



U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Antimicrobials Division (7510P)
 1200 Pennsylvania Ave., N.W.
 Washington, D.C. 20460

EPA Reg. Number:

335-1

Date of Issuance:

5/2/16

NOTICE OF PESTICIDE:

Registration
 Reregistration
 (under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Valsterane® Aseptic 35 BIO

Name and Address of Registrant (include ZIP Code):

Arkema Inc.
 900 First Avenue
 King of Prussia, PA 19406

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials 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 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 section 3(c)(7)(A). You must comply with the following conditions:

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

Signature of Approving Official:

Julie Chao, Product Manager 33
 Regulatory Management Branch 1, Antimicrobials Division (7510P)

Date:

5/2/16

2. You are required to comply with the data requirements described in the DCI identified below:
 - a. Hydrogen Peroxide GDCI-000595-1127

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>.

3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 335-1.”
4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 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. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated November 6, 2015

If you have any questions, please contact Zebora Johnson by phone at (703) 308-7080, or via email at johnson.zebora@epa.gov.

Sincerely,



Julie Chao, Product Manager 33
Regulatory Management Branch 1

Enclosure: Approved Label

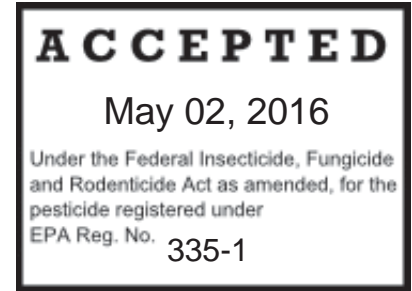
COMMERCIAL STERILANT FOR ASEPTIC PACKAGING OF ADICIFIED AND LOW ACID FOODS

COMMERCIAL STERILIZATION OF FOOD PACKAGING MATERIALS AND HARD NON-POROUS FOOD-CONTACT SURFACES AND FOOD PROCESSING EQUIPMENT

VALSTERANE® ASEPTIC 35 BIO

VALSTERANE® ASEPTIC 35 BIO is an effective ready to use commercial sterilant to treat food packaging materials and hard non-porous food-contact surfaces and food processing equipment used in aseptic processing and packaging of foods including low acid foods.

ACTIVE INGREDIENT:	
Hydrogen Peroxide	35.0%
INERT INGREDIENTS	<u>65.0%</u>
Total	100.0%



**KEEP OUT OF REACH OF CHILDREN
DANGER / PELIGRO**

STRONG OXIDIZING AGENT

FIRST AID
<p>IF IN EYES: - Hold eye open and rinse slowly and gently for 15 – 20 minutes.</p> <ul style="list-style-type: none"> - Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. - Call a poison control center or doctor for treatment advice.
<p>IF ON SKIN: - Take off contaminated clothing.</p> <ul style="list-style-type: none"> - Rinse skin immediately with plenty of water for 15 – 20 minutes. - Call a poison control center or doctor for treatment advice.
<p>IF INHALED: - Move person to fresh air.</p> <ul style="list-style-type: none"> - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth – to – mouth, if possible. - Call a poison control center or doctor for treatment advice.
<p>IF SWALLOWED: - Call poison control center or doctor immediately for treatment advice.</p> <ul style="list-style-type: none"> - Have person sip a glass of water if able to swallow. - Do not induce vomiting unless told to do so by a poison control center or doctor. - Do not give anything by mouth to an unconscious person.
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>
<p>NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.</p>

Net Wt.: _____

Weight per gallon: 9.44 lb.

Lot No.: _____

Manufactured and Distributed by:
 ARKEMA INC.
 900 First Avenue, King of Prussia, PA 19406
 USA (610) 205 7000
 For emergency, call: CHEMTREC®
 (800) 424 – 9300

EPA Reg. No.: 335-xxxx
EPA Est. No.:

VALSTERANE® ASEPTIC 35 BIO
 EPA Reg. No. 335-XXX
 Revision 1a: April 29, 2016
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PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or clothing. May be fatal if inhaled. Harmful if swallowed. Do not breathe breath vapor or spray mist. Wear a respirator with an organic vapor removing cartridge with a pre-filter approved for pesticides (MSHA/NIOSH approval prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval prefix TC14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P, or HE pre-filter. Consult the MSDS for information about respirators and cartridges that have been tested and shown to be effective in removing hydrogen peroxide from air. Wear chemical goggles, rubber gloves, and protective clothing when handling this product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

PHYSICAL AND CHEMICAL HAZARDS

Strong oxidizing agent. Corrosive. Contact with combustibles may cause fire. Contamination may cause rapid decomposition, generation of large quantities of oxygen and heat.

ENVIRONMENTAL HAZARDS

This product is toxic to birds, fish and aquatic invertebrates. Do not discharge effluent containing this product into oceans, lakes, streams, ponds, estuaries other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage plant authority. For guidance contact your State Water Board or Regional Office of the U.S. Environmental Protection Agency.

DIRECTIONS FOR USE

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

Aseptic Processing and Packaging

This product may be used to achieve commercial sterility of food packaging materials and aseptic food processing equipment when used in accordance with the system manufacturers' directions and applicable FDA regulations.

This product is an effective commercial sterilant to treat hard non-porous food-contact surfaces and food processing equipment.

This is a ready-to-use solution. To sterilize pre-cleaned surfaces, apply VALSTERANE® ASEPTIC 35 BIO on the interior and/or exterior of food containers and closure systems (caps, seals, etc.) or appropriate hard non-porous food processing equipment surfaces. Use immersion, coarse spray or circulation techniques as appropriate to sterilize the equipment. Apply this product (i.e., 350,000 ppm of hydrogen peroxide) at a minimum temperature of 75°C. The hydrogen peroxide solution must remain in contact with the surface for a minimum of 30 seconds; longer contact times may be required in certain aseptic food processing lines. This product when used per label directions is effective against *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584)

This product may be used for aseptic processing of low acid foods that has a scheduled process with the FDA. Validated food processing systems that have control over the contaminant load on food packaging surfaces or food processing equipment prior to fill may vary concentration, temperature, and/or contact time to achieve commercial sterility. Such use must comply with all applicable FDA regulations, including, but not limited to, 21 CFR parts 108, 110, 113 and 114.

The use of this product in aseptic food processing operations includes testing required for process validation. Food subject to these FDA regulations may not be sold in a treated package until the scheduled process for the food processing operation has been accepted by the FDA.

VALSTERANE® ASEPTIC 35 BIO meets or exceeds the hydrogen peroxide monograph of the Food Chemicals Codex (FCC).

This product is not for use as a sterilant on medical devices.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL

STORAGE

Store in original vented container in a dry location away from heat and out of direct sunlight. In case of fire involving product, use water. In case of large quantities of spilled material, dike with sand or earth. Dilute with large quantities of water.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide spray mixture, or rinsate, is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest WPA Regional Office for guidance.

CONTAINER HANDLING

(For Nonrefillable Containers)

Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip the container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two or more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

(For Refillable Totes, Rail Cars and Tank Trucks)

Return for reuse.