

10163-253

3-28-2006

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MAR 28 2006

Ms. Cindy Baker
Gowan Company
P.O. Box 5569
Yuma, AZ 85366-5569

Subject: Label Amendment to Add Citrus, Grapes, and Pome Fruits

EPA Registration No. 10163-253
Onager™ 2E Ovicide/Miticide
Your submissions dated February 28, 2002; August 24, 2005

Dear Ms. Baker:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable subject to the comments listed below. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

1. As you agreed in your letter of August 24, 2005, you will submit the following data as specified in EPA's reviews dated 23-May-2005 and 21-Sept-2005 (Tom Bloem, OPP/HED):
 - an orange processing study (Guideline 860.1520);
 - a full set of apple and pear field trial trials (Guideline 860.1500) conducted with the EC formulation.

You will submit these data within 2 years from the date of this letter (March, 2008).

2. You have agreed to satisfy the following data requirements by conducting studies in accordance with 40 CFR Part 158 should the Agency disagree with other options such as waivers and submittal of data generated for other countries or regulatory agencies. Please

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refer to the Ecological Risk Assessment Memorandum for the subject uses dated August 2, 2005 for details:

- Freshwater fish early life-stage study (Guideline 72-4(a));
- Freshwater fish full life-cycle study (Guideline 72-5);
- Avian reproduction (Guideline 71-4);
- Estuarine/marine fish LC₅₀ study (Guideline 72-3(a));
- Estuarine/marine mollusk LC₅₀ study (Guideline 72-3(b));
- Estuarine/marine shrimp LC₅₀ study (Guideline 72-3(c));
- Estuarine/marine fish full life-cycle study (Guideline 72-5);
- Estuarine/marine invertebrate life-cycle study (Guideline 72-4(b)).

You will submit these data by March, 2009.

3. You will submit production information (pounds or gallons produced) for this product for the fiscal year in which the added uses are conditionally registered, in accordance with FIFRA Section 29. The fiscal year begins October 1 and ends September 30. The production information will be submitted to the Agency no later than November 15 following the end of the preceding fiscal year.

This information should be submitted to:

U.S. Environmental Protection Agency
Office of Pesticide Programs (7504C)
Document Processing Desk
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

4. Make the following label changes:

- Separate the statements beginning with "*Have the product container with you ...*" from the Note to Physician statements, and place under the heading "*Hot Line Number*". Please refer to the boxed format example provided with PR Notice 2001-1.
- Change "*Onager*" to "*Onager 2E*" throughout the label.
- Revise "*Onager 2E Miticide is a 1 pound active ingredient per gallon...*" to read "*Onager 2E Miticide is a 2 pound active ingredient per gallon...*"
- Delete "*unless otherwise stated*" from the statement "*Do not make more than one application of Onager Miticide per year...*" Only one application per year is allowed for the approved uses.
- On the table under application directions for grapes and for citrus, revise "*For applications by ground equipment ...*" to read "*Application by ground equipment*"

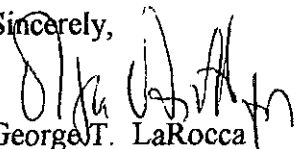
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only." Only ground application is approved for these uses.

You should note that if you fail to satisfy any of the conditions imposed on this registration, e.g., you fail to submit the required data by the specified deadlines or the data submitted were not generated in accordance with applicable test guidelines, EPA may issue notice to cancel these uses under FIFRA 6(e).

If you have any questions regarding this action, please contact Olga Odiott of my team at (703) 308-9369.

Sincerely,



George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division (7505C)

Enclosure

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Onager™ 2E

Ovicide/Miticide

EMULSIFIABLE CONCENTRATE FOR AGRICULTURAL USE ONLY

ACTIVE INGREDIENT: Hexythiazox	% By Wt.
<i>trans</i> -5-(4-Chlorophenyl)-N-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide	24.2%
OTHER INGREDIENTS	<u>75.8%</u>
	TOTAL 100%

Onager 2E contains 2 lbs. active ingredient per gallon

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

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.

