

SUBJECT: PRODUCT CHEMISTRY REVIEW - Antimicrobials Division  
DP Barcode D255526 Reg. No. Or File Symbol 65402-3  
Manufacturing-Use [ ] or End-Use Product [X] Case #

TO: Marshall Swindell/Tony Kish  
PM Team No. 33

FROM: Anna Skapars, Chemist Anna Skapars  
Chemistry-Toxicology Team (CTT)  
Efficacy and Science Support Branch (ESSB)

THRU: Michele E. Wingfield, Branch Chief   
Efficacy and Science Support Branch (ESSB)

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

- Note to PM:

Please note that Registrant delivered revised correct CSFs on 5/4/99. These three CSFs supersede rejected CSFs dated 3/29/99.

Three revised corrected CSFs dated 5/3/99 are filled out correctly, they are in compliance with PR Notice 91-2 and all agree with the label and all three, the basic CSF, Alternate #1 and Alternate #2, dated 5/3/99, are acceptable.

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Manufacturing-Use [ ] or End-Use Product [✓] Case# \_\_\_\_\_

TO: Marshall Swindell / Tony Kisk  
PM Team No. 31

FROM: Anna Skapars, Chemist Anna Skapars 5-4-99  
Chemistry-Toxicology Team (CTT)  
Efficacy and Science Support Branch (ESSB)

THRU: Michele E. Wingfield, Branch Chief  
Efficacy and Science Support Branch (ESSB)

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

Note to PM:

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These three CSFs supersede rejected CSFs dated 3-29-99.


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PM Team No. 33

FROM: Anna Skapars, Chemist Anna Skapars  
Chemistry-Toxicology Team (CTT)  
Efficacy and Science Support Branch (ESSB)

THRU: Michele E. Wingfield, Branch Chief  
Efficacy and Science Support Branch (ESSB)



SUMMARY OF INFORMATION REVIEWED AND FINDINGS

- Registrant is updating basic and two alternate Confidential Statements of Formula (Alt. #1 and Alt. #2).
- All three CSFs agree with the label, however, there is an error in certified limits and they should be resubmitted.
- Please note that certified limits for the active ingredient must be the same in all three CSFs. Note that certified upper limit for the active ingredient in Alternate #2 is different from the basic and Alt. #1.
- Note that certified upper and lower limits for diluent [REDACTED] are reversed in all three CSFs and lower certified limit is not included for the basic CSF.
- For registrant's information, the Columns 14a and 14b for certified limits do not have to add up to 100%, only Column 13b must add up to 100%.
- Submit correct revised basic, and alternate #1, and Alternate #2 CSF's.

NEFT INGREDIENT INFORMATION IS NOT INCLUDED

SUBJECT: PRODUCT CHEMISTRY REVIEW - Antimicrobials Division  
DP Barcode 7255526 Reg. No. or File Symbol 65402-3  
Manufacturing-Use [ ] or End-Use Product [✓] Case# \_\_\_\_\_

TO: Marshall Swindell / Tony Kish  
PM Team No. 93

FROM: Anna Skapars, Chemist Anna Skapars 5-3-99  
Chemistry-Toxicology Team (CTT)  
Efficacy and Science Support Branch (ESSB)

THRU: Michele E. Wingfield, Branch Chief  
Efficacy and Science Support Branch (ESSB)

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

Registrant is updating basic and two alternate Confidential Statements of Formula (Att. #1 and Att. #2)

All three CSFs agree with the label however there is an error in certified limits and they should be resubmitted.

Please note that certified limits for the active ingredient must be the same in all three CSFs. Note that certified upper limit for the active ingredient in Alternate #2 is different from the basic and Att. #1.

Note that certified upper and lower limits for diluent are reversed in all three CSFs and lower certified limit is not included for the basic CSF.

For registrant's information the columns 14a and 14b for certified limits do not have to add up to 100%, only column 13b must add up to 100%.

Submit correct revised basic, and alternate #1, and alternate #2 CSFs.