

US EPA ARCHIVE DOCUMENT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

February 24, 2004

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Miltrol

DP Barcode: D298577

Reg. No. Or File Symbol: 79652-R

Manufacturing-use OR

End-use Product

TO: Velma Noble PM 31 / Jacqueline Campbell-McFarlane, Team Reviewer
Regulatory Management Branch I
Antimicrobials Division (7510C)

FROM: Robert A. Turpin, Chemist *R.T.*
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THRU: Karen P. Hicks, CT Team Leader
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Karen P. Hicks
2/24/04

HRU: Michele E. Wingfield, Chief
Product Science Branch
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Product Formulation

Active Ingredient(s)	% by wt.
3-(trimethoxy silyl) propyldimethyl octadecyl ammonium chloride	0.5

BACKGROUND: In response to the Agency's letter, dated November 12, 2003, the applicant has submitted a revised Confidential Statement of Formula for review. Further, the applicant was requested to respond to the requirements of OPPTS test Guideline 830.1600, Description of Materials Used to Produce the Product.

Inert ingredient information not included.

Product ingredient source information not included.

FINDINGS:

1. The Confidential Statement of Formula, dated January 15, 2004, is unacceptable. The applicant lists the amount of the source ingredient, [REDACTED] of the total batch. The source ingredient is, however, a [REDACTED] solution of the active ingredient contributing 0.5% of the a.i. to the end product. The Confidential Statement of Formula must reflect the percent composition as [REDACTED] (a.i.=0.5%) and the upper and lower certified limits as 0.55% and 0.45%, respectively.

2. The applicants response to the Agency's request for data responsive to the requirements of 830.1600 was to refer to the CSF. The listing of the ingredients on the Confidential Statement of Formula is not an adequate response to the requirement. In a separate report in support of the product registration application the applicant must include -

(i) For each active ingredient that is derived from an EPA registered product:

(A) The name of the EPA registered product.

(B) The EPA registration number of that product.

(ii) For each inert ingredient:

(A) Each brand name, trade name, common name, CAS registry number, or other commercial designation of the ingredient.

(B) All information the applicant knows (or that is reasonably available to him) concerning the composition (and, if required by the Agency, chemical and physical properties) of the ingredient, including a copy of technical specifications, data sheets, or other documents describing the ingredient.

(C) If requested by the Agency, the name and address of the producer of the ingredient or, if that information is not known to the applicant, the name and address of the supplier of the ingredient.

The surfactants identified as [REDACTED] are not known to the Agency. These products may be miss-identified.

RECOMMENDATIONS:

1. The applicant must revise the Confidential Statement of Formula according to the findings in 1 & 3, above. The surfactants identified in finding 3 may be [REDACTED]

2. The applicant must submit a report describing the materials used to produce the product according to the guideline cited in finding 2, above.