



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

December 11, 2008

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Doina Bujor, Regulatory Manager
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

RE: Product Name: Procone Plant Group Regulator Solution
EPA Reg. No: 73049-32
Application for Label Notification Dated October 23, 2008 to Update Storage and
Disposal Language per PR Notice 2007-4

Dear Ms. Bujor:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under PR Notice 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification, received and reviewed" and will be placed accordingly in our records.

Questions concerning this action should be directed to Ms. Diana Hudson at (703) 308-8713 or email at hudson.diana@epa.gov.

Sincerely,

Linda Hollis

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

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0080



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73049-32	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) PROCONE Plant Growth Regulator Solution	PM# 91	
5. Name and Address of Applicant (Include ZIP Code) Valent BioSciences Corporation 870 Technology Way Libertyville, IL 60048 <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 or identical in composition and labeling to: <input checked="" type="checkbox"/> EPA Reg. No. _____ Product Name _____	

Section - II

Amendment - Explain below. Final printed labels in response to Agency letter dated _____
 Resubmission in response to Agency letter dated _____ "Me Too" Application
 Notification - Explain below. Other - Explain below.

NOTIFICATION
Date Reviewed: 12-11-08
Reviewed By: D. Hudson

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of label per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. NO other changes have been made to the labeling or the Confidential Statement of Formula for this product. (see next page)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container

3. Location of Net Contents Information
 Label Container

4. Size(s) Retail Container

5. Location of Label Directions
 On Label
 On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
 Lithograph
 Paper glued
 Stenciled Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Doina Bujor	Title Regulatory Manager	Telephone No. (Include Area Code) 847-968-4724
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Certification
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 both under applicable law.

2. Signature
Doina Bujor

3. Title
Regulatory Manager

4. Typed Name
Doina Bujor

5. Date
Oct 23, 2008

6. Date Application Received (Stamped)

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4/13



October 23, 2008

Linda Hollis
 Biopesticides & Pollution Prevention Division
 Document Processing Desk (NOTIF)
 Office Of Pesticide Programs (7504P)
 U.S. Environmental Protection Agency
 Room S-4900, One Potomac Yard
 2777 South Crystal Drive
 Arlington, VA 22202-4501
 703-308-8269

RE: ProCone® (EPA Reg. No. 73049-32) Notification

Dear Ms. Hollis:

Valent BioSciences Corporation is submitting a notification for ProCone® Plant Growth Regulator Solution (EPA Reg. No. 73049-32) in accordance with PR Notice PR Notice 2007-4. The changes made to the label are to the Storage and Disposal statement.

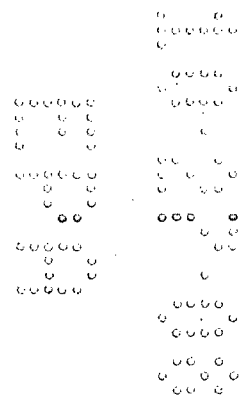
Present submission consists of:

- Application for Registration (EPA form 8570-1)
- One copy of the red-lined label
- One copy of the clean label.

Please contact me if you have any questions at 847-968-4724 or by e-mail at doina.bujor@valent.com.

Sincerely,

Doina Bujor
 Regulatory Manager



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NOTIFICATION

Date Reviewed: 12-11-08

Reviewed By: D. Hudson

**PROCONE®
PLANT GROWTH REGULATOR
SOLUTION**

Active Ingredient:	
Gibberellins GA4 + 7.....	4.0% w/w
Other Ingredients:.....	96.0% w/w
Total:.....	100.0% w/w

Contains 1 gram active ingredient per 23 ml or 19.8 grams per pint

**KEEP OUT OF REACH OF CHILDREN
WARNING / AVISO-**

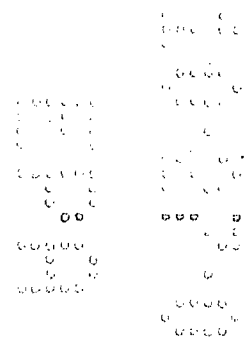
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

EPA Reg. No. 73049-32
EPA Est. No.

Batch Code: _____

Registrant:
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048

Net Contents:



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 eye. --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	--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.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies, you may also call toll-free 1-800-892-0099 for treatment information. For all other information call 1-800-89-Valent.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

**PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS & DOMESTIC ANIMALS**

WARNING

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Wear goggles and face shield. Do not get in eyes or on clothing. Avoid contact with skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Personal Protective Equipment (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for Category C on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear:

- * Long-sleeved shirt and long pants.
- * Chemical resistant gloves, such as barrier laminate, or butyl rubber, or nitrile rubber, or viton, or polyvinyl chloride (PVC), or neoprene rubber.
- * Shoes plus socks.
- * Protective eyewear.

