



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:

68467-1

Date of Issuance

MAR 21 1995

Term of Issuance:

Unconditional

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Name of Pesticide Product:

Mycogen

Bacillus
thuringiensis susp.
kurstaki European
Corn Borer Control
Protein

Name and Address of Registrant (include ZIP Code):

Mycogen Plant Sciences
Mycogen Corporation
4980 Carroll Canyon Road
San Diego, CA 92121

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 registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) and is subject to the following terms and conditions:

1. The EPA Registration Number on the labeling shall read: "EPA Reg. No. 68467-1."
2. The pesticide product may be used only for seed production as specified in the terms and conditions of this registration and on the labeling.
3. Mycogen Plant Sciences (Mycogen) shall enter into a written agreement with each of its cooperators that requires each cooperator to comply with all the terms and conditions of this registration. A cooperator means any person who has been granted permission from Mycogen for the use of the pesticide product on property owned or controlled by that person.

Signature of Approving Official:

[Handwritten Signature]

Date:

MAR 21 1995

4. Mycogen shall be liable under the Federal Insecticide, Fungicide and Rodenticide Act for the actions of a cooperator that does not comply with any term or condition of this registration.
5. Plants that contain the pesticide product may only be grown in the States of California, Florida, Illinois, Iowa, Nebraska, and Wisconsin and the Territory of Puerto Rico. The maximum acres grown in each State shall be:

<u>State/ Territory</u>	<u>Hybrid Seed Production</u>	<u>Foundation Seed Stock Production</u>
California		0.1
Florida		0.2
Illinois		25.0
Iowa		0.2
Nebraska	100	3.2
Wisconsin		0.1
<u>Puerto Rico</u>		<u>60.0</u>
Totals	100	88.8

For the purposes of this registration: Hybrid seed production means the crossing of unrelated inbred lines to produce hybrid seed. Foundation seed stock production means the maintenance and increase of inbred lines to produce seeds that will be used to produce hybrid seed.

6. This registration of the pesticide product will automatically expire on midnight of September 15, 1996, unless EPA extends the registration.
7. No plants or plant propagation materials that contain the pesticide product may be sold or distributed except that such plants and materials may be distributed between Mycogen and its cooperators and may be distributed for storage under Mycogens' control.
8. Any plant that contains the pesticide product must be spatially, temporally, or reproductively isolated. Temporal isolation must be conducted pursuant to paragraphs 9 and 10.
 - a. "Spatially isolated" means that any area with a plant that contains the pesticide product is surrounded by a border that is free of corn plants and is at least 660 feet wide.
 - b. "Temporally isolated" means that any area with a plant that contains the pesticide product is surrounded by a border that contains corn plants and that is less than 660 feet in width, and any plant

- that contains the pesticide product is planted either 30 days before or after any corn plant in the border.
- c. "Reproductively isolated" means that any corn plant that contains the pesticide product is detasseled prior to pollen shed.
9. Mycogen or a cooperator shall do one of the following where a field that contains the pesticide product is temporally isolated and the pollen shed of plants containing the pesticide product might occur when another plant that does not contain the pesticide product is located within 660 feet and has receptive silks:
- a. emasculate any plant that contains the pesticide product prior to pollen shed,
- b. cover the tassels of any plant that contains the pesticide product with a pollen bag prior to pollen shed, or
- c. destroy any seed produced by any corn plant that is within 660 feet and that does not contain the pesticide product.
10. Temporal isolation may be used only if Mycogen or a cooperator has the authority to:
- a. enter sites within 660 feet of any plant that contains a pesticide product,
- b. monitor those sites for corn plants with receptive silks, and
- c. destroy any seed produced by such corn plants.
11. Equipment used for planting and harvesting must be carefully cleaned of seed corn that contains the pesticide product at the plot site. Grain from all plots must be harvested or destroyed. Any seed or plant material that contains the pesticide product must be either destroyed, securely stored for future plantings or research, or used to produce additional seed pursuant to this registration.
12. After harvest in California, Illinois, Iowa, Nebraska, Wisconsin no corn may be grown during the next growing season in any field that was used to grow corn that contains the pesticide product. Mycogen or a cooperator shall monitor such fields after harvest and during the next growing season for any germinating corn plants and shall destroy any such plants by incorporation into the soil.
13. After harvest in Florida and Puerto Rico, any field used to grow corn that contains the pesticide product must either be:

- a. planted in the next growing season with a crop other than corn. Mycogen or a cooperator shall monitor the fields during the growth of such crop for any germinating corn plants, and destroy any germinating corn plants by incorporation into the soil, or
 - b. irrigated, and allowed to remain fallow for at least 30 days in Florida and at least 60 days in Puerto Rico. During this fallow period, Mycogen or a cooperator shall monitor such fields for germinating corn plants and destroy any corn plants that appear by incorporation into the soil.
14. After the registration expires, no plants or plant propagation materials that contain the pesticide product may be planted, grown, or harvested.

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

Sincerely,



Janet L. Andersen, Acting Director
Biopesticides and Pollution
Prevention Division

MYCOGEN

Bacillus thuringiensis subsp. *kurstaki* European Corn Borer Control Protein

Pure form of the plant pesticide, *Bacillus thuringiensis* subsp. *kurstaki* delta endotoxin protein as produced in corn cells.

