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EDUCATION AND DEBATE

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A survey of members of the European Surveillance System on Contact Allergy and the EU project "StanDerm" to identify allergens tested in cosmetic series across Europe

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Abstract

Background: There is currently no agreed cosmetic series for use across Europe.

Objectives: To establish allergens currently tested in local and national cosmetic series.

Method: Members of the European Surveillance System on Contact Allergy and the European Cooperation in Science and Technology project TD1206 ("StanDerm") were surveyed to establish their current practice.

Results: A wide range of allergens was tested but there was significant variation between centres on the allergens considered to be important in screening for allergy to cosmetics. The number of allergens tested in addition to the baseline series varied between 2 and 50.

Conclusions: There is a need for further investigation to establish the frequency and relevance of reactions to cosmetic allergens to enable an agreed evidence-based cosmetic series to be produced. Criteria for inclusion need to be established.

KEYWORDS
allergic contact dermatitis, cosmetic, diagnosis

1 | INTRODUCTION

One of the main outcomes of the European Surveillance System on Contact Allergy (ESSCA) meeting in Manchester, UK in September 2016, was to develop a recommended European Cosmetic Series. As a first step, a survey was undertaken to establish which cosmetics were currently tested by members across Europe.

As European guidance on hairdressing[1] and photo-patch[2]/sunscreen allergens has recently been produced these were excluded. Furthermore, because of the debate over relevant screening allergens to test for fragrance allergy, this was excluded from the remit as there is currently no consensus[3] and a separate ongoing debate.[4]

2 | METHODS

Members of the ESSCA and the European Cooperation on Science and Technology (COST) action TD1206 (StanDerm)[5] project were requested to provide a list of allergens they test to exclude contact allergy to cosmetics during 2017. They were further requested to indicate if the allergens were in local or national baseline series or local or national cosmetic series. A local baseline series means allergens were screened in every patient.

3 | RESULTS

Allergens tested by country and centre are shown in **Table** 1. Of the 13 countries surveyed, only four (Belgium, Finland, Germany and the United Kingdom) had nationally agreed series to screen for cosmetic allergy, among other things. Some allergens that were agreed to be cosmetic related, such as the formaldehyde releasers, were present in some national baseline series and, if not, were tested in local or national cosmetic series (eg, 23 of 26 centres tested to imidazolidinyl urea 2% pet.). At the other extreme, panthenol 5% pet was included only in the Belgian and Finnish national cosmetic series, in the local baseline series of one centre in Portugal, and in the cosmetic series of one of seven UK centres. Furthermore, the number of allergens tested above the baseline series to exclude allergy to cosmetics varied widely from two in centre Croatia 1 and 50 in United Kingdom 1.

4 | DISCUSSION

The results show a significant variation in practice throughout Europe and suggest that an evidence-based series for diagnosing allergy to cosmetics would be of value. This variation may be because the perceived importance of certain allergens varies from country to country, or it may be related to cost, or a combination of these factors. Allergens within the European baseline series typically produce a frequency of at least 0.5% to 1% allergic reactions in those tested.[6] This includes several cosmetic related allergens that would not need retesting in a separate series, but would need to be considered as changes to the baseline series occur, and as certain allergens are considered for deletion because of the low frequency of allergic reactions.[7]

In creating a cosmetic series, the threshold for inclusion could potentially be lower, perhaps from 0.1% to 0.2% among those tested, to minimize the risk of missing a relevant contact allergy. Whilst a

