

Article

A Survey of Preservatives Used in Cosmetic Products

Patrycja Poddebniak and Urszula Kalinowska-Lis * 

Department of Cosmetic Raw Materials Chemistry, Faculty of Pharmacy, Medical University of Lodz, 90-419 Łódź, Poland; patrycja.poddebniak@stud.umed.lodz.pl

* Correspondence: urszula.kalinowska-lis@umed.lodz.pl

Abstract: The aim of this study was to indicate the type of preservatives used in selected categories of cosmetic products sold in Poland (part of the EU market) and determine the frequency of their use. The tested products consisted of 200 leave-on cosmetics, viz. body lotions (n = 100) and face creams (n = 100) and rinse-off cosmetics (n = 100) and mascaras (n = 25). The product labels of 325 adult cosmetic products from international brands were analyzed for the presence of preservatives based on the INCI compositions. The survey focused on preservatives included in Annex V of the Regulation (EC) No. 1223/2009 of the European Parliament and Council of 30 November 2009 on cosmetic products. The tested products contained 29 different preservatives belonging to eight chemical groups. Most preservatives were alcohols or their derivatives, carboxylic acids or their salts, or parabens. The most common types were phenoxyethanol, present in 198/325 (60.9%) formulations, followed by sodium benzoate, in 137 (42.2%), potassium sorbate, in 116 (35.7%), benzyl alcohol, in 76 (23.4%), and methylparaben in 33 (10.2%). Also, 33 of the 60 preservatives included in Annex V of Regulation (EC) No. 1223/2009 were not used in any of the tested preparations. In each category of products, the most common were combinations of two preservatives per single product (34.8% of all products), followed by single-preservative products (25.5%) and three-preservative products (19.4%).

Keywords: preservatives; cosmetic regulations; frequency of use; market trends; safety testing; sensitization



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1. Introduction

Cosmetic products should not contain any microorganisms potentially harmful to human health throughout their entire period of use. The most common microorganisms found in contaminated cosmetics include *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli*, *Klebsiella oxytoca*, *Burkholderia cepacia*, *Enterobacter gergoviae*, *Candida albicans*, and *Serratia marcescens*. Contaminated cosmetic products should not be sold or used. Microbial contamination can influence the color and smell of the cosmetic, and reduce the stability of products; in addition, toxins produced by microorganisms may cause allergies, skin irritations, and other undesirable reactions. Therefore, to inhibit the development of microorganisms and maintain the microbiological purity of the cosmetic during manufacture, packing and storage, thus ensuring the safety of its users, preservatives are added to cosmetic products [1–4].

Preservatives are biologically active organic compounds and have strong effects on the growth and function of living cells and, as such, do not have a beneficial effect on the skin. They can be divided into several groups: carboxylic acids (aliphatic and aromatic) and their salts, alcohols (aliphatic and aromatic), parabens, compounds releasing free formaldehyde, isothiazolinones and other heterocyclic compounds, heavy-metal derivatives (organic mercury and silver compounds), and other compounds, like biguanides and quaternary ammonium salts [5].

The preservatives used in cosmetic products must meet several criteria. Among others, they should not be toxic and should not cause sensitization or irritation or damage the natural skin microbiome; also, they should not penetrate the skin or mucous membranes

or affect the color and fragrance of the product. They should still exhibit activity against a broad spectrum of fungi and bacteria at the lowest possible concentrations. They are expected to be stable, to be resistant to light and oxygen, and not to react with other recipe ingredients. A good preservative should also have better solubility in the aqueous phase than the oil phase. The preservative system should be appropriately selected for the target group of the cosmetic [3,5].

To be permitted for use in cosmetic ingredients, a preservative must comply with Annex V of the Regulation of the European Parliament and of the Council of the European Community (EC) No. 1223/2009 [6]. Annex V currently includes about 60 positions; however, it is constantly being updated. Recent changes to Regulation 1223/2009 include the prohibition of zinc pyrithione and restrictions on the use of salicylic acid and its salt. In addition, formaldehyde donors should be labeled with the warning “releases formaldehyde” when the total concentration of released HCHO in the finished product exceeds 0.001%. The list does not include preservatives of natural origin, such as essential oils or plant extracts. Permissible concentrations of preservatives listed in the above-mentioned regulations range from 0.0015% to 2.500%. Preservatives must be used in the minimum concentration that guarantees effective protection of the formulation but does not exceed the concentration at which they could cause irritation and undesirable side effects in users.

Preservatives may cause hypersensitivity reactions and allergies, the most common symptom of which is allergic contact dermatitis, but contact urticaria has also been reported. They can also irritate the skin and mucous membranes [4,7]. Thiomersal and formaldehyde donors have been found to have a negative impact on the human body. Methylisothiazolinone (MI) is banned for use in leave-on cosmetics due to its sensitizing effect. Also, quaternary ammonium compounds are irritating and toxic to mucous membranes and skin [7–10].

The preservatives should be compatible with the other ingredients of the recipe. The presence of certain ingredients may reduce the effect of the preservative, while others may enhance its effect. Some emollients, e.g., milk proteins, hydrolyzates of proteins, and silicon derivatives, may have an antagonistic impact on the preservation system. Undesirable side reactions in the preparations may occur when parabens or phenolic preservatives are combined with non-ionic surfactants. High concentrations of solid minerals, e.g., talc, carbonates, silicates, and solid polymeric organic substances, e.g., cellulose and starch, may act antagonistically by the absorption of preservatives. Some mineral raw materials or even plant extracts may occur to be sources of contamination, especially for spores, mycotoxins, and *Clostridium* [5].

The type of material the packaging of a cosmetic product is made of may affect the effect of preservatives. The use of lipophilic preservatives carries a higher risk of absorption through the containers. Incompatibility between preservatives and containers may appear when using nylon with parabens or polyethylene with some phenolic compounds, mercury, and benzoates [5].

The synergistic effect of preservatives with other recipe ingredients has been quite well described. Ingredients of preparations that have a positive effect on the action of preservatives are called “preservatives boosters”. Their presence in the cosmetic formulation allow to reduce the concentration of a conventional preservative and minimize the potential adverse effects caused by the preservative. Preservative boosters come from a range of cosmetic ingredients, including surfactants, humectants, emulsifiers, chelating and buffering agents, and antioxidants, and while they do not act as preservatives themselves, they do possess some antimicrobial properties [5,11,12]. Some synthetic preservative boosters are non-ionic surfactants and emulsifiers, such as lauric acid, glyceryl caprylate, and sorbitan caprylate. They disrupt cell membranes or increase their porosity, which facilitates penetration of antimicrobial substances. Similarly, ethylhexylglycerin can reduce the surface tension at the cell membrane of microorganisms and allow the preservative to penetrate more effectively. Ethylhexylglycerin can enhance the antimicrobial activity of

synthetic preservatives, such as phenoxyethanol, dehydroacetic acid, benzyl alcohol, and methylparaben [10,13]. However, humectants (e.g., glycerol and sorbitol) and gelling substances (e.g., polyacrylic acid, agar, and xanthan gum) can effectively enhance preservative activity by the reduction in the amount of biologically available water. Chelating agents, such as EDTA, may facilitate the activity of many preservatives, e.g., benzalkonium chloride, methylparaben, and propylparaben. EDTA chelates the iron necessary for microbial metabolism and growth [5].

