

US EPA ARCHIVE DOCUMENT



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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: The Bionox Corporation  
"BIONOX NO. 1"  
EPA File Symbol 46506-R  
Conference of May 27, 1982

Participants: Granville M. Moore, Bionox Corporation  
Kyle Sibmovic, PhD, Litton Bionetics Medical Laboratories  
Robert J. W. Kuray, Attorney, Bionox Corporation  
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Purpose: To discuss the type of carrier modification for the AOAC  
Sporicidal Test that would be appropriate for demonstrating  
efficacy of the subject product, Bionox No. 1, as a surface  
sterilizing agent for specified types of hard non-porous  
surfaces such as unhinged instruments.

Conclusions: (1) Injection needles (about 1" long, 24 gauge) were suggested  
as an acceptable substitute for the silk suture loop carrier  
specified in the AOAC Sporocidal Test.

(2) If preliminary testing indicates that the injection needle  
is a suitable carrier, data will be developed on 720  
carriers, 360 injection needles and 360 porcelain peni-  
cylinders, to fulfill the efficacy data requirements  
specified in the DIS/TSS-9 enclosure for sterilizers.

(3) Further consultation will be required, if the injection  
needle is not a satisfactory carrier.

(4) Omission of a titration analysis intended to be conducted  
for the storage stability study does not negate the study  
when the presence of chlorine in the product is indicated  
in a subsequent analyses.

(5) Revised labeling will accompany the efficacy data. Claims  
for sterilization will be restricted to the treatment of  
precleaned unhinged instruments. Claims for the treatment  
of precleaned food-contact surfaces will not be acceptable  
at an antimicrobial level higher than the disinfectant  
level of activity.