



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

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

Memorandum

DATE: 9-NOV-1999

SUBJECT: PP# 8F04954. Mesotrione (Proposed Name). Request for Petition Method Validation of ZA1296. MRID#s 44505224. DP Barcode: D260569. Chemical #: 122990. Case #: 289589. Submission #: S541377.

FROM: Sarah Levy, Chemist *Sarah Levy*
Registration Action Branch 1
Health Effects Division (7509C)

THROUGH: George Kramer, Ph.D., Chemist *George Kramer*
Melba Morrow, DVM, Branch Senior Scientist *Melba Morrow*
Registration Action Branch 1
Health Effects Division (7509C)

TO: Francis Griffith, Chief
Analytical Chemistry Laboratory
Biological and Economics Analysis Division (7503W)

Zeneca has proposed that 40CFR be amended by establishment of a tolerance for the residues of mesotrione (proposed name), ZA1296, (2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexandione) resulting from the application of ZA1296 Herbicide in or on the following raw agricultural commodities (RACs): 0.01 ppm in/on field corn; field corn, fodder; and field corn, forage.

The HED Metabolism Committee has provisionally concluded that the tolerance expression for corn and rotational crops should be enforced as the parent ZA1296 and the metabolite MNBA (4-methylsulfonyl-2-nitrobenzoic acid) (J. Stokes, 4/22/97). However, upon full evaluation of the submitted residue data, this decision may be revised by the Metabolism Assessment Review Committee (MARC).

The petitioner has submitted a copy of their proposed method and an Independent Laboratory Validation (ILV) in the following volumes which are appended to this memorandum as Attachments 2 and 3, respectively:

ZA1296: Liquid Chromatographic Determination with Fluorescence Detection of ZA1296 and 4-(Methylsulfonyl)-2-nitrobenzoic Acid in Crops After Conversion to 2-Amino-4-(methylsulfonyl)-benzoic Acid (Addendum to TMR0643B). MRID# 44505216.

ZA1296: Independent Laboratory Confirmation of an Analytical Method for Liquid Chromatographic Determination with Fluorescence Detection of ZA1296 and 4-(methylsulfonyl)-2-nitrobenzoic acid in Crops After Conversion to 2-amino-4-(methylsulfonyl)-benzoic acid. MRID# 44505215.

Registration Action Branch 1 (RAB1) has conducted a preliminary review of the ILV. The method analyzed for both mesotrione and MNBA. Acceptable recoveries were obtained by the laboratory. A summary of the laboratory's findings may be found on page 11 of the ILV report. RAB1 requests that Analytical Chemistry Laboratory (ACL) conduct a PMV on the submitted analytical method. Samples should be run in duplicate per the experimental design specified in Attachment 1. Please include the following with your report: copies of the standard curves, sample calculations, and representative chromatograms for controls and fortified samples. Any deficiencies in the method, as written, should also be noted and reported. Please comment on the length of time necessary to complete a set of samples.

One of the purposes of conducting a PMV is to determine whether all necessary instructions are included in the submitted method. For this reason, we are requesting that laboratory staff scientists have minimal contact with the petitioner during this PMV. Any problems encountered should be documented and included in your report. The petitioner will be informed of any deficiencies in the method and asked to resolve them.

If you have not done so already, please obtain the necessary analytical reference standards from the EPA Repository. If the analytical reference standard of mesotrione is not available from the Repository, then please contact Barbara Kaminski ((302) 886-1229), the Regulatory Product Manager at Zeneca, directly requesting several hundred milligrams of each standard along with the required MSDS be provided directly to ACL. In your final report, please note which standards are available from the Repository as of date. Also confirm the Repository ordering codes for mesotrione.

The Registration Division Product Manager for is Jim Tompkins (703-305-5697). He should be contacted directly concerning the priority for completion of this PMV.

Please address your written reports to: K. Whitby, Chief, RAB1, Health Effects Division (7509C).

Attachment 1 - Experimental Design for PMV.

Attachment 2 - Proposed Enforcement Method, MRID# 44505216.

Attachment 3 - ILV of Proposed Enforcement Method, MRID# 44505215.

Attachment 4 - Proposed Section F (OPPTS: 860.1550).

cc: (with Attachment 1 only): PP#8F04954, S.F., S. Levy, J. Tompkins (PM25/RD-7505C)

RDI: Chemists (11/4/99), G. Kramer (11/9/99), M. Morrow (11/10/99)

S. Levy: CM#2: (703)305-0783: 7509C: RAB1

METHOD: ZA1296: Liquid Chromatographic Determination with Fluorescence Detection of ZA1296 and 4-(Methylsulfonyl)-2-nitrobenzoic Acid in Crops After Conversion to 2-Amino-4-(methylsulfonyl)-benzoic Acid (Addendum to TMR0643B).
MRID# 44505216.

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
Field corn	Mesotrione	0.00		
		0.01		
		0.02		
Field corn	MNBA	0.00		
		0.01		
		0.02		
Field corn, fodder	Mesotrione	0.00		
		0.01		
		0.02		
Field corn, fodder	MNBA	0.00		
		0.01		
		0.02		
Field corn, forage	Mesotrione	0.00		
		0.01		
		0.02		
Field corn, forage	MNBA	0.00		
		0.01		
		0.02		