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TO: Cynthia Giles-Parker
Product Manager PM 22
Registration Division (H7505C)

FROM: Paul J. Mastradone, Ph.D., Chief PJM
Environmental Chemistry Review Section #1
Environmental Fate & Ground Water Branch/EFED (H7507C)

THRU: Henry Jacoby, Chief Henry Jacoby 12/22/92
Environmental Fate & Ground Water Branch/EFED (H7507C)

Attached, please find the EFGWB review of...

Reg./File # : 055947-RUN

Common Name : SAN 582 H

Product Name : FRONTIER Herbicide (SAN 582 H)

Company Name : Sandoz Crop Protection Corporation

Purpose :Review environmental fate studies in support of registration

Type Product :Herbicide Action Code: 100, 101 EFGWB #(s): 92-0094, 92-0095, 92-0752, 92-1154, 92-1347
Review Time: 36.0 days

EFGWB Guideline/MRID/Status Summary Table: The review in this package contains...

161-1			162-4			164-4			166-1		
161-2	422662-07	Y	163-1	420348-06, 420348-07	Y	164-5			166-2		
161-3	422662-08	Y	163-2			165-1	423805-01	Y	166-3		
161-4			163-3			165-2			167-1		
162-1			164-1	422662-02 thru 422662-06	Y	165-3			167-2		
162-2	417068-01	Y	164-2			165-4			201-1		
162-3	423672-01	Y	164-3			165-5			202-1		

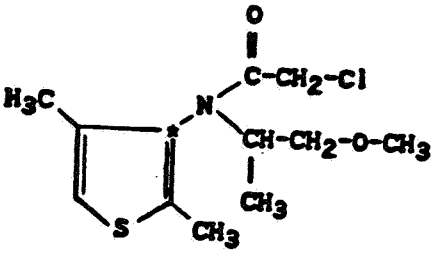
Y = e (Study satisfied the Guideline)/Concur P = Partial (Study partially satisfied the Guideline, but additional information is still needed)
S = Supplemental (Study provided useful information, but Guideline was not satisfied) N = Unacceptable (Study was rejected)/Non-Concur

1.0 CHEMICAL:

Common name: SAN 582 H

Chemical name: 2-chloro-N-[(1-methyl-2-methoxy)ethyl]-N-(2,4-dimethylthien-3-yl)-acetamide

Chemical Structure:



2.0 TEST MATERIAL:

^{14}C-SAN 582 H and unlabeled SAN 582 H

3.0 STUDY/ACTION TYPE:

Review environmental fate studies for registration

4.0 STUDY IDENTIFICATION:

Sabat, M., and C.C. Yu. 1992. SAN 582 H: Photodegradation Study in Aqueous Solution. Performed by the Metabolism/Pharmacokinetics Section of Sandoz Agro, Inc., Des Plaines, Iliniois. MRID No. 422662-07.

Sabat, M., and C.C. Yu. 1992. SAN 582 H: Photodegradation Study on Soil. Performed by the Metabolism/Pharmokinetics Section of Sandoz Agro, Inc., Des Plaines, IL. MRID No. 422662-08.

Tong, T.R. 1991. Soil Adsorption and Desorption of SAN-582 H, Unaged, by the Batch Equilibrium Method. Environmental Chemistry Section of Sandoz Crop Protection Corporation, Des Plaines, IL. MRID No. 420348-06.

Bade, T.R. 1992. Stability of SAN-582 H and its Metabolites in Stored Frozen Soil Samples QUA #89/11/27. Performed by Analytical Sciences-Residue Chemistry of Sandoz Crop Protection Corporation, Des Plaines, IL. MRID No. 422662-06.

Clouser, A.R. 1992. Reanalysis of Soil Samples from North Carolina, 1988 Season for Residues of SAN 582 H and Oxalamide. Field test contracted to Stewart Agricultural Research Services, Inc., Macon, Missouri. Laboratory analyses performed by the Analytical Sciences Section of Sandoz Crop Protection Corporation, Des Plaines, IL. MRID No. 422662-04, vol. 1-3.

