

11603-29

11/13/2009

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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCE

Christie Hitchcock  
Celsius Property B.B., Amsterdam (NL)  
c/o Makhteshim Agan of North America, Inc.  
4515 Falls of Neuse Rd., Suite 300  
Raleigh, NC 27609

NOV 13 2009

Subject: Notification(s) for Label Revisions under PRN 2007-4 and 98-10

1. Updated warranty statement
2. Added emergency responder phone number in first aid section

Dear Ms. Hitchcock:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notices (PRN) 2007-4 and 98-10 dated October 16, 2009 for:

**EPA Registration 11603-29**

**Galigan Oxyfluorfen Technical**

The Registration Division (RD) has conducted a review of the request(s) for applicability under 2007-4 and 98-10 and finds that the label changes requested fall within the scope of 2007-4 and 98-10. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identify the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact me directly at 703-305-6249 or Nicole Williams of my staff at 703-308-5551.

Sincerely,

A handwritten signature in black ink, appearing to be "Linda Arrington".

Linda Arrington  
Notifications & Minor Formulations Team Leader  
Registration Division (7505P)  
Office of Pesticide Programs

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United States  
**Environmental Protection Agency**  
 Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 11603-29	2. EPA Product Manager Linda Arrington	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Galigan® Oxyfluorfen Technical	PM# <u>23</u> Registration Support Branch	
5. Name and Address of Applicant (Include ZIP Code) Agan Chemical Manufacturers Ltd. c/o Makhteshim Agan of North America, Inc. 4515 Falls of Neuse Rd, Suite 300, Raleigh, NC 27609 <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**

<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.

**NOTIFICATION**

**NOV 13 2009**

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

Notification per PRN 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 false statements 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.

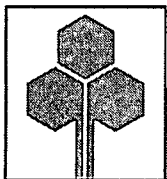
*See Page 2 for PRN 2007-4*

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" 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		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
				<input checked="" type="checkbox"/> Glass	<input checked="" type="checkbox"/> Paper
				Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 55 lbs or less; greater than 55 lbs		5. Location of Label Directions <input checked="" type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other Self-Adhesive	

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Christie Hitchcock		Title Regulatory Specialist		Telephone No. (include Area Code) 919-256-9342	
<p align="center"><b>Certification</b></p> <p>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.</p>					6. Date Application Received (Stamped)
2. Signature <i>Christie Hitchcock</i>		3. Title Regulatory Specialist			
4. Typed Name Christie Hitchcock		5. Date 10-16-09			



Makhteshim Agan of  
North America, Inc.

**M A N A**

October 16, 2009

Re: Galigan® Oxyfluorfen Technical, EPA Reg. No. 11603-<sup>29</sup>39  
Page Two attachment to 8570-1 form

Notification of label change per PR Notice 2007-4: This notification is consistent with the guidance of PR Notice 2007-4 and requirements of EPA's regulations at 40 CFR §§156.10, 156.140; 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statements to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§156.10, 156.140, 156.144, 156.146, and 156.156, 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.

Christie Hitchcock  
Regulatory Specialist  
Regulatory Affairs, MANA  
on behalf of Agan Chemical Manufacturers, Ltd.



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October 16, 2009

Document Processing Desk (NOTIF)  
Registration Division (7504P)  
OPP, USEPA  
Ariel Rios Building  
1200 Pennsylvania Ave, NW  
Washington, DC 20460

Re: Galigan® Oxyfluorfen Technical; EPA Reg. No. 11603-29  
Notification per PRN 98-10 and 2007-4

To Whom It May Concern:

On behalf of Agan Chemical Manufacturers, Ltd., Makhteshim Agan of North America, Inc. is notifying the Agency of several updates for the above mentioned label as allowed in PR Notices 98-10 and 2007-4. The changes are summarized below:

- Updated the Warranty Statement that is now consistent with EPA's guidance document dated 10-17-06) (allowed per PRN 98-10 §II(J))
- Added Emergency Responder phone number in First Aid section (allowed per PRN 2001-01 §III(I))
- Updated container disposal instructions per PRN 2007-4

In support of this submission, the following documents are attached:

- Application for Pesticide Registration (EPA Form 8570-1)
- One copy of final printed labeling

Please contact me at 919-256-9342 or by email at [chitchcock@manainc.com](mailto:chitchcock@manainc.com) if you have any questions regarding this submission or would like a copy of the annotated label showing the changes for your files.

