

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

March 20, 2019

Prachi Pandya Federal Regulatory Affairs Associate SBM Life Science Corp. 1001 Winstead Dr., Suite 500 Cary, NC 27513

Subject: Notification per PRN 98-10 – Add label claim, graphic, internet address, Product Name: Insecticide TD Granule EPA Registration Number: 92564-49 Application Date: 2/8/2018 Decision Number: 538248

Dear Ms. Pandya:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, please contact Jacquelyn Herrick by phone at 703-347-0559, or via email at <u>herrick.jacquelyn@epa.gov</u>.

Sincerely,

fel Herrick for

Venus Eagle, Product Manager 01 Invertebrate & Vertebrate Branch 3 Registration Division (7505P) Office of Pesticide Programs

(Front Panel)

NOTIFICATION 92564-49

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated: 03/20/2019

Insecticide TD Granule

(ABN) Bayer Advanced 12-Month Tree & Shrub Protect and Feed Ready-To-Use Granules II; Bianova Advanced[™] 12-Month Tree & Shrub Protect and Feed Ready-To-Use Granules II; BioAdvanced[®][™] 12-Month Tree & Shrub Protect and Feed Ready-To-Use Granules II: BioAdvanced[®][™] Science-Based Solutions 12-Month Tree & Shrub Protect and Feed Ready-To-Use Granules II; Fortifend Advanced[™] 12-Month Tree & Shrub Protect and Feed Ready-**To-Use Granules II**

Fertilizer Claims:

- Feeds for up to 3 months •
- Keeps on feeding for up to 3 months
- Continuous feeding for up to 3 months
- Improves plant growth
- Improves plant health
- Revitalizes trees and shrubs
- Spurs tree and shrub recovery
- Stimulates Tree & Shrub recovery
- Advances plant health
- Increases plant health •
- Increases plant growth
- Promotes stronger roots systems .
- Provides slow release feeding (fertilizer)
- Provides slow release nitrogen
- Fertilizer Feeds for up to 3 months
- Improves Vitality of trees and shrubs

General & Combination Claims:

- (Dual Action) (2 in 1) Formula: Long lasting and Fast acting
- **Dual Action - Protect & Feeds**
- **Dual Action****
- Easy Measuring Cup
- No messy spraying
- Do it Yourself Tree Protection
- Feeds and protects against listed [*] insects in one easy step
- Protects for 12 months plus feeds
- 12-MONTH PROTECTION with one application
- Protects the entire tree or shrub especially new growth
- Systemic rainproof protection won't wash off .
- Kills listed [*] destructive insects including -Adelgids, Caterpillars, -Leafminers, Japanese Beetles, and other listed [*] insects
- Caterpillar Killer Formula
- No Spray
- Protects against listed [*] insects (including caterpillars) plus improves vitality of trees and shrubs
- No spraying! Measure and sprinkle at plant base
- A way to protect (and feed) trees and shrubs
- 100% sSatisfaction gGuaranteed (or your money back)*
- 33% more vs. 3 lb. size (4 lb. size)
- 25% more vs. 4 lb. size (5 lb. size)
- Kills destructive caterpillars (including gypsy moth, fall webworms).

- Protects trees and shrubs from listed [*] insects and feeds the roots
- Treats [X] trees[±] (x lb bottle)
- Treats 4 Trees[±] -(4 lb. bottle)
- Treats 10 Trees[±] -(10 lb. bottle)
- Patented formula protects your trees and shrubs from listed [*] insects plus feeds
- Ready to Spread Granules no mixing
- Fast releasing (dissolving) granules
- Easy to use granules

Pesticidal Claims:

- Stops Listed [*] Insect Feeding
- Protects trees, shrubs, and containerized plants from damaging listed [*] insects -with one easy treatment
- Helps keep trees and shrubs strong. Protects new growth
- Kills listed [*] insects that damage trees and shrubs
- Controls listed [*] insects that damage trees and shrubs
- Season long protection
- Year-long insect protection for trees and shrubs
- Systemic insecticide is absorbed through the roots, carried up into the plant and won't wash off
- Helps prevent listed [*] insects from damaging trees and shrubs
- Will not harm trees and shrubs
- For use on ornamental trees and shrubs and containerized plants
- Kills listed [*] insects & prevents new infestations
- Provides 12-Month listed [*] -Insect Protection
- Provides 12 months protection against listed [*] insects
- **Rainproof Protection**
- Apply granules around plant, water in, and walk awav
- Delivers 12 month listed [*] insect protection
- Delivers 12 months protection against listed [*] insects
- Delivers year long listed [*] insect protection
- Delivers year long protection against listed [*] insects
- Rainproof
- Kills listed [*] insects
- Listed [*] Insect protection
- For protection against listed [*] insects
- Protects Trees from roots to top