Plant essential oils, extracts and their active constituents, and hydrosols can act as natural preservative boosters by enabling the decrease in or even elimination of preservatives in cosmetics formulations, e.g., *Thymus vulgaris* (thyme) leaf oil, *Origanum vulgare* (oregano) leaf oil, *Salvia officinalis* leaf extract, and *Schizandra chinensis* fruit extract [12,14–16]. On the other hand, while essential oils and plant extracts are mixtures rich in organic substances, they may be harmful, especially for sensitized individuals and children. Certain essential oils and their constituents used in cosmetic products may cause skin sensitization and eye irritation. Some essential oils are phototoxic, such as lemon, bergamot and bitter orange. Therefore, the use of these substances in cosmetic preparations must comply with Annexes I and II of Regulation (EC) No. 1223/2009, as amended [6]. In addition, IFRA provides guidance on fragrance ingredients, including dermal limits for product categories, and the SCCS's opinion helps identify fragrance allergens, including natural extracts [17,18].

Currently, the use of natural and/or synthetic “preservative boosters” in cosmetics as supporting systems or even replacing conventional preservatives is probably the most leading trend and innovation related to the preservation of cosmetic recipes.

There is a group of cosmetic products with low microbiological risk that do not have to contain preservatives (PN-EN ISO 29621:2017 standard). A preparation should meet at least one of the below given criteria to be classified as a product of low microbiological risk. The inclusion criteria involve products with a pH lower than 3 or higher than 10 (e.g., chemical peels), products with an alcohol content above 20% (perfumes and tonics); antiperspirants with an aluminum salt content above 25%, products with water activity below 0.75 (e.g., products in the form of powders or based on fatty substances), formulations filled at a temperature above 65 °C, nail polishes with an organic solvent content above 10%, and hair products with an oxidizing agent's content higher than 3%. There is no need to carry out the preservation efficiency test (challenge test) for the formulations of low microbiological risk [19].

As the current extent of preservative use by manufacturers in cosmetics remains unknown, the aim of the present study was to examine the type of preservatives used in adult rinse-off and leave-on cosmetics (body lotions and face creams) and mascaras, and their frequency of use. The findings may play an important role in ensuring the safety of consumers, many of whom may use a multitude of cosmetic products every day.

2. Results

The INCI composition of 325 cosmetic preparations was analyzed to indicate the type and number of preservatives present. Preparations from three categories were selected for analysis: leave-on cosmetics, including body lotions (n = 100) and face creams (n = 100), rinse-off cosmetics (n = 100), and mascaras (n = 25). The survey focused on preservatives included in Annex V of the Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, with the preservatives divided into individual chemical groups. The following data were acquired: the numbers of individual preservatives found in each cosmetic product category, the number of preservatives contained in a single product, and the frequency of use of the five most popular preservatives by individual cosmetic brands.

The percentage of preservatives in body lotions according to chemical group is presented in Figure 1. The most frequently used groups of preservatives were found to be alcohols and their derivatives and carboxylic acids and their salts. The most frequently recorded alcohols were phenoxyethanol (68%) and benzyl alcohol (36%), and the most

common carboxylic acids were sodium benzoate (36%) and potassium sorbate (30%). These were followed by parabens, including methylparaben (17%) and propylparaben (13%), the formaldehyde donor DMDM hydantoin (11%), and dehydroacetic acid (8%).

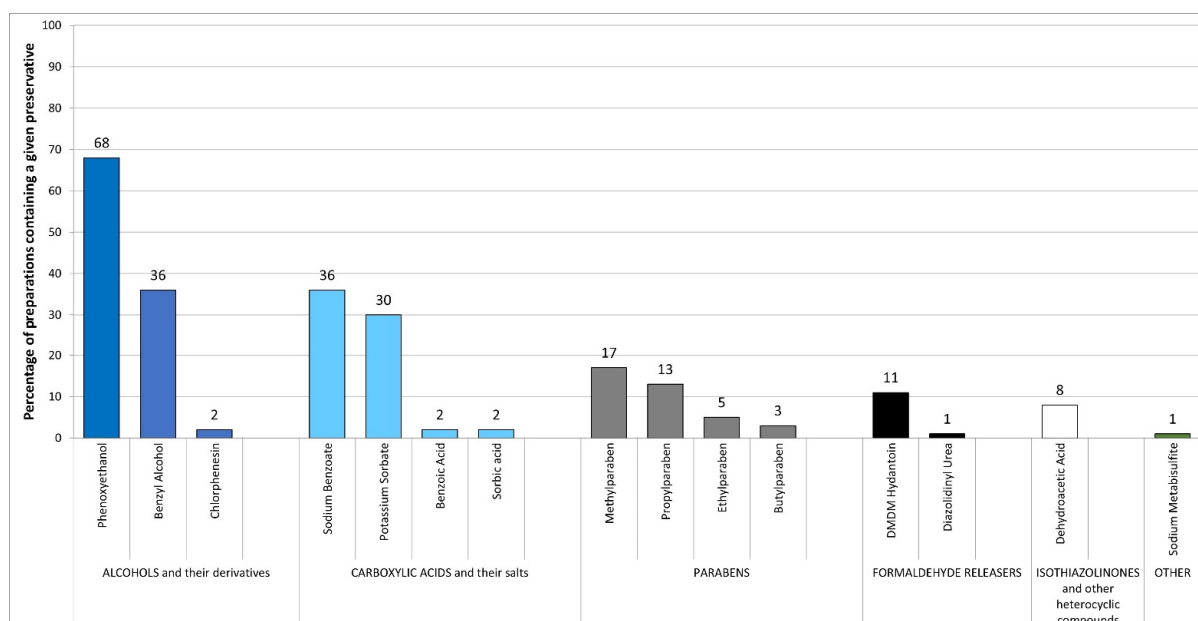


Figure 1. Frequency of use of preservatives in body lotions (n = 100).

A similar trend was noted in face creams (Figure 2). The most frequently used groups were the alcohols and their derivatives and the carboxylic acids and their salts. The most common alcohols were phenoxyethanol (68%) and benzyl alcohol (23%), and the most common carboxylic acids and their salts were sodium benzoate (31%), potassium sorbate (28%), benzoic acid (18%), and sorbic acid (10%). They were followed by parabens, mostly methylparaben (10%) and ethylparaben (6%), and dehydroacetic acid (6%).

