

HC YELLOW 5

The Expert Panel for Cosmetic Ingredient Safety (Panel) first published the Final Report on the Safety Assessment of HC Yellow 5 in 2007.¹ The Panel concluded that HC Yellow 5 is safe as a hair dye ingredient in the present practices of use and concentration as described in that safety assessment.

Because it has been at least 15 years since the final report was published, in accordance with Cosmetic Ingredient Review (CIR) Procedures, the Panel considered whether the safety assessment should be reopened. At the December 2022 meeting, the Panel reviewed updated (2022) information regarding product types and ingredient use frequencies as reported in the US Food and Drug Administration (FDA) Voluntary Cosmetic Registration Program (VCRP) database² and maximum use concentrations provided in response to the survey conducted by the Personal Care Products Council.³ Since this report was first considered, the frequency of use has decreased from 37 to 5 uses; it should be noted that non-hair dye uses were reported to the VCRP in 2022, including 2 uses in nail polish and enamel and 1 use in body and hand skin care products. In 2003, the maximum concentration of use for hair coloring preparations was reported to be 1.6%.¹ Results of the survey performed by the Council in 2022 had no reported concentrations of use.³ The updated and historical frequency and concentration of use are presented in Table 1.

In October 2022, an extensive search of the world’s literature was performed for studies dated 2003 forward, and no new toxicological data were found. The Panel did note that the European Union has banned HC Yellow 5 for use in cosmetic products;⁴ however, the reasoning behind this ban is not clear and does not appear to be based on any toxicological findings.

The Panel remarked on the reported use in non-coloring cosmetic products (nail polish and enamel; body and hand skin care preparations).² This use is not within the purview of this Panel. The Federal Food, Drug and Cosmetic Act (FD&C Act) mandates that color additives must be approved by FDA for their intended use before they are used. HC Yellow 5 is an unapproved color additive in cosmetics products, and thereby, such use is not permitted.

However, due to the “coal-tar hair dye exemption” of the FD&C Act, hair dye products labeled with the following caution statement do not require FDA approval prior to use:

Caution - This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.

Thus, use of this ingredient in hair dye products is permitted and is within the purview of this Panel.

In summary, the Panel reviewed 2022 frequency and concentration of use data and noted the lack of any new, available, relevant safety data. Considering this information, as well as the information provided in the original safety assessment, the Panel reaffirmed the 2007 conclusion for HC Yellow 5.¹

Table 1. Frequency (2022/2002) and concentration (2022/2003) of use.

	# of Uses		Max Conc of Use (%)	
	2022 ²	2002 ¹	2022 ³	2003 ¹
Totals	5	37	NR	0.2-1.6
<i>Hair Coloring Preparations</i>				
Hair Dyes and Colors (all types requiring caution statements and patch tests)	2	32	NR	1.6
Hair Tints	NR	5	NR	0.2
<i>Manicuring Preparations (Nail)</i>				
Nail Polish and Enamel	2	NR	NR	NR
<i>Skin Care Preparations</i>				
Body and Hand (exc shave)	1	NR	NR	NR

NR – not reported

REFERENCES

1. Andersen FA (ed.). Final Report on the Safety Assessment of HC Yellow No. 5. *Int J Toxicol.* 2007;26(Suppl. 2):113-124.
2. U.S. Food and Drug Administration Center for Food Safety & Applied Nutrition (CFSAN). Voluntary Cosmetic Registration Program - Frequency of Use of Cosmetic Ingredients. College Park, MD. 2022. (Obtained under the Freedom of Information Act from CFSAN; requested as "Frequency of Use Data" January 4, 2022; received January 11, 2022.)
3. Personal Care Products Council. 2022. Concentration of Use by FDA Product Category: HC Yellow No. 5. Unpublished data submitted by the Personal Care Products Council on July 6, 2022.
4. European Commission. Cosing database; following Cosmetic Regulation (EC) No. 1223/2009. <http://ec.europa.eu/growth/tools-databases/cosing/> Last updated 2022. Accessed 10/07/2022.