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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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MEMORANDUM

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF PREVENTION, PESTICIDE AND TOXIC SUBSTANCES

Date: 29 January 2009

SUBJECT: Penoxsulam. Section 3 Registration Application For Use of GF-443 T&V on Grape and Tree Nuts Including Pistachio. Summary of Analytical Chemistry and Residue Data.

PC Code: 119031
Decision No.: 394768
Petition No.: 8F7369
Risk Assessment Type: NA
TXR No.: NA
MRID No.: See MRID Summary Table

DP Barcode: D355914
Registration No.: 62719-ANG
Regulatory Action: Section 3
Case No.: NA
CAS No.: 219714-96-2
40 CFR: 180.605

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MRID Summary Table		
MRID No.	**Study Type**	**Comments**
46389701	860.1340 Crop commodities	DER; 46389701.der.doc
47444401	860.1300 Grape	DER; 47444401.der.doc
47444402	860.1380 Grape	DER; 47444402.der.doc
47444403	860.1500 Grape	DER; 47444403.de1.doc
	860.1520 Grape	DER; 47444403.de2.doc
47444404	860.1500 Almond	DER; 47444404.der.doc
47444405	860.1500 Pecan	

This document was originally prepared under contract by Dynamac Corporation (2275 Research Boulevard, Suite 300; Rockville, MD 20850). The document has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

Rec'd in RIC 4/1/2009 EW

Executive Summary

Penoxsulam is a sulfonamide herbicide currently registered for the selective control of grass, broadleaf, and sedge weeds. In the U.S., it was first registered for use on rice and subsequently has been registered for use on turf and for use in aquatic weed control. The herbicide's mode of action at the cellular level involves the inhibition of acetolactate synthase (ALS).

Dow AgroSciences LLC has submitted a Section 3 registration application for the end-use product GF-443 T&V (EPA File Symbol No. 62719-ANG), a 2 lb/gal suspension concentrate (equivalent to a flowable concentrate, FlC) formulation, for use on grapes and tree nuts. The proposed use allows broadcast or banded soil application to the orchard/vineyard floor as a winter dormant application followed by an application in the spring, for a maximum seasonal rate of 0.047 lb ai/A, with a minimum retreatment interval (RTI) of 30 days and a preharvest interval (PHI) of 60 days for grapes and tree nuts. In conjunction with the requested uses, Dow AgroSciences has submitted a petition (PP#8F7369) for the establishment of permanent tolerances for residues of penoxsulam [2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide] in or on the following raw agricultural commodities:

Almond, hulls	0.01 ppm
Grape	0.01 ppm
Nuts, tree, group 14	0.01 ppm
Pistachio	0.01 ppm

Permanent tolerances are established under §180.605(a) for residues of penoxsulam *per se* in/on rice grain and straw (0.02 and 0.50 ppm), and fish, crustacean shellfish, and mollusc shellfish at 0.01-0.02 ppm.

Data requirements for the proposed uses of penoxsulam on grapes and tree nuts were previously evaluated by ChemSAC (minutes of the 1/24/07 meeting), and recommendations were made concerning the plant metabolism, crop field trial, and processing studies submitted under PP#8F7369.

The nature of the residue in plants is understood for purposes of this petition. The residue of concern for tolerance expression and risk assessment is penoxsulam *per se*. An acceptable rice metabolism study reflecting foliar application was previously submitted. Under the current petition, an acceptable grape metabolism study reflecting soil application has been submitted. ChemSAC previously concluded that the subject grape metabolism study would be adequate to determine the nature of the residue for the proposed uses on grapes and tree nuts in consideration of the proposed use patterns. Both the rice and grape metabolism studies demonstrate that penoxsulam primarily degrades to its 5-OH metabolite (5-OH XDE-638); little translocation of penoxsulam or its metabolites into rice grain or grape vines was observed. HED notes that, should the use pattern for grapes or tree nuts change (i.e., from soil to foliar applications), additional nature of the residue data will be needed.

The nature of the residue in livestock is understood based on adequate goat and poultry metabolism studies. The studies indicated that penoxsulam is primarily excreted and not

significantly metabolized in either goats or poultry. The sulfonanilide bridge in penoxsulam does not appear to be cleaved. The residue of concern for penoxsulam in livestock is parent only.

An acceptable data collection method, LC/MS/MS Method GRM 04.09, was used for the determination of residues of penoxsulam in the grape storage stability study, grape and tree nut field trials, and grape processing study. The validated limit of quantitation (LOQ) is 0.01 ppm in grape and tree nut matrices. HED concludes that Method GRM 04.09 is also suitable for the enforcement of tolerances in grape and tree nut commodities. Because the method monitors two ion transitions, no confirmatory method is required, and because the method is similar to the tolerance enforcement methods for rice (Method GRM 01.25) and fish and shellfish (Method GRM 05.08), no independent laboratory validation (ILV), radiovalidation, or petition method validation (PMV) is required.

The FDA multiresidue protocol data show that penoxsulam is not adequately recovered using any of the protocol methods.

The only livestock feedstuff associated with the proposed uses is almond hulls which may be fed to dairy cattle; almond hulls are not considered a significant feedstuff of beef cattle, poultry, or swine. A dietary burden for cattle, poultry and swine was previously calculated based on the contribution of penoxsulam resulting from rice and aquatic uses, with the greatest contribution to the dietary burden (0.150 ppm) from treated water. At that time, HED concluded that if no inadvertent residues occurred in crops irrigated with penoxsulam-treated water, the aquatic uses of penoxsulam could result in a 40 CFR §180.6(a)(3) situation for ruminant and poultry commodities; i.e., there would be no reasonable expectation of finite residues in ruminant and poultry commodities and no ruminant or poultry feeding study would need to be submitted. Based on the available tree nut field trial results, the dietary contribution of almond hulls to the dairy cattle dietary burden would be minimal (0.001 ppm), and would not affect HED's previous conclusions concerning livestock tolerances.

The storage conditions and durations of samples from the grape and tree nut field trials and grape processing study are supported by adequate storage stability data.

Adequate crop field trial data have been submitted in support of the proposed uses on grapes and tree nuts. Residues of penoxsulam were nonquantifiable (<0.01 ppm) in/on all samples of grape, almond and pecan nutmeats, and almond hulls harvested following soil treatment. The submitted field trial data will support the proposed tolerances at the LOQ of 0.01 ppm for residues of penoxsulam in/on grape, the tree nut crop group, almond hulls, and, by translation of the almond data, pistachio.

An adequate grape processing study was submitted. Residues of penoxsulam were nonquantifiable (<0.01 ppm) in grape harvested following soil treatment at 5.8x the maximum proposed seasonal application rate or in the processed commodities of juice and raisin; therefore, no tolerances are needed for grape processed commodities.

Because grapes and tree nuts are not rotated, no data pertaining to rotational crops are required to support the proposed uses.

There are no Codex, Canadian or Mexican MRLs established for residues of penoxsulam in crops associated with this review. However, the petitioner noted that registration has been requested on grapes in France with a proposed MRL of 0.01 ppm (based on the analytical method LOQ).

Regulatory Recommendations and Residue Chemistry Deficiencies

There are no residue chemistry issues that would preclude granting registration for the requested uses of penoxsulam on grape and tree nuts or establishment of permanent tolerances for penoxsulam residues as follows:

Almond, hulls	0.01 ppm
Grape	0.01 ppm
Nut, tree, group 14	0.01 ppm
Pistachio	0.01 ppm

Prior to registration, the petitioner should submit a revised Section F to reflect the correct commodity definition for the tree nut crop group: "Nut, tree, Group 14." A human-health risk assessment is forthcoming in a separate document. (D355595).

Note to RD: As a result of the revisions to Table 1 of OPPTS Test Guideline 860.1000 (Memorandum dated 6/30/08, Chemistry Science Advisory Council), rice straw has been removed as a significant livestock feed item and therefore, the established tolerance for residues of penoxsulam in/on rice straw could be removed.

Background

The nomenclature of penoxsulam is summarized in Table 1, and the physicochemical properties are summarized in Table 2. The chemical names and structures of penoxsulam and all metabolites identified in the plant commodities are presented in Appendix I.

Table 1. Penoxsulam Nomenclature.

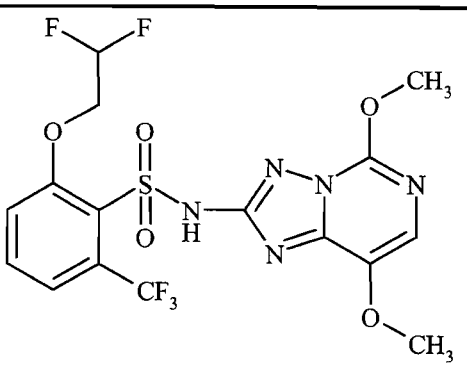
Compound	
Common name	Penoxsulam
Company experimental name	XDE-638
IUPAC name	6-(2,2-difluoroethoxy)-N-(5,8-dimethoxy-s-triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluoro-o-toluenesulfonamide
CAS name	2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c] pyrimidin-2-yl)-6-(trifluoromethyl) benzenesulfonamide

Table 1. Penoxsulam Nomenclature.	
CAS registry number	219714-96-2
End-use product (EP)	GF-443 T&V Herbicide (EPA Reg. No. 62719-ANG)

Table 2. Physicochemical Properties of Penoxsulam.			
Parameter	Value		Reference [1]
Melting point/range	Not available		
pH	5.2		MRID 45830707
Density	1.61 g/mL at 20 °C		MRID 45830707
Water solubility at 19 °C	Unbuffered pH 5 pH 7 pH 9	4.91 mg/L 5.66 mg/L 408 mg/L 1460 mg/L	MRID 45830720
Solvent solubility at 19 °C	Xylene 1-Octanol Methanol Ethyl acetate Acetonitrile Acetone Dimethylsulfoxide	0.017 g/L 0.035 g/L 1.48 g/L 3.23 g/L 15.3 g/L 20.3 g/L 78.4 g/L	MRID 45830720
Vapor pressure	7.16×10^{-16} mm Hg at 25 °C		MRID 45830720
Dissociation constant, pK_a	5.1 (ambient)		MRID 45830720
Octanol/water partition coefficient, $Log(K_{OW})$	Unbuffered pH 5 pH 7 pH 9	-0.354 1.137 -0.602 -1.418	MRID 45830720
UV/visible absorption spectrum	Not available		

[1] As referenced in DP# 326985, 1/30/07, D. Soderberg.

860.1200 Directions for Use

Dow AgroSciences provided a draft label for GF-443 T&V Herbicide (EPA File Symbol No. 62719-ANG), a 2 lb/gal FlC formulation of penoxsulam; the product is 100% repackaged from another 2 lb/gal FlC formulation (Grasp™ SC; EPA Reg. No. 62719-500) which is registered for use on rice in the U.S. The proposed uses on grapes and tree nuts are summarized in Table 3.

Table 3. Summary of Directions for Use of Penoxsulam.

Applic. Timing, Type, and Equip.	Formulation [EPA File Symbol No.]	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations
Grape						
Winter dormant + spring; Soil; broadcast to crop floor or banded at base of trunk; Ground; use of a hooded/shielded sprayer is required for application after petal fall.	2 lb/gal FlC [62719-ANG]	0.0312 (dormant) 0.0156 (spring)	2	0.0469	60	Winter dormant application followed by an application in the spring with an appropriate postemergence tank mix partner in spray volumes ≥20 gal/A. A minimum RTI of 30 days is specified. Application to vines that are not staked or trellised unless they are free standing, or to vines established <1 year, or to vines established <3 years unless they are on a trellis wire 3' above the soil surface is prohibited.
Tree Nuts						
Winter dormant + spring; Soil; broadcast to crop floor or banded at base of trunk; Ground; use of a hooded/shielded sprayer is required for application after flowering.	2 lb/gal FlC [62719-ANG]	0.0312 (dormant) 0.0156 (spring)	2	0.0469	60	Winter dormant application followed by an application in the spring with an appropriate postemergence tank mix partner in spray volumes ≥20 gal/A. A minimum RTI of 30 days is specified. Application to tree nut crops established <9 months is prohibited.

Note to RD: The proposed use pattern on the draft label differed from the use pattern described under Section G of the petition, where the petitioner stated that the maximum application rates for winter dormant applications were 0.0357 lb ai/A for grape and 0.0446 lb ai/A for tree nut, and that the maximum application rate for the second application was 0.0179 lb ai/A for both crops for maximum seasonal rates of 0.0535 lb ai/A for grape and 0.0624 lb ai/A for tree nuts. The rates specified under Section G correspond more closely with the use patterns reflected in the crop field trials. Given that the residues in the field trials are all < LOQ, HED has no concerns if the rates specified in Section G are the truly intended rates and become listed on the final label.

The following restrictions are specified for both grape and tree nut uses: (1) do not apply as an over-the-top application; (2) do not apply to any soil that is classified as a sandy soil or to soils with <1% organic matter; (3) do not apply until soil has been settled by packing and irrigation or rainfall and no cracks are present; (4) do not apply through any type of irrigation system; and (5) do not use treated plants for feed or forage, and do not feed or allow animals to graze treated areas.

The following general instructions are specified for both grape and tree nut uses: (1) for best weed control, apply as a single winter dormant application following final harvest up to February 15th; a sequential application may be applied up to 60 days prior to harvest; (2) direct spray toward the base of trees or vines, avoid direct or indirect application to green foliage or green bark; (3) a single rainfall or sprinkler irrigation of ≥0.5", or flood irrigation after application is necessary to activate the product; and (4) for all applications where postemergence weed control is desired and to improve foliar spray coverage, the addition of a crop oil concentrate or methylated seed oil is required.

Several tank mix partners are identified for both grape and tree nut uses. The tank mixing instructions state that in interpreting the labels of tank-mixed products, the most restrictive label limitations apply; a jar test for compatibility is recommended. The following tank mix partners are identified for postemergence (residual) control of grass and broadleaf weeds: glyphosate, glufosinate or paraquat. The following tank mix partners are identified for preemergence control of grass and broadleaf weeds: oxyfluorfen (GoalTender, Goal 2XL), isoxaben (Gallery), diuron (Karmex), pronamide (Kerb herbicide), simazine, norflurazon (Solicam), flumioxazin (Chateau), oryzalin (Surflan), or pendimethalin (Prowl).

Conclusions. The submitted use pattern information is adequate to allow evaluation of the residue data relative to the proposed use.

The crop field trial data submitted to support use of the 2 lb/gal FlC formulation of penoxsulam were generated using a 25 g/L oil dispersion (OD) formulation of penoxsulam. Because the OD and FlC formulations are prepared similarly (i.e., both are diluted with water for application and require constant agitation during application), and applications are made to the soil, the field trial data generated using the 25 g/L OD formulation may be translated to support the proposed use of the 2 lb/gal FlC formulation on grapes and tree nuts.

860.1300 Nature of the Residue - Plants

DER Reference: 47444401.der.doc
PP#3F6542; DP# 288152, 8/11/04, W. Cutchin

An acceptable rice metabolism study was previously reviewed in conjunction with the rice petition (PP#3F6542). Based on the submitted rice metabolism study, following foliar application, penoxsulam primarily degrades to its 5-OH metabolite (5-OH XDE-638) and at least two minor unknown metabolites in rice matrices; little translocation of penoxsulam residues or its metabolites into rice grain was observed.

Based on this study HED determined that the residue of concern for tolerance expression and risk assessment for penoxsulam in/on rice is parent only. HED further noted that for any future uses on other crops, additional nature of the residue data would be needed. Alternatively, the petitioner might submit crop field trial data that include residue data for the metabolite 5-OH XDE-638 as well as parent.

Grape

Dow AgroSciences has submitted a study investigating the metabolism of [phenyl-U-^{14}C]penoxsulam (PH label; specific activity 25.7 mCi/mmol) and [triazolopyrimidine-^{14}C]penoxsulam (TP label; specific activity 28.2 mCi/mmol) in grape grown outdoors in treated sandy clay loam soil. The test substances, diluted with water, were applied as a single spray application to the soil around grape vines at a target rate of 0.018 lb ai/A. The application rate corresponds to ~1.2x the maximum proposed application rate for application during the spring (growing stage) to grapes and tree nuts. The application was made when grapes were at the BBCH 55 growth stage (first flower buds enlarged), and mature grapes and leaves were harvested 118 days following treatment. The in-life phase of the study was conducted by Research For Hire (Porterville, CA), and the analytical phase of the study was conducted by Dow AgroSciences LLC, Regulatory Laboratories (Indianapolis, IN).

Total radioactive residues (TRR), determined by combustion/LSC, were below the LOQ (<0.0008 ppm) in grapes (both labels), and 0.016 and 0.013 ppm, respectively, in PH- and TP-label grape leaves following soil treatment at 0.017-0.018 lb ai/A.

Grape samples were not extracted due to very low radioactivity (<0.001 ppm). The majority of the radioactivity for both labels (~63-69% TRR) was released from grape leaves with acetonitrile (ACN) and water solvent extraction. The extracted residues were almost equally partitioned into organic (33-40% TRR) and aqueous (30% TRR) fractions. Nonextractable residues were <0.01 ppm in grape leaves. These procedures adequately extracted the majority of residues from grape leaves. Extraction and partitioning results were normalized by the petitioner, resulting in accountabilities of 100%; actual recoveries following extraction (extract + pellet) were 94.4% and 117.5%, and following partitioning were 113% and 119% for the PH- and TP-label leaves, respectively.

Residues were only tentatively identified in grape leaves by HPLC comparison with reference standards, due to low levels of individual components (each <0.01 ppm). No storage stability data are required to support the study because all samples were stored frozen and were analyzed within 3 months of collection.

The metabolite profiles were similar for both labels. Parent penoxsulam was not detected in grape leaves. The only residues identified were the di-hydroxy and 5-hydroxy penoxsulam metabolites, accounting for 6.3-10% TRR and 3.9-9.0% TRR (each ≤0.001 ppm), respectively. The majority of the aqueous-soluble residues (19.1-21.3% TRR, 0.002-0.003 ppm) were polar, eluting in the solvent front. Multiple low level components, present individually at ≤5.4% TRR, were characterized as organo- or aqueous-soluble and accounted for 24.5-29.2% TRR (≤0.004 ppm) in leaves.

Very low levels of soil-applied penoxsulam and its degradates were translocated into the grape vines. Based on the submitted study, the metabolism of penoxsulam proceeds via O-demethylation at both the 5-methoxy and 8-methoxy positions, as well as through undetermined alterations to form multiple, low-level unknowns.

Conclusions. ChemSAC previously concluded (minutes of 1/24/2007 meeting) that, provided the subject grape metabolism study had been accurately described by Dow, the study would be adequate to determine the nature of the residue for uses on grapes, tree nuts, and citrus in

consideration of the proposed use patterns: soil application with the second application made at a lower rate and at an earlier growth stage than reflected in the grape metabolism study.

The submitted grape metabolism study is acceptable. Very low levels (<0.001 ppm) of soil-applied penoxsulam and its degradates were translocated into grape. The application rate used in the study is slightly higher than the maximum application rate proposed for the second application to grapes and tree nuts, and, although the PHI reflected in the study is longer than the proposed PHI (118 days vs. 60 days), it is not anticipated that soil application at a higher rate or at a shorter PHI would result in significantly higher residues in grapes.

HED concludes that for purposes of this petition only, the nature of the residue in grapes and tree nuts is understood. The residue of concern for tolerance expression and risk assessment is penoxsulam *per se*.

HED notes that, should the use pattern for grapes or tree nuts change (i.e., from soil to foliar applications), additional nature of the residue data would be needed.

860.1300 Nature of the Residue - Livestock

PP#3F6542; DP# 288152, 8/11/04, W. Cutchin

Acceptable animal metabolism studies were reviewed in conjunction with the rice petition (PP#3F6542). The available goat and poultry metabolism data indicate that penoxsulam is primarily excreted and not significantly metabolized in either goats or poultry. Because no significant differences were observed in metabolism of phenyl and triazolopyrimidine ring-labeled penoxsulam in the goat metabolism study, the sulfonanilide-bridge in penoxsulam does not appear to be cleaved.

