Shaughnessy No.:114402

Date Out of EAB: 09 NOV 1984

To: Dick Mountfort
Product Manager 23
Registration Division (TS-767)

From: Samuel Creeger, Chief
Review Section #1
Exposure Assessment Branch
Hazard Evaluation Division (TS-769)

Attached, please find the EAB review of...

Reg./File # : 359-TNI

Chemical Name: Acifluorfen, Sodium Salt

Type Product : Herbicide

Product Name : Tackle

Company Name : Rhone Poulenc

Purpose : Response to previous reviews. New data.

Action Code(s): 166

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Deferrals to:

____ Ecological Effects Branch

____ Residue Chemistry Branch

X Toxicology Branch

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1.0 INTRODUCTION

Rhone-Poulenc has submitted its response to previous reviews for the herbicide Tackle (sodium salt of Acifluorfen). This response was forwarded to DYNAMAC for evaluation, since they have been responsible for all prior Tackle data evaluations.

2.0 STRUCTURE and DIRECTIONS FOR USE

See previous reviews.

3.0 SUBMITTED DATA

Two copies of the DYNAMAC evaluation of the Rhone-Poulenc submission have been appended to this review (the second should be sent to the registrant).

3.1 The results of the DYNAMAC evaluation of the soil metabolism studies are reproduced below, in their entirety.

DYNAMAC Results

Aerobic Soil Metabolism: Reported total ^{14}C recoveries ranged from 83-103% of that theoretically applied. Although the total percent of ^{14}C residues extracted decreased with time, a proportionately greater amount was released by the second extraction at each interval (Table 1). Fractionations of the extractable residues are also summarized in Table 1. The ^{14}C activity in the first extract was almost wholly (>90%) organosoluble, whereas that in the second extract was up to (appx.) 30% water soluble. The parent was the largest residue component, comprising (appx.) 90% of the recovered activity at the start of the incubation, and >40% after 6 months. Other identified metabolites formed only a very small proportion of extracted activity. At 6 months the amino and desnitro derivatives reportedly comprised 2.4% and 3.1%, respectively, of the ^{14}C recovered (Table 2).

Anaerobic Soil Metabolism: Reported total ^{14}C recoveries were (greater than or equal to) 95% of that applied. Results are summarized in Table 3. The proportion of total ^{14}C recovered that was removed in the initial extraction was similar for the 1- and 2-month samples (51 and 54%, respectively). However the amount released by the second extraction varied ((appx.) 28 and (appx.) 8% for the land 2-month samples, respectively). In both cases, a smaller proportion (76 and 88%) of the residues removed in the second extraction partitioned into dichloromethane. The figure for the first extraction was >97%. The major metabolite extractable from anaerobically incubated soil was the acetamide of the amino analog of acifluorfen. This formed 9.8 and 12.1% of the recovered residue at 1 and 2 months, respectively; the amino

analog (MC-14621) comprised 7.3 and 5.7% at the same times. Other major residue components were the parent and the desnitro derivative. According to the registrant, reanalysis of the ~~unidentified polar material demonstrated that only small amounts~~ of all previously identified compounds in the extract plus metabolite MC-14620 (see Figure 1) were present. Trace amounts of the acetamide and other metabolites (Table 3) were identified in the dichloromethane extracts of the flood water.

Volatility Study: Less than 1% of the ^{14}C applied to the volatility sample was recovered in the gas traps within 3 months of aerobic incubation.

3.2 Conclusions

The half-life of acifluorfen (calculated assuming first order kinetics, $r^2 = 0.979$) in an aerobically incubated loam soil was found to be (appx.) 170 days; degradation was more rapid under anaerobic conditions. Loss of ^{14}C by volatilization was very low under aerobic conditions (<1% of that applied within 3 months) and was not measured under anaerobic conditions. The parent (MC-10109) was the major residue component in aerobically aged soil, comprising 43% of recovered ^{14}C activity after 6 months. Bound residues accounted for (appx.) 24% of the activity at the same time. Three minor degradates were reported: amino, and desnitro acifluorfen and its methyl ester (MC-14621, MC-10879, MC-10108, respectively in Figure 1). However, it does not appear from the autoradiograms provided that MC-10074 (decarboxylated acifluorfen) MC10108, MC-14620 (the methyl ester of the amino analog), and MC-10879 can be resolved by TLC using solvent system A. A second normal phase system ("solvent system B") was described but no autoradiograms were included. If these compounds were resolved using this TLC system then this should have been indicated and sample autoradiograms presented.

The presence of three degradates, desnitro acifluorfen (MC-10879), the amino analog (MC-14621) and the acetamide of the amino analog, in an anaerobically incubated sample was confirmed using GC (MC-10879, MC-14621) or GC/MS (acetamide). These metabolites accounted for (appx.) 25% of the ^{14}C activity after 2 months anaerobic incubation (the parent was 4%); 35% of total ^{14}C could not be extracted. Autoradiograms of anaerobically incubated samples did not confirm that the TLC procedures used were adequate to obtain all the required separations. In the examples provided, MC-10879 and MC-14620 were not clearly resolved.

