



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

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

October 23, 1997

MEMORANDUM

SUBJECT: ID# 062719-ETL. Cloransulam-methyl. PC Code 129116. Amended Registration for Cloransulam-methyl on Soybeans. MRID 44046601. DP Barcodes: 227957 and 227958.

FROM: Brenda Tarplee, Chemist
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BW. Tarplee

THROUGH: Melba Morrow, Senior Scientist
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TO: Philip Errico, PM#25
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Attached is a review of additional residue data for cloransulam-methyl on soybean seed, forage, and hay, submitted by the registrant, DowElanco, in response to the registration of cloransulam-methyl. This information was reviewed by Dynamac Corporation under the supervision of RAB1, HED. The data assessment has undergone secondary review in the Branch and has been revised to reflect Agency policies.

The regulation establishing tolerances for residues of cloransulam-methyl on soybeans was concurrent to this review and made effective September 19, 1997. The current label allows one application (preplant incorporated, preplant surface, preemergence or postemergence) per season.

Field trials on soybeans were conducted to supplement the existing data to support soil application followed by a postemergent application, and these are now determined to be adequate. The data indicate that residues of cloransulam-methyl will not exceed the established tolerances of 0.02 ppm in/on soybean seed, 0.1 ppm in/on soybean forage, and 0.2 ppm in/on soybean hay from

this additional application. The label should retain the 14-day PHI for forage and cutting of hay and the 65-day PHI for seed.

This amended use pattern for cloransulam-methyl on soybeans (soil application **followed by a postemergent application**) will not significantly alter the occupational exposure and aggregate risk estimates previously determined for this registration, which did not exceed HED's level of concern (ID#5F4560).

cc: RF, SF, PP#5F4560, B. Tarplee (RAB1)
RDI: M.Morrow:RAB1:10/23/97
7509C:CM#2:Rm811Bay:308-6175:B.Tarplee:bt:10/23/97

**CLORANSULAM-METHYL
(DP Barcode D227958)**

Magnitude of the Residues in Soybean Commodities

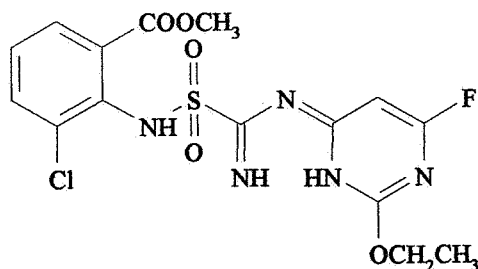
August 21, 1997

Contract No. 68-D4-0010

**Submitted to:
U.S. Environmental Protection Agency
Arlington, VA**

**Submitted by:
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CLORANSULAM-METHYL



MAGNITUDE OF THE RESIDUE IN SOYBEAN COMMODITIES

(DP BARCODE D227958)

INTRODUCTION

DowElanco previously submitted a petition (PP#5F4560) for the establishment of permanent tolerances for residues of the herbicide cloransulam-methyl [company code = XDE-565; chemical name = N-(2-carboxymethoxy-6-chlorophenyl)-5-ethoxy-7-fluoro-[1,2,4]triazolo-(1,5-C]pyrimidine-2-sulfonamide)] in/on soybean commodities in conjunction with a request for a Section 3 registration of an 84% water dispersible granular formulation [Product name = FirstRate Herbicide; EPA File Symbol No. 62719-ETL] for use on soybean. The petition requests permanent tolerances of 0.02 ppm in/on soybean, 0.1 ppm in/on soybean forage, and 0.2 ppm in/on soybean hay, expressed as parent only. Following evaluation (CBTS Nos. 16274 and 17118, DP Barcodes D219679 and D225138, 8/29/96, J. Garbus) of product and residue chemistry data submitted in support of the subject petition, CBTS recommended against the proposed registration on soybean and the proposed tolerances on soybean RACs because of the following reasons and/or deficiencies: (i) analytical reference standards need to be submitted; (ii) a revised Section B is needed; (iii) a successful Agency method validation needs to be conducted; (iv) a confirmatory method needs to be submitted; and (v) HED's Metabolism Committee concurrence is needed for the conclusion that the parent is the residue of concern.