HED determined that for tolerance expression and risk assessment, the residues of concern for penoxsulam in livestock (including poultry) is parent only.

860.1340 Residue Analytical Methods

DER Reference: 46789701.der.doc
PP#5F7012; DP# 326985, 1/30/07, D. Soderberg
PP#3F6542; DP# 288152, 8/11/04, W. Cutchin
PP#3F6542; DP# 303172, 7/19/04, W. Cutchin

Enforcement methods: Dow AgroSciences LLC previously proposed LC/MS/MS method GRM 01.25 for the enforcement of tolerances for residues of penoxsulam in/on rice commodities (PP#3F6542). Using this method, samples of rice matrices are extracted with ACN/water. An aliquot of the supernatant is diluted with water and cleaned up on a mixed-mode polymeric-anion exchange solid phase extraction (SPE) plate. Residues are eluted with ACN:formic acid (99.9:0.1, v:v), evaporated to dryness, and redissolved in mobile phase. Residues are quantitated by LC/MS/MS using a C8 column, a gradient mobile phase of ACN/methanol and water, each containing 0.1% acetic acid, and electrospray ionization in the positive ion mode. Residues are quantified using external standards. The validated LOQ was 0.01 ppm in/on rice forage, straw, grain, hulls, bran, and polished rice.

Method GRM 01.25 underwent a successful ILV; neither radiovalidation nor a confirmatory method was required. Based on the available information, HED has already concluded that the method is acceptable for tolerance enforcement and an Agency method validation was requested. At this time, the Agency method validation does not appear to have been completed. Current policy now places the determination of the need for Agency method validation within the purview of HED. HED believes that the available data show the method to be valid for enforcement purposes without further Agency review.

A second LC/MS/MS method, Method GRM 05.08, was submitted in conjunction with proposed use of penoxsulam in aquatic sites (PP#5F7012) for the determination of residues in meat, milk and fish. Using this method, residues are extracted with ACN/water, and the extract is diluted with 0.1 N HCl for cleanup on a 96-well polymeric SPE plate. A stable isotope penoxsulam internal standard is added to the extract prior to LC/MS/MS analysis, and two ion transitions are monitored.

Method GRM 05.08 also underwent a successful ILV; no radiovalidation data were required. Because the method monitors two ion transitions, no confirmatory method is needed. HED concluded that because Method 05.08 was similar to Method 01.25, using reasonable similar extraction procedures, the method would be suitable for enforcement purposes for fish and shellfish tissues, provided the petitioner supplied the stable isotope internal standard to the EPA National Pesticide Standards Repository.

Data-collection method: Dow AgroSciences has submitted an LC/MS/MS method, Method GRM 04.09, for the determination of residues of penoxsulam in/on acidic, dry, oily, and wet crops. This method was used for data collection in the grape storage stability study, grape and tree nut crop field trial studies, and grape processing study submitted under DP# 355914. Method GRM 04.09 is the same as the enforcement method for fish and shellfish, Method GRM 05.08.

Briefly, samples are extracted with ACN:water (80:20, v:v). The extract is diluted with 0.1 N HCl and purified through a 96-well polymeric reverse phase SPE plate. Residues are eluted with ACN into another 96-well SPE plate containing ACN:methanol:water (15:15:70, v:v:v, containing 0.1% acetic acid) mobile phase and a stable isotope internal standard. The final solution is analyzed by LC/MS/MS for residues of penoxsulam. The calculated method LOQs are 0.0044 ppm for acidic crops, 0.0052 ppm for dry crops, 0.0054 ppm for oily crops, and 0.0081 ppm for wet crops.

Acceptable method validation recoveries were obtained for penoxsulam from samples of acidic, dry, oily, and wet crop matrices fortified at 0.01 and 1.0 ppm. Acidic crop matrices included orange whole fruit, pulp, and peel; lemon whole fruit; and apple. Dry crop matrices included wheat, rice, and barley grain, forage, and straw; field corn grain, forage, and stover, and sunflower seed. Oily matrices included canola and soybean seed, olive oil, and olive fruit without seed; and wet matrices included grape, potato tuber, sugar beet root, and broccoli. Recoveries were within the acceptable range of 70-120% for all samples at all fortification levels.

No confirmatory analysis procedures were included for the proposed enforcement method; however, because the LC/MS/MS method monitors two ion transitions for penoxsulam, a confirmatory method is not needed.

No radiovalidation data were submitted for Method GRM 04.09. HED has concluded that radiovalidation of the method is not required because the extraction solvent used for the method is the same as that used in the rice and grape metabolism studies.

Conclusions. The submitted data are adequate to satisfy data requirements. Method GRM 04.09 is acceptable for data collection for grape and tree nut commodities based on acceptable concurrent method recoveries. No enforcement method was proposed in the subject petition; however, HED concludes that Method GRM 04.09 is suitable for the enforcement of tolerances in grape and tree nut commodities. ILV of Method GRM 04.09 is not required because the method is the same as Method GRM 05.08 for which a successful ILV was conducted. Based on the available information regarding method performance and the successful ILV of Method GRM 0508, an Agency Petition Method Validation (PMV) is not required.

860.1360 Multiresidue Methods

PP#3F6542; DP# 288152, 8/11/04, W. Cutchin

Testing results of penoxsulam analyzed according to the FDA Multi-Residue Method Test guidelines in PAM Vol. I, Appendix II (1/94) were previously submitted in conjunction with the rice petition (PP# 3F6542). The multiresidue method data indicate that penoxsulam is not adequately recovered using any of the multiresidue methods. These data have been forwarded to FDA for further evaluation.

860.1380 Storage Stability

DER Reference: 47444402.der.doc
DP# 328689, 12/18/06, D. Soderberg
PP#3F6542; DP# 288152, 8/11/04, W. Cutchin

Storage stability data were previously submitted (PP#3F6542) and indicate that residues of penoxsulam are stable under frozen storage conditions in rice grain, straw, and immature forage for up to 732 days (24 months), and in processed rice bran, hulls, and polished rice for up to 390 days (12.8 months).

In conjunction with the subject petition, Dow AgroSciences has submitted the results of a storage stability study with penoxsulam in grape. Homogenized samples of untreated grapes were fortified with penoxsulam at 0.10 ppm, stored frozen (~-20 °C), and analyzed at storage intervals of 0, 28, 90, 176, and 359 days. Grape samples were analyzed for residues of penoxsulam using LC/MS/MS Method GRM 04.09. The method is adequate for data collection based on acceptable concurrent method recoveries. The reported method LOQ is 0.01 ppm for penoxsulam in/on grape. The data indicate that residues of penoxsulam are stable in/on grape stored frozen for up to 359 days.

The storage durations and conditions of samples from the crop field trials and processing studies submitted to support this petition are presented in Table 4.

Table 4. Summary of Storage Conditions and Durations of Samples from Crop Field Trial and Processing Studies.

Matrix	Storage Temperature (°C)	Actual Storage Duration	Interval of Demonstrated Storage Stability
Grape	~-20	179-232 days (5.9-7.6 months)	Residues of penoxsulam are stable in/on grape stored frozen for up to 11.8 months.
Grape (for processing)		195 days (6.4 months)	
Grape, juice		189 days (6.2 months)	None available.
Raisin		187 days (6.2 months)	
Almond, nutmeat and hulls		202-234 days (6.6-7.7 months)	
Pecan, nutmeat		119-151 days (3.9-5.0 months)	

Conclusions. The storage conditions and durations of samples from the grape and tree nut field trials and grape processing study are supported by adequate storage stability data. The concurrent storage stability data for grape are adequate to support the grape field trials. Supporting storage stability data will not be required for juice or raisin samples from the grape processing study, because penoxsulam residues were nondetectable in/on the grape RAC treated at an exaggerated rate, thus a processing study would not have been required.

Although the stability of penoxsulam has not been demonstrated in five diverse crops, the available storage stability data for rice raw agricultural and processed commodities and grapes will be considered adequate to support the storage conditions and durations of almond and pecan nutmeat and almond hull samples from the tree nut field trials, given that soil applications were made, nonquantifiable residues were observed, and no stability issues are likely for penoxsulam.

860.1400 Water, Fish, and Irrigated Crops

There are no proposed uses that are relevant to this guideline topic.

860.1460 Food Handling

There are no proposed uses that are relevant to this guideline topic.

860.1480 Meat, Milk, Poultry, and Eggs

PP#5F7012; DP# 326985, 1/30/07, D. Soderberg

No animal feeding studies were submitted with this petition. The only livestock feedstuff associated with the proposed uses on grape and tree nuts is almond hulls which may be fed to dairy cattle; almond hulls are not considered a significant feedstuff of beef cattle, poultry, or swine.

A dietary burden for cattle, poultry, and swine was previously calculated based on the contribution of penoxsulam resulting from rice and aquatic uses. Dietary burdens of 0.220 ppm for beef and dairy cattle, 0.170 ppm for poultry, and 0.166 ppm for swine were calculated, with the greatest contribution to each dietary burden (0.150 ppm) coming from treated water. HED concluded that if no inadvertant residues occurred in crops irrigated with penoxsulam-treated water, the aquatic uses of penoxsulam could result in a 40 CFR §180.6(a)(3) situation for ruminant and poultry commodities; i.e., there would be no reasonable expectation of finite residues in ruminant and poultry commodities and no ruminant or poultry feeding study would need to be submitted. This conclusion was considered tentative, pending submission of a study on the magnitude of the residue in irrigated crops to support the aquatic uses. If significant residues are found in crops irrigated with penoxsulam-treated water, then livestock feeding studies may be required.

Conclusions. No additional data are required to support the proposed uses of penoxsulam on grapes and tree nuts. Based on the available crop field trial results, the dietary contribution of almond hulls to the dairy cattle dietary burden would be minimal (0.001 ppm), and would not affect HED's previous conclusions concerning livestock tolerances.

860.1500 Crop Field Trials

DER References: 47444403.del.doc (grape)
47444404.der.doc (tree nuts; includes review of MRID 47444405)

Table 5. Summary of Residue Data from Crop Field Trials with Penoxsulam.

Crop matrix	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT[1]	Median	Mean	Std. Dev.
Grape (proposed use = 0.0312 lb ai/A during the dormant stage + 0.0156 lb ai/A during the growing stage, for a total application rate of 0.0469 lb ai/A; 60-day PHI)									
Grape	0.054-0.056	59-60	8	<0.01	<0.01	<0.01	<0.01	<0.01	--
Tree Nuts (proposed use = 0.0312 lb ai/A during the dormant stage + 0.0156 lb ai/A during the growing stage, for a total application rate of 0.0469 lb ai/A; 60-day PHI)									
Almond, nutmeat	0.062-0.063	59-60	6	<0.01	<0.01	<0.01	<0.01	<0.01	--
Almond, hulls	0.062-0.063	59-60	6	<0.01	<0.01	<0.01	<0.01	<0.01	--
Pecan, nutmeat	0.062-0.064	55-60	6	<0.01	<0.01	<0.01	<0.01	<0.01	--

[1] HAFT = Highest average field trial result.

Grape

Dow AgroSciences has submitted crop field trial data for penoxsulam on grape. Four grape field trials were conducted in the United States in Zones 1 (NY; 1 trial), 10 (CA; 2 trials), and 11 (WA; 1 trial), during the 2007 growing season.

At each test location, two soil applications were made with a 25 g/L OD formulation of penoxsulam. The first application was made near the end of the grape vine dormant stage (bud swell; BBCH 0-5) at a target rate of 0.0357 lb ai/A, and the second application was made 81-130 days later, during the growing stage (BBCH 77-79), at a target rate 0.0179 lb ai/A, for a total seasonal rate of ~0.054 lb ai/A. The application rates used in the study correspond to ~1.1x the

maximum proposed rates for applications at the dormant and growing stages, and to ~1.2x the maximum proposed seasonal rate. Broadcast applications were made to the vineyard floor, using ground equipment, in ~20-26 gal/A spray volumes with crop oil concentrate as an adjuvant. Samples of untreated and treated grapes were harvested at commercial maturity, 59-60 days after the last application.

Grape samples were analyzed for residues of penoxsulam using LC/MS/MS Method GRM 04.09. The method is adequate based on acceptable concurrent method recoveries. The validated LOQ is 0.01 ppm for grapes.

The storage conditions and durations for grape samples are reported in Table 4. The storage stability data for grape submitted in conjunction with the subject petition adequately support the storage conditions and durations of samples from the grape field trials.

The results of the grape field trials are summarized in Table 5. Residues of penoxsulam were nonquantifiable (<0.01 ppm) in/on all samples of grape harvested 59-60 days following two soil broadcast applications of the 25 g/L OD formulation at a total rate of 0.054-0.056 lb ai/A.

Tree nut, group 14

Dow AgroSciences has submitted crop field trial data for penoxsulam on almonds and pecans, the representative crops of the tree nut crop group 14. Six tree nut trials were conducted in the United States during the 2007 growing season. Three almond trials were conducted in Zone 10 (CA), and three pecan trials were conducted in Zones 2 (GA), 4 (LA), and 8 (TX).

At each test location, two soil applications were made with a 25 g/L OD formulation of penoxsulam. The first application was made near the end of the dormant stage (bud swell) at a target rate of 0.0446 lb ai/A, and the second application was made 125-196 days later, during the growing stage, at a target rate of 0.0178 lb ai/A, for a total seasonal rate of ~0.062 lb ai/A. The application rates used in the study correspond to ~1.4x and 1.1x the maximum proposed rates for applications at the dormant and growing stages, respectively, and to ~1.4x the maximum proposed seasonal rate. Broadcast applications were made to the orchard floor using ground equipment, in ~21-29 gal/A spray volumes with crop oil concentrate as an adjuvant. Samples of untreated and treated almond nutmeat and hulls and pecan nutmeat were harvested at commercial maturity, 55-60 days after the last application.

Nutmeat and hull samples were analyzed for residues of penoxsulam using LC/MS/MS Method GRM 04.09. The method is adequate based on acceptable concurrent method recoveries. The validated LOQ is 0.01 ppm for nutmeat and hulls.

The storage durations for almond and pecan samples are reported in Table 4. HED has concluded that the available storage stability data support the storage conditions and durations of samples from the tree nut field trials.

The results of the tree nut field trials are summarized in Table 5. Residues of penoxsulam were nonquantifiable (<0.01 ppm) in/on all samples of almond nutmeat, almond hull, and pecan

nutmeat harvested 55-60 days following two soil broadcast applications of the 25 g/L OD formulation at a total rate of 0.062-0.064 lb ai/A.

Conclusions. The submitted grape and tree nut data are adequate to satisfy data requirements. Although a reduced number of trials was conducted for each crop, ChemSAC previously determined (minutes of 1/24/2007 meeting) that reduced sets of residue trials for grape (four trials) and tree nuts (six trials; three each for almonds and pecans) would be adequate, provided no residues were detected, because the proposed use is for soil application and penoxsulam is classified as a reduced risk herbicide.

The use patterns used in the studies differed from the proposed use patterns in that an OD formulation was used rather than an FlC formulation, the individual application rates were slightly higher than the maximum proposed rates, and the RTIs were longer than the proposed RTIs. Given that the formulation types are similar, the proposed use is for soil application, and nonquantifiable residues were observed, HED concludes that the crop field trial data adequately support the proposed use patterns for grapes and tree nuts.

Residues of penoxsulam were nonquantifiable (<0.01 ppm) in/on all samples of grape, almond and pecan nutmeats, and almond hulls harvested following soil treatment. The submitted field trial data will support the proposed tolerances at the LOQ of 0.01 ppm for residues of penoxsulam in/on grape, the tree nut crop group, almond hulls, and, by translation of the almond data, pistachio.

860.1520 Processed Food and Feed

DER Reference: 47444403.de2.doc

Dow AgroSciences has submitted a processing study for penoxsulam on grape. In a single crop field trial conducted in NY during the 2007 growing season, two soil applications were made with a 25 g/L OD formulation of penoxsulam. The first application was made near the end of the grape vine dormant stage (bud swell) at 0.180 lb ai/A, and the second application was made 81 days later, during the growing stage, at 0.090 lb ai/A, for a total seasonal rate of 0.270 lb ai/A (~5.8x the proposed maximum seasonal rate). Broadcast applications were made to the vineyard floor using ground equipment, in ~20 gal/A spray volumes with crop oil concentrate as an adjuvant. Mature grapes were harvested 60 days after the second application and processed into juice and raisins using procedures simulating commercial practices.

Grape, grape juice, and raisin samples were analyzed for residues of penoxsulam using LC/MS/MS Method GRM 04.09. The method was adequate based on acceptable concurrent method recoveries. The validated LOQ was 0.01 ppm for grape, juice, and raisin.

The storage durations for grape, juice, and raisin samples are reported in Table 4. The storage stability data submitted in conjunction with the subject petition for grape adequately support storage conditions and durations of RAC samples from the grape processing study. No storage stability data are available for grape processed commodities.

Residues of penoxsulam were nonquantifiable (<0.01 ppm) in/on grape following two soil broadcast applications of the 25 g/L OD formulation of penoxsulam, made at the end of

dormancy and during the growing stage, for a total rate of 0.270 lb ai/A (5.8x the proposed seasonal application rate). Following processing, residues of penoxsulam were also nonquantifiable in grape juice and raisin. Because residues were nonquantifiable in both the RAC and the processed fractions, no processing factors could be calculated.

The theoretical concentration factor for grape juice, based on separation into components, is 1.2x, and the theoretical concentration factor for raisins, based on loss of water, is 4.7x (OPPTS 860.1520, Tables 2 and 3).

Conclusions. The submitted processing data for grape are acceptable to satisfy data requirements. Residues of penoxsulam were nonquantifiable (<0.01 ppm) in grape harvested following soil treatment at 5.8x the maximum proposed seasonal application rate or in the processed commodities of juice and raisin; therefore, no tolerances are needed for grape processed commodities. Although no storage stability data are available for grape processed commodities, no additional data will be required because no quantifiable residues of penoxsulam were observed in/on grapes following treatment at a 5.8x exaggeration rate.

860.1650 Submittal of Analytical Reference Standards

Analytical standards for penoxsulam and its stable isotope (as well as metabolites penoxsulam 2-amino-8-methoxy, penoxsulam 5,8-dimethyl, and penoxsulam 5-hydroxy) are currently available in the EPA National Pesticide Standards Repository (personal communication with Dallas Wright, ACB, 10/2/08), with an expiration date of 3/8/2009.

860.1850 and 860.1900 Confined and Field Accumulation in Rotational Crops

Because grapes and tree nuts are not rotated, no data pertaining to rotational crops and no rotational crop restrictions are required to support the proposed uses.

860.1550 Proposed Tolerances

PP#5F7012; DP# 326985, 1/30/07, D. Soderberg

Tolerances are currently established for penoxsulam under 40 CFR §180.605 and are expressed in terms of penoxsulam *per se*. The tolerance expression proposed by Dow AgroSciences is consistent with 40 CFR §180.605.

There are no Codex, Canadian, or Mexican MRLs established for residues of penoxsulam in crops associated with this petition. However, the petitioner noted that registration has been requested on grapes in France with a proposed MRL of 0.01 ppm (based on the analytical method LOQ).

Adequate field trial data are available for grape and tree nuts. The data were not entered into the Agency's tolerance spreadsheet as specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP because penoxsulam residues were nonquantifiable in/on all samples. The available field trial data will support the proposed tolerances at the method LOQ of 0.01 ppm for penoxsulam in/on grape, the tree nut crop group, and almond hulls. No residue

data were submitted for pistachio; however, the available data for almond may be translated to pistachio, and will support the proposed tolerance of 0.01 ppm.

The grape processing study demonstrated that no tolerances are needed for grape juice or raisin to support the proposed use on grape.

The proposed uses on grapes and tree nuts would result in a minimal contribution to the dietary burden for dairy cattle only of 0.001 ppm based on use on almond hulls. As concluded previously (PP#5F7012), no tolerances are required for residues of penoxsulam in livestock commodities pending submission of a study on the magnitude of the residue in irrigated crops.

