

## ORIGINAL ARTICLE

# Comparison of Marketed Cosmetic Products Constituents with the Antigens Included in Cosmetic-related Patch Test

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**Background:** Currently, cosmetic series (Chemotechnique Diagnostics, Sweden) is the most widely used cosmetic-related patch test in Korea. However, no studies have been conducted on how accurately it reflects the constituents of the cosmetics in Korea. **Objective:** We surveyed the constituents of various cosmetics and compare with the cosmetic series, to investigate whether it is accurate in determining allergic contact dermatitis caused by cosmetics sold in Korea. **Methods:** Cosmetics were classified into 11 categories and the survey was conducted on the constituents of 55 cosmetics, with 5 cosmetics in each category. The surveyed constituents were classified by chemical function and compared with the antigens of cosmetic series. **Results:** 155 constituents were found in 55 cosmetics, and 74 (47.7%) of constituents were included as antigen. Among them, only 20 constituents (27.0%) were included in cosmetic series. A significant number of constituents, such as fragrance, vehicle and surfactant were not included. Only 41.7% of antigens in cosmetic series were found to be in the cosmetics sampled. **Conclusion:** The constituents not included in the patch test but possess antigenicity are widely used in cosmetics. Therefore, the patch test should be modified to reflect ingredients in the marketed products that may stimulate allergies. (*Ann Dermatol* 22(3) 262~268, 2010)

## -Keywords-

Allergic contact dermatitis, Cosmetic products, Cosmetics, Ingredients, Patch test

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## INTRODUCTION

According to Article 2 (1) of the Cosmetic Product Act effective from 1 July 2000, cosmetic products are goods that improve attractiveness by cleaning and beautifying, brightening, maintaining or enhancing hair and skin health.

With ever increasing interests in beauty these days, the use of cosmetic products is widening and the age of consumers are broadening as the choice and constituents expand. As a result, there is a gradual increase in side effects reported<sup>1</sup>. Side effects secondary to cosmetic product use are mostly due to irritation<sup>2</sup>, but may also manifest in allergic contact dermatitis (ACD), photo-contact dermatitis and exacerbation of existing skin diseases<sup>3</sup>. ACD accounts for less than 10%<sup>4-6</sup> of side effects reported. Cosmetic products are usually consisted of different chemical compounds, which render it difficult to determine the culprits in the event of contact dermatitis. However, from October 2008, all cosmetic products sold in Korea were mandated to disclose their full composition. As a result, it is possible for consumers to avoid products that contain known allergens that may cause ACD.

At present, cosmetic series (Chemotechnique Diagnostics, Malmö, Sweden) is the most widely used patch test to detect antigens in cosmetic products that cause ACD in Korea. However, no studies have been conducted on how accurate the antigens included in cosmetic series reflect the constituents in the marketed products in Korea. The objective of this study was to determine whether cosmetic series was an appropriate test for contact dermatitis secondary to products sold in Korea, by surveying the constituents of selected cosmetic products, classifying them into chemical entities and comparing them with antigens included in cosmetic series.

## MATERIALS AND METHODS

### Materials

According to the classification standard for each type of cosmetic product enshrined in Enforcement Regulations of Cosmetics Product of Korea, cosmetic products are classified into 11 categories: children, bathing, body cleansing, eye makeup, aroma use, hair dye, makeup, hair, nail polish, shaving and skin care. A review was conducted on all the constituents of 55 cosmetic products with 5 cosmetic products applicable for each category. Each product category was comprised of different products marketed by different manufacturers, both domestic and imported.

### Method

#### 1) Classification of ingredients

The surveyed ingredients were classified into 10 categories: fragrance, preservative, antioxidant, ultraviolet absorber, vehicle, humectant/emollient/emulsifier, surfactant, hair dye, nail polish resin and others.

#### 2) Determination of antigens from the cosmetic products tested

The database of MEDLINE, EMBASE, BIOSIS were searched to determine if any constituents were included as antigens, whether there were reports of stimulating ACD as antigens, and whether there were possibilities of causing contact dermatitis through cross reactions. The search words used with included "allergy", "cosmetics", "contact" and "contact dermatitis". Furthermore, additional bibliographic search was conducted along with reviews performed on publications using the 'Related Articles' function.

#### 3) Determination of whether cosmetic constituents were included as antigens in cosmetic series

The types and extent of inclusion of the surveyed cosmetic

constituents as antigens in cosmetic series were determined.