Bregger, T.E. 1992. SAN 582 H 7.5L/Soybeans Terrestrial Dissipation/Field Conditions Trial ID 0110215A. Field portion contracted to Heartland Technologies, Inc., Indianapolis, IN and analytical portion performed by Sandoz Corporation, Des Plaines, IL. MRID No. 422662-02, vol. 1 of 2.

Smith, K.L. 1992. SAN-582 H 7.5L/Corn Terrestrial Dissipation/Field Conditions. Field Contracting by Stewart Agricultural Research Services, Inc., Clarence, MO. Analyses by Sandoz Crop Protection Corporation, Des Plaines, IL. MRID No. 422662-03, vol. 1.

Laban, S.C., and T. Bade. 1992. Determination of SAN 582 H and its Oxalamide Metabolite in Soil. Method AM-0865-0791-D. Residue Chemistry Group of Sandoz Agro, Inc., Des Plaines, IL. MRID No. 422662-03, vol. 2.

Bade, T.R. 1992. Dissipation and Mobility of SAN 582 H in Soil after one Pre-emergence Application to Soybeans in Minnesota. Field test contracted to Agri-Growth Research, Inc., Hollandale, MN; laboratory analyses performed by the Analytical Sciences Section of Sandoz Crop Protection Corporation, Des Plaines, IL. MRID No. 422662-05, vol. 1 and 2.

Bade, T.R. 1990. Anaerobic Soil Metabolism of SAN-582 H: Project No. 414105. Environmental Chemistry and Toxicology Section of Sandoz Crop Protection, Des Plaines, IL. MRID No. 417068-01.

Das, Y.T. 1992. Metabolism of [Thienyl-3-^{14}C]SAN 582 H Under Anaerobic Aquatic Soil Conditions. Study performed by Innovayive Scientific Services, Inc., Piscataway, N.J. for Sandoz Crop Protection Corporation. MRID No. 423672-01.

Pierotti, M.V., and P.A. Moore. 1992. Confined Accumulation Study of SAN-582 H on Rotational Crops. Performed by Environmental Chemistry Section of Sandoz Agro, Inc., Des Plaines, IL. Field study site located in Geneseo, IL. MRID No. 423805-01.

Studies Previously Reviewed for EUP:

Fostiak, W., and T. Hsieh. 1988. Hydrolysis of SAN 582 H, Project No. 414105, Report No.4. Sandoz Crop Protection Corporation, Des Plaines, IL. MRID No. 415965-31.

Krueger, J.P., and T.R. Tong. 1990. Aerobic Soil Metabolism of SAN 582 H: Project No. 414105. Sandoz Crop Protection Corporation, Des Plaines, IL. MRID No. 415965-32.

Erstfeld, K.M. 1988. Adsorption and Desorption of SAN-582 H in Four Soils. Sandoz Crop Protection Corporation, Des Plaines, IL. MRID No. 45965-33.

Dykes, J. 1990. Soil Adsorption/Desorption with ^{14}C-SAN 582 H Extracted from Aged Soil. Unpublished study performed by Analytical Bio-Chemistry Laboratories Inc., Columbia, Missouri, for Sandoz Crop Protection, Des Plaines, IL. MRID No. 415965-34.

Sabourin, T.D. 1988. Accumulation of (^{14}C)SAN-582 H in Bluegill Sunfish. Unpublished study performed by Batelle Columbus Division, Columbus, Ohio, for Sandoz Crop Protection Corporation, Des Plaines, IL. MRID No. 415965-35.

5.0 REVIEWED BY:

George Tompkins
Entomologist, Review Section 1
EFGWB/EFED

Signature: George Tompkins
Date: NOV 24 1992

6.0 APPROVED BY:

Paul Mastradone
Section Chief, Review Section 1
EFGWB/EFED

Signature: Paul J Mastradone
Date: NOV 24 1992

7.0 CONCLUSIONS:

1. EFGWB concludes that the following studies submitted for registration of SAN 582 H for use on corn and soybeans are acceptable and satisfy the data requirements:

a). Photodegradation in Water (161-2), MRID No. 422662-07. SAN 582 H had a photodegradation rate under simulated light of 0.042 ± 0.02 day^{-1} with a half-life of 16.4 ± 1.1 days which reportedly corresponds to a rate of 0.029 day^{-1} and a half-life of 23.9 days at noon in spring at 40^{0}N. The four degradation products that were identified were:

