

8622-69

07/28/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

JUL 28 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

George Katsigras
Regulatory Affairs Specialist
ICL-IP America Inc.
95 MacCorkle Avenue SW
South Charleston, WV 25303

Subject: Bromicharge
EPA Reg. No. 8622-69
Application Dated: June 29, 2011
Receipt Date: June 30, 2011

Dear Mr. Katsigras:

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9 is acceptable.

Proposed Notification:

- Label revisions: Update Storage and Disposal per PR Notice 2007-4 and move after directions for use, update warranty statement, make certain marketing statements optional, move precautionary statement and first aid section from front panel, add statement "[See [side][back] panel[s] for additional precautionary statements [and First Aid]]." to front panel, add quotations to the Note to Physician statement

Comments:

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

This application for notification to revise the product label, as referenced above, is acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact Wanda Henson at (703) 308-6345 or via email at Henson.Wanda@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Monisha Harris".

Monisha Harris
Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 8622-69	2. EPA Product Manager W. Henson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BROMIcharge®	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) ICL-IP America, Inc. 95 MacCorkle Ave., S.W. South Charleston, WV 25303	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 _____	

Check if this is a new address

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

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

Notification for EPA Reg. No. 8622-69: Add Container Handling text per PR Notice 2007-4; move storage & disposal after directions for use; update warranty statement, make certain text optional, and move "see back panel for additional precautionary statements" above First Aid table.
 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. 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 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 - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container
		If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container vary from 1 lb to 50 lbs		5. Location of Label Directions On label
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" 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 George Katsigras	Title Regulatory Affairs Specialist	Telephone No. (Include Area Code) 304-720-3924
Certification 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 	3. Title Regulatory Affairs Specialist	
4. Typed Name George Katsigras	5. Date 29-JUNE-2011	



June 29, 2011

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Rm S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

**SUBJECT: Notification per PR Notice 98-10
for Bromicharge® (EPA Reg. No. 8622-69)**

Dear Sir/Madam:

Please process the enclosed notification for the above referenced product.

The purpose of this notification is to revise the label as such:

- Add language required by the Pesticide Container Rule under Storage and Disposal per PR Notice 2007-4.
- Update the warranty statement.
- Move Storage & Disposal statements after the Directions for Use.
- Make certain statements optional on the market label.
- Revise and move "See side panels for additional precautionary statements and first aid" due to the container's small size and there is not enough room in the front panel to fit the information.
- Add quotes to the Note of Physician statement.

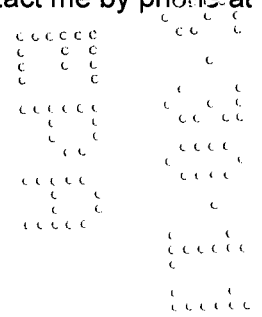
Enclosed are:

- Application form (EPA Form 8570-1)
- 1 copy of the proposed label
- An annotated copy of the proposed label

If you have any questions or need additional information, please feel free to contact me by phone at (304) 720-3924 or via email george.katsigras@icl-ip.com.

Sincerely yours,

George Katsigras
Regulatory Affairs Specialist



{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®

NOTIFICATION
Date Reviewed: 7/28/2011
Reviewed By: Z. Tanis

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

KEEP OUT OF REACH OF CHILDREN

CAUTION

[See [side] [back] panel[s] for additional precautionary statements [and First Aid]].

FIRST AID	
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 eye. 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 by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.
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 swallowed	<ul style="list-style-type: none"> Call 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 the poison control center or doctor. Do not give anything by mouth to an unconscious person.
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.	
<p align="center">NOTE TO PHYSICIAN</p> <p>"Probable mucosal damage may contraindicate the use of gastric lavage."</p>	

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 communiton and dusting. Avoid contact with strong oxidizers (other than sodium hypochlorite and chlorine), acids, alkaloidal and heavy metal salts.

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 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 (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 sanitization 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 dealer. Call 1-877-BROMINE for your local BROMITRON dealer's phone number.

{for BROMITRON}

BROMIcharge® is designed to be used in conjunction with BROMITRON, 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 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:

A BROMITRON Bromine Generator 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 BROMITRON Bromine Generator will activate the "burst" mode raising the available bromine level. (See the BROMITRON Bromine Generator Operator's Instruction 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 BROMITRON Bromine Generator manual or call your BROMITRON dealer. Call 1-877-BROMINE for your local BROMITRON dealer's phone number.

STORAGE AND DISPOSAL

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

PESTICIDE 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 HANDLING: Non-refillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Manufactured [in ___ Israel] [___ 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 to the extent consistent with applicable law, 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.