

Recommendation to include a textile dye mix in the European baseline series*

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Summary

Background. Disperse dyes are common sensitizers, but are not currently included in the European baseline series.

Objectives. To justify the inclusion of a textile dye mix in the European baseline patch test series.

Methods. A survey of the reported frequencies of contact allergy to textile dyes and textile dye mixes was performed by searching PubMed (<http://www.ncbi.nlm.gov.ludwig.lub.lu.se/pubmed>, last accessed 14 December 2014). The results from a multi-centre study performed within the European Environmental Contact Dermatitis Research Group (EECDRG) and published in 2014 formed the final basis for the recommendation.

Results. The EECDRG study performed in Europe and the United States showed that 2.1–6.9% of consecutively tested dermatitis patients reacted to a 6.6% wt/wt textile dye mix consisting of eight disperse dyes. The clinical relevance was ascertained in >30% of the positive cases. A high frequency of simultaneous sensitivity to Disperse Orange 3 (DO 3) and *p*-phenylenediamine (PPD) was seen. Active sensitization to the mix was not noted.

Conclusions. It is recommended to include a 6.6% textile dye mix consisting of eight disperse dyes in the European baseline series, even though one component, DO 3, may be superfluous, owing to its frequent cross-reactivity with PPD. This change would need further study.

Key words: allergic contact dermatitis; black rubber mix; clinical relevance; contact allergy; Disperse Blue 35; Disperse Blue 106; Disperse Blue 124; disperse dyes; Disperse Orange 1; Disperse Orange 3; Disperse Red 1; Disperse Red 17; Disperse Yellow 3; patch testing; *p*-phenylenediamine; simultaneous reactivity.

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The current European baseline patch test series consists of 29 patch test preparations, the minimum set recommended for routine testing of patients with suspected allergic contact dermatitis. In addition, supplementary series and single allergens, as appropriate, need to be added to adequately investigate the clinical problem. Any baseline patch test series needs to be re-evaluated on a regular basis, owing to the need for changes in composition. This may imply both inclusion of new allergens and exclusion of old substances, as well as changes of concentrations/vehicles of test preparations already present

in the baseline series (1). The major responsibility for this process, regarding the European baseline patch test series, has been delegated to the European Environmental Contact Dermatitis Research Group (EECDRG) by the European Society of Contact Dermatitis.

Contact Allergy to Textile Dyes and a Textile Dye Mix

Contact allergy to textile dyes is not uncommon, and the dyes most commonly implicated have been disperse dyes (DDs) (2). These are primarily used for the colouring of synthetic fibres. DDs are not, however, included in any commercially available baseline patch test series (3), in contrast to *p*-phenylenediamine (PPD), which, historically, has been considered to be a screening allergen for textile dye dermatitis (4), even though several studies have shown that testing with a baseline series including PPD is not sufficient to detect a DD allergy. When there is a suspicion of textile-related contact allergy, supplementation with a textile dye series is recommended. Testing with a piece of garment 'as is' and/or with an extract of the textile, as well as a 'use test' with the suspected garment (stop and wear again), can also be recommended, but false-negative test results are common.

The inclusion of one or more markers for textile dye allergy in the baseline series has been suggested. Several DDs were patch tested in consecutive dermatitis patients in Italy, with frequencies of positive patch test results ranging from 3.3% to 5.8% (Table 1) (4–6). In Table 1, some investigations on DDs are shown (7–10).

A textile dye mix (TDM) composed of four DDs was tested in parallel with the separate DDs in Italy, and patch testing with the TDM gave positive reactions in all subjects sensitized to one or more DDs (31/31) (11) (Table 2). In Table 2, several other studies in which a TDM was tested are shown (9, 12, 13). A TDM composed of Disperse Blue 106 (DB 106) and Disperse Blue 124 (DB 124) only has been tested in several countries since the late 1990s, with allergy frequencies ranging from 0.9% to 4.7% (14–18). Starting in 1999, a TDM composed of eight DDs was introduced into the baseline series of the Department of Occupational and Environmental Dermatology in Malmö, Sweden. This TDM was composed of Disperse Red 1 (DR 1), Disperse Yellow 3 (DY 3), Disperse Orange 3 (DO 3), Disperse Red 17 (DR 17), Disperse Blue 35 (DB 35), and Disperse Orange 1 (DO 1), each 0.5% wt/wt, and DB 124 and DB 106, each 0.1% wt/wt (19). These eight DDs had previously been included in a mix used for patch testing in Portugal (Francisco Brandão, Department of Dermatology, Hospital Garcia de Orta, Almada, Portugal, personal communication, 1998). From 1999

