



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 9, 2022

Jolanta Ozatalay
Regulatory Manager
Fine Agrochemicals Ltd.
1850 Mt. Diablo Blvd., Suite #405
Walnut Creek, CA 94596

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling and Formulation Amendment –Revision to the Basic Confidential Statement of Formula (CSF) and the Alternate CSF to Add Manufacturing Sites; and Amendment to Label to Add Optional NOP Claims and to Storage and Disposal Statements
Product Name: FAL 477
EPA Registration Number: 62097-47
EPA Receipt Date: 02/28/2022 and 03/30/2022
Action Case Number: 00342701 and 00352543

Dear Ms. Ozatalay:

The amended labeling and Confidential Statements of Formula (CSFs) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following acceptable CSF:

- Basic CSF dated 03/30/2022
- Alternate CSF dated 3/30/2022

Any CSFs other than that listed above are superseded/no longer valid.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company’s website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be

Page 2 of 2

EPA Reg. No. 62097-47

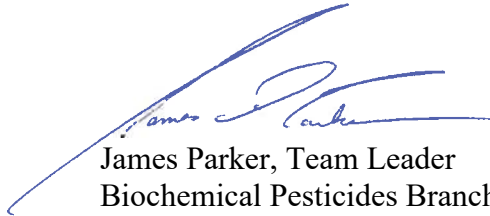
Action Case No. 00342701 and 00352543

considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

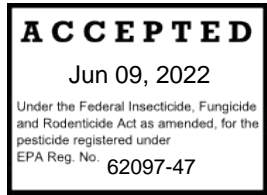
If you have any questions, please contact Chris Pfeifer of my team by phone at (703) 244-7991 or via email at pfeifer.chris@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "James Parker", is written over a horizontal line.

James Parker, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511M)
Office of Pesticide Programs

Enclosure

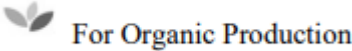


Note for reviewer- [] denotes optional text

FAL477

ABN: Novagib 5L

Plant growth regulator solution for use on apples [and cherries]



Active Ingredient: Gibberellins A ₄ A ₇	5.00%
Other Ingredients:	<u>95.00%</u>
Total:	100.00%

EPA Reg. No. 62097-47

EPA Est. No.

Net Contents: ½ gallon (1.89 liters)
 Lot/Batch No.:

**KEEP OUT OF REACH OF CHILDREN
 CAUTION**

[See attached label booklet for first aid, precautionary, storage and disposal statements, and Directions for Use.]

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.)

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.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none"> • 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.
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For information on this pesticide product (including general health concerns or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378, Monday through Friday, 8:00 AM to 12:00 PM Pacific Standard Time. In the event of a medical emergency, call your poison control center at 1-800-222-1222.</p>	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin, or clothing. Wear chemical resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.**PERSONAL PROTECTIVE EQUIPMENT (PPE)**

Applicators and other handlers must wear:

- * Long-sleeved shirt and long pants.
- * Socks and shoes.

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, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE 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, was thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

For terrestrial uses: 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 wash waters.

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 requirement specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation. Do not apply this product through any type of irrigation system.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labelling 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 the label about personal protective equipment (PPE) and restricted entry intervals. The requirements in this box only apply to uses of this product covered by the Worker Protection Standard.

Do no enter or allow 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)
- Shoes plus socks

GENERAL INFORMATION

- FAL477 is a plant growth regulator for use on apples [and sweet cherries].
- FAL477 improves the quality of harvested apples by reducing physiological russetting of the fruit.
- FAL477 may increase fruit weight.
- FAL477 may only reduce russetting caused by climatic factors affecting the fruit during the first 30-40 days of development. FAL477 will not reduce russetting caused by other factors (e.g., pest, disease or chemical action).
- [FAL477 improves the fruit size of sweet cherries.]
- Apply FAL477 using conventional spray application machinery or as otherwise directed in this label.
- Do not apply to low vigor trees, or trees under stress from drought, winter injury, etc.
- Apply under calm weather conditions, as a uniform fine mist spray, so that 85% of the spray volume is directed into the upper $\frac{2}{3}$ of the trees.
- Use a properly calibrated sprayer to ensure uniform and complete coverage of all foliage and developing fruit. Spray volume should be adjusted for tree size and density. Do not apply in more than 200 gallons of water/acre, preferably use less than 100 gallons of water/acre.
- Do not apply when the air temperature is lower than 40°F or greater than 90°F.
- FAL477 works best if climatic conditions allow an extended drying period. Consider application in the morning or evening when temperatures are lower and humidity tends to be higher than during the day.
- Rainfall within 6 hours of application may reduce the efficacy of FAL477.

Restrictions

- FAL477 must not be applied using irrigation equipment.
- Do not apply in water volumes greater than 100 gallons/acre to reduce the risk of russet caused by the spray water.
- Do not add any kind of wetting adjuvant or surfactant unless you are sure of its crop safety. Materials of this type have been shown to cause russetting.
- For apple russetting, do not apply more than 16 fl. oz. per acre per growing season.
- For cherries, do not apply more than 9.6 fl. oz. per acre per growing season.