1) Compound I which comprised a maximum of 1.8% of the applied radioactivity by day 19 (see Fig 21 for structure and Table I for structures of all other degradates of SAN 582 H) and proposed to be derived from ring cyclization of SAN 582 H;

2) M3 ([N-(2,4-Dimethyl-3-thienyl)-N-(2-methoxy-1-methylethyl)acetamide]) comprised a maximum of 0.6% of the applied dose on day 19 and proposed to be the dechlorination product of SAN 582 H;

3) M9 ([4-(2,4-dimethyl-3-thienyl)-5-methyl-3-morpholinone]) comprised a maximum of 1.2% of the applied dose on day 11 and 19;

4) M11 ([N-(2,4-dimethyl-3-thienyl)-2 hydroxy-N-(2-methoxy-1-methylethyl)-acetamide]) was observed at a maximum of 1.2% on day 11 and on day 19 was one of three components in a band whose total was 0.9% of the applied dose.

Several other bands were separated each consisting of less than 3.5% of applied radiocarbon and the identities are unknown.

b). Photodegradation on Soil (161-3), MRID No. 422662-08. SAN 582 H had a reported half-life of 5.3±0.3 days (photodegradation rate of 0.131±0.01 day^{-1}) under simulated light. This reportedly corresponds to a photodegradation rate of 0.089 day^{-1} and a half-life of 7.8 days based on sunlight irradiance data in spring at 40^{0}N latitude. By day 9 parent SAN 582 H (25.1%) and 10 other radioactive bands in the ethyl acetate extractable portion were identified by TLC analysis and these bands each ranged from 0.8 to 5.4% of applied radioactivity. Further identification identified band 3 (a maximum of 5.4% of applied) as M9 (the external cyclization product of SAN 582 H), band 4 (a maximum of 2.6% at day 9) as M11 (the hydroxylation product of SAN 582 H), and band 5 (a maximum of 2.1% at day 9) as M7 with trace amounts of M20 present. In the methanol water extract eleven radioactive bands were isolated by TLC analysis. Further identification showed band 1 as parent SAN 582 H (1.9% at day 9) and band 5 as M11 (a maximum of 2.1% at day 9). Attempts to identify the other bands (2,3,4,6-10, and 11) ranging from 0.4 to 5.0% of applied radiocarbon at day 9 were not successful.

c). Unaged Leaching and Adsorption/Desorption (163-1), MRID No. 420348-06. Unaged SAN 582 H was shown to range from highly mobile (K_{ad} value of 0.7 in the silt loam soil) to moderately mobile (K_{ad} value of 3.5 in the clay loam soil) in the four soils tested. The respective desorption (K_{des}) values ranged from 0.7 to 3.9. The results indicated that SAN 582 H had the potential to be a moderately mobile material in the Kenyon loam and clay loam soils and the potential to be highly mobile in the silt loam and sandy loam soil.

d). Aged Leaching and Adsorption/Desorption (163-1), MRID No. 420348-07 (responses to previous study MRID No. 415965-34 submitted in EUP). In the original study SAN 582 H was shown to have the potential to leach rapidly with reported Freundlich adsorption partitioning coefficients (K_{ad}) of 0.461 in the sand, 0.573 in the sandy loam, 0.867 in the silt loam, and 1.327 in the clay loam soils used. Several deficiencies in the original report were noted and the responses were addressed satisfactorily (see Discussion Of Individual Studies 10.2.1 through 10.2.3).

e). Anaerobic Soil Metabolism (162-2), MRID No. 417068-01. SAN 582 H degraded under anaerobic conditions with a half-life of 53.8 days. The major metabolite was oxalamide (reaching a maximum level of 8.7% of applied radioactivity by day 93). The minor metabolite "Fr 4" reached a maximum of 3.0% of applied by day 58 and decreased to 2.4% by day 93 ("Fr 4" was identified in another study, MRID No. 420348-07, as the sulfoxide of the thioglycolic acid of SAN 582 H). The metabolite "Fr 1A+B" reached a combined maximum of 3.5% of applied by day 93 and this fraction contained equal amounts of 1A and B. Fraction 1A was identified as the sulfonate.

