UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

DEC 4 [illegible]

MEMORANDUM:

Subject: Product Chemistry Review on
COPPER-COUNT®-N
EPA File Symbol: 10465-3

FROM: Radamés [illegible]a, Chemist
Product Chemistry Review Section
Registration Support Branch
Registration Division (H7505C)

TO: Joanne I. Miller, Acting PM 23
Fungicide-Herbicide Branch
Registration Division (H7505C)

THRU: Bipin Gandhi, Group Leader
Product Chemistry Review Section
Registration Support Branch
Registration Division (H7505C)

THRU: Lynn M. Bradley, Head
Product Chemistry Review Section
Registration Support Branch
Registration Division (H7505C)

NOTE: Appendix C contains CBI for multiple companies and is not to be released.

Requestor: Mineral Research and Development Corp.

EPA File Symbol : 10465-3

EPA MRID No.: 405516-01
405393-01
405393-02

CAS Registry No.: not given

Pesticide Chemical Code: 022702

Company Code No.: none

Chemical Name: had been claimed CBI (See Confidential Appendix A)

Common/Trade Name: not given

Use: fungicide/bactericide

Introduction

This submission proposes a change in formulation from copper ammonium carbonate complex to copper ammonia complex for the end product (EP), COPPER-COUNT®-N, a liquid copper fungicide/bactericide spray used on growing crops. We are instructed to review change under SOP 3068.2 for EP produced through integrated formulation system to determine if the chemistry is adequate to characterize "active ing. complex? ". Since this product was registered in 1970 there is no chemistry data in our files, because it was not required then. Because of this, the reviewer asked the PM for a currently registered product identical or substantially similar to COPPER-COUNT®-N. The product given by the registrant after a telephone call was K-Cop a fungicide produced by Griffin Corporation.

This review will address the submitted data as it relates to the product chemistry data requirements.

SERIES 61: Product Identity and Composition

61-1 Product Identity and Disclosure of Ingredients

COPPER-COUNT®-N is a liquid copper fungicide/bactericide manufactured by Mineral Research and Development Corp. of Charlotte, NC. The active ingredient in this product is copper metallic, which is derived from a copper ammonium complex. See Confidential Appendix A for a detailed discussion of product identity.

This product was registered, originally, with the description of the active ingredient as Copper Metallic (from Copper Ammonium Carbonate). A more appropriate description, now given by the registrant, would have been Copper Metallic (from a Copper Ammonia Complex). This is the same active ingredient that is in this product today. All of the toxicological studies were conducted using this active ingredient.

To verify this new description the registrant has submitted the results of two different analyses, X-Ray Diffraction and Scanning Electron Microscope Photograph. See Appendix A for a detailed discussion of the results of these analyses. For the purpose of clarity the registrant must submit a theoretical discussion of those analyses.

The product identity of the active ingredient has been claimed confidential in this submission, this information must be removed from the confidential statements, therefore the submission must be revised.

The applicant must submit the Chemical Abstracts Service (CAS) Registry Number [redacted] for the active ingredient.

Information regarding the identity of the impurities is discussed in the Confidential Appendix A.

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

61-2 Description of Beginning Materials and Manufacturing Process

Refer to Confidential Appendix A for a description of the beginning materials and manufacturing process for COPPER-COUNT®-N.

The product specifications provided by the applicant for [redacted] is incomplete. The registrant must provide information in order to verify the statement on it s impurities.

61-3 Discussion of the Formation of Impurities

Since COPPER-COUNT®-N is produced by an integrated formulation system the amount of impurities will center around the beginning materials and intentionally added inerts. See Confidential Appendix A for a detailed discussion of the formation of impurities.

SERIES 62: Analysis and Certification of Product Ingredients

62-1 Preliminary Analysis of Product Samples

The applicant has submitted the results of analyses of five representative samples from recent production batches of, COPPER-COUNT®-N which were analyzed for the % of AI, pH, specific gravity and trace metal contamination. Refer to Confidential Appendix B for the results of these analyses along with their respective mean and standard deviation.

A complete, detailed description of each step in the following analytical procedures: analysis of trace metals and analysis of specific gravity, must be provided by the registrant in order to fulfill the requirements of this section.

62-2 Certification of Ingredient Limits

Since COPPER-COUNT®-N is produced in an integrated formulation system as an end use product, the CSF (dated 1/28/88), has the certified limits of the AI and intentionally added inerts. Refer to Confidential Appendix B for a disclosure of these limits.