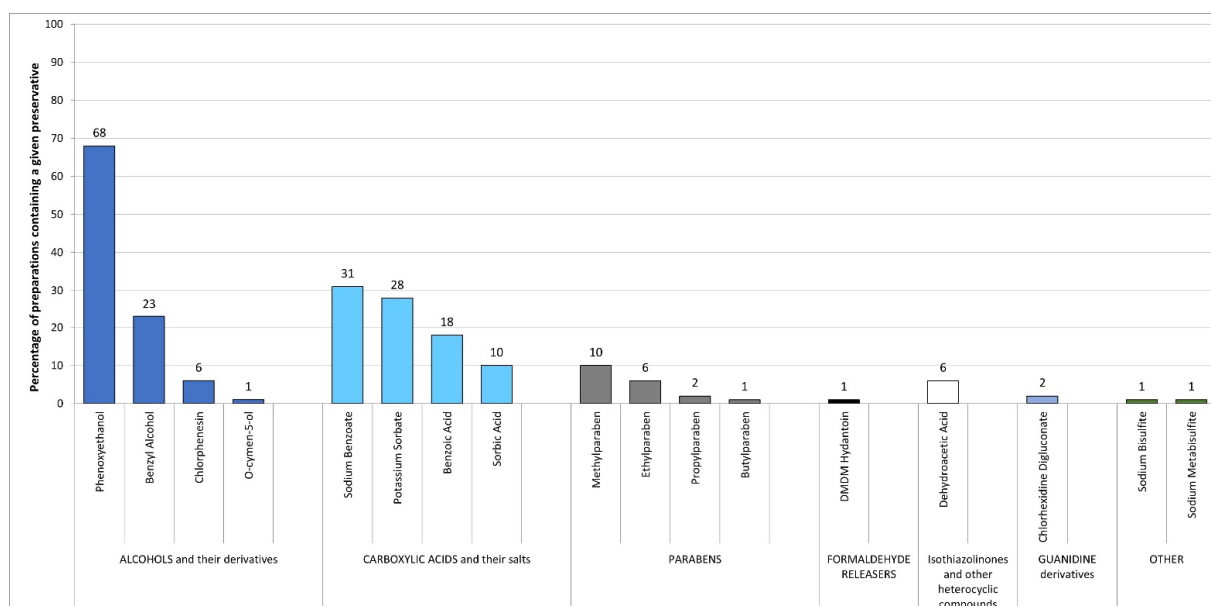


Figure 2. Frequency of use of preservatives in face creams (n = 100).

Hence, the most frequently identified preservatives in leave-on products (n = 200) (body lotions and face creams) were phenoxyethanol (68.0%), sodium benzoate (33.5%),

benzyl alcohol (29.5%), potassium sorbate (29.0%), methylparaben (13.5%), and benzoic acid (10.0%).

In the rinse-off category (Figure 3), the most popular preservatives were carboxylic acid salts: sodium benzoate (66%) and potassium sorbate (49%). These were followed by phenoxyethanol (40%), despite its leading in all other product categories, and methylchloroisothiazolinone and methylisothiazolinone (13% each). In addition, a new group of preservatives, i.e., quaternary ammonium salts, were found to be present in 1% to 4% of formulations.

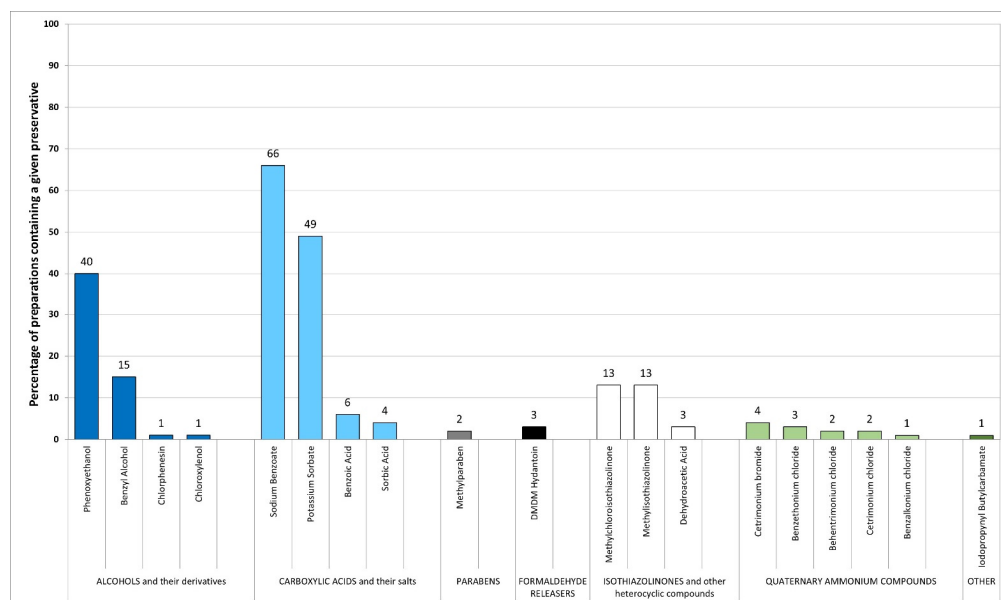


Figure 3. Frequency of use of preservatives in rinse-off cosmetics (n = 100).

The highest-rated preservative in the mascara category (Figure 4) was phenoxyethanol, found in as many as 88% of the products. Potassium sorbate and sodium dehydroacetate (36% each) were ranked second, followed by preservatives based on alcohols (benzyl alcohol), carboxylic acids and their derivatives (sodium benzoate and sorbic acid), and parabens (methylparaben, propylparaben, and ethylparaben), with prevalence ranging from 8% to 16%.

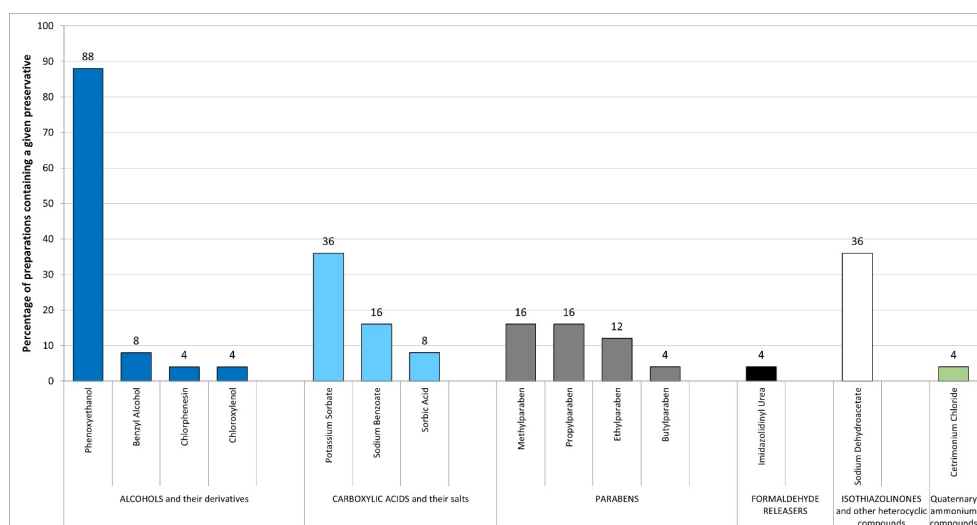


Figure 4. Frequency of use of preservatives in mascaras (n = 25).

A quantitative summary of preservatives according to product category is illustrated in Figure 5 and Table 1 and provides a general overview of the preservative content.