f). Anaerobic Aquatic Metabolism (162-3), MRID No. 423672-01. SAN 582 H degraded under anaerobic non-sterile conditions at 25^{0}C with a half-life of 36 days and at 5^{0}C with a half-life of 292 days. Under sterile conditions at 25^{0}C SAN 582 H degraded with a half-life of 377 days and at 5^{0}C with a half-life 1484 days. When incubated at 25^{0}C under non-sterile conditions SAN 582 H degraded to reach a low of 0.4% of applied dose by day 270. The primary metabolites were M3 (dechlorinated parent) reaching a maximum of 20.6% of the applied radioactivity by day 90, M11 (the hydroxylated derivative of the dechlorinated parent) reaching a maximum of 7.0% of the applied by 90 days, PL 3688 (the methylthio derivative of the dechlorinated parent) reaching a maximum of 4.9% of the applied by day 90, M13 (the sulfoxide of PL 3688) reaching a maximum of 12.4% of the applied by day 120, and M10 (the sulfone of PL 3688) reached a maximum of 9.8% of the applied by day 90. A polar component reached a maximum of 22.3% of the applied dose by day 60 and this component appeared to be a complex between M3 and some soil constituents. The deaminated form of the M3-Cysteine conjugate, N-(2,4-dimethyl-3-thienyl)-N-(2-methoxy-1-methylethyl)-2(thioethylenecarboxy)-acetamide, reached a maximum concentration of 4.6% of applied dose by 90 days. At 5^{0}C under non-sterile conditions the metabolic pattern was similar, but at a slower rate. Under sterile conditions at both 25^{0}C and 5^{0}C there was some breakdown of parent SAN 582 H but no significant levels of metabolites from microbial activity were observed.

g). Terrestrial Field Dissipation (164-1), MRID #'s 422662-02, 422662-03, 422662-04, 422662-05, and 422662-06. SAN 582 H applied at from 1.27 lb ai/A to 1.5 lb ai/A (the maximum application rate) dissipated with reported half-lives ranging from 8 days (Missouri and North Carolina) to 43 days (Minnesota). Detections of SAN 582 H were primarily in the 0-10 cm soil segments. However, some detections were made in the 10-20 and 20-30 cm soil segments (ranging from 0.01 to a 0.08 ppm) in the Minnesota field dissipation study. Oxalamide was detected no further than the 10-20 cm soil segment and no detections were reported after 117 days posttreatment. In each of the four field dissipation studies the rainfall plus any irrigation applied during the period of testing exceeded the 30 year averages of rainfall. Storage stability studies indicated that both SAN 582 H and oxalamide were stable when stored frozen in the soil for up to 29 months (870 days). Recoveries after 29 months of storage for SAN 582 H ranged from 78-89.5% and oxalamide recoveries ranged from 97.5-105% in soils from California, Wisconsin, and Minnesota.

h). Confined Accumulation in Rotational Crops (165-1), MRID No. 423805-01. SAN 582 H and its degradates (thiolactic acid conjugate of SAN 582 H, oxalamide, the sulfoxide of the thiolactic acid conjugate of SAN 582 H, and the sulfonate of SAN 582 H) accumulated very little in the rotational crops (wheat, lettuce, and carrots) planted 141, 322, and 332 days following soil treatment at the maximum field application rate of 1.5 lb ai/A, and the exaggerated rates of 3.0 lb ai/A for the soybean and 4.0 lb ai/A for the corn subplots. The maximum concentration of any degradate reported was the sulfoxide of the thiolactic acid conjugate of SAN 582 H at 0.01 ppm in the straw of the winter wheat (planted 141 DAT and harvested 387 DAT). Parent and metabolites were all <0.01 ppm when present in sufficient quantities to be identified in other portions of wheat and in the other rotational crops.

