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MEMORANDUM

SUBJECT: Review of EUP for F6285 Herbicide

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Conclusion :

(1). EFGWB concurs with the EUP for F6285 because:

(A). the following data requirements are fulfilled:

Hydrolysis (161-1)
Aerobic Soil Metabolism (162-1)*
Leaching-Adsorption/Desorption (163-1)

* since the submitted study has demonstrated the pattern of decline of the parent compound and identified two major degradation products, the Aerobic Soil Metabolism (162-1) data requirement is fulfilled for the EUP. When available, the aerobic soil metabolism study, currently in progress, should be submitted for review.

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(B). the following data requirements are waived:

Confined Rotational Crop (165-1)*
Bioaccumulation in Fish (165-4)**

* the proposed labels will be revised to exclude the use of rotational crops.

** waived due to its low K_{ow}. According to the registrant, the K_{ow} data have been validated by EPA. EFGWB concurs with this waiver request for the EUP on condition that the PM can verity these K_{ow} values.

(2). Based on the preliminary data submitted to support a requested EUP, this chemical appears to display some of the characteristics for those chemicals known to leach to groundwater (such as high mobility and persistence). EFGWB recommends that the registration be advised to implement this EUP in such a way to minimize the potential impact on groundwater supplies from the experimental use.

Background :

A. Introduction

F6285 is a herbicide currently being developed by FMC Corporation for control of annual grass, and annual and perennial broadleaf weeds on soybeans.

B. Directions for Use

F6285 can be preplant-soil-incorporated, or preemergence surface applied at a rate of 0.25-0.5 lbs a.i. per acre. If treatments are to be incorporated, incorporate to a depth of 1-3 inches. Do not apply more than once per season.

C. Environmental Fate Data

F6285 has been found very persistent in water ($t_{1/2}$ = 143-375 days at pH 5, 7, and 9), and in aerobic soil ($t_{1/2}$ = 114-122 days). According to the adsorption/desorption study, F6285 is very mobile with a range of K_d values of 0.2-0.8 (or K_{oc} = 26-77).

The major metabolite of F6285 is F6285 3-carboxylic acid which accounted for 24% of the recovered radioactivity for the carbonyl label and 12% of the recovered radioactivity for the phenyl label 90 days after application in an aerobic soil metabolism study.

Discussions :

The registrant, FMC Corporation, has submitted additional information to upgrade three studies [Hydrolysis (161-1); Aerobic Soil Metabolism (162-1); and Leaching-Adsorption/Desorption (163-1). These three studies were previously determined unacceptable (see EFGWB reviews of 91-0741 and 92-0100 for details). The registrant has also submitted waiver requests for the Confined Rotational Crop (165-1) and Bioaccumulation in Fish (165-4) data requirements (for the EUP only). The registrant's justifications for the above issues and EFGWB's correspondences are presented below:

A. Hydrolysis (161-1)

a. In response to the comments raised by EFGWB on the difference in the mass spectra of the parent compound (F6285) in the 30-day sample and the reference standard, the registrant reanalyzed a sample extract which was retained after the completion of the study and submitted its mass spectrum.

Comments by EFGWB:

Since this new mass spectrum of the Day 30 pH 7 TRIS Replicate II sample (see attachment #1) correlates with F6285 standard at m/z 307 and 386, its identity has been confirmed by mass spectrometer.

b. The registrant claimed that the fluctuations in the concentrations during the study was due to minor quenching or a binding to glass or other materials used during aliquoting.

Comments by EFGWB:

The justifications provided by the registrant are not sufficient to explain why the total radioactivities in the Day 14 and 21 samples were significantly higher than that in the Days 7 samples at all pH's. However, this deficiency is not significant enough to affect the understanding of the fate of F6285 in water. Therefore, the Hydrolysis (161-1) data requirement is fulfilled.

B. Aerobic Soil Metabolism (162-1)

The registrant claimed that: (1) two major degradation products (F6285 3-carboxylic acid, and F6285 3-hydroxymethyl) were adequately separated and identified by TLC/HPLC, and further confirmed by mass spectrometer; and (2) efforts were made to purify the samples by GC equipped with a capillary column prior to MS, but with no success.

The registrant is conducting a new study which will be carried out for a longer period of time (possibly up to one year) to define the fate of F6285 in the aerobic soil. In the new study, the registrant will attempt to develop GC/MS methods for spectral characterization of significant metabolites of F6285.

Comments by EFGWB:

1. Based on the additional information submitted by the registrant, EFGWB believes that the identity of two degradation products (F6285 3-carboxylic acid, and F6285 3-hydroxymethyl) have been confirmed. Reasons are given below:

   * F6285 3-carboxylic acid was identified by the following methods:

      a. using one-dimensional TLC;

      b. this chemical was treated with acid to form the desmethyl derivative which was further identified chromatographically;

      c. using mass spectrometry in either EI (Electron Impact) or CI (Chemical Ionization) mode. The EI mass spectra for the TLC-purified F6285 3-carboxylic acid gave a base peak at 293 and 295, and an M-45 (decarboxylated molecule) cluster of ions at 372, 374, and 374 (due to the presence of two chlorine atoms at the phenyl ring). The 373 ion peak for the protonated decarboxylated derivative (M-45) was also found in the CI mode. These spectral data are consistent with those of the reference standard.

   ** F6285 3-hydroxymethyl was identified by the following methods:

      a. using TLC and HPLC;

      b. using mass spectrometry in either EI (Electron Impact) or CI (Chemical Ionization) mode. This chemical was isolated by TLC prior to MS analysis. The EI spectral data indicates the presence of a base peak at 323 (due to fragmentation) and a molecular ion cluster at 402, 404, and 406 (due to two chlorine atoms at the phenyl ring). Its chemical identify was further confirmed by the CI mode. In that mass spectrum, a

molecular ion cluster at 403, 405, and 407 for M+1 was obtained. These mass spectra are corresponding to those of the reference standard.

2. When available, the aerobic soil metabolism study, currently in progress, should be submitted for review. This new study would probably provide additional data on the formation and decline of degradation products of F6285 and their identification.

3. Since the submitted study has demonstrated the pattern of decline of the parent compound, and identified two major degradation products, the Aerobic Soil Metabolism (162-1) data requirement is fulfilled for the EUP.

C. Leaching and Adsorption/Desorption

The Leaching-Adsorption/Desorption (163-1) data requirement is fulfilled because the registrant has submitted the following data for the test soils.

Soil Type	CEC, meq/100 g	Field Moisture Cap., %
#45 Sandy Loam	7.6	15.77
#46 Silt Loam	14.5	32.5
#47 Silty Clay Loam	14.1	26.8
#49 Sand	0.6	1.37

D. Confined Rotational Crop

The registrant has request a waiver of the Confined Rotational Crop (165-1) data requirement for the EUP. They intend to amend the labels to show a rotational crop restriction indicating that the rotational crop must be destroyed.

Comments by EFGWB:

EFGWB concurs with this waiver request for the EUP.

E. Bioaccumulation in Fish

Based on the low octanol/water partition coefficients for F6285 (K_{ow} = 31, 10, and 0.3 at pH 5, 7, and 9 respectively), the registrant has requested a waiver of the Bioaccumulation in Fish (165-4) data requirement.

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Comments by EFGWB:

According to the registrant, the K_{ow} data have been validated by the EPA Product Chemistry reviewer. EFGWB concurs with this waiver request for the EUP on condition that the PM can verity these K_{ow} values.

Submitter Name Removed

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