

12/10/84

FMC Corporation
Agricultural Chemical Group
2000 Market St.
Philadelphia, PA 19103

Attention: Eunice M. Cuirle

Gentlemen:

Subject: Command Herbicide

EPA File Symbol 279-GNLU

EPA File Symbol 279-GNIE

EPA File Symbol 279-GNLC ✓

The Agency has completed the Environmental Fate Review and the Ecological Effects Branch Review for the subject products. Our comments follow:

Environmental Fate

1. The half-life estimations reported are different from those calculated by the reviewer. The photodecomposition rate in water under sunlight was estimated by a plot of percent FMC 57020 remaining vs time while that in water containing acetone under simulated sunlight was estimated by a plot of log concentration vs. time.

Why wasn't log concentration vs. time used to estimate the half-lives in both sensitized and nonsensitized experiments?

- o No description about the temperature of the photolysis solutions.
- o No organic volatile traps were installed.
- o Actual recovery rates were not reported - only normalized % distribution of radio residue was reported.

CONCURRENCES

SYMBOL ▶	TS 767							
SURNAME ▶	Youtell							
DATE ▶	12-10-84							

Conclusion

FMC 57020 appears to undergo photodecomposition to give 2-chlorobenzoic acid (a major product) and many other degradates with a half-life about 87 days (67.5 days was reported) under natural sunlight.

Breakdown of FMC 57020 under the irradiation with a GE sunlamp was similar to that observed under sunlight. Acetone facilitated degradation, and the degradation rate increased with increasing concentration of acetone relative to FMC 57020.

This study is not acceptable for the following reasons:

1. Half-lives were not derived in a consistent manner.
2. Actual recoveries of radioactivity (loss due to non-trapped volatiles) were not reported.
2. Photodegradation of FMC 57020 in/on Soil. J. Wu, FMC Crop. P-0873, 5/11/84, Notebook Rf. E3013, E 2743, EPA Acc. No. 072819 (Rf. 3).

This study cannot be accepted for the following reasons:

1. Volatile compounds were not trapped; so, material balance was poor.
2. Soil was not sterilized; microbial metabolism is expected. The results from the 30-day control analysis indicate that degradation of FMC 57020 occurred through mechanisms other than photolysis.
3. The temperature of soil was not mentioned.
4. Degradation rate was neither reported nor can be estimated. Microbial degradation might have been involved.
5. Identification of degradation products was not done.
6. The Mylar film may have excluded those wavelengths that could cause photodegradation.
3. Degradation of FMC 57020 ¹⁴C-Methylene in Clay loam, Silt loam and Sandy loam Soil under Aerobic Conditions. L.W. Froelich, M-4860, June 7, 1982, Rf. E1536, E1838. EPA Acc. No. 072819 (Rf. 4).

The reported half-lives of FMC 57020 in the soils studied are different from those obtained by the reviewer. From the linear regression, the half-lives of 433.9 days in Cosad sandy loam, 95.4 days in Hagerstown clay loam and 104.3 days in Dunkirk silt loam were obtained using six data points including the new data from 112-day analysis.

It is noted that volatile organic compounds were not monitored (only CO₂ was monitored) and the recoveries were reported as a range (75.3 12.3%). Since it is not known whether the loss (-2.3 24.7%) was due to volatiles or extraction procedures, the half-life estimations from the normalized % values are not considered to be right.

This study is not acceptable for the aerobic soil metabolism data requirement until the points in our review of December 12, 1984, and the above questions addressed.

4. Analysis of FMC 57020 Soil Bound Residues. A. A. Bixler, FMC Corp. P0878, May 21, 1984, Rf. E1855, E2382, EPA Acc. No. 072819 (Rf. 5).

About 40% of the non-extractable residues after methanol/H₂O blending could be released by soxhlet extraction and acid digestion. Parent compound, FMC 57020 comprised 75-90% of the released residues.

Since the position of labeling was in methylene moiety of the compound, it can be expected that parent compound and ¹⁴CO₂ would comprise significant portions of the radioactivity recovered. Soil metabolism studies (this study and the study in section 3.3) with methylene-¹⁴C FMC 57020 can tell the decomposition rate of the compound. However, a study using ring-¹⁴C FMC 57020 would be beneficial in determining the soil metabolites of the compound.

5. Metabolism of Carbonyl-¹⁴C and Ring-¹⁴-C FMC 57020 in Soil under Aerobic and Anaerobic Conditions. T.A. Bixler, FMC Corp. P-0881, May 24, 1984, Notebook Rf. E2885, E3443, EPA. Acc. No. 072819 (Rf 6).

Since no volatile traps were attached, evolving possible volatile degradation products could not be detected. Recovery rates were reported as ranges for each experiment and not for each sample analysis. Since % distribution of radioactivity was normalized from the total radioactivity recovered, actual % distribution is not known.

Data compiled and used in calculations/tabulations for the document, but not contained in this section, need to be provided.

The reported estimated half-lives are different from those obtained by the reviewer.

