2-6-96

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: EPA File Symbol: 51036-EUT

From: Mark J. Perry, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

MJP 2-6-96

To: D. Edwards, PM-19 / M. Johnson
Registration Division (7505C)

Applicant: Micro Flow Company
P.O. Box 5948
Lakeland, FL 33807

FORMULATION FROM LABEL:

	% by wt.
Active Ingredient(s):	
Chlorpyrifos	2.5
Inert Ingredient(s):	97.5
Total:	100%

1/2

BACKGROUND

Micro Flo submitted acute oral, acute dermal, acute inhalation, eye irritation, dermal irritation and dermal sensitization studies in support of Chlorpyrifos 2.5G, EPA File Symbol 51036-EUT. Chlorpyrifos 2.5G is an agricultural use insecticide intended for use against rootworms on corn. All primary study reviews were performed by the California Department of Pesticide Regulation (CDPR).

CDPR graded the acute inhalation study supplementary due to inadequate reporting of the calculation methods used to determine the chamber concentration. More specifically, the review states that the study may be upgraded with a detailed explanation of how the "multi-factor" was determined. PRS has recieved information from the performing laboratory which explains how this parameter is calculated (see below).

All studies were performed by Stillmeadow Laboratories; assigned MRID numbers are 436332-04 through 436332-09.

RECOMMENDATION

1. Acute Oral; Category IV / Acceptable

2. Acute Dermal; Category III / Acceptable

3. Acute Inhalation; Category IV / Acceptable

The "multi-factor" converts the milligrams of test material per milliliter of collecting solution to milligrams of test material per liter of air sampled. See attachment for actual calculation.

4. Eye Irritation; Category III / Acceptable

5. Dermal Irritation; Category IV / Acceptable

6. Dermal Sensitization; Non-sensitizer / Acceptable

LABELING

See attached Label Review System printout for current precautionary labeling recommendations.

ID #: 051036-00247 CHLORPYRIFOS 2.5G

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS:

Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wear long-sleeved shirt and long pants, socks and shoes and waterproof gloves. Wash thoroughly with soap and water after handling.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

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STILLMEADOW, Inc.

12852 Park One Drive
Sugar Land, TX 77478
713-240-8828
Fax: 713-240-8448

FAX TRANSMISSION COVER SHEET

Date: *February 7, 1996*

To: *Mark Perry*

Fax: *703-308-8369*

Re: *Clarification of Multifactor, MRID 436332-06*

Sender: *Mark Holbert*

YOU SHOULD RECEIVE 1 PAGE(S), INCLUDING THIS COVER SHEET. IF YOU DO NOT RECEIVE ALL THE PAGES, PLEASE CALL 713-240-8828.

The following is a clarification of the multifactors calculated and used in STILLMEADOW, Inc. study No. 1366-94:

The multifactor is calculated by dividing the sampling extraction volume (25 mL) by the flow (0.681 Lpm) and by the amount of time the sample is taken (30 minutes).

The sample concentration obtained from the standard curve (mg/mL) is then multiplied by the multifactor 1.22 resulting in a concentration in mg/L.

Example multifactor: $\frac{25\ mL}{(0.681\ Lpm)(30\ min.)} = 1.22$

Concentration from standard curve: 1.58825 mg/mL

0.969148 x 1.22 = 1.182 mg/L

The multifactor for samples 1 and 4 will be 2.44 because the samples were diluted to 50% in methanol to allow the samples to fall within the standard curve.

$\frac{1.22}{0.50\ (50\%)}$ = multifactor of 2.44

Please let me know if you need any further clarification.

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ACUTE TOX ONE-LINER

1. PC CODE: 059101

2. CURRENT DATE: 2/6/96

3. TEST MATERIAL:
Chlorpyrifos 2.5%

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
81-1, Rat, Still-meadow, 1364-94, 10/10/94	436332-04	LD50 5050 mg/kg	IV	A
81-2, Rabbit, Still-meadow, 1365-94, 9/16/94	436332-05	LD50 2020 mg/kg	III	A
81-3, Rat, Still-meadow, 1366-94, 10/25/94	436332-06	LC50 2.5 mg/L	IV	A
81-4, Rabbit, Still-meadow, 1367-94, 9/19/94	436332-07	All clear by 7 days	III	A
81-5, Rabbit, Still-meadow, 1368-94, 9/9/94	436332-08	No irritation at 72 hrs.	IV	A
81-6, Guinea pig, Stillmeadow, 1369-94, 10/13/94	436332-09	Non-sensitizer	---	A

Core Grade Key:

A = Acceptable
S = Supplementary
U = Unacceptable

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TO: Ann Prichard, Program Specialist
Pesticide Registration Branch

FROM: Medical Toxicology Branch Date: December 5, 1995

PRODUCT REGISTRATION RECOMMENDATION SHEET

Formulated Product Name: Chlorpyrifos 2.5G
Chemical Code #: 253
SB 950 #: 221 **ID #:** 157123-EPAE
Document #: 342-571
EPA #: 51036 – EUT
Company Name: Micro-Flo Company

RECOMMENDATION:

Submitted as Additional Data in conjunction with the EPA/CDPR Sharing Project.

