Bacillus cereus Strain BP01 (119802) Technical Document

I. Overview

A. Active Ingredient Overview

- **Common Name:** B. cereus BP01
- **Microbial Name:** *Bacillus cereus* strain BP01
- **Trade and Other Names:** Mepichlor/BP01 4-2
- **OPP hemical Code:** 119802
- **Basic Manufacturer:**

  Micro Flo Company
  P.O. Box 5948
  Lakeland, FL 33807

B. Use Profile

- **Type of Pesticide:** microbial pesticide
- **Use Sites:** cotton
- **Target pests:** plant regulator
- **Formulation Types**: liquid
- **Method and Rates of Application:**

  Application rates, depending on the cotton variety and its vigor, vary from 0.03 - 0.38 g BPO1/A. The maximum application level for *Bacillus cereus* strain *BPO1* on cotton is 0.75 g/acre/year, with an average of 0.2 g/acre/year.

- **Type of Treatment:** foliar spray.
- **Equipment:** Conventional ground and aerial equipment.
- **Timing:** Applied from the match head square stage at 7 - 14 day intervals to within 30 days of harvest.
- **Use Practice Limitations:**

Do not apply through any type of irrigation equipment. Apply only on short staple and long staple (Pima) cotton. Do not apply more than 48 fl.oz. of Mepichlor/BP01 4-2 per acre per season. Do not exceed six (6) application per season. Do not apply when plants are under stress. Do not apply within 30 days of harvest. Do not graze or feed cotton forage to livestock.

C. Estimated Usage of Pesticide

These are the first registered products. Usage data are not available at this time.

D. Data Requirements

The data submitted sufficiently addressed requirements for registration. A recommendation for unconditional registration is suggested. If the registrant intends to use this product on other crops in addition to cotton, a honeybee study will be required.

E. Regulatory History

In December, 1996 the Agency received applications from Micro Flo Company to register one (1) technical product containing **Bacillus cereus** strain *BP01*and one end use product containing *Bacillus cereus* strain *BP01* as a new pesticidal active ingredient. Data waivers were granted for Avian Oral, Fish Toxicity/ Pathogenicity, Aquatic Invertebrate Toxicity /Pathogenicity, Plant Study, Nontarget Insect Honeybee Toxicity/Pathogenicity based on the requested use pattern and subsequent submissions by the registrant.

This action registers the first technical product using *Bacillus cereus* strain *BP01* as the active ingredient. The end use product contains an additional active ingredient already found in registered products.

A notice of receipt of the application for registration of *B.cereus* stain *BP01* as a new active ingredient was published in the Federal Register on March 19, 1997 with a 30 day comment period. No comments were received as a result of this publication. On June 25, 1997 a notice of filing for an exemption from the requirement for a tolerance was published in the Federal Register with a 30 day comment period. No comments were received.

II.

III. Science Assessment

A. Physical/Microbial/Chemical Properties Assessment

1. **Chemistry Assessment**

All product chemistry data requirements for *Bacillus cereus* strain *BP01* technical grade active ingredient are satisfied.

a. **Product Identity and Mode of Action**

The Agency has classified the *Bacillus cereus* strain *BP01* (Chemical ID No.: 119802), ATCC # 55675, as a microbial pesticide. *Bacillus cereus* strain *BP01* are gram positive rods which are motile, found in chains or filaments with one oval to cylindrical endospore located in the central or subterminal region. Vacuoles are present. This organism forms colonies which are opaque and irregular with low convex elevation and a dull, rough surface and erose to lobate margin. With age, there is a translucent spreading noted. This organism is indigenous to the U.S. and is noted to have synergistic properties when applied with various phytochemicals.

