep- tanoic (C7), caprylic (C8), capric (C10) and lauric acid (C12) and their esters with glycerin or propyl- ene glycol have been found to possess activity against enveloped viruses and various bacteria and fungi in vitro.
4. **Phenethyl alcohol:** Causes rapid, reversible breakdown in bacterial cell permeability barriers. Enhances activity of alternative or chemical preservatives.
5. **Chelating agents:** The chelators, EDTA, lactic acid, and citric acid increase permeability of cell membranes, making them more sensitive to antimicrobial agents.
6. **Phenolic antioxidants:** Delay auto-oxidation of unsaturated oils, influencing product color and odor.

Selection of appropriate preservative

Safety in cosmetics

Preservatives such as zinc pyrithione, triclocarban, piroctone olamine, chloroacetamide, hexamidine, dibromohexamidine isethionate, dimethyloxazolidine, climbazole, iodopropynyl butylcarbamate, 7-ethylbicyclooxazolidine, and ethyl lauroyl arginate hydrochloric acid must be used in the manufacture of cosmetics. The cosmetics sector is also keen on creating effective and non-toxic materials. In addition to safety and risk issues. Consideration should be paid to handling antibacterial agents during manufacturing [13].

Compatibility

A preservative in cosmetics must be compatible with chemical components and physical properties, such as tastelessness, odorlessness, and colorlessness. Container type affects concentration and activity, with lipophilic preservatives more prone to absorption. Combining preservatives with EDTA can enhance antimicrobial penetration into cells.

High concentrations of solid minerals (carbonates and silicates, among others) or organic solids (cellulose and starch) cause preservative absorption. Talc, for example, lowers the antibacterial action of more than 90% of methylparaben [14].

Stability

Preservatives' stability is influenced by factors like solubility, partition in oil/water or water/oil emulsions, formulation pH, temperature, and volatility during use.10 The preservative system should be stable, compatible, cost-effective, and maintain the final product's organoleptic properties, with factors like high solubility and good O/W partition coefficient affecting its stability [12].

Recent studies have raised concerns about the long-term safety of chemical preservatives like methylparabens and propylparabens in pharmaceutical and cosmetic products. Research focuses on finding alternatives and assessing water activity during formulation and manufacturing to prevent microbial instability [15].

COMPLIANCE WITH COSMETICS LEGISLATION

The EU and Japan regulate the use of preservatives through a positive list published by the official guidelines. (European Parliament and Council of the European Union. Regulation (European Commission) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetics. Stop. Your. Union L 2009, 342, 59.)

The Cosmetic Directive has streamlined European Union cosmetic regulation, while the US's regulation is more complex, primarily governed by the 1938 Federal Food, Drug, and Cosmetics Act and the 2004 Federal Food, Pharmaceutical, and Cosmetics Act.

In 1976, Council Directive 76/768/EC was adopted by the European Commission to round member states' laws on cosmetic products, aiming to harmonize regulations (Consolidated Version, 2007). While, The Cosmetic Ingredient Review Expert Committee (CIR) is an independent committee of industry-funded medical and scientific experts that reviews and evaluates the safety of cosmetic ingredients in the US, based on published literature and industry funds. https://eur-lex.europa.eu/eli/reg/2009/1223/oj

Cost

Cosmetics marketing relies heavily on ingredient costs, leading to the industry using less expensive components due to factors like raw material costs and product production, shipping, and marketing.

Essential oils and extracts are cost-effective natural preservation systems that can enhance the cosmetic and dermatological properties of finished products. The selection of raw materials now primarily depends on factors such as costs, market value, and availability [13].

Global regulations of preservatives and cosmetic preservatives

FDA (U.S. Food and Drug Administration)

The FDA has imposed restrictions on cosmetic production, including the use of certain chemicals like bithionol, mercury compounds, and halogenated salicylamide, while ensuring compliance with current good manufacturing practices.

Japan

The Japanese Ministry of Health, Labor, and Welfare regulates cosmetics under the Pharmaceutical Affairs Law (PAL). Microbiological quality acceptance criteria for cosmetic products limit aerobic microorganisms and yeasts/molds to 102 CFU/g or CFU/mL. Preservatives approved in Japan include chlorphenesin, phenoxyethanol, zinc pyrithione, triclosan, and chlorhexidine. EU Regulations prohibit certain preservatives, including dichlorophen, mercury, halogenated salicylanides, bithionol, hexachlorophene, and formalin.

European Union

Annex V-approved preservatives include salts, anions, and esters. EU Regulations prohibit certain ingredients, including mercury compounds, tetrachlorosalicylanilides, and dichlorosalicylanilides, from cosmetic use [26-30].

CONCLUSION

Preservation of cosmetics is an important issue in manufacture. Without keeping products safe from contamination, a lot of economic losses and health problems may occur. Legalizations and global regulations are placed to organize cosmetic production in safe conditions. Preservation systems in manufacture ensure keep cosmetics microbiologically stable and safe.

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CONFLICTS OF INTEREST

The author declares that there is no conflict of interest.

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