Each of the aforementioned deficiencies have been adequately addressed (Barcode D237713, 08/25/97, B. Tarplee). The regulation establishing tolerances for residues of cloransulam-methyl at 0.02 ppm in/on soybean seed, 0.1 ppm in/on soybean forage, and 0.2 ppm in/on soybean hay, expressed as parent plus its acid cloransulam calculated as parent ester, was effective September 19, 1997.

In support of an amendment to modify the use pattern, DowElanco has submitted additional data (1996; MRID 44046601) pertaining to magnitude of cloransulam-methyl residue in/on soybean commodities. The original petition review did not require additional soybean residue data based on acceptable field trials reflecting either soil applications (preplant incorporated, preplant

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surface applied, or preemergence) or postemergence application. The petitioner now wishes to support soil application followed by a postemergence application.

CONCLUSIONS AND RECOMMENDATIONS

1. The submitted soybean field trial data are acceptable and may be used to support an amendment to modify the proposed use pattern (soil application followed by a postemergence application) of cloransulam-methyl on soybeans.
2. The data indicate that residues of cloransulam-methyl will not exceed the established tolerance of 0.02 ppm in/on soybean seed harvested 61-112 days following the last of a treatment schedule consisting of single preplant incorporated broadcast application at 0.033-0.041 lb ai/A followed by a single postemergence broadcast application at 0.015-0.017 lb ai/A of the 84% WDG formulation. Residues of cloransulam-methyl were each below the LOD (0.003 ppm) or LOQ (0.01 ppm) in/on all treated soybean seed (n= 56 samples) following the above treatment schedule except for one sample collected from the MO site which bore detectable residue of 0.006 ppm.
3. The data indicate that residues of cloransulam-methyl will not exceed the established tolerances of 0.1 ppm in/on soybean forage and 0.2 ppm in/on soybean hay harvested 14 days following the last of the above treatment schedule. The residue decline study indicates that residues of cloransulam-methyl were lower at longer posttreatment intervals; residues declined at each increased sampling interval with residues below the LOQ (0.01 ppm) at 21 days posttreatment.
4. The previous tolerance petition review recommended a 14-day PHI for forage and cutting of hay and a 65-day PHI for seed. Based on the available data reflecting the amended proposed use pattern, these recommendation are still valid and appropriate. The previous CBTS comments concerning the adequacy of the rotational crop restrictions remain in effect.
5. Table 1 of OPPTS GLN 860.1000 considers aspirated grain fraction as a raw agricultural commodity of soybean. No soybean aspirated grain fraction data or tolerance are required because residues of cloransulam-methyl were below the LOQ (0.01 ppm) in/on treated soybean grain.

DETAILED CONSIDERATIONS

Residue Analytical Methods

Samples of soybean forage, hay, and seed from the submitted field trial study were analyzed for residues of cloransulam-methyl using GC/mass selective detection (MSD) Method GRM 94.07.R1 which was previously described under the original permanent tolerance petition review. Briefly, samples were extracted with acetone:0.1 N HCl (90:10, v:v), evaporated to dryness, redissolved in pH 7.5 buffer, and partitioned with hexane. The aqueous phase was discarded and the organic phase was acidified with 2 N HCl. The clear aqueous phase (with coagulated particulates removed) was cleaned-up on C18 and neutral alumina solid phase extraction (SPE) columns. The eluant was evaporated to dryness and residues were derivatized with trimethylsilyldiazomethane and evaporated again to dryness. The N-methyl-cloransulam-methyl derivative was redissolved in water and partitioned into toluene containing the internal standard, N-ethyl-cloransulam-methyl, for GC analysis. Sample analyses were performed by DowElanco Analytical Services Laboratory (Indianapolis, IN). The reported LOD and LOQ for cloransulam-methyl were 0.003 ppm and 0.01 ppm, respectively in/on all soybean matrices. Sample calculations and representative chromatograms were provided.

The petitioner included concurrent method recovery data. Samples of untreated soybean commodities from the field trials were fortified with cloransulam-methyl and analyzed concurrently with the field trial samples. The concurrent method recoveries are presented in Table 1. We note that the lower recoveries were obtained in soybean forage, hay, and seed at the higher fortification levels.

Table 1. Concurrent method recoveries of cloransulam-methyl from fortified samples of soybean commodities analyzed using GC methods.

