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MAG REGISTRATION FILE ROOM

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HAND DELIVERED

February 27, 2008

Document Processing Center (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, Virginia 22202-4501

Attention: Mr. James A. Tompkins
Team Leader 25

Subject: **Maverick® Herbicide, EPA Reg. No. 524-500;**
Submission of Additional Data to Support the Use of Sulfosulfuron with the Addition of Surfactant at Application for Weed Control in Pastures;
Agency Letter Dated February 4, 2008

Dear Mr. Tompkins:

On January 20, 2006, Monsanto submitted to the Agency a Petition requesting the establishment of pesticide tolerances for sulfosulfuron in or on grass forage and hay as part of crop group 17, and modification of tolerances for livestock commodities as a result of these new feed tolerances, to support the registration of the use of sulfosulfuron for weed control in pastures, hayfields and rangelands (*PP#6F7031*). A Final Rule establishing tolerances for sulfosulfuron in or on grass, forage at 14 ppm and grass, hay at 25 ppm was published on September 26, 2007 (*72 FR 54569*). Subsequent to the establishment of these tolerances, the use of sulfosulfuron for weed control on pastures was approved by the Agency on February 4, 2008, with the acceptance of supplemental labeling for Maverick herbicide for use in bermudagrass and bahiagrass pastures, provided that Monsanto would, amongst other things, remove the directions for use of the product with a nonionic surfactant from the label. At this time, Monsanto respectfully requests that the Agency reconsider this provision for registration in light of the additional data being submitted here and allow the use of Maverick herbicide on bermudagrass and bahiagrass pastures with additional surfactant added at the time of application.

Control of johnsongrass in pastures is a matter of extreme importance to livestock owners and hay growers, as exemplified by the Agency granting emergency exemption from registration under Section 18 of FIFRA for the use of Maverick herbicide for the control of johnsongrass in bermudagrass and bahiagrass pastures at the request of several southern states for the 2006 and 2007 growing seasons. The label approved for that use under Section 18 included the addition of a nonionic surfactant at the time of herbicide application, a practice common for postemergence weed control with sulfonylurea herbicides, of which sulfosulfuron is a member.

In an Agency document dated July 25, 2007 (DP# 328450), regarding the evaluation of the residue data submitted to support PP#6F7031, it was concluded that, although the proposed use pattern specifies that a nonionic surfactant is required at application, the data submitted do not reflect use of a spray adjuvant, and, therefore, the use of surfactant must be removed from the label or residue data that includes use of a nonionic surfactant at application must be submitted. Monsanto believes that the information and data

submitted here adequately demonstrate that the overwhelming majority of the amount of sulfosulfuron residue on pasture grass forage and hay following application of Maverick herbicide is a function of residues residing on the surface of the grass foliage and not within the plant tissue. The magnitude of the residue is, therefore, independent of the presence or absence of a surfactant at the time of application.

Enclosed for Agency consideration is an overview of the use of sulfosulfuron on pastures entitled, *Use of Sulfosulfuron for Weed Control on Pastures, Hayfields and Rangelands: Response to EPA Review—Additional Data to Support the Use of Nonionic Surfactants*. In support of the position presented therein, additional residue data pertinent to the use of a nonionic surfactant during the application of Maverick herbicide is submitted as R.D. 1697, which includes Monsanto report MSL0021114, *Sampling of Bermudagrass Forage from Comparison Trials with and without Surfactant for Sulfosulfuron Residue Analysis*. This information and data support the conclusion that the tolerances established for residues of sulfosulfuron in or on grass forage and hay are adequate and will not likely be exceeded following application with or without a nonionic surfactant.

Other points raised in the Agency review of this Petition are also addressed in this submission. Enclosed is a revised Section F relative to the original that was submitted January 20, 2006, reflecting the tolerances proposed by the Agency. The lack of availability of the ethyl sulfone chemophore metabolite of sulfosulfuron, 2-(ethylsulfonyl)-imidazo[1,2-*a*]pyridine, at the National Pesticide Standards Repository is noted and will be rectified as soon as practical.

It is imperative for consistent product performance that a nonionic surfactant be allowed to be part of the application of sulfosulfuron for the postemergence control of johnsongrass and other susceptible weeds in warm-season pasture grasses. If the Agency can see its way clear to approve the use of this adjuvant in the application of Maverick herbicide, the other conditions of the registration as stated in the letter of February 4, 2008, are acceptable, including the other label changes, namely, clearly stating that a maximum of two applications are allowed per year and that applications are to made in early spring through the fall. These changes are reflected in the revised supplemental labeling included in this submission. Monsanto appreciates the Agency suspending the requirement for additional personal protective equipment (PPE) for mixers/loaders until completion of the reassessment of the cancer risk classification. We eagerly await that decision and are confident that it will change the necessity for the additional PPE.

Included in this submission are the following items:

- Agency forms 8570-1, 8570-34 and 8570-35
- One copy of the overview document, *Use of Sulfosulfuron for Weed Control on Pastures, Hayfields and Rangelands: Response to EPA Review—Additional Data to Support the Use of Nonionic Surfactants*
- R.D. 1697, a 1-volume submission of supplemental residue data identified as MSL0021114, *Sampling of Bermudagrass Forage from Comparison Trials with and without Surfactant for Sulfosulfuron Residue Analysis*
- Transmittal Document
- A revised Section F reflecting the tolerances for sulfosulfuron proposed by the Agency
- Five copies of revised supplemental labeling for the use of Maverick herbicide on bermudagrass and bahiagrass pastures that retains the use of a nonionic surfactant, but is revised to clearly state that a maximum of two applications are allowed per year and that applications are to made in early spring through the fall.

The registration action for which this submission is being made is PP#6F7031, for which a PRIA service fee has already been paid; therefore, no additional fees should be required at this time. Please send any PRIA-related correspondence regarding this matter via electronic mail to Regulatory.Affairs@Monsanto.com.

If you should have any questions regarding this submission, please contact Dr. Russell P. Schneider at (202) 383-2866, or me directly at (314) 694-9035 or by electronic mail at stephen.a.adams@monsanto.com.

