

US EPA ARCHIVE DOCUMENT

224446
Record No.

Review No.
105001
Shaughnessey No.

EEB REVIEW

DATE: IN August 3, 1988 OUT December 15, 1988

FILE OR REG. NO. 241-GRU

PETITION OR EXP. NO. _____

DATE OF SUBMISSION June 10, 1988

DATE RECEIVED BY EFED August 2, 1988

RD REQUESTED COMPLETION DATA August 29, 1988

EEB ESTIMATED COMPLETION DATE August 29, 1988

RD ACTION CODE/TYPE OF REVIEW 165

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

DATA ACCESSION NO(S). 406607-00

PRODUCT MANAGER NO. J. Tice / M. Mautz

PRODUCT NAME(S) Counter XL

COMPANY NAME American Cyanamid Company

SUBMISSION PURPOSE Proposed new formulation (20G) for use on corn, sorghum and sugar beets. Response to previous EEB review

SHAUGHNESSEY NO.	CHEMICAL AND FORMULATION	% A.I.
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

December 15, 1988

MEMORANDUM

Subject: Granular Terbufos Hazard
Reply from American Cyanamid.

From: James J. Goodyear, Biologist
Ecological Effects Branch
Environmental Fate and Effects Division (TS-796C)

James J. Goodyear 12.15.88

Thru: Raymond W. Matheny, Head, Section I
Ecological Effects Branch
Environmental Fate and Effects Division (TS-796C)

Raymond W. Matheny 12.15.88

Thru: James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (TS-796C)

James W. Akerman 12/15/88

To: Marilyn A. Mautz
Insecticide and Rodenticide Branch
Registration Division (TS-767C)

The reply to my previously expressed (April, 1988) concerns about the effect of Terbufos granular formulation on endangered and nontarget species by Dr. James A. Gagne, Manager of Environmental Toxicology for the American Cyanamid Company has been noted and I will comment upon the issues that he raised.

"First, the formulation is not a Granule and thus Dr. Goodyear's comparisons of the 15G to the 20G are not exactly correct." If the Terbufos 20XL (or 20P) unit is not a granule, then what is it? A granule is something that resembles a small, hard particle. That definition seems to fit 20XL even if the [redacted] relatively soft or porous. From the point of view of analyzing its effect upon nontarget and endangered species, it would be a granule even if it were foam-like since it delivers a discreet dose of toxicant. In the later portion of American Cyanamid's document they are referred to as "granules".

"Second, the method of application was requested. The application methods are all the same as specified and approved on the currently reviewed Counter 15G label." EEB knows this. The label however, lists a number of methods of application (banded, knifed-in and in-furrow), which are to be used in specific areas. The different methods of application incorporate different percentages of the granules applied. In order to evaluate future Experimental Use Permanent applications, EEB will need to know the method of application being used in the experiments.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

"Third, Dr. Goodyear expressed concern about the use of the new formulation in areas where there are endangered species. It is our belief as discussed in the attached hazard assessment that the new formulation does not give rise to any new (and perhaps less) hazards to endangered species already specified for Counter 15G use patterns which are the same as for the new Counter XL formulation and thus we do not agree that a formal consultation with the U.S. Fish and Wildlife Service regarding possible additional or different impacts to endangered species is necessary for approval of this registration application."

The analysis submitted by Dr. Gagne concluded that, even without incorporation, an application of one pound of Terbufos 20XL would not exceed EEB's standard for endangerment of an amount of active ingredient equal to an LD₅₀ available to birds in a square foot of the field.

American Cyanamid Company's Table 5 lists the median granule sizes:

Mesh Size	Granule Wt in mg	Granules per Square Foot	
		@ 1 lb ai/A	@ 2 lb ai/A
16	1.47	35.7	70.8
18	0.85	61.2	122.4
20	0.51	102.0	204.1

EEB used the median size granule in its calculations. Since EEB examines a worse case scenario in its preliminary risk assessment, only the 2 lb ai/A rate was considered. Two pounds of active ingredient must be converted to pounds of 20P and divided by the average weight of a granule:

Eq. 1. Number of granules per acre.

$$\frac{2 \text{ lb ai}}{A} \cdot \frac{5 \text{ lb 20P}}{\text{lb ai}} \cdot \frac{4.5 \times 10^5 \text{ mg}}{\text{lb}} \cdot \frac{1 \text{ granule}}{.85 \text{ mg}}$$

$$= 5.3 \times 10^6 \text{ granules /A}$$

If this is multiplied by the number of square feet per acre, the answer agrees with American Cyanamid's calculation.

