

4-6-92

DP Barcode : D176254
 PC Code No : 012301
 EEB Out : APR 6 1992

To: MARIO FIOL
 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 # : _____
 Chemical Name : BROMACIL
 Type Product : _____
 Product Name : _____
 Company Name : DUPONT
 Purpose : REVIEW AND COMMENT ON PROPOSED MODIFICATION TO
 WORDING OF PRECAUTIONARY STATEMENT ON LABEL

Action Code : 642 Date Due : 5-29-92
 Reviewer : DAN RIEDER

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



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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

ADD 6 1002

SUBJECT: Request for Modification to Precautionary Label
Statements, and Waiver of certain Fate Data for
Bromacil and Bromacil Lithium Salt 0176254

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

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

The registrant of Bromacil, DuPont, has requested to modify the wording on their label for HYVAR X. They also have indicated that they propose to alter the usage of Bromacil in an effort to eliminate the need for some environmental fate testing requirements.

PROPOSED PRECAUTIONARY LABEL STATEMENT MODIFICATION

The proposed precautionary wording of the proposed label appears in several different places:

1. Under ENVIRONMENTAL HAZARDS it states: "Do not apply to open water nor to swamps, bogs, marshes or potholes while water (other than casual water) is present. Do not contaminate water by cleaning of equipment or disposal of wastes."
2. Under NON-CROP USE WEED CONTROL it states: "Do not apply to open water (such as lakes, reservoirs, rivers, streams, creeks, salt water bays or estuaries) not while water is present in fresh water wetlands (such as marshes, swamps, bogs or potholes) nor to salt marshes within tidal within tidal areas nor to areas where the herbicide is likely to move into water (such as ditches, steep banks along waterways or impervious substrates) nor to areas near desirable plants where roots of these plants may extend."



The EEB does not concur with these statements on the proposed label. The following is the recommended wording:

1. Under ENVIRONMENTAL HAZARDS: "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."

2. Under NON-CROP USE WEED CONTROL: There should be no precautionary statement here. The EEB emphatically recommends against wording such as, "Do not apply...to areas where the herbicide is likely to move into water" since that assumes that it is possible to apply this herbicide in areas that will not result in transport to water and that a user should be able to identify these areas.

REDUCTION IN USAGE TO AVOID CERTAIN FATE STUDIES

The registrant is proposing to eliminate the current use of Bromacil in drainage ditches to control undesirable woody plants. They request that this be justification to waive 4 of the environmental fate studies requested in The proposed label does retain the use on non-cropland areas such as RAILROAD, HIGHWAY AND PIPELINE RIGHTS-OF-WAY, PETROLEUM TANK FARMS, LUMBERYARDS, STORAGE AREAS AND INDUSTRIAL PLANT SITES. In addition, Bromacil would be used on citrus and pineapple.

The studies in question here are:

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

These studies primarily relate to fate of Bromacil in aquatic habitats. Because of it's solubility and use in close proximity to aquatic habitat, it is expected that exposure to aquatic organisms will occur.

The EEB has reviewed data on Bromacil and has determined that it has low toxicity to fish and aquatic invertebrates. Therefore, it is unlikely that the proposed uses will adversely impact to these organisms.

<u>MRID</u>	<u>STUDY TYPE</u>	<u>T.M.</u>	<u>RESULTS</u>	<u>CATEGORY</u>
41588703	MOLLUSK E.L.	95.1%	48 HR EC50=130 PPM	SUPPL
41588702	SHEEPSHEAD MINN	95.1%	96-HR LC50=162 PPM	CORE
41588601	SHRIMP	95.1%	96-HR LC50=112 PPM	CORE
40951502	BLUEGILL	95%	96-HR LC50=127 PPM	CORE
40951503	RAINBOW TROUT	96.6%	96-HR LC50=36 PPM	SUPPL
40951504	DAPHNIA MAGNA	96.6%	48-HR EC50=119 PPM	CORE

However, Bromacil does represent a potential hazard to aquatic and terrestrial plants. In that regard, the environmental fate information typically derived from 162-4 Aerobic Aquatic Metabolism and 164-2 Aquatic Field Dissipation would be useful in estimating amount and duration of exposure to plants. According to the July 19, 1989 EEB Inventory Summary Sheet for Bromacil, TIER II terrestrial (123-1) and aquatic (123-2) plant testing is required. These studies will provide the phyto-toxicity data for assessing hazard to non-target plants.

SUMMARY

The EEB recommends specific changes to the proposed precautionary label statements and notes the need for environmental fate information typically derived from the following EFGWB studies:

162-4 Aerobic Aquatic Metabolism
164-2 Aquatic Field Dissipation

If you have questions, please contact Dan Rieder.

NOTE TO PM: The question was posed whether the same comments on labeling and need for environmental fate information apply to Bromacil lithium salt.

1. Generally, if EFGWB considers these chemicals to be different chemically, EEB would assess them differently and the environmental fate data needed for Bromacil would also be needed for Bromacil lithium salt.

2. Whether EFGWB considers them to be the same chemically or not, the recommendations on labeling applies to both Bromacil and Bromacil Lithium Salt.

3. The question was not posed, nor has it been addressed as to whether phyto-toxicity data for Bromacil would suffice for, or apply to Bromacil lithium salt.

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

RECEIVED

DEC 14 1990

DU PONT COMPANY

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Ian Wellings, Ph.D.
Agricultural Products
P.O. Box 80038
Wilmington, DE 19880-0038

DEC - 6 1990

Dear Dr. Wellings:

Subject: "Hyvar" X Herbicide
EPA Reg. No. 352-287
Re: Application for amended registration
Your letter dated October 11, 1990

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. Please submit five (5) of your final printed labels incorporating these changes before distributing your product.

