

Cosmetic preservative labelling on the Thai market

Monthathip Bunyavaree, Pranee Kasemsarn and Waranya Boonchai

Department of Dermatology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand

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Summary

Background: Preservatives are added to cosmetics and other consumer products to prevent microbial growth and product degradation. Many cosmetic preservatives are skin sensitizers and frequent causes of contact dermatitis. The use of preservatives may vary by country and/or region, according to legislation, and may be reflected in differences in the prevalence rates of preservative allergy worldwide.

Objective: To examine the type and frequency of preservative use in cosmetics sold in Thai markets in metropolitan Bangkok, Thailand.

Methods: Preservatives contained in 1000 different cosmetics sold in Thai markets were documented and analysed, based on the labelling of ingredients.

Results: Most of the cosmetic and skincare products sold in Thai markets were international brands, with only a small proportion of cosmetic products being produced in Thailand. International brand cosmetics were more likely to contain non-formaldehyde-releasing preservatives than domestically produced brands. Isothiazolinone-based preservatives, which are responsible for the current increase in the prevalence of contact allergy, were found at a significant frequency in domestically produced, leave-on cosmetic products.

Conclusion: Preservatives in cosmetics were significantly different according to source of production and type of cosmetics.

Key words: contact allergy; cosmetics; ingredient label; preservatives; skin care products.

Preservatives in cosmetic products are essential to protect against the growth of microorganisms, which can both alter product composition and pose a health risk to the consumer. Allergic contact dermatitis resulting from cosmetic product use has been increasingly detected (1). Preservatives were found to be responsible in > 50% of cases (2–4). The frequency of preservative allergy is increasing globally (5), including in Thailand (3). Skin

care products available in Thai markets are manufactured both domestically and internationally. The composition of international brand cosmetic products may be modified to satisfy national or regional needs or requirements, as dictated by consumer taste, environmental factors, and legal regulation. Information regarding the use of preservatives in cosmetics and skin care products in Thailand is limited. The ASEAN Economic Community (AEC) will be formed by the end of 2015. The formation of the AEC will effectively establish a single market of 600 million people that will provide plentiful opportunities for the cosmetics industry. The Thai Food and Drug Administration (FDA) recently revised its cosmetic regulations to comply with AEC directives (6). According to our review of the literature, no previous study has reported on the preservatives used in cosmetics and skin care products sold in ASEAN markets or in metropolitan Bangkok, Thailand. Accordingly, the aim of this study was to examine the type and

Correspondence: Waranya Boonchai, Department of Dermatology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700 Thailand. Tel: +662 4197000, ext. 4320; Fax: +662 4115031. E-mail: wboonchai@yahoo.com

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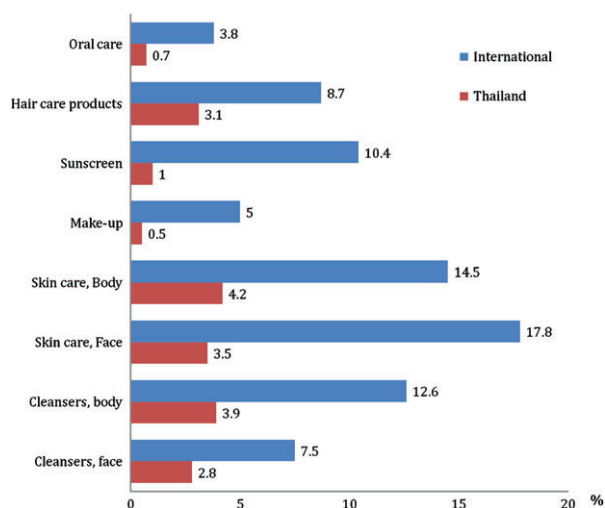


Fig. 1. Skin care and cosmetic product categories that were investigated.

frequency of preservative use in cosmetics sold in Thai markets in metropolitan Bangkok, Thailand, and also in AEC markets in the near future.

Materials and Methods

This was a cross-sectional study. Skin care and cosmetic product data were collected from several economic levels of Thai markets – market stalls, supermarkets,

superstores (serving middle-income and low-income people), and department stores (serving high-income people) – located in metropolitan Bangkok, Thailand during the 2014 study period. Product ingredients were also collected from the patch tested products that were brought in by the patients. The ingredients taken from product labels were entered into a Microsoft® Access™ database (Microsoft Corporation, Redmond, WA, USA). Skin care and cosmetic products were classified into eight categories (Fig. 1). Product preservatives were classified into two groups: formaldehyde releasers and non-formaldehyde releasers. Preservatives specific to each classification are listed in Tables 1 and 2. Other preservatives included alcohols, chloroacetamide, chloroxylenol, sorbic acid, and triclosan.