Sincerely,

Stephen A. Adams
Registration Manager

cc: Russell P. Schneider

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number
289625

Application for Pesticide – Section I

1. Company/Product Number Monsanto Company / EPA Reg. No. 524-500	2. EPA Product Manager James A. Tompkins	3. Proposed Classification ☒ None ☐ Restricted
4. Company/Product (Name) Monsanto Company / Maverick® Herbicide	PM # 25	
5. Name and Address of Applicant *(Include ZIP Code)* Monsanto Company 1300 I St., N.W., Suite 450 East Washington, DC 20005 ☐ Check if this is a new address	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section – II

☒ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated
☐ Notification – Explain below.
☐ Final printed labels in response to Agency letter dated
☐ "Me Too" Application.
☐ Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II)

Submission of additional data to support the Section 3 registration of sulfosulfuron for use on pastures (PP#6F7031). PRIA Service Fee already paid (if incorrect, please address any fee requirement to Regulatory.Affairs@Monsanto.com).

Section – III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No ***Certification must be submitted***	☐ Yes ☐ No If "Yes" Unit Packaging wgt. / No. per Container	☐ Yes ☐ No If "Yes" Package wgt. / No. per Container	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
☐ Lithograph
☐ Paper glued
☐ Stenciled
☐ Other _____

Section – IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. *(Include Area Code)*
Dr. Russell P. Schneider, Ph.D.	Senior Director of Regulatory Affairs and Public Policy	(202) 383-2866

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature	3. Title Registration Manager
4. Typed Name Stephen A. Adams	5. Date February 27, 2008

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, Missouri 63167

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Section 3 Registration of the Use of Sulfosulfuron on Pastures, Hayfields and Rangelands

DATA GUIDELINES

Supplemental Information

TRANSMITTAL DATE

February 27, 2008

SUBMISSION NUMBER

R.D. 1697

LIST OF SUBMITTED DATA:

Volume	Monsanto Study Number	Author	Title
1	MSL0021114	Moran, Sharon J.	Sampling of Bermudagrass Forage from Comparison Trials with and without Surfactant for Sulfosulfuron Residue Analysis MRID:

COMPANY OFFICIAL: Stephen A. Adams
Registration Manager

COMPANY NAME: Monsanto Company

COMPANY CONTACT: Russell P. Schneider / (202) 383-2866

Form Approved OMB Nos. 2070-0060;2070-0057;2070-0107;2070-0122;2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hour per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrants Name, Address and Telephone Number: Monsanto Company 1300 I Street, N.W., Suite 450 East Washington, DC 20005 Tele: (202) 383-2866	**EPA Registration Number/File Symbol** 524-500
Active Ingredient(s) and/or representative test compound(s) Sulfosulfuron	**Date** February 27, 2008
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158 Herbicide for winter and spring wheat, pastures, hayfields, forestry conifer release and general non-crop areas	**Product Name** Maverick® Herbicide

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

☐ I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

☒ I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

☐ I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

☐ I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1) (F) and 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	February 27, 2008	Stephen A. Adams Registration Manager

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

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DATA MATRIX

Date: February 27, 2008	EPA Reg. No./File Symbol: 524-500	Page 1 of 1
Applicant's/Registrant's Name & Address: Monsanto Company, 1300 "I" Street, N.W., Suite 450 East, Washington, D.C. 20005	Product: Maverick® Herbicide	
Ingredient Sulfosulfuron (MON 37500)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	VOL 1: Moran, S J; "Sampling of Bermudagrass Forage from Comparison Trials with and without Surfactant for Sulfosulfuron Residue Analysis"	This Submission	Monsanto	OWN	

Signature	Name and Title	Date
	Stephen A. Adams Registration Manager	2/27/08

EPA Form 8570-35 (12-2003) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Valent/KMF 118

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

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DATA MATRIX

Date: February 27, 2008	EPA Reg. No./File Symbol: 524-500	Page 1 of 1
Applicant's/Registrant's Name & Address: Monsanto Company, 1300 "I" Street, N.W., Suite 450 East, Washington, D.C. 20005	Product: Maverick® Herbicide	
Ingredient Sulfosulfuron (MON 37500)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Monsanto	OWN	

Signature	Name and Title	Date
	Stephen A. Adams Registration Manager	2/27/08

EPA Form 8570-35 (12-2003) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

Section F **Proposed Tolerances**

Current tolerances for the herbicide sulfosulfuron, 1-(4,6-dimethoxypyrimidin-2-yl)-3-[(2-ethane-sulfonyl-imidazo[1,2-a]pyridine-3-yl)sulfonyl]urea and its metabolites converted to 2-(ethylsulfonyl)imidazo[1,2-a]pyridine and calculated as sulfosulfuron in or on raw agricultural commodities, as listed in 40 CFR §180.552, are:

Commodity	Parts per million (ppm)
Cattle, fat	0.005
Cattle, meat	0.005
Cattle, meat byproducts	0.05
Goat, fat	0.005
Goat, meat	0.005
Goat, meat byproducts	0.05
Hog, fat	0.005
Hog, meat	0.005
Hog, meat byproducts	0.05
Horse, fat	0.005
Horse, meat	0.005
Horse, meat byproducts	0.05
Milk	0.006
Sheep, fat	0.005
Sheep, meat	0.005
Sheep, meat byproducts	0.05
Wheat, forage	4.0
Wheat, grain	0.02
Wheat, hay	0.3
Wheat, straw	0.1

In accordance with data submitted with this petition, Monsanto requests that permanent (§ 408) tolerances be established for residues of sulfosulfuron, 1-(4,6-dimethoxypyrimidin-2-yl)-3-[(2-ethanesulfonyl-imidazo[1,2-a]pyridine-3-yl)sulfonyl] urea and its metabolites calculated as sulfosulfuron in or on the following raw agricultural commodities, and that 40 CFR 180.552 be amended accordingly:

Commodity	Parts per million (ppm)
Grass forage	14
Grass hay	25

Since grass forage and hay are dietary components of ruminants, Monsanto also requests that in accordance with this new use of sulfosulfuron and a corresponding increase in the maximum theoretical dietary burden (MTDB) for ruminants, the following tolerances for sulfosulfuron, 1-(4,6-dimethoxypyrimidin-2-yl)-3-[(2-ethane-sulfonyl-

imidazo[1,2-a]pyridine-3-yl)sulfonyl] urea and its metabolites calculated as sulfosulfuron in or on the following raw agricultural commodities be changed to the following levels:

Commodity	Parts per million (ppm)
Cattle, fat	0.02
Cattle, meat	0.01
Cattle, meat byproducts	0.30
Goat, fat	0.02
Goat, meat	0.01
Goat, meat byproducts	0.30
Horse, fat	0.02
Horse, meat	0.01
Horse, meat byproducts	0.30
Sheep, fat	0.02
Sheep, meat	0.01
Sheep, meat byproducts	0.30
Milk	0.02

SUPPLEMENTAL LABELING

READ THE ENTIRE LABEL FOR MAVERICK® HERBICIDE BEFORE PROCEEDING WITH THE USE DIRECTIONS CONTAINED IN THIS SUPPLEMENTAL LABELING.