Mode of Action: When applied with mepiquat chloride, this plant regulator has been shown to promote uniform plant height in cotton, decrease vegetative growth and promote boll growth, leading to yield increases.

b. **Food Clearances / Tolerances**

An exemption from tolerance is acceptable based upon the lack of mammalian toxicity of this product and the lack of exposure with the growth regulator use pattern.

c. **Physical and Chemical Property Assessment**

Chemistry data that support the registration of Bacillus cereus strain BP01 are summarized in Table 1.

Table 1 Product chemistry data requirements

Guideline	Study	Result
151A-10	Product Identity	A sample of Bacillus cereus strain BP01 is file ATCC (#55675).

151A-11	Manufacturing Process	Technical manufactured using batch fermenta process; end-products are manufactured usir integrated process
151A-12	Discussion of formulation of unintentional ingredients	Products certified free of "pathogenic microbi contaminants, toxic chemical substances or unexpected materials."
151A-13	Analysis of sample	CR B. cereus was quantitated by TSA/blood a plates.
151A-15	Certification of limits	Limits listed in the CSF are adequate
151A-16	Analytical Method	Described in 151B-13, Analysis of Samples
151A-17(a)	Color	cereus BP01 - Light yellowish-brown
151A-17(b)	Physical State	B. cereus BP01 - Powdery flakes
151A-17(c)	Odor	B. cereus BP01 Earthy, Musty
151A-17(d)	Melting point	Waived
151A-17(e)	Boiling Point	Waived
151A-17(f)	Density	B. cereus BP01 - 0.224 g/mL
151A-17(g)	Solubility	Waived
151A-17(h)	Vapor Pressure	Waived
151A-17(I)	pH CR	B. cereus BP01 - 5.23 @ 21?C
151A-17(j)	Stability	Waived
151A-17(k)	Flammability	Waived
151A-17(l)	Storage Stability	Waived
151A-17(m)	Viscosity	n/a
151A-17(n)	Miscibility	Waived
151A-17(o)	Corrosion characteristics	Waived
151A-17(p)	Octanol/water partition coef.	Waived

B. Human Risk Assessment

All mammalian toxicology data requirements have been submitted and adequately satisfy the requirements as set forth in 40 CFR 158.740 for microbial pesticides for food, non-food, domestic outdoor and forestry uses. The mammalian toxicology data base includes acute toxicity studies. Based on the use sites, use patterns, application method, use rates, low exposure, and lack of significant toxicological concerns, as demonstrated in the submitted toxicology studies, the potential risks, if any, to humans are considered negligible.

0. Toxicology Assessment

Adequate mammalian toxicology data are available to support registration of the active ingredient *Bacillus cereus* strain *BP01*.

a. Acute Toxicity

All required acute mammalian toxicology studies have been submitted.

b. Subchronic and Chronic Tests

Tier II tests (Guidelines 152-40 through 152-49) involving acute oral, acute inhalation, subchronic oral, acute I.P., I.C., primary dermal, primary eye, immune response, teratogenicity, virulence enhancement, and mammalian mutagenicity (40 CFR 158.740(C)(2)(vi through xv) were not required since survival, replication, infectivity, toxicity, or persistence of the microbial agent was not observed in the test animals treated in the Tier I acute oral infectivity test. Tier II tests (Guidelines 152-50 through 53) involving chronic testing, oncogenicity testing, mutagenicity, and teratogenicity were not required (40 CFR 158.740(C)(2)(xvi through xix) since Tier II tests were not required. Tier II tests would have been required if the Tier II tests had shown potential for chronic effects, mutagenicity, or oncogenicity.

Bacillus cereus has been implicated in nosocomial infections in rare instances and in food poisoning incidents. No enterotoxin was found using the ELISA analysis. Quality control procedures in place during

manufacturing ensure that harmful levels of contaminating microorganisms are prevented.

Table # 2 summarizes the acute toxicity data submitted for *Bacillus cereus* strain *BP01*.

