TECHNICAL SUPPORT SECTION EFFICACY REVIEW-I

Disinfectants Branch

IN 12-14-87 OUT 03-29-88

Reviewed By Emily H. Mitchell WEL 6-6-88 Date 03-29-88

EPA Reg. No. or File Symbol 46506-1

EPA Petition or EUP No. None

Date Division Received 02-16-88

Type Product(s) Hospital Sterilant/Disinfectant

Data Accession No.(s) 405004-01, 405004-02, & 405004-03

Product Mgr. No. PM 32 (Kempter)

Product Name(s) BIONOX No. 1

Company Name(s) Bionox Corporation

Submission Purpose Resubmission with Efficacy Data and Proposed Label

Chemical & Formulation Liquids A & B Mixed

Active Ingredient(s):	%
Sodium Hypochlorite	0.5%

200.0 Introduction

200.1 Use(s):

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

200.2 Background Information:

The resubmission received 02-16-88 is an application to register a new product. Efficacy data and proposed product label were provided.

201.0 Data Summary (Accession No.(s) 405004-01, 405004-02, & 405004-03)

201.1 Brief Description of Test(s):

Sterilizer, A.O.A.C. Sporocidal Test
Bacillus subtilis and Clostridium sporogenes
Shaldra Biotest Inc.
P.O. Box 34317, W. Bethesda, MD 20817

Sterilizer, Confirmatory A.O.A.C. Sporocidal Test
Bacillus subtilis and Clostridium sporogenes
Bionox Corporation
6890 Loma Del Bribon
Tucson, AZ 85715

Virucidal Tests, EPA Virucidal Test, DIS/TSS-7, 1979
Herpes Simplex Types 1 and 2, Poliovirus 1 and 2, Coxsackie virus B5a, Vaccinia virus, Influenza A2 virus/Hong Kong, Respiratory Syncytial virus, Cytomegalovirus, Rotavirus SA-11, and Rhinovirus Types 13 and 14
Integrity Bioservices, Inc.
P.O. Box 34317, W. Bethesda, MD 20817

201.2 Test Summaries:

a. Bactericidal Tests (Sporicidal)

1. Method: A.O.A.C. Sporicidal Test Method

2. Modifications: None

3. Samples:

Lot #A	Lot #B	Test Dates
340861A	340961B	08-13-87
273861A	273861B	08-23-87
181871A	181871B	09-06-87

4. Exposure Time: 20 mins. at 20°C

5. Subculture Medium/Neutralizer: Fluid Thioglycollate Medium

6. Incubation of Subcultures: 21 days at 37°C, heat shock tubes 20 minutes at 80°C and reincubated 3 days at 37°C.

7. Test Bacteria:

Test Bacteria	ATCC No.	HCl Res.
Bacillus subtilis	19659	Not Listed
Clostridium sporogenes	3584	Not Listed

8. Carriers Tested:

Porcelain Penicylinders and Surgical Threads

9. Test Results:

Test Organisms	Lot No.	Carriers Tested	Number Carriers Tested	Number Positives/ Total Carriers
B. subtilis	Bionox A & Bionox B 340361	Penicylinder	60	0/60
		Surgical Threads	60	0/60
	Bionox A & Bionox B 181871	Penicylinder	60	0/60
		Surgical Threads	60	0/60
	Bionox A & Bionox B 273861	Penicylinder	60	0/60
		Surgical Threads	60	0/60

C. sporogenes	Bionox A & Bionox B 340861	Penicylinder	60	0/60
		Surgical Threads	60	0/60
	Bionox A & Bionox B 181871	Penicylinder	60	0/60
		Surgical Threads	60	0/60
	Bionox A & Bionox B 273861	Penicylinder	60	0/60
		Surgical Threads	60	0/60

10. Conclusions: Results show satisfactory performance vs. test bacteria. However, neutralization results were not reported. Also, tests were not performed on 3 weeks aged (shelf-life) test solution to support the 3 weeks shelf-life claim.

b. Sporicidal Test (Confirmatory)

