

62097-4

05/04/2010

4/6



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

May 4, 2010

Frederick T. Smith
Senior Regulatory Specialist
SciReg, Inc.
12733 Director's Loop
Woodbridge, VA 22192

Subject: Notification to Add Label Language per PRN 98-10
Product Name: Novagib Technical
EPA Reg. No: 62097-4
Your Submission Dated March 30, 2010

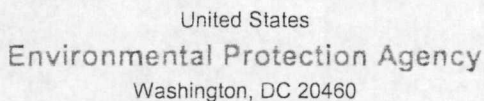
Dear Mr. Smith:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration Notice PRN 98-10, dated above. A screen of the request has been conducted for its applicability under PRN 98-10, and it has been determined that the action request falls within the scope of this document and is consistent with guidance in EPA's Label Review Manual. Our records have been duly noted, and the printed label with this application has been stamped "Notification Accepted" and will be placed in our records as current and updated. Should you have any questions regarding this action, you may contact Gina Casciano at (703) 605-0513 or via email at casciano.gina@epa.gov.

Sincerely,

Linda Hollis

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)



	Registration
	Amendment
x	Other

OPP Identifier Number

1. Company/Product Number 62097-4	2. EPA Product Manager L. Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Novagib Technical	PM# 90	
5. Name and Address of Applicant (Include ZIP Code) Fine Agrochemicals Ltd. Hill End House Whittington, Worcester WR5 2RQ UK <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 to a pesticide already registered and labeling to: <div style="display: flex; justify-content: space-between;"> <div>EPA Reg. No.</div> <div>Date: 5/4/10</div> </div> <div style="display: flex; justify-content: space-between;"> <div>Product Name</div> <div>Reviewer: G. Casciano</div> </div>	

☐ Amendment - Explain below.

☐ Resubmission in response to Agency letter dated _____

☒ Notification - Explain below.

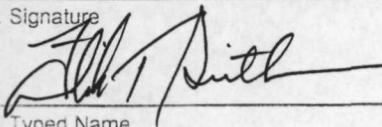
☐ Final printed labels in response to Agency letter dated _____

☐ "Me Too" Application.

☐ Other - Explain below.

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. 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.

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging		Unit Packaging		Water Soluble Packaging	
<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No	
* Certification must be submitted		If "Yes"		If "Yes"	
		Unit Packaging wgt.		Package wgt	
3. Location of Net Contents Information		4. Size(s) Retail Container		5. Location of Label Directions	
<input type="checkbox"/> Label <input type="checkbox"/> Container		55 lbs.		<input type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
		<input type="checkbox"/> Other _____			

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Frederick T. Smith	Title Agent	Telephone No. (Include Area Code) 703/494-6500
Certification I certify that the statements which 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 	3. Title Agent (SciReg, Inc.)	
4. Typed Name Frederick T. Smith	5. Date 3/31/10	

10

3/6

SciReg, Inc.
Science and Regulatory Consultants

March 31, 2010

Ms. Linda Hollis
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Dr.
Arlington, VA 22202-4501

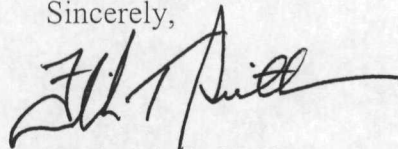
Re: Novagib Technical (EPA Reg. No. 62097-4)
-Notification consistent with PR Notice 98-10

Dear Ms. Hollis:

On behalf of Fine Agrochemicals Ltd. (Fine), SciReg, Inc. is submitting a notification consistent with PR Notice 98-10 add the statement, "This product may also be used to formulate products for any additional uses not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s)." Refer to Chapter 11, section V.A. of the Label Review Manual. Two copies of the revised label, one of which is highlighted to show the change, are included.

If you have any questions, please let me know.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures

46

NOVAGIB™ TECHNICAL

Technical Gibberellic Acid (GA₄ + GA₇)
(FOR MANUFACTURING USE ONLY)

For formulating products for use on nursery and orchard apple trees, non-bearing pear trees and sweet cherry trees. This product may also be used to formulate products for any additional uses not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s).

Active Ingredient	
Gibberellic Acid (GA ₄ + GA ₇)	93.1%
Other Ingredients	6.9%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Notification Accepted

Date: 5/4/10

Reviewer: G. Casciano

EPA Reg. No. 62097-4

EPA Est. No.

NET CONTENTS: 55 lbs. (25 kg)

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 SWALLOWED	<ul style="list-style-type: none"> • 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 a poison control center or doctor. • 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 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.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-858-7378 (National Pesticide Information Center) for emergency medical treatment information.	

March 31, 2010

Page 1

5/6

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes eye irritation. Avoid contact with eyes or skin. Harmful if inhaled. Do not get in eyes or on clothing. Avoid breathing spray dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash 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 product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your Regional Office of the EPA.

PHYSICAL AND CHEMICAL HAZARDS

FOR CHEMICAL EMERGENCY: spill, leak, fire, exposure, or accident call CHEMTREC, 1-800-424-9300.

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

This product is to be used for formulating products for use on nursery and orchard apple trees, non-bearing pear trees and sweet cherry trees. This product may also be used to formulate products for any additional uses not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s). Each formulator is responsible for obtaining EPA registration of its end-use products.

STORAGE AND DISPOSAL

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

Pesticide Storage: Keep containers tightly closed when not in use.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning, if available, 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.

WARRANTY DISCLAIMER AND LIMITATION OF LIABILITY

Fine Agrochemicals Limited ("FINE") warrants that this Product conforms to the specifications on this label. To the extent consistent with applicable law, FINE makes no other warranties and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for a particular purpose. No agent of FINE or any other person is authorized to make any representation or warranty beyond those contained herein.

It is impossible to eliminate all risks associated with this Product. Plant injury, lack of performance, or other unintended consequences may result because of factors such as

abnormal weather conditions, use of the Product other than in strict accordance with this label's instructions, presence of other materials, the manner of application or other factors, all of which are beyond the control of FINE or the seller. To the extent consistent with applicable law, all such risks shall be assumed by the Buyer.

To the extent consistent with applicable law: 1) FINE disclaims any liability whatsoever for special, incidental or consequential damages resulting from the handling or use of this Product and 2) FINE's liability under this label shall be limited to the amount of the purchase price or, at the election of FINE, the free replacement of the Product.

NOVAGIB™ is a trademark of Fine Agrochemicals Limited

Fine Agrochemicals Limited
Hill End House, Whittington
Worcester, WR5 2RQ
UNITED KINGDOM