

Ref. 2



Memorandum

Date July 25, 1990

From Food and Color Additives Review Section, HFF-415

Subject CAP 7C0208, Cosmetics, Toiletry, and Fragrance Association (CTFA), Submission of 11-19th86, Carbon black for cosmetics

To Direct Additive Branch, HFF-334
Attn: M. Kashtok, Ph.D

AD Introduction and Identity

CTFA has proposed that carbon black be permitted for use in coloring cosmetics generally, including those intended for use in the area of the eye. CTFA indicates that the color will be blended with other authorized color additives to give a wide variety of possible shades. The amount of color proposed for use is dependent upon the desired color effect consistent with good manufacturing practices.

Carbon black has been identified in this petition by the trade names High Purity Furnace Black (HPFB) (see FAP 6B 3901), Channel Black, C.I. Pigment Black 7, Furnace Black, and Gas Black. The Chemical Abstracts Service Registry Number is 1333-86-4. Carbon black has been described as finely divided particulates composed primarily of elemental carbon.

CTFA has outlined two methods of manufacture of the carbon black, one for HPFB and the other for channel process black. The one for HPFB is consistent with information provided in FAP 6B 3901 for HPFB. The channel process black is prepared by traditional gas impingement methods. The methods of manufacture of C.I. Black 7, Furnace Black, and Gas Black have not been described, but presumably are similar to normal commercial methods. In section H, Proposed Regulation, CTFA has proposed that carbon black used in cosmetics be manufactured either by a "high purity" furnace process or by the channel process. CTFA has not indicated whether their proposal is intended to cover post-treated carbon blacks. They should fully describe any post-treatment procedures and modify their proposal accordingly.

Analytical Methods

Carbon blacks are known to contain a variety of manufacturing impurities, most notably, polynuclear aromatic hydrocarbons (or simply PNA's). Depending on the nature of the feedstock, quenching and post-treatment procedures, other impurities may also be present. CTFA has provided in Section H specifications for carbon black that is proposed for use in cosmetic applications. Methodologies used for assessing compliance with these specifications have been identified.

000736

With respect to the presence of PNA's in carbon black, CTFA has identified 12 particular PNA's whose total extraction levels must not exceed 5 ppm (see methodology in FAP 6B3901). Additionally, they have proposed that benzo(a)pyrene levels be less than 20 ppb when tested using the same methodology. These specifications are the same limitations proposed for HPFB (FAP 6B3901) when it is used as an additive in plastics. For FAP 6B3901, at least 12 different lots of HPFB were analyzed by the manufacturer of HPFB. All of the batches of HPFB complied with these specifications. Thus, it has been demonstrated that HPFB can be manufactured in a manner that consistently complies with the specifications proposed for carbon black used in cosmetic applications. The Division of Colors and Cosmetics should comment on whether these specifications adequately characterize HPFB that might be used in cosmetic applications.

Although channel process carbon black will have to comply with the same limit for extractable PNA's, CTFA has not provided any information or cited any data that demonstrates that channel black does meet the proposed extraction limit. Channel process carbon black has always been regarded as having low levels of PNA's (see FAMF 277). Due to environmental concerns, world-wide manufacture of channel black has nearly ceased. At times, its availability has been in doubt. A number of food additive regulations permit carbon black use, but only if it is manufactured by the channel process. Although manufacturers have continued to identify the carbon black they are using as channel black, it has been felt that other grades of carbon black are being used instead. Because of these concerns, it is important that the results of analyses of representative lots of channel black be provided to demonstrate that channel black is able to comply with the PNA extractable limit proposed for carbon black used in cosmetic applications.

Other contaminants may also be present in HPFB. CTFA has proposed that residues of lead and arsenic be limited to a maximum of 20 ppm and 2 ppm, respectively. The Division of Colors and Cosmetics should determine whether these proposed specifications are necessary and appropriate.

Intended Use and Probable Exposure to the Color

CTFA has proposed that carbon black be used in various cosmetic products in amounts consistent with good manufacturing practice. As a consequence, their proposed regulation in Section H of this petition does not include any use limits for the carbon black in cosmetic formulations. In Section E, however, CTFA does discuss the maximum amounts of color that are likely to be used in different cosmetic applications as well as possible exposure to the color. The following table summarizes CTFA's use and

exposure information:

<u>PRODUCT TYPE</u>	<u>MAXIMUM COLOR CONC.</u>	<u>COLOR EXPOSURE/PERSON/DAY</u>
Lipstick	1%	0.73 mg
Eyeliners	30%	2.97 mg
Brush-on-brow	30%	1.65 mg
Eye shadow	30%	2.37 mg
Mascara	10%	2.47 mg
Blushers & rouge	2%	0.27 mg
Makeup, foundation, etc.	5%	13.2 mg
Nail enamel	2%	1.12 mg

CTFA has indicated that carbon black may also be used in soaps, temporary hair color rinse, or creams and lotions. They have not provided any use or exposure information for these uses because they expect that such uses will not result in significant exposure to the color.

