DATE OUT: _____

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]**
DP BARCODE No.: D217890 **REG./File Symbol No.:** 499-UGG
PRODUCT NAME: Whitmire TC-141 Avert Bait Powder

DATE: September 25, 1995

TO: George Larocca, PM 13
Insecticide-Rodenticide Branch
Registration Division(7505C)

FROM: Shyam B. Mathur, Ph.D., Chemist
Product Chemistry Review Section
Registration Support Branch/RD (7505W)

SBMathur 9-26-95

THRU: Harold Podall, Ph.D., Section Head
Product Chemistry Review Section
Registration Support Branch/RD(7505W)

HP 9/26/95

SUMMARY OF FINDINGS

1. 61-1 & 62-2: The basic formulation CSF(dated 6-13-95) needed to be upgraded. For the comments please refer to 61-1 in Confidential Appendix.
2. The information provided on the product label concur with the information provided in the CSF and is in compliance with PR Notice 91-2.
3. The data submitted corresponding to Guideline reference 61-2 and 61-3 satisfy the data requirements of 40CFR§158.162 and 158.167 respectively.
4. The data submitted corresponding to Guideline reference 62-3 satisfy the data requirements of 40CFR§158.180.
5. The data submitted corresponding to Guideline reference 63-3,7, 12,14,15,16,18,19,21 satisfy the data requirements of 40CFR §158.190.
6. The Registrant is recommended to submit the results of Storage stability(63-17) and corrosion characteristics studies(63-20) on completion to the Agency.

PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]
DP BARCODE No.: D217890 **REG./File Symbol No.:** 499-UGG
PRODUCT NAME: Whitmire TC-141 Avert bait Powder
DATE: September 25, 1995

1. Reviewer: S.B.Mathur 2. Company: Whitmire Research Laboratories Inc.

3. Type of Submission: Registration [X] Reregistration [ ]
New [X] Resubmission [ ] Amendment [ ] "ME-TOO" [ ]
Alternate Formulation [ ] Experimental Use Permit [ ]
Other (Specify)_____

4. If "Me-TOO" Registration, this product is [ ] is not [ ] similar or substantially similar to EPA's Reg. No.:_____

If not, comment in Confidential Appendix A on the differences between the registered and the new source where significant.

CONFIDENTIAL STATEMENT OF FORMULA

5. Type of formulation and the sources of active ingredients:

• Non-integrated formulation system.....[X]
• Are all technical grade active ingredients used registered?
• yes [X] • no [ ], If no, specify _____

• Integrated formulation system.....[ ]

6. Clearance of intentionally added ingredients in the formulation for the intended use (indicate in the Confidential Appendix those that are not cleared; the PC Codes should be provided by the chemist on the CSF for those that are cleared):

6(a) Formulation intended for food use under 40CFR§180.1001:
• yes [ ] • no [X] • Some are cleared, others are not [ ]
Cleared under list: • c[ ] • d[ ] • e [ ]
Are there any limitations for use as an inert under 40CFR§180.1001?
• yes [ ] • no [ ], If yes, specify _____

6(b) Formulation intended for non-food use:
• yes [X] • no [ ] • Some are cleared, others are not [ ]

6(c) Clearance by the FDA of certain formulations under 21CFR§170 to 199. Examples: (a) indirect food additives, such as food contact surface sanitizers; adhesives, coatings, paper and paperboard products that may contact food in packaging or holding; and (b) substances generally recognized as safe (GRAS).
• yes [ ] • no [ ] • Some are cleared, others are not [ ]
If yes, the entire formulation is cleared under 21CFR§_____.

7. The density, pH, and flammability values given on the CSF are identical with those of GRN 63-7, 63-12, and 63-15, respectively: • yes [X] • no [ ]

8. The nominal concentrations (NC) of the active ingredients and the upper and lower certified limits (UCL & LCL) are as follows:

Active ingredient(s)		% by weight NC	UCL	LCL
Abamectin Tech.(70%)	618-95	0.0714 (0.05)	0.0525	0.0475

9. The calculated NCs, based on the pure active ingredients (PAI), are identical to those on the label:
• yes [X] • no [ ]

10. The certified limits are within the standard limits as per 40CFR§158.175 or are adequately explained if different:
• yes [ ] • no [X]