Potential Marketing Claims for New Easy Open Cap:

- Ridged Cap makes the bottle easy to open
- EZ Open Ridged Cap
- Easy Open Ridged Cap
- Easy Screw Off Cap
- EZ Open Cap
- Easy Open Cap
- Cap Opens Easily
- [Cap][Lid] [Top] opens with ease
- Cap Opens with Ease

- No more struggling to [remove][open]the cap with the [new][EZ] ridged cap
- Comfort Cap
- Easy Twist Off Cap
- Remove Cap Easily
- Easy twist off design
- Fill line helps you [measure][pour] the right amount
- Fill line helps you see how much to use
- No more guessing how much to use
- Fill measuring cap to the FILL LINE [indicated on the exterior of the cap] [(X oz.)]

Marketing Claim for Brand Name Change:

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- New Name. Same Great Results.
- New Name. Same Familiar Formula.
- New Name. Same Performance.

*listed [The word "listed" can appear as a footnote on the same page as the claim with the phrase, *listed insects] **Protects & Feeds *Assuming 8" circumference

ACTIVE INGREDIENTS:	
Imidacloprid	0.55%
Clothianidin	
OTHER INGREDIENTS:	
TOTAL:	100.00%

Net Contents: 1 lb., 4 lb., 10 lb., 20 lb.

This product contains 0.0055 lbs of Imidacloprid + 0.00275 lbs of Clothianidin per one pound of product.

STOP - Read This Entire Label Before Use KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel [Booklet] for Additional Precautionary Statements

Not for sale, distribution or use in New York State. Text in [] is optional.

First Aid +			
If swallowed:	 Call a poison control center or doctor immediately for treatment advice Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. 		
If on skin or clothing:	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice. 		

NOTE: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may contact 877-229-3763 for emergency medical treatment information. [Active Ingredients: 0.55% Imidacloprid ([CAS # 138261-41-3]) and 0.275% Clothianidin ([CAS # 210880-92-5]-]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

- Harmful if swallowed or absorbed through skin.
- Avoid contact with skin, eyes, or clothing.

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

Wear long-sleeved shirt and long pants, socks, shoes, and chemical resistant gloves made out of waterproof material.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to aquatic invertebrates.

To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters, or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Sweeping any product that lands on a driveway, sidewalk, or street, back onto the treated area of the lawn or garden will help to prevent run off to water bodies or drainage systems.

[BACK PANEL]

This product provides 12-month long lasting systemic protection against damaging listed [*] insects including Adelgids, Aphids, Borers, Caterpillars, Japanese beetles, Leafminers, Scale, and Whiteflies plus feeds in a single application. Having beautiful trees and shrubs has never been easier.

- No spraying or mixing
- Just measure, sprinkle, and water-in
- Protects & feeds entire tree or shrub

READ THE LABEL FIRST!

(Note to PM: Reference Statement for Booklets)

[For FIRST AID STATEMENT, ADDITIONAL PRECAUTIONARY STATEMENTS and DIRECTIONS FOR USE: See Inside Booklet.] [Open resealable label for Additional Product Information]

[Peel back for additional Precautionary statements and Directions for Use]

[Open Resealable Label for Directions for Use & [and] [Precautionary Statements].

QUICK FACTS

- Provides year long (12-month) Listed [*] Insect Protection
- Provides year long (12-month) protection against listed [*] insects
- Will Not Harm Trees, Shrubs, and Containerized Plants
- Easy to Use. Apply Around Plant, Water in and Walk Away
- Rain or Moisture can not wash off this internal protection
- Rainproof Protection
- Dual action kills listed [*] insects and feeds your tree
- Two Products in one, an insect killer and a fertilizer
- Two-in-One formula kills listed [*] insects while feeding your tree
- Double Action [(2-in-1)] Protects and Feeds
- Easy to Use measuring (devise name, i.e. cup, cap, etc.).
- Provides slow release feeding
- Provides 12-month listed [*] insect protection
- Provides 12-month protection against listed [*] insects

[Choose from any marketing claims]