#### 4) Determination of the frequency in use of the antigen of the cosmetic series

Through comparison with surveyed cosmetic product ingredients, among the antigens of the cosmetic series, the types of antigens which were actually used for cosmetic products were determined, and the number of cosmetic products which included these antigens was also investigated.

## RESULTS

### Classification of constituents included in cosmetic products and included as antigens in the cosmetic products

As a result of surveying 11 types of cosmetic products (55 products in total, 5 product per type), 155 constituents were identified (Table 1). The constituents were classified as follows: 18 types of fragrance, 12 types of preser-

**Table 1.** Types of surveyed cosmetic products and number of product for each type

| Type           | No. of domestic products | No. of imported products | Total |
|----------------|--------------------------|--------------------------|-------|
| Children       | 3                        | 2                        | 5     |
| Bathing        | 3                        | 2                        | 5     |
| Body cleansing | 2                        | 3                        | 5     |
| Eye makeup     | 1                        | 4                        | 5     |
| Aroma use      | 1                        | 4                        | 5     |
| Hair dye       | 4                        | 1                        | 5     |
| Makeup         | 3                        | 2                        | 5     |
| Hair           | 4                        | 1                        | 5     |
| Nail polish    | 4                        | 1                        | 5     |
| Shaving        | 2                        | 3                        | 5     |
| Skin care      | 3                        | 2                        | 5     |
| Total          | 30                       | 25                       | 55    |

**Table 2.** Classification for each function of ingredient included in the cosmetic products and the number of ingredients acted as antigen, and the number of antigen included in the patch test

| Classification for function    | No. of ingredients | No. of ingredients acted as antigen (%) | No. of antigen included in the patch test (%) |
|--------------------------------|--------------------|---|---|
| Fragrance                      | 18                 | 18 (100.0)                              | 1 (5.6)                                       |
| Preservative                   | 12                 | 11 (91.7)                               | 9 (81.8)                                      |
| Antioxidant                    | 4                  | 4 (100.0)                               | 2 (50.0)                                      |
| Ultraviolet absorber           | 6                  | 4 (66.7)                                | 1 (25.0)                                      |
| Vehicle                        | 8                  | 8 (100.0)                               | 1 (12.5)                                      |
| Humectant/emollient/emulsifier | 20                 | 15 (75.0)                               | 5 (33.3)                                      |
| Surfactant                     | 11                 | 10 (90.9)                               | 1 (10.0)                                      |
| Hair dye                       | 2                  | 2 (100.0)                               | 0 (0.0)                                       |
| Nail polish resin              | 1                  | 1 (100.0)                               | 0 (0.0)                                       |
| Others                         | 73                 | 1 (1.4)                                 | 0 (0.0)                                       |
| Total                          | 155                | 74 (47.7)                               | 20 (27.0)                                     |

**Table 3.** Type of ingredients known to work as the antigen from the ingredients of surveyed cosmetic products and tendency of inclusion in the cosmetic series (Chemotechnique Diagnostics, Sweden)

| Classification for function    | Ingredients acted as antigen   |
|--------------------------------|--|
| Fragrance                      | Fragrance (32), linalool (9), butylphenyl methylpropional (8), limonene (7), geraniol (6), alpha-isomethyl ionone (5), cinnamal (5), citronellol (4), benzyl salicylate* (4), lyral (hydroxyisohexyl 3-cyclohexane carboxaldehyde) (3), coumarin (3), isoeugenol (2), eugenol (2), benzyl benzoate (2), hydroxycitronellal (2), benzyl cinnamate (1), cinnamic alcohol (1), citral (1) |
| Preservative                   | Paraben* (24), phenoxyethanol* (18), quaternium-15* (8), sorbic acid* (6), sodium benzoate (5), methylchloroisothiazolinone-methylisothiazolinone* (4), benzyl alcohol* (3), DMDM hydantoin* (2), 4-chloro-3-cresol* (2), iodopropynyl butyl carbamate* (1), chlorphenesin (1)   |
| Antioxidant                    | Tocopherol (17), BHT* (5), butylated hydroxytoluene (2), propyl gallate* (1)   |
| Ultraviolet absorber           | Benzophenone* (4), butyl methoxydibenzoylmethane (3), ethylhexyl methoxy-cinnamate (3), octyl salicylate (2)   |
| Vehicle                        | Glycerin (26), propylene glycol* (14), butylene glycol (8), pentylene glycol (3), isopropyl alcohol (2), polyethylene terephthalate (2), petrolatum (2), polyethylene glycol (1)   |
| Humectant/emollient/emulsifier | Castor oil (12), stearic acid (7), triethanolamine* (7), glyceryl stearate (6), panthenol (6), stearyl alcohol* (5), lanolin (5), cetyl alcohol* (4), bee glue/beeswax (4), sorbitan monooleate* (3), isopropyl myristate* (3), sorbitol (3), sorbitan palmitate (3), myristyl alcohol (1), sorbitan laurate (1)   |
| Surfactant                     | Sodium lauryl sulfate (12), cocamidopropyl betaine* (7), laureth (4), cocamide DEA(3), disodium lauroamphodiacetate (3), lauryl alcohol (2), glyceryl laurate (2), ammonium lauryl sulfate (2), TEA-lauryl sulfate (1), lauryl glucoside (1)   |
| Hair dye                       | p-Phenyldiamine (5), aminophenol (5)   |
| Nail polish resin              | Tosylamide formaldehyde resin (2)  |
| Others                         | Carnauba (6)   |

