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Reg. Std. File
3-7-91

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

CONFIDENTIAL

MAR 7 1991

MAR 7 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Oxon Italia S.P.A.: Response to the Atrazine Reregistration Standard: Product Chemistry (MRID # 41640401, DEB # 7221.)

FROM: R. B. Perfetti, Ph.D., Chemist
Reregistration Section
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

THRU: W. J. Boodee, Section Head
Reregistration Section
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

TO: Reto Engler, Ph.D., Chief
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

and

L. Rossi, Chief
Reregistration Branch
Special Review and Reregistration Division (H7508C)

Attached is a review of product chemistry data submitted by Oxon Italia S.P.A. in response to the atrazine Reregistration Standard. This information was reviewed by Dynamac Corporation under supervision of CBRS, HED.

This information has undergone secondary review in CBRS and has been revised to reflect the Branch policies.

Please see our conclusions in the attachment regarding the adequacy of the information provided by the Registrant.

Revised data tables A and B have also bee included.

If you need additional input please advise.

Attachment 1 : Review of Atrazine Product Chemistry Data.

Attachment 2 : Confidential Appendices A, B, C, and D.

cc: With Attachments 1 and 2: R. B. Perfetti, J. Burrell (PIB/FOD), Atrazine Reregistration Standard File, Atrazine Subject File, C. Furlow (PIB/FOD), L. Rossi (RB/SRRD), R. Engler (SACB/HED) and Dynamac.

cc: With Attachment 1: Circulate (7).

cc: Without Attachment: P. Fenner-Crisp (HED) and RF.

DYNAMAC
CORPORATION

Final Report

ATRAZINE (DEB No. 7221)
Task 4: Registrant's Response to Product Chemistry Data Requirements

December 21, 1990

Contract No. 68-D8-0080

Submitted to:
Environmental Protection Agency
Arlington, VA 22202

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

ATRAZINE (DEB NO. 7221)

REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

Task - 4

BACKGROUND

In response to the product chemistry requirements outlined by R. J. Taylor (PM 25, Registration Division) in a letter dated 3/22/90, Pesticide Development Services on behalf of Oxon Italia S.P.A. has submitted one volume of product chemistry data (DEB No. 7221; 1990; MRID 41640401) for the 96% technical (T; EPA Reg. No. 35915-6). These data and our conclusions are discussed below.

61-1. Product Identity and Disclosure of Ingredients

The PM 25 letter dated 3/22/90 does not require additional information pertaining to the identity of the Oxon Italia 96% T (EPA Reg. No. 35915-6).

61-2. Description of Starting Materials and Manufacturing Process

The PM 25 letter dated 3/22/90 requires additional information pertaining to the starting materials and the manufacturing process of the Oxon Italia 96% T (EPA Reg. No. 35915-6) including: (i) a general characterization of the formulation or production process; (ii) the identity of the producer(s) and information concerning the composition of the solvents used; (iii) a description of the equipment used; (iv) a description of the conditions that are controlled during each step of the process; (v) a description of the procedures used to assure consistent composition of the substance produced; and (vi) a description of any purification procedures.

In response, Oxon Italia has submitted (1990; MRID 41640401) the requested information concerning the supplier and composition of the reaction solvent along with a complete description of the manufacturing process for the product, which is presented in Confidential Appendix B. These data satisfy the requirements of 40 CFR §158.160 and §158.162 (Guideline Reference No. 61-2) regarding starting materials and the production process for the Oxon Italia 96% T (EPA Reg. No. 35915-6).

61-3. Discussion of Formation of Impurities

The PM 25 letter dated 3/22/90 requires additional information pertaining to the discussion of the formation of impurities in the Oxon Italia 96% T (EPA Reg. No. 35915-6) including a

discussion pertaining to: (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; (ii) each impurity which 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 the ingredients in the product after production; and (iii) contamination from packaging materials or production equipment, and process control, purification and quality control measures.

