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WASHINGTON, D.C. 20460

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Atrazine (SRR) Registration Standard

FROM: Charles L. Trichilo, Ph.D., Chief
Dietary Exposure Branchh
Health Effects Division (TS-769C)

TO: Reto Engler, Ph.D., Chief
Science Analysis and Coordination Branch
Health Effects Division (TS-769C)

and

C. Kent, Chief
Reregistration Branch (TS-767)
Special Review and Reregistration Division (TS-767)

Attached are the Product and Residue Chemistry chapters for the atrazine Second Round Review (SRR)prepared by Dynamac Corporation under supervision of Dietary Exposure Branch, HED. The original Standard was published in November, 1983. Please note that the SACB copy of this cover memo does not have the chemistry chapters attached.

The due date for these chapters is October 18, 1988.

This standard includes data available and reviewed up to August 19, 1988.

The Agency has determined that product chemistry data for all technical and manufacturing-use products must be resubmitted for each pesticide because new requirements have been introduced and previously submitted data must be updated. Therefore, in this SRR chapter, only product chemistry data for the technical grade of the active ingredient received in response to data submissions required in the Guidance Document dated November, 1984 will be evaluated with regard to adequacy in meeting the requirements of 40 CFR Part 158.120. New and/or updated data are

still required for all other product chemistry Guidelines topics.

Attached to the Product Chemistry chapter are comprehensive generic and product specific data requirement tables for the technical grade of the active ingredient and manufacturing-use products, respectively, of atrazine.

These chapters have undergone secondary review in Dietary Exposure Branch and have been revised to reflect the Branch policies.

It should be noted that a major portion of the Residue Chemistry data gaps in this SRR arise from Toxicology's heightened interest in the chloro- and hydroxy- metabolites of atrazine. In the original standard, TOX had considered these metabolites to be insignificant and that the parent molecule was the only residue of concern.

The Product Chemistry chapter contains Appendices A,B,C,D and E. These are to be protected. Only the copies of the standard in Dietary Exposure Branch and those sent to C. Kent, E. Eldredge and Toxicology Branch contain such information.

Finally, Special Review and Reregistration Division, please note that Dietary Exposure Branch has completed the data tables for the Residue Chemistry chapter and they are included in this package.

If you need additional input please advise.

Attachment 1 : Atrazine Residue Chemistry Review
Attachment 2 : Atrazine Product Chemistry Review
Attachment 3 : Confidential Appendices to Product Chemistry Review

cc: With Attachments 1, 2 and 3: R. B. Perfetti, J. Hauswirth (TOX), E. Eldredge (PMSD/ISB), Atrazine Registration standard file.

cc: With Attachments 1 and 2: P. Lombardo (FDA) and M. Cordle (USDA)

cc: Without Attachments: T. Farber (HED), S. Rathman (HED), F. Bishop (RD), H. Jamerson (RD), Atrazine SF, Circulation (7) and RF.

DYNAMAC
CORPORATION

Final Report

Atrazine (SRR)
Task 1: Product Chemistry Chapter

Contract No. 68–02–4226

September 30, 1988

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
11140 Rockville Pike
Rockville, MD 20852

ATRAZINE (SRR)

PRODUCT CHEMISTRY

TASK 1

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 proposed for registration, the Agency requires data and information on the manufacturing and formulation process and a discussion on the formation of manufacturing impurities and other product ingredients, intentional and unintentional. Furthermore, to assure that the composition of the product as marketed will not vary from that evaluated at the time of registration, applicants for registration 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 in 40 CFR §158.175(b)(2); these 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 pressure, and solubility in various solvents. Corresponding to each of the Topical Discussions listed below are the section numbers from Title 40 of the Code of Federal Regulations (40 CFR), Part 158, "Data Requirements for Registration", Subpart C, "Product Chemistry Data Requirements". The physical and chemical characteristics and some other topics are more fully described under specific Guidelines Reference Nos. in "Pesticide Assessment Guidelines - Subdivision D - Product Chemistry". These regulations and guidelines explain the minimum data the Agency will need to adequately assess the product chemistry of atrazine.

	Guidelines Reference No. from 40 CFR §158.190
Product Composition and Manufacture	61-(1-3)
Analysis and Certification of Product Ingredients .	62-(1-3)
Physical and Chemical Characteristics	63-(2-20)

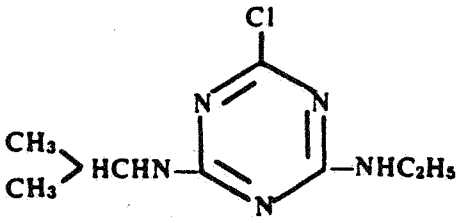
Current Agency policy requires that recent product chemistry data be available for each pesticide. Even though product chemistry data may have been submitted in the past, previously submitted data must be updated. When the Atrazine Guidance Document was

issued on 11/10/83, no such policy was in effect. Thus, for several product chemistry topics no additional data were required at that time, and the available data for these topics may now be outdated. Data for manufacturing-use products submitted in response to the Guidance Document are reviewed and evaluated in this chapter. Data reviewed previously for the Atrazine Guidance Document are not discussed again here. Any data not specifically required by the Guidance Document are now required in order to ascertain that the product chemistry data base remains current.

PRODUCT IDENTITY AND COMPOSITION

61-1 Product Composition

Atrazine is the common name approved by ANSI, BSI, E-ISO, F-ISO, JMAF, and WSSA for an herbicide having manufacturing-use products registered in the U.S. by Ciba-Geigy Corp.; E.I. duPont de Nemours Co. Inc.; Uniroyal Chemical Co. Inc.; Farmland Ind., Inc.; Aceto Chemical Co. Inc.; Industria Prodotti Chimici S.p.A.; Rumianca S.p.A.; Ida, Inc.; and Cedar Chemical Corp. The molecular structure is depicted below.



The IUPAC-approved chemical name is 6-chloro-*N*-ethyl-*N'*-isopropyl-1,3,5-triazinediyl-2,4-diamine. Variations in chemical nomenclature include 2-chloro-4-ethylamino-6-isopropylamino-1,3,5-triazine; 6-chloro-*N*-ethyl-*N'*-(1-methylethyl)-1,3,5-triazine-2,4-diamine (Chemical Abstracts, 9th Collective Index); and 2-chloro-4-(ethylamino)-6-(isopropylamino)-*s*-triazine (Chemical Abstracts, 8th Collective Index); 2-chloro-4-ethylamino-6-isopropylamino-*s*-triazine. Other names include AAtrex, Atranex, Atrataf, Azintox 500 Crisazina, Farmco Atrazine, Gesaprim, Griffex, DuPont Atrazine Herbicide, Vectal SC, Zeaphos, Atratol, Primatol A, and G-30027.

Other identifying characteristics and codes are :

Empirical Formula:	$C_8H_{14}ClN_5$
Molecular Weight:	215.7
CAS Registry No.:	1912-24-92
(atrazine + propachlor)	8070-76-6
(atrazine + metolachlor)	59316-87-9
(atrazine + ametryne)	39324-65-7

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(atrazine + terbutryn)	8066-10-2
(atrazine + simazine)	39331-45-8
Shaughnessy Code:	080803
(atrazine + propachlor)	080816
Wiswesser Line-Formula Notation:	T6N CN ENJ BMY1&1 DM2 FG
Advanced Wiswesser Line Notation:	(6N cN eN) bMY1&1 dM2 fG
U.S.D.A.:	ENT 28244

The above information was obtained from the following sources: Acceptable Common Names and Chemical Names for the Ingredient Statement on Pesticide Labels, 4th Ed., 1979, p. 18; Analytical Reference Standards and Supplemental Data: The Pesticides and Industrial Chemicals Repository, EPA-600/4-84-082, 1984, p. 17; British Crop Protection Council, The Pesticide Manual - A World Compendium, 8th Ed., 1987, p. 36; Farm Chemicals Handbook '88, p. C20; The Merck Index, 10th Ed. 1983, p. 125; Sittig, M., Pesticide Manufacturing and Toxic Materials Control Encyclopedia, 1980, pp. 505-507; and Herbicide Handbook of the Weed Science Society of America, 5th Ed., 1983, p. 30-35.

The atrazine manufacturing-use products including technicals (T) and formulation intermediates (FI) are listed below in Table 1. See Confidential Appendix A for disclosure of the ingredients in these products, as indicated in the table.

Table 1. Atrazine manufacturing-use products.

