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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Atrazine Product Chemistry Reregistration Standard Updates; Chemical No. 80803; Branch No.: 9040; DP Barcode No.: D171611

FROM: Edward Zager, Chief
Chemistry Branch II - Reregistration Support
Health Effects Division (H7509C)

TO: Lois Rossi, Chief
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Special Review and Reregistration Division (H7508C)

and

Esther Saito, Acting Chief
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Health Effects Division (H7509C)

Attached is the Update to the Product Chemistry Chapter of the Atrazine Reregistration Standard. This update was prepared by Acurex Corporation under supervision of CBRS, HED. The Update has undergone secondary review in the branch and has been revised to reflect Agency policies. The Residue Chemistry Chapter is forthcoming.

Revised product chemistry data requirement tables are included.

If you need additional input please advise.

Attachment 1: Atrazine Product Chemistry Reregistration Standard Update. (This document contains CBI.)

RDI: ARRathman: 8/04/92 MMetzger: 8/06/92 EZager: 8/06/92
cc: (with Attachment): CLOlinger (CBRS), Reg. Std. File, SF, Acurex
cc: (without Attachment): Circulation



ATRAZINE
(Chemical Code 080803)

TASK 3

**Reregistration Standard
Update**

Product Chemistry

July 14, 1992

Contract No. 68-DO-0142

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:

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ATRAZINE

(Chemical Code 080803)

REREGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK 3

INTRODUCTION

A Product Search Listing conducted on 7/29/91, identified 8 registered technical and manufacturing-use products of atrazine: the Ciba-Geigy 80% formulation intermediate (FI) (EPA Reg. No. 100-521); the Ciba-Geigy 97% FI (EPA Reg. No. 100-529); the Ciba-Geigy 43% FI (EPA Reg. No. 100-581); the Drexel Chemical Co. 97% technical (T) (EPA Reg. No. 19713-7); the Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-1); the Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-34); the Industria Prodotti Chimici 97% T (EPA Reg. No. 33660-35); and the Oxon Italia 96% T (EPA Reg. No. 35915-6). Additionally, Ciba-Geigy has an unregistered technical product.

The Atrazine Guidance Document dated 11/83 requires additional generic and product-specific product chemistry data for the manufacturing products. In response, Ciba-Geigy submitted data (1984; MRIDs 00142160 and 00153235; 1986; MRIDs 00164821 and 00164822; 1988; MRID 40566501) pertaining to the product chemistry of their atrazine products. These documents were reviewed by the Agency in the 10/88 Product Chemistry Second Round Review (SRR). The Product Chemistry SRR determined that data gaps for the Ciba-Geigy 80% FI (EPA Reg. No. 100-521) included preliminary analysis, certification of limits, and product-specific data pertaining to pH, oxidation or reduction potential, flammability, explodability, storage stability and corrosion characteristics; data gaps pertaining to the 97% FI (EPA Reg. No. 100-529) included product identity and disclosure of ingredients, preliminary analysis, certification of limits, and product-specific data pertaining to pH, oxidation or reduction potential, explodability, storage stability and corrosion characteristics; data gaps for the 43% FI (EPA Reg. No. 100-581) included preliminary analysis, certification of limits, and product-specific data pertaining to pH, oxidation or reduction potential, flammability, explodability and corrosion characteristics; data gaps for the Ciba-Geigy unregistered technical (no EPA Reg. No.) included preliminary analysis, certification of limits, enforcement analytical methods to verify certified limits, and product-specific data pertaining to pH and stability.

In a letter dated 4/19/91, Ciba-Geigy provided additional information regarding impurities in their 97% T. This was reviewed by the Agency (S. Funk; 8/30/91; CBRS No. 7935). Additional information was required for the manufacturing process and results of analyses. Ciba-Geigy responded (1991; MRID 42043501) with some of the requested information. This was reviewed by the Agency (S. Funk; 10/31/91; CBRS No. 8710) who found the impurity formation satisfactory. Additional information was required for the analytical

method and results of analysis. Enseco-California responded (11/08/91; no MRID No.) for Ciba-Geigy. This was reviewed by the Agency (S. Funk; 11/26/91; CBRS no. 8929). The Agency found the analytical method satisfactory. Specific requirements remain outstanding for results of analyses.

In response to the Guidance Document, Drexel Chemical Co. submitted data (1985; MRID 00149931) to support the reregistration of their 97% T (EPA Reg. No. 19713-7). The 10/88 Product Chemistry SRR determined that the data provided were not adequate. Data gaps included starting materials and manufacturing processes, discussion of formation of impurities, preliminary analysis, enforcement analytical methods, and product-specific data pertaining to oxidation or reduction potential, explodability, storage stability and corrosion characteristics. Drexel Chemical Co. submitted supplemental data (1990; MRIDs 41379801, 41379802 and 41379803) which are reviewed here for adequacy in fulfilling the requirements for the 97% T. Drexel has also submitted a request for alternate formulations (L.R. Haefele, 10/30/91). This was reviewed by the Agency (R.J. Taylor; PM-25; 3/20/92) and rejected.

Industria Prodotti Chimici submitted data (1984; MRID 00141156) in response to the Guidance Document to support reregistration for the 98% T (EPA Reg. No. 33660-1). The 10/88 Product Chemistry SRR determined that data gaps for this product included preliminary analysis, certification of limits, and product-specific data pertaining to octanol/water partition coefficient, pH, stability and explodability. The Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-34) and 97% T (EPA Reg. No. 33660-35) were registered since the 10/88 SRR. IPC has submitted Confidential Statements of Formula (CSF) (8/10/89 and 1/9/91, respectively) which are reviewed here.

In response to the Guidance Document, Oxon Italia submitted data (1990; MRID 41640401) to support the reregistration of their 96% T (EPA Reg. No. 35915-6). The Agency (R. Perfetti; 3/7/91; CBRS No. 7221) reviewed the submission and determined that data gaps include discussion of formation of impurities, preliminary analysis, certification of limits and enforcement analytical methods.

Each of the Topical Discussions listed below have corresponding 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 assess the product chemistry of atrazine adequately.

Product Composition and Manufacture	61-(1-3)
Analysis and Certification of Product Ingredients	62-(1-3)
Physical and Chemical Characteristics	63-(2-20)

SUMMARY

The following product chemistry data remain outstanding:

- o For the Ciba-Geigy unregistered technical (no EPA Reg. No.), data pertaining to preliminary analysis, and product-specific data pertaining to density, pH, and stability.
- o For the Ciba-Geigy 80% FI (EPA Reg. No. 100-521), data pertaining to the preliminary analysis, certification of limits, and product-specific data pertaining to pH, oxidation or reduction potential, flammability, explodability, storage stability and corrosion characteristics.
- o For the Ciba-Geigy 97% FI (EPA Reg. No. 100-529), data pertaining to the product identity and disclosure of ingredients, preliminary analysis, certification of limits, and product-specific data pertaining to pH, oxidation or reduction potential, flammability, explodability, storage stability and corrosion characteristics.
- o For the Ciba-Geigy 43% FI (EPA Reg. No. 100-581), data pertaining to the preliminary analysis, certification of limits, and product-specific data pertaining to pH, oxidation or reduction potential, flammability, explodability and corrosion characteristics.
- o For the Drexel Chemical Co. 97% T (EPA Reg. No. 19713-7), basic formulation data pertaining to product identity and disclosure of ingredients, discussion of formation of impurities, preliminary analysis, certified limits, enforcement analytical methods, and product-specific data pertaining to pH, stability, oxidation or reduction potential, explodability, storage stability and corrosion characteristics. Drexel must also clarify the situation regarding their claim for basic and alternate formulations. As per Mr. Taylor (R.J. Taylor; PM-25; 3/22/92), Drexel must provide full product chemistry for each unregistered source. They must also provide samples from each unregistered source of active ingredient.

- o For the Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-1), data pertaining to preliminary analysis, certification of limits, validation data, and product-specific data pertaining to octanol/water partition coefficient, pH, stability, and explodability.
- o For the Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-34), all product chemistry data are required.
- o For the Industria Prodotti Chimici 97% (EPA Reg. No. 33660-35), the formulator's exemption applies. No additional product chemistry are required.
- o For the Oxon Italia 96% T (EPA Reg. No. 35915-6), data pertaining to physical and chemical characteristics.

Note to SRRD: Drexel is claiming a basic formulation and multiple alternate formulations based upon unregistered sources of the technical material. PR 87-7 indicates that some to all of these unregistered sources are not permitted. Other claimed sources are registered but do not meet the definition of an alternate formulation. It would appear that Drexel should register these as separate products. CBRS recommends that SRRD confer with RD to resolve the registration situation for the Drexel technical material.

PRODUCT IDENTITY AND COMPOSITION

61-1. Product Identity and Disclosure of Ingredients

The Guidance Document dated 11/83 required data pertaining to product identity and disclosure of ingredients. Ciba-Geigy submitted data (1984; MRID 00142160; 1988; MRID 40566501) for its unregistered technical (no EPA Reg. No.), the 80% FI (EPA Reg. No. 100-521), and the 43% FI (EPA Reg. No. 100-581), which were reviewed in the 10/88 Product Chemistry SRR. The Agency determined that the requirements of 40 CFR §158.155 (Guideline Ref. No. 61-1) regarding product identity and composition were fully satisfied. It should be noted that the October, 1988 Product Chemistry SRR required the submission of ingredients statements for individual products. No additional data are required.

In response to the Guidance Document, Ciba-Geigy submitted data (1988; MRID 40566501) for its 97% FI (EPA Reg. No. 100-529) which were reviewed in the 10/88 Product Chemistry SRR and determined by the Agency to have not fully satisfied the requirements regarding this topic. Data gaps remain outstanding. Nominal concentrations must be provided. Additional data are required.

In response to the Guidance Document, Industria Prodotti Chimici submitted data (1984; MRID 00141156) for their 98% T (EPA Reg. No. 33660-1) which were reviewed in the 10/88 Product Chemistry SRR by the Agency and determined to have fully satisfied the

requirements of 40 CFR §158.155 (Guideline Ref. No. 61-1). No additional data are required.

