



Common Cosmetic Allergens in Skincare Products Labeled for Sensitive Skin Available in Thailand

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Abstract

Cosmetic products have been increasingly used among the general population. The incidence of cosmetic contact dermatitis appears to be rising alongside with the number of cosmetic products available. Companies are now formulating skincare products with the term “sensitive skin” to target people who are prone to have allergic reactions from cosmetic products. In this study, we would like to emphasize the prevalence of common contact allergens in the skincare products labeling “sensitive skin” including moisturizer, cleanser, serum, oil, toner and sunscreen that were available in Thailand during 2023. Lists of 41 allergens from cosmetic allergens classified by the US Food and Drug Administration and fragrance allergens presented in Annex III of the European Union Cosmetics Directive were used as reference. A total of 130 products were collected from department stores, supermarkets and convenient stores in Thailand, as well as the websites of top Thai beauty stores. Seventy percent of the products labeled for sensitive skin contain at least one allergen. Fragrance was the most common allergens, found in 20% of the products. Top five allergens were all fragrance allergens including Linalool (10%), Limonene (10%), Geraniol (5.3%), Citronellol (4.6%) and Benzyl alcohol (3.8%). In addition to fragrance, other allergens found were preservatives including Diazolidinyl urea, Dimethylol-dimethyl hydantoin and Imidazolidinyl urea. All were found in the same percentage of 0.8%. This study has shown that the products labeled “for sensitive skin” can still contain allergens, and potentially cause allergic reactions. Establishing regulations for labels like “sensitive skin” could benefit both physicians and individuals with allergy-prone skin.

Keywords: Sensitive Skin, Cosmetic Products, Skincare Products, Contact Allergens, Cosmetic Allergens

1. Introduction

The increased usage of cosmetic products among the general population has been rising and parallels the expanding lists of ingredients. Currently, there are more than 8,000 substances available for scientists to use in formulating cosmetic products (Smith, Clark, & Wilkinson, 2016). Studies have shown that 25% of women uses 15 or more products daily. In average, adults use 9 cosmetic products per day. Estimated usage for women is 12 products with 168 different ingredients. While for men, the average usage is 6 products with 85 ingredients (Sedlewicz, 2005).

Contact dermatitis is a common dermatologic condition for morbidity with a life prevalence of 15%. Research indicates that 27% of the population had at least one positive patch test to allergens. The number of case reports of cosmetic contact dermatitis has also been increasing with the rise of cosmetic products (Diepgen et al., 2016).

Vigan (1997) demonstrates that the estimated prevalence of allergy to cosmetic ingredients is 1-3%. The most common cause of cosmetic allergies is from fragrance (Minamoto, 2010). Among dermatitis patients, the prevalence of contact allergy to fragrance ranged from 5% to 12.8% (Bruynzeel et al., 2005). The second most common cause of cosmetic contact allergens is from preservative and can be divided into two different properties including antimicrobial and antioxidant. Antimicrobial includes Formaldehyde and Formaldehyde releasers (Imidazolidinyl urea, Diazolidinyl urea, Dimethylol-dimethyl hydantoin and Quaternium-15). As the use of Formaldehyde as a preservative has decreased, there has been a noted rise in



the occurrence of sensitivity to Formaldehyde releasers with cosmetics being the primary source of exposure. (Johansen, Frosch, & Lepoittevin, 2010)

Cosmetic allergies are more often triggered by leave on products such as moisturizers, serums, and sunscreen which maintain the prolonged contact with the skin. On the other hand, rinse off products such as cleansers are formulated to have the brief contact with the skin, resulting the reducing of the possibility of adverse reactions. Nonetheless, frequent usage and cumulative exposure could lead to the surpassing of the threshold for allergen tolerance. (Deza, & Giménez-Arnau, 2017).

