US Environmental Protection Agency
Office of Pesticide Programs

BIOPESTICIDE REGISTRATION ACTION DOCUMENT
Bacillus licheniformis Strain SB3086 (PC Code 006492)

February 2001

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U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division

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TABLE OF CONTENTS

REGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biopesticides and Pollution Prevention Division

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I. EXECUTIVE SUMMARY

Bacillus licheniformis strain SB3086 is the active ingredient of Novozymes Biofungicide Green Releaf, a microbial fungicide for use on lawns, conifers, tree seedlings, ornamental turf and ornamental plants in outdoor, greenhouse, and nursery sites. *Bacillus licheniformis* is a ubiquitous, saprophytic, common soil bacteria that contributes to nutrient cycling and displays antifungal activity. While numbers of *B. licheniformis* in soil are unknown and likely vary from soil to soil, the use of *B. licheniformis* at current label rates is not expected to add substantially to the effects of the naturally occurring *Bacillus* populations. The acute toxicity data performed resulted in an overall classification of Toxicity IV. The pathogenicity tests results indicate a pattern of clearance for *B. licheniformis* without complete clearance of the microbe from the major organs associated with removing microbes from the body during the duration of the studies.

A series of literature searches have been conducted to determine whether any adverse effects from *B. licheniformis* have been reported. There were no reports suggesting that *B. licheniformis* has detrimental effects on insect, avian, plant, and estuarine marine species. Based on the intended use pattern, and the results of toxicity and exposure data from the public scientific literature and from the data submitted by the applicant, the Agency has determined that this action will have no effect on currently listed endangered and threatened species. Published literature associating *B. licheniformis* with reproductive failures and mastitis in cattle, sheep and swine have been reported. These reports also indicate the possibility of reproductive effects on wild ruminant and boar species. Exposure to the wild ruminant and boar species is expected to be minimal because the product will be used on ornamental plants and turf grasses.

The lack of complete clearance during the duration of the conducted studies as well as the published scientific literature on *B. licheniformis* as a suspected causal agent isolated in cases of mammalian disease and occasional food poisoning suggest that more study of this microbe is warranted prior to approval for food/feed use. To mitigate any potential risk, the product label must have a precautionary statement informing the user to not use this product on plants intended for food or feed. Prior to any future approval of food and feed use sites, the registrant will be subjected to additional product chemistry data, and toxicity data requirements including: product identity and disclosure of ingredients, manufacturing process, formation of unintentional ingredients, analysis of samples, certification of limits, enforcement analytical method, and a study examining the oral route exposure in pregnant bovine or ovine species.

II. OVERVIEW

A. Product Overview

- **Microbial Pesticide Name:** *Bacillus licheniformis* strain SB3086
- **Trade Name(s):** Novozymes Biofungicide Green Releaf
- **OPP Chemical Code**: 006492
- **Basic Manufacturer:** Novozymes Biologicals, Inc.
  111 Kesler Mill Road, Salem VA 24153
- **US Agent:** James Messina of Exponent
  1730 Rhode Island Ave. NW, Suite 1100 Washington DC 20036

B. Use Profile

Type of Pesticide: Fungicide

Mechanism of action: The manufacturer suggests that based on the range of different plant pathogenic fungi inhibited by the active ingredient *Bacillus licheniformis* SB3086, the mechanism/mode of action is due to production of a small molecule antibiotic agent possibly in combination with a anti-fungal hydrolytic enzyme, such as xylanase, mannase, or protease. The precise nature of these agents has not yet been identified.

Use Sites:

Terrestrial Non-Food ornamental turf, lawns, golf courses, sports turf, turf farms, ornamental plants, conifers and arborculture

Outdoor Residential ornamental turf, lawns, ornamental plants, and conifers

Greenhouse Non-Food ornamental plants, conifers and arborculture

Target Pests for Active Ingredient:
Actinopelte Leafspot, Alternaria Leafspot/Leafblight, Anthracnose Leaf Blotch, Anthracnose *(Colletotichum graminicola*), Ascochyta Blight, Bipolaris Leafspot, Copper

Spot (*Gloeocercospora sorghi*), Black Spot on roses, Botrytis Leafspot/ Blight, Botrytis Flower Blight, Dichondra Leaf Spot (*Alternaria spp.*), Cephalosporium Leafspot,Cercospora Leafspot, Cercosporidium Leafspot, Coryneum Blight, Corynespora Leafspot, Curvularia Leafspot, Curvularia Flower Spot, Cylindrosporium Leafspot, Cylindrocladium Stem Canker, Dactylaria Leafspot, Didymellina Leafspot, Drechslera Ink Spot, Drechslera Leafspot, Dollar Spot (*Sclerotinia homoeocarpa*), Fabraea Leafspot, Fusarium Leafspot, Gloeosporium Black Leafspot, Gray Leaf Spot (*Pyricularia grisea, P. oryzae),* Gray Snow Mold (*Typhula spp.),* Leaf Blight Botrytis Flower Spot, Leaf Spot/Melting Out *(Drechslera poae*), Marssonina Leafspot, Monilinia Blossom Blight, Mycosphaerella Ray Blight, Myrothecium Leafspot, Nematostoma Leaf Blight, Ovulinia Flower Blight, Phyllosticta Leafspot,Dieback , Phytophthora Leaf Blight, Pink Snow Mold (*Microdochium nivale),* Powdery Mildew (*Microsphaera spp*., *Erysiphe cichoracearum*), Red Thread *(Laetisaria fuciformis),* Ramularia Leafspot, Rhizoctonia Blight (*Rhizoctonia solani, R. zeae, R. cerealis*), Rhizoctonia Web Blight, Rhizopus Blossom Blight, Rust (*Gymnosporangium spp., Puccinia spp., Uromyces spp.),* Scab (*Venturia inaequalis*) Sclerotinia Flower Blight, Septoria Leafspot, Sphaeropsis Leafspot, Stagonospora Leaf Scorch, Stem Rust *(Puccinia graminis)*, Tan Leafspot (*Curvularia*), and Volutella Leaf Blight.

Formulation Types Registered:

Type: End Use Product
Form: liquid concentrate

Method and Rates of Application:

Types of Treatment Foliar spray or soil drench

Equipment not specified

Timing : Treat lawns, golf courses or ornamental turf when disease symptoms are evident. Repeat application every 3- 14 days depending on level of disease. (Label provides recommendations in chart.)

