IN-DEPTH REVIEW

Allergens Causing Allergic Contact Dermatitis in Cosmetic Products: A Systematic Review

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ABSTRACT

Background: The increasing use of cosmetics worldwide has led to a rise in allergic reactions, particularly due to inadequate risk assessment. Identifying common allergens in cosmetic products causing dermatitis is crucial for effective prevention and management strategies.

Objectives: This systematic review aims to determine the list of allergens that most commonly cause allergic contact dermatitis in cosmetic products and to find the patch test positivity rate for cosmetic products.

Methods: This systematic review, following the PRISMA guidelines, investigated patch test results on cosmetic-induced contact dermatitis from January 2013 to September 2023 on PubMed, Cochrane, and Medline databases. Inclusion criteria comprised retrospective cohort and clinical trial studies reporting patch test positivity rates and positive allergens in cosmetics, with eligibility determined through independent screening, full-text evaluation, and data extraction. Exclusion criteria comprised abstract-only publications, non-English or Indonesian languages, review articles, and studies with incomplete text.

Result: 13 studies were included out of 2,162 initially screened articles, involving 111,097 participants. The selected studies encompassed ten retrospective studies, and three clinical trials conducted in various locations, including India, Brazil, North America, Korea, Sweden, and the Czech Republic. The patch test positivity rate ranged from 13% to 100%. The predominant allergens identified in cosmetics were nickel sulfate, fragrance mix I, cobalt chloride, para-phenylenediamine base, potassium dichromate, and balsam of Peru. **Conclusion:** This systematic review highlights the diversity in patch test positivity rates and identifies key allergens responsible for allergic contact dermatitis in cosmetic products, emphasizing the need for comprehensive evaluation and awareness of cosmetic safety.

INTRODUCTION

Cosmetics are materials or preparations applied to the skin, mouth, hair and nails for cleaning, beautifying the appearance, providing a pleasant aroma, or providing protection without affecting the structure and function of the body. The ingredients or preparations included in cosmetics include perfume, deodorant, lipstick, moisturizer, hair dye, nail varnishes, mascara, eye shadow, sunscreen, soap, shampoo, and toothpaste.^{1,2} Nowadays, the development of

the cosmetics industry has resulted in high cosmetic consumption behavior. In Europe, allergic reactions to cosmetics are increasing due to inadequate pre-sale risk assessment trials.^{3–5} Subsequently, it is estimated that 95% of the female population uses cosmetics regularly every day, and at least 1-3% of the female population is allergic to cosmetics.^{1,6}

The patch test is an examination to confirm the presence of allergies and identify allergens that cause contact dermatitis in cosmetics.7 This is done by exposing individuals with allergic symptoms to various allergens that cause skin reactions.⁸ Patch tests with standard allergens can detect allergens in almost 70-80% of contact dermatitis cases.⁹ In extensive lesions, patch tests are not recommended for contact dermatitis testing.^{10,11} Previous studies show that the most common allergens that cause allergic contact dermatitis in cosmetics preservatives include nickel sulfate. methylisothiazolinone, formaldehyde, and pphenvlenediamine, as well as several fragrance ingredients such as balsam of Peru fragrance-mix.² and Subsequently, retrospective data collected on patch test patients in Europe in 2013-2014 by the European Surveillance System on Contact Allergies (ESSCA) shows that nickel is the allergen with the highest frequency of positive reactions.¹²

This systematic review aims to determine the list of allergens that most commonly cause allergic contact dermatitis in cosmetic products and to find the patch test positivity rate for cosmetic products.

METHODS

Study Design

This systematic review uses the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) approach. A search was conducted for studies of patch test results on contact dermatitis due to cosmetics from January 2013 to September 2023, with the following keywords: "patch testing" "cosmetic" dermatitis OR patch test dermatitis OR "patch test" "cosmetic" "cosmetic dermatitis" OR patch test on "cosmetic dermatitis" OR patch test on cosmetic dermatitis. The search strategy used the PubMed, Cochrane and Medline databases. All keywords used to search for articles in each database are presented in Table 1.

Eligibility Criteria

The next step was to establish the inclusion and exclusion criteria. In this study, the articles included met the inclusion criteria, including the type of study (retrospective cohort, clinical trial, and case-report study) and reported results (positivity rate patch test, positive allergens in cosmetic products). Subsequently, exclusion criteria are articles with incomplete text and languages other than Indonesian and English, review articles or non-original research. Furthermore, studies involving non-human subjects, nonpeer-reviewed sources. duplicate publications, and those lacking sufficient data were also excluded.

