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Expert Environmental Assessment for a Color Additive Petition for Bismuth Citrate

Prepared for

Combe, Inc.
1101 Westchester Avenue
White Plains, NY 10604

Prepared by

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Environmental Assessment for a Color Additive
Petition for Bismuth Citrate

Executive Summary

The proposed environmental assessment for a color additive petition for bismuth citrate is proposed at a level not to exceed 2 0% by weight of the finished product This petition proposes the revision of Part 73 ("Listing of color additives exempt from certification"), Subpart C ("Cosmetics") of the Food and Drug Administration's regulations which provides a listing for the color additive bismuth citrate The color additive is currently for use in hair dyes, at a level not to exceed 0 5% by weight of the finished product

USE

A small amount of the hair crème containing bismuth citrate is applied to clean, dry hair, by hand on a daily basis for the first 2-3 weeks until the desired hair color is achieved Once the color is achieved, application is reduced to one or two applications per week Excess hair dye will be washed off during normal hair cleaning and rinsing Also, some hair will also be removed from either normal exfoliation or from hair removal by hair cuts and shaving

RESULTS

Based on the hair dye sales over the last seven years (Combe, Inc , 2007), the maximum amount of total bismuth citrate that could annually enter wastewater or landfills is 4,643 5 kg Since the molecular weight of bismuth citrate is 398 g/mol and that for bismuth is 209 g/mol, then the percentage of bismuth is 52.5% Therefore the total amount of bismuth metal potentially entering both wastewater and/or landfills each year is 2,437 8 kg or approximately 2.687 tons (Source· Combe, 2007) Based on the annual U S consumption of 2,280 tons, the increased percentage of bismuth citrate in hair dye manufactured by Combe would correspond to a maximum of about 0 12 % of the total bismuth used in the country Distributed across the U S , this would result in a non-measureable and insignificant increase in environmental concentrations in landfills, soils and waters

ASSESSMENT

The use and disposal of the subject color additive are not expected to threaten a violation of applicable laws and regulations, e g , the Environmental Protection Agency's regulations in 40 CFR parts 60 and 258 because, as discussed in this petition, only very small quantities of additional substances will be introduced into the environment as a result of its use and disposal

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Environmental Assessment for a Color Additive
Petition for Bismuth Citrate

1. Date: **27 August 2007**

2. Name of Sponsor: **Combe, Inc.**

3. Address: **1101 Westchester Avenue**
White Plains, NY 10604

4. Description of the proposed action:

a. Requested action:

The proposed environmental assessment for a color additive petition for bismuth citrate is proposed at a level not to exceed 2 0% by weight of the finished product This petition proposes the revision of Part 73 ("Listing of color additives exempt from certification"), Subpart C ("Cosmetics") of the Food and Drug Administration's regulations which provides a listing for the color additive bismuth citrate The color additive is currently for use in hair dyes, at a level not to exceed 0.5% by weight of the finished product

b. Need for action:

The color additive is intended to impart color to progressive hair dyes Bismuth citrate is useful in producing shades of brown color, which is of special importance in progressive hair dyes intended to mask graying hair

c. Locations of use/disposal:

Bismuth citrate will be widely used and disposed of in a pattern corresponding to the national population density The expected routes of disposal of hair dyes that contain bismuth citrate include entering publicly owned wastewater treatment plants when consumers wash the excess product off after use, as well as disposal of discarded hair dye containers into municipal solid waste (MSW) entering landfills and incinerators

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

The chemical that is the subject of this petition is bismuth citrate, CAS # 813-93-4, a white powder with a molecular weight of 398 09 g/mole Bismuth citrate is a synthetically prepared crystalline salt of bismuth and citric acid, consisting principally of $BiC_6H_5O_7$

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A typical structural formula is represented below (Figure 1)

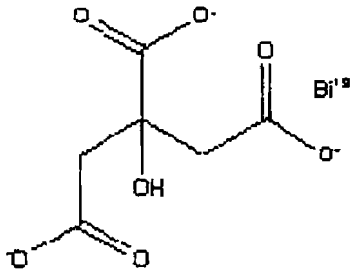

Figure 1 Bismuth citrate (ChemFinder com)

Bi(III) citrate compounds have complex structures, containing chains, sheets and other networks, and as a result many are labeled colloids (Sadler and Guo 1998).

