

US EPA ARCHIVE DOCUMENT

DATE OUT: 29/NOV/05

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

BARCODE No.: 323524

MRID No.: 466825-01

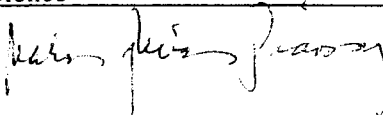
Reg./File Symbol No./Product Name: 432-1209/R & M Garden Dust 5%

432-1239/BES Garden Dust 5%

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

In the 8-month response to the IRED, the registrant submitted Confidential Statements of Formula (CSF) (one basic and five alternate formulations all dated 6/25/05 for Reg. No. 432-1209, one basic formulation for Reg. No. 432-1239 dated 6/25/05); draft labels (both received 11/03/03); and product chemistry data in MRID number 466825-01. The registrant is requesting FIFRA Section 4 reregistration of the subject products.

FINDINGS:

1. The CSFs for the basic and alternate formulations for the subject products are acceptable as presented. The nominal concentration of the active ingredient agrees with that on the labels, 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 presented in 40 CFR 158.175(b)(2). All ingredients listed on the CSFs are cleared for use in the formulation of pesticides.
2. The data submitted in MRID number 466825-01 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 section is acceptable in accordance with 40 CFR 156.10(i)(2)(ix).

CONCLUSIONS:

PRB has no objection to the reregistration of EPA Reg. Nos. 432-1209 and 432-1239.

THIS REVIEW CONTAINS FIFRA CBI

REVIEW OF PRODUCT CHEMISTRY DATA:**PRODUCT NAME: R & M Garden Dust 5% /EPA Reg. No: 432-1209****BES Garden Dust 5% /EPA Reg. No: 432-1239****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. Nos. 432-1209 and 432-1239 are both end-use products produced through a non-integrated formulation process. The active ingredient Carbaryl is claimed in the label at 5.0% and the inert ingredients are present at 95.0%. EPA Reg. No. 432-1209 uses the Technical Carbaryl, EPA Reg. No. 264-324 with Reg. Nos. 264-325, 19713-244, and 264-328 as alternate sources. The subject product, Reg. No. 432-1239 is a repack of Reg. No. 432-1209. Description of materials used in the formulation of these products are listed in MRID number 466825-01 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

Analytical methods for the determination of Carbaryl have been previously reviewed in connection with the registration process for Case number 0080. The registrant describes their method in MRID number 466825-01 which involves the use of High Performance Liquid Chromatography (HPLC). Through an internal standard method. Carbaryl is determined by comparing the reverse phase HPLC peak areas of the samples with that of the standards (dimethyl phthalate).

This method is adequate and meets guideline requirement 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	466825-01	Y
.1600 Description of Materials Used to Produce the Product	466825-01 and CSF	Y
.1620 Description of Formulation Process	466825-01	Y
.1650 Discussion of Formation of Impurities	"	Y
.1700 Preliminary Analysis	N/A	N/A
.1750 Certified Limits	466825-01 and CSF	Y
.1800 Enforcement Analytical Method	466825-01	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	466825-01	Y
.6303 Physical State	Powder	"	Y
.6304 Odor	Waived (PR Notice 92-5)		W
.6314 Oxidation/Reduction: Chemical Incompatibility	N/A; does not contain any oxidizing/reducing agent.	"	N/A
.6315 Flammability/Flame Extension	N/A; does not contain combustible liquids.	"	N/A
.6316 Explodability	N/A; not potentially explosive.	"	N/A
.6317 Storage Stability	A one-year, warehouse temperature test showed concentrations of carbaryl initially, and at 3, 6, 9, and 12 months to be 5.0, 5.3, 5.1, 5.1, and 5.0, respectively.	"	Y

.6319 Miscibility	N/A. (not to be diluted with petroleum solvents.	“	N/A
.6320 Corrosion Characteristics	The packaging material in the one year study was low density polyethylene plastic bags. No corrosive effects from the product were observed at the end of the study. The packaging tested is compatible with the subject products.	“	Y
.6321 Dielectric Breakdown Voltage	Not applicable; product is not labeled to be used around electrical equipments.	466825-01	N/A
.7000 pH	9.23 (10% aqueous suspension	“	Y
.7100 Viscosity	N/A. (not a liquid)		N/A
.7300 Density/Relative Density/Bulk Density	49.2 lbs/cu.ft.	466825-01	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 A830-1600 Description of Materials Used to Produce the Product

Description of materials used in formulation are listed in MRID number 466825-01 and on the GSE.
MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

830-1650 Description of Formulation Process

The product is formulated

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

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Not required for "non-integrated" products.

830-1750 Certified Limits

Carbaryl: Lower Limit: 5.25%; Nominal Conc.: 5.00%; Upper Limit: 4.75%