69461-1

4/22/2005

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

April 22, 2005

Ana Rodriguez-Koster Consultant, Lewis & Harrison Agent for MAREVA, Inc. 122 C St. NW, Suite 740 Washington, DC 20001

Subject: Notification Application Per PR Notice 98-10 Revacil EPA Registration No. 69461-1 Application Dated April 6, 2005

Dear Ms. Rodriguez-Koster:

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

Proposed Notification:

Minor label change to revise typographical error

General Comment:

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

A copy of the notification 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, or Lisa McKelvin at (703) 308-7496.

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

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Please read instructions on reverse befo	ore completing form.		Form Approve	d, <u>OMB No. 2070</u>	-0060, Approval expires 05-31-98
	United State	es	🗌 Registi	ration	OPP Identifier Number
EPA Env	vironmental Prote	ction Agenc	y 🗌 Amend	ment	265394
	Washington, DC	20460	—	Notification	
	Applic	ation for Pe	esticide - Section		
1. Company/Product Number 69461-1			Product Manager		3. Proposed Classification
4. Company/Product (Name) Revacil		PM# Team 3			Restricted
5. Name and Address of Applicant (In MAREVA, Inc. 1119 Cavalier Blvd. Chesapeake, VA 23323 <u>PLEASE SEND ALL CORN</u> "CONTACT POINT" LISTE Check if this is a new address of the second sec	<u>RESPONDENCE 1</u> <u>D BELOW</u>	(b)(I), to: <u>TO</u> EPA R		ar or identical i 	vith FIFRA Section 3(c)(3) n composition and labeling
		Secti	on - 11		
Amendment – Explain below. Resubmission in response to A Notification - Explain below.	gency letter dated		Final printed lat "Me Too" Applic Other - Explain	ation	Agency letter dated
Explanation: Use additional	page(s) if necessa	ry. (For Secti			
		•	CHANGES PER PR	-	
This notification is consistent with the labeling or the confidential state statement to EPA. I further undersube in violation of FIFRA and I may be Signature:	he provisions of PR Not ment of formula of this tand that if this notificat e the subject to enforce	tice 98-10 and El product. I unde tion is not consis ment action and	rstand that it is a violati tent with the terms of P penalties under section	R 152.46, and no on of 18 U.S.C. S R Notice 95-2 an s 12 and 14 of Fil	other changes have been made to Sec 1001 to willfully make any false d 40 CFR 152.46, this product may
		Sectio	on - III		
1. Material This Product Will Be Pac Child-Resistant Packaging	ckaged In: Unit Packaging		Water Soluble Paci		2. Type of Container
Yes*			Yes		Metal
No No	No		□ No		Plastic
*Certification must be submitted	If "Yes" Unit Packaging wgt	No. per container	lf "Yes" Package wgt.	No. per container	Glass Glass Other (Specify)
3. Location of Net Contents Informa	tion 4. Size	e(s) Retail Contai	ner	5. Location o	f Label Directions
Label Cont	tainer				I ng accompanying product
6. Manner in Which Label is Affixed	🗍 Pa	hograph Iper glued enciled	Other:		
		Sectio	on - IV		
1. Contact Point (Complete items dir	ectly below for identifica	ation of individua	I to be contacted, if nec	essary, to proces:	s this application)
		Title Agent for MA	itle Agent for MAREVA, Inc.		Telephone Nc. (Include Area Code) (202) 393-3903 x.17
I certify that the statements I have m acknowledge that any knowingly fals under applicable law.		I attachments the ent may be punis			6. Date Application Received (Stamped)
2. Signature	s. # Ste	3. Title	Agent for MAREVA, Ir)C.	
4. Typed Name Ana Rodriguez-Koster		5. Date 4/6/2005			

LEWIS & HARRISON

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

telephone 202.393.3903 fax 202.393.3906

Consultants in Government Affairs April 6, 2005

Document Processing Desk [NOTIF] Office of Pesticide Programs (7504C) US Environmental Protection Agency Room 266A, Crystal Mall 2 1801 S. Bell Street Arlington, VA 22202

ATTENTION:	Mr. Adam Heyward
	Product Manager, Team 34

SUBJECT: MAREVA, Inc. Revacil (EPA Reg. No. 69461-1) Notification per PR Notice 98-10

Dear Mr. Heyward:

