













## REVIEW

# The European baseline series and recommended additions: 2023

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## Abstract

The European baseline series was last updated in 2019. This article discusses the reasoning behind a further iteration of the series for 2023.

## KEYWORDS

allergen, baseline series, Europe, haptens, patch test, recommended addition

In 2017, the European Baseline Series (EBS) taskforce was formed as a working group of the European Society of Contact Dermatitis (ESCD). A revision of the EBS was published for 2019.<sup>1</sup> In brief, due to infrequent positive patch test results and lack of clinical relevance, it was agreed to delete primin 0.01% in petrolatum (pet) and clioquinol 5% in pet. It was further agreed to add propolis 10% in pet. and 2-hydroxyethyl methacrylate (2-HEMA) 2% in pet. Finally, it was agreed to use caine mix III 10% in pet instead of benzocaine 5% in pet. given the increased sensitivity of the mix in screening for contact sensitisation to local anaesthetics.

It was felt that some of the haptens proposed as potential further additions did not fully meet the criteria for inclusion in the EBS,<sup>2</sup> but that whilst further information was gathered to confirm or refute their importance, centres should consider the potential value of testing to them in their specific population. These were listed as recommended additions to the EBS.

The intention of the group was to institute an iterative process with a biennial update of the EBS coinciding with the Congress of the ESCD to which all members of the ESCD would have the opportunity to contribute. Due to the Covid-19 pandemic this process has been delayed.

Results of the European Surveillance System of Contact Allergy (ESSCA)<sup>3</sup> and an audit of the proposed changes once implemented<sup>4,5</sup> confirm that the existing haptens within the EBS occur with a frequency to merit their continued inclusion. The continued inclusion of methyl dibromo glutaronitrile (MDBGN) has, however, been questioned due to a lack of current clinical relevance.<sup>6</sup> However, it has been pointed out that relying on MDBGN results obtained with the TRUE Test might severely under-estimate sensitization prevalence owing to under-dosing.<sup>5</sup> Of the 2019 additions, all occurred with a frequency to merit continued inclusion (Table 1). Specifically:

- 2-hydroxyethyl methacrylate (2-HEMA) 2% pet.: It was noted that the European Union had recognized the frequency of problems caused by home use of nail acrylates and had limited the use of 2-hydroxyethyl methacrylate (HEMA) and 11,14-Dioxo-2,9-diazaheptadec-16-enoic Acid, 4,4,6,16-tetramethyl-10,15-dioxo, 2-[(2-methyl-1-oxo-2-propenyl)oxy]ethyl ester (Di-HEMA Trimethylhexyl Dicarbamate or Di-HEMA TMHDC) to professional use only<sup>7</sup> in November 2020. Further, whilst 2-HEMA might theoretically provoke active sensitisation cases have not been reported and late reactions to 2-HEMA are not necessarily proof of active sensitisation.<sup>8</sup>
- Caine mix III 10% pet.: Whilst the mix was more sensitive than testing to benzocaine 5% alone as a screen in detecting contact allergy to topical local anaesthetic, where allergy is suspected it is important to note that due to false patch negative test reactions, it is still important to test to the individual constituents.<sup>9</sup> This is similar to the situation with fragrance allergy and the fragrance mix (FM)<sup>10</sup> where the mix is an adequate screen but fails to detect all allergic reactions. Frequently a mix is a compromise to increase the scope of allergies covered by the EBS, but to reduce the risk of irritation individual constituents of FM I may be tested at a lower

concentration than they would be when tested alone<sup>11</sup> and was the strategy when developing FM II.<sup>12</sup>

Of those recommended additions to the EBS in 2019.

