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

> OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

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

NOV 2 7 2012

Registration Amendments to add the new crop use on cherry at flowering to increase fruit Subject: set and revise additional labeling language. ReTain Plant Growth Regulator Soluble Powder (EPA Reg. No.: 73049-45) ReTain (EPA Reg. No.: 73049-58) Your submissions dated July 5, 2012 Decision Numbers: 467003 and 467004, PRIA Category B680

Dear Dr. Bade:

The Biopesticides and Pollution Prevention Division (BPPD) has concluded its review of the supporting data and information submitted under cover letters dated July 5, 2012 to add the new crop use on cherry at flowering to increase fruit set and revise additional labeling language. BPPD's findings are summarized below.

New Use, Cherry at Flowering

BPPD has determined that the proposed new use on cherries at flowering to increase fruit set is acceptable. It is unlikely that this use on cherries at flowering will result in residues of Aviglycine HCI (AVG) in cherry fruit. This new cherry use of AVG meets the criteria for inclusion under 40 CFR 180.2020 (non-food determinations).

The labels submitted with these amendments referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(5), are acceptable provided that you:

- 1) Submit and/or cite all data required for registration/reregistration of your products under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2) Submit two (2) copies of your final printed labeling before you release the products for shipment. Final printed labeling means the label or labeling of the products when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels.

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Should you have any questions, you may contact Mr. Colin Walsh directly at (703) 308-0298 or via email at <u>walsh.colin@epa.gov</u>.

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Sincerely,

1616,

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

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73049-45 ReTain® Plant Growth Kegulator, updated November 2012

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Master Label

ReTain[®]

PLANT GROWTH REGULATOR **SOLUBLE POWDER** FOR USE ON APPLE, PEAR, STONE FRUIT, WALNUT, PECAN, CUCUMBER AND PINEAPPLE.

Active Ingredient:

| [S]-trans-2-Amino-4-(2-aminoethoxy)-3-butenoic acid hydrochloride1 | 5% w/w |
|--|--------|
| Other Ingredients | 5% w/w |
| Total |)0% |

EPA Reg. No. 73049-45 EPA Est. No. 33967-NJ-1

ACCEPTED NOV 2 7 2012

Registrant: Valent BioSciences Corporation 870 Technology Way Libertyville, IL 60048 1-800-6-VALENT

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 73949-45

Net Weight: 11.7 oz (333 grams)

A single application of one pouch will treat up to 1.0 acre of listed fruit crops, 0.5 acre of listed nut crops, 0.33 acre of pineapple, and 0.17 acre of cucumbers grown for seed at the maximum use rate.

KEEP OUT OF REACH OF CHILDREN CAUTION

| | FIRST AID | |
|------------------------|--|--|
| If inhaled | -Move person to fresh air. -If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. -Call a poison control center or doctor for further 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. | |

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-892-0099 (24 hours) for emergency medical treatment and/or transport emergency information. For all other information, call 1-800-6-Valent.

PLEASE SEE ATTACHED APPLICATION GUIDE FOR COMPLETE PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. Refer to Supplemental Labeling under "AGRICULTURAL USE REQUIREMENTS" in the DIRECTIONS FOR USE section for information about this standard

73049-45 ReTain® Plant Growth kegulator, updated November 2012

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APPLICATION GUIDE

ReTain[®]

PLANT GROWTH REGULATOR SOLUBLE POWDER FOR USE ON APPLE, PEAR, STONE FRUIT, WALNUT, PECAN, CUCUMBER AND PINEAPPLE

| Active Ingredient: | |
|--|-------|
| [S]-trans-2-Amino-4-(2-aminoethoxy)-3-butenoic acid hydrochloride159 | % w/w |
| Other Ingredients | % w/w |
| Total | % |

EPA Reg. No. 73049-45 EPA Est. No. 33967-NJ-1

Registrant: Valent BioSciences Corporation 870 Technology Way Libertyville, IL 60048 1-800-6-VALENT

Net Weight: 11.7 oz. (333 grams)

KEEP OUT OF REACH OF CHILDREN CAUTION

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if inhaled or absorbed through skin. Avoid breathing spray mist. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- · Long sleeved shirt and long pants
- · Shoes plus socks
- Waterproof gloves

Hand-wand applicators must wear dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with N, R, P or HE filter when applying this product.

