

50534-7

01/12/2009

1/9



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Adora Clark, Ph.D.
GB Biosciences Corporation
P.O Box 18300
Greensboro, NC 27419-8300

JAN 12 2009

SUBJECT: Label Amendment to Add Additional Crops
Chlorothalonil Technical
EPA Reg. No. 50534-7
Your Submission Dated September 28, 2007

Dear Dr. Clark:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) which adds the following crops: Fruiting Vegetables Group 8; Cucurbits Group 9; Persimmon; Rhubarb; Horseradish; Ginseng; Yam; Okra; Lupin; Lentil; and Brassica, Head and Stem Subgroup 5A, as amended, is acceptable provided that you make the following label changes:

In a letter dated July 11, 2007 we asked that you do the following:

1. On page 4, under Conditions of Sales and Limitation of Warranty and Liability, first paragraph, the sixth line must read as follows: "control of GB Biosciences Corporation and Seller. To the extent permitted by applicable law, all such risks shall be..."
2. On page 4, under Conditions of Sales and Limitation of Warranty and Liability, second paragraph, the sixth line must read as follows: "reasonably foreseeable to or beyond the control of Seller or GB Biosciences Corporation, and to the extent permitted by applicable law, buyer....."
3. On page 4, under Conditions of Sales and Limitation of Warranty and Liability, third paragraph, the second line must read as follows: "or special damages resulting from the use of handling of this product. To the extent permitted by applicable law, the..."

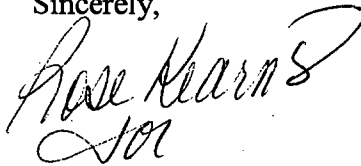
4. You must also submit the following:

- The analytical reference standard for 4-hydroxy chlorothalonil at the EPA National Pesticide Standards Repository has expired. By 4/1/09 you must either recertify the lot in the repository and send in an updated Certificate of Analysis, or submit a new standard (different lot #) if the previous lot will not be recertified.
- To support the use of the FIC formulation on non-bell peppers, by 12/31/2011 you must conduct one additional side-by-side field trial (860.1500) with non-bell peppers. The trial must reflect side-by-side plots receiving applications of the FIC and WDG formulations at 1x the proposed maximum seasonal rate and the trial must be conducted in Zone 8. If the trial indicates that residues in/on samples treated with the FIC formulation are higher than in/on samples treated with the WDG formulation, two additional field trials will be required, so that a total of three field trials are available reflecting application of the FIC formulation to non-bell peppers.
- Immunotoxicity 870.7800; due date is 2/1/2011
- Acute Neurotoxicity Study 870.6200; due date is 2/1/2010

Submit one copy of your final printed labeling before you release the product for shipment.

If you have any questions regarding this correspondence, contact Rose Kearns of my staff by phone at 703-305-5611 or via email at kearns.rosemary@epa.gov or myself at 703-308-9443 or via email at kish.tony@epa.gov.

Sincerely,



Tony Kish
Product Manager Team 22
Fungicide Branch
Registration Division (7505P)

Technical Chlorothalonil

Fungicide

For Formulation Purposes Only

Active Ingredient:	
Chlorothalonil (tetrachloroisophthalonitrile)	98.5%
Other Ingredients:	1.5%
Total:	100.0%

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.)

See additional precautionary statements and directions for use on label.

EPA Reg. No. 50534-7

EPA Est. _____

Net Weight

**ACCEPTED
with COMMENTS
In EPA Letter Dated**

**JAN 12 2009
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.**

50534-7

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 inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or ambulance then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a poison control center or doctor for further 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">• Call 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 by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
Note to Physician Possible mucosal damage may contraindicate the use of gastric lavage. Persons suffering with temporary allergic skin reactions may respond to treatment with oral antihistamines and topical or oral steroids.	
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	

5/9

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER/PELIGRO

Corrosive. Causes irreversible eye damage. May be fatal if inhaled. Causes skin irritation. Do not get in eyes, on skin, or on clothing. Do not breathe dust. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

Note to User: This product may produce mild bronchial irritation and temporary irritation of the skin characterized by redness or rash on exposed skin areas. Affected persons should consult a physician.

Environmental Hazards

This product is toxic to fish and wildlife. 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 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 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 should 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 GB BIOSCIENCES CORPORATION or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold GB BIOSCIENCES and Seller harmless for any claims relating to such factors.

