



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

SEP 2 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Terbufos [Counter® XL (AC 301,467) systemic insecticide-nematicide; Id. No. 241-GRU] for Field Corn, Grain Sorghum, and Sugar beets; [re: 241-EUP-RRO; RCB#2797].
MRID 406607-03 & -04. RCB#4136.

FROM: Kenneth W. Dockter, Chemist
Special Registration Section I
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THRU: A.R. Rathman, Section Head
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TO: J. Tice, PM# 16
Registration Division (TS-767)

American Cyanamid Company, Agricultural Research Division is requesting registration of Counter® XL (AC 301,467; 20% terbufos) for use on field corn, grain sorghum, and sugar beets. The registered formulation (Counter®; EPA Reg. No. 241-238) contains 15% ai.

For the 1987 growing season, the Company had requested an EUP to test the use of AC 301,467 on field corn, grain sorghum, and sugar beets.

RCB reviewed that request and recommended against the EUP (See K. Dockter memo of 3/4/88; 241-EUP-RRO; RCB#2797). Also, we noted to the PM, at that time, that the Company should be informed that the data generated from that EUP program would not likely satisfy the outstanding deficiencies (identified in the Terbufos FRSTR), which should be resolved prior to registration of this product. They are:

- Additional ¹⁴C poultry and ruminant metabolism studies
- Validation data, on metabolites, for the corn, the sorghum, and the sugar beet analytical methods
- Additional field trials on corn, sorghum, and sugar beets
- Additional manufacturing data
- Validation data for certification of limits
- Additional data for pH, impurities, odor, and stability
- Residue storage stability studies.

Present Considerations

We have examined the current submission which contains:

Vol 1 (no MRID): includes a Data Matrix and the label for the proposed product, Counter® XL,

Vol 5 (MRID 406607-03): Counter® terbufos 15G residues in sugar beets (root data only),

Vol 6 (MRID 406607-04): Validation of GC method M-1747 for terbufos residues in sugar beet roots, and

a Confidential Statement of Formula (CSF) for the proposed product, AC 301,467; Id. # 241-GRU, (identified as 241-EUP-RRO) dated 8/27/87.

The Data Matrix cites enclosure of a, "1-yr storage and stability data for AC 301467/COUNTER XL". It is not contained in the current submission as received by RCB.

The proposed label for Counter® XL dated 5/11/88 would allow additional applications not contained on the EUP label. The latter had only at-planting applications. The XL draft label also contains an at-cultivation use on corn, post-emergence uses on corn and sugar beets, and an at-bedding use on sorghum. A portion of the sorghum use directions are missing (See ATTACHMENT I - copy of page 7?). Also, the use directions are incomplete for banded postemergence use over corn seedlings. The rate is listed as "9-12 per 1,000 ft of row". We assume the term "oz" was accidentally left out.

A report dated 7/15/87 (MRID 406607-04), "COUNTER terbufos (CL 92,100): Validation of GC method M-1747 for the Determination of Total CL 92,100-Related Residues in Sugar Beet Roots ..." was provided in the present package. This method involves extraction of total CL 92,100-related residues from finely-ground sugar beet roots with 10% methanol in methylene chloride. After filtration, the extract is washed with distilled water and the solvent evaporated to dryness. The residue is dissolved in hexane and partitioned with acetonitrile and the acetonitrile is evaporated to dryness. The compounds are converted to terbufoxon sulfone (CL 94,302) by oxidation with m-chloroperbenzoic acid in methylene chloride. The solvent is evaporated and final cleanup is achieved by dissolving the residue in acetone and treating with aqueous phosphoric acid-ammonium chloride precipitation solution. After filtration and extraction, the methylene chloride is evaporated to dryness. The residue is then dissolved in a measured volume of acetone and quantified by GC (3% OV-210 Supelcoport column) using a flame

photometric detector (525-nm phosphorus filter). The method sensitivity is 0.01 ppm. Samples fortified at levels of 0.01-1.0 ppm gave recoveries of 63-100%. The spiking solution was a 1:1:1 mixture of terbufos, terbufos sulfoxide (CL 94,301), and terbufos sulfoxide (CL 94,365). The report includes detailed analytical data and typical gas chromatograms.