onwards, this composition of a mix was tested at several concentrations, starting at 3.2%, then 6.6%, and finally 6.6% and 8.0%, in parallel. The first composition in 1999, with a total concentration of 3.2%, had a pick-up rate of 1.5% (19). Similar results were obtained in a joint study with the same mix a few years later (20). In 2006, the concentration was raised to 6.6%, and this TDM has been patch tested not only in Sweden and Belgium (21), but also in seven dermatology departments in Sweden (22), and in 12 clinics in nine countries in Europe and the United States (3). The frequencies of TDM-positive patients were 3.7% in the European/US study (3) and 2.5% in the Swedish study (22), with overall clinical relevance of 31% and 37%, respectively. In the recent Swedish study encompassing seven dermatology departments from all over Sweden, a TDM at 8.0% was tested in parallel, and this mix picked up 2.8% of those allergic to this mix, in contrast to 2.5% for the 6.6% mix (22). The composition of the 6.6% mix is as follows: DB 35, DY 3, DO 1, DO 3, DR 1, and DR 17, all at 1.0% wt/wt, and DB 106 and DB 124, both at 0.3% wt/wt. In the 8.0% mix, all DDs were tested at 1.0% wt/wt.

Allergic Contact Dermatitis Caused By DDs

The dermatitis seen in relation to contact allergy to DDs is variable, ranging from eczema, sometimes prurigo-like, and at other times persistent erythematous-wheal-like or transient urticarial dermatitis, to erythema multiforme-like lesions (4). Sometimes, the subjective symptoms and dermatitis range from diffuse itching to blister formation, oedema on the face, lymphomatoid dermatitis (23), pigmented purpuric contact dermatitis (24), and eczematid-like purpura and folliculitis (25). Non-pruritic erythema, such as macular erythema, has even been observed in contact allergy to DB 106 and DB 124 from a bra (26). Hand eczema is not uncommon, in some studies especially in occupational cases, and dermatitis may appear on the thighs, buttocks, hips, neck, trunk, axillae, face, and skin folds, and around the genitalia. Involvement of skin folds was observed in 27% of DD-positive patients, mainly comprising Disperse Blue-sensitive women (10).

Exposure to DDs

Allergenic DDs have infrequently been identified in the garments of patients allergic to textile dyes when patch tested (27). However, there are still many reports of positive patch test reactions to these DDs in the literature, and in which clinical relevance has been considered to be high (27, 28). Furthermore, in a recent investigation,

Table 1. Individual disperse dyes (DDs) tested simultaneously in various patch test investigations when dermatitis patients have been screened

Individual DDs	Concentration (wt/wt)	No. of patients positive/total tested	%	Country of origin, year of publication, reference no.
DB 124/DR 1/DO 3/DY 3	All 1%	19/576	3.3	Italy, 1990, 6
DB 124/DR 1/DO 3/DY 3	All 1%	41/861	4.8	Italy, 1991, 5
DB 124/DR 1/DO 3/DY 3/ DR 17/DBI 1/DO 76/DY 9/ DY 54/DB 3/DB 35	All 1%	43/746	5.8	Italy, 1991, 5
DO 3/DY 3/DR 1	Not stated	Three children each positive for one DD; unclear how many of 329 were tested with DDs		Portugal, 1992, 8
DO 3/DY 3/DR 1	Not stated	236/6203	3.8	Italy, 1997, 7
DB 124/DO 3/DY 3/DR 1/DBI 1/DB 3	All 1%	31/1012	3.1	Italy, 1998, 10
DB 124/DB 106/DR 1/DY 3/DO 3	Not stated	437/6478	6.7	Italy, 2002, 11

DB, Disperse Blue; DBI, Disperse Black; DO, Disperse Orange; DR, Disperse Red; DY, Disperse Yellow.