On behalf of MAREVA, Inc. ("Mareva"), we are submitting a "Notification" pursuant to PR Notice 98-10 for their product, **Revacil** (EPA Reg. No. 69461-1). The purpose of this Notification is to correct a typographical error present in the optional language. Specifically, we are revising the statement "[This product] [REVACIL] [sanitizer] is registered as a swimming pool, spa and hot tub utizer, not as a disinfectant." to include square brackets ("[]") at the sentence's beginning and end, in order to eliminate ambiguity

.d clearly identify it as optional language. Please note that a similar statement ("[Swimming pool sanitizer and algistat – Not a disinfectant]") already appears on the label's front panel as optional language and has been previously accepted by the Agency. Furthermore, this is consistent with the labels for all similar products (see, for example, Arch Chemical's Baquacil Swimming Pool Sanitizer and Algistat, EPA Reg. No. 72674-19), which do not include such a statement.

Also please note that this alternate language does not alter the ingredient statement, signal word, use classification, precautionary nguage, first aid statements, physical/chemicals properties, use directions, or storage and disposal language; accordingly, it is consistent with the notification requirements set forth in PR Notice 98-10.

Enclosed please find the following documents in support of this Notification:

- 1. Application for Pesticide Notification (OPP ID No. 265394), which includes a signed statement certifying compliance with PR Notice 98-10;
- 2. One (1) copy of the product label with changes highlighted; and,
- 3. Two (2) clean copies of the product label.

Insofar as Lewis & Harrison, LLC is acting as both the "Company Official" and "Company Contact," please direct all correspondence directly to us. Furthermore, if you have any questions, or require any additional information, please feel free to contact me by phone at 202-393-3903 ext. 17, by fax at 202-393-3906, or by email at alkoster@lewisharrison.com.

Thank you for your assistance with this Notification.

Sincerely the Railing us to a

n Rodriguez-Koster Jent for MAREVA, Inc.

Enclosures

cc: Nadine Lohr (MAREVA, Inc.) Revacil (EPA Reg. No. 69461-1) Notification per PR-Notice 98-10 HAND DELIVERED

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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. 1119 Cavalier Blvd. Chesapeake, VA 23323 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 HAZARDS 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:	 Call a poison control center or doctor immediately for treatment advice. 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.
IF ON SKIN OR CLOTHING:	 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:	 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:	 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 doctor, or going f	t container or label with you when calling a poison control center or

(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.

[[This product] [REVACIL] [sanitizer] 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.

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 REVABLUE 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 [16 oz.] [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 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 [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] [surface] [with water] [and filter].
- * 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.] [Have your authorized dealer of REVACIL [sanitizer] check your water for proper water balance.]
- * After [your] [spa] [hot tub] water has been balanced, add REVACIL [sanitizer] to give a concentration of 50 ppm. (1 [fl.] oz. of product [for] [per] 150 gallon of [spa] [hot tub] water).
- * Circulate [water] [for] 30 minutes then check the REVACIL [sanitizer] [level] [concentration] [with REVACIL TEST STRIPS] [and]. Adjust if necessary.

[Normal] 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] [spa's level of REVACIL] should never [be allowed to] drop below 30 ppm.

* To raise the [REVACIL] sanitizer level 10 ppm, add 0.2 oz. per 150 gal. of [spa] water.]

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[[This product][Revaci]] is compatible with other [pool][spa] maintenance products such as [REVATOP] [REVABLUE] [REVAOUT] [REVAKLAR] REVApH-UPI [REVApH-DOWN][REVALKALINITY] [REVACALCIUM-UP] **[REVAFLOCK] [REVAKLAR] [REVAPURE] [REVAFILTER] [REVANET]** [REVAPIPE] [REVASTOP-FOAM] [REVASTOP-CHLORINE] [REVASTOP MUSTARD ALGAE] [REVA-SPA Shock] [REVA-SPA Stain and Scale Control] [REVA-SPA Water Line Control] [REVA-SPA Foam Dispenser] [REVA-SPA Water Clarifier] [REVA-SPA Test Strips].]

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 auidance.

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.)']

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 23323 (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.

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^{1 ()} Parenthesis denotes alternate text for distributor labels. N.Jonas & Co., Inc. is used solely for illustrat urposes. Additional distributor names may be substituted for Jonas. *O*/