According to the Seventh Amendment of the European Cosmetics Directive, 26 fragrance contact allergens must be included on the labels of cosmetic products if the concentrations exceed 10 parts per million (ppm) in leave on products and 100 ppm in rinse off products. U.S. Food and Drug Administration (FDA) have also listed cosmetic allergens that cause most allergic reactions including natural rubber, fragrance, preservatives, dyes or chemicals and metals on their official website (Food and Drug Administration, 2022). FDA has been focusing on cosmetic allergens by monitoring adverse event from cosmetic products (Katz, Valenzuela, & Sadrieh, 2016), conducting scientific research on the mechanism and frequency of allergic reactions as well as assessing consumers' awareness of allergens presented in cosmetics (Vukmanović, & Sadrieh, 2017). Both fragrance allergens from the Annex III of EU Cosmetic Regulation and cosmetic allergens from FDA have been used as reference by many researchers (Martins, Ferreira, Almeida, & Sousa, 2022).

The goal of treating allergic contact dermatitis involves avoiding allergens. Choosing suitable products is crucial for managing allergic contact dermatitis. Nowadays, the labels such as "for sensitive skin" are often used for marketing purposes to appeal to individuals with sensitive or allergy-prone skin. Unlike the regulations for sunscreen labels, there is no regulatory oversight for using the term "sensitive" on cosmetic products. However, there is limited data regarding the common allergens or ingredients found in products labeled "for sensitive skin" in Thailand. Understanding the prevalence of common allergens in products with "sensitive" labels could benefit physicians by informing patients of the risks of potential allergen exposure associated with these products. It could also provide patients with information about the risks of exposure to certain allergens from these products and offer insights for further studies or investigations aimed at improving or regulating the use of this specific label.

2. Objective

To examine the prevalence of contact allergens based on cosmetic allergens classified by the US Food and Drug Administration and fragrance allergens presented in Annex III of the European Union Cosmetics Directive in skincare products labeled "sensitive skin" available in Thailand.

3. Materials and Methods

3.1 Study design

This cross-sectional study was conducted from April to November 2023. To assess the occurrence of allergens in skincare products designed for sensitive skin. The data collection focused on products available in Thailand during 2023. Products were from top 4 beauty shops in Thailand in terms of the highest company income in 2022 (EVEANDBOY, Sephora, Boots and Watsons), top 3 biggest supermarkets in Thailand (Big C, Makro and Lotus) and top 3 convenient stores according to the greatest number of branches (Seven eleven, Lotus's go fresh and mini Big C) (Thai Franchise Center, 2022). Information regarding the ingredients was obtained from the product labels as well as the product official websites. The inclusion criteria include the skincare products labeled with the term "sensitive skin". The exclusion criteria were the products not available in Thailand with no sensitive skin labeling.

3.2 Study protocol

Types of skincare products collected include cleanser, moisturizer, serum, toner, sunscreen and oil. The data collection includes product brand, name, country of origin, type of product, rinse off or leave on

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product and ingredient allergens. A compilation of cosmetics allergens was created by referring to cosmetics allergens classified by FDA (Food and Drug Administration, 2022) and fragrance allergens presented in Annex III of the European Union Cosmetics Directive.

3.3 Outcome assessment

The primary outcome was to examine the frequency of allergens found in skincare products for sensitive skin as well as demographic data of product types and country of origin.

3.4 Statistical analysis

The data were analyzed using descriptive analyses.

4. Results and Discussion

4.1 Results

Following the data collection process, a total of 130 products were collected. Most of the products were leave on products (60%) and 40% were rinse off products. Cleansers were the most common type of skincare products found (40%). Followed by moisturizer (28%), serum (19%), toner (8%), sunscreen (3%) and oil (2%). Most of the products were made from North America (35%). Europe was the second most common (30%), followed by Asia (31%) with 14% were from Thailand. Products from Australia were the least found (3%). (Table 1, 2)

Table 1 Type of skincare products in percentage

Type of skincare	N(%)
Cleanser	52(40)
Moisturizer	36(28)
Serum	25(19)
Toner	10(8)

Table 2 Country of origin in percentage

Country of origin	N(%)
Thailand	3(2)
Asia (other than Thailand)	20(15)
Europe	39(30)
North America	45(35)
Australia	5(4)

Eleven out of the forty-seven allergens were found in products of this study. Eight were fragrance allergens and three were preservative allergens. Allergens were more found in leave on products than wash off products. Seventy percent of the product contained at least one allergen. Most of the allergens found were products from Europe (45.2%). France was the most common (22.6%) followed by United Kingdom (9.4%), Russia (7.5%), Spain (3.8%) and Germany (1.9%). Asia was in the second place (26.5%) (South Korea (18.9%), Singapore (3.8%) and Thailand (3.8%)), followed by North America (20.8%) (Canada (1.9%) and United states of America (18.9%) and Australia (7.5%) respectively.

