

FILE

DP Barcode : D178396
PC Code No : 036101
EEB Out :

SEP 22 1992

To: WALTER WALDROP, (ATTN. T. STOWE)
Product Manager 71
Special Review and Reregistration Division (H7508W)

From: Douglas J. Urban, Acting Chief
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 036101
Chemical Name : TRIFLURALIN
Type Product : HERBICIDE
Product Name : TREFLAN
Company Name : DOWELANCO
Purpose : REVIEW REBUTTAL RE: TIER II AQUATIC PLANT
STUDY AND COMMENT ON REQUIREMENTS

Action Code : 629 Date Due : 8-4-92
Reviewer : Dana Lateulere

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)		
71-3			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)			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

Seismarium upgrade



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of Rebuttal from DowElanco regarding previous review of non-target plant studies with Trifluralin; updated EEB data requirements (including response to previous inquiry in action DP Barcode D174857, 2/12/90).

FROM: Douglas Urban, Acting Chief
Ecological Effects Branch
Environmental Fate and Effects Division

TO: Walter Waldrop, PM 71
Attn. Terri Stowe
Reregistration Branch
Special Review and Reregistration Division

Douglas Urban
4/17/92

EEB has reviewed the rebuttal submitted by DowElanco regarding previously submitted non-target plant studies. DowElanco wishes the Agency to reconsider the classification of invalid for MRID No. 419345-02, Aquatic Plant Toxicity, Selenastrum capricornutum. The study was classified as invalid because the measured concentrations at test termination had decreased to <5% of the initial levels. DowElanco states that constant concentrations of trifluralin cannot be attained under test conditions based on its rapid photo decomposition and dissipation in water. EEB has reconsidered the classification and has determined that the study will be upgraded to core.

EEB has statistically analyzed the data from the original study and has determined the following:

5 day EC50 = 7.52 ug/L
NOEC = 5.37 ug/L
LOEC = 11.7 ug/L

These values were determined using the mean of the initial (day 0) and terminal (day 7) measured concentrations in comparison with the solvent (acetone) control. Based on the afore mentioned chemical properties of trifluralin, the mean concentrations used may be conservative in determining the full degree of toxicity. DowElanco states the dissipation of trifluralin is "logarithmic". If that is the case, the actual concentration the algae was subjected to may have been lower than the mean measured concentrations. Thus, trifluralin may be more toxic to green algae than this study reports. However, as there is no way at this time to verify the concentrations from day 1 thru day 6, the mean measured concentrations will be used. In future risk assessments it will be necessary to consider the uncertainty of these test concentrations and thus the determined EC50, along with trifluralin's volatility.

The EEB data requirements will be upgraded to include this change. The following is a list of the outstanding data requirements for the reregistration of trifluralin as of 8/11/92:

#72-3 Acute Toxicity to Estuarine and Marine Organisms;

- a) Fish
- b) Mollusc

#72-a Vertebral lesion NOEC Study on Fish - this is a special circumstance test EEB has requested, a protocol has been submitted (see note for #72-b below).

#72-7b Actual Field Testing

(Note: DP Barcode D174857 (2-24-92) included MRID No. 413862-01-Daphnid Life Cycle and MRID No. 413862-02-Fish Early Life Stage requesting they be used as substitution for #72-7b Actual Field Testing. DowElanco was informed in previous reviews that neither these studies, nor the vertebral lesion study, may substitute for Field Testing. Field Testing may be required for reregistration pending review of the vertebral lesion study. The following reviews may be referenced for questions regarding EEB's stand on this issue:

Record No. 249501, submitted 7/28/89 reviewed by A. Buikema 8/15/89.

Record No. 257117, submitted 12/26/89 reviewed by A. Buikema 1/5/90.

These reviews pertained to protocol submissions for the vertebral lesion study - no other submissions have been received by EEB.)

#123-1 Tier 2 Seed Germination (cabbage and onion only)
Tier 2 Seedling Emergence

#123-2 Tier 2 Aquatic Plant Growth and Reproduction

The following species:

- Lemna gibba
- Skeletonema costatum
- Anabaena flos-aquae
- a freshwater diatom

(DowElanco questioned the need for further aquatic testing. In response, New Subdivision J, 158.470 Plant Protection Data Requirements states "herbicides applied aerially, by air blast, or through sprinkler irrigation to terrestrial food and terrestrial nonfood sites require testing on Lemna gibba, Skeletonema costatum, Anabaena flos-aquae and a freshwater diatom". Attached is an excerpt from the OPP REFS Database listing of trifluralin's uses, which include aerial application and irrigation systems as registered uses.)

