BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AMENDED PETITION OF THE COLOR PIGMENTS MANUFACTURERS ASSOCIATION, INC.

To Delete C.I. Pigment Brown 24 (Chemical Abstracts Service Number 68186-90-3) from the List of Chemicals Subject to Reporting Under Section 313 of the Emergency Planning and Community Right-to-Know Act

November 3, 2017

David J. Wawer
Executive Director
Color Pigments Manufacturers Association, Inc.
1400 Crystal Drive, Suite 630
Arlington, Virginia 22202
(571) 348-5130

I. INTRODUCTION

Pursuant to Section 313(e)(1) of the Emergency Planning and Community Right-to-Know Act ("EPCRA"), 42 U.S.C. § 11023(e)(1), the Color Pigments Manufacturers Association, Inc. ("CPMA") hereby petitions the Environmental Protection Agency ("EPA") to delete the complex inorganic color pigment, Chromium Antimony Titanate, also known as Chrome Antimony Titanium Buff Rutile, C.I. Pigment Brown 24, Chemical Abstracts Service Number 68186-90-3, ("CAT" or "CATBR") from the list of chemicals subject to reporting under Section 313. Section 313(e)(1) allows any person to petition the EPA to modify the list of toxic chemicals for which Toxic Release Inventory ("TRI") reporting is required. As explained below, this petition amends (and supersedes) a petition addressing CAT that was filed by CPMA in 1998, and to which EPA never responded.

The CPMA is an industry trade association representing small, medium and large color pigments manufacturing companies. In addition, the Association represents color pigments manufacturers that sell pigments and certain colored products and suppliers of intermediates and other chemicals products that serve color pigments manufacturers. The Association provides advocacy programs in support of the color pigments industry on matters pertaining to the environment, health, safety issues and trade. Color pigments are widely used in product compositions of all kinds, including paints, inks, plastics, glass, synthetic fibers, ceramics, color cement products, textiles, cosmetics and artists' colors.

A. Previous CPMA CAT Petitions

On June 27, 1989, CPMA, formerly known as the "Dry Color Manufacturers' Association", submitted a petition for removal of CATBR from the list of chemicals and compounds requiring reporting under EPCRA, Section 313 (the "1989 Petition"). On January 8, 1990, EPA denied the 1989 Petition. 55 Fed. Reg. 650. EPA indicated that the denial was based on the potential carcinogenicity of all Chromium compounds and, as a result, the implication that CATBR may potentially be carcinogenic was sufficient to deny the 1989 Petition. EPA stated that:

> "The denial is based on the Agency's determination that CATBR is a potential carcinogen. Based on evidence of the carcinogenicity of chromium and certain chromium compounds,

> the National Toxicology Program considers all chromium compounds to be potential carcinogens. EPA believes that CATBR, a chromium compound, can be retained in the lung and taken up by cells, therefore, EPA concludes that CATBR can reasonably be anticipated to cause cancer in humans via inhalation." 55 Fed. Reg. 652.

On November 20, 1998 CPMA submitted a second CAT Petition (the "1998 Petition"). The 1998 Petition contained information developed in studies sponsored by CPMA and additional data on CAT, trivalent Chromium, environmental toxicity, the bioavailability of metal ions and human health developed after EPA's review of the 1989 Petition.

EPCRA Section 313(e)(1) requires that EPA initiate a rulemaking in response to Petitions for additions or deletions from the TRI within 180 days of receipt. EPA's semiannual regulatory agendas listed the response to the 1998 Petition as a planned regulatory activity from 2001 to 2006.

EPA indicated in telephone calls through 2006 that EPA had unresolved concerns with the bioavailability of trivalent Chromium. EPA never issued a final response to the 1998 Petition.

In order to maintain the option of supplementing the 1998 Petition under review at EPA, CPMA did not insist on a final disposition. On May 22, 2007, in a letter to Daniel Bushman, Ph.D., the EPA coordinator, CPMA requested that EPA suspend review of the 1998 Petition pending further assessment of available data. CPMA submits the following update of the 1998 Petition (hereafter the "Amended Petition"). Because no response to the 1998 Petition was ever published, this submission is still timely and must be considered by EPA.

B. New Information Incorporated in the Amended Petition

Significant new data, which further substantiates the safety of CAT to humans and the environment, has been developed and published by industry and various national and international agencies since 1998. This Amended Petition incorporates the following new information:

- 1999, Food and Drug Administration regulation of CAT as a colorant for polymers in contact with food. (https://www.fda.gov/ohrms/dockets/98fr/081699a.pdf)
- 1999, Canadian Soil Quality Guidelines for the Protection of Environmental and Human Health. (http://ceqg-rcqe.ccme.ca/download/en/262)

- 2002, The Organization for Economic Cooperation and Development, Screening Information Data Set ("SIDS") Initial Assessment Report. (http://www.inchem.org/documents/sids/sids/68186903.pdf)

- 2007, The EPA Framework for Metals Risk Assessment document. (https://www.epa.gov/sites/production/files/2013-09/documents/metals-risk-assessment-final.pdf)

- 2011, the REACH Dossier for CAT, incorporating the following studies completed since 1998 (https://echa.europa.eu/registration-dossier/-/registered-dossier/15427/1):

    - 2000 OECD 202 (GLP) toxicity to Daphnia.
    - 2000 OECD 201 (GLP) toxicity to algae and cyanobacteria.
    - 2000 OECD 422 repeated dose study with reproductive and developmental toxicity (GLP).
    - 2001 in vitro cytogenicity study.
    - 2006 elution study of the analog pigment Nickel Antimony and Titanium Yellow Rutile (NAT) in artificial sweat.
    - 2010 The Bomhard subchronic 90 day feeding exposure study in rats. Although this study was described in the 1998 Petition, the REACH dossier incorporated the Bomhard study to document distribution in vivo.

- 2017 Proposed Canadian Federal Environmental Quality Guidelines. (http://www.ec.gc.ca/ese-ees/6BF7BB79-F88E-4A2C-AA78-FF6C9C812A94/Chromium_En.pdf)

- A current updated description of CAT properties and uses.

C. Standard of Review

EPCRA Section 313(c) established the initial list of toxic chemicals for which facilities that manufacture, process, or otherwise use a listed toxic chemical in excess of specified threshold quantities must file annual release reports. The reportable categories of "Chromium Compounds" and "Antimony Compounds" include CAT.

EPCRA Section 313(d)(3) provides that a chemical may be deleted if the Administrator determines that there is not sufficient evidence to establish any of the following health and environmental effects criteria provided in EPCRA Section 313(d)(2):

(A) The chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases.

(B) The chemical is known to cause or can reasonably be anticipated to cause in humans -
  (i) Cancer or teratogenic effects, or
  (ii) Serious or irreversible -
    (I) reproductive dysfunctions.
    (II) neurological disorders.
    (III) inheritable genetic mutations, or
    (IV) other chronic health effects.

(C) The chemical is known to cause or can reasonably be anticipated to cause, because of -
  (i) its toxicity,
  (ii) its toxicity and persistence in the environment, or
  (iii) its toxicity and tendency to bioaccumulate in the environment, or
  (iv) a significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting under this section.

Pursuant to EPCRA Section 313(d)(2), this determination shall be based on tests, or appropriately designed and conducted epidemiological or other population studies. This Amended Petition demonstrates that CAT is a practically insoluble, inert substance that does not have any adverse health or environmental effects.

