Apr 11 1990

APR 18

Mr. Ken J. Morris
West Agro, Inc.
11100 N. Congress Avenue
Kansas City, MO 64153

Dear Mr. Morris:

Subject: Economan Acid Sanitizer
EPA File Symbol 4959-UR
Mega-San Acid Sanitizer
EPA File Symbol 4959-UE
Your Applications of February 9, 1990

A review of your applications for new registration shows the following deficiencies.

The following comments apply to Economan Acid Sanitizer.

CHEMISTRY

a. Based on your Confidential Statement of Formula you may declare no more than 7.6% Phosphoric Acid.

Note that for the active ingredients the lower certified limit must be declared in the label.

Note also that Propionic Acid should be declared as an active ingredient. In acid formulations all acids should be declared in the label.

b. Enclosed product chemistry data is in compliance with 40 CFR Part 158 and is acceptable.

18 months storage and stability data is in compliance with part 158, Guidelines Ref. No. 63-17, and is acceptable and it satisfies the 12 months storage stability data requirement for this product.

Pringle 4-11

58560:I:Pringle:K-12:KENCO:04/10/90:05/10/90:DD:VO:SW:EK:DD

The following comments apply to Mega-San Acid Sanitizer.

CHEMISTRY

a. According to your Confidential Statement of Formula you may declare no more than:

Decanoic Acid 2.6%
Nonanoic Acid 2.7%
Phosphoric Acid . . . 25.6%

Note that the lower certified limit must be declared in the label.

Also note that in acid formulations all acids must be declared as active ingredients.

Therefore, you must declare Propionic Acid as an active ingredient.

b. This formulation is not cleared under the Federal Food, Drug and Cosmetic Act for use as food contact surface sanitizer.

You must submit the entire formulation to FDA for an opinion letter and submit to EPA verification from FDA that this formulation is cleared by FDA for use as food contact surface sanitizer.

Enclosed product chemistry data is in compliance with 40 CFR part 158 and is acceptable. 18 months storage and stability data would be acceptable on an interim basis. The results of remaining 4 months must be submitted to satisfy 12 months storage stability data requirement, Guideline ref. no. 63-17.

The following comments apply to both products.

Efficacy Supported by the Data

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

Additional Information Required to Support Efficacy

The following must be provided to complete the review:

a. Phenol resistance of the test organisms employed.

b. Subculture/Neutralizer medium used.

c. Incubation time and temperature of the subcultures.

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

Labeling

a. Change statement "Sanitize equipment...of water." to incorporate the concentration (ppm) of the principal active ingredient.

b. Add the following statement to the label, "For mechanical operations, the limitation that the prepared use solution may not be re-used for sanitizing but may be re-used for other purposes such as cleaning. For manual operations, the recommendation that fresh sanitizing solution should be prepared at least daily or more often if the solution becomes diluted or soiled."

c. Add the heading: "Statement of Practical Treatment" above the word "External". Under "Internal" "If swallowed, delete "or milk", wherever it appears in heading.

d. Under Precautionary Statements add a heading such as "Physical and Chemical Hazards" add appropriate statements under it.

e. Under Storage and Disposal heading add a "Pesticide Disposal" statement.

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

STUDY	TOX CATEGORY
Acute Oral	111
Acute Dermal	NOT ESTABLISHED, TEST NOT REQUIRED
Acute Inhalation	NOT REQUIRED
Skin Irritation	1 TEST NOT REQUIRED
Eye Irritation	1 TEST NOT REQUIRED

CRP STATUS

These products do not require special packaging.

These products cannot be marketed in channels of trade until they are registered. If you have any further questions, please contact Ms. Barbara Pringle 703-557-0484.

Sincerely yours,

WF

Walter C. Francis
Acting Product Manager (32)
Antimicrobial Program Branch
Registration Division (H7505C)