The data reviewed are adequate to make a complete acute toxicological evaluation of the subject product.

All potential hazards associated with the use of the subject product, as indicated by the data reviewed, are adequately identified on the product label.

Registration is recommended.

Charles Kahn
Associate Pesticide Review Scientist

12/6/95
Date

Staff Toxicologist

12-6-95
Date

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TO--File: Registration **Program Specialist:** Ann Prichard
Branch: Registration
FROM--Medical Toxicology

DATA PACKAGE SUMMARY AND RECOMMENDATION SHEET

Active Ingredient: Chlorpyrifos
Formulated Product Name: Chlorpyrifos 2.5G
Formulation: 2.5% Chlorpyrifos and 97.5% Inert ingredients
Chemical Code #: 253
SB 950 #: 221 **ID #:** 157123-EPAE
Document #: 342-571
EPA #: 51036 - EUT
Company Name: Micro-Flo Company

SUMMARY: ("One-liners" from each study worksheet,significant information not mentioned in worksheets, other pertinent information for ongoing review or registration. Attach additional sheets if needed)

MFG-CRCH-2 and the subject product are the same formulation (See Micro-Flow Company Letter dated October 2, 1995).

MFG-CRCH-2 Acute Toxicity Categories

Acute Oral LD50	IV
Acute Dermal LD50	III
Acute Inhalation LC50	Study Not Acceptable
Eye Irritation	III
Dermal Irritation	IV

MFG-CRCH-2 Acute Toxicity Studies

Acute Oral LD50
342-571; 142553; Acute Oral LD50; 811; rat; Stillmeadow Incorporated, Sugar Land, TX; 10/10/94; Lab. Study No.: 1364-94; MFG-CRCH-2 (tan colored granules); oral doses of 1500, 3500, 4300, 4800 and 5050 mg/kg (dosed as a 30% w/v concentration in deionized water); mortalities (M) 1/5, 0/5, 0/5, 1/5, 0/5 and (F) 0/5, 1/5, 2/5, 1/5, 2/5, respectively; clinical observations- reduced activity, ataxia, piloerection, body tremors, hunching, moribundity, hypersensitivity, brown discoloration of face and head hair, ocular discharge, ptosis, diarrhea and withdrawn testes; no meaningful effect on body weight; necropsy- swelling and discoloring of the lungs, enlarged adrenal glands, discoloration of liver, lymph nodes, pancreas and contents of gastrointestinal tract; LD50 (M) > 5050 mg/kg and (F) 6080 mg/kg; Toxicity Category IV; study acceptable. (Kahn, 12/1/95)

Acute Dermal LD50
342-571; 142555; Acute Dermal LD50; 812; rabbit; Stillmeadow Incorporated, Sugar Land, TX; 9/16/94; Lab. Study No.: 1365-94; MFG-CRCH-2 (tan colored granules); dose of 2020 mg/kg (moistened with 1.98 ml/g deionized water); 5/sex/dose; 24 hour exposure period (occluded); mortalities 0/10; clinical observations- lacrimation, decreased defecation, diarrhea, soft feces, mucous coating on feces and skin irritation at the test sites; no meaningful effect on body weight; necropsy- discoloration of the liver and kidneys, gastrointestinal tract distended with gas and fluid in the peritoneal cavity; LD50 > 2020 mg/kg; Toxicity Category III; study acceptable. (Kahn, 12/4/95)

Acute Inhalation LC50
342-571; 142556; Acute Inhalation LC50; 813; rat; Stillmeadow Incorporated, Sugar Land, TX; 10/25/94; Lab. Study No.: 1366-94; MFG-CRCH-2 (tan granules); inhalation dose of 2.5 mg/l (analytical value) and 9.91 mg/l (nominal value); test material ground and screened prior to animal dosing; 5/sex/dose; 4 hour exposure period; MMAD ± GSD = 3.073 - 3.614 ± 2.708 - 3.001 µm; mortalities 0/10; clinical observations- decreased activity, nasal discharge, red crust around nose, piloerection, ptosis and salivation; body weights were essentially unaffected; necropsy- discolored and swollen lungs in two males; reported LC50 > 2.5 mg/l (analytical value); Toxicity Category not determined; study unacceptable but upgradeable upon submission of a detailed explanation as to how the two different "Multi Factors" (2.44 and 1.22) used to calculated the chamber concentration were determined. (Kahn, 12/4/95)

