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

AUG 29 1996

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: PP No. 5F4560: New Chemical: Chloransulam-methyl EPA Reg. No. 63719-ETU, Chemical No. 129116) in/on Soybean Rac's. Evaluation of Analytical Methods and Residue Data. Case No.286828 MRID Nos. 436689-01 thru 04 and 436689-19 thru 32. DP Barcodes D219679 & D225138 CBTS Nos. 16274 & 17118

FROM: Joel Garbus, PhD., Chemist Joel Garbus
Tolerance Petition Team I
Chemistry Branch Tolerance Support (7509C)

THRU: E. Haeberer, Acting Chief E. T. Haeberer
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TO: D. McCall, Acting Section Head
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DowElanco, Indianapolis IN, has petitioned the Agency for permanent tolerances resulting from the use of the herbicide chloransulam-methyl on soybeans. The petitioner was granted a crop-destruct EUP (62719-EUP-28) for this use in September, 1994. A request for temporary tolerances associated with an EUP (5G4535) has been withdrawn.

The current petition requests permanent tolerances of 0.02 ppm in/on soybeans, 0.1 ppm in/on soybean forage, and 0.2 ppm in/on soybean hay, expressed as parent only.

Chloransulam-methyl (XDE-565 or DE-565) is a triazolopyrimidine sulfonamide: N-(2-carboxymethyl-6-chlorophenyl)-S-ethoxy-7-fluoro (1,2,4)triazolo(1,5-C)pyrimidine-2-sulfonamide. It is a new chemical with no prior food uses.

Executive Summary

CBTS recommends against the proposed registration on soybeans and the proposed tolerances on soybean rac's for the following reasons:

a) analytical reference standards need to be submitted

b) a revised Section B is needed (See Conclusions 2a and 2b)

c) a successful Agency method validation needs to be conducted.

d) a confirmatory method needs to be submitted

e) HED's Metabolism Committee concurrence is needed for the conclusion that the parent is the residue of concern

Conclusions

1. The petitioner has submitted complete and adequate product chemistry data. There is no indication that reference analytical standards and MSDS's have been submitted to the Agency's repository. The petitioner should provide CBTS with the repository ordering number for chloransulam-methyl and for chloransulam-ethyl.

2a. CBTS concludes the use directions of the proposed label are not adequate as regard application to the primary crop. The label should specify a 14 day interval for forage and cutting of hay and a 65 day PHI for beans.

2b. The petitioner needs to clarify the section of the label concerning rotational crops. The petitioner has provided neither a rationale nor experimental justification for the proposed plantback intervals for rotational crops, with the exception of the 4 month interval for the replanting of small grains. The label does not mention rotation to most vegetable and tuber crops even though the confined study indicates that these crops could be planted four months after application.

In general, the Agency considers plantback intervals greater than 1 year as impractical unless there is a compelling reason such as phytotoxicity. The petitioner should provide its rationale or provide experimental data to support the plantback intervals proposed for corn, sorghum, cotton, peanuts, sugarbeets, sunflowers, and tobacco.

There is no explanation of the need for a two year interval for sugarbeets, sunflowers, and tobacco. If phytotoxicity is the cause of the longer plantback intervals, the label should state this.

3a. Pending concurrence from HED's Metabolism Committee and for the purposes of this petition, i.e. , use of chloransulam-methyl on soybeans, the residue of concern is considered to be the parent only.

3b. The ruminant metabolism study is satisfactory. The metabolism of chloransulam-methyl by ruminants appears to be similar to that of plants. Pending concurrence from HED's Metabolism Committee and for the purposes of this petition, i.e., use of chloransulam-methyl

on soybeans, the residue of concern is considered to be the parent only. Considering the exaggerated rate of the dose and the low level of residues, it is unlikely that detectable residues of chloransulam-methyl would be found in ruminant tissues or milk from the proposed use.

3c. The poultry metabolism study is satisfactory. Pending concurrence from HED's Metabolism Committee, CBTS would conclude that the residue of regulatory concern in poultry for this use is chloransulam-methyl *per se*. Considering the exaggerated rate of the dose and the low level of residues, it is unlikely that detectable residues of chloransulam-methyl would be found in poultry, tissues or eggs from the proposed use.

