Shaughnessy No.: 128501

Date Out of EAB: JUN 26 1987

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

From: Therese M. Dougherty, Chief for
Review Section #1
Exposure Assessment Branch
Hazard Evaluation Division (TS-769)

Attached, please find the EAB review of...

Reg./File # : 476-EEEL, 476-EEEA

Chemical Name: SC-0224

Type Product : Herbicide

Product Name : SULFOSATE

Company Name : Stauffers

Purpose : Anaerobic Soil Metabolism of Sulfosate.

Date Received: 6/2/87 Action Code(s): 121

Date Completed: 6/23/87 EXPEDITE EAB #(s) : 70716-17

Days: 3.5

Deferrals to: X Ecological Effects Branch

____ Residue Chemistry Branch

____ Toxicology Branch

Monitoring study requested by EAB: ☐

Monitering study voluntarily conducted by registrant: ☐

1.a CHEMICAL: SULFOSATE (See 2, below).

1.b Physical Properties:

Not included in this submission.

2. TEST MATERIAL: 98% radiochemically pure, specific activity 30 mCi/mmol CMAMP. $(CH_3)_3S^+$ $O=P(O)(OH)^*CH_2NHCH_2COOH$

99% radiochemically pure, specific activity 20 mCi/mmol. $(^*CH_3)S^+$ $O=P(O)(OH)CH_2NHCH^2COOH$

3. STUDY/ACTION TYPE:

Review of Anaerobic soil metabolism studies for registration for non-crop herbicidal uses.

4. STUDY IDENTIFICATION: Acc. # 40214008-9.

1) Anaerobic Soil Metabolism Study: Fate of the Carbomethoxymethylaminomethyl-phosphonic Acid Moiety
2) Anaerobic Soil Metabolism Study: Fate of the Trimethyl Sulfonium Moiety.

5. REVIEWED BY:

Akiva D. Abramovitch, Ph.D.
Chemist
Environmental Chemistry Review Section 1/EAB/HED/OPP

Akiva Abramovitch
Date: JUN 26 1987

6. APPROVED BY:

Therese M. Dougherty, Chief Halbert J. Manning for
Supervisory Chemist
Environmental Chemistry Review Section 1/EAB/HED/OPP

Date: JUN 26 1987

7. CONCLUSIONS:

The anaerobic metabolism data on Sulfosate can be considered satisfactory for the CMAMP moiety. However, the lack of information on the identity of volatiles from the ^{14}C-TMS moiety, the poor accounting for the ^{14}C material balance and discrepancies concerning degradation under aerobic conditions in this study and in the study reported in the EAB review of of June 30, 1986, makes the study on the TMS moiety unacceptable. The degradation of the TMS under both aerobic and anaerobic conditions should be reevaluated in conjunction with the leaching and adsorption/desorption, field dissipation hydrolysis and photolysis data pending submission of data by the registrant with regard to the leaching potential of the TMS moiety. Obviously, the degradation rate of the TMS moiety under aerobic and anaerobic conditions is important in making this assessment. A fast degradation to $^{14}CO_2$ under both aerobic and anaerobic soil conditions would make the likelihood of groundwater contamination by a mobile TMS moiety less likely to occur.

The CMAMP moiety of SC-0224 undergoes similar degradation under both aerobic and anaerobic conditions. $^{14}CO_2$ was the major degradate from both radio-

labeled moieties and over 43% of the radiolabeled carbons were mineralized to $^{14}CO_2$ within the 66 day study. Under aerobic conditions, over 60% of the ^{14}C-material was $^{14}CO_2$ within 30 days indicating that the degradation rate of the CMAMP to CO_2 was about 2x faster under aerobic than anaerobic conditions.

The flooded water contained less than 4% of the applied radiolabeled material in the anaerobic degradation studies of both radiolabeled TMS and CMAMP moieties.

The anaerobic metabolism study submitted by the registrant was not originally listed as a requirement for the proposed terrestrial non-food use but was submitted in response to concerns raised by the Ecological Branch about the use of sulfosate near and on aquatic sites. Therefore, this study should also be referred to EEB for evaluation.

