

7/5/2-1

8/10/2001

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg.
Number:

71512-1

Date of Issuance:

AUG 10 2001

NOTICE OF PESTICIDE:

 x Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Omega 500

Name and Address of Registrant (include ZIP Code):

ISK Biosciences Corporation
7470 Auburn Road, Suite A
Concord, OH 44077

Attention: Michael Peplowski

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(C) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Make the following label changes:
 - a. Revise the EPA Registration Number to read, "EPA Reg. No. 71512-1".
 - b. Change application dosage rates for potatoes from "ounces (oz.)" to "fluid ounces (fl.oz.)".

Signature of Approving Official:

Date:

AUG 10 2001

3. Submit the following health effects data:

- a. Guideline 870.3465 - 28-day inhalation toxicity study in rats. Due December 2003.
- b. Guideline 870.6300 - Developmental neurotoxicity study in rats (TGAI test material). Submit protocol for Agency approval by July 2002 and submit the study two (2) years after approval of protocol.
- c. Guideline 870.6200 - Subchronic neurotoxicity screening battery in rats, conditionally required based on the results of the developmental neurotoxicity study. This study must be submitted, if required by the Agency, two (2) years after notification by the Agency.
- d. Guideline 860.1850 - Processed commodity study on potatoes at a higher treatment level, 5X. Due July 2002.
- e. Dislodgeable foliar residue data to address the "11 days" for reaching the target MOE of 100. Due December 2002.

4. Submit the following environmental fate and effects data:

- a. Guideline 835.2240 (161-2) - Photolysis in water. Due December 2002.
- b. Guideline 835.2410 (161-3) - Photodegradation in soil. Due December 2002.
- c. Guideline 835.6100 (164-1) - Terrestrial Field Dissipation. A concurrent storage stability study must also be conducted and submitted. Due December 2004.
- d. Guidelines 850.1300 and 850.1400 (72-4(a)(b)) - Early Life Stage Fish and Invertebrate Life Cycle (Estuarine/Marine). Due December 2002.
- e. Guidelines 850.1300 or 850.1400 (122-1 or 123-1) - Tier I or Tier II Terrestrial Plant Growth, seedling emergence and vegetative vigor. Due December 2002.
- f. Guidelines 850.4400 or 850.5400 (122-2 or 123-2) - Tier I or Tier II Aquatic Plant Growth, duckweed, freshwater green algae, marine diatom, blue-green algae, and a freshwater diatom. Due December 2002.

5. You will submit production information (pounds or gallons produced) for this product for the fiscal year in which the product is 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 (7505C)
Document Processing Desk
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Submit one copy of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Enclosure

7505C:CGrable:cg:8/7/01

4 8 12



OMEGA 500F

AGRICULTURAL FUNGICIDE

ACTIVE INGREDIENT:

Fluazinam* 40.0%

OTHER INGREDIENTS: 60.0%

Total: 100.0%

*3-chloro-*N*-[3-chloro-2,6-dinitro-4-trifluoromethyl]phenyl]-5-trifluoromethyl-2-pyridinamine (CA)

Contain 4.17 pounds Fluazinam Per Gallon (500 grams per liter)

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.)

See side panel for additional precautionary and first aid statements.

Read entire label carefully and use only as directed.

**For 24-Hour Emergency Medical Assistance call 1-888-484-7546.
For Chemical Emergency: Spill, leak, fire, or accident, call CHEMTREC
1-800-424-9300.**

ISK Biosciences Corporation
7470 Auburn Road, Suite A
Concord, Ohio 44077

EPA Reg. No. 71512-1
EPA Est. No. 69695-FRA-1

**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

AUG 10 2001

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

71512-1

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS**WARNING**

Causes skin irritation. Harmful if absorbed through skin. Causes moderate eye irritation. Harmful if inhaled or swallowed. Do not get on skin or on clothing. Avoid contact with eyes. Avoid breathing spray mist. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before use. Do not take internally.

