

69461-1

12/22/2003

1/6



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 22, 2003

Wendy A. McCombie
Lewis & Harrison Consultants,
The Agent for
MAREVA Inc.
122 C Street, N.W., Suite 740
Washington, D.C. 20001

Subject: **REVACIL**
EPA Registration No. 70369-1
Application Date: December 4, 2003
EPA Received Date: December 8, 2003

Dear Mrs. McCombie:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

- Add Statements to label (See L & H letter dated 12/4/03)

General Comments

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,

A handwritten signature in black ink, appearing to read "Adam Heyward".

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

REVACIL

[SWIMMING POOL] [SPA] [AND] [HOT TUB] [SANITIZER] [AND] [ALGISTAT]
 [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] [owner's] guide" for specific
 information)
 [Chlorine Free]
 [1-877-REVACIL]
 [Swimming pool sanitizer and algistat – Not a disinfectant]

Active Ingredient:

Poly
 (iminoimidocarbonyliminoimido-
 carbonyliminohexamethylene hydrochloride..... 20.0%
Inert Ingredients: 80.0%

KEEP OUT OF REACH OF CHILDREN

WARNING

See [Side] [Back] Panel for [Additional] [Precautions] [Precautionary
 Statements] and First Aid [Treatment]

Net Contents:

MAREVA, Inc.
 604A Greentree Road
 Chesapeake, VA 23320
 USA

EPA Reg. No. 69461-1
 EPA Est. No. 69461-FRA-1

[Product of France] [Made in France]

[Member of National Spa & Pool Institute logo]

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

WARNING. Causes substantial 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.

(Note to Reviewer: Boxed format or bullets may be used in First Aid Section if
 label space permits.)

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Avoid alcohol. • 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.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none"> • 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.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

(If container size is 5 gallons or greater, use the following statement:)

ENVIRONMENTAL HAZARDS

This product 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.

(If container size is less than 5 gallons, use the following statement:)

ENVIRONMENTAL HAZARDS

This product is toxic to fish.

NOTIFICATION

Date Reviewed: 12.22.03
 Reviewed By: A. Hayward

*Bracketed text denotes alternate marketing language and use directions.

o/p

[This product] [REVACIL] [sanitizer] is registered as a swimmer 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.

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

[Start up] [Treating the pool] [Pools Previously Treated with Chlorinating Chemicals]

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

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

(Note to reviewer: Directions may be lettered or numbered on final printed labeling.)

Freshly Filled and Dechlorinated Pools

Start up with REVACIL [sanitizer]

Note: If the pool water contains algae or is hazy, consult the problem-solving section of the "Pool [Owner's] [Care] Guide," available from your authorized [Dealer of REVACIL] [REVACIL Dealer] [(See REVABLU section)].

* Backwash or clean pool filter. Check pool pH; adjust to 7.0 – 7.8 if necessary.

* Add REVACIL [sanitizer] to give a content of 50 ppm (1/2 gallon product/10,000 gallons of [pool] water).

* After 24 hours, check pH and REVACIL [sanitizer] concentration with the test kit for REVACIL [sanitizer] and adjust if necessary

[Maintenance] Normal Pool Routine

* Every week, check REVACIL [sanitizer] concentration and pH.

* Maintain REVACIL [sanitizer] 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 [sanitizer] level 10ppm, add 1 pint per 10,000 gallons of [pool] water. Consult the booklet, "The Pool [Owner's] [Care] Guide for REVACIL [sanitizer]," for calculation instructions.

NOTE: REVACIL [sanitizer] AND CHLORINE ARE INCOMPATIBLE.

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

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

Problem-Solving and Supplemental Pool Information.

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

REVACIL [sanitizer] is not compatible with many detergents and some supplemental algacides (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 [Owner's] [Care] Guide for REVACIL," available from your [Authorized Dealer of REVACIL [sanitizer]] [REVACIL [sanitizer] Authorized Dealer].

[Treating the spa or hot tub]

Important - REVACIL [sanitizer] is incompatible with chlorinating [and] [or] brominating chemical products.

(Note to reviewer: Directions may be lettered or numbered on final printed labeling.)

Start up with REVACIL [sanitizer]

- * 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 [spa] [hot tub] water to your [REVACIL [sanitizer] Authorized dealer] [Authorized Dealer of Revacil [sanitizer]] to check it for proper water balance.
- * After your [spa] [hot tub] water has been balanced, add REVACIL [sanitizer] to give a concentration of 50 ppm. (1 oz. of product for 150 gallon of [spa] [hot tub] water)
- * Circulate for 30 minutes then check the REVACIL [sanitizer] level. Adjust if necessary.

