

Should Paraben Mix Be Removed from The European Baseline Series?

Dear Editor:

The European Baseline Series (EBS) of contact allergens is used throughout Europe as a screening test to diagnose contact allergy as a proxy for allergy contact dermatitis and other hypersensitivity skin diseases (1). Parabens are alkyl esters of p-hydroxybenzoic acid with antimicrobial effects used as preservatives in cosmetics, foods, and drugs that have been included in the so called "baseline series" (2) for more than 40 years. Parabens, which are considered allergologically safe biocides and are classified as safe by the US Food and Drug Administration (FDA) and the Scientific Committee on Consumer Safety (SCCS) in Europe (2-4), are frequently present in cosmetics (5). Despite extensive and progressively expanding use worldwide, studies confirm that parabens are seldom responsible for allergic contact dermatitis to cosmetics, and the frequency of sensitivity to parabens has been low and stable for many decades (2). The frequency of positive reactions to paraben mix is less than 0.5% in most clinical series, although it seems that when it occurs it is often of high clinical relevance (6). Nevertheless, several authors have stated that these patients rarely or never have to avoid foods or cosmetics that contain parabens to control their dermatitis (2). Paraben allergy most frequently occurs in patients with long-lasting stasis dermatitis or disruption of skin integrity, with high use of topical drugs, and in

those who do not get better under normal treatment and/or skin care (5).

The EBS has been periodically adapted by the European Environmental and Contact Dermatitis Research Group (EECDRG) and the European Society of Contact Dermatitis (ESCD), according to frequency studies, but ensuring that tested haptens remain relevant (1). Bruze *et al.* recommend that haptens should be considered for inclusion in a baseline series when the contact allergy prevalence is 0.5-1.0% or above (7). So, why not exclude paraben mix from the EBS?

We analysed all the EBS tests performed at our institution in the last 21 years (2000-2020) to evalu-

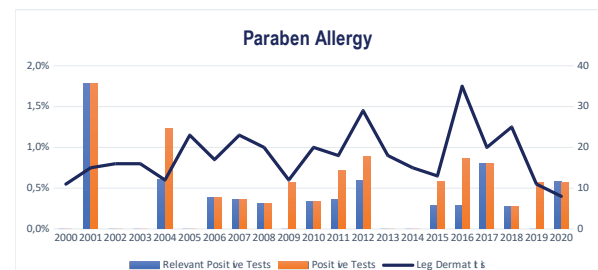


Figure 1. Schematic representation of positive tests to paraben mix 16% pet, relevant positive tests and number of patients with leg dermatitis patch tested during 2000-2020.

Table 1. MOAHLFA index of the whole population tested and of patients with positive tests to paraben mix 16% pet during 2000-2020

	Total of tested patients (n = 5885)		Paraben mix positive (n = 29)		P-value
	n	%	n	%	
M (men)	1701	28.9%	10	34.5%	P=0.514
O (occupational dermatitis)	1260	21.4%	2*	9.5%	P=0.478
A (atopic dermatitis)	1304	22.2%	6*	28.6%	P=0.765
H (hand dermatitis)	2146	36.5%	7*	33.3%	P<0.05
L (leg dermatitis)	377	6.4%	9*	42.9%	P=0.141
F (face dermatitis)	1201	23.0%	7*	33.3%	P<0.05
A (age >40 years)	2968	56.9%	16*	76.2%	P=0.514

*for this item there is only complete information for 21 patients

ate the frequency of positive reactions to paraben mix 16% pet (Chemotechnique diagnostics, Vellinge Sweden). In total, 5885 patients were patch tested (MOAHLFA index – Table 1), of whom 29 (10 men and 19 women) patients presented with a positive reaction (1+ or more according to ESCD guidelines) to paraben mix (0.49%), with positivity rates varying between 1.79% and 0.0% and progressively falling for the past 20 years (Figure 1). Present or past clinical relevance was found in 19/29 (65.5%) patients (6 men and 13 women), and was related to the use of topical drugs in 16 patients (55.2%) and cosmetics in three patients (10.3%).

Paraben reactions occurred mostly in patients with history of leg ulcer, leg dermatitis, and/or chronic venous insufficiency, which is in agreement with the overrepresentation of the group of patients with leg dermatitis compared with the whole population tested (Table 1). The proportion of patients with positive reactions to paraben mix was significantly higher in patients with leg dermatitis compared with patients without leg dermatitis ($P < 0.05$), as well in patients aged > 40 ($P < 0.05$), in whom these leg comorbidities are more frequent. Additionally, the higher number of reactions frequently coincided with the highest number of patients with leg dermatitis patch tested in the same year (Figure 1).

Cosmetics were considered the causative factor in only three patients, which explains the identical percentage of facial and atopic dermatitis in the paraben mix positive group and the total population tested. As expected, both hand and occupational dermatitis were underrepresented in the group of positive reactions to parabens.

In 34.5% of the patients, positive tests were considered not relevant or of unknown relevance. Therefore, in total only 0.32% of all paraben mix reactions were clinically relevant.

Patch test reactivity to paraben mix of 0.49% supports the ongoing discussion that parabens should not continue in the baseline series, a position that is further strengthened by the fact that only 0.32% represent relevant reactions (8). As the most relevant sensitizations are related to topical medications and, less frequently, from cosmetics, paraben mix should be part of the topical drugs and cosmetic series.

References:

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