125401
SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 9-30-85 OUT 02 DEC 1985

FILE OR REG. NO 279-GNLE, 279-GNLG, 279-GNLU

PETITION OR EXP. NO.

DATE OF SUBMISSION 9-16-85

DATE RECEIVED BY HED 9-26-85

RD REQUESTED COMPLETION DATE 12-2-85

EEB ESTIMATED COMPLETION DATE 11-25-85

RD ACTION CODE/TYPE OF REVIEW 106

TYPE PRODUCT(S) : I, D, H, F, N, R, S Herbicide

DATA ACCESSION NO(S).

PRODUCT MANAGER NO. R. Taylor (25)

PRODUCT NAME(S) Command Products

COMPANY NAME FMC Corporation

SUBMISSION PURPOSE Submission of data in response to EEB's review of fish early life stage toxicity test using rainbow trout

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
125401	2-(2-chlorophenyl)-methyl-4-4-dimethyl-3-isoxazolidinone	

XX 641

EEB REVIEW

Command Herbicide

100 Submission Purpose and Label Information

100.1 Submission Purpose and Pesticide Use

The registrant (FMC Corp.) submitted data from a freshwater fish early life-stage test in support of registration of Command for use on soybeans.

101 Hazard Assessment

101.2 Likelihood of Adverse Effects on Nontarget Organisms

Freshwater fish

On the basis of data reviewed previously (LC_{50} = 19 mg/l for rainbow trout; LC_{50} = 34 mg/l for bluegill sunfish), EEB did not anticipate a hazard to freshwater fish from the proposed use of Command on soybeans. For this reason, a freshwater fish early life-stage test was not required. FMC Corp. did conduct the test, however, and data from that test indicate the MATC for Command technical on rainbow trout is between 2.29 mg/l and 4.35 mg/l. The MATC would be approximately 50 to 90 times the value for the aquatic estimated environmental concentration (0.05 ppm) calculated by the Exposure Assessment Branch for use of Command on soybeans. These figures support EEB's original conclusion, that use of Command on soybeans at proposed rates will not result in hazard to freshwater fish.

101.4 Adequacy of Toxicity Data

The registrant submitted a fish early life-stage test on rainbow trout. The study was determined to be supplemental, due to significant deviations from the recommended protocol.

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103 Conclusions

EEB has reviewed the submitted fish early life-stage test on rainbow trout. As noted above (Sec. 101.4), the study was determined to be supplemental. The data will be placed in the EEB file for future reference.

Allen W. Vaughan 11/26/85
Allen W. Vaughan, Entomologist
Ecological Effects Branch
Hazard Evaluation Division (TS-769)

Norman Cook 11.26-85
Norman Cook, Section Head
Ecological Effects Branch
Hazard Evaluation Division (TS-769)

11/25/85
Michael Slimak, Chief
Ecological Effects Branch
Hazard Evaluation Division (TS-769)

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DATA EVALUATION RECORD

1. Chemical: Command (FMC 57020)

2. Test Material: Technical, 95.6% a.i.

3. Study Type: Chronic fish early life-stage toxicity test (freshwater)

   Species Tested: Rainbow trout (Salmo gairdneri)

4. Study ID: Anon. 1985. The toxicity of FMC 57020 to rainbow trout (Salmo gairdneri) embryos and larvae. (Submission of requested raw data.) Prepared by Springborn Bionomics, Inc., Wareham, MA. Submitted by FMC Corp., Princeton, NJ. Reg. Nos. 279-GNLE, 279-GNLG, 279-GNLU. Acc. No. 073830.

5. Reviewed By:

   Allen W. Vaughan
   Entomologist
   EEB/HED

   Signature: Allen W. Vaughan
   Date: 11/26/85

6. Approved By:

   Norman J. Cook
   Supervisory Biologist
   EEB/HED

   Signature: Norman J. Cook
   Date: 11.26.85

7. Conclusions:

   This study is scientifically sound, and determines that the maximum acceptable toxicant concentration (MATC) for Command technical to rainbow trout is between 2.29 mg/l and 4.35 mg/l.

   The study does not fulfill the guideline requirement for a fish early life-stage toxicity test, for the following reasons:

   1. test was initiated with "eyed" eggs which were exposed to the toxicant for only 6-8 days prior to hatch. 10 days would be the minimum acceptable period of exposure in this test.

   2. test duration was only 50 days post-hatch. Sixty days would be the appropriate minimum duration.

8. Recommendations: N/A

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9. Background: This submission, containing raw data from a fish early life-stage toxicity test with the technical pesticide, was submitted by the registrant in response to a request from EEB. EEB had reviewed the study previously and had determined the need for raw data to validate the study.