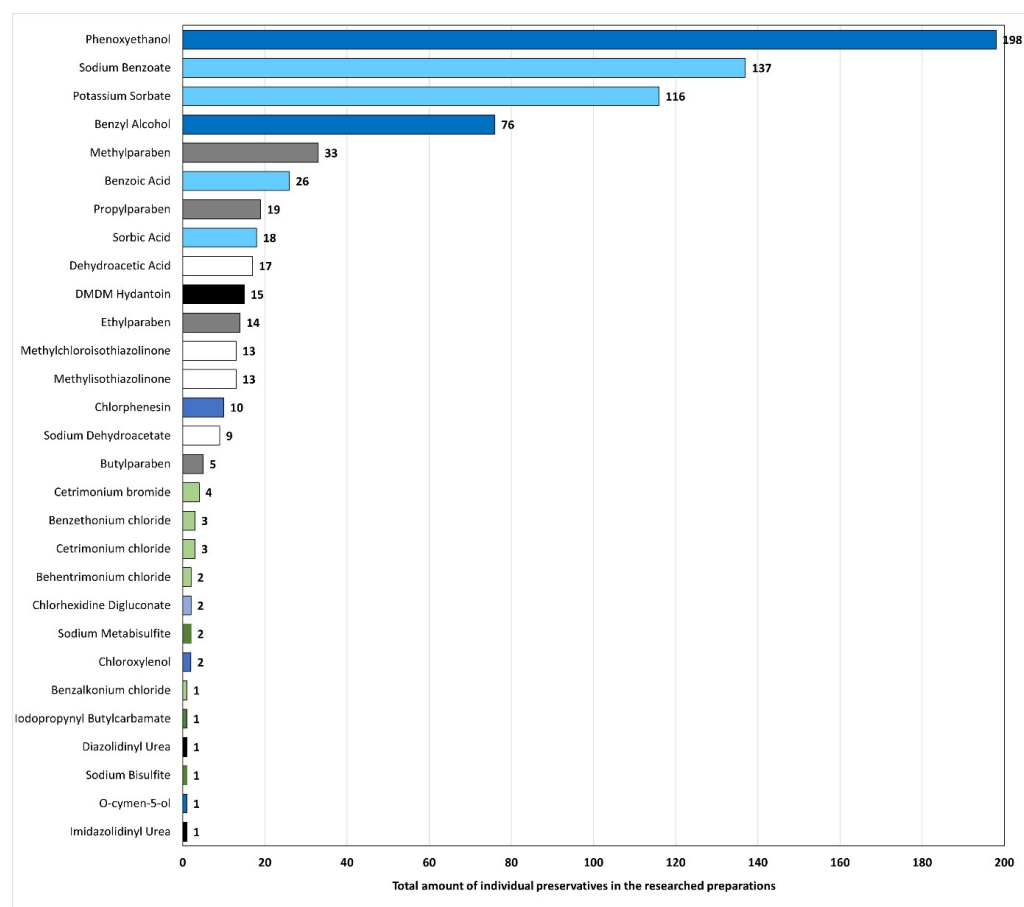


Figure 5. Number of occurrences of the preservatives identified in the tested products (n = 325).

Table 1. Number of occurrences of preservatives according to individual product category and total amounts.

Preservative	Body Lotions (n = 100)	Face Creams (n = 100)	Rinse-off Products (n = 100)	Mascaras (n = 25)	Total (n = 325)
1 Phenoxyethanol	68	68	40	22	198 (60.9%)
2 Sodium Benzoate	36	31	66	4	137 (42.2%)
3 Potassium Sorbate	30	28	49	9	116 (35.7%)
4 Benzyl Alcohol	36	23	15	2	76 (23.4%)
5 Methylparaben	17	10	2	4	33 (10.2%)
6 Benzoic Acid	2	18	6	0	26
7 Propylparaben	13	2	0	4	19
8 Sorbic Acid	2	10	4	2	18
9 Dehydroacetic Acid	8	6	3	0	17
10 DMDM Hydantoin	11	1	3	0	15
11 Ethylparaben	5	6	0	3	14
12 Methylchloroisothiazolinone	0	0	13	0	13
13 Methylisothiazolinone	0	0	13	0	13
14 Chlorphenesin	2	6	1	1	10
15 Sodium Dehydroacetate	0	0	0	9	9
16 Butylparaben	3	1	0	1	5

Table 1. Cont.

	Preservative	Body Lotions (n = 100)	Face Creams (n = 100)	Rinse-off Products (n = 100)	Mascaras (n = 25)	Total (n = 325)
17	Cetrimonium Bromide	0	0	4	0	4
18	Benzethonium Chloride	0	0	3	0	3
19	Cetrimonium Chloride	0	0	2	1	3
20	Behentrimonium Chloride	0	0	2	0	2
21	Chlorhexidine Digluconate	0	2	0	0	2
22	Sodium Metabisulfite	1	1	0	0	2
23	Chloroxylenol	0	0	1	1	2
24	Benzalkonium Chloride	0	0	1	0	1
25	Iodopropynyl Butylcarbamate	0	0	1	0	1
26	Diazolidinyl Urea	1	0	0	0	1
27	Sodium Bisulfite	0	1	0	0	1
28	O-cymen-5-ol	0	1	0	0	1
29	Imidazolidinyl Urea	0	0	0	1	1

The 325 tested products included 29 different preservatives belonging to eight chemical groups (Figure 5). The presented analyses show that the most common preservative types were alcohols and their derivatives, carboxylic acids and their salts, and parabens. The most common individual preservative was phenoxyethanol, which was found in 198 (60.9%) of the 325 analyzed cosmetic compositions. In addition, sodium benzoate and potassium sorbate were present in 137 (42.2%) and 116 (35.7%) products. In fourth place was benzyl alcohol, present in 76 (23.4%) cosmetics. Methylparaben, the most common among all parabens, was present in 33 (10.2%).

It was found that 13 out of 29 of the identified preservatives were relatively uncommon, appearing in fewer than five products. The least common preservatives included the quaternary ammonium salts cetrimonium bromide, benzethonium chloride, cetrimonium chloride, behentrimonium chloride, and benzalkonium chloride and the miscellaneous preservatives chlorhexidine digluconate, sodium metabisulfite, chloroxylenol, iodopropynyl butylcarbamate, diazolidinyl urea, sodium bisulfite, o-cymen-5-ol, and imidazolidinyl urea.

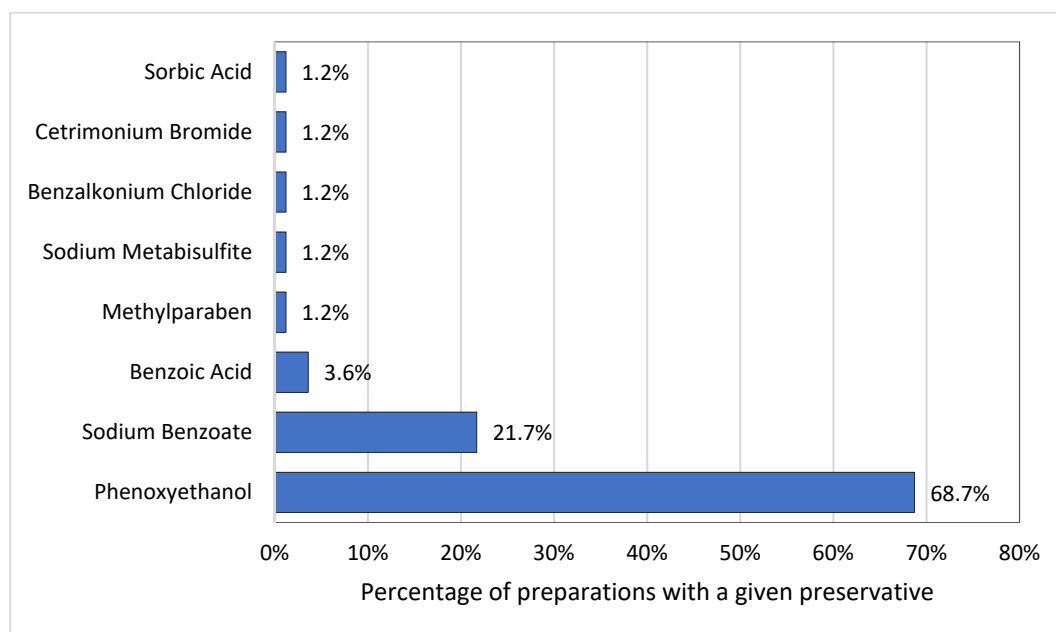
Of the 60 preservatives included in Annex V of the Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, 33 were not used in any of the tested preparations. These included various acids (e.g., salicylic acid, formic acid, and propionic acid) and their salts, formaldehyde donors (e.g., methenamine, benzylhemiformal, and 7-ethylbicyclooxazolidine), alcohols and their derivatives (e.g., chlorobutanol, dichlorobenzyl alcohol, and 2-bromo-2-nitropropane-1,3-diol), phenolic compounds, (e.g., o-phenylphenol, p-chloro-m-cresol, triclosan), and glutaral and thimerosal.

