MEMORANDUM OF MEETING

PM #25-R. Taylor
EAB-S. Creeger, R. Moraski and C. Fletcher
FMC Corp.-R. Cook and J. Lauber

On January 24, 1984, we met with representatives of FMC Corp. to discuss data needed to support use of FMC 57020 (herbicide) on soybeans under an EUP and registration.

EUP

Hydrolysis
Aqueous photolysis
Aerobic soil metabolism
Leaching
Rotational crop data or temp. tolerance, etc.

Registration

Hydrolysis
Aqueous photolysis
Soil photolysis
Aerobic soil metabolism
Anaerobic soil metabolism
Leaching
Aged leaching
Field dissipation
Rotational crop data (confined and field)
Fish accumulation

Comments

Photolysis data are requested under the EUP due to the large (70,000 acres) amount of acreage and poundage (70,000 lb ai) involved. Soil photolysis data are preferred but sensitized aqueous photolysis data will suffice for the EUP.

If the registrant can show that only parent compound is present after 30 days of aerobic aging, then the aged leaching study could be waived.

Current field dissipation data do not conclusively show the absence of leaching of residues beyond 12 inches. The study will have to be repeated or the registrant will have to address the issue by some or all of the following:

- Analyze the frozen 7-day samples for residues including the product found in the anaerobic study

• Conduct a short (@ 60 days) field study with artificial rainfall if necessary, to determine if a slug of chemical moves through the soil profile. These studies should be run on the plots on which the previous field studies were run, plus another study on a sandy soil should be run. Results of the data may result in the necessity for additional data.

• Protocols for conducting additional studies should be submitted for EAB review. The protocols should include provisions for: sandy soil, rainfall or irrigation immediately after application and during the first 2-weeks post-application to simulate a worst-case situation (check rainfall charts for this), soil sampling to sufficient depth to define extent of leaching, analysis for parent and metabolite A, soil incorporation of the active ingredient per label instructions.

Samuel M. Creeger
February 6, 1984
EAB/HED

55, 1800

FMC Corporation

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

FMC

Jan 24
10 am

December 20, 1983

Mr. Robert J. Taylor (PM-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
(Experimental Use Permit No. 279-EUP-93)

On June 27, Mr. Ronald F. Cook, Dr. R. A. Robinson and I met with Ms. Janet Remmers, RD, Dr. Richard V. Moraski and Mr. Clinton Fletcher, EAB, HED, to discuss FMC's progress and plans for FMC 57020 herbicide. Highlights of this meeting were:

Dr. Moraski and Mr. Fletcher agreed that there would be nothing to learn from conducting a field dissipation study with monitoring for leaching and potential ground water contamination of FMC 57020. This is because FMC 57020 will move downward in the soil profile and has the potential to end up in the ground water. Consequently, there is no need to generate data to confirm this acknowledged potential.

In place of the monitoring study, Dr. Moraski and Mr. Fletcher indicated that computer modeling would provide adequate rate of movement information for the full registration of FMC 57020 as long as nothing unusual developed in the soil dissipation study.

We wish to review with Dr. Moraski and Mr. Fletcher recently developed information concerning FMC 57020 herbicide and obtain their comments and suggestions. Specifically, we wish to discuss:

1. Soil dissipation study (four locations)
2. Computer modeling to predict movement of FMC 57020 in soil.

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I'd appreciate it if you would set up a meeting for us with Dr. Moraski and Mr. Fletcher. Mr. Ronald F. Cook, Residue Analysis Manager of our Research and Development Department will accompany me. Agreeable dates for us are 1/24, 1/25 or 1/26 at 10:00 am or 1 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 meeting.

Sincerely yours,

Jack Lauber

J. J. Lauber
Manager
Product Registration

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

r48B4
dd24

63

4

123401

FILE

June 28, 1983

REPORT OF MEETING, JUNE 27, 1983.

SUBJECT: FMC 57020 4 EC Herbicide, EUP Permit No. 279-EUP-93

Participants:	C. Fletcher, EAB, HED	R. Cook,	FMC
	R. Moraski, "	R. Robinson,	"
	J. Remmers, HRB, RD	J. Lauber,	"

EAB met with FMC representatives to discuss EAB review of FMC 57020, dated 12/3/82.

FMC wanted further clarification of the following EAB comments:

1. EAB's recommendation that the FMC field dissipation study include monitoring for leaching and contamination of ground water. FMC acknowledged that FMC 57020 has the potential to leach in soil and, most likely, will contaminate ground water. The soil characteristics of FMC 57020 are very similar to atrazine (a compound known to leach). Will it be necessary to go below 12 inches of soil depth to show it will leach. Note: FMC said the field dissipation study is already underway.) Rather than deeper sampling, FMC offers to conduct modeling simulation studies to predict the extent of leaching.

   EAB response: No, it will not be necessary to show that it leaches since the company acknowledges that the compound most likely will leach below 12 inches. However, in the registration submission, FMC should explain why soil was not sampled below 12 inches when FMC 57020 is known to leach. EAB recommended to FMC they contact Bob Holst for information concerning the PESTANS model or other modeling for information in this area.

2. When is a tank mix soil dissipation study necessary? FMC 57020 will be tank mixed with other pesticides.

   EAB response: This data requirement has been deemphasized in the Guidelines. Given the list of chemicals to be tank mixed with FMC 57020, EAB is unable to predict circumstances that would trigger this data requirement. The registrant should be in a better postion to know how their chemical would affect the other chemicals.

3. Must a fish accumulation study be conducted.

   EAB response: Yes. Based on the facts that FMC 57020 is water soluble, is stable in water and will have the potential to reach water, a fish accumulation study will be necessary. However, EAB acknowledges that FMC 57020 has a low partition coefficient of 350.

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Note: In follow up comments after the meeting, EAB suggested that FMC become aware of the Agency's groundwater contamination policy (since FMC will have to conform to such policy). FMC should also become aware of the Toxicology Branch, HED, concerns for groundwater contamination.

