Primary Evaluator: William Cutchin, Chemist Date: 7/19/04
SIMB/HED

Reviewer: Richard Loranger, BSS
RAB2/HED

Contractor: Dynamac Corporation
20440 Century Blvd.,
Suite 100
Germantown, MD 20874

STUDY REPORT

45830716 Anderson, C.; West, S. (2002) Multiresidue Method Testing for XDE-638 According to PAM I, Appendix II, as Updated January, 1994: Lab Project Number: 47420: 021184. Unpublished study prepared by ABC Laboratories, Inc. and Dow AgroSciences, LLC. 50 p.

EXECUTIVE SUMMARY

Penoxsulam was analyzed according to the FDA Multi-Residue Method Test guidelines in PAM Vol. I, Appendix II (1/94). Testing using Protocols B and G was not required because penoxsulam is not an acid, phenol, or substituted urea. When tested, penoxsulam did demonstrate natural fluorescence; however, no peak above the baseline was observed using the HPLC/UV system described under Section 401 DL2, therefore, Protocol A testing was terminated. Testing using Protocol C indicated that further testing through Protocols D, E, and F was required; poor sensitivity observed during the testing indicated that Florisil column clean-up would be required for Protocol D. Penoxsulam could not be recovered using the Florisil column clean-up test in Protocols E and F, and testing under these protocols was terminated. Because the Florisil column clean-up steps in Protocol D are similar to those of Protocols E and F, testing under Protocol D was not conducted.

Penoxsulam is not adequately recovered using any of the multiresidue methods.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS

Under the conditions and parameters used in the study, the multiresidue method data are classified as scientifically acceptable. These data has been forwarded to FDA for further evaluation.

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP Barcode D288152.

COMPLIANCE

Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would impact the validity of the study.

A. BACKGROUND INFORMATION

Penoxsulam (company code XDE-638; PC Code 119031) is an herbicide intended for the control of *Echinochloa* grasses, broadleaf weeds, and sedge weeds in both water-injected (transplanted paddy) and postemergence (direct-seeded) rice. A single postemergence application of penoxsulam is to be made to rice from the one-leaf growth stage (7-12 days after seeding) to 60 days prior to rice harvest. The application is to be made by aerial or ground equipment once per growing season at a maximum rate of 0.045 lb ai/A (50 g ai/ha). Penoxsulam is to be formulated as a granular (for water-seeded rice) or suspension concentrate (for direct-seeded rice) formulation.

TABLE A.1. Penoxsulam Nomenclature.

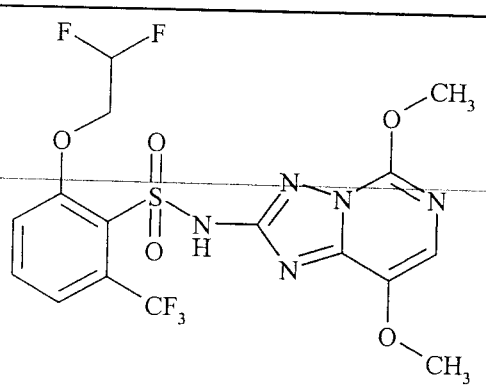
Compound	
Common name (proposed)	Penoxsulam
Company experimental name	XDE-638
IUPAC name	6-(2,2-Difluoroethoxy)-N-(5,8-dimethoxy-s-triazolo[1,5-c]pyrimidin-2-yl)-α,α,α-trifluoro-o-toluenesulfonamide
CAS name	2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c] pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide
CAS #	219714-96-2
End-use product/EP	GF-443 SC SF (File Symbol 62719-LNN); GF-947 Granule SF (File Symbol 62719-LNG); GF-947 Granule CA (File Symbol 62719-LNR).

TABLE A.2. Physicochemical Properties of Technical Grade Penoxsulam.

Parameter	Value	Reference
Melting point/range	Not available	
pH	Not available	

TABLE A.2 Physicochemical Properties of Technical Grade Penoxsulam.

Parameter	Value		Reference
Density	Not available		
Water solubility	pH	Solubility (mg/L)	45830720
	(unbuffered)	4.91	
	5	5.66	
	7	408	
	9	1460	
Solvent solubility	Solvent	Solubility (g/L)	45830720
	DMSO	78.4	
	NMP	40.3	
	DMF	39.8	
	acetone	20.3	
	acetonitrile	15.3	
	ethyl acetate	3.23	
	methanol	1.48	
	octanol	0.035	
	xylene	0.017	
	heptane	<1 µg/mL	
Vapor pressure	7.16×10^{-16} mm Hg at 25 °C		45830720
Dissociation constant, pK_a	5.1		45830720
Octanol/water partition coefficient, $Log(K_{OW})$	pH	$Log(K_{OW})$	45830720
	(unbuffered)	-0.354	
	5	1.137	
	7	-0.602	
	9	-1.418	

B. MATERIALS AND METHODS

Penoxsulam was analyzed according to the FDA Multi-Residue Method Test guidelines in PAM Vol. I, Appendix II (1/94). Testing using Protocols B and G was not required because penoxsulam is not an acid or phenol, and is not a substituted urea. Penoxsulam was tested through Protocols A, C, E, and F. Protocol D testing required Florisil clean-up due to the lack of a selective detector for penoxsulam, and testing was not conducted because of poor Florisil clean-up recoveries in Protocols E and F.

C. RESULTS AND DISCUSSION

TABLE C.1. Results of Multiresidue Methods Testing with Penoxsulam.

PAM I Protocol	Results	Comments
A	Penoxsulam was found to be naturally fluorescent; however, no peak above the baseline was observed using the HPLC/UV system described under Section 401 DL2. Protocol A testing was terminated.	
B		Not evaluated because penoxsulam is not an acid or phenol.

TABLE C.1. Results of Multiresidue Methods Testing with Penoxsulam.

PAM I Protocol	Results	Comments
C	Penoxsulam did not chromatograph acceptably under Level I conditions using three columns, DB-1, DB-17, and DB-225, with electron capture detection (ECD) at 200 °C. Level II testing was performed using the DB-1 column with ECD and electrolytic conductivity detection in the halogen mode (ELCD-X) at 230 °C. Using ECD, two peaks were observed, one peak within the acceptable relative retention time limits and one peak outside the limits. Using ELCD-X, two peaks were observed, both within the limits but with low sensitivity.	
D		The results of Protocol C testing indicated that Florisil column clean-up would be required for Protocol D. Testing under Protocol D was not conducted because penoxsulam was not recovered from the similar Protocol E/F Florisil column clean-up steps.
E	No penoxsulam was observed to elute (0% recovery) through the Florisil clean-up steps 303/304 C1 or C2. Testing under Protocols E and F was terminated.	
F		
G		Not evaluated because penoxsulam is not a substituted urea compound.

D. CONCLUSION

The results of the study indicate that the FDA Multiresidue Testing protocols in PAM Vol. I are not applicable to penoxsulam.

E. REFERENCES

None.

F. DOCUMENT TRACKING

RDI: R. Loranger (7/9/04)
Petition Number(s): 3F06542
DP Barcode(s): D288152
PC Code: 119031

Template Version April 2003