

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

NOV 2 7 2002

Prasad Rao Aventis CropScience 2 T.W. Alexander Drive Research Triangle Park, North Carolina 27709

Subject:

Prep brand Ethephon Plant Regulator for Cotton

EPA Registration No. 264-380

Your label amendment application dated August 12, 2002

Dear Mr. Rao,

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended is acceptable, provided that you comply with the following conditions.

- 1. You must make the following changes to the label:
- a. At every place in the label where it occurs, "PREP" (without any additional product name) or "PREP brand Ethephon" must either be changed to a nonspecific term such as "this product" or else changed to "PREP brand Ethephon Plant Regulator for Cotton", the complete name of the subject product. "PREP" and "PREP brand Ethephon" are also part of the name of EPA Reg. No. 264-418.
- b. In the "IF IN EYES:" subsection of the "FIRST AID" section, in the second statement add "eye" after "then continue rinsing".
- c. In the first sentence in the "PERSONAL PROTECTIVE EQUIPMENT (PPE)" section, add "made of any waterproof material" after "chemical resistant gloves".
- d. In the first sentence in the second-to-last paragraph in the "AGRICULTURAL USE REQUIREMENTS" section, change "chemical resistant gloves such as any waterproof gloves" to "chemical resistant gloves made of any waterproof material, such as nitrile, butyl, neoprene, or barrier laminate".

- e. Move the sentence "Do not contaminate water, food, or feed by storage or disposal." in the "STORAGE" subsection of the "STORAGE AND DISPOSAL" section to just after the "STORAGE AND DISPOSAL" heading, change the name of the "STORAGE" subsection to "PESTICIDE STORAGE", and provide appropriate statements for spills specifically (not solely spills), in this subsection.
- f. In the fourth sentence of the fourth paragraph in the "GENERAL INFORMATION" section, change "Harvest at optimun boll opening..." to "Harvest at optimum boll opening...".
- g. In the second paragraph of the "Pre-treatment With Defoliants Prior to PREP Treatment" subsection of the "PRECONDITIONING FOR DEFOLIATION" section, change "...section on how th test for Boll Maturity..." to "...section on how to test for Boll Maturity...".
- 2. Submit one copy of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration may be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

If you have any questions about this letter, please contact John Bazuin at (703)305-7381.

Sincerely yours,

Cynthia L. Giles-Parker

Product Manager (22)

(5/

Fungicide Branch

Registration Division (7505C)

Attachment: Label stamped "ACCEPTED with COMMENTS"

PREP[™] brand Ethephon

PLANT REGULATOR FOR COTTON

FOR COMMERCIAL USE OR AGRICULTURAL USE ONLY.
NOT FOR RESIDENTIAL USE.

ACTIVE INGREDIENT:
Ethephon (2-chloroethyl) phosphonic acid*
INERT INGREDIENTS:
*This product contains 4 pounds ethephon per gallon.

EPA Reg. No. 264-380

EPA Est. No. 264-PA-01

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.)

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577

For PRODUCT USE Information Call 1-888-AVENTIS (1-888-283-6847)

The use of this product for a variety of plant growth regulation uses is covered by United States and foreign patents including U.S. Patent 4,240,819. No license is granted to use this product in countries other than the United States or for any use not contemplated by this label. Liability for patent infringement may result from use or sale of this product outside the United States.

FIRST AID

IF IN EYES:	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.
	Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING:	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:	Immediately call a poison control center or doctor for treatment advice.
	Do not induce vomiting unless told to do so by a poison control center or doctor.
	Have person sip a glass of water if able to swallow.
	Do not give anything by mouth to an unconscious person.

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

NOTE TO PHYSICIAN: Treat symptomatically. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred. No specific antidote is available. Probable mucosal damage may contraindicate the use of gastric lavage.

PRECAUTIONARY STATEMENTS

DANGER

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Corrosive. Causes irreversible eye damage and skin irritation. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing.