FMC was told that the question may arise as to whether their chemical, FMC 57020 may in some way complex with chemicals with which it is tank mixed and leach/carry it also into groundwater. If a field monitoring study is required (based on model predictions), it may be necessary to monitor for the tank mixed chemical also. (This would be an example of when a tank mix soil dissipation study would be required.)

Clinton Fletcher
Review Section No. 1
Exposure Assessment Branch

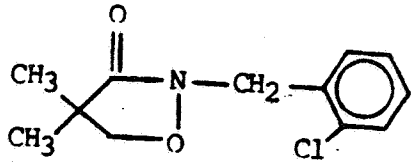
1.0 INTRODUCTION

FMC has submitted a letter summarizing points discussed in a pre-registration conference for the herbicide FMC 57020 being tested on soybeans under a current EUP. FMC requests confirmation of the points.

1.1 Chemical

Chemical name: 2-((2-chlorophenyl)-methyl)-4,4-dimethyl-3-isoxazolidinone

Chemical structure:



2.0 DISCUSSION

Points will be summarized and commented upon as listed in the FMC letter.

2.1 FMC point: EAB will accept a computer modeling study predicting extent of leaching to support registration of FMC 57020. FMC acknowledges that, based on lab studies, FMC 57020 will move downward in the soil profile and has the potential to end up in groundwater. EAB agrees there is no need to generate data to confirm this acknowledged potential.

EAB comment: However, it will be necessary for FMC to define the extent of leaching, in terms of depth and concentration of FMC 57020, with actual field data. In the soil dissipation study, if residues are found below the 6 inch soil level, then soil samples must be taken to sufficient soil depth to define the extent of leaching. EAB notes that soil samples are being taken at the 6-12 inch depth in the soil dissipation study.

2.2 FMC point: EAB stated that dissipation studies for tank mixes of FMC 57020 with other herbicides are not necessary at the present time.

EAB comment: EAB confirms that dissipation studies for tank mixes of FMC 57020 with other herbicides are not necessary.

2.3 FMC point: EAB stated that a fish accumulation study will be necessary to support registration of FMC 57020.

EAB comment: EAB confirms that a fish accumulation study will be necessary to support registration of FMC 57020.

Clinton Fletcher

Clinton Fletcher
Review Section No. 1
Exposure Assessment Branch
Hazard Evaluation Division.

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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)

USE FMC 57020 4 EC HERBICIDE AT A RATE OF 0.5 TO 1.25 POUNDS ACTIVE INGREDIENT (A.I.) (1.0 - 2.5 PINTS) PER ACRE IN A PREEMERGENCE BROADCAST, PREPLANT INCORPORATED, OR BAND APPLICATION. USE LOWER RATE FOR LOWER ORGANIC MATTER AND COARSER TEXTURED SOILS AND HIGHER RATE FOR HIGHER ORGANIC MATTER AND FINER TEXTURED SOILS.

APPLY IN A MINIMUM OF 10 GALLONS OF FINISHED SPRAY PER ACRE WITH GROUND EQUIPMENT OR 2 GALLONS PER ACRE BY AIRCRAFT, OR APPLY IN A UNIFORM MANNER BY MEANS OF SPRINKLER IRRIGATION.

TANK MIXTURES - USE FMC 57020 4 EC HERBICIDE AT A RATE OF 0.5 TO 1.25 POUNDS A.I. (1.0 TO 2.5 PINTS) PER ACRE WITH METRIBUZIN HERBICIDE AT A RATE OF 0.1 TO 0.6 POUNDS A.I. PER ACRE OR LINURON HERBICIDE AT A RATE OF 0.3 TO 1.5 POUNDS A.I. PER ACRE.

R614A30
RK21

FMC 57020 HERBICIDE

SOYBEAN USE DIRECTIONS (PROPOSED)

- o FMC 57020 4EC OR 6EC HERBICIDE
- o 0.5 TO 1.25 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
RK24

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FMC 57020 HERBICIDE

EPA LETTER OF JANUARY 10, 1984

PRIOR TO REGISTRATION AND FOR ANY PERMANENT TOLERANCE REQUEST, WE WILL NEED THE FOLLOWING:

OF THE ENVIRONMENTAL FATE DATA SUBMITTED, ONLY THAT WHICH WAS PERTINENT TO THIS EUP WAS REVIWED AT THIS TIME. WE NOTE THAT FMC 57020 HAS A POTENTIAL TO LEACH INTO GROUNDWATER. WE RECOMMEND THAT A FIELD DISSIPATION STUDY INCLUDE MONITORING FOR LEACHING AND FOR POTENTIAL GROUNDWATER CONTAMINATION IN SANDY SOILS LOW IN ORGANIC MATTER.

L13B1
RK23

158.130 ENVIRONMENTAL FATE DATA REQUIREMENTS

	TERRESTRIAL FOOD CROP
DEGRADATION STUDIES - LAB	
HYDROLYSIS	(R)*
PHOTODEGRADATION:	
IN WATER	R
ON SOIL	CR
IN AIR	CR
METABOLISM	
AEROBIC SOIL	(R)
ANAEROBIC SOIL	R
MOBILITY STUDIES	
LEACHING (ADSORPTION/DESORPTION)	R
VOLATILITY	
LAB	CR
FIELD	CR
DISSIPATION STUDIES - FIELD	
SOIL	R
SOIL, LONG TERM	CR
ACCUMULATION STUDIES	
ROTATIONAL CROPS	
CONFINED	(CR)
FIELD	CR
IN FISH	(CR)

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*KEY: R = REQUIRED; CR = CONDITIONALLY REQUIRED; ( ) = BRACKETS (I.E., (R), (CR)) INDICATE REQUIREMENTS THAT APPLY WHEN AN EXPERIMENTAL USE PERMIT IS BEING SOUGHT.

FMC 57020

SOIL METABOLISM

BACKGROUND

FIELD SOIL DISSIPATION

PERSISTENCE

MOBILITY

PESTANS MODELING

PREDICTED MOBILITY

VOLATILITY

FMC 57020 AEROBIC SOIL METABOLISM STUDY
MATERIAL BALANCE/PRODUCT DISTRIBUTION
2 MONTH INTERVAL.

