



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Ms. Tamara Murphy Regulatory Project Manager Syngenta Crop Protection, Inc. P.O. Box 18300 Greensboro, NC 27419-8300

JAN 20 2011

Subject:

Add new uses on bananas, citrus, grapes, and sugar beets and establish a tolerance

on imported potatoes

Product Name: Fluazifop-P-butyl Technical

EPA Registration Number: 100-1001

Decision Number: 423996

The amendment referred to above, submitted in connection with registration under section 3(C)(7)(A) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), is conditionally accepted provided that you:

- 1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) or 4(a) when the Agency requires all registrants of similar products to submit such data.
- 2. Submit all data listed below by February 28, 2013:
  - Guideline 860.1380: Storage Stability for processed commodities
  - Guideline 860.1520: Citrus Processing Study
  - An aspirated grain fraction study for soybean
  - Three (3) additional field trials are needed for soybean seed with two (2) of the trials to include residue decline studies
  - Guideline 870.3250: 90-day dermal Study
  - Guideline 870.3465: 90-day/28-day Inhalation Study
  - Guideline 870.6200: Neurotoxicity Battery
  - Guideline 870.7800: Immunotoxicity Study
  - <u>Guideline 835.1230 or 835.1240:</u> Leaching and adsorption/desorption of fluazifop-p-butyl and fluazifop-p-acid in U.S. soils.
  - <u>Guideline 835.2120:</u> A hydrolysis study examining the ratio of enantiomers or enantiomer excess in water is needed for fluazifop-p-butyl and fluazifop-p-acid to determine whether fluazifop-p-butyl or fluazifop-p-acid undergo enantiomerization in water as seen for some compounds such as pyrethroids.
  - Guideline 835.2240: Photodegradation in Water for fluazifop-p-acid.
  - <u>Guideline 835.4100:</u> Aerobic soil metabolism study with fluazifop-p-butyl that identifies the ratio of enantiomers of fluazifop-butyl and fluazifop-acid in an American soil.

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## Data Requirements Continued:

- <u>Guideline 835.6100:</u> Terrestrial Field Dissipation Study examining degradation of all major degradates
- Validation of analytical methods used in field studies.
- Storage stability studies to support terrestrial field dissipation studies.
- Analytical chemistry methods capable of identifying and quantifying each separate enantiomer and fluazifop-butyl and fluazifop-acid in soil, water, and tissue.
- <u>Guideline 850.4150:</u> Vegetative Vigor (Tier I) for Fluazifop-p-butyl and Degradate X
- <u>Guideline 850.4550:</u> Algal Plant Toxicity (Tier I) for Fluazifop-p-butyl and Degradate X
- <u>Guideline 850.4400:</u> Aquatic Plant Growth (Tier I) for Fluazifop-p-butyl and Degradate X
- Guideline 850.1075: Freshwater Fish Acute LC<sub>50</sub> for Degradate-X
- Guideline 850.1010: Freshwater Invertebrate Acute LC<sub>50</sub> or EC<sub>50</sub> for Degradate-X
- Guideline 850.1075: Estuarine/Marine Fish LC<sub>50</sub> for Degradate-X
- <u>Guideline 850.1025 and 850.1055</u>: Estuarine/Marine Invertebrate (Mollusk) shell deposition or embryo-larval EC<sub>50</sub> for Degradate-X
- Guideline 850.1035 and 850.1045: Estuarine/Marine Invertebrate (Shrimp) for Degradate X
- <u>Guideline 850.1400:</u> Fish Early Life-Stage for Degradate X
- Guideline 850.1300 and 850.1350: Aquatic Invertebrate Life-Cycle for Degradate X
- Guideline 850.1500: Fish Full Life-Cycle for Degradate X
- 3. To the proposed Fluazifop-P-butyl Technical label, make the changes listed below:
  - a. Assure that the EPA establishment number and Net Weight are added.
  - b. Revise the Storage and Disposal section to comply with PR Notice 2007-4 pesticide removal and container handling requirements.
  - c. List the individual citrus fruits in parentheses after, "Citrus Fruits" in the terrestrial food use sites section so that it reads as follows:
     "Citrus Fruits (Calamondin, Citrus citron, Citrus hybrids, Grapefruit, Kumquat, Lemon, Lime, Mandarin (Tangerine), Orange (all), Pummelo, and Satsuma mandarin)"

