

US EPA ARCHIVE DOCUMENT

3/30/93

DP Barcode : D184356
PC Code No : 128992
EEB Out :

To: Phillip Hutton
Product Manager 18
Registration Division (H7505C)

From: Anthony F. Maciorowski, Chief
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 001812-00327
Chemical Name : Finitron
Type Product : Insecticide
Product Name : Finitron Technical (GX-071 Technical)
Company Name : Griffin Corporation
Purpose : Submission of aquatic toxicity data in support of registration.

Action Code : 406 Date Due : 11/30/92
Reviewer : C. Laird Date In : 11/24/92

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)	424611-01 424611-02	P S	72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed)
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur

DP BARCODE: D184356

CASE: 004595
SUBMISSION: S425770

DATA PACKAGE RECORD
BEAN SHEET

DATE: 03/31/93
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 406 RESUBMISSION
CHEMICALS: 128992 Sulfluramid 98.5000%

ID#: 001812-00327 GX-071 TECHNICAL
COMPANY: 001812 GRIFFIN CORPORATION
PRODUCT MANAGER: 18 PHILLIP HUTTON 703-305-7690 ROOM: CM2 213
PM TEAM REVIEWER: MICHAEL MENDELSON 703-305-5409 ROOM: CM2 203
RECEIVED DATE: 09/02/92 DUE OUT DATE: 11/11/92

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 184356 EXPEDITE: N DATE SENT: 11/05/92 DATE RET.: / /
CHEMICAL: 128992 Sulfluramid
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 11/30/92 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	11/11/92	04/6/93
BRAN: EEB	11/24/92	03/30/93
SECT: RS2	11/24/92	03/30/93
REVR : CLAIRD	11/24/92	03/30/93
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

Attention Curtis Laird:

Attached are two fathead minnow studies. One study is on sulfluramid and the other is on a manufacturing impurity. Please review the studies and indicate whether the results would dictate the need for additional data, etc. for the current indoor and manufacturing use products. Thanks.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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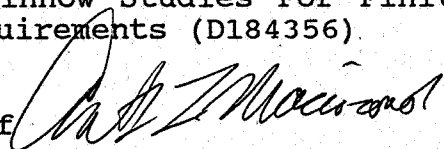


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 30 1993

MEMORANDUM

SUBJECT: EEB Review of Two Fathead Minnow Studies For Finitron Including Update of Data Requirements (D184356).

FROM: Anthony F. Maciorowski, Chief 
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

TO: Michael Mendelsohn, PM Team 18
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Ecological Effects Branch (EEB) has reviewed the two freshwater fish studies: one study on sulfluramid (now called Finitron) and the other one on a manufacturing impurity (the branched isomer). EEB has determined the following:

A. MRID No. 424611-01

This study is scientifically sound, but is classified supplemental; it supports the guideline requirement for a warmwater fish for an indoor use only. The study appears to indicate that the 96-hour LC₅₀ value for Finitron TGAI (96.7% linear, 3.3% branched) is > 10 ppm nominal ai (9.92 ppm measured ai). This study may meet the guideline requirement in support of registration of an outdoor or manufacturing use, but this is dependent upon the results of further aquatic testing and clarification of the TGAI being produced for manufacturing purposes.

Specifically: if further aquatic testing shows that 9-10 ppm measured ai is the maximum achievable solubility for Finitron; and the TGAI is representative of the TGAI produced during manufacturing, this study can be upgraded. It can then be used to support the guideline requirement for a warmwater fish for an outdoor use and a manufacturing use.

TGAI Issue: Clarification of the TGAI, including the ratio of linear and branched isomers, is required because the material tested does not fall within the certified limits for TGAI that appear on the confidential statement

of formula. This is critical because the toxicity of this TGAI varies with the ratio of linear and branch isomers present in the TGAI.

B. MRID No. 424611-02

This study is scientifically sound and is classified acceptable to support a guideline requirement for a warmwater fish (for Finitron as 100% ai branched isomer) for manufacturing, indoor, and outdoor uses. The study indicates the 96-hour LC₅₀ value for this material is 0.19 ppm measured ai. EEB did not require this study, and is not clear why this study was submitted.

Relative to other data gaps and requirements, EEB provides the following summary. However, note that the following discussion is based on the assumption that TGAIs tested in each study are representative of the TGAI produced during manufacturing.