Product	EPA Reg. No.	Registrant	Ingredients Disclosure?
80% FI	100-521	Ciba-Geigy Corp.	yes
97% FI	100-529	Ciba-Geigy Corp.	yes
90% FI	100-572	Ciba-Geigy Corp.	yes
43% FI	100-581	Ciba-Geigy Corp.	yes
98.7% T	352-492[a]	E.I. duPont de Nemours Co. Inc.	yes
97% T	400-373[b]	Uniroyal Chemical Co. Inc.	yes
96% FI	400-374[b]	Uniroyal Chemical Co. Inc.	yes
99.5% T	1990-376[b]	Farmland Ind., Inc.	yes
80% FI	2749-92[b]	Aceto Agricultural Chemicals Corp.	yes
98% T	2749-277	Aceto Agricultural Chemicals Corp.	yes
98.8% T	11603-9	Makhteshim-Agan (America) Inc.	yes
80% FI	11603-10[b]	Makhteshim-Agan (America) Inc.	yes
95% T	13801-7[bc]	Intrachem, S.A.	no
94% T	15061-3[b]	Soluja, Limitée	yes
96.5% T	15590-1[b]	Central Agricultural Chemical Co.	no
100% T	18861-2[c]	Marzone Chemicals Ltd.	no
98% T	19713-7	Drexel Chemical Co.	yes
98% T	33660-1	Industria Prodotti Chimici, S.p.A.	yes
98% T	40643-1[bc]	Rumianca, S.p.A.	no
96% T	45115-63[c]	Ida, Inc.	no
100% T	56077-22[bc]	Cedar Chemical Corp.	no

[a] Transferred from Shell Chemical Co. (EPA Reg. No. 201-411).
[b] Product has been suspended, according to on-line tracking.
[c] Registration jackets were unavailable for review.

The Atrazine Guidance Document dated 11/10/83 concluded that the available data regarding product identity and disclosure of ingredients satisfied the requirements of 40 CFR §158.155, Guideline Reference No. 61-1. However, current Agency interpretation of the guidelines requires submission of ingredients statements for individual products under this topic. The data summarized in Confidential Appendix A satisfy the requirements of 40 CFR §158.155 (Guideline Reference No. 61-1) concerning product identity and disclosure of ingredients for the Ciba-Geigy unregistered TGAI and the 80, 90, and 43% FIs (EPA Reg. No. 100-521, -572, and -581), DuPont 98.2% T (EPA Reg. No. 352-492); Farmland 99.5% T (EPA Reg. No. 1990-376); Makhteshim-Agan 98.8% T (EPA Reg. No. 11603-9); and Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-1). The submitted data for the Ciba-Geigy 97% FI (EPA Reg. No. 100-529), Uniroyal 97% T and 96% FI (EPA Reg. No. 400-373 and -374), Aceto 80% FI and 98% T (EPA Reg. No. 2749-92 and 2749-277), Drexel 98% T (EPA Reg. No. 19713-7), Makhteshim-Agan 80% FI (EPA Reg. No. 11603-10), and Soluja 94% T (EPA Reg. No. 15061-3) do not satisfy these requirements because they failed to provide EPA Registration Numbers, CAS Registry Numbers, nominal concentrations, purposes, and/or certified limits for

ingredients. No information on these topics was available for the other technical products (EPA Reg. No. 13801-7, 15590-1 18861-2, 45115-63, 56077-22). The following additional data are required.

- For each manufacturing use product that consists of the technical grade of the active ingredient only or is produced by an integrated system, the following information must be provided: (i) the CA-approved chemical name, CAS Registry Number, any common names, the nominal concentration, upper and lower certified limits in accordance with 40 CFR §158.175, and the purpose of each active and inert ingredient in the product; (ii) the molecular, structural and empirical formulas, and the molecular weight or weight range of each active ingredient in the product; (iii) the chemical name and nominal concentration of each impurity of toxicological significance associated with the active ingredient or present in any sample at a level equal to or greater than 0.1% by weight of the TGAI; and (iv) sufficient information to enable the Agency to identify the source and qualitative composition of all ingredients that are not characterized. Impurities must be identified as such. For each manufacturing-use product that is produced from an EPA-registered product, the following information must be provided: (i) the chemical and common name of each active ingredient as listed on the source product, its nominal concentration in the product based upon the nominal concentration in the source product, and upper and lower certified limits in accordance with 40 CFR §158.175; (ii) the CA-approved chemical name of each inert ingredient in the product, its CAS Registry Number, any common names, nominal concentration, purpose, and upper and lower certified limits in accordance with 40 CFR §158.175; and (iii) sufficient information to enable the Agency to identify the source and qualitative composition of all ingredients that cannot be characterized. All requirements apply to EPA Reg. Nos. 13801-7, 15590-1 18861-2, 45115-63, 56077-22. For ingredients in other products, the following data must be provided: EPA Registration Numbers (2749-92, 2749-277, 11603-10); CAS Registry Numbers (400-373, 2749-277, 19713-7, 40643-1); purpose (2749-92, 19713-7, 40643-1); nominal concentration (100-529, 19713-7, 40643-1); and certified limits (400-373, 400-373, 2749-92, 11603-10, 15061-3).

61-2. Beginning Materials and Manufacturing Process

Atrazine is prepared by the reaction of cyanuric chloride with one equivalent of ethylamine followed by one equivalent of isopropylamine in the presence of an acid-binding agent (Sittig, M., Pesticide Manufacturing and Toxic Materials Control Encyclopedia, 1980, pp. 505-507).

The Atrazine Guidance Document dated 11/10/83 required additional information on the beginning materials and manufacturing processes for all atrazine manufacturing-use products. The information discussed in Confidential Appendix B satisfies the requirements of 40 CFR §158.160, §158.162, and §158.165 (Guidelines Reference No. 61-2) regarding beginning materials and production/formulation processes for the Ciba-Geigy unregistered TGAI and 43, 80, 90, and 97% FIs (EPA Reg. No. 100-521, -529, -572, -581), DuPont 98.7% T (EPA Reg. No. 352-492), Farmland 99.5% T (EPA Reg. No. 1990-376), Makhteshim-Agan 98.8% T (EPA Reg. No. 11603-9), and Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-1). The data submitted for the Uniroyal 97% T (EPA Reg. No. 400-373), Aceto 98% T (EPA Reg. No. 2749-277), Soluja 94% T (EPA Reg. No. 15061-3), Drexel 98% T (EPA Reg. No. 19713-7), and Rumianca 98% T (EPA Reg. No. 40643-1) do not satisfy these requirements because they do not discuss the source and properties of beginning materials, the proportions used and order in which they are added, the equipment used, the conditions controlled, and/or quality control procedures. No information was available on the beginning materials or manufacturing/formulating processes for the remainder of the manufacturing-use products listed in Table 1 above.

The following additional data are required:

- For each manufacturing-use product that is produced from an EPA-registered product, the following information must be provided: (i) the name and EPA registration number of the EPA-registered product; (ii) the brand name, trade name, or other commercial designation and information concerning the composition of each inert ingredient; (iii) a general characterization of the formulation or production process (e.g., batch or continuous); (iv) the identity of the materials used to produce the product, their relative amounts, and the order in which they are added; (v) a description of the equipment used; (vi) a description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process; and (vii) a description of the procedures used to assure consistent composition of the substance produced (quality control methods). For each manufacturing use product that consists of the technical grade of the active ingredient only or is produced by an integrated system, the following information must be provided

in addition to that listed above: (i) the name and address of the producer if different from the registrant; (ii) the brand name, trade name or other commercial designation of each starting material, the name and address of its producer, and information concerning its composition; (iii) a flow chart of the chemical equations of each intended reaction occurring at each step of the process and of the entire process; and (iv) a description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produced). All of these requirements apply to EPA Reg. Nos. 400-373, 400-374, 2749-92, 2749-277, 11603-10, 13801-7, 15061-3, 18861-2, 19713-7, 45115-63, and 56077-22. For EPA Reg. No. 40643-1, the properties of starting materials, production equipment used, and conditions controlled must be described.