Selection Process

TO and SW independently screened titles and abstracts to identify suitable studies during selection. Full-text papers were found and evaluated for eligibility using the inclusion and exclusion criteria. Any disagreements among the reviewers were handled through mutual discussion and then with the consensus of the third reviewer (HK).

Database	MeSH Terms	Number of articles
PubMed	(((((((("patch testing"[All Fields] AND "cosmetic"[All Fields]) AND ("dermatiti"[All Fields] OR "dermatitis"[MeSH Terms] OR "dermatitis"[All Fields] OR "dermatitides"[All Fields])) OR ("patch tests"[MeSH Terms] OR ("patch"[All Fields] AND "tests"[All Fields]) OR "patch tests"[All Fields] OR ("patch"[All Fields] AND "test"[All Fields]) OR "patch test"[All Fields])) AND "cosmetic"[All Fields]) OR "patch test"[All Fields])) AND "cosmetic"[All Fields]) AND ("dermatiti"[All Fields] OR "dermatitis"[MeSH Terms] OR "dermatitis"[All Fields] OR "dermatitides"[All Fields])) OR "patch test"[All Fields]) AND "cosmetic dermatitis"[All Fields]) OR ("patch tests"[MeSH Terms] OR ("patch"[All Fields]) OR ("patch tests"[MeSH Terms] OR ("patch"[All Fields]) OR ("patch tests"[MeSH Terms] OR ("patch"[All Fields]) OR ("patch tests"[All Fields]) OR "patch test"[All Fields]) AND "cosmetic dermatitis"[All Fields] AND "tests"[All Fields]) OR "patch tests"[All Fields] OR ("patch"[All Fields] AND "test"[All Fields]) OR "patch test"[All Fields])) AND "cosmetic dermatitis"[All Fields]) OR (("patch tests"[MeSH Terms] OR ("patch"[All Fields]) OR (("patch tests"[MeSH Terms] OR ("patch"[All Fields]) OR ("patch"[All Fields]) AND "test"[All Fields]) OR "tests"[All Fields]) AND "cosmetical"[All Fields] OR ("patch"[All Fields]) AND ("cosmetical"[All Fields] OR action] OR "cosmetics"[MeSH Terms] OR "cosmetics"[All Fields] OR "cosmetics"[All Fields]) OR "patch test"[All Fields]) AND ("cosmetical"[All Fields] OR "cosmetically"[All Fields] OR "cosmetics"[All Fields] OR "cosmetics"[All Fields]) AND ("dermatiti"[All Fields] OR "dermatitis"[All Fields])))	2162
Cochrane Database	"patch test" AND "cosmetics"	52
Medline	"patch test" AND "cosmetics"	43

Table 1. Medical Subject Heading (MeSH) terms used to search for articles in each database.

Data Extraction

Data extraction and study search results were obtained by taking information from studies, including author and year of publication, study design, study location, number of subjects, patch test positivity rate, allergen results, and cosmetic products discussed in the study. Next, the findings in the studies were recorded via Microsoft Excel and the three most common allergens that cause allergic contact dermatitis in cosmetic products were taken from each article. Two reviewers (TO and SW) independently extracted data. Any disagreements among the reviewers were handled through mutual discussion and then with the consensus of the third reviewer (HK).

RESULTS

Study Selection

From the search results, a total of 2,257 articles were found in the initial search from three databases, namely PubMed 2,162 articles, Cochrane 52 articles and Medline 43 articles, then the articles were discarded after eliminating 95 duplicate articles. A total of 2,162 articles were screened, and 2,067 were excluded based on title, abstract and

year of publication. Ninety-three articles were assessed for eligibility, and 13 studies were included in the systematic review (**Figure 1**).