In a May 23, 1991 notice providing guidance regarding EPCRA delisting petitions, EPA stated:

> "EPA will not continue to make weight-of-evidence determinations on metal ion availability. EPA will grant a petition to delist a member of a metal compound category only if the Agency can determine with a high degree of certainty that the metal ion will not become available at a level that can reasonably be anticipated to induce adverse effects." 56 Fed. Reg. 23703.

The petitioner must additionally show that the metal ion of a compound will not become available. The May 23, 1991 notice further states:

> "There are a number of factors which must be considered in determining availability of the metal ion. These factors are listed below:
>
> - Hydrolysis at various pHs.
> - Solubilization in the environment at various pHs
> - Photolysis.
> - Aerobic transformations - abiotic and biotic.
> - Anaerobic transformations - abiotic and biotic.
> - Biological transformation, ...
> - Bioavailability of the ion when the compound is ingested.
> - Bioavailability of the ion when the compound is inhaled.
> - Bio-accumulation and subsequent food chain. magnification" 56 Fed. Reg. 23703.

This Amended Petition addresses the issues raised by EPA regarding the availability of metal ions from CAT. In addition to addressing the requirements set forth at 56 Fed. Reg. 23703, we will emphasize those deficiencies which were noted by EPA in the Notice of denial for the 1989 Petition at 55 Fed. Reg. 650.

II. CHEMICAL AND PHYSICAL PROPERTIES OF CHROMIUM ANTIMONY TITANATE

Several trade names exist for CAT pigments.[1] However, all CAT pigments, regardless of trade name, are represented by the one CAS Number 68186-90-3.

CAT is a Titanium (IV) oxide crystalline matrix of rutile formed by extremely high temperature calcination with trivalent chromium (also "Cr III" or "Chromium III") oxide and Antimony (or "Sb") (V) oxide. As a result of the calcination, the Chromium III ions and Antimony (V) ions are diffused into the rutile lattice of the molecule, taking positions in the lattice by replacing the Titanium (or Ti) (IV) ions. They are chemically bound and locked into this lattice as one crystalline compound upon cooling. The result is a crystalline molecule composed of a rutile lattice containing all three elements of Chromium (III), Antimony (V), and Titanium (IV) surrounded by oxygen ions which make up the rest of the crystal and thus impart the extremely high stability commonly associated with these pigments.

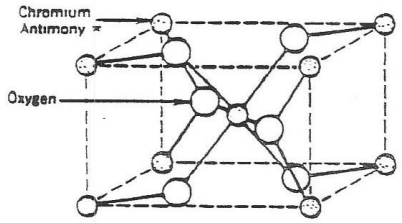
Occasionally, other materials, called modifiers, containing one or more other elements, such as the modifier "aluminum oxide", may be combined within the CAT molecule to produce special physical-chemical characteristics, usually color.

As discussed below, we now know that these compounds are so stable that they can withstand solid waste incineration without breakdown.

---

[1] Registration Evaluation and Authorization of Chemicals ("REACH") dossier for CAT and the Organization for Economic Cooperation and Development, Screening Information Data Set ("SIDS") Initial Assessment Report.

The structure of CAT, in a simplified representation:



*includes titanium

Source: Pigment Handbook: Volume 1: Properties and Economics Second Edition. Edited by Peter A. Lewis. Copyright (c) 1988 John Wiley & Sons, Inc., p. 385. Reprinted by permission of John Wiley & Sons, Inc.

The basic chemical formula of CAT is $(Ti,Cr,Sb)0_2$. CAT exhibits outstanding chemical, heat and light stability with extremely high resistance to light and weather. CAT remains insoluble in water, organic acids, dilute alkalies, and most inorganic acids. In order to perform the solubility study of constituent metals from CAT, the testing laboratory working on behalf of a CPMA member needed to dissolve the compound. After several attempts, the laboratory concluded:

> "Tests to perform solubility studies on Chrome Antimony Titanate Buff Rutile were unsuccessful. Attempts to solubilize the material in any solvent including boiling sulfuric acid were unsuccessful to even perform calibration curves... " [2]

An extraction study was completed using 95% and 8% ethanol. No Chrome or Titanium were detected at the method detection limit of .04 and .06 parts per million respectively. Based upon the absence of Titanium at a method detection limit of 10 parts per billion, the researchers concluded that the CAT under study had a solubility of less than 20 parts per billion. [3]

The REACH dossier provides an additional study for the analog substance Nickel Antimony Titanate. The 7 day study reported the concentrations of Nickel, Antimony and Titanium extracted from

---

[2] NPIRI, Raw Materials Data Handbook, Volume 4, 4-37 (prepared by the National Printing Ink Research Institute), The Shepherd Color Company Laboratory Analysis, January 11, 1988 and December 7, 1995. Mobay Corporation Letter and Data Attachments, November 21, 1988. CPMA joint testing of CAT (1997).

[3] Extraction study provided by a member company, March 2, 1995.

artificial sweat and solutions of 1.0 pH and 8.5 pH. All results were reported at .0007 micrograms per square centimeter or less for Titanium and .0001 micrograms per square centimeter or less for Nickel and Antimony. [4]

The REACH dossier for CAT provides a study summary which indicates that CAT exhibits a measured melting point at 2000 degrees centigrade. Based on measurements, the average particle size for CAT exceeds .75 microns, well above the nanoscale of 0 to 100 nanometers. Given this particle size, toxicological concerns involving nanoscale materials would not apply to CAT.

III. USES OF CHROMIUM ANTIMONY TITANATE

The primary use for CAT is in color pigment applications for the coloration of plastics, high temperature engineering resins, high performance industrial coatings, exterior paints, ceramic bodies, porcelain enamels, and roofing granules.[5] The permanent light reflective properties of CAT in use make it an important choice in energy saving roofing materials and exterior coatings. On August 16, 1999, in response to a request from industry, CAT was also regulated by the Food and Drug Administration ("FDA") as a colorant for polymers in contact with food. FDA concluded that:

> "FDA has evaluated the data in the [food contact] petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in 21 CFR 178.3297 should be amended..." 64 Fed. Reg. 44407.

The FDA regulation cited above expanded the already broad uses of CAT in commerce by adding new applications, including the most sensitive applications in contact with food.

---

[4] REACH Dossier, Specific Investigations, study date 2006, GLP.

[5] NPIRI, Raw Materials Handbook, Volume 4, 4-37.

IV. BASIS FOR DELISTING CAT

Due to the non-bioavailability of CAT and its extreme stability, it presents no acute or chronic health hazard to humans or the environment. As explained below, the literature search reveals no evidence of significant human or ecological toxicity resulting from exposure to CAT. Thus, CAT does not satisfy any of the criteria listed in the EPCRA Section 313(d)(2), and must be delisted.

