

Research Article

Preservatives in a Selection of Consumer Products Purchased in the United Arab Emirates

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Abstract

Background: In both Europe and the USA it is mandatory that personal care products are labelled with an ingredient list. This facilitates the possibility to assess exposure to known contact allergens. However, if the products are incorrectly labelled it might pose an obstacle for patients trying to avoid allergens and obstruct the evaluation of clinical relevance for the clinician.

Objectives: To investigate the consistency between labelling and chemically detected amounts of 7 preservatives in consumer products bought on the unregulated market of the United Arab Emirates (UAE) and compare the results with previous studies of the consistency on the European market.

Material/Methods: 64 personal care products and 2 washing-up liquids purchased in the UAE had their ingredient label examined and were analyzed with high-performance liquid chromatography with regard to formaldehyde, methylchloroisothiazolinone/methylisothiazolinone, methyl-, ethyl-, propyl- and butylparaben. Formaldehyde was first screened with the chromotropic acid method.

Results: According to labelling, the most prevalent preservatives were parabens, phenoxyethanol and sodium benzoate. Parabens were detected in 33 (50%) products. Formaldehyde was detected in 16 (24%) products; in 2, a conditioner and a wash-up liquid, the concentration was above 500 ppm. MCI/MI or MI was found in 18 (27%) products. In 4 products, 3 wet wipes and 1 shampoo, the amount of MI was >100 ppm, i.e. higher than allowed within the EU. 23 (36%) products had ingredient labelling that deviated from the analytically detected amounts of the 7 investigated preservatives. In 9 of these labelled preservatives could not be detected, in 14 non-labelled preservatives were found and in 1 both deviations occurred.

Conclusion: The consistency between labelled and detected preservatives on the unregulated market of UAE is similar to that of the European market just as the current regulation came into act. Many products were incorrectly labelled which might affect consumer safety.

Keywords: Allergic Contact Dermatitis; Preservatives; Consumer Product Safety; Methylchloroisothiazolinone/Methylisothiazolinone; Formaldehyde; Parabens; High-Performance Liquid Chromatography; Chromotropic Acid Method

Introduction

Preservatives are added to water-containing consumer products to inhibit microbial growth which may destroy or alter the product. However, many preservatives can cause contact allergy and they are, second to fragrances, the most common cause of cosmetic-related contact allergy [1]. Some preservatives, such as those containing methylchloroisothiazolinone (MCI) are strong contact allergens, while others like parabens, relatively rarely cause allergic contact dermatitis [2]. Some, like formaldehyde and formaldehyde donors, are ubiquitous and the extensive exposure contributes to high frequencies of contact allergy [3]. Recently, the association between exposure and allergy frequencies has been illustrated by the much debated rapid increase in the prevalence of contact allergies to methylisothiazolinone (MI) in several European countries [4-9]. This has been attributed to an increased exposure of MI due to the regulation that came into act in 2005 which allowed MI to be used in 100 ppm in cosmetics and personal care products [10].

On both the European and US market, a complete list of all ingredients, in descending order of concentration, used in cosmetic and personal care products must be enclosed with the product [11,12]. Provided that the labelling is correct and complete, the regulations ensure that individuals with a contact allergy can avoid their allergen. However, studies from Europe have shown that even products sold in regulated markets are labelled incorrectly [13-16]. The objective with this study was to survey an un-regulated market's compliance regarding labelling and actual content of preservatives with that of the EU market and to compare the findings with previous studies performed in Europe. The presence of 7 common preservatives in 66 products bought in the United Arab Emirates (UAE) was chemically investigated and compared with the information given by the manufacturers, as labelled on the packages. The aim by comparing this market's compliance with European legislation was to get a measurement of consumer safety in the UAE population with regard to the consumers' possibility to assess their exposure to common preservatives. The investigated preservatives, which are all common in personal care products, were MCI, MI, formaldehyde and methyl-, ethyl-, propyl- and butylparabens.

