

29964-19

8/9/2013

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

AUG 9 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

D'Ann J. Cord
Pioneer Hi-Bred International, Inc.
7100 N.W. 62nd Ave.
P.O. Box 1000
Johnston, Iowa 50131-1000

Subject: Optimum® Leptra™
EPA Reg. No: 29964-19
Application for Notification Dated May 7, 2013

Dear Ms. Cord:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under PRN 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. The label submitted with this application has been stamped "Notification accepted" and will be placed in our records.

Questions concerning this action should be directed to Ann Sibold at 703 305-6502 or email at sibold.ann@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kimberly Nesci".

for Kimberly Nesci, Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Pioneer Hi-Bred International, Inc. / 29964-19	2. EPA Product Manager Ann Sibold	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) Optimum [®] Intrasect [™] Leptra [™]	PM # 92.	
5. Name and Address of Applicant (Include ZIP Code) Pioneer Hi-Bred International, Inc. 7100 NW 62 nd Avenue Johnston, IA 50131-0552 <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.

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

See attachment

Section - III

1. Material This Product Will Be Packaged In:

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	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper w/ polyurethane liner <input checked="" type="checkbox"/> Other (Specify) Seed containers
* 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
 Label Container

4. Size(s) Retail Container

5. Location of Label Directions
 On Label
 On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
 Lithograph Other: FIFRA label on file with EPA
 Paper glued
 Stenciled

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Jamie Staley	Title U.S. Registration Manager	Telephone No. (Include Area Code) 515-535-6946
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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.

2. Signature 	3. Title U.S. Registration Manager	6. Date Application Received (Stamped)
4. Typed Name Jamie Staley	5. Date May 7, 2013	

Explanation:

Notification of primary brand name change per PR Notice 98-10: Change the primary brand name of 29964-19 from "Optimum[®] Intrasect[™] Leptra[™]" as stated on EPA's stamped FIFRA product label dated January 25, 2013 to "Optimum[®] Leptra[™]".

This notification is consistent with the provisions of PR Notice 98-10 and EPA Regulation 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

Optimum® Leptra™

(OECD Unique Identifier: DAS-Ø15Ø7-1xMON-ØØ81Ø-6xSYN-IR162-4)

Active Ingredients

<i>Bacillus thuringiensis</i> Cry1F protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS-Ø15Ø7-1	≤0.0017%*
<i>Bacillus thuringiensis</i> Cry1Ab protein and the genetic material (vector PV-ZMBK07) necessary for its production in corn event MON-ØØ81Ø-6	≤0.0013%*
<i>Bacillus thuringiensis</i> Vip3Aa20 protein and the genetic material (via elements of pNOV1300) necessary for its production in corn event SYN-IR162-4	≤0.02%*

Inert Ingredients

Phosphinothricin acetyltransferase (PAT) protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn events DAS-Ø15Ø7-1	≤0.00046%*
Phosphomannose isomerase (PMI) protein and the genetic material (via elements of pNOV1300) necessary for its production in corn event SYN-IR162-4	≤0.00048%*

* Percentage (wt/wt) on a dry wt. basis for whole plant (forage).

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS _____

EPA REGISTRATION NUMBER: 29964-19

EPA ESTABLISHMENT NUMBER: 029964-IA-001

Pioneer Hi-Bred International, Inc.
7300 NW 62nd Avenue
Johnston, IA 50131

Notification Accepted

Date: AUG 9 2013

Reviewer: *A. Schold*

DIRECTIONS FOR USE

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

The plant-incorporated protectant must be used as specified in the terms and conditions of the registration.

This plant-incorporated protectant (PIP) may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

Optimum® Leptra™ combines the insect protection features of 1507xMON810 and Agrisure® Viptera (MIR162) in the same corn hybrid (inbred). Optimum® Leptra™ hybrids protect corn crops from leaf, stalk and ear damage caused by lepidopteran corn pests such as the European corn borer and other lepidopteran pests. In order to minimize the risk of the corn pests developing resistance to Optimum® Leptra™, an insect resistance management plan must be implemented.

INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant active ingredient per registrant per year.

Corn seed bags or bag tags for products containing Optimum® Leptra™ must include the refuge size requirement in text and graphical format.

The following information regarding commercial production must be included in the grower guides for cotton and non-cotton growing areas:

Corn-Belt/Non-Cotton Growing Areas

Optimum® Leptra™ grown outside cotton-growing areas (e.g., the Corn Belt), growers must adhere to the following refuge requirements.

- Growers must plant a structured refuge of at least 5% non-Bt corn and/or non-lepidopteran resistant Bt corn which may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within 1/2 mile of the Bt cornfield(s).
- When planting the refuge in strips across the field, refuges must be at least one (1) row wide.
- Foliar insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, stalk borer, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, sugarcane borer, beet armyworm and dingy cutworm may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Microbial Bt insecticides must not be applied to non-Bt corn and/or non-lepidopteran resistant Bt corn refuges.

Cotton-Growing Areas

Optimum[®] Leptra[™] grown in cotton-growing areas:

- Growers must plant a structured refuge of 20% non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn that may be treated with insecticides as needed to control lepidopteran stalk-boring and other pests.
- Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.
- External refuges must be planted within 1/2 mile of the *Bt* cornfield(s).
- When planting the refuge in strips across the field, refuges must be at least four (4) rows wide.
- Foliar insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, stalk borer, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, sugarcane borer, beet army worm and dingy cutworm may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.
- Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, Stoddard).

Crop	Pests
Field Corn	black cutworm beet armyworm corn earworm dingy cutworm European corn borer fall armyworm southwestern corn borer western bean cutworm lesser corn stalk borer southern corn stalk borer stalk borer sugarcane borer