

DP Barcode:

D167840

PC Code No.: 128845 & 128887

EFGWB Out:

nii 26 1992

TO:

Joanne Miller

Product Manager 23

Registration Division (H7505C)

FROM:

Paul J. Mastradone, Ph.D., Head

Environmental Chemistry Review Section #1

Environmental Fate & Ground Water Branch/EFED (H7507C)

THRU:

Henry Jacoby, Chief

Environmental Fate & Ground Water Branch/EFED (H7507C)

Attached, please find the EFGWB review of ...

Reg./File #:

352-538

Common Name:

Thifensulfuron methyl and Tribenuron methyl

Product Name:

Harmony Extra

Company Name:

DuPont

Purpose:

Review request to shorten from 60 to 45 days the interval when used on fallow land prior

to planting rotational crops.

Type Product: Herbicide

Action Code: 320

EFGWB #(s): 91-0889

Review Time: 5 days

EFGWB Guideline/MRID/Status Summary Table: The review in this package contains...

161-1	162-4	164-4 166-1
161-2	163-1	164-5 166-2
161-3	163-2	165-1 166-3
161-4	163-3	165-2 167-1
162-1	164-1	165-3
162-2	164-2	165-4 201-1
162-3	164-3	165-5 202-1

Y = Acceptable (Study satisfied the Guideline)/Concur P = Partial (Study partially satisfied the Guideline, but additional information is still needed) S = Supplemental (Study provided useful information, but Guideline was not satisfied). N = Unacceptable (Study was rejected)/Non-Concur

DP BARCODE: D167840

CASE: 007612 SUBMISSION: S401286 DATA PACKAGE RECORD

BEAN SHEET

DATE: 08/21/91 Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 320 AMD-LBL REV-DAT REQ H/E R

CHEMICALS: 128845 Methyl 3-((((4-methoxy-6-methyl-1,3,5-triazin-2-yl 50.0000%

128887 Methyl 2- N-(4-methoxy-6-methyl-1,3,5-triazin-2-yl 25.0000%

ID#: 000352-00538 HARMONY EXTRA HERBICIDE

COMPANY: 000352 E. I. DU PONT DENEMOURS AND COMPANY, INC.

PRODUCT MANAGER: 23 JOANNE MILLER 703-557-1830 ROOM: CM2 237 PM TEAM REVIEWER: MARY ERMUSELE-MATZER 703-557-0546 ROOM: CM2 256

RECEIVED DATE: 08/18/91 DUE OUT DATE: 12/06/91

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 167840 EXPEDITE: N DATE SENT: 08/21/91 DATE RET.: / / CHEMICAL: 128845 Methyl 3-(((4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino)ca

DP TYPE: 001 Submission Related Data Package

ADMIN DUE DATE: 10/30/91 CSF: N LABEL: N

* * * DATA REVIEW INSTRUCTIONS * * *

Please review this supplemental labeling for stale seedbed use with data attached. Thank You.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

1.0 CHEMICAL:

Common Names: Thifensulfuron methyl (DPX-M6316) and tribenuron

methyl (DPX-L5300)

Chemical Names: Methyl-3-[[[[(4-hydroxy-6-methyl-1,3,5-triazin-2-

yl)amino]carbonyl]amino]sulfonyl]-2-thiophenecarboxylate (thifensulfuron methyl or DPX-M6316)

Methyl-2-[[[N-(4-methoxy-6-methyl-1,3,5-triazin-2-yl) methylamino] carbonyl] amino] sulfonyl] benzoate

(tribenuron methyl or DPX-L5300)

Trade Name: Harmony Extra (75% a.i. - 50% thifensulfuron methyl

plus 25% tribenuron methyl)

Chemical Structures:

Thifensulfuron methyl

Tribenuron methyl

Chemical/physical properties:

Thifensulfuron methyl	Tribenuron methyl
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molecular wt: 387.4 395.4 melting pt: 186°C 141°C

solubility: 2.4 mg/mL (pH 6) 280 mg/L @25°C vapor press: 2.7 X 10^{-6} mm Hg @25°C 2.7 X 10^{-7} mm Hg

2.0 TEST MATERIAL: N/A

3.0 <u>STUDY/ACTION TYPE:</u>

Review request to shorten the crop rotation interval of Harmony Extra from 60 to 45 days when it is used for broadleaf weed control on fallow land prior to planting rotational crops.

