69461-1 07/20/2000
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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JUL 2 0 2000

Ms. Ana Rodriguez-Koster, Lewis & Harrison, LLC, Agent for Mareva, Inc. Z.A.C. de Saint Esteve 122 C Street, N.W., Suite 740 Washington, D.C. 20001

Dear Ms. Ana Rodriguez-Koster:

Subject:

Response to the Agency's Letter Dated June 9, 2000

Revacil

**EPA Registration Number 69461-1** 

Your Amended Application Dated June 20, 2000

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable subject to the comments listed below. A stamped copy is enclosed for your records.

- 1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
- a) Revise the 'First Aid Statement" to include the Inhalation statements as follows:

#### If inhaled:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.
- 2. Submit five (5) copies of the final printed labeling before you release the product for shipment.

CONCURRENCES							
SYMBOL \$ 7510C							
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DATE \$7/20/00			• • • • • • • • • • • • • • • • • • • •				

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OFFICIAL FILE COPY

If you have any questions, please contact LaVerne Dobbins at (703) 308-6378.

Sincerely,

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

# REVACIL

SWIMMING POOL, SPA AND HOT TUB SANITIZER AND ALGISTAT

Active ingredient: Poly (iminoimidocarbonyliminoimi

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carbonyliminohexamethylene hydrochloride) .......20% Inert ingredients ......80%

EPA Reg. No. 69461-1

EPA Est. No. 69461-FRA-001

#### **WARNING**

KEEP OUT ♣
OF REACH OF
CHILDREN

See side panel for additional precautions and First Aid treatment.

**CHLORINE-FREE** 

Do not use in freestanding spas/hot tubs. Do not use in unpainted plaster pools previously exposed to metals which may cause staining. (See current "pool care guide") for specific information.

Net Contents:

ACCEPTED with COMMENTS in EPA Letter Dated:

JUL 20 2000

Under the Federal Insecticide, Funcicide, and Rodenticide Act as amended, for the pesticide, registered under EFE, kep. No. 69461—

#### PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING. Causes susbstantical but temporary eye injury. Harmful if swallowed.

Do not get concentrate in eyes or on clothing. Avoid contact with skin. Avoid breathing vapor or mist. Wash thoroughly with soap and water after handling. Wear goggles or shield when handling concentrate. Keep container closed.

<b>~</b> [	FIRST AID				
~	IF SWALLOWED: -	Call a poison control center or doctor immediately for treatment			
19		advice.			
# <b>69</b>		- 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.			
ું દું હુ		Do not give anything by mouth to an unconscious person.			
hrsecti dentición of STOC OR C	IF ON SKIN -	Take off contaminated clothing.			
	OR CLOTHING: -	Rinse skin immediately with plenty of water for 15-20 minutes.			
		Call a poison control center or doctor for treatment advise.			
	IF IN EYES:  -	Hold eye open and rinse slowly and gently with water for 15-20			
op H		minutes. Remove contact lenses, if present, after the first 5			
ದ್ಯಾಪ್ಪ ರಾಜ್ಯಪ		minutes, then continue rinsing eye.			
- 특별품원		Call a poison control center or doctor for treatment advice.			
	HOTLINE NUMBER  Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-FAST-MED for emergency medical treatment information.				
១៩៦ឌ	Have the product container or label with you when calling a poison control center or doctor,				
1	or going for treatment. You may also contact 1-800-FAST-MED for emergency medical				
Į	treatment information				

#### **Environmental Hazards**

This products is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other water 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 to sewer systems without notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA.

## NOTICE TO BUYER - LIMITED WARRANTY FROM MAREVA INC. [N. JONAS AND CO., INC.]

("Mareva") [("N. Jonas and Co., Inc.)"] warrants that this product conforms to the chemical description on the label and that it is reasonably fit for the purposes stated on the label when used in accordance with Mareva's [N. Jonas and Co., Inc.'s] directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonably foreseeable to Mareva [N. Jonas and Co., Inc.], and you as buyer or user assume the risk of any such use. Mareva [N. Jonas and Co., Inc.] will replace the product or refund the purchase price at your option should this warranty be breached within one year of sale. THE DURATION OF ANY IMPLIED WARRANTIES UNDER APPLICABLE STATE LAWS SHALL LIKEWISE BE LIMITED TO A PERIOD OF ONE YEAR.

Some states do not allow limitations on how long an implied warranty lasts, so the above limitations may not apply to you.

IN NO EVENT SHALL MAREVA [N. JONAS AND CO., INC.] BE LIABLE FOR ANY SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES, INCLUDING LOST PROFITS, ON ANY THEORY WHATSOEVER, INCLUDING NEGLIGENCE, and no person is authorized to alter the terms of Mareva's [N. Jonas and Co., Inc.'s] warranty. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

For warranty assistance, write Business Manager, REVACIL [BIGUAN], Mareva Inc. [N. Jonas Mid Co., Inc.], Zone Industrielle du Bois de Leuze, Saint-Martin de Crau, France 13310 [4520 Adams, Circle; Bensalem, PA 19020] or contact your REVACIL [BIGUAN] authorized dealer. This warranty gives you specific legal rights, and you may have other rights that vary from state to state.

