INERT INGREDIENT INFORMATION IS NOT INCLUDED

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 10-12-84 OUT 10-16-84

Dorothy M Portner 10/16/84

Reviewed By Dorothy M. Portner Date 10-16-84

EPA Reg. No. 46506-R

EPA Petition or EUP No. None

Date Division Received 10-03-84

Type Product Hosptial Disinfectant

Data Accession No(s). 254969 & 254970

Product Manager PM-32 (Castillo)

Product Name Bionox No. 1

Company Name The Bionox Corporation

Submission Purpose Resubmission with additional data/information and revised product labels

Type Formulation A two-component solution to be simultaneously dispensed in a special spraying device for use

Active Ingredient(s):	%
Solution A Sodium hypochlorite	0.5
Solution B	[redacted]

200.0 Introduction

200.1 Use

See proposed labels product labels attached.

200.2 Background Information

The submission, received 10-3-84, included proposed revised labels and the following data information:

1. A copy of the Litton Bionetics bound test report, dated January 1984 (Accession No. 254969)

   This final report included the Appendix of the report which was omitted from this data report when evaluated in TSS Review of 7-19-84 under Accession No. 253675. The Appendix clarifies the procedures employed in developing the efficacy data, including the attached description of the Bionox Spraying System required for application of the product.

2. The document entitled "Degradation of Bionox No. 1" (Accession No. 254970)

   The degradation data showing product stability at room temperature was provided so that a product storage statement at 4°C, which reflects the conditions employed in developing the efficacy data, would not be required on the label.

Bionox science review

Page _____ is not included in this copy.

Pages 3 through 6 are not included in this copy.

The material not included contains the following type of information:

___ Identity of product inert ingredients

___ Identity of product impurities

___ Description of the product manufacturing process

___ Description of product quality control procedures

___ Identity of the source of product ingredients

___ Sales or other commercial/financial information

_X_ A draft product label

___ The product confidential statement of formula

___ Information about a pending registration action

___ FIFRA registration data

___ The document is a duplicate of page(s) _____

___ The document is not responsive to the request

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Technical Support Section Efficacy Review-II

Disinfectants Branch

EPA.Reg. No.or File Symbol 46506-R

Data Division Received 10-03-84

Data Accession No(s). 254969 & 254970

Product Manager No. PM 32 (Castillo)

Product Name Bionox No. 1

Company Name The Bionox Corporation

202.0 Recommendations

202.1 Efficacy Supported By Data

The submitted final data report with Appendix from Litton Bionetics clarifies the procedures employed in developing the previously submitted efficacy data.

The submitted 20-week degradation study provides acceptable evidence of product stability during storage at room temperature (76-80°F). Therefore, statement specifying storage of the product at 4°C will not be required on the label, even though the supporting efficacy data were developed with samples stored at 4°C.

202.2 Labeling

Directions for disinfecting non-hinged medical instruments and smaller articles must identify the types of smaller articles intended to be disinfected. Since disinfecting items (instruments/small articles) with a lumen are impractical with this product, the directions must indicate that disinfection of items with a lumen is not recommended.

The label directions must also indicate that the specific instructions provided with Bionox Spraying Device are to be followed in the application of Bionox No. 1 for disinfecting. These instructions must be identical in principle to the ones indicated in the Appendix of the submitted Litton Bionetics report to be relative to the supporting data developed for this product.

Emphasis of this product for emergency conditions, as indicated by the large type size, is unwarranted.