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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

July 01, 2003

MEMORANDUM:

Subject: EPA Reg. No.: 60063-1/Chlorothalonil Technical Fungicide  
DP Barcode: D289659  
Case No.: 0097

From: Maria Rivera Piansay, Chemist *Maria Rivera Piansay*  
Product Reregistration Branch  
Special Review and Reregistration Division (7508C) *MRP*

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

Applicant: Sipeam Agro USA, Inc.  
300 Colonial Center Parkway, Suite 230  
Roswell, GA 30076

FORMULATION FROM EPA Reg. No. 60063-1 LABEL:

<u>Active Ingredient(s)</u> :	<u>% by wt.</u>
Chlorothalonil.....	98.0%
<u>Inert Ingredient(s)</u> : .....	2.0%
Total:	100.0%

BACKGROUND:

In the 8 month response to the *Chlorothalonil* RED, the registrant has submitted a new acute inhalation study (MRID number 459053-01) intended to upgrade the acute inhalation toxicity classification for the reregistration of EPA Reg. No. 60063-1.

The data requirements on acute oral, acute dermal, primary eye irritation, primary skin irritation and skin sensitization were previously satisfied as per the acute toxicity reviews by H. Mukhoty of PRB/SRRD on 03/30/00 and 05/09/00 (Barcode numbers D263509 and D265853, respectively).

RECOMMENDATIONS:

The submitted new acute inhalation study in MRID number 459053-01 is acceptable to support reregistration of the subject product. This study is classified as category II for acute inhalation.

H. Mukhoty of PRB/SRRD has previously assigned the subject product a category I for acute inhalation based on the study found in MRID number 436784-03. However, based on "weight-of-evidence" (reinforced by the new study), it appears that a category II classification is more appropriate for this product. therefore, the Agency will re-classify the inhalation category for the subject product from a category I to a category II.

All acute toxicity data requirements for the subject product are satisfied.

The acute toxicity profile for EPA Reg. No. 60063-1 is currently:

Acute Oral	IV	Acceptable
Acute Dermal	III	Acceptable
Acute Inhalation	II	Acceptable
Primary Eye	I	Self-validated
Primary Dermal	IV	Acceptable
Skin Sensitization	Non-sensitizer	Acceptable

LABELING:

**ID #:** 060063-00001            **CHLOROTHALONIL TECHNICAL**

**RESTRICTED USE CLASSIFICATION RECOMMENDED**

Due to eye irritation toxicity category.

The PM Team should decide if restricted use classification is necessary or if alternative labeling will allay the requirement for restricted use classification.

**SIGNAL WORD:    DANGER**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS\*:**

Corrosive. Causes irreversible eye damage. Maybe fatal if inhaled. Harmful if absorbed through skin. Do not get in eyes or on clothing. Avoid contact with skin. Do not breathe dust. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

**FIRST AID:**

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Call a poison control center or a doctor for treatment advice.

**IF INHALED:** Move person to fresh air. If the person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice

**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 PHYSICIAN:** The following note to physician statement is required for the subject product:

*Probable mucosal damage may contraindicate the use of gastric lavage.*

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NOTE TO PM/CRM/Registrant: The proposed label should contain a Note to Physician which addresses the category I primary eye irritation classification.

The following statements are suggested types of information that may be included:

- technical information on symptomatology,
- use of supportive treatments to main life functions,
- medicine that will counter act the specific physiological effects of the pesticide,
- company telephone number to specific medical personnel who can provide specialized medical advice

\* The designation of Personal Protective Equipment (PPE) for manufacturing-use products does not fall under the jurisdiction of EPA, therefore, PPE has not been specified for this product.

**DATA REVIEW FOR ACUTE INHALATION TOXICITY (§81-1, 870.1300)**

**Product Manager:** Cynthia Giles-Parker, 22  
**MRID No.:** 459053-01

**Reviewer:** Maria Rivera Piansay  
**Study Completion Date:** 04/04/03  
**Report No.:** 02-5462

**Testing Laboratory:** Huntingdon Life Sciences  
**Author:** G.M. Hoffman

**Quality Assurance (40 CFR §160.12):** included

**Test Material:** Sipcam Technical Chlorothalonil (99.49%), Lot no. 2L09D1(4), off-white powder  
**Species:** Sprague-Dawley derived albino rat  
**Age:** approx. 8 weeks  
**Weight:** males (mean): 309g; females (mean): 219g  
**Source:** Charles River Laboratories

**Summary:**

1. <b>LC<sub>50</sub> (mg/kg):</b> >0.0515 mg/L	4. <b>MMAD:</b> ave.: 3.267µm
2. <b>Toxicity Category:</b> II	5. <b>GSD:</b> ave. 2.039
3. <b>Classification:</b> Acceptable	

**Procedure (Deviations From §81-5):** none

**Results:**

**Reported Mortality**

Exposure Concentration (mg/L)	(Number Deaths/Number Tested)		
	Males	Females	Combined
0.0515	1/5	0/5	1/10

**Chamber Atmosphere**

Dose Level	MMAD (Mean)	GSD (Mean)	% Particles ≤ 1.0 µm	% Particles ≤ 4.0 µm	% Particles ≤ 10 µm
0.0515	3.267	2.039	7.42	63.12	95.91

Chamber Environment	Dose Level (mg/L)
	0.0515
Chamber Volume (L)	100
Airflow (Lpm)	20.0
Mean Temperature (°C)	23.4
Mean Relative Humidity (%)	31.7

#### **Clinical Observations:**

One male animal was sacrificed in poor condition at about one hour post exposure. There were no signs of toxicity noted during the exposure period. Clinical signs noted immediately following exposure included lacrimation in 2/10 animals, red nasal discharge in 8/10 and gasping in one. Few days after exposure similar signs were seen in a few animals. All signs cleared during the remainder of the 14-day observation period. Body weights were not affected by exposure to the test substance.

#### **Gross Necropsy:**

Necropsy at terminal sacrifice revealed no abnormalities.

### ACUTE TOX ONE-LINER

1. PC CODES: 081901
2. CURRENT DATE: July 01, 2003
3. TEST MATERIAL: Sipcam Technical Chlorothalonil (99.49%), Lot no. 2L09D1(4), off-white powder

Study Species/ Lab Study#/Date	MRID #	Results	Tox. Cat.	Core Grade
acute inhalation/rat/Huntingdon Life Sciences/02-5462/04/04/03	459053- 01	LC <sub>50</sub> : >0.0515 mg/L	II	A

Core Grade Key:

A = Acceptable

S = Supplementary (upgradeable)

U = Unacceptable

V = self-Validated