A. Ecotoxicity of CAT

Studies conducted and assembled for the REACH dossier support strongly the safe use of CAT in the environment. No mortality occurred at concentrations of 5,000 and 10,000 mg/L CAT in a 96 hour acute toxicity study in fish (Leuciscus idus). [6] No immobility at any dose group or in controls occurred in a short term study of CAT in Daphnia. [7] A recent study of the aquatic toxicity of CAT to algae and cyanobateria resulted in a no observed effect level greater than 100 mg/L. [8]

B. Mammalian Toxicity Experimental Data

Laboratory testing demonstrates that CAT does not produce acute toxic effects as a result of ingestion. In addition, studies conducted during the 1970's by the Bayer Institute of Toxicology, confirmed the lack of acute toxicity (acute oral, skin, eye and mucus membrane) by studies on Male Wister-II-Rats

[6] REACH dossier Short Term Toxicity to Fish.

[7] REACH dossier Short Term Toxicity to Aquatic Invertebrates, GLP, OECD Guideline 202.

[8] REACH dossier Toxicity to Aquatic Algae and Cyanobacteria, OECD Guideline 201, GLP.

and white New Zealand Rabbits, using among other inorganic pigments, CAT. [9] [10] [11]

Chromium is an essential trace element in the diet of higher animals and man. [12] [13] [14] Chromium occurs commonly in foods at levels of .03 to .5 PPM (mg/kg=ug\g=PPM), and has been reported as high as 1.75 PPM (roughly 5 ug Cr. per ounce) in whole grain bread. [15] The recommended Chromium intake level for adults is 50 to 200 ug/day. Multivitamins and other dietary supplements have varying amounts of Chromium. A typical multivitamin has 50 ug to 75 ug Cr per 1.3 gram caplet, which gives it a level of approximately 38 PPM Chromium. [16] Chromium picolinate dietary supplements contain Chromium at a

---

[9] Duke Laboratories, "Examination of Ferro Corporation Inorganic Pigment Samples for Rat LD-50", July 8, 1977, p.1, See also Hita Research data below.

[10] The Hita Research Laboratories, Chemical Bio-testing Center, Chemical Inspection and Testing Institute, did a comprehensive review of a similar molecule, Nickel Antimony Titanate (NAT), an analogous substance in a study titled "Pharmacological Studies of Tipaque Titanium Yellow with regards to its Toxicity". This study included a comprehensive feeding study of rats, as well as, environmental and epidemiological monitoring studies involving dogs, cats, gold fish, killifish and germinating plant seeds. The study concluded that: "In view of the results of the above experiments, we have drawn the following conclusion and judgement. In the continuous experiment of oral administration of Titani yellow to rats, observation was made on the growth curve of animals but no difference was noticed between the dosed group and the control and growth was not inhibited by the administration of the specimen. Administered rats indicated smooth growth showing no evidence of toxicity.

No meaningful difference was observed between treated group and the control in regard to the blood image, weight and volume of various internal organs. In the pathohistological investigation, no pathologic change was observed in the internal organs of treated rats. Titani yellow exercised no influence upon small fish nor did it inhibit the growth of plant seed. It indicated no toxicity due to ionic action."

[11] Bayer, Institute of Toxicology, Acute Toxicity of Inorganic Pigments, 1972, 1977.

[12] Toxicological Profile for Chromium, U.S. Department of Health & Human Services, 1991, p. 5, Agency for Toxic Substances and Disease Registry.

[13] Concepts and Models of Inorganic Chemistry, B. Douglas, D.H. McDaniel, J.J. Alexander, 2nd ed., 1983, p. 721, John Wiley & Sons, New York.

[14] Advance Inorganic Chemistry, F.A. Cotton and G. Wilenon, 4th ed., 1980, p. 1310-1311, 1344, John Wiley & Sons, New York.

[15] Toxicological Profile, footnote 12 above.

[16] For example, see Superior Brand multivitamins.

level of 200 ug per tablet. These oral supplements are designed to completely dissolve in the digestive tract within 60 minutes, insuring that all of the Chromium is bioavailable. [17] However, only 2.8% of the trivalent Chromium from Chromium picolinate supplements is estimated to be bioavailable. The oral absorption of Chromium is poor, estimated at between .5 and 3%. [18] Dietary Cr(III) has also been shown to decrease the insulin resistance in diabetics. [19]

CAT has been shown to have 3 to 10 PPM of Cr(III) available under simulated gastric digestion, a level of Chromium well below that present in vitamins and dietary supplements. Therefore, CAT could not exhibit acute toxicity due to available Cr(III). This fact is borne out by numerous feeding studies discussed below.

A Duke University Laboratories study on CAT revealed that CAT was relatively harmless by oral ingestion, having an LD-50 Value in excess of 10,000 mg/Kg. [20] A subchronic oral toxicity analytical study of the effect of CAT in the diet of rats at levels up to 10,000 PPM for three months failed to show any overt signs, internally or externally, of reaction to the treatment. [21] This published, controlled study was also used in the REACH dossier for Toxicokinetic analysis of CAT. [22] It is clear from these studies and the low level of available Cr(III) from CAT that it does not pose a hazard via oral ingestion.

---

17 For example, see Chromium picolinate supplements.

18 Chromium in the Natural Environment, J.O. Nriagu and Nieboer, ed., 1988, p. 45, J. Wiley & Sons, New York.

19 Linday, L.A., Med. Hypotheses, 1997, 49(1), 47-49.

20 See Note 4 above, Duke Laboratories, this test was suspended at 10,000 mg/Kg. The LD-50 is not calculated from actual mortality.

21 Bomhard et.al, Subchronic Oral Toxicity and Analytical studies on Nickel Rutile Yellow (NAT) and Chrome Rutile Yellow (CAT), Toxicity Letter, 1982, p.189.

22 REACH Dossier Toxicokinetics.

C. Lack of Chronic Hazards From CAT

There is no indication that CAT produces a carcinogenic response or other chronic effects in either humans or animals. A literature search found no evidence of chronic hazards attributable to exposure to CAT. All available testing strongly indicates that CAT is toxicologically analogous to rutile Titanium dioxide which is the principle component of the CAT molecule. [23]

The Corning Hazleton Laboratories conducted an Ames test for CAT using approved GLP protocols. The researchers found no mutagenic activity as a result of exposure to CAT. [24] The results of these tests were completely negative.

A study was undertaken on CAT using EPA approved protocol for the Mouse Lymphoma Forward Mutation Assay Procedure under GLP conditions. The protocol induces forward mutation at the thymidine kinase locus in the mouse lymphoma cell line. [25] Again, no mutagenic activity could be discerned as a result of exposure to CAT. The study results were completely negative. [26]

The REACH dossier for CAT contains a summary of a recent Repeated Dose Study with Reproductive and Developmental Toxicity Screening utilizing the OECD 422 protocol under GLP conditions. At doses of 0, 250, 500 and 1000 milligrams per kilogram body weight, no effects occurred in parental or offspring animals. The no observed adverse effect level was determined to be greater than 1000 milligrams per kilogram body weight per day. [27]

While nearly all Cr(VI) compounds show signs of carcinogenic/mutagenic activity, only some Cr(III) compounds do. A common model for Cr carcinogenicity suggest that accumulation of intracellular Cr(III)

---

[23] Ferin J., Oberdorster G., "Biological Effects and Toxicity Assessment of Titanium Dioxides: Anatase and Rutile," Am. Ind. Hyg. Assoc. J. 46 (2):69-72 (1985). See also, Lee, K.P., et al. reference 54 below.

[24] Corning Hazleton Laboratory, report attached.

[25] Corning Hazleton Laboratory, report attached.

[26] Ibid.