	SANDY LOAM CARBONYL-^{14}C	SILT LOAM RING-^{14}C
FMC 57020	35.4	62.9
UNIDENTIFIED METABOLITES	3.1	1.6
POLAR RESIDUES	3.1	2.2
BOUND RESIDUES	9.4	11.2
CARBON DIOXIDE	49.0	22.1
TOTAL	100.0	100.0

FMC 57020 ANAEROBIC SOIL METABOLISM STUDY
MATERIAL BALANCE/PRODUCT DISTRIBUTION

	SILT LOAM RING-^{14}C	
	30 DAY	60 DAY
FMC 57020	24.7	8.3
METABOLITE "A"	22.5	23.4
UNIDENTIFIED METABOLITES	7.4	7.1
POLAR RESIDUES	7.5	16.0
BOUND RESIDUES	14.4	16.4
CARBON DIOXIDE	23.5	28.8
TOTAL	100.0	100.0

- RESULTS

AEROBIC

- DEGRADES AT MODERATE RATE
- DEGRADATION OCCURS VIA MINERALIZATION

ANAEROBIC

- MINERALIZATION PATHWAY IS SHUT DOWN
- PARENT COMPOUND IS CONVERTED TO METABOLITE "A" BY REDUCTION

FMC 57020

SOIL DISSIPATION STUDY

4 LOCATIONS

MIDWEST - SILT LOAM
NORTHEAST - SANDY LOAM
SOUTHEAST - SANDY CLAY LOAM
SOUTHWEST - SILT LOAM

TREATMENT

2 LB AI/A BROADCAST (PRE-PLANT INCORPORATED)
2 LB AI/A BROADCAST (PRE-EMERGENT)

SAMPLING

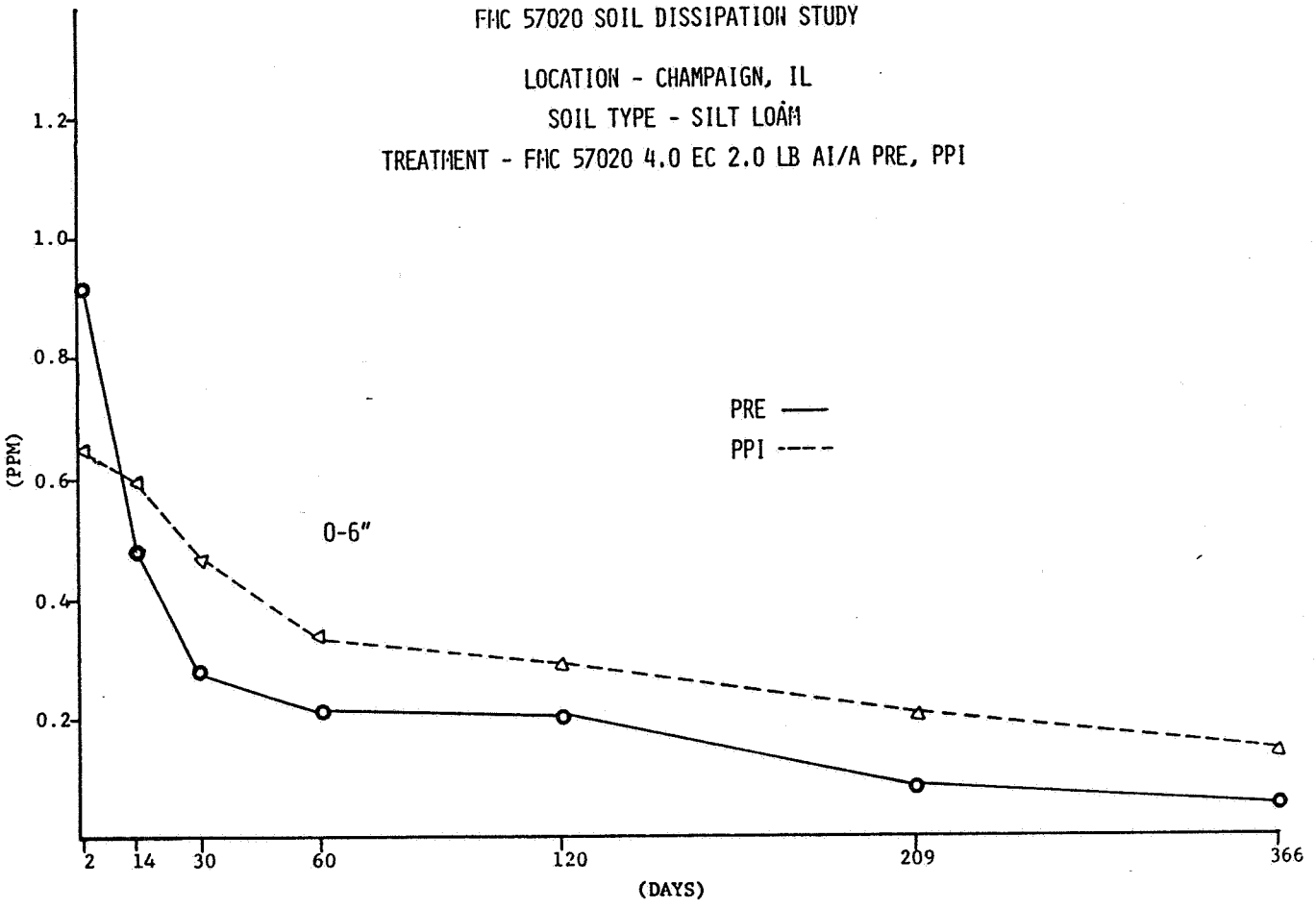
@ 0, 7, 14, 30, 60, 120, 150, 180, 360, 500 DAYS

SOIL CORES

0-6" AND 6-12"