\*Ingredient included in the cosmetic series (Chemotechnique Diagnostics, Malmö, Sweden). ( ): The number of cosmetic products included with each ingredient from 55 cosmetic products. BHT: butylated hydroxytoluene, DMDM: dimethylol dimethyl, DEA: diethanolamide, TEA: triethanolamine.

vatives, 4 types of antioxidants, 6 types of ultraviolet absorbers, 8 types of vehicle, 20 types of humectants/emollients/emulsifiers and 11 types of surfactants, 2 types of hair dyes, 1 type of nail polish resin, and 73 others (Table 2). Among them, 74 (47.7%) ingredients were included as antigen: 18 types of fragrance, 11 preservatives, 4 antioxidants, 8 vehicles, 10 surfactants and others. And, with the exception of constituents included in others, most ingredients were included as antigens (Tables 2, 3).

#### Constituents included as antigen in cosmetic series

Among 74 constituents known to be antigens, only 20 (27.0%) were included in cosmetic series. A significant number of constituents such as fragrance, vehicle and surfactant were not included in cosmetic series, while all except 2 preservatives were included (Tables 2, 3).

#### The constituents used in actual cosmetic products from the antigens of the cosmetic series and the number of cosmetic products including the above

Among 48 antigens included in cosmetic series, only 20 antigens (41.7%) were identified in the marketed cosmetic products surveyed (Table 4). Preservatives accounted for the largest proportion by far. Paraben, phenoxyethanol and propylene glycol were most frequently included, in

24, 18, and 14 products, respectively. In addition, quaternium, cocamidopropyl betaine, triethanolamine and others were also relatively frequently used.

## DISCUSSION

Pursuant to the classification standard for each type following the Enforcement Regulations of the Cosmetics Product of Korea, the cosmetic product is classified for 11 categories (children, bathing, body cleansing, eye make-up, aroma use, hair dye, makeup, hair, nail polish, shaving and skin care). As such, the types included in the cosmetic product are so diverse that the entire population would be contacted with the cosmetic products several times a day regularly. Over 5,000 types of substances, including 800 types or more natural substances, vehicle, fragrance and other compounds are found<sup>4,7</sup>. Most of the constituents are safe for consumers, but approximately 2% of consumers are reported to experience side effects<sup>4,8</sup>. These side effects mostly present as irritation<sup>2</sup> but there are other types of manifestations, such as, ACD, photo-contact dermatitis, damage to hair and nails, folliculitis and exacerbation of existing skin diseases<sup>3</sup>. Among them, ACD accounts for less than 10%<sup>4-6</sup> but the trend is on the increase as the use of cosmetics increases and the constituents included become diversified<sup>1,9</sup>. Nielsen et al.<sup>9</sup>

**Table 4.** Ingredients used for the cosmetic products from the antigen of the cosmetic series and the number of cosmetic products including the above

| Classification for function    | Ingredients                     | No. of cosmetic products |
|--------------------------------|---------------------------------|--------------------------|
| Fragrance                      | Benzyl salicylate               | 4                        |
| Preservative                   | Paraben                         | 24                       |
|                                | Phenoxyethanol                  | 18                       |
|                                | Quaternium 15                   | 8                        |
|                                | Sorbic acid                     | 6                        |
|                                | Isothiazolinone (Kathon CG)     | 4                        |
|                                | Benzyl alcohol                  | 3                        |
|                                | DMDM hydantoin                  | 2                        |
|                                | 4-Chloro-3-cresol (PCMC)        | 2                        |
|                                | Iodopropynyl butylcarbamate     | 1                        |
|                                | BHT                             | 5                        |
| Antioxidant                    | Propyl gallate                  | 1                        |
| Ultraviolet absorber           | 2-hydroxy-4-methoxybenzophenone | 4                        |
| Vehicle                        | Propylene glycol                | 14                       |
| Humectant/emollient/emulsifier | Triethanolamine                 | 7                        |
|                                | Stearyl alcohol                 | 5                        |
|                                | Cetyl alcohol                   | 4                        |
|                                | Isopropyl myristate             | 3                        |
|                                | Sorbitan                        | 3                        |
| Surfactant                     | Cocamidopropyl betaine          | 7                        |

