



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 8, 2006

MEMORANDUM:

Subject: EPA Reg. No.: 432-1210/R & M Garden Dust 10%
DP Barcode: 327132
Case No.: 0080

From: Marianne Lewis, Biologist
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

Marianne Lewis 3/8/06

To: Venus Eagle, CRM
Product Reregistration Branch
Special Review and Reregistration Division (7508C)

Applicant: Bayer Environmental Science
P.O. Box 12014, 2 T.W. Alexander Dr.
Research Triangle Park, NC 27709

FORMULATION FROM EPA Reg. No. 432-1210 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Carbaryl.....	10.0%
<u>Inert Ingredient(s):</u>	<u>90.0%</u>
Total	100.0%

BACKGROUND: In the 8 month response to the Carbaryl RED, the registrant cited acute toxicity studies to support the reregistration of EPA Reg. No. 432-1210. The MRID's are as follows: 419191-01 (81-1), 466856-16 (81-2), 466856-19 (81-5), 466856-20 (81-6). Two (81-2, & 81-5) of studies were conducted by SafePharm Labs. The acute oral study (81-1) was conducted by Stillmeadow, Inc. The skin sensitization study (81-6) was conducted by CIT. The test material used in each of the studies was EPA Reg. No. 264-333. In response to a rebatching request PRB/SRRD on 10/18/05 determined that the subject product could cite these four studies conducted with EPA Reg. No. 264-333.

On 10/18/05, the Agency determined that an acute inhalation study (81-3) and a primary eye irritation study (81-4) must be conducted on EPA Reg. No. 432-1210 due to the inerts.

The registrant has now submitted an acute inhalation study (MRID# 467617-01) and a primary eye irritation study (MRID# 467620-01). Both studies were conducted by Product Safety Labs and the test material used in each was the subject product

RECOMMENDATIONS:

- The two studies (81-3 & 81-4) submitted are acceptable to support the reregistration of EPA Reg. No. 432-1210.

The acute toxicity profile for EPA Reg. No. 432-1210 is currently:

Acute Oral	III	Acceptable
Acute Dermal	III	Acceptable
Acute Inhalation	IV	Acceptable
Primary Eye	IV	Acceptable
Primary Dermal	IV	Acceptable
Skin Sensitization	non sensitizer	Unacceptable

NOTE: The acute toxicity study requirements have been satisfied for the subject product.

Chamber Environment	Dose Level
	2.06 mg/L
Chamber Volume	6.7 L
Airflow	31.7 Lpm
Temperature (°C)	20 - 22
Relative Humidity (%)	42 - 47

Clinical Observations: All appeared to be active and healthy throughout study

Gross Necropsy Findings: No observable abnormalities noted

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: John Hebert, 07
MRID No.: 467620-01

Reviewer: Marianne Lewis
Study Completion Date: 1/30/06
Report No.: 18802

Testing Facility: Product Safety Labs
Author: G. Moore

Quality Assurance (40 CFR §160.12): Included

Test Material: Sevin-10 Ready To Use 10% Dust, EPA Reg. No. 432-1210, tan/brown powder

Dosage: 0.1 mL (0.07 g)
Species: New Zealand albino rabbit
Sex: 2 males, 1 female
Weight: not given
Age: young adult
Source: Robinson Services, Inc.

Summary:

Toxicity Category: IV

Classification: Acceptable

Procedure (Deviations From §81-4): none

Results:

OBSERVATIONS	(number "positive"/number tested)			
	Hours			
	1	24	48	72
Corneal Opacity	0/3	0/3	0/3	0/3
Iris	3/3	0/3	0/3	0/3
Conjunctivae				
Redness	3/3	0/3	0/3	0/3
Chemosis	0/3	0/3	0/3	0/3
Discharge	0/3	0/3	0/3	0/3

Prior to instillation, 2 drops of ocular anesthetic (tetracaine hydrochloride ophthalmic solution) placed in both eyes.

At 1 hr., 3/3 iritis and 3/3 diffuse crimson red conjunctivae. By 24 hrs., all had cleared.

ACUTE TOX ONE-LINER

1. PC CODE: 056801
2. CURRENT DATE: February 20, 2004
3. TEST MATERIAL: Sevin-10 Ready To Use 10% Dust, EPA Reg. No. 432-1210, tan/brown powder, Carbaryl: 10.0%

Study/Species/ Lab/Study#/Date	MRID #	Results	Tox. Cat.	Core Grade
acute inhalation toxicity/rat/ Product Safety/18801/2-10-06	46761701	LD ₅₀ > 2.06 mg/L MMAD = 3.7 μm; GSD = 2.20	IV	A
primary eye irritation/rabbit/ Product Safety/18802/1-30-06	46762001	At 1 hr., 3/3 iritis and 3/3 diffuse crimson red conjunctivae. By 24 hrs., all had cleared.	IV	A

Core Grade Key:

- A = Acceptable
- S = Supplementary (upgradeable)
- U = Unacceptable
- V = self-Validated

6

LABELING: (Commerical)

ID #: 000432-01210 R & M GARDEN DUST 10%

SIGNAL WORD: CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with eyes, skin, or clothing. Wear long sleeved shirt, long pants, shoes, socks, and chemical resistant gloves (such as or made out of any waterproof material, selection category A).

FIRST AID:

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Note to CRM/PM/Registrant:

The proposed label should contain a Note to Physician which addresses the presence of a

cholinesterase inhibitor. The following statements are some suggested types of information that could be included, if applicable, in the Note to Physicians:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

LABELING: (Homeowner)

ID #: 000432-01210 R & M GARDEN DUST 10%

SIGNAL WORD: CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with eyes, skin, or clothing. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

FIRST AID:

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Note to CRM/PM/Registrant:

The proposed label should contain a Note to Physician which addresses the presence of a cholinesterase inhibitor. The following statements are some suggested types of information that could be included, if applicable, in the Note to Physicians:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.