1. Bobwhite Quail Acute Oral Study (MRID No. 406126-15): This study was classified supplemental in March, 1989. The study appears to indicate that the LD₅₀ value is 474 (357-2120) mg/kg ai for Finitron TGAI (identified as GX-071, Lot 4, 99% a.i. in the study). It supports the guideline requirement for an avian acute oral LD₅₀ study for an indoor use only. To support an outdoor use or manufacturing use another study using doses that better bracket the LD₅₀ (i.e., a series of doses which includes doses which produce > 50% mortality) is required.
2. Bobwhite Quail Dietary Study (MRID No. 406126-17): This study was classified supplemental in March, 1989. The study appears to indicate that the LC₅₀ value is 461 (381-794) ppm ai for Finitron TGAI (identified as GX-071, Lot 4, 99% ai in the study). It supports the guideline requirement for an avian dietary LC₅₀ study for an indoor use only. To support an outdoor use or manufacturing use either: (1) another upland gamebird dietary LC₅₀ study is required; or (2) chemical analyses data, which show nominal and actual concentrations are similar using the diet mixing technique described, are required.
3. Mallard Duck Dietary Study (MRID No. 406126-16): This study was classified core in March, 1989. The study indicates that the LC₅₀ value is 165 (100-316) ppm ai for Finitron TGAI (identified as GX-071, Lot 4, 99% ai in the study). It supports the guideline requirement for an avian dietary LC₅₀ study for indoor, outdoor, and manufacturing uses.

4. Rainbow Trout Acute (MRID No. 408475-01): This study was classified supplemental in March, 1989. The study appears to indicate that the 96-hour LC₅₀ value is > 10 ppm nominal ai (> 0.21 ppm measured ai) for Finitron TGAI (identified as GX-071, Batch # 10, % ai not given). It supports the guideline requirement for a coldwater fish LC₅₀ study for an indoor use only. To support an outdoor use or manufacturing use another study, using techniques that provide for maximum chemical dissolution (see attached guidance) and including chemical analyses, is required.
5. Daphnia Acute Study (MRID No. 408475-02): This study was classified supplemental in March, 1989. The study appears to indicate that the 48-hour EC₅₀ value is > 10 ppm nominal ai (> 2 ppm measured ai) for Finitron TGAI (identified as GX-071, 98% a.i.). It supports the guideline requirement for a freshwater aquatic invertebrate EC₅₀ study for an indoor use only. To support an outdoor use or manufacturing use another study, using techniques that provide for maximum chemical dissolution (see attached guidance) and including chemical analyses, is required.
6. Bobwhite Quail Dietary Study (MRID No. 417994-01): This study was classified core in September, 1991. The study indicates that the LC₅₀ value is 286 (156-625) ppm ai for Finitron TGAI containing 96.5% linear and 3.5% branched isomers. It supports the guideline requirement for an avian dietary LC₅₀ study (for this isomer ratio) for indoor, outdoor, and manufacturing uses.

In closing, EEB presents the following:

- 1) No further data are required to support an indoor (i.e., cockroach use) of Finitron.
- 2) Identification of the linear and branched isomer ratio is required for the following MRID Nos: 406126-15, 406126-16, 406126-17, 408475-01, and 408475-02. Further, the percent active ingredient is required for MRID No. 408475-01.

Additionally, all TGAIs tested must be representative of the TGAI produced during manufacturing. This is critical since the eco-toxicity of this TGAI varies with the ratio of linear and branched isomers present in the TGAI. We note that the ratio tested in the fathead minnow study (MRID No. 424611-01) does not match that stated in the confidential statement of formula provided with the submission from the Registration Division. The ratio tested matches more closely that proposed as a new isomer

ratio by the registrant when they tested bobwhite quail (MRID No. 417994-01).

- 3) There is only one acceptable study available to support indoor, outdoor, or manufacturing uses for Finitron TGAI containing linear and branched isomers ¹⁷. This study is the mallard duck dietary LC₅₀ study (MRID No. 406126-16).
- 4) To support the manufacturing use the following data are required:
 - i) Upland gamebird acute oral LD₅₀ study using TGAI (71-1);
 - ii) Upland gamebird dietary LC₅₀ study using TGAI (71-2) (unless acceptable chemical analyses data are submitted for the study reviewed in March, 1989) and the TGAI tested is representative of that manufactured.
 - iii) Coldwater fish 96-hour study using TGAI (72-1) and techniques that provide for maximum chemical dissolution (see attached guidance) and including chemical analyses;
 - iv) Freshwater aquatic invertebrate EC₅₀ study using TGAI (72-2) and techniques that provide for maximum chemical dissolution (see attached guidance) and including chemical analyses.
 - v) Warmwater fish 96-hour study using TGAI (72-1) and techniques that provide for maximum chemical dissolution (see attached guidance) and including chemical analyses unless the TGAI issue is resolved for the fathead minnow study (MRID No. 424611-01).
- 5) To support an outdoor use (i.e., fire ant use) the data outlined in (4) above are required as a minimum. Further ecological effects data may be required, but this will be determined during such a review.
- 6) The TGAI issue raised above is a major issue that requires resolution. If it is not satisfactorily resolved, then all ecological effects testing may have to be repeated using a TGAI representative of one produced during manufacturing.

