125401

MEMO OF MEETING ON 2/27/84

S. Creeger and C. Fletcher, EAB and R. Perfetti, RCB met with RD representative and FMC Corporation representatives to discuss future registration data requirements for the herbicide FMC 57020 for preplant (soil incorporated) or post emergence (surface applied) use on soybeans. The application rate is 0.5 to 1.5 lb a. i./A.

FMC presented ^{14}C rotational crop data and sought EAB guidance on the next step for registration. The data showed oat straw planted 10 months after application contained measurable levels of ^{14}C. Other crops showed little or no ^{14}C activity. EAB stated that the data would support a 10 month crop rotation restriction on the label provided the residues in the dried oat straw were identified as undistinguishable or were shown to be incorporated into natural plant constitutents. If parent ^{14}C residues are present then they must be shown to be present at a level less than the limit of detection when using the cold method of analysis. EAB noted that the data would not support grazing of immature crops. (FMC commented that a 10 month rotation restriction would be acceptable.)

FMC asked about the protocol submitted on the special field leaching study. EAB commented that the protocol had not yet been routed for review. However, based on quick overview EAB requested FMC to submit a more complete protocol. EAB asked questions about details of the protocol:

EAB Question	FMC Response
Specify location	Maryland Eastern Shore
Field size	One-half acre
Herbicide soil incorporated	Will conduct both broadcast and incorporated study
Prefer soil with <1% OM	Soil will be at least <2% OM
Irrigation should simulate major rainstorm	Irrigation will include "major rainfall event"

EAB made other comments: If residues found at 4 feet, soil must be sampled deeper. FMC should sample soil in 1 foot increments and should submit hydrology data of area and estimate rainfall for area (EAB will verify data). FMC should

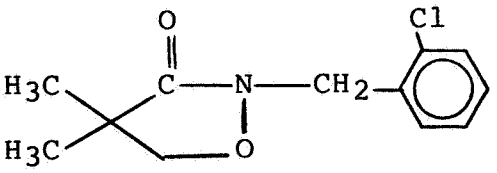
specify soil textural class for the 1 foot increments. Also, soil should be analyzed for parent compound and Metabolite A found in the anaerobic soil metabolism study. If residues are found, additional studies in other locations may be required.

FMC commented that study will run for 60 days.

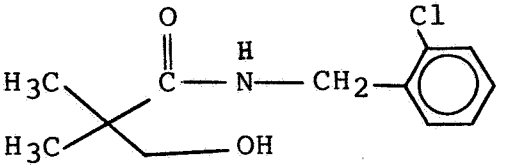
Concerning the field dissipation studies reviewed earlier, rainfall data and soil characterization must be submitted.

Clinton Fletcher
Review Section No. 1

STRUCTURES



FMC 57020



Metabolite A

Water sol.: 1,100 ppm

FMC Corporation

Agricultural Chemical Group
2000 Market Street
Philadelphia Pennsylvania 19103
(215) 299 6000

February 13, 1984

Mr. Robert J. Taylor
Product Manager 25
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
Room 245, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Mr. Taylor:

Subject: FMC 57020 Herbicide

We wish to have a conference-meeting with Dr. Samuel M. Creeger, Environmental Assessment Branch, and Dr. Robert S. Quick, Residue Chemistry Branch, in order to review the results of our radio-labeled crop rotational studies with FMC 57020. Our objective is to obtain Agency guidance concerning the need for residue field trials and rotational (inadvertent) crop tolerances for FMC 57020.

557-7700

8th floor Conf.

I'd appreciate it if you would arrange the meeting for us with Drs. Creeger and Quick. Mr. Ronald F. Cook, Residue Analysis Manager, and Dr. Robert A. Robinson, Metabolism Manager, ~~will accompany me.~~ Acceptable dates for us are Monday, February 27, Tuesday, February 28, or Thursday, March 1 at 10:00 am or 1:00 pm. Please let me know which date and time would be most convenient for you. You can reach me at (215) 299-6503.