4.0 STUDY IDENTIFICATION:

Nathan, III, E.C. 1991. Recropping following use of Harmony Extra herbicide. Summary of accumulation in confined rotational crops studies (165-1) submitted in support of shortening from 60 to 45 days the rotational interval when Harmony Extra is applied to fallow land for broadleaf weed control. DuPont Report No. AMR-2111-91. MRID no. 41912801. This is a summary of four confined rotational crop studies: two for thifensulfuron methyl (Acc. no. 254641, reviewed 11/30/84 and MRID 40340318, reviewed 01/22/88) and two for tribenuron methyl (MRID

nos. 40245525 and 00152753, reviewed 04/21/89). (Note: The registrant's submission cites MRID no. 00073993 [DuPont report no. AMR-427-85] in support of this request. According to EFGWB records, DuPont report no. AMR-427-85 corresponds to MRID no. 00152753.)

5.0 REVIEWED BY:

Arnet W. Jones, Agronomist Review Section 1, EFED/EFGWB Signature: weth force

Date:

OCT 26 199

6.0 APPROVED BY:

Paul J. Mastradone, Chief Review Section 1, EFED/EFGWB Signature:

Date:

OCT 2

7.0 <u>CONCLUSIONS:</u>

- 7.1 EFGWB concludes that the data support shortening the crop rotation interval of Harmony Extra (75% a.i. 50% thifensulfuron methyl plus 25% tribenuron methyl) from 60 to 45 days when it is used for broadleaf weed control on fallow land prior to planting rotational crops. Linda Taylor of Toxicology Branch advised this reviewer that there are no toxicological concerns for thifensulfuron methyl and its degradates the triazine amine, 0-demethyl triazine amine, and triazine urea in rotational crops (see Discussion item 10.4).
- 7.2 In a confined crop rotation study (MRID no. 254641) in which crops were planted in soil 30 days following treatment with thifensulfuron methyl (DPX-M6316) at a rate of 94 g a.i./ha (2.7 times the maximum field use rate), total radioactive residues in peas, sunflowers, and beets ranged from 0.001 to 0.054 ppm (Table I). The maximum concentration of parent thifensulfuron was 0.002 ppm (sunflower foliage, 43 days after planting).
- 7.3 In a separate confined crop rotation study (MRID no. 40340318) in which thifensulfuron methyl was applied to wheat foliage which was incorporated into the soil 45 days after treatment, parent was not detected in any crop tissue samples. The degradate triazine amine (see Discussion item 10.4) was present at 0.032 ppm in pea foliage 42 days after planting (day 87) and in sunflower and beet foliage at 0.008 and 0.005 ppm, respectively. Triazine urea was found in foliage of peas, sunflowers, and beets in concentrations of 0.006, 0.001, and 0.001 ppm, respectively. O-demethyl triazine amine was present in pea foliage at 0.002 ppm at day 87.
- 7.4 With regard to the tribenuron methyl (DPX-L5300) component of Harmony Extra, EFGWB concludes that the data support a 45-day rotational interval. See Discussion and the EFGWB review of 04/21/89 for details.

- 7.5 The data presented in support of the shortened rotational interval may underestimate the total residues likely to accumulate in rotational crops due to Harmony Extra application because:
 - (a) Data were presented separately for each individual active ingredient. Accumulated residues would be the sum of residues of the two individual active ingredients. Summation of residue accumulation data in rotational crops for each active ingredient is not possible for the studies presented because of differences among soils, crop species, application and sampling schedules, etc.
 - (b) Data were presented on a crop fresh weight basis. Since fresh plants contain a significant amount of water, reporting residue concentrations on plant fresh weight basis will result in lower concentrations than the same data for plant dry weight.
 - (c) Data were reported in triazine amine equivalents, not in parent molecule equivalents.

Because of the low residue levels reported and the general lack of toxicological concern, this possible underestimation of residue levels does not affect EFGWB's conclusions regarding shortening the rotational interval. See Discussion for details.