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, 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 washwater 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 State/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 in this labeling 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 12 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
- Waterproof gloves
- Shoes plus socks

GENERAL INFORMATION FOR USE

IMPORTANT: Before application, read all use directions thoroughly. Use ReTain[®] only as directed. For specific information on the best use practices for your location, <u>consult with your Valent Agricultural Specialist (1-800-6-Valent)</u>.

ReTain contains 15% (wt/wt) [S]-*trans*-2-amino-4-(2-aminoethoxy)-3-butenoic acid hydrochloride, commonly known as aminoethoxyvinylglycine, aviglycine HCl, or AVG HCl. AVG HCl is a potent plant growth regulator produced by fermentation. AVG HCl inhibits the production of ethylene in plant tissues. Ethylene affects plant processes such as flower development, fruit set, fruit maturation, fruit ripening, and fruit abscission.

GENERAL APPLICATION INSTRUCTIONS

IMPORTANT

- Do not apply this product through any type of irrigation system.
- ReTain is packaged in a water-soluble bag sealed inside a metalized polyester pouch. Each water-soluble bag contains 11.7 oz (333 grams) of ReTain. Once the outer pouch is opened, the entire water-soluble bag must be used.
- Because the proper timing of ReTain application is particularly important to product performance, serious consideration is to be given, on a block-by-block basis, to any site conditions (e.g., elevation, sun exposure, soil texture), growing condition(s) (e.g., prevailing or anticipated weather patterns such as high temperature, chilling, drought or flood conditions, nutrient levels) or production practices (e.g., crop load, pruning severity) that could impact flowering, fruit set, or fruit maturation during the course of the season.
- On tree crops and cucumbers, apply ReTain in a sufficient amount of water to ensure that flowers, fruits, and foliage receive thorough spray coverage using calibrated spray equipment. Adjust water volumes based on plant size and spacing. However, excessive spray application volumes resulting in spray runoff will reduce product efficacy.
- On pineapple, apply Retain to the plant core (apex of the meristem) of pre-flowering plants is a sufficient amount of water to ensure thorough coverage.
- Prepare spray solution by mixing the required amount of product with water in a clean, empty spray tank. Dispose of any unused spray material at the end of each day
- Avoid applications during the heat of the day. For best results, apply ReTain under slow drying conditions, e.g. early in the morning or at night, in order to maximize absorption.
- Maintain solution pH between 6 and 8.
- For apple, pear, stone fruit, walnut, pecan and cucumber, do not apply ReTain to plants or fruit under stress (e.g. heat, water, disease, insect). Injured or stressed plants or fruits may not respond to ReTain.

- ReTain may be applied to pineapple plants under stress conditions that induce Natural Induction (NI) of flowering, also known as Naturally Differentiated Flowering (NDF).
- Do not use overhead cooling or irrigation equipment for at least 8 hours following ReTain application.
- Do not apply ReTain if rain is expected within 8 hours of application.

COMPATIBILITY WITH OTHER AGRICULTURAL PRODUCTS

ReTain can be tank-mixed with DiPel[®], Biobit[®], and Xentari[®] biological insecticides. Compatibility and performance data for ReTain with other agricultural products are not available.

Do not tank mix ReTain with other products unless compatibility has been verified. If considering tank mixing ReTain 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 (1-800-6 Valent).

