US EPA ARCHIVE DOCUMENT

UNDATED

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: Efficacy Review for Product Stericid
DP Barcode: 248244
EPA File Symbol No. 71814-R

FROM: Michele E. Wingfield, Chief
Efficacy and Science Support Branch
Antimicrobials Division (7510C)

TO: Tracy Lantz
Velma Noble - PM 31
Regulatory Management Branch I
Antimicrobials Division (7510C)

Applicant: GMS Marketing Services

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Didecyldimethyl ammonium chloride	7.800
Alkyl dimethylbenzyl ammonium chloride	17.060
Glutaraldehyde	10.725
Inert Ingredients:	64.415
Total:	100.00

BACKGROUND:

Alternative medical waste treatment technologies are approved by individual states health agencies which have approval processes in place. The State and Territorial Association for Alternative Treatment Technologies (STAATT) has provided guidance to state regulators and manufacturers of alternative medical waste treatment technologies and have recommended performance criteria for these technologies. In essence, manufactures must demonstrate that their process will result in a 4 $\log_{10}$ reduction of bacterial spores and a 6 $\log_{10}$ reduction against *Mycobacterium bovis*. These performance criteria apply to treatments which employ grinder/chemical technologies as well as strictly chemical technologies. In addition to state

approval, products that utilize an antimicrobial pesticide chemical in their treatment process must have that antimicrobial pesticide registered for use with a specific device.

GMS Marketing Services is seeking registration of their product, Stericid, to be used in conjunction with the "SteriMed" system as a treatment for medical waste. Included in the registration package are the following: "SteriMed" - Medical Waste Treatment System Efficacy Tests - Final Report (MRID # 446024-04,) Evaluation of Medical Waste Treatment System for Inactivation of Giardia Cysts (MRID # 446024-05,) Operating Manual for SteriMed Infectious Medical Waste Sanitizer, Confidential Statement of Formula, proposed product labeling, and, and approval letters for the technology from several state health and regulatory agencies.

As outlined in the operating manual, the SteriMed unit shreds medical waste into small pieces of ≈ 12 mm in diameter, while at the same time mixing the shredded waste with a 0.5% v/v concentration of the Stericid solution for a cycle time of 12 minutes. The treated waste is either disposed of by discharging into the sewage system or discharged into a separating unit which removes the liquid (to be discharged in the sewage system) from the solid, which is disposed of in a waste container.

RECOMMENDATIONS:

The proposed product, Stericid, when used in conjunction with the SteriMed medical waste treatment device has demonstrated the required $\log_{10}$ reduction of bacterial spores and mycobacterium as outlined in the STAATT guidance for alternative medical waste treatment technologies. In addition, the Stericid/SteriMed system has received preliminary approval (final approval is pending EPA registration of the antimicrobial agent) as an alternative medical waste treatment from several state health agencies including; New York, Arkansas, Florida Oregon and Delaware. Based upon these approvals and the demonstration of the recommended $\log_{10}$ reductions, this product qualifies for registration as medical waste treatment when used as directed in the SteriMed medical waste treatment system.

LABELING:

The proposed product name "Stericid" is in violation of FIFRA. No name, brand, or trademark under which a pesticide product is marketed or distributed may be false or misleading in any particular. The name "Stericid" implies broader effectiveness or a higher level of efficacy (e.g., sterilization) than has been demonstrated or will be allowed for medical waste treatments. Names of products which suggest levels of activity higher than that which the product provides are unacceptable.

Under the "Directions for Use" replace the term "to sanitize" with the term <u>to treat</u>. This product in not a sanitizer of medical waste it is a treatment of medical waste. This revision should also be made in the operating manual.

OPERATING MANUAL:

On page 9 of the operating manual under the safety instructions, it is recommended that the SteriMed unit be "sterilized by a full working cycle including chemical but excluding waste before any of the parts which were in contact with medical waste may be touched." The Stericid product is not a sterilant, therefore, it is a violation of FIFRA to claim that the product may be used to sterilize the unit prior to maintenance by service personnel. This statement must be revised to remove the implied sterilant claim.