The data were analysed by the use of descriptive analysis. Pearson's chi-square test or Fisher's exact test was performed with PASW STATISTICS 18.0 (SPSS™ Inc., Chicago, IL, USA). A *p*-value of < 0.05 was considered to be statistically significant.

Results

A total of 1000 cosmetic and skin care products were reviewed. Of these, 197 (19.7%) products were domestically produced in Thailand, and 803 (80.3%) were international brands produced outside of Thailand. Among the 1000 products reviewed, 87.6% contained only non-formaldehyde-releasing preservatives

Table 1. Comparison of preservatives used in domestically produced and in international brand products, and in leave-on and in rinse-off products, that are sold in Thai markets

Preservatives	% limit of content (6)	All preservatives*, n (%)	Product origin, n (%) n = 1000		Product type, n (%) n = 1000	
			Domestically produced products n = 197	International brand products n = 803	Leave-on products n = 593	Rinse-off products n = 407
Formaldehyde-releasing preservatives	0.05	124 (12.4)	32 (16.2)	92 (11.5)	67 (11.3)	57 (14.0)
DMDM hydantoin	0.6	54 (5.4)	16 (8.1)	38 (4.7)	21 (3.5) [†]	33 (8.1) [†]
Quaternium-15	0.2	2 (0.2)	0 (0.0)	2 (0.2)	0 (0.0)	2 (0.5)
Imidazolidinyl urea	0.6	33 (3.3)	13 (6.6) [‡]	20 (2.5) [‡]	18 (3)	15 (3.7)
Diazolidinyl urea	0.5	34 (3.4)	2 (1.0) [‡]	32 (4.0) [‡]	27 (4.6) [†]	7 (1.7) [†]
2-Bromo-2-nitropropane-1,3-diol	0.1	1 (0.1)	1 (0.5)	0 (0.0)	1 (0.2)	0
Non-formaldehyde-releasing preservatives		958 (95.8)	176 (89.6) [‡]	782 (97.4) [‡]	568 (95.8)	390 (95.8)
MCI/MI	0.0015	101 (10.1)	18 (9.1)	83 (10.3)	15 (2.5) [†]	86 (21.1) [†]
MI alone	0.01	61 (6.1)	17 (8.6)	44 (5.5)	22 (3.7) [†]	39 (9.6) [†]
Parabens	0.8 [§]	432 (43.2)	85 (43.1)	347 (43.2)	320 (54) [†]	112 (27.5) [†]
Others	–	490 (49.0)	80 (40.6) [‡]	410 (51.1) [‡]	292 (42.9)	198 (48.6)

MCI, methylchloroisothiazolinone; MI, methylisothiazolinone.

*Eighty-two products contained both formaldehyde-releasing preservatives and non-formaldehyde-releasing preservatives.

^{†,‡}*p* < 0.05.

[§]The limit of individual paraben ester is restricted to 0.4%.

Table 2. Frequency of preservative labelling in 1000 cosmetics and toiletries sold in Thai markets

Preservatives	All preservatives*	Products containing certain preservatives n (% of total)			
		Leave-on products n = 593		Rinse-off products n = 407	
		Domestic n = 106	International n = 487	Domestic n = 91	International n = 316
Formaldehyde-releasing preservatives					
DMDM hydantoin	54 (5.4)	9 (8.5) [†]	12 (2.5) [†]	7 (7.7)	26 (8.2)
Quaternium-15	2 (0.2)	0	0	0	2 (0.6)
Imidazolidinyl urea	33 (3.3)	5 (4.7)	13 (2.7)	8 (8.8) [‡]	7 (2.2) [‡]
Diazolidinyl urea	34 (3.4)	2 (1.9)	25 (5.1)	0	7 (2.2)
2-Bromo-2-nitropropane-1,3-diol	1 (0.1)	1 (0.9)	0	0	0
Non-formaldehyde-releasing preservatives					
Methylchloroisothiazolinone	101 (10.1)	7 (6.6) [†]	8 (1.6) [†]	11 (12.1) [‡]	75 (23.7) [‡]
Methylisothiazolinone	162 (16.2)	18 (17.0) [†]	19 (3.9) [†]	17 (18.7) [‡]	108 (34.2) [‡]
Parabens	432 (43.2)	59 (55.7)	261 (53.6)	26 (28.6)	86 (27.2)
Others	490 (49.0)	34 (32.1) [†]	258 (53.0) [†]	46 (50.5)	152 (48.1)

*Eighty-two products contained both formaldehyde-releasing preservatives and non-formaldehyde-releasing preservatives.