When using Maverick herbicide as permitted according to this supplemental labeling, read and follow all applicable directions, restrictions, and precautions on this supplemental labeling and on the label booklet provided with the pesticide container. This supplemental labeling must be in the possession of the user at the time of pesticide application.

MAVERICK® HERBICIDE

EPA Reg. No. 524-500

Maverick is a registered trademark of Monsanto Technology LLC.

FOR CONTROL OF JOHNSONGRASS, PURPLE AND YELLOW NUTSEDGE, AND GREEN KYLLINGA IN BERMUDAGRASS AND BAHIAGRASS PASTURES

Keep out of reach of children

CAUTION!

In case of an emergency involving this product or for user safety information on this product, call collect, day or night (314) 694-4000.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

This label must be in the possession of the user at the time of application.

See "DIRECTIONS FOR USE" and "MIXING INSTRUCTIONS" sections of the label booklet for Maverick herbicide for essential product performance information.

RECOMMENDATIONS

Maverick herbicide may be used in early spring through fall to control or partially control johnsongrass, purple and yellow nutsedge, green kyllinga and other weeds in well-established bermudagrass and bahiagrass pastures. Apply Maverick herbicide up to 2.0 ounces per acre. A follow-up application can be made after suitable regrowth of weeds and no sooner than 40 days after the previous application. Use higher rates of this product for control of large, established weeds or when growth is heavy or dense. DO NOT EXCEED TWO APPLICATIONS OR A MAXIMUM OF 2.66 OUNCES OF THIS PRODUCT PER ACRE PER YEAR.

Addition of nonionic surfactant at 0.25 percent by volume (1 quart per 100 gallons of spray solution) is required. Use only nonionic surfactants that contain at least 90 percent active ingredient. Do not use surfactants that alter the pH of the spray solution below pH 5. Spray solutions of between pH 6.0 and 8.0 provide optimum results.

Grass forage may be grazed immediately after application. Do not harvest for hay within 14 days of application.

No crop, except wheat, may be planted into pastures that have been treated with this product within 12 months after application. All crops other than wheat may be seeded only after completion of a successful field bioassay as indicated in the FIELD BIOASSAY section.

FIELD BIOASSAY

A field bioassay must be completed before rotating any crop other than wheat into pastures that have been treated with this product. To conduct an effective field bioassay, grow strips of the crop you intend to grow the following season in fields previously treated with Maverick herbicide. Crop response to the bioassay will determine if the crop(s) grown in test strips can be grown safely in areas previously treated with this product.

Read the "LIMIT OF WARRANTY AND LIABILITY" in the label pamphlet for Maverick herbicide before using. These terms apply to this supplemental labeling and if these terms are not acceptable, return the product unopened at once.

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MONSANTO COMPANY
800 N. LINDBERGH BLVD.
ST. LOUIS, MISSOURI 63167

[*insert print plate number*] [*insert date*]

Use of Sulfosulfuron for Weed Control on Pastures, Hayfields and Rangelands: Response to EPA Review—Additional Data to Support the Use of Nonionic Surfactants

Executive Summary

Control of johnsongrass in pastures is of great economic importance to ranchers and livestock growers throughout the U.S. Johnsongrass can be highly poisonous to grazing animals, especially ruminants like cattle and sheep. Having no other chemical means to control johnsongrass in bermudagrass pastures, the U.S. Environmental Protection Agency (EPA) granted an exemption from the requirement for registration, under Section 18 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), for the specific use of sulfosulfuron, formulated and sold as Maverick® Herbicide, EPA Reg. No. 524-500, for controlling johnsongrass in bermudagrass pastures and hayfields in the states of AL, AR, GA, LA, MS and TX during the 2006 and 2007 growing seasons. This action was made possible by the establishment of time-limited tolerances for residues of sulfosulfuron in or on grass forage and hay at 11 and 40 parts per million (ppm), respectively (*70 FR 69457*).

In January 2006, Monsanto submitted a Petition (PP#6F7031) for the establishment of permanent tolerances for residues of sulfosulfuron in or on grass (Crop Group 17) forage and hay in order to support the use of sulfosulfuron for weed control on grass pastures, hayfields and rangelands under Section 3 of FIFRA. The Petition included the required residue data collected at a total of 13 locations of bermudagrass and bluegrass pastures, and rangeland grasses, following a maximum single application rate of 0.094 pounds a.i. per acre and a maximum annual application rate of 0.125 pounds a.i. per acre per year resulting from sequential applications a minimum of 40 days apart and a minimum of 14 days prior to harvesting hay from the field, but with no restriction on pasture grazing.

In September 2007, in response to our Petition, the EPA established permanent tolerances for sulfosulfuron residues in grass (Crop Group 17) forage and hay at 14 and 25 ppm, respectively, based on the residue data submitted (*72 FR 54569*). This action would then allow for full Section 3 registration of the use of Maverick herbicide for weed control on pastures, hayfields and rangelands at a maximum single application rate of 2 ounces of product per acre and a maximum annual application rate of 2.66 ounces of product per acre per year. Included on the labeling submitted for this use were instructions to add a nonionic surfactant to the spray mix at a concentration of 0.25% by volume; however, because the applications made in the field residue trials were conducted without the nonionic surfactant added to the spray mixture, the EPA has ruled that the use of the surfactant must be removed from the label until Monsanto can submit residue data that includes the use of a nonionic surfactant (DP#328450). It is our assumption that the Agency's decision assumes that the presence of the surfactant in the application will increase uptake of the molecule into the foliage, including increased uptake by the desirable grass forage, which would lead to higher residue levels.

