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Effect of the Amount of Phenoxyethanol as a Preservative in Cosmetic Preparations on the Incidence of Skin Irritating Side Effects: A Review

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Abstract: Phenoxyethanol is one of the most widely used preservatives in the cosmetics industry, commonly found in moisturizers, lotions, facial cleansers, and baby care products. Despite its widespread use, published studies have reported inconsistent findings on its irritant potential across product types and concentration ranges, and no comprehensive review has systematically compared phenoxyethanol irritation outcomes across multiple cosmetic formulations and testing methods. This study aims to analyze the irritation potential of phenoxyethanol as a preservative in various cosmetic formulations through a systematic review approach. This study employed a systematic literature review following PRISMA guidelines. Data synthesis was conducted using qualitative comparative analysis to systematically compare irritation test outcomes across phenoxyethanol concentration ranges, cosmetic product types, and irritation testing methods (in vivo and in vitro). Findings were grouped into three concentration categories. In the low-concentration group (0.1%–<0.5%), all formulations showed excellent safety profiles, including a face mist containing 0.2% phenoxyethanol with vitamin E and a body scrub cream containing 0.1% phenoxyethanol with DMDM hydantoin, both of which showed no significant irritation in in vivo tests. In the medium concentration group (0.5%–1%), all formulations, including moisturizing gel, body lotion, deodorant stick, blush on cream, hair tonic, and sunscreen lotion, consistently showed no significant irritation across in vivo human panelist tests, animal models, and in vitro HET-CAM testing. In contrast, the high concentration group (>1%), represented by a coffee grounds body scrub cream at 1.5%–1.6%, showed increased irritation. These findings confirm that phenoxyethanol at concentrations of 0.1%–1% is safe and does not cause significant irritation across various cosmetic preparations, supporting the 1% maximum limit established by BPOM Regulation Number 25 of 2025. Exceeding this limit increases the risk of irritation, particularly for individuals with sensitive skin.

Keywords: Concentration; Cosmetics; Phenoxyethanol; Preservative; Skin Irritation.

Introduction

Main Along with the times, cosmetics are a daily necessity. Beauty products are among the human needs that support appearance and personal hygiene habits, with various types and brands of facial care products widely available on the market [1]. Looking beautiful is the dream of teenagers who are growing up towards adulthood. Nowadays, teenagers are more comfortable dressing up. Therefore, many adolescent students use skin care and cosmetic products at school [2]. Cosmetics are ingredients or preparations intended for use on the external parts of the human body, such as the epidermis, hair, nails, lips, and external genital organs, or teeth and oral mucous membranes, especially to clean, fragrance, change the appearance and/or improve body odor, or protect or maintain the body in good condition [3].

Cosmetics are classified by application, including decorative cosmetics that conceal facial imperfections to provide a more attractive (aesthetic) appearance and offer psychological benefits, such as self-confidence [4]. Another type of cosmetic is skin care, which aims to maintain skin hygiene and health [5]. The types of cosmetics included in facial care, based on their application, are cleansers, toners, moisturisers, horn cell peels (peeling), massage creams, and masks. Cosmetic treatments are for the face, such as moisturizers, toners, and serums. Cosmetics for the body, such as bath soaps, body lotions, scrubs and others. As well as decorative cosmetics such as lipstick, blush, and foundation [6].

Most cosmetic formulations use organic compositions and contain a lot of water. Cosmetic products can be degraded by microorganisms. Microbial contamination in cosmetics poses a health risk, as it can cause irritation or infection, especially in damaged skin, eyes, or babies [7]. In cosmetic formulations, one essential component must be present: preservatives. Preservatives are one of the ingredients needed in the formulation of creams. The addition of preservatives as antimicrobials helps prevent damage to the cream caused by microorganisms [8]. Preservatives are used to increase the shelf life of the formulation and inhibit the growth of microorganisms. Thus, preservatives prevent damage from bacteria (Gram-positive and Gram-negative), fungi, and yeast that can cause disease or otherwise interfere with the product's smooth final appearance [9].

