105001
SHAUGHNESSEY NO.

14
REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 1/24/83 OUT 3/23/83

FILE OR REG. NO. 241-238

PETITION OR EXP. PERMIT NO.

DATE OF SUBMISSION 1-18-83

DATE RECEIVED BY HED 1-24-83

RD REQUESTED COMPLETION DATE 4-4-83

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RD ACTION CODE/TYPE OF REVIEW 315/Amendment

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

DATA ACCESSION NOS(S). 249264

PRODUCT MANAGER NO. W. Miller (16)

PRODUCT NAME(S) Counter 15G

COMPANY NAME American Cyanamid Company

SUBMISSION PURPOSE Proposed Conditional Registration of Aerial Application (or Ground Application, Without Incorporation, Over the Plants) to Field Corn

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
105001	Terbufos	15%

11 pages

100 Pesticide Label Information

100.1 Pesticide Use

It is proposed to amend the existing label for COUNTER 15G with supplemental labeling to permit aerial application (or ground application, without incorporation, over the plants) post-emergence on field corn. At present, application is at planting in spring and/or post-emergence in late spring by ground equipment only, to the soil, with incorporation and/or press-wheel implanting.

100.2 Formulation Information

Terbufos (S-[[1,1-dimethylethyl) thio] methyl] 0,0-diethyl phosphorodithioate) 15%
Inerts.....85%

100.3 Application Methods, Directions, Rates

Supplemental labeling has been submitted as follows:

" FOR USE IN FIELD CORN

(EPA Reg. No. 241-238)

DIRECTIONS FOR USE

BEFORE USING, READ PRECAUTIONARY STATEMENTS ON BAG

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. COUNTER 15-G shold be applied with a granular pesticide applicator properly calibrated to assure placement and proper dosage. See label for specific instruction.

Crop	Pests Controlled	Rate of COUNTER 15-G	Application	Remarks
FIELD CORN Post-Emergence	European Corn Borer (1st or 2nd generation) Banks Grass Mite	6.7 lbs. per acre	Broadcast granules over the top of the plants by ground or air equipment prior to denting.	DO NOT enter field until 7 days post-treatment. DO NOT make more than one application after plant emergence. DO NOT graze or cut for forage within 30 days of treatment. Consult your state experiment station, state extension service, or pest management consultant for proper timing of application. "

100.4 Target Organisms

See Section 100.3

100.5 Precautionary Labeling
(appears on existing label accepted by EPA 9/20/82)

ENVIRONMENTAL HAZARDS

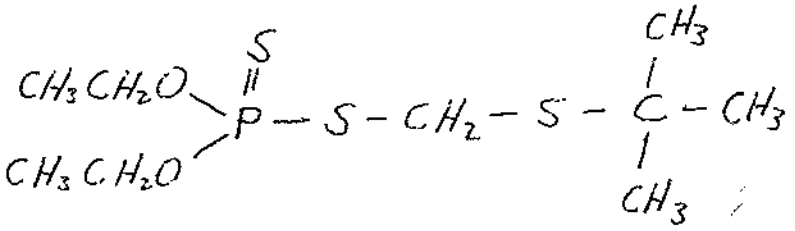
"This product is toxic to fish, birds and other wildlife. Treated granules exposed on soil surface may be hazardous to birds and other wildlife. Keep out of any body of water. Do not apply where runoff is likely to occur. Do not contaminate water by cleaning of equipment or disposal of wastes."

101 Physical and Chemical Properties

101.1 Chemcial Name

See Section 100.2

101.2 Structural Formula



101.3 Common Name

Terbufos

101.4 Trade Name

Counter ™ 15G

101.5 Molecular Weight

288.43

101.6 Physical State

granular

101.7 Solubility (from Phase II Product Chemistry Report)

Terbufos is considered to be soluble in acetone, aromatic hydrocarbons (toluene, benzene), chlorinated hydrocarbons, and alcohol. Solubility in water is approximately 10-15 ppm.