Previous FCARS assessments of exposure to color additives in cosmetic products have been developed using cosmetic use information developed by the cosmetic industry (CAMF No. 9, 6-29-83 submission) and color exposure scenarios developed by the Hart Panel (Risk Anal. 6(2)117-154, 1986). Although CTFA provided exposure estimates for most of the color applications, FCARS has, where possible, developed separate estimates of carbon black exposure using color use/exposure scenarios similar to those used for evaluating exposure to FD&C Red No. 3 (CAP 9C0096, 12-11-86 memorandum). Recent assessments of color exposure have not addressed products used in the area of the eye. Further, cosmetic use information provided by the cosmetic industry (CAMF No. 9) did not provide daily use information for eye-area products. Therefore, FCARS has used carbon black exposure information provided in this petition for eye area products.

FCARS has evaluated carbon black exposure for individuals using 90th percentile amounts of each cosmetic product per day. The 90th percentile cosmetic use amounts have been calculated by multiplying the 90th percentile frequency of use per day by the average amount of cosmetic product used per application (CAMF No. 9). Color use for each cosmetic application was then calculated by multiplying the maximum color concentration in the cosmetic product by the 90th percentile amounts of color used each day. Although this calculation leads to an estimate of the amount of color used each day for each cosmetic product, it does not yield an estimate of color exposure each day. Cosmetic products are often worn off or washed off. To account for these losses, FCARS has used correction factors proposed by the Hart Panel to estimate the percent of applied color that is available for absorption. The percent of applied color that is absorbed should also be considered when estimating color exposure. Considering that FCARS does not have any information on dermal absorption of

carbon black (or its components), we have made the highly conservative assumption that all of the applied color that is available for absorption is absorbed.

CARBON BLACK EXPOSURE FROM COSMETIC PRODUCTS

<u>COSMETIC PRODUCT</u>	<u>MG PRODUCT USED/DAY^a</u>	<u>COLOR CONC.</u>	<u>COLOR USED PER DAY (mg)</u>	<u>% COLOR AVAIL FOR FOR ABSORB^b</u>	<u>COLOR EXPOSURE (mg/p/day)</u>
Ingested cosmetics					
Lipstick	20	1%	0.2	50	0.1
External cosmetics					
Eyeliner	10	30%	3.0	50	1.5
Brush-on-brow	5.5	30%	1.6	50	0.8
Eyeshadow	7.9	30%	2.4	50	1.2
Mascara	25	10%	2.5	50	1.2
Blushers & rouge	14	2%	0.3	50	0.2
Makeup, found.	265	5%	13	50	6.5
Nail enamel	56	2%	1.1	0	---

^a The amount of cosmetic product used each day has been calculated from average application rate for the cosmetic product and the 90th percentile frequency of use of the cosmetic product.

^b See discussion in text.

Use information presented above for the eye-area cosmetic products reflects the amount of product used per application. Although CTFA suggested that an individual might use all four eye-area products three times daily, available cosmetic use information (CAMF No. 9) shows that the 90th percentile frequency of use of each of these products is only about 1 time per day. FCARS finds CTFA's estimates of consumer use of eye-area cosmetic products and color exposure to be unreasonably high.

The exposures estimated above for 90th percentile users of each of the cosmetic products are considered to be conservative. Since ingested and external cosmetics involve different routes of exposure, they should not be added together to derive an estimate of total exposure to carbon black. In fact, because it is unlikely that an individual might be a 90th percentile user of each of these cosmetic products, total exposure from external cosmetics should not be estimated by adding together the 90th percentile exposures derived for each of the cosmetic products. For the above uses, though, it is estimated that carbon black exposure is likely to fall in the range of 1-10 mg/person/day.

CTFA has suggested that exposure to carbon black from soaps, hair rinses, creams and lotions is not significant. They have not,

however, provided any information on these proposed uses that supports this claim. The amounts of each of these cosmetic products used each day are high relative to the amounts used in cosmetic products where CTFA has estimated exposure to carbon black (up to 10 g/day versus up to 0.3 g/day). It appears that some of these uses could significantly add to the exposures estimated for other uses that CTFA has described. CTFA should provide additional use information for these applications. Likely use levels of carbon black as well as estimates of daily use amounts for each of the cosmetic products should be provided. CTFA should also provide any other information that will be helpful in estimating exposure to carbon black from these products.