Commodity	Fortification Level, ppm	Percent Recovery *
Soybean, forage	0.01-5.00	63.4-68.0 (4); 70.5-73.5 (6)
Soybean, hay	0.01-5.00	61.4-65.5 (3); 70.2-90.4 (7)
Soybean, seed	0.01-1.00	57.2-69.5 (16); 71.7-97.5 (15)

* Number of samples in parentheses; recovery values outside the acceptable 70-120% range are listed separately.

Along with the previously submitted method validation data presented from the original permanent tolerance petition, the concurrent method recoveries demonstrate that GC/MSD Method GRM 94.07.R1 is adequate for the purpose of collection of residue data for cloransulam-methyl in/on soybean forage, hay, and seed.

Storage Stability Data

Samples of soybean forage, hay, and seed from the submitted field trial study were stored frozen at the field within 7 hours of harvest. The samples were then shipped frozen to the analytical laboratory for analysis. Samples were stored frozen at the laboratory until sample preparation and analysis. The total storage intervals were 137-174 days (~5-6 months) for hay, 133-177 (~4-6 months) for forage, and 104-155 days (~3-5 months) for seed. The previous permanent tolerance petition review concluded that residues of cloransulam-methyl are stable under frozen conditions for up to 6 months in/on soybean forage and hay, and for up to 3 months in/on soybean seed.

The petitioner included in the current submission additional storage stability data for soybean forage, hay, and seed. These data indicate that cloransulam-methyl is stable under frozen storage conditions for up to 375 days (~12 months) in/on soybean seed. The reported average recoveries were 96.1% initially, and 99.0% following 13 days, 98.9% following 32 days, 101.6% following 91 days, 110.0% following 168 days and 95.1% following 375 days of storage. No details (i.e., sample source, storage conditions, fortification levels, and fresh fortification recoveries) of the storage stability study were included.

Magnitude of the Residue in Soybean Commodities

Established tolerances: Tolerances have been established for cloransulam-methyl residue (expressed as parent plus its acid cloransulam calculated as parent ester) in/on soybean seed at 0.02 ppm, soybean forage at 0.1 ppm, and soybean hay at 0.2 ppm.

Proposed use pattern: The petitioner did not include a revised label with the current submission. The accompanying transmittal letter of the study submission stated that the label allowing the proposed use pattern (preplant incorporated application followed by a postemergence application) will be submitted under separate cover so that the petitioner may include other issues the Agency may have in regards to label statements prior to registration. For the purpose of clarity, the use directions described in the original petition review are reiterated below.

"Cloransulam-methyl for use on soybeans is formulated as an 84% active wettable granular material packaged in water-soluble packets under the trade name FirstRate herbicide. It is recommended for preplant, pre- and postemergence use in the control of broad leaf weeds at rates of 0.04 lb ai/A (0.64 oz ai/A) for preplant and preemergence use and 0.016 lb ai/A (0.26 oz ai/A) for postemergence use. Only one application per season is allowed. Applications are to be made in 10-20 gallons of water per acre. Applications are facilitated by the use of water-soluble packets; one packet treats 1.6-4.0 acres. Cloransulam-methyl can be tank-mixed with any approved soybean herbicide provided tests show that they are compatible. Non-ionic surfactants, crop oil, or urea ammonium nitrate may be added as adjuvants. Aerial application is prohibited."

"According to the label, small grains may be replanted after 4 months; corn, sorghum, cotton, and peanuts after 9 months; and sugar beets, sunflowers, and tobacco after 2 years following a successful field bioassay. With the later crops, if the field bioassay is successful, (i.e., lack of obvious phytotoxicity), the test crops may be planted the following growing season."

In the original petition review, CBTS concluded that the proposed use directions to the primary crop are not adequate because the label needs to specify a 14-day interval for forage and cutting of hay and a 65-day PHI for soybean. With regards to the rotational crop restrictions, CBTS stated that a two-year prohibition on the rotational planting of tobacco, sugar beets, and sunflowers is impractical. The petitioner was required to provide its rationale or provide experimental data to support the plantback intervals proposed for corn, sorghum, cotton, peanuts, sugar beets, sunflowers, and tobacco.

These deficiencies were addressed and a revised Section B of the label was provided specifying a 14-day interval for forage and cutting of hay and a 65-day PHI for soybean. The revision also included a statement indicating that the rationale for rotational crop plantback intervals is due to the potential of phytotoxicity to susceptible plants. (Barcode D237713, 08/25/97, B. Tarplee).

