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CHEMICAL FILE
009823

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 0 4 1992

OFFICE OF PESTICIDE PROGRAMS
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 2-(2,4-dichloro-5-methylsulfonylamidophenyl)-4-difluorolmethyl-2,4-dihydro-5-methyl-3H-1,2,4-triazol-3-one
FMC 97285

Tox. Chem No.: 951
Chem. No.: 129081
Submission No. S419570

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THRU: Mike Ioannou, Section Head 8-26-92
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and
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Registrant: FMC Corporation, letter of April 10, 1992
EPA Reg. No. 279-EUP-REO. A herbicide for use on soybeans.

Action Requested: 1. The registrant has provided the information requested in toxicology review (DER 009263) of February 18, 1992.

2. Request for a waiver of an acute inhalation toxicity study on the use formulation of FMC 97285 based on the minimal exposure of researchers investigating the efficacy of this herbicide.

Conclusion: 1. The acute toxicity studies submitted on the technical and use formulation are acceptable and support the experimental use of FMC 97285.

2. An acute inhalation toxicity study is not required in support of this experimental use; however, the registrant is committed to provide an acute inhalation study in support of the registration of this 39.6% use formulation.

1.1 2.

Consideration Given this Request

1. Toxicology review (DER 009263) of February 18, 1992 questioned the use of a different batch of the technical material in the dermal toxicity, eye and dermal irritation, and sensitization studies than used in the acute oral toxicity studies. The registrant was also requested to declare the purity of batch No. 31-89-0478.

   FMC Response:
   The acute oral toxicity studies in the rat and mouse were conducted during the development of FMC 97285 when a limited supply was available. Acute dermal, eye and dermal irritation, and sensitization studies were conducted with a material that "more closely emulates the potential manufacturing process" of FMC 97285. Batch No 31-89-0478 is 92.5% pure.

   With this deficiency satisfied, the acute dermal, eye and dermal irritation, and dermal sensitization studies are acceptable and upgraded from Supplementary to Core-Guideline Classification.

2. Toxicology review of February 18, 1992 acknowledged the data waiver for an acute inhalation toxicity study for the experimental use of the 39.6% use formulation. An acute inhalation toxicity study was requested in support of the registration of the 39.6% use formulation.

   FMC Response:
   The registrant is committed to provide an acute inhalation toxicity study in support of the registration of the 39.6% use formulation.

3. The Confidential Statement of Formula for the use formulation (39.6%) was not available with the toxicology review of February 18, 1992. The question was raised as to whether the formulation contained inert ingredients that would require additional precautionary labeling.

   FMC Response:
   "Inert ingredients in the formulation include materials such as [redacted] "The 39.6% formulation does not contain inerts that would require additional percautionary labeling".

4. Positive control data was not included in the guinea pig sensitization studies conducted with the technical or use formulation.

   FMC Response:

   The registrant has provided positive control data (MRID 422864-01) for the dermal sensitization study conducted with the technical (MRID 419116-10) and the positive control data (MRID 422864-02) for the 39.6% formulation (MRID 419116-16).

   With this deficiency satisfied, these dermal sensitization studies are acceptable and upgraded from Supplementary to Core-Guideline Classification.