Materials and Methods

Selection of products

In January 2013, consumer products such as soaps, shampoos, wet tissues, moisturizers and wash-up liquids were purchased in stores in Abu Dhabi, the capital of the UAE. Products were selected from different retail classes in order to get products that covered a wide spectrum of the community market ranging from those sold in

supermarkets to more luxurious stores. A total of 66 products were collected; 30 rinse-off products and 36 leave-on products – consisting of 6 shampoos, 8 shower gels, 5 conditioners, 5 facial masks, 4 liquid soaps, 2 wash-up liquids, 4 lightening facial creams, 4 hair oils, 15 wet tissues and 13 moisturizers. All products were catalogued and the preservatives declared upon the ingredient labelling were noted. All products were within expiration date. They were kept at room temperature at time of investigation. All products, except the washing-up liquids, would have been regulated by the Cosmetics Regulation (EC 1223/2009) if bought in Europe. In Europe, washing-up liquids are regulated by Detergents Regulation (EC 648/2004) which states that consumer-available detergent products must have a website address on the label where information on chemical composition can be found.

Chemicals

Formaldehyde, 2,4-dinitrophenylhydrazine (2,4-DNPH), and sodium hydroxide were obtained from Acros Organics (Geel, Belgium), chromotropic acid and acetic acid from Merck (Darmstadt, Germany), sulphuric acid from Sigma-Aldrich Chemie (GmbH, Stenheim, Germany), acetonitrile and methanol from Prolabo (Leuven, Belgium), anhydrous disodium hydrogen phosphate from Janssen Chimica (Geel, Belgium), ammonium acetate from J.T.Baker (Deventer, Holland), diethyl ether from Lab-Scan, (Gliwice, Poland), tetrahydrofuran from Prolabo (Fontenay-sous-Bois, France), methylparaben, ethylparaben and propylparaben from FlukaChemie AG (Buchs, Switzerland), butylparaben from Lancaster (Morecambe, England), MCI/MI from formerly Rohm and Haas Company (Philadelphia, PA, USA); now The Dow Chemical Company, (Midland, Michigan, USA), milliQ water from Millipore, (Molsheim, France).

Chemical analysis

All investigated preservatives were analyzed using methods based on isocratic HPLC systems. For formaldehyde all products were first screened with the semiquantitative chromotropic acid method which has been described in detail by Frick-Engfeldt et al [17]. All products yielding a positive or doubtful result when screened were analyzed by HPLC.

High Performance Liquid Chromatographic (HPLC)

The HPLC system used was from Thermo Separation Products (San Jose, CA, USA) and consisted of a Spectra Series P200 gradient pump, a Spectra System UV1000 detector and a SP4400 ChromJet integrator. The system was software controlled and UV spectra monitored using Chromeleon®7 Chromatography Data System (Thermo Fisher Scientific, Waltham, MA, USA). The system

was equipped with a Rheodyne 7125 injector with a 20-ml loop. The column (4.6mm internal diameter X250 mm) was packed with Nucleosil C18 (5 mm). Isocratic elution was performed for all preservatives using the mobil phases listed in Table 1. The flow rate was 1 ml/min.

The paraben samples were diluted another 10-25× before analysis. Samples containing wet tissues were diluted 10× before analysis. Standard solutions were prepared in the concentrations listed in Table 2. The formaldehyde

Table 1. Chromatographic conditions for HPLC analyses of the 7 preservatives as well as data on detection limits, recoveries and manufacturer of reference substances.

Preservative	Mobile phase (v/v)	Column	UV-detection (nm)	Detection limit (ppm; w/w)	Recovery (%; w/w)*		
					Moisturiser	Liquid soap	Shampoo
Formaldehyde	acetonitrile/water 60/40	Nucleosil C18 250×4.6 mm (5 μm particles)	345	0.5	100	94-100	94-98
Methylparaben	tetrahydrofuran/water/ acetonitrile/methanol 5/40/30/25	Kromasil C18 250×4.6 mm (5 μm particles)	280	3	100-102	98.6-101	100-101
Ethylparaben	tetrahydrofuran/water/ acetonitrile/methanol 5/40/30/25	Kromasil C18 250×4.6 mm (5 μm particles)	280	2	98.6-100	102.2-104	99.9-102
Propylparaben	tetrahydrofuran/water/ acetonitrile/methanol 5/40/30/25	Kromasil C18 250×4.6 mm (5 μm particles)	280	2	98.6-99.7	100-104	96.9-97.5
Butylparaben	tetrahydrofuran/water/ acetonitrile/methanol 5/40/30/25	Kromasil C18 250×4.6 mm (5 μm particles)	280	2	98.8-100	103-104	93.9-94.9
Methylisothiazolinone	methanol/water 30/70	Nucleosil C18 250×4.6 mm (5 μm particles)	280	1	65.3-89.7	81.8-100	74.2-91
Methylchloro-isothiazolinone	methanol/water 30/70	Nucleosil C18 250×4.6 mm (5 μm particles)	280	1.5	94.3-100	82.1-102	93-105