Eq. 2. American Cyanamid's calculation of the number of granules per square foot.

$$\frac{5.3 \times 10^6 \text{ granules}}{A} \cdot \frac{A}{43,560 \text{ ft}^2} = \frac{122.5 \text{ granules}}{\text{ft}^2}$$

However, it is not true that granules are evenly broadcast over the field. They are, instead, deposited in a band centered on the crop row. The use rate closest to 10 lb/A given in the labeling is 10.2 lb/A. This requires the application of 10 oz per 1,000 linear feet of row with 32 inches between rows. We can interpolate for 10 lb/A by multiplying by a simple ratio (10/10.2). In order to apply 10 lb of formulated product, 9.8 oz (.61 lb) should be applied per 1,000 linear feet.

Eq. 3. Pounds of product to be applied per linear foot of row to treat one acre with ten pounds.

$$\frac{10}{10.2} \cdot \frac{10 \text{ oz}}{1000 \text{ ft}} \cdot \frac{1 \text{ lb}}{16 \text{ oz}} = \frac{0.61 \text{ lbs}}{1000 \text{ ft}}$$

The bands treated are only 7 inches wide, so the area treated is:

Eq. 4. Rate of treatment of row bands.

$$\frac{0.61 \text{ lb}}{1000 \text{ ft}} \cdot \frac{1}{7 \text{ in}} \cdot \frac{12 \text{ in}}{\text{ft}} \cdot \frac{4.5 \times 10^5 \text{ mg}}{\text{lb}} = \frac{476 \text{ mg}}{\text{ft}^2}$$

Eq. 5. Number of granules in one square foot assuming the same rate of application.

20P- 0.85 mg/granule

$$\frac{476 \text{ mg}}{\text{ft}^2} \cdot \frac{1 \text{ granule}}{0.85 \text{ mg}} = \frac{561 \text{ granules}}{\text{ft}^2}$$

15G- 0.066 mg/granule (Hill and Camardese, 1983)

$$\frac{476 \text{ mg}}{\text{ft}^2} \cdot \frac{1 \text{ granules}}{0.066 \text{ mg}} = \frac{7219 \text{ granules}}{\text{ft}^2}$$

Using the quail LD₅₀ of 269 mg/kg of 15G and 305 mg/kg of 20P and the weight of a songbird (50 g) and the weight of a northern bobwhite quail (178 g) as typical of an upland game bird and using 0.85 mg/granule of 20P (American Cyanamid's submission) and 0.066 mg/granule (Hill and Camardese, 1983) we can calculate the number of granules of formulated product that would equal the LD₅₀ of a songbird. The weights of the birds were obtained from Dunning (1984). Dr. Gagne's weight of 236 g is based upon the weights of the birds used in the LD₅₀ tests. Laboratory raised birds are larger than wild caught birds. Dunning's figure is based upon Tomlinson's work (1975), which found a mean 178 g for 847 birds.

Eq. 6. Number of granules of Terbufos 20P that equals an LD₅₀.

Songbird

$$\frac{305 \text{ mg}}{\text{kg}} \cdot \frac{0.05 \text{ kg}}{\text{songbird LD}_{50}} \cdot \frac{1 \text{ granule}}{0.85 \text{ mg}} = \frac{18 \text{ granules}}{\text{songbird LD}_{50}}$$

Upland game bird

$$\frac{305 \text{ mg}}{\text{kg}} \cdot \frac{0.178 \text{ kg}}{\text{UGB LD}_{50}} \cdot \frac{1 \text{ granule}}{0.85 \text{ mg}} = \frac{64 \text{ granules}}{\text{UGB LD}_{50}}$$

Eq. 7. Number of granules of Terbufos 15G that equals an LD₅₀.