[27] REACH Dossier Toxicity to Reproduction and Developmental Toxicity/ Teratogenicity.

induces mutation, which may ultimately lead to cancer. [28] According to this model, Cr(III) must become absorbed into the cell, where it can then enter the nucleus and bind to cellular DNA. Cr(III) is believed to complex with DNA proteins sites and alter their function, leading to mutation, cell transformations, and possibly cancer.

In this scenario, Cr(III) must do several things. Cr(III) must be bioavailable, it must enter the cell, it must accumulate within the cell and enter the nucleus of the cell and be available for binding to DNA proteins once inside the nucleus. Intracellular bioavailability is thought to be the major determinant in Chromium carcinogenesis. [29]

A study of Cr(III) casts doubt on its ability to cause DNA damage at all in low concentrations. The author states "there is considerable doubt that sublethal doses of trivalent Chromium can produce tissue levels high enough to induce clastogenic damage in vivo." [30] The study further notes "...the virtual non-toxicity of orally administered trivalent Chromium in any dose...", suggesting that dietary trivalent Chromium in reasonable amounts does not exhibit a genotoxic risk. [31]

Additionally, CAT has very low extractable Chromium which severely limits the amount of bioavailable Chromium to the target cells. Since the bioavailable Chromium from CAT is Cr(III), mobility into target cells would be limited. The Cr(III) ion and its complexes are generally excluded from cells. [32] Poor availability and cellular exclusion would prevent significant levels of intracellular Cr(III) from accumulating, thus eliminating the most important of the proposed cancer initiation steps.

In summary, CAT's chemical properties make it a poor potential carcinogen. It has a maximum bioavailable Cr (III) level of 10 PPM (10 ug\g CAT), which is well below the 50 to 200ug caplet levels observed in dietary supplements.

---

28 Chromium in the Natural Environment, J.O. Nriagu and E. Nieboer, ed., 1988, p.476, J. Wiley & Sons, New York.

29 Ibid.

30 McCarty, M.F. Med. Hypotheses, 49(3), 263-269, (1997).

31 Ibid.

32 Chromium in the National Environment, p. 475.

D. Carcinogenic/Chronic Toxicity Issues Regarding Antimony

The International Agency for Research on Cancer (IARC) has not classified Antimony or Antimony compounds in general as to their carcinogenicity to humans. However, direct testing of CAT which contains Antimony reveals an absence of carcinogenic behavior from these compounds. As discussed above, Ames testing showed no evidence of carcinogenic activity in CAT. [33] In a Mouse Lymphoma forward mutation assay, conducted using EPA approved protocols, CAT did not exhibit signs of cell line mutation. [34] This direct testing of CAT pigment suggests that these products are not mutagens or carcinogens.

E. Ambient Workplace Exposure Potential

Approximately 493 workers at four manufacturing sites operated by members of CPMA were found to have routine job assignments with potential exposure to CAT in the manufacture of complex inorganic color pigments. The greatest potential exposure to CAT would occur at this small number of United States Manufacturing sites.

The highest potential for exposure occurs during the dry pigment operations. These potential exposure areas include the grinding, blending, crushing, milling and packaging of the pigments.

Manufacturers routinely monitor worker exposure in the plants manufacturing these pigments to assure that the dust control methods are working efficiently.

F. Absence of Adverse Health Effects

CAT has been manufactured for many years, and, to our knowledge, no adverse health effects have ever been reported from worker exposure to CAT pigment products in customer facilities.

---

[33] Corning Hazleton Labs, Ames testing for CPMA, 1995.

[34] Corning Hazleton Labs, mouse lymphoma testing for CPMA, 1995.

G. Environmental Effects and Compound Dissociation

Oxidation of Cr(III) from CAT in Soils

Past research has shown that Cr(III) can be oxidized to Cr(VI) by oxidized Manganese species in soils. This process is described in the following excerpt:

> "...Bartlett and James (1979) discovered that rapid oxidation of a portion of Cr(III) salts or hydroxides added to almost any soil with pH above 5 took place readily, provided that the soil sample was fresh and moist and directly from the field. They showed that oxidized Manganese, present in most fresh moist field soil samples, served as the electron link between the added Cr(III) and oxygen of the atmosphere. The amount of Cr(III) oxidized to Cr(VI) was proportional to the Manganese reduced (and exchangeable) and also to the amount of Manganese reducible by hydroquinone before adding Cr(III). These findings were verified by Amacher and Baker (1982). [35]

Bartlett and James used soluble (salts) or partially soluble (at pH = 5, hydroxides) Cr(III) sources for their study. They also made certain that the soil samples were kept moist. Soil samples only showed evidence for the Cr(III) to Cr(VI) transformation when the soil matrix was wet, strongly suggesting that water is an integral component to the oxidative mechanism. [36]

In moist samples, soluble Cr(III) compounds will certainly be dissolved to some extent. The moisture would allow migration of soluble Cr(III) species to the oxidized Manganese surfaces where the redox reaction forming Cr(VI) are alleged to occur. The presence of solubilized Cr(III) ions and a solution matrix for their migration appear key to the redox chemistry described. However, there are other factors that must also be satisfied for the oxidation of Cr(III) to occur in soils. In nature, the most stable forms of Chromium are predominantly those of Cr(III).[37] Chromium is quite abundant in the Earth's crust, occurring at 100 to 300 PPM in ambient soils. [38] The relative abundance of Cr(III) and scarcity of Cr(VI) in the natural

---

35 Chromium in the Natural Environment, J.O. Nriagu and E. Nieboer, ed., 1988, p.273, J. Wiley & Sons, New York.

36 Ibid, p. 337 [Chromium in the Natural Environment].

37 Toxicological Profile for Chromium, U.S. Department of Health and Human Services, 1991, p.9, Agency for Toxic Substance and Disease Registry, see also Advanced Inorganic Chemistry F.A. Cotton and G. Wilkenson, 4th ed., 1980, p. 1310-1311, 1344, John Wiley & Sons, New York.

38 Trace Elements in Soils, H. Albert and M. Pinta, 1977, pp. 13-17, Elsiver, New York. Citation taken from Chronium in the Natural Environment, J.O. Nriagu and E. Nieboer, ed., 1988, pp. 336, J. Wiley & Sons, New York.

environment strongly suggests that the conditions favorable to the oxidation of Cr(III) to Cr(VI), or those which preserve the higher oxidation state, Cr(VI), cannot widely occur in nature.

In general, the oxidation of metal ions to higher valent oxo anions (such as Chromates) is accomplished much more readily in basic solutions. [39] Published electrochemical data indicate that Cr(VI) is slightly stable under basic conditions, but highly unstable under acidic condition. [40] [41] In acidic soils, the presence of naturally occurring Fe(II) and organic matter has been shown to reduce Cr(VI) to the more stable Cr(III) state. [42] The lower the pH, the greater the stability of the Cr(III) state.

There are no literature references demonstrating that insoluble Cr(III) compounds, such as CAT, are subject to oxidation by oxidized Manganese (or "Mn") species in soils. The soluble Cr(III) from CAT would, however, be subject to oxidation in soils. CAT has a maximum solubility of 3 to 10 PPM as demonstrated by repeated acid extractions. Under acidic conditions, the reduced state of Chromium is more stable. Any Cr(III) leached from CAT would likely remain as Cr(III). Furthermore, 3 to 10 PPM of soluble Cr(III) is at the same level as that observed naturally in some soils. [43] Even if oxidation could occur to an appreciable extent, Cr(VI) would not be expected to form at a level exceeding those that may naturally occur due to ambient levels of (generally 100 to 300 PPM and in some cases as high as 4000 PPM) Cr(III). Under less acidic and basic conditions, CAT is virtually insoluble and oxidation of Cr(III) from CAT would not be expected due to its unavailability.

