EFFICACY EVALUATION - TEAM 2

RISK ASSESSMENT & SCIENCE SUPPORT BRANCH
ANTIMICROBIALS DIVISION

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EPA Reg. No. or File Symbol: D240757 21164-6

Product Name: Akta Klor 25

Product Type: Sanitizer

Company Name: Vulcan Chemical Technologies, Inc.

MRID No(s): 444024-01

Product Manager/Reviewer & Team No.: Robert Brennis/Delores Williams #32

Submission Purpose: Review submitted data for efficacy amendment changes

Product Formulation:

Active Ingredient

Sodium Chlorite	25.0%
Inert Ingredients	75.0%
	100.0%

200.0 **INTRODUCTION**

The registrant, Vulcan Chemical, Inc., has submitted an efficacy study, AOAC Official Method 955.16 Chlorine (Available) in Disinfectants Test, to support the claim of killing bacteria in a manner equivalent to known concentrations of available chlorine by Akta Klor 25. The product was tested against *Salmonella typhi* (ATCC #6539).

200.1 **USE(S):**

See attached label.

200.2 **BACKGROUND INFORMATION**

The active ingredient of Akta Klor 25 is Sodium Chlorite at a concentration of 25%.

201.0 **DATA SUMMARY**

Three lots of the disinfectant at a concentration of 7.5% ai were tested in the study. None of the samples tested demonstrated any growth of *Salmonella typhi* (ATCC# 6539). The test organism did not deviate from expected phenol resistance patterns.

The test disinfectant was effectively neutralized by Lecithin and Tween 80. Neutralization was demonstrated by the occurrence of growth in the culture tubes. The neutralization growth medium was shown to support the growth of low numbers of *S. typhi*.

201.1 **BRIEF DESCRIPTION OF TESTS**

The study was conducted according to the United States Environmental Protection Agency, Pesticide Assessment Guidelines, Subdivision G, Section 91-2 (k) (1) (I) (ii), and Section 91-30 Method No. 9. Chlorine (Available) in Disinfectants Test, Chapter 6, Disinfectants, Official Methods of Analysis of the AOAC, 15th Edition, 1990 Section 955.16 (Appendix I).

The test organism was prepared directly from a stock culture obtained from ATCC. It was reconstituted onto nutrient agar slants and transferred four times into nutrient broth (incubated at 35±2C for 18-24hr after each transfer). The colony forming units (CFU)/ml were determined for the test culture. Clorox regular bleach solution was used as the standard NaOCl stock in this test and was analyzed according to Iodometric Method I, Standard Methods for the Examination of Water and

Wastewater to determine ppm Cl. The dilutions 200 ppm, 100 ppm, and 50 ppm of Cl in sterile phosphate buffer solution were used in the test.

The disinfectant was prepared by adding one part (1.0 ml) of Akta Klor 7.5 to six parts (6.0 ml) of Foam Add 10 (activator). After 10 minutes, 512 parts (512 ml) of >400 ppm $CaCO_3$ sterile synthetic hard water were added. This chorine dioxide concentration was considered a worst case. The available chlorine dioxide concentration was determined using the Iodometric Method for the Determination of Available Chlorine Dioxide (50-250 ppm available ClO_2).

Dilutions of the prepared solutions of Vulcan Chlorine Dioxide Foam Disinfectant and each of the available chlorine solutions (200, 100, and 50 ppm) were prepared by adding 0.05 ml of *S. typhi* to 10 ml of test solution (thioglycollate medium, FTM, containing 0.07% Lecithin and 0.5% Tween 80). A total of ten increments of 0.05 ml *S. typhi* were added to the test solution and ten 0.05 ml samples were taken out. All tubes were incubated at 35±2C for 48±4 hours. In order to be considered to have an equivalent disinfecting activity as 200 ppm available Cl, the test disinfectant must show absence of growth in as many consecutive culture tubes as the 200 ppm available Cl sample.

Phenol resistance of *S. typhi* was measured using the procedure outlined in the AOAC Official Method 955.11. The following phenol dilutions were used in the test: 1:50, 1:60, 1:70, 1:80, 1:90, and 1:100. A drop (0.05 ml) of *S. typhi* was added to each of the phenol dilutions (10 ml) and incubated for five, ten and fifteen minutes. After the proscribed incubation time, a drop was transferred to 10 ml of FTM with Lecithin and Tween 80 and incubated at 35±2C for 48 hours.

The effectiveness of the neutralizer was determined by adding *S. typhi* (200 CFU) to the disinfectant, 200 ppm Cl solution and the 1:50 phenol dilution (0.1 ml of each was added separately to 10 ml of FTM with Lecithin and Tween 80). The tubes were incubated at 35±2C for 48±4 hours. Growth would occur only when the disinfectant was effectively neutralized. The ability of the neutralizing growth medium to support *S. typhi* growth was validated by serial dilution (10-fold) of the *S. typhi* culture suspension into FTM containing Lecithin and Tween 80. A 0.05 ml sample from each dilution was then placed onto nutrient agar and were incubated at 35±2C for 48±4 hours, and then observed for growth of the bacterium.

201.2 **RECOMMENDATIONS**

The results of the test demonstrate that Akta Klor 15 was germicidally equivalent to ≥200ppm NaOCl using the AOAC Germicidal Equivalency Concentration Test against *Salmonella typhi*.

202.1 **EFFICACY SUPPORTED BY THE DATA**

The efficacy of Akta Klor 25 was demonstrated to be equivalent to that of ≥200ppm NaOCl when tested against *Salmonella typhi*.

202.2 **EFFICACY NOT SUPPORTED BY THE DATA**

Not Applicable

203.0 **LABELING**

See attached label.