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

JAN 18 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: SAN 582H: Product Chemistry Data Submitted in Support of Registration (MRID Nos. 415965-01 through 415965-18, DEB No. 7060).

FROM: Michael T. Flood, Ph.D., Chemist
Tolerance Petition Section II
Chemistry Branch I
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Michael Flood

THROUGH: Richard D. Schmitt, Ph.D., Chief
Chemistry Branch I
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Richard D Schmitt

TO: Joanne Miller, PM 23
Fungicide-Herbicide Branch
Registration Division H7505C

and

Toxicology Branch II
Health Effects Division H7509C

Attached is a review of the Product Chemistry for SAN 582H, 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 Chemistry Branch I and reflects current Branch policies. Data submitted for the end-use product, MRID Nos. 415965-19 through 415965-30, were not reviewed.

The submitted product chemistry data are sufficient for purposes of this temporary tolerance petition. For permanent tolerances, however, data gaps listed in the enclosed report must be satisfied.

If you need additional input, please advise us.

Attachments: 1 - Product Chemistry Review
2 - Confidential Appendices

cc: with Attachments 1 and 2: PP#0G3892, SAN 582H Registration Standard File, M. Flood, PMSD/ISB.
cc: with Attachment 1 only: RF, SF, Circu.

H7509C:CBTS:Reviewer(MTF):CM#2:Rm810:557-4362:typist(mtf): 1/16/91.
RDI:SectionHead:ETHaeberer:1/16/91:BranchSeniorScientist: RALoranger:1/16/91.

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DYNAMAC
CORPORATION

Draft Report

SAN 582H - DEB No. 7060
Task 5: Product Chemistry Data Submitted in Support of Registration

November 21, 1990

Contract No. 68-D8-0080

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
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SAN 582H

PRODUCT CHEMISTRY DATA SUBMITTED IN SUPPORT OF REGISTRATION

TASK 5

Sandoz Crop Protection Corp. is currently seeking registrations for a 91.62% technical (T; EPA File Symbol No. 55947-EUP-RR) and a 7.5 lb/gal (78.54%) end-use product (EP), which contain the herbicidal active ingredient SAN 582H. In support of the registration of the 91.62% T, Sandoz has submitted 18 volumes of product chemistry data (DEB No. 7060; 1990; MRIDs 41596501-41596518). Data submitted for the EP (1990; MRIDs 41596519-41596530) will not be reviewed in this document.

INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA §3(c)(2)(A)] requires the Environmental Protection Agency to establish guidelines for registering pesticides in the United States. The Agency, in turn, requires registrants to provide quantitative data on all added ingredients, active and inert, which are equal to or greater than 0.1% of the product by weight.

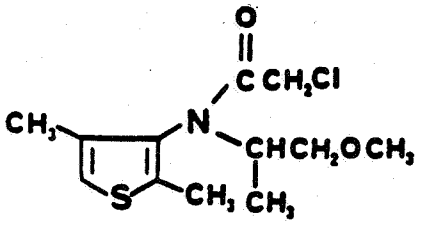
To establish the composition of products to be registered, the Agency requires detailed information on the manufacturing process and/or formulation processes, and a discussion of the formation of manufacturing impurities. Furthermore, to assure that the composition of the product as marketed will not vary from that evaluated at the time of registration, prospective pesticide registrants are required to propose certified upper and lower composition limits for the added ingredients, and upper limits for toxicologically significant impurities. Standard certified limits for pesticide product ingredients are established according to 40 CFR §158.175(b)(2); these limits may be modified with appropriate and acceptable explanation by the registrant.

The Agency also requires data on the physical and chemical properties of the pesticide active ingredient and its formulations, such as melting and boiling points, ambient vapor pressures, and solubility in various solvents. Corresponding to each of the Topical Discussions listed below are the Guideline Reference Numbers from "Pesticide Assessment Guidelines - Subdivision D - Product Chemistry", referred to in Title 40 of the Code of Federal Regulations (40 CFR), Part 158, "Data Requirements for Registration", Subpart C, "Product Chemistry Data Requirements". These regulations and guidelines explain the minimum data that the Agency needs to adequately assess the product chemistry of SAN 582H.