A summary of the recommended tolerance for the current petition is presented in Table 6. The proposed tolerances should be revised to reflect the correct commodity definition cited in Table 6.

Table 6. Tolerance Summary for Penoxsulam.

Commodity	Proposed Tolerance (ppm)	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments; *Correct Commodity Definition*
Almond, hulls	0.01	--	0.01	
Grape	0.01	--	0.01	
Nuts, tree, group 14	0.01	--	0.01	*Nut, tree, group 14*
Pistachio	0.01	--	0.01	At this time, pistachio is not part of the tree nut crop group and a separate tolerance should be established.

References

DP#: 303172
Subject: PP# 3F6542. New Chemical - Penoxsulam (XDE-638) in/on Rice. Request for Petition Method Validation.
From: W. Cutchin
To: F. Siegelman
Dated: 7/19/04
MRIDs: 45830714 and 45830715

DP#: 288152
Subject: Penoxsulam. Petition for the Establishment of Permanent Tolerances for the Use on Rice. Summary of Analytical Chemistry and Residue Data. PP#3F6542.
From: W. Cutchin
To: P. Errico/J. Miller
Dated: 8/11/04
MRIDs: 45830712-17, 45830719-20, and 46267601

DP#: 328689
Subject: Penoxsulam. Frozen Storage Stability of XDE-638 (Penoxsulam) in Rice (Raw Agricultural Commodities: Grain, Straw, and Immature Forage) and its Processed Products (Bran, Hulls, and Polished Rice).
From: D. Soderberg
To: P. Errico/J. Miller
Dated: 12/18/06
MRIDs: 46449901

DP#: 326985
Subject: Penoxsulam. Section 3 Registration Application for Use of GF-443 SC in Aquatic Sites and Request for a Tolerance Exemption (PP#5F7012) on Fish and Shellfish. Summary of Analytical Chemistry and Residue Data.
From: D. Soderberg
To: J. Miller
Dated: 1/30/07
MRIDs: 46703504-07, and 46703509

Attachments:
International Residue Limit Status sheet
Appendix I - Chemical Name and Structure Table

Template Version September 2005

INTERNATIONAL RESIDUE LIMIT STATUS

Chemical Name: 2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c] pyrimidin-2-yl)-6-(trifluoromethyl) benzenesulfonamide	Common Name: Penoxsulam	X Proposed tolerance □ Reevaluated tolerance □ Other	Date: 10/01/08

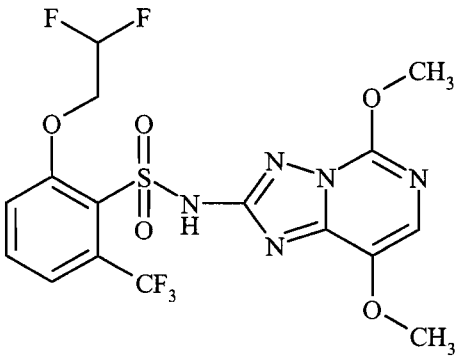
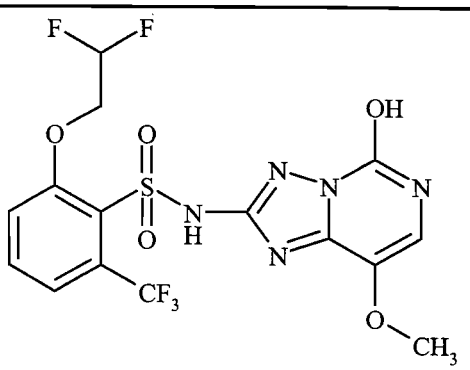
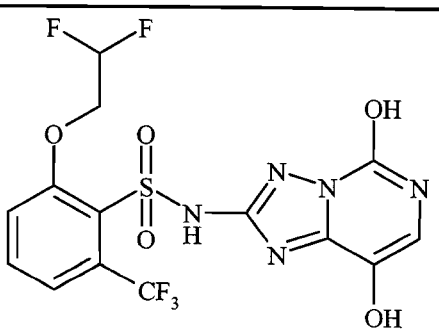
Codex Status (Maximum Residue Limits)	U. S. Tolerances
X No Codex proposal step 6 or above □ No Codex proposal step 6 or above for the crops requested	Petition Number: PP#8F7369 DP#: 355914 Other Identifier:
Residue definition (step 8/CXL): N/A	Reviewer/Branch: M. Doherty/RAB2
	Residue definition: penoxsulam *per se*

Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
		Almond, hulls	0.01
		Grape	0.01
		Nuts, tree, group 14	0.01
		Pistachio	0.01

Limits for Canada	Limits for Mexico
X No Limits □ No Limits for the crops requested	X No Limits □ No Limits for the crops requested
Residue definition: N/A	Residue definition: N/A

Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)

Notes/Special Instructions: S.Funk, 10/02/2008.

APPENDIX I. Chemical Names and Structures of Penoxsulam and Metabolites.		
Common name; Company code	Chemical name	Chemical structure
Penoxsulam; XDE-638	2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c] pyrimidin-2-yl)-6-(trifluoromethyl) benzenesulfonamide	
Penoxsulam-5-OH; 5-OH XDE-638	2-(2,2-difluoroetheoxy)-N-(5,6-dihydro-8-methoxy-5-oxo[1,2,4]triazolo[1,5-c]-pyrimidin-2-yl)-6-(trifluoromethyl)-benzenesulfonamide	
Penoxsulam-5,8-DiOH; Di-OH XDE-638	2-(2,2-difluoroethoxy)-*N*-[1,2,4]triazolo[1,5-c]pyrimidin-2-yl-6-(trifluoromethyl)benzenesulfonamide	

Penoxsulam/XDE-638/PC Code 119031/Dow AgroSciences LLC
DACO 7.2.1, 7.2.2, and 7.2.3/OPPTS 860.1340/OECD IIA 4.2.5, 4.2.6 and 4.3
Residue Analytical Method - Crop Commodities

Primary Evaluator — Michael A. Doherty, Chemist, RAB II — Date: 1/21/09

Peer Reviewer — Dennis McNeilly, Chemist, RAB II — Date: 1/21/09

This DER was originally prepared under contract by Dynamac Corporation (2275 Research Boulevard, Suite 300; Rockville, MD 20850; submitted 11/17/2008). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

46389701 Schelle, G.; Hastings, M. (2004) Validation Report for Method GRM 04.09 - Determination of Residues of Penoxsulam in Agricultural Commodities by High Performance Liquid Chromatography with Tandem Mass Spectrometry Detection. Project Number: 041009, GRM/04/09. Unpublished study prepared by Dow AgroSciences LLC. 55 p.

EXECUTIVE SUMMARY:

Dow AgroSciences has submitted an LC/MS/MS method, Method GRM 04.09, for the determination of residues of penoxsulam in/on acidic, dry, oily, and wet crops. This method was used for data collection in the grape storage stability study, grape and tree nut crop field trial studies, and grape processing study submitted under DP# 355914. Method GRM 04.09 is the same as the enforcement method for fish and shellfish, Method GRM 05.08 (DP# 326985, 1/30/07, D. Soderberg), and is similar to the enforcement method for rice, Method GRM 01.25 (DP# 288152, 8/11/04, W. Cutchin).

Briefly, samples are extracted with acetonitrile (ACN):water (80:20, v:v). The extract is diluted with 0.1 N HCl and purified through a 96-well polymeric reverse phase solid phase extraction (SPE) plate. Residues are eluted with ACN into another 96-well SPE plate containing ACN:methanol:water (15:15:70, v:v:v, containing 0.1% acetic acid) and a stable isotope internal standard. The final solution is analyzed by LC/MS/MS for residues of penoxsulam. The calculated method limits of quantitation (LOQs) are 0.0044 ppm for acidic crops, 0.0052 ppm for dry crops, 0.0054 ppm for oily crops, and 0.0081 ppm for wet crops.

Acceptable method validation recoveries were obtained for penoxsulam from samples of acidic, dry, oily, and wet crop matrices fortified at 0.01 and 1.0 ppm. Acidic crop matrices included orange whole fruit, pulp, and peel; lemon whole fruit; and apple. Dry crop matrices included wheat, rice, and barley grain, forage, and straw; field corn grain, forage, and stover, and sunflower seed. Oily matrices included canola and soybean seed, olive oil, and olive fruit without seed; and wet matrices included grape, potato tuber, sugar beet root, and broccoli. Recoveries were within the acceptable range of 70-120% for all samples at all fortification levels.

No confirmatory analysis procedures were included for the proposed enforcement method; however, because the LC/MS/MS method monitors two ion transitions for penoxsulam, a confirmatory method is not needed.

No radiovalidation data were submitted for Method GRM 04.09. HED has concluded that radiovalidation of the method is not required because the extraction solvent used for the method is the same as that used in the rice and grape metabolism studies (DP# 288152 and DP# 355914, respectively).

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the analytical method test data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 355914.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an impact on the validity of the study.

A. BACKGROUND INFORMATION

Penoxsulam is a sulfonamide herbicide currently registered for the selective control of grasses, broadleaf weeds, and sedge weeds. The herbicide's mode of action at the cellular level involves the inhibition of acetolactate synthase (ALS). In the U.S., it was first registered for use on rice and subsequently has been registered for use on turf and in aquatic weed control. Dow AgroSciences has submitted a petition for use on grapes and tree nuts including pistachio. The nomenclature of penoxsulam is summarized in Table A.1, and the physicochemical properties are summarized in Table A.2. The proposed use allows broadcast or banded soil application to the orchard/vineyard floor as a winter dormant application followed by an application in the spring, for a maximum seasonal rate of 0.047 lb ai/A, with a minimum retreatment interval (RTI) of 30 days and a preharvest interval (PHI) of 60 days for grapes and tree nuts.

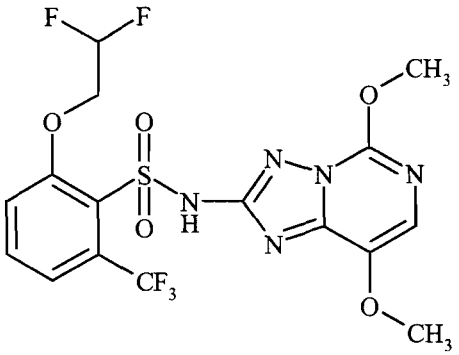
TABLE A.1. Penoxsulam Nomenclature.	
Compound	
Common name	Penoxsulam
Company experimental name	XDE-638
IUPAC name	6-(2,2-difluoroethoxy)-N-(5,8-dimethoxy-s-triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluoro-o-toluenesulfonamide
CAS name	2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c] pyrimidin-2-yl)-6-(trifluoromethyl) benzenesulfonamide
CAS registry number	219714-96-2
End-use product (EP)	GF-443 T&V Herbicide (EPA File Symbol No. 62719-ANG)

TABLE A.2. Physicochemical Properties of Penoxsulam.			
Parameter	Value		Reference [1]
Melting point/range	Not available		
pH	5.2		MRID 45830707
Density	1.61 g/mL at 20 °C		MRID 45830707
Water solubility at 19 °C	Unbuffered pH 5 pH 7 pH 9	4.91 mg/L 5.66 mg/L 408 mg/L 1460 mg/L	MRID 45830720
Solvent solubility at 19 °C	Xylene 1-Octanol Methanol Ethyl acetate Acetonitrile Acetone Dimethylsulfoxide	0.017 g/L 0.035 g/L 1.48 g/L 3.23 g/L 15.3 g/L 20.3 g/L 78.4 g/L	MRID 45830720
Vapor pressure	7.16×10^{-16} mm Hg at 25 °C		MRID 45830720
Dissociation constant, pK_a	5.1 (ambient)		MRID 45830720
Octanol/water partition coefficient, $Log(K_{OW})$	Unbuffered pH 5 pH 7 pH 9	-0.354 1.137 -0.602 -1.418	MRID 45830720
UV/visible absorption spectrum	Not available		

[1] As referenced in DP# 326985, 1/30/07, D. Soderberg.

B. MATERIALS AND METHODS

B.1. Data-Gathering Method

Dow AgroSciences has submitted an LC/MS/MS method, Method GRM 04.09, for the determination of residues of penoxsulam in/on acidic, dry, oily, and wet crops. The method, entitled "Determination of Residues of Penoxsulam in Agricultural Commodities by High Performance Liquid Chromatography with Tandem Mass Spectrometry Detection," was used for data collection in the grape storage stability study, grape and tree nut crop field trial studies, and grape processing study submitted under DP# 355914.

B.1.1. Principle of the Method:

Briefly, samples are extracted with ACN:water (80:20, v:v). The extract is diluted with 0.1 N HCl and purified through a 96-well polymeric reverse phase SPE plate. Residues are eluted with ACN into another 96-well SPE plate containing ACN:methanol:water (15:15:70, v:v:v, containing 0.1% acetic acid; mobile phase) and a stable isotope internal standard of penoxsulam (penoxsulam-^{13}C-$^{15}N_2$). The final solution is analyzed by LC/MS/MS for residues of penoxsulam.

The method parameters are presented in Table B.1.1.

TABLE B.1.1. Summary Parameters for the Analytical Method Used for the Quantitation of Penoxsulam Residues in Crops.

Method ID	Method No. GRM 04.09
Analyte	Penoxsulam
Extraction solvent/technique	Prior to extraction, samples are frozen in liquid nitrogen, then ground with a hammer mill. Ground samples are homogenized in ACN:water (80:20, v:v), shaken for 60 minutes, and then centrifuged.
Cleanup strategies	The supernatant is diluted with 0.1 N HCl and transferred to a 96-well polymeric reverse-phase SPE plate. The plate is washed with methanol:water (40:60, v:v), and residues are eluted with ACN. The eluate is collected in a second 96-well SPE plate, mobile phase (ACN:methanol:water:acetic acid; 15:15:70:0.2, v:v:v:v), and a stable isotope internal standard of penoxsulam (penoxsulam-^{13}C-$^{15}N_2$) are added.
Instrument/Detector	HPLC utilizing a reverse-phase C8 column and a gradient mobile phase of ACN/methanol and water, each containing 0.1% acetic acid, with tandem MS/MS detection using electrospray ionization operating in the positive ion mode with multiple reaction monitoring. The following ion transitions are monitored : Penoxsulam: m/z 484/195 Penoxsulam-^{13}C-$^{15}N_2$: m/z 487/198 Penoxsulam confirmation transition: m/z 484/164
Standardization method	External and internal standardization using an 8-point calibration curve (linear regression with 1/x weighting) of penoxsulam standards. The method notes that linear regression analysis forced through zero or quadratic curve fit may also be used for standardization.
Stability of std solutions	The stability of the standard solutions was not addressed.
Retention times	4.9-5.0 minutes (based on representative chromatograms)

B.2. Enforcement Method

Not applicable to this submission.

C. RESULTS AND DISCUSSION

Method validation data are presented in Table C.1.1. The method validation recoveries for penoxsulam were adequate from samples of acidic, dry, oily, and wet crop matrices fortified at 0.01 and 1.0 ppm. Acidic crop matrices included orange whole fruit, pulp, and peel; lemon whole fruit; and apple. Dry crop matrices included wheat, rice, and barley grain, forage, and straw; field corn grain, forage, and stover, and sunflower seed. Oily matrices included canola and soybean seed, olive oil, and olive fruit without seed; and wet matrices included grape, potato tuber, sugar beet root, and broccoli (head and stem). Recoveries were within the acceptable range of 70-120% for all samples at all fortification levels. Overall average recoveries (and coefficients of variation) were 92% (4.1%) for acidic crops, 98% (4.5%) for dry crops, 91% (8.5%) for oily crops, and 89% (9.3%) for wet crops.

The method characteristics of Method GRM 04.09 are presented in Table C.1.2. The petitioner calculated LOQs and limits of detection (LODs) for the four different types of crop matrices based on the recovery results for samples fortified at 0.01 ppm. The LOQ was calculated as 10x the standard deviation for the results, and the LOD was calculated as 3x the standard deviation. The respective LOQs and LODs were 0.0044 and 0.0013 ppm for acidic crops, 0.0052 and 0.0016 ppm for dry crops, 0.0054 and 0.0016 ppm for oily crops, and 0.0081 and 0.0024 ppm for wet crops.

No confirmatory analysis procedures were included for the proposed enforcement method; however, because the LC/MS/MS method monitors two ion transitions for penoxsulam, a confirmatory method is not needed.

No radiovalidation data were submitted for Method GRM 04.09. HED has concluded that radiovalidation of the method is not required because the extraction solvent used for the method is the same as that used in the rice and grape metabolism studies (DP# 288152 and DP# 355914, respectively).

C.1. Data-Gathering Method

TABLE C.1.1. Recovery Results from Method Validation of Crop Matrices using the Data-Gathering Analytical Method. [1]

Matrix	Spiking Level (ppm)	Recoveries Obtained (%)	Mean Recovery ± Std. Dev. [CV][2] (%)
Acidic crops			
Orange, whole fruit	0.01	88, 90, 101	93 ± 7.0 [7.5]
	1.00	90, 91, 93	91 ± 1.5 [1.7]
Orange, wet pulp	0.01	89, 92, 94	92 ± 2.5 [2.7]
	1.00	89, 89, 94	91 ± 2.9 [3.2]

TABLE C.1.1. Recovery Results from Method Validation of Crop Matrices using the Data-Gathering Analytical Method. [1]

Matrix	Spiking Level (ppm)	Recoveries Obtained (%)	Mean Recovery ± Std. Dev. [CV][2] (%)
Orange, peel	0.01	89, 95, 95	93 ± 3.5 [3.7]
	1.00	93, 94, 100	96 ± 3.8 [4.0]
Lemon, whole fruit	0.01	87, 90, 91	89 ± 2.1 [2.3]
	1.00	87, 91, 91	90 ± 2.3 [2.6]
Apple, whole fruit	0.01	88, 99	94
	1.00	92, 95	94
Dry crops			
Wheat, grain	0.01	104, 105, 110	106 ± 3.2 [3.0]
	1.00	99, 101, 105	102 ± 3.1 [3.0]
Wheat, forage	0.01	98, 100, 100	99 ± 1.2 [1.2]
	1.00	96, 98, 99	98 ± 1.5 [1.6]
Wheat, straw	0.01	98, 101, 102	100 ± 2.1[2.1]
	1.00	100, 100, 100	100
Barley, grain	0.01	98, 99, 106	101 ± 4.4 [4.3]
	1.00	100, 102, 102	101 ± 1.2 [1.1]
Barley, forage	0.01	87, 88, 93	89 ± 3.2 [3.6]
	1.00	93, 97, 98	96 ± 2.6 [2.8]
Barley, straw	0.01	91, 91, 95	92 ± 2.3 [2.5]
	1.00	99, 100, 101	100 ± 1.0 [1.0]
Corn, field, grain	0.01	93, 95	94
	1.00	97, 100	99
Corn, field, forage	0.01	91, 101	96
	1.00	93, 97	95
Corn, field, stover	0.01	95, 96	96
	1.00	92, 96	94
Rice, grain	0.01	96, 99	98
	1.00	101, 101	101
Rice, forage	0.01	95, 96	96
	1.00	96, 101	99
Rice, straw	0.01	94, 99	97
	1.00	95, 98	97
Sunflower, seed	0.01	93, 93	93
	1.00	102, 104	103
Oily crops			
Canola, seed	0.01	79, 85	82
	1.00	99, 100	100
Soybean, seed	0.01	80, 87	84
	1.00	99, 99	99
Olive, oil	0.01	91, 95	93
	1.00	75, 96	86
Olive, fruit without seed	0.01	89, 91	90
	1.00	95, 95	95

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TABLE C.1.1. Recovery Results from Method Validation of Crop Matrices using the Data-Gathering Analytical Method. [1]

Matrix	Spiking Level (ppm)	Recoveries Obtained (%)	Mean Recovery ± Std. Dev. [CV][2] (%)
Wet crops			
Grape	0.01	89, 90, 91, 92, 94	91 ± 1.9 [2.1]
	1.00	90, 92, 93, 95, 97	93 ± 2.7 [2.9]
Potato, tuber	0.01	76, 82	79
	1.00	96, 96	96
Beet, sugar, root	0.01	74, 80	77
	1.00	96, 98	97
Broccoli, flower head and stem	0.01	73, 75	74
	1.00	94, 95	95

[1] Fortification standards were prepared in ACN; calibration standards were prepared in ACN:methanol:water:acetic acid (15:15:70:0.2, v:v:v:v).
[2] Standard deviation and CV were only calculated for ≥ 3 values.