YOUR AUTHORIZED DEALER GIVES NO WARRANTY IN ADDITION TO MAREVA'S [N. JONAS AND CO., INC.'S] WARRANTY AND DISCLAIMS ALL OTHER WARRANTIES INCLUDING THOSE OF FITNESS OR MERCHANTABILITY.

This Product is registered as a swimming pool, spa and hot tub sanitizer, not as a disinfectant.

#### DIRECTIONS FOR USE

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

## Treating the pool Pools Previously Treated with Chlorinating Chemicals

Important - REVACIL is incompatible with chlorinating chemical products. Consult your authorized Dealer of REVACIL for information on balancing your pool water.

Check with chlorine test kit for free and combined chlorine prior to the beginning of neutralization. To destroy chlorine, add STOP CHLORE chlorine neutralizer per label directions. Filter overnight.

Check with chlorine test kit. If free chlorine is detected, repeat neutralizer treatment.

## Freshly Filled and Dechlorinated Pools Start up with REVACIL

Note: If the pool water contains algae or is hazy, consult the problem-solving section of the "Pool Care Guide," available from your authorized Dealer of REVACIL.

- \* Backwash or clean pool filter. Check pool pH; adjust to 7,0 7,8 if necessary.
- \* Add REVACIL to give a content of 50 ppm (1/2 gallon product/10,000 gallons of pool water).
- \* After 24 hours, check pH and REVACIL concentration with the test kit for REVACIL and adjust if necessary

#### Normal Pool Routine

- \* Every week, check REVACIL concentration and pH.
- \* Maintain REVACIL concentration at about 50 ppm. If concentration falls 10 ppm or more, add a top-up dose. The level should not be allowed to drop below 30 ppm. For example, to raise the REVACIL level 10ppm, add 1 pint per 10,000 gallons of water. Consult the booklet, "The Pool Care Guide for REVACIL," for calculation instructions. NOTE: REVACIL AND CHLORINE ARE

NOTE: REVACIL AND CHLORINE ARE INCOMPATIBLE.

Refer to the Pool Owner's Guide for REVACIL for information on how to deal with accidental chlorination.

REVACIL®, REVATOP®, STOP CHLORE®, and STOP METAL® are trademarks of Mareva

ACCEPTED with COMMENTS in EPA Letter Dated:

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## **Prob**lem-Solving and Supplemental Pool Information.

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Do not use in freestanding spas/hot tubs. Do not use in unpainted plaster pools previously exposed to metals which may cause staining.

REVACIL is not compatible with many detergents and some supplemental algaecides (such as those based on copper). If algae development, cloudiness, or pool problems occur or additional information on water quality is desired, consult "The Pool Care Guide for REVACIL," available from your Authorized Dealer of REVACIL.

#### Treating the spa or hot tub

Important - REVACIL is incompatible with chlorinating or brominating chemical products.

#### Start up with REVACIL

- \* Remove chlorine or bromine source and disconnect feeder. Discontinue use of ionizers and electrochlorinators if present.
- \* Drain existing water in spa.
- \* Clean spa/hot tub with water.
- \* Fill spa/hot tub surface with water.
- \* Bring a sample of water to your REVACIL Authorized dealer to check it for proper water balance.
- \* After your water has been balanced, add REVACIL sanitizer to give a concentration of 50 ppm. (1 oz. of product for 150 gallon of water)
- \* Circulate for 30 minutes then check the REVACIL sanitizer level. Adjust if necessary. Spa/Hot Tub Maintenance
- \* Every week, check REVACIL concentration and pH. Adjust if necessary.
- \* The REVACIL level should be maintained between 30 and 50 ppm.
- \* The REVACIL level should never drop below 30 ppm.
- \* To raise the sanitizer level 10 ppm, add 0.2 oz. per 150 gal. of water.

## STORAGE AND DISPOSAL. [Bulk/Non-Residential Label]

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

#### Pesticide storage.

Keep container closed when not in use. Store in original container in an area inaccessible to children. Protect from freezing. In case of a leak or spill, soak up with absorbent, such as sand earth, or sawdust, and shovel into waste container. Remove waste to chemical waste area, and dispose of in accordance with pesticide disposal instructions.

Pesticide wastes are toxic. 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 according to label instruction, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA regional Office for guidance.

Container Disposal

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

## [Residential/Small Container Label] Storage

Keep container closed when not in use. Store in original container in an area inaccessible to children. Protect from freezing. In case of a leak or spill, soak up with absorbent, such as sand earth, or sawdust, and shovel into waste container. Remove waste to chemical waste area, and dispose of in accordance with pesticide disposal instructions.

#### Disposal

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Securely wrap original container in several layers of newspaper and discard in trash.

Manufactured by 1998, Mareva Inc. Made in France

Zone Industrielle du Bois de Leuze - 13310 Saint Martin de Crau - FRANCE

With CONTAINTS in EPA Letter Dated:

JUL 2 0 2000

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
Fungicide, for the pesticide,
amended, for the pesticide,
registered under EPA Reg. No. 69461-/

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