Regarding the numbers of combined uses of preservatives in a single product (Table 2), the most common group comprised preparations containing combinations of two preservatives (34.8% of all analyzed preparations), followed by single-preservative products (25.5%) and three-preservative products (19.4%). A similar trend was noted for individual product categories, i.e., two preservatives, followed by one and three preservatives. Higher numbers were also observed, but these were rarer: i.e., preparations with four (8.9%), five (3.7%), six (1.2%), seven (0.9%), or even eight preparations (0.9%). Interestingly, out of 325 products, 15 (4.6%) did not contain a preservative listed in Annex V of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council. In these cases, the preservatives were replaced by plant substances with antimicrobial properties, for example, rosemary extract and essential oil, lavender, grapefruit seeds, grapevine, and green tea leaves. Polyhydroxyl compounds, i.e., polyols such as pentyleneglycol, butylene glycol, and caprylyl glycol, also frequently appeared, which can protect cosmetic products against microbial contamination at higher concentrations.

Table 2. Number of preservatives per single product, given as total amounts and according to product category.

Percentage of Preparations with a Specific Number of Preservatives					
Number of Preservatives per Single Product	Body Lotions (n = 100)	Face Creams (n = 100)	Rinse-off Products (n = 100)	Mascaras (n = 25)	Total (n = 325)
0	4	10	-	4	.
1	21	31	27	16	25.5
2	41	25	38	36	34.8
3	17	16	23	28	19.4
4	12	11	5	4	8.9
5	2	3	5	8	3.7
6	-	2	2	-	1.2
7	1	1	-	4	0.9
8	2	1	-	-	0.9

The most frequently used preservative in single-preservative products was phenoxyethanol (68.6%), followed by sodium benzoate (21.7%). Benzoic acid was present as a single preservative in only 3.6% of products, while methylparaben, sodium metabisulfite, benzalkonium chloride, cetrimonium bromide, and sorbic acid were each present in 1.2% of products (Figure 6).

**Figure 6.** Frequency of use of preservatives in single-preservative products (n = 83).

The frequency of individual preservatives in two-preservative products is shown in Figure 7. Again, the highest rated was phenoxyethanol, which appeared in 50.4% of two-preservative cosmetics. Sodium benzoate (42.5%) and potassium sorbate (40.7%) were ranked second and third and were most commonly used together. These were followed by benzyl alcohol (29.2%), sorbic acid (6.2%), benzoic acid, and sodium dehydroacetate (4.4% each), and then dehydroacetic acid and DMDM hydantoin (3.5% each). The remaining preservatives were present in 2.7% to 0.9% of products.

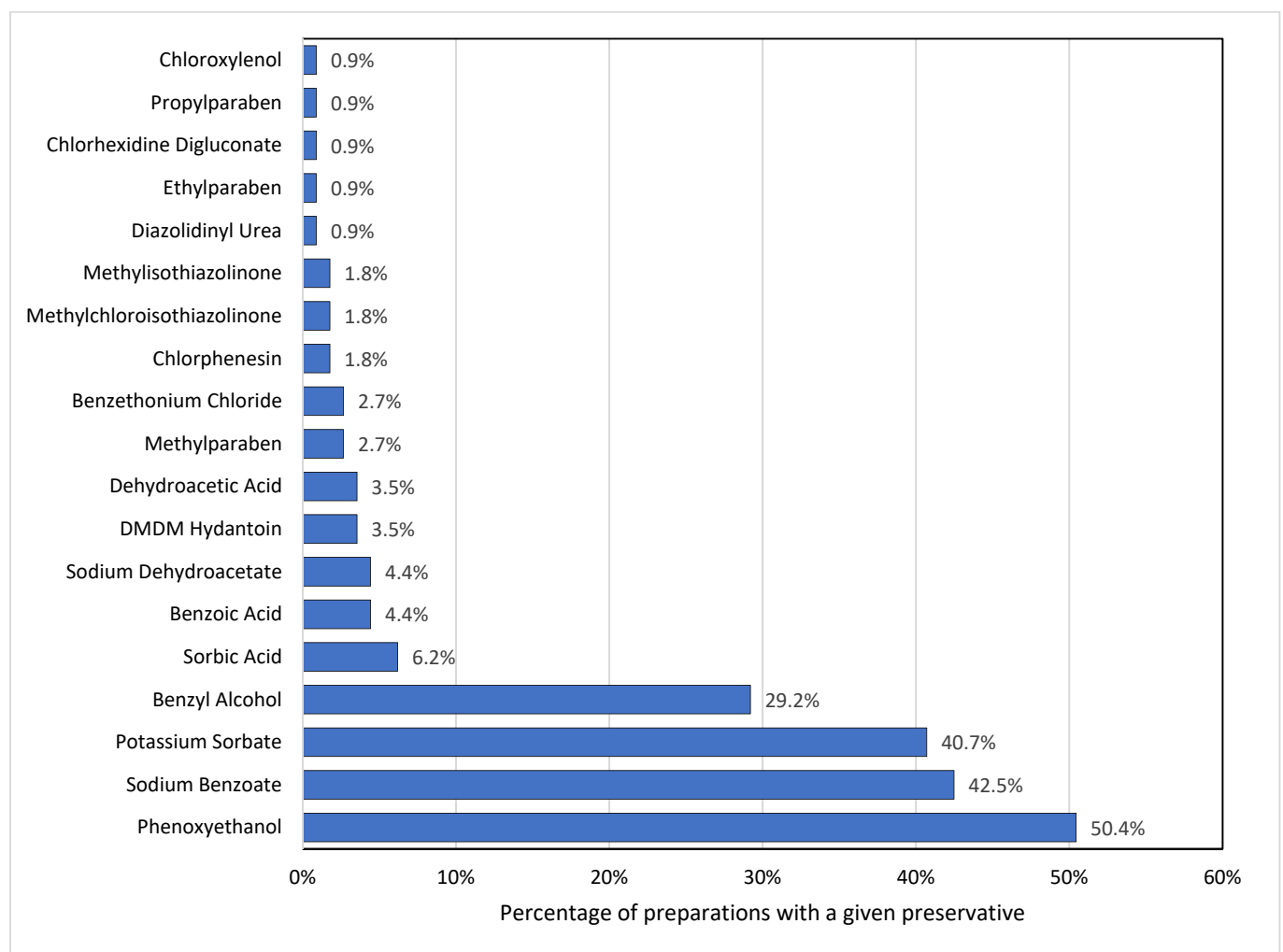


Figure 7. Frequency of use of preservatives in two-preservative products (n = 113).

Finally, the frequencies of the five most common preservatives in the investigated cosmetics, viz. phenoxyethanol, sodium benzoate, potassium sorbate, benzyl alcohol, and methylparaben, were analyzed according to individual cosmetic brand and product category. In each category, a hundred cosmetics from ten different brands were analyzed. As shown in Figures 8–10, cosmetics manufacturers selected various preservatives from among these five. Most brands used five or four of these preservatives in their products; only some brands used only two or three.