1. Revise your "Environmental Hazards" Statement to read "Do not contaminate water when disposing of equipment washwaters".
2. Remove "other than casual water" from "Environmental Hazards Statement".

Bromacil

Bromacil lithium Salt

Sincerely,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (H7505C)

5



AGRICULTURAL PRODUCTS
Walker's Mill, Barley Mill Plaza
P.O. Box 80038
Wilmington, Delaware 19880-0038

October 11, 1990

Mr. Robert J. Taylor
Product Manager (25)
U. S. Environmental Protection Agency
Office of Pesticide Programs
Document Processing Desk (H 7505C)
401 M Street, SW
Washington, D.C. 20460

SUBJECT: Application for Amended Registration
Revised Package Label for "Hyvar" X Herbicide
EPA Reg. No. 352-287

Dear Mr. Taylor:

Accompanying this letter is an application for registration of a revised package label for "Hyvar" X Herbicide. The label revisions can be described under the following two main headings:

I. Revisions Aimed at Redefining Wetland Areas

- The following revised statement has been used in the "Precautionary Statements" section of the label under the "Environmental Hazards" heading:

"Do not apply directly to open water nor to swamps, bogs, marshes or potholes while water (other than casual water) is present."

This statement replaces the sentence in the currently registered "Hyvar" X Herbicide label which reads:

"Do not apply directly to water or wetlands."

- Further clarification of the proposed exclusions has been provided in the first paragraph of the section on "Non-Crop Use" under "Weed Control" on page 2 of the label.

This addition to the paragraph states:

"Do not apply directly 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 water marshes within tidal areas nor to areas where the herbicide is likely to move into water (such as the insides of ditches, steep banks along waterways or impervious substrates) nor to areas near desirable plants where roots of these plants may extend."

- After having provided the user with the above restrictions to the use of this product in aquatic areas, specific sites that may be treated are listed on page 3 in the "Brush Control" section under the "Broadcast Treatment" paragraph. The footnote to this section states that:

"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."

The objective of the revised "Wetlands" statement is to define, more specifically, restricted areas such as open water or wetlands when they are flooded. The restrictive language clearly prohibits the use of "Hyvar" X Herbicide in open water areas and forbids the direct or indirect addition of this product to surface waters. The exclusions have been further defined by describing specific open water sites, seasonally flooded wetlands, tidal areas, steep banks and impervious substrates from which the herbicide may move. It is important to understand that only limited areas of non-crop sites are treated with "Hyvar" X for weed and brush control. The total site does not receive herbicide treatment.

An effort has been made to design a more complete and user-friendly label by not only telling the user where he cannot apply the product, but by listing specific sites that may be treated. Justification for usage on these sites is based on the low toxicity of bromacil to animals.

II. Revisions Excluding the Use of Bromacil on Aquatic Sites

In the currently registered label under the section on "Brush Control", "Hyvar" X Herbicide is recommended for use in drainage ditches to control undesirable woody plants. Based on this use, the Agency has considered "Hyvar" X Herbicide and the related "Hyvar" XL Herbicide (EPA Reg. No. 352-346) and "Hyvar" DF Herbicide (EPA Reg. No. 352-546) to be formulations that have an aquatic use pattern. As a consequence of this use pattern, the Agency has requested a number of aquatic studies to be conducted to support the continued use of bromacil, the active ingredient in the "Hyvar" products, in drainage ditches. Most of these requests have been made as part of the Registration Standard for bromacil.

FATE STUDIES

- 62-4 Aerobic Aquatic
Metabolism
- 64-2 Aquatic Field
Dissipation
- 65-3 Accumulation in
Irrigation Crops
- 65-5 Bio-
Accumulation
Mutagen

Mr. Robert J. Taylor
page 3

The drainage ditch use has been removed from the revised "Hyvar" X Herbicide label, and will shortly be removed from the labels for "Hyvar" XL Herbicide and "Hyvar" DF Herbicide. Once this use has been removed, there will no longer be a use recommendation in effect for these bromacil products that triggers the need for aquatic studies. A specific request will be filed with the Special Review and Reregistration Division of the Agency asking that the requirements to generate the aquatic studies be waived in view of the label changes.

The revised "Hyvar" X Herbicide label is being used as a model for the proposed changes in the definition of wetlands and for the exclusion of the herbicide from the inside of drainage ditches. Once the Agency has approved these changes in their present form or in a modification of the present wording, we will proceed to revise the other relevant bromacil labels to make them consistent with the accepted version of the "Hyvar" X label.

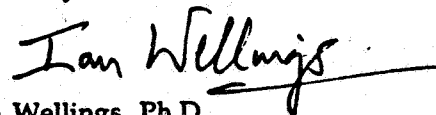
*refers to
bromacil
within salts*

In order to complete this submission, the following items are attached:

- A filled out EPA Form 8520-1, Application for Pesticide Amendment.
- The proposed revised label for "Hyvar" X Herbicide coded as D-080790/081390. Six (6) copies of the label are included with changes highlighted on one (1) copy.

Please note that in this proposed amended labeling for "Hyvar" X Herbicide, there are no revisions that include new crop uses or upward changes of rate.

Sincerely,



Ian Wellings, Ph.D.
Registration Specialist
Registration & Regulatory Affairs

cc: Mr. Philip T. Hundemann
Review Manager - EPA
Special Review & Reregistration Division

IW/pjb:2



RIN 6995-94

EEB BROMACIL REVIEW

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.

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.