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To: LOIS ROSSI PM 70
Product Manager
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 # : 012301 REREG CASE NO: 0041 LIST A
Chemical Name : BROMACIL AND BROMACIL LITHIUM SALT
Type Product : HERBICIDE
Product Name :
Company Name : DUPONT
Purpose : REVIEW REQUEST FOR WAIVER OF ECO-TOX TESTING
WITH BOTH BROMACIL AND BROMACIL LITHIUM SALT, REGISTRANT
ASSERTS TESTING WITH ONE SHOULD SUFFICE FOR THE OTHER
Action Code : 614 Date Due : 3-24-92
Reviewer : RIEDER Date In : 7-7-92

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)		
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

Fate Review attached



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

AUG 4 1992

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Request for Waiver of Certain Data for
Bromacil and Bromacil Lithium Salt D173923

FROM: Douglas J. Urban, Acting Chief
Ecological Effects Branch
Environmental Fate and Effects Division H7507C 7/31/92

TO: Mario Fiol PM 73
Reregistration Branch
Special Review and Reregistration Division H7508W

BACKGROUND

This memorandum amends, and adds to, the information and conclusions presented in the EEB memorandum from Douglas Urban to Mario Fiol dated April 6, 1992.

The registrant of Bromacil, Dupont, is requesting that EEB consider the environmental behavior of bromacil lithium salt and bromacil acid in deciding whether ecological toxicity testing from one would suffice for the other. They claim that in the environment, in the stomachs/crops of animals and even in water of a spray tank, bromacil lithium salt is immediately converted to the un-ionized bromacil. Therefore, they contend that testing with un-ionized bromacil will adequately characterize the toxicity of both bromacil and bromacil lithium salt.

In addition, DuPont is modifying the label for Bromacil to avoid use sites with high potential to result in aquatic exposure. In return, they hope to avoid the following fate data requirements:

- 162-4 Aerobic Aquatic Metabolism
- 164-2 Aquatic Field Dissipation
- 165-3 Accumulation in Irrigation Crops
- 165-5 Bio-accumulation in Nontarget Organisms

DISCUSSION

Applicability of Data

The EEB defers questions of environmental fate of chemicals to the EFGWB. The EFGWB agrees that the bromacil lithium salt converts very quickly to bromacil such that in water and soil, the ingredient to which nontarget organisms would be exposed would be bromacil, regardless of what was applied.

However, with regard to comparisons of the toxicity of these two chemicals to birds, in addition to depending on the likelihood that in the crop of birds the conversion would be immediate, EEB accessed the Toxicology Branch mammal data for the two chemicals. Based on those data, it is apparent the two chemicals are similar in their toxicity to mammals. This tends to support the registrants position.

The rationale discussed above supports a decision to allow aquatic testing (plant and animal) and bird testing with bromacil to suffice for bromacil lithium salt. Thus the following tests would only have to be done using one active ingredient (bromacil or bromacil lithium salt) and the results would be used to characterize risk for the other.

Guideline No. Study Type

71-1(a)	avian acute oral
71-2(a)	avian dietary, upland gamebird
71-2(b)	avian dietary, waterfowl
72-1(a)	fish acute, warmwater species
72-1(c)	fish acute, coldwater species
72-2(a)	aquatic invertebrate acute
72-3(a)	estuarine/marine fish acute
72-3(b)	estuarine/marine mollusk acute
72-3(c)	estuarine/marine shrimp acute
123-2	aquatic plant testing

The question remains concerning the potential that the two active ingredients elicit different responses from terrestrial plants in spite of this quick change from the bromacil lithium salt to the bromacil. The EEB is not, at this time, waiving the terrestrial plant test requirements (123-1 a and b). However, we are willing to consider efficacy data showing the similarities of the two active ingredients in their effect on weed species. Efficacy tests should be submitted on each weed species for which both active ingredient is considered to be efficacious. The submission of these efficacy studies should be accompanied by an **Assessment of Efficacy Tests which summarizes the efficacy test results** for both active ingredients. If the available information

indicates that bromacil and bromacil lithium salt are similar in phyto-toxic properties, 123-1 testing for one of the chemicals may be waived in lieu of testing with the other. If such similarity cannot be demonstrated, then terrestrial plant testing with both chemicals would be required.