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KILLS	Adelgids, aphids, borers, caterpillars, Japanese beetles, leafminers, scale, whiteflies, and other listed[*] insects.
WHERE TO USE	Outdoor ornamental trees and shrubs and containerized plants.
	Restriction: Do not apply to plants grown for food.
	Not for use on lawns.
HOW TO USE	1. Measure distance around tree trunk or height of shrub or determine container size.
	2. Apply required amount of product around plant base and water in.
HOW MUCH TO USE	Trees: approximately 1/4 cup for every inch of distance around trunk
	Shrubs: approximately 3/4 cup for every foot of height
	Containerized Plants: approximately 3 Tablespoons + 1 Teaspoon for each five gallon container
	(Note: Number of cups and tablespoons, or teaspoons will depend on bulk density of the formulation)
	10 Teaspoons for each five gallon container; treats up to 42 - five gallon containers (32 fl oz size)
	For questions or comments, call toll-free 1-877-229-3724 or visit our website at [www.bianovaadvanced.com][www.BioAdvanced.com] [www.bioadvancedsciencebasedsolutions.com][www.fortifendadvanced.com]insert company website here]

EPA Reg. No. 92564-49

EPA Est. No. XXXX-AA-XX

FERTILIZER ANALYSIS 2-1-1X-X-X

Information regarding the contents and levels of metals in this product are available on the Internet at http://www.aapfco.org/metals.html.

This product contains 0.0055 lbs of Imidacloprid + 0.00275 lbs of Clothianidin per one pound of product.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

- Harmful if swallowed or absorbed through skin.
- Avoid contact with skin, eyes, or clothing.
- Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

Wear long sleeved shirt and long pants, socks, shoes, and chemical resistant gloves made out of waterproof material.

ENVIRONMENTAL HAZARDS

- This pesticide is toxic to aquatic invertebrates.
- To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters, or surface
 waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or
 rain does not blow or wash pesticide off the treatment area. Sweeping any product that lands on a driveway, sidewalk, or street,
 back onto the treated area of the lawn or garden will help to prevent run off to water bodies or drainage systems.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Before use, read and follow all label directions.

BEFORE YOU USE	Restrictions:
Read and follow directions	- Do not apply near lakes, streams, rivers, or ponds.
when using.	- Do not apply to soils which are waterlogged or saturated.
	- Bucket or measuring utensils must not be used for any food or drinking water purposes after use with this product.
	 Do not allow people or pets to enter the treated area until the product has been watered in and allowed to dry.
	- Do not apply this product, by any application method, to linden, basswood, or other Tilia species.
	- Do not make more than one application per year.
	- Do not apply more than 0.4 lbs of the active ingredients (0.267 lbs imidacloprid + 0.133 lbs clothianidin) per acre per year. This bag [bottle] [jug] contains [X] lbs of the active ingredients.
	- Do not apply to plants grown for food.
	Apply this product only as specified on this label.
	- Do not use on lawns.

HOW TO USE	Apply the required amour	nt around	the base of the tree or	shrub. For co	ee trunk or height of the shrub. ontainerized plants, determine potting soil in the plant container.	
FOR USE ON	Outdoor ornamental trees, shrubs, and containerized plants.					
	Restriction: Do not apply					
CONTROLS	Adelgids Aphids		Fungus Gnat Larvae Japanese Beetles, Adult		Psyllids Royal Palm Bugs	
	Armored Scales (suppression)		Lace bugs		Root Weevil Larvae (including	
	Borers		Leaf Beetles (includir	ng Elm Leaf.	black vine weevils)	
	Roundheaded (including Eucalyptus Longhorned Borers) Flatheaded (including		Viburnum Leaf, and Lily Leaf Beetles)	Sawfly Larvae		
				ng Glassy-	Soft Scales (including lobate lac scales)	
	Bronze Birch, and Alde	,	winged Sharpshooter)		Thrips	
	Pine Bark Beetles (inclu		Leafminers (including		Whiteflies	
	Ips beetles) (suppressio	,	Boxwood Leafmine	ers)	White Grub larvae (such as	
	Caterpillars (including gypsy moths, fall webworms, and tent caterpillars) Mealybugs Pine Tip Moth		Mealybugs Pine Tip Moth Larvae	/ae	Japanese Beetles, Chafers, European Chafer, Oriental Beetle, Asiatic Garden Beetle)	
		 grams ai) approximately ¼ cup product around the tree trunk. Example: For a tree measuring 10 inches around, apply (4.6 grams ai) approximately 2 ½ cups (ten – ¼ cups) product in a circle 2 feet from the tree trunk. Use a flexible tape measure, or other measuring device when measuring the distance around a tree. 				
	Tree With 2 or More Trunks	Measure the distance in inches around each tree trunk at approximately 4.5 feet from ground level, add together, and multiply by 0.75. This measurement times 1/4 cups is the amount of product to apply around the tree trunk.				
		Example: A tree has 4 trunks. They measure 20, 10, 5, and 5 (inches) or a total of 40 inches. $40 \times 0.75 = 30$ then multiply $30 \times (0.46 \text{ grams ai}) \frac{1}{4}$ cups = (13.8 grams ai) 7 $\frac{1}{2}$ cups.				
	Shrubs	Measure the height of the shrub to the nearest foot. For each foot of height apply approximately ³ / ₄ cup product evenly around the shrub base.				
	Containerized Plants	Contai	ner Size	Amount	Product Needed	
		1 ga	allon	2 teasp		
		. 3			oons	
		-	allon	4 teasp		
		2 ga		-		
		2 ga 3 ga	allon	2 Table	poons	
		2 ga 3 ga 5 ga	allon allon	2 Table	ooons espoons espoons + 1 Teaspoon	