The applicant should submit a statement of the precision and accuracy of the analytical methods.

62-3 Analytical Methods to Verify Certified Limits

The method employed by Mineral Research and Development Corp. to determine the percent of metallic copper in COPPER-COUNT®-N is [redacted]

An [redacted] was employed to quantify the level of contaminants in the formulated product.

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

SERIES 63: Physical and Chemical Characteristics

Summarized below are several physicochemical properties of the end product (EP), as furnished by the applicant.

Guidelines Reference No. (40 CFR 158.120) and Name of Property	EP
63-2 Color	Blue Violet
63-3 Physical State	Liquid
63-4 Odor	Vinegar Like
63-5 Melting Point	195°C (PAI)
63-6 Boiling Point	N.R.
63-7 Density	1.162 g/ml @ 25°C
63-8 Solubility	is insoluble in water CCl_4..... 0.80 ppm acetone... 31.0 ppm octanol... 32.0 ppm

Guidelines Reference No. (40 CFR 158.120) and Name of Property	EP
63-9 Vapor Pressure	N.A.
63-10 Dissociation Constant	N.A.
63-11 Octanol/ Water Partition Coefficient	N.A.
63-12 pH	7.1 @ 25°C
63-13 Stability	no adverse sensitivity to either high temperature or sunlight.
63-14 Oxidizing or Reducing Action	N.G
63-15 Flammability	N.R.
63-16 Explodability	N.G.
63-17 Storage Stability	N.G.
63-18 Viscosity	N.G.
63-19 Miscibility	N.R.
63-20 Corrosion Characte- ristic	N.G.
63-21 Dielectric Breakdown Voltage	N.A.

PAI means pure form of the active ingredient.
N.A. means not applicable.
N.R. means not required.
N.G. means not given.

The following physical and chemical characteristic must be provided as required by 40 CFR § 158.120 to support the registration of COPPER-COUNT®-N: information on the tendency of the product to act as an oxidizing or reducing agent, information on the impact explosion characteristics (if any), data concerning the storage stability of the product, the viscosity of the EP, information on the corrosion characteristics of the EP.

Conclusions and Recommendations

The reviewer understands that the new description of the complex that contains the active ingredient in COPPER-COUNT®-N is just a better identification of the product; and that there has not been any significant change in the formulation of COPPER-COUNT®-N. However in order to fulfill the requirements to review the change under SOP 3068.2, we made a comparison between COPPER-COUNT®-N and another registered product, K-Cop. The conclusion of the comparison is that the two product are substantially similar. See Appendix C for a detailed discussion.

The actual label of COPPER-COUNT®-N reads that the AI is copper metallic from copper ammonium complex. Instead of saying "from copper ammonium complex" the label should give the chemical name of the complex that has been claimed confidential in this submission (see Confidential Appendix A). The label should be revised accordingly.

The product chemistry data requirements for the EP has not been completely satisfied. The following additional data are required.

SERIES 61: Product Identity and Composition

1. The product identity of the active ingredient has been claimed confidential in this submission, this information must be removed from the confidential statements, therefore the submission must be revised.

2. The applicant must submit the Chemical Abstracts Service (CAS) registry number [redacted] for the active ingredient.

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

3. The product specifications provided by the applicant for [redacted] is incomplete. The registrant must provide information in order to verify the statement on it s impurities.

4. For the purpose of clarity the registrant must submit a theoretical discussion of the X-Ray Diffraction and Scanning Electron Microscope Photograph analyses.

SERIES 62: Analysis and Certification of Product Ingredients

1. A complete, detailed description of each step in the following analytical procedures: analysis of trace metals and analysis of specific gravity, must be provided by the registrant in order to fulfill the requirements of this section.

2. The applicant should submit a statement of the precision and accuracy of the analytical methods.

SERIES 63: Physical and Chemical Characteristics

1. The following physical and chemical characteristic must be provided as required by 40 CFR § 158.120 to support the registration of COPPER-COUNT®-N:

   a) information on the tendency of the product to act as an oxidizing or reducing agent.

   b) information on the impact explosion characteristics (if any).

   c) data concerning the storage stability of the product.

   d) the viscosity of the EP.

   e) information on the corrosion characteristics of the EP.

Attachments:

Confidential Appendix A
Confidential Appendix B
Confidential Appendix C

Note to PM : A Confidential Appendix C is attached. This Appendix contains information for assisting in determining if significant differences exist in the content of the two compared EPs. This information contains CBI for multiple products and is **not to be released**.