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 eyes. 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 INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. 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

FOR MEDICAL EMERGENCIES INVOLVING THIS PRODUCT, CALL TOLL FREE 1-888-478-0798

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed or inhaled. Causes moderate eye irritation. Avoid breathing vapor or spray mist. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

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

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.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when cleaning equipment or when disposing of equipment washwaters.

PHYSICAL OR CHEMICAL HAZARDS

Do not use, pour, spill or store near heat or open flame.

NET CONTENTS 1 Gal.

EPA Reg. No. 10163-253
EPA Est. No. 67545-AZ-01

Gowan

**ACCEPTED
with COMMENTS
in EPA Letter Dated**

MAR 28 2006

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

10163-253

Gowan Company
P. O. Box 5569
Yuma, AZ 85366-5569

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GENERAL INFORMATION

Onager 2E Ovicide/Miticide is recommended for use as a foliar application in labeled crops. Onager Miticide provides effective control of major spider mite species. It is an emulsifiable concentrate to be mixed with water and applied as a spray.

Onager controls mites through activity on eggs and immature stages. Control is achieved from either direct contact with the spray or from contact with treated plant surfaces. Through its ovicidal activity, Onager controls newly deposited mite eggs and eggs which are laid after application. Onager is also highly effective in controlling immature mite stages of target mite species that are sprayed or move onto treated surfaces. Adult mites are not directly affected. However, eggs produced by females in contact with treated surfaces will be rendered inviable. Onager provides extended residual control of pest mite species without disrupting beneficial insects and mites. The degree and duration of control is dependent on the rate used, growth stage of the mite, species of mite, and climatic conditions under which the material is applied.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Follow all directions on the EPA approved label and any supplemental 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 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 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:

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

Managing Mite Resistance: Repeated use of miticides with similar modes of action may lead to buildup of resistant strains of mites. For resistance management, apply Onager only once per year. To reduce the potential for developing mite resistance, do not apply a miticide with a similar mode of action more than once per year (Onager and Apollo® should not be applied to the same crop in any one year). If additional miticide applications are needed, use a product with a different mode of action, such as a contact adulticide. Read and follow product label before applying any miticide.

Mixing Directions: If this product is packaged in water-soluble bags, please read and observe the following directions for use:

- Packets containing Onager are water-soluble. Avoid exposing inner bags to moisture.
- Do not allow bags to become wet prior to adding to the spray tank.
- Do not handle inner bag with wet hands.
- Reseal outer bag in a manner that protects remaining packets from moisture.
- Turn on spray tank agitation prior to adding water-soluble packets.
- To prepare the spray mixture, drop the required number of unopened packets to meet desired ounces, as determined under **APPLICATION DIRECTIONS**, into the spray tank while filling with water to the desired level (whenever possible direct the fill water over the top of the packets to increase the rate of solubility). Where dosages of Onager are expressed as fractions of packets, prepare the tank mix load to the lower of the nearest whole packet.
- Depending on the water temperature and the degree of agitation, the packets should be completely dissolved within approximately three to five minutes from the time they were added to the spray tank.
- Once the packets have completely dissolved, add other chemicals following conventional mixing order practices.
- Tank-mix solutions containing boron will affect the solubility of the water-soluble film. Thoroughly rinse the spray tank of any boron-containing spray solution prior to adding any water-soluble packets. When preparing tank mixes containing boron, add the correct amount of Onager to the spray tank first. Make sure that the water-soluble packets are completely dissolved. Add boron preparations to the spray tank last. High concentrations of boron may cause dissolved water soluble bag material to precipitate and form insoluble residue in the spray tank system.