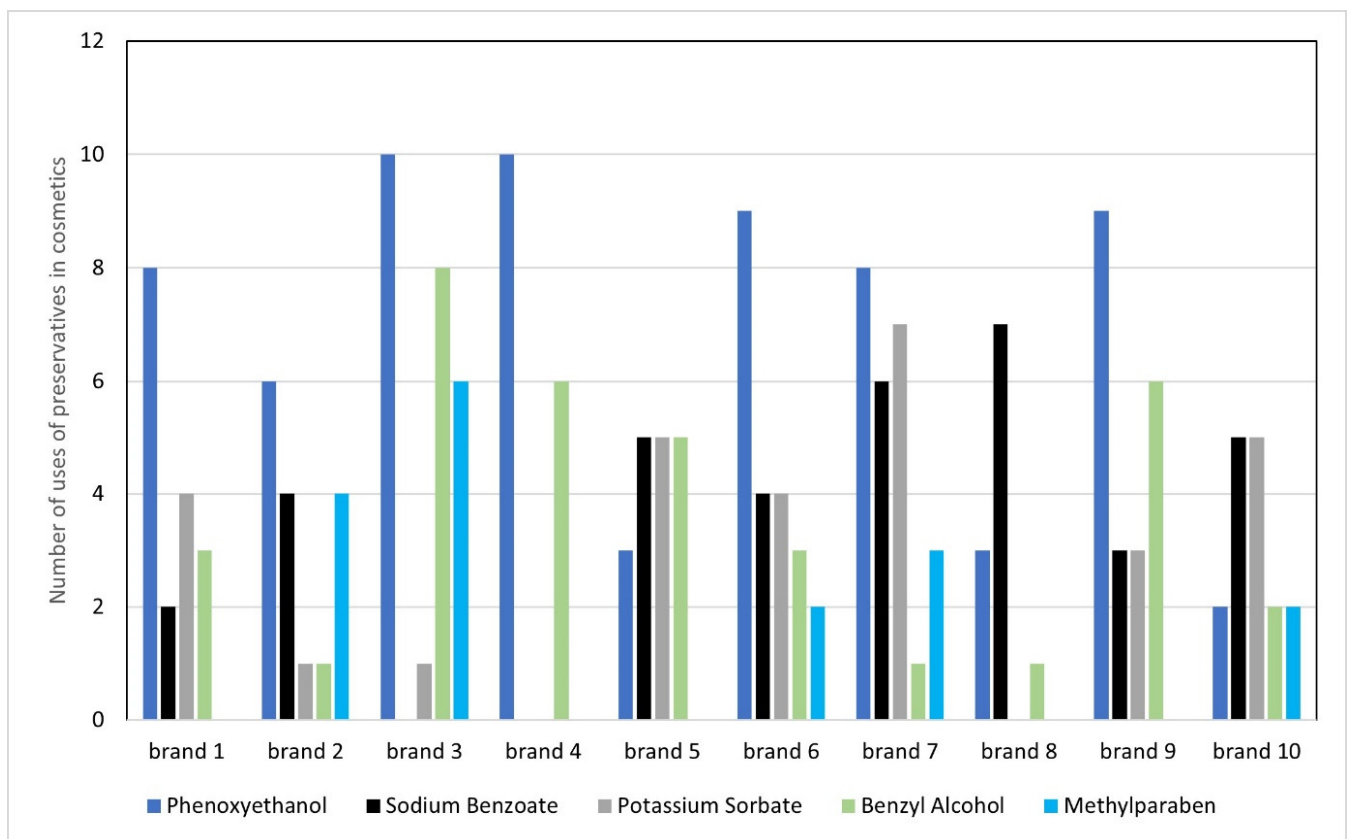


Figure 8. Prevalence of preservatives in body lotions (n = 100) from ten different cosmetic brands.

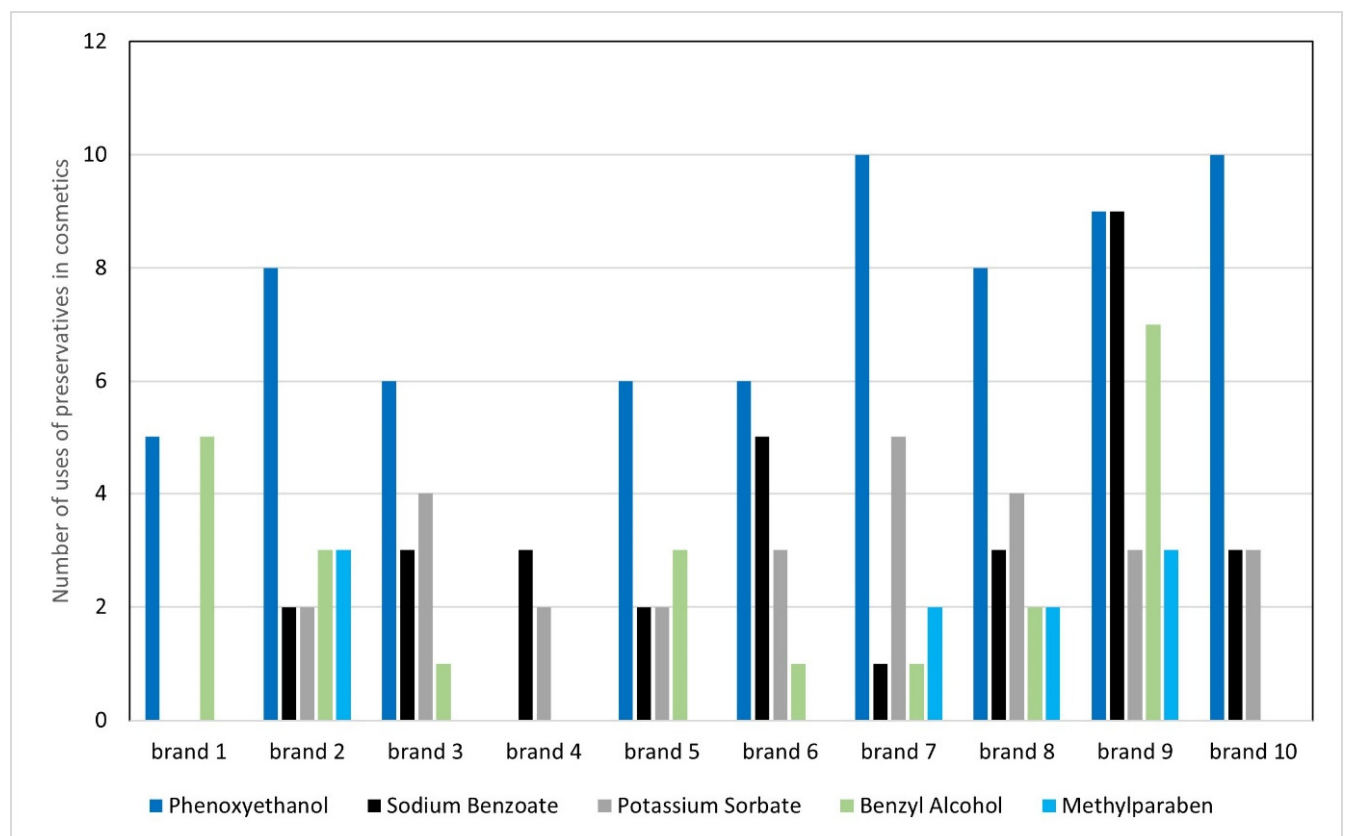


Figure 9. Prevalence of preservatives in face creams (n = 100) from ten different cosmetic brands.

