
Safety Assessment of Basic Red 76 as Used in Cosmetics

Status: Draft Final Report for Panel Review
Release Date: May 10, 2019
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The 2019 Cosmetic Ingredient Review Expert Panel members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; Ronald A. Hill, Ph.D.; Curtis D. Klaassen, Ph.D.; Daniel C. Liebler, Ph.D.; James G. Marks, Jr., M.D., Ronald C. Shank, Ph.D.; Thomas J. Slaga, Ph.D.; and Paul W. Snyder, D.V.M., Ph.D. The CIR Executive Director is Bart Heldreth, Ph.D. This safety assessment was prepared by Priya Cherian, Scientific Analyst/Writer.

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review (CIR)

FROM: Alexandra Kowcz, MS, MBA
Industry Liaison to the CIR Expert Panel

DATE: January 22, 2019

SUBJECT: Tentative Report: Safety Assessment of Basic Red 76 as Used in Cosmetics
(release date January 7, 2019)

The Council respectfully submits the following comments on the tentative report, Safety Assessment of Basic Red 76 as Used in Cosmetics.

Cosmetic Use - Please include the suggested conditions for hair-dye patch testing from reference 9, e.g., 45 minute open application of the hair dye after mixing with developer.

Dermal Penetration, Animal - Please revise: "Approximately 1.44%, 0.046%, and 0.0049% of the direct dye cream was present in the stratum corneum...". Rather than measuring the dye cream, they were measuring Basic Red 76 found in the dye cream.

Genotoxicity - It should be made clear that Basic Red 76 was negative in the chromosomal aberration assay in Chinese hamster V79 cells at a concentration of 106.3 mg/ml.

Carcinogenicity, Summary - NICNAS states that their assessment was based on third party summaries of studies, such as summaries found on the ECHA website. Therefore, it is not clear why the CIR report states: "according to several animal studies provided by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)". If NICNAS did not have the studies, how could they provide them to be cited in the CIR report? This should be changed to: "according to third party summaries of studies cited by NICNAS." It should also be stated that NICNAS did not have any specific evidence that Basic Red 76 is metabolized to *o*-anisidine.

Summary - Please correct "direct dye cream lotion" to "direct dye cream" as stated earlier in the report.

In addition to the concentration of Basic Red 76, please state the dose that was associated with adverse effects in the 12 week rat study (highlighted sentence).

It is not correct to include the genotoxicity study in mouse lymphoma cells in the sentence describing "mixed results". The results in mouse lymphoma cells were only negative.

Discussion - As Basic Red 76 is an ingredient used in hair dye products, please correct: "used as a rinse-off product" to "used in rinse-off products".