---

39 Concepts and Models of Inorganic Chemistry, B. Douglas, D.H. McDaniel, J.J. Alexander, 2nd ed., 1983, p. 638, John Wiley & Sons, New York.

40 Langes Handbook of Chemistry, J. Dean, ed., 12th ed., 1979, p. 6-8, McGraw-Hill, Inc. New York.

41 Mancuso, Ind. Med. Surg., 1951, 20, pp. 393-407.

42 Rary, L.E., Rai, Dhanpat, "Chromate Reduction by Subsurface Soils Under Acidic Conditions", Soil Sci. Soc. Am.J., 1991, 55(3), 676-683 (Abstract attached).

43 Bartlett, R. J. Background levels in Vermont soils, 1982, Vt. Agr. Exp. Sta. RR 29, Burlington, Vermont. Citation taken from Chromium in the Natural Environment, J.O. Nriagu and E. Nieboer, ed., 1988, pp. 336-337, J. Wiley & Sons, New York.

Factors favoring the oxidation of Cr(III) to Cr(VI) in soils may occur, but do not do so in nature to any great extent. Ambient soils contain substantial amounts of naturally occurring Chromium which would be subject to such oxidation. CAT contains available Cr(III) at concentrations similar to that of typical soils. Factors favoring the extraction of available Cr(III) from CAT (low pH) are those which inhibit oxidation to Cr(VI). The conclusion is that formation of Cr(VI) via soil oxidation of Cr(III) from CAT is unlikely to occur, and if it did, would in the worst case yield roughly the same level of Cr(VI) as from naturally occurring Cr sources.

These conclusions are reflected in the Canadian Soil Quality Guidelines for the Protection of the Environmental and Human Health, 1999. [44] These guidelines establish soil criteria for total Chromium, made up of primarily Cr (III) at 64 to 87 milligrams per kilogram, while criteria for Cr (VI) is set at .4 to 1.4 milligrams per kilogram. [45]

Environment Canada also recently published "Draft Federal Environmental Quality Guidelines for Hexavalent Chromium". [46] These guidelines specify a Cr(VI) a value of .5 micrograms per liter as a goal for freshwater in Canada. [47] This document also supports the discussion provided above stating, for example:

> "Chromium compounds bind tightly to soil and are not likely to migrate to groundwater (Velma et al. 2009) In most soils, Chromium III is the predominant form of chromium. The fate of chromium in soil is greatly dependent upon its speciation and is a function of redox potential and the pH..." [48]

---

44 Canadian Soil Quality Guidelines for the Protection of the Environmental and Human Health, 1999.

45 Ibid.

46 Draft Federal Environmental Quality Guidelines for Hexavalent Chromium, Fate, Behavior and Partitioning in the Environment.

47 Ibid.

48 Ibid, p. 3.

1. Hydrolysis at Various pHs

CAT will not hydrolyze within a range of pHs from 1-10. CAT is not reactive with water. As discussed below, these pigments are almost completely insoluble in all but the strongest acid solutions (pH less than or equal to one). As a result, hydrolysis at various pHs is not possible. CAT is, in fact, almost completely insoluble in water, organic acids, dilute alkalies, and most inorganic acids.[49]

2. Solubilization in the Environment at Various pHs The Availability of Cr(III) from CAT

The Chromium in CAT is present in the + 3 valence state. Simple dissolution of CAT would therefore be expected to yield some soluble Cr(III). The level of Cr(III) extractable from CAT has recently been re-measured. [50] Under strongly acidic conditions (hydrochloric acid solution, pH = 1.15), the extractable Cr(III) is 3.1 PPM. Two subsequent extractions performed on the same sample using fresh aliquot of hydrochloric acid yielded little or no additional solubilization of Cr(III) (less than 2 PPM). This indicates that a limited amount of Cr(III) is subject to dissolution, and once removed, there is little or no further leaching of Cr(III) from CAT.

a. Expected Test Results

Extractions performed using higher pH solutions (pH = 5 and pH = 10) yielded extractable Cr(III) of less than 1 PPM in the initial extracts in both instances. Subsequent extractions on the same samples yielded no detectable Cr(III). As in the case of the acid extractions, CAT is virtually impervious to Cr(III) removal once it has been subject to extraction.

---

[49] NPIRI, Raw Materials Data Handbook, Volume 4, 4-37 (prepared by the National Printing Ink Research Institute), The Shepherd Color Company Laboratory Analysis, January 11, 1988 and December 7, 1995. Mobay Corporation Letter and Data Attachments, November 21, 1988. CPMA joint testing of CAT. See also extraction study provided by member company, March 2, 1995.

[50] Shepherd Color Company analytical report, December 7, 1995.

Therefore, only under severely acidic conditions is any Cr(III) extractable from CAT. Between pH values of 5 to 10, CAT is, for all practical purposes, insoluble.

b. Ambient Cr(III) Levels

The level of extractable Cr(III) observed in CAT is on the order of that observed in some soils. Vermont soils are reported to yield 0.4 to 3.7 PPM extractable Chromium in 1 M hydrochloric acid. [51] The nominal concentration of total Chromium in soils usually ranges from 100 to 300 PPM, but may vary from as low as traces up to 4,000 PPM. [52] Of the total, generally 0.01 to 1.0% is available by extraction. [53]

In the case of CAT, which typically contains (40,000 PPM) 4% Chromium by weight total, the maximum observed extractable Cr(III) is 10 PPM. Thus, CAT contains .00001g extractable Cr per 0.04g total Chromium, which means CAT contains only 0.025% extractable Chromium. For typical soils, 0.025% is the lowest percentage of extractable Cr reported.

CAT contains at least 10 times more total Chromium than the highest Cr bearing soils, which have 4,000 PPM or 0.4% total Chromium. Yet CAT still exhibits an extractable Chromium concentration comparable to the more leech resistant soils at 0.025%.

The conclusions are that 1) CAT is no more likely to provide soluble Chromium to the environment than ambient soils, 2) CAT would yield soluble Cr(III) only under very acidic conditions, and none at all in environments where the pH is greater than 5, and 3) the level of Cr(III) that is extractable from CAT is equal to that observed in ambient soils.

Regulation of CAT as an environment hazard based on its potential to release of Cr(III) to the environment is inappropriate. Evidence shows that CAT is not a potentially significant source of Cr(III), and therefore will not threaten the environment on that account.

---

51 Bartlett, R. J. Background levels in Vermont soils, 1982, Vt. Agr. Exp. Sta. RR 29, Burlington, Vermont. Citation taken from Chromium in the Natural Environment, J.O. Nriagu and E. Nieboer, ed., 1988, pp. 336-337, J. Wiley & Sons, New York.

52 Ibid.

53 Ibid.

3. Photolysis

CAT is extremely light stable. This characteristic is, in fact, a primary benchmark of the value of these color pigments. Without extreme stability to light over years, CAT would not have value as a color pigment for high temperature plastics, coatings, ceramics and outdoor applications such as roofing tiles.

