

Proposal for a revised international standard series of patch tests

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Worldwide, there are 3 major standard series of patch tests, the European, North American and Japanese, together presenting 32 allergens, the differences between them being the result of regional variation in allergen distribution as well as differences in dermatological opinion. We propose a "minimal" international standard series of 20 allergens, together with an "extended" international standard series of 14 allergens.

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There is no unanimity worldwide as regards the contents of a standard series (1, 2). There are 3 major options in building a standard series, in relation to potential regional variations (3).

1. The revised European standard series, as recommended by the European Environmental and Contact Dermatitis Research Group (EECDRG) (4), in 1994 (21 allergens+primitin, optional).
2. The North American standard series (5, 6) according to the North American Contact Dermatitis Group (20 allergens).
3. The Japanese standard series according to the Japanese Society for Contact Dermatitis (25 allergens).

A comparison of the 3 lists (Table 1) suggests that 32 allergens are potentially considered in the international standardization process. Note that neomycin sulfate in lists (a) and (b) is synonymous with fradiomycin sulfate in list (c).

The discrepancies in comparing lists (a), (b), and (c) are due to 2 main factors:

1. There are regional variations, related either to the natural occurrence of allergens (e.g., urushiol) or to significant variability in the use of some allergens in various regions, due to different medical, cosmetic, industrial or environmental habits.
2. A different approach of the 3 research groups regarding each individual allergen, thus reach-

Table 1. Comparative lists of allergens in 3 different standard series

Compound	EECDRG ^{a)} %	NACDG ^{b)} %	JCDS ^{c)} %
1. potassium dichromate	0.5	0.25	0.5
2. neomycin sulfate	20	20	—
3. thiuram mix	1	1	1.25
4. p-phenylenediamine base	1	1	1
5. cobalt chloride (CoCl ₂ 6H ₂ O)	1	—	1
6. benzocaine	5	5	—
7. formaldehyde	1 (aq.)	1 (aq.)	1 (aq.)
8. colophony	20	20	20 (rosin)
9. clioquinol	5	—	—
10. balsam of Peru	25	25	25
11. N-isopropyl-N-phenyl paraphenylenediamine (IPPD)	0.1	—	—
12. wool (lanolin) alcohols	30	30	30
13. mercapto mix	2	1	2
14. epoxy resin	1	1	1
15. paraben mix	16	—	15
16. p-tert-butylphenol-formaldehyde (BPF) resin	1	1	1
17. fragrance mix	8	—	8
18. quaternium 15	1	2	—
19. nickel sulfate (NiSO ₄ 6H ₂ O)	5	2.5	2.5
20. Cl+Me-isothiazolinone	0.01 (aq.)	—	0.01 (aq.)
21. mercaptobenzothiazole (MBT)	2	1	—
22. primin	0.01	—	0.01
23. imidazolidinyl urea	—	2 (aq.)	—
24. cinnamic aldehyde	—	1	—
25. carba mix	—	3	—
26. ethylenediamine dihydrochloride	—	1	1
27. black rubber (PPD)	—	0.6	0.6
28. fradiomycin sulfate	—	—	20
29. caine mix	—	—	7
30. dithiocarbamate mix	—	—	2
31. urushiol	—	—	0.002
32. thimerosal (thiomersal)	—	—	0.1
33. ammoniated mercuric chloride	—	—	1
34. petrolatum	—	—	(as is)

^{a)} The revised European standard series as recommended by the EECDRG, 1994. The concentrations quoted refer to petrolatum except where otherwise stated.

^{b)} North American standard series according to the North American Contact Dermatitis Research Group. The concentrations quoted refer to petrolatum except where otherwise stated.

^{c)} The Japanese standard series according to the Japanese Society for Contact Dermatitis. The concentrations quoted refer to petrolatum except where otherwise stated.

ing dissimilar conclusions. The 3 groups are working independently, and have not confronted their opinions to reach a worldwide consensus.

Most decisions reached by each group are partly based upon multicentre studies and/or thorough literature reviews (3).