In response, Oxon Italia has submitted (1990; MRID 41640401) a discussion of impurities formed during the production of the 96% T (EPA Reg. No. 35915-6), which is presented in Confidential Appendix C. This information does not satisfy the requirements of 40 CFR §158.167 (Guideline Reference No. 61-3) regarding discussion of formation of impurities for the Oxon Italia 96% T because no information was submitted on the potential for formation of nitrosamines and dioxins.

62-1. Preliminary Analysis

The PM 25 letter dated 3/22/90 requires additional information pertaining to the preliminary analysis of the Oxon Italia 96% T (EPA Reg. No. 35915-6) including: (i) complete and detailed descriptions of the methods used for sample analysis, including statements of their precision and accuracy; and (ii) identification and quantification of all nitrosamines by methods sensitive to 1 ppm of N-nitroso contaminants in six samples of the product; two samples analyzed shortly after production, two at three months after production, and two at six months after production (we note that analysis for nitrosamines must be conducted on six samples from one representative batch of the product collected at the intervals specified above).

In response, Oxon Italia has provided (1990; MRID 41640401) descriptions of the analytical methods used for sample analysis along with precision and linearity data, and preliminary analysis for nitrosamines in six batches of the 96% T (EPA Reg. No. 35915-6). These data are presented in Confidential Appendix D, and do not satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis for the Oxon Italia 96% T (EPA Reg. No. 35915-6) because: (i) the method submitted for the determination of atrazine along with triazine compounds related to atrazine does not differentiate between the various compounds; (ii) a description of the analytical method used and validation data were not provided for one impurity listed on the Confidential Statement of Formula (CSF); and (iii) the samples used for preliminary analysis of nitrosamines were not taken from a single representative batch of the product, and they were not analyzed according to the specified sampling

regimen. In addition, precision data submitted for two impurities mentioned in the discussion of formation of impurities revealed concentration levels above 0.1% (w/w) in samples of the 96% T (EPA Reg. No. 35915-6) used for the precision studies; these impurities are not listed on the CSF. Preliminary analysis data are now required for these impurities.

62-2. Certification of Limits

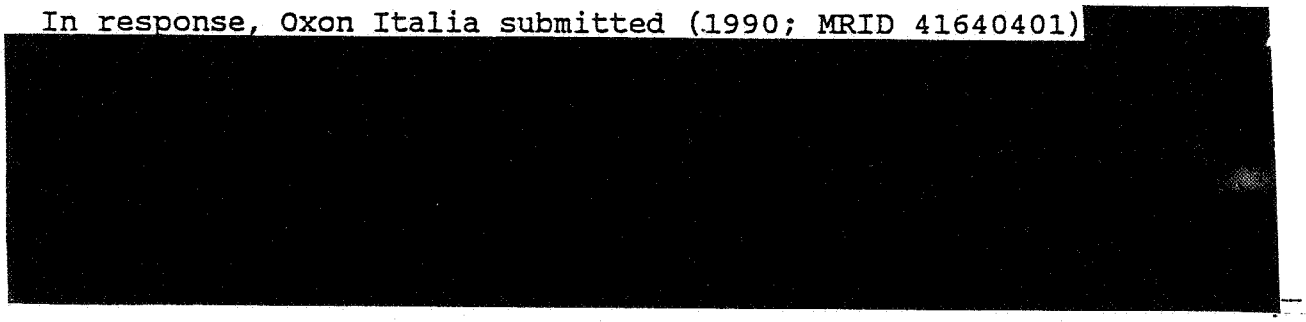
The PM 25 letter dated 3/22/90 requires additional information pertaining to the certified limits of the Oxon Italia 96% T (EPA Reg. No. 35915-6) including submission of a revised CSF on EPA Form 8570-4 with upper and lower limits in the correct columns.