No new residue data resulting from the application of AC 301,467, per se are submitted. The Company contends, in M. Galley's cover letter, that: "... application of the new formulation to the field (showed) no differences from the ... 15 G product ...". Also, in an attachment in response to our memo of 3/4/88, the Company argues further that the over-tolerance case we cited (0.11 ppm) was from a study conducted in Crookston, MN in 1973, and involved immature sugar beet roots sampled 73 days after postemergence treatment at 3.4 lb ai/A. In addition, the Company claimed they were, "not requesting postemergence uses in the EUP or on the proposed registration label for COUNTER XL". But, as we have noted, earlier in this memo, they are. Moreover, the overtolerance case we cited in our 3/4/88 memo was from a study conducted in MI (not MN) in 1974 (not 1973), and the samples were taken from mature (not immature) sugar beets 174 days after an in-furrow treatment of 3.4 lb ai/A (Sample Number 3216.38 in Exhibit D-2-VIII of PP#5F1640). This overtolerance residue was cited in the Residue Chemistry Chapter of the FRSTR where- in additional data are requested for sugar beets.

A report (MRID 406607-03) of 4 Counter® (Cl 92,100/15G) treated sugar beet studies conducted in 1986 in ID, CO, ND, & MN shows, in the MN trial, a maximum of 0.027 ppm terbufos residues in roots 139 days after knifed-in treatment with 18 oz product (2.7 oz ai)/1,000 foot row; 30-inch row spacing. A maximum use rate of 4.41 lb ai/A is reported. The EUP label specified a limit of 3.92 lb ai/A. These studies do not completely satisfy the request in the FRSTR since California, the largest sugar beet producing state, was not included.

With respect to corn, the Residue Chemistry Chapter of the FRSTR has asked for additional data reflecting at-planting plus postemergence applications to field corn. Processing studies utilizing wet and dry milling are also now required. Similarly, the FRSTR has requested residue data reflecting the maximum rate for knifed-in applications to sorghum plus a processing study to determine terbufos residues in flour, starch, and grain dust. Since these same uses are proposed on the Counter XL label, we consider it inappropriate to approve this label until adequate data are submitted.

The CSF provided in the current submission is for product AC 301,467 insecticide/nematicide, Reg/File # 241-EUP-RRO, and

has attached letters for [REDACTED] which are duplicates of those submitted with the aforementioned request for an EUP. Registration Division should determine whether the inerts are approved for use on food crops.

Conclusions and Recommendation:

Additional field trial data and processing studies have been requested in the Residue Chemistry Chapter of the Terbufos FRSTR (Final Registration Standard and Tolerance Reassessment) to determine residues expected in sugar beets, field corn, and grain sorghum commodities from uses proposed on the Counter XL label.

The aforementioned data deficiencies should be resolved prior to registration of this product.

Accordingly, we recommend against the proposed registration of Counter® XL (AC 301,467; Id. No. 241-GRU, containing as ai 20% terbufos) for use on field corn, grain sorghum, and sugar beets.

We also remind Registration Division to check the clearance of inert ingredients in Counter XL for use on food crops.

cc: K. Dockter (RCB), Terbufos S.F., Amended Use file, E. Eldredge (ISB/PMSD), Circulation (7), RF.

RDI: RALoranger:8/31/88:KHArne:9/1/88

TS-769:RCB:CM#2:RM 802:77886:K.W. Dockter:edited by Kd:9/2/88

GRAIN	Greenbugs	
	Corn leaf aphids	Corn root aphids
SORGHUM	Knifed-in	Knifed-in
At Bedding	6-12oz. per 1,000 ft. row for any row spacing (minimum 20-inch row spacing) or no more than 19.6 lbs. per acre.	Drill granules 1-4 inches directly below the seed OR 1-4 inches below the seed and up to 5 inches to the side of the seed.
GRAIN	Greenbugs	
	Corn leaf aphids	Corn root aphids
SORGHUM	Knifed-in	Knifed-in
At Planting	6-12oz. per 1,000 ft. of row for any row spacing (minimum 20-inch row spacing) or no more than 19.6 lbs. per acre.	Drill granules 1-4 inches directly below the seed OR 1-4 inches below the seed and up to 5 inches to the side of the seed.
	Banded or In-furrow 6oz. per 1,000 ft. of row for any row spacing (minimum 20-inch row spacing).	Banded Place granules in a 7-inch band over the row, in front of or behind the presswheel and lightly incorporate.
		In-Furrow Place granules directly in the seed furrow behind the planter shoe.

Only one application per year may be used.