For ornamental plants, treat when conditions favorable for disease development and repeat every 7 to 14 days until conditions are no longer favorable for disease.

Rates of Application: 5 -25 fl.oz. per 1000/ft.^{2}
Method of Application: foliar spray or soil drench

C. Estimated Usage

Estimates based on existing commercial use cannot be made since this is the first proposed registration of this active ingredient.

D. Data Requirements

The data requirements for granting this unconditional registration under Section 3(c)(7)(C) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) have been reviewed by the Biopesticides and Pollution Prevention Division (BPPD). For *Bacillus licheniformis* strain SB3086, the product identity and analysis data, as well as the information submitted for acute mammalian toxicology and ecological effects are sufficient to allow the proposed use patterns. Based on submitted information, the Agency foresees no unreasonable adverse effects to human health and the environment from the use of this microbial pesticide as labeled and recommends a unconditional registration of this new active ingredient for the proposed uses. Additional data will be required for food or feed use patterns or aquatic or more extensive use patterns.

E. Regulatory History

The Environmental Protection Agency, under the Toxic Substances Control Act (TSCA), reviewed submissions and published literature to perform a risk assessment of genetically modified *B. licheniformis* strains used for enzyme production in February, 1997. (*Bacillus Licheniformis* TSCA Section 5(h)(4) Exemption: Final Decision Document.)

Bacillus licheniformis is a "Direct-Fed Microorganism" reviewed and approved by the Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) and listed in the Association of American Feed Control Officials (AAFCO) "Official Publication 2002". The current listing of approved direct-fed microorganisms is not strain specific. This original listing of direct-fed microorganisms was proposed in 1991, adopted in 1993 and amended in 2001. Direct fed microbial products containing *B. licheniformis* have been in use in animal feed products since the early 1980's. The literature evaluated by CVM predates 1993. The CVM has not re-evaluated the listing of *B. licheniformis* as a direct-fed microorganism in light of the recent reports in the published literature that associate *B. licheniformis* with reproductive failures and mastitis in cattle, sheep and swine.

Sybron Chemicals Inc. submitted an application for Sybron Biofungicide December 29, 2000 for registration of Sybron Biofungicide Green Releaf. On June 29, 2001 supporting data were transferred to Novozymes. The name of the product has been changed to Novozymes Biofungicide Green Releaf. On June 26, 2002, the Federal Register notice (Volume 67, Number 123) announcing receipt of the application was published.

III. SCIENCE ASSESSMENT

A. Physical and Chemical Properties Assessment

Product Identity:
The agency has classified *Bacillus licheniformis* strain SB3086 as a microbial fungicide. Novozymes Biofungicide Green Releaf contains living *Bacillus licheniformis* strain SB3086 as the active ingredient. *Bacillus licheniformis* strain SB3086 is a natural soil isolate, and is a saprophytic organism. The optimal growth conditions for this bacteria range from 18^{B}C - 50^{B}C.

Product chemistry data which support the registration of *Bacillus licheniformis* strain SB3086 are summarized in Table 1. These data are acceptable to support the current use sites which do not include food or feed use. Additional product chemistry data are required to support future amendments that include food or feed use sites.

Table 1. Physical and Chemical Properties for *Bacillus licheniformis* Strain SB3086

OPPTS GUIDELINE Number	STUDY	RESULT	MRID#
885.1100	Product Identity and Disclosure of Ingredients	**ACCEPTABLE**	458202-01, 457771-01, 453021-01
885.1200	Manufacturing Process	**ACCEPTABLE**	458202-01, 457771-01, 453021-01
885.1300	Formation of Unintentional Ingredients	**ACCEPTABLE**	458202-01, 453021-01
885.1400	Analysis of Samples	**ACCEPTABLE**	458202-01, 457771-01, 453678-01, 453021-01
885.1500	Certification of Limits	**ACCEPTABLE**	458202-01, 457771-01, 453021-01
885.1800	Enforcement Analytical Method	**ACCEPTABLE**	458202-01, 457771-01
830.6302, 830.6303, 830.6304, 830.6317, 830.6320, 830.7000, 830.7100, 885.7300	Product Chemistry	**ACCEPTABLE**	458202-01, 457771-01, 453021-02

B. Human Risk Assessment

There is a reasonable certainty that no harm will result from exposure to *Bacillus licheniformis* strain SB3086. This includes all anticipated non-occupational exposures and

all other potential aggregate and cumulative exposures for which there is reliable information. There is no anticipated dietary exposure from this product since this product is only to be used on sites that do not include food or feed use (such as ornamental plants and ornamental turf).

1. Human Toxicity Assessment

a. Acute Toxicity

All mammalian toxicology data requirements have been submitted and adequately satisfy data requirements to support registration for use sites that do not include food or feed use. Published literature were evaluated in addition to the acute toxicity/ pathogenicity studies indicated below

The acute oral, acute pulmonary toxicity/pathogenicity, acute dermal irritation and acute eye irritation studies resulted in Toxicity Category IV classifications. The toxicity/pathogenicity tests results indicate a pattern of clearance for *B. licheniformis* without complete clearance of the microbe from the major organs associated with removing microbes from the body. The lack of complete clearance as well as the published scientific literature on *B. licheniformis* as a suspected causal agent isolated in cases of mammalian disease and occasional food poisoning suggest that more study of this microbe is warranted prior to approval for food/feed use.

The submitted literature compiled in MRID 45539003, appears to associate *B. licheniformis* pathogenicity with ingestion of moldy feed and the reported disease incidents are limited to placentitis and spontaneous abortion in cows and sheep. Without complete clearance of the microbe during the duration of the conducted studies, it is difficult to ascertain if the lack of clearance in the submitted infectivity tests are due to procedural techniques or represent an asymptomatic condition that could lead to ruminant abortion with exposure to pregnant animals given the mammalian adverse effects reported in the literature. While not a significant cause of ruminant abortion, the increased reporting of *B. licheniformis* isolated from spontaneous abortion in cattle in Scotland and the results of the intravenous inoculation experiment in Denmark (Agerholm et.al., 1999) suggest that a study examining the oral route exposure in pregnant bovine or ovine species will be needed to be submitted and evaluated prior to Agency approval of *B. licheniformis* pesticide products for food/feed use.

