



THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

Color Additive Petition (CAP) 7C0208
Revised Environmental Assessment

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P R E S I D E N T

1. **Date** August 7, 2003
2. **Name of Sponsor** Cosmetic, Toiletry, and Fragrance Association, Inc.
3. **Address** 1101 17th Street, N.W., Suite 300
Washington, D.C. 20036-4702
4. **Description of the Proposed Action**

a. Requested action

This petition proposes the establishment of a new section in Part 74 (“Listing of color additives subject to certification”), Subpart C (“Cosmetics”) of the Food and Drug Administration’s regulations to provide a permanent listing for the color additive High Purity Furnace Black (HPFB). The color additive is proposed for use in coloring cosmetics generally, including those for use in the area of the eye, in amounts consistent with good manufacturing practice. In accordance with 21 C.F.R. Section 70.5(a), specific language is required to provide for the intended use of the color in cosmetics intended for use in the area of the eye.

b. Need for action

The color additive is intended to impart color to cosmetics. When blended with other authorized color additives, the color provides a wide variety of possible shades. HPFB is particularly useful in providing an intense black color, which is of special importance in cosmetics such as mascara, eye liner, and the like.

c. Locations of use/disposal

Cosmetic products containing HPFB may be produced in any cosmetic manufacturing facility in which such products are normally produced. Such products are designed for consumer use and are not expected to be disposed of in bulk. Typical environments of

use of these products will be the home. Wastes containing small quantities of these products, and consequently containing the carbon black, may be expected to reach sewage treatment plants because of consumers' washing product off after use, and to reach municipal solid waste disposal landfills and incinerators because of consumers' disposing of empty product containers.

5. Identification of chemical substance that is the subject of the proposed action

The identity of the chemical that is the subject of this petition is high purity furnace black (HPFB). HPFB is a form of carbon black, which consists of elemental carbon. Thus, the molecular formula is C, and the molecular weight is 12.01. The CAS Reg. No. is 1333-86-4. HPFB is a finely divided black powder. The HPFB that is the subject of this petition is prepared by methods designed to yield a product identical to current commercial carbon blacks, but containing only extremely low levels of polynuclear aromatic hydrocarbon (PAH) impurities. High purity furnace black contains no additives.

6. Introduction of substances into the environment

a. Introduction of substances as a result of manufacture

Under 21 C.F.R. § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Moreover, to the best of our knowledge, there are no extraordinary circumstances pertaining to the manufacture of HPFB. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b. Introduction of substances as a result of use

Little or no introduction of substances into the environment will result from the use of HPFB in the manufacture of cosmetics because it is almost completely incorporated into the cosmetics and essentially all is expected to remain with this material throughout use of the product. The HPFB is expected to be distributed widely across the United States in patterns corresponding to national population density.

c. Introduction of substances as a result of disposal

Disposal of cosmetics containing HPFB is expected to occur nationwide with the cosmetics ultimately being deposited in municipal solid waste landfills or combusted as a result of the disposal of empty product containers; in addition, HPFB may enter wastewater treatment plants when consumers wash the product off following use.

1) Landfills

We expect only very low levels of HPFB to leach into landfills. Moreover, even if a very small amount of HPFB migrates from the cosmetics in landfills, we expect extremely low quantities to enter the environment. This finding is based

on the regulations of the Environmental Protection Agency (EPA), in 40 C.F.R. Part 258, governing municipal solid waste landfills.

2) Combustion

The color additive that is the subject of this petition is composed of carbon, an element commonly found in nature and in municipal solid waste (MSW). The complete combustion of this compound will produce carbon dioxide. Because the market volume of the HPFB to be used in cosmetics is a small fraction of the MSW generated and disposed of in the United States, adding cosmetics containing HPFB to waste that is combusted will not alter significantly the emissions from municipal waste combustors. Because of the low levels of combustion products compared to the amounts currently generated by municipal waste combustors, we do not expect that the combustion of cosmetics containing HPFB will cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations, i.e., 40 C.F.R. Part 60 and relevant State and local laws.