Thank you in advance for your assistance in setting up this conference-meeting.

Sincerely yours,

Jack Lauber

J. J. Lauber
Manager, Product Registration

cc: D. B. Carlson
R. F. Cook
J. R. Graham
J. F. McCarthy
R. A. Robinson

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r17A1/dd30

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FMC 57020 HERBICIDE

FEBRUARY 27, 1984

AGENDA

1. INTRODUCTION - REGISTRATION STATUS OF FMC 57020; PROPOSED LABEL
2. REVIEW OF SOYBEAN RESIDUE STUDIES
3. REVIEW OF RADIO-LABELED CROP ROTATION DATA WITH FMC 57020
4. DISCUSSION OF INADVERTENT RESIDUE CHEMISTRY PROGRAM
5. DISCUSSION OF FMC PROTOCOL CONCERNING A FIELD MOBILITY STUDY WITH FMC 57020

FMC PARTICIPANTS: MR. RONALD F. COOK, RESIDUE ANALYSIS MANAGER

DR. ROBERT A. ROBINSON, METABOLISM MANAGER

DR. JACK LAUBER, REGISTRATION MANAGER

R118A1
RK30

FMC 57020 HERBICIDE

CROP REGISTRATION OBJECTIVES

INITIAL: SOYBEANS

FUTURE: TOBACCO
POTATOES
COTTON

R124A1
DD30

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FMC 57020 HERBICIDE

SOYBEANS

- EXPERIMENTAL USE PERMIT (279-EUP-93)

  1983: 800 ACRES, 2,400 LB. A.I., 29 STATES

  1984: 935 ACRES, 2,805 LB. A.I., 29 STATES

- EXPERIMENTAL USE PERMIT/TEMPORARY TOLERANCE (PENDING)

  1985: 70,000 ACRES, 70,000 LB. A.I., 29 STATES

- REGISTRATION APPLICATION/TOLERANCE PETITION

  TO BE SUBMITTED: AUGUST, 1984

L618B24
DD30

FMC 57020 HERBICIDE

SOYBEAN USE DIRECTIONS (PROPOSED)

- o FMC 57020 4EC OR 6EC HERBICIDE
- o 0.5 TO 1.25 (PERHAPS 1.50) LBS AI/ACRE
- o BROADCAST APPLICATION (PRE-EMERGENCE OR PREPLANT) - MAIN USE
- o BAND APPLICATION
- o ALONE OR IN COMBINATION WITH METRIBUZIN OR LINURON (TANK MIX)

R59A5
RS24

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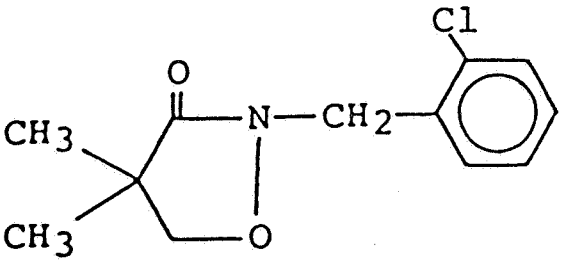
FMC 57020 HERBICIDE

CHEMICAL NAME: 2-(2-CHLOROPHENYL) METHYL-4, 4-DIMETHYL-3-ISOXAZOLIDINONE

STRUCTURAL FORMULA:



FMC 57020

TOTAL ^{14}C RESIDUES

(PPM EQUIVALENT TO PARENT CHEMICAL)

IN SOYBEAN PLANTS FROM FIELD TREATMENT

	2 LB		3 LB	
	^{14}C LABEL		^{14}C LABEL	
	CARBONYL	RING	CARBONYL	RING
30 DAY	3.51	2.38	3.59	3.72
60 DAY	0.74	0.70	1.40	1.40
BEAN	0.10	0.10	0.15	0.23