Spa/Hot Tub Maintenance

- * Every week, check REVACIL [sanitizer] concentration and pH. Adjust if necessary.
- * The [level of] REVACIL [sanitizer] [level] should be maintained between 30 and 50 ppm. [When the level of REVACIL is 30 ppm or less, add enough REVACIL to bring the level up to 50 ppm.]
- * The REVACIL level should never [be allowed to] drop below 30 ppm.
- * To raise the sanitizer level 10 ppm, add 0.2 oz. per 150 gal. of water.

3/10

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 disposal: 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:)

[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] Disposal: Securely wrap original container in several layers of newspaper and discard in trash.

NOTICE TO BUYER (AND USER) [- LIMITED WARRANTY FROM MAREVA INC.(N. JONAS AND CO., INC.)¹]

Mareva, Inc. (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, [product name] [REVACIL] (BIGUAN), Mareva, Inc. (N. Jonas and Co., Inc.), Chesapeake, VA 23320 (4520 Adams Circle; Bensalem, PA 19020) or contact your [product name] [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] [WARRANTIES] AND DISCLAIMS ALL OTHER WARRANTIES INCLUDING THOSE OF FITNESS OR MERCHANTABILITY.

¹ () Parenthesis denotes alternate text for distributor labels. *N. Jonas & Co., Inc.* is used solely for illustrative purposes. Additional distributor names may be substituted for Jonas.

4/10

510

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 05-31-98



EPA

United States
Environmental Protection Agency
Washington, DC 20460

- Registration
- Amendment
- Other (NOTIFICATION)

OPP Identifier Number
265394

Application for Pesticide - Section I

1. Company/Product Number 70369-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Revacil	PM# Team 34	
5. Name and Address of Applicant (Include ZIP Code) MAREVA, Inc. 604 A Greentree Road Chesapeake, VA 23320 <i>PLEASE DIRECT ALL CORRESPONDENCE TO THE CONTACT POINT LISTED BELOW</i> <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

- Amendment - Explain below.
- Resubmission in response to Agency letter dated _____
- Notification - Explain below.
- Final printed labels in response to Agency letter dated _____
- "Me Too" Application
- Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Notification of Minor Label Changes per PR Notice 98-10

Notification to add optional language in accordance with PR Notice 98-10

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Signature: *Wendy A. McCombie*

Date: **DEC 4, 2003**

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
*Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Wendy A. McCombie, Lewis & Harrison 122 C St. NW Suite 740, Washington DC 20001	Title Agent for MAREVA, Inc.	Telephone No. (Include Area Code) 202-393-3903 ext. 13
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Wendy A. McCombie</i>	3. Title Agent for MAREVA, Inc.	
4. Typed Name Wendy A. McCombie, Lewis & Harrison	5. Date DEC 4 2003	

319

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001

telephone 202.393.3903
fax 202.393.3906

6/6

December 4, 2003

HAND DELIVERED

U.S. Environmental Protection Agency
Antimicrobial Division
c/o Document Processing Desk [NOTIFY]
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

ATTENTION: Adam Heyward
Product Manager, Team 34

SUBJECT: MAREVA Inc.
Revacil (EPA Reg. No. 69461-1)
Notification of Minor Label Changes Per PR Notice 98-10

Dear Mr. Heyward:

On behalf of MAREVA Inc., we are submitting an application for pesticide notification to propose some minor changes to the label for their product, **Revacil (EPA Reg. No. 69461-1)** in accordance with PR Notice 98-10. These changes include:

- a) Adding the statement "When the level of REVACIL is 30 ppm or less, add enough REVACIL to bring the level up to 50 ppm," as optional language for the Normal Spa Maintenance section; and,
- b) Adding the phrase, "be allowed to," to the sentence, "The REVACIL level should never drop below 30 ppm" as optional language for the Normal Spa Maintenance section.

In support of this minor label changes notification for **Revacil**, we are submitting the following documents:

- 1) Application for Pesticide Notification (OPP ID No. 265394);
- 2) One (1) copy of the proposed product label, with the changes highlighted; and
- 3) Three (3) copies of the proposed product label.

Insofar as Lewis and Harrison serves as the "Company Contact" and "Company Agent" for MAREVA Inc., please relay all correspondence regarding this notification submission directly to us. If you have any questions, please contact me at 202-393-3903.

Thank you very much for your cooperation.

Sincerely,



Wendy A. McCombie
for,
MAREVA, Inc.

WAM/wm
Enclosures