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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Wednesday, June 27, 2007

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 81943-2/ Symmetry Algaecide
DP Barcode: D336606

To: Adam Heyward, PM 34/ Aster Grahn
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Phoenix Environmental Care, LLC.

FORMULATION FROM LABEL:

Active Ingredient(s):		% by wt.
Copper as elemental		8
Other Ingredient(s):		92
	Total:	100.00%

1) BACKGROUND: Phoenix Environmental Care, LLC, has submitted an acute inhalation toxicity study to support their product, "Symmetry Algaecide". The study was conducted by Stillmeadow, Inc. No other study reports were included in the submission.

The inhalation study was submitted to support a change in the signal word of the product. The registrant's cover letter states that the signal word for this product is based upon "the original acute toxicology data generated in support of the K-TEA registration."

The test material is named "PEX-002". The registrant's cover letter states that PEX-002 is a company code for Symmetry.

2) RECOMMENDATIONS: PSB findings are:

a) The acute inhalation toxicity study is acceptable.

b) The Chemistry and Toxicology Team (CTT) has reviewed the regulatory files for Registration Number 81943-2 and cannot locate any acute toxicity review for this product. A data matrix lists "Cite-all" as the method of support for each of the six acute toxicity study requirements. Nothing was located which speaks to any studies which were actually referenced to support the acute toxicity of 81943-2.

c) CTT has compared the Confidential Statements of Formula (CSFs) for both 81943-2 and 67690-24 ("K-Tea") and considers these two products to be Substantially Similar. Thus, CTT will allow the registrant to cite acute toxicity data that is derived from testing of K-Tea.

d) A 12/13/1994 PRS/RSB/RD acute toxicity review was found for K-Tea (the cited product). At that time, K-Tea was assigned the registration number 1812-307. The results of that review were:

Study	Toxicity Category	Status
Acute Oral Toxicity	III	Acceptable
Acute Dermal Toxicity	---	Unacceptable
Acute Inhalation Toxicity	II	Minimum (Acceptable)
Primary Eye Irritation	III	Acceptable
Primary Skin Irritation	IV	Minimum (Acceptable)
Dermal Sensitization	Sensitizer	Minimum (Acceptable)

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (OPPTS 870.1300)
(NOSE-ONLY EXPOSURE)

Product Manager: 34
MRID No.: 470450-01

Reviewer: CSC and Ian Blackwell
Study Completion Date: January 18, 2007
Report No.: 10402-06

Testing Laboratory: Stillmeadow, Inc., Sugar Land, TX
Author: Lori Carter, B.A.

Quality Assurance (40 CFR §160.12): A Quality Assurance statement was included. A statement of Good Laboratory Practice (GLP) compliance also was included stating that the study was conducted in compliance with 40 CFR Part 160, U.S. EPA (FIFRA).

Test Material: PEX-002
Lot #: B0614601 / Dark blue liquid

Species: 10 Sprague-Dawley, albino rats
Sex: 5 Males and 5 Females. Females were nulliparous and non-pregnant.
Age: Young adult (~9 weeks old)
Source: Texas Animal Specialties, Humble TX
Weight: Males: 284-352 grams; Females: 199-223 grams
Housing: Temperature: 22±2°C
Humidity: 30-70%
Photoperiod: 12-hour light/dark cycle
Acclimation: At least 5 days

Concentration:

Group	Gravimetric Exposure Concentration (mg/L)	Nominal Concentration (mg/L)
I	1.11	9.12

Summary:

1. **LC_{50} (mg/L) 4-hr exposure**: > 1.11 mg/L in male and female rats
2. **The estimated 4-hr acute inhalation LC_{50} for PEX-002 is greater than 1.11 mg/L in male and female rats.**
3. **Average MMAD**: 2.5 µm
4. **Toxicity Category**: III **Classification**: Acceptable

Procedure (Deviation from 870.1300):

- The laboratory report indicates that: "there were no deviations from the protocol that affected the quality or outcome of the study."

- The Certificate of Analysis provided for the test substance, PEX-002, reported the percentage of active ingredient (i.e., copper) as 8.14%. The Confidential Statement of Formula (CSF) and the product label for Symmetry Algaecide (the subject of the registration amendment) list copper as the active ingredient at 8%. No additional information was provided to link the test substance and the product, Symmetry Algaecide.

Results:

Reported Mortality

Exposure Concentration (mg/L)	Number of Deaths / Number Tested		
	Males	Females	Combined
1.11	0 / 5	0 / 5	0 / 10

Chamber Atmosphere

Exp. Conc. (mg/	Sample	MMAD (µm)	GSD (µm)	Cumulative % of Particles Collected at Effective Cutoff Diameter (µm)							
				<18.	<10.	<4.3	<2.6	<1.7	<0.9	<0.5	<0.
1.11	1	3.0	5.0	94.9	83.0	67.8	47.4	20.3	11.8	6.78	5.08
	2	2.0	5.7	100.	90.2	73.1	58.5	34.1	26.8	21.9	12.2

Chamber Environment During Exposure

Exposure Level (mg/L)	1.11
Chamber Volume (L)	500
Mean Airflow (Lpm)	187
Mean Temperature (°C)	21
Mean Relative Humidity (%)	68

Clinical Observations: All animals survived exposure to the test atmosphere. Body weight gain was unaffected by exposure to the test substance, except in one male and one female that lost weight between Days 0 and 7. Prominent in-life observations included activity decrease and piloerection in both sexes. All animals were considered asymptomatic by Day 4.

Gross Necropsy Findings: The gross necropsy conducted on each animal at study termination revealed no observable abnormalities.