

US EPA ARCHIVE DOCUMENT



105001
SHAUGNESSEY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 12-19-85 OUT 2/17/86

FILE OR REG. NO. 241-238

PETITION OR EXP. NO. _____

DATE OF SUBMISSION 11-18-85

DATE RECEIVED BY HED 12-16-85

RD REQUESTED COMPLETION DATE 2-21-86

EEB ESTIMATED COMPLETION DATE 2-17-86

RD ACTION CODE/TYPE OF REVIEW 305

TYPE PRODUCTS(S) : I,D,H,F,N,R,S Insecticide

DATA ACCESSION NO(S) 260452

PRODUCT MANAGER NO. W. Miller (16)

PRODUCT NAME Counter 15 G

COMPANY NAME American Cyanamid

SUBMISSION PURPOSE Proposal to change the label for sugar

- beets: 1) decrease rate for added wireworms;
- 2) add "knifed in" application for cyst nematodes.

SHAUGNESSEY NO.	CHEMICAL & FORMULATION	% A.I.
<u>105001</u>	<u>terbufos - granular</u>	<u>15</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____

9 pages

SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

DATE IN 12-19-85 OUT

FILE OR REG. NO. 241-238

PETITION OR EXP. NO.

DATE OF SUBMISSION 11-18-85

DATE RECEIVED BY HED 12-16-85

RD REQUESTED COMPLETION DATE 2-21-86

EEB ESTIMATED COMPLETION DATE 2-17-86

RD ACTION CODE/TYPE OF REVIEW 305

TYPE PRODUCT(S) : I, D, H, F, N, R, S

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. W. Miller (11)

PRODUCT NAME(S) CANTIN

COMPANY NAME American Chemical Society

SUBMISSION PURPOSE Proposed study in application

letter for approval application

SHAUGHNESSEY NO. CHEMICAL, & FORMULATION § A.I.

Blank lines for additional information

EEB REVIEW

Counter 15 G

100. SUBMISSION PURPOSE AND LABEL INFORMATION

100.1 Purpose

The purpose of this submission is to request changes to the sugar beet label for Counter 15 G granular terbufos insecticide. Registrant seeks to add wireworms as a pest with added application method of in-furrow at 4-8 oz. per 1000' of row. Also, the sugar beet root maggot could be controlled by the in-furrow method at 4-8 oz. per 1000' row.

This submission also requests addition of control for sugar beet cyst nematodes with knifed-in applications at 18 oz. per 1000' row. This rate would become the new maximum application rate for Counter 15 G on a per acre basis.

100.2 Formulation Information

Terbufos (S-[[1,1-diimethylethyl) thio] methyl] o,o-diethyl phosphodithioate) 15 %
Inerts 85 %

100.3 Application Methods, Directions, Rates

The changes to the current Counter 15 G label:

Accession # 260452 EXHIBIT 1 (facimilie)

<u>Crop</u>	<u>Pests</u>	<u>Rate</u>	<u>Application</u>	<u>Remarks</u>
Sugar beets at planting	Sugar beet root maggots Wireworms	<u>In-furrow</u> 4-8 oz. per 1000' row for any row spacing (minimum 20")	<u>In-furrow</u> Apply in furrow at planting time, 2-3 inches behind the seed drop zone after some soil has covered the seed.	Do no place granules in direct contact with seed as crop injury may occur. Only one application per year may be made .

Accession # 260452 EXHIBIT 2 (facimilie)

CROP	PESTS	RATE	APPLICATION	REMARKS
Sugar beets at planting	Suppress sugar beet cyst nema- tode	18 oz. per 1000' of row for any row space (minimum 20") or no more than 29 lb per acre	<u>Knifed-in</u> Drill granu- les 2 inches to the side of the seed and 2-4" below the seed	do not place granules in direct contact with the seed as crop injury may result. Only one application per year may be used.

100.4 Target Organisms

Indicated in 100.3

100.5 Precuatory Labeling

(appears on existing labels)

ENVIRONMENTAL HAZARDS

"This product is toxic to fish, birds and other wildlife. Treated granules exposed on soil surface may be hazardous to birds and other wildlife. Keep out of any body of water. Do not apply where runoff is likely to occur. Do not contaminate water by cleaning of equipment or disposal of wastes."

(on supplemental labels)

"Cover granules that may be exposed on the ends of treated rows and turns and loading areas by deep discing immediately after treating fields."

101. HAZARD ASSESSMENT

101.1 Discussion

This review is conducted as an incremental risk assessment for the changes requested for the Counter 15 G label for sugar beets.

Application rates are reduced for the in-furrow applications for root maggots and wireworms. Also this method of application is new for root maggots and should result in reduced exposure as compared to the banded method now allowed for root maggots.

The new addition of control for cyst nematodes requires a new maximum label dose of 18 oz. per 1000' of row. The current max. dose is 16 oz. per 1000' of row. However, this application is to be made by "knifing-in" 2-4" below the seed. Except for accidental spills or non-compliance with label directions for covering exposed granules, this application should result in little or no exposure of granules on the soil surface.

These applications will be limited to once a year.

101.2 Likelihood of Adverse Effects to Nontarget Organisms

Terbufos is very highly toxic to both aquatic and terrestrial organisms. Several fish kills have been reported to have occurred after agricultural use. Several field studies shows a very high potential for acute mortality of mammals and birds when granules are exposed on the surface of cornfields after labeled use. The terbufos file should be consulted for complete documentation.

The proposed changes to the label however, do not appear to pose an incremental hazard, because proper use as directed should result in less exposure from these particular amendments, as compared to currently registered uses.