- 7.6 EFGWB notes that the triazine degradates generated from both active ingredients tend to be persistent and mobile and may pose a threat to ground water and surface water. A small-scale prospective ground water study for thifensulfuron methyl was requested by the Agency.
- 8.0 RECOMMENDATIONS:

See Conclusions.

9.0 BACKGROUND:

Harmony Extra (active ingredients are 50% by wt. thifensulfuron methyl and 25% by wt. tribenuron methyl) is a postemergence herbicide used to control broadleaf weeds in wheat and barley. It is formulated as a water-dispersable granule and can be applied aerially or by ground equipment. The maximum application rate is 1 oz. of formulated granules per acre (0.75 oz. total a.i./A). A 60-day crop rotation interval is currently approved for Harmony Extra. The registrant (DuPont) wishes to shorten the rotation interval from 60 to 45 days when Harmony Extra is used to treat broadleaf weeds on fallow land prior to planting a rotational crop (corn, cotton, rice, grain sorghum, or soybeans). More than one application may be made, however, the total application rate may not exceed 1 ounce of formulated product per acre, the rate currently approved for wheat and barley.

9.1 Environmental Fate Summaries

The following environmental fate summaries are based on supplemental and acceptable data. See Section 9.2 for the status of environmental fate data requirements.

9.1.1 Thifensulfuron Methyl (DPX-M6316)

Thifensulfuron methyl (DPX-M6316), one of the two active ingredients in Harmony Extra, hydrolyzes with a half-life of 3-6 days at pH 5. It is stable to hydrolysis at pH 7 and 9. The primary degradate, triazine amine, is stable to hydrolysis. DPX-M6316 undergoes aqueous photolysis at pH 5 with a half-life of 30-72 hr; at pH 7 and 9 the half-life is 3-6 days. It photolyzes in soil with a half-life of 7-14 days. Thifensulfuron methyl has an aerobic soil half-life of 1-2 wks and is very mobile. The degradate triazine amine has a soil half-life of 6-8 months and is also very mobile. Because this degradate has a significant potential to leach through soil and contaminate ground water, a prospective ground water study was requested. Half-lives of 7-28 days were reported for thifensulfuron methyl in flooded sediments. Terrestrial field dissipation half-lives were 3-20 days, with some leaching of residues evident. Small quantities of residues accumulated in confined rotational crops planted 30 days after treatment with thifensulfuron methyl. Thifensulfuron methyl does not accumulate in bluegill sunfish.

'9.1.2 Tribenuron Methyl (DPX-L5300)

The primary route of dissipation of tribenuron methyl (DPX-L5300) appears to be hydrolysis with rapid degradation occurring at neutral and acidic pH values. Hydrolytic half-lives at pH 5, 7, and 9 are <1, 3-6, and >>30 days, respectively. Neither parent nor degradates appears to photolyze in water or soil. In aerobic soil conditions, reported half-lives were <1 day (pH 4.3) and 9 days (pH 7.5). Similar pH-dependent anaerobic degradation rates were reported. Degradation rates were similar in sterile and non-sterile soils. Degradates associated with the triazine moiety of the parent include triazine amine, O-demethyl triazine amine, and N-demethyl triazine. These degradates are more persistent than degradates associated with the phenyl moiety of the parent molecule (saccharin, ester sulfonamide, and acid sulfonamide). Additional leaching data are required, but preliminary data indicate that parent and degradates are mobile in soil. Tribenuron methyl and its degradates do not appear to accumulate significantly in rotational crops.