61-3. Discussion of the Formation of Impurities

The Atrazine Guidance Document dated 11/10/83 required additional data regarding the formation of impurities in atrazine manufacturing-use products. The information discussed in Confidential Appendix C satisfies the requirements of 40 CFR §158.167 (Guidelines Reference No. 61-3) regarding discussion of the formation of impurities in the Ciba-Geigy 43, 80, 90, and 97% FIs (EPA Reg. No. 100-581, -521, -572, and -529), DuPont 98.7% T (EPA Reg. No. 352-492), Farmland 99.5% T (EPA Reg. No. 1990-376), Makhteshim-Agan 98.8% T (EPA Reg. No. 11603-9), and Industria Prodotti Chimici 98% T (EPA Reg. No. 19713-7). The data submitted for the Aceto 98.8% T (EPA Reg. No. 2749-92), Soluja 94% T (EPA Reg. No. 15061-3), and Drexel 98% T (EPA Reg. No. 19713-7) do not satisfy these requirements because the discussions did not consider all impurities reported in preliminary analysis of the products, and/or not all sources or causes of impurities were considered. No information was available regarding impurities in the other manufacturing-use products listed above in Table 1.

The following additional data are required:

- For each manufacturing use product that consists of the technical grade of the active ingredient only or is produced by an integrated system, a discussion regarding the origin of the following potential impurities must be provided: (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. For each manufacturing-use product that is produced from an EPA-registered product, a discussion must be provided for each impurity associated with the active ingredient 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 possible carryover of impurities present in the registered product which serves as the source of the active ingredient, the possible carryover of impurities present in the inert ingredients in the product, possible reactions occurring during the formulation of the product, post-production reactions between any of the product's active ingredients and any other component of the product or its packaging, and possible contamination from packaging materials or production equipment. These requirements apply to the 400-373, 400-374, 2749-92, 2749-277, 11603-10, 13801-7, 15061-3, 15590-1, 18861-2, 19713-7, 40643-1, 45115-63, and 56077-22.

ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

62-1. Preliminary Analysis

The Atrazine Guidance Document dated 10/11/83 required additional preliminary analysis data for the atrazine manufacturing-use products. Nitrosamine analysis data submitted for various atrazine products are summarized below. The data summarized in Confidential Appendix D satisfy the requirements of 40 CFR §158.170 (Guidelines Reference No. 62-1) regarding preliminary analysis of the TGAI used to produce the Ciba-Geigy FIs (EPA Reg. No. 100-521, -529, -572, and -581), DuPont 98.7% T (EPA Reg. No. 352-492), Farmland 99.5% T (EPA Reg. No. 1990-376), and Industria Prodotti Chimici (EPA Reg. No. 33660-1). The corresponding data for the Makhteshim-Agan 98.8% T (EPA Reg. No. 11603-9) and Drexel Chemical 98% T (EPA Reg. No. 19713-7) do not satisfy these requirements because analyses were incomplete or were conducted on one sample only. No preliminary analysis data were available for the remaining products listed above in Table 1.

Ciba-Geigy Corp. (1976; MRID 00024669) reported [redacted] analyzed by Method AG-304R (not described).

Shell Chemical Co. (1982; MRID 00118413) [redacted]

[redacted] These data satisfy the requirements concerning nitrosamine analysis for this product.

Solchem Inc. (1978; MRID 00148729) [redacted] These data do not satisfy the requirements concerning nitrosamine analysis for this product because the change in nitrosamine levels over time was not monitored.

Marzone Chemicals. Ltd. (1978; MRID 00024677) [redacted] These data do not satisfy the requirements concerning nitrosamine analysis for this product because the change in nitrosamine levels over time was not monitored.

Drexel Chemical Co. (1982; MRID 00125334) [redacted] These data do not satisfy the requirements concerning nitrosamine analysis for this product because the decline or increase in nitrosamine levels over time was not monitored.

Industria Prodotti Chimici S.p.A. (1985; MRID 00149678) [redacted] These data do not satisfy the requirements concerning nitrosamine analysis for this product because the decline or increase in nitrosamine levels over time was not monitored.

Monsanto Co. (1981: MRID 00093878) [redacted]

No other data were available regarding nitrosamine levels in any of the other atrazine manufacturing-use products.

Nitrosamine analysis data for the DuPont 98.7% T (EPA Reg. No. 352-492) satisfy the corresponding data requirements. Nitrosamine analysis data for the Makhteshim-Agan 98.8% T (EPA Reg. No. 11603-9), Marzone Chemicals 100% T (EPA Reg. No. 18861-2), Drexel Chemical 98% T (EPA Reg. No. 19713-7), and Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-1) do not satisfy the corresponding data requirements because they did not monitor the change in nitrosamine content of the products over time during storage.

The following additional data are required:

- For each manufacturing use product produced by an integrated system, the registrant must provide preliminary analyses of five or more representative samples of each technical grade of active ingredient contained in the product to identify all impurities that are associated with the TGAI and present at ≥0.1% by weight of the TGAI. If the product is produced by a batch process, at least five separate batches should be represented. The preliminary analysis should be conducted at the point in the production process after which no further chemical reactions designed to produce or purify the substance are intended. 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 analysis is conducted, along with the mean and relative standard deviation of the analytical results. Based on the preliminary analysis, a statement of the composition of the technical grade of active ingredient must be provided. If the technical grade of active ingredient cannot be isolated, a statement of the composition of the practical equivalent of the technical grade of active ingredient must be submitted. These requirements are applicable to EPA Reg. Nos. 400-373, 2749-277, 13801-7, 15061-3, 15590-1, 18861-2, 19713-7, 40643-1, 45115-63, and 56077-22. In addition, all nitrosamines must 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 must be proposed for all nitrosamines found. These nitrosamine analysis requirements are applicable to all atrazine manufacturing-use products with the exception of EPA Reg. No. 352-492.

62-2. Certified limits

The Atrazine Guidance Document dated 11/10/83 required additional data pertaining to the certification of ingredient limits for the atrazine manufacturing-use products. The data summarized in Confidential Appendix A satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) concerning certified limits for the Ciba-Geigy FIs (EPA Reg. No. 100-521, -572, and -581), DuPont 98.2% T (EPA Reg. No. 352-492), Uniroyal 97% T and 96% FI (EPA Reg. No. 400-373 and -374), Farmland 99.5% T (EPA Reg. No. 1990-376), the Makhteshim-Agan 98.8% T (EPA Reg. No. 11603-9), and Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-1); however, the certified limits for each of these products must be submitted on EPA Form 8570-4 (Rev. 2/85). The submitted data for the Ciba-Geigy 97% FI (EPA Reg. No. 100-529), Aceto 80% FI and 98% T (EPA Reg. No. 2749-92 and -277), the Makhteshim-Agan 80% FI (EPA Reg. No. 11603-10), Soluja 95% T (EPA Reg. No. 15061-3), Drexel 98% T (EPA Reg. No. 19713-7), and Rumianca 98% T (EPA Reg. No. 40643-1) do not satisfy these requirements because insufficient information was provided to accurately determine certified limits or explanations were not provided for proposed certified limits that were not within the normal range of expected values according to 40 CFR §158.175(b)(2).

The following additional data are required:

- The registrants must propose upper and lower limits for each active and inert ingredient, if such limits would differ from the standard certified limits determined by the Agency according to 40 CFR §158.175(b)(2). Also, if the manufacturing-use product contains the technical grade of the active ingredient only or is produced by an integrated system, upper limits must be proposed 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. The registrant must certify the accuracy of the information presented, and that the certified limits will be maintained. An explanation of how each certified limit was established (e.g., sample analysis using a validated analytical procedure, quantitative estimate based on the amounts of ingredients used, etc.) must be provided, along with information on the accuracy and precision of any analytical procedures used. Certifications must be submitted on EPA Form 8570-4 (Rev. 2/85). These requirements are applicable to EPA Reg. Nos. 13801-7, 15590-1, 18861-2, 45115-63, and 56077-22. For the EPA Reg. Nos. 100-529, 2749-92, 2749-277, 11603-10,

15061-3, 19713-7, and 40643-1, explanations of how certified limits were established must be provided, and certification of ingredient limits must be submitted on EPA Form 8570-4 (Rev. 2/85). For the Ciba-Geigy unregistered TGAI and EPA Reg. Nos. 100-521, 100-572, 100-581, 352-492, 1990-376, 11603-9, and 33660-1, certification of ingredient limits must be submitted on EPA Form 8570-4 (Rev. 2/85).

62-3. Enforcement Analytical Methods

The Atrazine Guidance Document dated 11/10/83 required additional data pertaining to the analytical methods to verify certified limits for the atrazine manufacturing-use products.

Ciba-Geigy Corp. (1983; MRID 00142160)

[redacted] This method is adequate for enforcement purposes.