Thus, this study provides useful information about the rate of decline of acifluorfen and the nature of the residue under aerobic and anaerobic conditions. However, due to apparent poor TLC separations some metabolite identifications must be regarded as tentative; this affects <7% (aerobic) and <11% (anaerobic) of the total ^{14}C recovered.

A number of additional shortcomings were noted. No comment was made on the presence of other peaks in the GC traces for the soil extracts (when compared with those for the standards). These may be due to either the work-up procedure or to the presence of additional metabolites (indicating poor separation by TLC). Reverse-phase TLC revealed the presence of the parent and five metabolites in the "origin and polar materials" from the TLC (solvent system A) plates of the anaerobic samples. The data on metabolite distribution do not appear to have been corrected using this information. Finally, the moisture content of the soil at 0.33 bar was not reported.

4.0 The following executive summary was taken from the DYNAMAC review, and is quoted in its entirety.

4.1 EXECUTIVE SUMMARY

Only additions to or alterations of the conclusions in previous reviews (Dynamac Corp., March 1983 - Accession No. 071323-071327, August 1983 Accession No. 250467 and June 1984 - Accession No. 252764) are discussed here.

The half-life of acifluorfen in an aerobically incubated soil was found to be (appx.) 170 days; anaerobic degradation was more rapid (half-life <1 month). The dominant residue components after 6 months aerobic incubation were the parent and bound materials. After 2 months under anaerobic conditions the acetamide of amino acifluorfen was the major degradate extracted from soil, the amino analog itself was also significant, and desnitro acifluorfen was also formed.

The tentative half-life of 59 days reported in the last review (Dynamac Corp., June 1984) for acifluorfen applied at 0.75 lb ai/A to a silt loam soil in Mississippi can now be confirmed. Leaching of the parent below 3 inches was negligible under the climatic conditions prevailing during the study (<2 inches of rain were recorded during the first 30 days posttreatment). Information from three sites (two silt loam and one sandy loam soil) receiving multi-pesticide treatments (including 0.75-1.50 lb ai/A acifluorfen), and higher rainfall posttreatment than the Mississippi site, suggests that leaching of acifluorfen is possible under wetter conditions.

General conclusions from laboratory and field dissipation studies are that degradation rates in soil are variable, breakdown may be slow under aerobic conditions but is rapid under flooded or anaerobic conditions.

5.0 The following recommendations (summary of current status of data requirements) were taken from the DYNAMAC review, and are quoted in their entirety.

5.1 RECOMMENDATIONS

The submission of data to fulfill registration requirements (Subparts N and K) are summarized below:

Hydrolysis studies: One study (Norris and Hassell, November, 1980, Acc. No. 071323) was submitted and reviewed. The study was scientifically valid and satisfied all data requirements. No further data are required.

Photodegradation studies in water: One study (Somma et al., September, 1982, Acc. No. 071324) was submitted and reviewed. The study is scientifically valid and is in compliance with data requirements. No further data are required.

Photodegradation studies in air: No studies were submitted, but these data are not required at this time.

Aerobic soil metabolism studies: Five studies were submitted and reviewed.

One study (Gemma and Wargo, October, 1982, ASD Report No. 82/053, Acc. No. 071324) is scientifically invalid because of improper sample storage and erratic recovery of soil residues.

A second study (Piznik and Wargo, September, 1982, Acc. No. 071324) is scientifically invalid because it could not be demonstrated that the study was conducted under aerobic conditions.

Estimates of half-lives from the third study (Wargo, July, 1982, Acc. No. 071-324) were too variable to be useful in fulfilling registration requirements.

The fourth study (Gemma and Wargo, October, 1982, ASD Report No. 82/053, Acc. No. 071324) was not adequately designed to provide the required data. This study is considered to be supplemental information.

The fifth study (Gemma and Wargo, August, 1984, Acc. No. 254534) was found to be scientifically valid and to satisfy data requirements.

No further data are required.

Anaerobic soil metabolism studies: Three studies were submitted and reviewed.

One study (Wargo, July, 1982, Acc. No. 071324) was submitted as supplementary information not intended to fulfill data requirements.

The second study (Piznik and Wargo, September, 1982, Acc. No. 071324) is not scientifically valid because of the inadequate mass balance. In addition, the validity of the aerobic portion of this study has not been verified.

The third study (Gemma and Wargo, August 1984) Acc. No. 254534 was found to be scientifically valid and to satisfy data requirements.

No further data are required.

Anaerobic aquatic metabolism studies: No data were submitted, but these studies are not required because acifluorfen does not have forestry, aquatic, or aquatic impact use.

Aerobic aquatic metabolism studies: No data were submitted, but these studies are not required because acifluorfen does not have an aquatic or aquatic impact use.

Leaching and adsorption/desorption studies: Two studies were submitted.

