

33427-4

3/11/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Fred Trudwig, Jr.
Regulatory Affairs Manager Crop Protection
Aceto Corporation
4 Tri Harbor Court
Port Washington, NY 11050-4661

MAR 11 2013

SUBJECT: CDC ANTI-CLOG® #1 UNITS
EPA Registration Number: 33427-4
Application Dated: November 5, 2012
Receipt Date: November 8, 2012

Dear Mr. Trudwig:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

- To add label language for efficacy claims for control of Legionnaire's Disease Bacteria (LDB).

General Comments

The stamped copy of accepted label is attached. Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0199 or Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

Attachments: Stamped label, Efficacy review

CONCURRENCES

SYMBOL	SURNAME	DATE						

2/4

(TOP PANEL)

CDC ANTI-CLOG® #1 UNITS

PREVENTATIVE MAINTENANCE FOR AIR CONDITIONER CONDENSATE SYSTEMS. CONTROL OF LEGIONNAIRE'S DISEASE BACTERIA in preliminary laboratory tests. FOR INDUSTRIAL USE ONLY.

ACTIVE INGREDIENTS:

Alkyl (60% C14, 30% C16, 5% C12, 5% C18) Dimethyl Benzyl Ammonium Chloride - 20%

Alkyl (68% C12, 32% C14) Dimethyl Ethylbenzyl Ammonium Chloride - 20%

INERT INGREDIENTS: - 60%

TOTAL - 100%

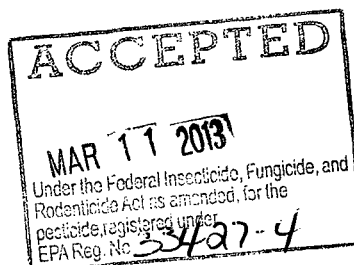
KEEP OUT OF REACH OF CHILDREN

DANGER

ACETO CORPORATION
4 TRI HARBOR COURT
PORT WASHINGTON, NY 11050-4661

PATENT PENDING
EPA REG. NO. 33427-4
EPA EST. NO. 33427-NY-1

NET CONTENTS
BATCH NO:



(FRONT PANEL)

DO NOT REMOVE UNIT HOUSING

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS. See other precautions on the back panel of this container and on the use directions enclosed.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

- DO NOT USE IN:** HUMIDIFIERS, HUMIDIFIER SECTIONS OF AIR CONDITIONING SYSTEMS OR EVAPORATIVE COOLERS.
- Clean condensate pan and drain before installing unit.
- Place unit in pan, pad side down.
- In pans with drain connections, place unit under the cooling coil in the middle of pan length.
- Unit must be in contact with condensate.
- This unit is designed and approved only for use in drain pans of Air Conditioning Systems and Refrigeration Systems.
- Has been proven to control the growth of, or inactivate, Legionnaire's Disease Bacteria in experimental laboratory conditions for two (2) months when approximately 15 gallons of water flow over Anti-Clog Units # 1 per day. We recommend replacing Anti-Clog Units #1, every 2 months, if that is the intent.

(RIGHT SIDE PANEL)

STORAGE AND DISPOSAL

STORAGE: Store in a dry place no lower in temperature than 50°F or higher than 120°F. Avoid heat, sunlight, friction, contaminating substances; especially anionics, shock, and crushing.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available.

(LEFT SIDE PANEL)

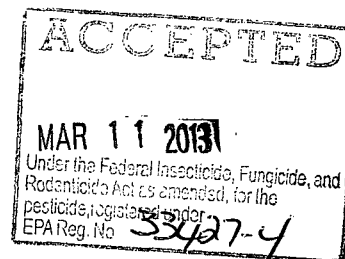
CONTROLS: Growth of slime forming bacteria which is the major cause of drain blockages. Clean condensate drain and pan.

(BACK PANEL)

DO NOT REMOVE UNIT HOUSING
PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER



CORROSIVE. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or clothing. Wear chemical goggles, protective clothing, and rubber gloves. May be fatal if swallowed, absorbed through the skin, or inhaled. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or smoking tobacco. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS: This product is toxic to fish.

FIRST AID:

- If in eyes:
 - Hold eye open and rinse slowly and gently with water for 15-20 minutes.
 - Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
 - Call a poison control center or doctor for treatment advice.
- If on skin:
 - Take off all 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:
 - Call a poison control center or doctor immediately 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.
- If inhaled:
 - Move person to fresh air.
 - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
 - Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For spill, leak, fire, exposure or accident call CHEMTREC® 1-800-424-9300. Outside the USA 1-703-527-3887.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

{the following information contained in the "[]" will appear on the product label that is offered for sale with LDB claims, or as a separate technical information bulletin to accompany final print labeled products}

[Claim for Technical Information Bulletins and Label Language

“There is not enough scientific evidence to demonstrate that controlling the growth of Legionnaire’s Disease Bacteria (LDB) in condensate pans is necessary and/or adequate step in preventing the spread of this disease bacterium, although this possible mode of

transmission cannot be entirely disregarded. Even in the absence of complete knowledge about LDB disease transmission and causal relationships of environmental LDB levels and disease outbreak, it is prudent to minimize slime growth and excessive bacterial contamination in condensate pans. This precaution is supported since the limited ecological studies on LDB have shown that the presence of the organism was usually associated with heavy fouling of cooling systems. By reiterating these established recommendations, this does not imply that any type of chemical treatment of air conditioning components will control the growth of LDB, reduce transmission of LDB, or prevent Legionnaire's disease. Regular treatment with CDC Anti Clog # 1 Units, following label directions will control the growth of fouling organisms in condensate pans.

In preliminary laboratory tests, CDC Anti Clog #1 Units has been shown to inactivate pure cultures of LDB. However, the ability of this formulation to control the growth of, or inactivate, LDB in operating water systems exposed to ultraviolet light, organic material, other microbial contamination, and aeration has not been documented. These preliminary finding also do not address the problem of long-term preventive maintenance of these water systems.]