77

18

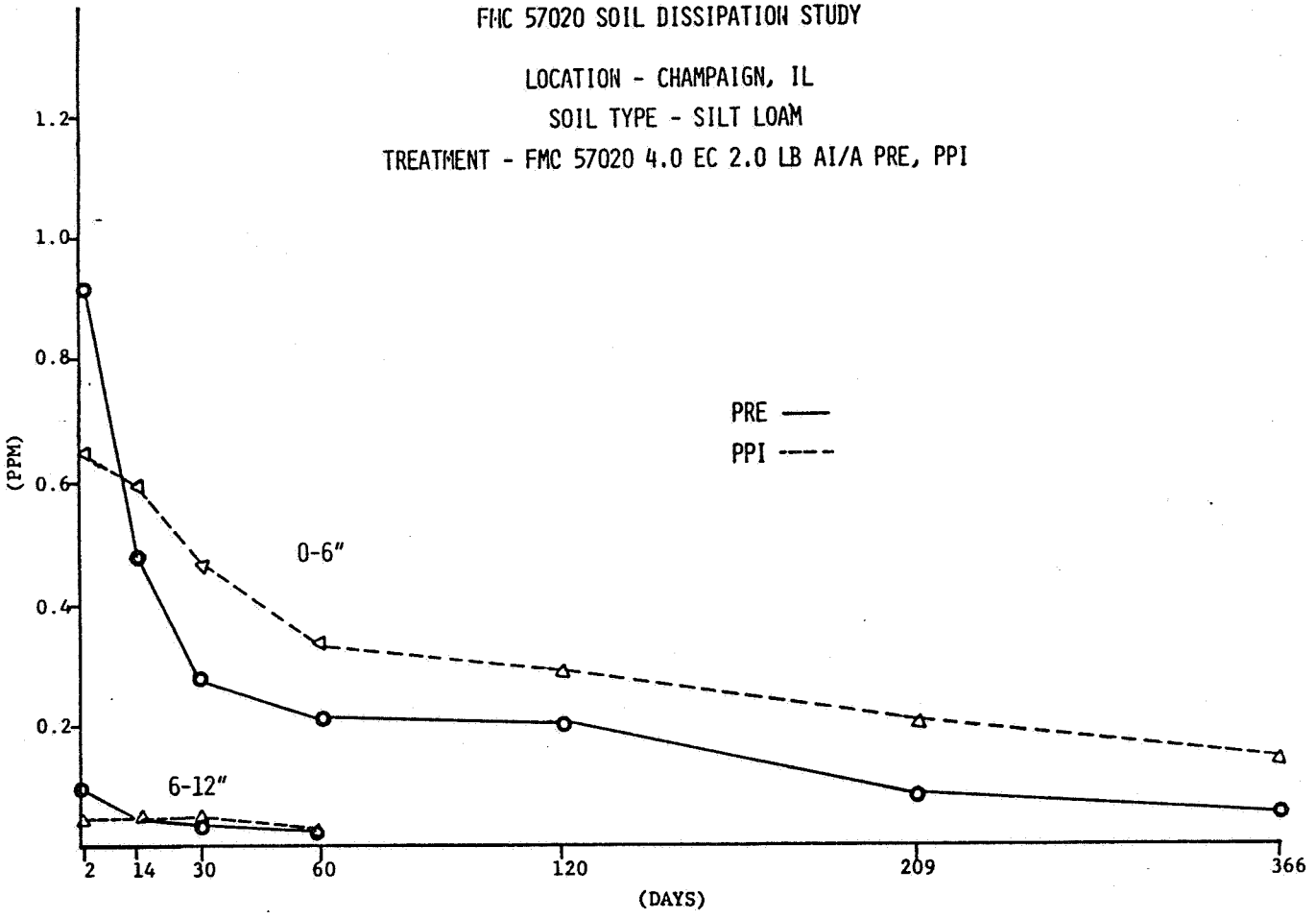

FMC 57020 SOIL DISSIPATION STUDY
LOCATION - CHAMPAIGN, IL
SOIL TYPE - SILT LOAM
TREATMENT - FMC 57020 4.0 EC 2.0 LB AI/A PRE, PPI
PRE
PPI
0-6"
(PPM)
1.2
1.0
0.8
0.6
0.4
0.2
2
14
30
60
120
209
366
(DAYS)