4a. Considering the parent as the residue of concern for this use on soybeans, the revised method appears to be suitable as an enforcement method. The method has been successfully independently validated. CBTS has no objection to the use of an internal standard (chloransulam-ethyl) in the final extract as long as it is made available to the EPA Repository.

4b. However, the method employs diazomethane as a derivitizing agent. The method will be sent to AMS/BEAD, Beltsville, for its approval as suitable method in light of this feature and if judged suitable will be subjected to Agency validation.

4c. Validation of the analytical method was provided by comparing the levels of XDE-565 in radioactive forage samples determined by the GC/MS method to the results of the radiometric analyses of the same samples. Results were similar for both methods.

4d. Chloransulam-methyl has been subjected to FDA's multiresidue protocols. It was recovered through application of the alternate conditions for protocol C.

4e. A confirmatory method should be submitted for residues in soybean commodities. If a sufficient number of ions are monitored, it is possible for the GC/MS method to be modified to serve this purpose.

5. Storage stability studies show no significant decrease in residue levels of chloransulam-methyl over the intervals that field trial samples were stored.

6a. The petitioner presents the results of 25 field trials carried out with soybeans treated with chloransulam-methyl. The trials were conducted over two growing seasons at 16 sites located in the major soybean producing regions. The number and siting of the trials conform with the Agency guidance on the conduct of field trials.

3

6b. Based on the residue data, CBTS concludes that the proposed tolerances are appropriate for the soybean rac's, grain, forage and hay.

6c. A soybean processing study indicates that no tolerances are needed for soybean processed commodities.

7. No feeding studies have been submitted. Based on the results of animal metabolism studies it is unlikely that finite residues would occur in secondary animal commodities from this use. Therefore, a consideration of secondary residues in animal commodities is not necessary. Tolerances for such residues are not required.

8. No field trials were conducted with rotational crops. The proposed label restrictions on plantback intervals are based upon confined rotational crop studies or remain unexplained as noted in Conclusion 2b.

9. Currently there are no international or Codex MRL's associated with chloransulam-methyl.

Recommendation

CBTS recommends against the proposed registration on soybeans and the proposed tolerances on soybean rac's for the following reasons:

a) analytical reference standards need to be submitted (Conclusion 1)

b) a revised Section B is needed (See Conclusions 2a and 2b)

c) a successful Agency method validation needs to be conducted (Conclusion 4b)

d) a confirmatory method needs to be submitted (Conclusion 4a)

e) HED's Metabolism Committee concurrence is needed for the conclusion that the parent is the residue of concern

The petitioner should submit a revised Section B or additional rotational crop data as discussed in Conclusions 2a and 2b. Analytical standards of chloransulam-methyl and the internal standard chloransulam-ethyl need to be made available to the Agency's standards repository.

The proposed enforcement method will be sent to AMS/BEAD at Beltsville for Agency concurrence and validation. The petitioner needs to submit a confirmatory method for residues in soybean commodities.

4

DETAILED CONSIDERATIONS

Product Chemistry

Data to meet product chemistry requirements were submitted with the request for EUP 62719-EUP-28 and are referenced in the current submission. See attached appendices for a summary and discussion of the submitted product-chemistry data.

Impurities in the TGAI do not present a residue problem of concern to CBTS when the material is formulated and used as described in this petition.

Directions for Use

Chloransulam-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 postemergent use in the control of broad leaf weeds at rates of 0.04 lb ai/A (0.64 oz ai/A) for preplant and preemergent use and 0.016 lb ai/A (0.26 oz ai/A) for postemergent 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 acres) Chloransulam-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.

Comment and Conclusions

CBTS concludes the use directions of the proposed label are not adequate as regard application to the primary crop. The label should specify a 14 day interval for forage and cutting of hay and a 65 day PHI for beans.

In regard to the rotational crop instructions, CBTS does not normally consider that a two year prohibition on the rotational planting of tobacco, sugar beets, and sunflowers is practical.

