

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Nang-Ly Chow, Ph.D. Bayer CropScience LP P.O. Box 12014; 2 T.W. Alexander Drive Research Triangle Park, NC 27709

FEB 27 2012

Subject: Notification Under PRN 98-10 to Remove Expired Patent Number

Tembotrione Technical EPA Reg. No. 264-859

Your Application, Dated September 29, 2011

Dear Dr. Chow:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the subject product. The Registration Division (RD) has conducted a review of this request for applicability under PRN 98-10 and finds that the label change requested falls within the scope of the PRN. The label has been date-stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at (703) 305-1243 or Susan Stanton of my staff at (703) 305-5218.

Sincerely,

Kathryn Montague, Product Manager 23

Herbicide Branch

Registration Division (7505P) Office of Pesticide Programs

APlease read instructions on reverse before completing form.			Form Approved. OMB No. 2070-0060. Approval expires 05-31-98					
<b>⊕</b> EPA	United St Environmental Pro Washington, D	tection	Agency		Regi_atio		OPP Identifier Number	
K				V	Other			
Application for Pesticide - Section I								
1. Company/Product Number 2. EPA Product Manager 3. Proposed Classification								
264-859			Ms. Kathryn V. Montague					
Company/Product (Name)     Tembotrione Technical			PM Team 23 None Restricted					
5. Name and Address of Application (Include ZIP Code)			Expedited Review. In accordance with FIFRA Section 3(c)(3)     (b)(i), my product is similar or identical in composition and labeling     to:					
Bayer CropScience			EPA Reg. No. NOTIFICATION					
PO Box 12014, 2 Alexander Drive, Research Triangle Park, NC 27709								
Check if this is a new address			FEB 2 7 2012					
		Sec	ction — II					
Amendment – Expla	Amendment – Explain below.							
Resubmission in response to Agency letter dated			Agency letter dated					
Notification - Explain below.			☐ "Me Too" Application. ☐ Other - Explain below. ☐ Other - Explain					
Explanation: Use a	Explanation: Use additional page(s) if necessary. (For Section 1 and Section II.)							
Submission of a Pesticide Notification under the Provisions of PR Notice 98-10: for removing the expired patent number for the active ingredient (was on page 1, Ingredient section).  Contact: george.sabbagh@bayer.com								
<u> </u>		Sec	tion – III		<del></del>			
1. Material This Product	Will Be Packaged in:							
Child-Resistant Packaging	Unit Packaging	Water 9	Soluble Packag	ing	2. Т	ype of C	ontainer	
Yes	Yes	Ye	es				Metal	
□ No	□ No	☐ No	)				Plastic Glass	
		L					Paper	
* Certification must be submitted	If "Yes", Unit No. per Packaging wgt. container	If "Yes" Packag		No. pe contai			Other (Specify)	
3. Location of Net Contents	s Information	4. Size(s	s) Retail Contai	ner	5 Locati	on of Lat	pel Directions	
Label Container		0.23(	, , , , , , , , , , , , , , , , , , ,			On Lat		
6. Manner in Which Label is Affixed to Product								
Lithograph Paper glued								
Soction IV								
Section – IV  1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)								
Name Nang-Ly Chow, Ph.D.			Title Telaphone No. Policy Phone: 919-549-2147 Fax: 919-549-2971					
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.								
Signature				egistrat	ion Manager	د د د د	( (	
Nang. Ly ( Kow)				<b>Q</b> - 2-4-	- 0			
4. Typed Name: Nang-Ly Chow, Ph.D.			5. Date: S	Septer	mber 29, 201	1	, , , ,	

## Bayer CropScience



September 29, 2011

Document Processing Desk (NOTIF) Office of Pesticide Program (H7504P) U.S. EPA, Room S4900 One Potomac Yard Arlington, VA 22202 -4525

ATTN: Ms. Kathryn V. Montague (PM 23) Registration Division (7505P)

Subject: Tembotrione Technical (Reg. No: 264-859): Submission of a Pesticide Notification Under the PRN 98-10, for Removing the Expired Patent Number for the Active Ingredient

Dear Ms. Montague:

Bayer CropScience (BCS) is submitting a pesticide Notification under the Provisions of PR Notice 98-10 for the Tembotrione Technical product (Reg. No.: 264-859). The Notification is only for one change, that we have removed the BCS patent number for the active ingredient chemical since it has expired. The patent number was previously included in the Ingredient Section with a \* notation to the active ingredient. We understand that removing of the 'patent number' qualifies as a 'Non-Notification" change under PRN 98-10; but for a proper record, BCS wishes to inform the Agency of the change via the Notification process. For your quick review, enclosed are the EPA Form 8570-1 and one copy of the updated label for the Technical.

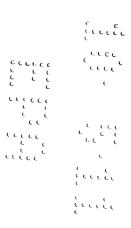
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR §152.46, and no other changes have been made to the labeling or the confidential statement of formula for this product. I understand that it is a violation of 18 U.S.C. Section 1001 to willfully make 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, these products may be in violation of FIFRA and I may be subjected to enforcement action and penalties under Section 12 and 14 of FIFRA.

We thank the Agency for reviewing the Notification. If you should need other information on the submission, please contact Dr. George Sabbagh via <a href="mailto:george.sabbagh@bayer.com">george.sabbagh@bayer.com</a> who will assume the regulatory responsibilities for tembotrione and the end-use Laudis® Herbicide product.

Sincerely,

Nang. Ly chow

Nang-Ly Chow, Ph.D. Registration Manager With Enclosure Notification -9/29/2011



#### NOTFICATION

FEB 27 2012

# **TEMBOTRIONE** Technical

FOR FORMULATION PURPOSES ONLY.		
Formulators who use this product are responsible for obtaining EPA supple	mental distributor registration for their formulated product.	
ACTIVE INGREDIENT:		
Tembotrione: 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methylsulfonyl)	nyl]benzoyl]-1,3-cyclohexanedione * 96.2%	
OTHER INGREDIENTS:	3.8%	
*(CAS Number 335104-84-2)	Total 100.0%	
EPA Reg No. 264-859	EPA Est. No.	

# KEEP OUT OF REACH OF CHILDREN CAUTION

For <u>MEDICAL</u> And <u>TRANSPORTATION</u> Emergencies <u>ONLY</u> Call 24 Hours A Day 1-800-334-7577 For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

#### **FIRST AID**

IF SWALLOWED:	Immediately call a poison control center or doctor for treatment advice.				
	Do not induce vomiting unless told to do so by a poison control center or doctor.				
	Have person sip a glass of water if able to swallow.				
	Do not give anything by mouth to an unconscious person.				
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 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.				
	For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.				
Have	the product container or label with you when calling a poison control center or doctor or going for treatment.				

#### PRECAUTIONARY STATEMENTS

#### **CAUTION**

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed or absorbed through the skin. Avoid contact with skin, eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

#### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the itistructions for category A on an EPA chemical resistance category selection chart.

Formulators and other handlers must wear: Long sleeved shirt and long pants, socks, shoes and chemical resistant gloves made of any waterproof material such as natural rubber ≥ 14 mils. Follow manufacturer's instructions for cleaning/maintaining PPE infino such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

(((

#### **ENVIRONMENTAL HAZARDS**

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.

#### STORAGE AND DISPOSAL

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

#### PESTICIDE STORAGE

Keep container tightly closed when not in use. Avoid cross contamination with other pesticides.

#### PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Improper disposal of excess pesticide or rinsate is a violation of Federal law. For questions about proper disposal, contact your state pesticide and environmental control agency.

#### **CONTAINER DISPOSAL**

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Dispose of in a sanitary landfill or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

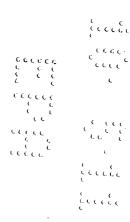
#### DIRECTIONS FOR USE

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

This product may be used only for formulation into a herbicide for the uses listed below:

- 1. The following approved uses:
  - for post-emergence control of annual broadleaf and grass weeds in field and silage corn, seed corn, hybrid seed corn inbreds, sweet corn and popcorn
  - for suppression of annual broadleaf and grass weeds in field and silage corn, seed corn, hybrid seed corn inbreds, sweet corn and popcorn
- 2. Uses for which the U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration and
- 3. Uses for experimental purposes that are in compliance with U.S. EPA requirements

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



#### IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer 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 Bayer CropScience. To the extent consistent with applicable law, all such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE 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 Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE 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 BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

#### **NET CONTENTS:**

Produced for



Bayer CropScience LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, North Carolina 27709 1-866-99BAYER (1-866-992-2937)

Tembotrione Technical (MASTER) 09/28/07, Notification 07/08/08, Notification 05/19/2011