Use patterns including aerial application require the following studies:

- #201-1** Droplet Size Spectrum
- #201-2** Drift Field Evaluation

Questions regarding this review, contact Dana Lateulere, 308-2856.

Walt

Quad III/2
April 23, 1992



Document Processing Desk (H7504C)
Office of Pesticide Programs (RS-179)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attention: Ms. Terri Stowe (H7508W)

RE: EPA Review of Non-Target Plant Studies with Trifluralin (RS-179)

In the Agency's letter of March 27, 1992 (attached), DowElanco was requested to do additional Tier II seed germination testing for cabbage and onions. DowElanco will consent to re-test these two crops under Guideline Reference No. 123-1A and provide the data to EPA by March 31, 1993.

The letter also stated that MRID No. 41934502 on Aquatic Plant Growth was deficient. The EPA review of this study (J00989) concluded that it was invalid because the concentrations of trifluralin at the end of the study were less than 5% of the initial concentrations. Since water samples were only collected at the beginning and end of the study for analysis of trifluralin, the EPA review concluded that the "actual" exposure concentrations could not be determined. This EPA conclusion is drawn for a study that was conducted according to EPA required guidelines and in which measured concentrations have not, in the past, been a routine or guideline requirement.

As is well documented, Trifluralin easily undergoes aqueous photolysis and rapidly dissipates from water. The conditions of the test systems for algae require illumination at $80 \mu\text{E}/\text{m}^2/\text{sec}$ in static solutions. Because of the rapid photo decomposition, constant concentrations of trifluralin cannot be attained under these conditions. That is the reason concentrations were measured in this study. Large sub samples of solution cannot, however, be taken from test containers during the study for analysis of trifluralin without destructively sampling the algae and, theoretically, altering the growth patterns of the algal populations.

A conservative estimate of exposure to trifluralin in this study was calculated by using the geometric mean of the initial and final concentrations measured in the test solutions at each treatment level. This assumes trifluralin dissipates in a logarithmic fashion, which is consistent with the type of dissipation from water due to photolysis found by Zepp and Cline (Environ. Sci. and Tech., Vol. 11, pp. 359-366; 1977). Assuming that the exposure pattern in the field and in the laboratory are similar, it may even be more accurate to conclude that the initial measured concentration at each treatment level is most appropriate for calculating the EC50 and no-effect concentration for this study. This study therefore provides a very conservative estimate for the potential toxicity of trifluralin to algae and should be acceptable for determining the effects of trifluralin concentrations in the field to algal populations.

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EPA Review of Non-Target Plant Studies with Trifluralin (RS-179)
April 23, 1992

Attention: Terri Stowe (H7508W)

Page Two

Over 99% of all concentrations of trifluralin found in water samples collected from the field are below 1 $\mu\text{g/L}$ (Meyerhoff and Francis, 1988, MRID No. 40809601) and over 98% are below 0.2 $\mu\text{g/L}$. The lowest trifluralin concentration (about 0.4 $\mu\text{g/L}$) measured at the end of this algal study in test vessels where no effects on algae were found is still higher than almost all trifluralin concentrations found in the field. Given that the EC50 for trifluralin in this study with Selenastrum capricornutum was 12.2 $\mu\text{g/L}$ and the no-effect concentration was 5.37 $\mu\text{g/L}$ based on the geometric mean of measured exposure concentrations (initial actual concentrations of about 167 and 78 $\mu\text{g/L}$, respectively), it is highly unlikely that concentrations of trifluralin found in the field would significantly affect algal populations.

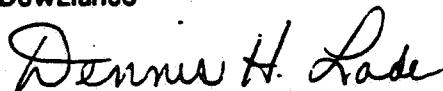
Another study with Selenastrum capricornutum and trifluralin is certainly not needed, particularly since this study was conducted using the EPA required guidelines. The safety factors associated with potential exposure of algae in the field should not trigger a requirement for additional Tier 2 studies.

