

100-9219

3/23/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Thomas J. Parshley
Senior Regulatory Product Manager
Syngenta Crop Protection, LLC
P.O. Box 18300
Greensboro, NC 27419-8300

MAR 23 2012

RE: Product Name: Trichoderma Hamatum Isolate 382
EPA Reg. No: 100-9219
Application for Notification Dated: March 1, 2012 to change primary brand name from Trichoderma Hamatum Isolate 382 to a new primary brand name Incept® per PR Notice 98-10.

Dear Mr. Parshley,

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticides Registration Notice (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. Our records have been duly noted, and the label submitted with this application has been stamped as "Notification Accepted" and will be placed accordingly in our records.

Questions concerning this action should be directed to Mary Paden (703) 308-0411 or email at paden.mary@epa.gov.

Sincerely,

Sheryl K. Reilly
Sheryl K. Reilly, Ph.D., Chief
Microbial Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)

CONCURRENCES

SYMBOL	▶ 7511(P)						
SURNAME	▶ Paden						
DATE	▶ 23 MAR 12						

Please read instructions on reverse before completing form.



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

NOTIFICATION

Revised Copy

Application for Pesticide - Section I

1. Company/Product Number 100-9219	2. EPA Product Manager Sheryl K. Kelly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Trichoderma hamatum Isolate 382	PM# BPPD	
5. Name and Address of Applicant (Include ZIP Code) Syngenta Crop Protection, LLC P. O. Box 18300 Greensboro, NC 27419 <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. Notification Accepted Product Name Date: 03/23/2012	

Section - II

Reviewer: *Mary Pader*

<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.)
 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.

Syngenta Crop Protection, LLC is submitting Notification of a new primary brand name for *Trichoderma hamatum* Isolate 382 (EPA Reg. No. 100-9219). The new primary brand name is Incept®.

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" Unit Packaging wgt.	No. per container
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 5 to 1300 lb		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph	<input type="checkbox"/> Paper glued	<input checked="" type="checkbox"/> Other <u>Pressure Sensitive</u>	
		<input type="checkbox"/> Stenciled			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Thomas J. Parshley	Title Senior Regulatory Product Manager	Telephone No. (Include Area Code) 336-632-7207
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 <i>Thomas J. Parshley</i>	3. Title Senior Regulatory Product Manager	
4. Typed Name Thomas J. Parshley	5. Date March 21, 2012	

Syngenta Crop Protection, LLC
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com



March 1, 2012

Document Processing Desk (NOTIF)
Biopesticides and Pollution Prevention Division (7511P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: Sheryl K. Reilly, Ph.D (Chief, Microbial Pesticides Branch)

**SUBJECT: TRICHODERMA HAMATUM ISOLATE 382 -- EPA REG. NO. 100-9219
NOTIFICATION TO CHANGE PRIMARY BRAND NAME**

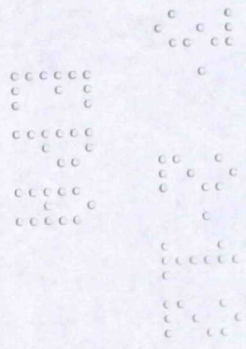
Syngenta Crop Protection, LLC is submitting Notification of a new primary brand name for *Trichoderma hamatum* Isolate 382 (EPA Reg. No. 100-9219). The new primary brand name is Incept®. One copy of the label with the new primary brand name highlighted is attached, along with a CD of the label with the new primary brand name for electronic comparison, a Certificate with Respect to Label Integrity form, and EPA Form 8570-1.

We trust that you will find this submission in order; however, should you have any questions, please contact me at 336-632-7207.

Sincerely,

Thomas J. Parshley
Senior Regulatory Product Manager

Enclosures



Notification Accepted
Date: 03/23/2012
Reviewer: Mary Tadeu

Incept®

MICROBIAL PESTICIDE

FOR USE IN COMPOST AND SOILLESS GROWING MEDIA

Active Ingredient:

Trichoderma hamatum isolate 382* 0.9%

Other Ingredients: 99.1%

Total: 100.0%

*Contains at least 2.84 X 10⁸ cfu/ounce (1 x 10⁷ CFU/gram) of *Trichoderma hamatum* isolate 382

EPA Reg. No. 100-9219

EPA Est. 70002-PA-004

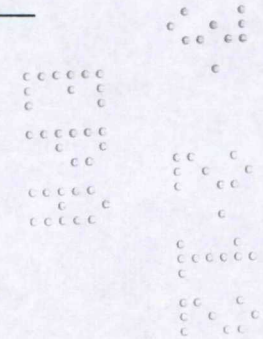
KEEP OUT OF REACH OF CHILDREN.