Guidelines Reference No.
from 40 CFR §158.155-190

61-1. Product Identity and Disclosure of Ingredients

2-Chloro-N-[(1-methyl-2-methoxy)ethyl]-N-(2,4-dimethyl-thien-3-yl)-acetamide is the active ingredient (AI) in the 91.62% T produced by Sandoz. The molecular structure is illustrated below:



Other identifying characteristics and codes are:

Empirical Formula:	$C_{12}H_{18}ClNO_2S$
Molecular Weight:	275.79
CAS Registry No.:	87674-68-8
EPA File Symbol No.:	55947-EUP-RR
Company Product No.:	SAN 582H

Sandoz submitted product identity data (1990; MRID 41596501) and a Confidential Statement of Formula (CSF) for the 91.62% T (EPA File Symbol No. 55947-EUP-RR). Refer to Confidential Appendix A for disclosure of the ingredients in the product. The submitted data do not satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) regarding product composition for the 91.62% T (EPA File Symbol No. 55947-EUP-RR) because an impurity present at 0.1% by weight or greater must be identified. If this component cannot be identified as a discrete chemical substance, the registrant must supply sufficient information to enable the Agency to identify its source and qualitative composition. We note that the nominal concentration value for one of the impurities has been entered incorrectly. A corrected CSF must be submitted on EPA Form 8570-4 (Rev. 2-85). The following additional data are required:

- Each impurity determined to be present at ≥0.1% by weight of the 91.62% technical must be individually identified and listed on the CSF, and a nominal concentration must be provided. For any impurity determined to be of

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toxicological concern, a nominal concentration and an upper certified limit are required, regardless of the amount present. Sufficient information must be submitted to enable the Agency to identify the source and qualitative composition of all ingredients that cannot be characterized.

61-2. Starting Materials and Manufacturing Process

Sandoz submitted (1990; MRID 41596501) the names and addresses of the suppliers of the starting materials along with technical specification information, and a detailed description of the manufacturing process for the 91.62% T (EPA File Symbol No. 55947-EUP-RR). Also included in the submission were the chemical equations for each intended reaction of each step of the process, the relative amounts of starting materials and the order in which they are added, a description of the conditions controlled during each step of the process, and details of purification and quality control measures taken to assure the consistent composition of the product. The submitted data are presented in Confidential Appendix B, and do not satisfy the requirements of 40 CFR §158.160-165 (Guideline Reference No. 61-2) regarding starting materials and the production process for the 91.62% T (EPA File Symbol No. 55947-EUP-RR) because a description of the production equipment used and the duration of each step and of the entire process were not included. The following additional data are required:

- O A description of the equipment used and the duration of each step and of the entire manufacturing process are required.

61-3. Discussion of the Formation of Impurities

Sandoz submitted (1990; MRID 41596501) a discussion of the formation of impurities in the 91.62% T (EPA File Symbol No. 55947-EUP-RR). The discussion included confirmed and theoretical impurities formed as a result of carryover of the starting materials or their impurities, intended and side reactions occurring during the manufacturing process, degradation of ingredients in the product after production, and post-production reactions between ingredients in the product. The submitted information is presented in Confidential Appendix C, and does not satisfy the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) for the 91.62% T (EPA File Symbol No. 55947-EUP-RR) because a discussion of the source of several impurities listed on the CSF was not provided. In addition, the registrant did not submit discussions pertaining to the possible formation of impurities resulting from contamination of the product by packaging materials or production equipment. A discussion of the

possibility for formation of N-nitroso contaminants is also required because the active ingredient, SAN 582H, is a tertiary alkylamine. The following additional data are required:

- A discussion regarding the origin of the following potential impurities must be provided for: (i) each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the registrant, and (ii) each impurity which the registrant has reason to believe may be present in the product at a level equal to or greater than 0.1% (w/w) based on the composition of each starting material, intended and side reactions which may occur in the production of the product, the possible degradation of ingredients in the product after production, post-production reactions between the ingredients in the product, possible contamination from packaging materials or production equipment, and process control, purification and quality control measures. Also, a thorough discussion of the possibility of the formation of nitrosamine contaminants during the manufacturing process is required.