*given as a range of quadruple samples for formaldehyde and MCI/MI and as a range of double samples for the parabens

Sample Preparation

Double samples of approximately 1 g of each product was weighed and placed in graded test tubes to which solvents were added up to the 10 ml grading and stirred in a vortex mixer. This was done for all products with exception for the analyses of wet tissues. Double samples of each tissue brand were prepared by dissolving 1 tissue in 40 ml of solvent. For the analysis of MCI, MI and the 4 parabens the mobile phase was used as solvent (Table 1, 2) while tetrahydrofuran:water (9:1 v/v) was used when preparing samples of formaldehyde (Table 2).

samples were treated according to a method where 2,4-dinitrophenylhydrazine (2,4-DNPH) is used as a derivatizing agent and has been described in detail by Horev et al [18].

Recovery

To estimate the recovery of a preservative, quadruple samples were made where a known amount of the preservative was added to products not containing the actual preservative. The preservative was added to the products to give a concentration corresponding to

Table 2. Solvents and concentrations used during sample preparation.

Analyte	Solvent	Standard concentrations (%)	Dilution of weighed samples
methylchloroisothiazolinone (MCI)*	methanol/water 30/70	0; 0.00006; 0.00015; 0.0003	10
methylisothiazolinone (MI)*	methanol/water 30/70	0; 0.00014; 0.00035; 0.0007	10
Parabens** - Methylparaben - Ethylparaben - Propylparaben - Butylparaben	tetrahydrofuran/water /acetonitrile/methanol 5/40/30/25	0; 0.00125; 0.0025; 0.005	100-250
Formaldehyde	tetrahydrofuran/water 90/10	0; 0.0002; 0.0005; 0.0010	10

*preparations of the standards were made on a stock solution consisting of MCI:MI in the ration 3:1. The two preservatives were analysed in the same runs.

** preparations of the standards were made on a stock solution containing all the listed parabens in the same concentrations. The four parabens were analysed in the same runs.

approximately 10 ppm and the spiked samples were then analyzed according to the specific methods. In Table 1 the recoveries are listed.

Results

According to the ingredient labelling 23 products did not contain any of the 7 analyzed preservatives while 41 products were declared to contain at least one of them (Table 3). Parabens were most commonly declared and were listed on 24 of the 66 products followed by phenoxyethanol and sodium benzoate which were also commonly declared (Table 3).

Table 3. The number of products with labelling of preservatives as well as the number of products where the 7 investigated preservatives were chemically detected together with the found concentration range.

Preservative	Maximum allowed concentration in EU (%)	Declared in no of products						Present in no of products						Concentration range (ppm; w/w)
		Leave-on			Rinse-off			Leave-on			Rinse-off			
		Moisturisers/ Facial creams	Hair oils	Wet tissues	Shampoos/ conditioners	Soaps/shower gels/facial mask	Washing-up liquids*	Moisturisers/ Facial creams	Hair oils	Wet tissues	Shampoos/ conditioners	Soaps/shower gels/facial mask	Washing-up liquids*	
<i>Analyzed preservatives</i>														
Formaldehyde	0.2						4		5	5	1	1	6-851	
Methylchloroisothiazolinone (only)	-			2									2.6-11.3**	
Methylisothiazolinone (only)	0.01			2				1	3	1			1.2-201.5***	
Methylchloroisothiazolinone/methylisothiazolinone	0.0015			4	5	5			4	4	4	1	4.7-15.3§	
Parabens (esters of 4-hydroxybenzoic acid)	0.8	14		2	3	5		15		5	4	7	2	90-7905
methylparaben	0.4	14		1	3	5		14		5	4	7	1	90-4070
ethylparaben	0.4	2		1		1		2		1			2	190-210
propylparaben	0.4	12		1	1	2		11		1		1		73-3620
butylparaben	0.4	1		1	1	2			1			1		210-220
<i>Preservatives noted on the ingredient lists</i>														
Benzalkonium chloride	0.1			1										
Benzoic acid	3.0 (rinse-off shampoos) 2.0 (other products)			1										
Benzyl alcohol	1.0	2		1	1	1								
Benzyl benzoate		2		1										
2-Bromo-2-nitropropane-1,3-diol ^a	0.1			1										
Cetrimonium chloride	0.1				1									
Dehydroacetic acid	0.6			2										
DMDM hydantoin ^a	0.6	2		1	5	1								
Imidazolidinylurea ^a	0.6	2				1								
Iodopropionylcarbamate	0.02 (rinse-off) 0.01 (leave-on) 0.0075 (deodorants)			4										
Isobutylparaben	0.4	1												
Phenoxyethanol	1.0	7		5	2	6								
Polyaminopropylbiguanide	0.3			4										
Sodium benzoate (not an INCI name)				4	5	5								
Sodium dehydroacetate	0.6			1										
Sorbic acid	0.6			2										
<i>Products with no declared preservatives</i>														
<i>Products lacking any declaration</i>														
<i>Products with only Arabic declaration</i>														

