

US EPA ARCHIVE DOCUMENT



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

APR 29 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: ~~PP#01~~ SAN-582H Herbicide in/on Field Corn
Additional Metabolism Data, Crop Residue Data,
Processing Study.

MRID #'s 416624-19, 417068-11, 417068-12.
DP Barcode: D170003. CBTS # 8788.

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

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

TO: C. Giles-Parker/J. Stone, PM#22
Fungicide-Herbicide Branch
Registration Division (H7505C)

and

Toxicology Branch II
Health Effects Division (H7509C)

Background

Sandoz Crop Protection Corporation previously proposed temporary tolerances of 0.01 ppm for the combined residues of SAN-582H, 2-chloro-N-[(1-methyl-2-methoxy)ethyl]-N-(2,4-dimethylthien-3-yl)-acetamide, and its oxalamide metabolite, N[(1-methyl-2-methoxy)ethyl]-N-(2,4-dimethylthienyl)-oxalamide, in/on corn forage, silage, grain and stover. The original data were submitted in the temporary tolerance petition PP#0G3892. That petition contained numerous deficiencies with respect to permanent tolerances (M.Flood, memo of 1/24/91), but CBTS eventually recommended for temporary tolerances of 0.01 ppm for SAN-582H, per se, in/on corn grain, forage and fodder (M.Flood, memo of 2/13/92).

The original analytical method for SAN-582H and its oxalamide metabolite, Method AM-0840-0790-0, was judged to be unsuitable due to unacceptably high recoveries. Consequently,

submitted field trial data were rejected for permanent tolerances. We concluded that "Either the samples must be reanalyzed using a revised method -- in which case appropriate storage stability data are necessary -- or new residue trials must be carried out with analyses by the revised method" (memo of 1/24/91). Sandoz then submitted a new analytical method -- for SAN-582H only. CBTS recommended that this method be validated for corn and soybeans at EPA laboratories (PP#0G3892, M. Flood memo of 6/11/91).

The present submission consists of a report of residue analyses from field trials on corn held during 1988, a corn processing study, and a mass balance investigation of SAN-582 in the goat to complement the previously submitted metabolism study.

Summary of Deficiencies Remaining to Be Resolved

All deficiencies listed in our 1/24/91 memo for PP#0G3892 regarding permanent tolerances for SAN-582H remain to be resolved.

Conclusions and Recommendations (pertaining to this memo only)

1. Because of unacceptable recoveries, the samples from the field trials held in 1988 and the samples from the processing study must be reanalyzed with an acceptable analytical method. Such residue analyses must be supported by adequate storage stability data. Alternatively, new field trials and a new processing study should be conducted and analyzed by an acceptable analytical method.
2. The company's material balance study for a lactating goat is acceptable. Deficiencies in the original goat metabolism study remain.

Detailed Considerations

Residue Data

Field trial data on corn have been submitted in the following report:

"Analysis of Corn Samples for SAN-582H and its Oxalamide Metabolite (1988 Season)," N. Jimenez, 9/28/90, Project No. 414108-7. MRID # 417068-11

Fourteen field trials were conducted in 1988 in ten states: CO, IA(2), IL(2), IN(2), MN(2), NC, NE, OH, SD and WI. The 6.0 EC formulation of SAN-582H was applied preemergence, preplant incorporated and postemergence separately to individual plots. The rates of application for all three treatments were 1.5 lbs

ai/A for fine to medium textured soils and 1.25 lbs ai/A for coarse designated soils (CO and NC). Forage from corn treated postemergence was harvested 13-55 days after treatment; forage from corn treated preemergence and preplant incorporated was harvested 49-68 days after treatment. Grain and fodder were harvested 83-185 days after treatment.

All residue levels of SAN-582H and the oxalamide metabolite were non detectable, at a claimed detection limit of 0.01 ppm. The analytical method was AM-0840-0790-0. No new recovery data are present in the submission. Our conclusion remains the same as that from the earlier submitted residue data.

Processing Study

The following processing study was submitted:

"Residues of SAN-582H and Its Oxalamide Metabolite in Corn and Wet and Dry Processing Fractions," T.R. Bade, 9/27/90, Project No. 414108-6. MRID # 417069-12

SAN-582H was applied preplant at 1.5, 4.5 and 7.5 lbs ai/A. The label rate is 1.5 lbs ai/A. Separate corn grain samples obtained from these treatments were subjected to wet and dry milling at the Food Protein Research and Development Center, Texas A&M University. The products from dry milling were germ, hulls, flour, large grits, meal, presscake, crude oil (expelled), crude oil (extracted), soapstock and refined oil. The products from wet milling were hulls, germ, gluten, starch, presscake, crude oil, refined oil and soapstock. Commodities were analyzed using method AM-0840-0790-0. Neither SAN-582H nor the oxalamide metabolite could be detected in the raw or in any processed commodity. Recoveries were obtained at 0.01 and/or 0.1 ppm. As in the corn analyses reported in our 1/24/91 memo, recoveries were erratic. Recoveries for the corn processed commodities listed in our Overview of Residue Chemistry Guidelines, 10/89, are given in the following table.

Table I

Recoveries for Dry and Wet Milled
Corn Processed Fractions

	Fort. Level (ppm)	Percent Recoveries	
		SAN-582H	Oxalamide
DRY MILLING			
Whole Grain	0.01	101	127
Flour	0.01	110	70
Large Grits	0.01	121	125
Meal	0.01	80	60
Crude Oil (expelled)	0.01	50	10
	0.1	102	11
Crude Oil (extracted)	0.01	56	82
	0.1	180	186
Refined Oil	0.01	130	83
WET MILLING			
Whole Grain	0.01	188	63
Starch	0.01	59	41
Crude Oil	0.1	67	5
Refined Oil	0.01	164	26

These recoveries are unacceptable. In addition, we are unable to conclude from the submitted chromatograms that SAN-582H or its oxalamide metabolite could be detected if it were present at 0.01 ppm or even 0.1 ppm [see, for example, chromatograms of corn crude oil (expelled, either dry or wet milled) control fortified at 0.1 ppm]. These analyses must either be redone with an acceptable method -- in which case supporting storage stability data should be submitted -- or a new processing study carried out with analyses by an acceptable method.

Metabolism Data

As a supplement to the previously submitted goat metabolism study, reviewed in our 1/24/91 memo, Sandoz has submitted the

following report:

"Material Balance Investigation in a Goat Ora.
Administered ¹⁴C -SAN-582H," C. Yu and D. Nietz
9/13/90, Project No. 414105-15. MRID # 416624

A lactating goat received 10 mg/kg (250 ppm in
SAN-582H in an oral dose. Urine, feces and milk were
twice daily for 5 days. The SAN-582H was radiolabel
in the thienyl ring.

In the first 24 hr., 58% and 25% of the adminis-
tered was excreted in the urine and feces, respectively. 4
days, 59.17%, 28.08% and 0.09% of the administered do-
se was excreted in urine, feces and milk, respectively. The
recovery, therefore, was 87.34%.

Comment

In the study reviewed in our 1/24/91 memo, materi-
al balance was poor. The registrant stated that several samples
were collected, and considerable amounts of radiocarbon were
still present in the GI tract of that animal, which was
sacrificed 7 hours after the final dose. This material
study is acceptable. Our previous questions concerning
original goat metabolism study remain.

cc: SF, RF, Circu., Mike Flood, E. Haerberer, C. Furlo
PP#OG3892.
H7509C:CBTS:Reviewer(MTF):CM#2:Rm800A:305-6362:typist(
RDI:SectionHead:ETHaerberer:4/28/92:BranchSeniorScienti
4/29/92.