1-8-87
25/1

Shaughnessy No.: 104201-- oryzalin
084301-- benefin

Date out of EAB: JAN 8 1987

To: Robert Taylor
Product Manager 25
Registration Division (TS 767)

From: Herbert L. Manning, Acting Chief HLM
Review Section #1
Exposure Assessment Branch
Hazard Evaluation Division (TS 769)

Attached, please find the EAB review of...

Reg./File # :1471-148

Chemical Name:Benefin and Oryzalin

Type Product :Herbicide

Product Name :Balan XL (contains the two active ingredients above)

Company Name :Elanco (division of Eli Lilly and Company)

Purpose :response to review of July 8, 1985 in support of registration for use on on turf grass

Date received: 8/15/86

Date completed: JAN 8 1987

Action Code(s):575

EAB # (s) :6801

days :

Deferrals to: _____ Ecological Effects Branch

_____ Residue Chemistry Branch

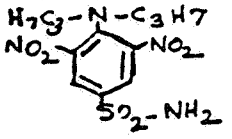
_____ Toxicology Branch

Monitoring study requested by EAB: /___/

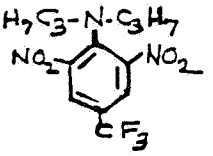
Monitoring study voluntarily conducted by registrant: /___/

1. CHEMICAL

chemical name: 3,5-Dinitro-N^4,N^4-dipropylsulfonilamide
common name: Oryzalin
CAS #: 19044-88-3
PC #: 104201
structure:



chemical name: N-Butyl-N-ethyl-α,α,α-trifluoro-2,6-dinitro-p-toluidine
common name: Benefin (obsolete), Benfluralin (ISO)
CAS #: 1861-40-1
PC #: 084301
structure:



2. TEST MATERIAL: not applicable

3 STUDY/ACTION TYPE:

response to review of data in support of registration for use on turf grasses

4. STUDY IDENTIFICATION: not applicable

5. REVIEWED BY:

Typed Name: E. Brinson Conerly
Title: Chemist, Review Section 1
Organization: EAB/HED/OPP

E. Brinson Conerly 1/8/87

6. APPROVED BY:

Typed Name: Herbert L. Manning
Title: Acting Chief, Review Section 1
Organization: EAB/HED/OPP

Herbert L. Manning JAN _ 8 1987

7. CONCLUSIONS:

The following are the turf use data requirements for these active ingredients, and their status as of this review:

Oryzalin	
hydrolysis	satisfied
aqueous photolysis	not satisfied
aerobic soil metabolism	not satisfied
leaching	not satisfied
field dissipation	not satisfied
fish accumulation	not satisfied
Benefin:	
hydrolysis	satisfied
aqueous photolysis	not satisfied
aerobic soil metabolism	not satisfied
leaching	not satisfied
field dissipation	not satisfied
fish accumulation	not satisfied

8. RECOMMENDATIONS:

Based upon the Agency's replies to the registrant's responses, the issues cited are still not resolved.

9. BACKGROUND:

The applicant has responded to Agency comments (Review of July 8, 1985) on submissions designed to fulfill data requirements for the following:

aqueous/soil photolysis
aerobic soil metabolism
field dissipation
fish accumulation

The following are the responses and our replies:

I.B. Agency comment: All other requirements in the guidelines need to be satisfied.

Applicant response: The BALAN Data Call-in will cover the data gaps. These data will be submitted in February 1986.

Agency reply: Various data will be or have been reviewed individually.

III.1. Aqueous/Soil Photolysis

Agency comment: Data on material balance. A previous review mentioned that a study was underway to resolve deficiency. To date, it has not been submitted.

Applicant response: The study referred to is enclosed and is titled "Photolysis of Oryzalin in Aqueous Solution". Soil photolysis is not required for terrestrial non-food use. XL 2G is for use on turf.

Agency reply: This study was reviewed 8/27/86 and found not acceptable.

2. Aerobic Soil Metabolism Studies

Agency comment: Volatile degradation products have not been trapped for identification and quantitation.

Applicant response: Data concerning volatile metabolites have not been provided because the purpose of this study, as stated in section 162-1 of the Environmental Fate Guidelines, "is to determine the nature and extent of pesticide degradation products to which rotational crops and nontarget organisms will be exposed..." Pesticide degradation products which volatilize from soil are not of concern when considering this exposure. Also, the requirement for data concerning volatiles has been imposed by the reviewer and is not included in Agency established reporting requirements. Test procedures, 162-1, state that (1) the rate, type, and degree of metabolism of the pesticide and its major degradates should be

determined in soil, (2) residues in soil should be identified when feasible, and (3) data should be collected until patterns of decline of the test substance are established in soil. These data have been reported and fulfill the established data reporting requirements.

The loss of dinitroaniline herbicide-related residues from soil in laboratory and field studies is well documented (References 1-9). Therefore, the production of volatile degradation products observed in the benefin and oryzalin soil metabolism studies is consistent with published data on the fate of similar compounds on soil.

Agency reply:
The purpose of the study, as stated in section 162-1 of the Environmental Fate Guidelines, "is to determine the nature and extent of pesticide degradation products to which rotational crops and nontarget organisms [emphasis added] will be exposed." Unless nontarget organisms are considered to be limited to soil biota, other species, such as field workers, may be affected by volatile degradates. Further, the phrase "in soil" does not occur in part (vi) related to residue determination, contrary to the applicant's rendition of the guidelines. In addition, we are unable to find in the guidelines any statement which says that volatile degradates are "not of concern". The Agency comment is not resolved.

3. Field Dissipation

Agency comment: Data were not available on the identification and quantitation of established degradation products in field soils.

Applicant's response: The nature and magnitude of degradation products of benefin and oryzalin in field soil has been determined using radiolabeled compounds (References 2 and 10-13). Since major degradation products were not present in these studies, samples from the field dissipation study were only assayed for parent compound.

Agency reply: The studies to which the applicant refers have been reviewed by the Agency and found unacceptable. This comment is not resolved.

4. Fish Accumulation Study

Agency comment: Data are needed concerning 38% of the ^{14}C residue unaccounted for in bluegill sunfish.

Applicant's response: Radioactive residues were extracted by sequentially blending fish tissue with hexane and methanol. As stated in the report, the hexane and methanol extracts contained 12% and 50% of the total radioactivity, respectively. The remaining radioactivity, 38% as determined by combustion analysis, was present in the solvent-extracted tissue.

Also regarding fish accumulation, please refer to our submission and letter of October 17, 1985. Accession number 260119 has been assigned to these data.

Agency reply: The bluegill sunfish accumulation study does not present the combustion data which the applicant describes. Please provide this additional information for completeness of the files. The study was previously reviewed and found otherwise acceptable.

The same study on aqueous degradation (acc. # 260119) has been presented many times, together with the rationale that since the subject compound is so short lived, fish exposure will be minimal. Therefore, the reasoning continues, fish accumulation is not of concern. This reasoning has been rejected by the Agency several times, and this reviewer agrees with that position. This comment is not resolved.

5. Leaching in tile-drained fields and orchards

Agency comment: not quoted by the applicant

Applicant's response: This product is for use on turf and will not be used in orchards.

Agency reply: The information is noted.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: not applicable

11. COMPLETION OF ONE-LINER: no information added

12. CBI APPENDIX: not applicable