62-1. Preliminary Analysis

Sandoz submitted data (1990; MRID 41596502) from preliminary analysis of five batches of the 91.62% T (EPA File Symbol No. 55947-EUP-RR), which are presented in Confidential Appendix D. These data do not satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis of the 91.62% T (EPA File Symbol No. 55947-EUP-RR) because the registrant did not include preliminary analysis for all impurities listed on the CSF. In addition, if further discussion of the formation of impurities reveals the potential for formation of N-nitroso compounds, preliminary analysis for N-nitroso contaminants will be required. The following additional data are required:

- The registrant must provide preliminary analysis for each impurity present at 0.1% or greater of the TGAI from five or more representative samples of the product. Complete and detailed descriptions of the methods used for sample analysis must be submitted, including statements of their precision and accuracy. The preliminary analysis report should include the identity and quantity of each ingredient for which the analysis is conducted, along with the mean and relative standard deviation of the analytical results. In addition, if further discussion of formation of impurities reveals the potential for formation of N-nitroso contaminants, all nitrosamines will need to be identified and quantified by methods

sensitive to 1 ppm of N-nitroso contaminants in six samples of each manufacturing-use product; two samples of each must be analyzed shortly after production, two at 3 months after production, and two at 6 months after production. Upper limits will be required for all nitrosamines found.

62-2. Certified Limits

Sandoz submitted data (1990; MRID 41596503) and a CSF which establish certified limits for the 91.62% T (EPA File Symbol No. 55947-EUP-RR), and describe how the limits were established. Data are presented in Confidential Appendix A, and do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits for the 91.62% T (EPA File Symbol No. 55947-EUP-RR) because additional information is required pertaining to the identity of an impurity listed on the CSF; upper certified limits will be required if the impurity is determined to be of toxicological significance. The following additional data are required:

- The registrant must propose upper certified limits for each toxicologically significant impurity associated with the active ingredients and found to be present in any sample of the product (standard certified limits cannot be used for impurities). Certified limits should be based on the sources and magnitude of variability in the manufacturing process and the stability of the ingredients following production. Certifications must be submitted on EPA Form 8570-4 (Rev. 2-85).

62-3. Enforcement Analytical Methods

Sandoz submitted (1990; MRID 41596502) a gas chromatography (GC) method (method AM-0825-0189-0) for the determination of SAN 582H in the 91.62% T (EPA File Symbol No. 55947-EUP-RR).

[redacted]

QUALITY CONTROL PROCEDURE INFORMATION IS NOT INCLUDED

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Sandoz also submitted an enforcement analytical method for the determination of the impurities in the 91.62% T (EPA File Symbol No. 55947-EUP-RR). This method is presented in Confidential Appendix E.

The submitted methods (1990; MRID 41596502) do not satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods for the 91.62% T (EPA File Symbol No. 55947-EUP-RR) because incomplete validation data have been submitted for the analytical methods used to quantitate the active ingredient and impurities; the number of samples and type of samples used for precision studies were not specified. In addition, since an impurity listed on the CSF is identified by preliminary analysis as being related to the active ingredient and thus of toxicological concern, an enforcement analytical method must be submitted to quantify this component. Furthermore, because additional data are required for the 91.62% T (EPA File Symbol No. 55947-EUP-RR) regarding product composition, discussion of the formation of impurities and preliminary analysis, additional impurities of toxicological significance may yet be identified. The following additional data are required:

- Analytical methods which are suitable for enforcement purposes must be provided for each impurity that is determined to be toxicologically significant. Complete validation studies of method accuracy and precision must be submitted for the methods used for enforcement purposes.