One study (Norris and Miller, December, 1980, Acc. No. 071235) is scientifically valid and fulfills all data requirements.

The second study (Norris and Guardigli, May, 1982, Acc. No. 071325) supplies supplementary data.

No further data are required.

Laboratory and field volatility studies: No data were submitted, but these data are not required at this time.

Terrestrial field dissipation studies: Two studies were submitted and reviewed.

One study (Norris and Ku, April, 1981, Acc. No. 071325) is scientifically invalid because the data were variable and inaccurate; samples appeared to be contaminated with acifluorfen.

The second study (Guyton, October, 1983, Acc. No. 252764) was scientifically valid. Appropriate plot descriptions and climatic data have now been submitted (Guyton, August, 1984 Acc. No. 254535.)

No further data are required.

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Aquatic field dissipation studies: No data were submitted, but no data are required because acifluorfen does not have an aquatic or an aquatic impact use.

Forestry dissipation studies: No data were submitted, but no data are required because acifluorfen does not have a forestry use.

Long-term field dissipation studies: No data were submitted, but these data are not required at this time.

Confined accumulation studies on rotational crops: Two studies were submitted, reviewed, and found to be scientifically valid.

One (Gemma, et al., September, 1982, ASD Report No. 82/042, Acc. No. 071326 and Spare et al., October, 1982 Acc. No. 071326) does not fulfill data requirements because the application rate was too low.

The second study (Gemma et al., September, 1982, ASD Report No. 82/046, Acc. No. 071326) fulfills the data requirements for a maximum application rate of 0.50 lb ai/A with a 12 month rotational crop interval for root crops, leafy vegetable crops, and grain from cereal crops. Data requirements have not been fully satisfied for wheat straw and forage because the metabolite identification has not been confirmed.

Additional studies must be submitted to establish rotational crop intervals for application at 0.75 lb ai/A.

Field accumulation studies on rotational crops: No data were submitted. Data may be required if the issues raised in the confined accumulation studies on rotational crops are not satisfactorily addressed.

Accumulation studies on irrigated crops: No data were submitted; however, data are not required because acifluorfen has no aquatic food crop or aquatic noncrop use, is not used in and around holding ponds used for irrigation purposes, and has no uses involving effluents or discharges to water used for crop irrigation.

Laboratory studies of accumluation in fish: One study (Thompson and Cranor, January, 1981, Acc. No. 071327) was submitted and reviewed. The study is scientifically valid and partially fulfills data requirements by providing data on the quantity of acifluorfen residues accumulated in fish.

The required characterization of residues in fish may be waived if the levels of residues are sufficiently low to be of no toxicological concern. Judgement is deferred to the Toxicological Branch.

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Field accumulation studies on nontarget organisms: No data were submitted; however requirements for these studies depend upon the results from laboratory studies of accumulation in fish and toxicological data.

Reentry studies: One worker exposure study has been submitted, but has not been reviewed by Dynamac.

Ancillary studies reviewed:

Static studies of accumulation in fish (Forbis and Boudreau, March, 1981, Acc. No. 071327).

Methods evaluation studies (Ku and Miller, November, 1980. Acc. No. 071325 and Ku and Norris, May, 1981, Acc. No. 071325).

6.0 EAB CONCLUSIONS

EAB concurs with the DYNAMAC findings.

Virtually all data required to satisfy the full registration of Acifluorfen for use on terrestrial field crops has been provided by the registrant. The following deficiencies remain:

Accumulation in Rotated Crops

The confined accumulation studies reviewed to data are inadequate to support the proposed 0.75 lb ai/A application rate. With reference to the rotational interval, one study (Gemma et al., September, 1982, ASD Report No. 82/046, Acc. No. 071326) provides sufficient data to support a maximum application rate of 0.50 lb ai/A with a 12 month rotational crop interval for root crops, leafy vegetable crops, and grain from cereal crops. To date, insufficient dat have been provided to support rotation of wheat straw and forage, due to failure to confirm metabolite identification.

Accumulation in Field Crops

The necessity of this data requirement will be evaluated upon satisfaction of the Confined Accumulation studies.

Accumulation in Fish

Remaining low level residues in fish have not been sufficiently characterized. The satisfaction of this data requirement depends upon the results of the EAB deferral to Toxicology Branch on whether or not there is reasonable concern over these low level residues.

7.0 EAB RECOMMENDATIONS

The issue of Rhone-Poulenc's failure to adequately characterize ~~low level residues should be deferred to Toxicology Branch to~~ determine their level of concern. EAB can request additional characterization efforts on the part of the registrant, if requested to do so by TB.

The registrant should be informed of the DYNAMAC findings. A copy of the review is appended, for your convenience.

Specific questions should be submitted to EAB in writing, to permit their forwarding to the contractor for evaluation. If the registrant wishes to meet with the DYNAMAC reviewer, suitable request and lead time should be made.

Emil Regelman
Chemist
EAB/HED
November 7, 1984