SPRAYING GUIDE FOR APPLE RUSSET REDUCTION

When used to reduce russetting of fruit, apply FAL477 in 2-4 consecutive applications. Make the first application of 4.0 – 6.6 fluid ounces (fl. oz.) in 100 gallons of water per acre at the beginning of petal fall. Repeat this at 7 – 10 day intervals applying a total of 13.2 – 16.0 fl. oz. per acre. Determine rate and frequency of application by varietal susceptibility to russet, weather conditions and tree size. Large trees of susceptible varieties suffering high rainfall require the most frequent applications at the highest rate. In general, 4 applications give the best control of russet.

- Apply all sprays as a fine mist to ensure maximum coverage and spray retention on flowers and foliage. Use a properly calibrated sprayer.
- Apply in conditions conducive to slow drying.

- Always refer to the partner product label when applying FAL477 in tank mixtures and follow all precautions and directions given. The efficacy of FAL477 may be reduced by compounds causing a high pH in the spray tank.

SPRAYING GUIDE FOR SUPPRESSION OF PREHARVEST FRUIT CRACKING IN - APPLES

FAL-477 can be used to suppress cracking in ‘Stayman’ apples. Other apple varieties prone to cracking may also benefit from applications of FAL-477 for suppression of cracking.

When used to suppress cracking of apples, apply FAL477 in 3 – 6 consecutive applications. Make the first application of 6.4 – 12.8 fl. oz. in sufficient water to achieve good coverage of the fruit, 2 – 3 weeks before fruit cracking is expected to occur. This would normally be between mid-June and mid-July but will be affected by geography, climate and other factors. Repeat this at 14 – 21 day intervals. The use of the higher number of applications at the higher rates with the shorter time interval gives the strongest suppression of cracking. In general, at least 4 applications are required for best cracking suppression.

- There are many factors that affect cracking in apples; therefore, the use of FAL477 does not guarantee that cracking will not occur. Use FAL477 as one part of a management program to produce the highest quality crop.
- Apply in conditions conducive of slow drying.
- Always refer to the partner product label when applying FAL477 in tank mixtures and follow all precautions and directions given. The efficacy of FAL477 may be reduced by compounds causing a high pH in the spray tank.
- A non-ionic wetting agent can be used to improve coverage and enhance penetration.
- Application after cracking has started will greatly reduce the efficacy of FAL477.

[SPRAYING GUIDE FOR IMPROVED FRUIT SIZE IN SWEET AND TART CHERRIES*

When used to improve fruit size in sweet and tart cherries, apply FAL477 in 1-4 consecutive applications. Make the first application of 1.2 – 2.4 fl. oz. in 100 gallons of water (5-10 ppm), preferably beginning at first white stage but no earlier than tight cluster stage. Repeat applications may be made in 7-14 day intervals after the first application up to petal fall, applying a total of 1.2 – 9.6 fl. oz. per acre.

- Apply all sprays as a fine mist to ensure maximum coverage and spray retention on tree. Use a properly calibrated sprayer.
- Apply in conditions conducive to slow drying.
- Always refer to the partner product label when applying FAL477 in tank mixtures and follow all precautions and directions given. The efficacy of FAL477 may be reduced by compounds causing a high pH in the spray tank.
- **Multiple applications and high rates of FAL477 in excess of those stated above may reduce return bloom the next season in certain varieties.]**

***Not for use in California.**

STORAGE AND DISPOSAL

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

Pesticide Storage: Keep containers tightly closed when not in use. Store below 75°F (24°C).

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

[for container size 5 gallons or less] Container Handling: Non-refillable container. Do not reuse or refill this container. 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. Then offer for recycling or reconditioning, or puncture and dispose of in sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.]

[for container size greater than 5 gallons] CONTAINER HANDLING: Non-refillable 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. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning, if available, 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.]

WARRANTY DISCLAIMER AND LIMITATION OF LIABILITY

Fine Agrochemicals Limited ("FINE") warrants that this Product conforms to the specifications on this label. To the extent consistent with applicable law, FINE makes no other warranties and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for a particular purpose. No agent of FINE or any other person is authorized to make any representation or warranty beyond those contained herein.

It is impossible to eliminate all risks associated with this Product. Plant injury, lack of performance, or other unintended consequences may result because of factors such as abnormal weather conditions, use of the Product other than in strict accordance with this label's instructions, presence of other materials, the manner of application or other factors, all of which are beyond the control of FINE or the seller. To the extent consistent with applicable law, all such risks shall be assumed by the Buyer.

To the extent consistent with applicable law: 1) FINE disclaims any liability whatsoever for special, incidental or consequential damages resulting from the handling or use of this Product and 2) FINE's liability under this label shall be limited to the amount of the purchase price or, at the election of FINE, the free replacement of the Product.

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