If this product is **NOT** packaged in water-soluble bags, please read and observe the following directions for use:

- Turn on spray tank agitation. Pour recommended amount of this material on the surface of water in a nearly filled spray tank.
- Add balance of water to fill the tank.
- Keep agitator running during filling and spraying operations. Do not allow mixture to stand.

Compatibility: Onager is compatible with most agricultural chemicals. However, all possible combinations have not been evaluated. Before full-scale mixing of Onager with other products, test mix small proportionate quantities of each to ensure compatibility.

Phytotoxicity: As is common with most emulsifiable concentrate formulations, adverse effects such as spotting or discoloration of the treated surfaces can occur. Some conditions known to contribute to phytotoxicity include, but are not limited to, high temperatures, poor spray drying conditions, excessive spray deposit or run-off, certain spray mixtures, stage of crop development or tank mixes with other pesticides.

Application Information: Use sufficient spray volume to obtain thorough, uniform coverage of all plant surfaces. Apply using ground equipment only unless otherwise specified under the crop comments or on supplemental labeling supplied by Gowan Company.

Important: Onager 2E Miticide is a 1 pound active ingredient per gallon emulsifiable concentrate formulation to be diluted with water for application in commercial plantings only. Do not use in home plantings.

Use Recommendations: For best results, apply Onager 2E Miticide at first sign of mites before adult mite build up. Onager 2E Miticide will not control adult spider mites. Use higher rates on moderate to high mite infestations, large trees with dense foliage, or for extended residual control.

rest rate of Onager Mticide may be used in conjunction with other IPM strategies, or for shorter residual control later in the season. The less than label rates is not recommended since it will result in poor performance and contribute to resistance development. If adult mites present in medium to high populations, better results may be obtained using Onager 2E Mticide in combination with a registered contact insecticide. Onager 2E Mticide may be tank mixed with horticultural grade oil. Refer to all precautions regarding phytotoxicity on the oil label. Do not make more than one application of Onager Mticide per year unless otherwise stated.

PREHARVEST INTERVAL

Required days between the last application and harvest are given in () after each crop name.

APPLICATION DIRECTIONS

	PEST	RATE OZS./ACRE	COMMENTS
√ (35) (in California Only)	Twospotted spider mite, Pacific spider mite, Strawberry spider mite, Carmine spider mite	6-10	Apply Onager before boll opening and prior to adult mite buildup. Complete coverage of foliage is essential to optimal performance. (For air applications, use recommended per acre rate and apply a minimum of 2 gallons of finished spray per acre.) <ul style="list-style-type: none"> Do not apply more than a total of 10 oz. formulated product per acre per year. Do not make more than one application per year.
UTS GROUP AND PISTACHIOS: (including but not limited to: Almond, Beech Nut, Brazil Nut, Butternut, Cashew, Chestnut, Chinquapin, Filbert (Hazelnut), Pecan, Pecan, Pistachios, and Walnut and English) (28)	European red mite, Twospotted spider mite, McDaniel spider mite, Strawberry spider mite, Pacific spider mite, Pecan leaf scorch mite, Willamette mite, Citrus Red Mite	8-12	For air applications, apply a minimum of 5 gallons finished spray per acre. <ul style="list-style-type: none"> Do not make more than one application per year.
FRUITS GROUP (including) (including but not limited to: Apples, Cherries (sweet & tart), Peaches, Plums, Plumcots, and Prunes) (28)	European red mite, Twospotted spider mite, McDaniel spider mite, Strawberry spider mite, Pacific spider mite, Pecan leaf scorch mite, Willamette mite	6-12	For air applications, apply a minimum of 5 gallons finished spray per acre. <ul style="list-style-type: none"> Do not make more than one application per year.
S (28)	Tetranychid Mites (such as European Red Mite and Twospotted Spider Mite)	6-12	For application by ground equipment, use sufficient volume of water to obtain complete coverage but not less than 20 gallons per acre. <ul style="list-style-type: none"> Do not make more than 1 application per year. Do not apply more than 12 ounces per acre per year.
(28) and TX ONLY)	Tetranychid Mites (such as European Red Mite and Twospotted Spider mite)	6-12	For application by ground equipment, use sufficient volume of water to obtain complete coverage but not less than 20 gallons per acre. <ul style="list-style-type: none"> Do not make more than 1 application per year. Do not apply more than 12 ounces per acre per year.
FRUIT GROUP (including but not limited to: Apple, Pear, Loquat, Mayhaw, Pear, and Prune) (28)	European red mite, Twospotted spider mite, McDaniel spider mite, Pacific spider mite, Willamette mite	6-12	For application by ground equipment, use sufficient volume of water to obtain complete coverage but not less than 20 gallons per acre. For application by air, use sufficient volume of water to obtain complete coverage but not less than 10 gallons per acre. <ul style="list-style-type: none"> Do not make more than one application per year. For D'Anjou or Bosc pear varieties, use higher labeled rates (8-12 oz./acre).

