

70791-1

10-2-1998

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., SW.
Washington, D.C. 20460

EPA Reg. Number:
70791-1

Date of Issuance:
OCT - 2 1998

NOTICE OF PESTICIDE:
 X Registration
 Reregistration

Term of Issuance:
Time- Limited

Name of Pesticide Product:
SPECTRUM 500 TM

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

ENVIRON SYSTEMS, INC.
50 AIRPORT PARKWAY
SAN JOSE, CALIFORNIA 95110-1000

Note: Changes in labeling 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 EPA registration number.

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

Registration is in no way to be construed as an endorsement or recommendation of this product by the 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 registered on a time-limited basis in accordance with FIFRA sec. 3(c)(7)(A). This registration will expire on Oct. 2, 2000 unless the following information is provided:

1. Submit the phenol coefficient data for the studies conducted in support of this registration.

Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for preregistration of your product under FIFRA section 4.

2. Make the following label changes:

- a. Revise the EPA Registration Number to read, "EPA Reg. No. 70791-1."
- b. Under directions for Hospitals, Medical and Dental office, delete the organisms "*Escherichia coli* and *Candida albicans* since efficacy test were not conducted on these organisms.
- c. Add the following statements to the directions for use in Hospitals, Medical and Dental Offices:
"This product is not to be used as a terminal sterilant high level disinfect on any surface or

instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or

otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

- d. The terms "Non-Toxic, Not harmful to humans, animals or plants" "Does not irritate the eyes or skins." are considered to be safety claims and therefore must be deleted. See 40 CFR 156.10(a)(5) for Further information.
- e. With respect to food processing plants, delete all reference to food processing plants, food storage, etc.. or add the following qualifer:
- "Non-food handling areas of Food processing plants, Food storage areas, Kitchens, Restaurants, and Bars"
- f. In the directicns for "Household Use" delete the statement "including food contact surfaces." A tolerance or an exemption from the requirement of tolerance must be established for the active ingredient in this product for use on food contact surfaces and food handling areas of food processing plants, etc...
- g. In addition, delete the following claims and/or cites under Household use:
- * Anti-fungi, "It is also a non Acid Toilet Bowl disinfectant/cleaner: Apply SPECTRUM 500 TM wiping directly onto toilet surfaces and allow to stand for at least 30 second" and "AOACtest were conducted to confirm SPECTRUM
- h. Delete the phrase "It also has a slight pleasing odor. All fragrances must be identified on the confidential statement of formula and on the label if you desire to make references on the label to the odor of the product, i.e. lemon, flora, etc.

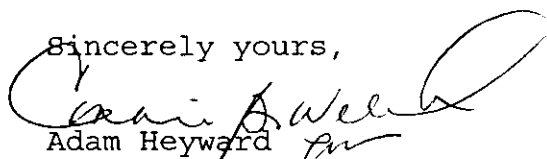
2. This product has been placed in tox category IV. Precautionary labeling statements are normally not required. However if you desire to place precautionary labeling on this product, you may do so. In order to maintain label consistency, we recommend you use toxicity category III wording. You may propose alternate precautionary labeling which will require EPA review. Please refer to EPA Label Review Manual (2nd Edition) for assistance.

3. Submit three (3) copies of the revised final printed label for the record.

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.

Sincerely yours,



Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510W)

Enclosure

SPECTRUM 500™

ACCEPTED
OCT - 7 1999
Under the Federal Insecticide, Fungicide, and
Rodenticide Act as amended, for the
pesticide, registered under
EPA Reg. No. 70791-1

DISINFECTS IN 30 SECONDS Ready-To-Use Disinfectant

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

SPECTRUM 500™ is formulated as a ready-to-use disinfectant bactericide, cleaner, deodorizer solution. **SPECTRUM 500™** is ready-to-use and requires no further dilution. *It works in 30 seconds.*

FOR HOSPITALS, MEDICAL AND DENTAL OFFICES AND NURSING HOMES, SPECTRUM 500™ has been evaluated under AOAC guidelines and found to be effective against a broad spectrum of gram negative and gram positive organisms as represented by: *Pseudomonas aeruginosa, Salmonella choleraesuis, and Staphylococcus aureus.* *This product is not to be used as a terminal sterilant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enters normally sterile areas of the body.*

This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization.

FOR SCHOOLS, PUBLIC REST ROOMS, ATHLETIC FACILITIES, FOOD STORAGE AREAS, KITCHENS, RESTAURANTS, BARS, TRANSPORTATION TERMINALS, HOTELS, AND OTHER NON-MEDICAL INSTITUTIONAL AND INDUSTRIAL USE [e.g. mfg. or processing plants or commercial buildings]: **SPECTRUM 500™** delivers cleaning and germicidal effectiveness against *Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, and similar microorganisms.* AOAC use dilution tests were conducted to confirm **SPECTRUM 500™**'s effectiveness.

FOR HOUSEHOLD USE: SPECTRUM 500™ is an anti-bacterial cleaner and disinfectant. It may be applied to household surfaces. *AOAC efficacy and toxicology tests were conducted to confirm SPECTRUM 500™'s effectiveness.*

Directions for Use AND CONTACT TIME: EITHER WIPE ON, MOP OR SPRAY TO COVER SURFACE. LEAVE SURFACE WET WITH SOLUTION FOR 30 SECONDS. ALLOW TO AIR DRY OR WIPE DRY.

THIS PRODUCT MUST BE USED BY:

Active Ingredient:
p-chloro-m-xyleneol.....0.01%
other ingredients.....99.99%

**EPA Reg. 70791-1
EPA Est. No. 70791-MEX-001**

Net Contents:

Please Recycle Empty Container

EnviroSystems, Inc.

50 Airport Parkway, San Jose, CA 95110-1011

For information on product usage or questions call 1-888-622-2888

h/n

Oct-07-98 09:18A ENVIROSYSTEMS, INC. 408-487-3260 P.02