ENVIRONMENTAL FATE ASSESSMENT

The information provided in acceptable studies submitted for the EUP and registration of SAN 582 H indicate that SAN 582 H is stable to hydrolysis and the primary means of dissipation for SAN 582 H applied on the soil surface are by photolysis (soil photolysis half-life of 8 days, several degradates reported none individually exceeding 5.4% of applied radioactivity) and once below the soil surface by microbial metabolism with a reported aerobic soil metabolism half-life of 38 days (major degradate reported was oxalamide at 14.8% of applied radioactivity by day 90) and an anaerobic soil metabolism half-life of 53.8 days (major degradate reported was oxalamide at 8.7% of applied by day 93).

Depending on the soil characteristics SAN 582 H has the potential to be a moderate to a highly mobile material with reported Freundlich adsorption partition coefficients (K_{ads}) ranging from 0.461 to 1.33 in the aged portion and 0.7 (silt loam soil) to 3.5 (clay loam soil) in the unaged portion of the leaching and adsorption/desorption studies. Although SAN 582 H has the potential to be highly mobile, this was not demonstrated in any of the four field dissipation studies in which SAN 582 H and oxalamide (the primary degradate in the aerobic and anaerobic soil metabolism studies) were not detected below the 20-30 cm soil segments. SAN 582 H has a rapid to moderately rapid dissipation rate with reported half-lives ranging from 8 days (Missouri and North Carolina) to 43 days (Minnesota) in the four terrestrial field dissipation studies.

SAN 582 H appears to have a low potential to bioaccumulate with a reported bioconcentration factor of 57 and a whole body elimination half-life of 10.7 days in fish. SAN 582 H and its degradates had a low potential to accumulate in rotational crops (wheat, lettuce and carrots) planted 141 to 332 days following soil treatment (treated at the maximum field application rate of 1.5 lb ai/A and exaggerated rates of 3.0 and 4.0 lb ai/A) with the maximum concentration of any degradate reported at 0.01 ppm.

ENVIRONMENTAL FATE SUMMARY

SAN 582 H appears to be stable to hydrolysis at pH's of 5, 7, and 9 without significant degradation of parent material after 30 days at 25°C. The aqueous photolysis half-life of SAN 582 H under simulated light was 16.4±1.1 days with a photodegradation rate of 0.042±0.02 day^{-1}. This corresponds to an approximate half-life of 23.9 days with a photolysis rate of 0.029 day^{-1} at noon in spring at 40°N, indicating that aqueous photolysis will not be a major mechanism of degradation. The four degradation products that were identified were: compound I (1.8% of the applied radioactivity) was proposed to be derived from ring cyclization of SAN 582 H; M3 ([N-(2,4-Dimethyl-3-thienyl)-N-(2-methoxy-1-methylethyl)acetamide]) comprised 0.6% of the applied dose; M9 ([4-(2,4-dimethyl-3-thienyl)-5-methyl-3-morpholinone]) comprised 1.2% of the applied dose; and M11 ([N-(2,4-dimethyl-3-thienyl)-2 hydroxy-N-(2-methoxy-1-methylethyl)-acetamide]) was one of three components in a band whose total was 0.9% of the applied dose. In addition, several other bands, each consisting of <3.5% of applied radiocarbon were not identifiable.

The soil photolysis half-life of SAN 582 H under simulated light was 5.3±0.3 days (photolysis rate of 0.131±0.01 day^{-1}) corresponding to a half-life of 7.8 days and a photodegradation rate of 0.89 day^{-1} based on sunlight irradiance data in spring at 40°N latitude. Identifiable radioactive bands in the ethyl acetate extractable portion included parent SAN 582 H (25.1%), M9

(5.4% of applied), M11 (2.6% at day 9), and M7 (2-chloro-N(2,4-dimethyl-3-thienyl)-N-(2-hydroxy-1-methylethyl)-acetamide) at approximately 2.1% with trace amounts of M20 (1,5-dihydro-1-(2-methoxy-1-methylethyl)-8-methyl-thieno(3,4-f)(4,1)oxazepin-2-(3H)-one) present. In the methanol water extract, parent SAN 582 H (1.9% at day 9), M11 (2.1%) and 9 other bands (ranging from 0.4 to 5.0% of the applied radiocarbon at day 9) were found but not identifiable.

