

Refs



Memorandum

Date: July 2, 2003

From: Division of Petition Review (HFS-265)

Subject: CAP 7C0208- Carbon Black (HPFB) for Use as a Colorant in Cosmetics
(Including Eye Area Use)
Final Toxicology Review

To: Martha Peiperl
Division of Petition Review (HFS-265)

Through: Carl Johnson, Ph.D. Carl E. Johnson
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CAP 7C0208

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Association**
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RELATED PETITIONS

CAP 9C0092, CAP 7C0131, FAP 5B4464

INTRODUCTION

The Cosmetic, Toiletry and Fragrance Association submitted a petition to use carbon black (high purity furnace black) as a colorant in cosmetics, including those intended to be used in areas around the eye. Carbon black was provisionally listed as a color additive for use in food, drugs, and cosmetics, but that listing was removed on 9/23/1976. The main concern that led to de-listing the color additive was the possible presence of carcinogenic polycyclic aromatic hydrocarbons (PAHs; synonyms include polynuclear aromatic hydrocarbons (PNAs) and polyhalogenated aromatic hydrocarbons). The presence of PAHs in the proposed carbon black color additive remains the principal safety concern.

Several memos concerning the safety of the proposed color additive have already been written (OFAS toxicology memos dated 12/8/1986, 11/1/1990, 5/29/1991, 10/14/1992, 6/12/1997, 6/8/1999; OCAC toxicology and chemistry memos dated 12/15/1987, 3/23/1998, 7/15/1999, 3/1/2001, 2/20/2003, 4/22/2003). CTFA has submitted written responses and additional data

to address the safety concerns of OFAS and the Office of Cosmetics and Colors (OCAC) (most recent submission received 2/7/2002, CAP 7C0208, Vol. 6). OCAC chemistry and toxicology reviewers recently completed memos stating that CTFA has sufficiently answered all questions about the safety of the proposed color additives (Dr. A.L. Sher, chemistry memo to M. Peiperl, 2/20/2003; Dr. M.E.K. Kraeling, toxicology memo to M. Peiperl, 4/22/2003). OCAC has no further questions or concerns about the safety of the proposed color additive under the intended uses (Dr. A.L. Sher, chemistry memo to M. Peiperl, 2/20/2003; Dr. M.E.K. Kraeling, toxicology memo to M. Peiperl, 4/22/2003).

CHEMICAL IDENTITY

Originally, CTFA identified two formulations of high purity furnace black (HPFB) as the "carbon black" color additive. In their most recent submission (dated 2/7/2002), CTFA stated that only one type of HPFB is now proposed for use as the color additive. The "higher-jet grade" product proposed as the color additive contains small particles with a surface area range of 200 to 260 m²/g material.

Several different manufacturing processes have historically been used to create products named "carbon black". Synonyms for carbon black (CAS Registry # 1333-86-4; Color Index # CI 77266) include: high purity furnace black, channel black, CI pigment Black 7, furnace black, and gas black. The proposed HPFB will be subject to batch certification by OCAC. Final specifications for HPFB, carbon black, are listed in the final OCAC chemistry memo (Dr. A.L. Sher, chemistry memo to M. Peiperl, 2/20/2003).

Impurities

Several potential impurities are introduced into carbon black in the manufacturing process from quench water, natural gas flame, and heating of the sheet metal surface. Potential impurities include: inorganic alkali and alkaline earth metal salts (quench water); heteroatoms H, S, and O (gas); trace metals (feedstock, process additives, equipment erosion); and adsorbed organic, non-alkylated PAHs. The following twelve PAHs account for most of the PAHs extracted from HPFB: fluoranthene; pyrene; cyclopenta(*c,d*)pyrene; chrysene; benzo(*a*)anthracene; benzo(*e*)pyrene; benzo(*a*)pyrene; benzo(*g,h,i*)perylene; indeno(1,2,3-*c,d*)pyrene; dibenz(*a,h*)anthracene; anthanthrene; and, coronene. Limits on impurities are listed in the final OCAC chemistry memo (Dr. A.L. Sher, chemistry memo to M. Peiperl, 2/20/2003). Total PAHs are not to exceed 0.5 ppm, with benzo(*a*)pyrene and dibenz(*a,h*)anthracene not to exceed 5 ppb.