Harmful or fatal if swallowed. Avoid contamination of food.

with COMMENTS In EPA Letter Dated: ·

NOV 27 2002

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

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear long-sleeved shirt and long pants, chemical resistant gloves (such as Nitrile, Butyl, Neoprene and/or Barrier Laminate), shoes plus socks and protective eyewear.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing. Wash the outside of gloves before removing.

ENVIRONMENTAL HAZARD

Avoid spray drift to nearby crops as this product may cause temporary modifications in plant growth. Do not contaminate water used for irrigation or domestic purposes.

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

Do not exceed the rate of PREP™ brand Ethephon Plant Regulator for Cotton per acre per year recommended on this label.

SPRAY DRIFT

Avoid spray drift. Do not apply when weather conditions may cause drift. Do not allow this product to drift on to non-target areas. Drift may result in illegal residues or injury to adjacent crops and vegetation, in the form of leaf yellowing and defoliation. To avoid spray drift, DO NOT apply aerially when wind speed is greater than 10 mph or during periods of temperature inversions. Use of larger droplet size will also reduce spray drift.

AVOIDING SPRAY DRIFT AT THE APPLICATION SITE IS THE RESPONSIBILITY OF THE APPLICATOR.

The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator is responsible for considering all these factors when making decisions.

The following drift management requirements must be followed to avoid off-target movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.

- 1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.
- 2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.

Where states have more stringent regulations, they should be observed.

The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory below:

ERIAL DRIFT REDUCTION ADVISORY

[This section is advisory in nature and does not supersede the mandatory label requirements].

INFORMATION ON DROPLET SIZE

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable environmental conditions (See Wind, Temperature and Humidity, and Temperature Inversions).

CONTROLLING DROPLET SIZE

Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.

Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

BOOM LENGTH

For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

APPLICATION HEIGHT

Applications should not be made at a height greater than 10 feet above the top of the target plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

SWATH ADJUSTMENT

When applications are made with a crosswind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator should compensate for this displacement by adjusting the path of the aircraft upwind. Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.).

WIND

Drift potential is lowest between wind speeds of 2 - 10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE AND HUMIDITY

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

TEMPERATURE INVERSIONS

Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. noke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and apidly dissipates indicates good vertical air mixing.

SENSITIVE AREAS

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

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 requirements specific to your State or Tribe, consult the agency responsible for pesticide regulations.

Read entire label before using this product.

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), notification to workers and restricted-entry interval. The requirements in this ax only apply to uses of this product that are covered by the Worker Protection Standard.

up not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 48 hours. The REI is 72 hours in areas where average rainfall is less than 25 inches per year.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated such as plants, soil or water is coveralls over long-sleeved shirt and long pants, chemical resistant gloves such as any waterproof gloves, chemical resistant footwear plus socks, and protective eyewear. For overhead exposure, chemical-resistant headgear is also required.

Notify workers of the application by warning them orally and posting warning signs at entrances to treated areas.

STORAGE AND DISPOSAL

STORAGE

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

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, 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 Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL

Triple rinse (or equivalent) the empty containers. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary lar.cfill, or by incineration or if allowed by state and local authorities, by burning. If container is burned, stay out of smoke.

GENERAL INFORMATION

A foliar spray of PREP™ brand Ethephon Plant Regulator for Cotton will accelerate opening of mature unopened cotton bolls and enhance defoliation which can result in earlier harvest with an increased recoverable yield. PREP™ brand Ethephon treatment allows increased efficiency from a once-over harvest.

Some premature drop of small, immature bolls may be associated with treatment. Do not apply before sufficient, mature, unopened bolls have developed to produce the desired yield of cotton.

A boll is mature when it is too hard to be dented when squeezed between thumb and fingers, too hard to be sliced with a sharp knife, and when the seed coat becomes light brown in color.