Under aerobic soil conditions SAN 582 H degraded with a half-life of 38 days and the major metabolite was oxalamide (14.8% of the applied by day 90 and decreased to 8.5% of applied by day 365). Under anaerobic soil conditions SAN 582 H degraded with a reported half-life of 53.8 days. The major metabolite was oxalamide reaching a maximum level of 8.7% of applied radioactivity (by day 93). Other minor metabolites found were the sulfoxide of the thioglycolic acid of SAN 582 H (3% of applied by day 58) and the sulfonate (~1.7%). Under anaerobic aquatic non-sterile conditions at 25^{0}C SAN 582 H degraded with a half-life of 36 days, and at 5^{0}C with a half-life of 292 days. Under sterile conditions SAN 582 H degraded with a half-life of 377 days at 25^{0}C and 1484 days at 5^{0}C. The primary metabolites of SAN 582 H when incubated at 25^{0}C under non-sterile conditions were M3 (20.6% of the applied radioactivity by day 90), M11 (7.0% of applied radioactivity by 90 days), PL 3688 (4.9% of applied radioactivity by day 90), M13 (12.4% of applied radioactivity by day 120), M10 (9.8% of applied radioactivity by day 90), a polar component (22.3% of applied radioactivity by day 60) appeared to be a complex between M3 and some soil constituents, and the deaminated form of the M3-Cysteine conjugate (4.6% of applied dose by 90 days). At 5^{0}C under non-sterile conditions the metabolic pattern was similar, but at a slower rate.

In the unaged portion of the leaching and adsorption/desorption study the reported Freundlich adsorption (K_{ads}) values for SAN 582 H ranged from 0.7 (silt loam soil) to 3.5 (clay loam soil) indicating that SAN 582 H has the potential, depending on soil characteristics, to be a highly mobile to a moderately mobile material. In the aged portion of the leaching and adsorption /desorption studies SAN 582 H had adsorption values (K_{ads}) ranging from 0.461-1.33 demonstrating that SAN 582 H has the potential to be highly mobile in soil.

In the field dissipation studies the half-life of SAN 582 H, applied preemergence at a rate of 1.27 lb ai/A to 1.5 lb ai/A (maximum proposed field appliction rate) to soybeans or corn, varied from 8 days (Missouri and North Carolina) to 43 days (Minnesota). Detections of SAN 582 H were primarily in the 0-10 cm soil segments, although SAN 582 H was detected in the 10-20 and 20-30 cm soil segments in the Minnesota field dissipation study. SAN 582 H was detected until 157 days after application in the Indiana field dissipation study. Oxalamide was detected no

further than the 10-20 cm soil segment in any of these four field dissipation studies and no detections were reported after 117 days posttreatment. The rainfall in each of the four locations exceeded the 30 year average for that location. Both SAN 582 H and oxalamide appeared to be stable when stored frozen in the soil for up to 29 months.

In Bluegill sunfish SAN 582 H had a whole body bioconcentration factor of 57 and a whole body elimination half-life of 10.7 days, indicating a relatively low potential for accumulation in fish.

The confined rotational crop data indicates that parent SAN 582 H and its degradates (thiolactic acid conjugate of SAN 582 H, oxalamide, the sulfoxide of the thiolactic acid conjugate of SAN 582 H, and the sulfonate of SAN 582 H) accumulated very little in the rotational crops (wheat, lettuce, and carrots) planted 141, 322, and 332 days following soil treatment. The soil treatment was made at the maximum field application rate of 1.5 lb ai/A and also at the exaggerated rates of 3.0 lb ai/A for the soybean and 4.0 lb ai/A for the corn subplots. The maximum concentration of any degradate reported was the sulfoxide of the thiolactic acid conjugate of SAN 582 H at 0.01 ppm in the straw portion of the winter wheat planted 141 DAT and harvested 387 DAT. Parent and metabolites were all <0.01 ppm when present in sufficient quantities to be identified in other portions of wheat and in the other rotational crops.

