



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

Office of Chemical Safety and Pollution
Prevention

July 25, 2011

MEMORANDUM

Subject: Name of Pesticide Product: NEU1140F Copper Soap
EPA Reg. No.: 67702-2
DP Barcode: D391305
Decision No.: 447643
Action Code: R340
PC Code: 023306 Octanoic acid, copper salt

From: Breann Hanson, Biologist *B. Hanson* *E. McAndrew*
Technical Review Branch (TRB)
Registration Division (RD; 7505P)

To: Rosemary Kearns, RM Team 22
Fungicide Branch
Registration Division (7505P)

Applicant: W. Neudorff GmbH KG
c/o Walter G. Talarek PC
1108 Riva Ridge Dr.
Great Falls, Virginia 22066-1620

FORMULATION FROM LABEL:

<u>Active Ingredient:</u>	<u>% by wt</u>
023306 Copper Octanoate (Copper Soap)	10.0
<u>Other Ingredients:</u>	90.0
Total:	100.0%

Metallic copper equivalent – 1.8%

ACTION REQUESTED: The Risk Manager requests: “RD-TRB – ACUTE TOX – Registrant has submitted revised labelling and a acute inhalation toxicity study 484464-01 for review and comment... ”

BACKGROUND: Walter G. Talarek PC, on behalf of W. Neudorff GmbH KG (herein the “registrant”) has submitted an acute inhalation toxicity study (MRID 48446401) to amend the labelling of their currently registered product NEU1140F Copper Soap, EPA Reg. No.: 67702-2. The study was performed at Eurofins|Product Safety Laboratories (PSL), Dayton, New Jersey, US. Included in the data package was the study volume, proposed master label, letter from the registrant and other administrative volumes.

The study was submitted to amend their label in order to delete references in the precautionary and first aid statement sections to inhalation exposure.

The acute oral (MRID 43947504), acute dermal (MRID 43947505), primary eye irritation (MRID 43947506), primary dermal irritation (MRID 43947507) and dermal sensitization (MIRD 44116101) studies listed on the data matrix were previously reviewed by the Health Effects Division (HED) (S. Diwan, DP Barcodes: D230195, D230567) for registration of a 10% copper octanoate formulation (NEU1140F) and were located by this reviewer in the jacket for 67702-2; all were classified as Acceptable.

COMMENTS AND RECOMMENDATIONS:

1. The acute toxicity profile for NEU1140F Copper Soap, EPA Reg. No.: 67702-, is as follows:

Acute oral toxicity	III	Acceptable	MRID 43947504*
Acute dermal toxicity	III	Acceptable	MRID 43947505*
Acute inhalation toxicity	IV	Acceptable	MRID 48446401
Acute eye irritation	IV	Acceptable	MRID 43947506*
Primary skin irritation	IV	Acceptable	MRID 43947507*
Dermal sensitization	Negative	Acceptable	MRID 44116101*

* previously reviewed by HED

2. Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #: 067702-00002
PRODUCT NAME: NEU1140F Copper Soap

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals: Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

First Aid:

If on skin:

- 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.

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 to an unconscious person.

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.

3. TRB has no objection to the precautionary or first aid label statements noted on the submitted master label for 67702-2

4. The RM needs to ensure that the basic and any alternate CSFs for the product were previously approved by the TRB Product Chemistry Team.

Reviewer: Breann Hanson
Risk Manager (EPA): Rose Kearns, RM 22

Date: July 25, 2011

STUDY TYPE: Acute Inhalation Toxicity - Rat; OPPTS 870.1300; OECD 403

TEST MATERIAL: NEU1140F Copper Soap (Copper Octanoate: 10.59%; Lot#: PG 6-34-1; EPSL Reference Number: 110222-12H; blue, opaque solution; pH: 6.40)

CITATION: Durando, J. (2011) NEU1140F Copper Soap - Acute Inhalation Toxicity Study in Rats. Laboratory Study Number: 31649. Unpublished study prepared by Eurofins|Product Safety Laboratories. April 5, 2011. MRID 48446401.