In lieu of summarizing and submitting efficacy tests, the registrant may conduct the required (123-1 a and b) terrestrial plant tests with both bromacil and bromacil lithium salt.

Label Modifications

According to EFGWB, the fate data are not required provided that bromacil products are not applied in close proximity to aquatic habitat as the registrant claims. One concern for EEB, and which was previously addressed in the EFGWB memorandum dated July 17, 1992 is that certain wording on the proposed label seems to contradict the guidance which precludes application in close proximity to water. Under BRUSH CONTROL the guidance reads, "It is permissible to treat the berm of ditches, seasonally dry flood plains, deltas, marshes, swamps, bogs, and transitional areas between upland and lowland sites." Deletion of this sentence would eliminate the apparent contradiction.

Under NON-CROP USE WEED CONTROL: The wording should be changed to: "Do not apply to open water (such as lakes, reservoirs, rivers, streams, creeks, salt water bays or estuaries) nor while water is present in fresh water wetlands (such as marshes, swamps, bogs or potholes) nor to salt marshes within tidal areas nor to ditches, steep banks along waterways or impervious substrates nor to areas near desirable plants where roots of these plants may extend."

Under ENVIRONMENTAL HAZARDS, the statement should read: "Do not apply directly to water, areas where surface water is present or to intertidal areas below mean high water mark. Do not contaminate water by when disposing of equipment washwater."

Waiving Fate Data

The EEB concurs with EFGWB decision to not require the 4 fate studies listed below.

- 162-4 Aerobic Aquatic Metabolism
- 164-2 Aquatic Field Dissipation
- 165-3 Accumulation in Irrigation Crops
- 165-5 Bio-accumulation in Nontarget Organisms

This does not imply that EEB concludes that Bromacil will never reach surface water. It does mean that estimating exposure in such waters will be done with data available from other fate studies.

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SUMMARY

Most eco-tox data do not have to be obtained for both bromacil and bromacil lithium salt. Testing with one will suffice for the other. The exceptions are 123-1 (a & b) terrestrial plant testing. The registrant has the option of submitting available information on the phyto-toxic characteristics of each (bromacil and bromacil lithium salt) or performing the 123-1 terrestrial plant tests with both chemicals.

Certain label wording contradict the apparent claim that use in close proximity to surface water is prohibited. Deleting such wording will eliminate the apparent contradiction. See the attached memorandum from EFGWB dated July 17, 1992.

The ENVIRONMENTAL HAZARD statement must be changed as indicated. This is a reiteration of the required modification in the April 6, 1992 EEB memorandum.

The EEB concurs with EFGWB's decision to waive these fate studies: 162-4, 164-2, 165-3, and 165-5. Note that, according to the EFGWB memorandum, this waiver is conditioned on the deletion of the wording that allows application of bromacil to berms of ditches, seasonally dry flood plains, deltas, marshes, swamps, bogs and transitional areas between upland and lowland sites.

If you have questions concerning this waiver response, please contact Dan Rieder 305-5314.



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DP Barcode: D173915, D176273
EFGWB #: 92-0481, 92-0690
PC Code: 012301, 012302

SUBJECT: Bromacil and its Lithium Salt- Label Amendment and Data Waiver Requests submitted by E.I. Du Pont de Nemours and Company. Letters dated October 11, 1990 and January 16, 1992 respectively.

FROM: Dana S. Spatz, Chemist
Chemistry Review Section #2
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

TO: Lois Rossi, Chief
Reregistration Branch
Special Review and Reregistration Division (H7508W)

THRU: Emil Regelman, Supervisory Chemist
Chemistry Review Section #2
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Henry Jacoby, Chief
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

JUL 17 1992

Du Pont has requested data waivers for several Environmental Fate data requirements and has submitted a label amendment request. EFGWB has the following conclusions on each of these requests.

