

517-21 58200-9
JAN 14 1995

Dr. Stephen F. Hiu
Igene Biotechnology, Inc.
9110 Red Branch Road
Columbia, Maryland 21045

Dear Dr. Hiu:

Subject: ClandoSan 618
EPA Reg. No. 58200-9
Your Submissions of October 10, 1994 and November 3, 1994

The amendment submitted on October 10, 1994 in connection with registration under FIFRA sec. 3(c)(7)(A), is acceptable provided that you:

1. Submit and/or cite all data required for registration and reregistration of your product under FIFRA sec. 3(c)(5) and sec. 4 when the Agency requires all registrants of similar products to submit such data.

2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

- a. On the front panel, change the first sentence under Environmental Hazards to "For terrestrial uses, not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark."

- b. Under "Product Description", in the second paragraph, delete "and contains no artificial or synthetic substances, additives, fibers, or preservatives and no halogenated hydrocarbons or any other materials derived from petrochemical sources." These claims are implied safety claims and are considered to be misleading. The product label may state what the product contains but may not state what it does not contain.

- c. In the first sentence under "For band application to all crops ---:", change the word "bank" to "band".

3. Submit five (5) copies of your final printed labeling before you release the product for shipment.

BEST AVAILABLE COPY

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 bearing the amended labeling constitutes acceptance of these conditions.

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

The revised Confidential Statement of Formula submitted on November 3, 1994 is not acceptable for the reasons stated below. Further consideration will be given to this submission upon receipt of a revised CSF which addresses the following comments:

The percentages stated in column 13b do not equal 100%. Adjust the percentages so that the total is exactly 100%. Also, note that the percentage of potash is below the minimum certified limit for that chemical. Other certified limits are not in accordance with the table of standard certified limits (Refer to 40 CFR 158.175).

Sincerely yours,

/s/

James A. Tompkins
Acting Product Manager (21)
Fungicide-Herbicide Branch
Registration Division (7505C)

Enclosure

7505C:C.Grable:cg:1/4/95

BEST AVAILABLE COPY

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FRONT PANEL

IGI®

IGENE Biotechnology, Inc.

CLANDOSAN®

618

CHITIN NEMATICIDE

ACCEPTED
with COMMENTS
In EPA Letter Dated

JAN 04 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
58200-9

FOR ORNAMENTALS AND LAWN AND TURF GRASSES
[FOR AGRICULTURAL CROPS]

U.S. PATENT NO. 4,536,207

OTHER U.S. AND FOREIGN PATENTS PENDING

EPA EST. 54137-LA-001

EPA REG. NO. 58200-9

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

In case of contact with eyes, immediately flush eyes with plenty of water. Get medical attention if irritation persists.

If inhaled, seek medical assistance and remove to fresh air.

If ingested, induce vomiting and get medical assistance.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS (& DOMESTIC ANIMALS)

CAUTION: Avoid contact with eyes.

PERSONAL PROTECTIVE EQUIPMENT

Applicators and other handlers must wear:

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

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.

ENVIRONMENTAL HAZARD

Do not apply directly to water. Do not contaminate water when disposing of equipment washwater.

ACTIVE INGREDIENTS:

Chitin (Poly-N-acetyl-D-glucosamine) Protein	25%
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INERT INGREDIENTS:

	75%
--	-----

1988 IGENE Biotechnology, Inc.
The IGI logo and ClandoSan®618 are trademarks
of IGENE Biotechnology, Inc.

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FRONT PANEL (CONTINUED)

NET WEIGHT 50 LBS.
(22.7 Kg)

IGI®

IGENE Biotechnology, Inc.
9110 Red Branch Road
Columbia, Maryland 21045-2020
1-800-346-6421

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MATERIAL SAFETY DATA

SECTION I: IDENTIFICATION

Product Name: ClandoSan®618
 Description: Dried granular chitin-protein material that is isolated from crustacean exoskeletons, especially crab and shrimp shells, and blended with agricultural grade urea and an organic buffer.

SECTION II: PHYSICAL & CHEMICAL CHARACTERISTICS

Boiling Point: N/A
 Vapor Pressure (mm HG): N/A
 Vapor Density (air=1): N/A
 Solubility in Water: Insoluble
 Melting Point: N/A
 Appearance and Odor: Tan granule with faint fishlike ammonia odor, accentuated after irrigation.
 Bulk Density: 34-45 lbs./cu. ft.
 Evaporation Rate: N/A

SECTION III: FIRE & EXPLOSION HAZARD

Flash Point: N/A
 Flammability Limits: N/A
 LEL: N/A
 UEL: N/A
 Extinguisher Media:
 Special Fire Fighting Procedures: None known
 Unusual Fire and Explosion Hazard: None known

SECTION IV: REACTIVITY DATA

Incompatibility (Materials to Avoid): None known
 Hazardous Decomposition Products: N/A
 Hazardous Polymerization: None known

SECTION V: HEALTH HAZARD DATA

Routes of Entry: Inhalation, skin contact, ingestion
 Carcinogens: None known
 Emergency First Aid Procedures
 Eye Contact: In case of contact with eyes, immediately flush eyes with plenty of water. Get medical attention if irritation persists.
 Inhalation: Seek medical assistance and remove to fresh air.
 Ingestion: Induce vomiting and get medical assistance.