The different types of preservatives available, phenoxyethanol is one of the most commonly used in the cosmetics industry. Phenoxyethanol is an organic compound that has effective antimicrobial capabilities against various

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microorganisms. This compound is widely used in various cosmetic products such as moisturizers, facial soaps, and lotions, as well as in baby care products [10]. The use of phenoxyethanol in cosmetics has been strictly regulated by the Food and Drug Supervisory Agency Regulation, specifically Regulation of the Food and Drug Supervisory Agency Number 25 of 2025 concerning Technical Requirements for Cosmetic Ingredients, which states that phenoxyethanol is safe for consumers, including children. All ages when used as a preservative in cosmetic products with a maximum concentration of 1% [11]. This phenoxyethanol can cause adverse effects when added at more than 1% in cosmetics. Side effects include irritation of the skin and eyes, and allergic reactions [12].

Skin irritation is one of the main issues in the safety of cosmetic products, as it can cause symptoms such as peeling skin, redness and burning, permanent brain damage, kidney damage, and cancer [13]. Although safe limits for phenoxyethanol have been set by regulations, published studies have reported inconsistent findings regarding its potential irritant effects across different product types and concentrations. Testing of phenoxytanol irritation potential using in vitro and in vivo methods at regulatedly permitted concentrations, and found that phenoxytanol persistently produced an erythema response seen in repeated exposure tests, indicating the presence of cumulative irritation potential [14]. Meanwhile, other tests reported that cases of allergic contact dermatitis due to phenoxyethanol are relatively rare, but emphasized that this condition still needs to be watched out for because it can develop into a prolonged skin disease if not detected early. The differences in findings across these studies indicate that the safety profile of phenoxitanol in different cosmetic formulations and at different concentrations still requires more systematic and comprehensive study [15].

The difference in the research underlying this study is that there is no review study that specifically analyzes and compares the results of phenoxyethanol irritant tests, both in vitro and in vivo, from various types of cosmetic formulations at various concentrations below the maximum limit of 1%. Most of the available studies are partial, reporting only one product type, one test method, or a specific concentration range, so they do not provide a comprehensive picture of the relationship among phenoxyethanol concentrations, the type of cosmetic product, and the level of irritation caused. In addition, highlighting that the safety of phenoxyethanol in vulnerable groups such as infants and individuals with sensitive skin is still a scientific debate and has not been studied specifically in existing studies [16].

Based on these differences, this study aims to analyze the irritating potential of phenoxyethanol as a preservative in cosmetic formulations through a systematic review of studies that report the results of irritation tests, both in vitro and in vivo, on various types of products and concentrations. In contrast to previous partial studies, this review provides a new scientific contribution through a more comprehensive cross-product synthesis and cross-testing method, producing a more complete picture of the safety profile of phenoxyethanol in cosmetics. The results of this study are expected to provide accurate and useful scientific information for the cosmetics industry in formulating products that are safe for consumers.

Research Methods

The method used to collect the data for this is a systematic literature review. This process involves searching for and collecting previously published articles from various scientific journals. The literature search follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to ensure transparency and reproducibility in article selection. The article search was done on Google Scholar. The search was limited to articles published between 2016 and 2026 to ensure the relevance and up-to-date nature of the data used. The keywords used in the search were phenoxyethanol, irritation test, and cosmetics, combined using the Boolean AND and OR operators. The articles obtained were then selected based on the inclusion criteria that had been set, namely: (1) Experimental journal of cosmetics containing phenoxyethanol, (2) Cosmetic preparations listed the amount of phenoxyethanol used, and (3) Cosmetic preparations were subjected to irritation tests. Articles are excluded if they do not include specific concentrations of phenoxyethanol, do not report the results of irritation tests quantitatively or qualitatively, are duplicate articles, or are opinions, editorials, and case reports without experimental data. The Population, Intervention, Control, and Outcomes (PICO) framework was used to establish inclusion criteria for this study. Table 1 presents the PICO framework applied in this study. The obtained articles are selected to determine their relevance to the desired topic. After identifying the relevant articles, they are analyzed to get the results.

