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

APR 27 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: Simazine: Product Chemistry Data for the Oxon Italia
S.p.A. 95% TGAI.
[CB #:11409;MRID:426542-01;DP Barcode:D188295]

FROM: Dennis McNeilly, Chemist *Dennis McNeilly*
Special Review Section II
Chemistry Branch II - Reregistration Support
Health Effects Division [H7509C]

THRU: Francis B. Suhre, Section Head *Francis B. Suhre*
Special Review Section II
Chemistry Branch II - Reregistration Support
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TO: Venus Kunst, PMT 71
Accelerated Reregistration Branch
Special Review and Reregistration Division [H7508C]

Attached please find a review of residue chemistry data submitted by Pesticide Regulatory Services representing Oxon Italia S.p.A. in response to a CBRS Memorandum (F. Toghrol, 2/20/92) requesting additional product chemistry information. These data were reviewed by Dynamac Corp. under the supervision of CBRS, HED and have undergone secondary review in CBRS. Conclusions are consistent with Chemistry Branch policies.

The submitted information do not satisfy Product Chemistry GLDNs 61-2 and/or 62-1. For a detailed discussion of the outstanding data requirements see the attached Confidential Appendix.

If you need additional input please advise.

Attachment 1: Review of Simazine Product Chemistry Data for the Oxon Italia S.p.A. 95% TGAI.

CC (With Confidential Appendix):D.McNeilly;SF;RF;Reg Std File;Dynamac.
CC (Without Confidential Appendix):Circulation.
RDI:FBS,04/22/93;MM,4/22/93;EZ,04/23/93.
H7509C:DMM;dmm;CM-2;Rm 804F;X305-5934;04/22/93



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Final Report

SIMAZINE
Shaughnessy No. 080807
(CBRS No. 11409; DP Barcode
D188295; Case 0070)

TASK 4
Registrant's Response to Product
Chemistry Data Requirements

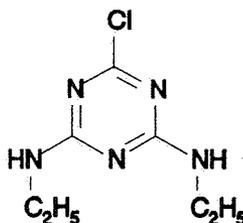
April 1, 1993

Contract No. 68-D2-0053

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

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

SIMAZINE



Shaughnessy No. 080807; Case 0070

(CBRS No. 11409; DP Barcode D188295)

Task 4

REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

BACKGROUND

An Agency Memorandum (F. Toghrol, 2/20/92) requires additional information pertaining to the product identity, starting materials, preliminary analysis, certified limits, stability, storage stability, and corrosion characteristics for the Oxon Italia S.p.A. 95% technical (T; EPA Reg. No. 35915-10). In response to these requirements, Oxon Italia has submitted a single volume of product chemistry data (MRID 42654201). The submitted data and our conclusions are discussed below.

GLN 61-2 (description of starting materials and manufacturing process)

The Agency Memorandum (F. Toghrol, 2/20/92) requires additional information concerning the relative amounts and specifications of the starting materials used in the manufacture of the Oxon Italia 95% T (EPA Reg. No. 35915-10). In response, Oxon Italia has submitted (1993; MRID 42654201) information concerning the relative amounts and specifications of some of the starting materials for the 95% T, which is presented in the Confidential Appendix. This information does not satisfy the outstanding requirements of 40 CFR §158.160-162 (Guideline Reference No. 61-2) regarding the starting materials and manufacturing process for the Oxon Italia 95% T (EPA Reg. No. 35915-10) because the registrant has not submitted the source and specifications for two of the starting materials. Additional information is required under GLN 61-2.

GLN 62-1 (preliminary analysis)

The Agency Memorandum (F. Toghrol, 2/20/92) requested new preliminary analysis data reflecting all components listed on the revised statement of composition for the Oxon Italia 95% T (EPA Reg. No. 35915-10). In response, Oxon Italia has provided (MRID 42654201) preliminary analysis data for six samples of the 95% T. These data are presented in the Confidential Appendix and do not satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis for the Oxon Italia 95% T (EPA Reg. No. 35915-10) because additional information pertaining to the samples used in the analysis are required (i.e., different batches, date of production). The registrant must also specify the methods used in the preliminary analysis study.