Table 2 a. Acute Mammalian Toxicity *of: Bacillus licheniformis* strain SB3086
Tier I Guideline Studies for Technical Grade Active Ingredient (TGAI)

OPPTS GUIDELINE NUMBER	STUDY	RESULT	MRID#
885.3050	Acute Oral Toxicity/ Pathogenicity	*B. licheniformis* strain SB3086 at 1 x 10^8 cfu/animal was not toxic, infective, or pathogenic to rats. **ACCEPTABLE**	456017-01
885.3150	Acute Pulmonary Toxicity/ Pathogenicity	*Bacillus licheniformis* SB3086 does not appear to be toxic, infective, and/or pathogenic to rats when dosed at 1.1 x 10^8 cfu/animal. **ACCEPTABLE**	453502-04
885.3200	Acute Intravenous Toxicity/Pathogenicity	*Bacillus licheniformis* strain SB3086 (1 x 10^7 cfu/animal) was not toxic, infective, or pathogenic to rats. **ACCEPTABLE**	456017-02

(i) Acute Oral Toxicity/Pathogenicity - Rat (Guideline 885.3050)
Rats exhibited no clinical signs of toxicity except very slight or slight diarrhea in three treated males on day 1. *Bacillus licheniformis* SB3086 was detected in cecal contents on day 3 and cleared from the cecum by day 14. No statistically valid counts of the organism were noted in the kidney, brain, liver, lungs, spleen, lymph nodes, or blood samples. Necropsy studies showed no abnormalities. Based on the presented/submitted data, the test organism (1 x 10^8 cfu/animal) was not toxic, infective, or pathogenic to rats. These data, MRID 456017-01, are classified as ACCEPTABLE.

ii) Acute Pulmonary toxicity/pathogenicity study (Guideline 885.3150).
Bacillus licheniformis SB3086 does not appear to be toxic, infective, and/or pathogenic to rats when dosed at 1.1 x 10^8 cfu/animal. There were sporadic, transient weight losses, but all recovered to the normal weight gain trend. Male No. 8922 had rales on day 1 and male No. 8925 had malocclusion on days 3, 14, 17, 21, 23, and 36. Female No. 8938 had brown material around the nose on day 29 and female No. 8940 had red material around the right eye on days 13 and 19. The rats in the control group were

normal throughout the study. The registrant suggested that these clinical signs were treatment-related, but not test material-related. These data, MRID 456017-04, are classified as ACCEPTABLE.

iii) Acute Injection Toxicity/Pathogenicity - Rats (Guideline 885.3200)
No clinically significant signs from rats with the exception of red-crusted nose and respiratory gurgle noted from one treated female on day 14. The dosed *Bacillus licheniformis* SB3086 was detected in the liver and spleen with gradual clearance (>99%) by day 35; sporadic viability of the dosed *B. licheniformis* SB3086 in the selected tissues was found to be statistically invalid. Necropsy studies showed no abnormal findings with the exception of pale lungs noted in three males and three females of the treated group. Based on the presented/submitted data, the test organism (1×10^7 cfu/animal) was not toxic, infective, or pathogenic to rats. These data, MRID 456017-02, are classified as ACCEPTABLE.

Table 2b. Acute Mammalian Toxicity *of: Bacillus licheniformis* strain SB3086
Tier I Guideline Studies for End-use Products (EP)

OPPTS GUIDELINE NUMBER	STUDY	RESULT	MRID#
870.1100	Acute Oral Toxicity	LD_{50}> 5000 mg/kg in Rats No deaths, no physical abnormalities and no weight loss observed. **ACCEPTABLE,** **Toxicity Category IV**	453021-05

OPPTS GUIDELINE NUMBER	STUDY	RESULT	MRID#
870.1200	Acute Dermal Toxicity -Rabbits	No mortality occurred during the course of the study. Signs of dermal irritation (erythema) were noted on Days 1 and 4. Upon necropsy at Day 14, a mottled lung was noted in one animal. LD_{50}> 5050mg/kg for *Bacillus licheniformis* strain SB3086 in male and female New Zealand White rabbits **ACCEPTABLE** **Toxicity Category IV**	456488-01
870.1300	Acute Inhalation (End-Use Product WP)	Provided data indicates a very slight respiratory gurgle is noted from three males and one female at the 4.5 hour observation. Swelling/crusting around the eye was noted on one female from 4.5 hours through day 4. Individual data were not reported. One female had a decrease weight loss. The acute lethal dose (LC_{50}) was greater than 2.56 mg/L. **ACCEPTABLE** **Toxicity Category IV**	456017-03
870.2400	Primary Eye Irritation	When dosed with 710-140 at 0.1 mL/animal, 710-140 was non-irritating to the eye in rabbits. **ACCEPTABLE** **Toxicity Category IV**	456017-04

OPPTS GUIDELINE NUMBER	STUDY	RESULT	MRID#
870.2500	Primary Dermal Irritation	Two males had very slight erythema 1, 48, and 72 hours after patch removal with clearance by day 7. One female had very slight erythema one hour after patch removal with clearance by 24 hours. Primary irritation index was 0.6. **ACCEPTABLE** **Category IV**	456017-05
870.2600	Delayed Contact Hypersensitivity in Guinea Pigs	710-140 Biofungicide Formulation does not appear to be a dermal sensitizer. **ACCEPTABLE**	456017-06

iv. Hypersensitivity incidents

The company must report any findings of hypersensitivity or other health incidents in workers, applicators, or anyone exposed to the biopesticide under FIFRA reporting requirements Section 6(a)(2).

b. Published Scientific Literature on *B. licheniformis* Infections

The twenty-four publications that were compiled in MRID 45539003 provide supplemental information for assessing risk. The scientific literature submitted on *B. licheniformis*, implicates the microbe as a sporadic mammalian pathogen. *B. licheniformis* diseases appears to be limited to cows and sheep as very unusual events associated with the ingestion of moldy hay, and secondarily, there is also an association with bovine abortion. The majority of the earliest reported cases appear to be limited to the United Kingdom. It is now reported as a low incidence disease in the same hosts in the Americas. Of the cases reported in USA, 3.6% of 14.5% bacterial related abortions and stillbirths were associated to *Bacillus spp.* (predominately *B.*

licheniformis). The reported cases appeared to be associated with cattle feeding upon moldy hay. The consistency of the morphological, biochemical, analytical, serological, or other tests are reported in each documented reports (literature) including the sporadic events.

c. Subchronic Toxicity and Chronic Toxicity

Subchronic and chronic toxicity were not required because survival, replication, infectivity, toxicity, or persistence of the microbial agent was not observed in the test animals treated in the acute oral infectivity test.

d. Effects on the Immune and Endocrine Systems

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee(EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen- and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The Agency has no information to suggest that *Bacillus licheniformis* strain SB3086 has an effect on the immune and endocrine systems. No specific tests have been conducted with *Bacillus licheniformis* strain SB3086 to determine such effects. However, as is expected from a non-pathogenic microorganism, the submitted toxicity/pathogenicity studies in rodents indicated that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient. It is unlikely that this organism would have estrogenic or endocrine effects because it is practically non-toxic to mammals.