Table 2 Toxicity data requirements

Guideline	Study	Result
		TIER I Acute toxicity studies
152B-10	Acute oral toxicity	B. cereus BP01 - Toxicity category IV B. cereus BP01 - Toxicity category IV
152B-11	Acute dermal toxicity	B. cereus BP01 - Toxicity category II*
152B-12	Acute inhalation	B. cereus BP01 - Toxicity category IV
152B-13	Primary eye irritation	B. cereus BP01 - Toxicity category IV
152B-14	Primary dermal irritation	B. cereus BP01 -Not required
152B-15	Dermal sensitization	Not Required (no dermal exposure)
152B-16	Hyper-sensitivity/ incidents	Incident data must be reported in a timely ma

*Although initially given a Toxicity Category II, based upon the dosage administered (2g/animal v 2g/kg as required), dermal irritation is not anticipated with this organism. Label language will reflect that of Toxicity Category III.

c. **Effects on the Immune and Endocrine Systems**

There is no known metabolite that acts as an "endocrine disrupter" produced by this microorganism. The toxicity/pathogenicity studies in the rodent (required for microbial pesticides) indicate that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient. Therefore, no adverse effects to the endocrine or immune systems are known or expected. However, EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...". Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disruptor effects.

1. **Dose Response Assessment**

No toxicological endpoints are identified.

2. **Dietary Exposure and Risk Characterization**

While the proposed use pattern will result in dietary exposure with possible residues on food and feed, negligible risk is expected for both the general population and infants and children. Submitted acute toxicology tests confirm that based upon the use sites, use patterns, application method, use rates, low exposure, and lack of significant toxicological concerns, the potential risks, if any, to humans are considered negligible an exemption from the requirement of a tolerance is warranted. Acute exposure could occur from the proposed outdoor use sites but would be very low because of the low applications rates. The application rate is 2 to 24 fl.oz./A based on growth stage of the crop and previous application history. Maximum number of applications per season is six (6). No residue data were required since Tier I acute oral toxicity tests did not reveal "survival, replication, infectivity, toxicity, or persistence of the microbial agent" per 158.740(C)(2)(vi).

3. **Occupational, Residential, School and Day care Exposure and Risk Characterization**

a. **Occupational Exposure and Risk Characterization**

Based on the application methods, the potential for dermal, eye and inhalation exposures for pesticide handlers and applicators exists. Because of the lack of significant mammalian toxicity, worker exposure data (i.e., occupational exposure data) to the active ingredient is not required at this time, the Agency is requiring the appropriate Signal Word and Statements of Precaution.

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

No indoor residential, school or day care uses currently appear on the label. The use site is for growing cotton. Nondietary exposure to these sites, where children are present, is not likely to occur, but the health risk is expected to be minimal to nonexistent based on submitted studies.

4. **Drinking Water Exposure and Risk Characterization**

The microorganism *Bacillus cereus* is ubiquitous in many soils throughout the world. *Bacillus cereus* is not known as an aquatic bacterium and therefore is not expected to proliferate in aquatic habitats. Although the potential exists for a minimal amount of the *B. cereus* strain *BP01* which is applied to enter ground water or other drinking water sources, the amount would in all probability be undetectable or more than several orders of magnitude lower than those levels which are tested and are considered necessary for safety. Moreover, **Bacillus cereus** strain *BP01* is not considered to be a risk to drinking water. Drinking water is accordingly not being screened for *B. cereus* 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 *B. cereus* through drinking water. Therefore, the potential of significant transfer to drinking water is minimal to nonexistent.

5. **Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children**

A battery of acute toxicity/pathogenicity studies is considered sufficient by the Agency to perform a risk assessment for microbial pesticides. *Bacillus cereus* has been implicated in nosocomial infections in rare instances and in food poisoning incidents. In the ELISA Analysis of Enterotoxin test data submitted there was no evidence of enterotoxin (diarrhoeal type) production in the culture filtrates of *Bacillus cereus* strain *BP01* or the end use product. Data relating to the post application die off of *B.cereus* species v background soil population counts demonstrates that this organism is very stable in the soil and rhizosphere. Also, for food uses of microbial pesticides, the acute toxicity/pathogenicity studies have allowed for the conclusion that an exemption from the requirement of a tolerance is appropriate and adequate to protect human health, including that of infants and children.