Based upon information from Registration Division (R.J. Taylor; 3/22/90; PM-25) the Agency, (R. Perfetti; 3/7/91; CBRS 7221) stated that information regarding product identity was not required for Oxon Italia's 96% T (EPA Reg. No. 35915-6); it also stated that data might be required to satisfy the requirements of the Registration Standard. As a technical material, this product meets the definition of a manufacturing use product (40 CFR §158.153 (L)). For this reason, data are required for this product to satisfy the requirements of 40 CFR §158.155. Data were submitted by Oxon Italia in response to the CBRS review (W.L. Anthony; 4/22/92; CBRS No. 9030) and were found adequate. No further data are required.

In response to the SRR, Drexel Chemical Co. submitted data (1990; MRID 41379801) for a material manufactured for them by an unregistered source. In a letter (L. Haefele; 10/30/91), Drexel included a CSF, 10/30/91, which defined this material as the basic formulation for their 97% T (EPA Reg. No. 19713-7). This same letter included additional CSFs (10/30/91) through which Drexel was claiming alternate formulations from several registered and unregistered sources. The Agency reviewed (R.J. Taylor; PM-25; 3/20/92) and rejected this request for basic and alternate formulations. The Agency required the submission of complete product chemistry data for each unregistered source of atrazine. One registered source of atrazine was tentatively accepted based upon a comparison of the 10/30/91 CSF and the manufacturer's label. The above submission is reviewed here and summarized in Confidential Appendix A. These data do not satisfy the requirements of 40 CFR §158.155 (Guideline Ref. No. 61-1) for Drexel's 97% T (EPA Reg. No. 19713-7) basic formulation. A new CSF must be submitted which includes revised nomenclature. A nominal concentration must be provided for an additional impurity. This impurity was found at >0.1% during the preliminary analysis. Additional data are required for this material. Drexel must clarify the registration situation for the other claimed sources. Drexel must submit full product chemistry data for the other unregistered sources. Additional data are required.

Industria Prodotti Chimici has submitted CSFs (8/10/89 and 1/9/91) for the 98% T (EPA Reg. No. 33660-34) and 97% T (EPA Reg. No. 33660-35), respectively. These submissions are reviewed in Confidential Appendix B. Based upon this information, the 97% T is clearly a repackaged product; a formulation's exemption applies. No further product chemistry data are required. A similar situation is claimed for the 98% T. However, since it is based upon a canceled product, this claim is rejected. All data pertaining to this topic are required for the 98% T product.

61-2. Starting Materials and Manufacturing Process

The Guidance Document dated 11/83 requires submission of generic and product-specific data concerning the starting materials used and the manufacturing process. In response to the Guidance Document, Ciba-Geigy submitted data (1984; MRID 00142160; 1988; MRID 40566501) for the unregistered technical (no EPA Reg. No.), the 80% FI (EPA Reg. No. 100-521), the 97% FI (EPA Reg. No. 100-529), and the 43% FI (EPA Reg. No. 100-581), which were reviewed in the 10/88 Product Chemistry SRR and determined by the Agency to have fully satisfied the requirements of 40 CFR §158.160-165 (Guideline Ref. No. 61-2). No additional data are required.

In response to the Guidance Document, Industria Prodotti Chimici submitted data (1984; MRID 00141156) that the Agency reviewed in the 10/88 Product Chemistry SRR; they concluded it satisfied this topic for the 98% T (EPA Reg. No. 33660-1). No additional data are required.

The Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-34) and 97% T (EPA Reg. No. 33660-35) have been registered since the 10/88 Product Chemistry SRR. The 97% T is subject to a formulation's exemption; no data are required for this topic. IPC has not submitted any data for this topic to support the reregistration of the 98% T. All data pertaining to this topic are required for this product.

In response to the Guidance Document, Oxon Italia submitted data (1990; MRID 41640401) for the 96% T (EPA Reg. No. 35915-6) which were reviewed by the Agency (R. Perfetti; 3/7/91; CBRS No. 7221) and determined to have fully satisfied the requirements of this topic. No additional data are required.

In response to the SRR, Drexel Chemical Co. submitted data (1990; MRID 41379801) for a material manufactured for them by an unregistered source. In a letter (L. Haefele; 10/30/91), Drexel included a CSF, 10/30/91, which defined this material as the basic formulation for their 97% T (EPA Reg. No. 19713-7). This same letter included additional CSFs (10/30/91) through which Drexel was claiming alternate formulations from several registered and unregistered sources. The Agency reviewed (R.J. Taylor; PM-25; 3/20/92) and rejected this request for basic and alternate formulations. The Agency required the submission of complete product chemistry data for each unregistered source of atrazine. One registered source of atrazine was tentatively accepted based upon a comparison of the 10/30/91 CSF and the manufacturer's label. The above submission is reviewed here and summarized in Confidential Appendix A. These data do not satisfy the requirements of 40 CFR §158.160-165 (Guideline Ref. No. 61-2) for Drexel's 97% T (EPA Reg. No. 19713-7) basic formulation. Additional data are required for this material. Drexel must clarify the registration situation for the other claimed sources. Drexel must submit full product chemistry data for the other unregistered sources. Additional data are required.

61-3. Discussion of Formation of Impurities

The Guidance Document dated 11/83 specified generic and product-specific data requirements regarding a detailed discussion of the formation of impurities. In response, Ciba-Geigy submitted data (1984; MRID 00142160) for the unregistered technical (no EPA Reg. No.), 80% FI (EPA Reg. No. 100-521), 97% FI (EPA Reg. No. 100-529), and 43% FI (EPA Reg. No. 100-581) which were reviewed by the Agency in the 10/88 Product Chemistry SRR and determined to have fully satisfied the requirements of this topic. In a letter dated 4/19/91, Ciba Geigy reported the discovery of an additional impurity in technical atrazine. This was reviewed by the Agency (S. Funk; 8/30/91; CBRS No. 7935) who required additional information regarding the formation of this impurity. In response, the registrant submitted additional information (1991; MRID 42043501). This submission was reviewed (S. Funk; 10/31/91; CBRS No. 8710) and found to satisfy the requirements of this guideline. No additional data are required.

In response to the Guidance Document, Industria Prodotti Chimici submitted data (1984; MRID 00141156) for their 98% T (EPA Reg. No. 33660-1) which were reviewed in the 10/88 Product Chemistry SRR and determined by the Agency to have fully satisfied the requirements of this topic. No additional data are required.

The Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-34) and 97% T (EPA Reg. No. 33660-35) have been registered since the 10/88 Product Chemistry SRR. The 97% T is subject to a formulation's exemption; no data are required for this topic. IPC has not submitted any data for this topic to support the reregistration of the 98% T. All data pertaining to this topic are required for this product.

In response, Oxon Italia submitted data (1990; MRID 41640401) to support the reregistration of their 96% T (EPA Reg. No. 35915-6). The Agency (R. Perfetti; 3/7/91; CBRS No. 7221) reviewed the submission and determined that the registrant failed to provide a discussion for the possible formation of nitrosamines and dioxins. Oxon Italia subsequently submitted a discussion on the formation of dioxins and nitrosamines (W.L. Anthony; 4/22/92; CBRS No. 9030). The Agency concluded that formation of nitrosamines and dioxins is not of concern for the Oxon Italia manufacturing process. No further data are required.

In response to the SRR, Drexel Chemical Co. submitted data (1990; MRID 41379801) for a material manufactured for them by an unregistered source. In a letter (L. Haelele; 10/30/91), Drexel included a CSF, 10/30/91, which defined this material as the basic formulation for their 97% T (EPA Reg. No. 19713-7). This same letter included additional CSFs (10/30/91) through which Drexel was claiming alternate formulations from several registered and unregistered sources. The Agency reviewed (R.J. Taylor; PM-25; 3/20/92) and rejected this request for basic and alternate formulations. The Agency required the submission of complete product chemistry data for each unregistered source of atrazine. One registered source of atrazine was tentatively accepted based upon a comparison of the

10/30/91 CSF and the manufacturer's label. The above submission is reviewed here and summarized in Confidential Appendix A. The data summarized in Confidential Appendix A does not satisfy the requirements of 40 CFR §158.167 (Guideline Ref. No. 61-3) for Drexel's 97% T (EPA Reg. No. 19713-7). A discussion of possible nitrosamine or dioxin formation was not provided. Drexel must clarify the registration situation for the other claimed sources. Drexel must submit full product chemistry data for the other unregistered sources. Additional data are required.

62-1. Preliminary Analysis

The Guidance Document dated 11/83 specifies the submission of generic and product-specific data pertaining to the preliminary analysis. Ciba-Geigy submitted data (1984; MRID 00142160; 1986; MRID 00164821) to support the reregistration of the 80% FI (EPA Reg. No. 100-521), 97% FI (EPA Reg. No. 100-529), 43% FI (EPA Reg. No. 100-581), and for the unregistered technical (no EPA Reg. No.). These submissions were reviewed in the SRR where it was determined that data pertaining to nitrosamine analysis sensitive to 1 ppm for six samples, two of each at the time of manufacture, three month storage interval and six month storage interval for each of the three registered FIs must be provided. In a letter dated 4/19/91, Ciba Geigy submitted analytical results for dioxins and dibenzofurans in technical atrazine. These data were reviewed by the Agency (S. Funk; 8/30/91; CBRS No. 7935) who required additional data. In response, the registrant submitted additional information (1991; MRID 42043501). This submission was reviewed (S. Funk; 10/31/91; CBRS No. 8710); additional analytical data, a detailed protocol, and supporting data were required. In support of Ciba-Geigy, Enseco-California responded (11/8/91) by submission of the analytical method, SSOP LM-CAL-3002. This was reviewed by the Agency (S. Funk; 11/26/91; CBRS No. 8929) who found the protocol acceptable with minor revisions. In addition, Ciba-Geigy must collect and analyze seven or more samples of the unregistered atrazine technical for dioxins with a limit of quantitation ≤ 1 ppb. These requirements remain outstanding. Additional data are required for these products.

