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

AUG 13 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Harmony® Extra Herbicide - Supplementary Information in Support of Tolerance Petitions for Thifensulfuron Methyl and Tribenuron Methyl on Oat Grain and Straw

TO: Joanne Miller/Steven Robbins
Product Manager/PM Team Reviewer (23)
Registration Division (H7505C)

FROM: Linda L. Taylor, Ph.D. 8/12/93
Toxicology Branch II, Section II,
Health Effects Division (H7509C)

THRU: K. Clark Swentzel 8/12/93
Section II Head, Toxicology Branch II
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and

Marcia van Gemert, Ph.D. 8/12/93
Chief, Toxicology Branch II/HFAS/HED (H7509C)

Registrant: Du Pont
Chemical: Methyl-3-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]-2-thiophene carboxylate and Methyl-2-[[[[N(4-methoxy-6-methyl-1,3,5-triazin-2-yl)methylamino]carbonyl]amino]sulfonyl]benzoate
Synonym: thifensulfuron methyl (formerly DPX-M6316); tribenuron methyl (formerly DPX-L5300); metabolite-metsulfuron methyl (IN T6376)
Submission: S437508
DP Barcode: D189493
Caswell No.: 573S/419S/419H
Identifying No.: 1F03961/1F03962
Shanghnessy No.: 128845/128887/122010
MRID No.: 425596-01, 425596-02, 425596-03, 425596-04

Action Requested: Please review this submission of primary eye, primary dermal and dermal sensitization studies and advise as to the acceptability of the data to support the tolerance petitions.

Background: Harmony® Extra Herbicide is registered for use on wheat and barley. Both Thifensulfuron and Tribenuron have established permanent tolerances on barley and wheat grain and straw, and

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Thifensulfuron is registered for use on soybeans. The toxicology data available to support this request were listed in Table A of a previous TB II memo (dated 8/19/92). Several acute studies reviewed in that TB II memo were classified Core Supplemental but could be upgraded with the submission of additional data and information. The current submission provides the requested data and information.

MRID # 425596-01 [Supplement # 2 for MRID # 409215-01 (Primary Eye Irritation Study with IN M6316-25 in Rabbits)]: The Batch # of the test material was provided and is 25, as in the code for the test material:IN T6316-25. Under General Information (page 4 of the supplement), it is stated that the test material was milled to an average particle size of 5.4 μ. Body-weight data indicate that 5 of the 6 rabbits gained weight during the study (range of 4-119 grams; average 58) and one rabbit lost 18 grams. A statement that no clinical signs of toxicity were observed in any of the rabbits was provided in Appendix II. The data and information are adequate, and the study may be upgraded to Core Minimum. This study satisfies the guideline requirement (81-4) for a primary eye irritation study in rabbits.

MRID # 425596-02 [Supplement # 2 for MRID # 409215-02 (Primary Dermal Irritation Study with IN M6316-25 in Rabbits)]: The Batch # of the test material is listed as 25 on page 4 of the submission (General Information). Individual body weights were provided on page 7. It is to be noted that each rabbit lost weight ($\approx$ 212 grams) following treatment. One rabbit was noted to have exhibited diarrhea one day after treatment. The data/information provided are adequate, and the study is upgraded to Core Minimum. This study satisfies the guideline requirement (81-5) for a primary dermal irritation study in rabbits.

MRID # 425596-03 [Supplement # 1 for MRID # 408588-01 (Primary Eye Irritation Study with IN T6376-41 in Rabbits): On page 4 of the submission (General Information), it is stated that the test material was ground into a fine powder to maximize the weight/volume ratio. Additionally, a statement indicating that no clinical signs of toxicity were observed was included as Appendix II. Appendix I of the supplement indicates that no final body-weight data were collected during this study. Although useful in assessing toxicity, TB II concludes that the absence of such data does not detract from the usefulness of the study in setting the toxicity category of the test material. The data/information provided are adequate, and the study is upgraded to Core Minimum. This study satisfies the guideline requirement (81-4) for a primary eye irritation study in rabbits.

MRID # 425596-04 [Supplement # 1 for MRID # 408588-02 (Primary Dermal Irritation Study with IN T6376-41 in Rabbits): The Batch # of the test material is listed as 41 on page 4 of the submission (General Information). Individual body weights were provided (Appendix I). Two rabbits lost weight (one lost 252 grams; one lost

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9 grams) and four gained weight (24-131 grams) following treatment. No clinical signs of toxicity were observed during the study. The data and information are adequate, and the study may be upgraded to Core Minimum. This study satisfies the guideline requirement (81-5) for a primary dermal irritation study in rabbits.

MRID # 425596-00 [Cover letter dated 11/13/92 for MRID # 408588-03 (Closed-Patch Repeated Insult Dermal Sensitization Study (Buehler Method) in Guinea Pigs with IN T6376-41): The batch # of the test material is stated to be 41, as indicated in the title [T6376-41]. This study may be upgraded to Core Minimum, and it satisfies the guideline requirement (81-6) for a dermal sensitization study.

CONCLUSION: The current submission provides adequate data/ information with which to upgrade the studies classified Core Supplementary. All data requirements have been satisfied for both active ingredients. TB II has no objection to the request for registration of the new use of Du Pont Harmont® Extra Herbicide on oats and a tolerance for Thifensulfuron methyl and tribenuron methyl on oat grain and straw, provided neither RfD [see TB II memo dated 8/19/92] is exceeded as a result of these residue levels. NOTE: Three of the upgraded studies are on Metsulfuron methyl (IN T6376), which is a metabolite/degradation product of the two active ingredients.