Sincerely,

  
Christie Hitchcock  
Regulatory Specialist

Enclosures

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# GALIGAN<sup>®</sup> OXYFLUORFEN TECHNICAL

A HERBICIDE FOR FORMULATING USE ONLY

<b>ACTIVE INGREDIENT</b>	<b>% BY WT.</b>
Oxyfluorfen: 2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene .....	97.4%
<b>INERT INGREDIENTS:</b> .....	<u>2.6%</u>
	<b>TOTAL 100.0%</b>

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

**NOTIFICATION**

**NOV 13 2009**

**MANUFACTURED FOR:**  
Agan Chemical Manufacturers, Ltd.  
c/o Makhteshim Agan of North America, Inc.  
4515 Falls of Neuse Road, Suite 300  
Raleigh, NC 27609

EPA Reg. No. 11603-29

EPA Est. No. \_\_\_\_\_

**NET CONTENTS: \_\_\_ LBS**

<b>FIRST AID</b>	
<b>IF ON SKIN OR CLOTHING:</b>	<ul style="list-style-type: none"> <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>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <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>
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>• Call a 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 a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>IF INHALED:</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Prostar at 1-877-250-9291 for emergency medical treatment information.</p>	

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS & DOMESTIC ANIMALS  
CAUTION**

Harmful if absorbed through skin. Harmful if inhaled. Do not get in eyes or on clothing. Avoid contact with skin, eyes, or clothing. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

**ENVIRONMENTAL HAZARDS**

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters 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 previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

**PHYSICAL HAZARDS**

Keep away from heat and open flame.

### DIRECTIONS FOR USE

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

Reformulators must be responsible for providing data to register products.

For formulation of herbicides only.

Only for formulation into an herbicide for the following use(s):

- Artichokes (Globe)
- Bananas
- Blackberry
- Broccoli
- Cabbage
- Cauliflower
- Cacao (Hawaii only)
- Citrus (Non-bearing)
- Clover (Grown for Seed)
- Clary Sage (Grown for Essence)
- Coffee
- Conifer (seedbeds, transplants, and container stock) and selected deciduous trees
- Corn
- Cotton
- Cottonwood
- Deciduous Trees
- Eucalyptus
- Fallow bed (cotton/soybean)
- Fallow land
- Tree fruit/Nuts/Vines (which includes Almond, Apple, Avocado, Beechnut, Brazilnut, Butternut, Cashew, Cherry, Chestnut, Chinquapin, Crab apple, Date, Feijoa, Fig, Filbert, Grapes, Hickory nut, Kiwi, Loquat, Macadamia nut, Mayhaws, Nectarines, Olives, Peach, Pear, Pecan, Persimmon, Pistachio, Plum, Pomegranates, Prune, Quince, and Walnut)
- Garbanzo beans
- Garlic
- Grass Seeds
- Guava (Hawaii only)
- Horseradish
- Jojoba
- Mint
- Non-crop use on right-of-way sites
- Nursery Stock
- Onions, Onions grown for Seed
- Ornamentals
- Papaya (Hawaii only)
- Pome Fruits
- Raspberry
- Shade Trees
- Soybeans
- Stone Fruit
- Taro

This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).

### STORAGE AND DISPOSAL

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

**PESTICIDE STORAGE:** Store in a cool, dry place.

**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 label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Or offer for reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

In case of minor spills, follow all precautions indicated above and clean up immediately. Sweep up and dispose of wastes and broken or empty containers in a landfill approved for pesticide use.

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**LIMITATION OF WARRANTY AND LIABILITY**

Read the entire directions for use, conditions of warranties and limitations of liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following **CONDITIONS, DISCLAIMER OF WARRANTIES, and LIMITATIONS OF LIABILITY.**

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Agan Chemical Manufacturers, Ltd. All such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** To the extent consistent with applicable law, Agan Chemical Manufacturers, Ltd. makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Agan Chemical Manufacturers, Ltd. is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Agan Chemical Manufacturers, Ltd. disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

**LIMITATIONS OF LIABILITY:** To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Agan Chemical Manufacturers, Ltd.'s election, the replacement of product.

Galigan is a registered trademark of Agan Chemical Manufacturers, Ltd

Galigan Technical (11603-29)(EPA app 7-28-06)(notif to EPA 10-16-09)