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.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

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 cleaning equipment or disposing of equipment washwaters or rinsate.

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 regulation.

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), and restricted entry interval. 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 foliar-treated areas during the restricted entry interval (REI) of 12 hours. Exception: if the product is tree-injected or topically applied to single buds, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

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.
- Chemical resistant gloves, such as barrier laminate, or butyl rubber, or nitrile rubber, or viton, or polyvinyl chloride (PVC), or neoprene rubber.
- Shoes plus socks.
- Protective eyewear.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store below 77°F (25°C). Keep containers tightly closed when not in use. Do not freeze.

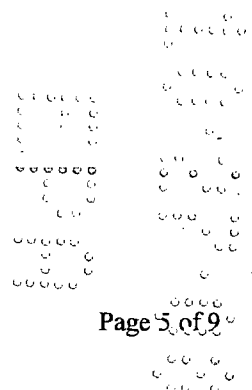
PESTICIDE DISPOSAL: Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility.

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 and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling if available. If recycling is not available puncture and dispose of the container in a sanitary landfill, or by other procedures approved by state and local authorities.

GENERAL INFORMATION

PROMOTION OF MALE AND FEMALE CONEBUD FORMATION OF MATURE TREES, SEEDLINGS AND GRAFTED OR ROOTED PROPAGULES OF PINACEAE FAMILY CONIFER SPECIES

ProCone is a plant growth regulator formulation containing gibberellins GA4+7 that may promote pollen and seed cone (strobilus) production for tree improvement programs and operational seed orchards. ProCone can be used on mature trees, seedlings, and grafted or rooted propagules of most conifer species of the family Pinaceae. ProCone may not be applied to Genus *Pinyon* (pine nuts). Timing is critical for optimal promotion of seed and pollen cone formation. Based on application timing, ProCone can differentially stimulate pollen or seed flowering of a number of conifer species. Response can be influenced by application technique and cultural practices. Application can be made: (1) topically to the terminal bud; (2) by injection into the main stem xylem-conducting tissue of developing shoots; (3) or by foliar spray applied to shoots, branches, and whole crowns of trees. Environmental factors such as light intensity, temperature, soil moisture, and nutrition may affect the response. For optimal response, ProCone should be used in conjunction with an appropriate cultural treatment program (which is also known to promote flowering).



APPLICATION INSTRUCTIONS

ProCone may not be applied to Genus *Pinyon* (pine nuts)

The following conifer species have been shown to be responsive to ProCone treatment:

<u>Species</u>	<u>Common Name</u>
<i>Larix leptolepsis</i>	Japanese larch
<i>Larix occidentalis</i>	Western larch
<i>Larix laricina</i>	Eastern larch
<i>Larix decidua</i>	European larch
<i>Picea abies</i>	Norway spruce
<i>Picea engelmannii</i>	Engelmann spruce
<i>Picea glauca</i>	White spruce
<i>Picea mariana</i>	Black spruce
<i>Picea sitchensis</i>	Sitka spruce
<i>Pinus banksiana</i>	Jack pine
<i>Pinus caribaea</i>	Caribbean pine
<i>Pinus contorta</i>	Lodgepole pine
<i>Pinus lambertiana</i>	Sugar pine
<i>Pinus palustris</i>	Longleaf pine
<i>Pinus radiata</i>	Monterey pine
<i>Pinus sylvestris</i>	Scots pine
<i>Pinus taeda</i>	Loblolly pine
<i>Pinus thunbergii</i>	Japanese black pine
<i>Pseudotsuga menziesii</i>	Douglas-fir
<i>Tsuga heterophylla</i>	Western hemlock

APPLICATION RATE

Response and phytotoxic effects are often clonally specific. To optimize response and minimize phytotoxic effects, dosage should be evaluated and adjusted on a clonal basis.

For injection into main stems of trees 5 to 20 cm in diameter at breast height (DBH) apply 0.75 to 1.5 mg GA4 + 7 (AI) (0.018 to 0.036 ml undiluted ProCone)/cm² cross sectional area at breast height.

