




STATE OF MAINE
DEPARTMENT OF AGRICULTURE, FOOD & RURAL RESOURCES
BOARD OF PESTICIDES CONTROL
28 STATE HOUSE STATION
AUGUSTA, MAINE 04333-0028

SETH BRADSTREET
COMMISSIONER
HENRY S JENNINGS
DIRECTOR

January 12, 2009

To: Pesticide Control Board Members
From: Wes Smith 
Re: Special Local Needs (24c) Registration for use of Ethrel (Ethepon Plant Regulator) EPA Reg# 264-267 on large-fruited greenhouse tomatoes.

Last month, in accordance with the new 24c policy, I sent you a copy of the above referenced 24c application. Questions were received regarding the mechanism of action in plants and its toxicity in humans. As requested, Lebelles has answered these questions in her attached memo.

Please bring the 24c package to the Board meeting.



JOHN ELIAS BALDACCI
GOVERNOR

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SETH BRADSTREET
COMMISSIONER
HENRY JENNINGS
DIRECTOR

To: Board Members
From: Lebelle Hicks PhD DABT
RE: 24c for Ethrel (EPA# 264-267) on Greenhouse Tomatoes

January 8, 2009

As discussed in Wes' December 22, 2008 memo regarding the consideration of a 24c for Ethrel; 21.7 % ethephon (2 lbs/gal) (EPA# 264-267) on greenhouse tomatoes, I had concern about worker exposure to ethephon following its use. The 24c label states that there is a 48-hour restricted entry interval (REI), when all personal protective equipment required on the label must be used when entering the treated areas.

EPA issued a re-registration eligibility decision for ethephon in 1995 and re-assessed tolerances in 2006. Ethephon is a simple organophosphate (OP) with the chemical formula (2-chloroethyl) phosphonic acid (CAS# 16672-87-0). Ethephon breaks down into ethylene (gas), phosphate and chloride. Ethylene gas is the compound given off by rotting fruit that increases the ripening or rotting of other fruit, this is why one bad apple spoils the whole bunch.

As an OP the toxicological mechanism of action for ethephon is cholinestase inhibition. Cholinergic symptoms of exposure are seen at very high doses (relative to other OPs) and the oral LD₅₀ in rats is 1,600 mg/kg. The major toxicological concern is the fact that ethephon is corrosive to skin. At skin exposure levels where there the skin remains intact, there is no cholinesterase inhibition observed. Therefore, protective clothing adequate to prevent skin damage will also prevent cholinesterase inhibition

Bayer provided a worker risk assessment for post application inhalation exposure consistent with standard EPA risk assessment methodology. This assessment indicated that the risks from inhalation post-application exposures would be within the acceptable range provided the REI was observed. This is standard EPA methodology for assessing risks.

The tolerance for ethephon on tomatoes is 2 ppm (40CFR180.300). Bayer submitted data indicating that residues from the greenhouse use on tomatoes would not exceed this tolerance.



Bayer CropScience



Mr. Wesley C. Smith
Board of Pesticides Control
Maine Department of Agriculture
28 State House Station
Augusta, ME 04333-0028

December 12, 2008

Bayer CropScience
RTP
P. O. Box 12014
RTP, NC 27709
Tel. 919 549-2000

RE: ETHREL® brand Ethephon Plant Regulator
Special Local Need Application
For Use on Large Greenhouse Tomatoes
EPA Reg. No. 264-267

Dear Mr. Smith;

On behalf of the greenhouse tomato growers in Maine, Bayer CropScience LP supports their request for use of Ethrel® brand Ethephon Plant Regulator, active ingredient ethephon, for use on large-fruited greenhouse tomatoes. The proposed Special Local Need request will allow use of Ethrel at the end of the season to speed the harvest and shorten the time to plant the next crop, as well as early season application to aid in uniformity of cluster fruit ripening.

IR-4 has conducted studies and is currently collecting data to submit their petition to EPA at the end of 2008. The petition will include all greenhouse tomato varieties. Ethrel has been registered for field tomatoes for many years, and is a valuable tool to promote uniform fruit ripening and increase harvest. Use in the greenhouse will help increase tomato production in an industry that has grown significantly in the past two decades. Currently there is no other product available that can be used to aid in the maturation process of this fruit.