Discussion of data: DowElanco submitted additional data (1996; MRID 44046601) depicting the magnitude of cloransulam-methyl residue in/on soybean seed, forage, and hay. These data were submitted in support of an amendment to modify the proposed use pattern of cloransulam-methyl on soybean. The petitioner now wishes to support soil application followed by a postemergence application.

A total of 21 trials was conducted in AR(1), GA(1), IA(2), IL(2), IN(2), KS(1), KY(1), LA(1), MI(1), MN(1), MO(1), MS(1), NC(1), ND(1), NE(1), OH(1), SD(1), and WI(1). The 84% WDG formulation of Cloransulam-methyl was applied to soybean plants using the following treatment types and/or schedule: preplant-incorporated (PPI), preemergence (PRE), and preplant-incorporated followed by postemergence application (PPI + POST). The application rates for each treatment type along with other details of the study are described in Table 2. All applications were made as a broadcast spray in ~20 gal/A of water using ground equipment.

Table 2. Types of treatments and applications rates using the 84% WDG formulation of cloransulam-methyl for the magnitude of the residue study on soybean commodities.

Treatment	Application Type	Target Rate ^a (lb ai/A)	Adjuvant	Application Timing and Other Relevant Details
1	Control	0	None	
2	PPI	0.038	None	The formulation was applied to the soil surface at 0 to 1 day before planting and incorporated by tilling the soil to a depth of 1-3 inches within 3 hours after application.
3	PRE	0.038	None	The formulation was applied to the soil surface at 0 to 3 days after planting.
4	PPI + POST	0.038 (PPI) + 0.015 (POST)	X-77 (0.25%, v:v) + UAN (2.5%, v:v)	For the POST treatments, the formulation was applied at the sixth to eighth trifoliolate growth stage.
5	PPI + POST	0.038 (PPI) + 0.015 (POST)	COC (1.2% (v:v))	
6	PPI + POST	0.038 (PPI) + 0.015 (POST)	COC (1.2% (v:v)) + UAN (2.5%, v:v)	

^a The actual application rates were reasonably well within the target application rates.

^b UAN = urea ammonium nitrate (28% nitrogen); COC = crop oil concentrate.

Treatments 1 to 4 were maintained at all sites, while Treatments 5 and 6 were conducted in seven sites to determine the effects of adjuvants on the residues of cloransulam-methyl in/on soybean grain. The petitioner provided adequate information concerning details of site locations, plot sizes, planting information, and maintenance chemicals.

Samples of soybean seed were collected either manually or by a mechanical harvester. Sampling was first made from the control plots followed treated plots. Each treated sample was collected from at least 12 randomly collected areas over the entire plot, excluding the end or border rows. A single composite sample collected from all control plots. Treated soybean seeds were collected at 102-149 days following PPI or PRE application (Treatments 2 or 3), and at 61-112 days after POST application (Treatments 4, 5, and 6).

A residue decline study was conducted on soybean forage and hay in two trial sites (IN and IL). Samples were collected from Treatment 4 at 0, 7, 14, 21, 28, and 35 days after the POST application. A single composite sample was collected at each sampling interval. Forage samples were collected when the soybean plants were at the beginning pod growth to full pod elongation (R3 to R4 stage). Hay samples were obtained by harvesting plants on the same sampling date as the forage samples and then drying them in a sheltered area. All samples were bagged and stored frozen at the field within 7 hours of harvest and shipped frozen to DowElanco Analytical Services Laboratory (Indianapolis, IN) for analysis.

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Residues of cloransulam-methyl in/on treated and untreated soybean commodities were determined using GC/MSD Method GRM 94.07.R1 with LOD and LOQ of 0.003 ppm and 0.01 ppm, respectively. Apparent residues of cloransulam-methyl were each nondetectable (<0.003 ppm) in/on untreated soybean seed (n=21 samples), forage (n=12 samples), and hay (n=12 samples).

Residues of cloransulam-methyl were each below the LOD (0.003 ppm) in/on treated **soybean seed** following PPI application (n=21 samples) and PRE application (n=21 samples). Residues of Cloransulam-methyl were each below the LOD (0.003 ppm) or LOQ (0.01 ppm) in/on all treated **soybean seed** (n= 56 samples) following PPI + POST applications, except for one sample collected from the MO site which bore detectable residue of 0.006 ppm. Residues of Cloransulam-methyl in/on treated **soybean forage and hay** from the decline study are presented in Table 3.