In response to the Guidance Document, Oxon Italia submitted data (1990; MRID 41640401) for the 96% T (EPA Reg. No. 35915-6) which were reviewed by the Agency (R. Perfetti; 3/7/91; CBRS No. 7221) who determined that the following data must be submitted: (i) preliminary analysis of atrazine and related triazine compounds by a method which can differentiate between the various compounds; and (ii) a detailed description of the analytical method used and validation data for one impurity listed on the Confidential Statement of Formula (EPA Form 8570-4, Rev. 2-85). Additionally, because precision data submitted for two impurities revealed them to be present at levels $>0.1\%$ in the 96% T (even though they are not listed on the Confidential Statement of Formula), preliminary analysis data must now be submitted for these impurities. Additional data were submitted to the Agency (W.L. Anthony; 4/22/92; CBRS No. 9030). Eight batches were analyzed for all impurities of concern and adequate analytical methods were provided for all impurities as well as related triazine compounds. No further data are required.

In response to the SRR, Drexel Chemical Co. submitted data (1990; MRID 41379802) for a material manufactured for them by an unregistered source. In a letter (L. Haefele; 10/30/91), Drexel included a CSF, 10/30/91, which defined this material as the basic formulation for their 97% T (EPA Reg. No. 19713-7). This same letter included additional CSFs (10/30/91) through which Drexel was claiming alternate formulations from several registered and unregistered sources. The Agency reviewed (R.J. Taylor; PM-25; 3/20/92) and rejected this request for basic and alternate formulations. The Agency required the submission of complete product chemistry data for each unregistered source of atrazine. One registered source of atrazine was tentatively accepted based upon a comparison of the 10/30/91 CSF and the manufacturer's label. The data are summarized in Confidential Appendix A. These data do not completely satisfy the requirements of 40 CFR §158.170 (Guideline Ref. No. 62-1) for Drexel's 97% T (EPA Reg. No. 19713-7) basic formulation because the analytical methods were not accompanied by validation results. Additionally, there were no determinations of nitrosamine levels sensitive to 1 ppm. Nitrosamine analyses for six samples, two of each at the time of manufacture, three months after production, and six months after production must be provided. Drexel must clarify the registration situation for the other claimed sources. Drexel must submit full product chemistry data for the other unregistered sources. Additional data are required.

In response, Industria Prodotti Chimici submitted data (1984; MRID 00141156) for the 98% T (EPA Reg. No. 33660-1) which were reviewed by the Agency in the 10/88 Product Chemistry SRR and determined to have not fully satisfied the requirements pertaining to this topic. Nitrosamine analyses sensitive to 1 ppm must be provided for six samples, two of each at the time of manufacture, three months after production, and six months after production. Upper limits must be proposed for all nitrosamines found. Additional data are required.

The Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-34) and 97% T (EPA Reg. No. 33660-35) have been registered since the 10/88 Product Chemistry SRR. The 97% T is subject to a formulation's exemption; no data are required for this topic. IPC has not submitted any data for this topic to support the reregistration of the 98% T. All data pertaining to this topic are required for this product.

62-2 Certified Limits

The Guidance Document dated 11/83 specifies submission of generic and product-specific data regarding certification of ingredient limits. In response, Ciba Geigy submitted data (1984; MRID 00142160; 1986; MRID 40566501) that the Agency reviewed in the 10/88 Product Chemistry SRR. They determined that certified limits must be submitted on EPA Form 8570-4, (Rev. 2-85) for the Ciba-Geigy 80% FI (EPA Reg. No. 100-521), the Ciba-Geigy 97% FI (EPA Reg. No. 100-529), the Ciba-Geigy 43% FI (EPA Reg. No. 100-581). The SRR also determined that the Ciba-Geigy 97% FI (EPA Reg. No. 100-529) does not satisfy the requirements because insufficient information was provided to accurately determine certified limits and 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). Additional data are required.

Ciba-Geigy has not submitted certified limits for their unregistered technical material. As a product which never enters commerce, certified limits do not apply. No data are required.

In response to the Guidance Document, Oxon Italia submitted data (1990; MRID 41640401) to support the reregistration of their 96% T (EPA Reg. No. 35915-6). The Agency (R. Perfetti; 3/7/91; CBRS No. 7221) reviewed the submission and determined that the registrant must submit a revised Confidential Statement of Formula on EPA Form 8570-4, Rev. 2-85, on which impurities are correctly identified. In addition, nominal concentrations are required for two impurities, which were revealed in precision studies to be present in quantities >0.1% in the 96% T. If these impurities are determined to be of toxicological concern, upper certified limits will also be required. In response to this review Oxon Italia submitted additional data (W.L. Anthony; 4/22/92; CBRS No. 9030). The CSF provided in this study is adequate; SRRD should ensure that RD has received a copy. No further data are required.

The 10/88 Product Chemistry SRR determined the Drexel 97% T (EPA Reg. No. 19713-7) does not satisfy the requirements because insufficient information was provided to accurately determine certified limits and 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). In response to the SRR, Drexel Chemical Co. submitted data (1990; MRID 41379802) for a material manufactured for them by an unregistered source. In a letter (L. Haefele; 10/30/91), Drexel included a CSF, 10/30/91, which defined this material as the basic formulation for their 97% T (EPA Reg. No. 19713-7). This same letter included additional CSFs (10/30/91) through which Drexel was claiming alternate formulations from several registered and unregistered sources. The Agency reviewed (R.J. Taylor; PM-25; 3/20/92) and rejected this request for basic and alternate formulations. The Agency required the submission of complete product chemistry data for each unregistered source of atrazine. One registered source of atrazine was tentatively accepted based upon a comparison of the 10/30/91 CSF and the manufacturer's label. The above submission is reviewed here and summarized in Confidential Appendix A. These data do not satisfy the requirements of 40 CFR §158.175 (Guideline Ref. No. 62-2) for Drexel's 97% T (EPA Reg. No. 19713-7) basic formulation. A new CSF must be submitted which includes revised nomenclature. Additional data are required for this material. Drexel must clarify the registration situation for the other claimed sources. Drexel must submit full product chemistry data for the other unregistered sources. Additional data are required.

In response to the Guidance Document, Industria Prodotti Chimici submitted data (1984; MRID 00141156) for the 98% T (EPA Reg. No. 33660-1) which were reviewed in the 10/88 Product Chemistry SRR and determined by the Agency to have not fully satisfied the requirements pertaining to this topic. Certified limits must be submitted on EPA Form 8570-4 (Rev. 2-85). Additional data are required.

The Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-34) and 97% T (EPA Reg. No. 33660-35) have been registered since the 10/88 Product Chemistry SRR. The 97% T is subject to a formulation's exemption; no data are required for this topic. IPC has not submitted any data for this topic to support the reregistration of the 98% T. All data pertaining to this topic are required for this product.

62-3 Enforcement Analytical Methods

The Guidance Document dated 11/83 specifies that analytical methods must be provided to determine the active ingredient and each toxicologically significant impurity for which a certified limit is required. In response to the Guidance Document, Ciba-Geigy submitted data (1984; MRID 00142160; 1986; MRID 00164821) for the 80% FI (EPA Reg. No. 100-521), the 97% FI (EPA Reg. No. 100-529), and the 43% FI (EPA Reg. No. 100-581) which were reviewed in the 10/88 Product Chemistry SRR. It was determined that this requirement is fully satisfied. No additional data are required.

Ciba-Geigy has not submitted analytical methods specific to the unregistered technical material. Since the requirement for certified limits does not apply to this material, there is no requirement for enforcement analytical methods. No data are required.

The 10/88 Product Chemistry SRR determined that validation data were required for the here Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-1). This data gap remains outstanding. Additional data are required.

In response to the Guidance Document, Oxon Italia submitted data (1990; MRID 41640401) to support the reregistration of their 96% T (EPA Reg. No. 35915-6). The Agency (R. Perfetti; 3/7/91; CBRS No. 7221) reviewed the submission and determined that the registrant must submit an enforcement analytical method for the atrazine-related triazine compounds. The method should be capable of differentiating between the related compounds. Enforcement analytical methods, including complete validation data, were required for all impurities of toxicological concern. Additional data were submitted (W.L. Anthony; 4/22/92; CBRS No. 9030) which resolved the remaining concerns. No further data are required.

In response, Drexel Chemical submitted data (1990; MRID 41379802) for the 97% T (EPA Reg. No. 19713-7), which are reviewed here and are summarized in the Confidential Appendix. In response to the SRR, Drexel Chemical Co. submitted data (1990; MRID 41379802) for a material manufactured for them by an unregistered source. In a letter (L. Haefele; 10/30/91), Drexel included a CSF, 10/30/91, which defined this material as the basic formulation for their 97% T (EPA Reg. No. 19713-7). This same letter included additional CSFs (10/30/91) through which Drexel was claiming alternate formulations from several registered and unregistered sources. The Agency reviewed (R.J. Taylor; PM-25; 3/20/92) and rejected this request for basic and alternate formulations. The Agency required the submission of complete product chemistry data for each unregistered source of atrazine.

One registered source of atrazine was tentatively accepted based upon a comparison of the 10/30/91 CSF and the manufacturer's label. The above submission is reviewed here and summarized in Confidential Appendix A. These data do not satisfy 40 CFR §158.180 (Guideline Ref. No. 62-3) regarding the enforcement analytical methods for Drexel's 97% T (EPA Reg. No. 19713-7) basic formulation. Additional validation data must be provided for the analytical methods. Drexel must clarify the registration situation for the other claimed sources. Drexel must submit full product chemistry data for the other unregistered sources. Additional data are required.

The Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-34) and 97% T (EPA Reg. No. 33660-35) have been registered since the 10/88 Product Chemistry SRR. The 97% T is subject to a formulation's exemption; no data are required for this topic. IPC has not submitted any data for this topic to support the reregistration of the 98% T. All data pertaining to this topic are required for this product.

PHYSICAL AND CHEMICAL CHARACTERISTICS

The Guidance Document dated 11/83 requires that physical and chemical data be provided to satisfy the requirements in the 40 CFR §158.190 (Guideline Ref. Nos. 63-2 through 63-21). The 10/88 Product Chemistry SRR allowed data sharing for several physical and chemical data topics. The 10/88 Product Chemistry SRR also indicates that published physical and chemical data for the PAIs of atrazine may be submitted to satisfy registration data requirements. These include data on solubility and vapor pressure of the atrazine PAI from the Weed Science Society of America Herbicide Handbook (5th Ed., 1983, p. 31). The 10/88 Product Chemistry SRR stated that the data for octanol/water partition coefficient were adequate for the Ciba-Geigy 97% FI (EPA Reg. No. 100-529) and the Drexel 97% T (EPA Reg. No. 19713-7); and these data may be shared by other registrants upon proper request in support of the reregistration of their products.