^aFormaldehyde donors

*The cosmetics regulation does not apply to washing up liquids; **detected amount of MCI in products containing the combination, no products contained MCI alone; *** detected amount of MI (both alone and in combination with MCI); § total amount of MCI/MI in products containing the combination

With regard to the 7 analyzed preservatives the declining order of presence in products according to declaration was methylparaben, propylparaben, MCI/MI, ethylparaben, butylparaben and MI and MCI declared alone. No products were declared to contain formaldehyde, however, 3 formaldehyde donors

were found in the ingredient lists; 2-bromo-2-nitropropane-1,3-diol in 1 leave-on product, DMDM hydantoin in 6 rinse-off products and 3 leave-on products and imidazolidinyl urea in 1 rinse-off product and 2 leave-on products (Table 3). No analyses of these preservatives were performed. Instead the content of free formaldehyde was measured in all products. Formaldehyde could be found in 7.7 % (4/52) of the products not declared to contain formaldehyde donors. In two products, 1 declared to contain DMDM hydantoin and one declared to contain imidazolidinyl urea, no formaldehyde could be detected. Overall formaldehyde was detected in 24% (16/66) of the products (Table 3). In 2 products, 1 conditioner and

1 wash-up liquid the amount was above 0.05% with values corresponding to 0.085 and 0.070%, respectively. According to declaration 2 leave-on products contained only MI and 2 only MCI while 10 rinse-off and 4 leave-on products were declared to contain both MCI and MI. Analyses showed that MI that was not declared

on the labelling could be found in 12% (3/25) of these products (including one of the two washing liquids). One wet tissue was labelled to contain only MCI but instead it only contained MI. Overall; MI was detected in 27 % (18/66) of the products (Table 3). In 4 products, 3 wet wipes and 1 shampoo, the amount was higher than allowed within the EU with found concentrations of 201.5, 119.5 and 109 ppm for the wet wipes and 109.5 for the shampoo. MCI was found in 4% (1/25) of the products (one of the washing liquids) without being declared. In three products declared to contain MCI no amounts could be detected.

24 products were declared to contain any of the 4 parabens investigated (Table 3). In 33% (8/24) the content did not match the labelling with regard to which of the four parabens that were present. Furthermore, one or more of the parabens could be found in 17.5% (7/40) of the products lacking declaration of containing parabens.

In total, there were 23 personal care products (36%) where the ingredient labelling of the 7 investigated preservatives was inconsistent with the analytically detected amounts (Table 4). In 10 (16%) the labelled preservatives could not be detected and in 14 (22%) preservatives not declared on the ingredient labelling was found (Table 4). The two washing liquids were only declared "preservatives". Chemical analysis showed that 1 contained formaldehyde, ethylparaben and MCI/MI while the other contained ethylparaben and methylparaben.

Discussion

It can be difficult to assess if a contact allergy to a preservative is clinically relevant since the concentration in personal care products often is so low that patch testing with the product itself gives rise to negative patch test results. Still, they might cause allergic contact dermatitis if used for a prolonged time. The mandatory labelling within the EU of personal care products has facilitated the exposure assessment to allergens and thereby enabled to diminish the risk of allergic contact dermatitis. Consequently, it is important that the labelling is correct so that the attentive consumer is not unknowingly exposed to substances that he or she is actively avoiding.

According to labelling, the most commonly declared preservatives amongst the investigated products were parabens followed by phenoxyethanol in different combinations. Furthermore, the number of preservatives used tended to be higher in leave-on than in rinse-off products (Table 3). These findings are in concordance with a recently published study from Germany [10] where the same pattern was seen. However, a higher rate of products declared to contain MCI/MI was found in

the products from UAE compared to those from Germany and the same was seen for formaldehyde releasers.

