

US EPA ARCHIVE DOCUMENT

DATE OUT: 15/MAR/2006

FEE: **PRODUCT CHEMISTRY REVIEW OF: AN End-Use Product [X]**
DP BARCODE #: D322944 RECEIVED DATE 27/AUG/2005 FILE SYMBOL: 121-OT
PRODUCT: Cutter Insect Repellent SS MRIDs 466680-01 & to -03 ACTION CODE: R31
COMPANY NAME: Spectrum, A Div of United Industries Corporation NON-FOOD USE [X]
PPC NUMBER OF THE TGAI IN THE PRODUCT: 070705 DECISION NO.: 361412

FROM: Sami Malak, Chemist *Sami Malak*
Technical Review Branch/RD (7505C)

SBR 03-16-06

TO: 10 Richard Gebken/Joseph Tavano
Insecticide-Rodenticide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 14/OCT2005 the applicant requested registration of subject product. In support of this application, the applicant included product chemistry data, a basic CSF dated 06/SEP/2005, a proposed label EPA received on 17/OCT/2005, Formulator's Exemption, and Certificate With Respect to Citation of Data..

FINDINGS:

- 1a. The subject product was produced by a non-integrated formulation system, meaning that the active ingredient in the product is registered. The product contains 15% Picaridin, Reg. No. 39967-48.
- 1b. The subject product, an insecticide, is intended for use as an insect repellent.
- 2a. The applicant should be advised to submit the results of product's storage stability and corrosion characteristics, two product chemistry data requirements of GRNS 830.6317 & 830.6320, respectively.
- 2b. With the exception of the data gaps in Finding 2(a) above, the submitted product chemistry data is adequate and support registration of subject product.
3. Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with registration of the technical source, Picaridin, Reg. No. 39967-48. An analytical method was included with submission, MRID #466680-03. The method is reviewed in this memorandum.
4. The label claim nominal concentration of 15% Picaridin, is consistent with that in the CSF, both are in compliance with the regulations of PR Notice 91-2. Further, the storage and disposal statement and the physical or chemical hazards statement are in compliance with the regulations of 40CFR§156.78.

5. The proposed basic CSF dated 06/SEP/2005 was filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2). All ingredients claimed on the CSF are cleared for use in pesticide formulations intended for non-food uses.

CONCLUSIONS:

After resolving Findings 2(a), the TRB will have no objections for registration of subject product. The proposed basic CSF dated 06/SEP/2005 and label, EPA received on 17/OCT/2005 are acceptable as per Findings 4 & 5 above.

NOT TO RM:

Please note a minor correction in the CAS number of one inert ingredient listed on page 2 of the CSF.

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 06/JUL/2005 was included with this submission claiming confidentiality of some of the submitted data on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C). Review of CBI data was removed to Confidential Appendix A.
2. A GLP statement dated 15/JUN/2005 was included with this submission to the effect that some of the submitted studies were conducted in compliance with the GLP requirements of 40CFR§160.

Group A, Series 830-Product Identity, Composition, and Analysis (40 CFR 155, 160, 162, 167, 175 & 180)

830-1550 Product Identity and Composition

This product contains one technical grade of an active ingredient currently, plus intentionally added inert ingredients cleared for non-food uses (refer to product's basic CSF dated 06/SEP/2005).

830-1600 Description of Materials Used to Produce the Product:
Refer to Confidential appendix A.

830-1650 Description of Formulation Process:
Refer to Confidential appendix A.

830-1670 Discussion of Formation of Impurities:
Refer to Confidential appendix A.

830-1700 Preliminary Analysis:
Refer to Confidential appendix A.

830-1750 Certified Limits:
Refer to Confidential appendix A.

830-1800 Enforcement Analytical Method:

Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with registration of the technical source, Picaridin, Reg. No. 39967-48. An analytical method was included with submission, MRID #466680-03, entitled : "Gas Chromatography Determination of KRB 3023 and Sunscreen Active Ingredient Content in Certain Repellent Formulations." KRB 3023 is the trade name for Picaridin.

The method uses FID and dibutyl phthalate internal standard for the determines the active ingredient and three sunscreens in the product. In this method, samples are extracted using acetone then mixed with an internal standard and aliquots are injected into the GC. The retention time for the PAI was reported at 5.5 minutes.

Method validation data regarding recovery, accuracy, precision, and linearity are adequate. Sample calculations and chromatograms are included with this submission.

Identity, Composition, Formulation, and Analysis, Subgroup A, Series 830.1550 to 830.1800 (40 CFR 158.155 to 158.180)