Songbird

$$\frac{269 \text{ mg}}{\text{kg}} \cdot \frac{0.05 \text{ kg}}{\text{songbird LD}_{50}} \cdot \frac{1 \text{ granule}}{0.066 \text{ mg}} = \frac{193 \text{ granules}}{\text{songbird LD}_{50}}$$

Upland game bird

$$\frac{269 \text{ mg}}{\text{kg}} \cdot \frac{0.178 \text{ to } 0.308 \text{ kg}}{\text{UGB LD}_{50}} \cdot \frac{1 \text{ granule}}{0.066 \text{ mg}} = \frac{725 \text{ to } 1255 \text{ gran}}{\text{UGB LD}_{50}}$$

There are other data available (Hill and Camardese, 1983 and Balcomb, 1984) on the toxicity of Terbufos and on its granule size that can be "plugged-in" to these same equations to calculate 11 granules/ songbird LD₅₀ and 254 to 726 granules/ Upland Game Bird LD₅₀. In some cases, in order to obtain an amount of Terbufos equal to one LD₅₀, birds may have to ingest 12 times as many granules of 15G as of 20P.

Eq. 8. The number of LD₅₀s per square foot at 2 lbs. a.i. per acre.

Songbird

$$\frac{476 \text{ mg}}{\text{ft}^2} \cdot \frac{\text{kg}}{305 \text{ mg}} \cdot \frac{\text{LD}_{50}}{.05 \text{ kg}} = \frac{31 \text{ LD}_{50}\text{s}}{\text{ft}^2}$$

Upland game bird

$$\frac{476 \text{ mg}}{\text{ft}^2} \cdot \frac{\text{kg}}{305 \text{ mg}} \cdot \frac{\text{LD}_{50}}{.176 \text{ kg}} = \frac{9 \text{ LD}_{50}\text{s}}{\text{ft}^2}$$

This, as American Cyanamid pointed out, is without the incorporation that is specified in the labeling. Such unincorporated patches do exist, especially at points where the tractor starts or stops and where it swings around to start a new row. Therefore, the worst case scenario is relevant to Terbufos 20P's and 15G's risk to birds.

EEB is aware of Erbach and Tollefson's 1983 paper. We disagree that their estimates were high since the fluorescent dye did not inhibit incorporation. We would expect at least 15% of the Terbufos to remain on the surface.

Eq. 9. Unincorporated Terbufos 20P granules (15%) per square foot.

$$\frac{561 \text{ granules}}{\text{ft}^2} \cdot .15 = \frac{84 \text{ granules}}{\text{ft}^2}$$

This is 5 LD₅₀s/ft² for a songbird and 1.3 LD₅₀s/ft² for a bobwhite quail. EEB is concerned that bird mortality will occur when the number of LD₅₀s/ft² equals or exceeds one. Since Terbufos 20P application would leave 5 to 31 LD₅₀s/ft² for songbirds and 1.3 to 9 LD₅₀s/ft² for upland game birds, EEB considers it to be a high risk to birds. This compares with Terbufos 15G, which would have 6 LD₅₀s/ft² for songbirds and 1.5 to 28 LD₅₀s/ft² for upland game birds. Both formulations pose a high risk of bird mortality. We have accounted for the slightly decreased toxicity of the 20P versus the 15G. Therefore, the main difference between two formulations is the size of the granule (approximately 0.85 mg versus 0.066 mg).

The experiments done by American Cyanamid in which humans attempted to find brown granules on brown soil cannot be considered to be relevant because not all soil is the same color as Terbufos and because human color perception, visual acuity and behavioral patterns do not match those of birds.

The pen study is interesting, but it is inconclusive because; 1) there was no mention of the conditions of the study (pen size, food type, concentration of the Terbufos, etc.), 2) there was no control pen and 3) no results or methods of analysis were given.

In Summary- Both formulations pose a high risk to birds with a high likelihood of avian mortality resulting from the proposed use. This has been confirmed for Terbufos 15G already in a Level I field test.

The registrant has provided data indicating that the 20P formulation may be slightly less-toxic (LD₅₀ = 305mg/kg 20P versus 173 mg/kg 15G) to upland game birds. However, the size of the 20P granule is significantly larger than the 15G (0.85 mg versus 0.066 mg) providing for more toxicant per dose received.

Literature Cited

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