Ciba-Geigy Corp. (1984; MRID 00142160)

[redacted]

These methods are adequate for enforcement purposes.

Farmland Industries, Inc. (1984; MRID 00141493) [redacted]

Drexel Chemical Co. (1982; MRID 00124099) submitted the following method for analysis of atrazine content in the 98% T (EPA Reg. No. 19713-7). [redacted] No precision or accuracy data were provided.

Industria Prodotti Chimici S.p.A. (1982; MRID 00141156) [redacted] No precision or accuracy data were provided.

In the same submission Industria Prodotti Chimici S.p.A. also described [redacted] This method is not specific for atrazine. No precision or accuracy data were provided.

Rumianca, S.p.A. (1977; MRID 00024345) submitted the following method for analysis of the active ingredient in the 98% T (EPA Reg. No. 40642-1). [redacted] No precision or accuracy data were provided.

Platte Chemical Co. (1986; MRID 00164190) [redacted] No validation data were provided.

The analytical methods for atrazine that were submitted by Ciba-Geigy (1984; MRID 00142160) are adequate for tolerance enforcement and may be shared by other registrants of atrazine manufacturing use products upon proper request. The analytical methods discussed in Confidential Appendix E are suitable for tolerance enforcement according to 40 CFR §158.180 (Guideline Reference No. 62-3), regarding analysis of impurities occurring in the Ciba-Geigy 43-97% FIs (EPA Reg. No. 100-521, -572, -581, and -529), DuPont 98.7% T (EPA Reg. No. 352-492), Farmland 99.5% T (EPA Reg. No. 1990-376), Aceto 98% T (EPA Reg. No. 2749-277), and Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-1). The methods submitted for the Makhteshim-Agan 97.8% T (EPA Reg. No. 11603-9), Soluja 94% T (EPA Reg. No. 15061-3) and Drexel 98% T (EPA Reg. No. 19713-7) do not satisfy these requirements because no validation data were provided. No methods were submitted for analysis of impurities in the other products listed above in Table 1.

The following additional data are required:

- Analytical methods which are suitable for enforcement purposes must be provided for each active ingredient and each other ingredient or impurity that is determined to be toxicologically significant. Suitability for enforcement purposes shall be determined from validation studies of method accuracy and precision submitted by the registrant. These requirements apply to the EPA Reg. Nos. 400-373, 400-374, 2749-92, 11603-9, 116031-10, 13801-7, 15061-3, 15590-1, 18861-2, 19713-7, 40643-1, 45115-63, and 56077-22. Validation data must be provided for the atrazine GLC analytical methods submitted by Drexel Chemical Co. (MRID 00124099), Industria Prodotti Chimici S.p.A. (MRID 00141156), and Rumianca, S.p.A. (MRID 00024345) if they are to be used for tolerance enforcement.

PHYSICAL AND CHEMICAL CHARACTERISTICS

The Atrazine Guidance Document dated 11/10/83 required data on density, octanol/water partition coefficient, pH, and corrosion characteristics of atrazine technical and manufacturing-use products. The physical and chemical characteristics for the various atrazine manufacturing-use products are summarized below in Table 2. Additional data, which were reviewed in the Product Chemistry Science Chapter of the Atrazine Registration Standard dated 7/25/83, have been considered in meeting data requirements but are not summarized here.

The data on solubility and vapor pressure of the atrazine PAI from the Weed Science Society of America Herbicide Handbook (5th ed., 1983, p. 31) were submitted separately by various registrants and can be shared to satisfy the corresponding data

requirements for atrazine technical products in general. The data on octanol/water partition coefficient submitted for EPA Reg. Nos. 100-529, 352-492, and 19713-7 are adequately documented and satisfy the corresponding data requirements; these data can be shared by other registrants in support of reregistration of their products (upon proper request). However, partition coefficients submitted for EPA Reg. Nos. 11603-9 and 33660-1 are not compatible with the other data submitted for this property; registrants of these products must explain the apparent differences or provide scientifically valid data. Data on the dissociation constant of atrazine satisfy the corresponding requirements.

All of the data summarized on color, physical state, odor, and melting point, and specific gravity are satisfactory. Only the data submitted for EPA Reg. Nos. 352-492 and 19713-7 satisfy the pH data requirements; the remaining data did not specify the measurement temperature. The submitted data on stability of the TGAI do not provide quantitative measurements nor specify the methods used, or do not discuss sensitivity to metal and metal ions. Satisfactory data were submitted on oxidizing or reducing action for EPA Reg. Nos. 352-492, 1990-376, and 33660-1) and on explodability for EPA Reg. No. 1990-376; all other data submitted on these topics and on flammability failed to satisfy data requirements because methods of analysis were not specified. Data on storage stability of EPA Reg. Nos. 100-581, 352-492, 11603-9, and 33660-1 satisfy the corresponding requirements; data submitted for other products represented tests of less than 1 year duration or provided no quantitative analysis. The available data on viscosity and miscibility of EPA Reg. No. 100-581 satisfy the corresponding data requirements. Corrosiveness data for EPA Reg. Nos. 19713-7 and 33660-1 are satisfactory, while corresponding data for other products provided no details of methods used.

Although the Atrazine Guidance Document did not require data on all of the topics discussed below in data gaps, additional data may be required because new products have been registered which were not considered previously, registration jackets of some products were unavailable for review, or reevaluation of the data in light of current Agency policies and guidelines has determined that the available data are not satisfactory. The following additional data are required:

- As required in 40 CFR §158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Guidelines Reference Nos. 63-2 through 63-13, data must be submitted for TGAIs on color, physical state, odor, melting point, specific gravity, pH, and stability specifically for the TGAI; and on octanol/water partition coefficient of the PAI. All of these data are required for EPA Reg. Nos. 400-373, 13801-7, 15061-3, 15590-1,

18861-2, 40643-1, 45115-63, and 56077-22. In addition, data are required on the following specific physical/ chemical characteristics for the products indicated by EPA Reg. Nos. in parentheses: density (Ciba-Geigy unregistered TGAI); octanol/water partition coefficient (11603-9, 33660-1); pH (1990-376, 2749-277, 11603-9, 33660-1); and stability (Ciba-Geigy unregistered TGAI, 352-492, 1990-376, 2749-277, 11603-9, 19713-7, 33660-1).

- 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 for manufacturing-use products on color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explodability, storage stability, and corrosion characteristics. All of these requirements apply to EPA Reg. Nos. 400-373, 400-374, 2749-92, 11603-10, 13801-7, 15061-3, 15590-1, 18861-2, 40643-1, 45115-63, and 56077-22. In addition, data are required on the following specific physical/chemical characteristics for the products indicated by EPA Reg. Nos. in parentheses: pH (100-521, 100-529, 100-572, 100-581); oxidizing or reducing action (all except 352-492, 1990-376, 33660-1); flammability (all); explodability (all except 1990-376); storage stability (all except 100-581, 352-492, 11603-9, 33660-1); and corrosion characteristics (all except 19713-7, 33660-1).

Table 2. Physical and chemical properties of the atrazine purified active ingredient (PAI) and technical (T) and formulation intermediate (FI) products.

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; EPA Reg. No.; MRID or Jacket)[a]
63-2. Color	white (98.2% T; TGAI; 1990-376; 00141493) (98% T; TGAI; 2749-277; Jacket) (98.8% T; TGAI; 11603-9; 00148730) (98% T; TGAI; 19713-7; Jacket) (98% T; TGAI; 33660-1; 00141156) (98% T; TGAI; 40643-1: 00024345) white to off-white (43% FI; MP; 100-581; 00142160) light tan to gray (80% FI; MP; 100-521; 00142160) (90% FI; MP; 100-572; 00142160) 1YR 9/1 [ASTM D 1535] (98.8% T; TGAI; 11603-9; 00164302)
63-3. Physical state	crystalline powder (90% FI; MP; 100-572; 00142160) (98.8% T; TGAI; 11603-9; 00148730) (98% T; TGAI; 33660-1; 00141156) (98% T; TGAI; 40643-1: 00024345) aqueous suspension (43% FI; MP; 100-581; 00142160)
63-4. Odor	none (98.2% T; TGAI; 1990-376; 00141493) (98% T; TGAI; 2749-277; Jacket) (98.8% T; TGAI; 11603-9; 00148730) (98% T; TGAI; 19713-7; Jacket) (98% T; TGAI; 33660-1; 00141156) (98% T; TGAI; 40643-1: 00024345) slight clay odor (80% FI; MP; 100-521; 00142160) (90% FI; MP; 100-572; 00142160) musty, paint-like odor (43% FI; MP; 100-581; 00142160) slight "amine-like" odor at 25 C (98.8% T; TGAI; 11603-9; 00164302)

(Continued)

Table 2. (continued).