In response to the Guidance Document, Ciba-Geigy submitted data (1984; MRIDs 00142160 and 00153235; 1966; MRID 00164822) pertaining to the physical and chemical characteristics of the 80% FI (EPA Reg. No. 100-521) and the 43% FI (EPA Reg. No. 100-581). These data were reviewed in the 10/88 Product Chemistry SRR where the Agency determined that data gaps for the Ciba-Geigy 80% FI (EPA Reg. No. 100-521) included pH (Guideline Ref. No. 63-12), oxidizing or reducing action (Guideline Ref. No. 63-14), flammability (Guideline Ref. No. 63-15), explodability (Guideline Ref. No. 63-16), storage stability (Guideline Ref. No. 63-17) and corrosion characteristics (Guideline Ref. No. 63-20); data gaps for the Ciba-Geigy 43% FI (EPA Reg. No. 100-581) included pH (Guideline Ref. No. 63-12), oxidizing or reducing action (Guideline Ref. No. 63-14), flammability (Guideline Ref. No. 63-15), explodability (Guideline Ref. No. 63-16) and corrosion characteristics (Guideline Ref. No. 63-20). The SRR determined data gaps for the Ciba-Geigy 97% FI (EPA Reg. No. 100-529) included pH (Guideline Ref. No. 63-12), oxidizing or reducing action (Guideline Ref. No. 63-14), flammability (Guideline Ref. No. 63-15),

explosibility (Guideline Ref. No. 63-16), storage stability (Guideline Ref. No. 63-17) and corrosion characteristics (Guideline Ref. No. 63-20). The 10/88 Product Chemistry SRR determined that data gaps for the Ciba-Geigy unregistered technical (no EPA Reg. No.) included density (Guideline Ref. No. 63-7), pH (Guideline Ref. No. 63-12), and stability (Guideline Ref. No. 63-13). Additional data are required.

In response to the Guidance Document, Industria Prodotti Chimici S. P. A. submitted data (1984; MRID 00141156) for the 98% T (EPA Reg. No. 33660-1). The October 1988 SRR determined that data gaps for the 98% T (EPA Reg. No. 33660-1) include octanol/water partition coefficient (Guideline Ref. No. 63-11), pH (Guideline Ref. No. 63-12), stability (Guideline Ref. No. 63-13), and explosibility (Guideline Ref. No. 63-16). The Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-34) and 97% T (EPA Reg. No. 33660-35) were registered since the 10/88 Product Chemistry SRR. Based upon data submitted for Guideline Ref. No. 61-1, a formulator's exemption applies to the 97% T (EPA Reg. No. 33660-35). Therefore, no data are required. IPC has claimed a formulator's exemption for the 98% T (EPA Reg. No. 33660-34), also. However, the data submitted do not support this. Therefore, all 63 series data are required for this product. Additional data are required.

Based upon information from Registration Division (R.J. Taylor; 3/22/90; PM-25) the Agency, (R. Perfetti; 3/7/91; CBRS 7221) stated that physicochemical data were not required for Oxon Italia's 96% T (EPA Reg. No. 35915-6); it also stated that data might be required to satisfy the requirements of the Registration Standard. As a technical material, this product meets the definition of a manufacturing use product (40 CFR §158.153 (L)). For this reason, data are required for this product to satisfy the requirements of 40 CFR §158.190. Additional data are required.

In response to the Guidance Document, Drexel Chemical Co. submitted data (1985; MRID 00149931) pertaining to the physical and chemical characteristics of the 97% T (EPA Reg. No. 19713-7). The 10/88 Product Chemistry SRR determined that data gaps included stability (Guideline Ref. No. 63-13), oxidizing or reducing action (Guideline Ref. No. 63-14), flammability, (Guideline Ref. No. 63-15), and explosibility (Guideline Ref. No. 63-16). Previously submitted physicochemical data are not applicable to Drexel's 97% T basic formulation since they have changed suppliers. In support of the reregistration of this material, Drexel has submitted data (1990; MRID 41379803) which are reviewed in this document.

Summarized in Table 1 are the physicochemical properties of Drexel Chemical Co.'s 97% T atrazine basic formulation.

Table 1. Physical and chemical properties of the atrazine technical grade of active ingredient.

Guidance Reference No.; Name of Property	Description [Method] (Product; Test Substance; EPA Reg. No.; MRID)
63-2. Color	white [observation] (97% T; TGAI; 19713-7; 41379803)
63-3. Physical State	crystalline solid [observation] (97% T; TGAI; 19713-7; 41379803)
63-4. Odor	odorless [observation] (97% T; TGAI; 19713-7; 41379803)
63-5. Melting Point	172-175 °C [measurement] (97% T; TGAI; 19713-7; 41379803)
63-6. Boiling Point	N/A, solid (97% T; ; 19713-7; 41379803)
63-7. Density, Specific Gravity or Bulk Density	0.35 g/mL [measurement] (97% T; TGAI; 19713-7; 41379803)
63-8. Solubility	at 20 °C in: water 30 mg/L methanol 1.4 g/100 mL octanol 0.82 g/100 mL ether 0.86 g/100 mL ethyl acetate 2.5 g/100 mL chloroform 7.8 g/100 mL [BCPC Pesticide Manual] (97% T; ; 19713-7; 41379803)
63-9 Vapor Pressure	40 µPa at 20 °C [BCPC Pesticide Manual] (97% T; ; 19713-7; 41379803)
63-10. Dissociation Constant	pK _a = 1.7 [BCPC Pesticide Manual] (97% T; ; 19713-7; 41379803)
63-11. Octanol/water partition coefficient	log P _{ow} = 2.7645 [OECD Method 107] (97% T; TGAI; 19713-7; 41379803)

(continued)

Table 1. (continued)

Guidance Reference No.; Name of Property	Description [Method] (Product; Test Substance; EPA Reg. No.; MRID)
63-12. pH	6-8 [manufacturing specifications] (97% T; ; 19713-7; 41379803)
63-13. Stability	Slow hydrolysis to hydroxy derivative at 70 °C at neutral pH. More rapid in acid or alkali. [BCPC Pesticide Manual] (97% T; ; 19713-7; 41379803)
63-14. Oxidizing or Reducing Action	N/A (97% T; ; 19713-7; 41379803)
63-15. Flammability	N/A (97% T; ; 19713-7; 41379803)
63-16. Explodability	N/A (97% T; ; 19713-7; 41379803)
63-18. Viscosity	not required for solid
63-19. Miscibility	not required for solid
63-21. Dielectric Breakdown Voltage	N/A, technical

Drexel stated that storage stability and corrosion studies (Guideline Ref. Nos. 63-17 and -20, respectively) will be submitted. The registrant's statement that flammability studies are "not applicable" is acceptable since this product is a solid with a low vapor pressure. Drexel must provide experimental results for pH and stability. Reliance upon manufacturing specifications and literature citations is not satisfactory where 40 CFR §158.190 specifies the TGAI. The registrant's "not applicable" claim for the oxidizing/reducing action and explodability (Guideline Ref. Nos. 63-14, and -16, respectively) is not acceptable. The registrant must provide experimental data for oxidizing/reducing action and explodability.

[These data do not satisfy the requirements of 40 CFR §158.190 (Guideline Ref. Nos. 63-2 through 63-21) regarding the requirements for physical and chemical characteristics for Drexel's atrazine 97% T (EPA Reg. No. 19713-7) basic formulation. Data gaps for the pH, stability, oxidizing/reducing action, explodability, storage stability, and corrosion characteristics (Guideline Ref. Nos. 63-12, -13, -14, -16, -17, and -20, respectively) remain outstanding. All physiochemical data are required for each other unregistered source. Additional data are required.]

[No data are required for the Industrial Prodotti Chimici atrazine 97% T (EPA Reg. No. 33660-35). All 63 series data are required for their 98% T (EPA Reg. No. 33660-34), with the exception of solubility (Guideline Ref. No. 63-8) and vapor pressure (Guideline Ref. No. 63-9). Additional data are required.]

[Data gaps for the Ciba-Geigy 80% FI (EPA Reg. No. 100-521) include pH (Guideline Ref. No. 63-12), oxidizing or reducing action (Guideline Ref. No. 63-14), flammability (Guideline Ref. No. 63-15), explodability (Guideline Ref. No. 63-16), storage stability (Guideline Ref. No. 63-17) and corrosion characteristics (Guideline Ref. No. 63-20). Data gaps for the Ciba-Geigy 43% FI (EPA Reg. No. 100-581) include pH (Guideline Ref. No. 63-12), oxidizing or reducing action (Guideline Ref. No. 63-14), flammability (Guideline Ref. No. 63-15), explodability (Guideline Ref. No. 63-16) and corrosion characteristics (Guideline Ref. No. 63-20). Data gaps for the Ciba-Geigy 97% FI (EPA Reg. No. 100-529) include pH (Guideline Ref. No. 63-12), oxidizing or reducing action (Guideline Ref. No. 63-14), flammability (Guideline Ref. No. 63-15), explodability (Guideline Ref. No. 63-16), storage stability (Guideline Ref. No. 63-17) and corrosion characteristics (Guideline Ref. No. 63-20). Data gaps for the Ciba-Geigy unregistered technical (no EPA Reg. No.) include density (Guideline Ref. No. 63-7), pH (Guideline Ref. No. 63-12), and stability (Guideline Ref. No. 63-13). According to the 10/88 Product Chemistry SRR, pH data gap for the Ciba-Geigy products pertain to the temperature of measurement. Additional data are required for the Ciba-Geigy products.]

[Data gaps for the Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-1) include octanol/water partition coefficient (Guideline Ref. No. 63-11), pH (Guideline Ref. No. 63-12), stability (Guideline Ref. No. 63-13), and explodability (Guideline Ref. No. 63-16). Additional data are required.]