The petitioner should provide its rationale or provide experimental data to support the plantback intervals proposed for corn, sorghum, cotton, peanuts, sugarbeets, sunflowers, and tobacco. If phytotoxicity is the concern, the label should state this.

5

Nature of the Residue - Plant Metabolism Studies

MRID 436689-21

Title: [14C]XDE-565: Nature of the Residue in Soybeans Following Postemergent Application.
Authors: P. Lewer and KL Finney-Brink
Date: 5/15/95
Site: DowElanco, Indianapolis, IN

The in-life portion of this study was conducted at DowElanco's Greenfield, IN research station. Chloransulam-methyl, uniformly labeled in either the aniline ring ("A" XDE-565) or in the pyridine ring ("P" XDE-565), was applied as a spray to soybeans at the V5 growth stage at a rate of 88 g/ha, about 5X the proposed rate of 17.5 grams per ha. Samples of forage and beans were obtained at intervals during the growth of the test crop, combusted and analyzed for total radioactivity.

Sample	Site of Label		TRR as chloransulam-methyl (PPM)
27 day forage	"A"	ring	0.278
	"TP"	ring	0.355
61 day forage	"A"	ring	0.041
	"TP"	ring	
140 Day bean	"A"	ring	0.032
	"TP"	ring	0.046

Treated forage samples were extracted with acetonitrile/water 8:2, and further fractionated into aqueous-soluble, organic-soluble, and insoluble. The insoluble phase was further separated into acid-soluble, lignin, and cellulose fractions. Mature beans were fractionated into oil, protein, aqueous-soluble, and insoluble fractions.

XDE-565 after application rapidly degraded into numerous metabolites with an overall half life of the parent of less than a day. Residues of parent in all fractions at all sample times were very low. Residues in forage at 27 days after application (DAA) were less than 0.015 ppm, less than 0.01 ppm in 61 DAA forage, and less than 0.01 ppm in mature beans. Fractions containing the highest levels of radioactivity were cleaned up and subjected to TLC and HPLC. Radioactive reference standards of the parent and potent metabolites were used as reference markers in the TLC analyses. Neither parent nor postulated metabolites were found in any fraction other than 0.006 ppm of parent in 27 DAA forage.

Comments and Conclusions Regarding Plant Metabolism

Pending concurrence from HED's Metabolism Committee and for the purposes of this use only, CBTS concludes that the residue of regulatory concern in soybean rac's is chloransulam-methyl *per se*.

Nature of the Residue - Animal Metabolism Studies

MRID 436689-23:

Title: Nature of the Residue of [14C] XDE-565 in Lactating Goats.
Authors: P. Lewer and KL Finney-Brink
Date: 5/18/95
Site: Hazelton Labs, Madison, WI and DowElanco, Indianapolis, IN

The in-life portion of this study was conducted at Hazelton Labs' Madison facility. Two lactating goats were fed either chloransulam-methyl, ^{14}C uniformly labelled in the aniline ring ("A" XDE-565) or in the pyrimidine ring ("TP" XDE-565). The daily dosing level for 5 days was equivalent to about 10 ppm chloransulam-methyl in the diet, 500 times the proposed tolerance proposed for soybeans and, according to the petitioner, about 190 times the maximum theoretical dietary burden expected from residue trial results. Milk, feces, and urine were collected daily. After 5 days, the animals were sacrificed, and tissue samples taken. Samples of the tissues and fluids were combusted and analyzed for total radioactivity.

Radioactivity in Tissues and Milk

Tissue	Site of Label "A" XDE-565 (ppm)	"TP" XDE-565 (ppm)
Milk	0.002	0.002
Muscle	0.002	0.002
Fat	<0.001	<0.001
Kidney	0.122	0.128
Liver	0.051	0.040
Blood	0.029	0.043

Radioactivity recovered in feces and urine accounted for 99.9% of the administered dose.

Liver and kidney tissues were chosen for the identification and characterization of radioactive metabolites.

The parent was detected at 0.066 ppm in kidney. The sum of all postulated metabolites in kidney was less than 10% of TRR or less than 0.05 ppm . Parent at <0.003 ppm was detected in liver. Liver tissue did contain a metabolite characterized as XDE-565 acid at

9.5% of TRR or 0.005 ppm. All other metabolites in liver and kidney were present at 0.009 ppm or less. Parent or postulated metabolites were not found at detectable levels in other tissues examined or in blood or milk.

