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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 16 1992

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#0F3918. SAN-582H in/on Field Corn.
Petition Method Validation Request.

FROM: Michael T. Flood, Ph.D., Chemist
Tolerance Petition Section II
Chemistry Branch I -- Tolerance Support
Health Effects Division (H7509C)

Mike Flood

THROUGH: Debra F. Edwards, Ph.D., Acting Chief
Chemistry Branch I -- Tolerance Support
Health Effects Division (H7509C)

Debra Edwards

TO: Donald A. Marlow, Chief
Analytical Chemistry Branch
Biological and Economic Analysis Division (H7503C)

Sandoz Agro, Inc. is proposing tolerances of 0.01 ppm for residues of its herbicide SAN-582H (Frontier Herbicide, dimethenamid) in/on field corn grain, forage and fodder. The tolerances are proposed for the parent compound only -- 2-chloro-N-[(1-methyl-2-methoxy)ethyl]-N-(2,4-dimethyl-thien-3-yl)-acetamide. Also pending are temporary tolerances requested for soybean grain, forage and hay (PP#1G3980).

A petition method validation (PMV) is requested for SAN-582H, per se, on corn grain, forage and fodder and soybean grain. All samples (including the control) should be run in triplicate at the requested fortification levels (see attached table). The standard, SAN-582H is available at the EPA Repository (telephone conversation with Pat Beyer, 6/9/92).

Sandoz originally submitted a method for SAN-582H and its oxalamide metabolite. That method produced unacceptable recoveries. The present method is for parent SAN-582H only and is not related to the earlier one. The method has been independently validated. The independent lab validation is included in the attachment.

Please return the requested information on the attached forms along with all other information concerning the PMV that are generated according to your SOP on PMV's, including fortification samples, standard curves and examples of sample

calculations.

Since a major reason for conducting a PMV is to assure that all necessary instructions are included in the method write up, discussions of this PMV with Sandoz Agro, Inc should be discouraged until CB-I's evaluation is complete. This should not be construed as preventing contact with the company to clarify minor points. CB-I does request that in your final PMV report a summary of company contacts (whether visits or telephone calls) be provided. For major problems encountered with this method, CB-I requests that ACB chemists contact this reviewer to ascertain whether or not the PMV should be terminated. Any terminated PMV report should include a description of the problems encountered so that CB-I can inform Sandoz of the problems and request a revision of the method plus new validation data before initiating a new PMV request.

Please forward results of the PMV directly to Elizabeth Haeberer, Section Head, Tolerance Petition Section II.

Attachment: "A Method for the Determination of Residues of
SAN-582H in Corn and Soil Samples" MRID #
418239-02.

cc(with attachment): P. Corneliussen (FDA, HFF426)

cc(without attachment): Mike Flood, E. Haeberer, PP#0F3918,
PP#0G3892, PP#1G3980, PM#22(Jim Stone), M.Bradley, Circu.,
RF, SF, C. Furlow(PIB/FOD).

H7509C:CBTS:Reviewer(MTF):CM#2:Rm800A:305-6362:typist(mtf):6/11/92.
RDI:BranchSeniorScientist:RALoranger:6/10/92.

Method

The method is entitled "A Method for the Determination of the Residues of SAN 582 H in Corn and Soil Samples", and is Appendix III of Sandoz's Report 414108-14 (MRID # 418239-02). The report also includes the independent laboratory validation of the method.

Do not use control values for recovery corrections.

Do not report control values as 0

<u>Commodity</u>	<u>Chemical Added</u>	<u>ppm Added</u>	<u>ppm Found</u>	<u>Percent Recovery</u>
Corn				
Grain	None	Control		
	SAN-582H	0.01 0.05		
Forage	None	Control		
	SAN-582H	0.01 0.05		
Fodder	None	Control		
	SAN-582H	0.01 0.05		
Soybean				
Seed	None	Control		
	SAN-582H	0.01 0.05		