8.0 RECOMMENDATIONS:

8.1 The following environmental fate studies and their status are required to support the proposed use on corn and soybeans:

STUDY	Status
Hydrolysis (161-1)	satisfied
Photodegradation in Water (161-2)	satisfied
Photodegradation on Soil (161-3)	satisfied
Aerobic Soil Metabolism (162-1)	satisfied
Anaerobic Soil Metabolism (162-2)	satisfied
Anaerobic Aquatic Metabolism (162-4)	satisfied
Leaching and Adsorption/Desorption (163-1)	satisfied
Terrestrial Field Dissipation (164-1)	satisfied
Confined Accumulation in Rotational Crops (165-1)	satisfied
Accumulation in Fish (165-4)	satisfied

8.2 The proposed label for SAN 582 H indicates both ground and aerial applications. Aerial applications of herbicides would trigger the following spray drift data requirements:

Droplet Size Spectrum (201-1)
Drift Field Evaluation (202-1)

Sandoz Agro Inc. has requested a waiver of the spray drift requirements for SAN 582 H(DP Barcode D182500). Since Sandoz Agro Inc. is a member of the Spray Drift Task Force, the data requirements for Droplet Size Spectrum (201-1) and Drift Field Evaluation (202-1) are reserved.

8.3 Based on available information it is unlikely that SAN 582 H would result in ground water contamination under normal use. However, SAN 582 H demonstrated that under certain conditions, properties of persistence and mobility are in the range associated with known leachers. Therefore, EFGWB recommends the following Ground Water label advisory:

"This chemical has demonstrated properties similar to those chemicals detected in ground water. Use of this chemical in sandy or karst areas may result in contamination of ground water."

9.0 BACKGROUND:

SAN 582 H 7.5L herbicide is a preemergence herbicide for selective control of annual grasses, annual broadleaf weeds, and yellow nutsedge in corn and soybeans at an application rate not exceeding 1.6 pints (1.5 lb ai) per acre in one crop year.

A previous study (MRID # 415965-34, Aged Leaching and Adsorption/Desorption) was submitted and reviewed in the EUP submission. At that time the study was deemed supplemental and further information was requested. The responses to that request were submitted in MRID # 420348-07 and are discussed in 10.2.1 through 10.2.3.

10.0 DISCUSSION OF INDIVIDUAL STUDIES:

10.1 See attached Data Evaluation Reports for individual studies.

10.2 163-1 Aged Leaching and Adsorption/Desorption

10.2.1 Sandoz Crop Protection Corporation responses (MRID # 420348-07) to EFGWB review of Aged Leaching and Adsorption/Desorption study: Soil Adsorption/Desorption with ^{14}C-SAN 582 H Extracted from Aged Soil, (MRID # 415965-34, EFGWB # 91-0101, 90-0893 dated 15 April 1991).

1. EFGWB Original Comment: The results of the analysis of the aged soil were not presented in tables or text regarding the material balance, metabolites, mineralization, or exact number of days the material was aerobically aged in the soil.

SANDOZ Response: The soil, used in the study "Soil Adsorption/Desorption with ^{14}C SAN 582H Extracted from Aged Soil", was aged aerobically with ^{14}C SAN 582H for 30 days at Sandoz Crop Protection (SCPC), in Des Plaines, IL.

The complete information regarding mineralization and material balance for day 0 and day 30 aerobic soil sample is shown in Table B (See attachment 1). The material balance for day 0 was 104.4% (rep 1) and 95.2% (rep 2), and 107.0% (rep 1) and 89.1% (rep 2) for day 30. An average of 0.035 ppm of the radioactivity (1.53 % of the 2.29 ppm applied) was collected as mineralized CO_2. An extraction scheme for SAN 582H treated soil is also attached. These analyses were performed by Sandoz during the conduct of the soil metabolism study.

EFGWB Rejoinder: The data provides the information required to determine the material balance which averaged 99.8% at day 0 and was 98.05% at day 30. The information provided indicates that by day 30, 1.53% of the applied SAN 582H had mineralized (CO_2). Additionally, the identification of Fraction IV was provided as the sulfoxide of the thioglycolic acid of SAN 582H. This information resolves the original comment.