3) Publicly Owned Treatment Works

The process whereby consumers wash off cosmetics containing HPFB will result in extremely low levels of HPFB entering wastewater treatment plants. Organic matter in wastewater, including algae, will bind to the HPFB and precipitate out in the sewage sludge. Applicable laws and regulations, including 40 C.F.R. Part 60 and relevant State and local laws, regulate the disposal of sewage sludge in a manner that will minimize introduction into the environment. Due to the extremely low levels at which HPFB may enter these systems and due to the dilution that occurs, we do not expect that the municipal wastewater treatment of the cosmetics will cause wastewater treatment plants to threaten a violation of applicable emissions laws and regulations.

7. Fate of substances released into the environment

As discussed under Format Item 6 above, only very small quantities, if any, of substances will be introduced into the environment as a result of use and disposal of the subject color additive. Consequently, no information need be provided on the fate of substances released into the environment as a result of such use and disposal.

8. Environmental effects of released substances

No information need be provided on the environmental effects of HPFB released into the environment as a result of its use and disposal because, as discussed under Format Item 6 above, only very small quantities of substances, if any, will be introduced into the environment as a result of this use and disposal. Therefore, the use and disposal of the subject additive are not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 C.F.R. Parts 60 and 258.

9. Use of resources and energy

There will be no significant incremental increase in the natural resources needed to manufacture or dispose of any increase that might be expected in the quantity of HPFB needed to manufacture the cosmetic products that will be produced using the color, nor is it expected that there will be a measurable increase in the total amount of cosmetic product produced.

Estimates of the increase in the amount of carbon black produced in order to color cosmetic products represent a minute fraction of the existing carbon black production. More specifically, the total amount of HPFB that will be used in cosmetics is not expected to exceed about 120,000 pounds per year. By comparison, as of 1994, the total production of carbon black in the United States was 1.5 million metric tons (3.3 billion pounds).¹ The production of HPFB is comparable to the production of ordinary furnace black in terms of the consumption of energy and resources.² Thus, the incremental increase due to production of HPFB for cosmetics represents an increased resource consumption of 0.0036% compared to current total production of carbon black.

Moreover, the HPFB will be used in place of other currently permitted color additives that are now used to color cosmetics. A major color that is expected to be replaced by HPFB is iron oxide, which is believed to require significantly more energy to produce than HPFB. For example, production of 1 metric ton of steel is estimated to require about 18.9 GJ (GigaJoules) of energy; additional energy would be consumed in processing to produce a fine powder of the type used in cosmetics. By comparison, non-feedstock energy input requirements for production of carbon black range from 1.55 to 2.0 GJ per ton.³ Thus, it is evident that the production of HPFB requires less energy than that needed to produce the currently used colors.

Based on the foregoing, there will be no meaningful increase in the use of resources and energy upon the clearance of HPFB as a color additive for cosmetics.

10. Mitigation measures

No potential adverse environmental impacts are identified for the proposed action. Therefore, mitigation measures need not be discussed.

¹ International Agency for Research on Cancer (IARC), *Monographs on the Evaluation of Carcinogenic Risks to Humans*, Vol. 65, p. 165 (1996).

² This is confirmed by a manufacturer of HPFB, who states further that the manufacturing process is very similar for ordinary furnace black and special black. Technology and process constraints are slightly different, but in essence, the two processes are nearly identical.

³ Energy consumption values are taken from the European Integrated Pollution Prevention and Control (IPPC) Bureau's "Best Available Techniques Reference Document on the Production of Iron and Steel" (December 2001) and the "Best Available Techniques Reference Document on the Production of Carbon Black" (May 2002).

11. Alternatives to the proposed action

No alternatives to the proposed action are being proposed as there are no significant environmental risks or benefits of the proposed action.

12. List of preparers

G.N. McEwen, Jr.; PhD., Physiology and Biophysics; MA, Life Science; expertise and experience in hazard evaluation, occupational and environmental safety and health, quality assurance; Vice President – Science, Cosmetic, Toiletry, and Fragrance Association.

13. Certification

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the Cosmetic, Toiletry, and Fragrance Association, Inc.

Date: *August 7, 2003*

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