In response, Oxon Italia has submitted an updated CSF dated 9/20/90 (1990; MRID 41640401) on the appropriate form. Data are presented in Confidential Appendix A, and do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits for the Oxon Italia 96% T (EPA Reg. No. 35915-6) because the impurities are listed as inerts on the CSF. In addition, precision data submitted for preliminary analysis (Confidential Appendix D) of two impurities mentioned in discussion of formation of impurities revealed concentration levels above 0.1% in samples of the 96% T used for the precision studies; these impurities are not listed on the CSF. Nominal concentrations are required for these impurities; upper certified limits will be required if these two impurities are determined to be of toxicological concern. A revised CSF should be submitted on EPA Form 8570-4 (Rev. 2-85).

62-3. Enforcement Analytical Methods

The PM 25 letter dated 3/22/90 requires additional information pertaining to analytical methods which are suitable for enforcement purposes for each active ingredient and each additional ingredient or impurity determined to be of toxicological concern in the Oxon Italia 96% T (EPA Reg. No. 35915-6).

In response, Oxon Italia submitted (1990; MRID 41640401)



The analytical method submitted for the determination of atrazine along with triazine compounds related to atrazine is discussed in Confidential Appendix D (Preliminary Analysis).

These data do not satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods for the Oxon Italia 96% T (EPA Reg. No. 35915-6) because an enforcement analytical method is required for triazine compounds related to atrazine which is capable of differentiating between the related compounds, and enforcement analytical methods, including complete validation data, must be submitted for all impurities of toxicological concern.

PHYSICAL AND CHEMICAL CHARACTERISTICS

The PM 25 letter dated 3/22/90 does not require additional information pertaining to the physical/chemical properties of the Oxon Italia 96% T (EPA Reg. No. 35915-6).

TABLE A. GENERIC DATA REQUIREMENTS FOR THE ATRAZINE 96% TECHNICAL (OXON ITALIA S.P.A) TECHNICAL GRADE OF THE ACTIVE INGREDIENT.[1]

Data Requirement	Test Substance[2]	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)? [Yes]	[No]	Reference (MRID No.)
40 CFR §158.155-190 Product Chemistry					
Product Composition					
61-2. Beginning Materials & Production Process	TGAI	R		X	41640401
61-3. Formation of Impurities	TGAI	R	X[3]		41640401
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	TGAI	CR	X[4]		41640401
Physical and Chemical Characteristics					
63-2. Color	TGAI	R		X[5]	
63-3. Physical State	TGAI	R		X[5]	
63-4. Odor	TGAI	R		X[5]	
63-5. Melting Point	TGAI	R		X[5]	
63-6. Boiling Point	TGAI	R		X[6]	
63-7. Density/Specific Gravity	TGAI	R		X[5]	
63-8. Solubility	TGAI or PAI	R		X[5]	
63-9. Vapor pressure	TGAI or PAI	R		X[5]	
63-10. Dissociation Constant	TGAI or PAI	R		X[5]	
63-11. Octanol/Water Partition Coefficient	PAI	CR		X[5]	
63-12. pH	TGAI	CR		X[5]	
63-13. Stability	TGAI	R		X[5]	
Other Requirements:					
64-1. Submittal of Samples	TGAI or PAI	CR		X[7]	

TABLE A. (Continued).

1. Data requirements pertain to the Oxon Italia 96% T (EPA Reg. No. 35915-6). Data were submitted specifically in response to the product chemistry requirements outlined by R.J. Taylor (PM 25, Registration Division) in a letter dated 3/22/90. Additional data requirements are listed in the following Table B, "Product Specific Data Requirements for the Atrazine 96% Technical (Oxon Italia S.P.A.) Manufacturing-Use Product."

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

3. A discussion must be provided regarding the potential for formation of nitrosamines and dioxins.

4. 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; (ii) a detailed description of the analytical method used and validation data for one impurity listed on the Confidential Statement of Formula; and (iii) preliminary analysis for nitrosamines on six samples from one representative batch of the product collected immediately after production (two samples), three months after production (two samples), and six months after production (two samples). In addition, because precision data submitted for two impurities revealed them to be present at levels above 0.1% in the 96% T (even though they are not listed on the CSF), preliminary analysis data must now be submitted for these impurities.

5. Data on this topic were not required in the PM 25 letter dated 3/22/90; however, additional data may still be required to satisfy requirements of the Atrazine Registration Standard and to determine reregistration eligibility.

