INERT INGREDIENT INFORMATION IS NOT INCLUDED

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 3-2-82 OUT 3-11-82

Reviewed By Dorothy M. Portner Date 3-11-82

EPA Reg. No. or File Symbol 46506-R

EPA Petition or EUP No.

Date Division Received 3-1-82

Type Product Sterilizing Solution

Data Accession No(s).

Product Manager 32

Product Name Bionox No. I

Company Name The Bionox Corporation

Submission Purpose Review of proposed procedural modifications to the AOAC Sporicidal Test

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

Active Ingredient(s):	%
Sodium hypochlorite	0.5

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 46506-R

Date Division Received 3-1-82

Data Accession No(s).

Product Manager No. 32

Product Name Bionox No. I

Company Name The Bionox Corporation

Review Of Proposed Test Protocol

The procedural modifications to the AOAC Sporicidal Test proposed for testing this product were received for review on March 1, 1982 in response to our letter of February 4, 1982. This review considers the appropriateness of the proposed procedural modifications in providing data that will fulfill the EPA efficacy requirements for sterilizing products in a manner that will be relevant to the use pattern intended for this product.

Type Of Carrier

The type of carriers specified in the AOAC Sporicidal Test represent surfaces that provide the most stringent conditions for testing a product for sporicidal activity. The proposed substitution of a glass slide for the silk suture loop carrier is not a comparable surface. If silk suture is not a compatible material with this product, cotton or a synethic thread, such as nylon, having the same gauge as the silk suture, would be considered as an appropriate replacement provided supplemental data are derived to show that the contamination level of spores dried on the substituted material is approximately 10^6 spores per loop for each test microorganism. As indicated in the DIS/TSS-2 enclosure, the substitution of a surface carrier which represents less stringent conditions than the surface carrier specified in the AOAC Method is an unacceptable modification.

Quenching Agent

The proposed use of a quenching agent to immediately stop the antimicrobial action of the product at the end of the intended exposure period (10 minutes) is an appropriate procedure to be included in the protocol employed in testing this product. However, the protocol should also include supplemental testing to provide chemical evidence that shows that sterile 0.1 N sodium thiosulfate will neutralize a product mixture containing equal parts of Solution A and Solution B.

Operating Technic

The proposed operating technic of testing 5 carriers in each of 12 tubes (60 carriers total) does not seem feasible because the testing to be conducted within the 10-minute period would be twice as much as specified in the AOAC Sporicidal Test. A time period of only 10 seconds would be allowed for the aseptic transfer of each of the 5 carriers into individual tubes of quenching solution instead of 20 seconds alloted in the method. Moreover, product efficacy for an exposure period as short as 10 minutes can not be determined with sufficient precision because of the inherent time elapse which occurs when 5 carriers are processed in one tube as specified in the AOAC Sporicidal Test.

The following modifications in the operating technic are suggested to test this product against one test microorganism (either spores of Bacillus subtilis or Clostridium sporogenes) dried on one of the two types of required carriers (either penicylinders or suture loops):

1. Dispense 2.5 ml of Solution A into each of 30 test tubes in the 1st row of the rack and 2.5 ml of Solution B into each of 30 tubes in the 2nd row; let come to temperature in a 20 C water bath.

2. Aseptically transfer one spore-contaminated carrier (either a penicylinder or a suture loop) to each of 30 tubes and place in the 3rd row of the rack in the 20 C water bath.

3. Every 20 seconds, transfer simultaneously the contents of one tube of Solution A in the 1st row and one tube of Solution B in the 2nd row to a tube containing the contaminated carrier in the 3rd row; swirl 3 or 4 times to mix. By the time the 30th carrier has been exposed to the product mixture, 9 minutes 40 seconds will have elapsed.

4. At the 10-minute contact time, aseptically transfer a carrier every 20 seconds to a tube containing 5 ml of sterile quenching solution.

5. Then aseptically transfer the carrier into the subculture medium; after completing this transfer, resubtransfer each carrier to a fresh tube of medium and incubate 21 days at 37 C. If no growth is observed after 21 days, heat-shock tubes 20 minutes at 80 C and reincubate 72 hours at 37 C.

The above 5-step procedure would be repeated once with each test microorganism/carrier combination that is tested on one batch sample, identified as Solution A and Solution B. Tests conducted on 3 batch samples, one of which is at least 60 days old, are required to substantiate this product as a sterilizing agent.

Enclosed
DIS/TSS-2