Comment and Conclusion

The ruminant metabolism study is satisfactory. The metabolism of chloransulam-methyl by ruminants appears to be similar to that of plants. Pending concurrence from HED's Metabolism Committee and for the purposes of this petition, i.e., use of chloransulam-methyl on soybeans, the residue of concern is considered to be the parent only. Considering the exaggerated rate of the dose and the low level of residues, it is unlikely that detectable residues of chloransulam-methyl would be found in ruminant tissues or milk from the proposed use.

Nature of the Residue- Poultry Metabolism Study;

MRID 436689-24:

Title: Nature of [^{14}C]XDE-565 Residues in Laying Hens
Author: J.P.Wright
Date: 05/04/94
Site: ABC Laboratories, Columbia, MO and DowElanco, Indianapolis, IN

The in-life portion of the poultry metabolism studies were conducted by ABC Laboratories, Columbia, MO. Groups of 10 hens were fed either chloransulam-methyl, ^{14}C uniformly labelled in the aniline ring ("A" XDE-565) or in the pyrimidine ring ("TP" XDE-565). The daily dosing level for 5 days was equivalent to about 9 ppm chloransulam-methyl in the diet, 450 times the proposed tolerance for soybeans and about 3000 times the maximum theoretical dietary burden. Eggs were collected throughout the dosing period. After 5 days, the hens were sacrificed and eggs and tissues examined for total radioactivity.

Radioactivity in Tissues and Milk

	Site of Label	
Tissue	"A" XDE-565 (ppm)	"TP" XDE-565 (ppm)
Muscle	0.005	0.144
Fat	0.003	0.006
Liver	0.051	0.040
Eggs	0.015	0.018

Radioactivity recovered in feces and urine accounted for 99.7% of the administered dose.

For characterization of the level and distribution of metabolites, liver, and muscle tissue and eggs were extracted with organic solvents and extracts partitioned into organic and water soluble phases. Residues were subjected to hydrolytic and solubilization procedures and further reextraction.

Aliquots of the extraction fractions were subjected to TLC and HPLC/MS. Reference standards of the parent and potential metabolites were used as reference markers in the TLC and HPLC analyses.

XDE-565 was found in eggs at 0.006 ppm, representing 35-40% of the TRR. In liver and muscle the major metabolite was cleavage product 5-ethoxy-7-fluoro-(1,2,4)triazolo[1,5c]pyrimidine-2-sulfonamide (ASTP). This metabolite represented 49% of the TRR (0.02 ppm) in liver and 57% of the TRR (0.08 ppm) in muscle. The remainder of the radioactivity in all tissues could not be accounted for by postulated metabolites and consisted of multiple components that could not be related to any reference standard.

Comments and Conclusions Regarding Poultry Metabolism

The poultry metabolism study is satisfactory. Pending concurrence from HED's Metabolism Committee, CBTS would conclude that the residue of regulatory concern in poultry for this use is chloransulam-methyl *per se*. Considering the exaggerated rate of the dose and the low level of residues, it is unlikely that detectable residues of chloransulam-methyl would be found in poultry, tissues or eggs from the proposed use.

Confined Rotational Crops

MRID 436689-19

Title: A Confined Rotational Crop Study with 14C XDE-565 Using Wheat, Lettuce, and Potatoes.
Authors: P. Lewer and K.L. Finney-Brink
Date: 12/15/94
Site: DowElanco, Indianapolis, IN

Chloransulam-methyl, ^{14}C-labeled in the aniline ring ("A"-XDE-565) or in the pyrimidine ring ("TP" XDE-565) was incorporated into confined soil at a rate equivalent to 55 g ai/ha, a rate 1.1-fold that of the maximum proposed preplant use. After 120 days, wheat, lettuce, and potatoes were planted in the treated soil. Samples of wheat forage were taken at the boot stage and samples of all other rac's (lettuce, potato tubers, wheat grain, wheat straw) were obtained at maturity. Samples were examined for total radioactivity.