10. Discussion of Individual Test: N/A

11. Materials and Methods

A. Test Animals were rainbow trout embryos obtained from Mount Lassen Trout Farm, Red Bluffs, CA.

B. Test System: glass aquaria with constant test volume of 11 l well water; flow-through exposure using proportional diluter; test duration = 57 days.

C. Dose: Flow-through bioassay using measured concentrations; dimethyl formamide solvent.

D. Design: Five concentrations (nominal = 1.27, 2.66, 5.31, 10.62, 21.24 mg/l; measured = 1.12, 2.29, 4.35, 8.45, 18.18 mg/l) plus control and solvent control (29 ul/l DMF); 2 reps. of each, 40 larvae/rep.

E. Statistics:

Percentage hatchability of embryos and survival, length, and weight of larvae after 49 days post-hatch exposure, were subjected to analysis of variance (Steel and Torrie, 1960). Data for percentage hatchability and survival were transformed to arc sin percentage prior to analysis. If treatment effects were indicated, the means of these parameters were compared to those from the control and solvent control using Dunnett's procedure (Steel and Torrie, 1960). When a treatment mean was significantly different from the control means (P=0.05), that treatment was considered to be a toxicant effect level.

12. Reported Results:

All rainbow trout exposed to 18.18 mg/l died as embryos (prior to hatching) or as larvae within 24 hours of hatching. Hatchability of embryos exposed to 8.45 mg/l or less was unaffected. No rainbow trout larvae survived 49 days of post-hatch exposure to 8.45 mg/l FMC 57020. Exposure to 4.35 mg/l of FMC 57020 for 57 days resulted in significantly decreased survival, mean total length and average wet weight in comparison to the controls.

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Rainbow trout larvae exposed to measured FMC 57020 concentrations of 2.29 mg/l or less suffered no apparent adverse effects. The maximum acceptable toxicant concentration (MATC) was, therefore, determined to be between 2.29 mg/l and 4.35 mg/l. Data on embryo hatchability, survival, mean total length, and average wet weight are attached.

13. Study Author's Conclusions/Q.A. Measures:

Maximum acceptable toxicant concentration (MATC): 2.29 mg/l < MATC < 4.35 mg/l.

Test was conducted according to the Springborn Bionomics protocol entitled "Methods for conducting early life-stage toxicity tests with rainbow trout (Salmo gairdneri)," 1983. The data and report were conducted in accordance with all pertinent EPA Good Laboratory Practice regulations. Also, the report was reviewed by FMC Corp., Toxicology Department's Quality Assurance Unit.

14. Reviewer's Discussion and Interpretation of the Study

A. Test Procedures: Following were the major deviations from recommended procedure:

1. test was initiated with "eyed" eggs (18 days post-fertilization). Standard procedure indicates that fertilized eggs may be used within 48 hours of spawning;

2. range of time-to-hatch was only 6-8 days, as opposed to 10 days minimum;

3. test duration was only 50 days post-hatch, instead of 60 days.

B. Statistical Analysis:

EEB's independent validation of the analyses performed by the authors indicates that the procedures used were appropriate. Results of EEB's validation support the reported results of the study. Copies of EEB's validation are attached to this review.

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C. Discussion/Results:

This study is scientifically sound, and determines that the MATC for Command technical to rainbow trout is between 2.29 and 4.35 mg/l. These figures would probably be slightly lower if the methodology had adhered more closely to the recommended protocol (i.e., longer period of exposure prior to hatch, and longer period of exposure overall). It is because of these deviations that the study is considered supplemental.

D. Adequacy of Study:

1. Classification: Supplemental
2. Rationale: Exposure period prior to hatch is too brief; overall test duration is too short.
3. Reparability: None

15. Completion of One-Liner: One-liner completed 11/22/85.

16. CBI Appendix: N/A

Table 4. Hatchability of embryos and survival, total length and wet weight of rainbow trout (*Salmo gairdneri*) larvae exposed to FMC 57020 for 57 days.

Mean measured concentrations (mg/L)		Embryo hatchability (%)	Larvae (30 days post-swim-up) Survival (%)	Mean total length (S.D) (mm)	Average wet weight (mg)
18.18	A	0[a]	—	—	—
	B	0[a]	—	—	—
8.45	A	72	0[a]	—	—
	B	72	0[a]	—	
4.35	A	81	82[a]	38(2)[a]	474[a]
	B	91	80[a]	37(3)[a]	452[a]
2.29	A	78	98	39(2)	571
	B	72	98	38(2)	532
1.12	A	68	98	40(2)	532
	B	80	95	39(2)	563
control	A	83	92	39(2)	586
	B	77	95	40(1)	529
solvent control (DMF)	A	82	88	40(3)	575
	B	85	85	41(2)	625

[a]Significantly (P=0.05) different from control.