FMC 57020

DISTRIBUTION OF ^{14}C RESIDUES FROM SOYBEANS

	2 LB AI/A				3 LB AI/A			
	RING-^{14}C		CARBONYL-^{14}C		RING-^{14}C		CARBONYL-^{14}C	
FRACTION	%	PPM	%	PPM	%	PPM	%	PPM
FAT/FATTY ACIDS	9.6	0.011	10.6	0.011	6.4	0.013	9.6	0.014
FMC 57020	0.4	<0.001	1.4	0.001	0.2	<0.001	0.7	0.001
METABOLITES	47.7	0.052	27.8	0.028	48.0	0.101	29.3	0.044
POLAR RESIDUES	14.7	0.016	38.4	0.038	11.9	0.025	41.7	0.063
BOUND RESIDUES	27.6	0.030	21.8	0.022	33.5	0.070	18.7	0.028
TOTAL	100.0	0.110	100.0	0.100	100.0	0.210	100.0	0.150

-PPM EQUIVALENT TO PARENT COMPOUND

FMC 57020

SOYBEAN METABOLITE DISTRIBUTION[1/]

	TREATMENT			
	2 LB		3 LB	
	%	PPM	%	PPM
OCB ALCOHOL	5.2	0.003	12.1	0.015
HYDROXY OCB ALCOHOLS[2/]	19.0	0.013	10.8	0.015
OCB ACID	0.8	<0.001	1.3	0.002
UNIDENTIFIED METABOLITES (4)	2.8	0.003[3/]	2.1	0.004[3/]
REMAINING RESIDUE	19.9	0.022[3/]	21.7	0.046[3/]
	47.7		48.0	

[1/] ETAC SOLUBLE FRACTION (AFTER ACID HYDROLYSIS)

[2/] INCLUDES THREE POSSIBLE MONOHYDROXYLATED ALCOHOLS. A FOURTH ISOMER (5-HYDROXY OCBA) WAS ELIMINATED BY CHROMOTOGRAPHY

[3/] AS FMC 57020 EQUIVALENT

FMC 57020

SOYBEAN METABOLISM SUMMARY

- TOTAL ^{14}C RESIDUES IN IMMATURE PLANTS 2-10 PPM (PARENT EQUIV.) BUT ONLY ~0.2 PPM IN MATURE BEANS. MAJORITY OF RESIDUES BOUND OR POLAR PRODUCTS.
- IMMATURE PLANTS CONTAIN PARENT COMPOUND AND SIX SIGNIFICANT (≥10%) METABOLITES. CLEAVAGE OF MOLECULE INDICATED (NOT OBSERVED IN RAT).
- NO SIGNIFICANT LEVELS OF PARENT CHEMICAL INDICATED IN SOYBEANS (~1 PPB).
- SUBSTANTIAL AMOUNTS OF SOYBEAN ^{14}C RESIDUE INCORPORATED INTO BOUND AND POLAR (WATER SOLUBLE) RESIDUES (0.03 - 0.07 PPM).
- SOME UBIQUITOUS INCORPORATION OF ^{14}C INTO NATURAL PRODUCTS (~0.01 PPM).
- LOW BUT DETECTABLE LEVELS OF O-CHLOROBENZYL ALCOHOL AND HYDROXYLATED O-CHLOROBENZYL ALCOHOLS (<0.01-0.01 PPM) DETECTED IN SOYBEANS FROM 2 LB AI/A TREATMENT.

FMC 57020

RESIDUE RESULTS

<0.01 PPM FMC 57020

(NO DETECTABLE RESIDUE)

MATURE SOYBEANS

(111-152 DAY PHI)

22 FIELD TRIALS

(11 PRE-PLANT INCORPORATED
& 11 PRE-EMERGENT)

9 STATES

(AR, IL, IN, MD, NC, NE,
NJ, MO, VA)