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; EPA Reg. No.; MRID or Jacket)[a]
63-5. Melting point	173-175 C (PAI; WSSA p. 31)
	175-177 C (97% FI;PAI;100-529; 00164822) (98.8% T; PAI; 11603-9; 00164302)
	170-175 C (98.8% T; TGAI; 11603-9; 00024351)
	171-174 C (Geigy TGAI; unregistered?; 00023497)
	170-176 C, [CIPAC MT 2] (98% T; TGAI; 33660-1; 00141156)
	170-177 C (98% T; TGAI?; 40643-1; 00024345)
63-7. Density, bulk density, or specific gravity	22 lb/cu.ft. (80% FI; MP; 100-521; 00142160)
	1.19 g/ml at 20 C (97% FI; MP; 100-529; 00023548)
	0.15-0.30 g/ml (97% FI; MP; 100-529; 00142160)
	30 lb/cu.ft.(90% FI; MP; 100-572;Jacket)
	sp.gr. = 1.12 at 20 C (43% FI; MP; 100-581; 00142160)
	9.32 lb/gal (43% FI; MP; 100-581;Jacket)
	loose bulk density = 0.333 g/ml; tamped bulk density = 0.55 g/ml [Method MMS-C-303-2] (96% T; TGAI; 352-492; 00152513)
	loose bulk density = 15-20 lb/cu.ft. ["normal methods"] (98.2% T; TGAI; 1990-376; 00141493)
	230 ± 50 g/L (98% T; TGAI; 2749-277; Jacket)
	1.23 g/ml at 20 C (98.8% T; TGAI; 11603-9; 00144883)

(Continued)

Table 2. (continued).

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; EPA Reg. No.; MRID or Jacket)[a]
63-7. Density (continued)	20-30 lb/cu.ft. at 25 C [ASTM D 1895] (98.8% T; TGAI; 11603-9; 00164302)
	22.3 lb/cu.ft (98% T; TGAI; 19713-7; Jacket)
	sp.gr.=1.240 at 20 C [CIPAC MT 3.2.1]; bulk density = 230 ± 50 g/L; tap density = 300 ± 50 g/L; [WHO 1962 ann.13] (98% T; TGAI; 33660-1; 00141156)
	Apparent density = 350 ± 50 g/L (98% T; TGAI; 40643-1: 00024345)
63-8. Solubility	at 27 C: water 33 ppm n-pentane 360 ppm diethyl ether 12,000 ppm methanol 18,000 ppm ethyl acetate 28,000 ppm chloroform 52,000 ppm dimethyl sulfoxide 183,000 ppm (PAI; WSSA Handbook, p. 31)
	in water: 22 ppm at 0 C, 70 ppm at 27 C, and 320 ppm at 85 C. (97% FI; PAI; 100-529; 00023497)
	33 ppm in water and 0.36% w/w in n-pentane at 20 C [Royal Society of Chemistry, Agrochemicals Handbook, 1984] (98.8% T; PAI; 11603-9; 00164302)
	In water: Temperature (C) ppmw 10.2 ± 0.1 21.9 ± 1.2 19.9 ± 0.1 30.5 ± 1 25 ± 0.2 33 ± 3.4 29.8 ± 0.2 40.9 ± 1.2 [Weed Res. 12:199 and 15:387] (98.8% T; PAI; 11603-9; 00026402)
	30 mg/L of water at 20 C. (98% T; PAI; 33660-1; 00141156)

(Continued)

Table 2. (continued).

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; EPA Reg. No.; MRID or Jacket)[a]
63-9. Vapor pressure	5.7×10^{-8} mm Hg at 10 C 3.0×10^{-7} mm Hg at 20 C 1.4×10^{-6} mm Hg at 30 C 2.3×10^{-5} mm Hg at 50 C) (PAI; WSSA Handbook, p. 31)
	4.0×10^{-7} ml Hg (sic) (97% FI; PAI; 100-529; 00164822)
	4×10^{-7} mm Hg at 20 C, 1.9×10^{-6} mm Hg at 30 C [Royal Society of Chemistry, Agrochemicals Handbook, 1984] (98.8% T; PAI; 11603-9; 00164302)
63-10. Dissociation constant	$pK_a = 1.68$ [OECD, 112] (98% T; PAI?; 33660-1; 00141156) (98.8% T; TGAI; 11603-9; 00026402)
	$pK_a = 1.7$ at 21 C (97% FI; PAI?; 100-529; 00022855)
	$pK_a = 1.64$ at 22 C (98% T; PAI?; 40643-1: 00024345)
63-11. Octanol/water partitioning coefficient	log P = 2.68 ± 0.10[b] (97% FI; PAI; 100-529; 00164822)
	log P = 2.75[c] (PAI; submitted by Ciba-Geigy; 00153235)
	$P_{o/w} = 418 \pm 14$ at 20 C [OECD Guidelines] (96% T; TGAI; 352-492; 00152513)
	$K_{o/w} = 4583 \pm 581$ [45 FR 77350] (98.8% T; PAI; 11603-9; 00164302)
	$\log P_{o/w} = 2.65$ at 23 C (98% T; PAI; 19713-7; 00149931)
	P = 0.9890 [M. Beroa, Res.Pew., 30, p.3] (98% T; TGAI; 33660-1; 00141156)
63-12. pH	6-8, 10% suspension (80% FI; MP; 100-521; 00142160) (90% FI; MP; 100-572; 00142160)

(Continued)

Table 2. (continued).

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; EPA Reg. No.; MRID or Jacket)[a]
63-12. pH (continued)	5-9 (97% FI; TGAI; 100-529; 00142160) 6-9 (43% FI; MP; 100-581; 00142160) 5.60 ± 0.01 at 25 C, 500 mg in 50 ml of dioxane:water (3:2) (96% T; TGAI; 352-492; 00152513) pH of 1% aqueous suspension =5.50 ± 0.05 (98.2% T; TGAI; 1990-376; 00141493) 6-7 (98% T; TGAI; 2749-277; Jacket) (98.8% T; TGAI; 11603-9; 00144883) 7.93 at 20-25 C, 10% suspension, mean of 41 lots (98% T; TGAI; 19713-7; 00149931) 6-7 [CIPAC MT 75] (98% T; TGAI; 33660-1; 00141156)
63-13. Stability	Stable in neutral, slightly acid, or slightly basic media. Hydrolyzed in low or high pH media as follows: Medium — Temperature — Half-life 0.1 N HCl — 20 C — 12 days 0.1 N NaOH — 20 C — 4 days 0.1 N HCl — 25 C — 5.4 days 0.1 N NaOH — 25 C — 2.9 days (97% FI; PAI?; 100-529; 00023548) No degradation observed in technical atrazine sample held at 90 C for 790 h and analyzed periodically by HPLC. (98.7% T; TGAI; 352-492; 00029717) half-life at 38 C in methanol:water solution - 32 h at pH 1.1, >1 yr at pH 7.0, 1 yr at pH 9.0. (98.7% T; TGAI; 352-492; 00030143) susceptible to hydrolysis at extremes of pH in presence of moisture; otherwise stable to moisture, heat, cold, sunlight (98.8% T; TGAI; 11603-9; 00164302)

(Continued)

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Table 2. (continued).

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; EPA Reg. No.; MRID or Jacket)[a]

63-13. Stability (continued)

Medium	Temperature	Half-life (h)
0.1 N HCl	20	9.5 days*
	30	70 ± 8
	50	9.7 ± 0.5
	70	1.4 ± 0.1
Buffer pH 5	20	86 days*
	30	1000 ± 200
	50	226 ± 22
	70	75 ± 5
Buffer pH 7	50	>4800
	70	4800
Buffer pH 9	50	>4800
	70	540 ± 120
0.1 N NaOH	20	5.0 days*
	30	38 ± 2
	50	6.1 ± 0.3
	70	0.9 ± 0.06

*Values extrapolated from data.
(97% FI; PAI?; 100-529; 00023963)[d]

stable at neutral, slightly acidic or basic pH range; hydrolyzed to hydroxyatrazine by strong acids at high temperature; sublimes at high temperature
(97% FI; PAI?; 100-529; 00023497)
(98% T; TGAI; 33660-1; 00141156)
(98% T; TGAI; 40643-1: 00024345)

63-14. Oxidizing or reducing action

none (80% FI; MP; 100-521; 00142160)
(90% FI; MP; 100-572; 00142160)
(98% T; TGAI; 2749-277; Jacket)
(98% T; TGAI; 19713-7; Jacket)

no apparent effect or reaction with 0.1 N potassium permanganate solution, or powdered iron or zinc metals after 24 hours (96% T; TGAI; 352-492; 00152513)

none [44 FR 16267]
(98.2% T; TGAI; 1990-376; 00141493)

contains no components that act as oxidizing or reducing agents
(98.8% T; TGAI; 11603-9; 00148730)

(Continued)

Table 2. (continued).

