

US EPA ARCHIVE DOCUMENT

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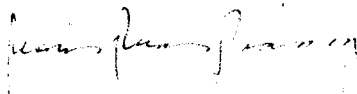
SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI []; MUP []; EUP [x]

BARCODE No.: 323494 Reg./File Symbol No. 432-1210

Product Name: R & M Garden Dust 10% MRID No.: 466824-01

COMPANY NAME: Bayer Environmental Science Action Code: 674

FROM: Maria Rivera Piansay, Chemist
Product Chemistry Team
PRB/SRRD (7508C)



TO: Karen Jones, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

INTRODUCTION:

An Interim Reregistration Eligibility Decision (IREDD), Case number 0080, was issued in March 1, 2005 for the Technical Grade Active Ingredient (TGAI) Carbaryl: 1-naphthyl methylcarbamate. According to the IREDD, the generic data base supporting the reregistration of Carbaryl have been reviewed and found to be substantially complete.

The registrant submitted Confidential Statements of Formula (CSF), one basic formulation (dated 6/25/05) and four alternate formulations (dated 6/26/05, 6/27/05, 6/28/05, 6/29/05); a draft label, EPA received 11/03/05; and product chemistry data in MRID number 466824-01. The registrant is requesting FIFRA Section 4 reregistration of EPA Reg. No. 432-1210.

FINDINGS:

1. The CSFs for the basic and the alternate formulations are acceptable as presented. The nominal concentration of the active ingredient agrees with that on the label, meeting PR Notice 91-2 (Accuracy of Stated Percentages for Ingredients Statement). The certified limits on the active and the inert ingredients are the standard limits as per 40 CFR 158.175(b)(2). (It should be noted that the pH of the product as a 10% aqueous suspension was measured to be 9.34 according to MRID number 466824-01, therefore, the entry "N/A" appearing in the basic and two alternate formulations dated 6/26 and 6/27/05 must be corrected administratively.)
2. The data submitted in MRID number 466824-01 satisfy the product chemistry data requirements under Subgroups A and B which pertain to Product Identity, Composition and Analysis, and Physical and Chemical Properties, respectively.
3. The active ingredient statement on the label is acceptable in accordance with PR Notice 91-2 and 40 CFR 158.155. The Physical and Chemical Hazards statements are not triggered since there are no physical/chemical hazards anticipated for this product. The Storage and Disposal statements are acceptable in accordance with 40 CFR 156.10(i)(2)(ix) and PR Notice 83-3.

CONCLUSIONS:

The registrant has satisfied the product chemistry data requirements for the reregistration of EPA Reg. No. 432-1210.

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REVIEW OF PRODUCT CHEMISTRY DATA:

PRODUCT NAME: R & M Garden Dust 10% EPA Reg. No: 432-1210
Group A: Series 830-Product Identity, Composition, and Analysis (40 CFR158.155, .160, .165, .167, .170, .175 & .180).

830-1550 Product Identity and Composition

EPA Reg. No. 432-1210 is an end-use product produced through a non-integrated formulation process. The active ingredient Carbaryl is claimed in the label at 10.0% and the inert ingredients are present at 90.0%. Description of materials used in the formulation of this product are listed in MRID number 466824-01 and on the CSF.

830-1600 Description of Materials Used to Produce the Product

Refer to Confidential Appendix A.

830-1620 Discussion of Formulation Process

Refer to Confidential Appendix A.

830-1670 Discussion of Formation of Impurities

Refer to Confidential Appendix A.

830-1700 Preliminary Analysis

Refer to Confidential Appendix A

830-1750 Certified Limits

Refer to Confidential Appendix A.

830-1800 Enforcement of Analytical Method

Methods for analysis of carbaryl have been previously reviewed in connection with the reregistration process for carbaryl. The registrant presented their method in MRID number 466824-01 which utilizes HPLC with UV detector. The method is acceptable and satisfies Guideline 830.1800.

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Product Chemistry Data**Subgroup A: Series 830.1550 - 830.1800 (40 CFR 158.155 - 158.180)**

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	MRID Number	Data Fulfilled
.1550 Product Identity and Composition	466824-01	Y
.1600 Description of Materials Used to Produce the Product	466824-01 and CSF	Y
.1620 Description of Formulation Process	466824-01	Y
.1650 Discussion of Formation of Impurities	"	Y
.1700 Preliminary Analysis	N/A	N/A
.1750 Certified Limits	466824-01 and CSF	Y
.1800 Enforcement Analytical Method	466824-01	Y

Subgroup B: Series 830.6302 -7950 (40 CFR 158.190)

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	VALUE OR QUALITATIVE DESCRIPTION	MRID Number	Data Fulfilled
.6302 Color	Light tan	466824-01	Y
.6303 Physical State	Powder	"	Y
.6304 Odor	"Not required under PR Notice 92-5."	"	Y
.6314 Oxidation/Reduction: Chemical Incompatibility	"Not applicable; R & M Garden Dust 10% does not contain any ingredient (technical or inert) which is considered to be an oxidizing or reducing agent."	"	N/A
.6315 Flammability/Flame Extension	"Not applicable; R & M Garden Dust 10% does not contain a combustible liquid."	"	N/A

.6316 Explodability	"Not applicable. No impact explosive characteristics are expected on the basis of the chemical nature of the formulation ingredients."	"	N/A
.6317 Storage Stability	The one-year, room-temperature study indicated chemical stability and the product is expected to have a shelf-life of at least two years.	466824-01	Y
.6319 Miscibility	N/A. (not to be diluted with petroleum solvents.		N/A
.6320 Corrosion Characteristics	The study, which was conducted with Storage Stability, indicated that the product is compatible with its commercial packaging when stored at room temperature for one year.	466824-01	G
.6321 Dielectric Breakdown Voltage	Not applicable; product is not labeled to be used around electrical equipments.		N/A
.7000 pH	9.34 (10% aqueous suspension)	466824-01	Y
.7100 Viscosity	N/A. (not a liquid)		N/A
.7300 Density/Relative Density/Bulk Density	47.0 lbs/cu. ft.	466824-01	Y

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived

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Confidential Appendix A

830-1600 Description of Materials Used to Produce the Product

Description of materials used in formulation are listed in MRID number 466806-01 and on the CSF.

830-1650 Description of Formulation Process

The formulation is a simple mixing and blending of active and inert ingredients conducted at room temperature.

830-1670 Discussion of Formation of Impurities

The formulation is a simple mixing and blending operation conducted at room temperature, therefore, no intended reactions occur. No new impurities are expected to be formed as a result of the formulation except those that may be carried-over from the technical material.

830-1700 Preliminary Analysis

Not required for "non-integrated" products.

830-1750 Certified Limits

Carbaryl: Lower Limit: 9.50%; Nominal Conc.: 10.00%, Upper Limit: 10.50%