To address any concern for Worker Exposure for greenhouse application, Dr. Curt Lunchick, BCS Product Safety and Toxicology expert, states the Personal Protection Equipment (PPE), Re-entry Interval (REI) and precautionary language included in the Agricultural Use section is acceptable to prevent adverse exposure or effects on workers in the greenhouse. Worker exposure risk assessment for mixer/loaders, applicators and reentry workers in greenhouse application was prepared and is enclosed for review.

In reply to Item #11 on EPA Form 8570-25 with regard to the Endangered Species Act, this product is currently registered in Maine and any additional use under this proposed special local need will have negligible, if any, impact on non-target organisms, including endangered species. Based on the final RED document for ethephon, there would be minimal affect with proposed use of Ethrel on tomatoes in greenhouse applications.

In support of this SLN petition we have provided residue data conducted on greenhouse tomato located in Colorado, Florida and Texas. Based on the studies, residues were found to be within range for large-fruited tomatoes. SLNs for this use are approved in Arizona, Colorado, Texas and Pennsylvania. An application is pending in California.



Mr. Wesley C. Smith
Ethrel Special Local Need Application
December 12, 2008
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Additional supporting documents include:

1. EPA Form 8570-25/Application to Register SLN
2. Draft SLN label – Ethrel brand Ethephon Plant Regulator
3. EPA Approved Label, dated March 6, 2001
4. Letter of support: Erika Roderick, IPM Department, Backyard Farms
5. Ethephon: Magnitude of the Residue on Tomato (Greenhouse). IR-4 PR No. 00250, author Keith Dorschner, Ph.D., excerpt Executive Summary pages 10-17, page 20.
6. A.Bloomberg, 2008. "Safety Assessment for Mixer/Loaders, Applicators and Reentry Workers During Use of ETHREL® brand Ethephon Plant Regulator for Use on large-Fruited Greenhouse Tomatoes." EPA Assessment Guidelines Series 875. Report No. 201969. December 10, 2008.

If you need additional information or documentation, please do not hesitate to contact me at linda.aschbrenner@bayercropscience.com or 919-549-2255.

Sincerely,

Bayer CropScience LP

A handwritten signature in cursive script that reads "Linda Aschbrenner".

Linda Aschbrenner
State Registration Manager



United States Environmental Protection Agency
Office of Pesticide Programs
Registration Division (TS-767)
Washington, DC 20460

**Application for/Notification of State Registration
of a Pesticide To Meet a Special Local Need**
(Pursuant to Section 24(C) of the Federal Insecticide,
Fungicide, and Rodenticide Act, as Amended)