PHYSICAL AND CHEMICAL CHARACTERISTICS

Data submitted by Sandoz (1990; MRIDs 41596504-41596518) regarding the physical and chemical characteristics of the 91.62% T (EPA File Symbol No. 55947-EUP-RR) are presented in Table 1. The following additional data are required:

- Data concerning explodability, storage stability, and miscibility must be provided as required by 40 CFR §158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Guidelines Reference Nos. 63-16, -17, and -19.

Table 1. Physical and chemical properties of the SAN 582H purified active ingredient (PAI) and 91.62% T (EPA File Symbol No. 55947-EUP-RR).

Guidelines Reference No., 40 CFR §158.190; Name of Property		Description [Method] (Substrate; MRID)
63-2.	Color	dark brown, >18 Gardner color scale [ASTM D1544] (TGAI; 41596504)
63-3.	Physical state	viscous liquid (TGAI; 41596504)
63-4.	Odor	weak tar-like [T-0319] (TGAI; 41596505)
63-5.	Melting point	n/a; SAN 582H is a liquid
63-6.	Boiling point	127 C at a pressure of 0.2 mm Hg [ASTM D1120, D850, D86] (TGAI; 41596506)
63-7.	Density, bulk density, or specific gravity	1.187 g/cm^3 at 25 C [pycnometer, ASTM D891, D792] (TGAI; 41596504)
63-8.	Solubility	Solvent / Solubility at 25 C (g/100 ml): water 0.1174; heptane 26.7; isooctane 19.4; p-xylene soluble in all proportions; tetrahydrofuran "; 2-propanol "; dimethylformamide "; [water-radioassay/centrifugation] [organics-GC method AM-0814] (TGAI; 41596507 and 41596508)
63-9.	Vapor pressure	2.76 x 10^{-4} mm Hg at 25 C [Thermal Evolution Analyzer, AM-0813] (PAI; 41596509)
63-10.	Dissociation constant	No dissociation between pH 1-11 at 25 C [spectrophotometer] (PAI; 41596510)
63-11.	Octanol/water partition coefficient	K_{ow} = 141 [radioassay] (PAI; 41596511)

(Continued.)

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Table 1. (Continued.)

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Substrate; MRID)
63-12. pH	4.23 at 25 C [T-0318, CIPAC MT 75] (TGAI; 41596512)
63-13. Stability	stable for 90 days at 54 C [CIPAC MT-46, GC method AM-0825-0189-0] (TGAI; 41596513) stable for 2 weeks at room temperature in the presence of iron and iron ions, not unusually sensitive to sunlight. [CIPAC MT-46, ASTM G 31-72, EPA SW-846, GC method AM-0825-0189-0] (TGAI; 41596514)
63-14. Oxidizing or reducing action	mildly reactive with potassium permanganate; contact with strong oxidizing agents should be avoided [AM-7068 (ASTM D93), T-0318, ASTM G 31-72, EPA SW-846, T-0323] (TGAI; 41596515)
63-15. Flammability	Flashpoint = 121 C [AM-7068 (ASTM D93)] (TGAI; 41596516)
63-16. Explodability	not submitted
63-17. Storage stability	not submitted
63-18. Viscosity	132 cP at 25 C [Brookfield LVT DVCP-II instrument] (TGAI; 41596517)
63-19. Miscibility	not submitted
63-20. Corrosiveness	corrosion rate of 0.190 mmpy on C1020-type steel at 55 C [ASTM G 31-72, EPA SW-846] (TGAI; 41596518)

TABLE A. GENERIC DATA REQUIREMENTS FOR THE SAN 582H (SANDOZ CROP PROTECTION CORP.) TECHNICAL GRADE OF THE ACTIVE INGREDIENT.[1]

