INERT INGREDIENT INFORMATION IS NOT INCLUDED

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 2-24-83 OUT 3-1-83

Reviewed By Dorothy M. Portner Date 3-1-83

EPA Reg. No. or File Symbol 46506-R

EPA Petition or EUP No.

Date Division Received 2-22-83

Type Product Hospital Disinfectant

Data Accession No(s).

Product Manager 32

Product Name Bionox No. 1

Company Name The Bionox Corporation

Submission Purpose Resubmission of proposed label for determination of the data required to support efficacy

Type Formulation Liquid concentrate to be mixed with equal parts of [redacted]

Active Ingredient(s):	%
Sodium hypochlorite	0.5

200.0 Introduction

200.1 Use

See attached proposed label.

200.2 Background Information

The submission, received 2-22-83 in response to a directive indicated in the conference of 1-12-83, included a proposed label for representation of this product solely as a hard surface disinfectant. Since the efficacy claims and the patterns of use intended for this product were not precisely delineated at this conference, the data requirements to support product efficacy were deferred until receipt of proposed labeling.

Bionox science review

Page _____ is not included in this copy.

Pages 3 through 4 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

Date Division Received 2-22-83

Data Accession No(s).

Product Manager No. 32

Product Name Bionox No. 1

Company Name The Bionox Corporation

202.0 Recommendations

202.1 Data Required To Support Efficacy Claims

Based on the efficacy claims and pattern of use indicated on the proposed labeling submitted, the data indicated in (c) of the DIS/TSS-1 enclosure are required. The testing should be conducted for a 10-minute contact time by the AOAC Germicidal Spray Products Test in accordance with the use directions for the spray equipment to be employed with this two component product. If disinfection is intended in less than 10 minutes, as claimed on the center panel of the proposed label, all required data should be developed at the shortest contact time to be claim instead of 10 minutes as specified in the method. A complete description of all models of spray equipment to be marketed, including the directions for use, is required for the file record since this equipment is collateral to the use of this product. The information indicated in the DIS/TSS-3 enclosure is required for reporting of data, including the neutralization procedures employed as indicated in the DIS/TSS-2 enclosure. The data and requested information should be included in the same submission for expediency of the review.

202.2 Labeling

Any revisions required in the proposed labeling will be indicated after the efficacy data have been reviewed.