TABLE C.1.2. Characteristics for the Data-Gathering Analytical Method Used for the Quantitation of Penoxsulam Residues in Crop Matrices.

Analyte	Penoxsulam
Equipment ID	Zorbax SB-C8 column (4.6 x 75 mm, 3.5 µm) and an LC/MS/MS system with electrospray interface (Sciex API 3000)
Limit of quantitation (LOQ)	0.0044 ppm for acidic crops, 0.0052 ppm for dry crops, 0.0054 ppm for oily crops, and 0.0081 ppm for wet crops; calculated as 10x the standard deviation of the recovery results for samples fortified at 0.01 ppm.
Limit of detection (LOD)	0.0013 ppm for acidic crops, 0.0016 ppm for dry and oily crops, and 0.0024 ppm for wet crops; ; calculated as 3x the standard deviation of the recovery results for samples fortified at 0.01 ppm.
Accuracy/Precision	Percent recoveries and CVs indicate acceptable accuracy/precision for residues of penoxsulam from acidic, dry, oily, and wet crop matrices fortified at 0.01 and 1.00 ppm. Overall average recoveries (and CVs) were 92% (4.1%) for acidic crops, 98% (4.5%) for dry crops, 91% (8.5%) for oily crops, and 89% (9.3%) for wet crops.
Reliability of the Method [ILV]	Not required as the method has not been proposed for enforcement purposes.
Linearity	The instrument response was linear (stated coefficient of determination, r^2, ≥0.9985) for penoxsulam standards, prepared in acetonitrile:methanol:water (15:15:70, v:v:v, each containing 0.1% acetic acid), in the range of 0.00005-0.05 µg/mL, using both the quantitation ion and the confirmation ion.
Specificity	The control chromatograms generally have no peaks above the chromatographic background, and the spiked sample chromatograms contain only the analyte peak of interest. Peaks were well defined and symmetrical. There appeared to be no carryover to the following chromatograms.

C.2. Enforcement Method

Not applicable to this submission.

C.3. Independent Laboratory Validation

An independent laboratory validation study was not submitted.

D. CONCLUSION

Adequate method validation data have been submitted for LC/MS/MS Method 04.09. A confirmatory method is not required because the method monitors two ion transitions for penoxsulam. HED has concluded that radiovalidation data are not required because the extraction solvent used for the method is the same as that used in the rice and grape metabolism studies (DP# 288152 and DP# 355914, respectively).

E. REFERENCES

DP#: 288152
Subject: Penoxsulam. Petition for the Establishment of Permanent Tolerances for the Use on Rice. Summary of Analytical Chemistry and Residue Data. PP#3F6542.
From: W. Cutchin
To: P. Errico/J. Miller
Dated: 8/11/04
MRIDs: 45830712-45830717, 45830719-45830720, and 46267601

DP#: 326985
Subject: Penoxsulam. Section 3 Registration Application for Use of GF-443 SC in Aquatic Sites and Request for a Tolerance Exemption (PP#5F7012) on Fish and Shellfish. Summary of Analytical Chemistry and Residue Data.
From: D. Soderberg
To: J. Miller
Dated: 1/30/07
MRIDs: 46703504-46703507, and 46703509

F. DOCUMENT TRACKING

Petition Number: 8F7369
DP#: 355914
PC Code: 119031

Template Version June 2005

Penoxsulam/XDE-638/PC Code 119031/Dow AgroSciences LLC
DACO 6.3/OPPTS 860.1300/OECD II 6.2.2, 6.2.3 & IIIA 8.2, 8.4.1, 8.4.2
Nature of the Residues in Plants - Grape

Primary Evaluator — Michael A. Doherty, Chemist, RAB II — Date: 1/21/09

Peer Reviewer — Dennis McNeilly, Chemist, RAB II — Date: 1/21/09

This DER was originally prepared under contract by Dynamac Corporation (2275 Research Boulevard, Suite 300; Rockville, MD 20850; submitted 11/17/2008). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

47444401 Byrne, S.; Smith, K. (2007) A Nature of the Residue Study with (Carbon 14)-Penoxsulam Applied to Soil in Which Grape Vines are Growing. Project Number: 060033. Unpublished study prepared by Dow AgroSciences, LLC and Research for Hire. 84 p.

EXECUTIVE SUMMARY:

Dow AgroSciences has submitted a study investigating the metabolism of [phenyl-U-^{14}C]penoxsulam (PH label; specific activity 25.7 mCi/mmol) and [triazolopyrimidine-^{14}C]penoxsulam (TP label; specific activity 28.2 mCi/mmol) in grape grown in treated sandy clay loam soil. The test substances, diluted with water, were applied as a single spray application to the soil around grape vines grown outdoors at a target rate of 0.018 lb ai/A. The application was made when grapes were at the BBCH 55 growth stage (first flower buds enlarged), and mature grapes and leaves were harvested 118 days following treatment. The in-life phase of the study was conducted by Research For Hire (Porterville, CA), and the analytical phase of the study was conducted by Dow AgroSciences LLC, Regulatory Laboratories (Indianapolis, IN).

Total radioactive residues (TRR), determined by combustion/LSC, were below the LOQ (<0.0008 ppm) in grapes (both labels), and 0.016 and 0.013 ppm, respectively, in PH- and TP-label grape leaves following soil treatment at 0.017-0.018 lb ai/A.

Grape samples were not extracted due to very low radioactivity (<0.001 ppm). The majority of the radioactivity for both labels (~63-69% TRR) was released from grape leaves with acetonitrile (ACN)/water solvent extraction. The extracted residues were almost equally partitioned into organic (33-40% TRR) and aqueous (30% TRR) fractions. Nonextractable residues were <0.01 ppm in grape leaves. These procedures adequately extracted the majority of residues from grape leaves. Extraction and partitioning results were normalized by the petitioner, resulting in accountabilities of 100%; actual recoveries following extraction (extract + pellet) were 94.4% and 117.5%, and following partitioning were 113% and 119% for the PH- and TP-label leaves, respectively.

Residues were only tentatively identified in grape leaves by HPLC comparison with reference standards, due to low levels of individual components (each <0.01 ppm). No storage stability data are required to support the study because all samples were stored frozen and were analyzed within <3 months of collection.

The metabolite profiles were similar for both labels. Parent penoxsulam was not detected in grape leaves. The only residues identified were the di-hydroxy and 5-hydroxy penoxsulam metabolites, accounting for 6.3-10% TRR and 3.9-9.0% TRR (each ≤0.001 ppm), respectively. The majority of the aqueous-soluble residues (19.1-21.3% TRR, 0.002-0.003 ppm) were polar, eluting in the solvent front. Multiple low level components, present individually at ≤5.4% TRR, were characterized as organo- or aqueous-soluble and accounted for 24.5-29.2% TRR (≤0.004 ppm) in leaves.

Very low levels of soil-applied penoxsulam and its degradates were translocated into the grape vines. Based on the submitted study, the metabolism of penoxsulam proceeds via O-demethylation at both the 5-methoxy and 8-methoxy positions, as well as through undetermined alterations to form multiple, low-level unknowns.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the plant metabolism data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 355914.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an impact on the validity of the study.

A. BACKGROUND INFORMATION

Penoxsulam is a sulfonamide herbicide currently registered for the selective control of grasses, broadleaf weeds, and sedge weeds. The herbicide's mode of action at the cellular level involves the inhibition of acetolactate synthase (ALS). In the U.S., it was first registered for use on rice and subsequently has been registered for use on turf and in aquatic weed control. Dow AgroSciences has submitted a petition for use on grapes and tree nuts including pistachio. The nomenclature of penoxsulam is summarized in Table A.1, and the physicochemical properties are summarized in Table A.2. The proposed use allows broadcast or banded soil application to the orchard/vineyard floor as a winter dormant application followed by an application in the spring, for a maximum seasonal rate of 0.047 lb ai/A, with a minimum retreatment interval (RTI) of 30 days and a preharvest interval (PHI) of 60 days for grapes and tree nuts.

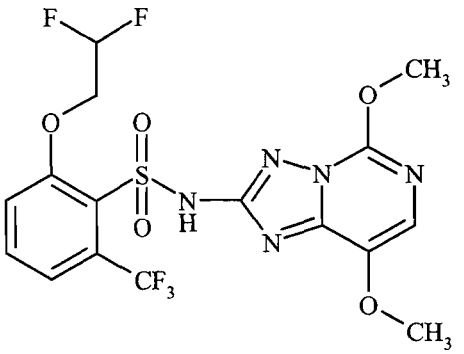
TABLE A.1. Penoxsulam Nomenclature.	
Compound	
Common name	Penoxsulam
Company experimental name	XDE-638
IUPAC name	6-(2,2-difluoroethoxy)-N-(5,8-dimethoxy-s-triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluoro-o-toluenesulfonamide
CAS name	2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c] pyrimidin-2-yl)-6-(trifluoromethyl) benzenesulfonamide
CAS registry number	219714-96-2
End-use product (EP)	GF-443 T&V Herbicide (EPA File Symbol No. 62719-ANG)

TABLE A.2. Physicochemical Properties of Penoxsulam.			
Parameter	Value		Reference [1]
Melting point/range	Not available.		
pH	5.2		MRID 45830707
Density	1.61 g/mL at 20 °C		MRID 45830707
Water solubility at 19 °C	Unbuffered pH 5 pH 7 pH 9	4.91 mg/L 5.66 mg/L 408 mg/L 1460 mg/L	MRID 45830720
Solvent solubility at 19 °C	Xylene 1-Octanol Methanol Ethyl acetate Acetonitrile Acetone Dimethylsulfoxide	0.017 g/L 0.035 g/L 1.48 g/L 3.23 g/L 15.3 g/L 20.3 g/L 78.4 g/L	MRID 45830720
Vapor pressure	7.16×10^{-16} mm Hg at 25 °C		MRID 45830720
Dissociation constant, pK_a	5.1 (ambient)		MRID 45830720
Octanol/water partition coefficient, $Log(K_{OW})$	Unbuffered pH 5 pH 7 pH 9	-0.354 1.137 -0.602 -1.418	MRID 45830720
UV/visible absorption spectrum	Not available		

[1] As referenced in DP# 326985, 1/30/07, D. Soderberg.

B. EXPERIMENTAL DESIGN

B.1. Test Site and Crop Information

The field test sites were located at Research For Hire (Porterville, CA). A summary of the test site information is provided in Table B.1.1, and a summary of the crop information is provided in Table B.1.2.

Three established outdoor grape vines were used for the study, one for each label and one for controls. The soil around each treated vine was surrounded with a wooden square (4.5 x 4.5 ft, inside dimension) buried in the soil (~2 feet deep) and lined with plastic; the soil was characterized as sandy clay loam soil. Plot maintenance simulated typical cultural practices; glyphosate and gibberellic acid applications were made during the growing season. Starting a few hours following treatment, ~1 acre cm of irrigation water was applied each day for a week; afterwards irrigation water was applied via a drip irrigation system (~2.54 acre cm of well water per week until harvest). Topical irrigation was conducted to ensure that the test substance moved into the root zone of the grape vine and to minimize photodegradation of the test substance. The crop also was not protected from rain. Daily weather conditions (rainfall, temperature, and humidity) were reported for the in-life period of the study.

TABLE B.1.1. Test Site Information.

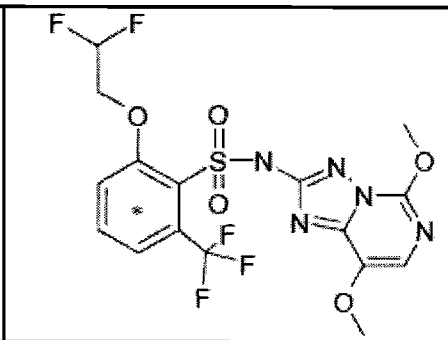
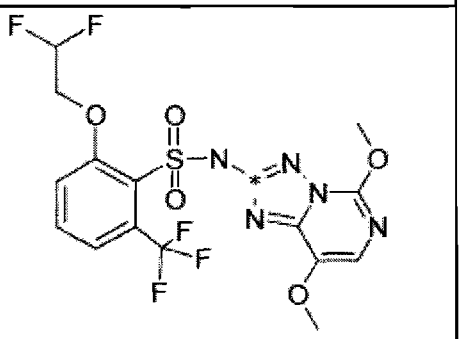
Type	Method	Soil characteristics			
		Type	%OM	pH	CEC (meq/100 g)
Soil Treatment	Spray application to the soil surrounding the grape vine	sandy clay loam	1.4	7.5	26.6

TABLE B.1.2. Crop Information.

Crop; crop group	Variety	Growth stage at application	Growth stage at harvest	Harvested Matrix
Grape; miscellaneous crop	Thompson seedless	BBCH 55, first flower buds enlarged	Mature	Grapes and leaves

B.2. Test Materials

The radiolabeled test substances were received as a solution in ACN. The characteristics of the test substances are presented in Table B.2.1.

TABLE B.2.1. Test Material Characteristics.		
Chemical structure		
Radiolabel position	[phenyl-U-^{14}C]penoxsulam (PH label)	[triazolopyrimidine-2-^{14}C]penoxsulam (TP label)
Lot No.	INV2025 (060033)	INV2024 (060033)
Purity	100% (96.9% by HPLC)	100% (98.0% by HPLC)
Specific activity	25.7 mCi/mmol; 53.18 µCi/mg	28.2 mCi/mmol; 58.35 µCi/mg

B.3. Study Use Pattern

The test substances were diluted with water for spray application to the soil around the grape vines at a target rate of 0.018 lb ai/A. Application was made when grapes were at the BBCH 55 growth stage, using a hand sprayer. Details of the study use pattern are presented in Table B.3.1.

TABLE B.3.1. Use Pattern Information.	
Chemical name	[phenyl-U -^{14}C]penoxsulam or [triazolopyrimidine-2-^{14}C]penoxsulam
Application method	The test substance, diluted with water, was applied to the soil using a backpack style R&D sprayer pressurized with CO_2.
Application rate	0.017-0.018 lb ai/A (PH - 19.1 g ai/ha; TP - 19.7 g ai/ha)
Number of applications	1
Timing of applications	BBCH 55, first flower buds enlarged
PHI	118

B.4. Identification/Characterization of Residues

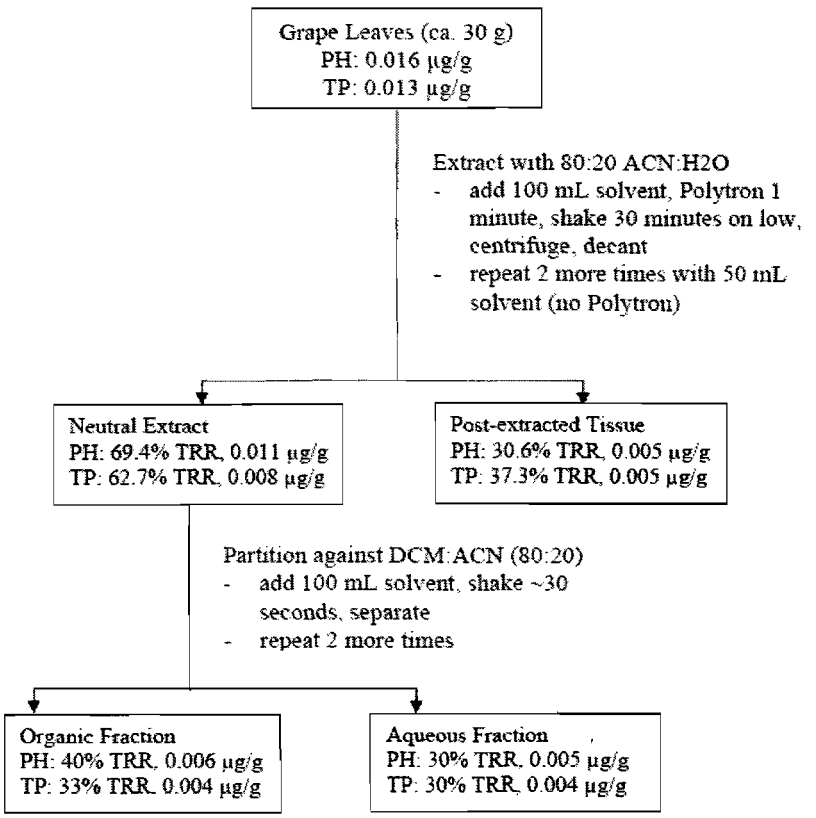
B.4.1. Sample Handling and Preparation

Grape leaves were hand-picked, and grape bunches were cut from the vine using scissors 118 days after application. Each sample was bagged and frozen. Samples were shipped frozen within 4-5 days of collection to Dow AgroSciences (Indianapolis, IN) for analysis. Samples were stored frozen (-20 °C) prior to and following preparation (cryogenic milling) for analysis. Because of low radioactivity in the grapes, only the leaf samples were extracted for residue characterization.

Milled grape leaves were extracted 3x with ACN:water (80:20, v:v) and centrifuged. The pooled extracts were partitioned into organic solvent using dichloromethane:ACN (3x; 80:20, v:v). The aqueous and organic phases were concentrated for HPLC analysis. A flowchart of the extraction

procedures for grape leaves is presented in Figure B.4.1.1 (copied without alteration from MRID 47444401).

Figure B.4.1.1. Extraction Procedures for Grape Leaves.



B.4.2. Analytical Methodology

TRR were determined in the samples by combustion/LSC. TRR in the leaf extracts were determined by direct LSC, and radioactivity in the nonextractable solids was determined by combustion/LSC. The limits of detection and quantitation for combustion/LSC were reported as 0.0002 and 0.0008 ppm, respectively, for fruit.

The aqueous and organic phases of the grape leaf extracts were analyzed by HPLC. The aqueous phase was concentrated to a low volume, and the organic phase was concentrated to dryness and redissolved in ACN/water; concentrated samples were stored refrigerated pending analysis. The HPLC system utilized a C8 column, UV detection (286 nm), and fraction collection, and a linear gradient mobile phase of water:acetic acid (99.5:0.5, v:v) and ACN:acetic acid (99.5:0.5, v:v). Tentative metabolite identifications were made by comparison of HPLC retention times with those of the reference standards. Metabolite identifications were not confirmed because no single component represented >0.01 ppm. The reference standards used in the study are presented in Appendix I.

C. RESULTS AND DISCUSSION

The storage conditions and durations for grapes matrices are presented in Table C.1. Samples of grapes and leaves were stored frozen for up to 49 and 69 days, respectively, from harvest to analysis. No storage stability data are required to support the sample storage conditions and durations because all samples were analyzed within <3 months of collection.

TRR in grape matrices are reported in Table C.2.1. Following soil treatment with PH- or TP-labeled penoxsulam at 0.017-0.018 lb ai/A, TRR, determined by combustion/LSC, were below the LOQ (<0.0008 ppm) in grapes (both labels), and 0.016 and 0.013 ppm, respectively, in PH- and TP-label grape leaves harvested 118 days after application.

The distribution of radioactivity in grape leaves is presented in Table C.2.2; grape samples were not extracted due to very low radioactivity (<0.001 ppm). The majority of the radioactivity for both labels (~63-69% TRR) was released from grape leaves with ACN/water solvent extraction. The extracted residues were almost equally partitioned into organic (33-40% TRR) and aqueous (30% TRR) fractions. Nonextractable residues were <0.01 ppm in grape leaves. These procedures adequately extracted the majority of residues from grape leaves. Extraction and partitioning results were normalized by the petitioner, resulting in accountabilities of 100%; actual recoveries following extraction (extract + pellet) were 94.4% and 117.5%, and following partitioning were 113% and 119% for the PH- and TP-label leaves, respectively.