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; EPA Reg. No.; MRID or Jacket)[a]
63-14. Oxidizing or . . (continued)	no observable decomposition or increase in temperature when product was placed in contact for 24 hours with water, carbon dioxide, iron plates, or zinc plates (98% T; TGAI; 33660-1; 00141156)
63-15. Flammability	none (80% FI; MP; 100-521; 00142160) (90% FI; MP; 100-572; 00142160) (43% FI; MP; 100-581; 00142160) (98% T; TGAI; 2749-277; Jacket) (98.8% T; TGAI; 11603-9; 00148730) (98% T; TGAI; 19713-7; Jacket) (98% T; TGAI; 40643-1: 00024345) not flammable, 20-170 C [CIPAC MT 12] (98% T; TGAI; 33660-1; 00141156)
63-16. Explodability	product is not shock sensitive but presents a slight dust explosion hazard (80% FI; MP; 100-521; 00142160) (90% FI; MP; 100-572; 00142160) not explosive (43% FI; MP; 100-581; 00142160) (98% T; TGAI; 2749-277; Jacket) (98% T; TGAI; 19713-7; Jacket) (98% T; TGAI; 33660-1; 00141156) (98% T; TGAI; 40643-1: 00024345) no impact explodability [44 FR 16265] (98.2% T; TGAI; 1990-376; 00141493) no tendency to undergo violent reactions in tests for impact explosivity (98.8% T; TGAI; 11603-9; 00148730)
63-17. Storage Stability	no significant decomposition following 7 weeks at 70 C, 28 weeks at 50 C, or 6 months at room temperature. (80% FI; MP; 100-521; 00142160) (90% FI; MP; 100-572; 00142160) Stable for at least 3 years at room temperature under dry conditions. (97% FI; MP; 100-529; 00023548)

(Continued)

Table 2. (continued).

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; EPA Reg. No.; MRID or Jacket)[a]
63-17. Storage stability (continued)	no significant decomposition following 16 weeks at 50 C, 9 months at 40 C, or 12 months at room temperature. (43% FI; MP; 100-581; 00142160)
	active ingredient content of one sample unchanged after 5 years storage at ambient temperature (96% T; TGAI; 352-492; 00152513)
	stable for 2 years under normal storage conditions (98% T; TGAI; 2749-277; Jacket)
	samples from five batches lost 0.3-0.6% of active ingredient concentration over 2 years of storage at 8-28 C (98.8% T; TGAI; 11603-9; 00148730)
	no chemical degradation in over 2 years of warehouse storage (98% T; TGAI; 19713-7; Jacket)
	no degradation in samples from three batches stored at 25 C and analyzed by GLC up to 360 days after manufacture (98% T; TGAI; 33660-1; 00141156)
63-18. Viscosity	80-100 centipoise at 30 rpm, 20 C [Brookfield] (43% FI; MP; 100-581; 00142160)
63-19. Miscibility	miscible with water, immiscible with organic solvents (43% FI; MP; 100-581; 00142160)
63-20. Corrosiveness	not corrosive to tin, steel, or plastic (97% FI; TGAI; 100-529; 00142160)
	noncorrosive (98.8% T; TGAI; 11603-9; 00144883) (98% T; TGAI; 40643-1: 00024345)
	no evidence of corrosion to polyethylene packaging material after 439 days (98% T; TGAI; 19713-7; 00149931)

(Continued)

Table 2. (continued).

Guidelines Reference No., 40 CFR §158.190; Name of Property	Description [Method] (Product; EPA Reg. No.; MRID or Jacket)[a]
63-20. Corrosiveness (continued)	microscopic examination revealed no corrosion of iron plates immersed for 14 days in 100 g of atrazine (98% T; TGAI; 33660-1; 00141156)

[a] PAI = purified active ingredient. TGAI = technical grade of the active ingredient. FI = formulation intermediate. MP = manufacturing-use product. Hyphenated numbers represent EPA Registration Numbers. Eight-digit numbers are MRID documents from the Pesticide Document Management System (PDMS). "Jacket" refers to the pesticide registration jacket maintained by Registration Division, OPP, EPA. WSSA Handbook is the 5th Edition of the Herbicide Handbook of the Weed Science Society of America.

[b] Solutions of atrazine (99.6%) in octanol-saturated water (0.1 and 0.01%) were spiked with [^{14}C]Atrazine (94.8%), mixed with corresponding solutions in water-saturated octanol, mixed for 24 hours at 25 C, and centrifuged; octanol and water phases were analyzed by liquid scintillation spectrometry.

[c] Atrazine was dissolved in water-saturated octanol and partitioned three times to octanol-saturated water. Phase separation was effected by centrifugation, and atrazine concentrations in both phases were determined by HPLC (Ellgehausen et al, 1980. Ecotoxicology and Environmental Safety 4:134-157).

[d] Solutions were extracted with dichloromethane and analyzed by GLC at various intervals. The hydrolysis product was identified as hydroxy-atrazine. Half-lives were calculated from the Arrhenius parameters.

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[This list was obtained from a search of the Pesticide Document Management System data base conducted 6/17/88 for documents dealing with the product chemistry of atrazine.]

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00053791 Shell Development Company (1977) Estimation of Fiber Contamination in Triazine Herbicides and Vendex(R): Miticide and Their Formulations. Method MMS-C-378-3 dated Jan, 1977. (Unpublished study received Mar 30, 1978 under 201-403; CDL:233494-L)

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00055660 Rumianca S.p.A. (19??) Determination of Water Content in Technical Atrazine. Undated method. (Unpublished study received Aug 29, 1977 under 40643-1; CDL:231465-O)

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00071689 Cummings, G.L. (1981) Letter sent to E.R. Butts dated Feb 10, 1981: Dyfonate + Lasso + Triazine tank mix compatibility: Project A-817. (Unpublished study received Apr 7, 1981 under 476-2190; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:244846-C)

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00082600 Ciba-Geigy Corporation (19??) Bicep (1.75:1) Basic Manufacturing Process. (Unpublished study received Sep 30, 1981 under 100-623; CDL:246034-C)

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00101694 Stauffer Chemical Company (19??) Dyfonate 4E, 4ED + Eradicane 6.7E + Triazine. (Unpublished study received Oct 10, 1979 under 476-2056; CDL:241112-E)

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00155924 Ciba-Geigy Corp. (1985) Bicep 6L [Physical and Chemical Data]: PC 85-026. Unpublished study. 1 p.

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TABLE A. GENERIC DATA REQUIREMENTS FOR THE ATRAZINE TECHNICAL GRADE OF THE ACTIVE INGREDIENT.[1]

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
40 CFR §158.155-190 Product Chemistry					
Product Composition					
61-2. Beginning Materials and Production Process	TGAI	Partially	00024345, 00024350, 00124099, 00141156, 00141493, 00142160, 00144883, 00155625, 40566501, 400-373, 2749-277.	Yes[3]	6 months
61-3. Formation of Impurities	TGAI	Partially	00024350, 00124099, 00141156, 00141493, 00142160, 00144883, 00155625, 2749-9.	Yes[4]	6 months
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	TGAI	Partially	00024352, 00141156, 00141493, 00142160, 00144883, 00152499, 00164821, 1990-376, 19713-7.	Yes[5]	12 months
Physical and Chemical Characteristics					
63-2. Color	TGAI	Partially	00024345, 00141156, 00141493, 00148730, 00164302, 2749-277, 19713-7.	Yes[6]	6 months
63-3. Physical State	TGAI	Partially	00024345, 00141156, 00148730.	Yes[6]	6 months

(Continued, footnotes follow)

TABLE A. (Continued).

