

SUBJECT: PRODUCT CHEMISTRY REVIEW: Antimicrobials Division

DP Barcode: D251977 **Reg. No. Or File Symbol:** 65402-3
Manufacturing-use ☐ **OR End-use Product** ☒

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

FROM: Anna Skapars, Chemist
Chemistry-Toxicology Team (CTT)
Efficacy and Science Support Branch
Antimicrobials Division (7510C)

THRU: Karen Hicks, Team 2 Leader
Efficacy and Science Support Branch
Antimicrobials Division (7510C)

THRU: Michele E. Wingfield, Chief
Efficacy and Science Support Branch
Antimicrobials Division (7510C)

Kor 1/15/99

Michele E. Wingfield

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

- Registrant is proposing alternate Confidential Statements of Formula by changing the amount of some inert ingredients in each alternate formula.
- The proposed alternate formulas would be acceptable, however, the total weight in each formula must be the same in part I before the reaction and in part II after the reaction in the final product.
- One alternate formula in which the total weight in both parts, before the reaction and after reaction, are the same 1,000 lbs., this CSF is acceptable.
- Submit revised basic formula and two alternate formulas in which the total weight would be the same before and after the reaction.
- If there are more than one alternate formula, they should be identified as alternate #1, #2 or other designation.

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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 proposing alternate Confidential Statements of Formula by changing the amount of some inert ingredients in each alternate formula.

The proposed alternate formulas would be acceptable however, the total weight in each formula must be the same in part I before the reaction and in part II after the reaction in the final product.

One alternate formula in which the total weight in both parts, before the reaction and after reaction, are the same 1,000 lbs, this CSF is acceptable.

Submit revised base formula and two alternate formulas in which the total weight would be the same before and after the reaction.

If there are more than one alternate formula they should be identified as alternate #1, #2 or other designation.