Eye Irritation
342-571; 142557; Eye Irritation; 814; rabbit; Stillmeadow Incorporated, Sugar Land, TX; 9/16/94; Lab. Study No.: 1367-94; MFG-CRCH-2 (tan colored granules); dosed with the equivalent of 0.1 ml/eye (by volume -74.9 mg); test material ground before application to the rabbit eye; 9 rabbit eyes tested (3 eyes washed and 6 eyes not washed); mortalities- 0/6; (unwashed eyes) at Day 1 post-dose -Grade 3 (4/6) and -2(2/6) conjunctival irritation; at Day 7 post-dose -Grade 1 (1/6) conjunctival irritation; at Day 10 post-dose -No eye irritation; Toxicity Category III; study accepted. (Kahn 12/4//95)

Dermal Irritation
342-571; 142558; Dermal Irritation; 815; rabbit; Stillmeadow Incorporated, Sugar Land, TX; 9/9/94; Lab. Study No.: 1368-94; MFG-CRCH-2 (tan colored granules); dermal dose of 500 mg/site (test material moistened with 1.10 ml of deionized water); 4 hours exposure period (semi-occluded); 6 rabbits tested; mortalities- 0/6; at 24 hours post patch removal -Grade 1 (3/6) erythema, at 72 hours post patch removal -No skin irritation; Toxicity Category IV; study acceptable. (Kahn, 12/5/95)

CONCLUSIONS: Do data support registration, if applicable? For formulated product, do data support registration of product as labelled?

The submitted MFG-CRCH-2 acute oral toxicity, the acute dermal toxicity, the primary eye irritation, and the primary dermal irritation studies are acceptable.

The acute inhalation toxicity study is unacceptable.

Although MFG-CRCH-2 acute inhalation toxicity study is unacceptable, it could be upgraded to an acceptable study upon submission of a detailed explanation as to how the two different "Multi Factors" (2.44 and 1.22) used to calculated the chamber concentration were determined.

According to the use instructions (the subject product is a granular material), this product is not applied as a spray and inhalation exposure will be minimal. An acceptable acute inhalation toxicity study on the subject product is not being required at this time.

RECOMMENDATIONS: What type of registration action is being requested? In case of ongoing registration, register or do not register? What other specific studies or data are requested?

Submitted as a Section 3 Registration.

The data reviewed are adequate to make a complete acute toxicological evaluation of the subject product.

All potential hazards associated with the use of the subject product, as indicated by the data reviewed, are adequately identified on the product label.

Registration is recommended.

Charles Kohn — 12/6/95
Associate Pesticide Review Scientist **Date**

[signature] — 12-6-95
Staff Toxicologist **Date**

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MRID 436332-04

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

DEPARTMENT OF PESTICIDE REGULATION

MEDICAL TOXICOLOGY BRANCH

TOXICOLOGY STUDY EVALUATION WORKSHEET
(acute and special studies)

I. STUDY IDENTIFICATION

Active Ingredient: Chlorpyrifos
Formulated Product Name: MFG-CRCH-2
Chemical Code #: 253
SB 950 #: 221 **ID #:** 157123-EPAE
Document #: 342-571 **Record #:** 142553
EPA #: NA 51036-EUT
Study Type: 811 - Acute Oral LD50
Full Study Title: Acute Oral Toxicity Study In Rats
Company Sponsor: Micro-Flo Company
Conducting Laboratory: Stillmeadow Incorporated, Sugar Land, TX
Report Date: October 10, 1994
Study Interval: July 20, 1994 to August 31, 1994

II. SUMMARY OF WORKSHEET

A. **STUDY STATUS: Is report complete?** No
Is study acceptable? Yes

- \- Meets EPA guidelines
- Yes Minor variances from guidelines
- \- Major variances from guidelines
- \- Could be upgraded with additional information (see VI-A)

- Yes Has useful data
- \- Insufficient data
- \- Non EPA validated study
- Other_____

B. **CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?:** No **If so, in what area?** NA

C. **ONE LINER-One or two sentence summary of the study:**
342-571; 142553; Acute Oral LD50; 811; rat; Stillmeadow Incorporated, Sugar Land, TX; 10/10/94; Lab. Study No.: 1364-94; MFG-CRCH-2 (tan colored granules); oral doses of 1500, 3500, 4300, 4800 and 5050 mg/kg (dosed as a 30% w/v concentration in deionized water); mortalities (M) 1/5, 0/5, 0/5, 1/5, 0/5 and (F) 0/5, 1/5, 2/5, 1/5, 2/5, respectively; clinical observations- decreased activity, ataxia, piloerection, body tremors, hunching, hypersensitivity, moribundity, brown discoloration of face and head hair, ocular discharge, ptosis, diarrhea and withdrawn testes; no meaningful effect on body weight; necropsy- swelling and discoloring of the lungs, enlarged adrenal glands, discoloration of liver, lymph nodes, pancreas and contents of gastrointestinal tract; LD50 (M) > 5050 mg/kg and (F) 6080 mg/kg; Toxicity Category IV; study acceptable. (Kahn, 12/1/95)

D. **ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?:** Yes

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Charles Kahn
Associate Pesticide Review Scientist