GB BIOSCIENCES 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 GB BIOSCIENCES, and Buyer and User assume the risk of any such use. GB BIOSCIENCES 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 GB BIOSCIENCES 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 GB BIOSCIENCES 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 GB BIOSCIENCES OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

GB BIOSCIENCES 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 GB BIOSCIENCES.

DIRECTIONS FOR USE

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

FOR FORMULATION PURPOSES ONLY

Formulators using this product are responsible for obtaining EPA registration for their formulated product which may be labeled for the use patterns as listed on this label.

This product is intended for formulation into a fungicide/mildewicide for the following uses:

1. Terrestrial Food and Feed Crops, Greenhouse Crops

almonds	cranberry	passion fruit
apricot	cucumber	peach
asparagus	- <u>eggplant</u>	peanuts
banana	filberts (hazelnuts)	- <u>pepino</u>
beans (succulent and dry)	garlic	- <u>peppers (includes bell pepper, chili pepper, cooking pepper, pimento, sweet pepper)</u>
blueberry	- <u>ginseng</u>	- <u>persimmon</u>
broccoli	- <u>gourds</u>	pistachio
Brussels sprouts	- <u>groundcherry</u>	plum
cabbage	- <u>horseradish</u>	potato
carrot	<u>kohlrabi</u>	prune
cauliflower	leeks	- pumpkin
<u>cavalo broccolo</u>	- <u>lentil</u>	- <u>rhubarb</u>
celery	- <u>lupine</u>	shallot
<u>chayote</u>	mango	soybean
cherry	melon	- squash (summer, winter)
Chinese broccoli	mint	- <u>tomatillo</u>
Chinese cabbage	- <u>Momordica spp. (Bitter melon, Balsam apple)</u>	- tomato
<u>Chinese cabbage (napa)</u>	mushrooms	- <u>yam</u>
<u>Chinese mustard cabbage</u>	nectarine	- <u>zucchini</u>
- <u>Chinese waxgourd</u>	- <u>okra</u>	
cocoa bean	onions (dry, green, seed)	
coffee bean	papaya	
corn (sweet, for seed)	parsnip	

2. Terrestrial Non-Food, Greenhouse, Nursery

turf	conifers
sod farms	Christmas trees
ornamental plants, trees, shrubs	forest stand
grasses grown for seed	

- 8
9
3. **Additive for aqueous paints, stains, coatings, adhesives, caulks, sealants, grouts, joint compounds, and wood preservative stains.** Product incorporation into coatings and adhesives used for indirect food contact, require approval from FDA via a food additive petition.
 4. This product must not be formulated into products labeled for use on home lawns.
 5. This product may be used to formulate product for additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with the U.S. EPA submission requirements regarding support of such use(s).
 6. This product may only be used to manufacture wettable powder formulations that 1) are packaged in water-soluble packets the outside of which contain a pictogram depicting that users should not cut, rip, or tear, or 2) bear the labeling "For use in closed mixing/loading systems only."
 7. This product must not be formulated into a product intended as a mildewcidal paint additive designed for direct sale to retail customers, e.g., in a 'pillow pack' or other small volume one-use package.
 8. This product may only be formulated into mildewcidal paint additive products that are labeled as follows: This product may only be added to paint products that are labeled A) with product-specific instructions for the use of a respirator during application, or B) as follows 'When applying with a sprayer, wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any R, P, or HE filter. If oil is not present in the paint product or recommended for use as an additive in the paint product, add "N" as an additional respirator type.'
 9. This product must not be used to formulate products for use as in-container preservatives.
 10. This product may be used for experimental purposes that are in compliance with U.S. EPA requirements.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

Pesticide Storage

Store in a cool place. Protect from excessive heat.

Pesticide Disposal

Pesticide wastes are toxic. Improper disposal of excess pesticide, pesticide formulation, or rinsate is a violation of federal law. If these wastes can not be disposed of by use according to label instructions, contact your State Pesticide or Environmental

9
9

Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal

Completely empty bag into formulation equipment. Then dispose of empty bag in a sanitary landfill or by alternative methods allowed by state and local authorities.

©2007 GB Biosciences

For non-emergency (e.g., current product information) call
Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:
GB Biosciences Corporation
Greensboro, NC 27409
www.syngenta-us.com

TECH CHLO 50534-7 AUG07 AMEND – df – 8/27/07
050534-00007.20070727.TECH-CHLO-AUG07-AMEND-HIGHL.PDF