CAUTION

Batch Number: _____

Expiration Date: Not for sale or use after: _____

Net Contents: _____ pounds



Manufactured for:
Syngenta Crop Protection, LLC
P. O. Box 18300
Greensboro, North Carolina 27419-8300

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.
Have the product container or label with you when calling doctor, or going for treatment.	
HOTLINE 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

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes moderate eye irritation. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Mixers, loaders, applicators and other handlers must wear:

- Long-sleeved shirts and long pants
- Shoes plus socks
- Waterproof gloves
- Dust/mist-filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95.

Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

[NPDES statement on labels of packages less than 50 lb.]

Do not apply to water, or to areas where the surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water or rinsate.

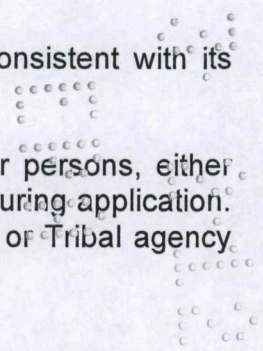
[NPDES statement on labels of packages greater than 50 lb.]

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, ocean, 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.

DIRECTIONS FOR USE

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

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirement specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.



AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the **restricted-entry interval (REI)** of 12 hours.

Exception: If the product is soil-injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

For early entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, wear coveralls, shoes, socks, and waterproof gloves.

PRODUCT INFORMATION AND PRECAUTIONS

Incept is intended for use by commercial greenhouse and nursery growing operations. **Incept** is to be uniformly mixed into soilless growing media mixes and composts prior to seeding or transplanting of ornamentals and vegetable bedding plants. Soilless growing mixes are typically composed of a combination of one or more of the following: peat, bark, perlite, vermiculite, coir, wood chips, composts and other substrate materials to be used in the greenhouse and nursery growing operation.

Incept is used to prepare a disease-suppressive soilless growing media or compost.

Incept can induce systemic resistance to diseases of roots and above-ground plant parts. **Incept** also suppresses the activity of disease causing plant pathogens in soilless growing media. It provides protection against diseases caused by soilborne plant pathogens such as *Pythium*, *Phytophthora* and *Fusarium* spp., *Rhizoctonia solani*, *Sclerotium rolfsii* and *Thielaviopsis basicola*. On some plant species it also protects the foliage against powdery mildew, Botrytis blight, Phytophthora blights and dieback diseases and against Botryosphaeria dieback. Crops highly susceptible to damping-off diseases or already infected with a pathogen should be treated at planting with chemical fungicides compatible with **Incept**. Refer to Chemical Compatibility section of this label for additional information concerning fungicides. Do not prepare tank mixes of fungicides with **Incept**.

Incept must be added and mixed uniformly into soilless growing media or mature composts during or immediately after the preparation (i.e., blending and mixing) of the growing media. **Incept** may also be applied as a drench application to soilless growing media or mature composts. **Incept** colonizes the compost or soilless growing media before disease-causing microorganisms have an opportunity to do so. It is also effective in media containing 50% or more light Sphagnum peat by volume, but not media prepared with dark decomposed peat.

Temperature

Incept is sensitive to long-term exposure to temperatures above 100°F. Mature composts stored in large piles often are high in temperature (above 100°F). Addition of water to compost-amended soilless growing media during the blending process to reach a moisture content of 45 to 55% (weight basis) decreases the temperature of the final mix under most conditions to below 95°F and allows **Incept** to colonize the medium. It also is the optimum moisture content for initiation of plant growth. Organic particles in plant growth media with a moisture content of 50% typically begin to stick together. However, the medium is dry enough so that water cannot be squeezed from the mix and wet enough so that it is not dusty. After **Incept** has established itself in a compost or soilless growing media, it is effective over a wide range of temperatures which include low temperature propagation during winter and high summer temperature conditions.

Ammonia Content

The ammonia content of most types of composts does not pose concerns for **Incept**. However, mature composted manures and sewage sludges stored in high temperature piles often contain high enough concentrations of ammonium N to be toxic to plant roots and to fungi such as *Trichoderma* spp. The quantity of such composted manures incorporated into soilless growing media must be low enough so that the ammonium concentration is below that known to be toxic to plants. Typically, a 5 to 15% content amendment rate (on a volume basis) for these types of composts is optimum for most applications and avoids ammonium toxicity problems for the active ingredient in **Incept**.

Moisture Management

It is essential that the physical properties of the soilless growing medium relative to water retention and drainage are sufficient to grow a particular crop based on typical cultural practices for that crop. **Incept** does not suppress Phytophthora or Pythium root rots in poorly drained media.

Plant Precautionary Guidelines

Due to the large number of species and varieties of ornamentals and nursery plants, including those grown in propagation benches, plug-produced seedlings and tissue culture explants, bedding plants and transplants, greenhouse crops, nursery crops and

trees produced in containers, it is impossible to test every one for tolerance to **Incept**. The user should determine if **Incept** can be used without adverse effects prior to commercial use. In a small area, test the rates for a particular group of plants, i.e., foliage plants, bedding plants, etc., for plant tolerance prior to widespread use.