Table 1. PICO Framework

PICO	Framework
P (Population)	Cosmetic preparations containing phenoxyethanol
I (Intervention)	Testing of skin irritation in cosmetic preparations containing phenoxyethanol
C (Comparison)	Comparison between different cosmetic products
O (Outcome)	Testing of skin irritation produced by phenoxyethanol in cosmetic preparations

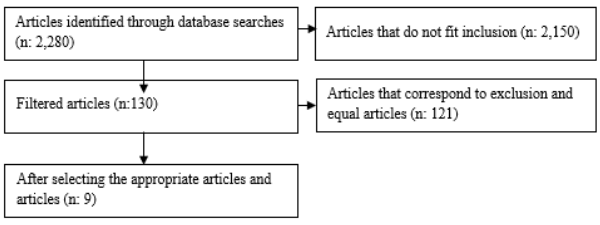

Figure 1. Article search flow process

Results and Discussion

A study of nine research journals on cosmetic formulations found that phenoxethanol concentrations varied widely, ranging from 0.1% to 1.6%. To facilitate systematic analysis, the findings were grouped by concentration range and irritant test methods, namely the in vivo method (human paste test and tests on test animals) and the in vitro method (HET-CAM). This grouping allows for

the identification of patterns of relationships between phenoxyethanol concentrations, product types, and reported levels of irritation in a more systematic and comprehensive manner

Table 2. Phenoxyethanol concentration in cosmetic products

Cosmetic Products	Phenoxytanol Concentration (%)	Irritation Test Method	Irritation Test
Watermelon mesocarp extract moisturizing gel [27]	0,5%	Patch test (11 panelis, 2 jam)	There was no irritation reaction and it was considered to be at a safe concentration.
Sunscreen body lotion chitosan & white turmeric [29]	1%	Direct application (30 respondents, 4 hours)	There was no irritation reaction and it was considered to be at a safe concentration.
Avocado peel extract body scrub cream [21]	0,1% + DMDM hydantoin 0,1%	Patch test (12 panelis)	There was no irritation reaction and it was considered to be at a safe concentration.
Deodorant stick ektrak mentimun [30]	1%	Smudging (30 panelists before and after cycling test)	There was no irritation reaction and it was considered to be at a safe concentration.
Green tea leaf water fraction hair tonic [25]	0,8%	Dermal acute irritation test (rabbits, 72 hours)	There was no irritation reaction and it was considered to be at a safe concentration.
Coffee grounds body scrub cream [40]	1,5 – 1,6 %	Applying (30 panelists, 20 minutes)	A small number still show a positive reaction, indicating a higher potential for irritation.
Blush on cream ekstrak wortel [32]	1%	Open patch test (10 panelists)	There was no irritation reaction and it was considered to be at a safe concentration.
Face mist of kenikir leaf extract [17]	0,2% + Vitamin E 2%	Facial application (3 volunteers, 2 hours, 3 days)	There was no irritation reaction and it was considered to be at a safe concentration.
Lotion tabir surya BZP-4 & OCT [33]	0,5%	HET-CAM (In vitro, 3 replikasi)	There was no irritation reaction and it was considered to be at a safe concentration.

In the low-concentration group, all formulations studied showed an excellent safety profile. The lowest concentration was found in a face mist formulation of kenikir leaf extract (Cosmos caudatus Kunth.) containing 0.2% phenoxyethanol and 2% vitamin E as an additional preservative; the three-day irritation test showed no irritation among all volunteers [17]. Vitamin E is one of the ingredients that can be used as a preservative because of its ability to prevent oxidation processes. Vitamin E is the main defence against oxygen damage [18]. The combination of the two can provide broad-spectrum antimicrobial activity that inhibits the growth of gram-positive, gram-negative, and fungal bacteria [19]. Oxidation can be inhibited by using antioxidants in combination with protection against temperature, air, and light [18].

