#3918

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

EXPEDITE

JAN 22 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: SAN582H: Product Chemistry Data Submitted to Support Registration.

DP Barcode: D183774. CBTS # 10761.
MRID #'s 425129-00 through 425129-12.

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

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

TO: Cynthia Giles-Parker/James Stone, PM 22
Fungicide-Herbicide Branch
Health Effects Division (H7505C)

and

Toxicology Branch II
Health Effects Division (H7509C)

This review is being expedited at the 1/11/93 request of Lawrence E. Culleen, Acting Director, Registration Division. The negotiated due date is 2/5/93.

Attached is a review of the Product Chemistry for SAn 582H, 2-chloro-N-(2,4-dimethyl-3-thienyl)-N-(2-methyoxy-1-methylethyl)-acetamide, submitted in support of registration, prepared by the Dynamac Corp. under supervision of Chemistry Branch I (CBTS). This review has undergone secondary review and revision in CBTS and reflects current Branch policies.

Data gaps listed in the enclosed report must be satisfied before permanent tolerances can be established. The remaining data gaps include solubility in water (Guideline Reference No. 63-8) and Corrosion Characteristics (Guideline Reference No. 63-20). In its transmittal letter dated 9/21/92, Sandoz Agro Inc. reported that the corrosion study was to be completed in 12/92.

If you need additional input, please advise us.

Attachments: 1. Product Chemistry Review.
2. Confidential Appendix

cc: with Attachments 1 and 2: PP#0F3918, SAN 582H, M.Flood, Dynamac Corp.

cc: with Attachment 1 only: RF, SF, Circu.

cc: without Attachments: E.Haeberer.

H7509C:CBTS:Reviewer(MTF):CM#2:Rm804P:305-6362:typist(mtf):1/22/93
RDI:SectionHead:ETHaeberer:1/22/93:BranchChief:DEdwards:
1/22/93.

DYNAMAC
CORPORATION
Environmental Services

Final Report

SAN 582H
Shaughnessy No. 129051 (CBTS No. 10761; DP Barcode D183774)

TASK 4
Registrant's Response to Product Chemistry Data Requirements

January 11, 1993

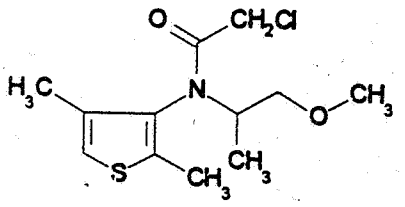
Contract No. 68-D2-0053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268

3

SAN 582H



Shaughnessy No. 129051

(CBTS No. 10761; DP Barcode D183774)

Task 4

REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

BACKGROUND

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

In response to Agency Memoranda (CBTS No. 8787, dated 7/29/92, and CBTS Nos. 9629 and 9630, dated 7/29/92, by M. Flood), Sandoz Agro, Inc. has submitted a transmittal letter and twelve volumes of product chemistry data (CBTS No. 10761; 1992; MRIDs 42512900-42512912) in support of registration of the 96.9% technical (T; EPA File Symbol No. 55947-RUR). The registrant had previously submitted product chemistry data in support of the registration of a 91.6% technical (EPA File Symbol No. 55947-EUP-RR); these data were reviewed by CBTS (CBTS No. 7060, dated 1/18/91, by M. Flood). The manufacturing process has been modified to [redacted] and new product chemistry data have been submitted to support the registration of the 96.9% T (EPA File Symbol No. 55947-RUR). Data submitted here and data reviewed in two previous Agency Memoranda (CBTS No. 8787, dated 7/29/92, and CBTS Nos. 9629 and 9630, dated 7/29/92, by M. Flood) are in support of the 96.9% T. The submitted data and our conclusions are discussed below.

61-1. Product Identity and Disclosure of Ingredients

The Agency Memorandum (CBTS No. 8787, dated 7/29/92, by M. Flood) requires additional information concerning an impurity of toxicological concern present in the Sandoz 96.9% T (EPA File Symbol No. 55947-RUR). In response, Sandoz has submitted (1992; MRID 42512901) supplemental information including a Confidential Statement of Formula (CSF) dated 9/15/92 for the 96.9% T. These data are presented in the Confidential Appendix and satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding the product identity of the Sandoz 96.9% T (EPA File Symbol No. 55947-RUR). No additional data are required.

61-2. Description of Starting Materials and Manufacturing Process

The Agency Memorandum (CBTS No. 8787, dated 7/29/92, by M. Flood) requires additional information concerning the duration of each step and of the entire manufacturing process of the Sandoz 96.9% T (EPA File Symbol No. 55947-RUR). In response, Sandoz has submitted (1992; MRID 42512901) supplemental information for the manufacturing process of the 96.9% T. This information is presented in the Confidential Appendix and satisfies the requirements of 40 CFR §158.160 and §158.162 (Guideline

§158.160 and §158.162 (Guideline Reference No. 61-2) regarding the starting materials and the production process for the Sandoz 96.9% T (EPA File Symbol No. 55947-RUR). No additional information is required.