When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program have been developed, *Bacillus licheniformis* strain SB3086 may be subjected to additional screening and/or testing to

better characterize effects related to endocrine disruption. Based on the weight of the evidence of available data, no endocrine system-related effects have been identified for *Bacillus licheniformis* strain SB3086.

2. Dose Response Assessment

No toxicological endpoints are identified.

3. Aggregate Exposure and Risk Characterization

a. Dietary

i. Food

The present use sites for products containing *Bacillus licheniformis* strain SB3086 do not include food or feed sites therefore dietary exposure and risk from the consumption of residues are likely to be minimal to non-existent for the general population including infants and children.

ii. Drinking Water

The microorganism *Bacillus licheniformis* is ubiquitous. It is not considered to be a risk to drinking water. Accordingly, drinking water is not being screened for *Bacillus licheniformis* strain SB3086 as a potential indicator of microbial contamination or as a direct pathogenic contaminant. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure to strain SB3086 through drinking water. Therefore, the potential of significant transfer to drinking water is minimal to nonexistent.

4. Occupational and Residential Exposure and Risk Characterization

a. Occupational and Residential Exposure and Risk

The potential for occupational and residential risk is expected to be minimal based on the evaluations of submitted Tier I acute toxicity tests (Tables 2a & 2b). For additional extensive use patterns, potential risks from occupational exposure will be mitigated through the use of appropriate Personal Protective Equipment or other Agency requirements on a case by case basis.

b. Residential, School and Day Care Exposure and Risk Characterization

In the above settings children may be exposed to this pesticide on treated lawns, ornamental turf, recreational fields and ornamental plants. *Bacillus licheniformis* strain SB3086 is a natural soil isolate. The general population including infants and children are exposed to *Bacillus licheniformis* strain SB3086 and other strains of these *Bacilli* in untreated soils.

The potential for occupational and residential risk from exposure to lawns and ornamental plants treated with *Bacillus licheniformis* strain SB3086 is expected to be minimal based on the evaluations of submitted Tier I acute toxicity tests (Tables 2a & 2b). For additional extensive use patterns, potential risks from occupational exposure will be mitigated through the use of appropriate Personal Protective Equipment or other Agency requirements on a case by case basis.

5. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

Bacillus licheniformis strain SB3086 is not registered for use on food or feed sites. The potential aggregate exposure, derived from dermal and inhalation exposure via mixing, loading and applying *Bacillus licheniformis* strain SB3086, the dietary exposure from drinking water containing this organism, should fall well below the currently tested microbial safety levels. In summary, the potential aggregate exposure, derived from non-dietary and non-occupational exposure, should be minimal.

6. Cumulative Effects

Bacillus licheniformis strain SB3086 is practically non-toxic to mammals. No mechanism of toxicity in mammals has been identified for this organism. Therefore no cumulative effect with other related organisms is anticipated.

C. Environmental Assessment

1. Environmental Fate

Bacillus licheniformis is a ubiquitous, saprophytic, common soil microbe that contributes to nutrient cycling and displays antifungal activity. While numbers of *B. licheniformis* in soil are unknown and likely vary from soil to soil, the numbers of total *Bacillus* organisms are

estimated at 10^7 cfu/g soil (TSCA, 1997). The added soil density of *B. licheniformis* from the proposed use rates would be 0.42% to 1.5%. This represents a very small proportion of the naturally occurring bacilli in the soil and therefore is not expected to add substantially to the effects of the naturally occurring *Bacillus* populations.

2. Ecological Toxicity

The Agency determined that the submitted data that were performed with test substance formula 710-132 can be bridged to address ecological guideline requirements for the end use product, Novozymes Biofungicide Green Releaf formula 710-140.

Table 3: Eco-Toxicology Summary

Guideline No.	Study	Status, Classification & Comments	MRID #
154-16 *885-4050	Avian oral toxicity/ pathogenicity	ACCEPTABLE, No signs of illness or abnormal behavior noted in young mallards (*Anas platyrhynchos*) dosed with formula 710-132 at a total dosage of approximately 4.5×10^{10} cfu/kg of body weight. No evidence of pathogenicity due to the treatment was observed during gross necropsy at test termination. The no mortality dosage of 710-132 administered to mallards in this study was approximately 9×10^9 cfu/kg per day for five days. A statistically significant ($p<0.01$) reduction in body weight gain among birds in the sterile filtrate and in the 710-132 treatment group when compared to the negative control was considered to be related to treatment. During the dosing period (Day 0 thru Day 4), reductions in weight gain in the sterile filtrate control group were more pronounced than for the 710-132 treatment group, which suggests that reductions in body weight gain are related to formulation ingredients other than the active microbial agent. The Microbial Testing Guidelines call for testing of the technical grade active ingredient, not the formulated product. These data do, however, show that the formulated product is also not harmful to mallards at field use rates.	45302106
154-17 *885-4100	Avian Pulmonary/Inhalation Testing,	WAIVED There are no reports in the literature suggesting that *B. licheniformis* is an avian pathogen. The route of exposure to birds is also likely to be primarily by the oral route. In addition, avian oral feeding pathogenicity studies and mammalian inhalation studies do not show toxic or pathogenic effects.	

