

8-28-89

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-I

Antimicrobial Program Branch

IN 07/17/89 OUT 08/28/89
Srinivas Gowda WEG
Reviewed By Srinivas Gowda Date 9/5/89 08/28/89
EPA Reg. No. or File Symbol 46506-1
EPA Petition or EUP NO. NONE
Date Division Received 12-07-88
Type Product Hospital Disinfectant/Sterilant
MRID No.(s) None
Product Manager PM 32 (Kempter)
Product Name Bionox® Solution A & Bionox® Solution B
Company Name The Bionox Corporation
Submission Purpose Amendment to add virucidal claims for the
product as a sterilant against HIV-1 (AIDS virus)
and HBV (Hepatitis B virus). No revised labeling
was submitted.
Type Formulation A two-component solution to be simultaneously
dispensed in a special spraying device for use
Active Ingredient(s): %
Solution A
Sodium Hypochlorite (2365 ppm available chlorine).....0.5%
Solution B
(This solution should be used as an Activator with Solution A)

200.00 Introduction

200.1 Use (s)

Refer to the most recently accepted labeling dated 09-21-88 and proposed labeling dated 12-07-88.

200.2 Current Submission

The current submission is a proposed amendment to add virucidal claims for the product as a sterilant against HIV-1 (AIDS virus) and HBV (Hepatitis B virus). No revised labeling was submitted.

200.3 Previously Accepted Virucidal Claims: The accepted label bears the following virucidal efficacy claims for the product when used as a disinfectant.

Virucidal against Herpes Simplex Types 1 & 2, Polio virus types 1 & 2, Influenza type A₂ (Hong Kong), Adenovirus Type 2, Coxsackie B5a, Vaccinia virus, Rhinovirus virus, Cytomegalovirus, Rotavirus SA-11, and Respiratory Syncytial Virus when used as directed on the label as a disinfectant for 2 minutes at 20°C.

200.4 Factors Affecting Amount/Type of Data Required:

Sterilizers are antimicrobial products "...intended to destroy viruses and all living bacteria, fungi, and their spores, on inanimate surfaces" [40 CFR 162.3(ff) (2)(i)(D)]. Sterilization is an absolute term and denotes killing of all microorganisms, including the most resistant spore forms, against which these products are tested. Sterilization is the highest level of antimicrobial activity. Therefore, EPA will allow registrants of sterilizer products to make claims against HBV and AIDS viruses when these products are used according to label directions for sterilization procedure, and when approved in connection with the specific product registration.

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EFFICACY REVIEW-II

Antimicrobial Program Branch

EPA Reg. No. or File Symbol 46506-1
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MRID No.(s) None
Product Manager PM 32 (Kempter)
Product Name Bionox® Solution A & Bionox® Solution B
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202.0 Recommendations

EPA will allow registrants to make HBV (Hepatitis B virus) and HIV (AIDS virus) virucidal claims for sterilizer products when used in accordance with label directions for the sterilization procedure, and when approved in connection with the specific product registration.

203.0 Labeling:

- a. The proposed statement "Completely inactivates the HIV (AIDS) and Hepatitis viruses when used in accordance with the direction for sterilization" should be revised to read "Completely inactivates the HIV-1 (AIDS virus) and HBV (Hepatitis B virus) viruses when used in accordance with the direction for sterilization". Note: Unless the claim for effectiveness of the product as a Sterilant against HIV-1 (AIDS virus) and HBV (Hepatitis B virus) is submitted in labeling, the claim is not, and cannot be accepted.
- b. "VIRUCIDAL" claim must be keyed by a symbol to the paragraph listing the specific tested viruses. Change "VIRUCIDAL" to "VIRUCIDAL*".
- c. Agency does not review Additional Brand Name labels (Agrinox). Additional brand name labeling must be identical in contents to the basic labeling.