8. RECOMMENDATIONS:

The anaerobic soil metabolism study should be repeated to address the degradation of the TMS moiety under anaerobic conditions.

The results of the aerobic and anaerobic soil metabolism data should be evaluated in the future in conjunction with all the the other available data necessary to assess the field dissipation and the mobility of the TMS moiety.

9. BACKGROUND:

A. Introduction: This submission is in response to environmental fate data requirements for registration set forth on sulfosate in a March meeting between the Registrant, D. Campt, E. Tinsworth and representatives of EAB. An aquatic anaerobic data are of interest to EEB.

B. Directions for Use: See label in earlier submissions. The maximum application rate of the active ingredient is 4 lb/acre.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

10.1 A. Study Identification: Anaerobic Soil Metabolism Study: Fate of the Carbomethoxymethylaminomethylphosphonic Acic Moiety. acceptable

The study was conducted by J.B. McBain, S.K. Benedict and L.G. Jackson of Stauffer Chemical Company in California in April, 1987.

B. Materials and Methods:

A stock solution of [^{14}C-CMAMP] SC-0224 (2.25 mg, see section 2) that was combined with 57 mg of "cold" SC-0224 and 2.33 mg of "cold" TMS was prepared and bioassayed by LSC (1.2x 10^4 dpm/micro gm). Then, 10 ml of the solution was added to the surface of 100 gm air dried Sorrento loam soil samples and placed in a 1 liter biometer flask in the dark at 23°C. The soil was identical to the one used for the aerobic soil metabolism studies and fully characterized (see attachment). The moisture was adjusted to 75% of the soil moisture capacity by adding 47.8 ml of water to the treated soil and 57.8 ml to flasks with untreated soils used as controls. The fortification at the soil surface was at a level of 30 ppm. Each flask was fitted with a polyurethane foam to trap volatiles and a 1.0 M NaOH solution trap for CO_2.

For three days, the flasks were under aerobic conditions (aerobic metabolism half life was previously determined as 3 days) and then each soil was flooded with water under nitrogen to initiate anaerobic conditions. Soil and traps samples were taken at 0, 3, 33 and 66 days from the day of treatment. Aerobic soils were extracted twice with 1.0 M ammonium hydroxide solution. Separation of soil and extracts was done at 10,000 xG and the decanted extract was then neutralized immediately to pH 7 with concentrated HCl to minimize base induced hydrolysis of CMAMP to AMP. Similarly, anaerobic soils were initially separated at 10,000 xG from the flood water and then identical work up to the one described for the aerobic soils, above, followed. Water samples were evaporated to dryness on a HVRE and the residue redissolved in 10 ml of water for analysis. Polyurethane plugs were replaced and placed in ethyl acetate for extraction and the amount of radioactive material in the ethyl acetate and in the NaOH solutions were quantified by LSC. The amount of CO_2 in the NaOH solution was quantified by precipitation with $BaCl_2$ to $BaCO_3$. Soil extracts and floodwater were purified by cation exchange micro column chromatography and then analyzed by TLC in reference to authentic samples of parent and potential degradates (see attachment for TLC analysis).

C. Reported Results:

Over the 66 day study, 43% of the applied radioactive material was recovered as $^{14}CO_2$ and removed as $Ba^{14}CO_3$. No radiolabeled material was retained by the polyurethane foam and floodwater contained only 2-3% of the applied material mainly as the parent CMAMP. The amount of extractable radioactive material was 67%, 38%, 15% and 16% at days 0, 3, 33, and 66, respectively. Unchanged CMAMP accounted for over 96% of the extractable radiolabeled material from the soil. The amount of bound material was about 30% between days 0 and 33 and then decreased to 23% at day 66 when the study was terminated. The distribution of radiolabeled meterial is shown in the attachment to this report (appendix).