^{†,‡} $p < 0.05$.

(non-FRPs), 4.2% contained only formaldehyde-releasing preservatives (FRPs), and 8.2% contained both FRPs and non-FRPs. None of the investigated products was free of preservatives. The three preservatives most commonly found in cosmetics and skin care products sold in Thai markets were parabens, followed by methylchloroisothiazolinone (MCI)/methylisothiazolinone (MI) and MI alone. The prevalence rates and prevalence ranking of these three preservatives were the same in both the domestic group and the international product group. The frequency of each preservative is shown in Table 1. Methylidibromo glutaronitrile was not found in any of the studied products.

Among the eight categories of cosmetic and skin care products, parabens were most frequently found in six categories. For the body cleanser and hair care product categories, MCI and MI were the most commonly observed preservatives (Fig. 2).

FRPs and non-FRPs were found in both leave-on and rinse-off products (Table 1). Parabens were most commonly found in leave-on products, whereas MI alone and MCI/MI were most commonly found in rinse-off products.

Regarding domestically produced leave-on cosmetic products, DMDM hydantoin was the most commonly used FRP, and MCI/MI was the most commonly used non-FRP. For rinse-off cosmetic products, the most commonly used FRP in domestically produced products was imidazolidinyl urea, and the most commonly used FRP found in international brand products was MCI/MI (Table 2).

Discussion

Most of the cosmetic and skin care products that we identified as being sold in Thai markets were made in foreign countries, with only 20% being domestically produced in Thailand. Domestically produced cosmetic products were often found to be herbal, plant-derived products, which are currently fashionable and in relatively high demand. Preservatives constitute one of the main causes of cosmetic allergy, which has been increasing in frequency over the last decade (3). Preservatives in leave-on cosmetic products are more often the cause of skin reactions than preservatives in rinse-off cosmetic products (7). Diazolidinyl urea and parabens were more commonly used in leave-on cosmetic products sold in Thailand, leading to allergic contact dermatitis rates of 3.6% and 9.2%, respectively (3). The prevalence rates of diazolidinyl urea and parabens allergies in Singapore were lower, at 1.37% and 2.58%, respectively (8).

The use of cosmetic preservatives varies between leave-on and rinse-off products, owing to formula compatibility, skin-sensitizing potential, and regulatory oversight in each region. Legislation from the EU Cosmetics Directive mandated a change in the cosmetic preservative concentration of MCI/MI from a ratio of 3:1 to a maximum concentration of 15 ppm in all cosmetic products (9, 10). In a subsequent 2014 amendment, the same 15 ppm MCI/MI maximum concentration was applied to rinse-off skin products, and MI concentrations of up to 0.01% in both leave-on and rinse-off cosmetic products were specified (11). This helps to explain why