INTENDED USE

Carbon black is proposed as a color additive for coloring cosmetics, generally, including those intended for use in the eye area. Amounts of carbon black used in cosmetics are proposed to be consistent with current good manufacturing practice. CTFA estimated a cumulative daily exposure (cEDI) to carbon black, in cosmetic formulations, of 1.0 mg/kg body weight/day

to HPFB to be between 1 and 10 mg/person/day (3/23/98 memo, Dr. E. Jensen to R. White; 7/1/03 memo Dr. D. Folmer to M. Peiperl). As noted above, the safety concerns about proposed uses of carbon black relate to PAH contaminants, but not the carbon itself.

SUMMARY OF OCAC MEMO

The Cosmetic Toxicology Branch in the Office of Cosmetics and Colors has evaluated the safety of the proposed carbon black color additive. The OCAC toxicologists concluded that they have no safety concerns regarding the proposed use of carbon black as a color additive in cosmetics (see Dr. M.E.K. Kraeling toxicology memo to M. Peiperl, 4/22/2003). OCAC concluded that lifetime cancer risk from PAH contaminants was extremely low, because data submitted with the petition showed that bioavailability of PAH impurities in carbon black was negligible. OCAC toxicologists also concluded: no benzo(*a*)pyrene is likely to be extracted from the carbon black into the cosmetic foundation; maximum potential lifetime cancer risk from PAH contaminants is 1.25×10^{-9} , which is lower than the CTFA estimate of lifetime cancer risk of approximately 7.5×10^{-8} (calculated using a more conservative approach); and, the acceptable safety margin is dependent on the color additive meeting the specifications proposed by the Color Technology Branch of OCAC (Dr. A.L. Sher, chemistry memo to M. Peiperl, 2/20/2003). Thus, any final regulation to list carbon black as a color additive for cosmetic uses must incorporate the OCAC chemistry specifications, including limits on the amount of extractable benzo(*a*)pyrene and dibenz(*a,h*)anthracene (each less than 5 ppb), with total extractable PAHs less than 0.5 ppm.

CONCLUSIONS

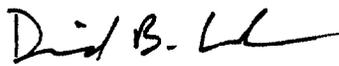
The color additive itself, carbon black, is relatively inert, and there is no data suggesting it is mutagenic or carcinogenic. The insolubility and lack of toxicity of carbon black, coupled with a history of safe use of activated carbon in medicine, contribute to our conclusion that there are no safety concerns for carbon black itself under the proposed uses.

The main safety concern regarding the proposed use of carbon black as a color additive in cosmetics has been low levels of potentially carcinogenic PAH contaminants. Because the data presented in the petition show that PAH contaminants in HPFB are not likely to be bioavailable under the proposed conditions of use, there are no concerns regarding the safe use of carbon black as a color additive in cosmetics (including those used in the eye area). Any PAH contaminants in HPFB under the proposed manufacturing conditions will be tightly bound to carbon molecules (including sulfur-containing PAH metabolites; see attached email correspondence between Dr. M. Kraeling (OCAC) and Dr. D. Carlson). The very low estimated lifetime cancer risk of the contaminants noted above is conservative because: (1) the calculations assume that all PAH contaminants are carcinogenic, although there is evidence to the contrary; and, (2) the cancer risk estimates assume that PAHs will be bioavailable and absorbed by the consumer, although there is a low likelihood of absorption of any PAHs. We are confident that the approach used to estimate the carcinogenic risk of PAH contaminants is scientifically sound and consistent with past FDA regulations. The benzo(*a*)pyrene toxic

scientifically sound and consistent with past FDA regulations. The benzo(a)pyrene toxic equivalency approach for assessing PAH toxicity is similar to the commonly accepted use of Toxic Equivalency Factors (TEFs) to predict toxicity of dioxin-like compounds.

Our safety conclusions are dependent on the final regulation requiring batch certification of carbon black, using high jet grade, High Purity Furnace Black. The color additive must be manufactured using current good manufacturing practice consistent with the specifications noted by CFSAN chemists.

We have no further questions about the safe use of carbon black as a color additive in cosmetics, as proposed in CAP 7C0208.



David B. Carlson, Ph.D.

cc:

HFS-265: Biddle, Varner, Whiteside, Edwards

HFS-128: Kraeling