9

Crop	Site of Label		TRR as XDE-565 equivalents (PPM)
Lettuce	"A"	ring	0.003
	"TP"	ring	0.005
Potato tubers	"A"	ring	0.007
	"TP"	ring	0.011
Wheat forage	"A"	ring	0.004
	"TP"	ring	0.007
Wheat grain	"A"	ring	0.021
	"TP"	ring	0.020
Wheat straw	"A"	ring	0.031
	"TP"	ring	0.065

After solvent extraction and fractionation, samples were examined for levels of XDE-565 by the method described below. None of the crop samples contained analytically detectable levels of XDE-565.

Crop	Site of Label		XDE-565 residue levels (PPM)
Lettuce	"A"	ring	<0.0004
	"TP"	ring	<0.0008
Potato tubers	"A"	ring	<0.0018
	"TP"	ring	<0.0013
Wheat forage	"A"	ring	<0.0015
	"TP"	ring	<0.0013
Wheat grain	"A"	ring	<0.0001
	"TP"	ring	<0.0006
Wheat straw	"A"	ring	<0.0009
	"TP"	ring	<0.0016

One identifiable component (triazolopyrimidine sulfonic acid) was found in wheat straw. This component represented 6.6% of the TRR (0.004 ppm). Another unidentified component accounted for 8.9% (0.006 ppm) of the TRR. No other individual metabolites or resolvable components were detected at levels >0.005 ppm. Significant portions of the radioactivity were associated with natural plant components: starch, lignin, cellulose, etc.

10

Comment and Conclusions

The results of the confined rotational crop studies described above indicate that any crops could be rotated to treated soybeans after 120 days without detectable residues of XDE-565. However, according to the proposed 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. No mention is made of vegetables, tubers, or other crops even though the results of the confined study indicates that vegetables and tubers could also be replanted at four months.

The petitioner needs to clarify the section of the label concerning rotational crops. The petitioner has provided neither a rationale nor experimental justification for the proposed plantback intervals for rotational crops, with the exception of the 4 month interval for the replanting of small grains.

In general, the Agency considers plantback intervals greater than 1 year as impractical unless there is a compelling reason such as phytotoxicity.

There is no explanation of the need for a two year interval for sugarbeets, sunflowers, and tobacco.

The petitioner should provide its rationale or provide experimental data to support the plantback intervals proposed for corn, sorghum, cotton, peanuts, sugarbeets, sunflowers, and tobacco. If phytotoxicity is the concern, the label should state this.

Residue Analytical Methods: Soybean Rac's and Soybean Processed Commodities

The petitioner has provided two reports of its validations of proposed enforcement analytical methods: the analytical method as originally developed and amended by the petitioner for soybean rac's and the method as applied to soybean processed commodities.

MRID 436689-25:

Title: Amended Report for Validation Report for the Determination of Residues of XDE-565 in Soybean Grain, Forage, and Hay by Capillary Gas Chromatography/Mass Spectrometry
Author: D.D. Shackleford
Date: 05/11/95
Site: DowElanco, Indianapolis, IN

MRID 436689-27:

Title: Validation Report for the Determination of Residues of XDE-565 in Soybean Meal, Hulls, and Crude and Refined Oil by Capillary Gas Chromatography/Mass Spectrometry
Author: D.D. Shackleford
Date: 04/22/95
Site: DowElanco, Indianapolis, IN

Summary of proposed enforcement method

These documents present both the method as originally developed and the revisions to the method that were found to be needed in the course of the petitioner's and the independent laboratory's validations of the method. The summary given here is of the revised method.

Ten gram samples of ground soybean grain, hay, or forage samples are homogenized with 90% acetone/10% 0.1 N HC1. After extraction and centrifugation, aliquots of the supernatant are evaporated to dryness and taken up in a pH 7.5 buffer and partitioned against hexane. The organic phase is discarded and the aqueous phase is acidified with 2N HC1. After the removal of coagulated particulate material, the clear aqueous phase is purified on a C_{18} column, followed by further purification on neutral alumina. The eluant fraction containing the analyte (as determined for each batch of alumina) is derivitized with diazomethane to N-methyl XDE-565, the sample taken to dryness, and reconstituted with water. An internal standard of N-ethyl XDE-565 in acetone is added to each sample. After mixing, an aliquot of the organic phase is subjected to capillary gas chromatography on DB-5 with detection and quantitation by MS/selected ion monitoring at m/z 166 for N-methyl XDE-565 and m/z 212 for N-ethyl XDE-565. Levels of XDE-565 are subsequently calculated from the ratio of m/z 166 to m/z 212.