12/6/95
Date

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Staff Toxicologist

12-6-95
Date

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:

Species: Rat
Strain: HSD: Sprague-Dawley SD
Source of animals: Harlan Sprague Dawley, Inc. Houston, TX
Age at start: Young adults [weighing (M) 180-264 g and (F) (182-232 g]
Route of administration: Gavage
Vehicle: 30% w/v test article in deionized water
Period of treatment: Single dose

B. BACKGROUND (including relationship of this study to other studies): NA

C. TREATMENT LEVELS AND GROUP SIZE:

	Units (mg/kg)				
	1500	3500	4300	4800	5050
# Male Rats:	5	5	5	5	5
# Female Rats:	5	5	5	5	5
			Mortality		
# Dead Male Rats:	1	0	0	1	0
# Dead Female Rats:	0	1	2	1	2

IV. STUDY DESIGN AND EVALUATION

A. TEST PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

1. **Test article:** MFG-CRCH-2 (tan colored granules);
* 2. **Analysis of dosing material:** Not reported
3. **Animal selection:** OK
4. **Animal husbandry:** Housed individually in suspended, wire bottom, stainless steel cages - Temperature 72±5°F and Relative Humidity 30-80%
5. **Mortality:** See III-C
6. **Number of animals:** See III-C
* 7. **Randomization of animals:** Not reported
8. **Dose level selection:** OK
9. **Route of administration:** OK
10. **Exposure conditions:** OK
11. **Controls:** OK
12. **Observations:** Observed for mortality or other signs of gross toxicity at least 3 times on day of dosing and at least once daily thereafter for14 days
13. **Necropsies:** OK
14. **Appropriateness of methods:** OK
15. **Treatment of results:** OK
16. **Test report:** OK
17. **Consistency:** OK
18. **Good Laboratory Practice:** OK
19. **Other:** OK

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

RESULTS

A. EFFECTS REPORTED:
Clinical observations- decreased activity, ataxia, piloerection, body termors, hunching, hypersensitivity, moribundity, brown discoloration of face and head hair, ocular discharge, ptosis, diarrhea and withdrawn testes. No meaningful effect on body weight. Mortalities (M) 1/5, 0/5, 0/5, 1/5, 0/5 and (F) 0/5, 1/5, 2/5, 1/5, 2/5, respectively. Necropsy- swelling and discoloring of the lungs, enlarged adrenal glands, discoloration of liver, lymph nodes, pancreas and contents of gastrointestinal tract.

B. ACUTE TOXICITY VALUE(LD50,LC50,etc):
LD50 (M) > 5050 mg/kg and (F) 6080 mg/kg

C. TOXICITY CATEGORY:
IV

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). None **What are they and can they be corrected with additional information?** NA **Be specific:** NA

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? No **Are there any recommendations specific to this study?** NA

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MRID 436332-0

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

DEPARTMENT OF PESTICIDE REGULATION

MEDICAL TOXICOLOGY BRANCH

TOXICOLOGY STUDY EVALUATION WORKSHEET
(acute and special studies)

I. STUDY IDENTIFICATION

Active Ingredient: Chlorpyrifos
Formulated Product Name: MFG-CRCH-2
Chemical Code #: 253
SB 950 #: 221 **ID #:** 157123-EPAE
Document #: 342-571 **Record #:** 142555
EPA #: NA 51036-EUT
Study Type: 812 - Dermal LD50
Full Study Title: Acute Dermal Toxicity Study In Rabbits
Company Sponsor: Micro-Flo Company
Conducting Laboratory: Stillmeadow Incorporated, Sugar Land, TX
Report Date: September 16, 1994
Study Interval: July 21, 1994 to August 4, 1994

II. SUMMARY OF WORKSHEET

A. **STUDY STATUS: Is report complete?** No
Is study acceptable? Yes

- \- Meets EPA guidelines
- Yes Minor variances from guidelines
- \- Major variances from guidelines
- \- Could be upgraded with additional information (see VI-A)

- Yes Has useful data
- \- Insufficient data
- \- Non EPA validated study
- Other_____

B. **CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?** No **If so, in what area?** NA

C. **ONE LINER-One or two sentence summary of the study:**
342-571; 142555; Acute Dermal LD50; 812; rabbit; Stillmeadow Incorporated, Sugar Land, TX; 9/16/94; Lab. Study No.: 1365-94; MFG-CRCH-2 (tan colored granules); dermal dose of 2020 mg/kg (moistened with 1.98 ml/g deionized water); 5/sex/dose; 24 hour exposure period (occluded); mortalities 0/10; clinical observations- lacrimation, decreased defecation, diarrhea, soft feces, mucous coating on feces and skin irritation at the test sites; no meaningful effect on body weight; necropsy- discoloration of the liver and kidneys, gastrointestinal tract distended with gas and fluid in the peritoneal cavity; LD50 > 2020 mg/kg; Toxicity Category III; study acceptable. (Kahn, 12/4/95)