In response to EPA's conclusion, Monsanto contends that the magnitude of the sulfosulfuron residue at day-zero, upon which the tolerance for grass forage was set, is totally independent of the presence or absence of a surfactant in the tank-mix at application, because there is insufficient

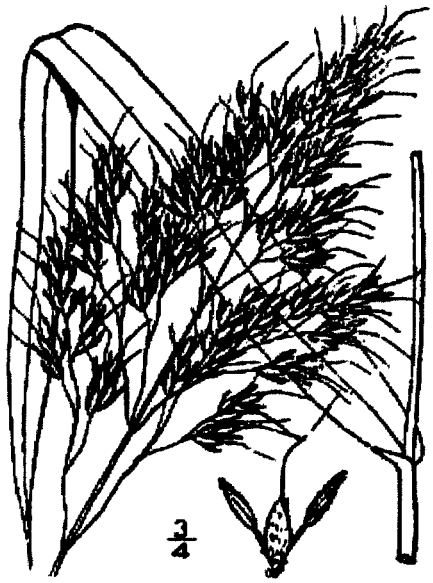
time between application and sample collection to realize a significant increase in the amount of penetration of the molecule across the waxy leaf coating. At day-zero the residue measured is essentially all surface residue, with very little systemic residue present.

If a measurable increase in sulfosulfuron residue within the plant tissue would be realized due the presence of the surfactant at application, it would be observed at the 14-day sampling and in the dried hay sample. To test this, Monsanto conducted a field study comparing the magnitude of sulfosulfuron residues obtained following application of Outrider® Herbicide, EPA Reg. No. 524-500, at a rate of 2 ounces per acre (0.094 pound a.i. per acre) with and without surfactant at a concentration of 0.25% by volume in the spray mix in side-by-side field trials. The results clearly demonstrated that the difference in residue level obtained with and without surfactant is insignificant relative to the overall residue level and the established tolerances. It is Monsanto's contention that the overwhelming majority of the residue measured on the grass forage at day-zero and on the forage cut 14 days after application is the result of surface residues residing on the outside of the leaf surface, not systemic residue in the leaf tissue. The magnitude of this topical, surface residue is totally independent of the presence or absence of a nonionic surfactant in the spray mix during application. This additional data proves that the residue data already presented to EPA and the tolerances they support are adequate to cover the use both with and without surfactant added to the spray mix at application.

Monsanto respectfully requests that the EPA grant the Section 3 registration of sulfosulfuron for weed control on pastures, hayfields and rangelands with the use of surfactant without further delay, in order to allow farmers and ranchers to use the product for this critical need in the upcoming 2008 growing season.

Importance of Weed Control on Pastures, Hayfields and Rangelands

A number of plants are known to produce cyanide. Among these are the sorghum grasses, which include sudangrass, johnsongrass, hybrid forage sorghum, and grain sorghum. Johnsongrass (*Sorghum halapense*) is a coarse, perennial grass that can reach up to 7 feet tall or more. Johnsongrass is listed as an invasive and noxious weed by the U.S. federal government and by several states. Thought to have originated in the Mediterranean region, it was introduced into the U.S. in the early 1800's for soil stabilization and for forage and hay. Since that time, it has spread rapidly and today can be found virtually throughout U.S. (Figure 1.)



USDA PLANTS Database, USDA NRCS PLANTS Database
Bugwood org

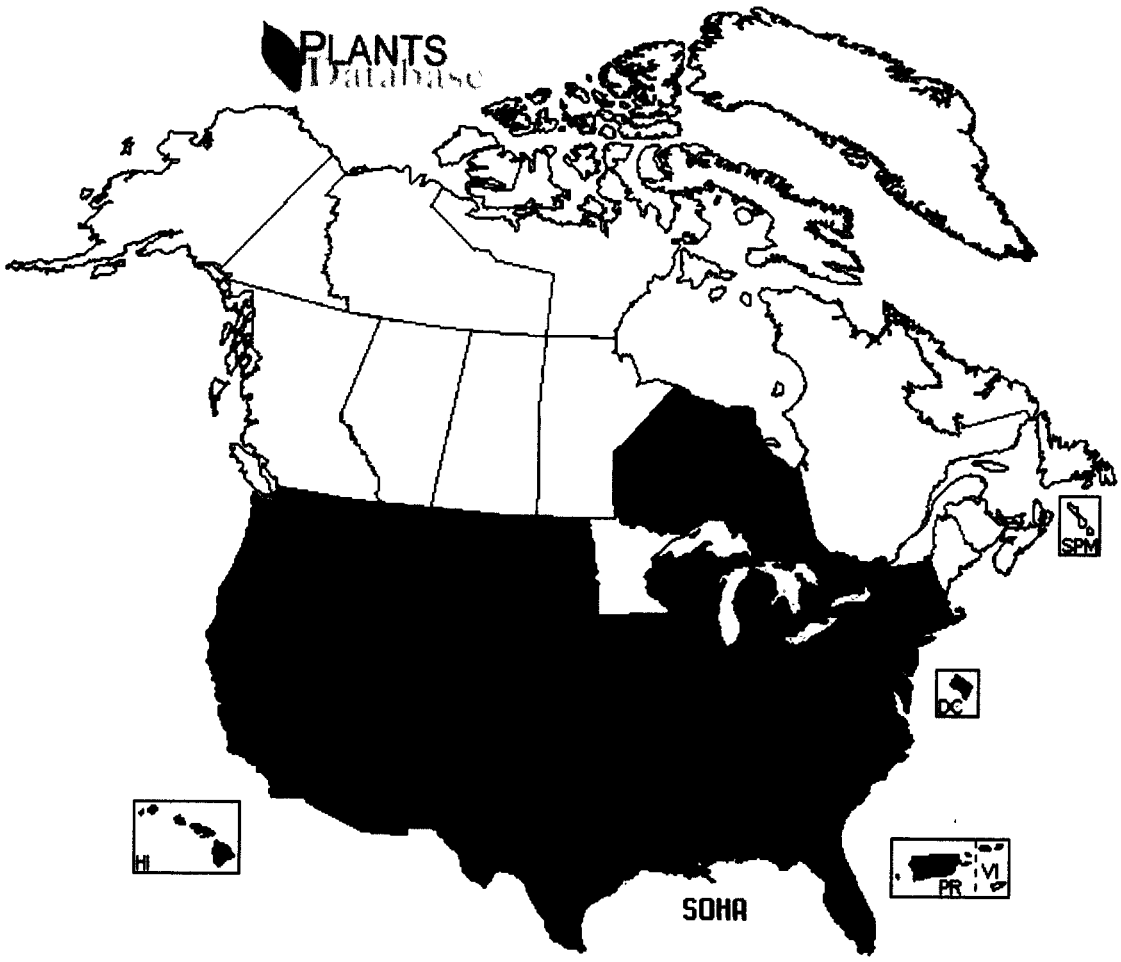
Johnsongrass is common in bermudagrass pastures and can be moderate to highly poisonous to all types of animals, especially ruminants. Johnsongrass produces sugar conjugates known as cyanogenic glycosides. These compounds break down through enzymatic hydrolysis into glucose sugar and release large quantities of cyanide. The intact conjugate of cyanide and glucose is not poisonous, but when the cyanide is released, hydrocyanic acid, also known as prussic acid, is formed.