101.3 Endangered Species Considerations

EEB's endangered species program has resulted in two previous OES biological opinions involving sugar beets. These opinions were obtained for phorate (a similarly toxic OP insecticide) and carbofuran, a very highly toxic carbamate insecticide. Neither of these opinions found "jeopardy" for any terrestrial or aquatic endangered species. Accordingly, no "may affect" determination is made for use of terbufos on sugar beets because there are no ecologically important qualitative differences in the hazards posed by each of these chemicals.

101.4 Adequacy of Toxicity Data

The data gaps for terbufos have been identified by the published re-registration guidance. Some of these data have subsequently been provided.

Although no additional data are necessary for this particular review, several additional data gaps have been identified since the publication of the re-registration guidance. These include extensive monitoring requirements imposed by the Exposure Assessment Branch/HED and chronic fish testing imposed by EEB. "Reserved" requirements for aquatic field studies are pending the monitoring data.

N.B. - SPECIAL NOTE TO THE PRODUCT MANAGER AND PM TEAM :

(Case, 1986.)

Should the Agency not receive the required monitoring data by the established due date, EEB will impose the requirement for the aquatic field study (72-7) because of the known hazards to fish, recently reported fish kills and reported contamination of rivers and streams by terbufos. The imposition of 72-7 will be in the form of a memo advising you of the imposition of this requirement, the ecological evidence linking terbufos to a presumption of hazard and the need for a 3(c)(2)(B) letter.

101.5 Adequacy of Labeling

No changes for these amendments. Terbufos labels should be revised to conform to the required labeling as provided by the re-registration guidance, or amendments.

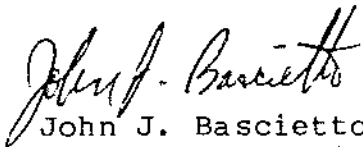
102. Classification

Provided in re-registration guidance document or amendments.


103 Conclusions

EEB has reviewed the proposed changes to the label for Counter 15G systemic insecticide (granular terbufos) for addition of in-furrow control of wireworms and sugar beet root maggots in sugar beets, at 4-8 oz per 1000' row; addition of knifed-in control of sugar beet cyst nematodes at 18 oz. per 1000' row. These proposals are detailed in Accession 260452, which contained no ecological effects data.

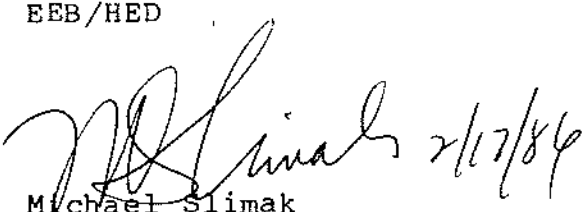
EEB concludes that proposals provide for minimal increase of exposure and risks to nontarget organisms. The actual applications should result in less exposure of granules on soil surfaces, but the addition of new pests to the label could increase the market and hence the potential for exposure to nontarget organisms, particular by non-compliance with label directions or accidental misuse.



John J. Bascietto
Wildlife Biologist
EEB/HED



Douglas Urban
Acting Sec. Head (3)
EEB/HED



Michael Slimak
Chief,
EEB/HED

NOV 19 1985

Mr. Mark W. Galley
Senior Registration Coordinator
Plant Industry Registration
American Cyanamid Company
P.O. Box 400
Princeton, NJ 08540

Dear Mr. Galley:

Subject: Terbufos Registration Standard

This letter transmits our current recorded status regarding data requirements under the terbufos registration standard.

General Chemistry

All outstanding general chemistry data as required in Tables A & B of the Standard have been received. The physical and chemical characteristics data have been reviewed, and are acceptable. In accordance with current Agency policy, the remaining general chemistry data have been filed for future review when the Standard is scheduled for its comprehensive review.

EPA accession number 256567 has been assigned to the additional general chemistry data submitted with your letter of February 8, 1985.

Environmental Fate

As described in our letter of March 11, 1985, the lab volatility study is not required to support the current registered use of terbufos as soil incorporated granules.

The remaining environmental fate data required under the Standard are: photodegradation in water (161-2), field rotational crop study (165-2) and monitoring studies (soil, water, sediment and fish). As described in our letter of March 11, 1985, the study sites for the monitoring studies are to include an estuarine/corn use, water shed in addition to the three geographical areas specified in the Standard. Our above mentioned letter recommended that approval of your proposed protocol be obtained prior to your initiation of these monitoring studies. According to our files, an acceptable protocol for these monitoring studies has not been received.

Please note that as specified in the Terbufos Registration Standard, these environmental fate data must be submitted no later than June, 1986.

Toxicology

The acute dermal and inhalation studies have been received and are currently under review. As explained in our letter of August 27, 1985, the rat and rabbit teratology studies have been filed and will be reviewed when the remaining chronic toxicity studies are received. The outstanding toxicological studies are: Chronic feeding in two species, mouse oncogenicity study and mutagenicity studies (in vivo cytogenetics test for chromosomal aberrations using bone marrow preparations of rats and dominant lethal test in rats or mice).

Fish and Wildlife

The outstanding fish and wildlife studies are: avian reproduction; actual field testing; estuarine and marine acute toxicity; and a fish earlylife stage study.

Labeling

The amended labeling for your technical terbufos product which was transmitted with your letter of May 2, 1985, fulfills the requirements specified in our letter of January 31, 1985. Further action on your amended label awaits completion of our review of the acute dermal and inhalation studies described in the above toxicology paragraph.

Sincerely,



William H. Miller
Product Manager (16)
Insecticide-Rodenticide Branch
Registration Division (TS-767)