D. Study Author's Conclusions:

In addition to the conclusions listed in the results, above, the registrant concluded that the rate and route of metabolism of the ^{14}C CMAMP moiety of [^{14}C-CMAMP] SC-0224 appear to be comparable in both aerobic (EAB review of June 30, 1986) and anaerobic soil (this review). CMAMP degradation resulted in 43% formation of $^{14}CO_2$ within the 66 day study.

E. Reviewer's Discussions and Interpretation of Study Results:

The study appears to provide valid scientific results (see also 10.1 E, below). Analysis was conducted solely by TLC but registrant has indicated that other analytical methods were not applicable. Therefore, the reviewer is satisfied with the information provided in C, above. In comparing the results obtained in both the aerobic and the anaerobic metabolism studies, the reviewer noted that in the aerobic study after 30 days 13.9% of the applied radiolabeled material was extracted, 17.9% was unextracted and 60.5% was $^{14}CO_2$ for a total of 91.4%. In the anaerobic study, 15.8% was extractable, 30.0% was bound and 39.5% was $^{14}CO_2$ after 33 days for a total of 88%. These results indicate a slower degradtion rate to CO_2 under anaerobic conditions for the CMAMP moiety than under aerobic conditions

by about a factor of 2. The reviewer noted that 23.86% of the radiolabeled CMAMP was converted to $^{14}CO_2$ within the initial 3 day aerobic incubation and when anaerobic conditions were initiated, it took 30 additional days for the level of $^{14}CO_2$ to reach 39.5% and 33 additional days to reach 43%. The aerobic soil degradation data (EAB review of Jun. 30, 1986) show 30% formation of $^{14}CO_2$ within the initial 5 days, 41% after 9 days and 60% after 30 days. The level of CMAMP in the extract was 15-16% between days 33 and 66.

10.2 A. Study Identification: Anaerobic Soil Metabolism Study: Fate of the Trimethyl Sulfonium Moiety.

The study was conducted by J.B. McBain, S.K. Benedict and L.G. Jackson of Stauffer Chemical Company in California in April, 1987.

B. Materials and Methods:

A stock solution of [^{14}C-TMS] SC-0224 (2.85 mg, 0.74 mCi, see section 2) that was combined with 50 mg of "cold" SC-0224 and 6.25 mg of "cold" CMAMP was prepared and bioassayed by LSC (8.25×10^4 dpm/50 microliter). Then, 10 ml of the solution was added to the surface of 200 gm air dried Sorrento loam soil samples and placed in a 1 liter biometer flask in the dark at 23°C. The soil was identical to the one used for the aerobic soil metabolism studies and fully characterized (see attachment). The moisture was adjusted to 75% of the soil moisture capacity by adding 47.8 ml of water to the treated soil and 57.8 ml to flasks with untreated soils used as controls. The fortification at the soil surface was at a level of 30 ppm. Each flask was fitted with a polyurethane foam to trap volatiles and a 1.0 M NaOH solution trap for CO_2. For three days, the flasks were under aerobic conditions (aerobic metabolism half life was previously determined as 3 days) and then each soil was flooded with water to initiate anaerobic conditions. Soil and traps samples were taken at 0, 3, 33 and 66 days from the day of treatment. Aerobic soils were extracted twice with acetone and then twice with 1.0 M ammonium formate solution. Separation of soil and extracts was done at 10,000 xG and the extract was then decanted. Similarly, anaerobic soils were initially separated at 10,000 xG from the flood water and then identical work up to the one described for the aerobic soils, above, followed. Water samples were evaporated to dryness on a HVRE and the residue redissolved in 10 ml of water for analysis. Polyurethane plugs were replaced and placed in ethyl acetate for extraction and the amount of radioactive material in the ethyl acetate and in the NaOH solutions were quantified by LSC. The amount of CO_2 in the NaOH solution was quantified by precipitation with $BaCl_2$ to $BaCO_3$. Soil extracts and floodwater were analyzed by TLC in reference to authentic samples of parent and the TMS moiety (see attachment).