D. **ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?:** Yes

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Charles Kahn
Associate Pesticide Review Scientist

12/6/95
Date

Staff Toxicologist

12-6-95
Date

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III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:

Species: Rabbit
Strain: New Zealand White
Source of animals: Ray Nichols Rabbitry, Lumberton, TX
Age at start: Young adults - 3-6 months of age [weight (M) 2.650-2.875 kg and (F) 2.500- 2.850 kg]
Route of administration: Dermal (occluded)
Vehicle: Each dose of test material moistened with 1.98 g of deionized water
Period of treatment: Single (24 hour exposure - occluded)

B. BACKGROUND (including relationship of this study to other studies): NA

C. TREATMENT LEVELS AND GROUP SIZE:

	Units (mg/kg)
	2020
# Male Rabbits:	5
# Female Rabbits:	5
	Mortality
# Dead Male Rabbits:	0
# Dead Female Rabbits:	0

IV. STUDY DESIGN AND EVALUATION

A. TEST PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

1. **Test article:** MFG-CRCH-2 (tan colored granules)
* 2. **Analysis of dosing material:** Not reported
3. **Animal selection:** OK
4. **Animal husbandry:** Individually housed in suspended, stainless steel cages with wire bottoms - Temperature 72±5°F and Relative Humidity 30 - 80%
5. **Mortality:** See III-C
6. **Number of animals:** See III-C
* 7. **Randomization of animals:** Not reported
8. **Dose level selection:** OK
9. **Route of administration:** OK
10. **Exposure conditions:** OK
11. **Controls:** OK
12. **Observations:** Observed for mortality or other signs of gross toxicity at least three times on day of dosing and at least once per day for 14 days thereafter
13. **Necropsies:** Gross necropsies all animals
14. **Appropriateness of methods:** OK
15. **Treatment of results:** OK
16. **Test report:** OK
17. **Consistency:** OK
18. **Good Laboratory Practice:** OK
19. **Other:** OK

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

V. RESULTS

A. EFFECTS REPORTED:
Clinical observations- lacrimation, decreased defecation, diarrhea, soft feces, mucous coating on feces and skin irritation at the test sites. No meaningful effect on body weight. Mortalities 0/10. Necropsy- discoloration of the liver and kidneys, gastrointestinal tract distended with gas and fluid in the peritoneal cavity.

B. ACUTE TOXICITY VALUE(LD50, LC50, etc):
LD50 > 2020 mg/kg

C. TOXICITY CATEGORY:
III

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). None **What are they and can they be corrected with additional information?** NA **Be specific:** NA

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? No **Are there any recommendations specific to this study?**
NA

MRID 436332-0

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CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
MEDICAL TOXICOLOGY BRANCH
TOXICOLOGY STUDY EVALUATION WORKSHEET
(acute and special studies)

I.STUDY IDENTIFICATION

Active Ingredient: Chlorpyrifos
Formulated Product Name: MFG-CRCH-2
Chemical Code #: 253
SB 950 #: 221 **ID #:** 157123-EPAE
Document #: 342-571 **Record #:** 142556
EPA #: NA 51036-EUT
Study Type: 813 - Acute Inhalation LC50
Full Study Title: Acute Inhalation Toxicity Study In Rats
Company Sponsor: Micro-Flo Company
Conducting Laboratory: Stillmeadow Incorporated, Sugar Land, TX
Report Date: October 25, 1994
Study Interval: September 1, 1994 to September 15, 1994

II. SUMMARY OF WORKSHEET

A. **STUDY STATUS: Is report complete?** No
Is study acceptable? No

- Meets EPA guidelines
- Minor variances from guidelines
Yes Major variances from guidelines
Yes Could be upgraded with additional information (see VI-A)

Yes Has useful data
- Insufficient data
- Non EPA validated study
Other_____

B. **CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?** No **If so, in what area?** NA

C. **ONE LINER-One or two sentence summary of the study:**
342-571; 142556; Acute Inhalation LC50; 813; rat; Stillmeadow Incorporated, Sugar Land, TX; 10/25/94; Lab. Study No.: 1366-94; MFG-CRCH-2 (tan granules); inhalation dose of 2.5 mg/l (analytical value) and 9.91 mg/l (nominal value); test material ground and screened prior to animal dosing; 5/sex/dose; 4 hour exposure period; MMAD $\pm$ GSD = 3.073 - 3.614 $\pm$ 2.708 - 3.001 µm; mortalities 0/10; clinical observations- decreased activity, nasal discharge, red crust around nose, piloerection, ptosis and salivation; body weights were essentially unaffected; necropsy- discolored and swollen lungs in two males; reported LC50 > 2.5 mg/l (analytical value); Toxicity Category not determined; study unacceptable but upgradeable upon submission of a detailed explanation as to how the two different "Multi Factors" (2.44 and 1.22) used to calculated the chamber concentration were determined. (Kahn, 12/4/95)