Guideline No.	Study	Status, Classification & Comments	MRID #
154-18 *885-4150	Wild Mammal Testing	WAIVED. The standard mammalian toxicity test data submitted to the Agency indicate no adverse effects to rodents during the acute oral and intra tracheal toxicity and pathogenicity testing at the maximum hazard dose. These data show a lack of toxicity to mammals from exposure to high levels of *B. licheniformis* spores. In light of numerous literature reports of association with reproductive failures and mastitis in cattle, sheep and swine, it is recommended that the product label have a precautionary statement informing the user that the treated vegetation not be allowed to come in contact with livestock. These reports also indicate the possibility of reproductive effects on wild ruminant and boar species. The added soil density of *B. licheniformis* from the proposed use rates would be 0.42% to 1.5%. This represents a very small proportion of the naturally occurring *Bacilli* in the soil and therefore is not expected to add substantially to the effects of the naturally occurring *Bacillus* populations. Exposure to the wild ruminant and boar species is expected to be minimal because the product will be used on ornamental plants and ornamental turf grasses. Therefore no further wild mammal testing is required.	
154-19 *885-4200	Fresh water fish toxicity/ pathogenicity (30 day study) rainbow trout (*Oncorhynchus mykiss*)	ACCEPTABLE. The 30-day LC_{50} of Formula 710-132 was > $1.1x10^6$ cfu/mL (117 X the maximum hazard EEC based on direct application at the maximum use rate to a 15 cm deep body of water) with 95% confidence limits of $6.6x10^5$ and $1.7x10^6$ cfu/mL. Formula 710-132 did not appear to be pathogenic to rainbow trout. The sterile filtrate was acutely toxic to the trout with 100% mortality observed after 5 days exposure suggesting that the observed mortalities at high concentrations in the treatment and sterile filtrate control groups were due to formulation ingredients in the filtrate rather than the active microbial agent. The Microbial Testing Guidelines call for testing of the technical grade active ingredient (TGAI) specifically because the formulation ingredients at high concentrations are known to be toxic to aquatic species.	45302107, 45602501

Guideline No.	Study	Status, Classification & Comments	MRID #
154-20 *885-4240	Fresh water aquatic invertebrate toxicity/pathogenicity	ACCEPTABLE. The NOAEC of Formula 710-132 was 120X (1.2×10^6 cfu/mL) based on survival and length measurements of the daphnids. The 21-Day LC_{50} was 181.7X (1.8×10^6 cfu/mL) with 95% confidence limits of 161.2X to 204.8X ($1.6\text{-}2.0\text{x}10^6$). The Microbial Testing Guidelines call for testing of the technical grade active ingredient (TGAI), not the formulated end use product (EP). Survival was 90% (2 died) at the end of the test in the microbes (1×10^7cfu/mL TGAI) alone at the 1000X test concentration was not toxic in terms of survivorship, reproduction, length, and weight relative to the control. These data show that the TGAI and EP are not harmful to aquatic invertebrates at field use rates.	45367802, 45602501
154-22 *885-4300	Nontarget plant toxicity/pathogenicity	WAIVED. There are no reports in the literature suggesting that *B. licheniformis* has detrimental effects on plants. In addition, extensive research with this *B. licheniformis*, including the 710-140 formulation, has not indicated any pathogenicity, phytotoxicity, or any other adverse effects on plants.	455771-01
154-23 *885-4340	Nontarget insect toxicity/pathogenicity	WAIVED. Hazard to aquatic and *terrestrial* insects from the proposed uses of Green Releaf® biofungicide are not expected. There are no reports in the literature suggesting that *B. licheniformis* has detrimental effects on insect species. *B. licheniformis* does not produce the entomopathogenic toxins which are characteristic of those members of the genus *Bacillus* that display insecticidal activity. In addition, any *B. licheniformis* SB3086 that reaches the aquatic environment is expected to behave as the wild strain. In addition, honey bee testing did not show any apparent detrimental effects.	
154-24 *885-4380	Honeybee toxicological/pathogenicity	ACCEPTABLE. Honeybee larvae exposed to $1.6\text{x}10^6$ cfu/mL of 710-132 (formulated product - EP) had no statistically significant effect on larvae survival when compared to larvae exposed to a similar quantity of sterile filtrate or larvae exposed to water only. No adverse behavioral or developmental abnormalities were noted in emerged adult honeybees exposed to the 710-132 treatment. Slight, but not significant, formulation ingredient effects were noted at the high test doses.	45302108

*885 series = OPPTS Microbial Pesticide Test Guideline Numbers.

Avian Pulmonary/Inhalation Testing, Tier I, USEPA OPPTS 885.4100
The Agency requires avian inhalation testing on products containing microbes that are known to be, or are related to known avian pathogens, including reported opportunistic pathogens. A series of literature searches have been conducted to determine whether any adverse effects from *B. licheniformis* have been reported on avian species. These searches include The Extension Toxicology Network (Extoxnet), Integrated Risk Information System (IRIS), National Library of Medicine (Medline/PubMed), Aquaculture Network: Mississippi-Alabama Sea Grant Consortium (AquaNIC), Current Research Information System, USDA (CRIS), and the National Agricultural Library Agriculture Online Access (Agricola). There are no reports in the literature suggesting that *B. licheniformis* is an avian pathogen. The route of exposure to birds is also likely to be primarily by the oral route. In addition, avian oral feeding pathogenicity studies and mammalian inhalation studies do not show toxic or pathogenic effects. Therefore, Avian Pulmonary/Inhalation testing is not required for Green Releaf® biofungicide.

Avian Oral Testing, Tier I, USEPA OPPTS 885.4050 (MRID No. 453021-06)
This study was conducted in accordance with Good Laboratory Practice Standards as published by the U.S. Environmental Protection Agency, Office of Pesticide Programs in 40 CFR Part 160 with certain exceptions that did not effect the integrity of the test.

Toxicity and pathogenicity of Green Releaf®, 710-132, to young mallards (*Anas platyrhynchos*) was determined by oral gavage at approximately $9x10^9$ cfu/kg of body weight per day for a five day period, and a 30 day observation time. This dosage corresponds to a total dosage of approximately 4.5×10^{10} cfu/kg of body weight. There were no signs of illness or abnormal behavior noted in the young mallards. No evidence of pathogenicity due to the treatment was observed during gross necropsy at test termination. The no mortality dosage of 710-132 administered to mallards in this study was approximately 9×10^9 cfu/kg per day for five days. A statistically significant ($p<0.01$) reduction in body weight gain among birds in the sterile filtrate and in the 710-132 treatment group when compared to the negative control was considered to be related to treatment. During the dosing period (Day 0 thru Day 4), reductions in weight gain in the sterile filtrate control group were more pronounced than for the 710-132 treatment group, which suggests that reductions in body weight gain are related to formulation ingredients other than the active microbial agent. The Microbial Testing Guidelines call for testing of the technical grade active ingredient (TGAI), not the formulated product (end use product - EP). These data do, however, show that show that both the active ingredient (TGAI), and the formulated product (EP) are not harmful to mallards at the proposed field use rates.