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
63-4. Odor	TGAI	Partially	00024345, 00141156, 00141493, 00148730, 00164302, 2749-277.	Yes[6]	6 months
63-5. Melting Point	TGAI	Partially	00023497, 00024345, 00024351, 00141156, 00164302, 00164822.	Yes[6]	6 months
63-6. Boiling Point	TGAI	No	N/A	Yes[7]	6 months
63-7. Density, Bulk Density or Specific Gravity	TGAI	Partially	00023548, 00024345, 00141156, 00141493, 00144883, 00152513, 00164302, 2749-277, 19713-7.	Yes[6]	6 months
63-8. Solubility	TGAI or PAI	Yes	00023497, 00026402, 00141156, 00164302.	No	
63-9. Vapor Pressure	TGAI or PAI	Yes	00164302, 00164822.	No	
63-10. Dissociation Constant	TGAI or PAI	Yes	00022855, 00024345, 00026402, 00141156.	No	
63-11. Octanol/Water Partition Coefficient	PAI	Partially	00141156, 00149931, 00152513, 00153235, 00164302, 00164822.	Yes[6]	6 months
63-12. pH	TGAI	Partially	00141156, 00141493, 00142160, 00144883, 00149931, 00152513.	Yes[6,8]	6 months
63-13. Stability	TGAI	Partially	00023497, 00023548, 00023963, 00024345, 00029717, 00030143, 00141156, 00164302	Yes[6]	6 months

(Continued, footnotes follow)

TABLE A. (Continued).

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
Other Requirements:					
64-1. Submittal of Samples	N/A	N/A	N/A	No	

1. Additional data requirements are listed in the following Table B, "Generic Data Requirements for Atrazine Manufacturing-Use Products", for registered technical products.

2. TGAI = technical grade of the active ingredient. PAI = purified active ingredient.

3. For each manufacturing use product that consists of the technical grade of the active ingredient only or is produced by an integrated system, the following information must be provided: (i) the name and address of the producer of the technical grade of the active ingredient; (ii) the brand name, trade name or other commercial designation, the name and address of the producer, and information concerning the composition of each starting material; (iii) a general characterization of the process (e.g., batch or continuous); (iv) a flow chart of the chemical equations of each intended reaction occurring at each step of the process, the necessary reaction conditions, and the duration of each step of the process and of the entire process; (v) the identity of the materials used to produce the product, their relative amounts, and the order in which they are added; (vi) a description of the equipment used; (vii) a description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process; (viii) a description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produced); and (ix) a description of the procedures used to assure consistent composition of the substance produced (quality control methods). All of these requirements apply to EPA Reg. Nos. 400-373, 400-374, 2749-92, 2749-277, 11603-10, 13801-7, 15061-3, 18861-2, 19713-7, 45115-63, and 56077-22. For EPA Reg. No. 40643-1, the properties of starting materials, production equipment used, and conditions controlled must be described.

4. For each manufacturing use product that consists of the technical grade of the active ingredient only or is produced by an integrated system, a discussion regarding the origin of the following potential impurities must be provided: (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

TABLE A. (Continued).

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. These requirements apply to EPA Reg. Nos. 400-373, 2749-277, 13801-7, 15061-3, 15590-1, 18861-2, 19713-7, 40643-1, 45115-63, and 56077-22.

5. For each manufacturing use product produced by an integrated system, the registrant must provide preliminary analyses of five or more representative samples of each technical grade of active ingredient contained in the product to identify all impurities that are associated with the TGAI and present at ≥0.1% by weight of the TGAI. If the product is produced by a batch process, at least five separate batches should be represented. The preliminary analysis should be conducted at the point in the production process after which no further chemical reactions designed to produce or purify the substance are intended. 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 analysis is conducted, along with the mean and relative standard deviation of the analytical results. Based on the preliminary analysis, a statement of the composition of the technical grade of active ingredient must be provided. If the technical grade of active ingredient cannot be isolated, a statement of the composition of the practical equivalent of the technical grade of active ingredient must be submitted. Based on the preliminary analysis, a statement of the composition of the technical grade of active ingredient must be provided. These requirements are applicable to EPA Reg. Nos. 400-373, 2749-277, 13801-7, 15061-3, 15590-1, 18861-2, 19713-7, 40643-1, 45115-63, and 56077-22. In addition, all nitrosamines must 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 must be proposed for all nitrosamines found. These nitrosamine analysis requirements are applicable to all atrazine manufacturing-use products with the exception of EPA Reg. No. 352-492.

6. As required in 40 CFR §158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Guidelines Reference Nos. 63-2 through 63-13, data must be submitted for TGAIs on color, physical state, odor, melting point, specific gravity, pH, and stability specifically for the TGAI; and on octanol/water partition coefficient of the PAI. All of these data are required for EPA Reg. Nos. 400-373, 13801-7, 15061-3, 15590-1, 18861-2, 40643-1, 45115-63, and 56077-22. In addition, data are required on the following specific physical/chemical characteristics for the products indicated by EPA Reg. Nos. in parentheses: density (Ciba-Geigy unregistered TGAI); octanol/water partition coefficient (11603-9, 33660-1); pH

TABLE A. (Continued).

(1990-376, 2749-277, 11603-9, 33660-1); and stability (Ciba-Geigy unregistered TGAI, 352-492, 1990-376, 2749-277, 11603-9, 19713-7, 33660-1).

7. Data on boiling point are not required because the TGAI is a solid at room temperature.

8. Data on pH are required if the test substance is dispersible in water.

TABLE B. GENERIC DATA REQUIREMENTS FOR ATRAZINE MANUFACTURING-USE PRODUCTS.[1]

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
40 CFR §158.155-190 Product Chemistry					
Product Composition					
61-1. Product Composition	MP & TGAI	Partially	00024345, 00141156, 00141493, 00142160, 00144883, 00152499, 40566501, 100-521, 100-572, 100-581, 400-373, 400-374, 2749-92, 2749-277, 11603-9, 11603-10, 19713-7, 15061-3, 33660-1.	Yes[3]	6 months
61-2. Beginning Materials and Production or Formulation Process	MP & TGAI	Partially	00142160, 40566501.	Yes[4]	6 months
61-3. Formation of Impurities	MP & TGAI	Partially	00142160.	Yes[5]	6 months
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	TGAI	Partially	00142160, 00164821, 00142160, 1990-376, 19713-7.	Yes[6]	12 months
62-2. Certified Limits	MP & TGAI	Partially	00024345, 00141156, 00141493, 00142160, 00144883, 00152499, 40566501, 100-521, 100-572, 100-581, 400-373, 400-374, 2749-92, 2749-277, 11603-9, 11603-10,	Yes[7]	12 months

(Continued, footnotes follow).

TABLE B. (Continued).

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
			19713-7, 15061-3, 33660-1.		
62-3. Enforcement Analytical Methods	TGAI	Partially	00024345, 00024350, 00124099, 00141156, 00141493, 00142160, 00144883, 00152499, 00164821, 2749-277.	Yes[8]	12 months
Physical and Chemical Characteristics					
63-2. Color	MP & TGAI	Partially	00142160.	Yes[9]	6 months
63-3. Physical State	MP & TGAI	Partially	00142160.	Yes[9]	6 months
63-4. Odor	MP & TGAI	Partially	00142160.	Yes[9]	6 months
63-7. Density, Bulk Density, or Specific Gravity	MP & TGAI	Partially	00142160, 00023548, 100-572, 100-581.	Yes[9]	6 months
63-12. pH	MP & TGAI	Partially	00142160	Yes[9,10]	6 months
62-14. Oxidizing or Reducing Action	MP	Partially	00141156, 00141493, 00142160, 00148730, 00152513, 2749-277, 19713-7.	Yes[9,11]	6 months
62-15. Flammability	MP	Partially	00024345, 00141156, 00142160, 00148730, 2749-277, 19713-7.	Yes[9,12]	6 months
63-16. Explodability	MP	Partially	00024345, 00141156, 00141493, 00142160, 00148730, 2749-277, 19713-7.	Yes[9,13]	6 months

(Continued, footnotes follow).

TABLE B. (Continued).