6. Introduction of substances into the environment:

Asato et al (1991) found that compounds containing Bi(III) and citrate participated in rapid ligand exchange at low pH (<7), while at high pH the citrates are "hardly coordinated to Bi(III)" They also report that high solubility only occurs under basic conditions, and both coordinated and uncoordinated citrates can be detected in solutions of high concentrations (Asato et al 1991)

Bismuth compounds have a wide variety of uses in medicine, cosmetics, and as semiconductor dopants (Bentley and Chasteen 2002). According to USGS (2006), in 2005 the global production of bismuth was estimated at above 4,000 tons, and U S consumption was about 2,280 tons Up to 2.3 mg/kg of bismuth can be found in the waste from coal incineration, and bismuth concentrations in oil can be as high as 0 4 mg/kg (Kjolholt 2003). Wastewater and solid waste concentrations of bismuth are the result of the use and disposal of cosmetics, chemicals, and pharmaceuticals

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

Under 21 CFR part 25 40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposals from use, rather than the production, of FDA-regulated articles Moreover, to the best of our knowledge, no extraordinary circumstances pertain to the manufacture of bismuth citrate Little or no introduction of substances into the environment will result from the manufacture of hair dyes because bismuth citrate is almost completely incorporated into the hair dyes and essentially all is expected to remain with this material throughout the use of the product

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

Release of bismuth citrate from use of hair dyes containing this compound is expected to occur nationwide through two main pathways 1) bismuth citrate may enter wastewater treatment plants when consumers, in the course of normal bathing and hair washing, wash the excess product off following use, 2) Bismuth citrate contained in either unused portions of hair dyes or in empty bottles which

ultimately are deposited in municipal solid waste landfills or perhaps combusted as a result of the disposal of product containers Alternately, bismuth attached to discarded hair (from cutting or from solid wastes deposited from wastewater operations) will also be deposited in landfills Bismuth citrate released from the use of the product is expected to be distributed widely across the United States in patterns corresponding to national population density.

DESCRIPTION OF USE

A small amount of the hair crème containing bismuth citrate is applied to clean, dry hair, by hand on a daily basis for the first 2-3 weeks until the desired hair color is achieved Once the color is achieved, application is reduced to one or two applications per week Excess hair dye will be washed off during normal hair cleaning and rinsing. Also, some hair will also be removed from either normal exfoliation or from hair removal by hair cuts and shaving

Oxidation of bismuth citrate adhered to the hair shaft produces the desired color in progressive hair dyes Potentially hazardous decomposition products of bismuth citrate could include. carbon monoxide, carbon dioxide, and bismuth oxides (MSDS) However, these reactions are likely to be minimal with bismuth citrate in hair dye products as currently utilized since concentrations in hair dye are small and reactions as described above are not likely to occur during product usage

Based on the hair dye sales over the last seven years (Combe, Inc., 2007), the maximum amount of total bismuth citrate that could annually enter wastewater or landfills is 4,643 5 kg Since the molecular weight of bismuth citrate is 398 g/mol and that for bismuth is 209 g/mol, then the percentage of bismuth is 52 5% Therefore the total amount of bismuth metal potentially entering both wastewater and/or landfills each year is 2,437 8 kg or approximately 2 687 tons (Source Combe, 2007) Based on the annual U S consumption of 2,280 tons, the increased percentage of bismuth citrate in hair dye manufactured by Combe would correspond to a maximum of about 0.12 % of the total bismuth used in the country. Distributed across the U S , this would result in a non-measureable and insignificant increase in environmental concentrations in landfills, soils and waters

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

1. Landfills:

Disposal of hair dyes, containing bismuth citrate, is expected to occur nationwide with the hair dyes ultimately being deposited in municipal solid waste landfills or combusted as a result of the disposal of product containers In a 2002 report submitted to the Australian National Occupational Health and Safety Commission, a hair dye manufacturer estimated that "up to 2 % of the finished dye product will remain in the bottles or tubes after application to hair" (Cosmetic Products, Ltd 2002) Applying the same estimate to hair dye containing bismuth citrate, it is estimated that on an annual basis 48 77 kg of bismuth will remain in the bottles or tubes and end up in municipal solid waste (2 percent of total bismuth used in manufacture or 02 X 2,487 6 kg = 48 8 kg) Some additional but

non-measureable quantity of bismuth will enter the landfill by disposal of human hair in either garbage disposal or disposed solids from wastewater. The remainder of the bismuth or 2,389 65 (2,487.6 kg – 48.8 kg = 2,389 7 kg) of bismuth will enter wastewater through either the rinsing of excess product during hair dye applications or from hair losses to the treatment system. Since much of the solid wastes generated from wastewater facilities ends up in landfills, a conservative assumption is that all of the bismuth contained in the product will ultimately end up being disposed in landfills Thus we can conservatively estimate that the majority of bismuth will find its way to landfills