Fragrance allergens

Out of 26 reference fragrance allergens, 8 were found in 26 skincare products designed for sensitive skin. Twenty percent of these products contained at least one of these allergens, with 11% having two or more, and 9% containing only one. The prevalence of each allergen ranged from 0.8% to 10%, with Linalool and Limonene being the most common. Each was found in 10% of the products. Geraniol was found in 5.3% of the products, Citronellol in 4.6%, Benzyl alcohol in 3.8%, Hexyl cinnamaldehyde and Citral in 2.3%, and Farnesol in less than 1%.

Preservative allergens



Out of 10 reference preservative allergens, 3 were found in 3 products designed for sensitive skin. These allergens were Diazolidinyl urea, Dimethylol-dimethyl hydantoin, and Imidazolidinyl urea, each detected in 0.8% of the products.

Table 3 Prevalence of allergens found in total and when grouped into leave on and wash off products

Type of allergens	Reference Allergens	Leave on N=78	Wash off N= 52	All N=130	Allergens in normal cosmetic products in other studies ^a (%)	Allergens in cosmetic products labeled sensitive skin in other studies ^b (%)
Fragrance allergens The European Parliament (2003)	Linalool	8(6.2%)	5(3.8%)	13(10%)	4.5-66%	4.5%
	Limone	10(7.7%)	3(2.3%)	13(10%)	14.7-48.5%	1.1%
	Geraniol	5(3.8%)	2(1.5%)	7(5.3%)	8-46%	3.4%
	Citronellol	4(3.1%)	2(1.5%)	6(4.6%)	3.4-64%	2.3%
	Benzyl alcohol	3(2.3%)	2(1.5%)	5(3.8%)	12.6-23%	3.4%
	Hexyl cinnamaldehyde	2(1.5%)	1(0.8%)	3(2.3%)	35.8%	1.1%
	Citral	3(2.3%)	0	3(2.3%)	2.2-17.9%	1.1%
	Farnesol	1(0.8%)	0	1(0.8%)	1.1-5.1%	N/A
Preservative allergens Food and Drug Administration (2022)	Diazolidinyl urea	1(0.8%)	0	1(0.8%)	N/A	1.1%
	Dimethylol-dimethyl hydantoin	0	1(0.8%)	1(0.8%)	8.85%	N/A
	Imidazolidinyl urea	0	1(0.8%)	1(0.8%)	1.12%	N/A

a. Beene et al., 2017; Bennike et al., 2017; Nardelli et al., 2011; Buckley, 2007

b. Martins et al., 2022

4.2 Discussion

Skincare products have been known to cause allergic reactions especially leave on products which are in close contact with the skin for a long period. This study has shown that allergens were more found in leave on products than wash off products. More than half of the sensitive skin products in this study contain at least one allergen. Fragrance allergens were the most common allergens in this study correlating with other previous findings that fragrance was the most common cause of cosmetic allergic contact dermatitis (Minamoto, 2010). Even though most of the products collected were from North America, allergens that were mostly found were the products of Europe.

The prevalence of the allergens found in this study are lower compared to normal cosmetic products in other studies (Beene et al., 2017; Bennike et al., 2017; Nardelli et al., 2011; Buckley, 2007). In contrast, when compared to another study of sensitive skin products, the prevalence of allergens in this study were all higher (Martins et al., 2022). Top five allergens from this study were all fragrance including Linalool, Limonene, Geraniol, Citronellol and Benzyl alcohol. However, the top five fragrance allergens found in sensitive skin products from a study in Portuguese were Linalool, Benzyl alcohol, Geraniol, Citronellol, Amyl cinnamal. (Martins et al., 2022). According to different studies Linalool, Limonene and Geraniol have the highest frequency of occurrence in cosmetics (Buckley, 2007; Uter et al., 2013; Bennike et al., 2017). In this study, both Linalool and Limonene were also the most common allergens found. Both allergens have given high frequencies of allergic contact reactions in international multicenter studies (Bennike, Zachariae, & Johansen, 2017; Dittmar, & Schuttelaar, 2018; Nath, Li.u, Green, & Atwater, 2017; Deza et al, 2016; Christensson, 2016) especially in oxidized Limonene and Linalool have given higher sensitization rates.