The validation data provided by the petitioner is summarized below.

Soybean rac's and processed commodities were fortified at levels of 0.005 to 0.5 ppm and carried through the analytical method.

Matrix	Number,	% Recovery Range	% Recovery Mean and S.D.
Grain	19	71-99	85 ± 6
Forage	18	74-92	87 ± 7
Hay	18	74-104	89 ± 9
Meal	17	70-106	90 ± 11
Hulls	18	92-102	97 ± 3
Crude Oil	18	84-11	97 ± 6
Refined Oil	18	94-105	100 ± 3

The petitioner has defined the Limit of Quantitation (LOQ) for the method as 10 times the standard deviation for concurrent recovery data. In a like manner, the Limit of Detection (LOD) is defined as 3 times the SD for any particular set of recovery data. Thus, for this set of experimental data, LOQ's ranged from 0.002 ppm to 0.009 ppm. However, the LOQ for the method has been set as 0.01 ppm. Likewise, experimentally, LOD's ranged from 0.0005 ppm to 0.0026 ppm. The LOD of the method has been set as 0.005 ppm

Further validation of the analytical method was provided by comparing the results obtained for levels of XDE-565 in radioactive forage samples by the GC/MS method to the results of the radiometric analyses of the same samples in the plant metabolism studies.

Site of Label	Radiometric Results (ppm)	GC/MS Results (ppm)
Aniline Ring	0.015	0.013
	0.012	0.012
Pyridine Ring	0.012	0.013
	0.010	0.013

The Independent Validation of the Analytical Method is the subject of a separate report.

MRID 436689-26:

Title: **Amended Report for** Independent Laboratory Validation of Method GRM 94.07.R1 for the Determination of Residues of XDE-565 in Soybean Grain, Forage, and Hay by Capillary Gas Chromatography/Mass Spectrometry .
Authors: K. Hostetler, B.J. Markley, and D.D. Shackleford
Date: 05/16/95
Site: Wildlife International Laboratories, Easton, MD

Wildlife International successfully validated the method on its second trial after problems encountered on the first trial were resolved in discussions with the petitioner. The resulting revisions in the procedure are incorporated into the revised method.

Soybean rac's were fortified at levels of 0.01 to 0.05 ppm and carried through the analytical method.

Matrix	Number	% Recovery range	% Recovery Mean plus S.D.
Grain	4	74-86	80 ± 6
Forage	4	92-107	101 ± 7
Hay	4	95-111	104 ± 8

13

Multiresidue methods study

MRID 436689-20:

Title: Behavior of DE-565 in Multi-Residue Method Testing Using Methods Outlined in FDA Pesticide Analytical Manual Volume: (PAM-I)
Authors: B.A. Conrath and L. Atkin
Date: 5/17/95
Site: ABC Laboratories, Columbia, MO

Because of its chemical structure, chloransulam-methyl is a candidate only for FDA's multiresidue protocols C, D, E, and F. Chloransulam-methyl did respond adequately to Protocol C under Level II conditions (GC at 230 degrees C) with an RT 4.5 X that of phosalone. The material failed to respond adequately to protocols D, E, and F.

The report will be forwarded to the FDA.

Comment and Conclusion re Analytical Methods

Based on the CBTS' conclusion (pending concurrence from HED's Metabolism Committee) that the parent is the residue of concern in soybean rac's, the upgraded, revised method appears suitable as an enforcement method. The method will be forwarded for Agency validation.

A confirmatory method should be submitted for residues in soybean commodities. If a sufficient number of ions are monitored, it is possible for the GC/MS method to be modified to serve this purpose.