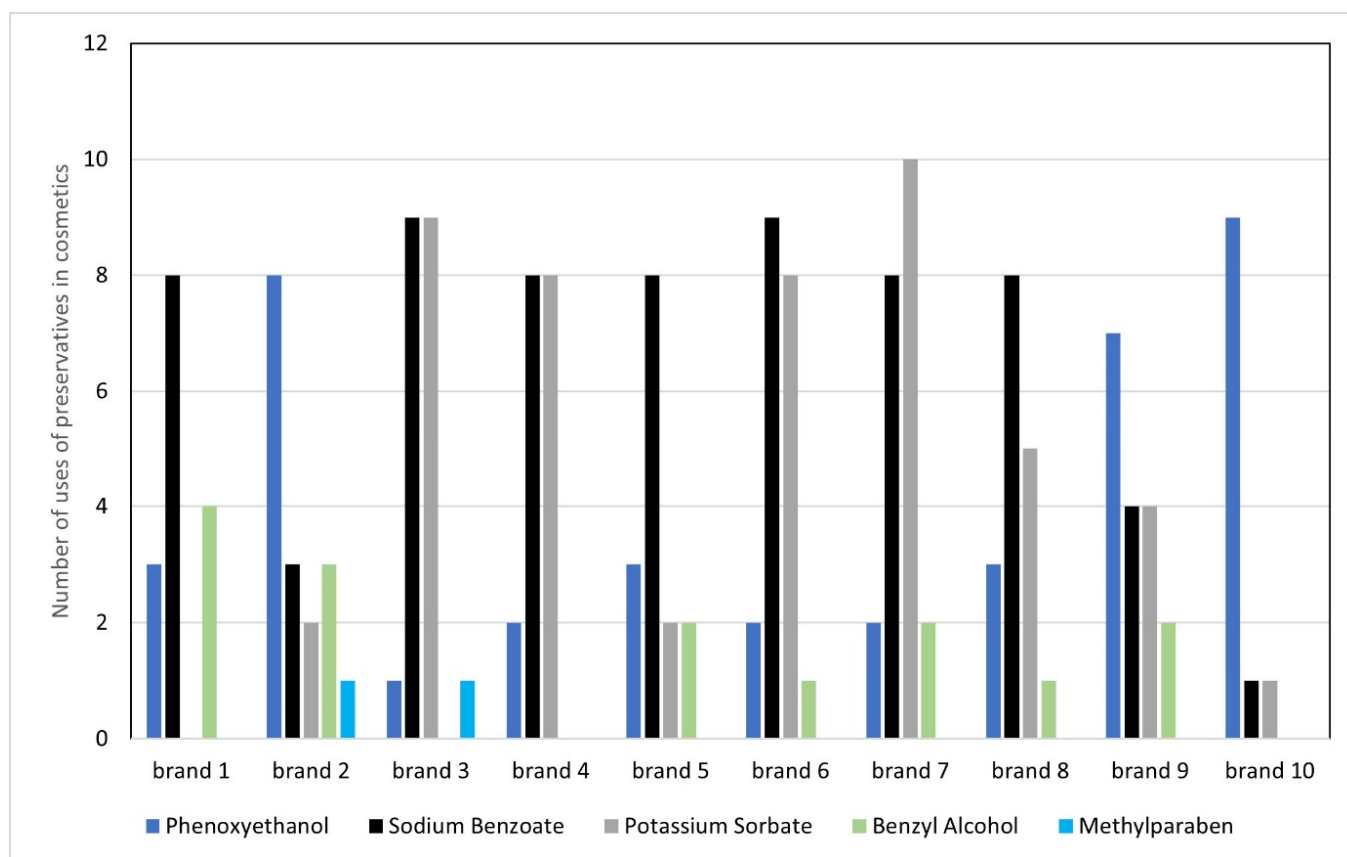


Figure 10. Prevalence of preservatives in rinse-off products ($n = 100$) from ten different cosmetic brands.

3. Materials and Methods

In October 2023, the labels of 325 cosmetic products for adults from international cosmetic brands available online in Poland were reviewed. The INCI compositions of these products were analyzed for the presence of preservatives; the surveyed preservatives were restricted to those listed in Annex V of the Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

Three categories of cosmetic products were overviewed:

- Leave-on cosmetics
 - Body lotions ($n = 100$, 10 products from 10 brands);
 - Face creams ($n = 100$, 10 products from 10 brands).
- Rinse-off cosmetics (gels, foams, liquids, and bath milks; shampoos and hair masks; shaving creams; liquids, gels, and foams for face and eye make-up removal) ($n = 100$, 10 products from 10 brands).
- Mascaras ($n = 25$, 23 brands).

4. Discussion

Panico et al. (2019) reviewed various ingredients in cosmetic products, including preservatives. Surprisingly, only 60% of the tested products contained at least one preservative, including 75% of the analyzed rinse-off products. In the present study, however, as many as 95.4% of the tested cosmetics, and every rinse-off product, contained at least one preservative. The most commonly identified preservatives by Panico et al. (2019) were phenoxyethanol (48.7%), sodium benzoate (35.6%), and potassium sorbate (22%). These three preservatives also dominated in the present study, as their frequencies of use were higher, from 6.6 *p.p.* to 13.7 *p.p.*, amounting to 60.9%, 42.2%, and 35.7%, respectively.

One clear difference was that no benzyl alcohol was used in Italian products, while it was present in 23.4% of the products in Poland. The more common preservatives, methylisothiazolinone (MI)/methylchlorisothiazolinone (MCI) and methylparaben, were used more in the Panico et al. study (9.9% and 15.2%, respectively), than in ours (4.0% and 10.2%, respectively). Similar to our study, sodium benzoate dominated in rinse-off products (57.6%) and phenoxyethanol in leave-on cosmetics (70.1%). However, among the rinse-off products, DMDM hydantoin (14.1%) and triclosan (4.7%) were more popular than in the present study (3.0% and 0%, respectively). For leave-on products, parabens were more popular in the study by Panico et al. than in the present study: methylparaben (20.8% vs. 13.5%), ethylparaben (14.3% vs. 5.5%), propylparaben (10.4% vs. 7.5%), and butylparaben (10.4% vs. 2.0%) [19].

Considerably different results than those in the present study were obtained in a review of preservatives in dermocosmetics (n = 1093), personal hygiene and cosmetic products sold in supermarkets (n = 249) on the Spanish market in 2015 [3]. In dermocosmetics, the most frequently used preservative was phenoxyethanol (43.1%), which was only present in 23.3% of supermarket cosmetics; in our study, it was the most common preservative, being present in 60.9%. The second-most common in Spain was citric acid, although it is not on the list of preservatives in Annex V to Regulation 1223/2009. The second- and third-most common preservatives in the present study were sodium benzoate (42.2%) and potassium sorbate (35.7%), respectively; in comparison, in Spain, sodium benzoate was present in 13.8% of dermocosmetics and 27.3% of supermarket products, while potassium sorbate was present in 8.7% and 13.3%, respectively. Benzyl alcohol was not recorded in the Spanish products but was noted in 23.4% of products in the present study. Methylparaben was identified in 14.5% of each Spanish preparation group, compared to 10.2% in the present study. Interestingly, methylisothiazolinone (MI) and methylchlorisothiazolinone (MCI) were observed in 18.1% and 14.9%, respectively, of Spanish supermarket products [3].