HOW TO APPLY	Trees and Shrubs:
	• For trees with distance around trunk less than 30 inches, apply the required amount of product evenly in a circle 2 feet from the tree trunk. Trees with distance around trunk greater than 30 inches, apply the product evenly in a circle 3-4 feet from the tree trunk.
	• For shrubs less than 3 feet tall, apply the required amount of product evenly in a circle 1 foot from the base of the shrub. Shrubs greater than 3 feet tall, evenly apply granules in a circle 2 feet from the base of the shrub.
	Brush or wash off any granules from plant foliage to prevent injury.
	Containerized Plants:
	Apply the required amount of granules evenly on top of potting soil and water thoroughly.
	• For the first 10 days, do not allow flushing through the container to the point where it flows out the bottom.
	• For indoor containerized plants, bring outdoors, make treatment, and return indoors when no excess water is present.
	Additional Directions:
	• Water in granules immediately after application with enough water to dissolve the granules and cause the soil to be wet to a depth of 3-4 inches. With watering, granules will slowly dissolve to release the insecticide and fertilizer into the soil.
	Pull back mulch and weed barrier before application.
	• Use this product as part of an overall tree and shrub health care program before problems start (preferably in the fall). (However,) This product can be applied anytime except when the soil is waterlogged or frozen. These conditions inhibit the movement of the product down into the root zone. During prolonged dry periods, saturate the soil around the tree or shrub well with water the night before making an application.
	• [For severe infestations, treat with a foliar insecticide such as (other Bayer Insecticide), then use this product as part of a routine care program.]
HOW IT WORKS	The insecticide dissolved in water moves down through the soil, where it is absorbed by the roots. Once absorbed, it moves up through the tree or shrub providing year-long listed [*] insect protection. This product even moves into new growth after application, thus protecting it, too! For listed [*] insect control, the insecticide must distribute completely through the tree or shrub. Depending on the size and health of the plant, this may take one week to three months (for very large trees). Rain or water cannot wash off this internal protection. In addition to listed [*] insect protection, a slow release nitrogen fertilizer is supplied for the tree or shrub.

(NOTE: Application to trees heavily infested may not prevent their eventual loss due to existing pest damage and tree stress.)

	STORAGE AND DISPOSAL			
Pesticide Storage	Store in original container in a cool, dry place, out of the reach of children, preferably a locked storage cabinet.			
Pesticide Disposal and Container Handling	 If empty: Non-refillable container. Do not refill or reuse container. Rinse the empty product container thoroughly and disperse the rinse water around trees or shrubs as part of application. Place empty container in trash or offer for recycling if available. 			
	 If partly filled: Call your local solid waste agency or toll free 1-877-229-3724 for disposal instructions. 			
	Never place unused product down any indoor or outdoor drain.			

NOTICE: Research and testing have determined that the "Directions for Use" are appropriate for the proper use of this product under expected conditions. The Buyer, to the extent consistent with applicable law, assumes responsibility for lack of performance or safety if not used according to the directions.

*Money Back Guarantee: If you are not satisfied with this product, we will gladly refund your original purchase price.

{Note to PM, batch code to be added at time of production}

BioAdvanced[™] [Fortifend Advanced[™]] [Bianova Advanced[™]] is a trademark of SBM Life Science Corp.

Produced for: [Distributed by]

SBM Life Science Corp. 1001 Winstead Drive, Suite 500 Cary, North Carolina 27513

Insecticide TD Granules (PENDING) 07/29/2016, 08/01/2016, 08/02/2016, 08/08/2016, 08/23/2016, 08/24/2016, 09/30/2016, 2/13/2016, 4/11/2017, 4/17/2017<u>11/03/2017</u> 03/20/2019 [Images]

[ART]