As mentioned in section 6.b above, based on the annual use of bismuth nationwide (2,280 Tons), the maximum percentage of bismuth disposal in landfills attributed to the bismuth from hair dyes would be less than 0.12% Based on the regulations of the Environmental Protection Agency (EPA), in 40 CFR part 25B, governing municipal solid waste landfills, disposal of this concentration of bismuth would not exceed regulatory limits

2. Combustion:

The color additive that is the subject of this petition is composed of carbon, hydrogen, and oxygen compounds commonly found in nature and in municipal solid waste (MSW) and bismuth an element commonly found in nature The complete combustion of these compounds will produce carbon dioxide, water and insoluable bismuth oxides (MSDS; Bismuth Citrate, Sciencelabs com) Because the market volume of bismuth citrate to be used in hair dyes is a small fraction (0 12%) of the bismuth generated and disposed of in the United States and because bismuth citrate will replace and compete with similar materials (see Format Item 9) adding the hair dyes to waste that is combusted will not alter significantly the emissions from municipal waste combustors. Because of the low levels of combustion products containing bismuth from this product, and when compared to the amounts currently generated by municipal waste combustors, the combustion of hair dyes containing bismuth citrate will result in an insignificant increase and therefore will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations, i e , 40 CFR part 60 16, Priority listed pollutants

3. Publicly owned treatment works:

Of this material, most will end up in associated sludges (due to precipitation) and waste solids (from filter screens) and ultimately end up in landfills. Applicable laws and regulations, including 40 CFR part 60 and relevant state and local laws, regulate the disposal of sludge in a manner that will minimize introduction into the environment Based on the literature review of the fate of bismuth, and the low levels of bismuth contained in the waste stream from hair dyes, this action will not result in any disruption of sewage treatment plant operations or pollution control functions

7. Fate of substances released into the environment

a. Physical/chemical properties:

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Water solubility – slightly soluble in cold or hot water, slightly soluble in alcohol, soluble in NH_4OH (CRC Handbook) Soluble salts of bismuth form insoluble basic salts on the addition of water (CRC Handbook) Citrate salts of bismuth are "uniquely water soluble at high pH with avoidance of hydrolysis, which typically gives BiO for other salts" (Briand 1999). The specific gravity of bismuth citrate is 3 458 (water = 1).

b. Environmental depletion mechanisms:

Aerobic and anaerobic biodegradation - Hazardous short term biodegradation products are not likely However, long term degradation products may arise. The products of degradation can be more toxic than elemental bismuth given its relatively low toxicity (www.sciencelab com MSDS) and little is known about its depletion mechanisms.

8. Environmental effects of released substances:

Environmental Toxicity

Bismuth compounds show relatively low toxicity when compared to many other heavy metal compounds, though it has physical properties that are similar to lead (Feldman et al 1999) Pharmaceutical products (e g., bismuth subcitrate, subnitrate, and subsalicylate) and bismuth trichloride (a by-product of municipal waste incineration) have low toxicities in humans, most likely due to their low intestinal absorption rate (<1%) (Feldman et al 1999) Lipophilic and volatile bismuth compounds like trimethylbismuth have toxic effects on animals in high doses The measured concentration of trimethylbismuth in landfill and sewage gases is four orders of magnitude lower than toxic doses (Feldman et al 1999) Measured toxicity levels were not available directly for bismuth citrate