For best results, thorough and uniform spray coverage is required. It is essential that the bolls are contacted by the spray to obtain optimum boll opening. Observe treated fields closely. Harvest at optimun boll opening and defoliation, generally 14 to 21 days after treatment. Sustained cold weather with average day and night temperatures of 65°F or lower after treatment with PREP™ brand Ethephon will delay the boll opening response.

DO NOT APPLY PREPTM BRAND ETHEPHON IF RAIN IS EXPECTED WITHIN 6 HOURS. Rainfall within 6 hours of application may reduce product performance.

Certified cotton seed growers should observe boll and seed maturity before treatment with PREP™ brand Ethephon. Bolls not completely mature might open with treatment of PREP™ giving lower quality seed.

IMPORTANT: Do not apply PREP™ brand Ethephon through any type of irrigation system.

SPRAY PREPARATION

Add 1/2 to 3/4 of the required amount of water to the spray tank. Start agitation. Add the required amount of PREP™ brand Ethephon, and the remaining amount of water. Prepare only as much spray solution as can be used on the day of mixing. Do not allow spray solution to stand overnight. Do not spill the concentrated product on spray equipment, or any airplane parts. ANY SPILLS SHOULD BE RINSED IMMEDIATELY WITH PLENTY OF /ATER.

Use of a nurse tank is highly recommended for avoiding possible spills of concentrated formulation on spray equipment or any airplane parts.

EQUIPMENT CLEANING

Spray deposits of PREP™ brand Ethephon, when left on aircraft acrylic plastic typè windshields for longer than 1 hour, may react with this material, forming an opaque film or spots on the surface which cannot be removed by washing with water or any other cleaner. Rinse windshields with water immediately after each tankload of PREP™ has been applied. Thoroughly rinse the aircraft with clean water after each day PREP™ is applied.

PREP™ brand Ethephon may also affect certain paints, and if accidental deposits on painted objects such as cars, trucks, agricultural equipment, etc. occurs, these objects should be rinsed with water as soon as possible (within 1 hour) to prevent permanent staining of the painted surface.

Because of the acidic nature of this product, prolonged exposure to spray deposit will damage acrylic plastics, certain paints, and metals.

Rinse thoroughly with a detergent and water all exposed acrylic plastic-type materials (e.g., aircraft windshields), and painted surfaces within an hour after exposure to spray deposits. At the end of each day, rinse thoroughly with a detergent and water all the metal parts of the aircraft and the associated spray equipment exposed to the spray deposits.

BOLL OPENING

Rates For Boll Opening

ONDITIONS EXPECTED J-7 DAYS AFTER	PREP™	ONE GALLON OF PREP™	SPRAY VOLUME <u>GAL./ACRE</u>		
TREATMENT	QUARTS/ACRE	TREATS	GROUND	AIR	
Hot and dry 80°F or higher	1.0 (1.0 lb a.i.)	4 Acres	15 to 50	2 to 5*	
Dry with temperature 75°F to 80°F	1.5 (1.5 lb a.i.)	2.5 Acres	15 to 50	2 to 5*	
Cool but higher than 65°F	2.0 (2.0 lb a.i.)	2 Acres	15 to 50	2 to 5*	
Rank cotton	2.0 (2.0 lb a.i.)	2 Acres	25 to 50	5	

*NOTE: For California and Arizona use a volume of no less than 5 gallons per acre for aerial applications

Time of Application (Boll Opening)

Apply when there are sufficient mature unopened bolls to produce the desired yield, but no later than when 60% of the polls are opened (see General Information section on how to test for boll maturity). Do not tank mix PREP^{IM} brand Ethephon with a desiccant if the cotton is to be spiritle harvested.