- Formaldehyde releasing preservatives<sup>13</sup>: The test concentration of formaldehyde was increased to 2% aqua (aq.) from 2014 with a doubling in the detection rate of formaldehyde allergy.<sup>14</sup> However, it was unclear to what extent testing with formaldehyde releasers yielded additional relevant information above screening with formaldehyde 2% aq. and quaternium-15 1% pet. A review of results from ESSCA demonstrated that formaldehyde 2% aq. is not a good predictor of allergy to the formaldehyde releasers.<sup>15</sup> Further, none of the individual formaldehyde releasers elicited positive patch test reactions with a frequency sufficient to warrant inclusion in the EBS.<sup>2</sup> However, the taskforce concluded that the formaldehyde releasers 2-bromo-2-nitropropane-1,3-diol 0.5% pet. and diazolidinyl urea 2% pet. should remain as recommended additions to the EBS (Table 2) as they occurred with a frequency at the threshold for inclusion. It was decided to remove quaternium 15 1% pet. from the EBS as it co-reacts most frequently with formaldehyde 2% aq. not yielding sufficient additional positive reactions to warrant inclusion. Further, quaternium 15 together with formaldehyde was restricted from use in cosmetic products by the European Union in 2019<sup>16</sup> and it would be anticipated that contact allergy from this source would further decline. It should be kept in mind that in occupational materials and cosmetic products acquired outside the European Union quaternium-15 may still be present and directed testing may be required when indicated.
- Sodium metabisulfite 1% pet. demonstrated frequent positive reactions across a wide geographic range<sup>3,5</sup> and it was decided to include this allergen within the EBS. Whilst relevance to this preservative was not always clear, the group agreed that it was probable that exposure to this allergen was wider than currently appreciated and that with time relevant exposures would become more clearly established. This is a particular issue in products where, unlike with cosmetics, pharmaceuticals and food, there is no ingredient labelling. For example, the presence of sulphites has been suggested in synthetic and natural rubber gloves,<sup>17</sup> catheter systems<sup>18</sup> and leather footwear.<sup>19</sup>
- Following on from the epidemic of contact allergy to methylisothiazolinone<sup>20</sup> both benzisothiazolinone (BIT) 0.1% pet. and octylisothiazolinone (OIT) 0.1% pet. were included as recommended additions to the EBS in 2019. Review of testing<sup>3,5</sup> demonstrated that BIT allergy occurred with an increasing frequency<sup>21</sup> meriting inclusion in the EBS although clinical relevance was not always clear. Nonetheless it was decided to include BIT in the EBS whilst keeping OIT to which allergy occurred less often as a recommended addition.
- Decyl glucoside 5% pet. and lauryl glucoside 3% pet. have both been recognized as common cosmetic haptens within North America.<sup>22</sup> Audit of testing in Europe<sup>3,5</sup> demonstrates allergy to decyl glucoside to be the more frequent meriting inclusion within the EBS. In view of frequent cross-reactions with lauryl glucoside<sup>23,24</sup>

TABLE 1 European baseline series: 2023

Compound	Concentration % (w/w) in pet except those in aqua <sup>a</sup>	Concentration in mg/cm <sup>2</sup>
Potassium dichromate	0.5	0.2
<i>p</i> -Phenylenediamine	1.0	0.4
Thiuram mix	1.0	0.4
TMTM	0.25	0.1
TMTD	0.25	0.1
TETD	0.25	0.1
PTD	0.25	0.1
Neomycin sulphate	20.0	8.0
Cobalt chloride	1.0	0.4
Caine mix III	10.0	4.0
Benzocaine	5.0	2.0
Cinchocaine (dibucaïne)	2.5	1.0
Tetracaine	2.5	1.0
Nickel sulphate	5.0	2.0
2-Hydroxyethyl methacrylate	2.0	0.8
Colophonium	20.0	8.0
Parabens	16.0	6.4
Methylparaben	4.0	1.6
Ethylparaben	4.0	1.6
Propylparaben	4.0	1.6
Butylparaben	4.0	1.6
N-Isopropyl-N'-phenyl- <i>p</i> -phenylenediamine	0.1	0.04
Lanolin (wool alcohols)	30.0	12.0
Mercapto mix	2.0	0.8
N-cyclohexylbenzothiazyl sulfenamide	0.5	0.2
Mercaptobenzothiazole	0.5	0.2
Dibenzothiazyl disulphide	0.5	0.2
Morpholinylmercaptobenzothiazole	0.5	0.2
Epoxy resin	1.0	0.4
<i>Myroxylon pereirae</i>	25.0	10.0
4- <i>tert</i> -Butylphenol formaldehyde resin	1.0	0.4
Mercaptobenzothiazole	2.0	0.8
Formaldehyde	2.0 <sup>a</sup>	0.6
Fragrance mix I	8.0	3.2
Cinnamyl alcohol	1.0	0.4
Cinnamal	1.0	0.4
Hydroxycitronellal	1.0	0.4
$\alpha$ -Amyl cinnamal	1.0	0.4
Geraniol	1.0	0.4
Eugenol	1.0	0.4
Isoeugenol	1.0	0.4
<i>Evernia prunastri</i> (oakmoss absolute)	1.0	0.4
Sesquiterpene lactone mix	0.1	0.04
Alantolactone	0.033	0.013
Dehydrocostus lactone and costunolide	0.067	0.027

