

9-15-88

TECHNICAL SUPPORT SECTION EFFICACY REVIEW-I

Disinfectants Branch

IN 08-16-88

OUT 09-15-88

Reviewed By Emily H. Mitchell *286 9/15/88* Date 09-15-88

EPA Reg. No. or File Symbol 46506-1

EPA Petition or EUP No. None

Date Division Received 08-29-88

Type Product(s) Hospital Sterilant/Disinfectant

Data Accession No.(s) 407743-01, 407743-02, & 407743-03

Product Mgr. No. PM 32 (Kempter)

Product Name(s) BIONOX No. 1

Company Name(s) Bionox Corporation

Submission Purpose Resubmission with Additional Efficacy Data and  
Proposed Label

Chemical & Formulation Liquids A & B Mixed

Active Ingredient(s):

%

Sodium Hypochlorite . . . . . 0.6%

200.0 Introduction

200.1 Uses:

A sterilant, disinfectant, fungicide, and virucide for use in hospitals, nursing homes, ambulances, factories, and other medical institutions.

200.2 Background Information:

The submission received 08-29-88, is a resubmission with efficacy data and proposed product label.

201.0 Data Summary (Accession Nos. 407743-01, 407743-02, & 407743-03)

201.2 Brief Description of Tests:

- a. Reports of Fungicidal Tests by Kyle H. Sibinovic, Ph. D. SHALDRA BIOTEST Inc., P.O. Box 34317 - W. Bethesda, Maryland 20817. A.O.A.C. 14th Edition, 1985. The fungi tested was Trichophyton mentagrophytes (dated 02-16-88).

201.3 Test Summaries:

a. Fungicidal Tests

1. Method: A.O.A.C. Fungicidal Test, 14th Edition, 1985.
2. Modifications: 5% fetal blood serum was incorporated into the fungal suspension.
3. Samples:

| <u>Lot No.</u>    | <u>Preparation Dates</u> | <u>Reported Dates</u> |
|-------------------|--------------------------|-----------------------|
| BIONOX A (015881) | 02-06-88                 |                       |
| BIONOX B (015881) | 02-06-88                 | 02-16-88              |
| BIONOX A (020881) | 02-06-88                 |                       |
| BIONOX B (020881) | 02-06-88                 | 02-16-88              |
| BIONOX A (181871) | 02-06-88                 |                       |
| BIONOX B (181871) | 02-06-88                 | 02-16-88              |

4. Dilution: Undiluted

5. Exposure Time: 10 minutes at 20°C.
6. Subculture Medium/Neutralizer: 2% Glucose Broth
7. Incubation of Subculture: 25-30°C for 10 days
8. Test Organisms:

| <u>Test Fungi</u>                  | <u>ATCC No.</u> | <u>Phenol Res.</u> |
|------------------------------------|-----------------|--------------------|
| <u>Trichophyton mentagrophytes</u> | 9533            | 1:70               |

9. Test Results:

| <u>Test Fungi</u>        | <u>Lot No.</u> | <u>Subculture 1</u> | <u>Subculture 2</u> |
|--------------------------|----------------|---------------------|---------------------|
| T. <u>mentagrophytes</u> | 015881         | 0/10                | 0/10                |
|                          | 020881         | 0/10                | 0/10                |
|                          | 181871         | 0/10                | 0/10                |

\* Mixed A with B in Equal Parts

10. Conclusions: Results show satisfactory performance of product against Trichophyton mentagrophytes undiluted with 5% blood serum at a contact time of 10 minutes.

- b. The submitted additional data/information is acceptable and clarifies the previous data report.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW-II

Disinfectants Branch

EPA Reg. No. or File Symbol 46506-1

Date Division Received 08-29-88

Data Accession No.(s) 407743-01, 407743-02, & 407743-03

Product Manager No. PM 32 (Kempter)

Product Name BIONOX No. 1

Company Name Bionox Corporation

202.0 Recommendations

202.1 Efficacy Supported by the Data:

- a. The submitted fungicidal data are acceptable to support effectiveness of the product as a fungicide against Trichophyton mentagrophytes (pathogenic fungi) when used undiluted in the presence of 5% blood serum at a contact time of 10 minutes at 20°C.
- b. The submitted additional data/information is acceptable and clarifies the previous data report.

203.0 Labeling

No adverse comments.