Under normal growing conditions, the intact glycoside is present in the plant at a modest level. When animals eat plants containing the intact glycosides, the glycosides are readily eliminated before the concentration of cyanide becomes harmful. Certain growing conditions that favor rapid growth can increase the concentration of cyanogenic glycosides in the plant. These conjugates can then be converted to prussic acid by any event that damages the plant tissue and causes the plant cell to rupture. These events, such as exposure to frost, or chopping, trampling or even chewing, allow the interaction of the cyanogenic compound and the enzymes that release cyanide from it.

Prussic acid is a potent, rapidly acting poison. Symptoms of prussic acid poisoning include anxiety, progressive weakness and labored breathing. Exposure can culminate in death if the concentration of the cyanogenic compounds in the plant is high enough and the conversion to prussic acid is favored. Prussic acid inhibits oxygen utilization at the cellular level, causing the animal to essentially suffocate.

Low johnsongrass infestations are tolerable, but high populations in pastures can lower the economic value of harvested hay and can even cause death in grazing livestock. The economic impact to the beef industry due to cattle loss alone is in the tens of millions of dollars annually. Other tangible economic benefits of controlling johnsongrass in pastures are associated with improved yield, protein value and overall quality of hay produced from these fields.

Figure 1. *Extent of Johnsongrass Infestation in the U.S.*



With the removal of imazapic from use on pastures, there is currently no herbicide product that can effectively control johnsongrass without injuring the desired grass stand. Even the safety of imazapic on bermudagrass pastures was marginal. Sulfosulfuron has proven to be efficacious in controlling johnsongrass and particularly safe on warm-season grasses like bermudagrass. Sulfosulfuron is currently registered for control of johnsongrass in non-crop grassy areas under EPA Reg. No. 524-500.

The economic importance of controlling johnsongrass in bermudagrass pastures is so great to ranchers and farmers that for the 2006 and 2007 growing seasons, EPA granted an exemption from registration under Section 18 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to the states of AL, AR, GA, LA, MS and TX. In these states, it is estimated that approximately 20 to 30,000 acres of pastures were treated with sulfosulfuron each year to control johnsongrass. There were no adverse effects associated with this use reported during the time of the Section 18 exemptions.

Sulfonylurea Herbicides—Mode of Action

Sulfosulfuron is a member of the sulfonylurea class of chemistry. Sulfonylureas are group 2 herbicides, according to the Weed Science Society of America (WSSA) classification system, and referred to as acetolactate synthase inhibitors (ALS). These herbicides inhibit the activity of the acetolactate enzyme that is needed in the synthesis of the branch chain amino acids, which are essential for building proteins and the production of new cells to support continued plant growth and to sustain life. ALS inhibitors are readily absorbed by both the roots and foliage and translocated within the plant in both the xylem and phloem to the site of action at the growing tip. Sulfonylurea herbicides exhibit both soil-applied preemergence activity and foliar-applied postemergence activity, and demonstrate a very broad range of selectivity at very low application rates. Application rates are on the order of grams per acre. Soil residual activity on the more susceptible plant species can even be seen at rates that are immeasurable by most conventional analytical methods.

Importance of Surfactant for Consistent Performance

Leaf epidermis variables including stomata density, cuticle wax structure and amount, and leaf hair presence and amount, all contribute to the amount of a compound absorbed into the plant. Chemical absorption is assisted by any material that facilitates closer contact between the pesticide and the leaf surface. This can be achieved by a surfactant, which reduces surface tension, bridges between unlike chemicals, and/or alters the permeability of the leaf cuticle.

Postemergence herbicides typically require a surfactant to facilitate efficacy of the product on weeds or to maintain the product in spray solution. The surfactant, as either a component of the formulation or added separately to the spray solution as a tank mix, allows the active ingredient in the herbicide to be used at an optimal rate to control the target weeds. Surfactants are typically added in the case of sulfonylureas such as sulfosulfuron due to the small amount of active ingredient relative to the large amount of surfactant needed in the spray solution.

Field Residue Data and Tolerance Assessment

To support the establishment of permanent tolerances applicable to Crop Group 17, grass forage, fodder and hay, as defined in 40 CFR 180.40, residue trials were conducted at 13 sites during the

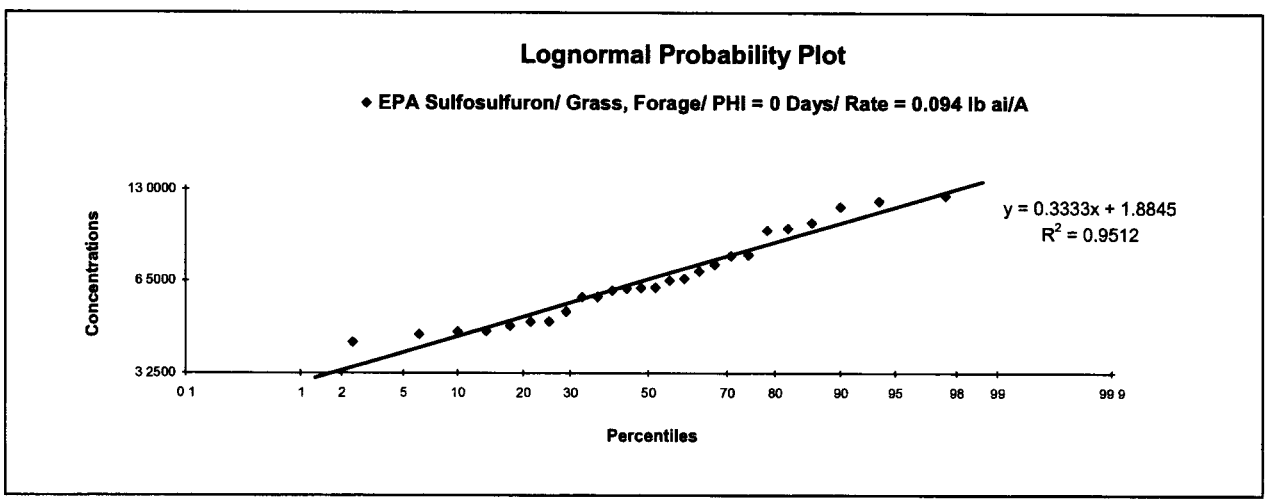
2004 growing season to determine the magnitude of the residues of sulfosulfuron, 1-(4,6-dimethoxypyrimidin-2-yl)-3-[(2-ethanesulfonyl-imidazo[1,2-a]pyridine-3-yl)sulfonyl]urea and its metabolites converted to 2-(ethylsulfonyl)-imidazo[1,2-a]pyridine (calculated as sulfosulfuron) in or on grass forage and hay following application of MON 37503, the commercially available wettable powder formulation of sulfosulfuron, to established stands of pasture and rangeland grasses. Individual trials were conducted at four (4) bluegrass pasture sites, five (5) bermudagrass pasture sites, and four (4) sites consisting of typical rangeland grasses, distributed across 12 states. The Residue Chemistry Test Guidelines, OPPTS 860.1500 Crop Field Trials, requires a total of 12 trials, four (4) trials for each of the three cultivars representing the crop group—bermudagrass, bluegrass and bromegrass or fescue. Since sulfosulfuron exhibits strong herbicidal activity on bromegrass and fescue, it was not possible to conduct residue trials on these representative grass species; therefore, four (4) sites of rangeland grasses were substituted in its place. This approach was discussed with and agreed upon by the Agency prior to study initiation. The data obtained from the residue trials were presented to the Agency as Monsanto Report MSL-19348 (MRID 46753801).