FIRST AID

IF ON SKIN: 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 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 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 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 the poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For 24-hour emergency medical assistance, call 1-888-484-7546.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

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 A on an EPA chemical-resistance category selection chart.

Applicators and other handlers must wear coveralls worn over long-sleeved shirt, long pants, socks and chemical resistant footwear, chemical resistant gloves made of any waterproof material such as polyethylene or polyvinyl chloride, and protective eyewear. When mixing and loading, or when cleaning equipment, also wear a chemical resistant apron.

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. Do not allow contact of contaminated clothing with unprotected skin.

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.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down. Do not allow contact between contaminated sprayer parts and unprotected skin. Ensure sprayer is washed down daily.

USER SAFETY RECOMMENDATIONS:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

This product is toxic to fish, aquatic invertebrates, and marine/estuarine organisms. 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 waters when cleaning equipment or disposing of equipment wash waters or rinsate. Do not apply when weather conditions favor drift from treated areas. Runoff and drift from treated areas may be hazardous to aquatic organisms in neighboring areas.

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 treated areas during the restricted entry interval (REI) of 48 hours.

PPE required for early entry to the 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 worn over long-sleeved shirt and long pants, socks and chemical-resistant footwear, chemical resistant gloves made of any waterproof material, and protective eyewear.

Omega 500F may cause allergic skin reactions in a small number of sensitive individuals. To prevent the potential for an allergic reaction: when entering treated crops, wear protective clothing (coveralls, socks and shoes) to avoid contact of unprotected skin by foliage; wash all protective clothing (coveralls) regularly, preferable daily; remove PPE immediately after leaving treated area, wash thoroughly, as soon as possible, and change into clean clothing; keep and wash PPE separately from other laundry; when entering treated crops, avoid contact of unprotected skin with treated foliage. People who have been sensitized to Omega 500F should not use or have further contact with the product.

Aerial application of this product is prohibited.

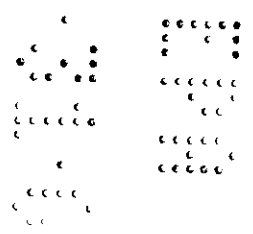
Do not cultivate within 25 feet of aquatic areas (lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, and estuaries) so as to allow growth of a vegetative filter strip.

Do not apply Omega 500F within 25 feet of aquatic areas (lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, and estuaries).

Do not apply this product when the wind direction is toward aquatic areas to minimize drift to those areas.

OMEGA 500F can be used effectively in dilute or concentrate sprays. Thorough, uniform coverage is essential for disease control.

NOTE: Slowly invert container several times to assure uniform mixture.



Dosage rates on this label indicate pints of OMEGA 500F per acre, unless otherwise stated. Under conditions that favor disease development, the high rate specified and the shortest application interval should be used.

The required amount of OMEGA 500F should be added slowly into the spray tank during filling. With concentrate sprays, premix the required amount of OMEGA 500F in a clean container and add to the spray tank as it is being filled. Keep agitator running when filling spray tank and during spray operations.

ROTATIONAL CROP (PLANTBACK) RESTRICTIONS:

Areas treated with Omega 500F may be replanted with peanuts and potatoes as soon as practical after the last application. Other root crops and leafy vegetables can be planted 30 days after the last application. All other crops can be planted 70 days after the last application.

FIELD AND ROW CROPS:

Apply OMEGA 500F in sufficient water to obtain adequate coverage of foliage. Gallonage to be used will vary with crop and amount of plant growth. Spray volume usually will range from 20 to 60 gallons per acre (200 to 600 liters per hectare) for dilute sprays and 5 to 10 gallons per acre (50 to 100 liters per hectare) for concentrate ground sprays. Application through sprinkler irrigation systems is not recommended unless specific directions are given for a crop. See application and calibration instruction below.