Fate in Wastewater Treatment Works

Volatile methyl and hydride derivatives of metals and metalloids, including trimethylbismuth, are documented in gases produced by microorganisms such as methanogenic archaea, sulfate-reducing bacteria, and peptolytic bacterium in anaerobic wastewater treatment facilities (Dopp et al 2004, Bentley and Chasteen 2002, Dodge and Wackett 2005, Michalke 2000) Michalke (2000) conducted experiments with incubated anaerobic sewage sludge and found that "the content of volatile metal(loid) derivatives in the headspace . does not correlate with the concentrations of the respective metal(loid)s in the sewage sludge " He found that the volatile compound trimethylbismuth was highly concentrated in the headspace gas, but of low concentration in the sewage sludge relative to other elements such as tin and arsenic, and suggested that bismuth may be more bio-available to microbes or more susceptible to volatilization (Michalke 2000)

The 0 12% increase in bismuth disposed of due to the proposed action will not change the reactions or processes in wastewater facilities

Fate in Landfills

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Under anaerobic, and sometimes aerobic, conditions in geogenic and anthropogenic systems, metals and metalloids can be subject to biomethylation (Dopp et al 2004, Bentley and Chasteen 2002) According to Dopp et al (2004), "biomethylation is thought to be an enzymatically controlled, stepwise methyl transfer to the metal(loid) ion via partly methylated species (ionic, water soluble), eventually leading to fully methylated species (neutral, volatile), because of their hydrophobic nature, methylated products can accumulate in the food chain " Metal(loid)organic compounds have been documented to adversely affect animals and humans, though the mechanisms of affect at the cellular level are not well-studied (Dopp et al 2004) Naturally occurring concentrations of metal(loid)organic compounds are in the range of nanograms per cubic meter of gas, liter of water, or kilogram of solid material (soil, sediment, waste, biological samples), and while higher concentrations in the range of micrograms may be found in habitats such as wetlands, higher concentrations typically indicate anthropogenic inputs (Dopp et al 2004)

Methylated bismuth species, such as trimethylbismuth, have been documented in gases from landfills and sewage, and in anaerobic sediments (Bentley and Chasteen 2002) Bentley and Chasteen (2002) estimated that 30 to 4980 kg of trimethylbismuth is generated on a worldwide annual basis

Bismuth citrate hair dye container disposal and disposal of hair containing adhered bismuth, will result in a 0 0024% (0 12% increase in bismuth citrate x 2% product in container) increase in bismuth loading, and will result in a concentration increase which cannot be measured using routine analytical methods

The use and disposal of the subject color additive are not expected to threaten a violation of applicable laws and regulations, e.g , the Environmental Protection Agency's regulations in 40 CFR parts 60 and 258 because, as discussed under Format Item 6 above, only very small quantities of substances will be introduced into the environment as a result of its use and disposal

Use of resources and energy

The proposed use of the subject substance will not have a significant impact on resources because bismuth citrate will replace another color additive currently regulated for use in hair dyes

Mitigation measures

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

Alternatives to the proposed action:

Because no environmental impacts can be attributed to the proposed actions, no alternatives need be considered or discussed

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Certification
The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of Toxicological & Environmental Associates, Inc

27 August 2007
(Date)

(Signature of Responsible Official)

Eldon C Blancher II, Ph D , Principal Senior Advisor
(Name and title of responsible official, printed)

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ScienceLab.com
Chemicals & Laboratory Equipment

Health	1
Fire	1
Reactivity	
Personal Protection	A

Material Safety Data Sheet
Bismuth citrate MSDS

Section 1: Chemical Product and Company Identification

Product Name: Bismuth citrate

Catalog Codes: SLB2278, SLB3778

CAS#: 813-93-4

RTECS: Not available

TSCA: TSCA 8(b) inventory No products were found

CI#: Not available

Synonym:

Chemical Name: Not available

Chemical Formula: C6H5BiO7

Contact Information:

Sciencelab.com, Inc.
14025 Smith Rd
Houston, Texas 77396

US Sales **1-800-901-7247**
International Sales: **1-281-441-4400**

Order Online ScienceLab com

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Bismuth citrate	813-93-4	100

Toxicological Data on Ingredients: Bismuth citrate LD50 Not available. LC50 Not available

Section 3: Hazards Identification

Potential Acute Health Effects: Hazardous in case of ingestion Slightly hazardous in case of eye contact (irritant), of inhalation.