1/ Providing the TGAI tested is representative of that manufactured.

If you have questions on the above, contact Curtis Laird or Norm Cook of my staff.

EEB Guidance for Toxicity Tests With
Poorly Soluble Materials (e.g., Finitron)

Existing OPP guidelines for aquatic toxicity tests require that chemicals be tested up to a maximum dissolved concentration of 100 ppm (mg/l) in an effort to obtain an LC₅₀ or EC₅₀. Current policy allows chemicals that are poorly soluble (solubility < 100 ppm) to be tested up to the maximum water solubility obtainable for the given test conditions employed, provided that certain prerequisites apply:

- 1) The technique used to maximize chemical dissolution in the test media under standard conditions for the test is justified. Consideration of the optimum techniques should include use of non-toxic solvents, saturation (solubility) columns, sonication, minor adjustments to environmental conditions (i.e., temperature, pH, etc.), etc., as appropriate. Minor adjustments should not extend outside the recommended range of conditions for the specific test organism.
- 2) Testing with a more soluble formulation (e.g., emulsifiable concentrate), if one exists, is provided in addition to testing with the technical-grade material. Testing with a more soluble formulation will not be required if it does not increase the solubility by 2X.
- 3) Measured concentrations of test media at appropriate intervals and from appropriate test chambers of all test levels are determined from centrifuged supernatant.

Studies that involve radical changes in environmental test conditions outside the recommended range of values for temperature, salinity, pH, etc. will be considered on a case-by-case basis.

Solubility is defined as the amount of chemical retained in the supernatant of a conventionally centrifuged sample of test media. This amount of test material is considered to represent a conservative measure of the most bioavailable fraction which may include some colloidal material not removed by centrifugation in addition to the truly dissolved fraction. A condition or mechanism is only considered to have increased solubility if the increase is two times or greater.

1. Chemical Name: F i n i t r o n (S u l f l u r a m i d ; N - Ethylperfluorooctanesulfonamide
2. Test Material: (100% C₈ Finitron; linear 96.7%, branched 3.3%)
3. Test Type: 96-hour LC₅₀ For a warmwater Fish

Test Species: Fathead Minnow (Pimephales promelas)

4. Study Identification: Hinman. M.L. (1992) MRD-92-209- (Sulfluramid)-Acute Toxicity Test With Fathead Minnows (Pimephales promelas); Project ID 120940; Prepared By Exxon Biomedical Sciences, Inc. for Griffin Corporation, Rocky Ford Road, Valdosta, Georgia 31601; MRID No. 424611-01.
5. Reviewed By:

Curtis E. Laird
Fishery Biologist
EEB/EFED

Signature: Curtis E. Laird
Date: 3-29-93

6. Approved By:

Norman J. Cook
Supervisory Biologist
EEB/EFED

Signature: Norman J. Cook
Date: 03-29-93

7. Conclusions:

The toxicity category for the fathead minnow was not established due to lack of mortality in all dosage levels tested. The highest level tested was 10 ppm a.i. nominal (9.92 ppm a.i. measured). This study may meet the guideline requirements in support of registration for an outdoor use, but this is dependent upon the results of further aquatic testing and clarification of the TGAI being produced for manufacturing purposes. Specifically, if further aquatic testing shows that 9 to 10 ppm measured a.i. is the maximum achievable solubility for Finitron, this study may be upgraded to core status for a warmwater fish species). Further, clarification of the TGAI, including the ratio of linear and branched isomers, is required because the material tested does not fall within the certified limits for TGAI that appear on the confidential statement of formula. This is critical since the toxicity of this TGAI varies with the ratio of linear and branched isomers present in the TGAI. However, this study can be used to support an indoor use only at this time.

Discrepancies found with this study are as follows:

- An LC₅₀ value was not achieved (see comment above concerning further aquatic testing).

- Fish were held for 4 days prior to testing instead of at least 14 days.
- Fish weight was 0.058 g instead of 0.5 to 5.0 g
- DMF solvent was not used at the maximum recommended level of 0.5 ml/L in the definitive study.
- The TGAI tested does not match the TGAI listed on the confidential statement of formula.