| CROP | OBJECTIVE / BENEFIT: | APPLICATION TIMING/ USE INSTRUCTIONS |
|---------------------------|--|---|
| Apple | Depending on cultivar, orchard conditions, application timing, and grower objectives, one or more of the following benefits will be associated with ReTain Delayed fruit maturity Improved harvest management Reduced preharvest fruit drop Additional time for increase in fruit size Additional time for color development Maintenance of fruit firmness Improved fruit quality (e.g., reduced incidence and/or severity of watercore and stem bowl cracking) Enhanced storage potential | Single Pick Harvest: Apply one pouch of ReTain per acre three to four weeks prior to the anticipated beginning of the normal harvest period of untreated fruit for the current season. ReTain applied three to four weeks before harvest will delay the harvest period up to 7 to 10 days. Applications made either too early or too late will significantly reduce the efficacy of the product. Multiple Pick Harvest: To improve the fruit quality and storage potential of later picked apples (2nd, 3rd, 4th picks) apply one pouch of ReTain per acre, one to two weeks prior to the anticipated beginning of the normal harvest period of untreated fruit for the current season. ReTain applied one to two weeks before harvest typically will not delay the start of the harvest (1st pick), but will help control the maturation rate of the later picks. |
| Pear | ReTain will offer one or more of the same benefits as listed for apples, depending on the cultivar, growing conditions, and grower objectives. | Apply one pouch of ReTain per acre 7 to 16 days prior to the anticipated <i>beginning of the normal harvest period of untreated fruit</i> for the current season. |
| per acre. and Honey | rvest management and fruit quality benefits from Re Jnder difficult coloring conditions, color developmen crisp [™] will be delayed when ReTain is applied at or e practices for your location, consult with your Valer | nt of certain bi-color apple cultivars such as Gala ne pouch per acre. For specific information on |
| thorough c orchard air | lume: ReTain efficacy requires that fruit and foliage overage adjust water volumes based on tree size and blast sprayer). Excessive spray application volumes ce. In most cases, 100 gallons per acre has been show | spacing and use calibrated spray equipment (i.e. that result in spray runoff will reduce product |
| concentrat concentrat | 5: For optimal response, use ReTain with a 100% or g ion of 0.05 to 0.1% (v/v) in the spray tank. To preve ion when high temperature (in excess of 86° F) weath ctant concentration greater than 0.1% (v/v). To redu | nt possible spotting, use the 0.05% (v/v) her conditions prevail or are anticipated. Do not |

APPLE AND PEAR – FOR HARVEST MANAGEMENT AND IMPROVEMENT OF FRUIT QUALITY

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Harvest: The normal harvest period for a particular orchard block refers to that time when fruits not treated with ReTain would be harvested for long term storage. To help determine the *beginning of the normal harvest period*, refer to historical trends for harvest dates and the "days from full bloom to harvest" interval for each cultivar in your area.

Additional Notes:

- Apply ReTain before laying reflective film or foil mulch under ReTain treated apple trees. ReTain may be applied either before or after laying fabric groundcovers under ReTain treated apple trees.
- ReTain has a 7 day preharvest interval (PHI) for Apple and Pear.
- Do not tank-mix ReTain with sunburn protection product. If sunburn protection products are used, apply at least 3 days before or after ReTain application.

STONE FRUIT (EXCEPT CHERRY) – FOR HARVEST MANAGEMENT AND IMPROVEMENT OF FRUIT QUALITY

| CROP | OBJECTIVE / BENEFIT | APPLICATION TIMING/ USE INSTRUCTIONS |
|--|---|---|
| Apricot Nectarine Peach Plum Prune (Interspecific variations of these crops, such as Plum-cot, Pluot [®] , and Aprium [®]) | Depending on cultivar, orchard conditions, and grower objectives, one or more of the following benefits will be associated with ReTain: Improved harvest management Additional time for increase in fruit size Maintenance of fruit firmness Reduced preharvest fruit drop Improved fruit quality Enhanced storage potential. | Apply one pouch of ReTain per acre one to two weeks prior to the anticipated beginning of the normal harvest period of untreated fruit for the current season. |

Water Volume: ReTain efficacy requires that fruit and foliage receive thorough spray coverage. To ensure thorough coverage adjust water volumes based on tree size and spacing and use calibrated spray equipment (i.e. orchard air blast sprayer). Excessive spray application volumes that result in spray runoff will reduce product performance. In most cases, 100 gallons per acre has been shown to be effective.

Use of Adjuvants: For optimal response, use ReTain with a 100% organosilicone surfactant. Use a final surfactant concentration of 0.05 to 0.1% (v/v) in the spray tank. To reduce foaming, add the adjuvant last and minimize agitation.

Harvest: The normal harvest period for a particular orchard block refers to that time when fruits not treated with ReTain would be harvested. To help determine the beginning of the normal harvest period, refer to historical trends for harvest dates and the "days from full bloom to harvest" interval for each cultivar in your area, and closely monitor the fruit maturity development for the current season.