INTEGRATED PEST MANAGEMENT

OMEGA 500F is an excellent disease control agent when used according to label directions for control of a broad spectrum of plant diseases. OMEGA 500F is recommended for use as part of an Integrated Pest Management (IPM) program, which may include the use of disease resistant crop varieties, cultural practices, biological control agents, pest scouting and disease forecasting systems aimed at preventing economic pest damage. Practices known to reduce disease development should be followed. Consult your state cooperative extension service or local agricultural authorities for additional IPM strategies established in your area. OMEGA 500F may be used in State Agricultural Extension advisory (disease forecasting) programs which recommend application timing based on environmental factors which favor disease development.

RESISTANCE MANAGEMENT

Some plant pathogens are known to develop resistance to products used repeatedly for disease control. OMEGA 500F is effective for strategic use in programs that attempt to minimize disease resistance to fungicides. Some other fungicides, which are at risk from disease resistance exhibit a single-site mode of fungicidal action. OMEGA 500F, with a multi-site mode of action, may be used to delay or prevent the development of resistance to single-site fungicides. Consult with your Federal or State Cooperative Extension Service representatives for guidance on the proper use of OMEGA 500F in programs that seek to minimize the occurrence of disease resistance to other fungicides. No known resistance has developed to OMEGA 500F and thus it is an excellent partner for those products which specify the use of a protectant or other fungicide which has a different mode of action.

Application and Calibration Techniques for Sprinkler Irrigation

Apply this product only through center pivot, motorized lateral move, traveling gun, solid set or portable (wheel move, side roll, end tow, or hand move) irrigation system(s). DO NOT apply this product through any other type of irrigation system.

Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from non-uniform distribution of treated water.

If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts.

DO NOT apply OMEGA 500F through irrigation systems connected to a public water system. 'Public water system' means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days per year.

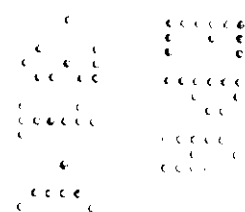
Controls for both irrigation water and pesticide injection systems must be functionally interlocked, so as to automatically terminate pesticide injection when the irrigation water pump motor stops. A person knowledgeable of the irrigation system and responsible for its operation shall be present so as to discontinue pesticide injection and make necessary adjustments, should the need arise.

The irrigation water pipeline must be fitted with a functional, automatic, quick-closing check valve to prevent the flow of treated irrigation water back toward the water source. The pipeline must also be fitted with a vacuum relief valve and low-pressure drain, located between the irrigation water pump and the check valve, to prevent back-siphoning of treated irrigation water into the water source.

Always inject OMEGA 500F into irrigation water after it discharges from the irrigation pump and after it passes through the check valve. Never inject pesticides into the intake line on the suction side of the pump.

Pesticide injection equipment must be fitted with a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump. Interlock this valve to the power system, so as to prevent fluid from being withdrawn from the chemical supply tank when the irrigation system is either automatically or manually turned off.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.



Spray mixture in the chemical supply tank must be agitated at all times, otherwise settling and uneven application may occur. DO NOT apply when wind speed favors drift beyond the area intended for treatment.

OMEGA 500F may be used through two basic types of sprinkler irrigation systems as outlined in Sections A and B below. Determine which type of system is in place, then refer to the appropriate directions provided for each type.

A. Center Pivot, Motorized lateral Move and Traveling Gun Irrigation Equipment

For injection of pesticides, these continuously moving systems must use a positive displacement injection pump, of either diaphragm or piston type, constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock and capable of injection at pressures approximately 2-3 times those encountered within the irrigation water line. Venturi applicator units cannot be used on these systems.

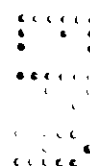
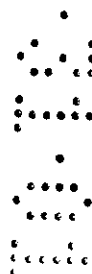
Thoroughly mix recommended amount of this product for acreage to be covered into the same amount of water used during calibration and inject into system continuously for one revolution or run. Mixture in the chemical supply tank must be continuously agitated during the injection run. Shut off injection equipment after one revolution or run, but continue to operate irrigation system until this product has been cleared from the last sprinkler head.