121 different low-price garments made from polyester or blends of polyester and other synthetic fibres were examined for the presence of the eight DDs present in the 6.6% TDM. The objects had been purchased in 13 countries in Europe, Asia, and North and South America. In a pair of brown tights made and bought in Italy (made from polyamide and elastane), the presence of DY 3, DB 106 and DB 124 was confirmed with high-performance liquid chromatography (29). Moreover, DO 1 was detected in underwear from India. Thus, even though these allergenic dyes seem to be rarely used in clothes nowadays, we still find them even in Europe. Furthermore, when extracts from all of these 121 garments were compared by the use of thin-layer chromatography, similar dye patterns were seen, especially in the orange, red, blue and yellow regions of the spectrum, indicating that there are common substances other than the eight DDs present in the extracts. Some of these may be allergenic. Furthermore, the eight DDs present in the 6.6% TDM are not pure (30). The DDs contain allergenic substances other than the actual dyes found by patch testing with thin-layer chromatograms (31, 32). Therefore, even though the eight DDs included in the TDM may be used less in textiles today, the TDM may be a useful marker of textile contact allergy, in the same way as tixocortol pivalate is a marker of corticosteroid contact allergy (33).

Simultaneous Patch Test Reactions to PPD

From a chemical point of view, most DDs are azo dyes; that is, the molecules contain an azo structure, one example being DO 3. *para*-Amino compounds such as PPD are known to cross-react with some DDs belonging to the azo group. As a consequence, high frequencies of simultaneous sensitivity to DO 3, TDM, and PPD (34), to TDM and black rubber mix (34) and to DO 3 and PPD (35)

are often seen. Cross-reactivity between azo dyes and PPD was frequent in DO 3-positive subjects, but not in Disperse Blue-allergic subjects (10).

Simultaneous reactivity to PPD was found in 53% of TDM-positive patients (3), and simultaneous reactivity to TDM was found in 76% of PPD-positive patients (3). Therefore, allergic patch test reactions to disperse azo dyes could be markers of sensitization to other *para*-substituted compounds, such as PPD or black rubber substances, or vice versa. However, the frequency of TDM contact allergy without any simultaneous contact allergy to the sensitizers PPD, *N*-isopropyl-*N'*-phenyl-*p*-phenylenediamine and benzocaine was 1.6% in the multicentre study in Europe including 2907 patients (3), a figure suggesting that TDM should be included in a baseline series.

The fact that PPD allergy and TDM allergy are connected may have an impact when patients suspected of having a strong allergy to PPD in a patch test preparation such as the 6.6% TDM are patch tested. This is because the majority of test reactions to mixes of DDs are usually strong allergic reactions, that is, ++ or +++ reactions (3, 22). Sixty-nine percent of the test reactions were strong (++/+++) in the aforementioned EECDRG study (3). Therefore, if one suspects a strong contact allergy to PPD, a DD of the azo type, or a TDM, in which azo-type DDs are abundant, it is best to place the separate patch tests on the patient's upper arm, several centimetres apart, so that the patient can remove the tests beforehand, should the tests start itching considerably before 48 hrs have passed.

Clinical Relevance

Concerning clinical relevance, in most studies in which DDs have been tested, clinical relevance has not been reported. This has more often been discussed in the single case studies. However, in the studies in which the 6.6%