Study Characteristics

The studies selected in this systematic review consisted of 10 retrospective studies and three clinical trials. The study location was in India, four studies; Brazil and North America, three studies each; and Korea, Sweden, Czech Republic, one study each. The study subjects in this systematic review totaled 111,097 who were patch-tested on cosmetic products in the form of hair dye, fragrance/perfume. nail varnish, soap, shampoo, deodorant, hair care products, moisturizing cream, henna tattoos, traditional foundation. perfume. kumkum/bindi. sunscreen, eye care products, lip care products and makeup. The patch test positivity rate ranges from 13%-100% based on the type of study used (Table 2)

Allergens Causing Allergic Contact Dermatitis in Cosmetic Products

In this review, the allergens most commonly found in cosmetic products were nickel sulfate and fragrance mix I (six studies), cobalt chloride (four studies), paraphenylenediamine base, potassium dichromate and balsam of Peru (three studies) (**Table 3**).

DISCUSSION

Cosmetics are substances or preparations used on the outside of the body for the specific purpose of cleaning, beautifying, increasing attractiveness and changing appearance without affecting the structure or function of the body.¹ Women, on average, use around 12 cosmetic products per day, which can contain up to 168 different components, while men use six cosmetic products with a maximum of 85 ingredients.² The prevalence of cosmetic ingredient contact dermatitis is more common in women aged 20 to 55 due to the use of cosmetics and care products.¹²

Patch testing is a method used to identify the internationally defined causative agent of contact dermatitis.¹³ Repeat allergic exposure to the same allergen or hapten results in activation of hapten-specific T cells, results in marked signs which of hypersensitivity 48-72 hours after exposure to the allergen or hapten.¹⁴ Sensitized have antigen-specific individuals Т lymphocytes that cause a reaction when the antigen is exposed to the skin due to previous sensitization.¹⁴ Indications for patch testing are patients with a differential diagnosis of contact dermatitis, patients with other skin conditions that may be aggravated by contact dermatitis, patients with chronic eczema of unknown aetiology and suspected cases of occupational contact dermatitis.14

The positivity rate of the pach test in this study was wide, ranging from 13-100%. This wide positivity rate is thought to be due to the small number of patients in some studies and the geographical factors of each country where the included studies were conducted. In this study, the patch test locations to determine allergens in allergic contact dermatitis due to cosmetics mainly were carried out in India with four studies, Brazil and North America with three studies each and in Korea, Sweden and Czechia with 1 study each.^{13,15–17,14,18,19,20–22} The common cultural use of 'Henna' and 'Binti' in Indian IgE-mediated women causes hypersensitivity reactions and contact dermatitis.²³ The active ingredient of hena is lawone (2-hydroxy-1, 4-naphthoquinone), which comes from the leaves and flowers of Lawsonia inermis, family Lythraceae, which



Figure 1. PRISMA diagram in this systematic review

grows in hot climates in north and west Africa and South Asia.²⁴ Natural henna ingredients rarely cause allergic reactions; most cases of allergic reactions are caused by paraphenylenediamine (PPD) ("black henna") dyes, diaminotoluene, and diaminobenzenes which are added to pure henna and aim to speed up the drying of the henna and strengthen the colour of the henna.²³

This study shows that the most common allergens that cause allergic contact dermatitis in cosmetics are nickel sulfate metal, fragrance-mix fragrances and preservatives such as methylisothiazolinone and formaldehyde.^{13–15,25,26} The active ingredient para-phenylenediamine (DPD) in hair dye is a common allergen in cosmetics that causes contact dermatitis.²⁷ Fragrance ingredients such as fragrance-mix, balsam of Peru and colophony, as well as emulsifying ingredients such as lanolin, amerchol L-101 and propylene glycol, are also common allergens in cosmetics that cause contact dermatitis.^{15,16,26–28}

The most common allergen mentioned in the study was nickel sulfate^{13,15,19,20,25,26} and

Table 2. Study Characteristics

No	Author	Study Design	Location of Study	Number of Subjects	Positivity rate	Allergens	Cosmetic Products
1	Lee et al. (2016)	Clinical trials	Korea	27	100%	Para- phenylenediamine base (100%); Nickel sulfate (26.10%); and Cobalt chloride (17.40%)	Hair dye
2	Sadago pan et al. (2017)	Retrosp ective study	India	358	43.85%	Potassium dichromate, Nickel sulfate, and Cobalt chloride	Hair dye, cosmetic cream
3	Sukakul et al. (2022)	Retrosp ective study	Sweden	3663	13.10%	Fragrance-mix I (48%) and Fragrance-mix II (17%)	Fragrance
4	Tichy et al. (2015)	Retrosp ective study	Czech Republic	1941	-	Nickel sulfate (15.40%); Balsam of Peru (11.60%); and Fragrance-mix I (7.10%)	Perfume
5	Hafner et al. (2020)	Retrosp ective study	Brazil	403	57.50%	R-TSF (29.70%); Para- phenylenediamine base (26.30%); and Kathon (21%)	Nail colour, hair colour, fragrance/pe rfume, shampoo, hair care products, moisturizing cream, soap, sunscreen, deodorant
6	Hasan et al. (2017)	Retrosp ective study	North America	582	30%	Nickel sulfate, Potassium dichromate, and Cobalt chloride	Skin care products, hair dye, henna tattoos
7	Silva et al. (2020)	Retrosp ective study	Brazil	267	69.50%	Nickel sulfate (56.25%), Cobalt chloride (23.43%), and Neomycin sulfate (18.22%)	Cosmetic