B. Solid Set and Portable (Wheel Move, Side Roll, end Tow, or Hand Move) Irrigation Equipment

With stationary systems, an effectively designed in-line venturi applicator unit is preferred which is constructed of materials that are compatible with pesticides; however, a positive-displacement pump can also be used.

Determine acreage covered by sprinkler. Fill tank of injection equipment with water and adjust flow to use contents over a thirty to forty-five minute period. Mix desired amount of OMEGA 500F for acreage to be covered with water so that the total mixture of this product plus water in the injection tank is equal to the quantity of water used during calibration.

Agitation is recommended. OMEGA 500F can be injected at the beginning or end of the irrigation cycle or as a separate application. Stop injection equipment after treatment is completed and continue to operate irrigation system until this product has been cleared from last sprinkler head.



DISEASES	RATE PER ACRE
CROP	
Peanut	
Sclerotinia blight (<i>Sclerotinia minor</i>)	1 to 1 1/2 pts.
APPLICATION DIRECTIONS	
Apply at 45-70 days after planting or when conditions become conducive to disease development, then make a second application approximately 3-4 weeks later. If disease conditions remain favorable, make a third application approximately 3-4 weeks after the second. If the high rate was used for the first two applications use the low rate for the third application. DO NOT use more than 4 pints per acre during any single growing season. DO NOT apply within 30 days of threshing for harvest. DO NOT allow livestock to graze in treated areas. DO NOT feed hay or threshings from treated field to livestock. OMEGA 500F may be applied through sprinkler system irrigation equipment. Use 1 1/2 pints in solid set, portable wheel move, center pivot, motorized lateral move or traveling gun sprinkler irrigation equipment. See calibration directions preceding this section.	
CROP	
Potato	
Late blight (<i>Phytophthora infestans</i>)	5 1/2 ounces
White mold (<i>Sclerotinia sclerotiorum</i>)	5 1/2 to 8 ounces
APPLICATION DIRECTIONS	
For Late blight and White mold control, begin applications when the plants are 6 to 8 inches tall or when conditions favor disease development. Repeat applications at intervals of 7 to 10 days. When White mold pressure is low to moderate, use 5 1/2 ounces. When conditions favor moderate to high White mold pressure, increase the rate to 8 ounces. DO NOT apply more than 3.5 pints per acre during each growing season. DO NOT apply within 14 days of harvest. OMEGA 500F may be applied through sprinkler system irrigation equipment. See calibration directions preceding this section.	

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited.

STORAGE: Store in original container, in a secured, dry place separate from other pesticides, fertilizer, food, and feed.

PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by the use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Do not reuse empty container. Triple rinse (or equivalent) and offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY AND LIMITATION OF DAMAGES

Seller warrants to those persons lawfully acquiring title to this product that at the time of first sale of this product by Seller that this product conformed to its chemical description and was reasonably fit for the purposes stated on the label when used in accordance with Seller's directions under normal conditions of use, and Buyers and users of this product assume the risk of any use contrary to such directions. **EXCEPT AS PROVIDED ELSEWHERE IN WRITING CONTAINING AN EXPRESS REFERENCE TO THIS WARRANTY AND LIMITATION OF DAMAGES, SELLER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OR GUARANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MECHANABILITY, AND NO AGENT OF SELLER IS AUTHORIZED TO DO SO.** In no event shall Seller's liability for any breach of warranty or guaranty exceed the purchase price of the product as to which a claim is made.

Buyers and users of this product are responsible for all loss or damage from use or handling of this product which results from conditions beyond the control of Seller, including, but not limited to, incompatibility with other products unless otherwise expressly provided in Directions for Use of this product, weather conditions, cultural practices, moisture conditions or other environmental conditions outside of the ranges that are generally recognized as being conducive to good agricultural and/or horticultural practices.