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4. Revise proposed tolerances: The proposed tolerances should be revised to reflect the tolerance levels and corrected commodity definitions as specified in Table 2 of the Agency's memorandum, "Revised Fluazifop-P-Butyl. Amended Human Health Risk Assessment to Support Use on Bananas, Citrus, Grapes, Sugar Beets, and the Establishment of a Tolerance on Imported Potatoes."

One copy of the product label stamped "Accepted with Comments" is enclosed for your records. Products shipped after 18 months from the date on this notice or the next printing whichever occurs first, must bear the new revised label. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA. Your release for shipment of this product constitutes acceptance of these conditions. This label supersedes all previous accepted labels. You must submit one copy of the final printed label before this product is released for shipment.

Sincerely,

Kathryn V. Montague Product Manager (23)

Herbicide Branch

Registration Division (7505P)

Fluazifop-P-butyl Technical

A Herbicide For Formulating Use Only

**Active Ingredient:** 

butyl(R)-2-[4-5-(trifluoromethyl)-2-pyridinyl)oxy]phenoxy)propanoate	93.0%
Other Ingredients:	7.0%
Total:	100.0%

## KEEP OUT OF REACH OF CHILDREN.

### **CAUTION**

See additional precautionary statements and directions on label.

ACCEPTED with COMMENTS In EPA Letter Dated:

JAN 2 0 2011

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

100-1001

EPA Reg. No. 100-1001

EPA Est.

Product of

Net Weight

FIRST AID		
If swallowed	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a poison control</li> </ul>	
	center or doctor.	
	Do not give anything by mouth to an unconscious person.	
lf on skin or	Take off contaminated clothing.	
clothing	Rinse skin immediately with plenty of water for 15-20 minutes.	
	Call a poison control center or doctor for treatment advice.	
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> </ul>	
	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	Move person to fresh air.	
	If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.	
	<ul> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>	
Have the produc	ct 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**

# **CAUTION**

Harmful if swallowed. Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

### **Environmental Hazards**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with 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.

# **Physical or Chemical Hazards**

Do not use or store near heat or open flame.

### 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, Inc. 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 this 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.

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### DIRECTIONS FOR USE

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

Formulators using product are responsible for obtaining EPA registration for their formulated product.

### STORAGE AND DISPOSAL

### **Prohibitions**

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

## **Pesticide Storage**

Keep container closed when not in use. Do not store near food or feed. Protect from freezing. In case of spill or leak on floor or paved surfaces, soak up with sand, earth or synthetic absorbent. Remove to chemical waste area.

## **Pesticide Disposal**

Pesticide wastes are toxic. Improper disposal or excess pesticides, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Agency, or the Hazardous Waste representative of 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 by other procedures approved by state and local authorities.

Only for formulation into a herbicide for the following uses:

#### Terrestrial - Food

Asparagus, Bananas, Carrots, Citrus Fruits, Dry Bulb Onions, Garlic, Grapes, Coffee, Cotton, Pecans, Rhubarb, Soybeans, Stonefruit (Apricots, Cherries, Nectarines, Peaches, Plums, Prunes), Sugar Beets, Sweet Potatoes, Yams, Tabasco Peppers.

### **Terrestrial - Nonfood**

Ornamentals, non-bearing citrus, nuts, berries, pome fruits.

- 2. Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- 3. Uses for experimental purposes that are in compliance with USEPA requirements.

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

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

**SCP 1001A** 

Fluazifop-P-Butyl Technical 1001 Amend 0909 - bb - 9-29-09

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