2. EFGWB Original Comment: This study can be upgraded to satisfactory upon submission of satisfactory data on the aged soil portion of the study containing more complete information regarding mineralization, material balances, metabolites, date of dosing, dates of termination of aerobic aging and analysis.

Sandoz Response: The date of dosing was March 29, 1988. The date of termination of aerobic aging was April 28, 1988 (ABC Labs #038481R, Page 65). Information regarding mineralization, material balances, metabolites was mentioned as part of SCPC's response to EPA's comment #1.

EFGWB Rejoinder: The actual dates of dosing and termination were provided so that the period of aging by aerobic soil metabolism could be determined to be 30 days. The other requested information was provided to answer comment #1. This information resolves the original comment.

3. EFGWB Original Comment: The submitted data in this study indicates that the test material, SAN 582H had been supplied to ABC Labs pre-aged on the appropriate soil and the aged material was then extracted. No information was submitted regarding the conditions of shipping, how long in transit, and how soon after the initial treatment of the soil the actual extraction occurred. It is also difficult to determine if the extraction to determine the metabolites after the aging was done at site of aging under aerobic conditions, and if the extraction was done precisely at the end of the study period.

Sandoz Response: The aerobically aged (30 days) soil samples were collected and immediately stored in a -70 C freezer until shipped. The aged soil samples were shipped with dry ice in an insulated shipping cooler to ABC Labs by Federal Express overnight service on December 22, 1989 (ABC Labs #038481, Page 68, atachment 3). ABC Labs received the samples on December 22, 1989 and immediately stored them in a -20 C freezer (ABC Labs #038481R, Pages 52, 53, and 55, attachment 3). A preliminary trial of extraction of ^{14}C SAN 582H aged soil was performed on February 28, 1990 (ABC Labs #038481R, Pages 59 and 60, attachment 3). Extraction of ^{14}C SAN 582H aged soil for the adsorption/desorption study was started on May 25, 1990 at ABC Labs and completed on May 31, 1991 (ABC Labs #038481R, Pages 65-68, attachment 3).

SAN 582H parent compound accounted for approximately 58% of the radioactivity in the soil metabolism study at day 30 after treatment (attachment 2, Figure 3), concurrent sample used in the aged soil adsorption/desorption studies by ABC Labs analysis were of the same magnitude (attachment 2, Table A). Thus, there is a strong indication that SAN 582H is stable in soil stored frozen until analysis. Our storage stability study indicated that SAN 582H and its oxalamide metabolite are stable in soil for at least one year when stored below 10^0F (-12^0C), (SCPC Report 414108-8, MRID 41662408).

EFGWB Rejoinder: It appears from the provided information that the 30 day aerobically aged soil samples (duplicate samples from the aerobic soil metabolism study) were collected and immediately frozen at -70°C from 28 April 1988 until 21 December 1989, at which time they were shipped in dry ice to ABC Labs. Upon receipt at ABC Labs on 22 December 1989, these samples were then kept at -20°C until extraction procedures began on 25 May 1990, and in the Sandoz response (p 5 of 27) it is mentioned that these extractions were completed on 31 May 1991 (it is believed by EFGWB that the completion date actually was 31 May 1990 since the signatures on the extraction pages, attachment 3, are dated 31 May 1990). EFGWB accepts the above information as resolving the original comment.

EFGWB CONCLUSION: EFGWB concludes that after reviewing the original study and the information sent in the responses to SAN 582H soil adsorption/desorption study, that this study (MRID # 415965-34) is valid and partially fulfills the Leaching and Adsorption/Desorption (163-1) data requirement. This study provides information on the aged portion of this data requirement. It can be concluded from this study that SAN 582H has the potential to be a highly mobile material in the soils utilized in the study. These reported K_d values ranged from 0.461 to 1.33.

11.0 COMPLETION OF ONE-LINER: Updated to include data from all acceptable and supplemental studies reviewed.

12.0 CBI APPENDIX: N/A