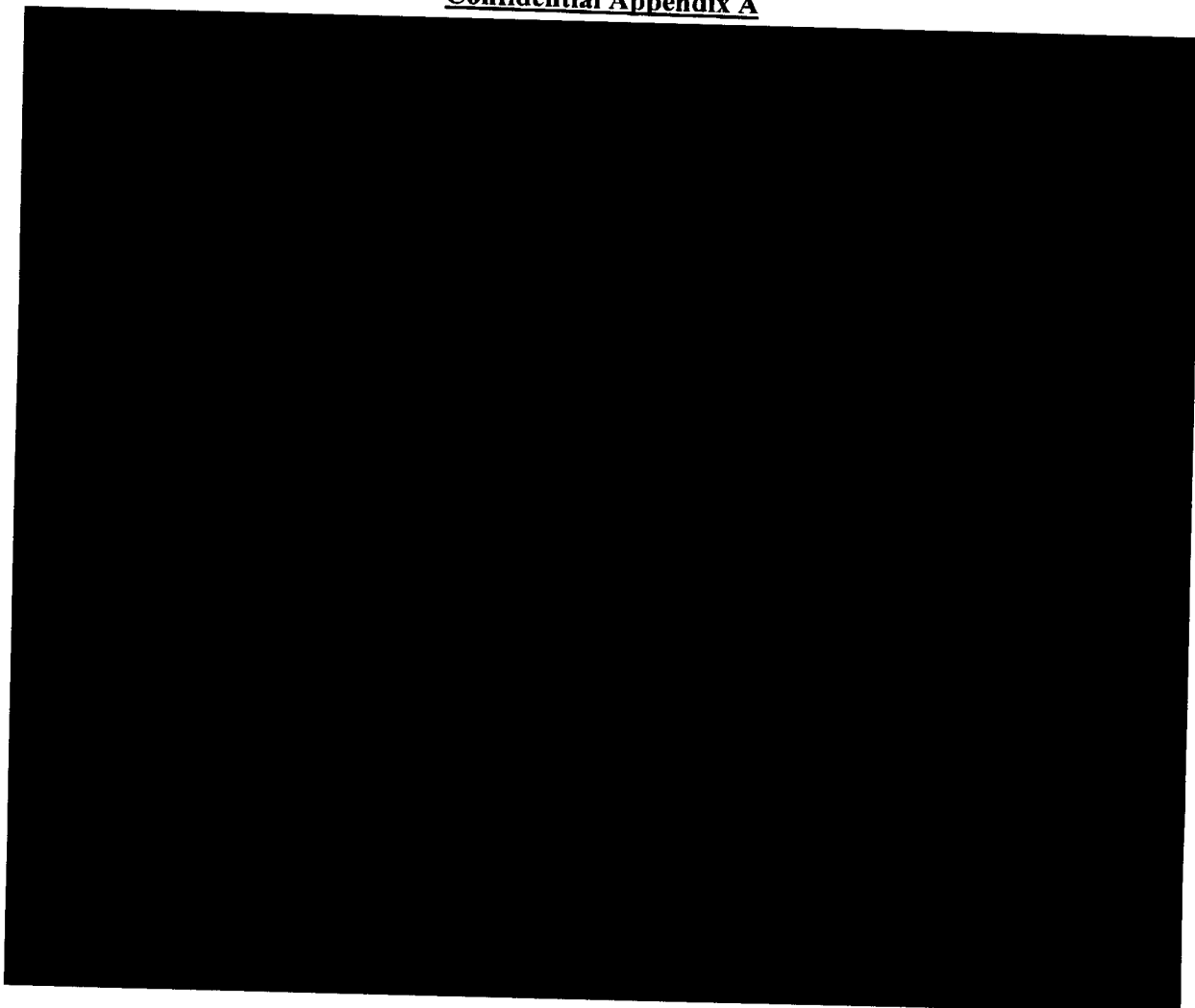
Guideline Reference NO.(GRN 830.)/Title	Data Fulfilled	MRID No.
.1550 Product identity and composition	Y	466680-01
.1600 Description of materials used to produce the product	Y	466680-01
.1620 Description of production process	NA	
.1650 Description of formulation process	Y	466680-01
.1670 Discussion of formation of impurities	Y	466680-01
.1700 Preliminary analysis	NA	
.1750 Certified limits	Y	466680-01
.1800 Enforcement analytical method	Y	466680-01

Explanations: Y =The requirements were fulfilled; N = The requirements not fulfilled; N/A = Not applicable; G = Data gap; U = Requires upgrading; I = Incomplete or in progress; W = Waived.

Physical and Chemical Properties, Subgroup B, Series 830.6302 to -830.7300 (40 CFR 158.190)

Guideline Reference NO.(GRN 830.)/Title	Data Fulfilled	Value or Qualitative Description	MRID No.
.6302 Color	Y	Medium yellow.	466680-01
.6303 Physical state	Y	Liquid.	466680-01
.6304 Odor	Y	Mild alcohol.	466680-01
.6314 Oxidation/reduction: Chemical incompatibility	Y	No oxidizing or reducing potential exist.	466680-01
.6315 Flammability/flame extension	Y	Flash point 64°F	466680-01
.6316 Explodability	NA	No impact explosive characteristics are expected on the basic of the chemical nature of the formulation ingredients.	466680-01
.6317 Storage stability	G		
.6319 Miscibility	NA	Not intended for dilution with petroleum solvents.	466680-01
.6320 Corrosion characteristics	G		
.6321 Dielectric breakdown voltage	NA	Formulation is not intended for use around electrical equipment.	466680-01
7000 pH	Y	5.11	466680-01
.7100 Viscosity	Y	12.5 CPS @ 20°C	466680-01
7300 Density/relative density/bulk density	Y	0.909	466680-01
Explanations: Y = The requirements were fulfilled; N = The requirements not fulfilled; N/A = Not applicable; G = Data gap; U = Requires upgrading; I = Incomplete or in progress; W = Waived.			

Confidential Appendix A



Information pertaining to Manufacturing Process has been removed