(Continues)

TABLE 1 (Continued)

Compound	Concentration % (w/w) in pet except those in aqua <sup>a</sup>	Concentration in mg/cm <sup>2</sup>
Sodium metabisulfite	1.0	0.4
Propolis	10	4.0
Methylchloroisothiazolinone (150 ppm) and methylisothiazolinone (50 ppm)	0.02 <sup>a</sup>	0.006
Budesonide	0.01	0.004
Tixocortol pivalate	0.1	0.04
Methyldibromo glutaronitrile	0.5	0.2
Fragrance mix II	14.0	5.6
Hydroxyisohexyl 3-cyclohexene carboxaldehyde	2.5	1.0
Citral	1.0	0.4
Farnesol	2.5	1.0
Coumarin	2.5	1.0
Citronellol	0.5	0.2
$\alpha$ -hexyl cinnamal	5.0	2.0
Hydroxyisohexyl 3-cyclohexene carboxaldehyde	5.0	2.0
Methylisothiazolinone	0.20 <sup>a</sup>	0.06
Benzisothiazolinone	0.1	0.04
Textile dye mix	6.6	2.64
Disperse blue-35	1	0.4
Disperse yellow-3	1	0.4
Disperse orange-1	1	0.4
Disperse orange-3	1	0.4
Disperse red-1	1	0.4
Disperse red-17	1	0.4
Disperse blue-106	0.3	0.12
Disperse blue-124	0.3	0.12
Decyl glucoside	5.0	2.0

the additional yield from testing lauryl glucoside in the EBS was insufficient to warrant inclusion. However, as additional glucoside allergy is detected by individual testing it is recommended that other glucosides be tested in a cosmetic series<sup>25</sup> when indicated.

- Compositae mix II 2.5% pet. did not provide a significant increased yield of relevant allergic reactions when combined with the sesquiterpene lactone mix (SLM) 0.1% pet. in detecting allergy to Compositae plants.<sup>3,5</sup> However, Compositae mix II 5% pet. is thought to be more sensitive without an increased risk of active sensitisation.<sup>26</sup> Accordingly, it was agreed to keep the Compositae mix II as a recommended addition to the EBS but to increase the concentration from 2.5% to 5% pet. Compositae mix II 5% pet. includes parthenolide 0.1% which in addition to Compositae mix II 2.5% pet.<sup>27</sup> was found to be a useful screen for allergy to Compositae plants.
- Linalool hydroperoxides 1% and 0.5% pet. and limonene hydroperoxides 0.3% and 0.2% pet. Reactions to both linalool<sup>28</sup> and limonene<sup>29</sup> hydroperoxides have been reviewed and in the group audit produced frequent positive reactions<sup>3,5</sup> leading some members to recommend inclusion in the EBS. In view of the known skin irritancy of the patch test formulations, difficulties in interpretation

and the need for, ideally, a single patch test concentration it was agreed after debate to keep these allergens in the recommended additions to the EBS.<sup>30</sup> The inclusion of two concentrations of each allergen was felt to be important to aid interpretation. Of note, whilst an exposure source to these hydroperoxides remains unclear,<sup>31</sup> challenge in sensitized individuals has shown relevance even in those with doubtful reactions.<sup>32</sup>

#### New allergens for 2023

- Sorbitan sesquioleate 20% pet. has been suggested as an addition to the EBS both on the basis of the frequency of its occurrence and because it is an ingredient of some hapten preparations used for testing leading to inaccurate diagnosis and inappropriate advice being given,<sup>33</sup> for example, FM I 8% pet and *Myroxylon pereirae* resin 25% pet. Although some countries have found a high prevalence<sup>34</sup> other members of the EBS taskforce commented that there was large geographic variation.<sup>35</sup> It was agreed to add sorbitan sesquioleate 20% pet. and its constituent sorbitan mono-oleate 5% pet. as recommended additions to the EBS until further data was acquired.

