

US EPA ARCHIVE DOCUMENT

AMENDMENT

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - I

ANTIMICROBIAL PROGRAM BRANCH

IN 02/06/97 OUT 03/18/97

Reviewed by Michael Nieves Date 03/18/97

EPA Reg. No. or File Symbol 21164-8 *Michael E. Byrd*

LAN Code 21164-8.397

Date Division Received 02-18-97

MRID No (s) 420608-01, 420608-02 and 435321-01

Product Manager PM 32 (RBrennis)

PM Team Reviewer Robert Travaglino

Product Name AKTA KLOR 15

Company Name Rio Linda Chemical Co., Inc.

Submission Purpose Amendment to add Food Contact Surface and Non-Food Contact Surface Sanitizing Claims with requested data/information and revised label

Type Formulation Liquid

Active Ingredient (s): _____ %

Sodium Chlorite.....15.0

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Product Name AKTA KLOR 15

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202.0

Recommendations

202.1

A. Sanitizing (FCS) Efficacy Not Supported by The Data

"GERMICIDAL AND DETERGENT SANITIZING ACTION AKTA KLOR 7.5" by Lucyna Kurtyka, MicroBio Test, Inc. (MBT), 14280 Sullyfield Circle, #200, Chantilly, Virginia 22021, dated 09/28/91 (MRID No. 420608-01)

The submitted Food Contact Surface Sanitizing data are unacceptable because the sanitizing data developed by the A.O.A.C. Germicidal and Detergent Sanitizing Test Method are not acceptable to support sanitizing efficacy for sanitizing rinses formulated with chlorine bearing chemicals. Data must be developed by A.O.A.C. Available Chlorine Germicidal Equivalent Concentration Method as indicated in Pesticide Assessment Guidelines Subdivision G, Product Performance §91-2(k)(1) for all sanitizing rinses formulated with chlorine bearing chemicals. See item (1) of DIS/TSS-4 enclosure.

B. Unacceptable Chemical Analysis Data:

"Measurement of Available Chlorine Dioxide from Akta Klor 7.5" by Richard Higby, Rio Linda Chemical Company, 410 N. 10th Street, Sacramento, California 95814, dated November 1, 1993 (MRID No. 435321-01)

1. The submitted chemical analysis data are not acceptable because the samples were not activated with the FOAM ADD 10 activator prior to use in the chemical analysis.

2. Available Chlorine Dioxide was not determined by the FDA recommended method titled "Iodometric Method for the Determination of Available Chlorine Dioxide (50-250 ppm available ClO_2)". The concentration and volume of Akta Klor sample (10 ml instead of recommended 2 ml), Potassium Iodide, sodium thiosulfate titrant, and hydrochloric acid employed were different. Also an automatic titrator, Schott T1200 was employed instead of recommended manual titration method using Calibrated Buret. No information was provided on the automatic titrator Schott T1200.

3. Complete procedural information and all the raw data were not provided.

4. No blanks (distilled water) were employed in the analysis.

5. On page 4 of 8, under the heading "Procedure" it states that a 10 ml aliquot of sample was pipetted into 100 ml deionized water, whereas, on page 6 of 8, it

states that a 10 ml aliquot of sample was pipetted into 150 ml of deionized water. Which one is correct.

6. Chemical analysis data were not developed under Good Laboratory Practice Standards of 40 CFR 160.

C. **Sanitizing (NFCS) Efficacy Not Supported by The Data:**

"SANITIZER TEST" by Lucyna Kurtyka, MicroBio Test, Inc. (MBT), 14280 Sullyfield Circle, #200, Chantilly, Virginia 22021, dated 09/27/91 (MRID No. 420608-02)

The review of this data will begin only after we receive the chemical analysis data [Parts per million of chlorine dioxide provided by the use solution (1.25 gm of Akta Klor 7.5 + 7.4 gm Foam Add + 1000 ml deionized water)]. This information is required to verify at what concentration (ppm) of available chlorine dioxide the data were developed.

203.0

Labeling:

Labeling review cannot be initiated until the deficiencies indicated above are resolved.