C. Reported Results:

Over the 66 day study, 57% of the applied radioactive material was recovered as $^{14}CO_2$ and removed as $Ba^{14}CO_3$. No radiolabeled material was retained by the polyurethane foam and floodwater contained <4% of the applied material mainly as the parent TMS. The amount of extractable radioactive material declined from 61% at day 0 to 2% at day 33 and 66. The amount of bound material was maintained at about 40% between days 0 and 33 and then decreased

to 16% at day 66 when the study was terminated. The distribution of radiolabeled meterial is shown in the attachment to this report (appendix). An unknown product formed under aerobic conditions was not present in anaerobic soils. TMS was the principal component of the acetone extract. The presence of DMSO in extracts was attributed to decomposition of TMS. While the major degradate was $^{14}CO_2$, other unidentified products were also present in small quantities. The data accounted for only 76% of the applied radioactive material at 33 and 66 days.

D. Study Author's Conclusions:

No additional conclusions to those listed in the results, above. The registrant concluded that the rate and route of metabolism of the ^{14}C TMS moiety of [^{14}C-TMS] SC-0224, appear to be comparable in both aerobic (EAB review of June 30, 1986) and anaerobic soil (this review). The TMS Degradation resulted in 46% formation of $^{14}CO_2$ within the 66 day study. The study author explained the shortfall in total ^{14}C recovery was consistent with the results in the aerobic soil metabolism study (EAB review of June 30, 1987) and was hypothesized to be due to volatile components other than $^{14}CO_2$.

E. Reviewer's Discussions and Interpretation of Study Results:

Major criticisms of this study concern the loss of ^{14}C material balance since only 76% of the radiolabeled material is accounted for and the diferences in the results obtained in the initial 3 days under aerobic conditions in this study and in the study reviewed in the EAB review of June 30, 1987. As noted, the registrant 31% CO_2 generation after 4 days in the aerobic study and only 0.81% after 3 days in this study. The reviewer feels it is unlikely that 30% of the radiolabeled material was converted to CO_2 on the fourth day of the aerobic incubation. The registrant hypothesized in both the aerobic (EAB review of June 30, 1986) and the anaerobic soil metabolism studies that this loss was due to volatiles other than $^{14}CO_2$ but did not attempt to prove this hypothesis. The reviewer feels that GLC analysis should be used to identify volatiles and other degradates that were detected by TLC but were not identified.

In comparing the degradation of the TMS moiety under both aerobic and anaerobic aquatic conditions (EAB review of June 30, 1987) the reviewer noted that after 28 days of the aerobic study 66.5% of the radiolabeled TMS moiety was converted to $^{14}CO_2$ and in the anaerobic study 49.9% was $^{14}CO_2$ within 33 days indicating a slower mineralization rate under anaerobic aquatic conditions. At day 4 of the aerobic study 31% of the applied radioactivity was in the form of $^{14}CO_2$ At day 7 of the aerobic study 53% was already converted to $^{14}CO_2$ and only 39% was $^{14}CO_2$ after 33 days under anaerobic conditions but the data indicates only 0.81% CO_2 evolution in the initial 3 days under aerobic conditions.

Due to these large differences between the degradation rate in the first 3-4 days under aerobic conditions in the two studies, and the poor accounting for the material balance obtained from the labeled TMS moiety in the two studies, it is difficult to determine and compare the rate of degradation of the TMS moiety under both aerobic and anaerobic conditions. Therefore, these studies with the TMS moiety should be repeated!

Additional comparisons are as follows: Less than 3% of the radioactive TMS material was extractable after 33 days under both conditions. Soil bound residues were <15% under aerobic conditions and 20% under anaerobic aquatic conditions in 33 days. The material balance was 76% in the anaerobic study and 78-85% in the aerobic study in tracing the fate of the TMS moiety.

11. COMPLETION OF ONE LINER:

Not completed.

12. CBI APPENDIX:

None.

Sulfosate environmental fate/exposure assessment review

Page _____ is not included in this copy.

Pages 8 through 23 are not included in this copy.