FMC 57020 SOIL DISSIPATION STUDY

LOCATION - CHAMPAIGN, IL

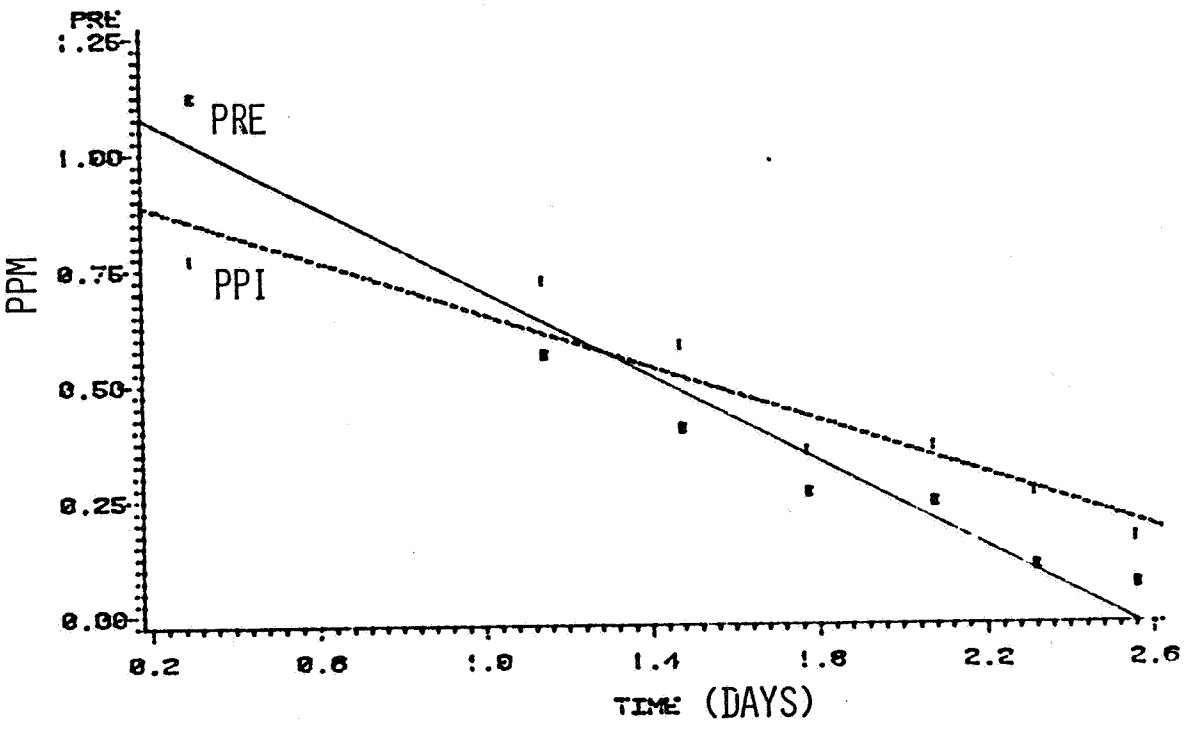
SOIL TYPE - SILT LOAM

TREATMENT - FMC 57020 4.0 EC 2.0 LB AI/A PRE, PPI



FMC57020 SOIL DISSIPATION DATA

LOC=CHAMPN



	CHAMPAIGN SILT LOAM	MARION SILT LOAM	P. GROVE SANDY LOAM	RALEIGH SANDY CLAY LOAM
PRE HALF-LIFE	18	20	15	19
PPI HALF-LIFE	40	39	18	22

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FMC 57020

SOIL MOBILITY

	ATRAZINE	FMC 57020
WATER SOLUBILITY	33 PPM	1100 PPM
SORPTION (K_D)		
SAND	1.65	1.54
SANDY LOAM	9.37	2.82
SILT LOAM	30.3	6.85
CLAY LOAM	9.13	2.57
TLC CLASS (MOBILITY)		
SAND	4 (MOBILE)	3 (INTERMEDIATE)
SANDY LOAM	2 (LOW)	2 (LOW)
SILT LOAM	3 (INTERMEDIATE)	2 (LOW)
CLAY LOAM	3 (INTERMEDIATE)	2 (LOW)
FIELD SOIL HALF-LIFE	30-60 DAYS	20-40 DAYS
FIELD USE RATE	2.0-3.0 LB AI/A	0.50-1.25 LB AI/A

● SOIL MOBILITY EXPECTATION

LOW TO INTERMEDIATE MOBILITY
SIMILAR TO ATRAZINE

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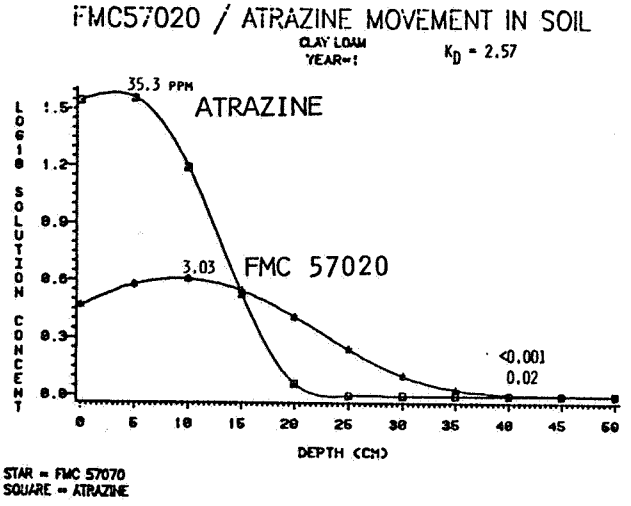
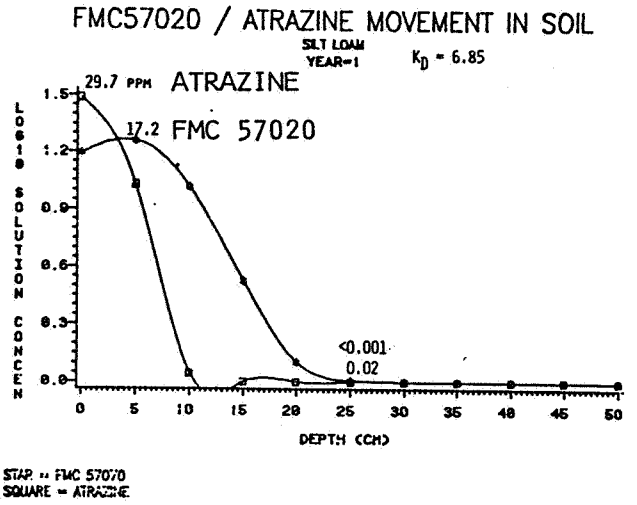
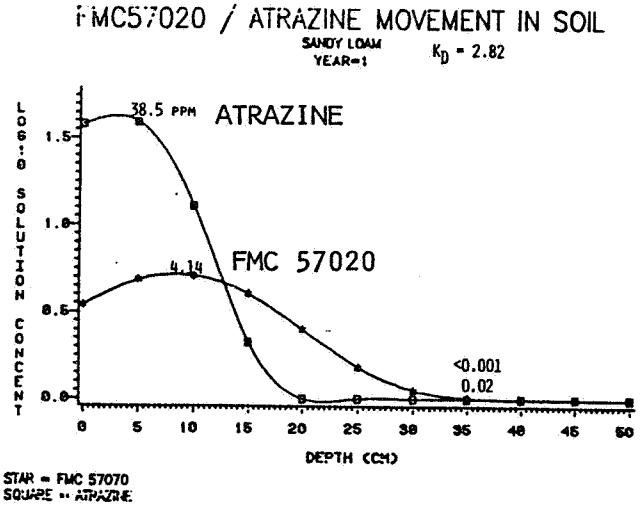
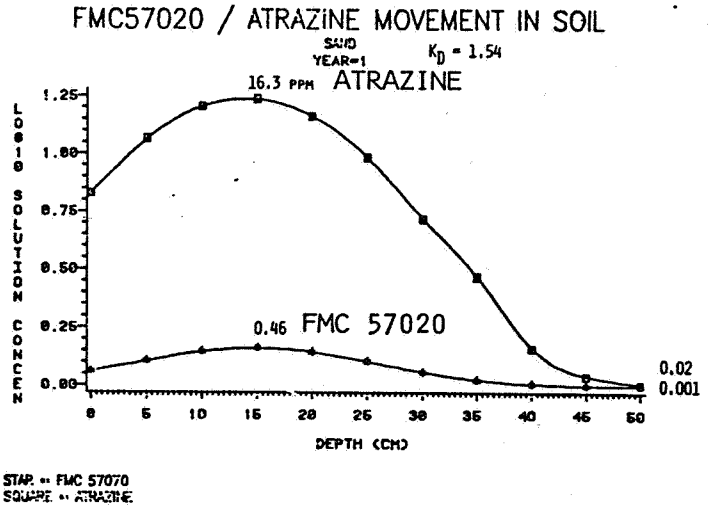
PESTANS SOIL PARAMETERS (FMC 57020)

