

7-25-94

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -II

ANTIMICROBIAL PROGRAM BRANCH

EPA Reg. No. or File Symbol 4959-41

Date Division Received 10-27-93

Type Product Food Contact Surface Sanitizer

MRID No (s) None

Product Manager PM 32 (Douglas)

Product Name ECONOSAN ACID SANITIZER

Company Name WESTAGRO, WEST AGRO, INC.

202.0 Recommendations

Clarifying Data/Information:

The submitted data/information resolves efficacy issues raised in the Agency letter dated Sept. 30, 1993.

203.0 Label:

No adverse comments.

5/13

DP BARCODE: D203231

CASE: 192729
SUBMISSION: S453166

DATA PACKAGE RECORD
BEAN SHEET

DATE: 05/11/94
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 301 RESUBMISSION
RANKING : 5 POINTS ()
CHEMICALS: 077702 Propionic acid 10.0000%
 217500 Nonanoic acid 3.0000%
 128955 Capric acid 3.0000%

ID#: 004959-00041 Econosan Acid Sanitizer
COMPANY: 004959 WEST AGRO, INC.
PRODUCT MANAGER: 32 RUTH DOUGLAS 703-305-7964 ROOM: CM2 278
PM TEAM REVIEWER: ROBERT TRAVAGLINI 703-305-6909 ROOM: CM2 276
RECEIVED DATE: 10/27/93 DUE OUT DATE: 01/25/94

* * * DATA PACKAGE INFORMATION * * *

2 BARCODE: 203231 EXPEDITE: Y DATE SENT: 05/11/94 DATE RET.: / /
CHEMICAL: 077702 Propionic acid
DP TYPE: 001 Submission Related Data Package
CSF: N LABEL: Y

ASSIGNED TO	DATE	IN	DATE	OUT	ADMIN DUE DATE: 06/25/94
DIV : RD	/	/	/	/	NEGOT DATE: / /
BRAN: AB	/	/	/	/	PROJ DATE: / /
SECT: EETMS	/	/	/	/	
REVR : SGOWDA	/	/	/	/	
CONTR:	/	/	/	/	

* * * DATA REVIEW INSTRUCTIONS * * *

Please review data submitted at EETMS' request to justify use directions on the label at a pH of 4 or less. pH data on a dilution of the formulation was also submitted by our request. Note that PCRS has accepted thier rational. Draft product labeling is also enclosed.

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
202223	RSB/PCRS	04/21/94	06/05/94	Y	Y	Y

Accepted
B. Vantuz
5/13/94

S. Gowda 5/13

Product Chemistry Review
RSB

MS
4/22/94

EPA Reg. No. or File Symbol 4959-UR
Date Division Received 10-27-93
Products Manager No. 32 (Ruth Douglas)
Product Name Ecosonan Acid Sanitizer
Company Name West Agro, Inc.

100.0 Comments:

This submission is in response to efficacy's request, clarification why the use dilution of this product must be maintained at a pH of 4 or below and submittal of the pH of solution 1 ounce of the product (Ecosonan Acid Sanitizer) per six gallons of water

- A. The reason for pH 4 or below for use dilution is to ensure that two fatty acids "nonanoic and decanoic" acids are maintained in their acid form since the acid form of these acids are germicidally active not their base-neutralized forms.

The pH of 1oz/6 gallons of water is pH 2.6 in deionized water and pH 2.95 in 500 ppm hard water.

This clarification is acceptable from chemistry point of view.

Note to PM:

Please forward this clarification from registrant to Efficacy, it is their requirement.

- B. Revised label there are no adverse comments.

Anna Skapas
4-22-94

4

To Dick Beach cc: T. Hemling	From M. McKinzie Date October 20, 1993
Subject Use Solution pH of Econosan Acid Sanitizer	
Reference:	

The pH of a 1 oz/6 gallon dilution of Econosan, in both deionized water and AOAC 500 ppm synthetic hard water, is shown below.

<u>Deionized</u>	<u>AOAC 500 ppm Hard</u>
2.61	2.95

The reason for stating that the end use sanitizing solution should have a pH of 4, or below, is to ensure that the fatty acid ingredients (nonanoic and decanoic acids) are maintained in their acid forms. It is, primarily, the acid forms of these ingredients which are germicidally active, as opposed to their base-neutralized forms. Though these acids are not actually neutralized at a pH of 4, maintaining the solution pH at or below this level guarantees a comfortable margin of safety.


Michael D. McKinzie