TABLE 1 Allergens tested to diagnose cosmetic allergy in 26 European centres

-		E	BE1	DE1-3	DK1	ES1	FI1	FR1	HR1	IT1	IT2	IT3	IT4	IT5	NL1	NL2	PT1	RS1	SI1	UK1	UK2	UK3	UK4	UK5	UK6	UK7	No. testing
Preservative																											
Benzyl alcohol	10% pet.			NC 1%		C		N			C		C		C	C	C		C	NC	NC	NC	NC	NC	NC	NC	18
Chloroacetamide	0.2% pet.			NC		C	NC	C				C	C				C		C	NC	NC	NC	NC	NC	NC	NC	17
Disodium EDTA	1% pet.														C		C			NC	NC	NC	NC	NC	NC	NC	9
Di-t-butylhydroquinone	1% pet.			NC		C	B	C							C	B	C			NC	NC	NC	NC	NC	NC	NC	15
Ethylhexylglycerin	5% pet.			NC																							3
Formaldehyde	2% aq.	E		N 1%																							26
2-Bromo-2-nitropropane-1,3-diol	0.5% pet.		NC	NC	B	C	NC	C			B		C		B		C		C	N	N	N	N	N	N	N	20
DMDM hydantoin	2% aq.			NC	B	C	NC	C			B				B	B	C		C	NC	NC	NC	NC	NC	NC	NC	19
Diazolidinyl urea	2% pet.		NC	NC	B	C	NC	C			B	C	C	C	B	B	N		C	N	N	N	N	N	N	N	23
Imidazolidinyl urea	2% pet.		NC	NC	B	C	N	C		B	B	C	C	C	B	B	N		C	N	N	N	N	N	N	N	24
Quaternium 15	1% pet.	E		NC 2%																							26
Iodopropynyl butylcarbamate	0.2% pet.		NC	N	B	C	B	C							B	B 0.5%	B			NC	NC	NC	NC	NC	NC	NC	18
Methyldibromoglutaronitrile	0.3% pet.	E																0.50%									26
Methylchloroisothiazolinone & methylisothiazolinone	0.02% aq.	E		N 0.01%														0.01%									26
Methylisothiazolinone	0.2% aq.	E		N 0.05%																							26
Sodium metabisulfite	1% pet.		NC	NC	C		B			B		B			B	B	C			N	N	N	N	N	N	N	18
Paraben mix*	16% pet.	E					NC																				26
Phenoxyethanol	1% pet.		NC		C	C		C				C			B		C			B			C				9
Potassium sorbate	5% pet.				B										C					B							3
Sodium benzoate	5% pet.			NC 2%	C			C					C			C	C			B					C		10
Sorbic acid	2% pet.		NC	NC	B	C						C	C				C			NC	NC	NC	NC	NC	NC	NC	16
p-Chloro-*m*-cresol	1% pet.				C	C	B			C			C				C			N	N	N	N	N	N	N	13
Antimicrobial																											
Benzalkonium chloride	0.1% pet.						NC	N		C			C		B				C	C							7
Chloroxylenol	1% pet.					C		C		C			C				C			N	N	N	N	N	N	N	12
Chlorhexidine diacetate	0.5% aq.				B								C							C							3
Chlorhexidine digluconate	0.5% aq.			NC	B	C	N	C		C			C				B			C			C				12
Triclosan	2% pet.			NC		C	NC	C				C	C				C			NC	NC	NC	NC	NC	NC	NC	16
Antioxidant																											
BHA (butylated hydroxyanisole)	2% pet.			NC		C		C		C	C		C		C	C	C			NC	NC	NC	NC	NC	NC	NC	18
BHT (butylated hydroxytoluene)	2% pet.			NC		C	B	C		C	C	C	C		C	C	C			NC	NC	NC	NC	NC	NC	NC	20
Caprylyl gallate	0.3% pet.			NC																							3
Propyl gallate	1% pet.		NC		C	C						C	C	C**			C			NC	NC	NC	NC	NC	NC	NC	14
Tocopheryl acetate	10% pet.				C	C							C							C			C				5

(Continues)

TABLE 1 (Continued)

-		E	BE1	DE1-3	DK1	ES1	FI1	FR1	HR1	IT1	IT2	IT3	IT4	IT5	NL1	NL2	PT1	RS1	SI1	UK1	UK2	UK3	UK4	UK5	UK6	UK7	No. testing
Emollient																											
Lanolin alcohols	30% pet.	E																									26
Lanolin	"as is"				C				C				C		B					C							5
Amerchol L101	50% pet.		N	NC	C	C		N							B	B	B			NC	NC	NC	NC	NC	NC	NC	17
Cetearyl alcohol	20% pet.		NC	N	C	C	NC	C			C	§	C	30%	C	C 5%	C			N	N	N	N	N	N	N	22
Panthenol (Dexpanthenol)	5% pet.		NC				NC										B			C							4
Propolis	10% pet.			N			NC	C		C	C	B		C	C	C	C		C	NC	NC	NC	NC	NC	NC	NC	20
Emulsifier/surfactants																											
Polysorbate 80	5% pet.				C	C						C		C	C		C						C				7
Sorbitan sesquioleate	20% pet.			N	C	C	NC	C			B	¶	B		B	C				NC	NC	NC	NC	NC	NC	NC	19
Cocamide DEA	0.5% pet.		C	NC			NC	N							C		C			NC	NC	NC	NC	NC	NC	NC	15
Cocamidopropyl betaine	1% aq.		NC	NC	C	C	B					B	C		C	C	C		C	NC	NC	NC	NC	NC	NC	NC	20
Dimethylaminopropylamine	1% pet.		NC			C	B	N			C				C		C			C			C				9
(Mono)Ethanolamine	2% pet.				B										C					C							3
Oleamidopropyl dimethylamine	0.1% aq.					C	B	C					C		C	C	C			NC	NC	NC	NC	NC	NC	NC	14
Triethanolamine (Trolamine)	2% pet.			NC 2.5%	C	C		C		C			C		C	2.5%	C			NC	NC	NC	NC	NC	NC	NC	18
Caprylyl/Capryl glucoside	10% aq.																			C							1
Cetearyl glucoside	10% pet.																			C							1
Coco-glucoside	10% aq.														C					C							2
Decyl glucoside	5% pet./10% aq.		NC			C	C	C						C	C					C						C	8
Lauryl glucoside	3% pet./10% aq.		NC			C	C	N									C			C	C		C		C		9
Solvent/vehicle																											
Propylene glycol	20% aq.			NC	C	C 5%					C	B 5%	C	C	C	C 5%	C			C		B	C				15
Specific function																											
axilla																											
Aluminium hydroxide	10% pet.																		C	C						C	3
Face, eye & lip																											
Colophonium	20% pet.	E																									26
Abitol	10% pet.					C		C												NC	NC	NC	NC	NC	NC	NC	9
Retinyl palmitate (Vitamin A ester)	0.5% pet.														C					C							2
Shellac	20% EtOH					C		C						C						C			C				5
Nail																											
Tosylamide/ formaldehyde resin	10% pet.		N		C		N	C			C			C	C	C	C			NC	NC	NC	NC	NC	NC	NC	16
Adipic acid/neopentyl glycol/trimellitic anhydride copolymer	1% pet.																			C			B	C	C		4

