

PM 33

71491-1

8/31/99

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7504C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg.
Number:

71491-1

Date of Issuance:

AUG 31 1999

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Spiriclens Spray

Name and Address of Registrant (include ZIP Code):

Adams Healthcare
Lortherton Way, Garforth,
Leeds, LS25 2JY
United Kingdom

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/reregistered 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 conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. 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 reregistration of your product under FIFRA section 4.

2. Make the following label changes:

- a. Revise the EPA Registration Number to read, "EPA Reg. No. 71491-1".
- b. Place the appropriate Establishment Number on the product labeling.
- c. The claims of general disinfection when used with a ten minute contact time are acceptable.

Signature of Approving Official:

Marshall Swindell, Product Manager 33

Date:

AUG 31 1999

- d. The claims of general disinfection when used undiluted with a five minute contact time are acceptable.
- e. Delete the graphic, Flame Symbol, from the product labeling.
- f. Revise your Precautionary Statements section to read:

Precautionary Statement
Hazard to Humans and Domestic Animals
Keep Out of Reach of Children

Caution. Causes moderate eye irritation. Avoid contact with eyes or clothing. Use in well ventilated areas. Harmful if swallowed. Wash thoroughly with soap and water after handling.

- g. Revise the Statement of Practical Treatment section to read:

IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists.

IF SWALLOWED: Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. If person is unconscious, do not give anything by mouth and do not induce vomiting.

- h. Change the signal word from *Warning* to *Caution*.
- i. Change the product descriptor just below the Directions for Use heading to read:

Spiriclens Spray is designed for use in the pharmaceutical industry. It is effective as a disinfectant on hard inanimate environmental surfaces in isolators, cleanrooms, sterile areas, and also on tools and equipment prior to introduction into these areas. Effective against vegetative bacteria.

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j. Revise the ingredient statement to read as follows:

Active ingredient:

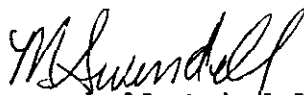
Isopropyl Alcohol USP.....	70.0%
Inert Ingredients.....	10.0%
Total.....	100.0%

3. Submit two copies of the revised final printed label for the record.

The revised Confidential Statement of Formula dated October 30, 1998, is acceptable. The ingredient statement on the label conforms to the recommendations of PR Notice 91-2.

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.



Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division (7505C)

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**SPIRICLENS® SPRAY
U.S.A. DRAFT LABEL**

**ACCEPTED
with COMMENTS
in EPA Letter Dated:
AUG 3 1 1999**

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
71491-1

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Spiriclens® Spray is designed for effective disinfection of hard surfaces such as worktops, equipment, and components in sterile/aseptic manufacturing and processing areas. Effective against vegetative micro-organisms.

To Disinfect Hard Surfaces, Equipment and Components:

Surfaces must be free from organic soiling prior to disinfection. For soiled surfaces, a precleaning step is required. Use a clean sponge or lint-free cloth. On precleaned surfaces, hold can upright and spray the surface from a distance of 8 inches for 3 to 4 seconds to ensure an even coverage. Allow the surface to remain wet for 10 minutes.

CAUTION
~~WARNING~~

Causes eye irritation. Do not spray near or get in eyes. Use in well ventilated areas. Harmful if swallowed.

STATEMENT OF PRACTICAL TREATMENT: In case of eye contact flush eyes immediately with plenty of water. Get medical assistance if irritation persists.

PHYSICAL OR CHEMICAL HAZARDS: Pressurized container and flammable contents. Protect from sunlight. Keep container away from heat. Do not spray on or near open flame or any incandescent material. Do not pierce or burn even after use.

(Flame Symbol Here)

HIGHLY FLAMMABLE

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE: Store in a cool place below 120°F.

PESTICIDE DISPOSAL: Wastes resulting from use of this product may be disposed of on site or at an appropriate waste disposal facility.

CONTAINER DISPOSAL: This container may be recycled in aerosol recycling centers. At present, there are only a few such centers in the country. Before offering for recycling, empty container by using the product according to the label (DO NOT PUNCTURE!). If the recycling is unavailable, wrap the container in several layers of newspaper and discard in the trash.

Spiriclens® Spray

(IPA 70% in Water)

DISINFECTANT/CLEANER

CONTENTS ARE STERILE

ACTIVE INGREDIENT:	Isopropyl Alcohol USP	70%
INERT INGREDIENT:	Water	30%
TOTAL		100%

KEEP OUT OF REACH OF CHILDREN

CAUTION
~~WARNING~~

**Additional precautionary
statements on back of can**

Net Contents 12/6 fl oz (360ml)

EPA Reg. No. xxxxx

EPA Est. No. 071491-GBR-001

Adams

HEALTHCARE

**Lotherton Way, Garforth,
Leeds, LS25 2JY
United Kingdom**