Additional Notes:

Pre Harvest Interval (PHI): ReTain has a 7 day (PHI) for labeled Stone Fruit.

NUT, POME AND STONE FRUIT CROPS – FOR INCREASING FRUIT AND NUT SET

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| CROP | OBJECTIVE / BENEFIT | APPLICATION TIMING/ USE INSTRUCTIONS |
|-------------------------------|---|--|
| Apple | To increase fruit set. | Apply one pouch of ReTain per acre, as a single application from pink stage to full bloom. Applications made prior to pink stage or after full bloom will significantly reduce efficacy of the treatment. Do not apply after petal fall. |
| Cherry | To increase fruit set. | Apply one pouch of ReTain per acre, as a single application during bloom. Applications between balloon stage to first bloom are more effective than earlier or later applications. Do not apply after petal fall. |
| European Pear cultivars | To increase fruit set. | Apply one pouch of ReTain per acre, as a single application from white bud stage to full bloom. Applications made prior to white bud stage or after full bloom will significantly reduce efficacy of the treatment. Do not apply after petal fall. |
| Pecan | To increase nut set in cultivars that experience low set. | Apply one to two pouches of ReTain per acre within 2 weeks after the surface of most of the stigma (apical end of the pistil) are no longer moist enough to retain pollen or dust. |
| | | Use higher rates on cultivars/orchards that have experienced lower nut set. Applications made either too early (pre-bloom) or too late (after full bloom) will reduce the efficacy of the treatment. |
| Walnut | Increased nut set in cultivars affected by pistillate flower abortion (PFA). | Apply one to two pouches of ReTain per acre, when most pistillate (female) flowers are receptive to pollination. ReTain may be applied as a single application of up to two pouches, or as sequential applications of one pouch per application. One application of ReTain at 5-30% pistillate flower bloom has been shown to be effective for a short pistillate flower bloom period. Sequential applications at 5-30% and 45-65% bloom are effective and cover a broader window of pistillate flower bloom. Applications made either too early (pre-bloom) or too late (full bloom or later) will significantly reduce efficacy of the treatment. |
| | | Use higher rates on cultivars/orchards that have experienced high incidences of poor nut set due to PFA. |

IMPORTANT:

- For apple and pear, do not apply more than one pouch for increasing fruit set. Do not use more than one pouch for harvest management and improvement of fruit quality. Do not apply more than 2 pouches of ReTain per acre per year.
- For sweet cherry, do not apply more than one pouch for increasing fruit set. Do not apply ReTain to sweet cherry trees when fruit are present.
- For pecan and walnut, do not apply more than 2 pouches of ReTain per acre per year.

Water Volume: ReTain efficacy requires that flower buds and flowers receive thorough spray coverage. To ensure thorough coverage use calibrated spray equipment (i.e. air blast sprayer) and adjust water volumes based on tree size and spacing. Use sufficient water volume to achieve thorough coverage without excessive runoff. In most cases, a spray volume of 100 to 200 gallons per acre has been shown to be effective.

Use of Adjuvants: Use of adjuvants with ReTain for bloom applications has not been fully researched. Some adjuvants will cause a bloom thinning effect and will reduce the benefits of ReTain.

CUCUMBER - FOR SEED PRODUCTION ONLY

| CROP | OBJECTIVE / BENEFIT | APPLICATION TIMING/ USE INSTRUCTIONS |
|---|--|--|
| Cucumber Gynoecious inbred breeding lines. | Promotion of staminate (male) flowers in gynoecious (female flowering) cucumber-breeding lines for the purpose of producing inbred and hybrid cucumber seed. | Apply ReTain directly to gynoecious plants to be converted to staminate flowers. Make one to six applications of 250 ppm to 1000 ppm AVG HCL beginning at early first leaf stage through tenth leaf stage. Use the appropriate skip row technique to achieve desired sex ratio of plants. |

Water Volume: Apply ReTain in a sufficient amount of water to ensure good thorough coverage. In most cases, 26 to 52 gallons per treated acre will be sufficient. The application rate and frequency of application will depend on the sensitivity of the individual inbred line to ReTain. Leaf yellowing can occur at high rates. If unacceptable leaf yellowing is noted, use lower concentrations in subsequent applications.