4. Expected Anaerobic, Aerobic, and Microorganism Transformations of CAT

During its formation, CAT is strongly heated in the presence of atmospheric oxygen. As a result, it is not prone to further aerobic reactions. Anaerobic transformations of this pigment have not been observed. However, such changes could, in theory, be generated in the laboratory using principals of solid state chemistry. Metal oxide stability depends on the ambient temperature and oxygen partial pressure. [54] However, anaerobic decomposition (reduction) of metal oxides requires high temperatures (ca. 700 F or higher), very low oxygen pressures (vacuum conditions, inert atmosphere blankets, or reducing atmospheres), or a combination of the two. Such conditions are not reasonably expected to occur in the terrestrial environment, and anaerobic transformations of CAT are not anticipated.

CAT pigment exists in a very stable rutile crystalline modification. Rutile is a naturally occurring mineral in the terrestrial environment. The Chromium(III) and Antimony (V) ions in CAT are dispersed evenly throughout the rutile matrix, along with Ti(IV) ions. More than 85% of the metals ions in CAT are Titanium, as it is composed of more than 80% TiO_2 by weight.

Microorganisms have the ability to create localized environments which favor the dissolution of metal compounds, even some metal oxides. Many organisms contain enzymes specifically designed for complexation of certain dissolved metal ions. These enzymes efficiently sequester some solubilized metal ions, which acts to drive the metal containing material to further dissolution. Generally speaking, the metal

---

[54] Ainsworth, N. 1988 Dissertation, "Distribution and biological effects of Antimony in contaminated grasslands". Citation taken from Toxicological Profile for Antimony, U.S. Department of Health & Human Services, Washington, D.C., 1992, p. 82, Agency for Toxic Substances and Disease Registry. (Attached).

ions are either transition metal or alkali/alkaline earths, which are used by living organisms for various metabolic functions.

Even though CAT contains Chromium(III), which can bind to metal selective enzymes, solubilization of CAT by microorganisms is very unlikely. For the most part, CAT constitutes a form of chemically inert Titanium dioxide. In order to dissolve the CAT rutile lattice, large amounts of Ti(IV) ions would need to be solubilized along with the smaller number of Chromium(III) and Antimony (V) ions. The crystalline lattice cannot selectively yield one type of ion. In aqueous systems, dissolution of Titanium (IV) from Titanium dioxide requires extremely acidic conditions. Acid concentrations greater than 1 molar (pH < 0) must be employed. It is unlikely that microorganisms can create an environment acidic enough for this to occur. Further, there are no known enzymes that will specifically bind to dissolved Titanium (IV). Without a complexing enzyme for Titanium (IV), the equilibrium cannot shift in favor of dissolution, making solubilization of Titanium ions more difficult. This is likely why, once the trace levels of Chromium (III) have been extracted from CAT, further extractions yield no more soluble Chromium. Titanium (IV) ions in the matrix are not prone to dissolution, and their presence inhibits solubilization of Chromium(III) and Antimony (V). Anaerobic microorganisms would confront the same challenges with respect to Titanium (IV) dissolution, and it is unlikely they would be able to solubilize CAT to any significant extent.

Titanium (IV) ions in CAT will act to inhibit solubilization of the pigments in the environment. Therefore, significant dissolution of CAT due to microorganism attack will not occur. As a worst case, Chromium (III) and Antimony (V) ions from the pigment's surface will be subject to dissolution. Levels of dissolution would be expected to the extent reported in the extraction testing of CAT, approximately 10 PPM Chromium (III) and 20 PPM Antimony (V).

H. Antimony Levels in the Environment

The level of Antimony in CAT (9% Antimony) is well above that observed in typical soils. However, the Antimony in the pigments is tightly bound inside a mineral lattice. Antimony which is not extractable appears to be inert in the environment.

Tests were conducted on the Antimony levels in plants and animals around a smelter contaminated with surface Antimony deposits. [55] The Antimony uptake by plants was found to be minor compared to the high background levels of Antimony in the soil. Further, the small amount of Antimony taken up by the plants correlated with the levels of extractable Antimony in the soil. This suggests that Antimony which is not extractable is also not bioavailable.

There is evidence to suggest that Antimony will not bioaccumulate in the food chain. Studies by the EPA and others on fish and other aquatic organisms reveal low bioconcentration of Antimony. [56] Studies of a contaminated smelter site reveal low bioconcentration of Antimony in small mammals which fed on contaminated plants. This is further reinforced by a feeding study of rats performed with CAT.

A study of the blood and wool Antimony levels in sheep grazed on Antimony contaminated land revealed that Antimony levels in the sheep were not elevated. [57] The study indicated that while Antimony levels at the site were 7 to 30 times higher than typical background levels, the conclusion was drawn that the Antimony was tightly bound in the soil and thus unavailable to the sheep.

Wistar rats were fed up to 1% or 10,000,000 PPB (parts per billion) CAT in their diets for three months. [58] Hematological, clinical, and biochemical tests were conducted at the end of the study. No adverse effects on food consumption or body weight gain were observed during the testing. No mortalities or overt signs of reaction to the treatment were observed.

---

[55] Callahan, M.A., Slimak, M.W., Gabel, M.W., et.al., Water-related environmental fate of 129 priority pollutants, U.S. Environmental Protection Agency, Washington, D.C., Office of Water Planning and Standards, 1197, Vol. 1, EPA 440/4-79-029a, 5-1 to 5-8, Citation taken from Toxicological Profile for Antimony, U.S. Department of Health & Human Services, Washington, D.C., 1992, p. 82, Agency for Toxic Substances and Disease Registry. (Attached).

[56] Ambient water quality criteria for Antimony, US Environmental Protection Agency, Washington, D.C., Report prepared for the Office of Water Planning and Standards, 1980, EPA 440/5-80-0 and 440/5-90-0. Citation taken from Toxicological Profile for Antimony, U.S. Department of Health and Human Services, Washington D.C., 1992, p. 82, Agency for Toxic Substances and Disease Registry. (Attached).

[57] Gebel, T., Kevekordes, S., Schaefer, J., von Platen, H., Dunkelberg, H., Mutation Research 368, 267-274 (1996).

[58] Bomhard, E., Loser, E., Dornemann, A., Toxicology Letters, 1982, 14, 189-194.

After this feeding study, Antimony was observed at a concentration of 27 PPB (ng\g=PPB) in the rat's livers. Human livers are reported to contain a background level of 23 to 167 PPB Antimony. [59] [60] The amount of Antimony in the rat's daily diet was large (900,000 PPB - Antimony), the time these animals were fed the Antimony containing material was long (over 90 days), and the amount of Antimony observed in the liver was small (only 27 PPB), which represents only 0.003% of the Antimony contained in a single day's food). The liver is a major site of Antimony concentration in orally exposed animals. [61]

However, uptake and retention of Antimony by major organs such as the liver is highly dependent on the chemical form and oxidation state of the Antimony compound. [62] Trivalent Antimony compounds are in general more toxic than those containing Antimony(V). CAT contains Antimony in a chemically inert form as Antimony(V).

The observed liver levels (27 PPB) noted in the animal experiment discussed above are at the bottom range of those observed in unexposed human livers (23-167 PPB). [63] These observations suggest that even in large, extended doses, CAT is not a significant source of bioavailable Antimony.

