

AMENDMENT

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - I

ANTIMICROBIAL PROGRAM BRANCH

IN 12/07/93 OUT 02/15/94

Srinivas Gowda

Reviewed by Srinivas Gowda Date 02/15/94

EPA Reg. No. or File Symbol 1677-129

EPA Petition or EUP No. None

Date Division Received 11-29-93

Type Product FCS Sanitizer/Hospital Disinfectant/Sterilant

MRID No (s) 430265-01 to 430265-09

Product Manager PM 31 (Lee)

Product Name OXONIA ACTIVE

Company Name Ecolab Inc.

Submission Purpose Amendment to add additional directions for use
as a third sink sanitizer and as a hatchery
egg sanitizer with revised label.

Also, amendment to add additional claim as a
sterilant for aseptic packaging equipment with
efficacy data and revised label.

Type Formulation Liquid

Active Ingredient (s): %

Hydrogen Peroxide.....27.5

Peroxyacetic Acid.....5.8

P 10

200.0 Introduction:

200.1 Uses (s)

See attached latest accepted label dated 09-30-93 and proposed label dated 11-29-93.

200.2 Background Information:

The submission received 11-29-93, is an amendment to add additional directions for use as a third sink sanitizer and as a hatchery egg sanitizer with revised label. Also, amendment to add additional claim as a sterilant for aseptic packaging equipment with efficacy data and revised label.

201.0 Data Summary

201.2 Brief Description of Test:

"Oxonia Active Sterilant Efficacy at 20°C" by Leanne J. Adkins, Ecolab Inc., 840 Sibley Memorial Highway, Mendota Heights, MN 55118, dated 04-26-93 (MRID No. 430265-01).

"Oxonia Active Sterilant Efficacy at 50°C" by Leanne J. Adkins, Ecolab Inc., 840 Sibley Memorial Highway, Mendota Heights, MN 55118, dated 04-26-93 (MRID No. 430265-02).

"Oxonia Active Sterilant Efficacy at 80°C" by Leanne J. Adkins, Ecolab Inc., 840 Sibley Memorial Highway, Mendota Heights, MN 55118, dated 06-07-93 (MRID No. 430265-03).

"The Evaluation of the Sporicidal Efficacy of Ecolab's Compound against Clostridium sporogenes and Bacillus subtilis at 20°C for six hours" by Mary K. Bennett, ViroMed Laboratories, Inc., 5500 Feltl Road, Minneapolis, MN 55343, dated 03-05-93 (MRID No. 430265-04).

"The Evaluation of the Sporicidal Efficacy of Ecolab's Compound against Clostridium sporogenes and Bacillus subtilis at 50°C for 15 minutes" by Mary K. Bennett, ViroMed Laboratories, Inc., 5500 Feltl Road, Minneapolis, MN 55343, dated 03-17-93 (MRID No. 430265-05).

"The Evaluation of the Sporicidal Efficacy of Ecolab's Compound against Clostridium sporogenes and Bacillus subtilis at 50°C for 15 minutes" by Mary K. Bennett, ViroMed Laboratories, Inc., 5500 Feltl Road, Minneapolis, MN 55343, dated 03-17-93 (MRID No. 430265-06).

"The Evaluation of the Sporicidal Efficacy of Ecolab's Compound against Clostridium sporogenes and Bacillus subtilis at 50°C for 20 minutes" by Mary K. Bennett, ViroMed Laboratories, Inc., 5500 Feltl Road, Minneapolis,

MN 55343, dated 07-28-93 (MRID No. 430265-07).

"The Evaluation of the Sporicidal Efficacy of Ecolab's Compound against Clostridium sporogenes and Bacillus subtilis at 80°C for 2.5 minutes" by Mary K. Bennett, ViroMed Laboratories, Inc., 5500 Feltl Road, Minneapolis, MN 55343, dated 03-05-93 (MRID No. 430265-08).

"The Evaluation of the Sporicidal Efficacy of Ecolab's Compound against Clostridium sporogenes and Bacillus subtilis at 80°C for 5 minutes" by Mary K. Bennett, ViroMed Laboratories, Inc., 5500 Feltl Road, Minneapolis, MN 55343, dated 04-01-93 (MRID No. 430265-09).

201.2

Conclusions:

See 202.0

202.0

Recommendations

202.2

Efficacy Supported by the Data:

- A. The submitted basic and confirmatory AOAC Sporocidal Test data (MRID Nos. 430265-01 and 430265-04) are acceptable to support effectiveness of the product as a sterilant against Bacillus subtilis and Clostridium sporogenes when tested at 6.4 ounces/gallon (5% solution) for a contact time of 6 hours at 20°C.
- B. Also, the submitted basic and confirmatory AOAC Sporocidal Test data (MRID Nos. 430265-02, 430265-05 and 430265-6) are acceptable to support effectiveness of the product as a sterilant against Bacillus subtilis and Clostridium sporogenes when tested at 6.4 ounces/gallon (5% solution) for a contact time of 15 minutes at 50°C.

The submitted additional confirmatory AOAC Sporocidal Test data (MRID No. 430265-07) are also acceptable to support effectiveness of the product as a sterilant against Bacillus subtilis and Clostridium sporogenes when tested at 6.4 ounces/gallon (5% solution) for a contact time of 20 minutes at 50°C.

- C. Also, the submitted basic and confirmatory AOAC Sporocidal Test data (MRID Nos. 430265-03 and 430265-08) are acceptable to support effectiveness of the product as a sterilant against Bacillus subtilis and Clostridium sporogenes when tested at 6.4 ounces/gallon (5% solution) for a contact time of 2.5 minutes at 80°C.

The submitted additional confirmatory AOAC Sporocidal Test data (MRID No. 430265-09) are also acceptable to support effectiveness of the product as a sterilant against Bacillus subtilis and Clostridium sporogenes when tested at 6.4 ounces/gallon (5% solution) for a contact time of 5 minutes at 80°C.

203.0

Labeling:

Include a disclaimer statement, "Not to be used on critical or semicritical items as a sterilant or as a high level disinfectant". (see next page for the required text of the complete disclaimer statement)

No other adverse comments.

J.S.V. Head,
EEMW
3/11/94

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"This product is not to be used (as a terminal sterilant/high level disinfectant) on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body."

204.0

For Your Information:

Please be advised that Environmental Protection Agency will retest your product to confirm your efficacy claim as a sterilant prior to allowing this new sterilization claim on the label.