Our present findings indicate that several of the most popular preservatives were present in cosmetic products on the Polish market: phenoxyethanol, sodium benzoate, potassium sorbate, benzyl alcohol, and methylparaben. As such, it is important to be aware of the safety aspects associated with their use.

The most popular preservative in our research was phenoxyethanol. It exhibits a broad spectrum of antimicrobial activity, being effective against Gram-positive bacteria, e.g., *Staphylococcus aureus*, Gram-negative bacteria, e.g., *Pseudomonas aeruginosa*, and yeasts, such as *Candida albicans* and molds. It demonstrates a lower inhibitory effect on the bacteria of the skin microbiome than other preservatives, such as methylparaben and methylisothiazolinone. According to the SCCS (2016), when used as a preservative in cosmetic products at a maximum concentration of 1%, phenoxyethanol is safe for all consumers, including children of all ages [20]. The ECHA (European Chemicals Agency) does not classify phenoxyethanol as a sensitizer and regards it as the best-tolerated preservative used in cosmetics [21]. Phenoxyethanol also does not appear to be particularly allergenic: one study found the frequency of allergy to 1% phenoxyethanol to be only 0.24% in patch tests on a group of 6932 patients [22].

Phenoxyethanol (PE), sodium benzoate (SB), and potassium sorbate (PS) were generally classified as safe, based on a local hazard evaluation including skin sensitization and irritation; however, they were classified as highly (PE and PS) and moderately (SB) irritating to the eye and should be used with caution for cosmetic products that may come into contact with this area. Systemic hazard assessment, comprising acute oral toxicity, carcinogenicity, mutagenicity and genotoxicity, and endocrine activity, found all three preservatives to have a low risk; however, PE was found to demonstrate moderate acute oral toxicity [10].

The dermal absorption rating was found to be 100% for each preservative considered here, although this value must have been overestimated. Due to a lack of reliable data, this worst-case scenario needed to be considered for risk assessment purposes [10]. None of the considered preservatives shows any risk of phototoxicity [10].

Extensive in vitro and in vivo tests confirmed that sorbic acid and its salts were not mutagenic, carcinogenic, teratogenic, and clastogenic. The low toxicity of sorbic acid can be explained by its rapid metabolism by similar pathways to other fatty acids. In humans, a few cases of non-immunological contact urticaria and pseudo-allergy have been reported [23].

Sodium benzoate may cause non-immune contact urticaria, with blisters, erythema, and itching. However, the tests were conducted at concentrations higher than those permitted in cosmetic preparations [24].

Benzyl alcohol (BA), whose presence was identified only in our cosmetics survey, may cause high eye irritation and moderate skin sensitization as well as moderate acute oral toxicity [10]. In turn, methylisothiazolinone (MI) and methylchloroisothiazolinone (MCI), ingredients popular in the Pastor-Nieto et al. study, have a high risk of causing skin sensitization, skin and eye irritation, and acute oral toxicity [10,25].

The skin-irritation potential of phenoxyethanol, the parabens methylparaben and propylparaben, and the formaldehyde releasers imidazolidinyl urea and DMDM hydantoin was evaluated in vivo using the repatch test and repeated open application test (ROAT). Phenoxyethanol and methylparaben showed minor skin irritation potential with a mild erythema reaction, while propylparaben and formaldehyde releasers demonstrated high irritancy potential. The results were confirmed by in vitro keratinocyte cytotoxicity assay, which found phenoxyethanol to be the safest among the tested preservatives. The red-blood-cell (RBC) test showed that at the maximum permissible concentrations, all tested preservatives, except propylparaben, had negligible hemolytic impact on RBCs. Propylparaben exhibited considerable damage to the RBC membrane. The HET-CAM assay indicated that the investigated preservatives had a minor irritating effect on blood vessels [26].

The safety of phenoxyethanol was also confirmed in a study by Bühner et al., in which the skin of premature newborns was disinfected with a solution of 0.1% octenidine and 2% phenoxyethanol. The solution did not cause serious skin damage in premature infants. Although 2-phenoxyethanol was easily absorbed by the skin, it underwent intensive oxidative metabolism to 2-phenoxyacetic acid [27].

Parabens, esters of para-hydroxybenzoic acid, are widely used in cosmetic, medicinal, and food products. They show high antimicrobial activity against fungi and Gram-positive bacteria and weaker activity against Gram-negative bacteria. Their effectiveness increases as the alkyl chain increases [1,28]. Parabens are considered *to be one of the least sensitizing preservatives in commercial use*. When parabens are used on healthy, undamaged skin, their sensitizing effect is low at around 1%, one of the lowest rates among all preservatives. Immediate allergic reactions that can lead to urticaria are very rare and often involve the use of preparations containing parabens on damaged skin [4,8,29]. In animal studies, methylparaben has not shown carcinogenic or teratogenic effects. There are reports of effects of parabens on estrogens, but these are minor and mainly involve butylparaben [1,29].

To sum up, the use of four parabens and their salts is safe when applied in permitted concentration ranges according to Annex V of the Regulation (EC) No. 1223/2009. Maximum concentrations of methylparaben (MeP) and ethylparaben (EtP) in ready-for-use products (0.4% (as acid) for single ester and 0.8% (as acid) for mixture of esters) are higher than for propylparaben (PrP) and butylparaben (BuP) (0.14% (as acid) for the sum of the individual concentrations and 0.8% (as acid) for mixtures of substances (MeP, EtP, PrP, and BuP)). These preservatives should not be used in leave-on products for application on the nappy area of children under three years of age [30].

The present survey also examined the numbers of combined uses of preservatives in a single product. Two-preservative preparations (34.8%) were most commonly used, followed by single-preservative products (25.5%) and three-preservative products (19.4%). Higher numbers of preservatives (from 4 to 8) per single product occurred less often, from 8.9% to 0.9%, respectively. Preservatives are combined to broaden the spectrum of their antimicrobial activity by synergistic effect. The use of combinations of benzyl

alcohol with chlorobutanol and benzyl alcohol with methylparaben may enhance antifungal activity of the formulation compared to the single use of preservatives. The combination of methylparaben and propylparaben increases the antibacterial effect of the preservative system, but also affects the solubility, and enables the protection of both phases of the emulsions [31]. It is speculated that alcohols (benzyl alcohol and pentyl alcohol) exhibit synergistic effects with benzalkonium chloride [32].

5. Conclusions

The Polish adult cosmetics market (part of the EU market) is dominated by several preservatives, particularly aromatic alcohols and carboxylic acids and their salts. The most common substances include phenoxyethanol, sodium benzoate, potassium sorbate and benzyl alcohol. These preservatives are commonly in almost all tested product categories. The most common in leave-on cosmetics are phenoxyethanol (68.0%), sodium benzoate (33.5%), benzyl alcohol (29.5%) and potassium sorbate (29.0%); the most common in rinse-off cosmetics are sodium benzoate (66.0%), potassium sorbate (49.0%) and phenoxyethanol (40.0%); the most common in mascaras are phenoxyethanol (88.0%), potassium sorbate (36.0%) and sodium dehydroacetate (36.0%). Methylparaben (13.5%) was also commonly used in leave-on products.

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