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

MAY 20 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ID No. 100-618: Review of Product Chemistry Data of Propiconazole (CGA-64250) (MRID. #405837-1, -2 and -3; RCB #3717).

FROM: W. T. Chin, Chemist
Tolerance Petition Section III
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

W. T. Chin

THRU: Philip V. Errico, Section Head
Tolerance Petition Section III
Residue Chemistry Branch
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Philip V. Errico

TO: Amy Rispin, Chief
Science Integration Staff
Hazard Evaluation Division (TS-769)

and

Lois Rossi, PM #21
Registration Division (TS-767)

BACKGROUND

Richard L. Conn of CIBA-Geigy Corp. submitted an updated product chemistry data package for propiconazole, 1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl-methyl]-1H-1,2,4-triazole, and a cover letter dated 4/8/88. This letter indicates that the primary purpose of this submission is to register an amended listing of impurities for propiconazole technical due to the revised manufacturing process. However, the percent active ingredient declared on the labeling will remain at 88.0% as currently registered. The original product chemistry data package submitted in 1981 in connection with PP#1G2530 (Acc. #244267) has not been amended in the interim.

The so-called "revised manufacturing process" is basically identical to the process submitted previously in 1981 in connection with PP#1G2530. The only difference is that [redacted] one of the beginning materials, is purchased directly from [redacted] companies, instead of being synthesized according to the step 2 of the old process.

CONCLUSION

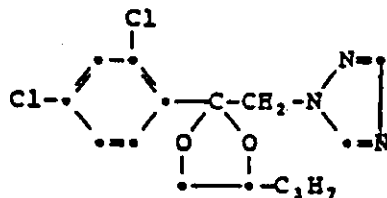
RCB concludes that the amended Product Chemistry data package for propiconazole technical is adequate and no additional information is needed. A summary of Generic Data for Technical Propiconazole is shown in Table A.

DETAILED CONSIDERATION ON PRODUCT CHEMISTRY OF PROPICONAZOLE

PRODUCT IDENTITY AND COMPOSITION

§61-1. Product Identity and Disclosure of Ingredients

Chemical Name	1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl-methyl]-1H-1,2,4-triazole
Empirical Formula	C ₁₅ H ₁₇ Cl ₂ N ₃ O ₂
Structural Formula	



Molecular Wt.	342.23
Common Name	Propiconazole
Trade Name	Tilt [®] , Banner [®]
Company Code Number	CGA-64250
Chemical Abstract Number	60207-90-1

In Confidential Appendix A attached to this memo, the updated Confidential Statement of Formula for propiconazole technical is shown. RCB concludes that no additional information is needed for this topic.

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§61-2. Description of Beginning Materials and Manufacturing Process

Refer to Confidential Appendix B attached to this memo for a description of the manufacturing process. RCB concludes that no additional information is needed for this topic.

§61-3. Discussion of the Formation of Impurities

Refer to Confidential Appendix C attached to this memo for discussions of the formation and sources of impurities. RCB concludes that no additional information is needed for this topic.

ANALYSIS AND CERTIFICATION OF PRODUCT INGREDIENTS

§62-1. Preliminary Analysis of Product Samples

Refer to Confidential Appendix D attached to this memo for the results of analyses of samples. RCB concludes that no additional information is needed for this topic.

§62-2. Certification of Ingredient Limits

Refer to Confidential Appendix A attached to this memo for disclosure of the ingredients in propiconazole technical. RCB concludes that no additional information is needed for this topic.

§62-3. Analytical Methods to Verify Certified Limits

The General Analytical Method IA-55 for the determination of propiconazole and its [redacted] impurities is submitted in MRID #405837-2 (p.6-91). It is a gas chromatographic method with a flame ionization detector to determine the parent compound and the [redacted] impurities simultaneously by different retention times of these compounds. Bis-2-ethylhexyl phthalate is used as an internal standard. Better than 90% recoveries can be routinely obtained with 3 to 60 ppm fortifications. Examples of calculations and chromatograms are adequately submitted. RCB concludes that for the purpose of verifying certified limits, this method is adequate. Therefore, no additional information is needed for this topic.