Storage Stability

MRID 436689-28:

Title: Frozen Storage Stability of XDE-565 in Soybean Forage and Hay:
Authors: J.D. Schwake and D.R. Foster
Date: 5/23/95
Site: DowElanco, Indianapolis IN

Data concerning the stability of chloransulam-methyl in stored soybean rac's as reported in this document are summarized as follows: Samples of soybean forage and hay, fortified with 0.20 ppm of XDE-565 were stored frozen at -20 degrees C and analyzed at intervals over a period of 6 months by DowElanco method GRM 94.07 (see above). The table below summarizes the results.

14

Days of Storage	% of DE-565 Remaining Forage	% of DE-565 Remaining Hay
0	103.4	98.4
29	99.9	104.0
	99.7	98.9
100	93.7	92.1
174		91.1
188	95.0	

Comment and conclusion regarding storage stability

Storage stability studies show no significant decrease in residue levels of chloransulam-methyl in soybean forage or hay over a 6 month interval. The volume of data (MRID 436689-29) regarding the magnitude of the field trial residues includes a statement to the effect that the stability of DE-565 in soybean grain has been demonstrated over an interval of 91 days ("Frozen Storage Stability Study of XDE-565 in Soybean Grain RES94082, an on-going study of DowElanco)

All field trial samples were stored for these periods or less.

Magnitude of the Residue - Soybean Rac's and Processed Commodities

The petitioner has supplied 3 volumes of residue data from field trials of the application of chloransulam-methyl to soybeans and from soybean processing studies.

MRID 436689-29:

Title: Magnitude-of the Residues of DE-565 in Soybean Forage, Hay, and Grain Following Preplant Incorporated and Postemergence Application
Authors: J.D. Schwake and D.R. Foster
Date: 5/23/95
Site: DowElanco, Indianapolis IN

MRID 436689-30:

Title: DE-565 Applied Postemergent and Preplant Incorporated to Soybeans-Residue Study to Provide Data for Registration
Author: D.R. Foster
Date: 5/17/95
Site: DowElanco, Indianapolis IN

Title: Magnitude of the Residues of DE-565 in Soybean Grain and its Processed Commodities
Authors: J.D. Schwake and D.R. Foster
Date: 5/11/95
Site: DowElanco, Indianapolis IN

Results of Field Trials

In the documents listed above, the petitioner presents the results of 25 field trials (10 in 1993 and 15 in 1994) with soybeans treated with chloransulam-methyl. The trials, conducted in 16 states, were at sites located predominantly in Region V (10 sites) with 2 sites in Region IV and 1 site each in Regions I, II, III and IV.

Chloransulam-methyl was applied either as a preplant-soil incorporated treatment (PPI) at 44-56 gm ai/ha (0.74 oz ai/A) or as a postemergent treatment (PE) at 17.5 g ai/ha (0.16 oz ai/A). Applications included surfactant plus ammonium nitrate as adjuvants. (In 5 trials, crop oil was used as the adjuvant.)

Mature soybean rac's were obtained 65 - 123 days after the PE treatment or 116-160 days after PPI treatment. Forage and hay were obtained at intervals of 14 to 81 days between application and sampling.

Samples were examined for XDE-565 by the method described above. Concurrent storage stability studies showed no degradation of XDE-565 in samples stored over the period between sampling and analysis.

No residues of chloransulam-methyl were detected in any of the soybean seed samples from any of the trials. Three forage samples had detectable residues, one was less than the LOQ of 0.01 and the remaining 2 samples containing residues of 0.032 and 0.013 ppm respectively. Seven hay samples contained detectable residue, four of which with residues below the calculated LOQ of 0.016 ppm. The three other soybean hay samples contained residues of 0.052, 0.122, and 0.037 ppm, respectively.

Based on the field trial data, the petitioner has proposed the following tolerances: 0.02 ppm in/on soybeans, 0.1 ppm in/on soybean forage, and 0.2 ppm in/on soybean hay, expressed as chloransulam parent only.