There is a group of studies which report that Antimony induced various degrees of stress and toxicity in cultured cardiac myocytes. [64] Highly potent and toxic soluble Antimony compounds have been

---

59 Toxicological Profile for Antimony, U.S. Department of Health & Human Services, Washington, D.C. 1992, pp. 34 and 35, Agency for Toxic Substances and Disease Registry.

60 Gurnani,N., Sharma, A., Talukder, G., The Nucleus, 37(1,2),71-96, (1994).

61 Fowler, B.A., Goering, P.L., University of Maryland School of Medicine, in Met. Their Compd. Environ., 1991, pp. 743-750, Merian & Ernest Eds., VCH, Weinheim, Federal Republic of Germany.

62 Ibid.

63 Ibid.

64 M.A. Tirmenstein, et al., Antimony-Induced Oxidative Stress and Toxicity in Cultured Cardiac Myocytes, Toxicology and Applied Pharmacology, 130, pp.41-47, (1995), M.A. Tirmenstein, et al., Antimony-induced Alterations in Homeostasis and adenine Nucleotide Status In Cultured Cardiac Myocytes, Toxicology,119, pp.203-211, (1997), Toraason, M. et al., Altered Ca^{2+} Mobilization During Excitation-Contraction in Cultured Cardiac Myocytes Exposed to Antimony, Toxicology and Applied Pharmacology, 146, pp.104-115 (1997).

used as medicines for the treatment of parasites for well over 50 years. In all cases, these studies involved direct cell exposure to the highly soluble and toxic chemical, potassium Antimonyl tartrate. Potassium Antimonyl tartrate is the most potent of the soluble toxic Antimony medicines compounds. There is no evidence in these studies which shows that highly insoluble compounds such as CAT could provoke such a toxic reaction. Additionally, there is no foreseeable means by which an individual could be exposed to Antimony through an exposure to CAT that could create such a reaction. (See pages 8-10 above regarding high dose feeding studies). These studies are not, therefore, relevant to a discussion of CAT.

I. Environmental Stability in the Solid Waste Stream

CAT pigments are capable of withstanding the most severe of environments. Experiments performed by BASF indicate that these compounds can be incinerated within plastic resin and will not be volatilized or otherwise lost. [65] These experiments involved incineration of plastic resin samples colored with CAT. [66] After incineration, the residuals were analyzed for CAT constituent elements. [67] Powder X-ray analysis revealed no degradation of the rutile structure. [68] The results confirmed that little or no loss of CAT occurred in the incineration process. [69]

This stability is created in the manufacturing process. The mixed metal oxides are fused into a single molecule during the manufacturing process at temperatures in excess of 1300 degrees centigrade. [70]

---

[65] Endriss, H. and Rade, D., "Metal Oxide Mixed Phase Pigments, Toxicological and Ecological Aspects" translated from Kunstoffe German Plastics, 79, (1989) 7, additional study of thermal decomposition provided by the author in private correspondence.

[66] Ibid.

[67] Ibid.

[68] Ibid.

[69] Ibid.

[70] Faulkner, E.B. and Schwartz R.J. High Performance Pigments, Wiley-VCH GmbH &Co. KgaA., Weinheim, 2009, p.44.

J. Biological Transformation and Bioavailability In-Vivo

As a result of the extreme stability of CAT pigments, biological transformations are not anticipated to occur. Additionally, CAT is not bioavailable in the lung and cannot be assumed to be absorbed by the lung. As discussed above, CAT is not carcinogenic or mutanogenic and does not show any propensity toward these characteristics. Therefore, even if CAT were not cleared as inert particles from the lung, no absorption in-vivo would be anticipated within the macrophage cell. This position is strongly supported by decades of use in thousands of work-places where no health effects from exposure to Antimony or trivalent Chromium were found as a result of exposure to CAT pigments. CAT is likely to be processed through the body in the same manner as its principal ingredient, rutile Titanium dioxide. Titanium dioxide has been tested extensively and does not produce a tissue response by inhalation, other than as a bulk inert dust. [71]

The uptake of CAT via phagocytosis would not be expected to lead to cancer initiation from Chromium exposure, since intracellular dissolution must follow phagocytic accumulation for the toxicity to be expressed. [72] The Cr(III) in CAT is not bioavailable, will not undergo dissolution and will therefore not lead to accumulation of Chromium inside cells. In general, it is stated that, "There is no corresponding evidence that Cr(III) compounds increase the risk of respiratory cancer....". [73] Further, "...attempts to identify the specific causative agent(s) of Chromium-associated lung cancer by biostatical methods alone have generally not been successful. The reasons for this include the fact that workplaces are often contaminated with a variety of trivalent and hexavalent Chromium compounds resulting in mixed exposures...". [74] Studies such as those by Mancuso et al. attributing lung cancer to Cr(III) compounds do not sufficiently address the

---

71 Lee K.P. et al. "Transmigration of Titanium Dioxide Particles in Rats After Inhalation Exposure," Experimental and Molecular Pathology 42, 331-343 (1985).

72 Chromium in the Natural Environment, J.O. Nriagu and E. Niebor, ed., 1988, p. 476, J. Wiley & Sons, New York.

73 Chromium in the Natural Environment, pp. 434 and 445.

74 Chromium and Chromium Compounds, IARC Monogr. Eval. Carcinog. Risk Chem. Man, 1988, 23, 205-323. Citation taken from Chromium in the Natural Environment, J.O. Nriagu and E. Nieboer, ed., 1988, pp. 465-466, J. Wiley & Sons, New York. (Attached).

possibility that Cr(VI) contamination is the responsible initiator. [75] [76] [77] Mancuso's conclusion that "carcinogenic potential extends to all forms of Chromium" [78] is controversial. The International Agency for Research on Cancer ("IARC") reviewed Mancuso's work and concluded that this generalized conclusion was not justified by his data. [79]

K. The Availability of Antimony from CAT in the Environment Expected test results

The level of Antimony extractable from CAT has been measured.[80] Under strongly acidic conditions (hydrochloric acid solution), pH=1.15) the extractable Antimony in CAT is 20 PPM. Extractions performed using higher pH solutions (pH=7 and pH=10) yielded slightly less extractable Antimony in each case.

CAT is inert and its constituent elements are not readily bioavailable. CAT contains 12% or 120,000 PPM Antimony total. Extractable Antimony from CAT is only 20 PPM. Non-extractable Antimony in CAT is therefore 119, 980 PPM or 99.98% of the total. The bulk of the Antimony in CAT remains tightly held in the crystalline lattice and unavailable for migration into the environment.

The EPA has stated that the Antimony in Sb_2O_3 (83.5% Sb), commonly used as a fire retardant in plastics and in car batteries, is tightly bound into the material and that use of this material would not result in significant consumer exposure to Antimony. [81] CAT contains much less Antimony, which is equally if not

---

75 Mancuso, T.F. Hueper, W.C., Ind. Med. Surg., 1951, 20 pp. 358-363.

76 Mancuso, Ind. Med Surg., 1951, 20, pp. 393-407.

77 Mancuso, T.F., Consideration of Chromium as an Industrial Carcinogen, Symp. Proc., Vol. III, International Conference on Heavy Metals in the Environment, 1975, pp. 343-356.