[All 63 series data are required for the Oxon Italia 96% T (EPA Reg. No. 35915-6), with the exception of solubility (Guideline Ref. No. 63-8) and vapor pressure (Guideline Ref. No. 63-9). Additional data are required.]

MASTER RECORD IDENTIFICATION NUMBERS:

MRID Documents containing data that have been previously reviewed by the Agency are designated in bold print in the following bibliographic listing of the Product Chemistry Citations (used). A summary of the subject memoranda and their associated MRID documents is presented below.

Product Chemistry Citations (used):

- 00141156** Industria Prodotti Chimici S. P. A. (1984) 98% T; EPA Reg. No. 33660-1; Atrazine Product Chemistry Data. Unpublished compilation 55 p.
- 00142160** Ciba-Geigy Corp. (1984); EPA Reg. No. 100-581; Product Chemistry of Technical Atrazine including Confidential Statement of Formula. Unpublished compilation. 108 p.
- 00149931** Drexel Chemical Co. (1985) Product Specific Chemistry Data: Drexel Atrazine Technical. Unpublished compilation. 7 p.
- 00153235** Ellgehausen, H.; Guth, J; Esser, H. (1980) Factors determining the bioaccumulation potential of pesticides in the individual compartments of aquatic food chains: Addendum to the Product Chemistry Data (Octanol/Water Partition Coefficient) submitted on May, 16, 1984 by Ciba-Geigy Corp. Ecotoxicology and Environmental Safety 4: 134-157.
- 00164821** Parshley, T. (1986) Letter sent to R. Taylor dated October 23, 1986: Additional product chemistry data requested in Agency letter of October 9, 1986 - Atrazine registration standard; Atrazine technical. Prepared by Ciba-Geigy Corp. 86 p.
- 00164822** Ciba-Geigy Corp. (1986) Atrazine Product Chemistry Including Octanol/Water Partition Coefficient Study. Unpublished compilation. 149 p.
- 40566501** Brown, R.; Lail, L. (1988) Technical Atrazine: Product Chemistry: Laboratory Project ID PC-87-023. Unpublished study prepared by Ciba-Geigy Corporation. Ciba-Geigy Corp. 97% FI; EPA Reg. No. 100-529; Ciba-Geigy Technical Atrazine Confidential Statement of Formula (3/8/88). 267 p.
- 41379801** Drexel Chemical Co. (1990) Drexel Atrazine Technical: Identity and Composition. Unpublished study. 36 p.
- 41379802** Drexel Chemical Co. (1990) Drexel Atrazine Technical: Analysis and Certification of Ingredient Limits. Unpublished study. 55 p.

- 41379803 Drexel Chemical Co. (1990) Drexel Atrazine Technical: Physical and Chemical Characteristics. Unpublished study. 7 p.
- 41640401 Ciocca, P.; Bresnahan, J. (1990) Atrazine Technical: Product Chemistry. Unpublished study prepared by Oxon Italia S.p.A. and Thermedics, Inc. 151 p.
- 42043501 Slaven, R. (1991) Atrazine Technical: Response to Agency's Letter of 9/6/91: Atrazine Contamination with 2,3,7,8-TCDF. Unpublished study prepared by Ciba-Geigy Corp. 41 p.
- 42094801 Ciocca, P. (1991) Atrazine Technical: Product Chemistry. Unpublished study prepared by Oxon Italia S.p.A. 32 p.

Confidential Statement of Formula, EPA Reg. No. 33660-34, dated 8/10/89
Confidential Statement of Formula, EPA Reg. No. 33660-35, dated 1/09/91

L.R. Haeefe (1991) Drexel Chemical Co. letter dated 10/30/91: Request for alternate formulations.

Agency Memoranda:

CBRS No(s). 7221

Subject: Oxon Italia S. P. A.: Response to the Atrazine Reregistration Standard:
Product Chemistry

From: R. Perfetti

To: R. Engler & L. Rossi

Dated: 3/7/91

MRID(s): 41640401

CBRS No(s). 7935

Subject: Chlorinated Dibenzofuran Impurity in Technical Atrazine. EPA Reg. No.
100-529. DP Barcode D164066.

From: S. Funk

To: J. Morrill and M. Copley

Dated: 8/30/91

MRID(s): 42043501

CBRS No(s). 8710

Subject: Chlorinated Dibenzofuran Impurity in Technical Atrazine. Additional data.
EPA Reg. No. 100-529. DP Barcode D169625.

From: S. Funk

To: J. Morrill
Dated: 10/31/91
MRID(s): 42043501

CBRS No(s). none
Subject: none
From: R.J. Taylor, PM-25
To: Drexel Chemical Company
Dated: 3/20/92
MRID(s): none

CBRS No(s). 8929
Subject: Chlorinated Dibenzofuran Impurity in Technical Atrazine. Method ID No. 100-529. DP Barcode D171379
From: S. Funk
To: J. Morrill
Dated: 11/26/91
MRID(s): none

CBRS No(s). 9030
Subject: ID#: 080803. Atrazine Technical: Product Chemistry. DP Barcode D172008
From: W.L. Anthony
To: V. Eagle
Dated: 4/22/92
MRID(s): 42094801

TABLE A. GENERIC DATA REQUIREMENTS FOR THE CIBA-GEIGY ATRAZINE TECHNICAL GRADE OF THE ACTIVE INGREDIENT.¹

Data Requirements	Test Substance ²	Does EPA have data to satisfy this requirement?	Bibliographic Citation ³	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
<u>40 CFR §158.155-190 Product Chemistry</u>				
<u>Product Composition</u>				
61-2. Beginning Materials and Production Process	TGAI	Yes	40566501 00142160	No
61-3. Formation of Impurities	TGAI	Yes	00142160	No
<u>Analysis and Certification of Product</u>				
<u>Ingredients</u>				
62-1. Preliminary Analysis of Product Samples	TGAI	Partially	00024669 00142160 00164821	Yes ⁴
<u>Physical and Chemical Characteristics</u>				
63-2. Color	TGAI	Yes	Guidance Document	No
63-3. Physical State	TGAI	Yes	Guidance Document	No
63-4. Odor	TGAI	Yes	Guidance Document	No
63-5. Melting Point	TGAI	Yes	00164822	No
63-6. Boiling Point	TGAI	N/A ⁵		No
63-7. Density, Bulk Density, or Specific Gravity	TGAI	No	Second Round Review 10/18/88	Yes ⁶
63-8. Solubility	TGAI or PAI	Yes	Second Round Review 10/18/88	No
63-9. Vapor Pressure	TGAI or PAI	Yes	00164822	No
63-10. Dissociation Constant	TGAI or PAI	Yes	Guidance Document	No

(Continued, footnotes follow)

TABLE A. (Continued)

Data Requirements	Test Substance ²	Does EPA have data to satisfy this requirement?	Bibliographic Citation ³	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-11. Octanol/Water Partition Coefficient	PAI	Yes	00153235 00164822	No
63-12. pH	TGAI	No		Yes ⁶
63-13. Stability	TGAI	No	Guidance Document	Yes ⁶
<u>Other Requirements</u>				
64-1. Submittal of Samples	TGAI or PAI	N/A		Reserved ⁷

¹Data requirements pertain to the Ciba-Geigy unregistered technical. Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for the Ciba-Geigy Atrazine Manufacturing Use Products.

²Test Substance: TGAI = technical grade of the active ingredient; PAI = purified active ingredient; MP = manufacturing use product.

³These references were submitted in response to the Atrazine Guidance Document (11/83). Underlining indicates documents that have been reviewed for this update.

⁴Ciba-Geigy has responded to the requirements of 40 CFR §158.170 (Guideline Ref. No. 62-1) regarding preliminary analysis of the unregistered technical atrazine (no EPA Reg. No.). The data provided do not fully satisfy the requirements. The registrant must collect and analyze seven or more samples of unregistered technical for the dioxins with a 1 ppb limit of quantitation. Additional data are required.

⁵N/A = not applicable

TABLE A. (Continued)

⁶The registrant has not responded to the requirements of 40 CFR §158.190 (Guideline Ref. No. 63-7) for the Ciba-Geigy unregistered technical (no EPA Reg. No.). All data pertaining to this topic are required for this product.

⁷If samples are needed, the Agency will request them.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR THE CIBA-GEIGY ATRAZINE MANUFACTURING-USE PRODUCTS.¹

Data Requirements	Test Substance ²	Does EPA have data to satisfy this requirement?	Bibliographic Citation ³	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
<u>40 CFR §158.155-190 Product Chemistry</u>				
<u>Product Composition</u>				
61-1. Product Identity and Disclosure of Ingredients	MP	Partially	00142160 40566501	Yes ⁴
61-2. Beginning Materials and Production Process	MP	Yes	00142160 40566501	No
61-3. Formation of Impurities	MP	Yes	00142160	No
<u>Analysis and Certification of Product Ingredients</u>				
62-1. Preliminary Analysis of Product Samples	MP	Partially	00024669 00142160 00164821	Yes ⁵
62-2. Certification of Ingredient Limits	MP	Partially	00142160 40566501	Yes ⁶
62-3. Analytical Methods to Verify Certified Limits	MP	Yes	00142160 00164821	No
<u>Physical and Chemical Characteristics</u>				
63-2. Color	MP	Yes	00142160	No
63-3. Physical State	MP	Yes	00142160	No
63-4. Odor	MP	Yes	00142160	No
63-7. Density, Bulk Density, or Specific Gravity	MP	Yes	00142160	No
63-12. pH	MP	Partially	00142160	Yes ⁷
63-14. Oxidizing or Reducing Action	MP	Partially	00142160	Yes ⁸
63-15. Flammability	MP	Partially	00142160	Yes ⁸

(Continued, footnotes follow)

TABLE B. (Continued)

Data Requirements	Test Substance ²	Does EPA have data to satisfy this requirement?	Bibliographic Citation ³	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-16. Explodability	MP	Partially	00142160	Yes ⁸
63-17. Storage Stability	MP	Partially	00142160	Yes ⁹
63-18. Viscosity	MP	N/A ¹⁰	00142160	No
63-19. Miscibility	MP	N/A	00142160	No
63-20. Corrosion Characteristics	MP	Partially	00142160	Yes ⁸
<u>Other Requirements</u>				
64-1. Submittal of Samples	MP	No		Reserved ¹¹

¹Data requirements pertain to the Ciba-Geigy 97% FI (EPA Reg. No. 100-529), 80% FI (EPA Reg. No. 100-521), and 43% FI (EPA Reg. No. 100-581). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for Ciba-Geigy Atrazine Technical Grade of the Active Ingredient."