The material not included contains the following type of information:

___ Identity of product inert ingredients

___ Identity of product impurities

___ Description of the product manufacturing process

___ Description of product quality control procedures

___ Identity of the source of product ingredients

___ Sales or other commercial/financial information

___ A draft product label

___ The product confidential statement of formula

___ Information about a pending registration action

X FIFRA registration data

___ The document is a duplicate of page(s) _____

___ The document is not responsive to the request

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information – Does Not Contain National Security Information (E.O. 12065)

6/3/87
36373 Hed

SC-0224
CHEMICAL NAME: SULFOSATE

2. IDENTIFYING NUMBER	3. ACTION CODE	4. ACCESSION NUMBER
476-EEEL	121	40214008
476-EEEA	121	40214009

TO BE COMPLETED BY PM

5. RECORD NUMBER: 196,920 / 196,921
6. REFERENCE NUMBER: 1
7. DATE RECEIVED (EPA): 5-27-87
8. STATUTORY DUE DATE:
9. PRODUCT MANAGER (PM): TAYLOR / J. Miller
10. PM TEAM NUMBER: 25

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS: 6-2-87
12. PRIORITY NUMBER: 49
13. PROJECTED RETURN DATE: 9-21-87

14. CHECK IF APPLICABLE

- ☐ Public Health/Quarantine
- ☐ Minor Use
- ☐ Substitute Chemical
- ☐ Part of IPM
- ☐ Seasonal Concern
- ☐ Review Requires Less Than 4 Hours

All

15. INSTRUCTIONS TO REVIEWER

A. HED
- ☐ Total Assessment - 3(c)(5)
- ☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

B. SPRD (Send Copy of Form to SPRD PM)
- ☐ Chemical Undergoing Active RPAR Review
- ☐ Chemical Undergoing Active Registration Standards Review

C. ☐ BFSD
D. ☐ TSS/RD
E. ☐ Other

F. INSTRUCTIONS: Review 2 anaerobic soil metabolism studies for sulfosate anion and cation.

16. RELATED ACTIONS

17. 3(c)(1)(D)
- ☐ Use Any or All Available Information
- ☐ Use Only Attached Data
- ☐ Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO
- ☒ TB
- ☐ EEB
- ☐ EF
- ☐ PL
- ☐ RCB
- ☒ EFB
- ☐ CH
- ☐ BFSD

19. To	TYPE OF REVIEW	NUMBER OF ACTIONS: Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED	TOXICOLOGY								
HED	ECOLOGICAL EFFECTS								
HED	RESIDUE CHEMISTRY								
HED X	ENVIRONMENTAL FATE	2							
TSS	CHEMISTRY								
TSS	EFFICACY								
TSS	PRECAUTIONARY LABELING								
BFSD	ECONOMIC ANALYSIS								

20. ☐ Label Submitted with Application Attached
21. ☐ Confidential Statement of Formula
22. ☐ Representative Labels Showing Accepted Uses Attached
23. Date Returned to PD (to be completed by HED)
24. Include an Original and 4 (four) Copies of This Completed Form for Each Branch Checked for Review.

EPA Form 8570-13 (Rev. 11-81) PREVIOUS EDITIONS ARE OBSOLETE.

2 4

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

Emil Regelman

JUN - 9 1987

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Request for Expeditious Review
(Sulfosate, SC-0224)

FROM: Edwin F. Tinsworth, Director
Registration Division (TS-767C)

TO: John W. Melone, Director
Hazard Evaluation Division (TS-769C)

Stauffer Chemical Company has requested an expeditious review of chronic toxicity and environmental exposure studies on their new chemical sulfosate. These data were recently submitted and have been routed for Agency review. Sulfosate is a new herbicide, proposed for noncropland use. Stauffer met with Douglas Campt in March, to discuss the sulfosate registrations. As a result of that meeting, Doug Campt indicated that the Agency would expedite any additionally required data so that a final determination could be made on the sulfosate registrations prior to next year's use season.

→ MSS
CC TOX
EAB
— I believe one of these is a groundwater protocol

IEO 143 25
6/9