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GENERAL LINEAR MODELS PROCEDURE

CLASS LEVEL INFORMATION

CLASS	LEVELS	VALUES
TRT	7	A B C D E F G

NUMBER OF OBSERVATIONS IN DATA SET = 28

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GENERAL LINEAR MODELS PROCEDURE

DEPENDENT VARIABLE: RESPONSE

SOURCE	DF	SUM OF SQUARES	MEAN SQUARE	F VALUE	PR > F	R-SQUARE	C.V.
MODEL	6	13803.27073720	2300.54512287	111.34	0.0001	0.969523	8.4520
ERROR	21	433.89964876	20.66188804		ROOT MSE		RESPONSE MEAN
CORRECTED TOTAL	27	14237.17038595			4.54553496		53.78058833

SOURCE	DF	TYPE I SS	F VALUE	PR > F	DF	TYPE III SS	F VALUE	PR > F
TRT	6	13803.27073720	111.34	0.0001	6	13803.27073720	111.34	0.0001

1 SAS 10:03 WEDNESDAY, NOVEMBER 20, 1985 3

GENERAL LINEAR MODELS PROCEDURE

DUNCAN'S MULTIPLE RANGE TEST FOR VARIABLE: RESPONSE
NOTE: THIS TEST CONTROLS THE TYPE I COMPARISONWISE ERROR RATE,
NOT THE EXPERIMENTWISE ERROR RATE

ALPHA=0.05 DF=21 MSE=20.6619

NUMBER OF MEANS	2	3	4	5	6	7
CRITICAL RANGE	6.6759	7.01172	7.24379	7.38102	7.49028	7.5756

MEANS WITH THE SAME LETTER ARE NOT SIGNIFICANTLY DIFFERENT.

DUNCAN GROUPING	MEAN	N	TRT
A	68.369	4	E
A			
B A	66.034	4	A
B A			
B A C	63.498	4	B
B C			
B C	60.390	4	D
B C			
B C	59.825	4	C
C			
C	58.349	4	F
D	0.000	4	G

Command herbicide
Rainbow trout
% embryo hatch

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VARIABLE	N	MEAN	STANDARD	MINIMUM	MAXIMUM	STD ERROR	SUM	VARIANCE	C.V.

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fetch 2013 clr
? 1 w216/1
W216 : INVALID.
? 1 216/1
    1                                SAS                          9:44 WEDNESDAY, NOVEMBER 20, 1985    1

                          GENERAL LINEAR MODELS PROCEDURE

                             CLASS LEVEL INFORMATION

                          CLASS     LEVELS    VALUES

                          TRT          6      A B C D E F


                        NUMBER OF OBSERVATIONS IN DATA SET = 12
    1                                SAS                          9:44 WEDNESDAY, NOVEMBER 20, 1985    2

                          GENERAL LINEAR MODELS PROCEDURE

DEPENDENT VARIABLE: RESPONSE

SOURCE             DF     SUM OF SQUARES      MEAN SQUARE     F VALUE       PR > F     R-SQUARE          C.V.

MODEL               5     9526.51157352     1905.30231470      523.10       0.0001     0.997711        3.1019

ERROR               6       21.85391044        3.64231841                  ROOT MSE                RESPONSE MEAN

CORRECTED TOTAL    11     9548.36548397                                  1.90848589                  61.52642561


SOURCE             DF         TYPE I SS     F VALUE    PR > F       DF       TYPE III SS     F VALUE    PR > F

TRT                 5     9526.51157352      523.10    0.0001        5     9526.51157352      523.10    0.0001
   1                                 SAS                          9:44 WEDNESDAY, NOVEMBER 20, 1985    3

                          GENERAL LINEAR MODELS PROCEDURE

                DUNCAN'S MULTIPLE RANGE TEST FOR VARIABLE: RESPONSE
                NOTE: THIS TEST CONTROLS THE TYPE I COMPARISONWISE ERROR RATE,
                      NOT THE EXPERIMENTWISE ERROR RATE

                          ALPHA=0.05  DF=6  MSE=3.64232

               NUMBER OF MEANS        2          3          4          5          6
               CRITICAL RANGE   4.66996    4.84023    4.91923    4.95925    4.97756

                MEANS WITH THE SAME LETTER ARE NOT SIGNIFICANTLY DIFFERENT.

                    DUNCAN    GROUPING           MEAN      N   TRT

                                  A            81.837      2   D
                                  A
                           B      A            79.442      2   C
                           B
                           B                   75.294      2   B

                                  C            68.445      2   A
                                  C
                                  C            64.140      2   E

                                  D             0.000      2   F
   1                                 SAS                          9:44 WEDNESDAY, NOVEMBER 20, 1985    4
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Command herbicide
Rainbow trout
% survival

650

10.