102 Behavior in the Environment

See Terbufos Environmental Fate and Exposure Assessment (10/20/82), completed as part of the ongoing Registration Standard and received from EFB. The following is summarized from this report.

102.1 Soil

Terbufos has a half-life of approximately 11 weeks in a silt loam soil under aerobic conditions. "Terbufos residues are immobile in four soils with a wide range of texture, organic matter content, and CEC, and dissipate fairly rapidly under field conditions."

102.2 Water

Hydrolytic half-lives are 4.5 - 8.5 days at pH 5 - 9. Formaldehyde is reportedly the principal degradate (50 - 70% of applied radioactivity); t-butyl mercaptan and 0,0 - diethylphosphorodithioic acid were also identified.

102.3 Plant

Terbufos residues were seen to accumulate in soybeans, reaching 11.7 ppm in forage and 4.3 ppm in seeds.

102.4 Animal

Terbufos accumulates in bluegill, channel catfish, and crayfish with bioconcentration factors of 14X, 11X, and 3X, respectively.

Environmental Fate Data Gaps

Studies requested by EFB in Phase II of the Registration Standard include:

1) photodegradation in water;

2) photodegradation in air;

3) laboratory volatility; and

4) field accumulation - rotational crops.

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103 Toxicological Properties

103.1 References from Toxicology Branch
(from 12/30/82 TB Phase II Chapter of Registration Standard)

Acute oral LD_{50} values for the rat range from 1.3-1.74 mg/kg using 85.8-96.7% a.i. test materials.

103.2-103.5 Minimum Requirements, Additional Terrestrial Laboratory Tests Additional Aquatic Laboratory Tests, and Field Tests

See the EEB Topical Discussions (12/16/82) for full tabular display of all available fish and wildlife toxicity data under the above categories.

104 Hazard Assessment

This proposed amendment will not increase the number of applications permitted (two), nor increase the application rate (1 lb a.i./acre is proposed for aerial or ground broadcast application, less than the maximum possible under existing ground application). However, with aerial application there most likely would be a greater application to field borders than with ground application, increasing exposure of non-target wildlife. Additionally, and critically, all existing terbufos registrations involve some form of incorporation or press wheel implanting whereas the proposed use, for newly labeled pests, involves strictly broadcast application, whether ground or aerial.

This poses a clear potential for increased exposure of terrestrial wildlife. Available data (Erbach and Tollefson, unpublished) indicate an average of 9.5% of applied granulars on the soil surface with various forms of incorporation and press wheel implanting when a granular pesticide is applied in front of the planter press wheel, as is done with terbufos (EPA Index, 1982). With the proposed applications, there would be no incorporation/implanting at all, likely resulting in greater number of granules on the ground surface. This could clearly increase exposure of terrestrial wildlife. It may also increase the potential for runoff to water bodies.

The registrant claims that "most of the material is trapped by the corn foliage and not available to birds that may be foraging in the fields nor as runoff to aquatic life." However, no justification is provided for this claim. The proposed supplemental labeling permits application any time post-emergence prior to denting. Denting occurs late in the growing season, shortly before maturity and approximately 4 months after planting (Charles Lewis, EEB, personal communication, 3/16/83). Hence, applications could be made well before plants were big enough to intercept a sizeable portion of the applied material. Rain could also wash the granules (on the corn) to the ground. It appears that far more than 9.5% of applied granules would be on the soil surface. Also, birds (particularly foliage-gleaners) may be exposed to granules stuck in/on the standing corn plants (or insects on the plants). In addition, any granules persisting in corn foliage would appear to be available to waterfowl and other birds using corn fields post-harvest when this foliage is laying on the ground.

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Simulated (pen) field testing conducted with another granular product (Dyfonate) has shown a significant increase in avian hazard with broadcast vs. incorporated treatments. This may also be the case with terbufos.

