

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

October 20, 2003

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Miltrol

DP Barcode: D294150

Reg. No. Or File Symbol: 79652-R

Manufacturing-use [] OR

End-use Product [X]

TO: Velma Noble PM 31 / Zenobia Jones, Team Reviewer
Regulatory Management Branch I
Antimicrobials Division (7510C)

FROM: Robert Turpin, Chemist *R.T.*
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THRU: Karen P. Hicks, CT Team Leader
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K.P.H.
10/23/03

THRU: Michele E. Wingfield, Chief
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Product Formulation

Active Ingredient(s)	% by wt.
3-(Trimethoxysilyl)-propyldimethyloctadecyl ammonium chloride	3.024

BACKGROUND: The applicant has submitted an application for registration of its product, Miltrol, an end-use product intended to be used as a mildewcide. In support of the application the applicant has submitted a Confidential Statement of Formula (CSF), a draft product label, and studies responding to the requirements of OPPTS Test Guidelines Series 830.

Inert ingredient information not included.

FINDINGS:

Product ingredient source information not included.

1. The CSF of the subject product is unacceptable. The nominal concentration of the active ingredient is calculated to be 0.36%, not 0.50% as shown on the CSF and product label.
2. The certified limits of the inert ingredients are within the default limits of 40 CFR 158.175, however, it is noted that the limits for the ingredient, [REDACTED] may be extended to the theoretical upper and lower limits of [REDACTED] respectively.
3. The data of MRID #460548-01, responding to the requirements of OPPTS Test Guideline 830.1700 and -1800 are acceptable. It is noted, however, that the conclusions of the study are not in agreement with the CSF that calculates to be 0.36%.
4. The data of MRID #460548-02, responding to the requirements of OPPTS Test Guidelines 830.6303, -6314, -6315, -7000, -7100, and -7300 are acceptable.
5. The data of MRID #460548-03, reporting the formulation process of producing the subject product is acceptable. The attached CSF, however, is unacceptable as noted above. The source of the active ingredient is a [REDACTED] concentration of 3-(Trimethoxysilyl)-propyldimethyloctadecyl ammonium chloride.

RECOMMENDATIONS:

1. The applicant must revise and resubmit the CSF, correcting the nominal concentration and certified limits of the active ingredient.
2. The applicant must respond to the requirements of 830.1600, -6303, -6317, and -6320.

PRODUCT CHEMISTRY REVIEW

4. **CONFIDENTIAL STATEMENT OF FORMULA**

4a. Type of formulation and source registration

- Non-integrated formulation system [X]
- Are all TGAls used registered? Yes [X] No []

- Integrated formulation system []
- If ME-TOO , specify EPA Reg. # of existing product:

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

Cleared for food use under 40 CFR §180.1001: Yes [] No [] NA [X]

4c. Physical state of product: Liquid

4d. The chemical IDs and analytical information (including that for the TGAls), density, pH, and flammability are consistent with that given in 830, Part B
Yes [X] No []

4h. NCs and CLs are acceptable: Yes [] No [X] Not acceptable [X]

4i. Active ingredient (s) NC LCL UCL

3-(Trimethoxysilyl)-propyldimethyloctadecyl ammonium chloride		0.36%	0.324%	0.396%
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4j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have a UCL?
Yes [] No [] Not applicable [X]

- All impurities of $\geq 0.1\%$ in the product have been identified?
Yes [] No [] Not applicable [X]

5. PRODUCT LABEL

5a. The active ingredients statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA? Yes [] No [X]

5b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: Yes [] No [X]
- 1.0% 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 contain a footnote indicating this? Yes [] No [] Not applicable [X]

5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?
Yes [] No [] Not applicable [X]

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 [] No [X] Not on label

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 [] *

* The applicant did not submit a study of the storage stability and corrosion characteristics, therefore, no determination of product expiration can be made.

4.

PRODUCT CHEMISTRY (830 Series, Part B)

Guideline	Acceptance of Information	MRJD No.
830.1550 ¹ Product Identity	A	CSF & 460548-03
830.1600 Description of Materials	G	
830.1620 Production Method ²	NA	
830.1650 Formulation process ³	A	460548-03
830.1670 Formation of impurities ⁴	NA	
830.1700 Preliminary Analysis ⁵	NA	460548-01
830.1750 Certified Limits ⁶	U	CSF & 460548-03
830.1800 Analytical Method ⁷	A	460548-01

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

¹See Confidential Appendix A for additional information

²For MP/EP products produced by an integrated formulation system.

³For products from a TGAI or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CIs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

6b. <u>Physical/Chemical Properties*</u>	Acceptance of data	Value or qualitative description	MRID No.
830.6302 Color	W		
830.6303 Physical state	A	Liquid	460548-02
830.6303 Odor	G		
830.7200 Melting point	NA		
830.7220 Density/Relative density/bulk density	A	0.9994 @ 22° C	460548-02
830.7000 pH ¹	A	5.54 @ 25° C	460548-02
830.6314 Oxidation/Reduction	A	Slightly reactive to KmnO ₄ and iron coupon after 5 min., no changes after 24 hrs.	460548-02
830.6315 Flammability	A	None flammable up to boiling @ 99° C	460458-02
830.6317 Storage stability	G		
830.7100 Viscosity	A	1.011 mm ² /s (cSt)	460458-02
830.6319 Miscibility ²	NA		
830.6320 Corrosion Character.	G		
830.6321 Dielectric breakdown	NA		

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

* Provide brief description, e.g., color--yellow or property value, e.g., density 1.25 g/cc; Unless otherwise indicated, the property should be at 25 °C.

¹ If product is dispersible with water

² If product is an emulsifiable liquid