8	Majid et al. (2014)	Retrosp ective study	India	550	41.45%	Nickel sulfate (29.30%); Potassium dichromate (21.40%); and Fragrance-mix I (19.95%)	Traditional cosmetics and perfume
9	Figueir edo et al. (2018)	Retrosp ective study	Brazil	1870	13.80%	Fragrance-mix I (70.90%); Balsam of Peru (20.10%); and Colophony (32.30%)	Fragrance
10	Gupta et al. (2015)	Clinical trials	India	80	67.50%	Para- phenylenediamine, Fragrance-mix I, and Thiuram mix	Hair dye
11	Kumar et al. (2014)	Clinical trials	India	50	50%	Gallate mix (40%); Cetrimide (28%); and Thiomersal (20%)	Face cream, hair dye, shaving cream, perfume, nail colour, foundation, kumkum/bin di
12	Warsha w et al. (2020)	Retrosp ective study	North America	50507	_	Methylisothiazolino ne (9.90%); Fragrance-mix I (8.50%); and Balsam of Peru (6.80%)	Personal care products (hair care, moisturizer, lotion, soap, perfume and fragrance, sunscreen, oral cleansing products, eye care products, lip care products and makeup)



13	Atwater Retrosp et al. ective (2021) study	North America	50799	22.30%	Methylisothiazolino ne (12.20%); Formaldehyde (7.80%); and Petrolatum (7.70%)	Cosmetic
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Table 3. The highest number of a	Illergens found in the study
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Allergen	Number of Studies
Fragrance-mix I and Nickel sulfate	6
Cobalt chloride	4
Para-phenylenediamine base, Potassium dichromate, and Balsam of Peru	3
Methylisothiazolinone	2
Formaldehyde; Gallate mix; Fragrance-mix II; R-TSF; Kathon; Neomycin sulfate; Colophony; Thiuram mix; Cetrimide; Thiomersal; and Petrolatum	1

fragrance-mix I.^{15,16,18,26,27,29} Other allergens found in this study include cobalt chloride, para-phenylenediamine base, potassium dichromate and balsam of Peru.^{11,30–36} Nickel sulfate is one of the most widely used metals in the world.³⁷ Nickel sulfate is the allergen with the highest prevalence of contact allergies and the most common positive hapten in patients undergoing patch testing for suspected contact dermatitis.¹⁴ Nickel ion is a potent allergen or hapten that can cause dermatitis.³⁷ Jewelry is the most common source of nickel allergy exposure and earrings. necklaces, includes medals. brooches, bracelets, watches and rings.² Cosmetics, especially pigmented mascara, eyeshadow, soap, and detergent, are examples of cosmetics that contain nickel.³⁸

The following most common allergen in this study was fragrance-mix I.^{15,16,26–28,39} Fragrance-mix I contains eugenol, isoeugenol, cinnamic alcohol, cinnamic aldehyde, amylcinnamaldehyde, geraniol, and hydroxytronellal.⁶ Fragrance-mix I includes many synthetic compounds in cologne, eau de toilette and aftershave.³⁸

Fragrance-mix I is also found in cosmetics for skin, nail, hair and eye care, toothpaste, sunscreen cream, and cleaning products for adults and children, including wet wipes and insect repellent.³⁸

Another allergen found in this review, cobalt chloride. was mentioned in four studies.^{13,19,20,25} Study by Reduta et al. in Poland in 2013 showed positive reactions to cobalt chloride, which occurred in 15.3% of people tested.⁴⁰ Cobalt is a heavy metal which has side effects in the form of nausea, vomiting, visual and heart problems and has effects.³⁷ carcinogenic side High concentrations of cobalt chloride in cosmetic ingredients such as henna, foundation, skin whitening cream, and eyeliner can increase the incidence of allergic contact dermatitis in patients.41