SECTION VI: PROTECTION MEASURES

Respiratory Protection: Not required
 Protective Gloves: Required
 Eye Protection: Avoid contact with eyes.

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BACK PANEL - LEFT COLUMN (CONTINUED)

PRODUCT DESCRIPTION

ClandoSan®618 is the registered trademark of IGENE Biotechnology, Inc. for a dried, granular chitin-protein material that is isolated from the tough polymer matrix of crustacean exoskeletons, especially crab and shrimp shells, and processed into pellets or granules by patented and patent pending processes developed by IGENE Biotechnology, Inc.

The commercial ClandoSan®618 product is composed of a blend of the crustacean chitin-protein complex with agricultural grade urea and an organic buffer and contains no artificial or synthetic substances, additives, fibers, or preservatives and no halogenated hydrocarbons or any other materials derived from petrochemical sources.

The ClandoSan®618 product acts in soils to stimulate the growth of normal soil microorganisms that produce enzymes that destroy harmful nematodes and their eggs.

LIMITED WARRANTY

To the best of manufacturer's knowledge and belief, the information contained herein is correct. The data outlined and statements made are intended only as a source of information. Appropriate tests under user's operating conditions should be run before use. Manufacturer makes no warranties, express or implied, including warranties of merchantability or fitness for a particular use. The parties agree that the buyer's exclusive remedy shall be a refund of the purchase price of the product. In no event shall manufacturer be liable for any incidental, consequential or special damages suffered or incurred by user or its officers, employees, subsidiaries, affiliates, representatives or customers, as a result of the use of the product not in accordance with this label, whether under theories of warranty, negligence, or strict liability. Manufacturer disclaims all liability for results and for any damages, injury or patent infringement with respect to the use of the product not in accordance with this label or any material supplied by the manufacturer, whether under theories of warranty, negligence, or strict liability.

MANUFACTURED FOR

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IGENE Biotechnology, Inc

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BACK PANEL - RIGHT COLUMN

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For control of all plant-pathogenic nematodes. 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:

- Coveralls
- Waterproof gloves
- Shoes plus socks
- Protective eyewear

APPLICATION METHODS:

PRE-PLANT SOIL INCORPORATION

ClandoSan®618 should be tilled, on a broadcast or band basis, or otherwise thoroughly mixed into soil 2-4 weeks before planting to stimulate proliferation of actinomyces and other soil microorganisms, which are responsible for the "earthy aroma" of freshly plowed fields.

For broadcast and band application under field, home garden, and nursery conditions, the product should be tilled to a depth of 6-8 inches below the surface where plant roots commonly extend and where plant pathogenic nematodes tend to proliferate. The same equipment may be used for both band and broadcast applications.

For bulk soil treatment in greenhouse, home garden and nursery situations, soil should be sieved to remove large particles and crop debris and then blended with ClandoSan®618 in an appropriate mixer to assure homogenization with little or no segregation of particles.

POST-PLANT SURFACE APPLICATION

For post-plant surface application to lawns, turfgrasses, sod farms, golf course greens and fairways, ClandoSan®618 can be distributed at any point in the growing season using conventional applicators, and should be immediately irrigated to assure adequate subsurface penetration.

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BACK PANEL - RIGHT COLUMN (CONTINUED)

USE SITES

ClandoSan® 618 can be applied to the following:

Fruits and Nuts	Includes caneberries, bushberries, vine fruits, strawberries, cranberries, pome fruits, stone fruits, nut crops -- tree and shrub (e.g., pecan, filbert) and other temperate fruits
Tropical and Subtropical Fruits and Nuts	Citrus, banana, and plantain, palm fruits and nuts (e.g., date, coconut), pineapple, and other fruits and nuts
Beverage Crops	Includes cocoa, coffee, tea, chicory, mint
Vegetables	Includes leaf/stem, root, seed and pod, fruiting vegetables, and cucurbits, including commercial annual (e.g., tomato, bean) and commercial perennial (e.g., asparagus, rhubarb); annual legumes (e.g., crotalaria, soybean)
Greenhouse (Commercial)	Includes nursery/seed crop
Fiber Crops	Includes cotton, flax, and others
Grain and Edible Seed Crops	Including corn, rice, wheat, barley, rye, oats, sorghum, alfalfa, other grains, other nongrains (e.g., squash, pumpkin), buckwheat, sesame, peanut, and sunflower
Seed Sprout Crops	Includes mung bean, red clover, soybean, alfalfa, and non-legume crops such as wheat, radish, and black mustard
Other Agricultural Crops	Crops for smoking and chewing; oil crops; temperate woody crops; and tropical/subtropical wood crops

