

ACCEPTED
with COMMENTS
in EPA Letter Dec 15

FORMASAN™

DEC 15 1962

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, this product is registered under EPA Reg. No. 48632-2

DIRECTIONS FOR USE
GENERAL CLASSIFICATION

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

FOR CLEANING

Lightly soiled areas - surfaces to be cleaned should be mopped or brushed with a solution containing 1-1/4 ounces of FORMASAN™ per two gallons of water. Rinse cleaned area with fresh water.

Heavily soiled areas - mop or brush soiled surface with a solution containing 2-1/2 - 3-1/2 ounces of FORMASAN™ per two gallons of water. Rinse cleaned area with fresh water.

GENERAL PURPOSE DISINFECTION

To disinfect walls, floors, furniture, sinks and other hard non-porous surfaces in research laboratories, hospitals, veterinary hospitals and animal care facilities, mop or brush with a fresh solution containing 1-1/4 ounces of FORMASAN™ per two gallons of water so as to maintain thoroughly wetted surfaces for ten minutes. All soiled surfaces must be precleaned prior to disinfection (follow directions for cleaning). Do not reuse used solution.

DEODORIZATION

Prior to deodorization of refuse cans, food storage areas, animal care facilities, animal cages, and other areas where obnoxious odors may develop, remove all garbage, refuse, food and/or animals. Preclean surfaces using pressurized water where possible before deodorization. To deodorize, mop or brush surfaces thoroughly with a solution containing 1-1/4 ounces FORMASAN™ per two gallons of water.

INCUBATORS, CONDITIONING CABINETS, ENVIRONMENTAL CHAMBERS,
ENVIRONMENTAL ROOMS, AND RELATED EQUIPMENT

Remove as many shelves, shelf channels, duct sheets, etc., as possible. Wipe or spray walls, ceiling, floor, door(s), door gasket(s), shelves, shelf channels, duct sheets, etc. with a solution containing 1-1/4 ounces of FORMASAN™ per two gallons of water so as to maintain thoroughly wetted surfaces for ten minutes. All soiled surfaces must be precleaned prior to disinfection (follow directions for cleaning). Be sure the solution gets into cracks, crevices, and corners where debris and microbial spores accumulate. BE CAREFUL NOT TO SATURATE THE SENSOR(S).

REFRIGERATORS, FREEZERS, CONSTANT TEMPERATURE BATHS, CENTRIFUGES,
FRACTION COLLECTORS AND SIMILAR EQUIPMENT

Wipe or spray all surfaces with a solution containing 1-1/4 ounces of FORMASAN TM per two gallons of water so as to maintain thoroughly wetted surfaces for ten minutes. All soiled surfaces must be precleaned prior to disinfection (follow directions for cleaning). Be sure the solution gets into cracks, crevices and corners where debris and microbial spores accumulate.

BIOLOGICAL SAFETY CABINETS, LAMINAR FLOW WORK STATIONS, CLEAN ROOMS AND RELATED EQUIPMENT

Wipe or spray all surfaces with a solution containing 1-1/4 ounces of FORMASAN TM per two gallons of water so as to maintain thoroughly wetted surfaces for ten minutes. All soiled surfaces must be precleaned prior to disinfection (follow directions for cleaning). Be sure the solution gets into cracks, crevices, and corners where debris and microbial spores accumulate. DO NOT SPRAY OR SPLASH THE LIQUID ON THE:

- 1). CEILING OF VERTICAL LAMINAR FLOW STRUCTURES
- 2). BACK WALL OF HORIZONTAL LAMINAR FLOW STRUCTURES

DOING SO COULD CLOG HEPA FILTERS AND IMPAIR THEIR EFFICIENCY.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC 15 1982

Under the Fungicide, Insecticide,
Fungicide and Rodenticide Act
as amended for the pesticide
registered under EPA Reg. No.
48532-2

- d. For the label size submitted, the STORAGE AND DISPOSAL heading and the Child Hazard Warning "KEEP OUT OF REACH OF CHILDREN" would require a 12 point type size minimum and the signal word DANGER (front panel only) would require a 18 point type size minimum.
- e. You are reminded that the EPA Establishment Number must appear on the label or on the immediate container.

We recommend that you verify your EPA Establishment No. with your Regional EPA office located in Quincy, Ill. for the appropriate EPA Establishment No. An application form is enclosed for your convenience.

- f. Future revisions may be required based on interpretations of warranty/disclaimer statements as declared on your label by our General Counsel for Program Support, Office of General Counsel. In lieu of future revisions, we prefer you delete the warranty/disclaimer statements from your label (left panel).
- g. Expand/revise the Directions for use section to include the following:

- 1. Revise the statement: (three locations)

...where debris and microbial spores accumulate;

to read:

...where debris and bacteria accumulate.

Note: Your product would not be expected to be sporicidal.

- 2. For effectiveness as a hospital disinfectant, revise the use dilution to read 2 1/4 ounce product per 2 gallons of water. (Four locations in the following section e.g., general purpose disinfecting, incubator... section, refrigerator... section and Biological safety cabinets... section.

- 3. Delete the statements: (two locations).

...and related equipment

Note: You must be specific.

- 4. Delete the statement: (one location)

...and similar equipment.

Note: you must be specific.

- 5. Add the following statement:

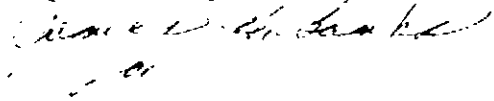
Prepare a fresh solution daily or when use solution becomes visibly dirty.

Note: The one-gallon container label was reviewed. We do not require a submission for all the different container sizes that you plan to market. It is the responsibility of the registrant to ensure that all the other size containers contain the same information as on the basic registered label.

3. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.


John H. Lee
Product Manager (31)
Disinfectants Branch
Registration Division (TS-767C)

enclosures