

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 23 2001

OBF Industries, Inc.
2719 Curtiss Street
Downers Grove, IL 60515

Attention: Frederick T. Smith
Agent

Subject: Premidyne
EPA Registration Number 59839-2
Your Amendment Dated April 18, 2001

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to revise the First Aid Statement per PR Notice 2001-1 and addition of sanitization claims is acceptable provided that you make the labeling change listed below before you release the product for shipment bearing the amended label.

Delete the "Reorder Numbers" on the last page of the label, it has no relevance to EPA registered products.

A stamped copy is enclosed for your records. Submit one copy of the final printed label before you release the product for shipment bearing the amended label.

If you have any questions regarding this letter, please contact Delores Williams at (703) 308-6372.

Sincerely,



Robert S. Brennis
Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

Premidyne™

Liquid Medical Waste Sanitizer

For the Disposal of Suction Canister Contents

The efficacy of this product has been demonstrated in the present of 10% to 50% whole blood.

Active Ingredient:

- Sodium Dichloro-s-Triazinetrione Dihydrate 99%
- Other Ingredients:..... 1%
- Total 100%

Available Chlorine: 55.5%

Keep Out of Reach of Children

DANGER

Precautionary Statements: Hazards to Humans and Domestic Animals. DANGER.

Corrosive. Causes irreversible eye damage. May be fatal if inhaled. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Do not breath dust, vapor, or spray mist. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

Net Contents:

This package contains 35 each water soluble units in the size checked below.

- 4 Grams (each unit sanitizes 500 ml of suction waste)
- 9.6 Grams (each unit sanitizes 1200 ml of suction waste)
- 12 Grams (each unit sanitizes 1500 ml of suction waste)
- 16 Grams (each unit sanitizes 2000 ml of suction waste)
- 24 Grams (each unit sanitizes 3000 ml of suction waste)

ACCEPTED
with COMMENTS
in EPA Lab

MAY 23 2001

59839-2

FIRST AID	
If in eyes:	<ul style="list-style-type: none"> • 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 inhaled:	<ul style="list-style-type: none"> • 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.
If on skin or clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for further treatment advice.
If swallowed:	<ul style="list-style-type: none"> • 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 a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-424-9300 for emergency medical treatment information.	
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 efficacy of this product has been demonstrated in the present of 10% to 50% whole blood.

For use in all areas of a medical facility where the suctioning of fluids may occur, *e.g.*, operating room, emergency room, acute care, for disposal of medical wastes from suction canisters.

Premidyne™ should be introduced 30 minutes before disposal of the canister contents.

Before the medical procedure begins, open the access port and insert the water soluble unit of Premidyne™ into the canister. Re-cap the canister. Begin the medical procedure. Activation of suction will provide thorough agitation. Following the procedure, transport canister to hopper and dispose of contents according to institutional procedures. Dispose of empty canister according to institutional procedures.

Environmental Hazards: This pesticide is toxic to fish and aquatic organisms.

Storage and Disposal

Pesticide Storage: Keep product dry in tightly closed container when not in use. Store in a cool, dry, well-ventilated area away from moisture, heat or open flame. Do not reuse empty container.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Dispose of empty container according to institutional procedures. If no institutional procedures are in place, securely wrap container in several layers of newspaper and discard in trash.

Limited Warranty and Disclaimer:

This manufacturer warrants (a) that this product conforms to the chemical description on the label; (b) that this product is reasonably fit for the purposes set forth in the directions, warnings and other statements on this label are based upon reasonable experts' evaluations of reasonable test of effectiveness and toxicity to laboratory animals. Tests have not been made on all varieties or in all states under all conditions. The manufacturer neither makes nor intends, nor does it authorize any agent or representative to make any other warranties expressed or implied, and it expressly excludes and disclaims all implied warranties or merchantability and fitness for particular purpose. This warranty does not extend to, and the Buyer shall be solely responsible for any and all loss or damage, which results from the use of this product in any manner, which is inconsistent with the label directions or warning.

Buyer's exclusive remedy and manufacturer's or seller's exclusive liability for any and all claims, losses, damages, or injuries resulting from the use or handling of this product, whether or not such liability in tort or otherwise, shall be limited, at the manufacturer's option to replacement or the repayment of the purchase price for, the quantity of the product with respect to which damages are claimed. In no event shall manufacturer or seller be liable for special, indirect, or consequential damages resulting from the use or handling of the product.

OBF Technologies, Inc.
2719 Curtiss Street
Downers Grove, IL 60515

EPA Reg. No. 59839-2
EPA Est. No. 71441-OH-002

Reorder No. PD500
Net Wt. 4 Grams (Sanitizes 500 ml)

Reorder No. PD1200
Net Wt. 9.6 Grams (Sanitizes 1200 ml)

Reorder No. PD1500
Net Wt. 12 Grams (Sanitizes 1500 ml)

Reorder No. PD2000
Net Wt. 16 Grams (Sanitizes 2000 ml)

Reorder No. PD3000
Net Wt. 24 Grams (Sanitizes 3000 ml)

Premidyne™ is a trademark
of OBF Technologies, Inc.
Patent Pending