Considering the current status of the standard series throughout the world, the members of the International Contact Dermatitis Research Group (ICDRG) discussed the possibility of using a shortened list of common allergens, that could be used internationally as a "minimal international standard series". The following allergens have been considered eligible candidates for such a list (Table 2).

Some allergens present in 1 (or more) of the 3

lists of Table 1 are not considered eligible candidates for the revised international standard series presented in Table 2. On the other hand, they are listed in an "extended series" (Table 3). Other allergens are also proposed in the extended series, since they are considered useful in the literature.

Some of the allergens recorded in Table 1 lack general interest, for different reasons. Therefore, they are not proposed as candidates for an extended international series. Nevertheless they could be used in specific circumstances. These allergens, dispersed in petrolatum, are: N-isopropyl-N'-phenylparaphenylenediamine (IPPD) 0.1%; cinnamic aldehyde 1%; carba mix 3% (often lacks clinical relevance); black rubber (PPD) mix 0.6%; caine mix 7%; dithiocarbamate mix 2%; ammoniated mercuric chloride 1%.

Table 2. Proposed allergens for a modified international standard series: the concentrations quoted refer to petrolatum except where otherwise stated.

	%
1. potassium dichromate	0.5
2. neomycin sulfate	20
3. thiuram mix ^{a)}	1
4. p-phenylenediamine base (PPD) ^{b)}	1
5. formaldehyde	1 (aq.)
6. colophony	20
7. balsam of Peru	25
8. wool (lanolin) alcohols	30
9. mercapto mix ^{c)}	1
10. epoxy resin	1
11. p-tert-butylphenol-formaldehyde (BPF) resin	1
12. fragrance mix ^{d)}	8
13. nickel sulfate (NiSO ₄ · 6H ₂ O)	2.5
14. mercaptobenzothiazole (MBT) ^{e)}	1
15. budesonide ^{f)}	0.1
16. quaternium 15 ^{g)}	2
17. Cl+Me-isothiazolinone ^{h)}	0.01 (aq.)
18. imidazolidinyl urea	2 (aq.)
19. tixocortol pivalate	1
20. dibromodicyanobutane ⁱ⁾	0.1

^{a)} Thiuram mix lacks high specificity and sensitivity.

^{b)} Some cases of hair dye dermatitis could be missed with the use of PPD alone.

^{c)} Mercapto mix lacks high specificity and sensitivity. The 1% mix, used in the North American standard series, is chosen since its stability has been proven by Hermal and approved by the FDA (7).

^{d)} If positive, breakdown is needed.

^{e)} MBT can identify cases of allergic contact dermatitis negative to mercapto mix, and vice versa.

^{f)} Despite its absence in the 3 standard series, budesonide is highly recommended in an international standard series, since it is considered an important marker for corticosteroid allergy (8).

^{g)} It is an important allergen in the United Kingdom, while it is not used in Japan.

^{h)} Mainly used in Japan.

ⁱ⁾ *Syn:* 1,2-dibromo-2,4-dicyanobutane; methyldibromogluta-nitrile. Present in Euxyl K 400[®] (dibromodicyanobutane+phenoxyethanol 1:4).

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Table 3. Proposed allergens for an extended international standard series: the concentrations quoted refer to petrolatum except where otherwise stated

	(%)
A. Allergens present in 1 (or more) of the 3 lists of Table 1 ^{a)}	
1. cobalt chloride (CoCl ₂ · 6H ₂ O) ^{a)}	1
2. benzocaine	5
3. clioquinol	5
4. paraben mix	16
5. primin	0.01
6. ethylenediamine dihydrochloride	1
7. urushiol	0.002
8. thimerosal (thiomersal)	0.1
B. Additional useful allergens	
9. sesquiterpene lactone mix	0.1
10. hydrocortisone 17-butyrate	1 (alc.)
11. 2,5 diazolidinylurea ^{b)}	2 (aq.)
12. cetylstearylalcohol	20
13. toluenesulphonamide formaldehyde resin	10
14. propylene glycol	10 (aq.)

^{a)} Cobalt is not traced as relevant in many cases. Petechial reactions should not be read as positive.

^{b)} It is not used in Japan.

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