Therefore, DowElanco believes additional studies are not warranted and desires the Agency to reconsider this request for an additional study. We propose a meeting to resolve this issue, at which DowElanco will be happy to present its case. Representing DowElanco at this meeting besides myself, will be Dr. Roger Meyerhoff.

If questions or comments, you may reach me at (317) 870-7269.

Sincerely,

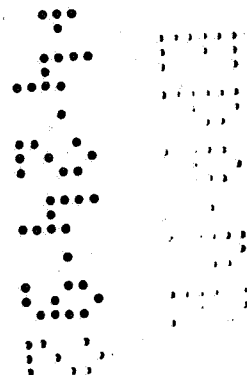
DowElanco



Dennis H. Lade, Ph.D.
Product Registration Manager

Attachment

DHL/taf
ltr5



Re. Aquatic fish study

BARCODE: D174857

REREG CASE #

CASE: 818802

DATA PACKAGE RECORD

DATE: 02/24/92

SUBMISSION: S412176

BEAM SHEET

Page 1 of 1

*** CASE/SUBMISSION INFORMATION ***

CASE TYPE: REREGISTRATION ACTION: 639 FLAGGED STUDY/IMM REVIEW
CHEMICALS: 036101 Trifluralin (a,a,a-trifluoro-2,6-dinitro-N,N-dipro 100.00 %

ID#: 036101

COMPANY:

PRODUCT MANAGER: 71 WALTER WALDROP

703-308-8062 ROOM: CS1 383

PM TEAM REVIEWER: TERRI STOWE

703-308-8043 ROOM: CS1 305

RECEIVED DATE: 02/12/90 DUE OUT DATE: 05/13/90

*** DATA PACKAGE INFORMATION ***

DP BARCODE: 174857 EXPEDITE: Y DATE SENT: 02/24/92 DATE RET.: / /

CHEMICAL: 036101 Trifluralin (a,a,a-trifluoro-2,6-dinitro-N,N-dipropyl-p-tol

DP TYPE: 001 Submission Related Data Package

ADMIN DUE DATE: 05/24/92

CSF: N

LABEL: N

ASSIGNED TO DATE IN

DATE OUT

DIV : EFED

BRAN: EEB

SECT:

REVR :

CONTR:

*** DATA REVIEW INSTRUCTIONS ***

Please review Trifluralin data for GLN 72-4a Fish Early Life Stage (MRID 41386202) and GLN 72-4b Life Cycle Invertebrate (Aquatic) (MRID 41386201). DowElanco is submitting this data to substitute for the GLN 72-7b Actual Field Testing - Aquatic Organisms study. Please review as soon as possible so that the registrant can be informed as to the status of this surrogate data. Please send a copy of the review to: Terri Stowe

SRRD/RB (H7508W)

Crystal Station I - 3rd floor

THANK YOU!!!

For the attached reregistration case, please identify all applicable data requirements and note those for which adequate data have not been submitted to the Agency.

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

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

Original review did not address this question.

Total Count of Sites = 541

Cont'd.

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# STATUS °SITE CODE°SITE NAME
#aaaaaaaaaéàaaaaaaaaaéàaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaa
# ACTIVE° 68000 °WIDE AREA AND GENERAL INDOOR/OUTDOOR TREATMENTS (ALL/UNSP
# ACTIVE° 68009 °FENCEROWS OR HEDGEROWS (ALL OR UNSPECIFIED)
# ACTIVE° 77002 °COMMERCIAL, INSTITUTIONAL OR INDUSTRIAL EQUIPMENT
# ACTIVE° 89003 °GARBAGE DUMPS
# ACTIVE° 90008 °CABLES (UNDERGROUND) (FOR VERTEBRATE PESTS ONLY)
# ACTIVE° 90015 °AERIAL APPLICATION
# ACTIVE° 90016 °NO SITE. USE WHEN NO SITE IS ASSOCIATED WITH PESTS
# ACTIVE° 90022 °ULTRA LOW VOLUME (ULV) APPLICATION
# ACTIVE° 99000 °PESTICIDES FOR MANUFACTURING, REFORMULATING OR REPACKAG U
# ACTIVE° 99001 °PESTICIDE PRODUCTS FOR FORMULATION OF OTHER PRODUCTS
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