2 LB AI/A BROADCAST TREATMENT

FMC 57020
SOYBEAN PROCESSING STUDY

APPLICATION

- AT PLANTING
- BROADCAST PRE-EMERGENCE
- 3 LB AI/A

SAMPLED

- MATURE BEANS @ 139 DAYS

ANALYSES

- UNPROCESSED BEANS
- SOYBEAN HULLS
- SOYBEAN MEAL
- SOYBEAN OIL
- SOYBEAN SOAPSTOCK

} <0.01 PPM FMC 57020 (NO DETECTABLE RESIDUE)

FMC 57020

CONCLUSION

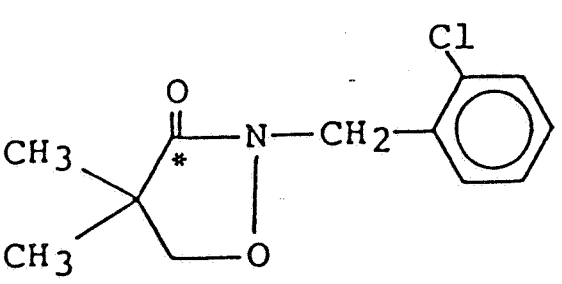
- SOYBEAN REGISTRATION WILL BE FOR BEANS ONLY WITH LABEL RESTRICTION AGAINST FEEDING FORAGE AND FODDER.
- TOLERANCE ON BEANS WILL BE NEGLIGIBLE TOLERANCE FOR PARENT COMPOUND BASED ON METHOD SENSITIVITY (0.05 PPM).
- STANDARD SOYBEAN PROCESSING STUDY IS ~~NOT~~ REQUIRED FOR FULL REGISTRATION.
- ? COW AND POULTRY METABOLISM AND FEEDING STUDIES ARE NOT REQUIRED FOR FULL REGISTRATION.

FMC 57020

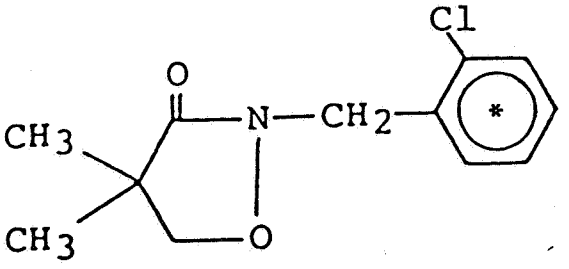
RADIOLABELED CROP ROTATION STUDY

STUDY PROTOCOL

- OUTDOOR TESTS CONDUCTED AT FMC RESEARCH FARM, CHAMPAIGN, IL.
- CARBONYL- AND RING-^{14}C FMC 57020 FORMULATED (4 EC) AND APPLIED AT 2 LB AI/A (PPI).



CARBONYL-^{14}C FMC 57020



RING-^{14}C FMC 57020

*DENOTES POSITION OF ^{14}C LABEL

- CHEMICALS APPLIED TO 1 X 10 FT TEST PLOTS (6/82). SOYBEANS PLANTED.
- SOYBEANS HARVESTED (10/82).
- ROTATIONAL CROPS PLANTED (4/83).

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FMC 57020

RADIOLABELED CROP ROTATION STUDY

STUDY PROTOCOL (CONT'D)

- ROTATIONAL CROPS SAMPLED

CORN	10/83
OATS	8/83
CABBAGE	8/83
SUGAR BEET	10/83

- SOIL SAMPLED (0-6", 6-12")
  - APPLICATION (6/82)
  - SOYBEAN HARVEST (10/82)
  - ROTATIONAL CROP PLANTING (4/83)
  - SUGAR BEET HARVEST (10/83)

- ROTATIONAL CROPS ASSAYED BY COMBUSTION ASSAY FOR TOTAL ^{14}C RESIDUES.

