

Shaughnessy No.: 128201

Date Out of EFGWB: MAR 20 1989

TO: S. Lewis/Lois Rossi, PM 21
Registration Division (TS-767C)

FROM: Emil Regelman, Supervisory Chemist
Environmental Chemistry Review Section #2
Environmental Fate and Ground Water Branch/EFED (TS-769C)

THRU: Hank Jacoby, Chief (acting)
Environmental Fate and Ground Water Branch/EFED (TS-769C)

Attached, please find the EFGWB review of . . .

Reg./File #: 352-441

Chemical Name: Quizalofop ethyl; ethyl 2-[4[(6-chloro-quinoxalin-2-yloxy)-
phenoxy]propanoate

Type Product: herbicide

Product Name: Assure

Company Name: DuPont

Purpose: Review of protocol for confined accumulation study.

Date Received: 2-17-88 Action Code: 352

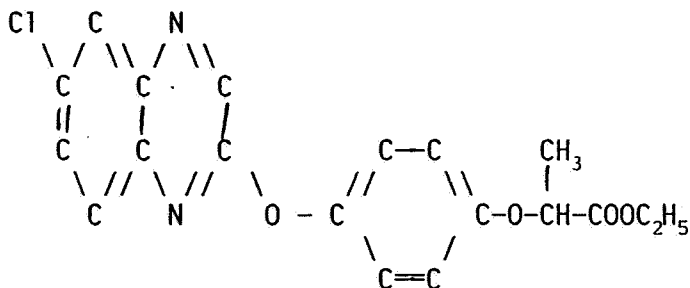
Date Completed: _____ EFGWB # (s): 90223

Total Reviewing time (decimal days): 2.5 days

Deferrals to: _____ Ecological Effects Branch, EFED
_____ Science Integration & Policy Staff, EFED
_____ Non-Dietary Exposure Branch, HED
_____ Dietary Exposure Branch, HED
_____ Toxicology Branch, HED

1. CHEMICAL:

Common Name: Quizalofop ethyl
Chemical Name: ethyl 2-[4[(6-chloro-quinoxalin-2-yloxy)-phenoxy]propanoate
Trade Names: Assure; DPX-Y6202
Formulations: 9.5% EC (Assure)
Company: DuPont
Structure:



Physical/Chemical properties:

Empirical formula: $C_{19}H_{17}ClN_2O_4$
Molecular weight: 372.5
Physical state: white, crystalline solid
Melting point: 91.7-92.1 deg. C
Vapor Pressure: 3×10^{-7} mm Hg @ 20 deg C
Solubility: 0.3×10^{-4} g in water at 20 deg. C

2. STUDY/ACTION TYPE: Review of protocol for confined accumulation study.

3. STUDY IDENTIFICATION:

Cadwgan, Jr., Gordon, Nov. 10, 1988. Protocol. Confined accumulation study of [phenyl(U)- ^{14}C] and [quinoxalin-phenyl(U)- ^{14}C]DPX-Y6202 on rotational crops (beets, cotton, peanuts and wheat), (study number AMR-1265-88). No MRID No.

Parsells, Albert J., Nov. 15, 1988. Letter to Mr. Robert J. Taylor, US EPA/OPP, with attached protocol cited above.

4. REVIEWED BY:

A. Reiter, Chemist
Environmental Chemistry Review Section II
EFGWB/EFED/OPP

A. Reiter

Date: March 15, 1989

5. APPROVED BY:

E. Regelman, Supervisory Chemist
Environmental Chemistry Review Section II
EFGWB/EFED/OPP


Date: MAR 23 1989

6. CONCLUSIONS:

A. Confined Accumulation Protocol: This protocol is generally acceptable. However, no leafy vegetable crop was cited (e.g., lettuce, spinach).

B. Short Term Aerobic Metabolism Study: This aspect of the submitted protocol satisfactorily addresses the suggestion made by E. Regelman (Memorandum of 4/4/88) that a biphasic degradation pattern occurs with quizalofop ethyl, and that an aerobic metabolism study with more sampling during the initial rapid degradation phase is needed.

7. RECOMMENDATIONS:

Crop Accumulation Protocol: The registrant must include a suitable leafy vegetable crop. The registrant is cautioned that TLC will not suffice as an analytical method for isolation and identification (confirmation) of residues of the active ingredient and its metabolites. The registrant must also include in the final report a statement of the study's material balance. It is assumed that all previously known and newly discovered significant metabolites will be isolated and confirmed. Finally, a storage stability study is needed to validate the accumulation study.

Short Term Aerobic Metabolism Study: This aspect of the protocol is satisfactory.

8. BACKGROUND:

A. Introduction:

Quizalofop ethyl is a herbicide to be used for the postemergent control of annual and perennial grass weeds in soybeans.

