25/JUL/2002

SUBJECT: Product Chemistry Review of PP 321 Technical (Cyhalothrin)

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DP BARCODE: D283597
EPA REG. NO.: 100-1013
REGISTRANT: Syngenta Crop Protection, Inc.
USE: Insecticide

INTRODUCTION:

This report includes the evaluation of the product chemistry data submitted previously(See PC report dated 04-19-01; D 273286)corresponding to 830 Series Subgroup A and the data submitted(under this Bean) corresponding to Subgroup B to support the registration of the PP 321 Technical. These data reflect the change in the manufacturing process for the technical. The registrant has provided the data under MRID Nos: 453401-01 and -02, along with the product label and the Confidential Statement of Formula. The EPA Reg. No. has been changed form 10182-131 to 100-1013. The subgroup B data has been submitted under MRID No. 456797-01(D283597).

SUMMARY OF FINDINGS:

1. The data submitted corresponding to guideline reference 830.1550(Product identity and composition) and 830.1750 (Certified limits) satisfy the data requirements of 40CFR§158.155 and 158.175 respectively.

2. The data submitted corresponding to guideline reference 830.1600 (Description of the materials used to produce the product) satisfy the data requirements of 40CFR§158.160.

3. The data submitted corresponding to guideline reference 830.1620 (Description of the Production Process) and 830.1670 (Discussion on the formation of impurities) satisfy the data requirements of 40CFR§158.162 and 158.167 respectively.

4. The data submitted corresponding to guideline reference 830.1700 (Preliminary analysis) and 830.1800 (Enforcement analytical method) satisfy the data requirements of 40CFR§158.170 and 158.180 respectively.

5. The data submitted corresponding to 830 Series Subgroup B (Physical/Chemical Properties) for the PP 321 Technical produced by the changed manufacturing process., satisfy the data requirements of 40CFR§158.190.

CONCLUSION:

1. The CSF for basic formulation (dated 02-05-01) is filled out correctly and completely and agree with the label claim nominal concentration and is acceptable.

The data submitted corresponding to guideline reference 830.1550(Product identity and composition) and 830.1750 (Certified limits) satisfy the data requirements of 40CFR§158.155 and 158.175 respectively.

2. The data submitted corresponding to guideline reference 830.1600 (Description of the materials used to produce the product) satisfy the data requirements of 40CFR§158.160 and are acceptable.

3. The data submitted corresponding to guideline reference 830.1620 (Description of the Production Process) and 830.1670 (Discussion on the formation of impurities) satisfy the data requirements of 40CFR§158.162 and 158.167 respectively and are acceptable.

4. The data submitted corresponding to guideline reference 830.1700 (Preliminary analysis) and 830.1800 (Enforcement analytical method) satisfy the data requirements of 40CFR§158.170 and 158.180 respectively and are acceptable.

5. The data submitted corresponding to 830 Series Subgroup B (Physical/Chemical Properties) for the Lambda Cyhalothrin technical produced by new process satisfy the data requirements of 40CFR158.190 and are acceptable.

REVIEW OF PRODUCT CHEMISTRY, OPPTS 830 SERIES

Chemical Name (IUPAC, ANSI, etc.)	PP 321 Technical; Lambda Cyhalothrin technical
Chemical Numbers (CAS; PC Code)	Reg. No. 100-1013 CAS No. 91465-08-6 PC Code 128867
Registration/Symbol No.	100-1013
Type of Product (T, FI, MP, EP)	87.0 % T (MUP)
DP Barcode	D283597 (For subgroup B); D273286(For subgroup A, previous submission))
Reviewer	Shyam B. Mathur Ph.D

Syngenta has submitted (2000; MRIDs 453401-01, and 453401-02) product chemistry data for Lambda Cyhalothrin technical (MUP). Subgroup B data under MRID No. 456797-01.