78 Ibid.

79 Chromium and Chromium Compounds, IARC Monogr. Eval. Carcinog. Risk Chem. Man, 1980, p. 23, 205-323. citation from Chromium in the Natural Environment, p. 465.

80 CPMA member's reports on extraction of CAT and NAT under various conditions, 1997.

81 US Environmental Protection Agency, 1983, Antimony metal, Antimony trioxide, and Antimony sulfide response to the Interagency Testing Committee, Federal Register 48: 717-725. Citation taken from Toxicological Profile for Antimony, U.S. Department of Health & Human Services, Washington, D.C., 1992, p. 93, Agency for Toxic Substances and Disease Registry.

more tightly bonded due to its more robust chemical make-up and extensive thermal history. [82] CAT will likewise pose no hazard due to its contained Antimony when used in plastics, paints, coatings, and ceramics.

L. Lack of Chronic Hazards from Antimony Used in CAT

Antimony compounds are in general not very toxic. They are not well absorbed and relatively well excreted. They are used in medicines as emetics, and to treat a number of tropical diseases.[83] Certain Antimony compounds have also been shown to have utility in the fight against the AIDS virus. [84] IARC has classified Antimony as being possibly carcinogenic to humans. [85] However, Leonard and Gerber note that claims of carcinogenicity of Antimony compounds are based on the study of impure compounds contaminated with other known carcinogens such as arsenic, so the claims may not be relevant. [86] Further, Leonard and Gerber conclude that, "...from what we know already, one may be confident that Antimony has a less mutagenic risk than many other metals, such as As, [hexavalent] Chromium, and Ni, among others...it appears that mutagenic, carcinogenic and teratogenic risks of Antimony compounds, if they exist at all, are not very important." [87]

---

82 Fowler, B.A., Goering, P.L., University of Maryland School of Medicine, in Met. Their Compd. Environ., 1991, pp. 743-750, Merian & Ernest Eds., VCH, Weinheim, Federal Republic of Germany.

83 IRAC website, http://www.iarc.fr/, last updated March 19, 1998.

84 Fowler, B.A., Goering, P.L., 743-750, (1991).

85 IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol 47, Lyon, France (1989).

86 Leonard A., Gerber G.B., Mutagenicity, Carcinogenicity and Teratogenicity of Antimony Compounds, Mutation Research, 1996, Vol. 366, pp. 1-8.

87 Ibid.

M. Bioaccumulation of CAT

CAT is an inert inorganic material which is not prone to dissolution. The USEPA has recognized that the type and solubility of metal species in wastes are key factors influencing the metal's bioavailability from the waste.[88] In addition to the solubility in water and mineral acids expressed above, CAT is insoluble in octanol and will not be absorbed into the fatty tissues of animals.[89] The Chromium(III) and Antimony(V) from CAT exists in a non-bioavailable form, and is not a source of these elements for plants and animals. Feeding and exposure studies have shown no propensity for bioaccumulation of CAT, Chromium, or Antimony in any of the tests. [90] No bioaccumulation of CAT pigment, or its constituent elements is thus expected.

N. Insignificant Release and the Absence of Emission of CAT and CAT Pigments

Toxic chemical release reporting data generated under Sec. 313 of EPCRA indicates that CAT does not adversely affect the environment. The total amount of CAT that was released from the four listed manufacturers into the environment for the calendar year 1997 [91] was approximately 34,111 pounds. Of this amount, 32,519 pounds were discharged into landfills and 1,582 pounds were released in the air through stacks, vents, ducts, pipes and other confined air streams, whose emission into the air are controlled by baghouses of at least 99.5% efficiency. The toxic chemical reporting data demonstrates that the amount of CAT released into the environment is not significant.

As discussed above, CAT exists as an inert insoluble solid which is incorporated into other materials, such as paints and plastics. Being sequestered in a resinous or polymeric matrix, the

---

88 60 Fed. Reg. 66,344-66,363 (December 21, 1995).

89 Testing results for octanol solubility supplied by Shepherd Color Company.

90 See for example, Bomhard et al. pp.189-194.

91 Prior to 1998 Petition.

Chromium(III) Antimony(V) with CAT is even less accessible and therefore less likely to impact the environment. Consequently, the potential concentration of this substance in the air is minimal. It is extremely unlikely that constituent ions would break free of the crystalline molecule and migrate through plastics, ceramics, or other resin matrices to impact the environment. [92] The general population is not directly exposed to this substance. Therefore, because of its inertness, insolubility and end-uses, CAT is highly unlikely to migrate into the environment.

V. CONCLUSION

EPA has developed guidance and a framework for the assessment of metals which recommend that metal compounds be differentiated, based upon the specific compounds present or the compounds in commerce which could present an exposure. [93] This is Abecause metals can exist in a variety of chemical and physical forms, and not all forms of a given metal are absorbed to the same extent. [94]

The Office of the Science Advisor of the EPA studied the problems associated with risk assessments of metals in a Risk Assessment Forum involving numerous experts. [95] In its 2007 report, entitled "Framework for Metals Risk Assessment" (the "Framework"), EPA provided a series of guiding principles for all metal related risk assessments. [96]

---

92 As an example of the added stability created by encapsulation, see J.C. Gage, and Litchfield, M.H., "The Migration of Lead from Paint Films in the Rat Gastro-Intestinal Tract", Journal of Oil Col. Chem. Assoc. 52, 236-243, (1969) see also J.C. Gage, and Litchfield, M.H., "The Migration of Lead From Polymers in the Rat Gastro-Intestinal Tract", Food and Cosmetics Toxicology, 6, 329-338, (1968).

93 Guidance for Evaluating the Oral Bioavailability of Metals in Soils for Use in Human Health Risk Assessment, EPA Publication Number OSWER 9285.7-8, 2007, p.1.

94 Ibid.

95 Framework for Metals Risk Assessment, Office of the Science Advisor, Risk Assessment Forum, EPA Publication Number 120/R-07/001, March 2007.

96 Ibid.

These principles incorporate a requirement that risk assessors identify and understand the specific form of the metal or form of the compound containing the metal generating the subject exposure, stating:

> "The absorption, distribution, transformation, and excretion of a metal within an organism, depends on the metal, the form of the metal or metal compound, and the organism=s ability to regulate and/or store the metal." [97]

It is therefore critical for any risk assessment of pigments containing metals to fully understand "the metal, the form of the metal" [98] and the ability of the target organism to absorb, regulate and store the specific metal of concern. [99]

CAT pigment does not yield an exposure to bioavailable metal and does not meet any of the health and environmental effects criteria specified under Section 313(d)(2) of EPCRA. CAT is not acutely or chronically toxic as demonstrated by extensive laboratory testing. New information, extensive literature searches, and a review of the chemically analogous rutile Titanium dioxide indicate that there is no evidence which demonstrates that exposure to CAT pigments is associated with any chronic hazard. Finally, CAT is not hazardous to the environment and will not breakdown under the most aggressive environmental conditions, including solid waste incineration.

For the foregoing reasons, the CPMA, on behalf of the manufacturers of CAT pigment, respectfully request that EPA delete CAT from the list of toxic chemicals for which toxic chemical release reporting is required.

Respectfully submitted,

David J. Wawer
Executive Director

---

97 Ibid, p.xv.

98 Ibid.

99 Ibid.