Processing Study

The petitioner has submitted the results of a processing study to determine residues in soybean-processing commodities. Soybeans from residue trials treated at 5X the proposed label rate were processed into meal, hulls, grain dust fractions, crude oil, and refined oil. The soybeans and fractions were examined for residues

of XDE-565. Residues of XDE-565 in the soybeans and all fractions were below the LOD of 0.005 ppm.

Comment

The Agency's guidance (June 1994) for the number of residue trials necessary for tolerances for soybean rac's suggests 20 trials divide among 3 areas. Regions V (15 trials), IV (3 trials), and II (2 trials) . The petition has provided data from 10 trials in Midwest corn belt (Region V), 3 in the deep South (Region IV), and 2 in Georgia (Region II). In addition, results are provided from 3 trials conducted, respectively, in Florida, Pennsylvania, and Texas. The sites account for 80-90% of soybean producing areas. The number and siting of the trials conforms with the Agency guidance.

Based on the conduct and results of the residue trials, CBTS concludes that the proposed tolerances are supported by the results of these studies.

Magnitude of the Residue-Meat, Milk, Poultry, and Eggs

As it is unlikely that finite residues would occur in secondary animal commodities from this use, a consideration of secondary residues in animal commodities is not necessary.

Rotational Crops

No field trials were conducted with rotational crops

The results of the confined rotational crop studies indicate that at least small grains, root crops and vegetables could be rotated to treated soybeans after 120 days. However, according to the proposed 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. Refer to the Confined Rotational Crops section of this review for our comments.

International and Codex Considerations

Currently there are no international or Codex MRL's associated with chloransulam-methyl.

Attachment A: Product Chemistry Review

cc: R.F.; Garbus; PP#5F4560
RBI:TPT1:08/21/96:RAL:08/28/96:EZ:08/29/96
H7509:CBTS:JG:jg:08/29/96:CM#2:805c:305-5405

17

SUMMARY REVIEW OF PRODUCT CHEMISTRY (SUBDIVISION D), GLN'S 61 TO 63

MRID: 436689-01

Title: Series 61: Product Identity and Composition of Chloransulam-methyl Technical
Author: James W. Ringer
Date: 4/28/95
Site: DowElanco Indianapolis, IN

61-1: Product Identity & Disclosure of Ingredients

IUPAC NAME: ?

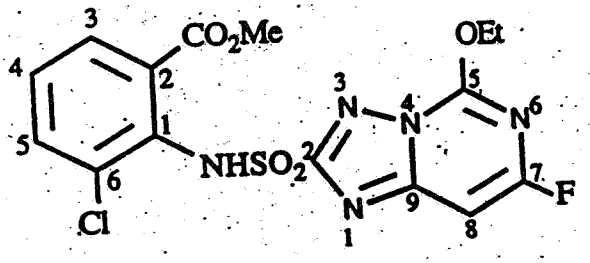
CA NAME: N-(2-carboxymethyl-6-chlorophenyl)-S-ethoxy-7-fluoro-(1,2,4)triazolo(1,5-C)pyrimidine-2-sulfonamide

COMMON NAME: chloransulam-methyl

CA NUMBER: 1471SO-3S-4

CODE NAMES: XDE-565, DE-565, XRM-565, XRD-565

STRUCTURE:



Comment: The product chemistry of chloransulam-methyl was submitted and reviewed by RD in conjunction with the registration of the pesticide and the issuance of the crop-destruct EUP. RD found the product chemistry data acceptable. The present submission is a description of a revised manufacturing process for the TGAI.

However, in the product chemistry data there is no indication that reference standards of chloransulam-methyl and chloransulam-ethyl have been submitted to the Agency's standard repository.

19

MRID 436689-31:

Table 1: Manufacturing and Impurity Data for Chloransulam methyl, TGAI, REG.NO.:63719-ETU

GLN	MRID	Status	Deficiency
61-1: Product Identity & Disclosure of Ingredients	430034-01	A	
61-2: Starting Materials & Manufacturing Process	430034-01	A	
61-3: Discussion of Impurities	430034-02	A	
62-1: Preliminary Analysis	430034-03	A	
62-2: Certification of Limits	430034-03	A	
62-3: Analytical Methods	430034-03	A	

A = Acceptable. N = Unacceptable (see Deficiency).

2d