

73049-461

04-06-2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 06 2011

Thomas Bade, Ph.D.
Regulatory Manager
Valent BioSciences
870 Technology Way
Libertyville, IL 60048

Subject: Protone SG, EPA Reg. No: 73049-461
Application for Label Amendment via Notification dated 3/7/11

Dear Dr. Bade:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under PRN 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 John Fournier at (703) 308-0169 or email at fournier.john@epa.gov.

Sincerely,

Linda Hollis

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

CONCURRENCES

SYMBOL	▶ 7511P						
SURNAME	▶ Fournier						
DATE	▶ 6 Apr 11						

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Valent BioSciences / 73049-461	2. EPA Product Manager S. Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) ProTone SG	PM# (92)	
5. Name and Address of Applicant (Include ZIP Code) Valent BioSciences 870 Technology Way Libertyville, Illinois 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: EPA Reg. No. 73049-461 Product Name ProTone SG	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

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

"Amend the ProTone SG Label to add Coffee as an allowed crop and to include typographical changes on the label." Changes are highlighted on the attached label.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
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"/> Text No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Thomas Bade Ph.D.	Title Regulatory Manager	Telephone No. (Include Area Code) 847-968-4726
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 or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Manager	
4. Typed Name Thomas Bade Ph.D.	5. Date March 7, 2011	

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ProTone® SG

**Plant Growth Regulator
SOLUBLE GRANULE**

NOTIFICATION

**FOR USE ON
GRAPES
AND COFFEE**

Reviewed: APR 06 2011
Reviewed By: J. Fournier, BPPD

Active Ingredient	
S-Abscisic Acid	20.0% w/w
Other Ingredients	80.0% w/w
Total	100.0% w/w

ProTone® SG contains a total of 20 g of S-Abscisic acid (S-ABA) in 100 g of product. S-Abscisic acid, commonly known as S-ABA, is a naturally occurring growth regulator found in plants. Application of ProTone® SG (S-ABA) to grape berries causes enhanced coloration of the berries.

KEEP OUT OF REACH OF CHILDREN CAUTION

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.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also call toll-free 1-800-892-0099 (24 hours) for emergency medical treatment and/or transport emergency information. For all other information, call 1-847-968-4700.	

This label must be in the possession of the user at the time of pesticide application.

EPA Registration No. 73049-461
EPA Establishment No. 33762-IA-001

Permittee: Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048
1-847-968-4700

Net Weight: 1.65 lb. (750 grams)
This container will treat 0.6 acres when applied at the maximum label rate.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants.
- Chemical Resistant Gloves
- Shoes plus socks.
- Protective eyewear

Follow the 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:

- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. 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 disposing of equipment wash-water or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with the terms of the Label. 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 State or Tribal 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 treated areas during the restricted entry interval (REI) of 4 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:

- Long-sleeved shirt and long pants (or Coveralls).
- Chemical resistant gloves (made of any waterproof material).
- Shoes plus socks.
- Protective eyewear.

GENERAL DIRECTIONS FOR USE ON GRAPES

Use only as directed. Read the label thoroughly and make sure it is understood before making applications. ProTone® SG improves red color development in grapes.

Application instructions:

- On grapes, S-ABA is known to accelerate and enhance the red color development of grape berries depending on cultivar, vineyard conditions, and growing region. One or more of the following benefits is often associated with treatment with S-ABA: improved fruit quality as a result of enhanced fruit color, earlier harvest, improved harvest management, and improved pack-out yield.
- In most cases color development resulting from ProTone® application will be visible five to seven days after application.
- Undesired effects can result from any deviations from the label directions in the rates, timings, water volumes, or the adoption of untested spray mixes, when applying ProTone® SG.

