





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE:

7/19/04

SUBJECT:

PP# 3F6542. New Chemical - Penoxsulam (XDE-638) in/on Rice. Request for

Petition Method Validation. MRID#s 45830714 and 45830715.

DP Barcode:

D303172

Decision No.:

305735

Chemical No.:

119031

Class:

Herbicide

Trade Name:

Penoxsulam

40 CFR:

EPA Reg No.:

62719

§180.XXX

TO:

Frederic Siegelman, Branch Chief

Analytical Chemistry Branch

Biological and Economics Analysis Division (7503C)

FROM:

William Cutchin, Chemist

Science Information Management Branch

Health Effects Division (7509C)

THRU:

Richard A. Loranger, Branch Senior Scientist Muhael and for RAL Registration Action Branch 2

Registration Action Branch 2 Health Effects Division (7509C)

Dow AgroSciences LLC has submitted a petition (PP#3F6542) for the establishment of permanent tolerances for residues of the herbicide penoxsulam [2-(2,2-difluoroethoxy)-N-(5,8-dimethoxy[1,2,4]triazolo[1,5-c]pyrimidin-2-yl)-6-(trifluoromethyl)benzenesulfonamide], in/on rice commodities. The proposed tolerances, expressed as the parent only, are as follows:

Rice grain	0.01 ppm
Rice straw	0.50 ppm
Rice hull	0.01 ppm
Rice bran	0.01 ppm
Polished rice	0.01 ppm

Plant methods

An enforcement method (MRID #45830714) and an ILV (MRID #45830715) for residues of penoxsulam (XDE-638) in plant commodities have been submitted in the following volumes which are appended to this memorandum as Attachments 2 and 3:

45830714 Hastings, M. (2002) Validation Report for Method GRM 01.25 - Determination of Residues of XDE-638 in Rice and Rice Processed Products by Liquid Chromatography with Tandem Mass Spectrometry: Lab Project Number: 010097. Unpublished study prepared by Dow AgroSciences LLC. 41 p.

45830715 Chickering, C. (2002) Independent Laboratory Validation of Dow AgroSciences LLC Method GRM 0.125 - Determination of XDE-638 in Rice and Rice Processed Products by Liquid Chromatography with Tandem Mass Spectrometry Detection: Lab Project Number: 020038: 47421. Unpublished study prepared by ABC Laboratories and Dow AgroSciences LLC. 67 p.

RAB2 has conducted a preliminary review of the ILV. Acceptable recoveries of penoxsulam were obtained by the laboratory from rice samples. The results of the ILV may be found on page 12 of MRID# 45830715.

RAB2 requests that ACB conduct a petition method validation (PMV) of Dow's proposed LC/MS/MS tolerance enforcement method, MRID 45830714, per the experimental design specified in **Attachment 1**. All samples should be run in duplicate. Please complete and return this attachment as part of your report. Also, please include in your report all relevant information and supporting documentation concerning the method validation, including modifications which were made, and indicate the suitability of the analytical method for enforcement purposes. Please include the Repository ordering code(s) for the reference standards.

Should you find that the necessary analytical reference standards and/or MSDSs are not available to you, please contact directly Rafael Herrera (Regulatory Leader) Dow AgroSciences LLC and

Plant Sciences Inc., Indianapolis, IN, 317-337-4672 to request they be provided.

Since one of the purposes of conducting an in-house PMV is to determine whether all necessary instructions are included in the submitted proposed enforcement method, your laboratory staff scientists should have minimal contact with the petitioner during the conduct of this trial. Any problems encountered in the method <u>as written</u> should be documented and included in your report. The petitioner will be informed of any deficiencies in the method and asked to resolve them.

The RD Product Manager for penoxsulam is Philip Errico and should be contacted directly (703-305-6663) if you require guidance concerning the priority for initiation/completion of this PMV.

Please address and send your report to William Cutchin, SIMB/HED, 7509C. If you need any further information please call at 703-305-7990.

Attachment 1- Experimental Design for PMV

Attachment 2- Proposed Enforcement Method for Rice Commodities, MRID# 45830714

Attachment 3- ILV of Enforcement Method for Rice Commodities, MRID# 45830715

cc (with Attachment 1 only): W. Cutchin, P. Errico (RD,7505c), PP#3F6542, Reading File.

cc (with Attachment 2 only): M. Clower (Division of Pesticide and Industrial Chemicals, HFS-335, FDA)

ATTACHMENT 1

METHOD: 45830714 Hastings, M. (2002) Validation Report for Method GRM 01.25 -

Determination of Residues of XDE-638 in Rice and Rice Processed Products by Liquid Chromatography with Tandem Mass Spectrometry: Lab Project Number:

010097. Unpublished study prepared by Dow AgroSciences LLC. 41 p.

Please: (i) Indicate the limit of detection and quantitation; (ii) Do not use control values for recovery calculations; and (iii) Do not report control values as zero; if less than the limit of detection, report as such.

Commodity	Chemical Added	ppm Added	ppm Found	Percent Recovery
Dow Method GRM 01.25 (LC/MS/MS) for Rice Commodities				
Rice grain	penoxsulam	0.00		
		0.01		
		0.10		
Rice straw penoxs	penoxsulam	0.00		
		0.01		
		0.50		



R100842

Chemical:

Benzenesulfonamide, 2-(2,2-difluoroethox

PC Code:

119031

HED File Code

11000 Chemistry Reviews

Memo Date:

07/19/2004

File ID:

00000000

Accession Number:

412-05-1000

HED Records Reference Center 09/03/2004