Exposure to Constituents of the Color

PNA's

As noted above, PNA's are known constituents of carbon blacks. CTFA has proposed specifications for HPFB for the maximum amount of extractable PNA's (5 ppm total for certain compounds, and 20 ppb for benzo(a)pyrene). If it is assumed that the PNA's that are bound to carbon black are completely transferred to the skin during use of the cosmetic product, it is possible to provide an upper-bound estimate of consumer exposure to the PNA's. For lipstick (carbon black intake of 0.1 mg/person/day), intakes of the specified PNA's and benzo(a)pyrene are estimated to be 0.5 ng/person/day and 0.002 ng/person/day, respectively. In the case of the external cosmetic products reviewed above (carbon black exposure up to 10 mg/person/day), exposures are estimated to be up to 100 times higher than from ingested lipstick, i.e., 50 ng/person/day for the specified PNA's and 0.2 ng/person/day of benzo(a)pyrene.

These upper-bound estimates of exposure to the PNA constituents do not represent likely levels of exposure. PNA's are known to be strongly bound to carbon blacks. Because of this, the bound PNA's may not be available for absorption from the cosmetic product. Under high temperature⁷ extraction conditions with aromatic solvents (such as proposed for the extraction limit) and in certain cases where substances can bind irreversibly to the carbon surface, PNA's can be displaced from the carbon surface. The types of ingredients commonly used in cosmetic formulations where carbon black use is proposed are not expected to exhibit strong interaction with the carbon surface. However, during manufacture of the cosmetic products, brief periods of heating of the ingredients may increase their interaction with the carbon black and increase the displacement of the PNA's from the carbon surface. This displacement may, however, be reversible. Under room temperature use conditions, the displaced PNA's may resorb onto the carbon black surface, especially in the case of highly

polar ingredients and aqueous emulsions. Considering that ethanol extracts from carbon black only about 3% as much benzo(a)pyrene as does toluene under the 48-hour reflux conditions used for assessing the purity of the carbon blacks, it seems unlikely that cosmetic ingredients will extract more than 10% of the PNA's from carbon black.

Assuming that no more than 10% of the PNA's are extracted from carbon black into cosmetic formulations, FCARS has revised its estimates of exposure to the PNA's and benzo(a)pyrene from the external cosmetic ingredients reviewed above, i.e., no more than 5 ng/person/day and 0.02 ng/person/day, respectively. These exposure figures reflect the amount of PNA's in cosmetic products on the skin that may be available for dermal absorption. As noted above, since we do not have information on the dermal absorption rate of PNA's, we have assumed that all of the PNA's on the skin that may be available for absorption are absorbed. The exposure estimated above for lipstick assumed that all of the PNA's bound to ingested lipstick are bioavailable. Since biological fluids exhibit little tendency to extract PNA's from carbon black (Carbon, Vol. 25, 135-145, 1987), we have assumed that when lipstick is ingested only those PNA's that might be extracted by the cosmetic ingredients are bioavailable, i.e., 10% of those on the black. Hence, exposures to the PNA's and benzo(a)pyrene from lipstick are about 0.05 and 0.0002 ng/person/day, respectively, for individuals who use 90th percentile amounts of lipstick each day. For related information on exposure to PNA's from HPFB used in plastics or from background dietary sources, see FAMF 277 and FAP 0B3901.

OTHER CONSTITUENTS

Although PNA's are known to be strongly bound to carbon blacks, no such information is known about other constituents of carbon black. Therefore, we have assumed that all non-PNA components are completely bioavailable from all cosmetic products. Exposures to such constituents are estimated by multiplying the estimated exposure to carbon black by the concentration of the constituents. For example, CTFA proposed specifications for carbon black of 20 ppm lead and 2 ppm arsenic. For lipstick, exposures to lead and arsenic are expected to be no greater than 2 ng/person/day and 0.2 ng/person/day, respectively.

CONCLUSIONS

FCARS has reviewed use information provided by CTFA and has estimated exposures to carbon black and certain constituents (PNA's, lead, and arsenic). These exposure assessments only address certain uses of carbon black. CTFA needs to provide additional use information (as outlined above) for carbon black applications involving soaps, hair rinses, creams, and lotions.

000741

They also need to provide analytical information for channel process black if it is to be covered by this petition (see above).



Gregory M. Cramer, Ph.D.

cap7c208.622

HFF-156; 335; 400; 410; 442(Bailey)

HFF-415:GMCramer:472-5680:7-16-90

RD Init:PMKuznesof 7-19-90;AMRulis 7-25-90

000742