In its review (DP#328450), the Agency concluded that, *"The submitted grass crop field trial data adequately reflect the proposed use pattern with respect to application rate, timing of applications, and harvest intervals; geographic representation is adequate."*

To establish the tolerance for grass forage (0-DAT), EPA chose to use a subset of the residue data that represented the single application of 0.094 pounds a.i. per acre (2 ounces of product per acre) because this use pattern produced the highest residues observed in the field trials. Monsanto agrees with this approach.

Visual inspection of the lognormal probability plot (Figure 2) generated with this data suggests that the dataset is reasonably lognormal with a good correlation coefficient (R^2). Based on this dataset, the appropriate tolerance for grass forage was assessed to be 14 parts per million (ppm).

Figure 2. *Lognormal Probability Plot of residue dataset for grass forage*

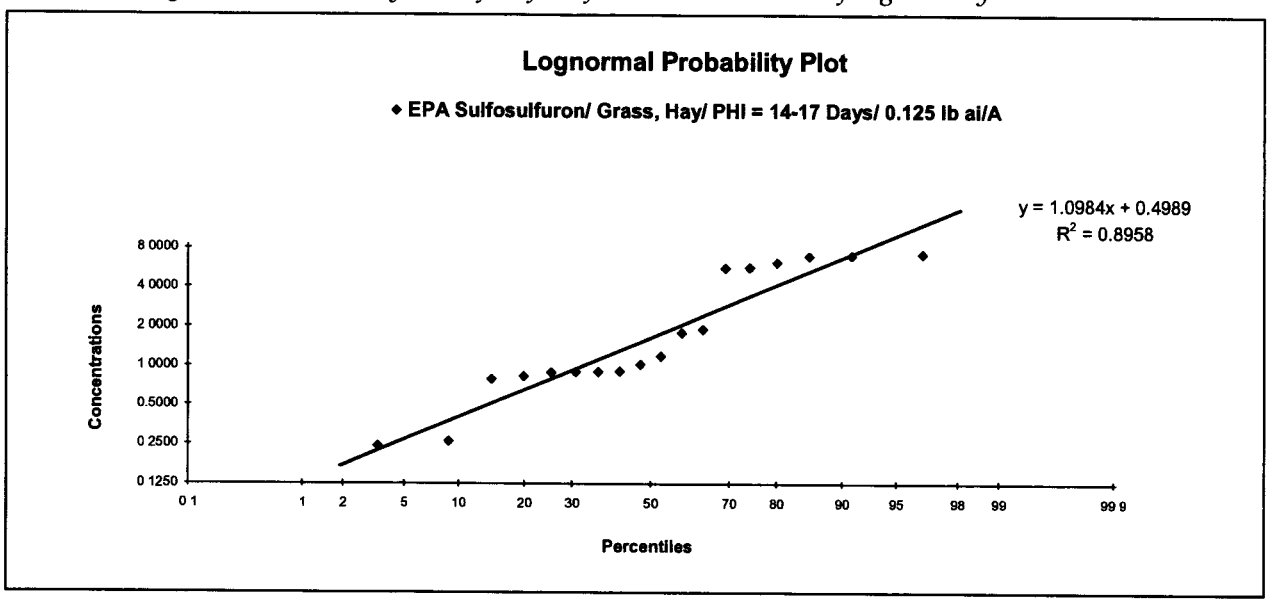


In assessing the tolerance for grass hay, the Agency chose 18 data points representing samples obtained following two applications of 0.062 pounds of a.i. per acre (1.33 ounces of formulated herbicide product per acre) or a total application rate of 0.125 pounds of a.i. per acre as the dataset

to use. This rate is the maximum rate of sulfosulfuron allowed per acre per year for weed control on a pasture or rangeland. Monsanto also agrees with this dataset selection for tolerance setting.

Visual inspection of the fit of this data on the lognormal probability plot (Figure 3) suggests that the dataset is reasonably lognormal, but there is more variability in this data than, for example, the data for the grass forage tolerance assessment. The appropriate tolerance was the point estimate of the 99th percentile, which was rounded to 25 parts per million (ppm).

Figure 3. *Lognormal Probability Plot of sulfosulfuron residue dataset for grass hay*