Freshwater Fish Testing, Tier I, USEPA OPPTS 885.4200 (MRID No. 453021-07, 456025-01) This study was conducted in accordance with Good Laboratory Practice Standards as published by the U.S. Environmental Protection Agency, Office of Pesticide Programs in 40 CFR Part 160 with certain exceptions that did not effect the integrity of the test.

Toxicity and pathogenicity of Green Releaf®, 710-132, to rainbow trout (*Oncorhynchus mykiss*) was determined in a 30-day study. The 30-day LC_{50} was > $1.1x10^6$ cfu/mL (117X the maximum hazard EEC based on direct application at the maximum use rate to a 15 cm deep body of water) with 95% confidence limits of $6.6x10^5$ and $1.7x10^6$ cfu/mL. Gross necropsies were performed on three fish from each control and 710-132 treatment group. None of the fish examined by gross necropsy exhibited signs of infection. Tissues of gills, intestines and muscles of exposed fish appeared normal and were comparable to tissues of fish from the negative control. Consequently, 710-132 did not appear to be pathogenic to rainbow trout. The sterile filtrate was acutely toxic to the trout with 100% mortality observed after 5 days exposure suggesting that the observed mortalities at high concentrations in the treatment and sterile filtrate control groups were due to formulation ingredients in the filtrate rather than the active microbial agent. The Microbial Testing Guidelines call for testing of the technical grade active ingredient (TGAI) specifically because the formulation ingredients at high concentrations are known to be toxic to aquatic species. Assuming direct application of the EP to the aquatic environment, the risk quotients (RQ) for trout based on LC_{50} values range from <0.001-0.005 for the 5 fl.oz/1000ft^2 application rate and 0.004-0.019 for the 18 fl.oz/1000ft^2 application rate. Based on the NOEC of 1305 ppm the RQ is 0.008 for the 5 fl.oz/1000ft^2 application rate and 0.029 for the 18 fl.oz/1000ft^2 application rate. These are worst case risk quotients because the product is not intended for direct application to water, nevertheless the worst case risk quotients are well below any levels of concern. These data show that the and EP (and therefore the TGAI) are not harmful to fresh water fish at field use rates.

Freshwater Aquatic Invertebrate Testing, Tier I, USEPA OPPTS 885.4240 (MRID #:453678-02, 456025-01) The study was conducted in compliance with Good Laboratory Practice Standards as published by the U.S. Environmental Protection Agency, Office of Pesticide Programs in 40 CFR Parts 160 with certain exceptions that did not effect the integrity of the test.

Toxicity and pathogenicity of Green Releaf® biofungicide end use product (EP) and the TGAI to *Daphnia magna* was determined in a 21-day renewal life-cycle study. With the EP, daphnids responded with a dose-dependent response with no mortality in the control and the three lowest test concentrations (36X, 54X, and 80X). Fifty percent mortality was observed in the 180X test concentration group, 90% mortality in the 268X test concentration

group and there were no surviving daphnids exposed to the 400X test concentration. Likewise, all daphnids died in the 500X and 1000X concentrations in the range finding study. The NOAEC was 120X (1.2×10^6 cfu/mL) based on survival and length measurements of the daphnids. The 21-Day LC_{50} was 181.7X (1.8×10^6 cfu/mL) with 95% confidence limits of 161.2X to 204.8X ($1.6\text{-}2.0\text{x}10^6$).

The Microbial Testing Guidelines call for testing of the technical grade active ingredient (TGAI), not the formulated end use product (EP) specifically because the formulation ingredients at high concentrations are known to be toxic to aquatic species. In the TGAI group survival was 90% (2 died) at the end of the test at 1×10^7cfu/mL TGAI, a 1000X EEC concentration. The 1000X test concentration was not toxic in terms of survivorship, reproduction, length, and weight relative to the control.

Assuming direct application of the EP to the aquatic environment, the risk quotients (RQ) for daphnids based on LC_{50} values range from <0.003-0.006 for the 5 fl.oz/1000 ft^2 application rate and 0.009-0.02 for the 18 fl.oz/1000 ft^2 application rate. Based on the overall study NOEC of 1257 ppm the RQ is 0.008 for the 5 fl.oz/1000 ft^2 application rate and 0.03 for the 18 fl.oz/1000 ft^2 application rate. These are worst case risk quotients because the product is not intended for direct application to water, nevertheless the worst case risk quotients are well below any levels of concern. These data show that the and EP and TGAI are not harmful to aquatic invertebrates at field use rates.

Wild Mammal Risk Assessment, Tier I, USEPA OPPTS 885.4150 (MRID not assigned) Novozymes Biologicals, Inc. has submitted a justification for a data waiver from wild mammal toxicity/pathogenicity studies (OPPTS 885.4150). The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil, water and plant-surface colonizer, whose level in the environment will not significantly increase with the use of Green Releaf®. In addition, human health data performed on rodent species showed no detrimental effects.

The mammal hazard assessment is being performed on the basis of rodent toxicity data prepared for human health risk assessment purposes and published literature reports. The standard mammalian toxicity test data submitted to the Agency indicate no adverse effects to rodents during the acute oral and itratracheal toxicity and pathogenicity testing at the maximum hazard dose. These data show a lack of toxicity to mammals from exposure to high levels of *B. licheniformis* spores. Therefore no further wild mammal testing is required.