8. Recommendations:

The registrant should conduct coldwater and aquatic invertebrate studies using techniques that provide for maximum chemical dissolution.

9. Background:

This study was submitted to support registration and to determine if additional data will be required to support the current manufacturing and indoor use products.

10. Discussion of Individual Test: N/A

11. Material Tested:

A. Test Animals:

Test animals were 0.058g fathead minnows; standard length was 1.6 cm.

B. Test Design:

Fish were tested in 2 liters glass tanks; temperature was $25 \pm 1^{\circ}\text{C}$; photoperiod was 16L/8D; loading was 0.24 g/L.

C. Dose:

Twenty fish per dose level; five dosage levels plus negative and positive controls (0, DMF control, 1, 3, 6, 8, and 10 ppm nominal a.i.; 0, DMF control [0.3 ml/L], 1.04, 3.12, 6.06, 8.08, and 9.92 ppm measured a.i., respectively). Two rangefinding tests were done at nominal levels of:

Test 1: 40, 20, 10, 5, 1 ppm nominal ai, DMF control (0.3 ml/L), control

Test 2: 30, 20, 10, 5, 1 ppm nominal ai, DMF control (0.5 ml/L), control

Precipitates found in both tests at concentrations ≥ 10 ppm nominal ai. So the highest level chosen for the definitive study was 10 ppm nominal a.i.. Test solutions renewed every 24 hours.

D. Statistical Analysis:

No statistical method given for this study

12. Reported Results:

The study author found the 96-hour LC₅₀ to be greater than 10 ppm nominal a.i. (9.92 measured a.i.) the highest level tested. Fish were 7-8 weeks old at test initiation.

13. Study Author's Conclusion/OA Material:

The Quality Assurance Unit gave inspections dates but not the methods and procedures used.

14. Reviewer's Discussion And Interpretation of The Study:

A. Test Procedure:

The test procedure did not follow completely the recommended EPA protocol of October 1982. DMF solvent was not used at the maximum recommended level of 0.5 ml/L in the definitive study to establish an LC₅₀ value. Further, concentration measurement techniques varied from those recommended by ASTM (see 14. C. below); and TGA1 tested

B. Statistical Analysis:

No statistical method mentioned

does not match the TGA1
listed on the confidential
statement of formula.
N/Cook
3.25.93

C. Discussion/Result:

The 96-hour LC₅₀ value was not established. Therefore, the toxicity category remains unknown. Based on the available data it appears the 96-hour LC₅₀ value is > 10 ppm nominal a.i. (9.92 measured a.i.). Further, the reported measured concentration values do not completely represent measurements taken at the beginning and the end of the test in all test chambers (as recommended by ASTM). The measured values of 1.04, 3.12, 6.06, 8.08, and 9.92 ai are the average of "new" solutions taken on day 0 and day 3 pre-exposure. (see attached Appendix A, columns 2 and 4: e.g., $(9.34 \text{ ppm} + 10.5 \text{ ppm})/2 = 9.92 \text{ ppm}$). However, since these "averaged" values are similar to those of "old" values (see Appendix A, column 3: e.g., 9.18 ppm versus 9.92 ppm) and test solutions were renewed

every 24 hours, the lack of "beginning" and "end" concentration measurements is not deemed critical.

D. Adequacy of Study:

1. Category: Supplemental
 2. Rationale: See section 7 above
 3. Rationale: Possibly upgradeable to core for outdoor uses providing further aquatic toxicity testing, performed using techniques that provide for maximum chemical dissolution, indicates that 9-10 ppm measured a.i. is the maximum achievable solubility for Finitron. However, this study supports an indoor use only at this time. Further, the registrant must show that the TGA1 tested represents TGA1 being manufactured.
15. Completion of One-Liner: Yes
16. CBI Appendix: N/A

W/Cook
3.29.93

Sulfluramid

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Pages _____ through _____ are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
 - Description of quality control procedures.
 - Identity of the source of product ingredients.
 - Sales or other commercial/financial information.
 - A draft product label.
 - The product confidential statement of formula.
 - Information about a pending registration action.
 - FIFRA registration data.
 - The document is a duplicate of page(s) _____.
 - The document is not responsive to the request.
-

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

DATA EVALUATION RECORD

1. Chemical: TGAI-100% branched isomers of Finitron: N-ethyl-6-trifluoromethyl tetradecafluoro-1-heptanesulfonamide
2. Test Material: 100% C₈ Finitron a.i. as branched isomers), a white waxy solid
3. Test Type: 96-Hour LC₅₀ study for warmwater fish

Test Species: Fathead Minnow (Pimephales promelas)

4. Study Identification: Hinman, M.L. (1992) MRD-92-210, (N-ethyl-6-trifluoromethyl tetradecafluoro-1-heptanesulfonamide); Project No. 121040; Prepared by Exxon Biomedical Sciences, Inc. for Griffin Corporation, Rocky Ford Road, Valdosta, Georgia 31601; MRID No. 424611-02.