Data Requirement	Test Substance[2]	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)? [Yes]	[No]	Reference (MRID No.)
40 CFR §158.155-190 Product Chemistry SAN 582H (SANDOZ CROP PROTECTION CORP.)					
Product Composition					
61-2. Beginning Materials & Production Process	TGAI	R	X[3]		41596501
61-3. Formation of Impurities	TGAI	R	X[4]		41596501
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	TGAI	CR	X[5]		41596502
Physical and Chemical Characteristics[6]					
63-2. Color	TGAI	R		X	41596504
63-3. Physical State	TGAI	R		X	41596504
63-4. Odor	TGAI	R		X	41596505
63-5. Melting Point	TGAI	NA[7]		X	
63-6. Boiling Point	TGAI	R		X	41596506
63-7. Density/Specific Gravity	TGAI	R		X	41596504
63-8. Solubility	TGAI or PAI	R		X	41596507 41596508
63-9. Vapor pressure	TGAI or PAI	R		X	41596509
63-10. Dissociation Constant	TGAI or PAI	R		X	41596510
63-11. Octanol/Water Partition Coefficient	PAI	CR		X	41596511
63-12. pH	TGAI	CR		X	41596512
63-13. Stability	TGAI	R		X	41596513 41596514
Other Requirements:					
64-1. Submittal of Samples	TGAI or PAI	CR		X[8]	

1. Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for SAN 582H Manufacturing-Use Products", for registered technical products.

TABLE A. (Continued).

2. Test substance: MP = manufacturing-use product; PAI = purified active ingredient; TEP = typical end-use product; TGAI = technical grade of the active ingredient.

3. A description of the equipment used and the duration of each step and of the entire manufacturing process are required.

4. A discussion regarding the origin of the following potential impurities must be provided for: (i) each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the registrant, and (ii) each impurity which the registrant has reason to believe may be present in the product at a level equal to or greater than 0.1% (w/w) based on the composition of each starting material, intended and side reactions which may occur in the production of the product, the possible degradation of ingredients in the product after production, post-production reactions between the ingredients in the product, possible contamination from packaging materials or production equipment, and process control, purification and quality control measures. Also, a thorough discussion of the possibility of the formation of nitrosamine contaminants during the manufacturing process is required.

5. Preliminary analysis for each impurity present at 0.1% or greater of the TGAI from five or more representative samples of the product must be provided. Complete and detailed descriptions of the methods used for sample analysis must be submitted, including statements of their precision and accuracy. The preliminary analysis report should include the identity and quantity of each ingredient for which the analysis is conducted, along with the mean and relative standard deviation of the analytical results. In addition, if further discussion of formation of impurities reveals the potential for formation of N-nitroso contaminants, all nitrosamines will need to be identified and quantified by methods sensitive to 1 ppm of N-nitroso contaminants in six samples of each manufacturing-use product; two samples of each must be analyzed shortly after production, two at 3 months after production, and two at 6 months after production. Upper limits will be required for all nitrosamines found.

6. As required by 40 CFR §158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Guidelines Reference Nos. 63-2 through 63-13, data must be submitted on physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, octanol/water partition coefficient, pH, and stability). There are additional data requirements listed in Table B pertaining to physicochemical characteristics of the technical product which is also a manufacturing-use product.

7. Data on melting point are not required since the technical product is a liquid at room temperature.

8. If samples are required, the Agency will request them.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR SAN 582H (SANDOZ CROP PROTECTION CORP.) MANUFACTURING-USE PRODUCTS.[1]

Data Requirement	Test Substance[2]	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)? [Yes]	[No]	Reference (MRID No.)
40 CFR §158.155-190 Product Chemistry					
Product Composition					
61-1. Product Composition	MP	R	X[3]		41596501
61-2. Beginning Materials & Production/Formulation Process	MP	R	X[4]		41596501
61-3. Formation of Impurities	MP	R	X[5]		41596501
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	MP	CR	X[6]		41596502
62-2. Certified Limits	MP	R	X[7]		41596503
62-3. Enforcement Method	MP	R	X[8]		41596502
Physical and Chemical Characteristics[9]					
63-2. Color	MP	R		X	41596504
63-3. Physical State	MP	R		X	41596504
63-4. Odor	MP	R		X	41596505
63-7. Density/Specific Gravity	MP	R		X	41596504
63-12. pH	MP	CR		X	41596512
62-14. Oxidizing/Reducing Action	MP	CR		X	41596515
62-15. Flammability	MP	CR		X	41596516
63-16. Explodability	MP	R	X[10]		
63-17. Storage Stability	MP	R	X[11]		
63-18. Viscosity	MP	CR		X	41596517
63-19. Miscibility	MP	CR	X[12]		
63-20. Corrosion Characteristics	MP	R		X	41596518

(Continued, footnotes follow)

TABLE B. (Continued).