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Geraniol was the only allergen from fragrance mix I found in this study. Geraniol is commonly used as perfumes in cosmetics and has been referred to as a relatively common trigger of allergic contact dermatitis. However, there are also evidences that Geraniol is considered a mild contact allergen and there is no study on patients' reactions to the specific products containing Geraniol and where the positive patch test linked to Geraniol (Hostýnek, & Maibach, 2004).

Four allergens from fragrance mix II were found. Fragrance mix II was developed as part of a project funded by the European Union, aimed at broadening the range of screening for fragrance allergies. Citronellol was the most common allergen found in 6 products followed by Hexyl cinnamaldehyde, Citral and Farnesol. Clinical reports have documented positive patch test reactions to Citronellol in ACD patients. While certain studies have reasonably shown that Citronellol can trigger allergic reactions under clinical patch testing conditions, they are unable to establish its clinical relevance (Hostýnek, & Maibach, 2004). Schnuch and Griem (2018) have shown that Citral and Farnesol were grouped as frequent allergens. While Hexyl cinnamaldehyde was grouped as less frequent allergens.

Benzyl alcohol was found in 5 products (3%), functions as a preservative, solvent, anesthetic, anti-itch, and viscosity-reducing agent. It is noteworthy that due to its fragrance characteristics and inclusion in the EU list of 26 fragrances requiring labeling in cosmetics, it might act as a hidden fragrance compound, even in formulations labeled as "fragrance-free." (Jacob, & Barron, 2007). Hydroxyisohexyl 3-cyclohexene carboxaldehyde (Lyrall), one of the components of FMII, has been reported as the most frequent fragrance allergens (Geier, 2002), but it was not found in any product in this study.

Allergic contact dermatitis from Limonene, Linalool and Benzyl alcohol have been reported in the selected group of patients. Geraniol, Hexyl cinnamaldehyde, Citral, Citronellol and Farnesol have all been reported to cause allergic contact dermatitis in general population with Geraniol and Farnesol being the most common (De Groot, 2020).

Preservatives have been recognized as frequent cosmetic allergens in many studies (Hamilton, & De Gannes, 2011). Preservatives found in this study were all Formaldehyde releasers (Imidazolidinyl urea, Diazolidinyl urea, Dimethylol-dimethyl hydantoin). Repeated exposure of Formaldehyde releasers can induce sensitization and lead to allergic contact dermatitis (Nelson, & Mowad, 2010). Dimethylol-dimethyl hydantoin is a more common preservative with the highest sensitization rate compared to Imidazolidinyl and Diazolidinyl urea (Yim, Nole, & Tosti, 2014; Travassos et al., 2011). It is also important to note that the concentration of these allergens used in cosmetic products might differ from the published reports, and it, therefore, can lead to different responses to skin reactions.

Currently there is no established federal standard or definition regulating the utilization of the term "for sensitive skin". Instead, FDA advises consumers to rely on the ingredient list as mandated by the Fair Packaging and Labeling Act (FPLA) from FDA which requires an ingredient declaration on cosmetic products sold directly to consumers at retail outlets. Nonetheless, some ingredients might be broadly listed as "fragrance" or "perfume". This study has revealed that products labeled for sensitive skin can still contain allergens and potentially lead to allergic reactions. The "sensitive skin" label appears to be used for marketing purposes and may not accurately reflect the product's suitability. More research and efforts to establish regulations for such labels could greatly benefit the field of contact dermatitis.

5. Conclusion

The study indicates that sensitive skin product labels often fail to exclude allergens, with over half of such products containing potential allergens. Linalool, Limonene, Geraniol, Citronellol and Benzyl alcohol are the most prevalent fragrance allergens identified. It underscores the necessity of individuals knowing and avoiding their specific allergens by carefully examining the product's ingredients. Furthermore, implementing regulatory standards for sensitive skin labeling could provide significant advantages for both medical professionals and individuals who are susceptible to allergies.

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7. References

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