At a concentration of 0.1%, the body scrub cream formulation based on avocado peel extract (Persea americana M.) uses a combination of phenoxyethanol 0.1% and DMDM hydantoin 0.1% as a dual preservative system [20][21]. The irritation test was carried out using the patch test method on 12 semi-trained panelists. The results showed no significant irritant reactions in the entire formula. However, there was one panelist who experienced mild redness caused by excessive rubbing during the application of the preparation, not due to the content of ingredients in the formulation. DMDM hydantoin functions as a highly water-soluble preservative and has broad-spectrum antimicrobial activity, most effective against fungi, yeast, and gram-positive and gram-negative bacteria [22]. The concentration of DMDM hydantoin used is 0.1%, the lowest within the safe range for cosmetic preparations (0.1%–1%) [23]. The combination of phenoxyethanol and DMDM hydantoin at this very low concentration proves that a dual preservation system can maintain antimicrobial effectiveness without increasing the risk of irritation.

Overall, both studies at these low concentrations confirmed that using phenoxyethanol at concentrations below 0.5%, combined with antioxidants or secondary preservatives, had an excellent safety profile. The lower the concentration of phenoxyethanol used, the less likely it is to cause a skin irritant response, especially when combined with ingredients with protective and antioxidant properties. Similar results were also found in a water-based formulation of green tea leaf water fraction containing 0.8% phenoxyethanol, where a 72-hour dermal acute irritation test in rabbits showed no erythema or oedema [24][25]. This test was carried out according to the BPOM 2014 guidelines, with observations at the 1st, 24th, 48th, and 72nd hours after the sticker was released, providing more physiologically controlled data. In addition to the irritation data, the study also reported the results of the Total Plate Number (ALT) test, showing 0 colonies/mL before and after a one-month stability test, which proved the effectiveness of phenoxyethanol 0.8% as a preservative capable of maintaining the microbiological sterility of the preparation [24][25].

At a concentration of 1%, phenoxyethanol is used in several cosmetic preparations such as watermelon mesocarp

extract moisturizing gel, chitosan and white turmeric combination body lotion, cucumber extract deodorant stick, and carrot extract blush on cream. In the watermelon mesocarp extract moisturizing gel with phenoxyethanol 0.5%, irritation tests on 11 panelists using the patch test method on the skin behind the ear showed no irritation reaction on the entire formula [26][27]. The use of phenoxytanol at this concentration is in accordance with the Handbook of Pharmaceutical Excipients guidelines which set the range of phenoxyethanol use in topical preparations between 0.5%–1.0%, so that these safe results can be predicted pharmaceutically. The same thing happened with the formulation of a body lotion combining chitosan and white turmeric with 1% phenoxyethanol, in which no side effects, such as redness, itching, or swelling, were observed among 30 respondents after 4 hours of use [28][29]. Phenoxyethanol has relatively low skin sensitivity, so its use at a concentration of 1% across various preparation bases consistently yields a good safety profile

In the formulation of cucumber fruit extract deodorant sticks that also used 1% phenoxyethanol, the irritation test of 30 panelists before and after the 6-cycle cycling test showed consistent results, i.e. none of the panelists experienced any irritation symptoms, with a percentage of non-irritation reaching 100% for all formulas [30]. The consistency of these results, even after the simulation of extreme storage conditions was significant because it indicated that the 1% phenoxyethanol in the matrix of stick preparations containing natural wax (beeswax and candelilla wax) did not degrade into irritant compounds during the cycling test process. Similar results were found in carrot extract blush on cream with 1% phenoxyethanol, where an open-label patch test of 10 panelists showed no redness, itching, or swelling [31][32]. Overall, the use of phenoxyethanol at concentrations of up to 1% in various forms of cosmetic preparations did not cause significant irritation to the panelists' skin.

