

US ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION (75-757)
WASHINGTON, DC 20480

EPA REGISTRATION NO.
58779-2

DATE OF ISSUANCE
AUG 27 1991

TERM OF ISSUANCE

NOTICE OF PESTICIDE: REGISTRATION
 RENEWAL
(Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended)

NAME OF PESTICIDE PRODUCT

Steris 20-D

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Steris Corporation
72 Corwin Drive
Painesville, OH 44077

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 section 3(c)(7)(A) and (B), since you have agreed to the conditions in our letter of August 26, 1991.

You are reminded that you must submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

Add the phrase "EPA Registration No. 58779-2" to your label before you release the product for shipment. Also submit five (5) copies of your final printed labeling before you release the product for shipment.

Sincerely yours,

John H. Lee
John H. Lee

Product Manager 31
Antimicrobial Programs Branch
Registration Division (H7505C)

BEST AVAILABLE COPY

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

DATE

STERIS 20-D

A Precursor For Peroxyacetic Acid

SPORICIDAL, VIRUCIDAL, BACTERIOCIDAL, FUNGICIDAL, TUBERCULOCIDAL

STERIS 20-D is a single use chemical sterilant. For use in hospitals, medical, surgical, dental offices/clinics. Suited to sterile processing of immersible instruments and accessories.

For use exclusively in the STERIS SYSTEM 1™ Processor.

ACTIVE INGREDIENTS:

Acetylsalicylic Acid 30%

Sodium Perborate Monohydrate 30%

INERT INGREDIENTS: 40%

TOTAL 100%

This container generates 0.67 ounces active ingredient per cup when diluted to 0.2% in the STERIS SYSTEM 1™ Processor

DANGER
KEEP OUT OF REACH OF CHILDREN

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Flush with plenty of water. Contact a physician immediately.

IF ON SKIN: Wash with soap and water. Get medical attention if irritation persists.

IF INGESTED: Do not induce vomiting. Drink large volumes of water. Get medical attention.

Manufactured By:

STERIS Corporation
72 Corwin Drive
Palmsville, Ohio 44077

EPA Reg. No 55779-
EPA Est. No. 55779-011-001
Net Contents 5.55 ounces

ACCEPTED
with COMMENTS
in EPA Letter dated

AUG 27 1991

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

58779-2

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PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

HAZARDS TO HUMANS

Corrosive - direct contact with undiluted powder causes eye damage and may cause skin irritation. Do not get in eyes, on skin, or on clothing. Wear protective goggles or face shield and gloves when handling broken or open containers or when in contact with use dilution.

PHYSICAL OR CHEMICAL HAZARDS

Do not store near heat or open flames. Do not open container except in STERIS 1™ PROCESSOR.

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 27 1991

Use STERIS 20-D only in the STERIS SYSTEM 1™ PROCESSOR. Reliable sterile processing is dependent upon contact of all external and internal surfaces of medical instruments with liquid sterilant. Ensure that instruments are thoroughly cleaned and mechanically prepared according to the manufacturer's instructions prior to sterile processing.

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this product is registered for the pesticide registration under EPA Reg. No. 58779-2

Immediately prior to use, remove the box surrounding the cup of STERIS 20-D and transfer the sealed cup into the processor's sterilant chamber. Follow the operating instructions located in the SYSTEM 1 Operator's Manual.

Do not attempt to manually open the STERIS 20-D cup. Do not use leaking/damaged cups of STERIS 20-D.

See the SYSTEM 1 Technical Monograph for materials compatibility data.

STORAGE AND DISPOSAL

STORAGE: Store upright in a cool, dry place. Avoid exposure to extreme conditions such as heat, moisture, sunlight, or contaminating substances.

DISPOSAL: Dispose of spent cups in trash receptacle. Dispose of damaged cups by placing cup in a sink in a well ventilated area. Open cup and flush with large volume of water until cup contents have dissolved. Dispose of thoroughly rinsed cup in proper receptacle.

Product No.: S2000 MSDS No.: To Be Assigned
Lot No To Be Assigned U.S. Patent No.: To Be Assigned
Expiration Date: To Be Assigned, min. 6 mon. Other U.S. and International Patents Pending

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