Terbufos is highly toxic to birds and very highly toxic to mammals (see Section 103). As indicated in the EEB Phase II Disciplinary Review,

> Granule weight estimates made by R. Balcomb of EEB indicate that there are approximately 4 million terbufos granules/lb of formulated product. Each granule thus weights approximately 0.1 mg. At 15% a.i, each granule would contain approximately 0.015 mg active ingredient. With an LD_{50} 28.6 mg a.i./kg (bobwhite quail), it would take aproximately 0.4 mg a.i., or about 27 granules, to reach the LD_{50} of a small bird such as a field sparrow or grasshopper sparrow (0.0139 kg), if such a bird had the same sensitivity to terbufos as the bobwhite quail. However, in toxicity screening studies by R. Balcomb, using the formulated product (COUNTER™ 15G), it was found that 10 granules were sufficient to kill all five redwinged blackbirds given this dose. Doses of one and five granules did not kill any of the blackbirds and a dose of 20 granules killed four of the five blackbirds receiving this dose. Doses of one and five granules did not kill any of the house sparrows tested and 10 granules killed two of the five birds receiving this dose.
>
> The above results suggest that an approximate LD_{50} for the redwinged blackbird is likely >5 and <10 granules, or > 0.075 and < 0.15 mg terbufos. With a red-winged blackbird weight of approximately 0.07 kg, the LD_{50} would be >1.1 and <2.1 mg a.i./kg body weight[1]. Since only granules were tested, it is not clear whether the increased toxicity compared to the 28.6 mg/kg value for bobwhite quail (>13X[1]) is due to differences in sensitivity between the two test species or increased toxicity of the formulation, or both. Elwood F. Hill of the USFWS Patuxent Wildlife Research Center is presently testing both technical terbufos and COUNTER 15G for acute oral toxicity to the bobwhite quail.

Tentative USFWS results available since the above was written (E. Hill, personal communication, 3/21/83), indicate that technical terbufos has an LD_{50} of 15 (12-19) mg/kg and COUNTER 15G has an LD_{50} of 26 (20-34) mg/kg, based on active ingredient, for the bobwhite quail. Since the granules were actually <u>less</u> toxic on an a.i. basis, it appears that the red-winged blackbird results above reflect a greater sensitivity of the species.

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[1] R. Balcomb has recently indicated (3/23/83, personal communication) that 0.05 kg may be more typical for the birds actually tested. This would change the roughly estimated LD_{50} slightly to >1.5-<3 mg/kg, >9.5X<19.1X the 28.6 mg/kg value.

Based on the submitted LD_{50} data and the above preliminary screening work (description of which is based on personal communication with R. Balcomb of EEB), it does not appear that a particularly large number of granules is needed to achieve an LD_{50} dose for small, sparrow-sized birds (from ca. >1 and <2[1], if as sensitive as the red-winged blackbird in the preliminary screen, up to about 27 if similar to the bobwhite quail), and substantially increasing the number on the surface could substantially increase the frequency of consumption and hazard. USFWS tentative results show terbufos technical to be roughly twice as toxic to bobwhite quail compared to the submitted data (LD_{50} of 15 vs. 28.6), implying that it may take only about half as many granules to achieve an LD_{50} dose as the ca. 27 indicated above (for small birds if sensitivity were similar to bobwhite quail). However, testing of the actual formulation that would be consumed in the field (LD_{50} of 16 based on a.i.) would indicate about 24-25 granules needed to achieve an LD_{50} dose for small birds of similar sensitivity as the bobwhite quail. As explained above, however, available information on certain other species indicates a substantially greater sensitivity to terbufos than that shown by the bobwhite quail.

As indicated in the Disciplinary Review,

> granules could be ingested intentionally by birds as grit, or inadvertently while foraging for insects, seeds, or other food items. Granules could also be stuck to the outer surface of avian prey items such as worms and be ingested in this manner. Residues could also be present within live and/or dead invertebrate or plant food items of birds. In turn, residues within small birds or mammals would be available to larger birds of prey.

