

US EPA ARCHIVE DOCUMENT

INERT INGREDIENT INFORMATION IS NOT INCLUDED

DATE OUT: _____

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Whitmire PT 320 Avert Gel
A MANUFACTURING-USE [] OR AN END-USE PRODUCT [X]
DP BarcodeD205684 Reg. No. 499-GOU

TO: George Larocca
PM Team No. 13

FROM: Shyam B. Mathur, Ph.D., Chemist 8/24/94
Product Chemistry Review Section
Registration Support Branch/RD (WH7505W)

S. B. Mathur
8/24/94

THRU: Harold Podall, Ph.D., Section Head
Registration Support Branch/RD (WH7505W)

HP 8/24/94

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

1. The CSF (dated 3-1-93) is NOT ACCEPTABLE. The Basic formulation CSF (dated 3/1/93) did not include the name and quantity of the Propellant used in each can. The propellant is the part of the formulation. In accordance with 40CFR§158.175, the CSF must have the certified limits of each inert used including the propellant.
2. [REDACTED] which is used as an inert should be mentioned as Preservative in the column 15 of the CSF (dated 3/1/93) [EPA Form 8570-4].
3. In case of inert [REDACTED] Column 13b should have [REDACTED] instead of [REDACTED].
4. The Registrant must indicate whether, the Flash Point was determined with the Propellant or without Propellant. If the propellant was not included as part of the formulation, then the reported value of the Flash point is not correct and can NOT BE ACCEPTED.
5. The Registrant is recommended to revise the Label with slight correction in order to avoid confusion in naming the active ingredient. See the attached label, the correction is highlighted and involves only in closing the parenthesis afterB1_a(5-O-demethyl avermectin A1_a)....

PRODUCT CHEMISTRY REVIEW

END-USE PRODUCT [X] MANUFACTURING-USE PRODUCT []
EPA Reg. No. (or File Symbol No.) 499-GOU

Registration [X]

Reregistration []
Case No.: _____

DP Barcode/Chemist:

1) D205684/Shyam Mathur/8-17-94 3)

2) 4)

1. Product Name: Whitmire PT 320 Avert Gel

2. Company: Whitmire Research Laboratories Inc.

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

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

- Non-integrated formulation system [X]
- Are all TGAIs used registered • yes [X] • no []
- Integrated formulation system []
- If "ME-TOO", specify EPA Reg. No. of existing product:

4b. Clearance of inerts for non-food or food use:

Cleared for food use under 40CFR§180.1001:

- yes [] • no []. If yes: • c [] • d [] • e []
- Cleared for non-food use: • yes [X] • no []

4c. Physical state of product: **Self-contained pressurized liquid**

4d. The chemical IDs, analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in GRN 61, 62, and 63-7,

63-12, and 63-15, respectively. • yes [] • no [X]

NOTE: The Basic formulation CSF (dated 3/1/93) did not include the name and quantity of the Propellant used in each can. The propellant is the part of the formulation. In accordance with 40CFR§158.175, the CSF must have the certified limits of each inert used including the propellant.

- 4e. Density (or bulk density for solids): 8.738 lbs/gal at at 20°C
- 4f. pH (if dissolved or dispersed in water): NA
- 4g. Flash point and/or flame extension: No Flash up to 200°F [Is the Flash point determined with the Propellant?]
- 4h. NCs and CLs are acceptable: • [X] • not acceptable []
- 4i. Active ingredient(s) NC LCL UCL
- A. Abamectin Tech. 0.010 0.0095 0.0105
(Insecticide)

ACTIVE INGREDIENT INFORMATION IS NOT INCLUDED

NOTE: (1). [REDACTED] which is used as an inert should be mentioned as Préservative in the column 15 of the CSF (dated 3/1/93) [EPA Form 8570-4].

(2). In case of inert [REDACTED] Column 13b should have [REDACTED] instead of [REDACTED]

- 4j. For products produced by an integrated formulation system:
- All impurities of toxicological significance have an UCL: • yes [] • no [] • not applicable [X]
 - All impurities $\geq 0.1\%$ in the product have been identified: • yes [] • no [] • not applicable [X]

5. PRODUCT LABEL

- 5a. The active ingredients statement (chemical IDs and NCs) is consistent with the CSF: • yes [X] • no []
- 5b. The formulation contains one of the following:
- 10% or more of a petroleum distillate: • yes [] • no [X]
 - 1% or more of methyl alcohol: • yes [] • no [X]
 - sodium nitrite at any level: • yes [] • no [X]
 - a toxic List 1 inert at any level: • yes [] • no [X]
 - arsenic in any form: • yes [] • no [X]
- 5c. If yes to any of the above, does the inert ingredients statement contains a footnote indicating this?
- yes [] • no [] • not applicable [X]

- 5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are given on the label:
 ● yes [**X**] ● no [] ● not applicable []
- 5e. 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 []
- 5f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information):
 ● yes [] ● no [**X**]

6. PRODUCT CHEMISTRY (GRN 61, 62, 63)

6a. <u>Chemical IDs/Manufacture/ Analytical Information</u>	<u>Accept of Information</u>	<u>MRID No.</u>
61-1 Chemical ID (see Appendix) ¹	A	426445-01
61-2a Manufacturing Process ²	A	426445-01
61-2b Formulation Method ³		
61-3 Discussion of Impurities ⁴	A	426445-01
62-1 Analysis ⁵	NA	
62-2 Certified Limits ⁶	U *	426445-01
62-3 Analytical Method for AIs ⁷	A	426445-01

* The Basic formulation CSF(dated 3/1/93) is NOT ACCEPTABLE since it does not include all the formulation components. The Registrant has not given the name and quantity of the propellant used in the formulation.

<u>6b. Physical/Chemical Properties</u>	<u>Accept of Data</u>	<u>Value or qualitat descrip⁸</u>	<u>MRID No.</u>
63-3 Physical State	A	Pressurized liquid	426445-01
63-7 Density/Bulk Density (gm/cc)	A	8.738 lbs/gal.	426445-01
63-12 pH of product ⁹	NA		
63-14 Oxid/Red Action	A	Not Oxi. or Red. agent	426445-01
67-15a Flash Point (°C) ¹⁰	A* See NOTE	> 200°F	426445-01
63-15b Flame Extension			
63-16 Explodability	A	Contains No explosive ingredients	426445-01
63-17 Storage Stability (% degradation of AIs at 20-30°C for ≥ 1 year)	NA	will submit on request	426445-01
63-18 Viscosity	A	126 cps	426445-01
63-19 Miscibility (with hydrocarbon solvents) ¹¹	NA	Not emulsi-fiable liq.	426445-01
63-20 Corrosivity (specify metals/conditions)	A	will submit on request	426445-01
63-21 Dielectric Breakdown Voltage ¹²	NA	Not to be used around high vol. equipment	426445-01

Explanations: A = Acceptable; N = not acceptable; NA = technically not applicable; G = data gap; U = requires upgrading; W = waived; E = EPA estimate.

* The Registrant must indicate whether, the Flash Point was determined with the Propellant or without propellant. If the propellant was not included as part of the formulation, then the reported value of the Flash point is not correct and can not be Accepted.

Attachment: Confidential Appendix A.

cc: Reviewer's Name and Central File (Reg. No. or Rereg Case No.)
H7505W:RD:RSB:PCRS:CS-1:Rmxxx:Reviewer:S.Mathur:08/17/94:703-308-8378:Code No. (Reg No. 499-GOU).
<PCFORM>.

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Product Chemistry Review For MED 42644501

Page 6 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 inert 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.

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.