Bacillus licheniformis is a ubiquitous, saprophytic, common soil microbe that contributes to nutrient cycling and displays antifungal activity. While numbers of *B. licheniformis* in soil

are unknown and likely vary from soil to soil, the numbers of total *Bacillus* organisms are estimated at 10^7 cfu/g soil (TSCA, 1997). The added soil density of *B. licheniformis* from the proposed use rates would be 0.42% to 1.5%. This represents a very small proportion of the naturally occurring *Bacilli* in the soil and therefore is not expected to add substantially to the effects of the naturally occurring *Bacillus* populations. A series of literature searches have been conducted to determine whether any adverse effects from *B. licheniformis* have been reported on mammalian species. These searches include the Extension Toxicology Network (Extoxnet), Integrated Risk Information System (IRIS), National Library of Medicine (Medline/PubMed), Aquaculture Network: Mississippi-Alabama Sea Grant Consortium (AquaNIC), Current Research Information System, USDA (CRIS), and the National Agricultural Library Agriculture Online Access (Agricola). In light of numerous literature reports of association with reproductive failures and mastitis in cattle, sheep and swine, *it is recommended that the product label have a precautionary statement informing the user that the treated vegetation not be allowed to come in contact with livestock. These reports also indicate the possibility of reproductive effects on wild ruminant and boar species.* Exposure to the wild ruminant and boar species is expected to be minimal because the product will be used on ornamental plants and turf grasses.

Nontarget Plant Risk Assessment , Tier I, USEPA OPPTS 885.4300 (MRID No. 455771-01) Novozymes Biologicals, Inc. has submitted a justification for a data waiver from terrestrial and aquatic plant toxicity/pathogenicity studies. The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil, water and plant-surface colonizer, whose level in the environment will not significantly increase with the use of Green Releaf®. In addition, literature reports and testing performed for efficacy evaluations showed no detrimental effects to plants.

Bacillus licheniformis has not been known to cause any pathogenicity in plants. *B. licheniformis* is not listed in the U.S. Department of Agriculture list of plant pathogens (Federal Plant Pest Act Regulations, 7CFR Part 330). *B. licheniformis* is a ubiquitous, saprophytic, common soil microbe that contributes to nutrient cycling, displays antifungal activity, but is not reported to have activity towards plant species. While numbers of *B. licheniformis* in soil are unknown and likely vary from soil to soil, the numbers of total *Bacillus* organisms are estimated at 10^7 cfu/g soil (Alexander, 1977; TSCA, 1997). The added soil density of *B. licheniformis* from the proposed use rates would be 0.42% to 1.5%. This represents a very small proportion of the naturally occurring *Bacilli* in the soil and therefore is not expected to add substantially to the effects of the naturally occurring *Bacillus* populations. A series of literature searches have been conducted to determine whether any adverse effects from *B. licheniformis* have been reported on plant species. These searches include the Extension Toxicology Network (Extoxnet), Integrated Risk Information System (IRIS), National Library of Medicine (Medline/PubMed), Aquaculture Network: Mississippi-Alabama Sea Grant Consortium (AquaNIC), Current Research

Information System, USDA (CRIS), and the National Agricultural Library Agriculture Online Access (Agricola). There are no reports in the literature suggesting that *B. licheniformis* has detrimental effects on plants, except in a beneficial sense because it inhibits the growth of microbial plant pathogenic species. In addition, extensive research with this *B. licheniformis*, including the 710-140 formulation, has not indicated any pathogenicity, phytotoxicity, or any other adverse effects on plants (MRID 455771-01). Therefore, hazards to plants from the proposed uses of Green Releaf® biofungicide are not anticipated.

Nontarget Insect Studies, Tier I, USEPA OPPTS 885.4340 (MRID No. not assigned)
Novozymes Biologicals, Inc. has submitted a justification for a data waiver from aquatic and terrestrial insect toxicity/pathogenicity testing. The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil, water and plant-surface colonizer, whose level in the terrestrial and aquatic environment will not significantly increase with the use of Green Releaf®, and that an extensive literature search yielded no reports of adverse effects to insect species.

Bacillus licheniformis is a ubiquitous, saprophytic microbe that contributes to nutrient cycling, displays antifungal activity, but is not reported to have activity towards insects. A series of literature searches have been conducted to determine whether any adverse effects from *B. licheniformis* have been reported on insect species. These searches include the Extension Toxicology Network (Extoxnet), Integrated Risk Information System (IRIS), National Library of Medicine (Medline/PubMed), Aquaculture Network: Mississippi-Alabama Sea Grant Consortium (AquaNIC), Current Research Information System, USDA (CRIS), and the National Agricultural Library Agriculture Online Access (Agricola). There are no reports in the literature suggesting that *B. licheniformis* has detrimental effects on insect species. *B. licheniformis* does not produce the entomopathogenic toxins which are characteristic of those members of the genus *Bacillus* that display insecticidal activity. In addition, any *B. licheniformis* SB3086 that reaches the aquatic environment is expected to behave as the wild strain. Therefore, hazard to aquatic and terrestrial insects from the proposed uses of Green Releaf® biofungicide are not expected. Because the honey bee represents an important pollinator species, and therefore may have greater exposure, honey bee testing has been performed and does not show any apparent detrimental effects.

Honey Bee Studies, USEPA OPPTS 885.4380 (MRID No. 453021-08)
This study was conducted in accordance with Good Laboratory Practice Standards as published by the U.S. Environmental Protection Agency, Office of Pesticide Programs in 40 CFR Part 160. An acceptable study was conducted based on OPPTS Series 885-4380, Honey bee testing Tier I.

Honeybee larvae were exposed to Green Releaf® 710-132 via their diet to evaluate the effect on survival and mortality. Honeybee larvae exposed to $1.6x10^6$ cfu/mL of 710-132 (formulated product - EP) had no statistically significant effect on larvae survival when compared to larvae exposed to a similar quantity of sterile filtrate or larvae exposed to water only. No adverse behavioral or developmental abnormalities were noted in emerged adult honeybees exposed to the 710-132 treatment. Slight, but not significant, formulation ingredient effects were noted at the high test doses. The reference substance (potassium arsenate) produced a survival rate of only 5% at capping and emergence confirming the validity of the test system.

Estuarine and Marine Animal Risk Assessment, Tier I, USEPA OPPTS 885.4280. Novozymes Biologicals, Inc. has submitted a justification for a data waiver from estuarine and marine animal testing (OPPTS 885.4280). The waiver request is based on the rationale that the active ingredient is a naturally-occurring soil, water and plant surface colonizer, whose level in the estuarine/marine environment will not significantly increase with the use of Green Releaf®. An extensive published literature search yielded no reports of adverse effects to estuarine/marine animals due to natural populations of *B. licheniformis*.