Stem Diameter (cm)	Dose of GA4+7 per tree (mg)	Volume of ProCone per tree (ml)	Diam. & depth of hole, cm (Volume, ml)	No. of holes
5	14.73 – 29.45	0.35 – 0.71	0.3x3 (0.21 ml)	1-2
10	58.91-117.81	1.42-2.83	0.4x3 (.38 ml)	4-8
15	132.54-265.07	3.18-6.36	0.5x3 (.59 ml)	6-12
20	253.62-471.24	5.65-11.31	0.6x3 (.85 ml)	7-14

Note: Spruce, fir, and larch respond best to upper rates; pines to lower rates. Hemlock, Douglas fir and pine may show signs of excessive precocious needle senescence at the upper rates.

For foliar application to trees 0.5 to 5 m in height in orchards or containers, the entire upper crown should be wetted to run-off with a spray solution containing 200-400 mg GA4 + 7/liter (4.8 - 9.6 ml ProCone/liter) containing a cationic surfactant, e.g. 0.05% (v/v) Aromox C/12 in water.

For topical application, to single buds, apply 210 micrograms GA4 + 7 to each bud in 0.1 ml of 50% v/v ProCone in water. ProCone can also be diluted with 95% ethanol.

APPLICATION TIMING

For most species, timing and number of applications depend on the method used and on the phenology of cone bud development. In most species, cone bud development occurs toward the end of shoot development, but the rate of shoot elongation and cone bud development will vary with year, climate, location, species and clone.

For spraying foliage and topical applications to buds of *Pseudotsuga*, *Tsuga*, and *Picea*, treatments should begin in the spring at the time of vegetative bud burst; two or three biweekly applications or up to six weekly applications have been effective. For *Pinus* species, up to 12 weekly or 6 biweekly applications have been effective. Treatments

during shoot elongation tend to promote pollen cones and treatments after shoot elongation tend to promote seed cones.

For injections into branches or into the main stem, single applications are effective. For *Picea* species, ProCone should be injected when new shoots are 70 to 90% elongated. For *Pinus*, a single early injection near the end of shoot elongation may promote pollen cones; later injections may be required for seed cones. More than one injection date may be necessary.

APPLICATION METHOD

Injections may be made into xylem-conducting tissues of developing shoots, branches and main stems by applying ProCone with pipettes or syringes into drilled holes of appropriate size. The ProCone application rate is adjusted to size of shoot, branch or stem by varying the number of holes and volume of ProCone per hole. Cross sectional area can be used as the basis for determining rates of ProCone for trees 5- to 20 cm in diameter or larger at breast height (DBH). This reduces the potential for underdosing large trees or overdosing small trees. The number of holes and spacing varies with size of holes, dose, and stem diameter. Holes should be evenly spaced around the circumference of stems and new holes drilled at each application date. For the mainstem, holes should be drilled with a portable drill at an angle of 30 degrees to horizontal and large enough to prevent spillage of the injected solution. For branches, holes should be drilled on the upper circumference. Following injection and after all liquid has been absorbed, holes can be plugged with a wood dowel or a piece of tape to prevent entrance of disease organisms. If ProCone is utilized in conjunction with a tree girdling program, first holes should be drilled at a height of 20 cm above the uppermost girdle and additional holes set at 5 cm increments down to just above the girdle line.

Foliar sprays should be applied to foliage (shoots, branches) over the whole crowns of conifers. Use of a surfactant, i.e. Aromox C/12, in aqueous foliar sprays of ProCone may improve foliage wetting and response. Foliar spraying is a convenient method of application to small seed orchard and container-grown trees up to 3 to 4 m in height. Low volume sprayers, such as mist blowers, have produced good coverage and response.

Topical application to single buds can be made with a pipette or syringe. Topical applications may be highly effective on small trees (seedlings) with few buds.

APPLICATION CONSIDERATIONS

1. Number, size and spacing of injection holes depends directly on tree size and amount of ProCone to be incorporated. Injection holes should be evenly spaced around the circumference of the stem. Holes should be large enough to prevent spillage of solution.
2. Response of conifer trees to ProCone treatments may depend on the physiological and hormonal status of the tree at the time of treatment.

3. Light intensity and quality may influence the response to ProCone.
4. To be optimally effective, ProCone treatments should be generally synchronized with bud/shoot development and not with calendar date.
5. Use of a surfactant, enhances foliage wetting and may increase response.
6. Non-destructive stem girdling, nitrate fertilization, root pruning, and drought (soil moisture stress) conditions may enhance ProCone effect.
7. A longer treatment period may be required to promote conebud differentiation throughout the entire crown.
8. ProCone treatment should not be expected to work if site and climatic conditions are not favorable for flowering (excessively wet and cool climate with low levels of insulation).

CONDITION OF SALE AND WARRANTY

Seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning the use of this product other than as indicated on the label. User assumes all risks of use, storage or handling not in strict accordance with accompanying directions.

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