9.2 Status of Environmental Fate Data Requirements

		Thifensulfuron	Tribenuron
Guidel	<u>ine No.</u>	Methyl (MRID; Date)	Methyl (MRID; Date)
161-1	Hydrolysis	satisfied (263760,	satisfied (00148651;
101 1	11,0101,010	252492; 04/10/87)	09/18/86)
161-2	Photolysis/Water	satisfied (263760;	satisfied (40245520;
		04/10/87)	04/19/89)
161-3	Photolysis/Soil	satisfied (263760;	satisfied (40245521;
161 6	The males of a /Adm	04/10/87) NA	04/19/89) NA
162-1	Photolysis/Air Aerob. Soil Metab.	satisfied (072846,	partially satisfied
102-1	Aerob. Soli Mecab.	245878, 40340317;	(40245522, 40927204;
		04/10/87, 01/22/88)	04/21/89)
162-2	Anaer. Soil Metab.	partially satisfied1	not satisfied
	Anaer. Aqua. Metab.	partially satisfied ¹	NA
•		(263760)	• · · · · · · · · · · · · · · · · · · ·
162-4	Aerob. Aqua. Metab.	NA	NA
163-1	Leach/Ads/Des	satisfied (263760;	partially satisfied
		04/10/87)	(00148653, 40245523;
		n de la companya de La companya de la co	04/20/89)
163-2		NA	NA NA
163-3		NA	not satisfied
164-1	Terr. Field Dissip.	satisfied (263760; 04/10/87)	not satisfied
164-2	Aqua. Field Dissip.	NA	NA
164-3	•	NA	NA
164-4	Tank Mix	NA	NA
164-5		NA	NA
165-1	Conf. Rotat. Crops	satisfied (254641,	satisfied (40245525,
		40340318; 01/22/88)	40927207; 04/21/89)
	Field Rotat. Crops	NA	NA NA
	Accum. Irrig. Crops	NA	NA (00 /19 /96)
165-4	Fish Accum.	satisfied (072646; 11/01/84)	waived (09/18/86)
165-5	Aq. Non-Target Org.	NA.	NA
201-1		not satisfied	not satisfied
202-1	Drift Field Eval.	not satisfied	not satisfied

The anaerobic soil metabolism data requirement can be fulfilled by submission of acceptable anaerobic aquatic metabolism data.

10.0 DISCUSSION OF INDIVIDUAL STUDIES:

10.1 Thifensulfuron Methyl (DPX-M6316)

Accession no. 254641 is a confined accumulation study in which peas, beets, and sunflowers were planted in a Sassafras sandy loam that was treated 30 days earlier with thifensulfuron methyl (DPX-M6316) radio-

labeled in the thiophene ring. The application rate in the confined accumulation study was 94 g a.i./ha, 2.7 times the maximum field application rate (35 g a.i./ha). Table I (copy attached) summarizes the results of this study. When data are divided by 2.7 to compensate for the exaggerated application rate, total residues in all plant parts analyzed, with the exception of sunflower foliage, were <0.01 ppm. The total residue concentration in sunflower foliage was 0.02 ppm and the concentration of parent thifensulfuron methyl was <0.001 ppm when the data are divided by 2.7 to adjust for the exaggerated application rate. Plant tissue was not analyzed for parent unless total 14 C residues exceeded 0.01 ppm.

Although the data presented in Acc. no. 254641 were judged to be acceptable, the EFGWB (formerly EAB) review noted that (1) material balances were not reported; (2) there was no soil analysis after application to confirm the pesticide application rate; and (3) soil sampling methods were not described.

In MRID no. 40340318 (EFGWB reviews of 01/22/88 and 03/18/88), wheat grown in greenhouse pots was treated at the 2-leaf stage with triazine-labeled thifensulfuron methyl at the maximum label rate of 2/3 oz a.i./ha. Wheat was treated 45, 74, and 75 days prior to planting beets, peas, and sunflowers. The results of this study are summarized in Tables II and III (attached). Total radioactive residues in plant parts used for human consumption were always <0.010 ppm; parent thifensulfuron methyl was not detected in any samples. Except for pea foliage analyzed 42 days after planting (day 87) and sunflower foliage analyzed 88 days after planting (day 133), all plant residues were <0.010 ppm. The degradate triazine amine (see Discussion item 10.4) was present at 0.032 ppm in pea foliage 42 days after planting (day 87) and in sunflower and beet foliage at 0.008 and 0.005 ppm, respectively. Triazine urea was found in foliage of peas, sunflowers, and beets in concentrations of 0.006, 0.001, and 0.001 ppm, respectively. O-demethyl triazine amine was present in pea foliage at 0.002 ppm at day 87. EFGWB concluded that neither thifensulfuron methyl nor its degradates accumulated in appreciable amounts in rotated beets, peas, and sunflowers, and that the accumulation in confined rotational crops data requirement (165-1) for thifensulfuron methyl was fulfilled.