- To prepare the treatment solution, add the required amount ProTone® SG to a spray tank about half-filled with water. Agitate while bringing the total volume of water to the required level. Mix thoroughly with agitation and bypass circulation to completely dissolve the ProTone™ SG, and then add surfactant. Discard any unused treatment solution at the end of each day following local, state or federal law.
- Use a non-ionic surfactant at the final adjuvant concentration directed by the adjuvant manufacturer. Use of an adjuvant will improve wetting and coverage of the grape bunches.
- Increased coloration of grape berries has been achieved with bunch directed sprays applied by calibrated commercial spray equipment. Apply ProTone® SG in a sufficient amount of water to ensure uniform, thorough, but not excessive coverage of the grape bunches. Product efficacy requires that all bunches, and berries within bunches, receive thorough and complete coverage. Adjust spray volumes to achieve thorough coverage based on vine size, spacing, trellis system, vine canopy, and spray equipment.
- Best results will be achieved from applications during the cooler parts of the day or night, avoiding the hottest period of the day. To maximize absorption and optimize product effectiveness, apply ProTone® SG under slow drying conditions, e.g. early in the morning, in the evening or night (coolest daily temperatures, medium to high relative humidity, and no wind). Do not make applications during the day or early evening when the fruit is still hot.
- ProTone® SG can enhance the red color of grape cultivars that have difficulty developing color and helps increase red color of grapes grown in poor coloring areas. However, under very poor color development conditions (e.g. excessively hot day and night temperatures, heavy crop load, poor growing conditions) application of ProTone® SG may not give adequate red color development. Serious consideration is to be given, on a block-by-block basis, to any vineyard conditions (elevation, sun exposure, soil texture, growing condition, prevailing or anticipated weather patterns such as high temperature, drought or flood conditions, nutrient levels) or production practices (vine size, vine spacing, vine canopy, crop load, trellis system, pruning) that impact fruit color development.
- Under conditions where red color development of grapes is good, (e.g. growing areas with a history of good red color development, years in which there is good red color development, cultivars that already develop sufficient red color), application of ProTone® SG will not provide significant additional red color or advance the harvest period.
- Do not apply ProTone® SG to plants or fruit under stress (e.g. heat, water, disease, insect and nutrient). Injured or stressed plants or fruit will show a reduced response to ProTone® SG.
- Do not overhead irrigate treated plants for at least 6 hours following application of ProTone® SG.

- Do not apply ProTone® SG if rain is expected within 6 hours of application.
- The proper application timing of ProTone® SG is important to product performance. When applying ProTone® SG, deviations from the label directions in the rates, timings, water volumes, or the use of untested spray mixes, may produce undesired results.

COMPATIBILITY WITH OTHER AGRICULTURAL PRODUCTS

Compatibility and performance data for ProTone® SG with other agricultural products is not available.

Do not tank mix ProTone® SG with compounds containing copper or iron ions. Do not tank mix ProTone® SG with any product unless compatibility has been verified. If considering tank mixing ProTone® SG with other products use the following **compatibility jar test** before mixing a whole tank:

Add water from the same water source to a clear glass or plastic jar. Add the pesticides in correct proportions. Mix thoroughly and let stand for a minimum 15 minutes. Separation, gelling, or generation of heat are all signs of incompatibility.

Even if a mix passes the jar test for compatibility, it is imperative to test it on a designated area to evaluate for phytotoxicity or ineffectiveness.

Always read and follow all label directions and precautions of each product. When using combinations of products the most restrictive of label limitations and precautions must be followed. Do not mix with any pesticide that has a prohibition against tank mixing. For further information consult your Valent agricultural specialist.