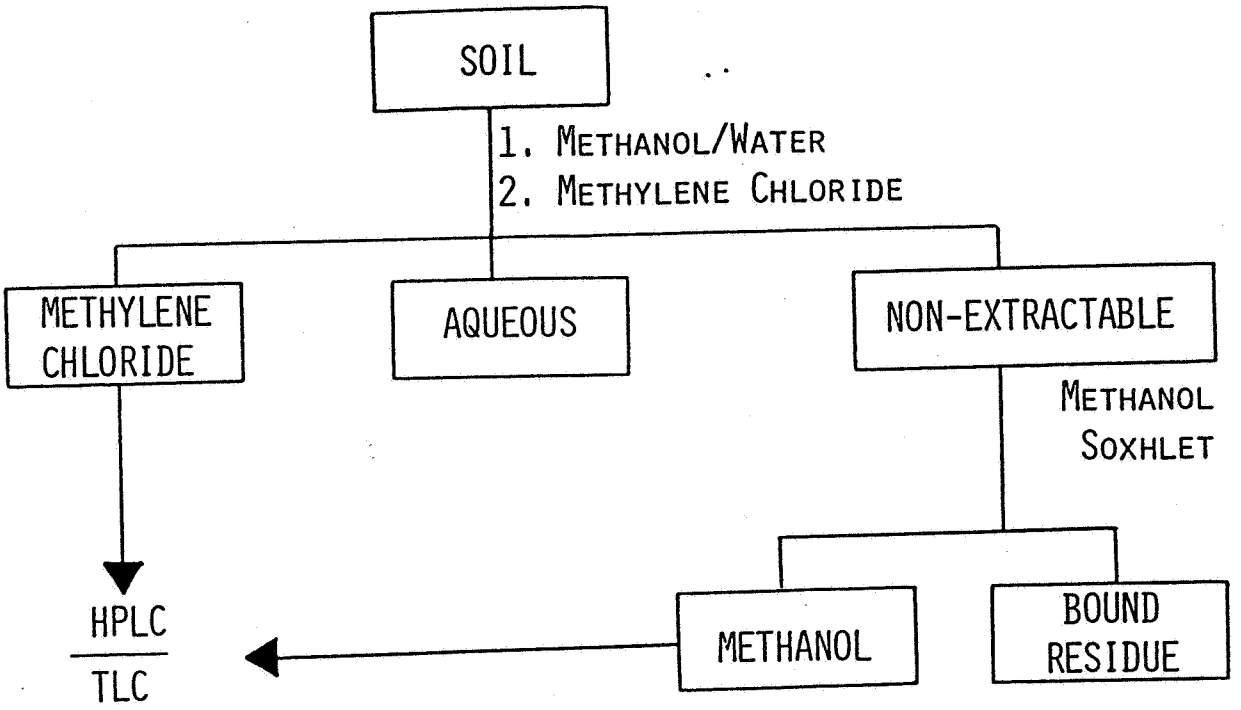
- MATURE RAC's SUBJECTED TO EXTRACTION/DIGESTION AND SOLVENT PARTITION.

- SOILS ASSAYED BY SOLVENT EXTRACTION. PARENT CHEMICAL ANALYZED BY CHROMATOGRAPHY.

FMC 57020

RADIOLABELED CROP ROTATION STUDY

SOIL EXTRACTION PROCEDURE



FMC 57020

OUTDOOR CROP ROTATION

SOIL RESIDUE SUMMARY (2 LB AI/A)

0-6" DEPTH

TIME (MONTHS)	PPM (FMC 57020 EQUIVALENTS)					
	CARBONYL-^{14}C			RING-^{14}C		
	0	4	10	0	4	10
FMC 57020	1.01	0.25	0.28	0.84	0.21	0.18
DEGRADATES	0.01	0.01	ND	0.01	ND	ND
AQUEOUS	<0.01	<0.01	0.01	0.01	0.01	<0.01
BOUND (NON-EXTRACTABLE)	0.07	0.15	0.23	0.05	0.15	0.15
TOTAL	1.09	0.41	0.52	0.91	0.37	0.33

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FMC 57020

OUTDOOR CROP ROTATION

SOIL RESIDUE SUMMARY (2 LB AI/A)