With regard to the question; can ingredient labelling be trusted? The chemical analysis of the 7 preservatives showed that 25% of the soaps/shower gels, 18% of the moisturizers/facial creams, 42% of the shampoos/conditioners and 53% of the wet tissues had ingredient labelling that deviated from the chemical analysis (Table 4).

Table 4. Deviations in the consistency between labelled and chemically found data of the 7 investigated preservatives.

Product type	No of analysed products	Number of products with inconsistent labelling (deviations)			Frequency of deviations (%)
		Preservative not declared but present	Preservative declared but not present	Products with both deviations	
Moisturisers/facial creams	17	1	2		17.6
Hair oils	4	1			25
Wet tissues	15	7	1	1	60
Shampoos/conditioners	12	2	4		50
Soaps/shower gels/facial masks	16	2	2		25
Total	64	13	9	1	35.9

This corresponds to figures seen in studies performed just around the time of the regulatory introduction of ingredient lists on consumer products [14-16]. However, there seem to have been an adaptation to a better adherence to the legislation, in at least Sweden, in recent years. Unpublished results from a survey conducted at the Department of Occupational and Environmental Dermatology in Malmö in 2005, where 67 skin care products marketed for use in industrial settings were analyzed 16.7% of the soaps and 3.2% of the moisturizers or protective creams had ingredient labelling that deviated from the chemical analysis and in a survey performed by the Swedish Medical Products Agency in 2012 10.8% of chemically investigated moisturizers were incorrectly labelled[13]. In a recent study 60 Israeli brand cosmetics were investigated with regard to 4 common preservatives (18) and all but one product was within the allowed concentrations by the European directive. Israel is not a part of the European Union, yet, the Israeli ministry of health demands its implementation by Israeli producers [18]. So, it seems that the EU regulation has led to improvements in the trustworthiness of ingredient labelling on the European market and on markets implementing the EU regulation. However, the results of the present study indicates that the concordance between labelling and chemically found preservatives in products on an unregulated market is about the same as it was in Europe in the late 90's just as the current regulation came into act. This might have significant

impact upon how clinical relevance is assessed in the country. It might also affect the possibility to assess clinical relevance in countries on regulated markets; in a globalized world where people and goods travel long distances products bought on un-regulated markets might end up in the bathroom cabinets in regulated markets.

It is evident that regulatory measurements can affect the contact allergy rates in society as shown by the recent epidemic of MI-allergy [19]. In this study, MI was detected in 27% of the analyzed products (Table 3). In 3 wet wipes and 1 shampoo the amount was higher than allowed within the EU. MCI was found in 4% of the products (one of the washing liquids) without being declared. In three products declared to contain MCI no amounts could be detected. One wet tissue was labelled to contain only MCI but instead it only contained MI. Since MCI is always used in combination with MI in commercially available preservatives it can be assumed that products declared to contain only MCI are incorrectly labelled.

Chemical analysis of the patients' own products is an important tool in the investigation of allergic contact dermatitis since patch testing with products that contain low concentrations of allergens might give "false negative results". Recently, Hauksson et al showed that repeated open applications of moisturizers containing such low concentrations of formaldehyde as 2.5-10 ppm can deteriorate or prolong the healing of dermatitis [20]. In the present study, formaldehyde in the range of 6-850 ppm was found in 8% of the products not declared to contain formaldehyde or any formaldehyde donors. In one of these products the content was above 0.05% and thus, if sold on the European market, it should have been labelled "contains formaldehyde". In two products the content was below 20 ppm, which is not necessarily a sign of incorrect labelling since other substances such as surfactants can release formaldehyde [21, 22].

Notable, is that many of the deviations stemmed from preservatives that were labelled on the package and then not found when analyzed. This might appear as a minor problem but there is a large number of patients who thoroughly work to avoid substances that they are allergic to and who sometimes get very restricted in what they can use. For these patients incorrect labelling leads to further restrain in life but for no reason.

Conclusion

The clinical relevance of preservative contact allergy can be difficult to assess since the concentration in products often is so low that a positive reaction is not elicited when patch testing the product. However, prolonged use

of the product can cause allergic contact dermatitis or worsen an existing dermatitis. Therefore, ingredient labelling is an important tool for allergic consumers to be able to actively avoid substances they are allergic too. This study shows that the compliance of labelling and chemically found preservatives on the unregulated market of UAE is similar to that of the European market just as the current regulation in Europe came into act. Many products were incorrectly labelled which might have a significant effect upon consumer safety.

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