APPLICATIONS, RATES, AND TIMINGS

CROP	OBJECTIVE / BENEFIT	APPLICATION INSTRUCTIONS
<p>Grapes (Table Grapes, Juice Grapes, Wine Grapes)</p>	<p>Enhanced red coloration of grapes.</p> <p>Contact Valent Corporation for more information.</p>	<p>Apply ProTone® within the period from 1 week before veraison (50 percent of the target fruit has softened) until anticipated harvest of target fruit. Application timing varies depending on the cultivar, vineyard conditions, and grower objectives.</p> <p>Spray Applications: Apply 75 to 250 grams of S-ABA (375 to 750 grams of ProTone® SG) per acre as a spray solution in a sufficient volume to achieve uniform and complete coverage of the grape bunches. In most cases 75 grams S-ABA (one-half bottle of ProTone® 20 SG) to 150 grams S-ABA (one bottle of ProTone® 20 SG) per acre per application will provide good results. In situations where greater color development is desired, use the higher S-ABA rate.</p> <p><u>Early timing:</u> First application should be made between 1 week before veraison and 3 weeks after veraison. A single application made during this period has been shown to be effective to enhance grape berry color.</p> <p><u>Late timing:</u> If additional color development is desired, up to three (3) applications of ProTone® SG can be used. Multiple applications are expected to improve color on cultivars for which there is an extended period between veraison and harvest</p> <p>Apply to marketable clusters with significant green color. Fruit may need to remain on the vine for 2 to 3 additional weeks for harvestable color to develop. Fruit must be firm at time of application with the potential to remain firm until harvest.</p>
<p>Application: Use bunch directed sprays that achieve thorough wetting of the fruiting zone. Bunches need to receive uniform and complete coverage without runoff. The spray volume required will depend on the trellis system, the vine canopy size and management, and commercial spray equipment used. Spray volumes ranging from 80 – 200 gallons/A have been shown to be effective when applied under slow drying conditions.</p>		
<p>Use of Adjuvants: Use a non-ionic surfactant at the final surfactant concentration directed by the surfactant manufacturer to improve wetting and coverage of grape bunches.</p>		

Determining Optimal Rates: Optimal ProTone® SG rates will vary according to the desired color effect, growing conditions & practices, application technique, environmental conditions, variety & cultivar, plant vigor, vine canopy and crop load. Different varieties or cultivars of the same species respond differently to ProTone® SG. For specific variety or cultivar information contact your Valent representative. With increasing temperature and lower humidity consider using the higher rates within the range given in the application rates, remembering not to apply to plants that are under stress.

CROP	DOSE	OBSERVATIONS
Coffee	40 to 400 grams A.I. (200 to 2000 grams product)	To suppress flower bud break from their latent dormancy of immature (<4 mm) and early mature (5 to 6 mm long) stages FOLIAR APPLICATIONS Applied in sufficient water volume to assure total coverage of developing buds along all laterals (arrange nozzles for coverage from bottom up as well as top down of laterals and leaves) Multiple applications at 3 to 7 day frequency may be required over a period of 14 to 40 days. Begin applications when developing buds are at the <4 mm length stage and prior to the beginning of the rainfall period. Use a non-ionic surfactant at 0.05% v/v
	0.5 to 2 grams A.I. / Liter (2.5 to 10 grams product)	SOIL APPLICATIONS: <u>Hand applied method:</u> Apply 1 liter of mix solution per tree, evenly distributed within the tree drip line. Multiple applications at 3 to 7 day frequency may be required over a period of 14 to 40 days. Begin applications when developing buds are at the <4 mm length stage and prior to the beginning of the rainfall period.
	500 to 2000 grams A.I. (2,500 to 10,000 grams product)	<u>Irrigation Drip Line Injection method:</u> Inject ProTone® SG within the last 30 to 40 minutes of the irrigation run, utilize the 500 PPM dose. Multiple applications at 3 to 7 day frequency may be required over a period of 14 to 40 days. Begin applications when developing buds are at the <4 mm length stage and prior to the beginning of the rainfall period.

CONVERSION TABLE:

Grams of S-ABA	Pounds of ProTone® SG	Grams of ProTone® SG
75	0.83	375
100	1.10	500
125	1.38	625
150	1.65	750
175	1.93	875
200	2.20	1000
225	2.48	1125
250	2.76	1250

STORAGE AND DISPOSAL

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

Pesticide Storage

Keep container tightly closed when not in use. Store product in a cool and dry place. Avoid extended storage conditions at temperatures above 25°C (77°F). Avoid exposure of product to light

Pesticide Disposal

To avoid waste, use all material in this container by application according to label directions. If waste cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

Container Handling

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. 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 or puncture and dispose of the container in a sanitary landfill, or by other procedures approved by state and local authorities.

Warranty and Disclaimer Statement:

To the fullest extent permitted by law, seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning 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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