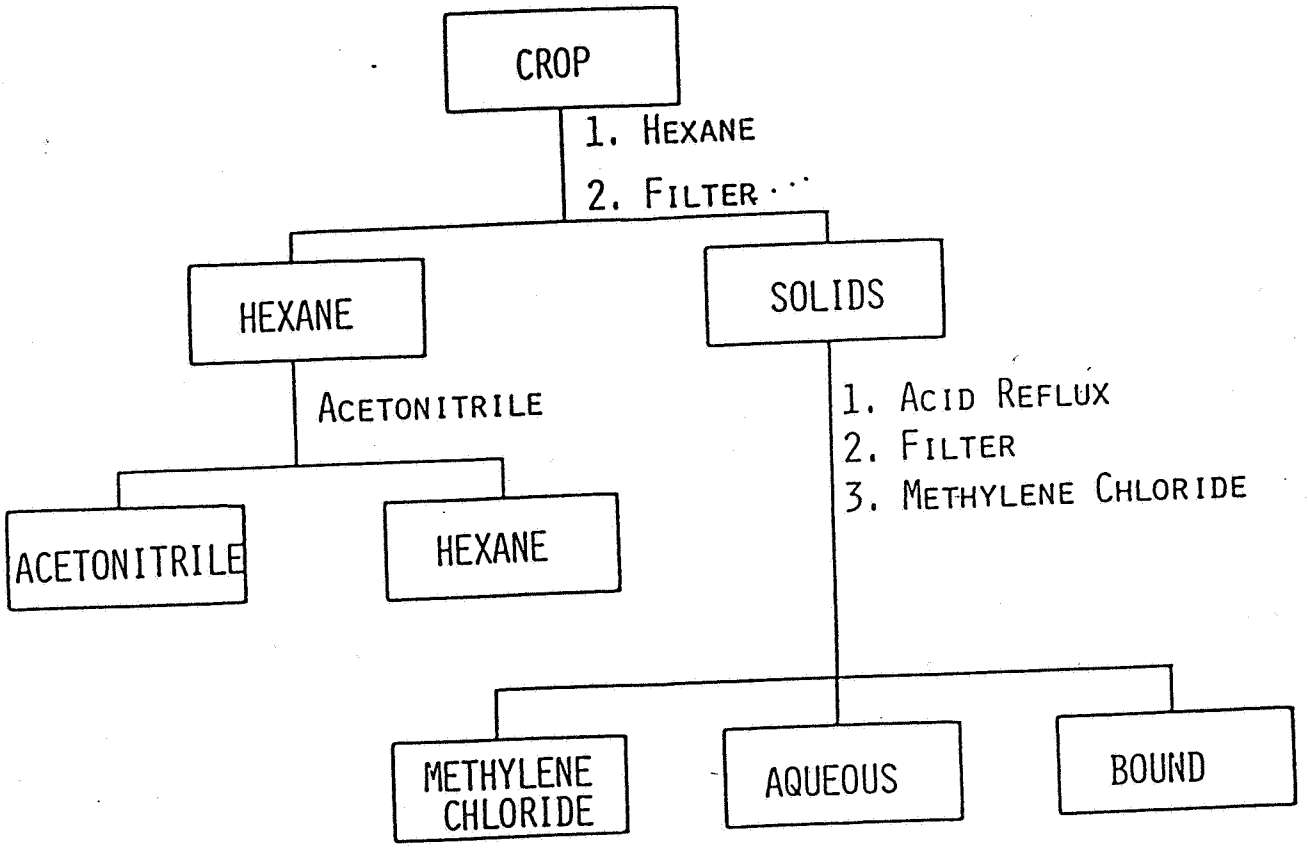
6-12" DEPTH

	PPM (FMC 57020 EQUIVALENTS)					
	CARBONYL-^{14}C			RING-^{14}C		
TIME (MONTHS)	0	4	10	0	4	10
FMC 57020	0.07	0.14	0.03	0.02	0.24	0.04
DEGRADATES	ND	<0.01	ND	ND	0.01	ND
AQUEOUS	ND	ND	<0.01	<0.01	0.01	<0.01
BOUND (NON-EXTRACTABLE)	0.02	0.05	0.03	0.01	0.13	0.05
TOTAL	0.09	0.19	0.06	0.03	0.39	0.09

