

DATE OUT: 24 Nov 2003

SUBJECT: EP [] MP [X] PRODUCT CHEMISTRY REVIEW
DP BARCODE No.: D294205
REG./File Symbol No.: 100-632
PRODUCT NAME: CYROMAZINE TECHNICAL
COMPANY: Syngenta Crop Protection, Inc.
FOOD USE: [] PC CODE: 121301
Decision No. 333368 Integrated Formulation []

TO: PM #03, Linda Arrington/Linda DeLuise
Insecticide Branch
Registration Division (7505C)

FROM: Bruce F. Kitchens, Chemist
Technical Review Branch
Registration Division (7505C)

Bruce F. Kitchens
24 Nov 2003 SBM 11/24/03

INTRODUCTION:

The registrant, Syngenta Crop Protection, Incorporated, is submitting a revised Confidential Statement of Formula (CSF) and additional product chemistry data for the registered manufacturing-use product, Cyromazine Technical. This revision is the result of a change in location of the production site and several changes in the basic formula. The active ingredient in this product is Cyromazine Technical at a label nominal concentration of 97.0% a.i. This product is intended for use in the manufacture of insecticide end-use products. In support of this request, the registrant has submitted a revised basic CSF dated 18 Aug 2003 and product chemistry data contained in MRID# 460672-01. The Technical Review Branch (TRB) has been asked to review this submission.

SUMMARY OF FINDINGS:

TRB has reviewed this submission and reports the following findings:

1. The registrant has submitted the following study:

Sparrow, Kay, Manufacturing Process Description and Support Data for Cyromazine Technical (CGA-72662), Syngenta Crop Protection, Incorporated, Greensboro, N.C., Study I.D. No. PC-03-088, Aug 2003, MRID# 460672-01.

2. This product is produced from an integrated formulation process. Meaning that the product is product from a series of intended chemical reactions.
3. The mean active ingredient nominal concentration from the 5-batch analysis was 97%.
4. The impurity profile has been adequately detailed. Each impurity has been identified and quantified with a nominal concentration. The registrant states that there are no impurities of toxicological concern in this product.
5. The nominal concentration of the active ingredient listed on the revised basic CSF and the label are not the same. The revised basic CSF lists the nominal concentration as 97%. The latest approved label lists the nominal concentration as 95%.
6. The active ingredients certified limits as proposed on the basic CSF are acceptable.
7. Inform the registrant that the label ingredient statement must be revised to agree with the CSF for the active ingredient.

CONCLUSIONS:

TRB has reviewed this submission and concludes the following:

1. The revised basic formula CSF for the manufacturing-use product, Cyromazine Technical dated 18 Aug 2003 is acceptable.
2. This submission meets the data requirements as specified in 40 CFR 158.155, 158.160, 158.162, 158.167, 158.175, and 158.180 with respect to product identity and composition, description of materials used to produce the product, description of production process, discussion of formation of impurities, certified limits, and enforcement analytical method.

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PRODUCT CHEMISTRY DATA (GROUP A)

<u>21. Chemical IDs/Manufacture/ Analytical Information</u>	<u>Data Required Fulfilled</u>	<u>MRID No.</u>
830-1550 Product Identity and Composition	Y	460672-01
830-1600 Description of Materials Used to Produce the Product	Y	⊗
830-1620 Description of Production Process	Y	460672-01
830-1650 Description of Formulation Process	NR	
830-1670 Discussion of Impurities	Y	460672-01
830-1700 Preliminary Analysis	Y	460672-01
830-1750 Certified Limits		
830-1800 Enforcement Analytical Method	Y	460672-01

Enforcement analytical method: (MRID No.460672-01)

(Example)

The active ingredient, Cyromazine and its impurities, was determined by reverse phase HPLC / UV detector (230 nm) using external standard by Analytical method BW-27/4.

Equipment and Parameters

HPLC: Thermo Separation Products SP 8800
 Detector: Thermo Separation Products ST 8773XR; layer thickness: 8 mm; Wavelength: 230 nm
 (UV detection), output voltage: 1 V
 Integrator: Thermo Separation Products SP 4270, AT-128
 Column: Nucleosil C18 (5um), 250 mm x 4.0 mm id
 Column temperature: 40C
 Size of sample: 10µL
 Eluent A: Water/Acetonitrile / methanol / Dodecylsulfate-Na/conc. Phosphoric acid (850ml
 + 100ml; +50ml + 0.75g + 0ml)
 Eluent B: Water/Acetonitrile / methanol / Dodecylsulfate-Na/conc. Phosphoric acid (350ml
 + 450ml +200ml + 0.75g + 2.0ml)
 Flow rate: 1.5 ml / min.
 Duration of time: ca. 50 minutes
 Retention time: 27.9 min.

Gradient Program:	Time (min)	Eluent A %	Eluent B %
	0	95	5
	40	20	80
	45	20	80
	50	95	5
	60	95	5