Data Requirement	Test Substance	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)? [Yes] [No]	Reference (MRID No.)
Other Requirements:				
64-1. Submittal of Samples	MP	CR	X[13]	"

1. Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the SAN 582H Technical Grade of the Active Ingredient", for those manufacturing-use products which consist only of the TGAI.

2. Test substance: MP = manufacturing-use product; PAI = purified active ingredient; TEP = typical end-use product; TGAI = technical grade of the active ingredient.

3. Each impurity determined to be present at ≥0.1% by weight of the 91.62% T must be individually identified and listed on the CSF, and a nominal concentration must be provided. For any impurity determined to be of toxicological concern, a nominal concentration and an upper certified limit are required, regardless of the amount present. Sufficient information must be submitted to enable the Agency to identify the source and qualitative composition of all ingredients that cannot be characterized.

4. A description of the equipment used and the duration of each step and of the entire manufacturing process are required.

5. A discussion regarding the origin of the following potential impurities must be provided for: (i) each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the registrant, and (ii) each impurity which the registrant has reason to believe may be present in the product at a level equal to or greater than 0.1% (w/w) based on the composition of each starting material, intended and side reactions which may occur in the production of the product, the possible degradation of ingredients in the product after production, post-production reactions between the ingredients in the product, possible contamination from packaging materials or production equipment, and process control, purification and quality control measures. Also, a thorough discussion of the possibility of the formation of nitrosamine contaminants during the manufacturing process is required.

6. Preliminary analysis for each impurity present at 0.1% or greater of the TGAI from five or more representative samples of the product must be provided. Complete and detailed descriptions of the methods used for sample analysis must be submitted, including statements of their precision and accuracy. The

TABLE B. (Continued).

preliminary analysis report should include the identity and quantity of each ingredient for which the analysis is conducted, along with the mean and relative standard deviation of the analytical results. In addition, if further discussion of formation of impurities reveals the potential for formation of N-nitroso contaminants, all nitrosamines will need to be identified and quantified by methods sensitive to 1 ppm of N-nitroso contaminants in six samples of each manufacturing-use product; two samples of each must be analyzed shortly after production, two at 3 months after production, and two at 6 months after production. Upper limits will be required for all nitrosamines found.

7. The registrant must propose upper certified limits for each toxicologically significant impurity associated with the active ingredient and found to be present in any sample of the product (standard certified limits cannot be used for impurities). Certified limits should be based on the sources and magnitude of variability in the manufacturing process and the stability of the ingredients following production. Certifications must be submitted on EPA Form 8570-4 (Rev. 2-85).

8. Analytical methods which are suitable for enforcement purposes must be provided for each impurity that is determined to be toxicologically significant. Complete validation studies of method accuracy and precision must be submitted for the methods used for enforcement purposes.

9. As required in 40 CFR §158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Guidelines Reference Nos. 63-2 through 63-20, data must be submitted on physicochemical characteristics of each manufacturing-use product (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explodability, storage stability, viscosity, miscibility, and corrosion characteristics). Additional data requirements regarding physicochemical properties of the manufacturing-use product, which contains only the technical grade of the active ingredient, are listed in Table A, "Generic Data Requirements for the SAN 582H Technical Grade of the Active Ingredient."

10. Sandoz has not responded to the data requirements for the 91.62% T; data are required pertaining to explodability.

11. Sandoz has not responded to the data requirements for the 91.62% T; data pertaining to storage stability must be submitted.

12. Sandoz has not responded to the data requirements for the 91.62% T; data pertaining to miscibility must be submitted.

13. If samples are required, the Agency will request them.

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