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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

September 16, 2002

MEMORANDUM

Subject: Review of Virucidal Data against Foot-and-Mouth Disease Virus for Low pH Phenolic 256, EPA Reg. No. 211-62

From: Brenda F. Mosley, Ph.D.
Product Science Branch
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

To: Adam Heyward - PM/34
Regulatory Management Branch II
Antimicrobials Division (7510C)

A.I. Chemical
Name: Ortho-Phenylphenol.....8.085%
Orthobenzyl-Benzyl-para-Chlorophenol.....6.650%

DP Barcode: D284019

Applicant: Central Solutions, Inc.
Kansas City, KS 66115

MRID# 456986-01

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I. BACKGROUND

Central Solutions, Inc. has submitted a request for addition of the Foot and Mouth Disease (FMD) Virus to the label of their product Low pH Phenolic 256. This product is currently registered as a disinfectant for use on hard, non-porous, inanimate surfaces commonly associated with poultry and swine areas.

Testing on Low pH Phenolic 256 was conducted at the Institute for Animal Health, Pirbright Laboratory, Surrey in the United Kingdom.

II. AGENCY STANDARD FOR LABEL CLAIM

FMD is a virus which causes a serious illness in hoofed animals. It is not considered to be a public health related pathogen, however, the ramifications of this disease being found in animals in the US (specifically cattle and pigs) poses a high economic concern. Historically, the Agency has not required the submission of efficacy data for non-public health related pests. The applicant is required to generate the data, maintain it in their files, and the Agency may call-in that data (when deemed necessary) on a case-by-case basis.

Due to the highly contagious nature of the FMD virus and the extreme economic implications that may arise should the virus be accidentally introduced and spread in the U.S., EPA requires the submission of valid efficacy data (testing and proof that the product effectively controls the virus) prior to approval of a label claim for a product for controlling against the FMD virus.

III. AGENCY STANDARDS FOR VIRUCIDAL TESTING

Test Requirements-Guideline: Subdivision-G 91-2(f) and DIS/TSS-7

The Agency will accept adequate data developed by any virological technique which is recognized as technically sound, and which simulates to the extent possible in the laboratory the conditions under which the product is intended for use. For virucides whose use-directions identify the product as one intended for use upon dry, inanimate, environmental surfaces (such as floors, tables, cleaned and dried medical instruments, etc.), carrier methods, which are modifications of either the AOAC International Use-Dilution Methods (for liquid surface disinfectants) or the AOAC International Germicidal Spray Products as Disinfectants test (for surface spray disinfectants), must be used in the development of the virological data. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of two different batches of disinfectant must be tested against a

recoverable virus titer of at least 10^4 from the test surface (petri dish, glass slide, steel cylinder, etc.) for a specified exposure period at room temperature. The virus is then assayed by an appropriate virological technique.

The FMD virus loses viability when dried on carriers, therefore, the Agency is accepting data generated by suspension methods.

Performance Standard

The product must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is present, at least a 3-$\log_{10}$ reduction in titer must be demonstrated beyond the cytotoxic level.

IV. SUMMARY OF THE DATA

Testing on Cenphene was conducted by the Institute for Animal Health using a method adopted by the UK for registration of disinfectants. This is a suspension method and incorporates the following basic parameters:

Disinfectant product: 1 batch of Cenphene - Lot No. 02201002

Virus: Foot-and-mouth disease virus strain OBFS (Type O British field strain), isolated during the 1968 outbreak.

Cell Line: BHK21 (Baby Hamster Kidney 21)

Hard Water: 342 ppm (as $CaCO_3$)

Serum: 1%

Procedure

The product was tested at dilutions of 1:64, 1:128, and 1:256 in 342 ppm synthetic hard water. Equal amounts of virus suspension and test disinfectant were mixed in a test tube with hard water containing fetal calf serum and solution pH was immediately measured. The samples were incubated at 4°C. After a 30 minute contact time, the virus/disinfectant mixtures were serially diluted ten-fold and applied to BHK21 cells to test for infectivity. Infectivity assays were performed in 6-well microtiter plates, three wells for each dilution. Each well was inoculated at 37°C with 200*u*L of each viral dilution. The plates were incubated at 37°C for 48 hours and checked for cytopathic effects from Foot and Mouth Disease Virus. Parallel virus controls and cytotoxicity controls were also conducted.

V. RESULTS

Dilutions of Cenphene - Lot No. 02201002 at 1:64, 1:128, and 1:256 reportedly completely inactivated the foot-and-mouth disease virus at 4° C at a contact time of 30 minutes. pH values measured 2.83 for the 1:64 dilution. Average pH values for the 1:128 and 1:256 dilutions measured 2.96 and 2.99, respectively.

VI. CONCLUSIONS

Cenphene - Lot No. 02201002 appears to be virucidal against Foot-and-Mouth Disease virus, type OBFS, at low pH when diluted 1:64, 1:128, and 1:256 at 4°C and a 30 minute contact time.

VII. RECOMMENDATIONS

PSB has completed its review of the submitted virucidal data and offers the following:

1. The submitted data was performed using the test material Cenphene - Lot No. 02201002. The applicant Central Solutions, Inc. states that Cenphene - Lot No. 02201002 is identical in formulation to the product Low pH Phenolic 256, EPA Reg. No. 211-62 and is simply an alternate brand name for the registration. **The applicant must submit a confidential statement of formula (CSF) or equivalent information as proof that the Cenphene formula is identical to that of Low pH Phenolic 256.**

2. Although the submitted data on Cenphene demonstrated the product's ability to inactivate FMDV when tested at dilutions of 1:64, 1:128, and 1:256 for a contact time of 30 minutes at 4° C, only one batch of the product was tested. **If Cenphene is proven to be identical in formulation to Low pH Phenolic 256, the applicant must test an additional batch of the product at a dilution of 1:256 at a contact time of 30 minutes at 4°C.**

3. The 1% soil load included in the testing is not sufficient to support a one-step claim for this application. Once the deficiencies have been satisfied on the data, the directions of use for the Foot and Mouth claim will have to include a pre-cleaning step.

VIII. LABELING

The proposed label for Low pH Phenolic 256, EPA Reg. No. 211-62, to add the foot and mouth disease virus under the heading "Virucidal*" is unacceptable until the applicant, Central Solutions, Inc. submits the additonal information under the conditions outlined in the Recommendations section, above.