Based on fish accumulation data (see Section 102), terbufos does not appear to have a high bioaccumulation potential. However, the availability of residues to birds of prey via prey items could be a frequently repeated phenomenon and as such pose a hazard to them, as is noted in the Disciplinary Review. Terbufos is up to 17.9X more toxic to small mammals than the bobwhite quail (see Section 103), and thus any field testing should also include mammals.

Actual field testing of existing labeled use on corn and an upgrading of the submitted avian reproduction studies have been requested by EEB in the Registration Standard (Phase II) for existing terbufos use. If proposed applications pose a substantial potential increase in hazard to terrestrial wildlife (as appears to be the case), data to assess the potential new exposure will likely include at least a separate field study with aerial application to evaluate such hazard.

Based on initial modeling by EFB (highest application rate and narrowest row spacing), it appears that actual aquatic residues under current terbufos corn use may exceed Restricted Use, RPAR, and Endangered Species levels of concern. It thus appears that there is a potential for substantial hazard to aquatic organisms. Acute LC_{50} tests for estuarine and marine organisms and both fish embryolarvae and invertebrate life-cycle studies have been requested by EEB in Phase II of the Standard. To

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[1] Rounded off, this lower limit would change to "ca. >1 and <3" granules, based on information in footnote #1 on page 5.

help resolve whether modeled residues likely occur under actual field use, EEB has requested that actual field monitoring be required by EFB, pending the outcome of further modeling requested but still not received from EFB (12/16/82 EEB memorandum). Aquatic field testing and other studies are reserved pending completion of the above requirements. It appears that proposed applications could result in substantially greater terbufos runoff if substantially more terbufos is on the soil surface or exposed to rain. EEB will require an estimate of actual expected exposure under the proposed amendment from EFB to determine whether aquatic testing and/or field monitoring will be needed for the present incremental risk assessment.

104.3 Endangered Species Considerations

All pesticides used on field corn are under current consultation by OES for potential hazard to endangered species ("corn cluster"). Terbufos is considered in EEB's Phase II of the Registration Standard and in recent draft "cluster" reports to pose a potential hazard to both terrestrial and aquatic species. Potential exposure cited in the "cluster" includes two bird species (Aleutian Canada Goose and Attwater's Greater Prairie Chicken), twelve fish species, 24 mollusc species, and two amphibian species.

106 RPAR Criteria

See Section 104 of this review and EEB Phase II of Registration Standard. It appears that there is a potential for substantial hazard to both terrestrial and aquatic non-target organisms under the existing use on corn. Testing/monitoring is presently required or reserved by EEB (in the Registration Standard Phase II) to evaluate this potential. The proposed amendment appears to present a potential for substantially increased exposure (and thus hazard) to both terrestrial and aquatic non-target organisms. See Section 107.7 regarding data needed to evaluate this proposal.

107 Conclusions

107.1 Environmental Fate and Toxicology Acknowledgement

Registration Standard Phase II reports of these branches were used in this review.

107.2 Classification Labeling

EEB has not completed its review. Classification labeling, if appropriate, can only be provided upon completion of this assessment. If/when the proposed use may be considered registerable, Restricted Use labeling may be appropriate, given the nature of this use pattern.

107.3 Environmental Hazards Labeling

EEB has not completed its review and cannot provide final labeling for use if/when the product is considered registerable and registered for the proposed use (e.g., labeling may not be sufficient to adequately mitigate hazard). Hence, the following suggestions are strictly tentative, pending final review.

Current labeling guidelines specify the following statements:

"This pesticide is toxic to fish and wildlife. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water or wetlands. Do not contaminate water by cleaning equipment or disposal of wastes. Cover or incorporate granules that are spilled during loading."

Sentence #2 on the existing label ("Treated granules exposed on soil surface may be hazardous to birds and other wildlife", Section 100.5) is not specified by current labeling guidelines but is certainly true based on available information and may be acceptable to EEB, pending final review.

