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.
SUBJECT: PRODUCT CHEMISTRY REVIEW - Antimicrobials Division
DP Barcode: D251927 Reg. No. or File Symbol: G5403-3
Manufacturing-Use [ ] or End-Use Product [ √ ] Case#____

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

FROM: Anna Skapars, Chemist
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

Regent is proposing alternate confidential statements of formula by changing the amount of some unit 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 CST 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.