Dilution Table: Parts Per Million (ppm) AVG HCl with varying Gallons (gal) of spray solution and pouches of ReTain for cucumber use.

| Gal Spray Solution | Pouches of ReTain | Grams AVG HCl | Ppm AVG HCl |
|--------------------|-------------------|---------------|-------------|
| 13 | 1 | 50 | 1000 |
| 26 | 1 | 50 | 500 |
| 52 | 1 | 50 | 250 |

Use of Adjuvants: Addition of an adjuvant to ReTain increases the likelihood of leaf yellowing in young cucumber plants.

Additional Note: Do not reapply ReTain within 24-hours of application. Use of ReTain on cucumber is for gynoecious breeding line and hybrid seed production only. Do not apply directly to, or allow spray to drift to cucumber crops grown for fresh or processed markets. Fruit from plants treated with ReTain is not to be used for human or animal consumption.

PINEAPPLE

| CROP | OBJECTIVE / BENEFIT: | APPLICATION TIMING/ USE INSTRUCTIONS |
|-----------|---|--|
| Pineapple | Reduce the incidence of Natural Induction (NI) of flowering, also known as Naturally Differentiated Flowering (NDF) and commonly | Apply 2 to 3 pouches of ReTain per acre, directing the spray pattern toward the plant core of pre-flowering pineapples. |
| | known as "kicking over". Reduction of NDF allows for artificial induction of flowers (forcing) at the appropriate plant maturity to give more uniform flowering and consequently more uniform fruit maturity. | Make the first application of ReTain 7 days prior to the first anticipated occurrence of conditions that favor NDF, typically in early November, near weeks 44 to 45. Make subsequent applications at 7 day intervals through the end of the susceptible NI period, typically near weeks 7 to 8 of the following year or prior to artificial induction of flowers (forcing), if this occurs during the NDF period. |
| | | Apply no more than 44 pouches of ReTain per acre per crop of pineapples. Conditions that favor NDF in pineapple include: cool temperatures (< 68°F); short photoperiod (< 12 hr); prolonged overcast and rainy weather plants weigh greater than 2.5 lb (for "sweet golden" cultivars) |

Water Volume: ReTain efficacy requires that the plant core receive thorough spray coverage. Insufficient spray application volumes or uneven application patterns will reduce product performance. Spray volumes of 185 to 250 gallons per acre have been shown to be most effective.

Adjuvants: ReTain may be used with a 100% organosilicone surfactants at a final surfactant concentration of 0.05% (v/v). To reduce foaming, add the adjuvant last and minimize agitation.

IMPORTANT:

- Apply ReTain to pineapple plants only <u>prior to</u> initiation of flowering. Subsequent applications of ReTain to pineapple plants and fruit that have undergone NDF will result in malformed fruit.
- Do not spray or allow drift onto pineapple plants that have initiated induction, are in bloom or have fruit.
- Do not apply ReTain to pineapples if chilling and other conditions that favor NDF have occurred prior to the first scheduled application.
- Continued control of NDF after the first application of ReTain, will require weekly applications of ReTain during the entire period of NDF susceptibility up to 7 days prior to forcing.
- If more than 7 days have elapsed since the previous ReTain application, pineapples will again become susceptible to NDF even if previously treated with ReTain
- If a chilling event or other conditions that favor NDF have occurred later than 7 days from the previous application, but before subsequent ReTain applications can be made, make no additional applications of ReTain to avoid the occurrence of malformed fruit.
- Combination effects and potential interactions between ReTain and other agricultural products have not been thoroughly tested. Tank-mixing ReTain with other agricultural products may reduce the efficacy of ReTain.
- ReTain requires an 8 hour rain-free period after application.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store product in a cool and dry place. Avoid extended storage conditions at temperatures above 25°C (77°F).

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of onsite or at an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Completely empty container into applicable equipment. If recycling is not available dispose of empty container in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

NOTICE TO USER

Warranty and Disclaimer Statement:

To the extent consistent with applicable law, 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. To the extent consistent with applicable law, user assumes all risks of use, storage or handling not in strict accordance with accompanying directions.

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