The characterization and identification of residues in grape leaves are summarized in Table C.2.3. Residues were only tentatively identified by HPLC comparison with reference standards, due to low levels (each <0.01 ppm). The metabolite profiles were similar for both labels. Parent penoxsulam was not detected in grape leaves. The only residues identified were the di-hydroxy and 5-hydroxy penoxsulam metabolites, accounting for 6.3-10% TRR and 3.9-9.0% TRR (each ≤0.001 ppm), respectively. The majority of the aqueous-soluble residues (19.1-21.3% TRR, 0.002-0.003 ppm) were polar, eluting in the solvent front. Multiple low level components, present individually at ≤5.4% TRR, were characterized as organo- or aqueous-soluble and accounted for 24.5-29.2% TRR (≤0.004 ppm) in leaves.

C.1. Storage Stability

The petitioner reports that all samples and extracts were stored frozen when not in use. Based on the provided study dates, combustion/LSC analysis of grape samples was conducted within 49 days of harvest, and extraction and HPLC analysis of grape leaf samples was conducted within 43 and 69 days of harvest, respectively.

TABLE C.1. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration	Interval of Demonstrated Storage Stability
Grape, fruit	-20	49 days	None required.
Grape, leaves		69 days	

C.2. Identification, Characterization, and Distribution of Residues

TABLE C.2.1. Total Radioactive Residues (TRR) in Grape Matrices.

Matrix	Timing and Applic. No.	PHI (days)	PH Label	TP Label
			ppm	ppm
Grapes	One spray application to the soil around the grape vine	118	<LOQ (<0.0008)	ND (<0.0002)
Leaves			0.016	0.013

TABLE C.2.2. Distribution of the Parent and the Metabolites in Grape Leaves Following Soil Application of [^{14}C]Penoxsulam at 0.017-0.018 lb ai/A.

Metabolite Fraction	[PH-^{14}C]penoxsulam		[TP-^{14}C]penoxsulam [1]	
	Grape Leaves		Grape Leaves	
	TRR = 0.016 ppm		TRR = 0.013 ppm	
	%TRR	ppm	%TRR	ppm
Solvent Extract	69.4	0.011	62.7	0.008
-Organic phase	39.7	0.006	32.7	0.004
Di-OH 638	6.3	0.001	10.0	0.001
5-OH 638	9.0	0.001	3.9	<0.001
Unknown (RT ~21.6 minutes)	2.5	<0.001	4.6	0.001
Unknown (RT ~22.1 minutes)	4.5	0.001	5.4	0.001
Others [2]	14.0	0.002	4.0	0.001
-Aqueous phase	30.1	0.005	29.7	0.004
Polars ≤4.1 minutes	21.3	0.003	19.1	0.002
Unknown (RT ~21.6 minutes)	--	--	2.1	<0.001
Unknown (RT ~22.1 minutes)	3.0	<0.001	--	--
Others [2]	5.2	0.001	8.4	0.001
Unextractable	30.6	0.005	37.3	0.005

[1] The petitioner did not report the correct data for the metabolites in the organic phase of TP-label leaves; the correct residue values were calculated by the study reviewer from the chromatograms.
[2] These unknowns were not included in the data summarized by the petitioner; for completeness, the study reviewer totaled all other unknowns and calculated the residue values from the chromatograms.

TABLE C.2.3. Summary of Characterization and Identification of Radioactive Residues in Grape Leaves Following Soil Application of [^{14}C]Penoxsulam at 0.017-0.018 lb ai/A.

Compound	[PH-^{14}C]penoxsulam		[TP-^{14}C]penoxsulam	
	Grape Leaves		Grape Leaves	
	TRR = 0.016 ppm		TRR = 0.013 ppm	
	% TRR	ppm	% TRR	ppm
Di-OH 638	6.3	0.001	10.0	0.001
5-OH 638	9.0	0.001	3.9	<0.001
Polar unknowns	21.3	0.003	19.1	0.002
Other unknowns (organo- and aqueous-soluble)	29.2	0.004	24.5	0.003
Total identified	15.3	0.002	13.9	<0.002
Total characterized	50.5	0.007	43.6	<0.006
Total extractable	69.4	0.011	62.7	0.008
Unextractable (PES)[1]	30.6	0.005	37.3	0.005

TABLE C.2.3. Summary of Characterization and Identification of Radioactive Residues in Grape Leaves Following Soil Application of [^{14}C]Penoxsulam at 0.017-0.018 lb ai/A.

Compound	[PH-^{14}C]penoxsulam		[TP-^{14}C]penoxsulam	
	Grape Leaves		Grape Leaves	
	TRR = 0.016 ppm		TRR = 0.013 ppm	
	% TRR	ppm	% TRR	ppm
Accountability[2]	100		100	

[1] Residues remaining after exhaustive extractions.
[2] Accountability = (Total extractable + Total unextractable)/(TRR from combustion analysis; see TABLE C.2.1) * 100.
Extraction and partitioning results were normalized by the petitioner; actual recoveries following extraction (extract + pellet) were 94.4% and 117.5%, and following partitioning were 113% and 119% for the PH- and TP-label, respectively.

C.3. Proposed Metabolic Profile

Very low levels of soil-applied penoxsulam and its degradates were translocated into the grape vines. Based on the submitted study, the metabolism of penoxsulam proceeds via O-demethylation at both the 5-methoxy and 8-methoxy positions, as well as through undetermined alterations to form multiple, low-level unknowns. The 5-hydroxy metabolite may have been formed in the soil or alternatively from penoxsulam taken up from the soil into the plant roots.

FIGURE C.3.1. Proposed Metabolic Profile of Penoxsulam in Grape.

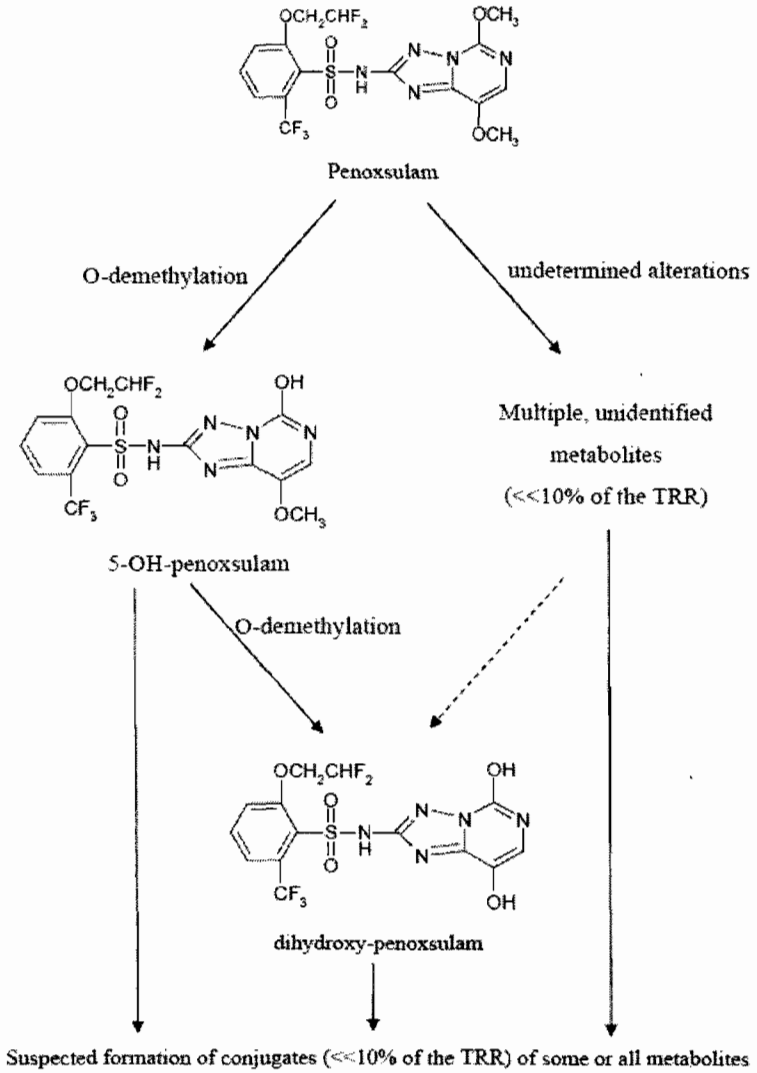
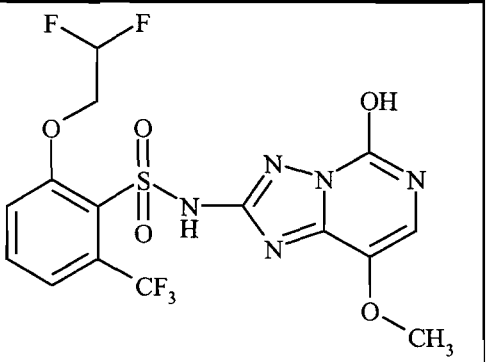
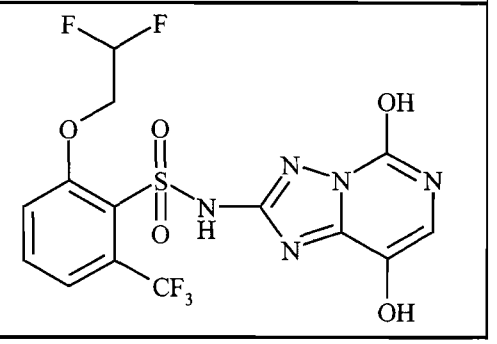


TABLE C.3.1. Identification of Compounds from Metabolism Study.		
Common name/code Figure C.3.1 ID No.	Chemical name	Chemical structure
Penoxsulam-5-OH; 5-OH XDE-638	2-(2,2-difluoroetheoxy)-N-(5,6-dihydro-8-methoxy-5-oxo[1,2,4]triazolo[1,5-c]-pyrimidin-2-yl)-6-(trifluoromethyl)-benzenesulfonamide	
Penoxsulam-5,8-DiOH; Di-OH XDE-638	2-(2,2-difluoroethoxy)-*N*-[1,2,4]triazolo[1,5-c]pyrimidin-2-yl-6-(trifluoromethyl)benzenesulfonamide	

D. CONCLUSION

TRR were below the LOQ (<0.0008 ppm) in grapes (both labels), and 0.016 and 0.013 ppm, respectively, in PH- and TP-label grape leaves harvested 118 days following soil treatment with phenyl-U-[^{14}C]penoxsulam or [triazolopyrimidine-^{14}C]penoxsulam at 0.017-0.018 lb ai/A.

Residues in grape samples were not further investigated due to very low radioactivity (<0.001 ppm). Residues were only tentatively identified in grape leaves due to low levels (each <0.01 ppm). The metabolite profiles were similar for both labels. Parent penoxsulam was not detected in grape leaves. The only residues identified were the di-hydroxy and 5-hydroxy penoxsulam metabolites, accounting for 6.3-10% TRR and 3.9-9.0% TRR, respectively. The majority (19.1-21.3% TRR) of the aqueous-soluble residues were polar, eluting in the solvent front. Multiple low level components, characterized as organo- or aqueous-soluble, accounted for 24.5-29.2% TRR in leaves.

No storage stability data are required to support the study, and acceptable methods were used for extraction and characterization/identification of residues.

Very low levels of soil-applied penoxsulam and its degradates were translocated into the grape vines. Based on the submitted study, the metabolism of penoxsulam proceeds via O-demethylation at both the 5-methoxy and 8-methoxy positions, as well as through undetermined alterations to form multiple, low-level unknowns.

E. REFERENCES

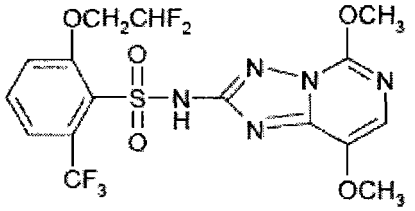
DP#: 326985
Subject: Penoxsulam. Section 3 Registration Application for Use of GF-443 SC in Aquatic Sites and Request for a Tolerance Exemption (PP#5F7012) on Fish and Shellfish. Summary of Analytical Chemistry and Residue Data.
From: D. Soderberg
To: J. Miller
Dated: 1/30/07
MRIDs: 46703504-46703507, and 46703509

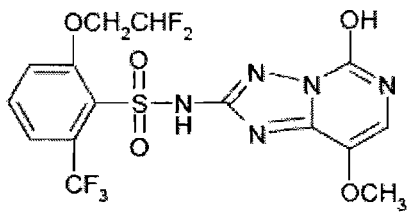
F. DOCUMENT TRACKING

Petition Number: 8F7369
DP#: 355914
PC Code: 119031

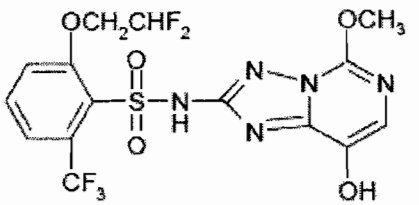
Template Version June 2005

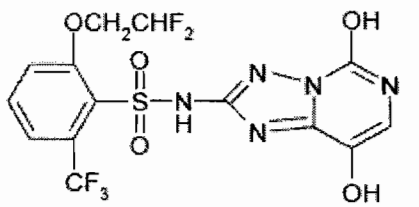
APPENDIX I. Chemical Names and Structures of Reference Standards Used in Grape Metabolism Study. [Copied without alteration from MRID 47444401]

Name	Penoxsulam		
			
Synonyms	XDE-638; DE-638		
Chemical Name	2-(2,2-difluoroethoxy)-*N*-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide		
SMILES Code	n1c(nc2n1c(ncc2OC)OC)NS(=O)(=O)c3c(cccc3C(F)(F)F)OCC(F)F		
CAS Number	219714-96-2		
Mol. Formula	$C_{16}H_{14}N_5SO_5F_5$	**Mol. Weight**	483 g/mole
Purity	99.1%		
GLP	Yes	**Exp. Date**	07 January 2007
TSN	TSN101649		

Name	5-OH XDE-638		
			
Synonyms	5-OH; Penoxsulam-5-OH		
Chemical Name	2-(2,2-difluoroethoxy)-*N*-(8-methoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide		
SMILES Code	n1c(nc2n1c(ncc2OC)O)NS(=O)(=O)c3c(cccc3C(F)(F)F)OCC(F)F		
CAS Number	Not Known		
Mol. Formula	$C_{15}H_{12}N_5SO_5F_5$	**Mol. Weight**	469 g/mole
Purity	>99%		
GLP	Yes	**Exp. Date**	29 July 2007
TSN	TSN101756		

4

Name	8-OH XDE-638		
			
Synonyms	8-OH; Penoxsulam-8-OH		
Chemical Name	2-(2,2-difluoroethoxy)-*N*-(5-methoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide		
SMILES Code	n1c(nc2n1c(ncc2OC)O)NS(=O)(=O)c3c(cccc3C(F)(F)F)OCC(F)F		
CAS Number	Not Known		
Mol. Formula	$C_{15}H_{12}N_5SO_5F_5$	**Mol. Weight**	469 g/mole
Purity	Not Provided		
GLP	Yes	**Exp. Date**	31 January 2005
TSN	TSN102455		

Name	5,8-Dihydroxy-XDE-638		
			
Synonyms	Di-OH; Penoxsulam-5,8-DiOH		
Chemical Name	2-(2,2-difluoroethoxy)-*N*-[1,2,4]triazolo[1,5-c]pyrimidin-2-yl-6-(trifluoromethyl)benzenesulfonamide		
SMILES Code	n1c(nc2n1c(ncc2OC)OC)NS(=O)(=O)c3c(cccc3C(F)(F)F)OCC(F)F		
CAS Number	Not Known		
Mol. Formula	$C_{14}H_{10}N_5SO_5F_5$	**Mol. Weight**	455 g/mole
Purity	Not Available		
GLP	Yes	**Exp. Date**	31 January 2005
TSN	TSN102456		

Penoxsulam/XDE-638/PC Code 119031/Dow AgroSciences LLC
DACO 7.3/OPPTS 860.1380/OECD IIA 6.1.1 and IIIA 8.1.1
Storage Stability - Grape

Primary Evaluator — Michael A. Doherty, Chemist, RAB II — Date: 1/21/09

Peer Reviewer — Dennis McNeilly, Chemist, RAB II — Date: 1/21/09

This DER was originally prepared under contract by Dynamac Corporation (2275 Research Boulevard, Suite 300; Rockville, MD 20850; submitted 11/17/2008). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

47444402 Schelle, G. (2007) Frozen Storage Stability of Penoxsulam in Grapes. Project Number: 060072. Unpublished study prepared by Dow AgroSciences, LLC. 33 p.

EXECUTIVE SUMMARY:

Dow AgroSciences has submitted the results of a storage stability study with penoxsulam in grape. Homogenized samples of untreated grapes were fortified with penoxsulam at 0.10 ppm, stored frozen (~-20 °C), and analyzed at storage intervals of 0, 28, 90, 176, and 359 days. The study was conducted by Dow AgroSciences Regulatory Laboratories (Indianapolis, IN).

Grape samples were analyzed for residues of penoxsulam using LC/MS/MS Method GRM 04.09. The method was adequate for data collection based on acceptable concurrent method recoveries. The reported method limit of quantitation (LOQ) was 0.01 ppm for penoxsulam in/on grape.

The data indicate that residues of penoxsulam are stable in/on grape stored frozen for up to 359 days.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the storage stability data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 355914.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an impact on the validity of the study.

A. BACKGROUND INFORMATION

Penoxsulam is a sulfonamide herbicide currently registered for the selective control of grasses, broadleaf weeds, and sedge weeds. The herbicide's mode of action at the cellular level involves the inhibition of acetolactate synthase (ALS). In the U.S., it was first registered for use on rice and subsequently has been registered for use on turf and in aquatic weed control. Dow AgroSciences has submitted a petition for use on grapes and tree nuts including pistachio. The nomenclature of penoxsulam is summarized in Table A.1, and the physicochemical properties are summarized in Table A.2. The proposed use allows broadcast or banded soil application to the orchard/vineyard floor as a winter dormant application followed by an application in the spring, for a maximum seasonal rate of 0.047 lb ai/A, with a minimum retreatment interval (RTI) of 30 days and a preharvest interval (PHI) of 60 days for grapes and tree nuts.

TABLE A.1. Penoxsulam Nomenclature.

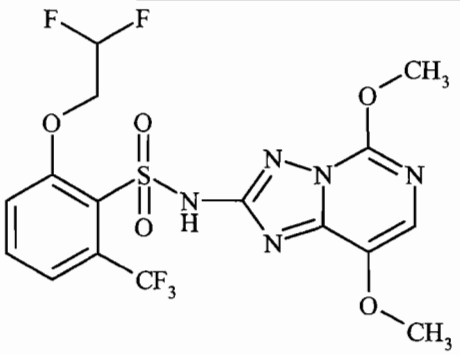
Compound	
Common name	Penoxsulam
Company experimental name	XDE-638
IUPAC name	6-(2,2-difluoroethoxy)-N-(5,8-dimethoxy-s-triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluoro-o-toluenesulfonamide
CAS name	2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c] pyrimidin-2-yl)-6-(trifluoromethyl) benzenesulfonamide
CAS registry number	219714-96-2
End-use product (EP)	GF-443 T&V Herbicide (EPA File Symbol No. 62719-ANG)

TABLE A.2. Physicochemical Properties of Penoxsulam.

Parameter	Value		Reference [1]
Melting point/range	Not available		
pH	5.2		MRID 45830707
Density	1.61 g/mL at 20 °C		MRID 45830707
Water solubility at 19 °C	Unbuffered pH 5 pH 7 pH 9	4.91 mg/L 5.66 mg/L 408 mg/L 1460 mg/L	MRID 45830720
Solvent solubility at 19 °C	Xylene 1-Octanol Methanol Ethyl acetate Acetonitrile Acetone Dimethylsulfoxide	0.017 g/L 0.035 g/L 1.48 g/L 3.23 g/L 15.3 g/L 20.3 g/L 78.4 g/L	MRID 45830720

TABLE A.2. Physicochemical Properties of Penoxsulam.			
Parameter	Value		Reference [1]
Vapor pressure	7.16×10^{-16} mm Hg at 25 °C		MRID 45830720
Dissociation constant, pK_a	5.1 (ambient)		MRID 45830720
Octanol/water partition coefficient, $Log(K_{OW})$	Unbuffered pH 5 pH 7 pH 9	-0.354 1.137 -0.602 -1.418	MRID 45830720
UV/visible absorption spectrum	Not available		

[1] As referenced in DP# 326985, 1/30/07, D. Soderberg.

