

Ref: 7

**Memorandum**

Date: July 1, 2003

From: Division of Petition Review (HFS-265)
Chemistry Review Group

Subject: CAP 7C0208 (MATS#197 M2.3.1): The Cosmetic, Toiletry, and Fragrance Association (CTFA), Carbon black for use as a color additive in cosmetics (including eye area use). Reevaluation of exposure and risk assessment for polyaromatic hydrocarbons (PAHs)

To: Division of Petition Review (HFS-265)
Regulatory Review Group I
Attn: M. Peiperl

You requested that we re-evaluate: (i) the exposure estimate to carbon black, or high purity furnace black (HPFB); and (ii) the risk assessment for polyaromatic hydrocarbon (PAH) contaminants in HPFB previously provided in the Chemistry Review Team (CRT) memorandum dated 3/23/98. This request was made in light of the amendment dated 2/7/02 to the subject petition by the Cosmetic, Toiletry, and Fragrance Association (CTFA) for the use of carbon black as a color additive in cosmetics (including eye area use). The amendment primarily contained specifications-related data, and was addressed by the Office of Colors and Cosmetics (OCC) in memoranda dated 2/14/03 (A. Sher to M. Peiperl), and 4/22/03 (M. Kraeling to M. Peiperl).

The 2/7/02 amendment proposed a modification to the identity of carbon black. Previously, CTFA had identified two grades of carbon black, or HPFB. These two grades of HPFB are called lower-jet grade and higher-jet grade. The two grades differ in their particle size and surface area with the lower-jet grade having a larger particle size and a smaller surface area in comparison to the higher-jet HPFB. In the 2/7/02 amendment, CTFA stated that they were no longer interested in the lower-jet black, and thus were now only seeking approval for the higher-jet black. We note that there were no changes in the specification limit for PAHs in HPFB (i.e., 0.5 mg/kg (ppm)) in the 2/7/02 amendment as evaluated in the OCC memoranda dated 2/14/03 and 4/22/03.

Exposure to HPFB was discussed in a 3/23/98 CRT memorandum (E. Jensen to R. White). CRT estimated the human exposure to HPFB (from both lower- and higher-jet grade) from use in eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushes and rouge, makeup and foundation, and nail enamel to be between 1 and 10 mg/p/d. In the 2/7/02 amendment, CTFA did not provide any information indicating that the intended use of HPFB would be modified in light of the limitation of HPFB to the higher-jet grade only. Thus, it is assumed that the use levels cited in the original petition are still relevant. Consequently, the exposure estimate for HPFB discussed in the 3/23/98 chemistry memorandum is still appropriate for the petitioned use of HPFB.

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A risk assessment for PAHs contained in HPFB was presented by CTFA (12/18/97 submission, p. 000840), which was reviewed by CRT in the 3/23/98 chemistry memorandum. CTFA estimated a lifetime cancer risk from PAHs in HPFB of 7.5×10^{-8} using their exposure estimate for HPFB (50 mg/p/d), an estimated PAH content of 43 $\mu\text{g}/\text{kg}$ (ppb) (determined using a toxic equivalency factor (TEF) based method for 22 PAHs relative to benzo[a]pyrene (B[a]P) and trace PAH levels in a HPFB sample), the FDA-determined unit risk for B[a]P ($1.75 \text{ (mg/kg bw/d)}^{-1}$), and the assumption that all PAHs present in HPFB used in cosmetic formulations migrate into the body.

CRT disagreed with CTFA's risk assessment for PAHs, noting that the assumptions made by CTFA regarding the exposure to HPFB (and, therefore, to PAHs) and the amount of PAHs available for absorption by the body from HPFB were too conservative. CRT thus chose to recalculate the lifetime cancer risk for PAHs in HPFB. CRT estimated a lifetime cancer risk of 1.25×10^{-9} using their upper limit exposure estimate for HPFB (10 mg/p/d), an estimated PAH content of 43 $\mu\text{g}/\text{kg}$ (ppb) (determined using a TEF-based method for 22 PAHs relative to B[a]P and the 0.5 mg/kg (ppm) specification level suggested for PAHs)¹, the FDA-determined unit risk factor for B[a]P ($1.75 \text{ (mg/kg bw/d)}^{-1}$), and the assumption that only 10% of the PAHs could be absorbed into the body.²

The 4/22/03 OCC memorandum summarized the exposure estimate and risk assessment for PAHs determined by CRT. We agree with OCC's summary.

The 4/22/03 OCC memorandum also pointed out a discrepancy between the risk assessment for PAHs performed by CTFA and CRT with that of the risk assessment for PAHs in carbon black for use as a colorant in food contact polymers (62 FR 25475, May 9, 1997, 21 CFR 178.3297). The risk assessment for PAHs from use of HPFB as a colorant in food contact polymers is detailed in the Federal Register notice. This risk assessment employed the conservative assumptions that PAHs were present at the specification limit of 0.5 mg/kg (ppm), and that all PAHs present were B[a]P. This results in a PAH level of 0.5 mg/kg (ppm; 500 $\mu\text{g}/\text{kg}$ (ppb)), which is approximately 10 times higher than the level estimated by CTFA and CRT (approximately 43 $\mu\text{g}/\text{kg}$ (ppb)). The Federal Register notice pointed out that, due to the numerous conservative assumptions made, the risk assessment for PAHs in the food contact polymer was a worst-case estimate. The 4/22/03 OCC memorandum noted, however, that even with the incorporation of an additional conservative factor of 10 (based on the worst-case level of PAHs from the use of carbon black in polymers), the lifetime risk calculated by CTFA and CRT would still both be below 1×10^{-6} .