Effect of Surfactant on Residues of Sulfosulfuron in or on Grass Forage and Hay

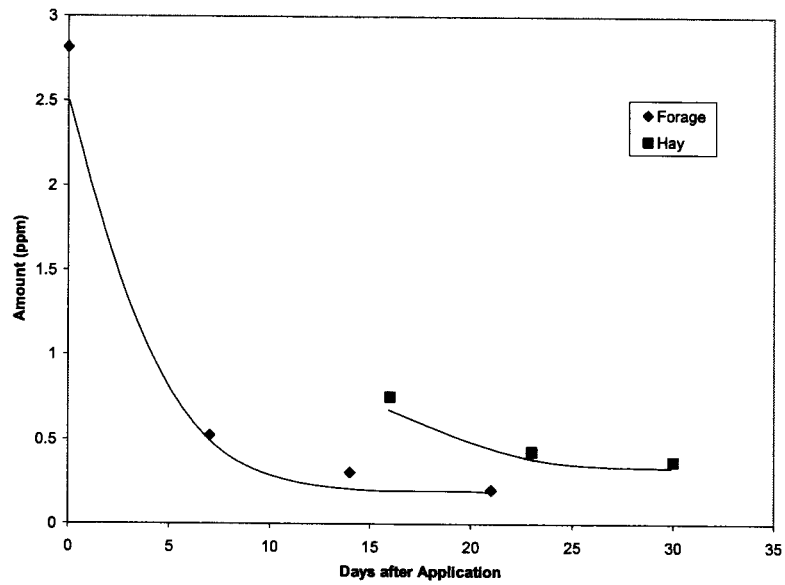
It is Monsanto's belief that a nonionic surfactant added to the aqueous spray mixture containing the herbicidal active ingredient sulfosulfuron and applied to grass pastures and rangelands has little, if any, affect on the overall magnitude of the residue found on the desirable grass forage and hay consumed by livestock that graze the treated fields.

As with other sulfonylurea herbicides, a surfactant is needed to increase the efficacy of the product and, more importantly, to ensure a consistent level of performance across a wide range of growing conditions. Sulfonylureas are systemic herbicides, required to be absorbed into the plant via either the plant roots or foliage and translocated to the site of action at the growing points of the plant in order to be efficacious. Surfactants are important adjuvants in the postemergence application of herbicidal sprays for the purpose of facilitating the penetration of the chemical across the waxy coating of the foliage and into the plant's circulatory system. The Agency has assumed that for this reason application of sulfosulfuron with a surfactant in the mix will result in higher residues of sulfosulfuron in the desirable grasses than without. Monsanto does not deny that this may be the case, however, Monsanto does believe that the overall penetration of this high unit-activity herbicide ingredient into the plant foliage is relatively small and insignificant compared to the amount of residue residing on the surface of the foliage. The overwhelming majority of the overall magnitude of the sulfosulfuron residue on grass forage and hay is represented by the residue ON the surface of the grass forage and hay, and far exceeds the

magnitude of that IN the plant. A very small amount of sulfosulfuron is needed in a susceptible plant for it to inhibit the ALS enzyme and block its life support system.

The residue decline curves for sulfosulfuron presented in MSL-19348 and reproduced here in Figure 4 below, are very typical of foliar dissipation curves of pesticides from turfgrass commonly reported in the literature.[1] This visual resemblance would suggest that the sulfosulfuron residues are topical residues that reside on the surface of the foliage. This type of residue decline is influenced by many interacting environmental forces, including evaporation, photolysis, hydrolysis, and the physical washing-off of the surface by precipitation events. There is no sign of a significant residue accumulation affect inside the plant in this residue decline curve.

Figure 4. *Sulfosulfuron residue decline curve following an initial application rate of 0.094 lb a.i./A*



0-DAT Forage. At day-zero relative to the herbicide application, it can safely be assumed that all residue is surface residue only—even a surfactant would not have time to markedly facilitate penetration in the little time between application and sample collection. Additional field trials conducted with the presence of surfactant at application would show no difference in the residue levels at day-zero.

A plot of all residue values measured for all 109 day-zero forage samples presented in MSL-19348 demonstrates that these residues are comfortably below the tolerance for sulfosulfuron in grass forage established by the subset of 26 of these day-zero forage residue values, as represented in Figure 5 below. Since the presence of a surfactant at application would have no impact on the magnitude of the residue in forage collected immediately after application, any variability in the magnitude would be the same as seen in the supporting data, and an exceedance of the tolerance would be highly unlikely. The current tolerance of 14 ppm for grass forage is well represented by the current residue data and is suitable for applications made with or without surfactant.

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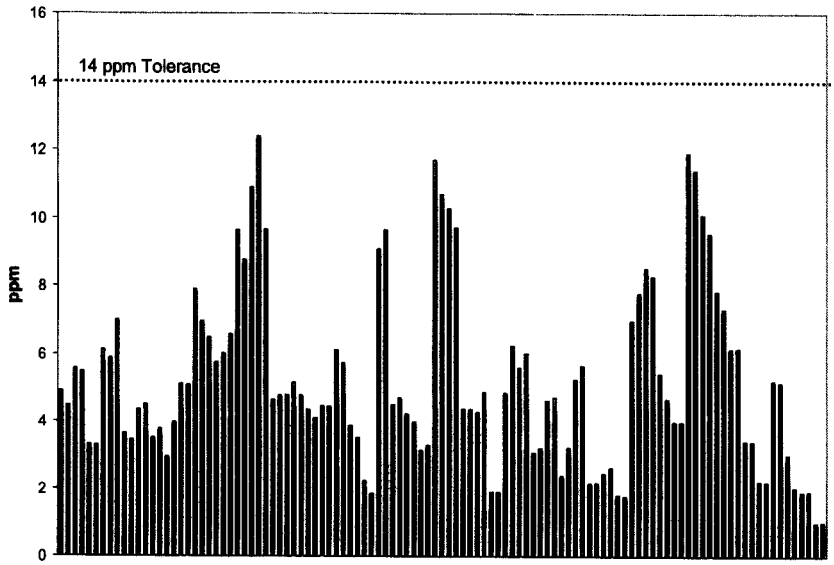
[1] J.E. Cowell, S.A. Adams, J.L Kunstman, and M.G. Mueth; *Comparison of Foliar Dissipation and Turf Dislodgeable Residue Sampling Techniques*, 1993, from **Pesticides in Urban Environments, Fate and Significance**; ACS Symposium Series 522.