	SAND	SANDY LOAM	SILTY LOAM	CLAY LOAM
SOLUBILITY	1100	1100	1100	1100
BULK DENSITY	1.50	1.50	1.50	1.50
DISPERSION COEFFICIENT	0.60	0.60	0.60	0.60
NO. OF APPLICATIONS	1.0	1.0	1.0	1.0
ACTIVE INGRED. KG AI/HA	1.12	1.12	1.12	1.12
DAYS BEFORE RECHARGE	1.0	1.0	1.0	1.0
RECHARGE RATE	15 & 30"	15"	15"	15"
SORPTION	1.54	2.82	6.85	2.57
SOIL POROSITY	0.395	0.435	0.485	0.476
WAVE COEFFICIENT	4.05	4.90	5.30	8.52
T 1/2	25	18 & 25	25 & 40	25


FMC57020 / ATRAZINE MOVEMENT IN SOIL
CLAY LOAM
YEAR=1
K_D = 2.57
35.3 PPM
ATRAZINE
3.03
FMC 57020
<0.001
0.02
LOG10 SOLUTION CONCENT
DEPTH (CM)
STAR = FMC 57070
SQUARE = ATRAZINE


FMC57020 / ATRAZINE MOVEMENT IN SOIL
SILT LOAM
YEAR=1
K_D = 6.85
29.7 PPM
ATRAZINE
17.2
FMC 57020
<0.001
0.02
LOG10 SOLUTION CONCEN
DEPTH (CM)
STAR = FMC 57070
SQUARE = ATRAZINE

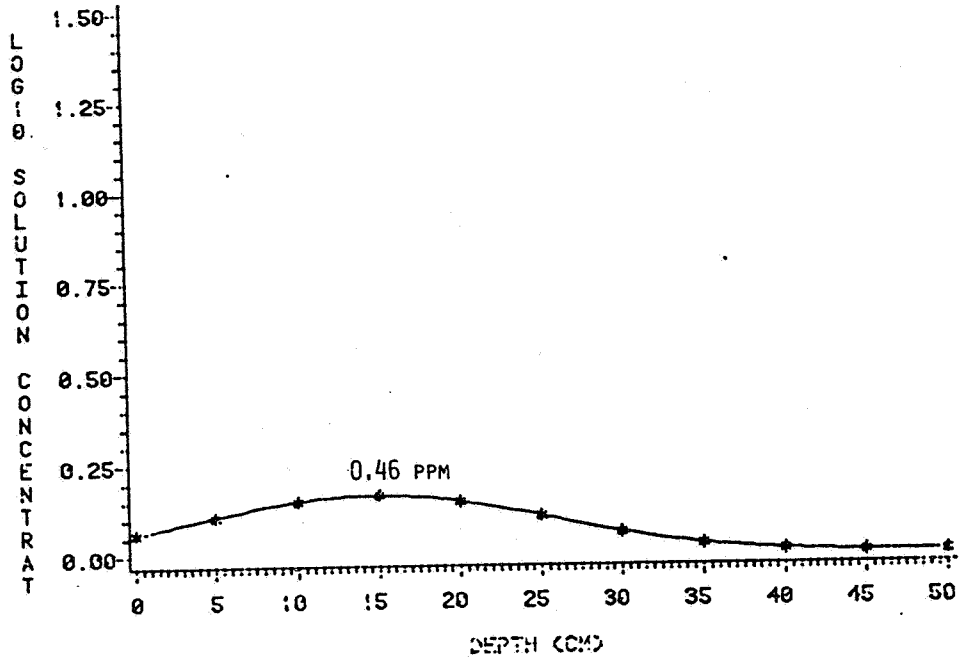

FMC57020 / ATRAZINE MOVEMENT IN SOIL
SANDY LOAM
YEAR=1
K_D = 2.82
38.5 PPM
ATRAZINE
4.14
FMC 57020
<0.001
0.02
LOG10 SOLUTION CONCENT
DEPTH (CM)
STAR = FMC 57070
SQUARE = ATRAZINE


FMC57020 / ATRAZINE MOVEMENT IN SOIL
SAND
YEAR=1
K_D = 1.54
16.3 PPM
ATRAZINE
0.46
FMC 57020
0.02
0.001
LOG10 SOLUTION CONCEN
DEPTH (CM)
STAR = FMC 57070
SQUARE = ATRAZINE

