

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-I

ANTIMICROBIAL PROGRAM BRANCH

Date RD Received 03-02-90 Review Start Date 03-07-90

Project Return Date 04-13-90 Review Completion Date 03-07-90

Reviewed by Arnold E. Layne ^{WEC} 3/12/90 Date 03-07-90

EPA Reg. No. or File Symbol 4959-UR

EPA Petition or EUP No. NONE

Date EPA Received 02-15-90

Type Product(s) FOOD CONTACT SURFACE SANITIZER

MRID No(s) 413921-08 and 413921-09

Product Mgr. No. 32 (FRANCIS)

Product Name ECONOSAN ACID SANITIZER

Company Name(s) WEST AGRO, INC.

Submission Purpose New application with efficacy data and proposed product labeling.

Type Formulation Liquid Concentrate to be used diluted.

<u>Active Ingredient(s)</u>	<u>%</u>
Decanoic Acid.....	3.0%
Nonanoic Acid.....	3.0%
Phosphoric Acid.....	8.5%
Sulfuric Acid.....	9.5%

200.0 Introduction

201.0 Use(s)

The proposed product (Econosan Acid Sanitizer) is an acid food contact surface sanitizer for use in/on circulating in place (CIP) and circulating out of place (COP) systems, tanks and backflush systems.

200.2 Background Information

The submission, received by RD on 3-2-90, is a new application with efficacy data and proposed product labeling.

201.0 Data Summary (MRID #413921-08 & 09)

The data reports, dated August 10, 1988 and October 13, 1988, were prepared by Mark R. Entrup, of Hill Top Biolabs, Inc., P.O. Box 429501, Cincinnati, OH 45242.

201.1 Brief Description of Tests

- a. A.O.A.C. Germicidal and Detergent Sanitizer Test Chapter 4, 14th Ed., 1984. (MRID #413921-08)
- b. A.O.A.C. Germicidal and Detergent Sanitizer Test Chapter 4, 14th Ed., 1984. (MRID #413921-09)

201.2 Test Summaries

a. Food Contact Surface Sanitizer

- 1. Method: Refer to 201.1 above.
- 2. Modification: All dilutions were prepared in synthetic hard water 500ppm as CaCO₃.

3. Samples:

<u>Batch No.</u>	<u>Date Prepared</u>	<u>Date Tested</u>
138-13A	05-20-88	07-29-88
138-13B	05-23-88	same
138-13F	05-24-88	same
138-13G	07-01-88	same

4. Dilution: 1:768

5. <u>Organisms</u>	<u>ATCC</u>	<u>Phenol Res.</u>
<u>Staphylococcus aureus</u>	6538	not listed
<u>Escherichia coli</u>	11229	not listed

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6. Exposure: 30 and 60 second exposure times.
7. Subculture Medium/Neutralizer: not listed
8. Incubation of Subcultures: not listed
9. Test Results:

<u>Batch No.</u>	<u>Flask</u>	<u>Percent Kill After 30 Second Exposure</u>	
		<u>S. aureus</u>	<u>E. coli</u>
138-13A	A	>99.999	>99.999
	B	>99.999	>99.999
138-13B	A	>99.999	>99.999
	B	>99.999	>99.999
138-13F	A	>99.999	>99.999
	B	>99.999	>99.999
138-13G	A	>99.999	>99.999
	B	>99.999	>99.999

Control bacterial counts were as follows:

S. aureus 4.7 x 10⁷ org/ml
E. coli 7.9 x 10⁷ org/ml

10. Conclusion: Results show adequate performance of the product as a food contact surface sanitizer against Staphylococcus aureus and Escherichia coli. However, additional information is required to complete the review.

b. Food Contact Surface Sanitizer

1. Method: Refer to 201.1 above.
2. Modification: All dilutions were prepared in synthetic hard water 500 ppms as CaCO₃.
3. Samples:

<u>Batch No.</u>	<u>Date Prepared</u>	<u>Date Tested</u>
138-13C	05-24-86	not listed
138-13D	05-20-88	not listed

4. Dilution: 1:768

<u>Organisms</u>	<u>ATCC</u>	<u>Phenol Res.</u>
<u>Staphylococcus aureus</u>	6538	not listed
<u>Escherichia coli</u>	11229	not listed

6. Exposure: 30 and 60 second exposure times.
7. Subculture Medium/Neutralizer: not listed
8. Incubation of Subcultures: not listed.
9. Test Results:

<u>Batch No.</u>	<u>Flask</u>	<u>Percent Kill After 30 Second Exposure</u>	
		<u>S. aureus</u>	<u>E. coli</u>
138-13C	A	>99.999	>99.999
	B	>99.999	>99.999
138-13D	A	>99.999	>99.999
	B	>99.999	>99.999

Control bacterial counts were as follows:

S. aureus 8.7 x 10⁷
E. coli 1.7 x 10⁸

10. Conclusion: Results show satisfactory performance of the product as a food contact surface sanitizer against Staphylococcus aureus and Escherichia coli. However, additional information is required to complete the review.

4-13-90

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW FORM - II

Antimicrobial Program Branch

EPA Reg. No. 4959-UR

Date EPA Received 02-15-90

Date RD Received 03-02-90

Project Return Date 04-13-90

Review Start Date 03-07-90

Review Completion Date 03-07-90

MRID No(s). 413921-08 & 413921-09

Product Manager No. 32 (FRANCIS)

Product Name(s) Econosan Acid Sanitizer

Company Name West Argo, Inc.

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202.0 Recommendations

202.1 Efficacy Supported by the Data

The submitted data supports the effectiveness of the product as a food contact surface sanitizer against Staphylococcus aureus and Escherichia coli when used at a dilution of 1:768 in 500 ppms of synthetic hard water (calculated as CaCO₃) for a contact time of at least 1 minute on hard, non-porous surfaces,

202.2 Additional Information Required to Support Efficacy

a. The following must be provided to complete the review:

1. Phenol resistance of the test organisms employed.
2. Subculture/Neutralizer medium used.
3. Incubation time and temperature of the subcultures.

For future reference, refer to DIS/TSS 2 and 3 enclosures, when submitting efficacy data.

203.0 Labeling

- a. Change statement "Sanitize equipment...of water." to incorporate the concentration (ppm) of the principal active ingredient.
- b. The formulation must be cleared by the Food & Drug Administration and documentation must be provided of FDA's clearance.
- c. Add a statement to the label pertaining to item 7 of DIS/TSS-17 enclosure.

BACKGROUND

The product will be used as a Sanitizer

RECOMMENDATIONS

The data submitted are adequate to place the product tested in the following toxicity category:

<u>STUDY</u>	<u>TOX CATEGORY</u>
Acute Oral	<u>III</u>
Acute Dermal	Not established Corrosive (test not requi.
Acute Inhalation	<u>Not required</u>
Skin Irritation	<u>Corrosive Tox I (Test not required)</u>
Eye Irritation	<u>Corrosive Tox I (Test not required)</u>

CRP STATUS

This product ~~does~~ does not require special packaging

LABEL

Review the label as follows:

Add a Subtitle " Statement of Practical Treatment " as a heading of the first aid indications

Delete the words "or milk"

NOTE TO P. M. : The corrosiveness potential of the material indicates that it will produce mechanical injury to the tissue . Thus , test as Dermal Id50 , Eye and Skin irritation are not required.