Both results indicate that using phenoxyethanol at concentrations below 1% is likely safe and does not trigger significant irritant reactions. According to the SCCS (Scientific Committee on Consumer Safety) report, the aggregate value of phenoxyethanol at a maximum concentration of 1% is 2.69 mg/kg body weight/day when a consumer uses various cosmetic products containing the same preservative, including rinse-off and leave-on products [16]. This value remains within the acceptable safety margin, supporting the toxicological basis for BPOM's 1% limit in Regulation Number 25 of 2025 [11].

Although all studies in this concentration range showed safe results, methodological differences should be noted. The number of panelists varied between 10–30 people, and the duration of observations ranged from 2–72 hours. This difference makes it difficult to make direct comparisons between studies and limits the ability to detect cumulative irritations or those that appear only in individuals with sensitive skin.

In comparison, sunscreen formulations use 0.5% phenoxyethanol as a preservative [33]. The irritation test was carried out using the HET-CAM (Hen's Egg Test–Chorioallantoic Membrane) method, which is an alternative non-animal method that uses the chorioallantoic membrane of fertile chicken eggs as a model. Observed parameters include hemorrhagic, lytic, and coagulative changes in the membrane, with three replications per formula [34][35]. The results showed that the single formulas BZP-4 1% (F1) and OCT 1% (F2) caused moderate irritation, respectively, and that this effect worsened with increasing concentration. In contrast, the combination formula BZP-4 1% + OCT 1% (F3) was non-irritating with an HET-CAM score of 0.98 ± 0.04 [36][37]. This is thought to be due to the emollient properties of OCT, which moderate the irritant potential of BZP-4, as well as to the contribution of the PEG-7 GC emulsifier, which is known not to irritate the skin.

This finding has important scientific implications: namely, that the irritating effect is not solely determined by phenoxyethanol as a preservative but is strongly influenced by the overall composition of the formulation. Synergistic interactions among active ingredients, emulsifiers, and other excipients can significantly modulate the irritation response, both increasing and decreasing its potential. It should be noted that the HET-CAM method, although internationally standardized and more ethical because it does not use mammals, has limitations in the form of physiological differences between the chorioalantois membrane and human skin, so the results of this test cannot be fully equated with the direct skin irritation test.

Slightly different findings were observed in coffee grounds-based cream scrub formulations that used phenoxyethanol at concentrations of 1.5% for Formula 1 and 1.6% for Formula 2, the highest concentration among all the journals reviewed [38][39]. An irritation test of 30 panelists for 20 minutes showed that in Formula 1, as many as 10% of the panelists experienced a reddish sensation, 5% experienced an itchy sensation, and 7% felt a burning sensation. Meanwhile, in Formula 2, as many as 5% of the panelists experienced redness, 3% experienced an itchy sensation, and 4% felt a burning sensation [40].

Although the overall level of irritation was relatively low and most of the panelists did not experience a reaction, these findings suggest a tendency to increase the incidence of irritation as the concentration of phenoxyethanol used increases, especially when concentrations exceed the maximum recommended limit of 1%. This is an important concern because using phenoxyethanol at concentrations above the recommended level can increase the risk of irritation in consumers, especially those with sensitive skin.

Facial skin types are classified into five categories: normal, oily, dry, combination, and sensitive [41]. Sensitive skin types are more sensitive to various ingredients, so the irritant response to phenoxyethanol can vary significantly between individuals. In the cosmetics industry, combination skin is used to describe skin with an oilier T-zone (forehead, nose, and chin), while skin on other parts of the body is usually smoother or drier [42][43]. The use of cosmetics must be adjusted to a person's skin type; if the cosmetics are not suitable for their skin type, they can cause acne, skin redness, or skin irritation [44]. This underscores the importance of considering skin-type variables in cosmetic safety studies, which, unfortunately, are not specifically addressed by most of the journals reviewed.

A review of nine journals revealed three different methodological approaches. The patch testing and direct application methods on humans were used by eight journals, with a total of 3–30 panellists and a duration of 20 minutes to 72 hours, providing high clinical relevance but with low standardisation. The dermal acute test method in rabbits

(Hair Tonic Journal) produces more controlled data with BPOM standard protocols, but the physiological differences in skin between rabbits and humans need to be considered. The HET-CAM method is the most internationally standardized approach with objective numerical score quantification, but it does not fully represent the response of human skin.

