8677-69 (12/23/2008



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

# DEC 2 3 2008

OFFICE OF PREVENTION, PESTICID ND TOXIC SUBSTANCE

**George Katsigras ICL Industrial Products** 95 MacCorkle Avenue SW South Charleston, WV 25303

Subject: Notification dated: December 3, 2008 **BROMIcharge** EPA Registration 8622-69

**Dear George:** 

This acknowledges receipt of your Notification submitted in accordance with the provisions of PR Notice 98-10 under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9.

**Proposed Notification** 

Addition of "IN.CLEAR water sanitization system" and "IN.CLEAR product manual" marketing language to Directions for Use.

**General Comments** 

Based on a review of the material, submitted the notification is acceptable.

Should you have any questions or comments concerning this letter, please contact Tom Luminello at (703) 308-8075.

Sincerely,

Emily H. Mitchell Product Manager 32 **Regulatory Management Branch II** Antimicrobials Division (7510P)

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Triease read	d instructions o	n reverse before	completing for	orm.

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\$epa	Environmental	nited States I Protectic ngton, DC 204				Registratio Amendme Other		OPP Identifier Number
		Applicatio	n for Pesticio	de - Secti	ion			· · · · ·
1. Company/Product Number	-		2. EPA I	roduct Mana	ger.		3. Pro	posed Classification
8622-69			E. Mitch	ell		<u>i</u>		None Restricted
4. Company/Product (Name) Bromicharge			<b>PM</b> 32					
5. Neme: and Address, of App ICL-IP America, Inc. 95 MacCorkle Ave., S.W. South Charleston, WV 25303	licant <i>(Include ZIP Co</i>	de)	(b)(i), îr to:	y product is	simi		in cor	FIFRA Section 3(c)(3) nposition and labeling
X Check if this	is a new address		1 A 444 A 440	ct Name _				
			Section - I	ļ				
Amendment - Explain Resubmission in resp X Notification - Explain	onse to Agency letter	dated		Final printed Agancy latte "Me Too" Aj Other - Expla	r date pplica	tion.	! -;=	
Explanation: Use addition	• •		<u> </u>					
Notification for Bromicharge (EPA Reg. No. 8622-69): Add optional marketing statements. Certification Statement for Notification made per 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. Lunderstand 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 formula of this product. Lunderstand 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 98-10 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.								
	· · ·		Section - II					
1. Material This Product Will	Be Packaged In:					<u> </u>		
Child-Resistant Packaging	Unit Packaging		Water Soluble P	ackaging		2. Type of Co	nteiner	
Yes	Yes		Yes				lotal Iastic	•
No	No	<u> </u>	No No				1055	
<ul> <li>Certification must be submitted</li> </ul>	If "Yes" Unit Packaging wgt.	No. per container	lf "Yes" Package wgt	No. per container	•		aper ther (S	pecify) <u>c</u>
3. Location of Net Contents I	nformation	4. Size(s) Ret	ail Container	1	5. Loc	ation of Lebel I	Directic	ις η του
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1. Contact Point (Complete	items directly below f	or identificatio			f noci	issary, to proce	ss this	applications) c
Namo		Ì	Title		<u>.                                    </u>			No. (Include Area Code)
George Katsigras			Regulatory Spe	cialist				0-3924ູູ້ໍ໌ຼັ
I certify that the stater I acknowledge that an both under applicable I	knowlingly false or i		all attachments the				ete.	6. Date Application Received (Stamped)
2. Signature			з. тию Regulatory	/ Specia	alist	t	-	
4. Typed Name	· · · · · · · · · · · · · · · · · · ·		5. Date			······································		
George Katsigras			3-Nov-2	800				

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.



ICL-IP AMERICA INC. 95 MacCorkle Avenue SW, South Charleston, WV 25303, USA Tel: (304) 720-3950, Fax: (304) 746-3101, www.icl-industrial.com, info@ameribrom.icl-ip.com Sent via FedEx:

December 3, 2008

Attention: Mr. Tom Luminello / PM 32 Document Processing Desk (NOTIF) Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency One Potamac Yard, Rm S-4900 2777 South Crystal Drive Arlington, VA 22202-4501

SUBJECT: Notification to add optional marketing statements for: BROMIcharge®, EPA Reg. No. 8622-69

Dear Mr. Luminello,

ICL-IP America Inc wishes to submit this notification to update the list of optional marketing statements for the aforementioned product. There are no other changes on the label. Please file the new proposed label as alternate.