Conclusion

FMC 57020 degrades in soil under aerobic conditions to give CO₂ as a major product. The rate and degree of degradation vary with soil type with a half-life range of 56-173 days. Under anaerobic conditions, FMC 57020 degraded to FMC 65317.

6. Metabolism of Carbonyl-¹⁴C FMC 57020 in a Sandy Loam Soil. T.A. Bixler, FMC Corp. P-0882 May 24, 1984, Rf. E3443, EPA Acc. No. 072819 (Rf. 7).

An estimated half-life of 28 days under aerobic conditions was reported, but no half-life estimation was done under anaerobic conditions.

FMC 57020 is mineralized (evolving CO₂) under aerobic conditions with an estimated half-life of 28 days in Cosad sandy loam soil.

Under anaerobic conditions, FMC 57020 readily degrades to give FMC 65317 as a major product with an estimated half-life of about 13 days (reviewer's estimation).

This study is accepted for the aerobic/anaerobic soil metabolism data requirement.

7. Soil Mobility of FMC 57020, L.P. Kinne, FMC Corp. M-4862, 6191 1982, Rf. E1530: 70-135. EPA Acc. No. 248476 (Rf 31).

FMC 57020 appears to have a low to intermediate mobility in Cosad sandy loam, Dunkirk silt loam and Hagerstown clay loam but a high mobility in Leon fine sand. FMC 57020 has a potential to leach into ground water.

8. Soil Adsorption/Desorption Characteristics of FMC 57020. L.W. Froelich, FMC Corp. Rf E1522, #1522, E 1896, June 7, 1982. EPA Acc. No. 248476 (Rf 32).

FMC 57020 has a low soil binding potential, consequently has a high leaching potential.

9. Soil Mobility of FMC 57020 Aged Residues, L.P. Kinne, FMC Corp. P-0891, Rf. E3399, E3573, June 6, 1984, EPA Acc. No. 072819 (Rf 10).

The radioresidue distribution after two months of aging in table 3 of Section 3.5 indicates that about 50% of radioactivity was mineralized. The rest of the radioactivity remaining on soil was distributed in FMC 57020 (ca. 35%), soil-bound residues (ca. 9%), unidentified organosolubles (ca. 3%) and polar compounds (ca. 3%).

The majority of the aged soil residues do not leach as much as parent FMC 57020. However, a small fraction of the aged residues leach more than the parent.

10. Soil Mobility of FMC 65317, A FMC 57020 Anaerobic Soil Degradate, L.P. Kinne, FMC Corp. P-0874, Rf. E3573, April 25, 1984. EPA Acc. No. 072819 (Rf. 11).

FMC 6317, an anaerobic soil metabolite has a very high mobility in soil.

11. Mobility of FMC 57020 Residue in Soil. S. Witkonton, FMC Corp., P-0916, July 31, 1984, Rf. E2P24:35-39, EPA Ac. No. 072819 (Rf. 12).

The logarithmic scale plot of residue decline in figure 4 does not make sense. If the compound follows the first-order decay, the equation would be

$$C = C_0 e^{-kt}$$

that is, $\ln C = -kt + \ln C_0$

So the plot would be made time vs log concentration. In figure 4, the plot was made with concentration vs. log time. Accordingly, the half-life of 10 days obtained is not valid.

The soil residue extraction procedure included a HCl reflux and an organic solvent partitioning (hexane for FMC 57020 and ethyl acetate for FMC 65317) and NaHCO_3 wash. The following questions are raised:

1. Do FMC-57020 and FMC 65317 form respective salts with HCl?
2. If they do not form the salts, are they soluble enough to be extracted efficiently in water?
3. If they form salts, isn't it necessary to basify the acid extracts before partitioning in an organic solvent?
4. What was the NaHCO_3 wash for?
5. It was reported that the method sensitivity for FMC 57020 and FMC 65317 in soil was validated to 0.10 ppm and that the detection limit was 0.02 ppm for both compounds. However, in table 2 (table 4 in report) none of the residue levels were between 0.02 ppm and 0.1 ppm.

The leaching potential of FMC 57020 residues cannot be determined from this study until you provide adequate explanations regarding the five questions above.

12. FMC 57020 Soil Mobility - PESTANS Modeling. F.D. Martin, FMC Corp. P0904, July 2, 1984, EPA. Acc. No. 072819 (Rf. 13).

- o The modeling studies were well done considering that the PESTANS model was validated prior to long term simulations and that annual recharge for long term simulations was overestimated. Extrapolation to other soil types is a valid and useful approach.
- o Unfortunately, the PESTANS model used by FMC was outdated and, in fact, incorrect. However, usage of the correct version would not lead to significantly different results.
- o The sand soil characterization in PESTANS is generous in favor of the registrant. I would not consider sand soil results reported valid, even if the correct version of PESTANS were used.

- o The correct version of PESTANS should be obtained from Dr. Enfield. As well, PRZM should be used in place of PESTANS if possible.
13. Dissipation of FMC 57020 Residues in Soil. S. Witkonton and C. Long. FMC Corp. p-0896. Rf E2924:14-15, June 13, 1984, EPA Acc. No. 072819 (Rf. 14).