B. EXPERIMENTAL DESIGN

B.1. Sample Handling and Preparation

Samples of untreated grape were obtained from a field trial study (Control-054-002). Stems were removed by hand, and the fruit was homogenized in the presence of liquid nitrogen. Homogenized samples were fortified with penoxsulam, prepared in acetonitrile (ACN), at a concentration of 0.10 ppm. Fortified and unfortified samples in HDPE containers were stored frozen (~-20 °C) and analyzed at 0-, 28-, 90-, 176-, and 359-day storage intervals. At each storage interval, three stored fortified samples, two freshly fortified samples, and one unfortified sample were analyzed.

B.2. Analytical Methodology

Residues of penoxsulam were determined in grape using LC/MS/MS Method GRM 04.09, titled "Determination of Residues of Penoxsulam in Agricultural Commodities by High Performance Liquid Chromatography with Tandem Mass Spectrometry Detection." This method was also used as the data-collection method in the associated grape field trial studies. Only a brief description of method GRM 04.09 was provided in the subject submission.

Briefly, homogenized samples were extracted with acetonitrile (ACN):water (80:20, v:v). The extract was diluted with 0.1 N HCl and purified through a 96-well polymeric reverse phase solid phase extraction (SPE) plate. Residues were eluted with ACN into another 96-well SPE plate containing ACN:methanol:water (15:15:70, v:v:v, containing 0.1% acetic acid) mobile phase and a stable isotope internal standard. The final solution was analyzed by LC/MS/MS for residues of penoxsulam. The reported method limit of detection (LOD) for penoxsulam in grape was 0.003 ppm, and the LOQ was 0.01 ppm.

C. RESULTS AND DISCUSSION

Concurrent method recovery data are presented in Table C.1. The data indicate that LC/MS/MS Method GRM 04.09 is adequate for the determination of residues of penoxsulam in/on grape. Concurrent method recoveries were within the acceptable range of 70-120%. Apparent residues of penoxsulam were not detected (<0.003 ppm) in/on five control samples of grape.

The results of the storage stability study are presented in Table C.2. The data indicate that residues of penoxsulam are stable in/on grape stored frozen for up to 359 days; corrected recoveries were 99-102% throughout the study. A graph of the residue stability of penoxsulam in/on grape is presented in Figure C.1 (copied without alteration from MRID 47444402).

TABLE C.1. Summary of Concurrent Recoveries of Penoxsulam from Grape.

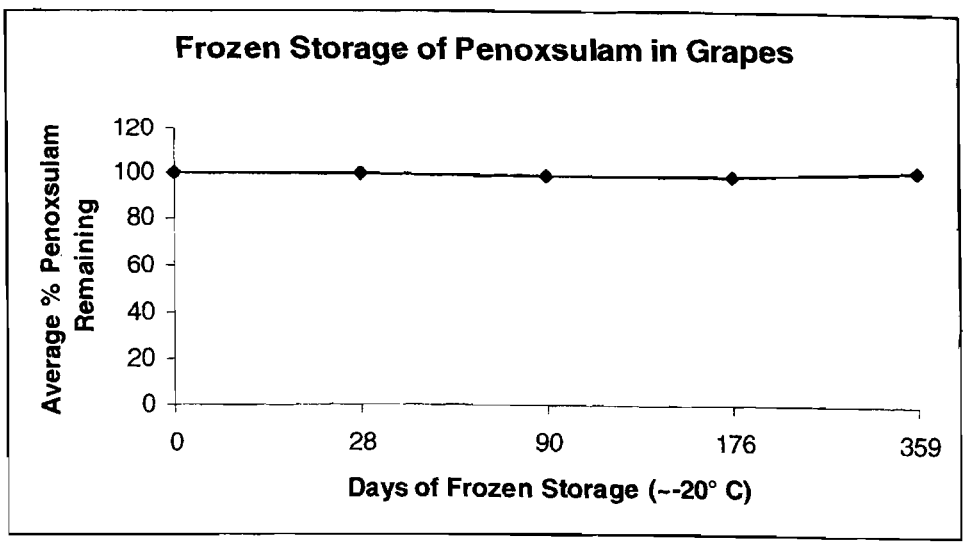
Matrix	Spike Level (ppm)	Storage Interval (days)	Sample Size (n)	Recoveries (%)	Mean (%)
Grape	0.10	0	2	87, 94	91
		28	2	89, 93	91
		90	2	87, 89	88
		176	2	95, 98	97
		359	2	87, 88	88

TABLE C.2. Stability of Penoxsulam Residues in Grape Following Storage at ~-20°C.

Commodity	Spike Level (ppm)	Storage Interval (days)	Recovered Residues (ppm)	Mean Recovered Residues (ppm)	Mean Recovery (%)	Corrected Recovery[1] (%)
Grape	0.10	0	0.0899, 0.0906, 0.0916	0.0907	90.7	100
		28	0.0889, 0.0920, 0.0920	0.0910	91.0	100
		90	0.0872, 0.0876, 0.0884	0.0877	87.7	100
		176	0.0949, 0.0953, 0.0966	0.0956	95.6	99
		359	0.0873, 0.0881, 0.0931	0.0895	89.5	102

[1] Corrected for mean concurrent recovery (see Table C.1.).

FIGURE C.1. Graph of Residue Stability of Penoxsulam in Grape.



D. CONCLUSION

The submitted storage stability results adequately demonstrate the stability of penoxsulam in/on grape stored frozen at ~-20 °C for up to 359 days (11.8 months). An acceptable method was used for the quantitation of residues.

E. REFERENCES

DP#:	326985
Subject:	Penoxsulam. Section 3 Registration Application for Use of GF-443 SC in Aquatic Sites and Request for a Tolerance Exemption (PP#5F7012) on Fish and Shellfish. Summary of Analytical Chemistry and Residue Data.
From:	D. Soderberg
To:	J. Miller
Dated:	1/30/07
MRIDs:	46703504-46703507, and 46703509

F. DOCUMENT TRACKING

Petition Number: 8F7369
DP#: 355914
PC Code: 119031

Template Version June 2005

Penoxsulam/XDE-638/PC Code 119031/Dow AgroSciences LLC
DACO 7.4.1/7.4.2/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial/Residue Decline - Grape

Primary Evaluator — Michael A. Doherty, Chemist, RAB II — Date: 1/21/09

Peer Reviewer — Dennis McNeilly, Chemist, RAB II — Date: 1/21/09

This DER was originally prepared under contract by Dynamac Corporation (2275 Research Boulevard, Suite 300; Rockville, MD 20850; submitted 11/17/2008). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

47444403 Rosser, S.; Schelle, G. (2008) Residues of Penoxsulam in Grapes. Project Number: 070001. Unpublished study prepared by Dow AgroSciences, LLC. 49 p.

EXECUTIVE SUMMARY:

Dow AgroSciences has submitted crop field trial data for penoxsulam on grape. Four grape field trials were conducted in the United States in Zones 1 (NY; 1 trial), 10 (CA; 2 trials), and 11 (WA; 1 trial), during the 2007 growing season.

At each test location, two soil applications were made with a 25 g/L oil dispersion (OD) formulation of penoxsulam. The first application was made near the end of the grape vine dormant stage (bud swell; BBCH 0-5) at a target rate of 0.0357 lb ai/A, and the second application was made 81-130 days later, during the growing stage (BBCH 77-79), at a target rate 0.0179 lb ai/A, for a total seasonal rate of ~0.054 lb ai/A. Broadcast applications were made to the vineyard floor using ground equipment, in ~20-26 gal/A spray volumes with crop oil concentrate as an adjuvant. Samples of untreated and treated grapes were harvested at commercial maturity, 59-60 days after the last application.

Grape samples were analyzed for residues of penoxsulam using LC/MS/MS Method GRM 04.09, which is the same as method GRM 05.08, used for the determination of residues of penoxsulam in fish and shellfish (PP#5F7012) and is similar to the enforcement method (LC/MS/MS GRM 01.25; PP#3F6542) for rice, except that an isotopic internal standard is used for Methods GRM 04.09 and GRM 05.08. The method was adequate based on acceptable concurrent method recoveries. The validated limit of quantitation (LOQ) was 0.01 ppm for grapes.

The maximum storage duration for grape samples was 232 days (7.6 months). Adequate storage stability data were submitted in conjunction with the subject petition to the support storage conditions and durations of samples from the grape field trials.

Residues of penoxsulam were nonquantifiable (<0.01 ppm) in/on all samples of grape harvested 59-60 days following two soil broadcast applications of the 25 g/L OD formulation of penoxsulam, made at the end of dormancy and during the growing stage, for a total rate of 0.054-0.056 lb ai/A.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 355914.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an impact on the validity of the study.

A. BACKGROUND INFORMATION

Penoxsulam is a sulfonamide herbicide currently registered for the selective control of grasses, broadleaf weeds, and sedge weeds. The herbicide's mode of action at the cellular level involves the inhibition of acetolactate synthase (ALS). In the U.S., it was first registered for use on rice and subsequently has been registered for use on turf and in aquatic weed control. Dow AgroSciences has submitted a petition for use on grapes and tree nuts including pistachio. The nomenclature of penoxsulam is summarized in Table A.1, and the physicochemical properties are summarized in Table A.2. The proposed use allows broadcast or banded soil application to the orchard/vineyard floor as a winter dormant application followed by an application in the spring, for a maximum seasonal rate of 0.047 lb ai/A, with a minimum retreatment interval (RTI) of 30 days and a preharvest interval (PHI) of 60 days for grapes and tree nuts.

TABLE A.1. Penoxsulam Nomenclature.

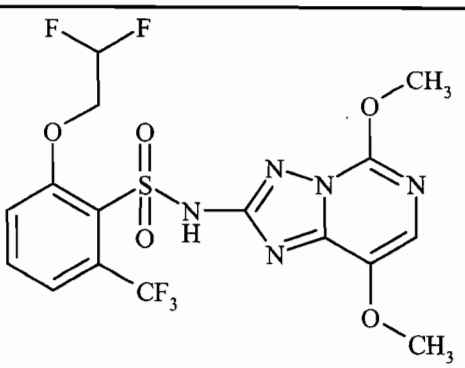
Compound	
Common name	Penoxsulam
Company experimental name	XDE-638
IUPAC name	6-(2,2-difluoroethoxy)-N-(5,8-dimethoxy-s-triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluoro-o-toluenesulfonamide

TABLE A.1. Penoxsulam Nomenclature.	
CAS name	2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c] pyrimidin-2-yl)-6-(trifluoromethyl) benzenesulfonamide
CAS registry number	219714-96-2
End-use product (EP)	GF-443 T&V Herbicide (EPA File Symbol No. 62719-ANG)

TABLE A.2. Physicochemical Properties of Penoxsulam.			
Parameter	Value		Reference [1]
Melting point/range	Not available		
pH	5.2		MRID 45830707
Density	1.61 g/mL at 20 °C		MRID 45830707
Water solubility at 19 °C	Unbuffered pH 5 pH 7 pH 9	4.91 mg/L 5.66 mg/L 408 mg/L 1460 mg/L	MRID 45830720
Solvent solubility at 19 °C	Xylene 1-Octanol Methanol Ethyl acetate Acetonitrile Acetone Dimethylsulfoxide	0.017 g/L 0.035 g/L 1.48 g/L 3.23 g/L 15.3 g/L 20.3 g/L 78.4 g/L	MRID 45830720
Vapor pressure	7.16×10^{-16} mm Hg at 25 °C		MRID 45830720
Dissociation constant, pK_a	5.1 (ambient)		MRID 45830720
Octanol/water partition coefficient, $Log(K_{OW})$	Unbuffered pH 5 pH 7 pH 9	-0.354 1.137 -0.602 -1.418	MRID 45830720
UV/visible absorption spectrum	Not available		

[1] As referenced in DP# 326985, 1/30/07, D. Soderberg.

B. EXPERIMENTAL DESIGN

Four grape field trials were conducted in the United States in Zones 1 (NY; 1 trial), 10 (CA; 2 trials), and 11 (WA; 1 trial), during the 2007 growing season. Each trial site included one untreated and one treated plot; each plot consisted of a minimum of 14 vines.

At each test location, two soil applications were made with a 25 g/L OD formulation of penoxsulam. The first application was made near the end of the grape vine dormant stage (bud swell; BBCH 0-5) at a target rate of 0.0357 lb ai/A, and the second application was made 81-130 days later, during the growing stage (BBCH 77-79), at a target rate 0.0179 lb ai/A, for a total seasonal rate of ~0.054 lb ai/A. Broadcast applications were made to the vineyard floor using ground equipment, in ~20-26 gal/A spray volumes with crop oil concentrate as an adjuvant. The study use pattern is presented in Table B.1.2.

Test site conditions are reported in Table B.1.1. The crop varieties grown are identified in Table C.3. The test crops were grown and maintained according to normal agricultural practices for each region; maintenance pesticides and fertilizers were used to produce a commercial quality crop. For each trial, monthly mean maximum and minimum temperatures and monthly total

rainfall amounts were provided, along with historical averages (time period was not specified). No unusual weather events were reported; the petitioner stated that temperature recordings were near average historical values for the study period, and that rainfall during the trial period was slightly lower at all trial sites compared to historical average rainfall amounts. Irrigation was used to supplement rainfall at all sites except the NY site. Approximately 0.5 inches of water was applied by flood or sprinkler irrigation within 7 days after each application, if that amount of rainfall did not occur during that period. At the CA1 trial site drip irrigation was used instead. At the CA2 site, furrow irrigation was applied after each application, and the irrigation water rose over the furrow covering the entire field. This was judged not to have an adverse effect on the trial.

B.1. Study Site Information

TABLE B.1.1. Trial Site Conditions.

Trial Identification: City, State; Year (Trial ID No.)	Soil characteristics			
	Type	%OM	pH	CEC
Plainview, CA; 2007 (070001-CA1)	Loam	0.9	6.5	NR[1]
Kingsburg, CA; 2007 (070001-CA2)	Sandy loam	1-2	~6-7	NR
Dundee, NY; 2007 (070001-NY1)	Sandy clay loam	2.6	5.0	NR
Ephrata, WA; 2007 (070001-WA1)	Sandy loam	1.0	7.6	NR

[1] NR= Not reported

TABLE B.1.2. Study Use Pattern.

Location: City, State; Year (Trial ID No.)	EP[1]	Application					Tank Mix/ Adjuvants[3]
		Method; Timing	Volume (gal/A)	Rate (lb ai/A)	RTI[2] (days)	Total Rate (lb ai/A)	
Plainview, CA; 2007 (070001-CA1)	25 g/L OD	1. Soil broadcast; BBCH 00-01	24.8	0.036	--	0.054	COC
		2. Soil broadcast; BBCH 77-79	25.1	0.018	130		
Kingsburg, CA; 2007 (070001-CA2)	25 g/L OD	1. Soil broadcast; BBCH 00-01	25.0	0.036	--	0.054	COC
		2. Soil broadcast; BBCH 77-79	25.6	0.018	87		
Dundee, NY; 2007 (070001-NY1)	25 g/L OD	1. Soil broadcast; BBCH 01-05	21.0	0.038	--	0.056	COC
		2. Soil broadcast; BBCH 77-79	20.2	0.018	81		
Ephrata, WA; 2007 (070001-WA1)	25 g/L OD	1. Soil broadcast; BBCH 01-03	24.3	0.036	--	0.054	COC
		2. Soil broadcast; BBCH 77-79	25.1	0.018	110		

[1] EP = End-use Product
[2] RTI = Retreatment Interval
[3] COC = Crop oil concentrate (1.25% v:v)

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones	Grape		
	Submitted	Requested	
		Canada	U.S.[1]
1	1		2 (2)
1A			
2			
3			
4			
5			
5A			
5B			
6			
7			
7A			
8			
9			
10	2		8 (5)
11	1		2 (2)
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
Total	4		12 (9)

As per OPPTS 860.1500, Tables 1 and 5 for grape; number of trials for a 25% reduction due to nonquantifiable residues are reported in parentheses. The Agency determined (Minutes of the 1/24/07 ChemSAC Meeting) that a reduced number of trials (4) would be acceptable, based on the expectation that residues would be nondetectable.

B.2. Sample Handling and Preparation

Single untreated control and duplicate treated grape samples, each weighing at least 1 kg, were collected at commercial maturity (BBCH 87-89), 59-60 days after the last application. Samples were frozen within 4 hours of sampling and were maintained frozen at the field sites for 11-35 days prior to shipment by freezer truck to Dow AgroSciences (Indianapolis, IN) for analysis.

At Dow AgroSciences, samples were prepared for analysis by grinding in the presence of liquid nitrogen. Samples remained in frozen storage (~-20 °C) at all times aside from homogenization and subsampling for analysis.

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B.3. Analytical Methodology

Residues of penoxsulam were determined in grape using LC/MS/MS Method GRM 04.09, entitled "Determination of Residues of Penoxsulam in Agricultural Commodities by High Performance Liquid Chromatography with Tandem Mass Spectrometry Detection." This method is the same as method GRM 05.08, used for the determination of residues of penoxsulam in fish and shellfish (DP# 326985, 1/30/07, D. Soderburg) and is similar to the enforcement method (LC/MS/MS GRM 01.25; DP# 288152, 8/11/04, W. Cutchin) for rice, except that an isotopic internal standard is used for Methods GRM 04.09 and GRM 05.08. Only a brief description of method GRM 04.09 was provided in the subject submission.

Briefly, homogenized grape samples were extracted with acetonitrile (ACN):water (80:20, v:v). The extract was diluted with 0.1 N HCl and purified through a 96-well polymeric reverse phase solid phase extraction (SPE) plate. Residues were eluted with ACN into another 96-well SPE plate containing ACN:methanol:water (15:15:70, v:v:v, containing 0.1% acetic acid) mobile phase and a stable isotope internal standard. The final solution was analyzed by LC/MS/MS for residues of penoxsulam. The reported method limit of detection (LOD) for penoxsulam in grape was 0.003 ppm, and the LOQ was 0.01 ppm.

C. RESULTS AND DISCUSSION

Sample storage conditions and durations for grape are presented in Table C.2. Storage durations for grape samples were 179-232 days (5.9-7.6 months). Storage stability data submitted in conjunction with the subject petition (47444402.der.doc) indicate that residues of penoxsulam are stable in/on grape stored frozen for up to 359 days (11.8 months). These data are adequate to support the storage conditions and durations of samples from the grape field trials.

Concurrent method recovery data are presented in Table C.1. The LC/MS/MS Method GRM 04.09 used to analyze grape samples for residues of penoxsulam is adequate for data collection based on acceptable concurrent method recovery data. Concurrent method recoveries were within the acceptable range of 70-120% for untreated grape fortified with penoxsulam at 0.01 or 0.1 ppm. Apparent residues of penoxsulam were nondetectable (<LOD; <0.003 ppm) in/on four samples of untreated grape. The validated LOQ was 0.01 ppm for penoxsulam in/on grape. Adequate sample calculations and chromatograms were provided.

Residue data from the grape field trials with penoxsulam are reported in Table C.3. A summary of the grape field trial data is presented in Table C.4. Residues of penoxsulam were nonquantifiable (<0.01 ppm) in/on all samples of grape harvested 59-60 days following two soil broadcast applications of the 25 g/L OD formulation of penoxsulam, made at the end of dormancy and during the growing stage, for a total rate of 0.054-0.056 lb ai/A.

TABLE C.1. Summary of Concurrent Recoveries of Penoxsulam from Grape.

Matrix	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean ± Std. Dev.[1] (%)
Grape	0.01	3	87, 88, 93	89 ± 3
	0.1	2	87, 93	90

[1] Standard deviation is only applicable for sample sizes of n ≥ 3 samples.

