

US EPA ARCHIVE DOCUMENT



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4-19-94

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: Modification to Precautionary Label Statements for
Hyvar L (EPA Reg. No. 352-425) and Hyvar X-L (EPA Reg.
No. 352-346)

From: *mf* Anthony F. Maciorowski, Chief *Joanne Edwards 4/19/94*
Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

To: Mario Fiol, Chemical Review Manager
Special Review and Reregistration Division (7508C)

The EEB has reviewed the proposed precautionary wording on the draft product labels referenced above. There is no objection to the proposed wording, as it complies with current Agency directive (PR Notice 93-3). The objectionable wording "Do not apply.. to areas where the herbicide is likely to move into water", has been removed. The EEB recommends against such wording since this assumes that it is possible to apply the herbicide in areas that will not result in transport to water and that a user should be able to identify these areas.

SRRD has asked that EEB review the labels and determine if the requirements for aquatic studies can be waived. EEB's position on data requirements for bromacil is unchanged (see previous EEB reviews). EEB cannot comment on "..developments in Florida which have required the company's rethinking of them.", since we have no background information.

If you have any questions, please contact Joanne Edwards. She may be reached at (703) 305-6736.



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CONCURRENCES

SYMBOL	7507C	7507C	7507C				
SURNAME	JSE	JOHNSON	[Signature]				
DATE	4/12/94	4/19/94	4/19/94				

RIN 6995-94

BROMACIL EEB REVIEW

Page is not included in this copy.

Pages 3 through 6 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.



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

RECEIVED
OCT 04 1993

DU PONT COMPANY

SEP 30 1993

Mr. Ian Wellings
E.I. DuPont de Nemours & Company
Agricultural Products
P.O. Box 80038
Wilmington, DE 19880-0038

Dear Mr. Wellings:

Subject: DuPont Hyvar XL Herbicide (Label Revising Active Ingredient Statement)
EPA Registration No. 352-346
Your Application Dated May 11, 1993

The scientific review and evaluation of the label submitted above have been completed. The following are our conclusions and/or comments.

1. The CSF dated January 15, 1993 for the alternate formulation must be revised as follows.

a. The active ingredient in your product is the lithium salt of bromacil,



Note that the label claim should agree with the nominal concentration as required in PR Notice 91-2.

b. The upper and lower limits for bromacil/lithium salt should be calculated on the basis of the nominal concentration in accordance with 40 CFR 158.175(b)(2).

c. The CSF dated January 15, 1993 should be revised and patterned after the enclosed sample CSF.

2. The CSF for the basic formulation should be updated using EPA Form 8570-4 (Rev 12-90). Certified limits should be specified for all components in the formulation. As required in 40 CFR 152.43, alternate formulations must have the same certified limits for each active ingredient as the basic formulation.

3. The labeling must be revised as follows:

a. The label ingredient statement should be revised as follows:

ACTIVE INGREDIENT

*Lithium Salt of Bromacil (5-bromo-3-sec-butyl-6-methyluracil)---21.9%

INERT INGREDIENTS-----78.1%

Total 100.0%

*Equivalent to 21.4% Bromacil. 1 gallon contains 2 pounds bromacil

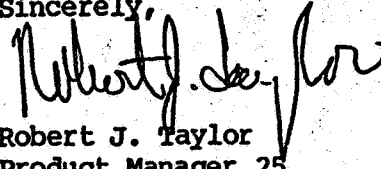
MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

b. Delete the following statement located directly above the ingredient statement: "1 GALLON CONTAINS 2 POUNDS BROMACIL."

c. The terms "ACTIVE INGREDIENT" and "INERT INGREDIENTS" as listed in the ingredient statement should be equally prominent.

Please submit revised labeling and a revised confidential statement of formula for our review.

Sincerely,



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

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EEB BROMACIL REVIEW

Page _____ is not included in this copy.

Pages 9 through 13 are not included.

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