Geographic representation of soybean data from the current submission along with those reviewed in the original permanent tolerance petition review is adequate. A total of 21 field trials were conducted for the current study, and these trials were conducted in Regions 2 (2 trials), 4 (3 trials), and 5 (16 trials).

Table 3. Residues of cloransulam-methyl in/on soybean forage and hay treated with the 84% WDG formulation at a treatment schedule consisting of single preplant incorporated (PPI) broadcast application followed by a single postemergence (POST) broadcast application.

Test State Application Type (Actual Rate in lb ai/A)	Posttreatment Interval (PTI) In Days	Uncorrected Residues of Cloransulam-methyl (Ppm)
Soybean Forage		
<u>IL</u> PPI (0.040) + POST (0.016)	0	0.610
	7	0.032
	14	0.007
	21	0.003
	28	<0.003
	35	<0.003
<u>IN</u> PPI (0.038) + POST (0.016)	0	0.608
	7	0.131
	14	0.012
	21	0.005
	28	0.003
	35	<0.003
Soybean Hay		
<u>IL</u> PPI (0.040) + POST (0.016)	0	2.433
	7	0.190
	14	0.018
	21	0.008
	28	0.003
	35	<0.003
<u>IN</u> PPI (0.038) + POST (0.016)	0	2.759
	7	0.510
	14	0.033
	21	0.015
	28	0.009
	35	0.004

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Study Summary: The submitted soybean field trial data are acceptable and may be used to support an amendment to modify the proposed use pattern (soil application followed by a postemergence application) of cloransulam-methyl on soybean.

The data indicate that residues of cloransulam-methyl will not exceed the proposed tolerance of 0.02 ppm in/on soybean seed harvested 61-112 days following the last of a treatment schedule consisting of single preplant incorporated broadcast application at 0.033-0.041 lb ai/A followed by a single postemergence broadcast application at 0.015-0.017 lb ai/A of the 84% WDG formulation. Residues of cloransulam-methyl were each below the LOD (0.003 ppm) or LOQ (0.01 ppm) in/on all treated soybean seed (n=56 samples) following the above treatment schedule except for one sample collected from the MO site which bore detectable residue of 0.006 ppm.

The data indicate that residues of cloransulam-methyl will not exceed the proposed tolerances of 0.1 ppm in/on soybean forage and 0.2 ppm in/on soybean hay harvested 14 days following the last of the above treatment schedule. The residue decline study indicates that residues of cloransulam-methyl were lower at longer posttreatment intervals; residues declined at each increased sampling interval with residues below the LOQ (0.01 ppm) at 21 days posttreatment.

The previous tolerance petition review recommended a 14-day PHI for forage and cutting of hay and a 65-day PHI for seed. Based on the available data reflecting the amended proposed use pattern, these recommendation are still valid and appropriate. The previous CBTS comments concerning the adequacy of the proposed rotational crop restrictions remain in effect.

Table 1 of OPPTS GLN 860.1000 considers aspirated grain fraction as a raw agricultural commodity of soybean. No soybean aspirated grain fraction data or tolerance are required because residues of cloransulam-methyl were below the LOQ (0.01 ppm) in/on treated soybean grain..

AGENCY MEMORANDA CITED IN THIS REVIEW

CBTS Nos.: 16809 and 17077
DP Barcodes: D222301 and D224625
Subject: PP No. 5F4560: New Chemical: Cloransulam-methyl EPA Reg. No. 63719-ETU, Chemical No. 129116 in/on Soybean RACs. Evaluation of Analytical Methods and Residue Data. Case No. 286828.
From: J. Stokes
To: D. McCall
Dated: 6/21/96
MRID(s): 43668901-43668904 and 43668919-43668932

MASTER RECORD IDENTIFICATION NUMBERS

The citations for the MRID documents cited in this document are presented below.

44046601 Bargar, E.; Schwake, J.; Foster, D. (1996) Magnitude of Residue of Cloransulam-methyl (DE-565) in Soybeans Following Pre-plant Incorporated, Pre-emergence, and Post-emergence Applications of NAF-75: Lab Project Number: RES95018. Unpublished study prepared by DowElanco. 138 p.