Potential Chronic Health Effects:
Hazardous in case of ingestion
Slightly hazardous in case of eye contact (irritant), of inhalation
CARCINOGENIC EFFECTS. Not available
MUTAGENIC EFFECTS. Not available
TERATOGENIC EFFECTS· Not available
DEVELOPMENTAL TOXICITY Not available
The substance is toxic to kidneys, liver.
Repeated or prolonged exposure to the substance can produce target organs damage

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Section 4: First Aid Measures

Eye Contact:
Check for and remove any contact lenses In case of contact, immediately flush eyes with plenty of water for at least 15 minutes Cold water may be used. Get medical attention if irritation occurs

Skin Contact:
In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Cold water may be used.Wash clothing before reuse. Thoroughly clean shoes before reuse Get medical attention

Serious Skin Contact: Not available.

Inhalation:
If inhaled, remove to fresh air If not breathing, give artificial respiration If breathing is difficult, give oxygen Get medical attention

Serious Inhalation: Not available

Ingestion:
Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: Not available

ammable Limits: Not available

Products of Combustion: These products are carbon oxides (CO, CO2)

Fire Hazards in Presence of Various Substances: Not available

Explosion Hazards in Presence of Various Substances:
Risks of explosion of the product in presence of mechanical impact Not available
Risks of explosion of the product in presence of static discharge Not available

Fire Fighting Media and Instructions:
SMALL FIRE: Use DRY chemical powder
LARGE FIRE Use water spray, fog or foam Do not use water jet.

Special Remarks on Fire Hazards: Not available

Special Remarks on Explosion Hazards: Not available

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Section 6: Accidental Release Measures

Small Spill:
Use appropriate tools to put the spilled solid in a convenient waste disposal container Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements

Large Spill:
e a shovel to put the material into a convenient waste disposal container Finish cleaning by spreading water the contaminated surface and allow to evacuate through the sanitary system

Section 7: Handling and Storage

Precautions:
ɜep away from heat Keep away from sources of ignition Empty containers pose a fire risk, evaporate the ,esidue under a fume hood Ground all equipment containing material. Do not breathe dust

Storage: Keep container tightly closed Keep container in a cool, well-ventilated area

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit

Personal Protection: Safety glasses Lab coat.

Personal Protection in Case of a Large Spill:
Splash goggles Full suit Boots Gloves Suggested protective clothing might not be sufficient, consult a specialist BEFORE handling this product

Exposure Limits: Not available

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid (Crystalline solid)

Odor: Not available

ɜste: Not available

Molecular Weight: 398 09 g/mole

Color: White

pH (1% soln/water): Not available

Boiling Point: Not available.

Melting Point: Decomposes

Critical Temperature: Not available

Specific Gravity: 3 458 (Water = 1)

Vapor Pressure: Not applicable

Vapor Density: Not available

Volatility: Not available

Odor Threshold: Not available

Water/Oil Dist. Coeff.: Not available

Ionicity (in Water): Not available

Dispersion Properties: See solubility in water.

Solubility: Partially soluble in cold water

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Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Not available.

Incompatibility with various substances: Not available.

Corrosivity: Non-corrosive in presence of glass

Special Remarks on Reactivity: Not available.

Special Remarks on Corrosivity: Not available

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Ingestion

Toxicity to Animals:
LD50: Not available
LC50: Not available

Chronic Effects on Humans: Causes damage to the following organs kidneys, liver

Other Toxic Effects on Humans:
Hazardous in case of ingestion
Slightly hazardous in case of inhalation

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans:
Due to the presence of dark line on gums, chronic bismuth toxicity may complicate diagnosis of chronic lead toxicity.

Special Remarks on other Toxic Effects on Humans: Not available

Section 12: Ecological Information

Ecotoxicity: Not available

BOD5 and COD: Not available

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise

Toxicity of the Products of Biodegradation: The products of degradation are more toxic

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal:

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Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

Federal and State Regulations: No products were found.

Other Regulations: OSHA Hazardous by definition of Hazard Communication Standard (29 CFR 1910 1200).

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada)

DSCL (EEC):
This product is not classified according
to the EU regulations

HMIS (U.S.A.):

Health Hazard: 1

Fire Hazard: 1

Reactivity: 0

Personal Protection: a

National Fire Protection Association (U.S.A.):

Health: 1

Flammability: 1

Reactivity: 0

Specific hazard:

Protective Equipment:
Not applicable
Lab coat
Not applicable
Safety glasses

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Section 16: Other Information

References: Not available

Other Special Considerations: Not available

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