D. **ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?** No

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Charles Kahn
Associate Pesticide Review Scientist

12/6/95
Date

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12-6-95

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:

Species: Rat
Strain: HSD:SD
Source of animals: Harlan Sprague Dawley, Inc, Houston, TX
Age at start: Young adults [weight (M) 211 - 223 g and (F) 204 - 231 g]
Route of administration: Inhalation
Vehicle: None reported (Test material ground and screened prior to use)
Period of treatment: Single (4 hour exposure period)

B. BACKGROUND (including relationship of this study to other studies): NA

C. TREATMENT LEVELS AND GROUP SIZE:

	Units (mg/l)*
	2.50
# Male Rats:	5
# Females Rats:	5
	Mortality
# Dead Males Rats:	0
# Dead Females Rats:	0

* 2.50 mg/l (analytical value)
9.91 mg/l (nominal value)
3.073 - 3.614 ± 2.708 - 3.001 µm (MMAD ± GSD)

IV. STUDY DESIGN AND EVALUATION

A. TEST PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

1. **Test article:** MFG-CRCH-2 (tan granules)
* 2. **Analysis of dosing material:** Report is not sufficiently detailed as to how the analytical value of the chamber concentration was calculated.
3. **Animal selection:** OK
4. **Animal husbandry:** Housed individually in suspended, stainless steel cages with mesh bottoms - Temperature 72±5°F and Relative Humidity 30 - 80%
5. **Mortality:** See III C
6. **Number of animals:** See III C
* 7. **Randomization of animals:** Not reported
8. **Dose level selection:** OK
9. **Route of administration:** OK
10. **Exposure conditions:** OK
11. **Controls:** OK
12. **Observations:** Observed for mortality or other signs of gross toxicity twice on day of exposure and at least once daily thereafter for 14 days days
13. **Necropsies:** Necropsy performed on all animals
14. **Appropriateness of methods:** OK
15. **Treatment of results:** OK
16. **Test report:** OK
17. **Consistency:** OK
18. **Good Laboratory Practice:** OK
19. **Other:** NA

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B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

V. RESULTS

A. EFFECTS REPORTED:
Clinical observations- decreased activity, nasal discharge, red dust around nose, piloerection, ptosis and and salivation. Body weights were essentially unaffected. Mortalities 0/10. Necropsy- discolored and swollen lungs in two males.

B. ACUTE TOXICITY VALUE(LD50,LC50,etc):
Reported LC50 > 2.5 mg/l (analytical value)

C. TOXICITY CATEGORY:
Not determined - study unacceptable

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). What are they and can they be corrected with additional information? Be specific:
Study unacceptable but upgradeable upon submission of a detailed explanation as to how the two different "Multi Factors" (2.44 and 1.22) used to calculated the chamber concentration were determined.

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? No **Are there any recommendations specific to this study?:**
NA

MRID 436332-07

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CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

DEPARTMENT OF PESTICIDE REGULATION

MEDICAL TOXICOLOGY BRANCH

TOXICOLOGY STUDY EVALUATION WORKSHEET
(acute and special studies)

I.STUDY IDENTIFICATION

Active Ingredient: Chlorpyrifos
Formulated Product Name: MFG-CRCH-2
Chemical Code #: 253
SB 950 #: 221 **ID #:** 157123-EPAE
Document #: 342-571 **Record #:** 142557
EPA #: NA 51036-EUT
Study Type: 814 - Eye Irritation
Full Study Title: Primary Eye Irritation Study In Rabbits
Company Sponsor: Micro-Flo Company
Conducting Laboratory: Stillmeadow Incorporated, Sugar Land, TX
Report Date: September 19, 1994
Study Interval: July 25, 1994 to August 4, 1994

II. SUMMARY OF WORKSHEET

A. STUDY STATUS: Is report complete? No
Is study acceptable? Yes

- Meets EPA guidelines
Yes Minor variances from guidelines
- Major variances from guidelines
- Could be upgraded with additional information (see VI-A)

Yes Has useful data
- Insufficient data
- Non EPA validated study
Other_____

B. CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect? None If so, in what area? NA

C. ONE LINER-One or two sentence summary of the study:
342-571; 142557; Eye Irritation; 814; rabbit; Stillmeadow Incorporated, Sugar Land, TX; 9/19/94; Lab. Study No.: 1367-94; MFG-CRCH-2 (tan colored granules); dosed with the equivalent of 0.1 ml/eye (by volume -74.9 mg); test material ground before application to the rabbit eye; 9 rabbit eyes tested (3 eyes washed and 6 eyes not washed); mortalities- 0/6; (unwashed eyes) at Day 1 post-dose -Grade 3 (4/6) and -2(2/6) conjunctival irritation; at Day 7 post-dose -Grade 1 (1/6) conjunctival irritation; at Day 10 post-dose -No eye irritation; Toxicity Category III; study accepted. (Kahn 12/4//95)

D. ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)? Yes

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Charles Kahn
Associate Pesticide Review Scientist

12/6/95
Date

Staff Toxicologist

12.6.95
Date

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III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION AND DURATION OF TREATMENT:

Species: Rabbit
Strain: New Zealand White
Source of animals: Ray Nichols Rabbitry, Lumberton, TX
Age at start: Young Adults (3-6 months of age)
Route of administration: Test material placed in the conjunctival sac of the right eye of each test animal while the other eye served as the control.
Vehicle: Undiluted (test material ground to a fine powder prior to dosing)
Period of treatment: Single

B. BACKGROUND (including relationship of this study to other studies): NA

C. TREATMENT LEVELS AND GROUP SIZE:

	Units (ml/eye)
# Rabbits:	0.1* / 9

	Mortality
# Dead Rabbits:	0

* By volume (74.9 mg)

IV. STUDY DESIGN AND EVALUATION

A. TEST PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

1. **Test article:** MFG-CRCH-2 (tan colored granules)
* 2. **Analysis of dosing material:** Not reported
3. **Animal selection:** OK
4. **Animal husbandry:** Housed individually in suspended, wire bottom, stainless steel cages - Temperature 72±5°F and Relative Humidity 30 -80%
5. **Mortality:** See III-C
6. **Number of animals:** See III-C
* 7. **Randomization of animals:** Not reported
8. **Dose level selection:** OK
9. **Route of administration:** OK
10. **Exposure conditions:** OK
11. **Controls:** Untreated eyes served as controls
12. **Observation:** Eyes were examined at 1, 24, 48 and 72 hours and 4, 7 and 10 days post-dose
13. **Necropsies:** Not required
14. **Appropriateness of methods:** OK
15. **Treatment of results:** OK
16. **Test report:** OK
17. **Consistency:** OK
18. **Good Laboratory Practice:** OK
19. **Other:** OK

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

V. RESULTS

A. EFFECTS REPORTED:
Mortalities- 0/6. (Unwashed eyes) at Day 1 post-dose -Grade 3 (4/6) and -2(2/6) conjunctival irritation. At Day 7 post-dose -Grade 1 (1/6) conjunctival irritation. At Day 10 post-dose -No eye irritation.

B. ACUTE TOXICITY VALUE(LD50, LC50, etc):
NA

C. TOXICITY CATEGORY:
III

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). None **What are they and can they be corrected with additional information?** NA **Be specific:** NA

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? None **Are there any recommendations specific to this study?**
NA

MRID 436332-0

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

DEPARTMENT OF PESTICIDE REGULATION

MEDICAL TOXICOLOGY BRANCH

TOXICOLOGY STUDY EVALUATION WORKSHEET
(acute and special studies)

I. STUDY IDENTIFICATION

Active Ingredient: Chlorpyrifos
Formulated Product Name: MFG-CRCH-2
Chemical Code #: 253
SB 950 #: 221 **ID #:** 157123-EPAE
Document #: 342-571 **Record #:** 142558
EPA #: NA 51036-EUT
Study Type: 815 - Primary Dermal Irritation
Full Study Title: Primary Skin Irritation Study In Rabbits
Company Sponsor: Micro-Flo Company
Conducting Laboratory: Stillmeadow Incorporated, Sugar Land, TX
Report Date: September 9, 1994
Study Interval: July 19, 1994 to July 22, 1994

II. SUMMARY OF WORKSHEET

A. **STUDY STATUS: Is report complete?** No
Is study acceptable? Yes

- \- Meets EPA guidelines
- Yes Minor variances from guidelines
- \- Major variances from guidelines
- \- Could be upgraded with additional information (see VI-A)

- Yes Has useful data
- \- Insufficient data
- \- Non EPA validated study
- Other_____

B. **CONCLUSIONS: Does this study as reported demonstrate a possible significant adverse health effect?:** No **If so, in what area?** NA

C. **ONE LINER-One or two sentence summary of the study:**
342-571; 142558; Dermal Irritation; 815; rabbit; Stillmeadow Incorporated, Sugar Land, TX; 9/9/94; Lab. Study No.: 1368-94; MFG-CRCH-2 (tan colored granules); dermal dose of 500 mg/site (test material moistened with 1.10 ml of deionized water); 4 hours exposure period (semi-occluded); 6 rabbits tested; mortalities- 0/6; at 24 hours post patch removal -Grade 1 (3/6) erythema, at 72 hours post patch removal -No skin irritation; Toxicity Category IV; study acceptable. (Kahn, 12/5/95)

D. **ARE DATA ADEQUATE TO SUPPORT REGISTRATION (if applicable)?** Yes

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Charles Kahn
Associate Pesticide Review Scientist

