INERT INGREDIENT INFORMATION IS NOT INCLUDED

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 7-03-84 OUT 7-19-84

Reviewed By Dorothy M. Portner 7/20/84 Date 7-19-84

EPA Reg. No. 46506-R

EPA Petition or EUP No. None

Date Division Received 6-28-84

Type Product Hospital Disinfectant Spray

Data Accession No(s).

Product Manager PM-32 (Castillo)

Product Name Bionox No. 1

Company Name The Bionox Corporation

Submission Purpose Resubmission with efficacy data and a proposed product label

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]	100.0

INERT INGREDIENT INFORMATION IS NOT INCLUDED

200.0 Introduction

200.1 Use

See attached proposed label.

200.2 Background Information

The submission, received 6-24-84, included a proposed label and basic data to support efficacy of this two-component product as a disinfectant.

201.0 Data Summary (Accession No. 253675)

The submitted data report, dated January 1984, was developed by K.H. Sibinovic at Bionectics Medical Laboratories, Litton Bionetics Inc., Kensington, Maryland.

A. Description of Product Tested

Each batch consisting of two 1-gallon opaque plastic containers, labeled Solution A (0.5% sodium hypochlorite with a specific gravity of 1.007 and pH of 12) and Solution B [redacted] with pH of approximately 3) was refrigerated at 4°C until assayed as indicated below:

Time (min.)	Available Chlorine in Final Mixture (ppm) Batch #1 (10-20-83)	Batch #2 (11-03-83)	Batch #3* (11-17-83)
0	2973	2783	2730
5	1241	1545	1274**
10	780**	906**	876
pH Sol. A	11.90	11.95	12.10
pH Sol. B	2.90	2.85	1.75
pH Mixture	7.20	7.10	5.70

* Manufactured 8-16-82 (containing 6053 ppm available chlorine in Solution A); stored at 4°C for 14 months then used to fulfill the bacteriological storage stability efficacy requirement.

** Interpolated value.

Note: The half-life for the 3 batch mixtures was between 4 and 6 minutes. The temperature of the mixture when assayed was not indicated.

B. Use Dilution-Germicidal Spray Modification

A special unit consisting of 2 tanks of approximately 2-gallon capacity, one for Solution A and the other for Solution B, is used to simultaneously deliver each solution through a small hose activated by an initial pressure of 60 psi to the spray gun where the solutions are mixed in equal proportions. Each penicylinder was completely exposed to one of the 3 batch mixtures for 10 minutes; the penicylinder was momentarily dipped in sterile 0.1 N $Na_2S_2O_3$ $6H_2O$ then placed in nutrient broth and incubated 48 hours at 37°C. The report indicates that the test procedure employed is given in detail in the Appendix, which was not included in this submission. The submitted data are indicated below:

Test Organism	Phenol Resistance	No. +/Total Cylinders Tested Batch #1	Batch #2	Batch #3
S. aureus	1:60	0/60	0/60	0/60
S. choleraesuis	1:90	0/60	0/60	0/60
P. aeruginosa	1:90*	0/60	0/60	0/60

* The reported phenol resistance for P. aeruginosa does not meet the resistance specified in the AOAC method; however, the data will be accepted without further testing since the chemical data indicate that the mixture solution would have an adequate chlorine concentration for disinfection of hard, non-porous surfaces.

Bionox science review

Page _____ is not included in this copy.

Pages 4 through 5 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 6-28-84

Data Accession No(s).

Product Manager No. PM 32 (Castillo)

Product Name Bionox No. 1

Company Name The Bionox Corporation

202.0 Recommendations

202.1 Efficacy Claims Supported By Data

The submitted data appear adequate to support efficacy of the solution mixture as a disinfectant when each component solution (A and B) is simultaneously dispensed through a special spraying device to apply and thoroughly wet precleaned hard, nonporous surfaces with the solution mixture for a 10-minute contact time.

However for acceptance of the data, the Appendix of the report must be submitted to provide a detailed clarifying description of the procedures employed in developing these data.

It was also noted that the submitted phenol resistance data for Pseudomonas aeruginosa was lower than the resistance specified in the AOAC method; this testing deficiency should be rectified when future AOAC tests are conducted.

202.2 Labeling

A. The following labeling revisions are required to provide adequate directions for use that reflect the efficacy data developed:

1. Identify the special spraying device that is required for proper application of this product as a disinfectant.

2. Indicate that all flat surfaces intended to be treated (with or without gross soil) must be thoroughly cleaned before spraying the product for disinfection.

3. Specify that the product is to be stored at 4°C until used since this was manner it was handled in developing the data.

4. Clarify the recommendation "fresh solutions of BIONOX No. 1 should be used, particularly if several days lapse between periods of use" by indicating that the solutions left in the sprayer at the end of each day's use are to be discard, if that is the intent.

5. Recommend a potable water rinse after disinfection if food contact surfaces in food processing plants and dairies are intended to be treated.

6. Delete the recommendation for disinfecting instruments; the application/directions for using this product are not adequate for this intent.

B. The efficacy claims indicated in the second paragraph on the left panel must be deleted because they are too broad and unwarranted.