



Setting a risk based detection limit of sensitizing disperse dyes on textiles

1. Calculation of Exposure

Exposure leading to allergic contact dermatitis (ACD) depends on the local area peak concentration of the skin, which dermatologists frequently express in $\mu\text{g}/\text{cm}^2$. The potential exposure to dyes from coloured textiles depends on the migration factor, which has been simulated by ETAD^[1] and other institutions.

The working group textiles of the BfR (German Institute for Risk Evaluation) developed an exposure model. In this default model it is assumed that a standard textile garment of $100\text{g}/\text{m}^2$ is dyed with 1% active dye ingredient, i.e. $1\text{g}/\text{m}^2$. Measured peak migrations corresponding to **good fastness properties** (≥ 4) showed migration factors of **0.01% to 0.03%** (corresponding to 0.01 to $0.03\ \mu\text{g}/\text{cm}^2$). For poor fastness (≤ 2) this factor was up to **0.3%** and the BfR default model would assume a peak migration of 0.5% ($0.5\ \mu\text{g}/\text{cm}^2$).

2. Identification of a threshold concentration

Local Lymph Node Assays (LLNA) were performed by CTL on 8 disperse dyes that were conclusively linked to cases of consumer sensitization by the BfR:

D.I. Disperse Blue 3, Blue 35, Blue 106, Blue 124, Yellow 3, Orange 3, Orange 37, Red 1.

The LLNA is the first method that allows the **determination of a threshold concentration for contact sensitization**, which is described as the threshold value (stimulation index EC 3). In the case of **Disperse Blue 106** an **EC 3 value of 0.015%** was determined, which is the strongest sensitizer in the above series. This value is close to the reference substance DNCB, which is a known human contact allergen. **In the CTL study a No Observable Effect Level (NOEL) of $1.4\ \mu\text{g}/\text{cm}^2$ has been derived.**

3. Calculation of a risk based analytical determination limit

The strongest known sensitizing disperse dyes, C.I. Disperse Blue 106, is taken as a base reference. Dinitrochlorobenzene (DNCB) is the closest analogue substance in terms of sensitizing potency.

Threshold concentration of Blue 106 $1.4\ \mu\text{g}/\text{cm}^2$

Expected area exposure for a 1% dyeing:

for a good fastness (≥ 4)	$0.01\ \mu\text{g}/\text{cm}^2$
default value (BfR)	$0.5\ \mu\text{g}/\text{cm}^2$
realistic peak exposure	$0.1\ \mu\text{g}/\text{cm}^2$

Setting a risk based limit:

If a safety margin of a **factor 1000** to the NOEL of $1.4\ \mu\text{g}/\text{cm}^2$ is set, the corresponding acceptable migration is $0.0014\ \mu\text{g}/\text{cm}^2$.

Assuming a realistic peak migration factor of 0.1 % this would correspond to an analytical **determination limit of 140 ppm of Disperse Blue 106** on the textile.

A **limit of 100ppm** would therefore seem adequate to exclude a risk of sensitization to Blue 106.

^[1] ETAD Project G1033 "extractability of Dyestuffs from textiles over a normal life time of use", March 1997.