Table 2. Disperse dye mixes used in various patch test investigations

Mix no.	Components	Concentration (wt/wt %)	No. tested	No. allergic	%	Simultaneous TDM + PPD/ TDM-positive (%)	Clinical relevance	Year of publication, country, reference no.
1	DB 35/DB 106/DO 3	1/1/1	78	2	2.6	Not given	Not stated	1994, Portugal, 14
2	DR 1/DR 17/DY 3/DB 35/DB 124	Not given	78	2	2.6	Not given	Not stated	1994, Portugal, 14
3	DR 1/DR 17/DY 3/DB 35/DB 124/DO 3/DR 1/DB 124	Not given	78	2	2.6	Not given	Not stated	1994, Portugal, 14
4	DY 3/DO 3/DR 1/DB 124/DB 1/DB 3	0.25/0.25/0.25/0.1	31*	31	100	Not given	Not stated	1994, Italy, 12
			67*	60	89.6	Not given	Not stated	1995, Italy, 13
5	DY 3/DO 3/DR 1/DB 124/DB 1/DB 3	1/0.25/0.25/0.5/1/1	1012	26	2.6	Not given	Not stated	1998, Italy, 10
6	DB 106/DB 124	0.5/0.5	1108	52	4.7	Not given	70% current clinical relevance	2001, Germany, 15
			3041	40	1.3	Not given	Not stated	2003, Germany, 16
			6856	67	1.0	Not given	Not stated	2006, UK, 17
			24 980	337	1.4	Not given	Not stated	2007, Germany, 19
7	DB 35/DY 3/DO 1/DO 3/DR 1/DR 17/DB 106/DB 124	0.5/0.5/0.5/0.5/0.5/0.5/0.1/0.1	3325	50	1.5	24	TDM-positive patients more often had dermatitis on the arms, face, neck, and axillary folds	2006, Sweden, 20
			1780	35	2.0 (Belgium 2.4; Sweden 1.8)	43	Not stated	2010, Sweden/Belgium, 21
8	DB 35/DY 3/DO 1/DO 3/DR 1/DR 17/DB 106/DB 124	1.0/1.0/1.0/1.0/1.0/1.0/0.3/0.3	2546	65	2.6 (Belgium 4.2; Sweden 2.1)	35	Not stated	2011, Sweden/Belgium, 22
			2907	108	3.7 (2.1–6.9)	53	31% of the TDM-positive patients for whom an assessment of clinical relevance was registered	2014, EECDRG centres, 4
8/9	DB 35/DY 3/DO 1/DO 3/DR 1/DR 17/DB 106/DB 124	1.0/1.0/1.0/1.0/1.0/1.0/0.3/0.3; 1.0/1.0/1.0/1.0/1.0/1.0/0.1/0.1	2122	52/59	2.5/2.8	58	37% of the TDM-positive patients for whom an assessment of clinical relevance was registered	2014, Sweden, 23

DB, Disperse Blue; DBI, Disperse Black; DO, Disperse Orange; DR, Disperse Red; DY, Disperse Yellow; EECDRG, European Environmental Contact Dermatitis Research Group; TDM, textile dye mix.

*Patients with known contact allergy to at least one of the separate dyes.

TDM was utilized, contact allergy to this mix was considered to explain or contribute to skin problems in just over 30% of the investigated patients, who were dermatitis patients suspected of having allergic contact dermatitis in general (3, 22).

Information for TDM-allergic Patients

An information sheet can be given to the allergic patient, with information on what types of garment are safe. Any garments manufactured from cotton, wool, silk or linen are safe. If polyester garments are worn, light-coloured clothes are safer than dark-coloured ones. It may be hazardous to wear dark-coloured synthetic underwear, owing to the risk of dyes leaking out if the person is sweating heavily.

Conclusion

Given the high frequency of allergy to textile dyes, there is a need for a marker of textile dye contact allergy in any baseline series. On the basis of recent studies, that is, those testing a 6.6% TDM in the Swedish centres and those testing the same TDM in Europe and the United States, in which contact allergy to this TDM was so common, a proposal for the inclusion of this mix into the European baseline series from 2015 is herewith made. The frequency of contact allergy to this TDM in the European study population was 3.7%, a figure that is sufficient to justify the

inclusion of a substance in any baseline series, provided that the clinical relevance is high (1), which also was the case, that is, in >30% of the patients in whom the contact allergy could explain the dermatitis or contribute to the dermatitis (3). The same was true for the Swedish study, in which the figure for clinical relevance was almost 40% (22). The composition of the 6.6% wt/wt pet. mix should be as follows: DB 35, DY 3, DO 1, DO 3, DR 1, and DR 17, all at 1.0% wt/wt, and DB 106 and DB 124, both at 0.3% wt/wt. With the Finn Chambers® technique, a standardized amount of 20 mg of the pet. preparation should be used. One manufacturer of patch test materials, Chemotechnique Diagnostics, Vellinge, Sweden, will have this test preparation available for purchase from 2015. When strong contact allergy to PPD and/or TDM is suspected, the tests should be placed on the arm of the patient, to facilitate early removal. Active patch test sensitization was not observed in any of the TDM studies.

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