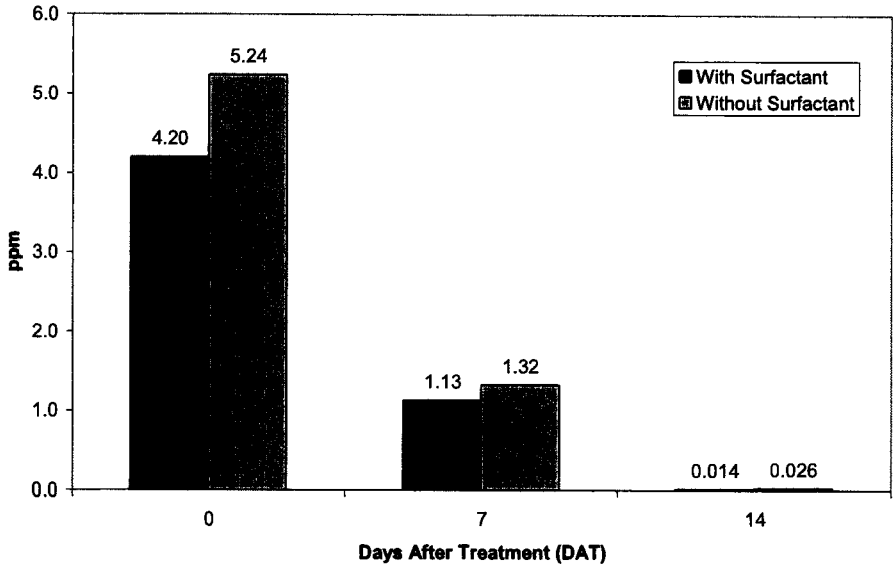
Figure 5. *Plot of All Day-Zero Forage Residue Values Versus Sulfosulfuron Tolerance (n=109)*



<u>*14-DAT Forage and Hay*</u>. If the presence of a surfactant were to have any measurable effect on the magnitude of sulfosulfuron residues in grass foliage, it would be realized in samples cut 14 days after treatment and collected as hay after field drying.

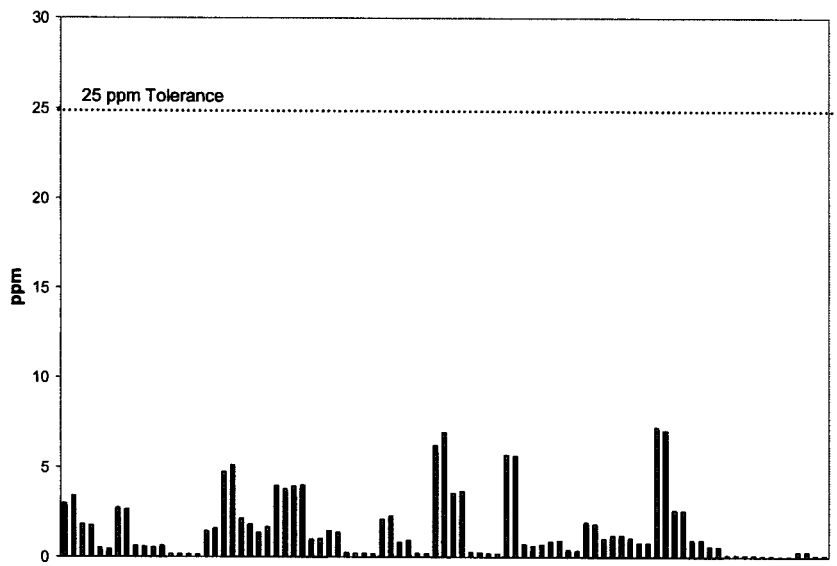
Monsanto conducted a small-scale residue study (MSL0021114) comparing the magnitude of the residues of sulfosulfuron in or on bermudagrass following application of Outrider herbicide at 2 ounces of product per acre (0.094 pounds a.i. per acre) with and without surfactant in the spray tank at a concentration of 0.25% by volume in side-by-side field trials. The data from this study clearly demonstrate that the difference in the residue level following application with and without surfactant at all sampling points is insignificant relative to the overall residue level and the established tolerances (Figure 6).

Figure 6. *Results from side-by-side sulfosulfuron residue trials with and without surfactant*



In this study, the 14-day sample represents grass forage as no drying in the field was allowed to occur before sample collection. The magnitude of the residue is 0.014 and 0.026 ppm, respectively, for with and without surfactant, far below the established tolerance of 25 ppm. The tolerance established for sulfosulfuron in grass hay is set significantly higher than any residue values measured in the supporting residue study, as illustrated in Figure 7, due to the inherent noise in the data used to generate the tolerance value. Even if the overall magnitude of sulfosulfuron residues were to be slightly increased in grass hay due to the presence of the surfactant at application, this data anomaly would accommodate the increase in variability without the likelihood of exceeding the established tolerance.

Figure 7. *Plot of all hay residue values versus sulfosulfuron tolerance (n=87)*



Conclusions

There is a critical need to control johnsongrass in grass pastures, hayfields and rangelands. The toxic effects of johnsongrass when consumed by horses, cattle and sheep that graze these lands cost ranchers and farmers millions of dollars a year in lost animals and quality of hay harvested from pastures infested with this invasive and noxious weed. There are currently no other options for chemical control of johnsongrass in established pastures than sulfosulfuron. Sulfosulfuron has demonstrated excellent control of johnsongrass and other weeds, primarily nutsedge, and safety on warm-season grasses, especially bermudagrass, and rangeland grasses.

In response to a Petition submitted by Monsanto in 2006, the EPA has established tolerances for sulfosulfuron in or on grass forage and hay as part of Crop Group 17, of 14 and 25 ppm, respectively. However, since a surfactant was not included in the field residue trial applications conducted to determine the magnitude of the residue to support these tolerances, the Agency has ruled that the use of a surfactant during application must be removed from the label until Monsanto can submit residue data that includes the use of a nonionic surfactant.

Monsanto has generated data from a side-by-side residue trial (MSL0021114) that shows that there is no difference in the magnitude of sulfosulfuron residues in grass forage and hay when the herbicide is applied with or without a surfactant. While it is critical that the surfactant be included in the application to ensure consistent uptake and performance in postemergence applications, it does not have a measurable effect on the overall magnitude of the residue in the desirable grass forage and hay. The amount of chemical needed to penetrate the natural barriers of the grass foliage in order to produce the desired herbicidal effect is extremely small compared the amount that is intercepted by and remains on the outside of the plant surface. Furthermore, it is illogical to infer that the magnitude of the residue on the day of application would be anything but surface residues whether applied with or without a surfactant, as there would be insufficient time for a surfactant to influence the movement of the chemical across the waxy barrier of the foliage to any great extent. The residue decline curves also suggest normal foliar dissipation of surface residue from day-zero until hay is collected 14 days after treatment.

The overwhelming majority of sulfosulfuron residue measured on grass forage and hay resides on the surface of the foliage, not in the plant tissue. The tolerances established for grass forage and hay as part of Crop Group 17 are more than adequate to cover any variability that might be realized by the presence of a surfactant during application.

Monsanto respectfully requests that the Agency accept this data and inference as sufficient information to allow the critical use of sulfosulfuron with the addition of a nonionic surfactant at a concentration of 0.25% by volume for weed control in pastures, hayfields and rangelands.

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