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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

Nov 5 1992  
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OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**MEMORANDUM**

**SUBJECT:** Audit Request for New Chemical, SAN-582H.

**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*  
*11/5/92*

**TO:** David L. Dull, Ph.D., Director  
Laboratory Data Integrity Assurance Division (EN-342)  
Office of Compliance Monitoring

Attached is a justification for requesting an audit of MRID No. 423368: "Common Moiety Approaches for Development: A Residue Method for Analysis of SAN 582H and Its Metabolites". The chemical is SAN-582 Herbicide, also known as Frontier Herbicide® -- 2-chloro-N-[(1-methyl-2-methoxy)ethyl]-N-(2,4-dimethyl-thien-3-yl)-acetamide. The PC Code is 129051. If the inspector has any further questions regarding this request, please contact Elizabeth Haeberer at 305-5374.

**Attachment:** Justification for audit request.

**bcc (with attachment):** Circu.; RF; PP#0F3918; Mike Flood, E. Haeberer, C. Olinger, Vivian Williams (H7509C); Jim Stone (H7505C).

AUDIT REQUEST FOR DATA SUBMITTED IN SUPPORT OF PP#0F3918.

Petitioner: Sandoz Agro Inc.

Chemical: SAN-582H Herbicide/Frontier Herbicide®/Dimethanamid  
2-chloro-N-[(1-methyl-2-methoxy)ethyl]-N-(2,4-  
dimethyl-thien-3-yl)-acetamide

Study: "Common Moiety Approaches for Development: A  
Residue Method for Analysis of SAN 582H and Its  
Metabolites," T. M. Bade, 5/26/92, ID No. 10582-10.  
(MRID # 423368)

### Discussion

SAN-582H Herbicide when applied to corn or soybeans is extensively metabolized. At normal sampling times, parent compound is not detected at a level of 0.01 ppm. The corn metabolism study demonstrates that numerous metabolites are formed, none of which exceeds ten percent of the residue. Analysis of corn samples for two individual metabolites -- the sulfonate conjugate of SAN-582 and the oxalamide metabolite -- has not shown detectable residues.

Under these circumstances, the registrant/petitioner frequently develops "common moiety" analytical methods. These are methods in which a class of metabolites is analyzed, so even if no one metabolite is present at detectable levels, the class of metabolites could be. Sandoz reports that it has been unsuccessful in developing a common moiety method. The submitted study, which is not a GLP study, is a summary of attempts to develop such a method. Based on this information, when other deficiencies have been resolved CBTS will recommend that a tolerance of 0.01 ppm be established for residues of parent only on corn grain, forage and fodder. Setting such tolerances on parent only would at least provide a basis for regulatory enforcement in the case of gross misuse. Clearly, it would be preferable to set tolerances for a class of metabolites which could be a measurable residue resulting from normal use conditions. In the absence of a common moiety method this is not possible.

Because the decision to set tolerances for parent only is based on the reported inability to develop a common moiety analytical method, CBTS requests that Sandoz's records pertaining to development of such a method be audited. We note that we have only received a summary of Sandoz's attempts.

2