TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 10-6-81 OUT 11-5-81

Dorothy M Portner

Reviewed By Dorothy M. Portner Date 11-5-81

EPA Reg. No. or File Symbol 46506-R

EPA Petition or EUP No.

Date Division Received 9-22-81

Type Product Sterilizing Solution

Data Accession No(s). 245913 (245972 labeling)

Product Manager 32

Product Name Bionox No. I

Company Name The Bionox Corporation

Submission Purpose New application with data and labeling

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

Active Ingredient(s):	%
Sodium hypochlorite	0.5

INERT INGREDIENT INFORMATION IS NOT INCLUDED

200.0 Introduction

200.1 Use

Sterilizing solution for use as indicated on the proposed attached label.

200.2 Background Information

The submission, received 9-22-81, is a new application and includes efficacy data and a proposed label.

201.0 Data Summary (Accession No. 245973)

The submitted data were included in a document identified as "Final Report Efficacy Testing Of Bionox Formulas" which was developed by K. H. Sibinovic of Litton Bionetics, Inc., Kensington, Maryland (February 1980) for World Anti-Pollution Materials Corporation. The microbiological studies included in this report are described below.

A. Sporicidal Testing

Test Procedure

The sporicidal data submitted were developed according to the attached test procedure.

Test Results

The attached sporicidal data on penicylinders were submitted.(Table 1) Acid resistance data indicating that both spore species on both penicylinders and suture knots survived in 2.5 N HCl for 10 minutes were also included in the report. The only reference to data developed for surgical knots was indicated in the conclusions given in the report. It was stated that for the most concentrated Bionox formulation (4000 ppm hypochlorite [redacted], the surgical knots were not completely satisfactory. What factors that made the surgical knots "not completely satisfactory" were not indicated.

B. Disinfecting Testing

Test Procedure

Tests to determine the efficacy of Bionox as a germicidal spray product were conducted according to the protocols as outlined in the AOAC Germicidal Spray Products Test but with the following modifications:

Modified slide test were similarly prepared; but instead of spraying the Bionox formula, each slide was placed in a petri dish to which equal volumes [redacted] and hypochlorite solution was mixed and the dish agitated. After the prescribed exposure interval, each slide was removed and placed in appropriate media. Incubation was for 72 hours at 37C. Phenol resistence data were developed for some but not for all of the microorganisms tested.

Bionox science review

Page _____ is not included in this copy.

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___ 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

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Test Results

The submitted data, developed by a modified AOAC Germicidal Spray Test, are given in Table 2.

Additional data, that were developed to compare Bionox with Hexachlorophene, are given in Table 3. The spraying apparatus employed in these tests was not described.

Comment

The submitted data have limited value as background information relative for the development of data for the subject product. The applicant verifies this intent in the following preface included with this data package: "The Litton Bionetics Inc. study included here is submitted, not as formal data (since "Clorox" was used as the active ingredient) but as a compendium of methods and procedures that will be used for our manufactured product. [redacted]

TABLE 2

RESULTS OF GERMICIDAL SPRAY TEST OR MODIFIED SLIDE TEST
USING BIONOX AT 200 PPM, 2000 OR 2400 PPM AT pH 6.0

Microorganism	200 ppm 0.02%, 10 min. exposure, Spray Test pH 6.0	2000 ppm 0.2%, 10 min. exposure, Spray Test pH 6.0	2400 ppm 0.24%, 10 min. exposure, modified slide Test pH 6.0
E. coli ATCC #11229	NG	---	NG
P. aeruginosa ATCC #15442	NG	---	NG
P. cepacia ATCC #13945	---	---	NG
K. pneumoniae ATCC #6539	NG	---	---
S. choleraesuis ATCC #10708	NG	---	---
P. mirabilis ATCC #14153	NG	---	---
S. marcescens ATCC #14576	NG	---	NG
S. faecium ATCC #10541	NG	---	---
S. aureus ATCC #6538	NG	---	NG
T. mentagrophytes ATCC #9533	NG	---	---
B. subtilis ATCC #19659	5/10	NG	NG
C. sporogenes ATCC #3584	5/10	NG	NG
B. pumilis ATCC #27142	---	---	NG
B. sterothermophilus ATCC #7953	---	---	NG

Table 3 - Results of Germicidal Spray test using BIONOX 200 ppm (0.02%) and hexachlorophene (0.2%) at a spray height of 15 cm and a spray volume totaling 4 ml per slide. Exposure time of 10 minutes.

Microorganism	BIONOX 200 ppm (0.02%) 10-Minute Exposure			Hexachlorophene 200 ppm (0.2%) 10-Minute Exposure
	pH 7.0	pH 6.5	pH 6.0	pH 6.0
Escherichia coli	NG	----	---	1/10
Pseudomonas aeruginosa	NG	----	---	5/10
Klebsiella pneumoniae	NG	----	---	10/10
Salmonella choleraesius	NG	----	---	2/10
Proteus mirabilis	NG	----	---	10/10
Serratia marcescens	1/10	NG	---	3/10
Streptococcus faecium	1/10	NG	---	1/10
Staphylococcus aureus	2/10	1/10	NG*	1/10
Trichophyton mentagrophytes	NG	----	---	NG

* Repeated at 15 and 30 minutes with no growth.

NG = no growth

--- = not done

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

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Date Division Received 9-22-81

Data Accession No(s). 245913 (245972 labeling)

Product Manager No. 32

Product Name Bionox No. I

Company Name The Bionox Corporation

202.0 Recommendations

202.1 Efficacy Not Supported By Data

The efficacy of this product formulation is not supported by the data submitted for a similar but not identical formulation. Moreover, the data developed were not sufficient to meet the EPA efficacy requirements.

202.2 Inappropriate Claims

The recommendation of this product mixture for treating heavily contaminated instruments is inappropriate and unacceptable since the mixture would not be effective in the presence of an organic soil load.

The broad recommendations of the product for mass casualties, military medical activities, and natural disasters are unwarranted and unacceptable.

202.3 Data Required To Support Efficacy

To support the product mixture as a sterilizing solution for treating pre-cleaned medical instruments in 10 minutes, data must be developed by the AOAC Sporicidal Test as indicated in the DIS/TSS-9 enclosure. For this testing to be conducted in a manner simulating actual usage, equal volumes of the [redacted] and the Bionox solution (sodium hypochlorite) should be added simultaneously and directly to the carrier (penicylinder or surgical silk suture) for exposure to the mixture at the maximum available chlorine concentration. Pre-preparation of this mixture for subsequent transfer to the surface to be treated as proposed in the label directions is an unacceptable procedure for this product because, with a use-life of the mixture measurable in minutes, the mixture will be ineffective if it is inadvertently allowed to stand several minutes before use. The procedural modifications employed in testing the product mixture by the AOAC Sporicidal Test must be provided in detail with the data report. The protocol describing the proposed procedural modifications may be submitted to the Agency for review and evaluation prior to initiation of the test.

The data derived as indicated above will also support sterilization claims for small flat surfaces, such as trays, that are treated by simultaneously adding equal volumes [redacted] and the Bionox solution to immerse the surface for a 10-minute contact time. However, recommendation of the mixture to treat large flat surface areas, such as walls, is unacceptable since the use directions are not applicable.