²Test Substance: MP = manufacturing use product.

³These references were submitted in response to the Atrazine Guidance Document (11/83). Underlining indicates documents that have been reviewed for this update.

⁴The registrant has responded to the requirements of 40 CFR §158.155 (Guideline Ref. No. 61-1); however, certain data remain outstanding. The registrant needs to submit nominal concentrations for the 97% FI (EPA Reg. No. 100-529). Additional data are required.

⁵The registrant has responded to the requirements of 40 CFR §158.170 (Guideline Ref. No. 62-1); however, certain data remain outstanding. The registrant needs to identify and quantify all the nitrosamines by methods sensitive to 1 ppm of N-nitroso

TABLE B. (Continued)

contaminants in six samples of the 80%, 97%, and 43% FI's (EPA Reg. Nos. 100-521, -529, - and -581); two samples of each must be analyzed shortly after production; two at three months after production, and two at six months after production. Upper limits must be proposed for all nitrosamines detected. Additional data are required.

⁶The registrant has responded to the requirements of 40 CFR §158.175 (Guideline Ref. No. 62-1); however certain data remain outstanding. The registrant needs to explain how the certified limits were established for the 97% FI (EPA Reg. No. 100-529), and provide the certified limits on EPA Form 8570-4 (Rev. 2.85) for the 97% FI (EPA Reg. No. 100-529), the 80% FI (EPA Reg. No. 100-521), and the 43% FI (EPA Reg. No. 100-581).

⁷The registrant has not responded to the requirements of 40 CFR §158.190 (Guideline Ref. No. 63-12) for the 97% FI (100-529), the 80% FI (EPA Reg. No. 100-521), or the 43% FI (EPA Reg. No. 100-581). All data pertaining to this topic are required for these products. The measurement temperature remains outstanding. Additional data are required.

⁸The registrant has not responded to the requirements of 40 CFR §158.190 (Guideline Ref. No. 63-14, -15, -16, and -20, respectively) regarding oxidizing/reducing action, flammability, explosibility and corrosion characteristics for the 97%, 80%, and 43% FIs (EPA Reg. Nos. 100-529, -521, and -581). These data gaps remain outstanding. Additional data are required.

⁹The registrant has not responded to the requirements of 40 CFR §159.190 (Guideline Ref. No. 63-17) regarding storage stability for the 97% and 80% FIs (EPA Reg. Nos. 100-529 and -521). This data gap remains outstanding. Additional data are required.

¹⁰N/A = Not Applicable

¹¹If samples are needed, the Agency will request them.

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

Data Requirements	Test Substance ²	Does EPA have data to satisfy this requirement?	Bibliographic Citation ³	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
<u>40 CFR §158.155-190 Product Chemistry</u>				
<u>Product Composition</u>				
61-2. Beginning Materials and Production Process	TGAI	Partially	<u>41379801</u>	Yes ⁴
61-3. Formation of Impurities	TGAI	Partially	<u>41379801</u>	Yes ^{4,5}
<u>Analysis and Certification of Product Ingredients</u>				
62-1. Preliminary Analysis of Product Samples	TGAI	Partially	<u>41379802</u>	Yes ^{4,6}
<u>Physical and Chemical Characteristics</u>				
63-2. Color	TGAI	Partially	<u>41379803</u>	Yes ⁴
63-3. Physical State	TGAI	Partially	<u>41379803</u>	Yes ⁴
63-4. Odor	TGAI	Partially	<u>41379803</u>	Yes ⁴
63-5. Melting Point	TGAI	Partially	<u>41379803</u>	Yes ⁴
63-6. Boiling Point	TGAI	N/A ⁷		No
63-7. Density, Bulk Density, or Specific Gravity	TGAI	Partially	<u>41379803</u>	Yes ⁴
63-8. Solubility	TGAI or PAI	Partially	<u>41379803</u>	Yes ⁴
63-9. Vapor Pressure	TGAI or PAI	Partially	<u>41379803</u>	Yes ⁴
63-10. Dissociation Constant	TGAI or PAI	Partially	<u>41379803</u>	Yes ⁴

(Continued, footnotes follow)

TABLE A. (Continued)

Data Requirements	Test Substance ²	Does EPA have data to satisfy this requirement?	Bibliographic Citation ³	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-11. Octanol/Water Partition Coefficient	PAI	Partially	<u>41379803</u>	Yes ⁴
63-12. pH	TGAI	Partially	<u>41379803</u>	Yes ^{4,8}
63-13. Stability	TGAI	Partially	<u>41379803</u>	Yes ^{4,8}
<u>Other Requirements</u>				
64-1. Submittal of Samples	TGAI or PAI	N/A		Yes ⁹

¹Data requirements pertain to the Drexel Atrazine 97% T (EPA Reg. No. 19713-7) basic formulation and the several alternate formulations claimed in Drexel's letter of 10/30/91. Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for the Drexel Atrazine Manufacturing Use Products."

²Test Substance: TGAI = technical grade of the active ingredient; PAI = purified active ingredient; MP = manufacturing use product.

³These references were submitted in response to the Atrazine Guidance Document (11/83). Underlining indicates documents that have been reviewed for this update.

⁴The registrant has responded to this requirement for the basic formulation, manufactured under contract for Drexel, of the 97% T (EPA Reg. No. 19713-7). They have not responded for any of the other claimed unregistered sources. Drexel must clarify the registration situation for the other claimed sources. Drexel must provide data for all other unregistered sources of the active ingredient.

TABLE A. (Continued)

⁵The registrant has responded to the requirements of 40 CFR §158.167 (Guideline Ref. No. 61-3); however, additional data are required regarding the Drexel Chemical 97% T (EPA Reg. No. 19713-7) basic formulation. The registrant needs to discuss the potential for nitrosamine or dioxin formation.

⁶The registrant has responded to the requirements of 40 CFR §158.170 (Guideline Ref. No. 62-1); however, additional data are required regarding the Drexel Chemical 97% T (EPA Reg. No. 19713-7) basic formulation. Data pertaining to nitrosamine analysis are required for all sources. All nitrosamines must be identified and quantified by methods sensitive to 1 ppm of N-nitroso contaminants in six samples of the technical; two samples must be analyzed shortly after production, two at three months after production, and two at six months after production. Upper limits must be proposed for all nitrosamines found.

⁷N/A = not applicable

⁸Citation of manufacturing specifications and literature is not satisfactory where 40 CFR §158.190 specifies TGAI as the test substance. Drexel must provide experimental data and cite or provide the experimental method for pH and stability of the basic formulation.

⁹The Agency is requiring the submission of samples. For each claimed unregistered source of the active ingredient, Drexel must submit 5 grams of the Pure Active Ingredient and 200 grams of the Technical Grade Active Ingredient. For each chemical source, Drexel must submit a copy of the analytical method used by the manufacturer. With the submission, Drexel must submit physiochemical data and any other corroborative information for the sample. Drexel is referred to R.J. Taylor's letter (3/20/92) for the submission address.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR THE DREXEL ATRAZINE MANUFACTURING-USE PRODUCTS.¹

Data Requirements	Test Substance ²	Does EPA have data to satisfy this requirement?	Bibliographic Citation ³	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
<u>40 CFR §158.155-190 Product Chemistry</u>				
<u>Product Composition</u>				
61-1. Product Identity and Disclosure of Ingredients	MP	Partially	<u>41379801</u>	Yes ⁴
61-2. Beginning Materials and Production Process	MP	Partially	<u>41379801</u>	Yes ⁵
61-3. Formation of Impurities	MP	Partially	<u>41379801</u>	Yes ⁶
<u>Analysis and Certification of Product Ingredients</u>				
62-1. Preliminary Analysis of Product Samples	MP	Partially	<u>41379802</u>	Yes ⁷
62-2. Certification of Ingredient Limits	MP	Partially	<u>41379802</u>	Yes ⁸
62-3. Analytical Methods to Verify Certified Limits	MP	Partially	<u>41379802</u>	Yes ⁹
<u>Physical and Chemical Characteristics</u>				
63-2. Color	MP	Partially	<u>41379803</u>	Yes ¹⁰
63-3. Physical State	MP	Partially	<u>41379803</u>	Yes ¹⁰
63-4. Odor	MP	Partially	<u>41379803</u>	Yes ¹⁰
63-7. Density, Bulk Density, or Specific Gravity	MP	Partially	<u>41379803</u>	Yes ¹⁰
63-12. pH	MP	Partially	<u>41379803</u>	Yes ¹¹
63-14. Oxidizing or Reducing Action	MP	Partially	<u>41379803</u>	Yes ¹²
63-15. Flammability	MP	Partially	<u>41379803</u>	Yes ¹⁰
63-16. Explodability	MP	Partially	<u>41379803</u>	Yes ¹²
63-17. Storage Stability	MP	No	<u>41379803</u>	Yes ¹³

(Continued, footnotes follow)

TABLE B. (Continued)

Data Requirements	Test Substance ²	Does EPA have data to satisfy this requirement?	Bibliographic Citation ³	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-18. Viscosity	MP	N/A ¹⁴		Yes ¹⁰
63-19. Miscibility	MP	N/A		Yes ¹⁰
63-20. Corrosion Characteristics	MP	No		Yes ¹³
<u>Other Requirements</u>				
64-1. Submittal of Samples	MP	No		Yes ¹⁵

¹Data requirements pertain to the Drexel Atrazine 97% T (EPA Reg. 19713-7). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for Drexel Atrazine Technical Grade of the Active Ingredient."

²Test Substance: MP = manufacturing use product.

³These references were submitted in response to the Atrazine Guidance Document (11/83). Underlining indicates documents that have been reviewed for this update.

