

DATE: August 30, 2001

SUBJECT: Product Chemistry Review of Thiabendazole Technical (MK-360)

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S. Mathur
8/30/01

TO: Cynthia Giles-Parker, PM 22
Fungicide Branch / RD (7505C)

DP BARCODE: D276231
EPA REG. NO.: 100-963
REGISTRANT: Syngenta Crop Protection, Incorporation
USE: Fungicide

INTRODUCTION:

The Syngenta Inc. has submitted Product chemistry data corresponding to 830 Series Subgroup A for the active ingredient Thiabendazole technical, which reflects [REDACTED] as a new supplier for this technical. The registrant has provided the updated Confidential Statement of formula and the product label. The product chemistry data have been submitted under MRID No. 453564-01. No data were submitted corresponding to 830 series Subgroup B (Physical/Chemical Properties) for the technical 99.5% produced in [REDACTED]

SUMMARY OF FINDINGS:

1. The product chemistry data submitted corresponding to guideline reference 830.1550 (Product identity & Composition), and 830.1750 (Certified limits) satisfy the data requirements of 40CFR§ 158.155 and 158.75 respectively.
2. The product chemistry data submitted (MRID No. 453564-01) corresponding to guideline reference 830.1600 (Description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.160.
3. The product chemistry data submitted (MRID No. 453564-01) corresponding to guideline reference 830.1620 (Description of production process) satisfy the data requirements for 40CFR§, 158.162.
4. The product chemistry data submitted (MRID No. 453564-01) corresponding to guideline reference 830.1670 (Discussion on the formation of impurities) satisfy the data requirements for 40CFR§ 158.167.
5. The product chemistry data submitted (MRID No. 453564-01) corresponding to the guideline reference 830.1700 (Preliminary analysis) satisfy the data requirements of 40CFR§ 158.170.
6. The product chemistry data submitted (MRID No. 453564-01) corresponding to guideline reference 830.1800 (Enforcement analytical method) satisfy the data requirements of 40CFR§ 158.180.

CONCLUSION:

1. The product chemistry data submitted corresponding to 830 Series Subgroup A satisfy the data requirements of 40CFR§ 158.155 to 158.180 and are acceptable.
2. The CSF for basic formulation (dated 03-01-01) is filled out correctly and completely. However the nominal concentration (99.5%) of the AI in the CSF does not agree with the product label claim which is 98.5%. Since the analytical results indicate that the technical is 99.5% pure, the registrant is advised to change the product label claim from 98.5% to 99.5% so that it is in compliance with PR Notice 91-2.

PRODUCT INFORMATION ONLY. THIS DOCUMENT IS NOT TO BE
SOURCE INFO NOT INCLUDED

Page 2 is not included in this copy.

Pages _____ through _____ 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.
- Internal deliberative information.
- Attorney-Client work product.
- Claimed Confidential by submitter upon submission to the Agency.

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.

REVIEW OF PRODUCT CHEMISTRY, OPPTS 830 SERIES

Chemical Name (IUPAC, ANSI, etc.) 2-thiazol-4-yl-1H-benzimidazole

Chemical Number (CAS; PC Code) CAS No.148-79-8; PC Code : 60101

Registration/Symbol No. 100-963

Type of Product (T, FI, MP, EP) 99.5% T/TGAI

DP Barcode D276231

Table 1: Manufacturing and Impurity Data for the Du Pont 98.5% T/TGAI.				
GLN	Requirement	MRID	Status ¹	Details and/or Deficiency ²
830.1550	Product identity and composition	453564-01	A	The registrant has submitted the Confidential Statement of Formula with NC of 99.5% of AI and certified limits as per 40CFR158.175.
830.1600	Description of materials used to produce product	453564-01	A	The registrant has provided sufficient information on the starting materials used in the production of the technical benimidazole
830.1620	Description of production process	453564-01	A	The registrant has provided the description of the production process in details. The reaction conditions in each step of the synthesis have been indicated. All the chemical reactions have been demonstrated in schemes..
830.1670	Discussion of formation of impurities	453564-01	A	All the impurities identified at the levels of 0.1% or greater have been identified and quantified. The registrant did not report any impurity of tox concern formed during the synthesis of the technical. The impurities were assayed by HPLC method. The nitrosamines were analyzed by HPLC-TEA.
830.1700	Preliminary analysis	453564-01	A	The registrant has provided five batch analysis of the technical, produced in commercial scale. The method for quantitation for the all impurities have been provided and validated. The nitrosamines were not detected.
830.1750	Certified limits	453564-01	A	Certified limits, including upper and lower certified limits for the ai, should be presented on a CSF for the technical product. The registrant must also list all the impurities present in the TGAI at levels of 0.1% or more.
830.1800	Enforcement analytical method	453564-01	A	High pressure Liquid Chromatography (HPLC)method was used for the assay of the MK-360 and impurities. The method was validated for accuracy, precision and linearity

¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; U = Upgrade
² Refer to CBI Appendix A for details.

No data were submitted for the 830 Series Subgroup B(Physical/Chemical)properties for the technical (99.5%) produced in [REDACTED]

Table 2: Physical and Chemical Properties for the DuPont technical DPX-A7881				
GLN	Requirement	MRID	Status ¹	Result ² or Deficiency
830.6302	Color			
830.6303	Physical state			
830.6304	Odor			
830.6313	Stability to normal and elevated temperatures, metals, and metal ions			
830.6314	Oxidation/reduction: chemical incompatibility			
830.6315	Flammability			
830.6316	Explosibility			
830.6317	Storage stability			
830.6319	Miscibility			
830.6320	Corrosion characteristics			
830.7000	pH			
830.7050	UV/Visible absorption			
830.7100	Viscosity			
830.7200	Melting point/ Melting range			
830.7220	Boiling point/ Boiling range			
830.7300	Density/ relative density/ bulk density			
830.7370	Dissociation constants in water			
830.7550	Partition coefficient (n-octanol/water), shake flask method			
830.7840	Water solubility: column elution method; shake flask method			
830.7950	Vapor pressure			

¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable.
² For example, "brown" for 830.6302; "155° C" for 830.7200.

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

Attachments: Confidential Appendix A

Page _____ is not included in this copy.

Pages 5 through 10 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.

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_____ A draft product label.

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