6. Data on boiling point are not required because the technical product is a solid at room temperature.

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

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR THE ATRAZINE 96% TECHNICAL (OXON ITALIA S.P.A) MANUFACTURING-USE PRODUCT.[1]

Data Requirement	Test Substance[2]	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)? [Yes]	[No]	Reference (MRID No.)
40 CFR §158.155-190 Product Chemistry					
Product Composition					
61-1. Product Composition	MP	R		X[3]	
61-2. Beginning Materials & Production/Formulation Process	MP	R		X	41640401
61-3. Formation of Impurities	MP	R	X[4]		41640401
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis	MP	CR	X[5]		41640401
62-2. Certified Limits	MP	R	X[6]		41640401
62-3. Enforcement Method	MP	R	X[7]		41640401
Physical and Chemical Characteristics					
63-2. Color	MP	R		X[3]	
63-3. Physical State	MP	R		X[3]	
63-4. Odor	MP	R		X[3]	
63-7. Density/Specific Gravity	MP	R		X[3]	
63-12. pH	MP	CR		X[3]	
62-14. Oxidizing/Reducing Action	MP	CR		X[3]	
62-15. Flammability	MP	CR		X[8]	
63-16. Explodability	MP	R		X[3]	
63-17. Storage Stability	MP	R		X[3]	
63-18. Viscosity	MP	CR		X[8]	
63-19. Miscibility	MP	CR		X[8]	
63-20. Corrosion Characteristics	MP	R		X[3]	

(Continued, footnotes follow)

TABLE B. (Continued).

Data Requirement	Test Substance	Guideline Status	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)? [Yes] [No]	Reference (MRID No.)
Other Requirements:				
64-1. Submittal of Samples	MP	CR	X[9]	

1. Data requirements pertain to the Oxon Italia 96% T (EPA Reg. No. 35915-6). Data were submitted specifically in response to the product chemistry requirements outlined by R.J. Taylor (PM 25, Registration Division) in a letter dated 3/22/90. Additional data requirements are listed in the preceding Table A, "Generic Data Requirements for the Atrazine 96% Technical (Oxon Italia S.P.A.) Technical Grade of the Active Ingredient."

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

3. Data on this topic were not required in the PM 25 letter dated 3/22/90; however, additional data may still be required to satisfy requirements of the Atrazine Registration Standard and to determine reregistration eligibility.

4. A discussion must be provided regarding the potential for formation of nitrosamines and dioxins.

5. 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; (ii) a detailed description of the analytical method used and validation data for one impurity listed on the Confidential Statement of Formula; and (iii) preliminary analysis for nitrosamines on six samples from one representative batch of the product collected immediately after production (two samples), three months after production (two samples), and six months after production (two samples). In addition, because precision data submitted for two impurities revealed them to be present at levels above 0.1% in the 96% T (even though they are not listed on the CSF), preliminary analysis data must now be submitted for these impurities.

6. 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 at levels above 0.1% in the 96% T; if these impurities are determined to be of toxicological concern, upper certified limits will also be required.

TABLE B. (Continued).

7. An enforcement analytical method must be submitted for triazine compounds related to atrazine which is capable of differentiating between the related compounds, and enforcement analytical methods, including complete validation data must be submitted for all impurities of toxicological concern.

8. Data are not required because the product is a solid at room temperature.

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

ATRAZINE (OXON ITALIA S.P.A.; DEB NO. 7221)

PRODUCT CHEMISTRY

TASK 4

(Final Report)

CONFIDENTIAL APPENDICES

Appendix A: 1 Page(s)
Appendix B: 2 Page(s)
Appendix C: 2 Page(s)
Appendix D: 2 Page(s)

Confidential Appendices to the Scientific Review of a Registration Standard Followup Report for the pesticide atrazine by the Dietary Exposure Branch [Confidential FIFRA Trade Secret/CBI].

Page_____ is not included in this copy.

Pages 14 through 20 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 Appendix

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