⁴In a letter (L.R. Haebele; 10/30/91), Drexel submitted new CSFs for a basic formulation from an unregistered source and several alternate formulations. Two of the alternate sources from registered materials do not satisfy the requirements for use as alternate formulations on the basis of incompatible label claims. The third registered source is not acceptable as an alternate formulation based upon incompatible certified limits of the active ingredients. Drexel has responded to the requirements of 40 CFR §158.155 for their 97% T (EPA Reg. No. 19713-7) basic formulation prepared for them by a contract manufacturer (no EPA Reg. No.). Drexel is also claiming 2 unregistered sources as alternate formulations. Drexel must clarify the registration status for the several sources. Drexel must submit full product chemistry for the other unregistered sources. Additional data are required.

TABLE B. (Continued)

⁵Drexel has responded to the requirements of 40 CFR §158.160-165 for the 97% T (EPA Reg. No. 19713-7) basic formulation prepared for them by a contract manufacturer (no EPA Reg. No.). The information provided satisfies these requirements for this material. The information provided also demonstrates full local control of the manufacturing process from raw materials to packaging of the final product. This seems to satisfy the Agencies policies regarding contract manufacturing, set forth in PR87-7. Drexel has claimed several alternate formulations. Drexel must clarify the registration status of these alternate materials. Drexel must submit full product chemistry data for the other unregistered sources. Additional data are required.

⁶The registrant has responded to the requirements of 40 CFR §158.167 (Guideline Ref. No. 61-3); however, for the Drexel Chemical 97% T (EPA Reg. No. 19713-7) basic formulation prepared by a contract manufacturer. Discussion is required pertaining to nitrosamine and dioxin formation.

⁷The registrant has responded to the requirements of 40 CFR §158.170 (Guideline Ref. No. 62-1); however for the Drexel Chemical 97% T (EPA Reg. No. 19713-7) basic formulation prepared by a contract manufacturer. Analyses for nitrosamines are required. All nitrosamines must be identified and quantified by methods sensitive to 1 ppm of N-nitroso contaminants in six samples of the technical; two samples must be analyzed shortly after production, two at three months after production, and two at six months after production. Upper limits must be proposed for all nitrosamines found. Validation data must be provided for the methods used during the preliminary analysis. Drexel has claimed several alternate formulations. Drexel must clarify the registration status of these alternate formulations. Drexel must submit full product chemistry data for the other unregistered sources. Additional data are required.

⁸The registrant has responded to the requirements of 40 CFR §158.175 for the 97% T (EPA Reg. No. 19713-7) basic formulation prepared by a contract manufacturer. Drexel has claimed several alternate formulations. Drexel must clarify the registration status of these alternate formulations. Drexel must submit full product chemistry data for the other unregistered sources. Additional data are required.

⁹The registrant has responded to the requirements of 40 CFR §158.180 (Guideline Ref. No. 62-3); for the Drexel Chemical 97% T (EPA Reg. No. 19713-7) basic formulation prepared by a contract manufacturer. Drexel has claimed several alternate formulations. Drexel must clarify the registration status of these alternate formulations. Drexel must submit full product chemistry data for the other unregistered sources. Additional data are required.

TABLE B. (Continued)

¹⁰The registrant has responded to this requirement for the 97% T (EPA Reg. No. 19713-7) basic formulation prepared by a contract manufacturer. These data are satisfactory. Drexel has claimed several alternate formulations. Drexel must clarify the registration status of these alternate formulations. Drexel must submit full product chemistry data for the other unregistered sources. Additional data are required.

¹¹Citation of manufacturing specifications and literature is not satisfactory where 40 CFR §158.190 specifies MP as the test substance. Drexel must provide experimental data and cite or provide the experimental method for pH and stability of the basic formulation.

¹²The registrant has responded to the requirements of 40 CFR §158.190 (Guideline Ref. No. 63-16 and -14) regarding explosability and oxidation/reduction for the Drexel Atrazine 97% T (EPA Reg. No. 19713-7) basic formulation prepared by a contract manufacturer. These data gaps remain outstanding. The registrant's "not applicable" claim for these properties are not acceptable. Drexel must provide experimental data and cite or provide the experimental method used. Drexel has claimed several alternate formulations. Drexel must clarify the registration status of these alternate formulations. Drexel must submit full product chemistry data for the other unregistered sources. Additional data are required.

¹³The registrant has agreed to submit storage stability and corrosion characteristic studies for the 97% T (EPA Reg. No. 19713-7) basic formulation, prepared by a contract manufacturer, at a later date. Storage stability and corrosion characteristic data is required for this material. Drexel has claimed several alternate formulations. Drexel must clarify the registration status of these alternate formulations. Drexel must submit full product chemistry data for the other unregistered sources. Additional data are required.

¹⁴N/A = Not Applicable

¹⁵The Agency is requiring the submission of samples. For each claimed unregistered source of the active ingredient Drexel must submit 5 grams of the Pure Active Ingredient, 200 grams of the Technical Grade Active Ingredient, and 200 grams of each Manufacturing Use Product. For each claimed source, Drexel must submit a copy of the analytical method used by the manufacturer. With the submission, Drexel must submit physiochemical data and any other corroborative information for the sample. Drexel is referred to R.J. Taylor's letter (3/20/92) for the submission address.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE INDUSTRIA PRODOTTI CHIMICI ATRAZINE TECHNICAL GRADE OF THE ACTIVE INGREDIENT.¹

Data Requirements	Test Substance ²	Does EPA have data to satisfy this requirement?	Bibliographic Citation ³	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
<u>40 CFR §158.155-190 Product Chemistry</u>				
<u>Product Composition</u>				
61-2. Beginning Materials and Production Process	TGAI	Partially	00141156	Yes ⁴
61-3. Formation of Impurities	TGAI	Partially	00141156	Yes ⁴
<u>Analysis and Certification of Product Ingredients</u>				
62-1. Preliminary Analysis of Product Samples	TGAI	Partially	00141156	Yes ^{4,5}
<u>Physical and Chemical Characteristics</u>				
63-2. Color	TGAI	Partially	00141156	Yes ⁴
63-3. Physical State	TGAI	Partially	00141156	Yes ⁴
63-4. Odor	TGAI	Partially	00141156	Yes ⁴
63-5. Melting Point	TGAI	Partially	00141156	Yes ⁴
63-6. Boiling Point	TGAI	N/A ⁶		No
63-7. Density, Bulk Density, or Specific Gravity	TGAI	Partially	00141156	Yes ⁴
63-8. Solubility	TGAI or PAI	Yes	00141156 SRR 10/18/88	No

(Continued, footnotes follow)

TABLE A. (Continued)

Data Requirements	Test Substance ²	Does EPA have data to satisfy this requirement?	Bibliographic Citation ³	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-9. Vapor Pressure	TGAI or PAI	Yes	00141156 SRR 10/18/88	No
63-10. Dissociation Constant	TGAI or PAI	Partially	00141156	Yes ⁴
63-11. Octanol/Water Partition Coefficient	PAI	Partially	00141156	Yes ^{4,7}
63-12. pH	TGAI	Partially	00141156	Yes ^{4,8}
63-13. Stability	TGAI	Partially	00141156	Yes ^{4,9}
<u>Other Requirements</u>				
64-1. Submittal of Samples	TGAI or PAI	N/A		Reserved ¹⁰

¹Data requirements pertain to the Industria Prodotti Chimici 98% T (EPA Reg. No. 33660-1), 98% T (EPA Reg. No. 33660-34) and 97% T (EPA Reg. No. 33660-35). Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for the Industria Prodotti Chimici Atrazine Manufacturing Use Products."

²Test Substance: TGAI = technical grade of the active ingredient; PAI = purified active ingredient; MP = manufacturing use product.

³These references were submitted in response to the Atrazine Guidance Document (11/83). Underlining indicates documents that have been reviewed for this update.

⁴The registrant has not responded for the 98% T (EPA Reg. No. 33660-34). All data pertaining to this topic are required for this product. A formulator's exemption applies to the 97% T (EPA Reg. No. 33660-35). No data pertaining to this topic are required

TABLE A. (Continued)

for this product.

⁵The registrant has responded to the requirements of 40 CFR §158.170 (Guideline Ref. No. 62-1); however, certain data remain outstanding. Nitrosamine analysis for the 98% T (EPA Reg. No. 33660-1) was insufficient because the change in nitrosamine levels was not monitored over time. All nitrosamines must be identified and quantified by methods sensitive to 1 ppm of N-nitrosamines contaminants in six samples of the technical; two samples must be analyzed shortly after production, two at three months after production, and two at six months after production. Upper limits must be proposed for all nitrosamines found. The registrant has not responded for the 98% T (EPA Reg. No. 33660-34). All data pertaining to this topic are required for this product. A formulator's exemption applies to the 97% T (EPA Reg. No. 33660-35). No data pertaining to this topic are required for this product.

⁶N/A = not applicable

⁷The registrant has responded for the 98% T (EPA Reg. No. 33660-1). The data submitted by I.P.C. does not agree with that from other sources. An explanation, supporting evidence, or replacement data are required. It should be noted that data pertaining to this topic have been submitted by other registrants and may be shared after receipt of a formal request to that effect. This request has not been made.

⁸The registrant has responded for the 98% T (EPA Reg. No. 33660-1). However, the measurement temperature must be specified. Additional data are required.

⁹The registrant has responded for the 98% T (EPA Reg. No. 33660-1). However, the experimental method must be cited or provided, quantitative results must be provided, and data on stability in the presence of metals or metal ions must be submitted. Additional data are required.