1. Method: A.O.A.C. Use Dilution Test, 12th Edition, 1975.

2. Modifications: None

3. Samples:

Lot No.	
06-20-79	12-13-78
02-06-79	12-12-78
12-13-78	12-01-78

4. Exposure:

10 minutes-Bacillus subtilis(penicylinders) at 20°C
20 minutes-Bacillus subtilis(suture loops) at 20°C
20 minutes-Clostridium sporogenes(penicylinders & suture loops) at 20°C

5. Subculture Medium/Neutralizer: Fluid Thioglycollate

6. Incubation of Subcultures: 21 days at 37°C tubes were heat shocked at 80°C for 20 minutes and reincubated 3 days at 37°C.

7. Test Bacteria:

Test Bacteria	ATTC No.	HCl Res.
Bacillus subtilis	19659	Not Listed
Clostridium sporogenes	3584	Not Listed

8. Carriers Tested:

Porcelain Penicylinders and Surgical Threads

9. Test Results:

Test Organisms	Lot No.	Carriers Tested	Number Carriers Tested	Number Positives/ Total Carriers
B. subtilis	06-20-79	Penicylinder	60	0/60
		Suture Loops	60	0/60
	12-13-78	Penicylinder	20	0/20
			20	0/20
			20	0/20
C. sporogenes	06-20-79	Penicylinder	60	0/60
		Suture Loops	60	0/60
	06-20-79	Penicylinder	20	0/20
			20	0/20
			20	0/20

10. Conclusions: Results show satisfactory performance vs. test bacteria. However, neutralization results were not reported.

c. Virucidal Tests

1. Method: EPA , 1976, DIS/TSS-7, February 6, 1979.

2. Modifications: None

3. Samples:

Viruses	Test Date
Herpes Simplex-1(F strain)	12/11/86
Herpes Simplex-2(G strain)	12/11/86
Poliovirus-1(Brunhilde-VR-ATCC-58)	01/23/87
Poliovirus-2(Strain-M-29)	01/23/87
Coxsackie virus B5a(NIAID-VO32)	12/15/86
Vaccinia virus(strain KB-2)	12/23/86
Influenza A2 virus Hong Kong(Strain A2HK)	08/10/87
Respiratory Syncytial virus(ATCC)	01/19/87
Cytomegalovirus	09/30/87
Rotavirus SA-11	10/23/87
Rhinovirus(Types 13 & 14)	01/06/88
Echovirus-8	01/23/87

4. Dilution: undiluted

5. Exposure: 3 minutes @ 20°C

6. Recovery Medium/Neutralizer/Diluent: Hanks BBS

7. Incubation: 37°C for 7-9 days

8. Test Virus Host System:

Herpes Simplex Virus I-HEP II
Herpes Simplex Virus II-HEP II
Poliovirus I-BGM
Poliovirus II-BGM
Influenza A2-MDCK
Adenovirus 2-HEP II
Coxsackievirus B5-BGM
Vaccinia Virus-Vero
Cytomegolovirus-HR215
Respiratory Syncytial Virus-HEP II
Rotovirus I-MA-104
Rhinovirus-MRC-5

9. Drying Time and Temperature: 20°C for 2 hours

10. Assay System for Virus Recovery: Presence of the virus was determined by cytopathic effect.

11. Method For Estimating 50 per cent end point: Reed Muench Method

12. Test Virus:

Herpes Simplex-1(F strain)
Herpes Simplex-2(G strain)
Poliovirus-1(Brunhilde-VR-ATCC-58)
Poliovirus-2(Strain-M-29)
Coxsackie virus B5a(NIAID-VO32)
Vaccinia virus(strain KB-2)
Influenza A2 virus Hong Kong(Strain A2HK)
Respiratory Syncytial virus(ATCC)
Cytomegalovirus
Rotavirus SA-11
Rhinovirus(Types 13 & 14)
Echovirus-8