61-3. Discussion of Formation of Impurities

The Agency Memorandum (CBTS No. 8787, dated 7/29/92, by M. Flood) requires additional discussion of the formation of post-production impurities and discussion of the formation of an impurity associated with the active ingredient which was found to be present at >0.1% in the 96.9% T (EPA File Symbol No. 55947-RUR). In response, Sandoz has submitted (1992; MRID 42512901) a discussion of the potential route for the formation of the impurity during the production of the 96.9% T, and a discussion of the possible formation of post-production impurities. This discussion is presented in the Confidential Appendix and satisfies the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding discussion of formation of impurities for the Sandoz 96.9% T (EPA File Symbol No. 55947-RUR). No additional information is required.

62-2. Certification of Limits

The Agency Memorandum (CBTS No. 8787, dated 7/29/92, by M. Flood) requires that an upper certified limit be proposed for an impurity of toxicological concern found to be present in the 96.9% T (EPA File Symbol No. 55947-RUR) and that the certified limits proposed for the SAN 582H technical reflect the variability in the preliminary analysis data. In addition, submission of a revised CSF was required to correct various errors. In response, Sandoz has submitted information and a CSF dated 9/15/92 (1992; MRID 42512902) for the 96.9% T (EPA File Symbol No. 55947-RUR). These data are presented in the Confidential Appendix and satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits for the Sandoz 96.9% T (EPA File Symbol No. 55947-RUR). No additional data are required.

PHYSICAL AND CHEMICAL CHARACTERISTICS

The Agency Memorandum (CBTS No. 8787, dated 7/29/92, by M. Flood) requires additional data pertaining to the physicochemical properties of SAN 582H. In response, Sandoz has submitted (1992; MRIDs 42512903-42512911) physical/chemical characteristics data for the 96.9% T (EPA File Symbol No. 55947-RUR). These properties are presented in Table 1. The registrant has noted (1992; MRID 42512900) that data pertaining to the vapor pressure, dissociation constant, and octanol/water partition coefficient (Guideline Reference Nos. 63-9, 63-10, and 63-11) of the PAI of the 96.9% T have been previously submitted and reviewed (CBTS No. 7060, dated 1/18/91, by M. Flood). The registrant has also noted (MRID 42512900) that the Agency Memorandum (CBTS Nos. 9629 and 9630, dated 7/29/92, by M. Flood) requires additional data for storage stability (Guideline Reference No. 63-17) that actually pertain to stability (Guideline Reference No. 63-13); we concur that the storage stability data requirements are fulfilled by the previous submission. We also note that the metals and metal ions stability data may be applied to the corrosion characteristics data requirements; however, the registrant has stated that a corrosion study will be completed by 12/92.

The submitted data satisfy the requirements of 40 CFR §158.190 (Guideline Reference Nos. 63-2 through 63-7, 63-12 through 63-15, and 63-18 through 63-20) for the 96.9% T (EPA File Symbol No. 55947-RUR). Data remain outstanding concerning the solubility in water (Guideline Reference No. 63-8) and the corrosion characteristics (Guideline Reference No. 63-20) of the 96.9% T.

5

Table 1. Physical and chemical properties of the 96.9% T (EPA File Symbol No. 55947-RUR) technical grade of the active ingredient (TGAI) and manufacturing-use product (MP).

Guidelines Reference No., 40 CFR §158.190; Name of Property		Description [Method] (Substrate; MRID)
63-2.	Color	**Gardner color >18** [ASTM D 1544] (TGAI/MP; 42512903)
63-3.	Physical state	**liquid with thin syrupy consistency** [visual] (TGAI/MP; 42512904)
63-4.	Odor	**strong, oily, sulfurous** [Test T-0319] (TGAI/MP; 42512905)
63-5.	Melting point	**N/A; TGAI is a liquid**
63-6.	Boiling point	**122.8 C at 0.1 mm Hg** [ASTM D1120, D850, and D86] (TGAI; 42512906)
63-7.	Density, bulk density, or specific gravity	**1.185 g/mL density at 25 C; 1.188 specific gravity 25/25 C** [ASTM D792 and ASTM D891 Method C] (TGAI/MP; 42512907)
63-12.	pH	**8.41 - 6.88; continuously decreasing over a 45 minute period; 1% aqueous solution** [pH Meter, Test T-0318] (TGAI/MP; 42512908)
63-13.	Stability	**stable at 54 ± 2 C for 14 days; an aqueous solution has a photodegradation half-life of 23.9 days under simulated sunlight (xenon lamp) demonstrating gradual photodegradation; stable upon exposure to metals and metal ions (C1020 type steel)** [CIPAC method MT 46, ASTM G31-72, and EPA SW-846-corrosivity] (TGAI; 42512909)
63-14.	Oxidizing/ reducing action	**does not exhibit unusual reactivity toward reducing agents, common solvents, fire extinguishing agents or water; reacts mildly with potassium permanganate, contact with strong oxidizing agents should be avoided** [Chemical reactivity, Test T-0323] (MP; 42512910)
63-15.	Flammability	**flash point = 91 C** [Pensky-Martens Closed Cup Tester, ASTM D93] (MP; 42512911)
63-18.	Viscosity	**106, 115 and 112 cP at 0.3, 0.6 and 1.5 RPM, respectively at 25 C** [Brookfield Digital Viscometer] (MP; 42512912)
63-19.	Miscibility	**N/A; not to be diluted with petroleum solvents** (MP; 42512900)

MASTER RECORD IDENTIFICATION NUMBERS

Citations for the MRID documents referred to in this review are presented below.