Table 1: Manufacturing and Impurity Data for the TGAI / MUP Lambda Cyhalothrin

GLN	Requirement	MRID	Status[1]	Details and/or Deficiency[2]
830.1550	Product Identity & Disclosure of Ingredients	453401-01	A	The basic formulation CSF dated 02-05-01 shows nominal concentration of 87% for cyhalothrin. The UCL and LCL are in compliance with 40CFR158.175.
830.1600 830.1620 830.1650	Starting Materials & Manufacturing Process	" " "	A	Described and provided MSDSs for all the starting materials The manufacturing process provided all the required details for the production of the technical.
830.1670	Discussion of Impurities	" " "	A	Full discussion on the formation of impurities was provided. Also included the discussion on the potential impurities during the process.
830.1700	Preliminary Analysis	453401-02	A	Five batch analysis was provided. The registrant described in details the method to identify and quantitate the AI and other impurities. The capillary GC method was used. The analysis revealed the presence of [redacted] impurities at or above 0.1%. All the method were validated for precision, linearity and accuracy.
830.1750	Certification of Limits	" " "	A	The UCL and LCL are in accordance with 40CFR158.175 for the AI.
830.1800	Analytical Methods		A	Full details of analytical method has been provided. The GC method was used to determine the AI and its limits. the method was validated for accuracy, precision and linearity.

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

Table 2: Physical and Chemical Properties for the

GLN	Requirement	MRID	Status[1]	Result[2] or Deficiency
830.6302	Color	456797-01	A	Amber
830.6303	Physical State	" "	A	very viscous liquid at 20C
830.6304	Odor	" "	A	odorless
830.6313	Stability	" "	A	stable at RT & 54C for 14 days; stable to Al & Fe and the corresponding acetates
830.6314	Oxidation/Reduction	" "	A	not an oxidizing or educing agent
830.6315	Flammability	" "	A	208C (406F)
830.6316	Explodability	" "	A	TS is not considered as an expolosive. Stable to thermal and mechanical shocks.
830.6317	Storage Stability	" "	A	stable for at least 2 years under ambient conditions
830.6319	Miscibility	" "	NA	
830.6320	Corrosion Characteristics	" "	A	non-corrosive to the packaging material for > 2 years
830.7000	pH	" "	A	5.62 at 25 C
830.7050	UV/Visible Absorption	" "	A	See Note 1
830.7100	Viscosity	" "	A	7.49 x 10(4) mPa s @ 20C; 1.31 x 10(4) mPa.s. @ 40C
830.7200	Melting Point/ Melting Range	" "	A	Pour point 13C
830.7220	Boiling Point/ Boiling Range	" "	A	B.P. could not be determined as the TS decomposed at 252C prior to boiling.
830.7300	Density/ Relative Density/ Bulk Density	" "	A	1.27 g / cc at 20C
830.7370	Dissociation Constant in Water	" "	A	Not measureable: weak acid, pKa > 9; hydrolysis prevents measuremets
830.7550 830.7560 830.7570	Partition Coefficient (Octanol/Water)	" "	A	Log P ow = 7.0 at 20C
830.7840 830.7860	Solubility	" "	A	See Note 2
830.7950	Vapor Pressure	" "	A	2 x 10(-10) kPa [2.0 x 10 (-12) atm] at 20C Henry's law constant = 1.8 x 10(-7) atm m(3) g / mol

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

Note 1: 830.7050. UV/Visible:

Neutral solution	1,931 l/mol.cm	@ 278 nm
Neutral solution	43,712 l/mol.cm	@ 206 nm
Acidic solution	2,096 l/mol.cm	@ 278 nm
Acidic solution	46,329 l/mol.cm	@ 204 nm
Basic solution	1,782 l/mol.cm	@ 308 nm
Basic solution	31,639 l/mol.cm	@ 220 nm

Note 2. 830.7840. Solubility:

Water 5.0 x 10(-3) mg / l at 20C

organic solvents at 20C in % wt/wt

Xylene	84.7 - 87.5
n-Heptane	74.2 - 75.8
Acetone	92.4 - 94.8
Ethyl acetate	87.5 - 90.0
Methanol	76.1 - 76.9
1,2-dichloroethane	89.8 - 92.4