For State Use Only
Registration No. Assigned

Date Registration Issued

<p>1. Name and Address of Applicant for Registration</p> <p>Bayer CropScience LP 2 T. W. Alexander Drive P.O. Box 12014 Research Triangle Park, NC 27709</p>	<p>2. Product Is (Check one)</p> <p>EPA-Registered <input checked="" type="checkbox"/></p> <p>New (not EPA-registered) <input type="checkbox"/> Attach EPA Form 8570-4, Certified Statement of Formula, fix now products.</p> <p>3. Active Ingredient(s) in Product ethephon</p> <p>EPA Registration Number 264-267</p> <p>EPA Company Number 264</p>
<p>4. Product Name</p> <p>Ethrel brand Ethephon Plant Regulator</p>	<p>5. If this is a food/feed use, a tolerance or other residue clearance is required. Cite appropriate regulations in 40 CFR Part 180, 21 CFR Part 193, and/or 21 CFR Part 561. 40CFR 180.300</p>
<p>6. Type of Registration (Give details in Item 12 or on a separate page, properly identified and attached to this form):</p> <p><input type="checkbox"/> a. To permit use of a new product.</p> <p><input checked="" type="checkbox"/> b. To amend EPA registrations for one or more of the following purposes:</p> <p><input type="checkbox"/> (1) To permit use on additional crops or animals.</p> <p><input checked="" type="checkbox"/> (2) To permit use at additional sites.</p> <p><input type="checkbox"/> (3) To permit use against Additional pests.</p> <p><input type="checkbox"/> (4) To permit use of additional application techniques or equipment.</p> <p><input type="checkbox"/> (5) To permit use at different application rates.</p> <p><input type="checkbox"/> (6) Other (specify below)</p>	<p>7. Nature of Special Local Need (Check one)</p> <p>a. <input type="checkbox"/> There is no pesticide product registered by EPA for such use.</p> <p>b. <input checked="" type="checkbox"/> There is no EPA-registered pesticide product which, under the conditions of use within the State, would be as safe and/or as efficacious for use within the terms and condition of EPA registration.</p> <p>c. <input type="checkbox"/> An appropriate EPA-registered pesticide product is not available.</p>
<p>10. Has a FIFRA Section 24(C) registration for this use of the product ever, by another State been (Check applicable box(es))</p> <p><input checked="" type="checkbox"/> Sought <input checked="" type="checkbox"/> Issued <input type="checkbox"/> Denied <input type="checkbox"/> Revoked</p> <p>If any of the above are checked, list States in Item 12 below.</p> <p><input type="checkbox"/> No FIFRA Section 24(C) Action</p>	<p>8. If this registration is an amendment to an EPA-registered product, is it for a "changed use pattern" as defined in 40 CFR 162.3(k)?</p> <p><input type="checkbox"/> Yes (discuss in Item 12 below) <input checked="" type="checkbox"/> No</p> <p>9. Has an EPA Registration or Experimental Use Permit for Use of this chemical ever been: (Check applicable box(es))</p> <p><input type="checkbox"/> Sought <input checked="" type="checkbox"/> Issued <input type="checkbox"/> Denied <input type="checkbox"/> Canceled <input type="checkbox"/> Suspended</p> <p>Previous Permit Action:</p> <p><input checked="" type="checkbox"/> Registration <input type="checkbox"/> Experimental Use Permit <input type="checkbox"/> No Previous Permit Action</p>
<p>Certification</p> <p>I certify that the statements 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.</p> <p>Signature of Applicant or Authorized Representative</p> <p><i>Zenia Aschberger</i></p> <p>Title State Registration Manager</p> <p>Telephone Number 919-549-2255</p> <p>Date December 12, 2008</p>	<p>11. Endangered Species Act- (Give details in Item 12 or on a separate page, properly identified and attached to this form)</p> <p>Identify the counties where this pesticide will be used. If Statewide, indicate "all." Provide a list of Federally protected endangered/threatened species which occur in the areas of proposed use.</p> <p>12. Comments</p> <p>SLNs approved for use in PA, AZ, TX, and CO. Pending application CA.</p> <p>SLN will allow use on large-fruited greenhouse tomatoes for early season to reach uniform maturity and use in late season (single fruit spray application) for higher yields from maturing crop.</p>

Determination by State Agency

This registration is for a Special Local Need and is being issued in accordance with section 24(c) of FIFRA as amended. To the best of our knowledge, the information above is correct, except as noted in "Comments" below or in attachments.

<p>Name, Title, and Address of State Agency Official</p> <p>Title</p> <p>Telephone Number</p> <p>Date</p>	<p>Comments (by State Agency Only)</p>	<p>Received by EPA</p>
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Bayer CropScience

Bayer CropScience LP
 P.O. Box 12014
 2 T. W. Alexander Drive
 Research Triangle Park, NC 27709
 1-866-99BAYER (1-866-992-2937)
<http://www.bayercropscienceus.com>

ETHREL® brand Ethephon Plant Regulator

For Use on Large-Fruited Greenhouse Tomatoes

EPA Reg. No. 264-267

SLN No. ME-XXXXXX

24(c) Supplemental Label

FOR DISTRIBUTION AND USE ONLY IN THE STATE OF MAINE

This label and the federal label for this product must be in the possession of the user at the time of pesticide application. Follow all applicable directions, restrictions, Worker Protection Standards (WPS) and precautions on this supplemental label and the main EPA-registered label.

DIRECTIONS FOR USE

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

A foliar spray of ETHREL® brand Ethephon Plant Regulator can be used to chemically accelerate fruit maturation or to facilitate uniform fruit ripening.

LARGE-FRUITED GREENHOUSE TOMATOES (greater than 1" in diameter).