¹⁰If samples are needed, the Agency will request them.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR THE INDUSTRIA PRODOTTI CHIMICI ASSOCIATES
ATRAZINE MANUFACTURING-USE PRODUCTS.¹

Data Requirements	Test Substance ²	Does EPA have data to satisfy this requirement?	Bibliographic Citation ³	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
<u>40 CFR §158.155-190 Product Chemistry</u>				
<u>Product Composition</u>				
61-1. Product Identity and Disclosure of Ingredients	MP	Partially	00141156	Yes ⁴
61-2. Beginning Materials and Production Process	MP	Partially	00141156	Yes ⁴
61-3. Formation of Impurities	MP	Partially	00141156	Yes ⁴
<u>Analysis and Certification of Product Ingredients</u>				
62-1. Preliminary Analysis of Product Samples	MP	Partially	00141156	Yes ^{4,5}
62-2. Certification of Ingredient Limits	MP	Partially	00141156	Yes ^{4,6}
62-3. Analytical Methods to Verify Certified Limits	MP	Partially	00141156	Yes ^{4,7}
<u>Physical and Chemical Characteristics</u>				
63-2. Color	MP	Partially	00141156	Yes ⁴
63-3. Physical State	MP	Partially	00141156	Yes ⁴
63-4. Odor	MP	Partially	00141156	Yes ⁴
63-7. Density, Bulk Density, or Specific Gravity	MP	Partially	00141156	Yes ⁴
63-12. pH	MP	No	00141156	Yes ^{4,8}
63-14. Oxidizing or Reducing Action	MP	Partially	00141156	Yes ⁴
63-15. Flammability	MP	Partially	00141156	Yes ⁴
63-16. Explodability	MP	Partially	00141156	Yes ^{4,9}
63-17. Storage Stability	MP	Partially	00141156	Yes ⁴

(Continued, footnotes follow)

TABLE B. (Continued)

Data Requirements	Test Substance ²	Does EPA have data to satisfy this requirement?	Bibliographic Citation ³	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-18. Viscosity	MP	Partially	00141156	Yes ^{4,10}
63-19. Miscibility	MP	Partially	00141156	Yes ^{4,10}
63-20. Corrosion Characteristics	MP	Partially	00141156	Yes ⁴
<u>Other Requirements</u>				
64-1. Submittal of Samples	MP	No		Reserved ¹¹

¹Data requirements pertain to the Industria Prodotti Chimici Atrazine 98% T (EPA Reg. No. 33660-1). 98% T (EPA Reg. No. 33660-34) and 97% T (EPA Reg. No. 33660-35). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for Industria Prodotti Chimici Atrazine Technical Grade of the Active Ingredient."

²Test Substance: MP = manufacturing use product.

³These references were submitted in response to the Atrazine Guidance Document (11/83). Underlining indicates documents that have been reviewed for this update.

⁴The registrant has not responded for the 98% T (EPA Reg. No. 33660-34). All product chemistry data are required for this product. A formulator's exemption applies to the 97% T (EPA Reg. No. 33660-35). No data pertaining to this topic are required for this product.

⁵The registrant has responded to the requirements of 40 CFR §158.170 (Guideline Ref. No. 62-1) for the 98% T (EPA Reg. No. 33660-1); however, certain data remain outstanding. The analysis for nitrosamines was not acceptable because the change in the nitrosamine levels over time was not monitored. All nitrosamines must be identified and quantified by methods sensitive to 1 ppm of N-nitroso contaminants in six samples of the technical; two samples must be analyzed shortly after production, two at three months after production, and two at six months after production. Upper limits must be proposed for all nitrosamines found.

TABLE B. (Continued)

⁶The registrant has responded to the requirements of 40 CFR §158.175 (Guideline Ref. No. 62-2) for the 98% T (EPA Reg. No. 33660-1); however, the information needs to be submitted on EPA Form 8570-4 (Rev. 2/85). Additional data are required.

⁷The registrant has responded to the requirements of 40 CFR §158.180 (Guideline Ref. No. 62-3) for the 98% T (EPA Reg. No. 33660-1); however, certain data remain outstanding. Validation data are required.

⁸The registrant has responded to the requirements of 40 CFR §158.190 (Guideline Ref. No. 63-12); however, the temperature of measurement must be provided. Additional data are required.

⁹The registrant has not responded to the requirements of 40 CFR §158.190 (Guideline Ref. No. 63-16) for the 98% T (EPA Reg. No. 33660-1); however, they must cite or provide the experimental method. Additional data are required.

¹⁰Data on viscosity is required if the product is a liquid. Data on miscibility is required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents. Based upon the information supplied for the 98% T (EPA Reg. No. 33660-1) under Guideline Ref. No. 63-3, these requirements do not apply to this product. Data is not required for the 97% T (EPA Reg. No. 33660-35) since a formulator's exemption applies. The registrant has not responded for the 98% T (EPA Reg. No. 33660-34). Data may be required for this product, depending upon physical state and usage directions.

¹¹If samples are needed, the Agency will request them.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE OXON ITALIA ATRAZINE TECHNICAL GRADE OF THE ACTIVE INGREDIENT.¹

Data Requirements	Test Substance ²	Does EPA have data to satisfy this requirement?	Bibliographic Citation ³	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
<u>40 CFR §158.155-190 Product Chemistry</u>				
<u>Product Composition</u>				
61-2. Beginning Materials and Production Process	TGAI	Yes	41640401	No
61-3. Formation of Impurities	TGAI	Yes	41640401 42094801	No
<u>Analysis and Certification of Product Ingredients</u>				
62-1. Preliminary Analysis of Product Samples	TGAI	Yes	41640401 42094801	Yes
<u>Physical and Chemical Characteristics</u>				
63-2. Color	TGAI	No		Yes ⁴
63-3. Physical State	TGAI	No		Yes ⁴ (X)
63-4. Odor	TGAI	No		Yes ⁴
63-5. Melting Point	TGAI	No		Yes ⁴
63-6. Boiling Point	TGAI	N/A ⁵		No
63-7. Density, Bulk Density, or Specific Gravity	TGAI	No		Yes ⁴
63-8. Solubility	TGAI or PAI	Yes	SRR 10/18/88	No
63-9. Vapor Pressure	TGAI or PAI	No	SRR 10/18/88	No
63-10. Dissociation Constant	TGAI or PAI	No		Yes ⁴

(Continued, footnotes follow)

(X) "typo; WP problem", cc 9/16/92
P.D.

TABLE A. (Continued)

Data Requirements	Test Substance ²	Does EPA have data to satisfy this requirement?	Bibliographic Citation ³	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-11. Octanol/Water Partition Coefficient	PAI	No		Yes ⁴ - ✓ [⊗]
63-12. pH	TGAI	No		Yes ⁴ - ✓
63-13. Stability	TGAI	No		Yes ⁴ - ✓
<u>Other Requirements</u>				
64-1. Submittal of Samples	TGAI or PAI	N/A		Reserved ⁶

¹Data requirements pertain to the Oxon Italia Atrazine 96% T (EPA Reg. No. 35915-6). Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for the Oxon Italia Atrazine Manufacturing Use Products."

²Test Substance: TGAI = technical grade of the active ingredient; PAI = purified active ingredient; MP = manufacturing use product.

³These references were submitted in response to the Atrazine Guidance Document (11/83). Underlining indicates documents that have been reviewed for this update.

⁴The registrant has not responded to this requirement for the 96% T (EPA Reg. No. 35916-6). As a technical material, this product meets the definition of a manufacturing use product, 40 CFR §158.153(L). For this reason, data are required for this product to satisfy this requirement.

⁵N/A = not applicable

⁶If samples are needed, the Agency will request them.

⊗ (see editing footnote on p 39.)

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR THE OXON ATRAZINE MANUFACTURING-USE PRODUCTS.¹

Data Requirements	Test Substance ²	Does EPA have data to satisfy this requirement?	Bibliographic Citation ³	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
<u>40 CFR §158.155-190 Product Chemistry</u>				
<u>Product Composition</u>				
61-1. Product Identity and Disclosure of Ingredients	MP	Yes	42094801	No
61-2. Beginning Materials and Production Process	MP	Yes	41640401	No
61-3. Formation of Impurities	MP	Yes	41640401 42094801	No
<u>Analysis and Certification of Product Ingredients</u>				
62-1. Preliminary Analysis of Product Samples	MP	Yes	41640401 42094801	No
62-2. Certification of Ingredient Limits	MP	Yes	41640401 42094801	No
62-3. Analytical Methods to Verify Certified Limits	MP	Yes	41640401 42094801	No
<u>Physical and Chemical Characteristics</u>				
63-2. Color	MP	No		Yes ⁴
63-3. Physical State	MP	No		Yes ⁴
63-4. Odor	MP	No		Yes ⁴
63-7. Density, Bulk Density, or Specific Gravity	MP	No		Yes ⁴
63-12. pH	MP	No		Yes ⁴
63-14. Oxidizing or Reducing Action	MP	No		Yes ⁴

(Continued, footnotes follow)

TABLE B. (Continued)

Data Requirements	Test Substance ²	Does EPA have data to satisfy this requirement?	Bibliographic Citation ³	Must additional data be submitted under FIFRA Sec. 3(C)(2)(B)?
63-15. Flammability	MP	No		Yes ⁴
63-16. Explodability	MP	No		Yes ⁴
63-17. Storage Stability	MP	No		Yes ⁴
63-18. Viscosity	MP	No		Yes ⁴
63-19. Miscibility	MP	No		Yes ⁴
63-20. Corrosion Characteristics	MP	No		Yes ⁴
<u>Other Requirements</u>				
64-1. Submittal of Samples	MP	No		Reserved ⁴

¹Data requirements pertain to the Oxon Atrazine 96% T (EPA Reg. No. 35915-6). Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for Oxon Atrazine Technical Grade of the Active Ingredient."

²Test Substance: MP = manufacturing use product.

³These references were submitted in response to the Atrazine Guidance Document (11/83). Underlining indicates documents that have been reviewed for this update.

⁴If samples are needed, the Agency will request them.

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ATRAZINE

(Chemical Code 080803)

REREGISTRATION STANDARD UPDATE

PRODUCT CHEMISTRY

TASK 3

(Final Report)

CONFIDENTIAL APPENDIX

Appendix A: 11 Page(s)

Appendix B: 1 Page(s)

Confidential Appendices to the Scientific Review of the Reregistration Standard Update Report for the pesticide atrazine by the Chemistry Branch II/Reregistration Section [Confidential FIFRA Trade Secret/CBI].

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Page _____ is not included in this copy.

Pages 46 through 56 are not included.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☒ Description of the product manufacturing process.
- ☒ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☐ The document is a duplicate of page(s) _____.
- ☐ The document is not responsive to the request.

☒ CONFIDENTIAL

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