

COTANCE / ETAD Information Note

Compliance with Directive 2002/61/EC (19th Amendment to Directive 76/769/EEC):

Alert concerning false positive findings by currently available analytical methods.

Background

In 1994 the Federal Republic of Germany enacted a regulation which restricted the use of certain azo dyes in consumer goods intended to involve more than temporary contact with the skin. The dyes affected were those which on reductive cleavage of one or more azo groups would form any of twenty listed carcinogenic aromatic amines. Subsequently, other EU member states (Austria, Netherlands) introduced similar restrictions. In the interests of harmonisation within the Single Market and consumer protection, restrictions on the marketing of certain azo colorants in textile and leather articles have been introduced under Directive 2002/61/EC. These restrictions apply also in the case of two additional aromatic amines, i.e. 4-aminoazobenzene (4AAB) and o-anisidine.

Problem

The currently available analytical test method involves reductive cleavage of the azo bonds and the identification of the primary aromatic amines formed. To be in compliance testing of the article must not produce one or more of the listed aromatic amines in detectable concentrations, i.e. above 30 ppm of a listed amine in the article or the dyed parts thereof.

The problem arising from the inclusion of 4AAB in the amine list is that under the conditions of the current test procedure a dye based on 4AAB would reduce not to 4AAB (itself an azo compound) but further to aniline and p-phenylenediamine (PPD). Neither of these amines is on the restricted list of 22 amines and they are formed under the test conditions from several important leather dyes which do not fall within the scope of the proposed restrictions. This means that the current analytical method does not differentiate between a restricted 4AAB dye and an unrestricted dye (or more often dye mixture) which reduces to aniline and p-phenylenediamine. **No leather dyes are known to be in commerce which would reduce to 4AAB (and hence aniline and PPD under the test conditions).**

The purpose of this information note is to alert dye manufacturers, downstream processors through to retailers, and regulatory control authorities of this situation, so that checked articles are not wrongly concluded to be non-compliant.

What measures are recommended to minimise the adverse effects of false positives?

The ideal measure would be the development of a testing method specific for dyes which would reduce to 4AAB. Unfortunately, it is not likely that such a method will be available in the foreseeable future. Allocation of resources to detect restricted dyes not known to be in commerce is scarcely justified. Delay in introducing a consumer protection measure should be avoided.

The dye manufacturer should:

- Review his product range to identify products which could cause a false positive finding on the finished article (see Appendix 1 for suggested approach). Analytical data as well as information on main dye components need to be taken into account.
- Provide customers, on request, a certification that a shipment of dyes does not include any restricted dyes (see Appendix 2).
- Communicate to customers, where relevant, the possibility of false positive analytical results (4AAB) on dyed leather.
- Provide customers with background information on the regulatory basis and the 4AAB issue.

The leather dyer should:

- Ensure that he has received certification of regulatory status for all dye deliveries.
- Determine which dyeing recipes could be expected to lead to false positive results (e.g. recipes containing both aniline-releasing and PPD-releasing dyes).
- Provide certification to customer, on request, that no restricted dye has been used but that analysis of the dyed leather could produce a false positive.

The manufacturers and retailers of finished leather articles should:

- Source from reliable suppliers who certify compliance with restrictions.
- If a regulatory authority checks compliance, a statement of the company's compliance program, including specifically the problem of false positive analytical results, should be made available when sample articles are provided for analysis.

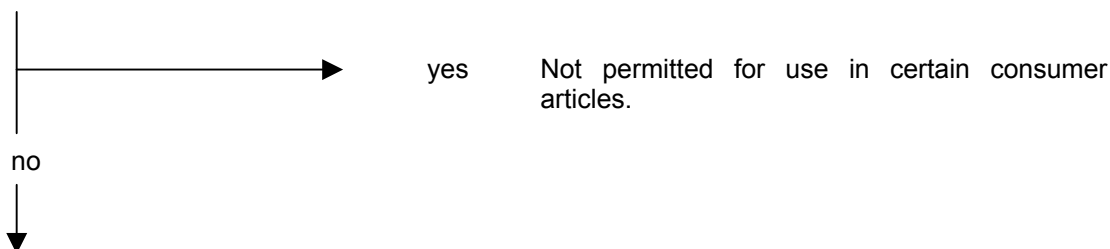
The regulatory authority and analytical testing laboratories responsible for checking compliance should

- be aware that no leather dyes which would reduce to 4AAB are known to be in commerce.
- recognize that the analytical methods currently available provide only an equivocal indication that a dye which reduces to 4AAB has been used (more likely to indicate use of a mixture of aniline- and PPD-releasing dyes).
- seek additional information before drawing any conclusion regarding compliance.