Crop Situation	ETHREL®	Specific Directions	Remarks
Directional application used to aid in uniform maturation of cluster tomatoes or individual fruit with irregular maturing.	0.15% – 0.35% solution of ETHREL in water Or 1-2.5 teaspoons per gallon Buffer to pH of 6.0	Apply directly to fruit to aid in uniform maturation.	This use should be done with a handheld sprayer or spray applicator directed specifically to individual fruit. Caution: To avoid damage to the plant, do not spray entire plant or foliage.
Crop Situation	ETHREL® Pints/Acre	Specific Directions	Remarks
Late-Season application	1¼ to 5 pints per acre.	This application should be used when fruit are marketable size.	Material may be sprayed on the plant foliage.
Late-Season application	Mix 1:6 ratio up to 5 pints per acre.		Apply with a brush or sponge directly to the stem in stripes 3-6 inches long just below the fruit. Caution: Avoid application to fruit if applying by brush or sponge.

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 intervals. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 48 hours.

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 made of any waterproof material such as polyethylene or polyvinyl chloride, chemical resistant footwear plus socks, and goggles or face shield. For overhead exposure, chemical-resistant headgear is also required.

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

Pre Harvest Interval (PHI): 48-hours – Re-entry Interval (REI): 48-hours

RESTRICTIONS/PRECAUTIONS

- DO NOT MIX ETHREL® WITH AMMONIUM THIOSULFATE. SUCH TANK MIXTURES MAY RESULT IN FORMATION OF TOXIC FUMES. Mix only the amount of spray you expect to use each day.
- Do not allow mixed solution to stand overnight.
- Do not contaminate water used for irrigation or domestic purposes. Do not contaminate water when disposing of equipment washwaters.
- Avoid spray drift to nearby crops as this product will cause modifications in plant growth.
- Plant injury or reduced yields may result.

IMPORTANT: Do not apply ETHREL® brand Ethephon Plant Regulator through any type of irrigation system.

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

For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

or

Visit our worldwide web site at www.bayercropscienceus.com

*As with any crop-protection product, always read and follow label directions.
For additional information call toll-free 1-866-99BAYER (1-866-992-2937).*

Ethrel is a registered trademark of Bayer.

BACKYARD

GROWN NOT TOO FAR FROM HERE

Linda Aschbrenner
State Registrations Manager
Bayer CropScience LP
P.O. Box 12014, 2 T. W. Alexander Drive,
Research Triangle Park, NC 27709, USA

November 6, 2008

Linda:

On behalf of Backyard Farms, thank you for considering the use of Ethrel on greenhouse tomatoes in Maine. Backyard Farms is a 24 acre hydroponic greenhouse that strives to produce quality tomatoes year round. Ethrel would make a great contribution to our ability to provide consistency in the quality of our tomatoes for our customers.

In order to provide tomatoes year round, Backyard Farms utilizes a unique growing technique. Every six months new plants are planted between our old crop, rather than waiting for a complete clean out. Shortly after planting the young crop, the tops are removed from the old crop causing stress on the fruits. By using this technique we are able to provide tomatoes year round, however, the quality of both crops is compromised during the transition. For up to 10 weeks, the new crop is deprived of sunlight because it is shaded by the crop that we continue to harvest. The result is that the young crop is delayed in vigor and productivity, while the fruit quality of the old crop declines due to softness and cracking.

Ethrel would allow a more efficient transition from the old crop to the new. Quicker removal of the old crop would minimize the new crops' deficiency and maximize the old crops' fruit quality. Over 80% of the tomatoes on the final clusters are lost due to softness and cracking, and over 50% of the first clusters on the new crop are deformed or aborted. Ethrel would be a useful tool in minimizing the economic losses that we experience with both crops; as well as promote consistency in our ability to provide a quality product to our customers year round.

Ethrel has been approved on supplemental labeling for greenhouse tomatoes in Pennsylvania and Arizona. We would like your support in the development of a supplemental label for Maine in order to assist Backyard Farms in its goal of continuously producing quality tomatoes.

If you have any questions or require any other information to move forward with this process please let me know. I look forward to working with you on this process.

Sincerely,



Erika Roderick
Integrated Pest Management Department