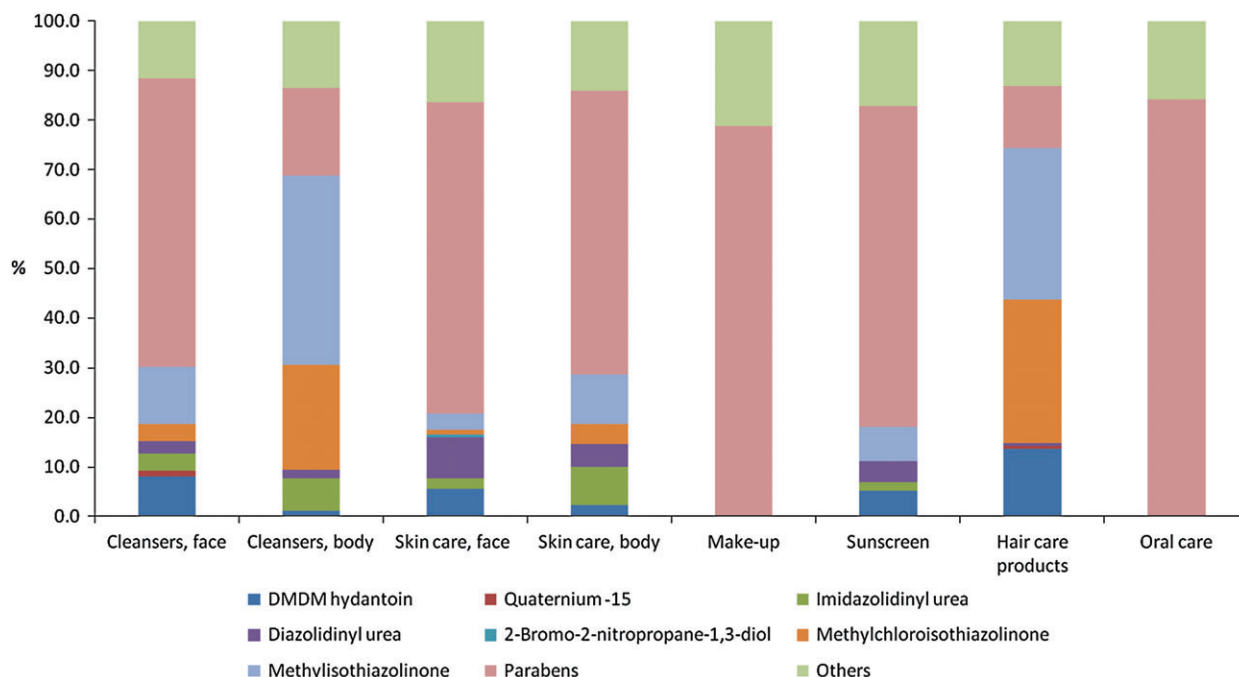


Fig. 2. Relative frequencies of formaldehyde-releasing and non-formaldehyde-releasing preservatives in skin care and cosmetic product categories.

both MCI/MI and MI were found across the spectrum of rinse-off cosmetic products that we reviewed. The use of MCI and MI as preservatives in leave-on products was significant in domestically produced cosmetic products. The significant use of MCI/MI in current commercialized cosmetic products was found to be responsible for an unprecedented rise in isothiazolinone allergy in Thailand, from 4.3% to 9.8% in 6 years (3, 12). The Thai FDA normally follows the EU Cosmetic Directive legislation for the regulation of preservative concentrations in cosmetics, and is about to issue similar legislation in Thailand in 2015, which may come into effect next year.

FRPs were more frequently used in cosmetics sold in Thailand than in those sold in Germany (13), especially those domestically produced in Thailand. The frequency of contact allergy to formaldehyde and formaldehyde releasers varied from country to country (14). However, the rate of FRP-related allergy was not as high as the rate of non-FRP-related allergy found in our previous study (3). Hair care products and shampoos sold in Thailand were found to mainly contain MCI/MI as a preservative, followed by DMDM hydantoin and parabens. The most common preservatives found in Israeli shampoos, according to labelling, were DMDM hydantoin and MCI/MI (15). Hair products in Germany primarily use parabens, and only 10% use MCI/MI (13). The type and amount of preservatives used in cosmetics were found to be diverse,

according to national and regional regulation, even in the era of globalization, perhaps also reflecting the rates of preservative sensitivity around the world (16).

The frequency of use of individual preservatives in cosmetic products sold in Thai markets reflected the sensitization rate of each preservative in the population. The most common preservatives found in our study were parabens and MCI/MI, with associated allergy prevalence rates of 9.2% and 4.3%, respectively (3). Over the last decade, non-FRPs were found to have approximately four times greater skin-sensitizing potential than FRPs (3).

This study focused on two important classes of preservative, but did not include other preservatives that are increasingly found in cosmetics, such as phenoxyethanol (15, 17) and chlorhexidine (18). Our ingredient labelling study did not include or evaluate ingredient concentrations. From our findings, we concluded that multiple preservatives with well-known skin-sensitizing potential are common ingredients in cosmetics sold in Thai markets in metropolitan Bangkok, Thailand. Repeated exposure to cosmetics and toiletries can lead to contact allergy later in life. Therefore, the oversight bodies responsible for regulating the cosmetics industry in each country/region should be promptly updated regarding allergy-related problems, and remain vigilant in their efforts to protect consumers from the adverse effects of preservatives.

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