

DATE OUT: 03/OCT/2001

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF: A TECHNICAL GRADE TGAI [X]**
DP BARCODE No.: 276030 EPA RECEIVED DATE: 20/JUN/2001 REG./File Symbol No. 60063-RT
PRODUCT NAME: Spicam Metolachlor Technical, 97% Metolachlor MRID.: 454337-07
COMPANY NAME: Spicam Agro USA, Inc. Action Code: 166

FROM: Sami Malak, Chemist *S. Malak*
Technical Review Branch/RD (7505C)

TO: 23 Joanne Miller/Eugene Wilson
Herbicide Branch/RD (7505C)

INTRODUCTION:

The applicant requested a FIFRA sec.3(c)(3)(B)(i)(I) "me-too" registration of subject product claiming its similarity to Metolachlor Technical, Reg. No. 100-587 (EPA's Form 8570-1 dated 29/SEP/2000). In support of this action, the applicant included product chemistry data, and a proposed basic formulation, CSF dated 10/OCT/2000.

FINDINGS:

1. The subject product, a technical grade of active ingredient, is intended for formulating herbicide products.
- 2a. The subject product is substantially similar to Metolachlor Technical, Reg. No. 100-587. The pending product contains 97% metolachlor as opposed to 96% in the registered product. This slight difference in the nominal concentration is acceptable, which is due to a cleaner manufacturing process resulting in less impurities relative to the impurity profile in the registered product. It was noted that density and the pH in both products are similar. The pending product, however, reported N/A for flammability in box 9 of the CSF as opposed to a value the registered product. It should be noted, however, that flammability is not required for a TGAI.
- 2b. The subject product contains a significant level [REDACTED] a list 2 ingredient known to be potentially toxic. The applicant may be advised to improve the manufacturing process in order to reduce its concentration or remove it completely.
- 3a. The submitted product chemistry data pertaining to the storage stability (GRN 830.6317), is adequate. The product is stable for a period of one year when stored in a simulated packaging material under ambient warehouse conditions.
- 3b. Previously submitted data was reviewed and found adequate.
4. The label claim nominal concentration of 97% is consistent with that on the CSF, both are in compliance with the regulations of PR Notice 91-2. Further, the storage and disposal statement and the physical or chemical hazards statement are in compliance with the regulations of 40CFR§156.10.
5. The submitted product's basic formulation, CSF dated 10/OCT/2000, was filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2). All ingredients claimed on the CSF are cleared for use in

Inert ingredient information not included.

pesticide formulations.

CONCLUSIONS:

1. From the product chemistry view point, the subject product is substantially similar to Metolachlor Technical, Reg. No. 100-587.
2. The applicant has satisfied product chemistry data requirements for a FIFRA sec. 3(c)(3)(B)(i)(I) "me-too" registration of subject product. Product's label and CSF are acceptable as per Findings 4 & 5 above.

NOTE TO CRM:

Please note Finding 2(b) above.

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 08/MAR/2001 was included with this submission claiming confidentiality of some of the submitted data on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C). Review of CBI data is to be found in Confidential Appendix A.
2. A GLP statement date 16/MAR/2001 was included with this submission to the effect that the submitted studies were conducted in compliance with the GLP requirements of 40CFR §160.

DATA SUBMITTED

MRID #454337-07: The submitted studies entitled: "Group B - Physical and Chemical Properties Testing of Metolachlor." The studies were authored by Holly A. Weber, Ph.D.; Performed by Midwest Research Institute of Kansas City, Missouri; Completed on 26/APR/2000 (12 pages).

GRN 830.6317 Storage Stability

In this study, samples of metolachlor, 97.8% pure, were stored in a simulated packaging material for a period of one year under ambient warehouse conditions. The amount of metolachlor was quantitated using gas chromatography equipped with flame ionization detector, initially, then at 3, 6, and 12 months of storage.

Test results relative to 100% at day zero were: 94.7, 98.4, and 95.8% at 3, 6, and 12 months of storage, respectively. There was no change in appearance of the test substance during the storage period. The chromatographic conditions and sample calculation were included with this submission.