12/6/95
Date

Staff Toxicologist

12-6-95
Date

III. PROTOCOL SUMMARY

A. ANIMALS, ROUTE OF ADMINISTRATION, AND DURATION OF TREATMENT:
Species: Rabbit
Strain: New Zealand White
Source of animals: Ray Nichols Rabbitry, Lumberton, TX
Age at start: Young Adults (3-6 months of age)
Route of administration: Dermal (semi occluded)
Vehicle: 1.10 ml of deionized water per dose
Period of treatment: Single (4 hour exposure)

B. BACKGROUND (including relationship of this study to other studies): NA

C. TREATMENT LEVELS AND GROUP SIZE:

	Units (mg/site)
# Rabbits:	500 / 6

	Mortality
# Dead Rabbits:	0

IV. STUDY DESIGN AND EVALUATION

A. TEST PROCEDURES AND REMARKS (e.g., OK, specific parameters; asterisks denote deficiencies, NA indicates not applicable or no comment).

1. **Test article:** MFG-CRCH-2 (tan colored granules)
* 2. **Analysis of dosing material:** Not reported
3. **Animal selection:** OK
4. **Animal husbandry:** Housed individually in suspended, wire bottom, stainless steel cages - Temperature 72±5°F and Relative Humidity 30-80%
5. **Mortality:** See III-C
6. **Number of animals:** See III-C
* 7. **Randomization of animals:** Not reported
8. **Dose level selection:** OK
9. **Route of administration:** OK
10. **Exposure conditions:** OK
11. **Controls:** OK
12. **Observations:** Observed for skin irritation at 1/2, 24, 48 and 72 hours post patch removal
13. **Necropsies:** Not required
14. **Appropriateness of methods:** OK
15. **Treatment of results:** OK
16. **Test report:** OK
17. **Consistency:** OK
18. **Good Laboratory Practice:** OK
19. **Other:** OK

B. ELABORATION OF METHODS OR PROTOCOL DESCRIPTION (if needed): NA

V. RESULTS

A. EFFECTS REPORTED:
Mortalities- 0/6. At 24 hours post patch removal -Grade 1 (3/6) erythema. At 72 hours post patch removal -No skin irritation.

B. ACUTE TOXICITY VALUE (LD50, LC50, etc):
NA

C. TOXICITY CATEGORY:
IV

VI. DISCUSSION

A. MAJOR DEFICIENCIES (if present). None **What are they and can they be corrected with additional information?** NA **Be specific:** NA

B. DISCUSSION OF RESULTS (if necessary). Were there significant adverse health effects? No **Are there any recommendations specific to this study?** NA

25 State of California

MRID 436332-0

PESTICIDE EVALUATION
Worker Health & Safety

Date: December 14, 1995

Phone: 324-3930

Subject: Product Name : Chlorpyrifos 2.5G
I.D. No. : EPA-157123E
EPA Reg. No. : 51036-~~0~~ EUT
Doc. No. : 342-571
Company : Micro-Flo Company
A.I. : Chlorpyrifos (2.5%)
Use : Insecticide

Recommendation : Register

Summary of Registration Request:

The proposed Section 3 Registration product is intended to control corn rootworms in corn. The product is to be applied at a rate of 8.0 - 10 pounds per acre (0.2 - 0.25 pounds active ingredient), or 10 to 12 ounces per 1,000 linear feet (0.25 - 0.3 ounces active ingredient) using ground based equipment to place the granules in a band over the seed row or to the base of plants just ahead of cultivation shovels.

Applicators and other handlers must wear: long-sleeved shirt and long pants, waterproof gloves, and shoes plus socks.

Dermal Sensitization:

Title: Dermal Sensitization Study in Guinea Pigs (DPR Rec. No. 142559)

Test Substance: MFG-CRCH-2 (Chlorpyrifos - 2.53% granules)

Test Animals: Hartley-Albino guinea pigs: 12 females and 12 males for range-finding and the test; 12 male and 12 female to test the positive control material.

Method: Modified Buehler - Following irritation screening to determine both the maximum dose producing no more than slight irritation, and the maximum non-irritating dose, five male and five female guinea pigs were treated with 400 mg of the granular test material moistened with deionized water. The animals were treated once weekly for a total of three treatments. After a two week rest, all 20 test animals were treated at a virgin test site with 400 mg of the test material moistened with 0.9 ml deionized water. Skin reactions were evaluated for irritation at 24 hours. In addition, the initial induction treatment and the challenge treatment were judged after 48 hours. Scoring was as follows: 0, 0.5, 1, 2, and 3; where 3 was equal to strong edema. DNCB was used as a positive control.

Conclusion: The test material did not elicit a skin reaction under conditions of the test.

Additional Data/Information Required: No

Labeling: The signal word, precautionary statements, health hazards, and protective equipment requirements have been reviewed. The labeling is acceptable.

Richard Bireley
(Assoc. Pest. Review Scientist)

James R. Sanborn
(Staff Toxicologist)

cc: Ann Prichard

SURNAME