

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION (WH-567)
WASHINGTON, D.C. 20460

EPA REGISTRATION NO.

DATE OF ISSUANCE

25 FEB 1983

TERM OF ISSUANCE

NAME OF PESTICIDE PRODUCT

NOTICE OF PESTICIDE: ☒ REGISTRATION
☐ REREISTRATION

(Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended)

Activated Dithionite
PR (Powder Activator P-1)

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Metrex Research Corp.
P.O. Box 272
Littleton, CO 80160

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. Make the labeling changes listed below before you release the product for shipment:

a. Add the phrase "EPA Registration No. 46781-1."

b. The claim "Do not use this solution beyond 14 days after mixing" must be revised to read "The shelf-life of the activated unused stock solution is 14 days."

c. Instructions to discard the used solution after each day's use must be included in the directions for use.

d. Revise the statement: Distributed by to read: Manufactured by, since you are responsible for your registered product.

☒ ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

DATE

- e. The product name as declared on your application form "Activated Dialdehyde (Powder Activator)" must be consistently declared throughout the label text and the front panel of the label. Abbreviated variations are not acceptable.
- f. 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 an 18 point type size minimum.
- g. Add the letter "s" to the statement "Inert Ingredient."
- h. Include the following precautionary statements on the front panel

Keep Out of Reach of Children
DANGER

- i. Revise your entire precautionary statements to read as follows:

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes burns. Causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing. May be absorbed through skin. Wear goggles or face shield and rubber gloves when handling.

HARMFUL IF SWALLOWED: Avoid contact with food. Use in ventilated area.

STATEMENT OF PRACTICAL TREATMENT

Eyes - In case of eye contact, immediately flush with water and seek prompt medical attention.

Skin - In case of skin contact, immediately flush thoroughly with water.

Ingestion: If swallowed, drink milk, egg whites, gelatin solution or, if these are not available, large quantities of water. Avoid alcohol. Call a physician.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

- j. Add the misuse statement to read:

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

This statement should appear directly below the statement
"Directions for Use."

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

- 1. Revise the entire container disposal statement to read:

STORAGE AND DISPOSAL

PROHIBITIONS:

Do not contaminate water, food or feed by storage or disposal.
Open dumping is prohibited. Do not reuse empty container.

PESTICIDE DISPOSAL

Pesticide, spray mixture, or rinse water that cannot be used according to label instructions must be disposed of according to Federal or approved state procedures under Subtitle C of the Resource Conservation and Recovery Act.

CONTAINER DISPOSAL (See 36 below)

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by incineration if allowed by state and local authorities.

GENERAL

Consult Federal, State or Local Disposal authorities for approved alternative procedures.

- m. Include the major areas in which the product is recommended for use e.g., For use in hospitals, Nursing Homes and Health Care Institutions.

- 3. Make the labeling changes listed below before you release the product for shipment (activator label only)

- a. Add the phrase "EPA Reg. No. 46781-1."
- b. Add the following statement:

DISPOSAL

DO NOT REUSE EMPTY CONTAINER.

WRAP CONTAINER AND PUT IN TRASH COLLECTION.

- c. Include the full product name as declared on the application form.
- d. Include the following precautionary statements:

Keep Out of Reach of Children

DANGER

4. Confirmation of Sporocidal Activity:

As indicated in our letter of October 1, 1982, the sporocidal activity of this product must be confirmed in the EPA Microbiology Laboratory, within six (6) months after registration. Arrangements for testing a production batch of each product formulation should be made by written request through the Branch Chief, Chemical and Biological Investigations Branch, Benefits and Field Studies Division, Building No. 402, ARC East (TS-768C), Beltsville, MD 20705.

- 5. The submitted confirmatory data are acceptable in support of efficacy for the formulation without [redacted] and also for the alternate formulation with [redacted] when used according to the following patterns of use:

For a one day usage period in the treatment of precleaned items that have been thoroughly wetted with an activated, unused solution, aged as long as 14 days,

- a. For sterilization in 10 hours at room temperature.
- b. For disinfection in 10 minutes at room temperature.

In order for the confirmatory data developed on an alternate formulation with [redacted] to have relevance to this registration, a revised Confidential Statement of Formula that declares the existence or intent of an alternate formulation with [redacted] is required.

- 6. 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)

Enclosure

INERT INGREDIENT INFORMATION IS NOT INCLUDED