Bacillus licheniformis is a ubiquitous, saprophytic, common soil microbe that contributes to nutrient cycling, displays antifungal activity, but is not reported to have activity towards estuarine/marine species. While numbers of *B. licheniformis* in soil are unknown and likely vary from soil to soil, the numbers of total *Bacillus* organisms are estimated at 10^7 cfu/g soil (EPA, 1997a.). The added soil density of *B. licheniformis* from the proposed use rates would be 0.42% to 1.5%. This represents a very small proportion of the naturally occurring *Bacilli* in the soil and therefore is not expected to add substantially to the effects of the naturally occurring *Bacillus* populations. A series of literature searches have been conducted to determine whether any adverse effects from *B. licheniformis* have been reported on estuarine/marine species. These searches include the Extension Toxicology Network (Extoxnet), Integrated Risk Information System (IRIS), National Library of Medicine (Medline/PubMed), Aquaculture Network: Mississippi-Alabama Sea Grant Consortium (AquaNIC), Current Research Information System, USDA (CRIS), and the National Agricultural Library Agriculture Online Access (Agricola). There are no reports in the literature suggesting that has detrimental effects on estuarine/marine species.

The proposed uses of on ornamental plants and turf grasses is not expected to result in increased exposure or adverse effects to estuarine/marine animals. Any *B. licheniformis* SB3086 that reaches the estuarine systems in the form of run-off is expected to behave as the wild strain *B. licheniformis*. Therefore, testing is not considered necessary to assess the risks of to estuarine/marine animal species. Hazard to estuarine/marine species from the proposed uses of Green Releaf® biofungicide are not anticipated.

IV. RISK MANAGEMENT AND RE/REGISTRATION DECISION

A. Determination of Eligibility

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment.

To satisfy criterion "A" above, *Bacillus licheniformis* strain SB3086 has well known properties. The Agency has no knowledge that would contradict the claims made on the label of this product. Criterion "B" is satisfied by the current label and by the data presented in this document. It is believed that this new pesticidal active ingredient will not cause any unreasonable adverse effects, is a broad spectrum microbial fungicide, and does provide protection as claimed satisfying criterion "C". Criterion "D" is satisfied in that *Bacillus licheniformis* strain SB3086 is not expected to cause unreasonable adverse effects when used according to label instructions.

Therefore, *Bacillus licheniformis* strain SB3086 is eligible for registration. The uses are listed in Table 4, Appendix A. These eligible uses are limited to non -food/feed sites.

B. Regulatory Position

1. Unconditional Registration

The data requirements are fulfilled and the Biopesticides and Pollution Prevention Division recommends unconditional registration of products that contain *Bacillus licheniformis* strain SB3086 as a new active ingredient (Novozymes Biofungicide Green Releaf).

2. CODEX Harmonization

There are no CODEX values for *Bacillus licheniformis* strain SB3086.

3. Risk Mitigation

To mitigate the potential for exposure to livestock of *Bacillus licheniformis* strain SB3086 the environmental hazard statement on end-use products must include the statements: “Do not use this product on plants intended for food or feed. Do not feed treated plants to livestock or domestic animals."

4. Endangered Species Statement

The Agency has determined that this registration action will have no adverse effects on currently listed endangered and threatened species.
Based on the intended use pattern, and the results of toxicity and exposure data from the public scientific literature and from the data submitted by the applicant, the Agency has determined that this action will have no effect on currently listed endangered and threatened species.

C. Labeling Rationale

1. Human Health Hazard (WPS and non-WPS)

Bacillus licheniformis strain SB3086 products with commercial use sites are subject to the Worker Protection Standard. Because of the low toxicity of *Bacillus licheniformis* strain SB3086 , the Re-Entry Interval for uses within the scope of WPS is four hours. Precautionary statements and personal protective equipment as specified below are required based on the acute toxicity categories of this organism.

2. Environmental Hazard

In light of numerous literature reports of association with reproductive failures and mastitis in cattle, sheep and swine, the product label must have a precautionary statement informing the user that the treated vegetation not be allowed to come in contact with livestock. These reports also indicate the possibility of reproductive effects on wild ruminant and boar species.

Precautionary labeling is required as indicated below.

V. ACTIONS REQUIRED BY REGISTRANTS

A. Precautionary Labeling

Bacillus licheniformis strain SB3086 products must state the following under the heading "Precautionary Statements":

Personal Protective Equipment required for Applicators and other handlers must wear:

Long sleeved shirt and long pants. Shoes plus socks, a NIOSH approved respirator with any N, P, R, or HE filter."

WPS labels must state the following under the heading "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.

B. Environmental Hazards Labeling

Provided the following statement is placed into the environmental hazards statement, the risk of *Bacillus licheniformis* strain SB3086 is minimal to nonexistent to non-target organisms including endangered species.

1. End-Use Product Environmental Hazards Labeling

"Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters. Do not use this product on plants intended for food or feed. Do not feed treated plants to livestock or domestic animals."

2. Manufacturing-Use Product Environmental Hazards Labeling

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems

without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

3. Application Rate

It is the Agency's position that the labeling for the pesticide products containing *Bacillus licheniformis* strain SB3086 as the active ingredient complies with the current pesticide labeling requirements. The Agency has not required a maximum number of applications per a season of this active ingredient.

C. Labeling

The attached label for Novozymes Biofungicide Green Releaf conforms with the labeling requirements for *Bacillus licheniformis* strain SB3086 . Some of the essential label requirements are highlighted below.

Signal word is "Caution," (toxicity category IV). The product shall contain the following information:

- Product Name
- Ingredient Statement
- Registration Number
- "Keep Out of Reach of Children"
- Signal Word (CAUTION)
- First Aid Statement (optional)
- Personal Protective Equipment (PPE) Requirements
- Environmental Hazard Statement
- Storage and Disposal Statement
- Agricultural Use Requirements
- Non-Agricultural Use Requirements
- Directions for Use

VI. APPENDIX A: USE SITES

Table 4 lists the use sites for the product. The registrant must comply with the appropriate labeling requirements before releasing these products for shipment.

Table 4. Use Site Registration/Reregistration

Novozymes Biofungicide Green Releaf, Use Sites: ornamental turf, lawns, golf courses, sports turf, turf farms, ornamental plants, conifers and arborculture	Official date registered:

VII. APPENDIX B: BIBLIOGRAPHY

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Bacillus Licheniformis TSCA Section 5(h)(4) Exemption: Final Decision Document

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