PRODUCT LABEL

11. The chemical names of the active ingredients on the label are identical to those on the CSF: • yes [X] • no [ ]

12. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label:
• yes [ ] • no [ ] • not applicable [X]

13. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses:
• yes [X] • no [ ]

PRODUCT CHEMISTRY DATA (SERIES 61, 62, 63)

14. Chemical IDs/Manufacture/ Analytical Information		Data Required Fulfilled	MRID No.
61-1	Chemical Identity(CSF)	U	6-13-95
61-2	St.Mat. / Form.Proce.	Y	436940-01
61-3	Discussion of Impurities	Y	" "
62-1	Preliminary Analysis	NA	
62-2	Certified Limits(CSF)	U	" "
62-3	Enforcement Analytical Method	Y	436940-01

15. Physical/Chemical	Properties	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
63-3	Physical State	Y	Solid Powder	" "
63-7	Density/Bulk Density	Y	4.6 lbs/gal.	" "
63-12	pH of Product	NA		
63-14	Oxid/Red Action	Y	None	" "
63-15a	Flammability-Flash	NA		
63-15b	Flame Extension	NA		
63-16	Explodability	Y	None	" "
63-17	Storage Stability	I	Note 1	" "
63-18	Viscosity	NA		
63-19	Miscibility	NA		
63-20	Corro.Charac.	I	Note 2	" "
63-21	Dielec.Bkd.Vltg.	NA		

Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.

Note 1. 63-17. Storage stability:

The Registrant informed that storage stability for one year at room temperature(normal warehouse conditions)on one lot stored in the same plastic tube as to be marketed is currently being run. Three tubes(3 injections)for initial, 3 months, 6 months, 9 months, and one year. At six months there appeared to be no variance.

Note 1. 63-20. Corrosion characteristics:

The Registrant stated that it is to be submitted upon request by the Agency.

62-3. Analytical methods to verify certified limits by Method NO. 94.0129): (MRID No. 436940-01)

This method describes a liquid chromatographic method for determination of Abamectin in TC-141. Abamectin is determined by direct comparison to an internal standard containing a known weight of Abamectin and dibutyl phthalate. A known weight of dibutyl-phthlate is added to the unknown sample, injected on the HPLC and the peak areas obtained are compared.

Equipment:

HPLC:	Perkin Elmer Analyst HPLC system
Detector:	Perkin Elmer LC-235 Diode Array Detector
Column:	C-18, 150 x 4.5 mm 5μ column(Supelco)
Flow rate:	1.5 ml/min
Wavelength:	255 nm
Solvent:	Water:Methanol(32% : 68%)

The Registrant described the complete analytical procedure with calculations.

61-3. Discussion on the formation of impurities:
(MRID No. 436940-01)

No impurities are expected to be introduced into the formulated product as a result of equipment, packaging or other sources including side reactions, reactions between ingredients or degradation of ingredients.

CONFIDENTIAL APPENDIX
PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]
DP BARCODE No.: D217890 **REG./File Symbol No.:** 499-UGG
PRODUCT NAME: Whitmire TC-141 Avert bait Powder

61-1. Product identity & dislcosure of ingredients:

The Registrant submitted the following basic formulation CSF(dated 6-13-95):

Ingredients	lbs	Percent by weight		
	13a	13b(NC)	14a(UCL)	14b(LCL)
[redacted]				
Total	1000.00	100.00		

Comments:

The basic formulation CSF(dated 6-13-95) needed to be upgraded for the following reason:

1. In accordance with PR Notice 91-2, the UCL and the LCL of an AI should be calculated on the basis of the NC following 40CFR §158.175b certified limit table.
   In this case, the NC of AI = 0.05%, therefore,
   UCL = 0.05 + (0.05 x 10% = 0.005%) = 0.055%
   LCL = 0.05 - 0.005 = 0.045%.

2. The UCL and LCL of the yeast should be calculated using the table described in 40CFR§158.175b.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Product Source Information has been removed

CONFIDENTIAL APPENDIX
PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]
DP BARCODE No.: D217890 **REG./File Symbol No.:** 499-UGG
PRODUCT NAME: Whitmire TC-141 Avert bait Powder

61-2. Manufacturing Process: (MRID No. 436940-01)

The Registrant provided following information on this topic:

[redacted]

Manufacturing Process Information has been removed