UNITED STATES ENVIRONMENTAL PROTECTION AGENC

3/2003

APR 2 3 2003

Lewis & Harrison, Agent for Abbott Laboratories 122 C Street NW, Suite 740 Washington, DC 20001

Attention: Ana Rodriguez-Köster

Subject: Water Bath Additive EPA Registration No. 275-139 Amendment Application Date: March 29, 2003 EPA Received Date: March 31, 2003

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable provide the following changes are made:

1. Delete the following statement: "Environmental Protection Agency Information".

2. Revised the sentence in the use directions to include the following, "....during specific operations which control microbial contamination in the water bath."

This letter acknowledge receipt of Abbott Laboratories application for amendment for:

• Change the primary name from "Aeroset Water Bath Additive" to "Water Bath Additive".

• Revised Direction for Use and Storage and Disposal statement.

We are changing our records to reflect the change in basic registered product name. From now all correspondence must refer to the name listed above.

If you have any comments or questions concerning this letter, please contact me at (703) 308-6341 or Portia Jenkins at (703) 308-6230.

CONCURRENCES								
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A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before releasing for shipment the product bearing the revised labeling.

Sincerely,

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Marshall Swindell Product Manager 33 Regulatory Management Branch 1 Antimicrobials Division (7510C)

Enclosure

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INICAL CHEMISTRY C80001M AEROSET"/

WATER BATH ADDITIVE REF 9D29-20

a Abbott

FOR U.S. CUSTOMERS ONLY

ENVIRONMENTAL PROTECTION AGENCY INFORMATION EPA REG. NO. 275-139 EPA EST. NO. 75196-JPN-001

FOR USE WITH THE AEROSET AND 68000 ANALYZERS This product is used to prevent and control microbial contamination in the water bath.

> Keep Out of Reach of Children GAUTON

Active Ingredients: 5-Chloro-2-methyl-4-isothiazolin-3-one 2-Methyl-4-isothiazolin-3-one Inert Ingredients Total

0.211% 0.075% 99.714% 100.000% :37-

FIRST AID

If in eyes: Hold eye open and rinse slowly and cently Hazards to Humans and Domestic Animals with water for 15 to 20 minutes. (Remove contact lenses, if present, after the first 5 minutes then continue rinsing the eye.) Call a poison control center or doctor for treatment advice. If on skin and/or on clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. If swallowed: Immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. Important: Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Note to physician: Probable mucosal damage may contraindicate the use of gastric lavage.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. The Water Bath Additive is poured into a smaller dispensing container, then placed in the analyzer. The Water Bath Additive is automatically dispensed into the water bath during specific operations. Do not use this product as a disinfectant.

> with COMMENTS in EPA Letter Dated:

> > APR 2 3 700

Under the Federal Insecticide. Fungicide, and Rodenzcide Act as amended, for the positicide

registered under EPA Reg. No. ~ 275-139

PRECAUTIONARY STATEMENTS

CAUTION. Causes substantial but temporary eye. injury and skin irritation. Harmful if swallowed or inhaled. Do not get in eyes, on skin or on clothing. Wear protective evewear and chemically resistant. gloves when adding this product to the Water Bath Additive container. Wash thoroughly with soap and water after handling. Prolonged or requently repeated skin contact may cause allergic reactions in some individuals.

USER SAFETY RECOMMENDATIONS

User should: Wash hands before eating. drinking, chewing gum, using tobacco, or using the toilet. Remove clothing immediately if product gets inside, then wash thoroughly and put on clean clothing. Remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly.

ENVIRONMENTAL AZARDS

This chemical is toxic to terrestrial and aquatic plants, fish and aquatic invertebrates.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal. Store at 15-30°C. Do not use empty bottle. Wrap bottle and place in trash.

Produced for: **ABBOTT Laboratories** 200 S. Abbott Park Road Abbott Park, IL 60064-6157

30-3035/R2