PHYSICAL AND CHEMICAL CHARACTERISTICS

§63-2. Color Clear yellow

§63-3. Physical State Viscous liquid

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

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<u>§63-4. Odor</u>	Very slight mild odor
<u>§63-6. Boiling Point</u>	180°C at 0.1 mm Hg
<u>§63-7. Density</u>	1.27 g/cm ³ at 20°C
<u>§63-8. Solubility</u>	Water (100 ppm), n-hexane (6%). It is miscible with methanol, isopropanol, acetone, methylene chloride, toluene and n-octanol.
<u>§63-9. Vapor Pressure</u>	1.0x10 ⁻⁶ Torr at 20°C 2.1x10 ⁻⁶ Torr at 25°C 3.6x10 ⁻⁶ Torr at 30°C 1.1x10 ⁻⁵ Torr at 40°C
<u>§63-10. Dissociation Constant</u>	pK _a value = @1 (very weak base)
<u>§63-11. Octanol/water Partition Coefficient</u>	K _{ow} = 892 (log P = 2.95)
<u>§63-13. Stability</u>	Very stable under normal conditions

Detailed methods for the determination of physical and chemical characteristics of propiconazole technical and its [REDACTED] impurities are submitted in MRID #405837-03. RCB concludes that no additional information is needed for this topic.

Attachment: Confidential Appendixes A, B, C and D.

cc without attachment: Circu., Amy Rispin, ~~XXXXXXXXXXXX~~
cc with attachment: (CBI) TOX, PM#21, RF, W.T.Chin, W.Boodee, PMDS/ISB, S.F.

RDI: P.VtErrico(5/x/88):R.D.Schmitt(5/x/88)
TS-769: RCB: CM2: RM812:557-4352: W.T.Chin,wc(5/x/88)

TABLE A. GENERIC DATA FOR TECHNICAL PROPICONAZOLE

Guideline Citation and Name of Test	Test Sub- stance	Guideline Status	Are Additional*		Reference Citation
			Data Required?		
			[YES]	[NO]	
<u>Product Identity and Composition:</u>					
\$61-1. Identity of Ingredients	TGAI	R	[]	[X]	MRID #405837-1
\$61-2. Materials and Process	TGAI	R	[]	[X]	as above
\$61-3. Formation of Impurities	TGAI	R	[]	[X]	as above
<u>Analysis and Certification of Product Ingredients:</u>					
\$62-1. Preliminary Analysis	TGAI	R	[]	[X]	MRID #405837-2
\$62-2. Certification of Limits	TGAI	R	[]	[X]	as above
\$62-3. Methods for Limits	TGAI	R	[]	[X]	as above
<u>Physical And Chemical Characteristics:</u>					
\$63-2. Color	TGAI	R	[]	[X]	MRID #405837-3
\$63-3. Physical State	TGAI	R	[]	[X]	as above
\$63-4. Odor	TGAI	R	[]	[X]	as above
\$63-6. Boiling Point	TGAI	R	[]	[X]	as above
\$63-7. Bulk Density	TGAI	R	[]	[X]	as above
\$63-8. Solubility	TGAI	R	[]	[X]	as above
\$63-9. Vapor Pressure	TGAI	R	[]	[X]	as above
\$63-10. Dissociation Constant	TGAI	R	[]	[X]	as above
\$63-11. Octanol/Water Parti- tion Coefficient	TGAI	R	[]	[X]	as above
\$63-13. Stability	TGAI	R	[]	[X]	Acc. #244267

TGAI: Technical grade active ingredient; R: Required

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PROPICONAZOLE
PRODUCT CHEMISTRY

Confidential Appendixes

Appendix A: 1 page
Appendix B: 2 pages
Appendix C: 2 pages
Appendix D: 1 page

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Page ___ is not included in this copy.

Pages 7 through 12 are not included in this copy.

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.

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.