Some important limitations are also worth noting. First, none of the journals specifically included panelists with sensitive skin as a separate subgroup, even though these groups may show different responses to phenoxyethanol. Second, the test's highly variable duration limits the ability to detect cumulative irritation from long-term exposure. Third, most studies did not report the purity or technical specifications of the phenoxyethanol used, which may affect the consistency of results across laboratories. Fourth, the small number of panelists in some studies limits the statistical power and representativeness of the results.

Cross-analysis of the nine journals revealed a scientifically relevant pattern. Data from all journals consistently show that phenoxethanol concentrations of 0.1%–1% in various cosmetic preparations have been proven safe and do not cause significant irritation in human or animal skin. In the results contained above, phenoxyethanol can act as an irritant at a specific concentration. In the skin, phenoxyethanol can penetrate the stratum corneum layer and reach the deeper layers of the epidermis. This substance can disrupt the natural lipid structure in the outer layer of the skin, which acts as a moisture barrier and protective against foreign substances. As a result, the integrity of the skin's protective gear decreases, making it more susceptible to damage [45].

In addition to concentration, formulation type and ingredient combinations have been shown to significantly affect the irritation profile. The use of phenoxyethanol, combined with secondary preservatives such as DMDM hydantoin or antioxidants such as vitamin E at low concentrations, results in an effective and safe system. On the other hand, the HET-CAM study demonstrates that the appropriate selection of emulsifiers and active ingredients can eliminate potential irritation, even when the main active ingredient is an irritant. This confirms that the safety evaluation of cosmetic preparations must be holistic, considering the entire formulation composition rather than just the concentration of preservatives.

The findings of this study have important practical implications for the cosmetics industry. The use of phenoxytanol at concentrations of 0.1%–1% in various cosmetic preparations has been shown to be safe, but formulations exceeding the 1% limit are associated with an increased incidence of irritation, warranting monitoring. The combination of phenoxyethanol with secondary preservatives or antioxidants can be an effective strategy for maintaining antimicrobial activity at lower, safer concentrations. Going forward, studies with a larger number of panelists, more uniform and longer test durations, and those specifically involving sensitive skin groups and vulnerable populations such as infants, are needed to produce more comprehensive and representative phenoxiethanol safety data for all consumer segments.

Conclusion

Based on a systematic review of nine research journals of cosmetic formulations, phenoxyethanol at concentrations of 0.1% to 1% in various cosmetic preparations, including face mist, hair tonic, moisturizing gel, body lotion, deodorant stick, blush on cream, sunscreen lotion, and body scrub cream, was proven to be safe and did not cause significant irritation in both in vivo and in vitro testing. This finding is consistent with the 1% maximum limit set by BPOM in Regulation Number 25 of 2025 and is supported by the SCCS report, which states that the aggregate value of phenoxyethanol at a concentration of 1% remains within safe limits. In contrast, the use of phenoxytanol at concentrations above 1% in coffee grounds cream scrub formulations (1.5% and 1.6%) was associated with an increased incidence of irritation, including redness, itching, and a burning sensation, which underscores the importance of adherence to regulatory concentration limits. The combination of phenoxyethanol with secondary preservatives or antioxidants at low concentrations has been shown to be an effective strategy in maintaining antimicrobial activity while minimizing the risk of irritation. Further research is recommended to conduct long-term irritation tests with standardized protocols, as well as special studies on vulnerable populations such as infants and individuals with sensitive skin.

Author's Contribution

A. Az-zahraa & D. Ratnasari: provided guidance and supervision throughout the research process for this review article. She also offered valuable feedback and revisions to ensure the manuscript's quality and accuracy. D. Valentin, T.N. Cahyani, T.P. Shella and M.A. Adzkia: contributed to the search and selection of sample data used in this review article.

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