SPONSOR: W. Neudorff GmbH KG

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 48446401), a group of five male and five female rats (age: 8-9 weeks; weight: 228-245 g males, 185-199 g females; source: SAGE™; strain: Sprague-Dawley derived, albino) was exposed by nose-only inhalation for 4 hours to NEU1140F Copper Soap (Copper Octanoate: 10.59%; Lot#: PG 6-34-1; EPSL Reference Number: 110222-12H; blue, opaque solution; pH: 6.40) at a gravimetric concentration of 2.01 mg/L, with an average mass median aerodynamic diameter (MMAD) of 2.83 microns and average geometric standard deviation (GSD) of 2.29. Body weights were recorded on prior to dosing (day 1) and again on days 3, 7 and 14. Animals were observed during exposure, at the end of exposure, and daily thereafter for 14 days. All animals were necropsied at study termination.

All animals survived the study period. One female lost body weight during the first week of the study period; all animals exceeded their initial body weights at study termination. Post-exposure, 4/5 male and 4/5 female animals exhibited abnormal respiration and 1/5 of those males also appeared hypoactive. All animals were asymptomatic by day 2 and along with the other 1/5 male and 1/5 female animals, appeared active and healthy for the remainder of the study period. No gross lesions were observed at necropsy.

LC₅₀ Males > 2.01 mg/L
LC₅₀ Females > 2.01 mg/L
LC₅₀ Combined > 2.01 mg/L

Based on the four-hour inhalation exposure LC₅₀, NEU1140F Copper Soap is in EPA Toxicity Category IV.

This acute inhalation study is classified as acceptable. It does satisfy the guideline requirement for an acute inhalation study (OPPTS 870.1300; OECD 403) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Nominal Conc. (mg/L)	Total Formulation Conc. (mg/L)	MMAD μ m	GSD	Mortality/Number Tested		
				Males	Females	Combined
94.6	2.01	2.73, 2.92	2.24, 2.34	0/5	0/5	0/10

Test Atmosphere / Chamber Description: The test atmosphere was generated using a ¼ inch JCO atomizer; the test substance was metered to the atomizer using a peristaltic pump; clean dry air was

passed through the atomizer at a nominal flow rate of 31.6 LPM and introduced into the chamber to uniformly distribute the test atmosphere by creating a vortex.

Total Formulation Conc. (mg/L)	2.01
Chamber Volume (L)	28
Nominal Airflow (L/min)	31.6
Temperature (° C)	19-20
Relative Humidity (%)	20-26
Time to T ₉₉ equilibrium (minutes)	4

Test atmosphere concentration: Gravimetric samples were collected from the breathing zone of the animals six times during exposure. This was done by drawing the test atmosphere at a known flow rate and time, through a filter; the filter was weighed before and after sampling. The mass collected was then divided by the total volume of air sampled. Collections were carried out for 2 minutes at airflows of 4 LPM.

Particle size determination: Two samples withdrawn from the breathing zone of the animals were analyzed using an eight stage ACFM Andersen Ambient Particle Sizing Sampler to determine the particle size distribution of the test atmosphere. The MMAD and GSD were determined graphically using two-cycle log-probit axes.

A. Mortality: There were no deaths.

B. Clinical observations: One female lost body weight during the first week of the study period; all animals exceeded their initial body weights at study termination. Post-exposure, 4/5 male and 4/5 female animals exhibited abnormal respiration and 1/5 of those males also appeared hypoactive. All animals were asymptomatic by day 2 and along with the other 1/5 male and 1/5 female animals, appeared active and healthy for the remainder of the study period.

C. Gross Necropsy: No gross lesions were observed at necropsy.

D. Reviewer's Conclusions: In agreement with the study author, the four-hour exposure LC₅₀ is greater than 2.01 mg/L. Based on these results, the test material is classified as EPA Toxicity Category IV.

E. Deficiencies: None.

PC Code: 023306
EPA Reg. No.: 67702-2

ACUTE TOX ONE-LINERS:

1. DP BARCODE: D391305				
2. PC CODE: 023306				
3. CURRENT DATE: July 25, 2011				
4. TEST MATERIAL: NEU1140F Copper Soap (Copper Octanoate: 10.59%; Lot#: PG 6-34-1; EPSL Reference Number: 110222-12H; blue, opaque solution; pH: 6.40)				
Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute inhalation toxicity / rat Eurofins PSL Study Number: 31649 5/APR/2011	48446401	LC ₅₀ Males > 2.01 mg/L LC ₅₀ Females > 2.01 mg/L LC Combined > 2.01 mg/L	IV	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, W = Waived