BACK PANEL - RIGHT COLUMN (CONTINUED)

Ornamental Plants

Including annual garden plants, temperate perennial non-food garden herbs, commercial greenhouse crops, (including nursery/seed crops) houseplants, home and retail greenhouse and conservatory plants, public display plantings, bulb, corm, and tuber ornamentals, tropical/subtropical garden evergreen plants, groundcovers; ornamental trees, shrubs, and vines; and forest tree nurseries.

Lawn and Turf

Including cool season winter grasses, summer grasses, and ornamental bunch grasses.

Do not use on crops which may be adversely affected by high rates of urea nitrogen (tobacco).

APPLICATION RATES:

For all uses, a single annual application is sufficient for nematode control. For best results, soil analysis for nematode typing and counts of adult forms and larvae should be undertaken both before and after each crop season.

For broadcast application: Recommended application rates are approximately 1 to 3 tons per acre on a broadcast basis (or 4.5 to 14.0 pounds per 100 square feet).

RATE CONVERSION CHART

CLANDOSAN®618 TONS PER ACRE	CLANDOSAN®618 APPROXIMATE LBS. PER 100 SQ. FT.
1.0	4.5
1.5	7.0
2.0	9.0
2.5	11.5
3.0	14.0

1 ACRE: 43,560 SQ. FT.

For bulk soil application: Apply on a 0.1 to 0.3 % weight/weight basis (i.e., 1 to 3 lbs. ClandoSan®618 for 1,000 lbs. of soil, 1 to 3 grams per kilogram of soil, or 2.5 to 7.4 lbs. per cubic yard of soil)

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BACK PANEL - RIGHT COLUMN (CONTINUED)

For homeowner use: One 50 lb. bag of ClandoSan®618 will cover approximately 1,000 square feet at an application rate of 1 ton per treated acre on a broadcast basis. For bulk soil treatment, apply approximately 1.5 to 4.4 ounces ClandoSan® per cubic foot.

For band application to all crops other than lawn and turfgrasses: Row spacings can be used to determine the amount of ClandoSan®618 recommended for band application. Band widths should be equal to one-half the distance between rows and the bands should be centered directly over the centerline of the intended planting row. As a result, only one-half of available acreage is treated when band application is used and recommended application rates per acre for band application are equal to one-half the rates recommended for broadcast application. Recommended application rates on this basis are as follows:

Distance Between Rows (inches)	18	24	30	36	48
Band Width (inches)	9	12	15	18	24
<hr/>					
Approximate Pounds of ClandoSan®618 Per 100 Feet of Banded Row, at Equivalent of:					
1 ton per treated acre	3.5	4.5	5.5	7.0	9.0
3 tons per treated acre	11.0	14.0	16.0	20.5	27.5

Application rates will vary according to the characteristics of the soil, types of plant-pathogenic nematodes, and extent of infestation. Acid soils (i.e., lower pH) or soils with a severe degree or type of infestation (i.e., root-knot nematode) will require the higher rates of application within the specified ranges. Do not adjust rates of application in order to meet fertilizer requirements for your soil.

In determining your soil fertility requirements, you must take into account the amount of urea nitrogen which will be applied through the use of this product. Total Kjeldahl nitrogen equals approximately 10.4 pounds per 100 pounds of product (4.6 pounds from urea, 2.8 pounds for the chitin-protein complex and 3.0 pounds from inert ingredients). Phosphorus as phosphoric acid (P_2O_5) equals 2.3 pounds per 100 pounds of product and potassium as potash (K_2O) equals 1.3 pounds per 100 pounds of product. The optimum soil temperature conditions for application of this product range from 40° to 95°F at a soil depth of 6 to 8 inches.

ClandoSan®618 has been shown to have controlled or slow release effects in soils and may not require reapplication at optimal rates which are recommended for first time use. For best results, soil analysis for nematode typing and counts of adult forms and larvae should be undertaken both before and after each crop season.

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BACK PANEL - RIGHT COLUMN (CONTINUED)

STORAGE AND DISPOSAL

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

STORAGE: Avoid exposure to extreme conditions such as heat, moisture, sunlight or contaminating substances.

DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

HOUSEHOLD STORAGE AND DISPOSAL: Store product only in this bag and keep in a locked storage area. To dispose, securely wrap original container in several layers of newspaper and discard in trash.