Rates For Preconditioning For Defoliation

CONDITIONS EXPECTED 5-7 DAYS AFTER PREP™		ONE GALLON OF PREP™	SPRAY VOLUME GAL./ACRE	
TREATMENT	QUARTS/ACRE	TREATS	GROUND	AIR
Hot and dry 80°F or higher	0.5 (0.5 lb a.i.)	8 Acres	15 to 50	2 to 5*
Cool but higher than 65° and also for rank cotton	1.0 (l.0 lb a.i.)	4 Acres	15 to 50	2 to 5*

^{*}NOTE: For Californi

Time of Application (Preconditioning)

Apply PREP™ brand Ethephon 4 to 7 days prior to application of defoliant or tank mixed with the defoliant (see section on Compatibility). Do not tank mix PREP™ with desiccants unless plant desiccation is required.

Pre-treatment With Defoliants Prior to PREP™ Treatment

If the cotton is overly rank or laying down in the middles and good spray coverage of the bolls with PREP™ brand Ethephon is difficult, a pretreatment with defoliants will be useful to improve boll coverage with PREP™. Use dosage rates of PREP™ recommended for boll opening. Read and observe all appropriate label use directions and precautions for the defoliant used.

Do not use a defoliant before there are sufficient mature unopened bolls to produce the desired yield (see General Information section on how th test for Boll Maturity).

COMPATIBILITY

PREP™ brand Ethephon is compatible with DEF, FOLEX, DROPP, HARVADE, METHYL PARATHION, GUTHION AND MALATHION, and may be applied in sequence or as a tank mixture (DO NOT TANK MIX WITH DEFOLIANTS OR DESICCANTS IN CALIFORNIA AND ARIZONA). In some cases slight reduction in boll opening response has been observed when tank mixes with defoliants were used.

Good agitation in the spray tank is essential and a tank mixture should not be allowed to stand without agitation for more than 5 to 10 minutes. Read and observe all appropriate label use directions and precautions for the defoliants and insecticides used.

PRECAUTION:

NOTE: UNDER CERTAIN CONDITIONS, TANK MIXTURES OF PREP™ BRAND ETHEPHON WITH DESICCANTS CONTAINING SODIUM CHLORATE COULD RESULT IN THE FORMATION OF HYPOCHLOROUS ACIDS WHICH ON HEATING WILL EMIT TOXIC CHLORIDE FUMES.

DO NOT MIX PREP™ BRAND ETHEPHON WITH AMMONIUM THIOSULFATE. SUCH TANK MIXTURES MAY RESULT IN FORMATION OF TOXIC FUMES.

WHEN TO HARVEST:

Do not harvest cotton sooner than 7 days after a treatment with PREP^M brand Ethephon. Observe the treated crop and harvest when optimum boll opening has been reached. Too early harvest might reduce the full advantage of the treatment and too late a harvest may result in reduced quality and ass of lint which will drop from the plant.

USE LIMITATIONS

- Do not exceed a maximum of 2.0 lb. ethephon active ingredient per acre per year through combined or repeated uses of any ethephon products.
- Boll Opening: Do not tank mix PREP™ brand Ethephon with a desiccant if the cotton is to be spindle harvested.
- Pre-Condition for Defoliation: Do not tank mix PREP^{IM} brand Ethephon with desiccants unless plant desiccation is required. Do not use a defoliant before there is sufficient mature unopened bolls to produce the desired yield (see General Information section on how to test for boll maturity.
- Do not plant another crop within 30 days after treatment.

USE PRECAUTIONS

Avoid spray drift to nearby crops as this product will cause modifications in plant growth. Plant injury or reduced yields will result.

Mix only the amount of spray you expect to use each day. Do not allow mixed solution to stand overnight.

For California and Arizona use a volume of no less than 5 gallons per acre for aerial applications.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and should be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Aventis CropScience. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: AVENTIS CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Aventis Cropscience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. AVENTIS CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT AVENTIS CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

Aventis CropScience USA LP P.O. Box 12014, 2 T.W. Alexander Drive Research Triangle Park, North Carolina 27709

PREP is a trademark of the Aventis Group.

PREP™ brand Ethephon Plant Regulator for Cotton (PENDING) Submitted 7/17/02.