13. Test Results:

		ID-50 (-log 10)			
Test Virus	Lot No.	Virus Control	Virus Disin.	Toxicity Control	Inactivation
Rotavirus SA-11	340861	7.5	1.5	1.5	6.0
	273861	7.5	1.5	1.5	6.0
Polio Virus I	340861	7.5	3.5	3.5	4.0
	273861	7.5	3.5	3.5	4.0
Rhinovirus Type 13	273861	7.5	1.5	1.5	6.0
Rhinovirus Type 14	340861	7.5	1.5	1.5	6.0
Respiratory Synctial Virus	273861	7.5	3.5	3.5	4.0
	340861	7.5	3.5	3.5	4.0
Cytomegalovirus	340861	7.5	1.5	1.5	6.0
	273861	7.5	1.5	1.5	6.0

		ID-50 (-log 10)			
Test Virus	Lot No.	Virus Control	Virus Disin.	Toxicity Control	Inacti-vation
Herpes Simplex I	228851	7.0	1.5	1.5	5.5
	273861	7.5	1.5	1.5	5.0
Herpes Simplex II	273861	7.5	1.5	1.5	6.0
	228851	6.5	1.5	1.5	5.0
Vaccinia Virus	340861	7.5	1.5	1.5	6.0
	273861	7.5	1.5	1.5	6.0
Polio Virus II	340861	7.5	2.5	2.5	5.0
	273861	7.5	2.5	2.5	5.0
Coxsackie B5a	340861	7.5	1.5	1.5	6.0
	273861	7.5	2.3	2.3	5.2
Influenza A2/Hong Kong	340861	7.5	1.5	1.5	6.0
	273861	7.5	1.5	1.5	6.0
Echovirus - 8	340861	7.5	2.5	2.5	5.0
	273861	7.5	3.0	3.0	4.5

14. Conclusions: This product showed satisfactory performance against the viruses tested when used as a mixture (Bionox A & Bionox B) on pre-cleaned hard, non-porous surfaces at a contact time of 10 minutes. However, clarification is needed for the percent inactivation of the tested viruses because EPA requires 100% in-activation.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW-II

Disinfectants Branch

EPA Reg. No. or File Symbol 46506-1

Date Division Received 02-16-88

Data Accession No.(s) 405004-01, 405004-02, & 405004-03

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 data are acceptable to support effectiveness of the product, as a sterilizer against Bacillus subtilis and Clostridium sporogenes when used as a mixture (Bionox A & Bionox B) on precleaned hard non-porous surfaces. However, neutralization results must be submitted. Also, the submitted efficacy data does not support 3 weeks shelf life claim. Refer to 202.2 below.

b. The submitted data are acceptable to support effectiveness of the product as a virucide against the tested viruses when used as a mixture (Bionox A & Bionox B) on hard non-porous surfaces. However, clarification is needed for the percent inactivation of the tested viruses because EPA requires 100% inactivation.

202.2 Efficacy Not Support by the Data:

a. Confirmatory data report not acceptable. If these studies were conducted by Litton Bionetics, copies of the original data report and protocol must be provided for the product file. If these data were previously submitted, also provided accession number and/or MRID number assigned.

b. No data submitted to support the fungicidal claim, therefore it must be deleted.

202.3 Additional Data/Information Required to Support Efficacy:

a. Submit neutralization results for all sporicidal data. Refer to the attached DIS/TSS-2 enclosure, item 7.

b. The product file indicates that the silk suture loop carrier is not compatable with this product, however, the validation report indicates the use of these carriers. Please clarify.

c. Clarification is needed for the percent inactivation of the tested viruses.

d. To support the 3 week shelf-life claim, additional sterilization data must be developed on 3 weeks aged use solution as indicated in DIS/TSS-9, enclosure with the reduced batch replication as indicated in DIS/TSS-2, enclosure.

e. Because of the rapid degredation of this product once the two components are mixed, what is the amount of available Cl_2 at 20 minutes after mixing?

203.0 Labeling

a. Label must bear the temperature at which the sterilizer is to be used.

b. In lieu of data, delete all 10 minutes contact time for sterilization claims.
*Note the claim for sterilization is 20 minutes, not 10 minutes.