RESTRICTIONS ON ALL CROPS

Do not graze or feed livestock on cover crops growing in treated areas.

Do not use water from treated fields for irrigating other crops.

Do not apply this product through any type of irrigation system.

Onager is an emulsifiable concentrate to be diluted with water for application in commercial plantings only.

Apply Onager prior to adult mite build up. Onager will not control adult spider mites. Use higher rates on moderate to high mite infestations on larger plants with a dense canopy. If adult mites are present in medium to high populations, better results may be obtained using Onager in combination with a registered contact adulticide. The use of less than label rates is not recommended with Onager.

Do not make more than one application of Onager per year.

Do not plant rotational crops other than those on this label within 120 days of this application.

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STORAGE AND DISPOSAL

DO NOT contaminate water, food or feed by storage or disposal.

STORAGE: Store product in original container only, away from other pesticides, fertilizers, food or feed.

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

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by incineration or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

FOR 24-HOUR EMERGENCY ASSISTANCE (SPILL, LEAK OR FIRE), CALL CHEMTREC® (800) 424-9300.

For other product information, contact Gowan Company or see Material Safety Data Sheet.

NOTICE OF CONDITIONS OF SALE AND WARRANTY AND LIABILITY LIMITATIONS

Important: Read the entire Directions for Use and Notice of Conditions of Sale and Warranty and Liability Limitations before using this product. If terms are not acceptable return the unopened container for a full refund.

Our recommendations for use of this product are based on tests believed to be reliable. However, it is impossible to eliminate all risk associated with the use of this product. Crop injury, inadequate performance, or other unintended consequences may result due to soil or weather conditions, off target movement, presence of other materials, method of use or application, and other factors, all of which are beyond the control of Gowan Company. All such risks shall be assumed by the Buyer and User.

Gowan Company warrants that this product conforms to the specifications on the label when used in strict conformance with Direction for Use, subject to the above stated risk limitations. GOWAN COMPANY MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY

TO THE FULLEST EXTENT PERMITTED BY LAW, GOWAN COMPANY'S EXCLUSIVE LIABILITY FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, OR ANY OTHER LEGAL THEORY IS STRICTLY LIMITED TO THE PURCHASE PRICE PAID OR REPLACEMENT OF PRODUCT, AT GOWAN COMPANY'S SOLE DISCRETION.

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Apollo is a registered trademark of AgrEvo USA Company

Onager is a registered trademark of Nippon Soda Company, Ltd.

Apollo is a registered trademark of AgrEvo USA Company

PRINTING ON WATER SOLUBLE BAG

Onager 2E, EPA Reg. No. 10163-253

Onager 2E

EPA Reg. No. 10163-253

Contains 24.2% hexythiazox

CAUTION

KEEP OUT OF REACH OF CHILDREN

Refer to outer bag for instructions

EPA Text Pending: Onager 2E pome citrus grapes (resent to EPA 08-24-05)