In MRID no. 40340318 thifensulfuron methyl was applied to wheat foliage which was incorporated into the soil 45 days after treatment. The proposed new use is for application to fallow land. Residues available for rotational crop uptake following application to fallow land may be higher than those available following application to a growing crop. This is because of interception and metabolism of pesticide by growing crop foliage (which would be expected to be greater than the amount of foliage present due to weeds on fallow).

EFGWB notes that total residue concentrations are reported in triazine amine equivalents (the triazine moiety of the molecule was radiolabeled). EFGWB believes that this method underestimates the total residue concentrations by a factor of approximately 2.5 (the molecular

weight of parent thifensulfuron methyl is about 2.5 times that of triazine amine) because it approximates only the concentration of labeled degradates. Reporting total residues in parent equivalents would provide a better estimate of the total concentrations of labeled and unlabeled degradates. (See EFGWB review of 04/21/89 for tribenuron methyl, MRID no. 40245525, p. 10.4.)

10.2 Tribenuron Methyl (DPX-L5300)

In MRID no. 00152753 cabbage, red beets, wheat, soybeans, and sorghum were planted 30 and 120 days after treatment of a Sassafras sandy loam soil with 35 g a.i./ha of phenyl-labeled tribenuron methyl (DPX-L5300). The maximum field application rate is 17.5 g a.i./ha. Data from this study are summarized in Tables IV and V (copies attached). Total 14C residues in tribenuron methyl equivalents were <0.01 ppm in the heads and foliage of cabbage, in the roots and foliage of beets, and in the grain of wheat, soybean, and sorghum, all of which were planted 30 and 120 days post-treatment. Total 14C residues exceed 0.01 ppm by a factor of 2 (the experimental application rate was twice the field rate) in wheat straw (0.054 ppm), mature soybean foliage (0.052 ppm), and mature sorghum foliage (0.082 ppm) planted 30 days post-treatment. Total 14C residues exceeded 0.01 ppm by less than a factor of 2 in the foliage of mature sorghum (0.019 ppm) planted 120 days post-treatment. Saccharin was the major and only identified phenyl moiety degradate in soil and plant tissue. There was no analysis for parent tribenuron methyl in plant tissue extracts (methylene chloride) because total 14C residues were <0.01 ppm. EFGWB concluded that this study provided supplemental information but could not be used toward fulfilling the accumulation in confined rotational crops data requirement because storage stability data were not presented for soil samples.

In MRID no. 40245525 a sandy loam soil was treated with triazine-labeled tribenuron methyl (DPX-L5300) at a rate of 32 g a.i./ha. Red beets, cabbage, and sorghum were planted 30 and 120 days following treatment. After 30 days, total $^{14}\mathrm{C}$ soil residues in tribenuron methyl equivalents decreased from 0.012 ppm immediately post-treatment to 0.0097 ppm at 30 days, with parent tribenuron methyl not detected. Total $^{14}\mathrm{C}$ residues in soil were 0.0085 and 0.004-0.007 ppm at 120 days and harvest (112-245 days post-treatment), respectively. Triazine amine was the major degradate detected at 30 days (0.004 ppm). Total $^{14}\mathrm{C}$ residues in tribenuron methyl equivalents were ≤ 0.01 ppm in beet roots, cabbage heads, and sorghum grain from crops planted 30 and 120 days post-treatment. Total $^{14}\mathrm{C}$ residues exceeded 0.01 ppm in the foliage of red beets, cabbage, and sorghum planted 30 and 120 days post-treatment. Parent DPX-L5300 was not detected in any plant tissue samples at or above the 1 ppb detection limit.

The EFGWB review concluded that the data supported a 30-day crop rotation interval for tribenuron methyl for root vegetables, leafy vegetables, and small grains. This conclusion was reached as a result of a 06/06/89 meeting in which H. Jacoby of EFGWB was advised by R.