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1]	Interval of Demonstrated Storage Stability
Grape	~-20	179-232 days (5.9-7.6 months)	Residues of penoxsulam are stable in/on grape stored frozen for up to 359 days (11.8 months).[2]

[1] Actual storage duration from harvest to analysis. Samples were analyzed on the day of extraction.
[2] Refer to 47444402.der.doc.

TABLE C.3. Residue Data from Crop Field Trials with Penoxsulam.

Trial: City, State; Year (Trial ID No.)	Zone	Grape Variety	Commodity or Matrix	Total Rate (lb ai/A)	PHI (days)	Penoxsulam residues (ppm)
Plainview, CA; 2007 (070001-CA1)	10	Crimson	Fruit	0.054	59	ND[1], ND
Kingsburg, CA; 2007 (070001-CA2)	10	Thompson	Fruit	0.054	60	ND, ND
Dundee, NY; 2007 (070001-NY1)	1	Concord	Fruit	0.056	60	ND, ND
Ephrata, WA; 2007 (070001-WA1)	11	White Riesling	Fruit	0.054	59	ND, ND

[1] ND= Not detected. Residues were below the LOD (<0.003 ppm).

TABLE C.4. Summary of Residue Data from Crop Field Trials with Penoxsulam.

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)[1]						
			n	Min.	Max.	HAFT[2]	Median (STMdR)	Mean (STMR)	Std. Dev.
Grape	0.054-0.056	59-60	8	<0.01	<0.01	<0.01	<0.01	<0.01	--

[1] The LOQ (<0.01 ppm) was used for residues reported below the LOQ in Table C.3.
[2] HAFT = Highest Average Field Trial.

D. CONCLUSION

The submitted field trial data reflect the use of two soil broadcast applications to grape, at the end of the dormant growing stage and during the growing stage, for a total seasonal rate of 0.054-0.056 lb ai/A, with a 59- to 60-day PHI. An acceptable method was used for the quantitation of residues of penoxsulam, and the study is supported by adequate storage stability data.

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E. REFERENCES

DP#:	288152
Subject:	Penoxsulam. Petition for the Establishment of Permanent Tolerances for the Use on Rice. Summary of Analytical Chemistry and Residue Data. PP#3F6542.
From:	W. Cutchin
To:	P. Errico/J. Miller
Dated:	8/11/04
MRIDs:	45830712-45830717, 45830719-45830720, and 46267601

DP#:	326985
Subject:	Penoxsulam. Section 3 Registration Application for Use of GF-443 SC in Aquatic Sites and Request for a Tolerance Exemption (PP#5F7012) on Fish and Shellfish. Summary of Analytical Chemistry and Residue Data.
From:	D. Soderberg
To:	J. Miller
Dated:	1/30/07
MRIDs:	46703504-46703507, and 46703509

DP#:	None; Min_340.1-24-07.doc
Subject:	Minutes of the 1/24/2007 ChemSAC Meeting: 2. Penoxsulam tree & vine use proposal (R. Loranger).
From:	Chemistry Science Advisory Council
To:	Chemistry Interest Group, HED
Dated:	NA
MRIDs:	None

F. DOCUMENT TRACKING

Petition Number: 8F7369
DP#: 355914
PC Code: 119031

Template Version June 2005

Penoxsulam/XDE-638/PC Code 119031/Dow AgroSciences LLC
DACO 7.4.5/OPPTS 860.1520/OECD IIA 6.5.4 and IIIA 8.5
Processed Food and Feed - Grape

Primary Evaluator — Michael A. Doherty, Chemist, RAB II — Date: 1/21/09

Peer Reviewer — Dennis McNeilly, Chemist, RAB II — Date: 1/21/09

This DER was originally prepared under contract by Dynamac Corporation (2275 Research Boulevard, Suite 300; Rockville, MD 20850; submitted 11/17/2008). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

47444403 Rosser, S.; Schelle, G. (2008) Residues of Penoxsulam in Grapes. Project Number: 070001. Unpublished study prepared by Dow AgroSciences, LLC. 49 p.

EXECUTIVE SUMMARY:

Dow AgroSciences has submitted a processing study for penoxsulam on grape. In a single crop field trial conducted in NY during the 2007 growing season, two soil applications were made with a 25 g/L oil dispersion (OD) formulation of penoxsulam. The first application was made near the end of the grape vine dormant stage (bud swell) at 0.180 lb ai/A, and the second application was made 81 days later, during the growing stage, at 0.090 lb ai/A, for a total seasonal rate of 0.270 lb ai/A (5x the nominal field trial rate). Broadcast applications were made to the vineyard floor using ground equipment, in ~20 gal/A spray volumes with crop oil concentrate as an adjuvant. Mature grape was harvested 60 days after the second application and processed into juice and raisins using procedures simulating commercial practices.

Grape, grape juice, and raisin samples were analyzed for residues of penoxsulam using LC/MS/MS Method GRM 04.09, which is the same as method GRM 05.08, used for the determination of residues of penoxsulam in fish and shellfish (PP#5F7012) and is similar to the enforcement method (LC/MS/MS GRM 01.25; PP#3F6542) for rice, except that an isotopic internal standard is used for Methods GRM 04.09 and GRM 05.08. The method is adequate based on acceptable concurrent method recoveries. The validated limit of quantitation (LOQ) is 0.01 ppm for grape, juice, and raisin.

Processing commenced within 6 days of harvest; the maximum storage duration from harvest/processing to analysis was 195 days (6.4 months) for grape, juice, and raisin samples. Adequate storage stability data were submitted in conjunction with the subject petition to the support storage conditions and durations of grape samples from the processing study; supporting storage stability data will not be required for grape juice or raisins because residues were nondetectable in/on the grape RAC treated at an exaggerated rate.

Residues of penoxsulam were nonquantifiable (<0.01 ppm) in/on grape following two soil broadcast applications of the 25 g/L OD formulation of penoxsulam, made at the end of dormancy and during the growing stage, for a total rate of 0.270 lb ai/A. Following processing, residues of penoxsulam were also nonquantifiable in grape juice and raisin. Because residues were nonquantifiable in both the RAC and the processed fractions, no processing factors could be calculated.

The theoretical concentration factor for grape juice, based on separation into components, is 1.2x, and the theoretical concentration factor for raisins, based on loss of water, is 4.7x (OPPTS 860.1520, Tables 2 and 3).

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the processed commodity residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 355914.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an impact on the validity of the study.

A. BACKGROUND INFORMATION

Penoxsulam is a sulfonamide herbicide currently registered for the selective control of grasses, broadleaf weeds, and sedge weeds. The herbicide's mode of action at the cellular level involves the inhibition of acetolactate synthase (ALS). In the U.S., it was first registered for use on rice and subsequently has been registered for use on turf and in aquatic weed control. Dow AgroSciences has submitted a petition for use on grapes and tree nuts including pistachio. The nomenclature of penoxsulam is summarized in Table A.1, and the physicochemical properties are summarized in Table A.2. The proposed use allows broadcast or banded soil application to the orchard/vineyard floor as a winter dormant application followed by an application in the spring, for a maximum seasonal rate of 0.047 lb ai/A, with a minimum retreatment interval (RTI) of 30 days and a preharvest interval (PHI) of 60 days for grapes and tree nuts.

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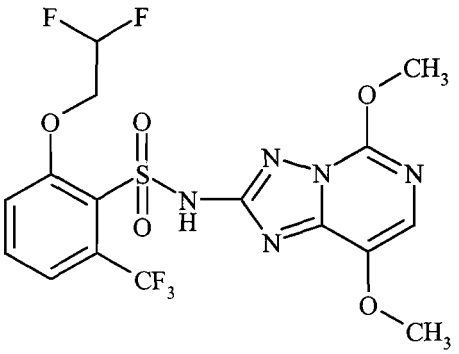
TABLE A.1. Penoxsulam Nomenclature.	
Compound	
Common name	Penoxsulam
Company experimental name	XDE-638
IUPAC name	6-(2,2-difluoroethoxy)-N-(5,8-dimethoxy-s-triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluoro-o-toluenesulfonamide
CAS name	2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c] pyrimidin-2-yl)-6-(trifluoromethyl) benzenesulfonamide
CAS registry number	219714-96-2
End-use product (EP)	GF-443 T&V Herbicide (EPA File Symbol No. 62719-ANG)

TABLE A.2. Physicochemical Properties of Penoxsulam.			
Parameter	Value		Reference [1]
Melting point/range	Not available		
pH	5.2		MRID 45830707
Density	1.61 g/mL at 20 °C		MRID 45830707
Water solubility at 19 °C	Unbuffered pH 5 pH 7 pH 9	4.91 mg/L 5.66 mg/L 408 mg/L 1460 mg/L	MRID 45830720
Solvent solubility at 19 °C	Xylene 1-Octanol Methanol Ethyl acetate Acetonitrile Acetone Dimethylsulfoxide	0.017 g/L 0.035 g/L 1.48 g/L 3.23 g/L 15.3 g/L 20.3 g/L 78.4 g/L	MRID 45830720
Vapor pressure	7.16×10^{-16} mm Hg at 25 °C		MRID 45830720
Dissociation constant, pK_a	5.1 (ambient)		MRID 45830720
Octanol/water partition coefficient, $Log(K_{OW})$	Unbuffered pH 5 pH 7 pH 9	-0.354 1.137 -0.602 -1.418	MRID 45830720
UV/visible absorption spectrum	Not available		

[1] As referenced in DP# 326985, 1/30/07, D. Soderberg.

B. EXPERIMENTAL DESIGN

B.1. Application and Crop Information

In a single crop field trial conducted in NY during the 2007 growing season, two soil applications were made with a 25 g/L OD formulation of penoxsulam. The first application was made near the end of the grape vine dormant stage (bud swell; BBCH 01-05) at 0.180 lb ai/A, and the second application was made 81 days later, during the growing stage (BBCH 77-79), at 0.090 lb ai/A, for a total seasonal rate of 0.270 lb ai/A. Broadcast applications were made to the vineyard floor using ground equipment, in ~20 gal/A spray volumes with crop oil concentrate as an adjuvant. The study use pattern is reported in Table B.1.1.

The test crops were grown and maintained according to normal agricultural practices for the region; maintenance pesticides and fertilizers were used to produce a commercial quality crop. Monthly mean maximum and minimum temperatures and monthly total rainfall amounts were provided, along with historical averages (time period was not specified). No unusual weather events were reported; the petitioner states that temperature recordings were near average historical values for the study period, and that rainfall during the trial period was slightly lower compared to historical average rainfall amounts.

TABLE B.1.1. Study Use Pattern.

Location: County, State; Year (Trial ID No.)	EP[1]	Application					Tank Mix/ Adjuvants
		Method; Timing	Volume (gal/A)	Rate (lb ai/A)	RTI[2] (days)	Total Rate (lb ai/A)	
Dundee, NY; 2007 (070001-NY1)	25 g/L OD	1. Soil broadcast; BBCH 01-05	20.2	0.180	--	0.270	Crop Oil Concentrate (1.25% v:v)
		2. Soil broadcast; BBCH 77-79	20.2	0.090	81		

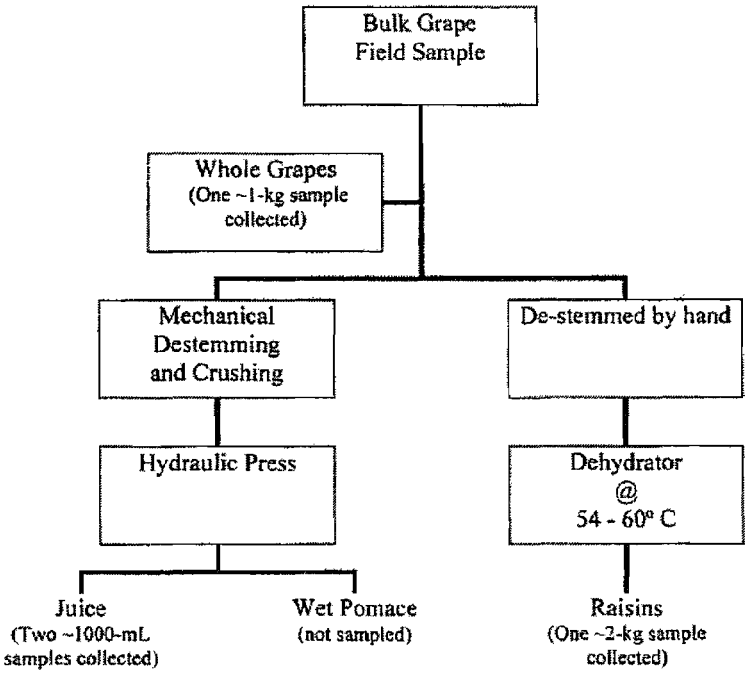
[1] EP = End-use Product
[2] RTI = Retreatment Interval

B.2. Sample Handling and Processing Procedures

Bulk samples, weighing at least 20 kg, of treated and untreated whole grapes were harvested at commercial maturity, 60 days after the second application. Samples were delivered to the processing facility, ACDS Research, Inc. (North Rose, NY), at ambient temperatures on the day of collection. Samples received at the processing facility were stored in a cooler at ~6 °C until processing.

Whole grape RAC subsamples were collected at the processing facility prior to processing into juice and raisins. Processing was initiated 6 days after receipt using simulated commercial practices. The grape processing procedures are summarized in Figure B.2.1, which was copied without alteration from MRID 47444403. Grape and processed juice and raisin samples were stored frozen and shipped via freezer truck to Dow AgroSciences (Indianapolis, IN), where they were stored frozen (~-20 °C) prior to analysis. All samples except juice were prepared for analysis by grinding in the presence of liquid nitrogen.

FIGURE B.2.1. Processing Flowchart for Grape.



B.3. Analytical Methodology

Residues of penoxsulam were determined in grape and processed fractions using LC/MS/MS Method GRM 04.09, entitled "Determination of Residues of Penoxsulam in Agricultural Commodities by High Performance Liquid Chromatography with Tandem Mass Spectrometry Detection." This method is the same as method GRM 05.08, used for the determination of residues of penoxsulam in fish and shellfish (DP# 326985, 1/30/07, D. Soderburg) and is similar to the enforcement method (LC/MS/MS GRM 01.25; DP# 288152, 8/11/04, W. Cutchin) for rice, except that an isotopic internal standard is used for Methods GRM 04.09 and GRM 05.08. Only a brief description of method GRM 04.09 was provided in the subject submission.

Briefly, juice or homogenized grape or raisin samples were extracted with acetonitrile (ACN):water (80:20, v:v). The extract was diluted with 0.1 N HCl and purified through a 96-well polymeric reverse phase solid phase extraction (SPE) plate. Residues were eluted with ACN into another 96-well SPE plate containing ACN:methanol:water (15:15:70, v:v:v, containing 0.1% acetic acid) mobile phase and a stable isotope internal standard. The final solution was analyzed by LC/MS/MS for residues of penoxsulam. The reported method limit of detection (LOD) for penoxsulam in grape was 0.003 ppm, and the LOQ was 0.01 ppm.

C. RESULTS AND DISCUSSION

Sample storage conditions and durations are summarized in Table C.2. Grape samples were processed within 6 days of harvest, and the RAC, juice, and raisin samples were stored frozen for 187-195 days (6.2-6.4 months) prior to analysis. Storage stability data submitted in conjunction

with the subject petition (47444402.der.doc) indicate that residues of penoxsulam are stable in/on grape stored frozen for up to 359 days (11.8 months). These data are adequate to support storage conditions and durations of RAC samples from the grape processing study. Supporting storage stability data will not be required for grape juice or raisins because residues were nondetectable in/on the grape RAC treated at an exaggerated rate.

Concurrent method recovery data are presented in Table C.1. The LC/MS/MS Method GRM 04.09 used to analyze grape and processed samples for residues of penoxsulam is adequate for data collection based on acceptable concurrent method recovery data. Concurrent method recoveries were within the acceptable range of 70-120% for untreated grape, juice, and raisin fortified with penoxsulam at 0.01 or 0.1 ppm. Apparent residues of penoxsulam were nondetectable (<LOD; <0.003 ppm) in/on one sample each of untreated grape and raisin, and two samples of untreated grape juice. The validated LOQ was 0.01 ppm for penoxsulam in/on all grape matrices. Adequate sample calculations and chromatograms were provided.

Residue data from the grape processing study are reported in Table C.3. Residues of penoxsulam were nonquantifiable (<0.01 ppm) in/on grape following two soil broadcast applications of the 25 g/L OD formulation of penoxsulam, made at the end of dormancy and during the growing stage, for a total rate of 0.270 lb ai/A. Following processing, residues of penoxsulam were also nonquantifiable in grape juice and raisin. Because residues were nonquantifiable in both the RAC and the processed fractions, no processing factors could be calculated.

The theoretical concentration factor for grape juice, based on separation into components, is 1.2x, and the theoretical concentration factor for raisins, based on loss of water, is 4.7x (OPPTS 860.1520, Tables 2 and 3).

TABLE C.1. Summary of Concurrent Recoveries of Penoxsulam from Grape Matrices.

Matrix	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean ± Std. Dev.[1] (%)
Grape [2]	0.01	3	87, 88, 93	89 ± 3
	0.1	2	87, 93	90
Grape juice	0.01	3	85, 87, 88	87 ± 2
	0.1	2	81, 81	81
Raisins	0.01	3	83, 90, 94	89 ± 6
	0.1	2	88, 89	89

[1] Standard deviation is only applicable for sample sizes of n ≥ 3 samples.
[2] The reported recoveries for grape are the same as those reported for the field trial study (47444403.de1.doc).

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1]	Interval of Demonstrated Storage Stability
Grape	~-20	195 days (6.4 months)	Residues of penoxsulam are stable in/on grape stored frozen for up to 359 days (11.8 months).[2]
Grape, juice		189 days (6.2 months)	None available
Raisin		187 days (6.2 months)	

[1] Actual storage duration from harvest/processing to analysis. Samples were analyzed on the day of extraction.

[2] Refer to 47444402.der.doc.

TABLE C.3. Residue Data from Grape Processing Study with Penoxsulam.

RAC	Processed Commodity	Total Rate (lb ai/A)	PHI (days)	Residues (ppm)	Processing Factor
Grape	Fruit (RAC)	0.270	60	ND[1], ND	--
	Juice			ND, ND	NC[2]
	Raisin			ND, ND	NC

[1] ND = Not detected. Residues were below the LOD (<0.003 ppm).
[2] NC = Not calculated. Residues were below the LOQ (<0.01 ppm) in both the RAC and processed samples.

D. CONCLUSION

The processing study demonstrates that residues of penoxsulam were nonquantifiable in/on grape and its processed commodities, juice and raisin following two soil applications, at the end of the dormant growing stage and during the growing stage, for a total seasonal rate of 0.270 lb ai/A, with a 60-day PHI. An acceptable method was used for quantitation of residues in/on grape, juice, and raisin, and the study is supported by adequate storage stability data.

E. REFERENCES

DP#: 288152
Subject: Penoxsulam. Petition for the Establishment of Permanent Tolerances for the Use on Rice. Summary of Analytical Chemistry and Residue Data. PP#3F6542.
From: W. Cutchin
To: P. Errico/J. Miller
Dated: 8/11/04
MRIDs: 45830712-45830717, 45830719-45830720, and 46267601

DP#: 326985
Subject: Penoxsulam. Section 3 Registration Application for Use of GF-443 SC in Aquatic Sites and Request for a Tolerance Exemption (PP#5F7012) on Fish and Shellfish. Summary of Analytical Chemistry and Residue Data.
From: D. Soderberg
To: J. Miller
Dated: 1/30/07
MRIDs: 46703504-46703507, and 46703509

F. DOCUMENT TRACKING

Petition Number: 8F7369
DP#: 355914
PC Code: 119031

Template Version June 2005

Penoxsulam/XDE-638/PC Code 119031/Dow AgroSciences LLC
DACO 7.4.1/7.4.2/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial/Residue Decline – Tree Nuts, Crop Group 14

Primary Evaluator Michael A. Doherty Date: 1/21/09
Michael A. Doherty, Chemist, RAB II

Peer Reviewer Dennis McNeilly Date: 1/21/09
Dennis McNeilly, Chemist, RAB II

This DER was originally prepared under contract by Dynamac Corporation (2275 Research Boulevard, Suite 300; Rockville, MD 20850; submitted 11/17/2008). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORTS:

47444404 Rosser, S.; Schelle, G. (2008) Residues of Penoxsulam in Almonds. Project Number: 070002. Unpublished study prepared by Dow AgroSciences, LLC. 41 p.