(Continues)

TABLE 1 (Continued)

-		E	BE1	DE1-3	DK1	ES1	FI1	FR1	HR1	IT1	IT2	IT3	IT4	IT5	NL1	NL2	PT1	RS1	SI1	UK1	UK2	UK3	UK4	UK5	UK6	UK7	No. testing
Phthalic anhydride/trimellitic anhydride/ glycols copolymer	1% pet.									C					C					C			B	C	C		6
2-Hydroxyethyl methacrylate	2% pet.				B		B		B	C	N		N		C		N		C	B			B		B		12
Hydroquinone	1% pet.			NC																							3

Note: Allergens in the European baseline are tested in all centres with variations being shown in the relevant column.

Abbreviations: aq., aqueous; B, local baseline series (allergens screened in every patient); BE, Belgium; C, local cosmetic series; DE, Germany; DK, Denmark; E, European baseline; ES, Spain; ETOH, ethanol; FI, Finland; FR, France; HR, Croatia; IT, Italy; N, national baseline series; NC, national cosmetic series; NL, The Netherlands; pet., petrolatum; PT, Portugal; RS, Serbia; SI, Slovenia; UK, United Kingdom.

*Methylparaben, ethylparaben, propylparaben, butylparaben.

**Gallate mix 1.5% pet.

§Cetyl alcohol 5% pet. & stearyl alcohol 30% pet.

¶Sorbitan oleate 5% pet.

patient's own products should also be tested where a reaction is suspected, these frequently produce false-negative reactions due to the lower concentration in the product and, therefore, would not provide a perfect fail-safe.

Current European Union regulations define a cosmetic broadly as "any preparation that is intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the physical appearance." Consequently, creating a cosmetic series potentially lends itself to a modular construction where the final sequence of allergens tested is based on the varying exposures of the patient (eg, hairdressing,[1] sunscreen[2] or fragrance).[4] This is the approach taken in the Information Network of Departments of Dermatology (IVDK), where allergens tested are derived from the combination of two smaller series. In particular, many medicaments contain allergens that are common with cosmetics. A common series containing preservatives, antioxidants, and emollient ingredients may, therefore, be of value for both cosmetic and medicament exposures. Conversely, antimicrobials, such as chlorhexidine, that are associated more commonly with medicaments may also be relevant in the context of cosmetic allergy[8] whilst allergens such as tosylamide/formaldehyde resin or phthalic anhydride/trimellitic anhydride/glycols copolymer[9] are purely cosmetic in the specific context of nail varnish.

At present, the frequency and relevance of reactions to these additional cosmetic allergens across Europe is not known. Collation of results is essential to enable a recommended evidence-based cosmetic series to be produced. While some countries[10] have published data, there is a need for a greater geographical spread and testing to a wider range of allergens to enable guidance to be produced. A recent study from the UK[11] highlighted that eight allergens tested in the cosmetic series of one centre produced no relevant reactions over an 8-year period. This led to a national review which resulted in 11 allergens being removed from the British group's facial series and the addition of eight others found to be relevant, but not tested by many.[12]

The significant variations in practice throughout Europe might not only be due to a lack of standardization but also due to different exposure profiles. A European cosmetic series should take this into account. After analysis of the country-specific data, a core European cosmetic series could be established and supplemented by a national "extension" cosmetic series dependent on local exposure. In conclusion, there is a need to develop an evidence-based cosmetic series to improve and standardize diagnosis and at the same time, eliminate allergens with a poor yield to ensure that the test is cost effective.

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CONFLICTS OF INTEREST

The IVDK, of which JG is an employee, is sponsored by the cosmetics and fragrance industries (associations) as well as by public funds; WU:

accepted travel reimbursement and partly honoraria for presentations given to cosmetic industry associations and received a lecture fee from mixed dermato-pharmaceutical sponsors for an educational lecture on contact allergy; SMW: accepted travel reimbursement to attend meetings with the cosmetics industry; The other authors do not declare any conflict of interest.

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