- Gardner of Toxicology Branch that the only residues of toxicological concern are concentrations of parent DPX-L5300 exceeding 0.01 ppm. Also, EFGWB concluded that this study fulfilled the accumulation in confined rotational crops data requirement. See the EFGWB review of 04/21/89 for details.
- 10.3 Harmony Extra currently is registered only for postemergence weed control in wheat and barley. Under the proposed new use corn, cotton, rice, grain sorghum, or soybeans could be planted 45 days after Harmony Extra application to fallow ground. Rotational crop residue data was submitted for pea, sunflower, and beets for thifensulfuron methyl. Acceptable residue data for tribenuron methyl was submitted for and cabbage, beets, and sorghum; the data provided for wheat and soybeans are considered supplemental by EFGWB. Although the residue data submitted does not pertain directly to those crops which would be included under the new use, EFGWB believes that the residue data support the proposed new use because of the low residue concentrations in rotational crops and the lack of toxicological concern for residues detected.
- 10.4 Since Harmony Extra is comprised of two active ingredients (thifensulfuron methyl and tribenuron methyl), the total residue accumulation
 in rotational crops is the sum of the accumulation of both active
 ingredients and all degradates. Accumulation in confined rotational
 crops data were submitted separately for each individual active ingredient in Harmony Extra. Summation of residue data for each active
 ingredient is not possible for the studies presented because of
 differences among soils, crop species, application and sampling
 schedules, etc.
- 10.5 For both active ingredients, triazine amine and 0-demethyl triazine amine are reported as degradates. However, the compound referred to as triazine amine in the thifensulfuron studies is not identical to the compound with the same name in the tribenuron methyl studies. The same is true for 0-demethyl triazine amine. The structures of parent molecules and degradates are attached.
 - In both cases, the tribenuron degradate contains a methyl group in the amine position; this methyl group is not present in the thifensulfuron degradates. EFGWB has been advised that there are no toxicological concerns for the tribenuron methyl degradates. Also, in personal communication with Linda Taylor of Toxicology Branch, this reviewer was advised that there are no toxicological concerns for thifensulfuron methyl and its degradates.
- 10.6 The triazine degradates generated from both active ingredients tend to be persistent and mobile and may pose a threat to ground water and surface water. A small-scale prospective ground water study for thifensulruron methyl was requested by the Agency. Because of the low application rate a study using a soil column lysimeter was deemed acceptable by the Agency. The study is ongoing.

- 10.7 Residue concentrations are provided on plant fresh weight basis which would lead to lower reported concentrations than if residue concentrations were reported as ppm in dry plant tissue. Because the fresh weights of plants vary substantially between species and by plant growth stage, EFGWB believes that residue data should be reported on a plant dry weight basis. Reporting on plant dry weight basis will enable accurate comparisons of residue accumulation between plant species and within a given species at various growth stages.
- Because many plant species are sensitive to Harmony Extra in very small quantities and because it may be applied aerially, EFGWB believes that there may be a significant risk to nontarget plants due to off-target spray drift. There are no specific precautions outlined in the proposed supplemental labeling which could reduce the risk of damage to nontarget plants from spray drift. (The label states "Do not apply during inversion conditions, when winds are gusty, or when conditions will favor poor coverage and/or off-target spray movement.") In contrast, the label for Harmony Extra for weed control in wheat and barley recommends several practices designed to minimize spray drift (see attached page from the catalog "DuPont Agricultural Products" [1990], p. 232). EFGWB believes that specific precautions aimed at reducing spray drift should be included in the label for this proposed new use.
- 10.9 Under the proposed new use, Harmony Extra could be applied to fallow ground 45 days prior to planting corn, sorghum, rice, soybeans, and cotton in the following states: AL, AR, DE, GA, IN, IL, KY, LA, MD, MO, MS, NC, OH, PA, SC, TN, and VA. For other crops, a 60-day rotational restriction applies.
- 11.0 COMPLETION OF ONE-LINER: N/A

12.0 CBI APPENDIX:

Although labeled "Trade Secret", the report makes no claim of confidentiality for any information on the basis of its falling with the scope of FIFRA Section 10(d)(1)(A), (B), or (C).

HARMONY		12	8845	
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