DMDM: dimethylol dimethyl, BHT: butylated hydroxytoluene.

studied the patch test twice, in 1990 and 1998 in Danish patients. The results demonstrated that the number of patients tested positive were twice in 1998 compared to 1990. Fragrance and preservatives were the most frequently identified antigen that provoked contact dermatitis in cosmetic products<sup>1,4-6,10,11</sup>. Products that most frequently caused contact dermatitis are skin care products, followed by hair products, makeup and nail polish<sup>4-6,10,11</sup>. In Korea, Lee et al.<sup>12</sup> divided cosmetic products in accordance with the Bauer classification into skin care products, toiletries, makeup products and fragrances. Skin care products caused the highest positive rate of positive patch test, followed by body cleansing and makeup products. However, it must be emphasized that different classification standards were applied to the cosmetic products investigated, and the number of hair and nail related products studied was too small to enable accurate comparison.

In Korea, the most widely used patch test to determine antigens in cosmetic products is cosmetic series, which includes 48 antigens. The ratio of antigen found in the cosmetic products surveyed to that included the patch test was only 41.7%. The constituents that exhibited the highest positive rates are thimerosal, octyl gallate, t-butylhydroquinone, paraben, and benzyl salicylate<sup>7,12</sup>. Only paraben and benzyl salicylate were found in the cosmetic products surveyed. Through this result, the ingredients with high antigenicity that are included in the cosmetic

series would not be widely used as the ingredient of cosmetic product in fact. However, notable is that constituents not being included in cosmetic series but have antigenicity are frequently included in marketed cosmetic products. Only 27.0% of as antigens found in the surveyed products were included in cosmetic series.

This study classified the ingredients of surveyed cosmetic products and looking into each function. One of the most common ingredients causing the contact dermatitis by the cosmetic product are preservatives<sup>5,6,10,11,13</sup>. The most widely used ones are parabens, imidazolidinyl urea, quaternium-15, formaldehyde, isothiazolinones and others<sup>14,15</sup>. Through this study, paraben is most frequently used, followed by quaternium-15, isothiazolinones and others. This study confirms that cosmetic series includes most preservatives found in marketed cosmetic products, except sodium benzoate and chlorphenesin, and through this, the cosmetic series is relatively well reflected for the preservative ingredient.

Although fragrances frequently cause contact dermatitis<sup>1,4,5,10</sup>, cosmetic series does not include any fragrance other than benzyl salicylate, a fragrance solvent. Approximately 1~4% of the general population is allergic to fragrances<sup>16,17</sup>. If patch test was used to investigate patients suspected of developing contact dermatitis, approximately 42~54% would demonstrate positive reaction<sup>1,6,18</sup>. The reason behind such a high positive rate is that fragrances are included not only in the perfume but

also in the various types of cosmetic product, detergent, medical product and others<sup>19,22</sup>. In this study, more than half of the tested products contained fragrance, which were confirmed to be included in various cosmetic product types other than the aroma products. Currently, the EU requires the labeling of 26 ingredients from the fragrance ingredients<sup>23</sup>, and the fragrance ingredients used in the cosmetic product confirmed through this study would be 17 kinds to show that various fragrances are used in relatively high frequency. As such, if ACD is suspected to be secondary to cosmetic products, it will be desirable to investigate using the patch test in conjunction with cosmetic series.

The most frequently used antioxidants are butylhydroxyanisole, butylated hydroxytoluene, tertiary butylhydroquinone, gallate esters (propyl gallate, octyl gallate, dodecyl gallate),  $\alpha$ -tocopherol (vitamin E) and ascorbic acid (vitamin C). Among them, propyl gallate, butylated hydroxytoluene and  $\alpha$ -tocopherol were confirmed to be present in the tested cosmetic products. Neither butylated hydroxytoluene nor  $\alpha$ -tocopherol was included in cosmetic series even though these 2 constituents are frequently used and can cause ACD<sup>24-27</sup>.