Chemical Compatibility

Incept may be applied to soilless growing media and composts and used with insecticides, fertilizers, and biological control products used on greenhouse and ornamental plants without interfering with activity of **Incept**. **Incept** is a fungus, and the interaction with some fungicides has not been widely tested. The soil-applied fungicides Subdue® Maxx, Subdue® GR and Aliette® WDG have been tested in plant disease protection programs and have been found to be compatible with **Incept** and may be applied according to their label instructions. The foliar-applied fungicides Daconil Weather Stik®, Daconil Ultrex Turf Care® and Dithane® M-45 have been tested in plant disease protection programs and have been found to be compatible with **Incept** and may be applied according to their label instructions. Other pest control products may be applied prior to or after the application of **Incept**. As noted in the Use Restrictions, do not prepare tank mixes of fungicides with **Incept**.

When using fungicides, insecticides, or any other product in combination with **Incept**, observe all directions for use, crops/sites, use rates, dilution ratios, precautions and limitations which appear on that product. Label dosage must not be exceeded and the most restrictive label precautions and limitations must be followed. Test plant safety and compatibility of fungicides and other products on soil treated with **Incept** on a small number of plants for safety before treating the entire crop.

Incept is compatible with fertilizers used for the production of greenhouse and nursery plants.

Use Restrictions

- Apply only to growing media or compost or directly to the surface of growing media by drench application.
- Chemigation: Do not apply this product through any type of irrigation system.
- Do not prepare tank mixes of fungicides with **Incept**.
- Do not apply after the Expiration Date listed on the product container.

APPLICATION TO SOILLESS GROWING MEDIA AND COMPOSTS

Mix with compost or soilless growing media

Growing Medium	Rate of Incept per 1 cu. yd.	Rate of Incept per 5 cu. yd.	Rate of Incept per 10 cu. yd.	Rate of Incept per 25 cu. yd.	Rate of Incept per 100 cu. yd.	Timing	Comments
Potting Mix	3 to 4 oz.	15 to 20 oz.	30 to 40 oz.	75 to 100 oz.	300 to 400 oz.	During the blending process	Add enough water to the potting mix to reach a moisture content of 45 to 55% on a weight basis. Store the inoculated potting mix below 100° F. If storage temperatures could exceed 100° F, apply as a drench.
Ground Beds or Propagation Benches	3 to 4 oz.	15 to 20 oz.	30 to 40 oz.	75 to 100 oz.	300 to 400 oz.	Immediately after preparation of the growing media	Store the inoculated potting mix below 100° F. If storage temperatures could exceed 100° F, apply as a drench.

Drench¹ to the surface of soilless growing media

Growing Medium	Rate of Incept	Timing	Comments
Potting Mix	3 to 4 oz. in 100 gallons of water	Prior to or immediately after seeding.	Apply suspension directly to the surface of the soilless growing media: <ul style="list-style-type: none"> • 1 pt. suspension/sq. ft. for six-inch tall pots or containers. • ½ pt. suspension/sq. ft. for shallow pots, flats, or plugs.
Ground Beds or Propagation Benches	3 to 4 oz. in 100 gallons of water	Prior to or immediately after seeding or transplanting.	Apply suspension directly to the surface of the soilless growing media immediately after seeding or transplanting into freshly prepared growing media: <ul style="list-style-type: none"> • 1 pt. suspension/sq. ft.

¹Prior to making drench applications, test a small batch of the suspension. Verify that your application spray equipment can properly apply the suspension without clogging or fouling the spray equipment.

STORAGE AND DISPOSAL

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

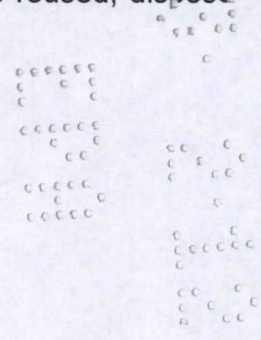
Pesticide Storage: Store **Incept** in a dry, cool location. Do not store above 75°F or below 40°F.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of onsite or at an approved east disposal facility

Container Handling

[Plastic or Bulk Bags greater than 150 lb.] – Non-refillable container. Do not re-use or refill this container. Completely empty bag into application equipment. Then offer for recycling, if available. Dispose of empty bag in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

[Fiber Drums with Polyliner (plastic bag) equal to or less than 150 lb.] – Non-refillable container. Do not re-use or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then offer for recycling if available or dispose of liner in a sanitary landfill, or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. If drum is contaminated and cannot be reused, dispose of it in the manner required for its liner.



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 buying or 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 must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, LLC or Seller. To the extent permitted by applicable law, 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. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and (2) Buyer and User assume the risk of any such use. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.**

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, 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.