Active Ingredient:

Bacillus thuringiensis Delta-endotoxin protein as produced by a *CryIA(b)* gene and its controlling sequences in corn0.0001 - 0.0018%*

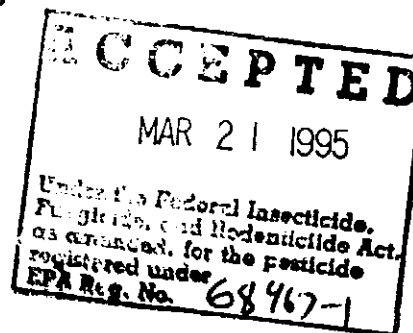
Inert Ingredient:

A substance produced by a marker gene and its controlling sequences in corn≤0.0009%

*Percent of total plant protein on a dry weight basis

EPA Reg No. 68467-1

Mycogen Plant Sciences
Mycogen Corporation
4980 Carroll Canyon Road
San Diego, CA 92121



Directions for Use:

It is a violation of federal law to use this product in any manner inconsistent with its labeling.

The plant pesticide product may be used only for seed production as specified in the terms and conditions of the registration and on the labeling.

Corn has been transformed to express a *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*) delta-endotoxin protein for control of the European corn borer (*Ostrinia nubilalis*).

The *B.t.k.* delta-endotoxin protein expressed in the corn plants controls the European corn borer.

Routine applications of insecticides to control European corn borer are unnecessary when corn containing the *B.t.k.* Delta-endotoxin protein is planted.

Growers are instructed to read the terms of the Seed Production Contract with Mycogen Plant Sciences (MPS) and the grower Compliance Manual prior to planting, for information on agronomic procedures, restrictions, requirements and insecticide resistance management.

Plants that contain the pesticide product may only be grown in the States of: California, Florida, Illinois, Iowa, Nebraska, Wisconsin, and Puerto Rico. The maximum acres grown in each State shall be:

STATE	HYBRID SEED PRODUCTION	FOUNDATION SEED STOCK PRODUCTION
California		0.1
Florida		0.2
Illinois		25.0
Iowa		0.2
Nebraska	100.0	3.2
Wisconsin		0.1
Puerto Rico		60.0
TOTALS	100.0	88.8

For the purposes of this registration: Hybrid seed production means the crossing of unrelated inbred lines to produce hybrid seed. Foundation seed stock production means the maintenance and increase of inbred lines to produce seeds that will be used to produce hybrid seed.

This registration of the pesticide product will automatically expire on midnight of September 15, 1996, unless EPA extends the registration.

No plants or plant propagation materials that contain the pesticide product may be sold or distributed except that such plants and materials may be distributed between MPS and its cooperators and may be distributed for storage under MPS' control.

Any plant that contains the pesticide product must be spatially, temporally or reproductively isolated. Temporal isolation must be conducted pursuant to

temporal isolation limitations 1 and 2 listed below. For the purposes of this registration:

- a. "Spatially isolated" means that any area with a plant that contains the pesticide product is surrounded by a border that is free of corn plants and is at least 660 feet wide.
- b. "Temporary isolated" means that any area with a plant that contains the pesticide product is surrounded by a border that contains corn plants and that is less than 660 feet in width, and any plant that contains the pesticide product is planted either 30 days before or after any corn plant in the border.
- c. "Reproductively isolated" means any corn plant that contains the pesticide product is detasseled prior to pollen shed.

Temporal Isolation Limitation 1

MPS or a cooperator shall do one of the following where a field that contains the pesticide product is temporally isolated and the pollen shed of plants containing the pesticide product might occur when another plant that does not contain the pesticide product is located within 660 feet and has receptive silks:

- a. emasculate (detassel) any plant that contains the pesticide product prior to pollen shed,
- b. cover the tassels of any plant that contains the pesticide product with a pollen bag prior to pollen shed, or
- c. destroy any seed produced by any corn plant that is within 660 feet and that does not contain pesticide product.

Temporal Isolation Limitation 2

Temporal isolation may be used only if MPS or a cooperator has the authority to:

- a. enter sites within 660 feet of any plant that contains a pesticide product,
- b. monitor those sites for corn plants with receptive silks, and
- c. destroy any seed produced by such corn plants.

Equipment used for planting and harvesting must be carefully cleaned of seed corn that contains the pesticide product at the plot site. Grain from all plots must be

harvested or destroyed. Any seed or plant material that contains the pesticide product must be either destroyed, securely stored for future plantings or research, or used to produce additional seed pursuant to this registration.

After harvest in California, Illinois, Iowa, Nebraska and Wisconsin, no corn may be grown during the next growing season in any field that was used to grow corn that contains the pesticide product. MPS or a cooperator shall monitor such fields after harvest and during the next growing season for any germinating corn plants and shall destroy any such plants by incorporation into the soil.

After harvest in Florida, and Puerto Rico, any field used to grow corn that contains the pesticide product must either be:

- a. planted in the next growing season with a crop other than corn. MPS or a cooperator shall monitor the fields during the growth of such crop for any germinating corn plants, and destroy any germinating corn plants by incorporation into the soil, or
- b. irrigated, and allowed to remain fallow for at least 30 days in Florida, and at least 60 days in Puerto Rico. During this fallow period, MPS or a cooperator shall monitor such fields for germinating corn plants and destroy any corn plants that appear by incorporation into the soil.

After the registration expires, no plants or plant propagation materials that contain the pesticide product may be planted, grown, or harvested.