Please don't hesitate to contact me by phone at 304-720-3924 or via email at <u>katsigrasg@ameribrom.icl-ip.com</u> if you have any questions regarding this submission.

Sincerely yours,

George Katsigras Regulatory Affairs Specialist

Enclosures:

EPA Form 8570-1 Last Approved label Annotated copy of alternate label Proposed label with optional marketing statements



#### PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

# CAUTION

Harmful if swallowed. Harmful if absorbed through the skin. Avoid breathing dust. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before re-use.

#### ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic organisms. Do not contaminate water by cleaning of equipment or disposal of waste.

#### CHEMICAL AND PHYSICAL HAZARDS

Will decompose above 1472°F (800°C), releasing toxic gases. Avoid communition and dusting. Avoid contact with strong oxidizers (other than sodium hypochlorite and chlorine), acids, alkaloidal and heavy metal salts.

#### STORAGE AND DISPOSAL

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

STORAGE: Store in a cool, dry, well-ventilated area, in well-closed original containers.

PESTICIDE DISPOSAL: Do not contaminate water, feed or food by storage or disposal. Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Triple rinse the container (or equivalent), then offer for recycle, reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by law and local authorities, by burning. If burned, stay out of smoke.

Manufactured in \_\_Israel or \_\_China for: ICL-IP America Inc., 95 MacCorkle Ave SW South Charleston, WV 25303 EPA Reg. No. 8622-69 EPA Est. No.

#### WARRANTY

Seller warrants that this product conforms to its chemical description and is reasonably fit for the purposes stated on the label when use in accordance with label directions under normal conditions of use, but neither this warranty nor any other warranty of MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, express or "implic", extends to the use of this product contrary to label instructions, or under Chr:o:mit conditions, or under conditions not reasonably foresceable to Seller, and Buyer ass\_mes ("e risk of any such use.

# **BROMIcharge®**

ACTIVE INGREDIENT: Sodium Bromide	99%
OTHER INGREDIENTS:	1%
ΤΟΤΑΙ	100%

KEEP OUT OF REACH OF CHILDREN

# CAUTION

	FIRST AID
lf in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
lf inhaled	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>
If on skin or clothing	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
lf swallowed	<ul> <li>Call poison control center, or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
poison con	the product container or label with you when calling a trol center or doctor, or going for treatment. You may also contact 10-420-9236 for emergency medical treatment information.
	NOTE TO PHYSICIAN mucosal damage may contraindicate the use of gastric lavage.

See side panels for additional precautionary statements.

LBS.

NET CONTENTS:\_\_\_\_\_

DIRECTIONS FOR USE

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

# FOR INDOOR OR OUTDOOR COVERED SPAS <u>ONLY</u> (Not for use in swimming pools)

BROMIcharge® is designed to be used in conjunction with IN.CLEAR, a water sanitization system for spas that uses BROMITRON Bromine Generator Technology, an electrolysis unit that converts bromide into hypobromite solution. The produced hypobromite solution (bromine) is then introduced into the spa to be treated as a sanitizer for spa water.

#### INITIAL DOSAGE:

Upon initial filling of spa with fresh water, add 1.2 pounds of *BROMIcharge®* per 100 gallons of spa water to a spa equipped with an IN.CLEAR water sanitization system (with BROMITRON Bromine Generator Technology). This will establish sufficient bromide reserve for the bromine generator to operate properly. This same treatment must be followed every 60 days upon draining and refilling the spa with fresh water.

#### MAINTENANCE:

An IN.CLEAR water sanitization system (with BROMITRON Bromine Generator Technology) will operate to produce available bromine as designed until the bromide reserve goes below required levels. *BROMicharge®* should be added if the bromide level drops below the initial charge. Dilution, splash out and leaks are primary reasons for the bromide level to drop. If the bromine generator does not produce enough available bromine, make sure the recommended level of 1440 ppm as sodium bromide is still present in the spa water. The level can be tested with a Total Dissolved Solids test (TDS meter), a salt test or by taking a water sample to a spa/pool store. If *BROMicharge®* is being added repeatedly the spa should be checked for leaks.