FMC 57020

RADIOLABELED CROP ROTATION STUDY

CROP EXTRACTION/DIGESTION SCHEME



FMC 57020

RADIOLABELED CROP ROTATION STUDY

SUMMARY OF ^{14}C CROP RESIDUE DISTRIBUTION

		PPM (FMC 57020 EQUIVALENTS)							
		CORN			OATS		CABBAGE	SUGAR BEETS	
FRACTION	^{14}C LABEL	SILAGE	STOVER	GRAIN	STRAW	GRAIN	HEAD	TOPS	ROOTS
ORGANOSOLUBLE	C	0.002	0.007	0.010	0.016	0.019	0.009	0.011	0.005
	R	0.003	0.008	0.005	0.027	0.037	0.006	0.027	0.008
POLAR (AQUEOUS)	C	0.006	0.006	0.004	0.018	0.030	0.012	0.015	0.006
	R	0.006	0.008	0.010	0.024	0.021	0.011	0.013	0.008
BOUND	C	0.005	0.014	0.002	0.036	0.021	0.011	0.016	0.010
	R	0.007	0.029	0.003	0.068	0.027	0.005	0.023	0.016
TOTAL	C	0.013	0.028	0.016	0.071	0.070	0.032	0.042	0.021
	R	0.016	0.045	0.019	0.118	0.085	0.022	0.063	0.032

C = CARBONYL-^{14}C FMC 57020

R = RING-^{14}C FMC 57020

ORGANOSOLUBLE = TOTAL ^{14}C IN HEXANE, ACETONITRILE AND METHYLENE CHLORIDE

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FMC 57020

RADIOLABELED CROP ROTATION

RESULTS/DISCUSSION

- LEVELS OF RADIOCARBON (MOSTLY FMC 57020) PERSIST IN SOIL
- ^{14}C RESIDUES INCORPORATED INTO ROTATIONAL CROPS
- MAJORITY OF RADIOCARBON IN ROTATIONAL CROPS WATER SOLUBLE AND/OR BOUND IN PLANT SOLIDS
- FMC SEEKS GUIDANCE ON CURRENT AND FUTURE STATUS OF ROTATIONAL CROP/INADVERTENT RESIDUE ISSUE

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FMC 57020

FIELD MOBILITY STUDY

OBJECTIVE

Determine leachability (vertical mobility) of FMC 57020 through a light textured agricultural soil under irrigated field conditions.

TEST SITE

Study will be conducted at a single loamy sand soil (>70% sand, <2% organic matter) location suitable for agricultural production of soybeans. The site and immediately adjacent areas will have no previous history of treatment with FMC 57020. Soil surface at the study site will be worked up in accordance with standard agricultural practice, but no crop will be planted. Treatment of the plot would be with FMC 57020 4.0 EC at 2 lb ai/A as a surface broadcast application (i.e., pre-emergent). Water will be applied to the plot by irrigation on post treatment days 1, 4, 9, 14, 19, 24, 29, 39, 49 and 59 at a rate of 0.5 in/application. Soil surface will be left undisturbed throughout the test.

SAMPLING

Soil core samples (0-1, 1-2, 2-3 and 3-4 ft) will be taken from the plot on days 0, 2, 5, 10, 15, 20, 25, 30, 40, 50 and 60. A total of 10 cores, randomly selected, will be composited to form the sample for each sampling day. An untreated area will also be sampled at 1 foot increments to 4 ft on days 0, 10, 20, 30 and 60.

ANALYSES

Residue levels of FMC 57020 (parent) and FMC 65317 (anaerobic soil metabolite) will be determined in the composite soil samples.

MISCELLANEOUS

The following supplemental information will be obtained.

- Soil textural classification
- Evapotranspiration rate (Pan evaporation)
- Rainfall data
- Temperature