**TABLE 2** Recommended additions to the European baseline series: 2023

Compound	Concentration % (w/w) in pet	Concentration in mg/cm <sup>2</sup>
2-Bromo-2-nitropropane-1,3-diol	0.5	0.2
Diazolidinyl urea	2.0	0.8
Octylisothiazolinone	0.1	0.04
Compositae mix II	5	2.0
<i>Anthemis nobilis</i> extract	1.2	
<i>Chamomilla recutita</i> extract	1.2	
<i>Achillea millefolium</i> extract	1.0	
<i>Tanacetum vulgare</i> extract	1.0	
<i>Arnica montana</i> extract	0.5	
Parthenolide	0.1	
Linalool hydroperoxides	1	0.4
Linalool hydroperoxides	0.5	0.2
Limonene hydroperoxides	0.3	0.12
Limonene hydroperoxides	0.2	0.08
Sorbitan sesquioleate	20.0	8.0
Sorbitan (mono)oleate	5.0	2.0

## AUTHOR CONTRIBUTIONS

**S. Mark Wilkinson:** Conceptualization; investigation; funding acquisition; writing – original draft; methodology; project administration; supervision. **Margarida Gonçalo:** Conceptualization; investigation; funding acquisition; project administration. **Olivier Aerts:** Methodology; conceptualization; investigation. **Sonia Badulici:** Conceptualization; investigation; methodology. **Heinrich Dickel:** Methodology; conceptualization; investigation. **Rosella Gallo:** Conceptualization; investigation; methodology. **Jose L. Garcia-Abujeta:** Methodology; conceptualization; investigation. **Ana M. Giménez-Arnau:** Conceptualization; investigation; methodology. **Curt Hamman:** Methodology; conceptualization. **Marcos Hervella:** Conceptualization; investigation; methodology. **Marléne Isaksson:** Conceptualization; investigation; methodology. **Jeanne D. Johansen:** Methodology; conceptualization; investigation. **Vera Mahler:** Conceptualization; investigation; methodology. **Bo Niklasson:** Conceptualization; methodology. **Paolo Pigatto:** Conceptualization; investigation; methodology. **Gyorgyi Ponyai:** Conceptualization; investigation; methodology. **Thomas Rustemeyer:** Methodology; conceptualization; investigation. **Marie L. A. Schuttelaar:** Conceptualization; investigation; methodology. **Radoslaw Spiewak:** Conceptualization; investigation; methodology.

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## CONFLICT OF INTEREST

OA: investigator, consultant and/or speaker for Leo Pharma and L'Oréal/La Roche Posay. AGA: Medical Advisor for Uriach Pharma/Neucor, Genentech, Novartis, FAES, GSK, Sanofi-Regeneron, Amgen, Thermo Fisher Scientific, Almirall, Celldex, Leo Pharma; Research Grants supported by Uriach Pharma, Novartis, Grants from Instituto Carlos III-FEDER; Educational activities for Uriach Pharma, Novartis, Genentech, Menarini, LEO-PHARMA, GSK, MSD, Almirall, Sanofi, Avene. MG: has participated in advisory boards and/or received lecture fees from Abbvie, Leo, Lilly, Novartis, Pfizer, Sanofi and Takeda. CH: owner and CEO of SmartPractice, a company producing and selling patch test preparations. MI: has worked as consultant for IFRA. BN: owner and CEO of Chemotechnique, a company producing and selling patch test preparations. LS: Medical advisor and Educational Activities for Abbvie, Almirall, Amgen, Eli Lilly, Leo Pharma, Novartis, Sanofi-Regeneron. RS: Scientific adviser and shareholder of Instytut Dermatologii, a company reselling patch test preparations. WU: accepted travel reimbursement and receives research funds from IFRA. The other authors declare no conflicts. VM: The views expressed in this paper are the personal views of the author and may not be understood or quoted as being made on behalf of or reflecting the position of the respective national competent authority, the European Medicines Agency, or one of its committees or working parties.

## DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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