Labeling for endangered species is specified in the EEB Phase II Disciplinary Review for Terbufos use on corn, sorghum, and sugar beets (crops on existing label) as follows:

> "Under the federal Endangered Species Act, it is a federal offense to use any pesticide in a manner that could jeopardize the continued existence of a federally-listed endangered/threatened species. Use of COUNTER™ 15G in the Texas counties of Aransas, Austin, Brazoria, Colorado, Ft. Bend, Galveston, Goliad, Harris, Refugio, or Victoria may jeopardize the Attwater's Greater Prairie Chicken. Use of COUNTER™ 15G in the California counties of Butte, Colusa, Glenn, Solano, Sutter, or Yolo from mid-August through the end of December or the counties of Merced, San Joaquin, or Stanislaus from mid-September through mid-March may jeopardize the Aleutian Canada Goose."
>
> "Prior to making aplications in these counties, the user must confirm that these species will not be exposed to the applied pesticide. If in doubt, the user must contact either the regional U.S. Fish and Wildlife Service Office (Endangered Species Specialist) or personnel of the state fish and wildlife agency."
>
> Labeling for aquatic endangered species is reserved pending formal consultation, if needed, with the U.S. Office of Endangered Species.

For corn, appropriate endangered species labeling will be developed as part of the "corn cluster". Hence, the endangered species labeling suggested above is tentative pending both completion of the "cluster" and completion of the present incremental risk assessment.

107.4 Data Adequacy Conclusions

No additional data were submitted for the present review.

107.5 Data Requests

See Section 107.7.

107.7 Findings

EEB has reviewed the proposed conditional registration of COUNTER" 15G (terbufos) for aerial application (or ground application without incorporation) post-emergence on field corn. EEB is unable to complete an incremental risk assessment [3(c)(7) finding]. Since the proposed amendment is for broadcast application (whereas all existing uses on corn involve ground application with incorporation and/or press wheel implanting), there are likely to be substantially more granules on treated fields (also a potential for exposure to granules in/on the corn plants, see Section 104). Field borders are also likely to be more exposed with aerial applications. These factors could result in a substantial increase in exposure to terrestrial wildlife. If more granules are present on the soil surface or otherwise exposed to rain, there may also be a substantial increase in runoff potential. Given the high toxicity of terbufos to both terrestrial and aquatic life, any substantial increase in exposure could result in a substantial increase in effects.

The registrant has claimed that "most of the material is trapped by the corn foliage and not available to birds that may be foraging in the fields nor as runoff to aquatic life" but provides no justification (see Section 104 for analysis). If the registrant can provide convincing evidence (to both EEB and EFB) that no substantial increase in terrestrial or aquatic exposure would occur due to the proposed use (this may require monitoring studies, which are reviewed by EFB), additional testing prior to that required by the Registration Standard would not appear to be required for hazard assessment under an incremental risk mode.

Otherwise, given the high toxicity of terbufos, testing to assess the potential new exposure will be likely to include at least a separate field test with aerial application (as proposed) to assess the potential hazard to birds and mammals. EFB will need to assess whether the proposed amendment will substantially increase potential aquatic residues. It is possible that additional aquatic testing and/or field monitoring would be needed to evaluate such potential exposure.

Since providing the exposure evidence described in the second paragraph above may require extensive field work and still leave open questions of safety requiring further ecological effects testing to resolve, it may well be preferable to go directly to ecological effects testing. If this latter route is chosen, EEB must be notified so that all specific data needs can be fully outlined. In either case, protocols for any testing must be submitted for full review by EEB and/or EFB.

References

Erbach, D. and Tollefson, J. No date. Granular insecticide application for corn rootworm control. Journal paper No. J- of the Iowa Agriculture and Home Economics Experiment Station, Ames. Projects 2459 and 2250 (unpublished).

Johnson, P. 1982. EPA Index to pesticide chemicals--terbufos. OPP/BFSD/ASIB.

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