Before entering the spa the bromine level should be tested. The available bromine level should be maintained between 2-3 ppm as active residual bromine level and can be tested with a suitable test kit found at any spa/pool store. If the available

bromine level is below 2 ppm as active residual bromine, pressing the "burst" button on the IN.CLEAR water sanilization system (with BROMITRON Bromine Generator Technology) will activate the "burst" mode raising the available bromine level. (See the IN.CLEAR product manual for details). Repeat if necessary until you reach 2 ppm as active residual bromine. If the bromine level is above 8 ppm then turn the spa off until the level drops below 5 ppm. The bromine generator only produces bromine when the spa is circulating. For more immediate results, dilution with fresh water will lower the bromine level. Outdoor spas should be covered when not in use.

Spa water has a tendency to foam and cloud that is directly proportional to the amount of use it receives. This is due to the accumulation of body fats and oils and contaminants too small for the filtration equipment. To a great extent, defoamer, clarifier, shock treatments, and demineralizers or sequestering agents can be used to clear the water. When this becomes impossible, draining, cleaning, and refilling the spa will be the most satisfactory way of solving this problem.

For problems beyond those listed above, consult your IN.CLEAR product manual or call your BROMITRON deater. Call 1-877-BROMINE for your local BROMITRON deater's phone number. {All text in brackets [xyz] is optional and may or may not be included on a final label.} {All text in braces {xyz} is administrative and won't appear on a final label.}

{Optional marketing statements; one or more statements may be combined}

[IN.CLEAR water sanitization system] [BROMITRON Bromine Generator] [BROMITRON Bromine Generator Technology]

# **BROMIcharge**<sup>®</sup>

ACTIVE INGREDIENT: Sodium Bromide	99%
OTHER INGREDIENTS:	1%
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Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-420-9236 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

See side panels for first aid and additional precautionary statements.

Manufactured in \_\_Israel or \_\_China for: ICL-IP America Inc., 95 MacCorkle Ave SW South Charleston, WV 25303 EPA Reg. No. 8622-69 EPA Est. No. \_\_\_\_\_

WARRANTY

Seller warrants that this product conforms to its chemical description and is reasonably fit for the purposes stated on the label when use in accordance with label directions under normal conditions of use, but neither this warranty nor any other warranty of MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to Seller, and Buyer assumes the risk of any such use.

# NET CONTENTS:\_\_\_\_\_LBS.

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

# CAUTION

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CONTAINER DISPOSAL: Triple rinse the container (or equivalent), then offer for recycle, reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by law and local authorities, by burning. If burned, stay out of smoke.

## DIRECTIONS FOR USE

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# FOR INDOOR OR OUTDOOR COVERED SPAS ONLY

(Not for use in swimming pools)

## {for IN.CLEAR}

BROMIcharge® is designed to be used in conjunction with IN.CLEAR, a water sanitization system for spas that uses BROMITRON, Bromine Generator Technology, an electrolysis unit that converts bromide into hypobromite solution. The produced hypobromite solution (b, or nine) is then introduced into the spa to be treated as a sanitizer for spa water.

## INITIAL DOSAGE:

Upon initial filling of spa with fresh water, add 1.2 pounds of *BROMIcharge*® per 100 gallons of spa water to a spa equipped with an IN.CLEAR water sanitization system (with BROMITRON Bromine Generator Technology). This will establish sufficient bromide reserve for the bromine generator to operate properly. This same treatment must be followed every 60 days upon draining and refilling the spa with fresh visiter.

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#### **MAINTENANCE:**

An IN.CLEAR water sanitization system (with BROMITRON Bromine Generator Technology) will operate to produce available bromine as designed until the bromide reserve goes below required levels. *BROMIcharge®* should be added if the bromide level drops below the initial charge. Dilution, splash out and leaks are primary reasons for the bromide level to drop. If the bromine generator does not produce enough available bromine, make sure the recommended level of 1440 ppm as sodium bromide is still present in the spa water. The level can be tested with a Total Dissolved Solids test (TDS meter), a salt test or by taking a water sample to a spa/pool store. If *BROMIcharge®* is being added repeatedly the spa should be checked for leaks.

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# {for BROMITRON}

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### INITIAL DOSAGE:

Upon initial filling of spa with fresh water, add 1.2 pounds of *BROMIcharge*® per 100 gallons of spa water to a spa equipped with a BROMITRON Bromine Generator. This will establish sufficient bromide reserve for the bromine generator to operate properly. This same treatment must be followed every 60 days upon draining and refilling the spa with fresh water.

## **MAINTENANCE:**

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