42512901 Williams, J. (1992) Addendum A2: Technical SAN 582H Product Identity and Composition. Unpublished compilation prepared by Sandoz Agro, Inc. 10 p.

42512902 Fickle, J. (1992) Addendum A1: Technical SAN 582H Certification of Limits. Unpublished compilation prepared by Sandoz Agro, Inc. 6 p.

42512903 Widlak, A. (1992) Color of SAN 582H, Technical. Unpublished study prepared by Sandoz Crop Protection. 12 p.

42512904 Widlak, A. (1992) Physical State of SAN 582H, Technical. Unpublished study prepared by Sandoz Crop Protection. 12 p.

42512905 Buck, B.L. (1992) Determination of Odor for SAN 582H Technical. Unpublished study prepared by Sandoz Agro, Inc. 19 p.

42512906 Chen, H. (1992) Boiling Point of SAN 582H, Technical. Unpublished study prepared by Sandoz Crop Protection. 15 p.

42512907 Pal, A. (1992) Density of SAN 582H, Technical. Unpublished study prepared by Sandoz Crop Protection. 12 p.

42512908 Pal, A. (1992) pH of SAN 582H, Technical. Unpublished study prepared by Sandoz Crop Protection. 12 p.

42512909 Wojtowicz, L. (1992) Stability of Technical SAN 582H. Unpublished study prepared by Sandoz Agro, Inc. 51 p.

42512910 Pal, A. (1992) Oxidizing or Reducing Action of SAN 582H, Technical. Unpublished study prepared by Sandoz Agro, Inc. 35 p.

42512911 Widlak, A. (1992) Flash Point of SAN 582H, Technical. Unpublished study prepared by Sandoz Crop. Protection. 12 p.

42512912 Widlak, A. (1992) Brookfield Viscosity of SAN 582H, Technical. Unpublished study prepared by Sandoz Agro, Inc. 12 p.

Chemical No: 129051
Chemical Name: SAN 582H
Registrant: Sandoz Agro, Inc.
Product(s): 96.9% T (EPA File Symbol No. 55947-RUR)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [a]	MRID Number
61-1	Product Identity and Disclosure of Ingredients	Y	42512901 CSF dated 9/15/92
61-2	Starting Materials and Manufacturing Process	Y	42512901
61-3	Discussion of Formation of Impurities	Y	42512901
62-1	Preliminary Analysis	Y [b]	
62-2	Certification of Ingredient Limits	Y	42512902 CSF dated 9/15/92
62-3	Analytical Methods to Verify the Certified Limits	Y [b]	
63-2	Color	Y	42512903
63-3	Physical State	Y	42512904
63-4	Odor	Y	42512905
63-5	Melting Point	N/A	
63-6	Boiling Point	Y	42512906
63-7	Density, Bulk Density or Specific Gravity	Y	42512907
63-8	Solubility	N [c]	
63-9	Vapor Pressure	Y [d]	
63-10	Dissociation Constant	Y [d]	
63-11	Octanol/Water Partition Coefficient	Y [d]	
63-12	pH	Y	42512908
63-13	Stability	Y	42512909
63-14	Oxidizing or Reducing Action	Y	42512910
63-15	Flammability	Y	42512911
63-16	Explodability	Y [a]	
63-17	Storage Stability	Y	42512900
63-18	Viscosity	Y	42512912
63-19	Miscibility	N/A	42512900
63-20	Corrosion Characteristics	N	42512909

[a] Y = Yes; N = No; N/A = Not Applicable. Data were submitted in response to the Agency Memoranda (CBTS No. 8787, dated 7/29/92, and CBTS Nos. 9629 and 9630, dated 7/29/92, by M. Flood). Data requirements followed by MRID citations reflect conclusions determined in this document (CBTS No. 10761).

[b] CBTS No. 8787, dated 7/29/92, by M. Flood.

[c] Per CBTS No. 8787 dated 7/29/92, the solubility of the TGAI in water must be submitted.

[d] CBTS No. 7060, dated 1/18/91, by M. Flood,

8

SAN 528H (SANDOZ; CBTS NO. 10761)

PRODUCT CHEMISTRY

TASK 4

(Final Report)

CONFIDENTIAL APPENDIX

4 Page(s)

Confidential Appendix to the Scientific Review of a Registration Standard Followup Report for the pesticide SAN 582H by the Chemistry Branch II Reregistration Support [Confidential FIFRA Trade Secret/CBI].

9

DIMETHENAMID

Page_____ is not included in this copy.

Pages 10 through 13 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

____ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

X CONFIDENTIAL APPENDIX

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.