5. Reviewed By:

Curtis E. Laird
Fishery Biologist
EEB/EFED

Signature: Curtis E Laird
Date: 3-29-93

6. Approved By:

Norman J. Cook
Supervisory Biologist
EEB/EFED

Signature: Norman J. Cook
Date: 03.29.93

7. Conclusions:

This study indicates Finitron TGAI, as 100% branched isomers, is highly toxic to fathead minnow with an LC₅₀ of 0.19 ppm. This study would fulfill the guideline requirements in support of registration for a warmwater fish study for the material tested. However, at the time of this review there is no requirement for testing this material.

8. Recommendations: N/A

9. Background:

This study was submitted to determine the toxicity of TGAI as 100% branched isomers and if additional data will be required to support the current manufacturing and indoor use products.

10. Discussion of Individual Test: N/A

11. Material Tested:

A. Test Animals:

Test animals were 0.089g fathead minnow from Aquatic Research Organisms, Hampton, NH 03842; standard length was 1.9 cm.

B. Test Design:

Fish were tested in 5.2 liters glass tanks; temperature was $25 \pm 1^{\circ}\text{C}$; photoperiod was 16L/8D.

C. Dose:

Twenty fish per dose level; five dosage levels plus both negative and positive controls: 0, DMF control, 0.05, 0.10, 0.30, 0.60, and 1.00 ppm nominal a.i. (0, DMF control (0.05 ml/L]), (0, DMF, 0.0416, 0.0868, 0.262, 0.522, and 0.921 ppm measured a.i., respectively). A rangefinding test was done at nominal levels of: 40, 20, 10, 5, 1 ppm nominal ai, DMF solvent control, control.). Test solutions were renewed every 24 hours.

D. Statistical Analysis:

Probit analysis

12. Reported Results:

The study author found the 96-hour LC_{50} to be 0.189 (0.159 to 0.224) ppm based on mean measured concentrations. New solutions were prepared daily to replace approximately 75% of the test solution.

13. Study Author's Conclusion/OA Measures:

The Quality Assurance Officer stated this study meets the requirements of 40 CFR Part 160.

14. Reviewer's Discussion and Interpretation of The Study:

A. Test Procedure:

The test procedure generally complied with the recommended EPA protocol of October 1982. However, concentration measurement techniques varied from those recommended by ASTM (see 14. C. below)

B. Statistical Analysis:

The binomial test shows the 96-hour LC₅₀ to be approximately 0.19 ppm with 95% confidence limits of 0.0868 and 0.267 ppm.

C. Discussion/Result:

TGAI, as 100% ai branched isomers of Finitron, is highly toxic to fathead minnow with an LC₅₀ of 0.19 ppm. Note that the measured concentration values do not completely represent measurements taken at the beginning and end of the test in all test chambers (as recommended by ASTM). The measured values of 0.0416, 0.0868, 0.262, 0.522, and 0.921 ppm are the averages of "new" solutions taken on day 0 and day 3 pre-exposure (see attached Appendix A columns 2 and 4: e.g., $(0.947 + 0.895)/2 = 0.921$). However, since these "averaged" values are similar to those of "old" values (see Appendix A, column 3: e.g., 0.874 ppm versus 0.921 ppm), test solutions were renewed every 24 hours, and a dose response was achieved, the lack of "beginning" and "end" concentration measurements is not deemed critical.

D. Adequacy of Study:

1. Category: Core for testing with this material.
2. Rationale: N/A
3. Repairability: N/A

15. Completion of One-Liner: Yes

16. CBI Appendix: N/A

Laird GX-071 (MRD-92-210) 96-Hour LC50 For Fathead Minnow

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
.921	20	20	100	9.536742E-05
.522	20	20	100	9.536742E-05
.262	20	15	75	2.069473
.0868	20	0	0	9.536742E-05
.04	20	0	0	9.536742E-05

THE BINOMIAL TEST SHOWS THAT .0868 AND .262 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS .1946409

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

Sulfluramid

Page 18 is not included in this copy.

Pages _____ through _____ are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
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