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?	Bibliographic Citation	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
63-17. Storage Stability	MP	Partially	00023548, 00141156, 00142160, 00148730, 00152513.	Yes[9]	15 months
63-18. Viscosity	MP	Partially	00142160.	Yes[9,14]	6 months
63-19. Miscibility	MP	Partially	00142160.	Yes[9,15]	6 months
63-20. Corrosion Characteristics	MP	Partially	00024345, 00141156, 00142160, 00144883, 00149931.	Yes[9]	15 months
Other Requirements:					
64-1. Submittal of Samples	N/A	N/A	N/A	No	

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

2. TGAI = technical grade of the active ingredient. PAI = purified active ingredient. MP = manufacturing-use product.

3. For each manufacturing use product that consists of the technical grade of the active ingredient only or is produced by an integrated system, the following information must be provided: (i) the CA-approved chemical name, CAS Registry Number, any common names, the nominal concentration, upper and lower certified limits in accordance with 40 CFR §158.175, and the purpose of each active and inert ingredient in the product; (ii) the molecular, structural and empirical formulas, and the molecular weight or weight range of each active ingredient in the product; (iii) the chemical name and nominal concentration of each impurity of toxicological significance associated with the active ingredient or present in any sample at a level equal to or greater than 0.1% by weight of the TGAI; and (iv) sufficient information to enable the Agency to identify the source and qualitative composition of all ingredients that are not characterized. Impurities must be identified as such. For each manufacturing-use product that is produced from an EPA-registered product, the following information must be provided: (i) the chemical and common name of each active ingredient as listed on the source product, its nominal concentration in the product based upon the nominal con-

TABLE B. (Continued).

centration in the source product, and upper and lower certified limits in accordance with 40 CFR §158.175; (ii) the CA-approved chemical name of each inert ingredient in the product, its CAS Registry Number, any common names, nominal concentration, purpose, and upper and lower certified limits in accordance with 40 CFR §158.175; and (iii) sufficient information to enable the Agency to identify the source and qualitative composition of all ingredients that cannot be characterized. All requirements apply to EPA Reg. Nos. 13801-7,
15590-1 18861-2, 45115-63, 56077-22. For ingredients in other products, the following data must be provided: EPA Registration Numbers (2749-92, 2749-277, 11603-10); CAS Registry Numbers (400-373, 2749-277, 19713-7, 40643-1); purpose (2749-92, 19713-7, 40643-1); nominal concentration (100-529, 19713-7, 40643-1); and certified limits (400-373, 400-373, 2749-92, 11603-10, 15061-3).

4. For each manufacturing-use product that is produced from an EPA-registered product, the following information must be provided: (i) the name and EPA registration number of the EPA-registered product; (ii) the brand name, trade name, or other commercial designation and information concerning the composition of each inert ingredient; (iii) a general characterization of the formulation or production process (e.g., batch or continuous); (iv) the identity of the materials used to produce the product, their relative amounts, and the order in which they are added; (v) a description of the equipment used; (vi) a description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process; and (vii) a description of the procedures used to assure consistent composition of the substance produced (quality control methods).. For each manufacturing use product that consists of the technical grade of the active ingredient only or is produced by an integrated system, the following information must be provided in addition to that listed above: (i) the name and address of the producer if different from the registrant; (ii) the brand name, trade name or other commercial designation of each starting material, the name and address of its producer, and information concerning its composition; (iii) a flow chart of the chemical equations of each intended reaction occurring at each step of the process and of the entire process; and (iv) a description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produced). All of these requirements apply to EPA Reg. Nos. 400-373, 400-374, 2749-92, 2749-277, 11603-10, 13801-7, 15061-3, 18861-2, 19713-7, 45115-63, and 56077-22. For EPA Reg. No. 40643-1, the properties of starting materials, production equipment used, and conditions controlled must be described.

5. For each manufacturing use product that consists of the technical grade of the active ingredient only or is produced by an integrated system, a discussion regarding the origin of the following potential impurities must be provided: (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

TABLE B. (Continued).

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. For each manufacturing-use product that is produced from an EPA-registered product, a discussion must be provided for each impurity associated
with the active ingredient 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 possible carryover of impurities present in the registered product which serves as the source of the active ingredient, the possible carryover of impurities present in the inert ingredients in the product, possible reactions occurring during the formulation of the product, post-production reactions between any of the product's active ingredients and any other component of the product or its packaging, and possible contamination from packaging materials or production equipment. These requirements apply to the 400-373, 400-374, 2749-92, 2749-277, 11603-10, 13801-7, 15061-3, 15590-1, 18861-2, 19713-7, 40643-1, 45115-63, and 56077-22.

6. For each manufacturing use product produced by an integrated system, the registrant must provide preliminary analyses of five or more representative samples of each technical grade of active ingredient contained in the product to identify all impurities that are associated with the TGAI and present at ≥0.1% by weight of the TGAI. If the product is produced by a batch process, at least five separate batches should be represented. The preliminary analysis should be conducted at the point in the production process after which no further chemical reactions designed to produce or purify the substance are intended. 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 analysis is conducted, along with the mean and relative standard deviation of the analytical results. Based on the preliminary analysis, a statement of the composition of the technical grade of active ingredient must be provided. If the technical grade of active ingredient cannot be isolated, a statement of the composition of the practical equivalent of the technical grade of active ingredient must be submitted. These requirements are applicable to EPA Reg. Nos. 400-373, 2749-277, 13801-7, 15061-3, 15590-1, 18861-2, 19713-7, 40643-1, 45115-63, and 56077-22. In addition, all nitrosamines must 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 must be proposed for all nitrosamines found. These nitrosamine analysis requirements are applicable to all atrazine manufacturing-use products with the exception of EPA Reg. No. 352-492.

TABLE B. (Continued).

7. The registrants must propose upper and lower limits for each active and inert ingredient, if such limits would differ from the standard certified limits determined by the Agency according to 40 CFR §158.175(b)(2). Also, if the manufacturing-use product contains the technical grade of the active ingredient only or is produced by an integrated system, upper limits must be proposed 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. The registrant must certify the accuracy of the information presented, and that the certified limits will be maintained. An explanation of how each certified limit was established (e.g., sample analysis using a validated analytical procedure, quantitative estimate based on the amounts of ingredients used, etc.) must be provided, along with information on the accuracy and precision of any analytical procedures used. Certifications must be submitted on EPA Form 8570-4 (Rev. 2/85). These requirements are applicable to EPA Reg. Nos. 13801-7, 15590-1, 18861-2, 45115-63, and 56077-22. For the EPA Reg. Nos. 100-529, 2749-92, 2749-277, 11603-10, 15061-3, 19713-7, and 40643-1, explanations of how certified limits were established must be provided, and certification of ingredient limits must be submitted on EPA Form 8570-4 (Rev. 2/85). For the Ciba-Geigy unregistered TGAI and EPA Reg. Nos. 100-521, 100-572, 100-581, 352-492, 1990-376, 11603-9, and 33660-1, certification of ingredient limits 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 active ingredient and each other ingredient or impurity that is determined to be toxicologically significant. Suitability for enforcement purposes shall be determined from validation studies of method accuracy and precision submitted by the registrant. These requirements apply to the EPA Reg. Nos. 400-373, 400-374, 2749-92, 11603-9, 116031-10, 13801-7, 15061-3, 15590-1, 18861-2, 19713-7, 40643-1, 45115-63, and 56077-22. Validation data must be provided for the atrazine GLC analytical methods submitted by Drexel Chemical Co. (MRID 00124099), Industria Prodotti Chimici S.p.A. (MRID 00141156), and Rumianca, S.p.A. (MRID 00024345) if they are to be used for tolerance enforcement.

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 for manufacturing-use products on color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explodability, storage stability, and corrosion characteristics. All of these requirements apply to EPA Reg. Nos. 400-373, 400-374, 2749-92, 11603-10, 13801-7, 15061-3, 15590-1, 18861-2, 40643-1, 45115-63, and 56077-22. In addition, data are required on the following specific physical/chemical characteristics for the products indicated by EPA Reg. Nos. in parentheses: pH (100-521, 100-529, 100-572, 100-581); oxidizing or reducing action (all except 352-492, 1990-376, 33660-1); flammability (all); explodability (all except

TABLE B. (Continued).

1990-376); storage stability (all except 100-581, 352-492, 11603-9, 33660-1); and corrosion characteristics (all except 19713-7, 33660-1).

10. Data on pH are required if the test substance is dispersible in water.

11. Data are required on oxidizing/reducing potential if product contains an oxidizing or reducing agent.

12. Data are required on flammability if the product contains combustible liquids.

13. Data are required if the product is potentially explosive.

14. Data on viscosity are required if the product is a liquid.

15. Data on miscibility are required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.