A. WAIVER OF ALL DATA REQUIREMENTS FOR THE LITHIUM SALT OF BROMACIL

It is Du Pont's position that in the environment, the lithium salt of bromacil does not exist as such under normal conditions because the lithium salt is protonated to form un-ionized bromacil in the pH 2 to 9 range. The pKa of bromacil is 9.1 and the solubility at pH's of environmental significance is 815 ppm.

EFGWB concurs with this assessment and agrees that studies conducted with bromacil can also serve to satisfy the environmental fate data requirements for the lithium salt. The data requirements for the lithium salt should not be waived, but should remain in effect until satisfied by studies conducted with bromacil.

*when are the
revisions to be
completed?
what will (may)
occur.*

*in ~~the~~ case bromacil
falls out, then we still
have lithium bromacil
hooked-up*

6

B. WAIVER OF THE ACCUMULATION IN CONFINED ROTATIONAL CROPS (165-1) DATA REQUIREMENT

It is Du Pont's position that since alternate crops are not rotated in pineapple or citrus groves, this data requirement does not apply.

This data requirement should be reserved. The only bromacil food crop registrations at this time are citrus and pineapple. These crops are not typically rotated, therefore the data requirement does not apply. However, should additional registrations on other crops be sought in the future, an assessment must then be made if the Accumulation in Confined Rotational Crops study is needed.

C. WAIVER OF THE LONG-TERM SOIL FIELD DISSIPATION (164-5) DATA REQUIREMENT

It is Du Pont's position that the soil field dissipation study (MRID 41677101) shows that there is no need for a long term soil dissipation study.

Because the soil field dissipation study is currently under review within the Branch, EFGWB cannot, at this time, draw any conclusions based on that data. However, for compounds such as bromacil, which are persistent (and could trigger the Long-Term Field Dissipation data requirement), and also show a tendency to leach, EFGWB has been favoring the Ground Water Monitoring studies to provide the information necessary to address concerns about the potential for the pesticide and/or its degradates to contaminate ground water. Therefore, the Long-Term Field Dissipation data requirement may be waived.

D. LABEL REVISION REDEFINING WETLAND AREAS AND EXCLUDING THE USE OF BROMACIL ON AQUATIC SITES

With the label revision, Du Pont has attempted to; 1) provide a definition of wetlands and 2) exclude the use of the herbicide from the inside of drainage ditches and any other body of water. One of Du Pont's goals with the label revision was to eliminate any use that triggered environmental fate aquatic studies.

EFGWB concurs with the conclusions made in the Agency letter dated December 6, 1990 from Robert Taylor (PM 25) to Ian Wellings (Du Pont) concerning the application for the amended label. However, there is a concern about a particular statement that was added to the label. It is not apparent from the label statement on page 3 of the HYVAR X label under the Brush Control section which states:

"It is permissible to treat the berm of ditches, seasonally dry flood plains, deltas, marshes, swamps, bogs and transitional areas between upland and lowland sites."

that all uses which trigger aquatic studies have been eliminated. With this statement on the label, the imposed aquatic data requirements (162-4, 164-2, 165-3, and 165-5) should remain in effect. If this statement is removed, then these data requirements can be waived.

As for the ground water statement currently in the Environmental Hazards section of the label, EFGWB recommends that it be replaced with the following label statement:

Should be removed?

GROUND WATER ADVISORY

"Bromacil is known to leach through soil and has been found in ground water as a result of normal field use. Users are advised not to apply in areas where soils are permeable, particularly where ground water is used for drinking water. Consult with the pesticide state lead agency for information regarding soil permeability and aquifer vulnerability in your area."

E. WAIVER OF THE AEROBIC AQUATIC METABOLISM, AQUATIC FIELD DISSIPATION, ACCUMULATION IN IRRIGATED CROPS, AND BIOACCUMULATION IN AQUATIC NON-TARGET ORGANISMS STUDIES

See discussion above.

RIN 6995-94

Page _____ is not included in this copy.

Pages 9 through 13 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.
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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.

BROMACIL
SOLUBILITY VS PH