GENERAL LINEAR MODELS PROCEDURE

CLASS LEVEL INFORMATION

CLASS	LEVELS	VALUES
TRT	5	A B C D E

NUMBER OF OBSERVATIONS IN DATA SET = 10

GENERAL LINEAR MODELS PROCEDURE

DEPENDENT VARIABLE: RESPONSE

SOURCE	DF	SUM OF SQUARES	MEAN SQUARE	F VALUE	PR > F	R-SQUARE	C.V.
MODEL	4	10.40000000	2.60000000	5.20	0.0499	0.806202	1.8085
ERROR	5	2.50000000	0.50000000		ROOT MSE		RESPONSE MEAN
CORRECTED TOTAL	9	12.90000000			0.70710678		39.10000000

SOURCE	DF	TYPE I SS	F VALUE	PR > F	DF	TYPE III SS	F VALUE	PR > F
TRT	4	10.40000000	5.20	0.0499	4	10.40000000	5.20	0.0499

GENERAL LINEAR MODELS PROCEDURE

DUNCAN'S MULTIPLE RANGE TEST FOR VARIABLE: RESPONSE

NOTE: THIS TEST CONTROLS THE TYPE I COMPARISONWISE ERROR RATE, NOT THE EXPERIMENTWISE ERROR RATE

ALPHA=0.05 DF=5 MSE=0.5

NUMBER OF MEANS	2	3	4	5
CRITICAL RANGE	1.8196	1.87547	1.89503	1.90553

MEANS WITH THE SAME LETTER ARE NOT SIGNIFICANTLY DIFFERENT.

DUNCAN GROUPING	MEAN	N	TRT
A A	40.5000	2	A
B A A	39.5000	2	B
B A A	39.5000	2	C
B B	38.5000	2	D
C C	37.5000	2	E

Command herbicide
Rainbow trout
Mean total length (mm)

VARIABLE	N	MEAN	STANDARD DEVIATION	MINIMUM VALUE	MAXIMUM VALUE	STD ERROR OF MEAN	SUM	VARIANCE	C.V.
TRT=A									
RESPONSE	2	40.50000000	0.70710678	40.00000000	41.00000000	0.50000000	81.00000000	0.50000000	1.746

GENERAL LINEAR MODELS PROCEDURE

CLASS LEVEL INFORMATION

CLASS	LEVELS	VALUES
TRT	5	A B C D E

NUMBER OF OBSERVATIONS IN DATA SET = 10

1

GENERAL LINEAR MODELS PROCEDURE

DEPENDENT VARIABLE: RESPONSE

SOURCE	DF	SUM OF SQUARES	MEAN SQUARE	F VALUE	PR > F	R-SQUARE	C.V.
MODEL	4	19895.40000000	4973.85000000	5.71	0.0417	0.820331	5.4277
ERROR	5	4357.50000000	871.50000000		ROOT MSE		RESPONSE MEAN
CORRECTED TOTAL	9	24252.90000000			29.52117884		543.90000000

SOURCE	DF	TYPE I SS	F VALUE	PR > F	DF	TYPE III SS	F VALUE	PR > F
TRT	4	19895.40000000	5.71	0.0417	4	19895.40000000	5.71	0.0417

1

GENERAL LINEAR MODELS PROCEDURE

DUNCAN'S MULTIPLE RANGE TEST FOR VARIABLE: RESPONSE

NOTE: THIS TEST CONTROLS THE TYPE I COMPARISONWISE ERROR RATE, NOT THE EXPERIMENTWISE ERROR RATE

ALPHA=0.05 DF=5 MSE=871.5

NUMBER OF MEANS	2	3	4	5
CRITICAL RANGE	75.9669	78.2996	79.1161	79.5543

MEANS WITH THE SAME LETTER ARE NOT SIGNIFICANTLY DIFFERENT.

DUNCAN GROUPING	MEAN	N	TRT
A	600.00	2	A
A			
A	557.50	2	B
A			
A	551.50	2	D
A			
A	547.50	2	C
B	463.00	2	E

Command herbicide
Rainbow trout
Avg. wet weight (mg)

1

VARIABLE	N	MEAN	STANDARD DEVIATION	MINIMUM VALUE	MAXIMUM VALUE	STD ERROR OF MEAN	SUM	VARIANCE	C.V.
TRT=A									
RESPONSE	2	600.00000000	35.35533906	575.00000000	625.00000000	25.00000000	1200.0000000	1250.0000000	5.893

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