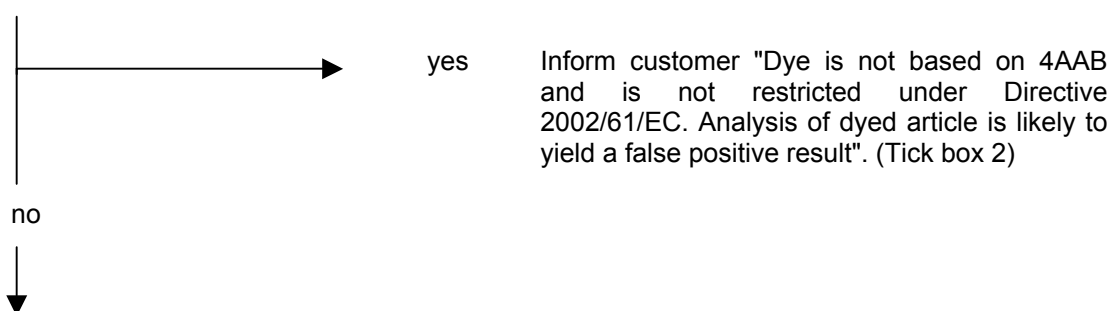
November 26, 2002

Review by dye manufacturer of product range

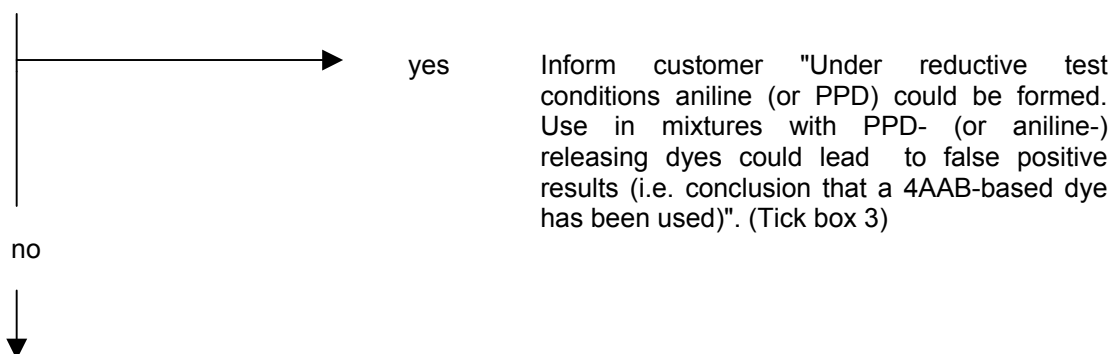
Do any dyes form any of the 22 listed amines by reductive cleavage of one **or** more azo bonds? (Note 1)



Do any individual dye formulations form aniline and PPD by reductive cleavage of azo bonds? [Consider individual dyes and dye mixtures]



Do any individual dye formulations form aniline **or** PPD by reductive cleavage of azo bonds?



Certification of compliance
(Tick box 1)

Note 1 This assessment is based primarily on consideration of the chemical structure of the individual dyes, but the possible presence of restricted dyes as impurities should be taken into account.

Model declaration of compliance with the restriction of certain azo colorants in leather articles under the Directive 2002/61/EC (19th Amendment to Directive 76/769/EEC)

The undersigned, duly authorised representative of (name of dye supplier)

.....

hereby certifies that the leather dyes listed below, which have been supplied to (name of leather dyeing and finishing company).

.....

Tick box if statement applies.

- 1 Are not restricted under the Directive 2002/61/EC of 19 July 2002 (OJ L243, 11.9.2002)
- List of dyes (state "all" or specify by name on product label)

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As explained in detail in the COTANCE-ETAD Information Note, dated, the following additional information is provided:

- 2 The following dyes included in the shipment although not restricted under the Directive 2002/61/EC could result in a false positive result on analysis of the dyed leather article:

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.....

- 3 The following dyes included in the shipment although not restricted under the Directive 2002/61/EC could, used in combination with other dyes (based on *.....), result in a false positive result on analysis of the dyed leather article.
* insert PPD or aniline (as appropriate)

.....
.....
.....

This company **is / is not** a member of ETAD (delete as appropriate).

Name:

Function:

Signature:

Date:

Place: