

100-1198

07/27/2005

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:
100-1198

Date of Issuance:
JUL 27 2005

NOTICE OF PESTICIDE:
 Registration
 Reregistration

Term of Issuance:
Conditional

Name of Pesticide Product:
Pinoxaden Technical

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(C) provided you agree in writing that:

1) The following data are required as conditions of registration:

(a) Guideline 860.1340: Additional validation data for pinoxaden and M2 residues in livestock commodities (ruminant and poultry) are required.

(b) Guideline 860.1380: A study demonstrating the storage stability of M2, M4 and M6 in barley processed fractions (bran, flour and pearled barley) for a minimum duration of 15 months and a study demonstrating the storage stability of M2, M4 and M6 in wheat processed fractions (AGF, bran, flour, middling, shorts and germ) for a minimum duration of 6 months are required.

(c) Guideline 72-1(a.c): fish acute toxicity tests are required for parent pinoxaden to replace supplemental studies.

(d) Guideline 72-2: a freshwater invertebrate acute toxicity test is required using parent pinoxaden to replace an unacceptable study.

Signature of Approving Official:

James Tompkins, Product Manager (25)
Herbicide Branch, Registration Division (7505C)

Date:

JUL 27 2005

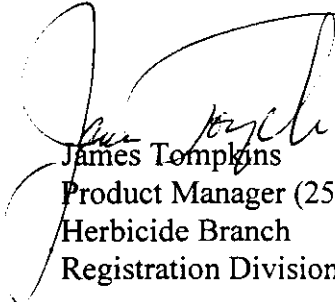
1) Conditions of Registration (continued)

- (e) Guideline 72-3a: an estuarine/marine fish acute toxicity test is required using parent pinoxaden to replace a supplemental study.
- (f) Guideline 72-3c: an estuarine/marine shrimp acute toxicity test is required using parent pinoxaden to replace a supplemental study.
- (g) Guideline 72-4a: a freshwater fish early life-stage study is required using parent pinoxaden
- (h) Guideline 72-4b: a freshwater invertebrate life-cycle study is required using parent pinoxaden
- (i) Guideline 71-2 (a,b): Avian dietary studies in mallard duck and bobwhite quail for the formulated product with adjuvant.
- (j) Guideline 72-1(a,c): Acute fish toxicity studies for the degradate NOA-407854 on warm water species only, for the degradate NOA-447204 on warm water & cold water species, and for the formulated product with adjuvant on warm water and cold water species
- (k) Guideline 72-2: Freshwater invertebrate life-cycle studies for the degradate NOA-447204 and formulated product with adjuvant.
- (l) Guideline 72-3b: Marine/estuarine shell deposition studies for the degradates NOA-407854 and NOA-447204.
- (m) Guideline 72-4a: Freshwater-fish early life-stage studies for the degradate NOA-407854, and the degradate NOA-447204
- (n) Guideline 72-4b: Freshwater invertebrate life-cycle studies for the degradate NOA-447204, and for the degradate NOA-407854 to replace a supplemental study.
- (o) Guideline 123-1 (a,b): Seedling emergence and vegetative vigor studies for each of the two main degradates (NOA-407854 and NOA-447204)
- (p) Guideline 123-2: Tier II Aquatic plant growth studies for the parent pinoxaden, degradates NOA-407854 and NOA-447204, and for the formulation with adjuvant.
- (q) 830 series subgroup A data are required for the pinoxaden technical produced on a commercial scale.

2. Change EPA Reg. No. on label from 100- to 100-1198.
3. Add an appropriate EPA establishment number on label.
4. The Conditions of Sale and Limitation of Warranty and Liability contains language asserting that the buyer has accepted the manufacturer's statement of his/her respective rights (these conditions are beyond the control of registrant X) and contains language which is overly broad implying the buyer has no legal right to recover damages from manufacturer (all such risks shall be assumed by the buyer). These statements must make it clear that it is the registrant's or manufacturer's warranty disclaimer, by using statements like "To the fullest extent permitted by law, the manufacturer shall not be liable for" or "It is the manufacturer's intention that"

You will submit one (1) copy of your final printed labeling before you release the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). A stamped copy of labeling is enclosed for your records.

If you have any questions, please contact Hope Johnson at 703-305-5410.



James Tompkins
Product Manager (25)
Herbicide Branch
Registration Division (7505C)

attachment

ATTACHMENT 1: STATUS OF SUBMITTED DATA REQUIREMENTS AND DATA GAPS

Ecotoxicity:

| Guide no. | Study description | Test material | Data required? | Data requirement satisfied? | MRID no. | Status | |
|-----------|-------------------------------------|--|----------------|-----------------------------|----------------|-----------------------------------|--|
| 71-1(a) | Acute Avian Oral, Bobwhite | Parent pinoxaden | yes | yes | 462031-03 | acceptable | |
| 71-2(a) | Avian Dietary Toxicity, Bobwhite | Parent pinoxaden | yes | yes | 462031-04 | acceptable | |
| | | Formulation + adjuvant | yes | no | none submitted | study required | |
| 71-2(b) | Avian Dietary Toxicity, Duck | Parent pinoxaden | yes | yes | 462031-05 | acceptable | |
| | | Formulation + adjuvant | yes | no | none submitted | study required | |
| 71-3 | Mammalian Acute Oral, Rat | Parent pinoxaden | yes | yes | 462032-14 | acceptable | |
| | | Formulation | yes | yes | 462032-17 | acceptable | |
| | | NOA-447204 (degradate) | no | n/a | 462032-15 | n/a - see note | |
| | | SYN-502836 (metabolite) | no | n/a | 462032-16 | n/a - see note | |
| | | SYN-519312 (metabolite) | no | n/a | 462032-18 | n/a - see note | |
| | | note: studies with the degradate and two metabolites were not required and have not been reviewed by HED | | | | | |
| 83-3(a) | Mammalian Reproductive, Rat | Parent pinoxaden | yes | yes | 462033-08 | acceptable | |
| 71-4(a) | Avian Reproductive, Bobwhite | NOA-407854 (degradate) | yes | yes | 462031-07 | acceptable | |
| 71-4(b) | Avian Reproductive, Duck | NOA-407854 (degradate) | yes | yes | 462031-08 | acceptable | |
| 71-5 | Field Testing, Terrestrial Animals | | reserved | n/a | none submitted | n/a | |
| 72-1(a) | Fish Acute Toxicity, Warmwater fish | Parent pinoxaden | yes | no | 462030-36 | supplemental - new study required | |
| | | deficiency: test fish were too old | | | | | |
| | | NOA-407854 (degradate) | yes | no | none submitted | study required | |
| | | NOA-447204 (degradate) | yes | no | none submitted | study required | |
| | | Formulation + adjuvant | yes | no | none submitted | study required | |

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| Guide. no. | Study description | Test material | Data required? | Data requirement satisfied? | MRID no. | Status | |
|------------|--|--|----------------|-----------------------------|-----------------------|-----------------------------------|--|
| 72-1(c) | Fish Acute Toxicity, Rainbow Trout | Parent pinoxaden | yes | no | 462030-34 + 464215-08 | invalid - new study required | |
| | | deficiency: test material was not stable | | | | | |
| | | NOA-407854 (degradate) | yes | yes | 462030-35 | acceptable | |
| | | NOA-447204 (degradate) | yes | no | 462030-37 | supplemental - new study required | |
| | | deficiency: TOC was too high | | | | | |
| | | Formulation + adjuvant | yes | no | 462030-39 | supplemental - new study required | |
| | | deficiency: precipitant present but not centrifuged prior to analytical determination | | | | | |
| 72-2 | Freshwater Invertebrate Acute Toxicity | NOA-447204 (degradate) | yes | no | 462030-41 | supplemental - new study required | |
| | | deficiency: TOC was too high | | | | | |
| | | Parent pinoxaden | yes | no | 462030-29 | unacceptable - see note below | |
| | | note: the study is repairable if the following required information is available, otherwise a new study is required: (1) if information can be supplied by the testing laboratory on timing of analytical sampling (0, 24 and 48 hours) with stock solution renewal and this timing is appropriate for reflecting the stability of the test material, the study could be upgraded; (2) additionally, measured concentration results prior to correction for percent recovery and the amount of dilution water and stock solution flows into mixing chambers are needed to evaluate nominal and measured concentrations appropriately | | | | | |
| | | NOA-407854 (degradate) | yes | yes | 462030-30 | acceptable | |
| | | Formulation + adjuvant | yes | no | 462030-31 | supplemental - new study required | |
| | | deficiency: precipitant present but not centrifuged prior to analytical determination | | | | | |
| 72-3(a) | Estuarine/Marine Fish Acute Toxicity | Parent pinoxaden | yes | no | 462030-38 | supplemental - see note below | |
| | | note: the study is repairable if the following required information is available, otherwise a new study is required: samples were centrifuged before analysis for the test material as required for poor solubility test materials to obtain the concentration of soluble test material (EPA, 1994). However, the samples were also acidified before centrifuging which potentially re-dissolved particulate test material. Provide documentation that acidification under this circumstance did not re-dissolve pinoxaden prior to centrifuging. Also need information on TOC concentration in dilution water, age of fish, and details of the primary stock solution preparation | | | | | |

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| Guide no. | Study description | Test material | Data required? | Data requirement satisfied? | MRID no. | Status |
|-----------|--|---|----------------|-----------------------------|----------------|-----------------------------------|
| 72-3(b) | Estuarine/Marine Mollusc Acute Toxicity - Shell deposition | Parent pinoxaden | yes | yes | 462030-32 | acceptable |
| | | NOA-407854 (degradate) | yes | no | none submitted | study required |
| | | NOA-447204 (degradate) | yes | no | none submitted | study required |
| 72-3(c) | Estuarine/Marine Shrimp Acute Toxicity | Parent pinoxaden | yes | no | 462030-33 | supplemental - see note below |
| | | note: the study is repairable if the following required information is available, otherwise a new study is required: samples were centrifuged before analysis for the test material as required for poor solubility test materials to obtain the concentration of soluble test material (EPA, 1994). However, the samples were also acidified before centrifuging which potentially re-dissolved particulate test material. Repairable if the TOC concentration in the dilution water is provided and it is below guideline limits, and documentation is provided that acidification of water samples prior to centrifugation does not result in dissolution of pinoxaden precipitant back into solution. | | | | |
| 72-4(a) | Early Life Stage, Fish | NOA-407854 (degradate) | yes | no | 462031-01 | unacceptable - new study required |
| | | note: Repairable to supplemental if the timing of use of a new stock batch (12 batches) with sample collection times is provided and the information supports the stability of the compound throughout exposure. The study is not upgradeable to acceptable because a NOAEC was not established and therefore a new study is required even if the stock batch and sample timing information is supplied. | | | | |
| | | Parent pinoxaden | yes | no | none submitted | study required |
| | | NOA-447204 (degradate) | yes | no | none submitted | study required |
| 72-4(b) | Life Cycle, Aquatic Invertebrate | NOA-407854 (degradate) | yes | no | 462030-42 | supplemental - new study required |
| | | Deficiency: Precipitant was present and no filtration or centrifugation was conducted on analytical samples collected from test chambers at the end of the each renewal cycle. Report states solubility of test material is >100 ppm but undissolved particles were observed after 2 to 3 days of mixing and approach described insufficient to support that insoluble material was not present or did not form during the exposure duration. | | | | |
| | | Parent pinoxaden | yes | no | none submitted | study required |
| | | NOA-447204 (degradate) | yes | no | none submitted | study required |
| 72-5 | Life Cycle, Fish | | reserved | n/a | none submitted | n/a |
| 72-6 | Aquatic Bioaccumulation | | reserved | n/a | none submitted | n/a |
| 72-7 | Simulated or Actual Field Testing, Aquatic Animal | | reserved | n/a | none submitted | n/a |

| | | | | | | | |
|-------------------------|---|---|-------------------------------------|---|---|---|--|
| | Seedling Emergence | Formulation + adjuvant | yes | yes | 462031-14 | acceptable | |
| | | NOA-407854 (degrade) | yes | no | none submitted | study required | |
| | | NOA-447204 (degrade) | yes | no | none submitted | study required | |
| 123-1(b) | Terrestrial Plants, Vegetative Vigor | Formulation + adjuvant | yes | yes | 462031-15 | acceptable | |
| | | NOA-407854 (degrade) | yes | no | none submitted | study required | |
| | | NOA-447204 (degrade) | yes | no | none submitted | study required | |
| 123-2 | Aquatic Plant Growth, Tier II | Parent pinoxaden | yes | no | 462031-16 (<i>Lemna</i>) | supplemental - new study required | |
| | | deficiency: test solutions were not renewed at least once. Perform new study at acidic to neutral pH | | | | | |
| | | NOA-447204 (degrade) | yes | no | 462031-17 (<i>Lemna</i>) | supplemental - new study required | |
| | | deficiency: test solutions were not renewed at least once. Perform new study at acidic to neutral pH. | | | | | |
| | | NOA-447204 (degrade) | yes | no | 462031-18 (<i>Lemna</i>) | supplemental - new study required | |
| | | deficiency: test solutions were not renewed at least once. Perform new study at acidic to neutral pH. | | | | | |
| | | Parent pinoxaden | yes | Tier I yes Tier II no | 462031-19 (<i>Selenastrum</i>) | supplemental - new study required | |
| | | deficiency: study was conducted for only 72 hrs not 96 to 120 hrs. Perform new study at acidic to neutral pH | | | | | |
| | | Parent pinoxaden | yes | no | 462031-20 (<i>Anabaena</i>) | supplemental - new study required | |
| | | deficiency: study inoculum was 3 times greater than upper limit coupled with reduced growth rate in controls. Perform new study at acidic to neutral pH | | | | | |
| | | Formulation + adjuvant | yes | no | 462031-21 (<i>Pseudokirchneriella</i>) | supplemental - new study required | |
| | | Parent pinoxaden | yes | yes | 462031-22 (<i>Skeletonema</i>) | acceptable | |
| | | Parent pinoxaden | yes | yes | 462031-23 (<i>Navicula</i>) | acceptable | |
| NOA-407854 (degrade) | yes | Tier I yes Tier II no | 462031-24 (<i>Selenastrum</i>) | supplemental - new study required | | | |

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| Guide. no. | Study description | Test material | Data required? | Data requirement satisfied? | MRID no. | Status |
|------------|---|---|----------------|-----------------------------|---|--|
| | | deficiency: study was conducted for only 72 hrs not 96 to 120 hrs. Perform new study at acidic to neutral pH | | | | |
| | | NOA-447204 (degrade) | yes | yes | 462031-25 (Senastrum) | acceptable |
| | | Formulation + adjuvant | yes | no | 464215-09 (Lemna) | supplemental - new study required |
| | | deficiency: precipitant formed but no filtering or centrifugation was conducted to measure soluble concentration. Perform new study at acidic to neutral pH | | | | |
| 124-1 | Field testing, Terrestrial plants | | reserved | n/a | none submitted | n/a |
| 124-2 | Field Testing, Aquatic plants | | reserved | n/a | none submitted | n/a |
| 141-1 | Honey Bee Acute Contact Honey Bee Acute Oral | | yes | yes | 462031-13 462031-10 462031-09 462031-11 462031-12 | acceptable supplemental supplemental supplemental |
| n/a | Earthworm toxicity | | no | n/a | 462031-26 462031-27 462031-28 | supplemental supplemental supplemental |

n/a: not applicable

reserved: not required for current assessment but reserve right to require if future conditions warrant

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PSL

Pinoxaden Technical

Herbicide

For formulation only into an herbicide for control of grass weeds in wheat (including durum) and barley

Active Ingredient:

Pinoxaden* 98.0%

Other ingredients: 2.0%

Total: 100.0%

*CAS No. 243973-20-8

KEEP OUT OF REACH OF CHILDREN.

DANGER / PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

EPA Reg. No. 100-

EPA Est. _____

____ gallons
Net Contents

ACCEPTED
with COMMENTS
in EPA Letter Dated

JUL 27 2005

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

100-1198

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| 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 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"> • Immediately call a poison control center or doctor. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give any liquid to the person. • Do not give anything by mouth to an unconscious person. |
| 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. |
| NOTE TO PHYSICIAN | |
| Probably mucosal damage may contraindicate the use of gastric lavage. | |
| Have the product container or label with you when calling a poison control center or doctor or going for treatment. | |
| HOT LINE NUMBER | |
| For 24 Hour Medical Emergency Assistance (Human or Animal) or Chemical Emergency Assistance (Spill, Leak, Fire, or Accident) Call 1-800-888-8372 | |

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER / PELIGRO

Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Avoid contact with skin or clothing. Harmful if absorbed through skin or swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

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

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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..

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Buyer is solely responsible for any risks created by the use or uses to which it or any User puts this product. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and Buyer and User assume the risk of any such use. SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall SYNGENTA or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

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DIRECTIONS FOR USE

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

Only for formulating into an herbicide for the following uses: control of grass weeds in wheat (including durum) and barley.

STORAGE AND DISPOSAL

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

Pesticide Storage

Store in a cool, dry place. Do not store near seeds, fertilizer, or foodstuffs

Pesticide Disposal

Pesticide wastes are toxic. Improper disposal of excess pesticides, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label restrictions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

For minor spills, leaks, etc., follow all precautions indicated on this label and clean up immediately. Take special care to avoid contamination of equipment and facilities during cleanup procedures and disposal of wastes. In the event of a major spill, fire, or other emergency, call 1-800-888-8372, day or night.

CONTAINER NOT SAFE FOR FOOD, FEED, OR DRINKING WATER!

NOA 407855 TECH – pd – 01/27/04
000100-XXXXX.20040130.NOA407855-TECHNICAL.pdf
PINOXADEN TECH – pd – 06/22/05
000100-XXXXX.20040130B.NOA407855-TECHNICAL-PIN-TECH.pdf
PINOXADEN TECH_ - pd – 07/18/05
000100-XXXXX.20040130C.NOA407855-TECHNICAL-PIN-TECH.pdf