47444405 Rosser, S.; Schelle, G. (2008) Residues of Penoxsulam in Pecans. Project Number: 070003. Unpublished study prepared by Dow AgroSciences, LLC. 35 p.

EXECUTIVE SUMMARY:

Dow AgroSciences has submitted crop field trial data for penoxsulam on almonds and pecans, the representative crops of the tree nut crop group 14. Six tree nut trials were conducted in the United States during the 2007 growing season. Three almond trials were conducted in Zone 10 (CA), and three pecan trials were conducted in Zones 2 (GA), 4 (LA), and 8 (TX).

At each test location, two soil applications were made with a 25 g/L oil dispersion (OD) formulation of penoxsulam. The first application was made near the end of the dormant stage (bud swell) at a target rate of 0.0446 lb ai/A, and the second application was made 125-196 days later, during the growing stage, at a target rate of 0.0178 lb ai/A, for a total seasonal rate of ~0.062 lb ai/A. Broadcast applications were made to the orchard floor using ground equipment, in ~21-29 gal/A spray volumes with crop oil concentrate as an adjuvant. Samples of untreated and treated almond nutmeat and hulls, and pecan nutmeat were harvested at commercial maturity, 55-60 days after the last application.

Nutmeat and hull samples were analyzed for residues of penoxsulam using LC/MS/MS Method GRM 04.09, which is the same as method GRM 05.08, used for the determination of residues of penoxsulam in fish and shellfish (PP#5F7012) and is similar to the enforcement method (LC/MS/MS GRM 01.25; PP#3F6542) for rice, except that an isotopic internal standard is used for Methods GRM 04.09 and GRM 05.08. The method is adequate based on acceptable concurrent method recoveries. The validated limit of quantitation (LOQ) is 0.01 ppm for nutmeat and hulls.

The maximum storage durations for treated samples were 234 days (7.7 months) for almond nutmeat and hulls, and 151 days (5.0 months) for pecan nutmeat. No storage stability data were submitted for tree nuts.

Residues of penoxsulam were nonquantifiable (<0.01 ppm) in/on all samples of almond nutmeat, almond hull and pecan nutmeat harvested 55-60 days following two soil broadcast applications of the 25 g/L OD formulation of penoxsulam, made at the end of dormancy and during the growing stage, for a total rate of 0.062-0.064 lb ai/A.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Storage stability data were not submitted for tree nut samples. However, the available data for other crops indicate that penoxsulam is stable under frozen storage conditions for the duration that tree nut samples were stored and are sufficient to support the tree nut samples. Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 355914.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an impact on the validity of the study.

A. BACKGROUND INFORMATION

Penoxsulam is a sulfonamide herbicide currently registered for the selective control of grasses, broadleaf weeds, and sedge weeds. The herbicide's mode of action at the cellular level involves the inhibition of acetolactate synthase (ALS). In the U.S., it was first registered for use on rice and subsequently has been registered for use on turf and in aquatic weed control. Dow AgroSciences has submitted a petition for use on grapes and tree nuts including pistachio. The nomenclature of penoxsulam is summarized in Table A.1, and the physicochemical properties are summarized in Table A.2. The proposed use allows broadcast or banded soil application to the orchard/vineyard floor as a winter dormant application followed by an application in the spring, for a maximum seasonal rate of 0.047 lb ai/A, with a minimum retreatment interval (RTI) of 30 days and a preharvest interval (PHI) of 60 days for grapes and tree nuts.

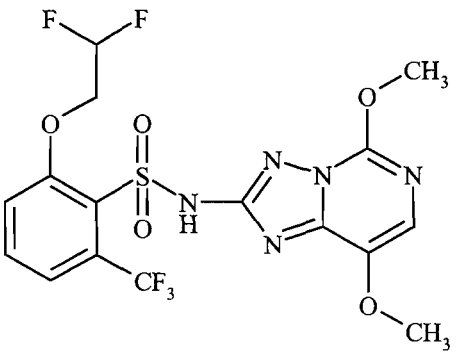
TABLE A.1. Penoxsulam Nomenclature.	
Compound	
Common name	Penoxsulam
Company experimental name	XDE-638
IUPAC name	6-(2,2-difluoroethoxy)-N-(5,8-dimethoxy-s-triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluoro-o-toluenesulfonamide
CAS name	2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c] pyrimidin-2-yl)-6-(trifluoromethyl) benzenesulfonamide
CAS registry number	219714-96-2
End-use product (EP)	GF-443 T&V Herbicide (EPA File Symbol No. 62719-ANG)

TABLE A.2. Physicochemical Properties of Penoxsulam.			
Parameter	Value		Reference [1]
Melting point/range	Not available		
pH	5.2		MRID 45830707
Density	1.61 g/mL at 20 °C		MRID 45830707
Water solubility at 19 °C	Unbuffered pH 5 pH 7 pH 9	4.91 mg/L 5.66 mg/L 408 mg/L 1460 mg/L	MRID 45830720
Solvent solubility at 19 °C	Xylene 1-Octanol Methanol Ethyl acetate Acetonitrile Acetone Dimethylsulfoxide	0.017 g/L 0.035 g/L 1.48 g/L 3.23 g/L 15.3 g/L 20.3 g/L 78.4 g/L	MRID 45830720
Vapor pressure	7.16×10^{-16} mm Hg at 25 °C		MRID 45830720
Dissociation constant, pK_a	5.1 (ambient)		MRID 45830720
Octanol/water partition coefficient, $Log(K_{OW})$	Unbuffered pH 5 pH 7 pH 9	-0.354 1.137 -0.602 -1.418	MRID 45830720
UV/visible absorption spectrum	Not available		

[1] As referenced in DP# 326985, 1/30/07, D. Soderberg.

B. EXPERIMENTAL DESIGN

Six tree nut trials were conducted in the United States during the 2007 growing season. Three almond trials were conducted in Zone 10 (CA), and three pecan trials were conducted in Zones 2

(GA), 4 (LA), and 8 (TX). Each trial site included one untreated and one treated plot; each plot consisted of 6 trees.

At each test location, two soil applications were made with a 25 g/L OD formulation of penoxsulam. The first application was made near the end of the tree nut dormant stage (bud swell) at a target rate of 0.0446 lb ai/A, and the second application was made 125-196 days later, during the growing stage, at a target rate of 0.0178 lb ai/A, for a total seasonal rate of ~0.062 lb ai/A. Broadcast applications were made to the orchard floor using ground equipment, in ~21-29 gal/A spray volumes with crop oil concentrate as an adjuvant. The study use pattern is presented in Table B.1.2.

Test site conditions are reported in Table B.1.1. The crop varieties grown are identified in Table C.3. The test crops were grown and maintained according to normal agricultural practices for each region; maintenance pesticides and fertilizers were used to produce a commercial quality crop. For each trial, monthly mean maximum and minimum temperatures and monthly total rainfall amounts were provided, along with historical averages (time period was not specified). No unusual weather events were reported; the petitioner stated that temperature recordings were near average historical values for the study period, and that rainfall during the trial period was slightly lower at the almond (CA) sites and at one pecan site (GA) compared to historical average rainfall amounts. Irrigation was used to supplement rainfall. Approximately 0.5 inches of water was applied by flood or sprinkler irrigation within 7 days after each application, if that amount of rainfall did not occur during that period.

B.1. Study Site Information

TABLE B.1.1. Trial Site Conditions.

Trial Identification: City, State; Year (Trial ID No.)	Soil characteristics			
	Type	%OM	pH	CEC
Almond Trials				
Terra Bella, CA; 2007 (070002-CA1)	Sandy loam	≤2	~6-7	NR[1]
Wasco, CA; 2007 (070002-CA2)	Clay loam	<2	~6-7	NR
Sanger, CA; 2007 (070002-CA3)	Sandy loam	0.8	7.7	NR
Pecan Trials				
Chula, GA; 2007 (070003-GA1)	Loamy sand	1.3	5.3	NR
Opelousas, LA; 2007 (070003-LA1)	Silty loam	1.8	5.8	NR
Claytonville, TX; 2007 (070003-TX1)	Clay loam	4.1	7.1	NR

[1] NR = Not reported.

TABLE B.1.2. Study Use Pattern.

Location: City, State; Year (Trial ID)	EP[1]	Application					Tank Mix/ Adjuvants[3]
		Method; Timing	Volume (gal/A)	Rate (lb ai/A)	RTI[2] (days)	Total Rate (lb ai/A)	
Almond Trials							
Terra Bella, CA; 2007 (070002-CA1)	25 g/L OD	1. Soil broadcast; bud swell/ 12-14 ft.	28.2	0.044	--	0.062	COC
		2. Soil broadcast; 12-14 ft.	29.2	0.018	125		
Wasco, CA; 2007 (070002-CA2)	25 g/L OD	1. Soil broadcast; bud swell/ 16-20 ft.	28.8	0.045	--	0.063	COC
		2. Soil broadcast; 16-20 ft.	28.8	0.018	134		
Sanger, CA; 2007 (070002-CA3)	25 g/L OD	1. Soil broadcast; bud swell/ 12-14 ft.	24.7	0.045	--	0.063	COC
		2. Soil broadcast; 12-14 ft.	24.4	0.018	156		
Pecan Trials							
Chula, GA; 2007 (070003-GA1)	25 g/L OD	1. Soil broadcast; bud swell/ 35-40 ft.	24.4	0.044	--	0.062	COC
		2. Soil broadcast; 35-40 ft.	21.8	0.018	188		
Opelousas, LA; 2007 (070003-LA1)	25 g/L OD	1. Soil broadcast; bud swell/ 28-30 ft.	20.5	0.046	--	0.064	COC
		2. Soil broadcast; 28-30 ft.	22.1	0.018	180		
Claytonville, TX; 2007 (070003-TX1)	25 g/L OD	1. Soil broadcast; Bud swell/ 30 ft.	20.8	0.045	--	0.063	COC
		2. Soil broadcast; 30 ft.	21.1	0.018	196		

[1] EP = End-use Product
[2] RTI = Retreatment Interval
[3] COC = Crop oil concentrate (1.25% v:v)

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones	Almond			Pecan		
	Submitted	Requested		Submitted	Requested	
		Canada	U.S.[1]		Canada	U.S.[1]
1						
1A						
2				1		2
3						
4				1		1
5						
5A						
5B						
6						1
7						
7A						
8				1		1
9						
10	3		5			
11						
12						
13						
14						
15						
16						
17						

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones	Almond			Pecan		
	Submitted	Requested		Submitted	Requested	
		Canada	U.S.[1]		Canada	U.S.[1]
18						
19						
20						
21						
Total	3		5	3		5

[1] As per OPPTS 860.1500, Tables 2 and 5 for almond and pecan as the representative crops of the tree nut crop group 14. The Agency determined (Minutes of the 1/24/07 ChemSAC Meeting) that a reduced number of trials (3 for each crop) would be acceptable, based on the expectation that residues would be nondetectable.

B.2. Sample Handling and Preparation

Single untreated control and duplicate treated samples, sufficient to produce at least 1 kg of almond hull and 1 kg of almond or pecan nutmeat per sample, were collected at commercial maturity, 55-60 days after the last application. Almonds and pecans were knocked from the trees and left on the ground to dry for 3-4 days prior to being collected. Almond hulls were removed by hand. Nutmeat was collected using a nut sheller or cracker. Samples were frozen within 24 hours of collection and were maintained frozen at the field sites for 4-38 days prior to frozen shipment to Dow AgroSciences (Indianapolis, IN) for analysis.

At Dow AgroSciences, nutmeat and hull samples were prepared for analysis by grinding in the presence of liquid nitrogen. Samples remained in frozen storage (~-20 °C) at all times aside from homogenization and subsampling for analysis.

B.3. Analytical Methodology

Residues of penoxsulam were determined in nutmeat or hull samples using LC/MS/MS Method GRM 04.09, entitled "Determination of Residues of Penoxsulam in Agricultural Commodities by High Performance Liquid Chromatography with Tandem Mass Spectrometry Detection." This method is the same as method GRM 05.08, used for the determination of residues of penoxsulam in fish and shellfish (DP# 326985, 1/30/07, D. Soderburg) and is similar to the enforcement method (LC/MS/MS GRM 01.25; DP# 288152, 8/11/04, W. Cutchin) for rice, except that an isotopic internal standard is used for Methods GRM 04.09 and GRM 05.08. Only a brief description of method GRM 04.09 was provided in the subject submissions.

Briefly, homogenized nutmeat or hull samples were extracted with acetonitrile (ACN):water (80:20, v:v). The extract was diluted with 0.1 N HCl and purified through a 96-well polymeric reverse phase solid phase extraction (SPE) plate. Residues were eluted with ACN into another 96-well SPE plate containing ACN:methanol:water (15:15:70, v:v:v, containing 0.1% acetic acid) mobile phase and a stable isotope internal standard. The final solution was analyzed by LC/MS/MS for residues of penoxsulam. The reported method limit of detection (LOD) for penoxsulam in nutmeat and hull was 0.003 ppm, and the LOQ was 0.01 ppm.

C. RESULTS AND DISCUSSION

Sample storage conditions and durations for tree nut are presented in Table C.2. Storage durations were 202-234 days (6.6-7.7 months) for almond nutmeat and hull, and 119-151 days (3.9-5.0 months) for pecan nutmeat. No data depicting the stability of penoxsulam in tree nut samples are available. Storage stability data from other crops are adequate to support the tree nut residue data.

Concurrent method recovery data are presented in Table C.1. The LC/MS/MS Method GRM 04.09 used to analyze nutmeat and hull samples for residues of penoxsulam is adequate for data collection based on acceptable concurrent method recovery data. Concurrent method recoveries were within the acceptable range of 70-120% for untreated almond nutmeat, almond hull, and pecan nutmeat fortified with penoxsulam at 0.01 or 0.1 ppm. Apparent residues of penoxsulam were nondetectable (<LOD; <0.003 ppm) in/on three samples each of untreated almond nutmeat, almond hull, and pecan nutmeat. The validated LOQ is 0.01 ppm for penoxsulam in/on each matrix. Adequate sample calculations and chromatograms were provided.

Residue data from the tree nut field trials with penoxsulam are reported in Table C.3. A summary of the almond and pecan field trial data is presented in Table C.4. Residues of penoxsulam were nonquantifiable (<0.01 ppm) in/on all samples of almond nutmeat, almond hull, and pecan nutmeat harvested 55-60 days following two soil broadcast applications of the 25 g/L OD formulation of penoxsulam, made at the end of dormancy and during the growing stage, for a total rate of 0.062-0.064 lb ai/A.

TABLE C.1. Summary of Concurrent Recoveries of Penoxsulam from Tree Nut Matrices.

Matrix	Spike Level (ppm)	Sample Size (n)	Recoveries (%)	Mean ± Std. Dev.[1] (%)
Almond, nutmeat	0.01	3	93, 101, 103	99 ± 5
	0.1	2	97, 98	98
Almond, hulls	0.01	3	100, 108, 110	106 ± 4
	0.1	2	96, 103	100
Pecan, nutmeat	0.01	3	104, 105, 110	106 ± 3
	0.1	2	97, 102	100

[1] Standard deviation is only applicable for sample sizes of n ≥ 3 samples.

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration[1]	Interval of Demonstrated Storage Stability
Almond, nutmeat and hulls	~-20	202-234 days (6.6-7.7 months)	None available
Pecan, nutmeat		119-151 days (3.9-5.0 months)	

[1] Actual storage duration from collection to analysis; almonds or pecans were left on the ground to dry for 3 to 4 days prior to collection. Samples were analyzed on the day of extraction.

TABLE C.3. Residue Data from Crop Field Trials with Penoxsulam.

Trial: City, State; Year (Trial ID No.)	Zone	Crop; Variety	Total Rate (lb ai/A)	PHI (days)	Commodity or Matrix	Penoxsulam residues (ppm)
Almond Trials						
Terra Bella, CA; 2007 (070002-CA1)	10	Almond; Nonpareil	0.062	59	Nutmeat	ND[1], ND
					Hull	ND, ND
Wasco, CA; 2007 (070002-CA2)	10	Almond; Price	0.063	60	Nutmeat	ND, ND
					Hull	ND, ND
Sanger, CA; 2007 (070002-CA3)	10	Almond; Nonpareil	0.063	60	Nutmeat	ND, ND
					Hull	ND, ND
Pecan Trials						
Chula, GA; 2007 (070003-GA1)	2	Pecan; Sumner	0.062	59	Nutmeat	ND, ND
Opelousas, LA; 2007 (070003-LA1)	4	Pecan; Native	0.064	55	Nutmeat	ND, ND
Claytonville, TX; 2007 (070003-TX1)	8	Pecan; Berkett	0.063	60	Nutmeat	ND, ND

[1] ND = Not detected. Residues were below the LOD (<0.003 ppm).

TABLE C.4. Summary of Residue Data from Crop Field Trials with Penoxsulam.

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels[1] (ppm)						
			n	Min.	Max.	HAFT[2]	Median (STMdR)	Mean (STMR)	Std. Dev.
Almond, nutmeat	0.062-0.063	59-60	6	<0.01	<0.01	<0.01	<0.01	<0.01	--
Almond, hulls			6	<0.01	<0.01	<0.01	<0.01	<0.01	--
Pecan, nutmeat	0.062-0.064	55-60	6	<0.01	<0.01	<0.01	<0.01	<0.01	--

[1] The LOQ (<0.01 ppm) was used for residues reported below the LOQ in Table C.3. Standard deviation was not applicable because all residue values were <LOQ.
[2] HAFT = Highest Average Field Trial.

D. CONCLUSION

The submitted field trial data reflect the use of two soil broadcast applications to almond or pecan, at the end of the dormant growing stage and during the growing stage, for a total seasonal rate of 0.062-0.064 lb ai/A, with a 55- to 60-day PHI. Following this use pattern, application of penoxsulam is not expected to result in quantifiable residues. An acceptable method was used for the quantitation of residues of penoxsulam, and the studies are supported by adequate storage stability data.

E. REFERENCES

DP#: 288152
Subject: Penoxsulam. Petition for the Establishment of Permanent Tolerances for the Use on Rice. Summary of Analytical Chemistry and Residue Data. PP#3F6542.
From: W. Cutchin
To: P. Errico/J. Miller
Dated: 8/11/04
MRIDs: 45830712-45830717, 45830719-45830720, and 46267601

DP#:	326985
Subject:	Penoxsulam. Section 3 Registration Application for Use of GF-443 SC in Aquatic Sites and Request for a Tolerance Exemption (PP#5F7012) on Fish and Shellfish. Summary of Analytical Chemistry and Residue Data.
From:	D. Soderberg
To:	J. Miller
Dated:	1/30/07
MRIDs:	46703504-46703507, and 46703509

DP#:	328689
Subject:	Penoxsulam. Frozen Storage Stability of XDE-638 (Penoxsulam) in Rice (Raw Agricultural Commodities: Grain, Straw and Immature Forage) and its Processed Products (Bran, Hulls, and Polished Rice)
From:	D. Soderberg
To:	P. Errico/J. Miller
Dated:	12/18/06
MRIDs:	46449901

DP#:	None; Min_340.1-24-07.doc
Subject:	Minutes of the 1/24/2007 ChemSac Meeting: 2. Penoxsulam tree & vine use proposal (R. Loranger).
From:	Chemistry Science Advisory Council
To:	Chemistry Interest Group, HED
Dated:	NA
MRIDs:	None

F. DOCUMENT TRACKING

Petition Number: 8F7369
DP#: 355914
PC Code: 119031

Template Version June 2005

13544

R168634

Chemical Name: Penoxsulam

PC Code: 119031
HED File Code:
Memo Date: 1/29/2009
File ID: 00000000
Accession #: 000-00-0130

HED Records Reference Center
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