If the methods previously accepted for enforcement (GLN 62-3) under CBRS Nos. 8184 and 8209 were used, then the method description and supporting statements of validation will not be required. Additional information is required under GLN 62-1.

MASTER RECORD IDENTIFICATION NUMBERS

A citation for the MRID document referred to in this review is presented below.

42654201 Ciocca, Paolo (1993) Simazine Technical; EPA Reg. No. 35915-10; Product Chemistry. Unpublished study prepared by Oxon Italia S.p.A. 107 p.

Case No. 0070
Chemical No. 080807

Case Name: Simazine
Registrant: Oxon Italia S.p.A
Product(s): 95% T (EPA Reg. No. 35915-10)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ^a	MRID Number
61-1	Product Identity and Disclosure of Ingredients	N ^b	
61-2	Starting Materials and Manufacturing Process	N ^c	42654201
61-3	Discussion of Formation of Impurities	Y	
62-1	Preliminary Analysis	N ^d	42654201
62-2	Certification of Ingredient Limits	N ^e	
62-3	Analytical Methods to Verify the Certified Limits	Y	
63-2	Color	Y	
63-3	Physical State	Y	
63-4	Odor	Y	
63-5	Melting Point	Y	
63-6	Boiling Point	N/A	
63-7	Density, Bulk Density or Specific Gravity	Y	
63-8	Solubility	Y	
63-9	Vapor Pressure	Y	
63-10	Dissociation Constant	Y	
63-11	Octanol/Water Partition Coefficient	Y	
63-12	pH	Y	
63-13	Stability	N ^f	
63-14	Oxidizing or Reducing Action	Y	
63-15	Flammability	N/A	
63-16	Explosibility	Y	
63-17	Storage Stability	N ^g	
63-18	Viscosity	N/A	
63-19	Miscibility	N/A	
63-20	Corrosion Characteristics	N ^h	

^a Y = Yes; N = No; N/A = Not Applicable. Data were submitted in response to an Agency Memorandum (CBRS Nos. 8184 and 8209, dated 2/20/92, by F. Toghrol). Data requirements followed by MRID citations reflect conclusions determined in this document (CBRS No. 11409).

^b CBRS Nos. 8184 and 8209, dated 2/20/92, by F. Toghrol; the purpose of components other than simazine must be identified, and nominal concentrations must be submitted for related impurities.

^c The registrant must submit the source and specifications for two starting materials.

^d Additional information pertaining to the samples used in the analysis is required (i.e., different batches, date of production). The registrant must also specify the methods used in the preliminary analysis study. If the methods previously accepted for enforcement (GLN 62-3) under CBRS Nos. 8184 and 8209 were used, then the method description and supporting statements of validation will not be required.

^e CBRS Nos. 8184 and 8209, dated 2/20/92, by F. Toghrol; the proposed certified limits do not encompass the nominal concentration for the active ingredient. Revised certified limits must be submitted on EPA Form 8570-4 (Rev. 12/90).

^f CBRS Nos. 8184 and 8209, dated 2/20/92, by F. Toghrol; raw data supporting the submitted statements and data depicting the stability of the TGAI in the presence of sunlight, metals, and metal ions are required.

^g CBRS Nos. 8184 and 8209, dated 2/20/92, by F. Toghrol; data reflecting at least one year of storage at warehouse conditions in the commercial packaging are required.

^h CBRS Nos. 8184 and 8209, dated 2/20/92, by F. Toghrol; raw data must be submitted.

CONFIDENTIAL

SIMAZINE (OXON ITALIA; CBRS NO. 11409)

PRODUCT CHEMISTRY

TASK 4

(Final Report)

CONFIDENTIAL APPENDIX

2 Page(s)

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

SIMAZINE

080807

Page _____ is not included in this copy.

Pages _____ through _____ 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.