The report says that "due to the rapid exponential decline of FMC 57020 residues linear regression equation yields a best fit line when ppm values are plotted against days expressed as a logarithmic scale (figures 2-5)". All of half-life estimations were done according to the plots. Please explain the mathematical equations in terms of log time and concentration. Also, see the comments in section 3.11.

The study cannot be accepted for the following reasons:

- o The registrant should re-plot/re-calculate the half-lives.
 - o For the half-life calculations, FMC 57020 levels in soils deeper than 6 inches should also be considered.
 - o Since there were indications that FMC 57020 is leaching, sampling should have been done at depths deeper than 12 inches.
14. Uptake of Soil-Aged ¹⁴C Labeled FMC 57020 Residues into Outdoor Rotational Crops - 10 Month Interval. S.F. El-Nagger, J.L. Reynolds, FMC Crop. P-0871, May 11, 1984, Rf E2238:1-115, E3366:27-40, EPA Acc. No. 072819 (Rf. 15).

The application of FMC 57020 at the rate of 2 lb ai/a (1.6-1.7X of maximum use rate) resulted in residue accumulation in rotational crops (corn, oats, cabbage and sugar beet) planted 10 months after chemical application. However, residue analysis showed that a majority of these residues were either plant tissue bound or polar. Organosoluble residues accounted for less than 0.02 ppm.

Results from the soil analyses indicate FMC 57020 has a potential to leach.

The data support a 10-month rotational crop interval for FMC 57020 when used at 2 lb ai/A/yr or less.

15. Uptake, Depuration and Bioconcentration of ¹⁴C FMC 57020 by Bluegill Sunfish. W.A. McAllister and L. Franklin, Analytical Bio-Chemistry Laboratories, Inc. for FMC Corp., PC-0018, May 21, 1984, EPA Acc. No. 072819 (Rf. 16).

Methylene-¹⁴C FMC 57020 was used in this study, so aromatic portion of the compound could not be well monitored. If ring-labeled FMC 57020 is used in a fish accumulation study, will the results be more or less the same as in this study?

This study was very well done. FMC 57020 has a moderate tendency to bioaccumulate in bluegill sunfish with a bioaccumulation factor of 40X for whole fish, but depuration occurs rapidly to low but measurable levels upon removal of the fish to uncontaminated environment.

This study can be acceptable depending on the adequate explanation regarding the labeling position.

16. Analysis of FMC 57020 Residues in Bluegill Sunfish and Water, T.A. Bixler, FMC Crop. p-0889, June 5, 1984. Rf E3623, EPA Acc. No. 072819 (Rf. 17).

Metabolite analysis of accumulated radiocarbon after exposure of bluegill sunfish to methylene-¹⁴C FMC 57020 showed that more than 50% in fillet and about 30-40% in viscera was attributed to parent compound. Nine minor degradation products, none exceeding 9% of the total ¹⁴C residues, were observed. There were indications that the radiocarbon was incorporated into fats/oils and higher molecular weight lipophilic/ polar metabolite conjugates.

The following environmental data requirements are satisfied for the registration of Command:

- o hydrolysis (EAB review dated 12/3/82)
- o aerobic soil metabolism
- o anaerobic soil metabolism
- o laboratory leaching/aged leaching
- o rotational crops

The following environmental data requirements on Command are not satisfied:

- o aqueous photolysis
- o fish accumulation
- o field dissipation
- o soil photolysis

The correct version of PESTANS modeling or if possible, PRZM modeling may be done for leaching potential. Note that such data are not required for registration.

ECOLOGICAL EFFECTS BRANCH REVIEW

Labeling comments:

Formulating-Use Label

The statement under Environmental Hazards should be amended to read as follows:

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

End-Use labels

The statement under Environmental Hazards should be amended to read as follows:

Do not contaminate water by cleaning of equipment or disposal of wastes. Do not apply directly to water or wetlands.

EEB has reviewed the proposed registration of FMC 57020 (Command) for use on soybeans. EEB is unable to complete a risk assessment for this use because pertinent environmental fate data are lacking, including aquatic and soil photolysis studies. As these data are needed to complete the aquatic organism hazard assessment, no conclusions can be made at this time.

Note - Percent a.i. for FMC 57020 technical was reported as 88.8% in the aquatic IC_{50} studies. Percent a.i. was not reported in any of the avian studies. For purposes of evaluation, EEB assumed that percent a.i. was 88.8% for the avian studies, as well. The registrant should verify this.

Residue Chemistry and Toxicology reviews are pending with the Agency. The results of these will be provided when they become available.

Sincerely yours,

Robert J. Taylor
Product Manager (25)
Fungicide-Herbicide Branch
Registration Division (TS-767C)

RD/FHB:JOB:51926:J.Yowell:RD-55:eg:Kendrick & Co.:898-1270:12/7/84:Del.12/13/84

COMMAND

Page _____ is not included in this copy.

Pages 9 through 25 are not included.

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 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.
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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.
