

8-3-93

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - I

ANTIMICROBIAL PROGRAM BRANCH

IN 03-31-93 OUT 06-11-93

Bruce H. Mann
Reviewed by Bruce H. Mann

Date 06-11-93

EPA Reg. No. or File Symbol # 4959-41

EPA Petition or EUP No. None

Date Division Received 03-15-92

Type Product Food Contact Surface Sanitizers (food contact surfaces).

MRID No (s) No data were submitted for review.

Product Manager (32)

PM-32 (Douglas)

Product Name Mega-San Acxid Sanitizer

Company Name West Agro, Inc.,

Submission Purpose An amendment with a minor label revision in sanitizing solution (proposed santizing solution claims that the solution should have a ph of 4 or below.

Type Formulation A liquid concentrate to be diluted for use.

<u>Active Ingredient (s):</u>	<u>%</u>
Decanoic Acid	3.00
Nonanoic Acid	3.00
Phosphoric Acid	28.50
Propionic Acid	10.00

Rejected
J. Vautour
8/3/93

202.0 Recommendations: Claims Related to Human Health:

202.1 Claims Related to Human Health:
Sanitization Claim(for food contact surfaces)
No data were submitted for review.

202.3 Additional Information Required To Support the Minor
Label revision:

- a. The applicant needs to submit the ph of at least one end use sanitizing solution(1 ounce of product/6 gallons of water).
- b. We need a clarification on why the end use santizing solution must be maintained at a ph of 4 or below.

203.0 Labeling:
The following comments are applicable for the proposed label dated 03-15-93 "Mega-San Acid sanitizer".

- a. The proposed label should expand the use directions to include this statement "The necessity for removal of gross food particles and soil by a pre-flush, or pre-scape, and when necessary, pre-soak treatment. Also, add and expand the directions for use include a potable water rinse after cleaning all surfaces with "West Agro chlorinated alkaline cleaner". For details, refer to item 3 of DIS/TSS-17 enclosure.
- b. The addition of the wordings "...Sanitizing solution should have a ph of 4 or below..." appear to be acceptable; however the information/clarification indicated above in 202.3 must be submitted for a determination.