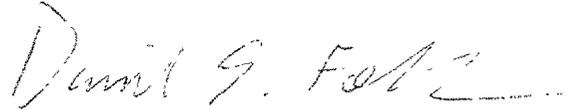
Summary

In light of the 2/7/03 amendment by CTFA and the OCC memoranda dated 2/14/03 and

¹ CRT estimated a PAH content of 44 $\mu\text{g}/\text{kg}$ (ppb), which is "essentially the same as that presented by CTFA" (43 $\mu\text{g}/\text{kg}$). Thus, CRT 43 $\mu\text{g}/\text{kg}$ in its calculation (see 3/23/98 chemistry memorandum).

² The 3/23/98 CRT memorandum points out that PAH availability is likely much lower than 10%. Therefore, this factor still provides a conservative estimate.

03, we have re-evaluated, and are satisfied with, the exposure estimate for HPFB and the risk assessment for PAHs presented in the 3/23/98 CRT memorandum. We have no further questions regarding this petition.



Daniel E. Folmer, Ph.D.

HFS-245 (Perfetti); 205 (Kuznesof, R/F)
HFS-265:DFolmer:208-3148: CAP7C0208_C_Memo.doc
Init: SECarberry: 7/1/2003
Final: def: 7/1/2003

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**Memorandum**

Date: January 21, 2004

From: Division of Petition Review (HFS-265)

Subject: CAP 7C0208- Carbon Black (HPFB) for Use as a Colorant in Cosmetics
(Including Eye Area Use)
Addendum to Final Toxicology Review (Carlson to Peiperl, 7/2/2003)

To: Celeste Johnston
Division of Petition Review (HFS-265)

Through: Carl Johnson, Ph.D. *Carl B. Johnson*
Toxicology Supervisor, DPR (HFS-265)

CAP 7C0208

**Cosmetic, Toiletry and Fragrance
Association**
1101 17th Street, NW, Suite 300
Washington, DC 20036-4702

The Chemistry Review Team (CRT memo, Folmer to Johnston, 9/30/03) has performed a more conservative assessment of the carcinogenic risks from PAH contaminants in carbon black (HPFB- high purity furnace black). CRT performed a preliminary risk assessment of cancer risk from PAHs in carbon black/HPFB in 1998 (Chemistry memo, Jensen to White, 3/23/98). The toxicology reviewer from Office of Cosmetics and Colors (OCAC), Dr. Margaret Kraeling, subsequently requested that the Quantitative Risk Assessment Committee review the various risk assessments submitted into the petition record by OCAC, OFAS, and the petitioner (CTFA) (Color Toxicology Branch memo, Kraeling to Peiperl, 7/15/99). The new risk assessment assumptions are consistent with the risk assessment calculated for the most recently regulated HPFB petition (FAP 5B4464, 62 FR 25475, May 9, 1997). In the new risk assessment, CRT conservatively assumed that all PAHs present in HPFB have the same toxicity as benzo[*a*]pyrene (B[*a*]P, the benchmark PAH often used to predict carcinogenicity). The upper-bound, lifetime cancer risk from HPFB under proposed uses is 1.5×10^{-8} (Chemistry memo, Folmer to Johnston, 9/30/03). This upper-bound lifetime cancer risk estimate is approximately 10 fold greater than the 1.25×10^{-9} risk previously estimated (Chemistry memos: Jensen to White, 3/23/98; Folmer to Peiperl, 7/1/03).

Dr. Chingju Sheu, the OFAS expert on risk assessment calculations, reviewed the CRT risk assessment and agreed with the final estimate of cancer risk (copy of e-mail from Sheu to

Johnston, 12/11/03 is attached).

Our previous conclusion that HPFB is safe for the proposed uses is unchanged. All of the cancer risk estimations used conservative assumptions about exposure and toxicity of PAHs in HPFB, and it is unlikely that the cancer risk from PAH contaminants will approach the upper-bound risk, which is well below the nominal threshold of concern (10^{-6}). Considering the new risk assessment and our previous comments (Final Toxicology Memo, Carlson to Peiperl, 7/2/03), we conclude there are no safety concerns for carbon black (HPFB) itself under the proposed uses.



David B. Carlson, Ph.D.

cc:

HFS-265: Biddle, Varner, Johnson

HFS-128: Kraeling

Attachments: E-mail from Sheu to Johnston, 12/11/03

Carlson, David

From: Johnston, Celeste
Sent: Thursday, December 11, 2003 12:46 PM
To: Carlson, David
Subject: CAP 7C0208 Risk Assessment Calculations
Follow Up Flag: Follow up
Flag Status: Flagged

-----Original Message-----

From: Sheu, Chingju W
Sent: Thursday, December 11, 2003 11:07 AM
To: Johnston, Celeste
Subject: Dr. Folmer's risk calculations

Celeste:

Dan provides a clear description of all the assumptions and calculations in arriving at the final cancer risk estimations. It was very easy to follow his memo and I fully concur with his risk assessment calculation.

Chingju

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