



Environmental Assessment
Color Additive Petition (CAP) 5C0247

Format Item 1, Date: September 15, 2003

Format Item 2, Name of Sponsor: Ebonex Corporation

Format Item 3, Address: PO Box 3247
Melvindale, MI 48122

Format Item 4, Description of the Proposed Action:

a. Requested Action:

Ebonex Corporation is requesting listing bone black pigment as a color additive for use in cosmetic industry including use in the area of the eye. We are requesting that 21CFR part 74 of the color additive regulation be amended to provide for the safe use of bone black to color externally applied cosmetics, including cosmetics intended for use of in the area of the eye. Use conditions for this color additive, bone black pigment, are considered in the following cosmetics; mascara, eye shadow, eyeliner, and face powder. Estimated levels of pigment will vary from 1-30% by weight depending upon the end usage, and cosmetic formulators current industry standards. Usage estimates from cosmetic formulators are as follows; mascara 10 - 30%, eye shadow & eyeliner 5 - 10%, face powder 1 - 5%(for use as a color toner).

b. Need for Action:

At the present time, black iron oxides are the only available options for black pigment colorization to the cosmetic industry. By amending the color additive standard to include bone black pigment, an additional black pigment option will give cosmetic formulators a choice for colorization, and to create new formulations for products for their respective companies.

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c. Locations of use/disposal:

Bone black will be widely used and disposed of in a pattern corresponding to the national population density. The expected routes of disposal of cosmetics that contain bone black include entering publicly owned wastewater treatment plants when consumers wash product off after use, as well as disposal of empty containers into municipal solid waste (MSW) entering landfills and incinerators.

Format Item 5, Identification of chemical substances that are the subject of the proposed action:

Common Name: Bone black, Ivory black, Animal charcoal
Formal Name: Bone black
Trade Name: Cosmic Black
CAS#: 8021-99-6

Chemical Formula: ~ 8 - 11% C ~ 85 - 90% $\text{Ca}_3(\text{PO}_4)_2$

Bone black is a black pigment manufactured by carbonizing bones. Carbon content is approximately 8 - 11% with the remaining composition being tricalcium phosphate. Impurities in bone black consists of approximately 1% silica and trace minerals (.1 - .0001%) This is a naturally occurring chemical.

Physical Properties:

Black, finely ground solid
37 - 45 lb/ft³ bulk density
pH 8.5 - 12
Insoluble in water
Flash point - N/A Boiling point - N/A
Stable with air contact
Easily disperses in water
Stable with light contact - able to withstand direct sunlight contact
withstand major fading
Degrades with HCL and KNO_3
Microbial contamination minimal due to initial charring process which
Is performed at temperature 700 - 1000°C

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Format Item 6, Introduction of substances into the environment:

- a. Introduction of substances into the environment as a result of manufacture:

To the best of our knowledge, no extraordinary circumstances pertain to the manufacture of bone black.

- b. Introduction of substances into the environment as the result of use:

Little of no introduction of substances into the environment will result from the use of bone black 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 the use of the product. Bone black is expected to be distributed widely across the United States in patterns corresponding to national population density.

- c. Introduction of substances into the environment as a result of disposal:

Disposal of cosmetics, containing bone black, 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 product containers; in addition, bone black may enter wastewater treatment plants when consumers wash off the product following use.

1. Landfills:

We expect only very low levels of bone black used in cosmetics to leach into landfills. Moreover, even if a very small amount of bone black 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 40CFR part 258, governing municipal solid waste landfills.

2. Combustion:

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The color additive that is the subject of this petition is composed of carbon and calcium phosphate, compounds commonly found in nature and in municipal solid waste (MSW). The complete

combustion of these compounds will produce carbon dioxide, calcium phosphate and water. Because market volume of the bone black to be used in cosmetics is a small fraction of the MSW generated and disposed of in the United States and because bone black will replace and compete with similar materials, adding the cosmetics 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 bone black will cause municipal waste combustors to threaten a violation of applicable emission laws and regulations.

3. Publicly owned treatment works:

The process of consumers washing off cosmetics containing bone black will result in extremely low levels of bone black entering wastewater treatment plants. Bone black is expected to bind to biosolids present in the wastewater and precipitate out in the sewage sludge. Local laws and regulations cover the disposal of sewage sludge in a manner that will minimize introduction into the environment. Due to extremely low levels of bone black that enter these systems, and due to the dilution that occurs, we do not expect that the municipal treatment of the cosmetics will cause wastewater treatment plants to threaten a violation of applicable emission laws and regulations.

Format Item 7, Fate of substance 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 the use and disposal of cosmetics containing the subject additive. Consequently, no information need be provided on the fate of substances released into the environment as a result of use and disposal.

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Format Item 8, Environmental effects of released substances:

No information need to be provided on the environmental effects of bone black 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 use and disposal of cosmetics containing bone black. Therefore, the use and disposal of the subject additive are not expected to threaten violation of applicable laws and regulations, e.g., the EPA's regulations in 40CFR parts 60 and 258.

Format Item 9, Use of resources and energy:

The proposed use of the subject substance will not have a significant impact on resources because bone black will replace other color additives currently regulated for use in cosmetics. No significant impact on energy use is expected because this use of bone black as a color additive represents a small fraction of the total amount of this substance that is produced and used.

Format Item 10, Mitigation measures:

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

Format Item 11, Alternative to the proposed action:

As discussed in Format Item 10 above, alternative actions were identified because not adverse environmental impacts were identified.

Format Item 12, List of preparers:

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Master of Arts in Teaching – Education
Ebonex Corporation Technical Director – Twelve (12) years

Consulted:

Dr. Victor Dietz

George Irvine – Technical consultant

FDA – Annette Mc Carthy, "Recommendations for Preparing an
Environmental Assessment for Color Additive
Petition(CAP) 5C0247"

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Format Item 13, Certification:

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the Ebonex Corporation.

Sept 16, 2003
Date

Shelly Toenniges
Signature of Responsible Official

Shelly Toenniges, Vice President - Technical
Name and title of responsible official, printed

Format Item 14, References:

Dr. Victor Dietz – Letter of statement

George Irvine – Technical Consultant

Letter of statement

1. Ministry of Agriculture, Fisheries, and Food "Use of Bovine Charcoal in Animal Feedstuffs" A C Dixon, Animal Health Division B
2. Drinking Water Inspectorate Water Industry Act 1999: sec 69
A Lloyd, Chairman of Committee

Condensed Chemical Dictionary 4th Edition Reinhold Publishing Co. New York 1950

Worldwide Limits for Toxic and Hazardous Chemical in Air, Water and Soil
Sittig, Marshall 1994

Bretherick's Handbook of Reactive Chemical Hazards Bretherick, L. 1990

Hazardous Chemical Data Book Weiss, G. 2nd Edition

Sax's Dangerous Properties of Industrial Materials Lewis, Richard J., 8th Edition 1992

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Merck Index 8th Edition listed under tricalcium phosphate

Ebonex Corporation MSDS 1995

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