Para-phenylenediamine (PPD) or 1,4phenylenediamine is an aromatic diamine that has a risk of irritation and is used as a colour-enhancing agent in hair dyes, temporary tattoos and henna.²⁴ Paraphenylenediamine (PPD) has been used in

hair dyes since the late 19th century and is a significant source of contact sensitization to the PPD allergen.^{24,42} A Study by Mukkana in England in 2017 involving patients with dermatitis due to PPD has shown a prevalence of positive patch tests for PPD material of 6.2% in North America, 4% in Europe, and 4.3% in Asia.⁴³

The following allergen found in this review is dichromate potassium or chromium dichromate. which is mentioned three times.^{13,15,20} Potassium dichromate is widely used in daily activities and is found in many detergents, bleaching agents, cement, implants, prostheses, cell phones and cosmetics such as eve shadows.⁴⁴ In Europe. the use of chromium has been banned since 1976, but the use of chromium metal in small quantities is still permitted.⁴⁴ Small amounts of chromium in cosmetics do not pose a significant risk of chromium carcinogenic effects but can potentially cause contact dermatitis.44

Balsam of Peru allergens were mentioned in 3 studies in this review.^{26,28,39} Balsam of Peru is a tree resin derived from Myroxylon pereirae.²⁸ Balsam of Peru is a fragrance ingredient containing benzyl cinnamate and benzyl benzoate, which can cause skin rashes in allergic individuals.⁴⁵ This resin's characteristic sweet and vanilla aroma consists of various fragrance components, and it is estimated that almost 50% of patients with fragrance allergies will react to this allergen.²⁶ Balsam of Peru is often found in perfumes, colognes, air fresheners, scented candles, cosmetics, oral cleaning, hair care, pet care, and household cleaners.45

Methylchloroisothiazolinone/

methylisothiazolinone (MCI/MI) is one of the most widely used preservatives in industrial, cosmetic, and household products.^{22,28}

Methylchloroisothiazolinone can be found in products such as detergent, shampoo, conditioner. cleansing wipes, make-up remover, face and body cream, deodorant, foundation, mascara, eye shadow, colour, and sunscreen.²² In 2017, the European committee set the maximum safe concentration of MCI/MI 0.0015% at (15 ppm) due to the increasing prevalence of sensitization to MI for cosmetic products.³⁸

Formaldehyde is an allergen commonly used as a preservative in cosmetics, household products.²² products. and industrial Formaldehyde can be found in cosmetic products such as facial cream, mascara, foundation. deodorant. shampoo. hair toothpaste conditioner. and topical antibiotics.³⁸ Currently, the incidence of sensitization due to formaldehyde has decreased due to the replacement of preservatives using safer formaldehvdereleasing agents.46,47

Gallate is an alkyl ester of trihydroxy benzoic acid consisting of propyl gallate, octyl gallate and dodecyl gallate and is used as a preservative.¹⁷ Propyl gallate is the most common gallate chemical found in foods and personal care products.⁴⁸ Most cosmetic products contain propyl gallate, including lipstick, lip gloss and other products applied to the lips.⁴⁸ Cases of sensitization from gallate-containing substances are relatively rare, with an estimated incidence of 3.92%, due to increased oral tolerance after repeated exposure.⁴⁶

This study also has several limitations. First, a notable geographical bias is observed, with a concentration of studies in specific regions like India, Brazil, and North America. Furthermore, the preponderance of retrospective studies in the selected pool introduces inherent biases that could impact our systematic review's overall robustness



and reliability. Moreover, the diversity in cosmetic products tested presents a potential source of variability in allergen exposure. The sample size in clinical trials is also significantly lower than in retrospective studies, giving the possibility of selection bias that may not represent general population.

CONCLUSION

conclusion. this systematic review In contributes meaningful insights into the prevalence and allergen profiles of cosmeticinduced contact dermatitis. Identifying key allergens, such as nickel sulfate and fragrance mix I, emphasizes the importance of targeted interventions and increased awareness within the cosmetics industry. For future studies, a more comprehensive global representation and a mix of study designs are recommended to enhance the reliability of the conclusions drawn from such investigations.

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