FMC57020 MOVEMENT IN SOIL

SAND

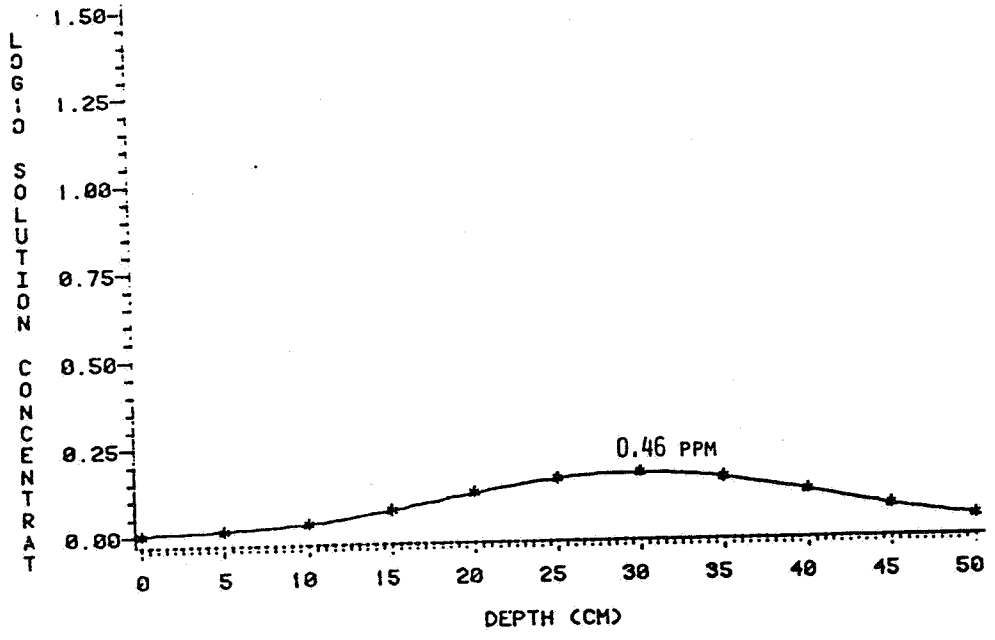
RECHARGE = 15"; YEAR = 1



FMC 57020 MOVEMENT IN SOIL

SAND

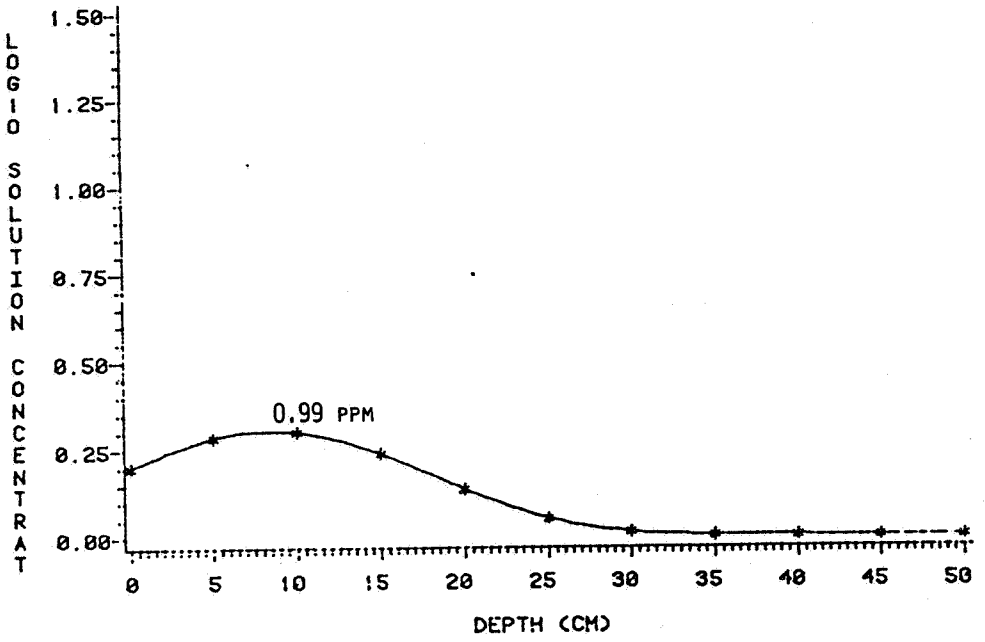
RECHARGE = 30"; YEAR = 1



FMC 57020 MOVEMENT IN SOIL

SANDY LOAM

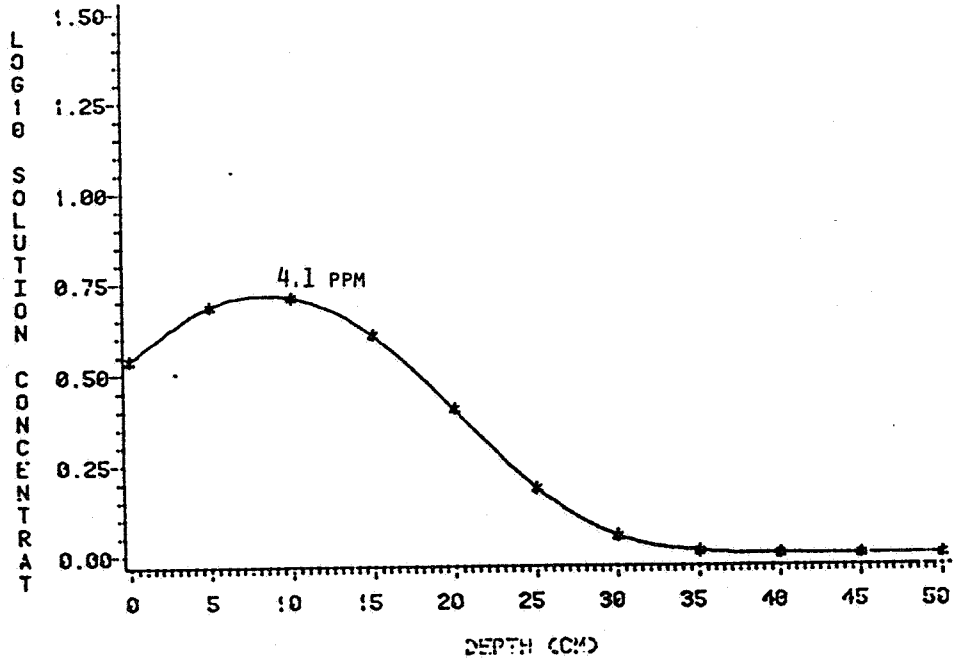
T 1/2 = 18 DAYS, YEAR=1



FMC57020 MOVEMENT IN SOIL

SANDY LOAM

T 1/2 = 25 DAYS; YEAR = 1



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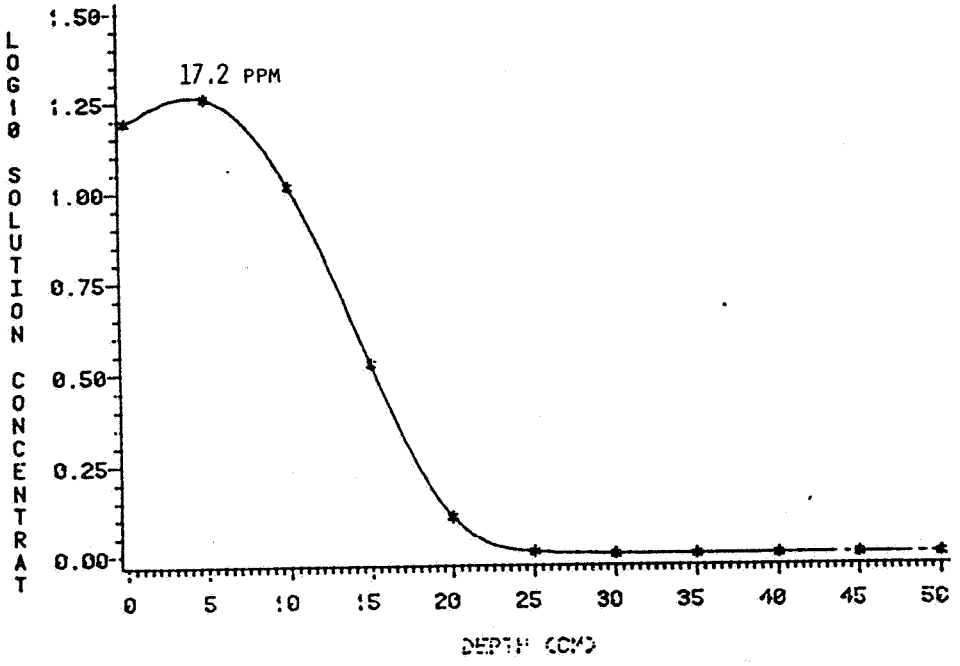
FMC57020 MOVEMENT IN SOIL

SILT LOAM

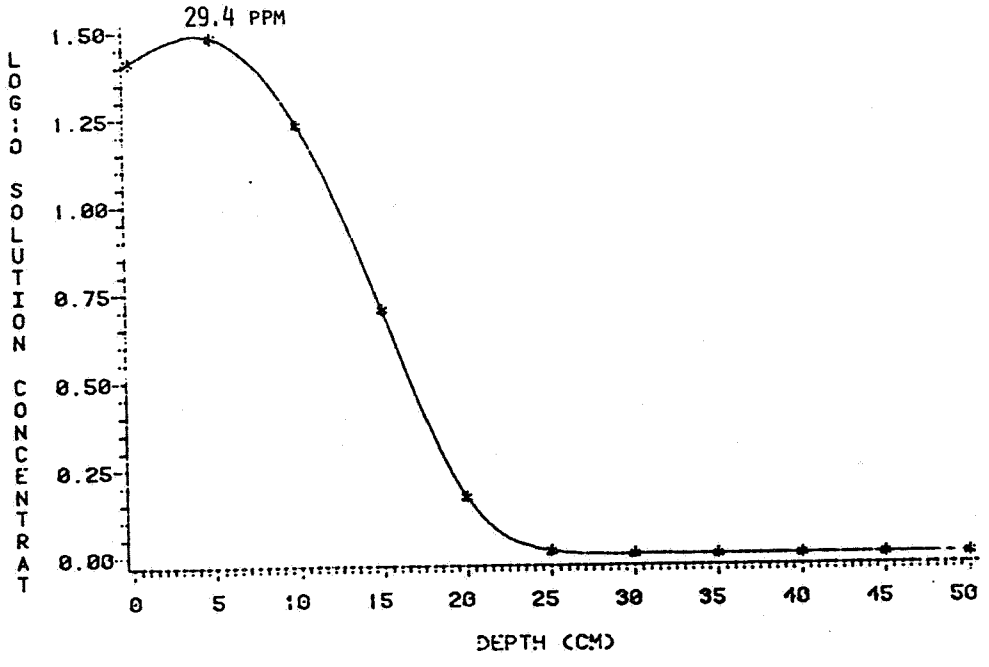
T 1/2 = 25 DAYS; YEAR = 1



FMC 57020 MOVEMENT IN SOIL

SILT LOAM

T 1/2 = 40 DAYS, YEAR=1



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FMC 57020
CONCLUSIONS

- NOT SOIL PERSISTENT
- LOW SOIL MOBILITY
- LOW POTENTIAL FOR GROUNDWATER CONTAMINATION

FMC 57020

PROJECTED HEALTH ADVISORY*

ORAL LD_{50} (RAT)	M 2,077 MG/KG F 1,369 MG/KG	III/CAUTION
2 YR CHRONIC STUDY	@ 1 YEAR	

NOEL = 100 PPM (5 MG/KG/DAY)

THEN

ADI = 5 MG/KG/DAY

ADI = 0.05 MG/KG/DAY

$$\text{HEALTH ADVISORY} = \frac{\text{ADI X 10 KG (BODY WEIGHT)}}{\text{1 LITER}}$$

$$\text{HEALTH ADVISORY} = \frac{.5 \text{ MG}}{\text{LITER}} \text{ OR 500 PPB}$$

*HEALTH ADVISORY (HA) EQUIVALENT TO NO ADVERSE RESPONSE LEVEL (SNARL) WHICH IS EQUIVALENT TO MAXIMUM PERMISSIBLE LEVEL (MPC)

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VOLATILITY STUDY

40 CRF 158.130 REQUIREMENTS

- CASE-BY-CASE BASIS
  - NEEDED?
  - WHEN?