Ultraviolet absorbers including benzophenone, along with butyl methoxydibenzoylmethane, ethylhexyl methoxycinnamate, and octyl salicylate were confirmed to be present in cosmetic products sold in the market. They may cause contact dermatitis and photo-contact dermatitis<sup>28</sup>. In the event of suspected photo-contact dermatitis, it would be desirable to implement the photo patch test on these ingredients together.

The vehicles, humectants, emollient, and emulsifier may also work as an antigen<sup>29,32</sup>. From the ingredients that are frequently used as the cosmetic product ingredient and may cause the ACD, the ingredients that are not included to the cosmetic series are petrolatum<sup>30</sup>, glycerin<sup>33</sup>, glycol (butylenes glycol, polyethylene glycol, pentylene glycol, hexylene glycol)<sup>33,34</sup>, lanolin<sup>35</sup>, castor oil<sup>36,37</sup>, propolis (bee-glue)<sup>38,39</sup> and others. Glycerin may rarely induce sensitization<sup>33</sup>. Glycol is the most widely used vehicle, in addition to propylene glycol included in cosmetic series, butylenes glycol and polyethylene glycol have been reported as relatively frequent causes of contact dermatitis<sup>29,33,34</sup>. Lanolin causes relatively high sensitization rates in local treatment agents used in patients with stasis dermatitis, which may stimulate allergic reactions in rare case of the cosmetic product ingredient<sup>35</sup>. Castor oil and propolis are used in many cosmetic products, such as lipstick and lotion<sup>36,39</sup>, and they have been reported to cause ACD in a number of cases<sup>36,37,39</sup>. The above constituents do not have high antigenicity but are

common ingredients of cosmetic product that should be investigated.

Cases of causing the ACD by the use of hair and nail related product is known to be the next most frequently caused case after the case of causing by the skin care products<sup>4-6,10,11</sup>. The ingredients with the main cause of the contact dermatitis by this product are p-phenylenediamine and tosylamide formaldehyde resin. However, cosmetic series did not include these constituents, therefore, in the event that it is suspicious clinically, an additional test required to determine presence of these antigens.

Although manufacturers of cosmetic products have recently been mandated to disclose the ingredients in Korea, data accessible to dermatologists are still limited. In this study, a variety of cosmetic product has been surveyed, but it has the subjects of a total of 55 cosmetic products that this result shall not be construed as displaying all ingredients of cosmetic product on the market. In the near future, a more thorough survey in conjunction with the Korea Food and Drug Administration by analyzing database will be necessary. However, this study demonstrated that constituents that may stimulate ACD are not being included in the patch test as antigens are commonly found in cosmetic products sold in Korea. Inclusion of ingredients frequently generate allergy to the patch test is therefore crucial. For example, fragrance is the frequent cause of the contact dermatitis and is broadly included in various types of cosmetic products as well as in the aroma product, but it is not reflected in the patch test of the cosmetic product. Therefore, it would be desirable to work together with the inspection.

In conclusion, the authors classified the cosmetic product into 11 categories and the survey has been conducted on entire ingredients of a total of 55 cosmetic products with 5 cosmetic products applicable for each category and classify it into 10 types for each chemical functions to compare with the antigens of the cosmetic series to obtain the following results:

1. A total of 55 cosmetic products were found to have of a total of 155 ingredients, and the number of ingredient working as the antigen was 74 kinds (47.7%) with 18 kinds of fragrance, 11 kinds of preservative, 4 kinds of antioxidant, 8 kinds of vehicle, 10 kinds of surfactant and others. And, with the exception of ingredient included in others most ingredients were worked as antigens.

2. Among 74 ingredients known to work as antigens, only 20 ingredients (27.0%) were included in the cosmetic series as the antigens. A significant number of ingredients, such as fragrance, vehicle and surfactant were not included, while the preservative ingredients displayed as

all included with the exception of 2 kinds from 11 kinds.

3. Only 20 (41.7%) of 48 antigens belonging to the cosmetic series were confirmed in actual cosmetic products. From them, the preservative ingredient had the largest ratio, and paraben, phenoxyethanol, and propylene glycol were used with the highest frequency.

Through the above result, the ingredients that are not included in the patch test but may provoke the ACD are widely used as the raw materials of cosmetic products. Therefore, the ingredients that may stimulate the allergy with relatively high frequency of use would be of help by included in the patch test, and in particular, notwithstanding the fact that the fragrance as the common cause of contact dermatitis is widely included in various types of cosmetic product, it is not reflected in the patch test of cosmetic product that it would be desirable to have the inspection together.

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