The Agency granted conditional registration for quizalofop ethyl on June 10, 1988 provided that an additional confined rotation study be completed. The draft protocol for this new study is reviewed herein.

In addition, the registrant has included an additional short-term labeled aerobic metabolism study to provide information on the soil metabolism during the suggested early rapid degradation phase.

Other outstanding data requirements (Ref. EAB memo of 4/4/88 include the following:

Aerobic Aquatic Metabolism - must be repeated and all metabolites > 10% of applied identified.

Field Dissipation - the fate of the metabolite Phenol 4 has not been resolved.

B. Directions for use:

The 9.5% EC (Assure, 0.8 lb ai/gal) is to be applied at 0.075-0.250 lb ai/acre depending on regional rainfall. In arid regions, a second application 2-3 weeks following the initial application is recommended; however, the total amount applied should not exceed the recommended rate.

9. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

PROTOCOL SUMMARY:

A. Accumulation Study:

The new accumulation study for confined rotational crops was required to provide additional data on the accumulation of quizalofop ethyl using test materials labeled in both the quinoxaline and phenyl rings. These test substances will be 97-98% radiopure. The specific activities of the phenyl- and quinoxaline-phenyl- labeled materials will be 65 uC/mg and 13.9 uC/mg, respectively. The protocol describes treatment of sandy loam soil at a slightly exaggerated rate (1.1X the normal field rate or 4.4 oz. ai/A). After treatment, the soil will be aged for 30 days (or 60 days should residues be detected at the 30 day interval). The rotational crops proposed include beets, cotton, peanuts and wheat which will be planted in plastic pots in a greenhouse. At maturity the crops will be fractionated and combusted for analysis of radioactive residues. Those fractions containing > 0.02 ppm of total radioactivity will be extracted and analyzed for active ingredient. Unextractable radioactivity will also be analyzed by combusting aliquots of each crop fraction.

During the study the plants will be maintained in the greenhouse with watering. A 12-hour photoperiod will be observed throughout the study duration. At harvest, the soil in which each crop was grown will be sampled with a Hoffer tube. Samples of crops harvested at the same time may be pooled and frozen for later analysis.

Soil analyses for the parent and known metabolites of quizalofop ethyl will be made on the day of application, at crop planting, and at crop harvest. The levels of quizalofop ethyl and radioactive metabolites will be optimized using multiple solvent systems and identification will be accomplished using co-chromatography with standard reference materials. Additionally, those significant metabolites not previously identified will be isolated, purified and confirmed by mass spectrometry or other techniques.

Soil characterization in the final report will include the following parameters: pH, % organic matter, texture, cation exchange capacity, bulk density, and source. The final report will describe the concentration and composition of radioactivity in the soil calculated as ppm based on dry weight of soil. For the plant tissues, the concentration will be calculated as ppm on a fresh weight basis.

Reviewer's comments:

1. A pre-application soil sampling and analysis is required.
2. No leafy vegetable crop was cited in the protocol, as is required by the guidelines (neither cotton nor peanuts will substitute for a leafy vegetable).
3. The registrant should be reminded that TLC will not suffice as a method for isolation and confirmation of the ai and degradates. EFGWB finds the analytical methodology in this protocol to be vague.
4. It is assumed that the term source in the soil characterization data refers to geographical source.
5. A storage stability study is needed for confirmation purposes.
6. It is assumed that all previously known and newly discovered metabolites will be isolated and confirmed. In addition, it is assumed that the registrant will include in the final report a statement of the study's material balance and that it will be within the prescribed limits of the guideline for this requirement.

B. Short-term Aerobic Metabolism Study:

In addition to the above accumulation study, the registrant's protocol also includes a short-term soil degradation study in pots maintained, presumably, under greenhouse conditions and designed to provide both the short term (first two weeks) and long term (1-6 months) half-lives of quizalofop ethyl using radiolabeled material. Soil will be sampled with a Hoffer tube in the following manner: at 3, 6, 12, and 18 hours, day 1 and each half-day thereafter during the short-term, rapid degradation phase; and at 2 week intervals for 1 to six months to define the long term, slower degradative phase. The samples collected during the short term phase will be extracted and immediately analyzed. The samples collected during the long term phase will be frozen for analysis at a later date. The methodology for quantitation and identification of residues will be the same as described above for the accumulation study.

Reviewer's Comments:

This aspect of the submitted protocol satisfactorily addresses the suggestion made by E. Regelman that a biphasic degradation pattern occurs with quizalofop ethyl, and that an aerobic metabolism study with more sampling during the initial rapid degradation phase is needed.

10. COMPLETION OF ONE-LINER: Not applicable.
11. CBI APPENDIX: Not applicable.