Quality control procedures in place during manufacturing ensure that harmful levels of contaminating microorganisms are prevented and the mammalian enterotoxin is not present.

There have been no confirmed reports of immediate or delayed allergic reactions to the delta- endotoxin itself despite significant oral, dermal and inhalation exposure to the microbial product.

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

Dermal exposure via the skin would be the primary route of exposure for mixer/loader applicators. Since unbroken skin is a natural barrier to microbial invasion of the human body, dermal absorption could occur only if the skin were cut, if the microbe were a pathogen equipped with mechanisms for entry through or infection of the skin, or if metabolites were produced that could be dermally absorbed. *Bacillus cereus* has been implicated in nosocomial infections in rare instances and in food poisoning incidents. In the ELISA Analysis of Enterotoxin test data submitted there was no evidence of enterotoxin (diarrhoeal type) production in the culture filtrates of *Bacillus cereus* strain *BP01* or the end use product. Data relating to the post application die off of *B.cereus* species v background soil population counts demonstrates that this organism is very stable in the soil and rhizosphere. Also, for food uses of microbial pesticides, the acute toxicity/pathogenicity studies have allowed for the conclusion that an exemption from the requirement of a tolerance is appropriate and adequate to protect human health, including that of infants and children. The quality control procedures have ensured that the diarrheal enterotoxin is not present in this product.

Inhalation would be the primary route of exposure for mixer/loader applicators. Because the pulmonary study showed no adverse effects, the risks anticipated for this route of exposure are considered minimal.

The Oral LD50 of *Bacillus cereus BP01* is greater than 5000 mg/kg. The Acute Oral Toxicity/Pathogenicity test data results show that *Bacillus cereus BP01* is not toxic, pathogenic or infective when a 1 X 108 cfu dose was administered orally. Based upon the use pattern, oral exposure is not likely to occur because of the 30 day preharvest interval. In summary, the Agency believes that the potential aggregate exposure, derived from dermal and inhalation exposure via mixing, loading and applying *Bacillus cereus*, the oral dietary exposure by drinking water contaminated by *B.cereus* strain *BP01*, should fall well below the currently tested microbial safety levels.

C. Environmental Assessment

Non-target Toxicity Studies - Tier I Guideline Requirements for Bacillus cereus BP01 and associated data waivers.

FIFRA Guideline No. Study MRID# Results Summary Study Classification

154-16 Avian Oral 441773-12 LC50>4.44 x 107 cfu/ml; however the test substance concentration was not verified Invalid/ Supplemental

154-19 Fish Tox/Path data waiver data waiver granted based on the expectation that results will be similar to aquatic invertebrate study (MRID# 441773-14)

154-20 Aquatic Invert Tox/Path 441773-13 B. cereus BP01 was toxic to daphnids at concentrations ranging from 3.9 x 107 to 6.7 x 108 cfu/L. Attenuated B. cereus BP01 and the sterile filtrate of B. cereus were toxic to daphnids at 50 mg/l. Acceptable/Core

441773-14 percent mortality in the negative and sterile filtrate controls was greater than the maximum acceptable for guideline tests Invalid/inadequate

154-22 Plant Study 441773-15*

154-23 Nontarget Insect data waiver data waiver based on the current agronomic practices for cotton where the risks from the number and types of pesticides applied throughout the growing season far outweigh the risks associated with application of BP01 technical. inadequate**

154-24 Honeybee Tox/Path data waiver A @ inadequate**

Mepichlor/BP01 2-4 Efficacy Study 441810-08*

* These studies were not required for registration of this microbial pest control agent. In order to expedite review of the data package, these studies were not formally reviewed but results were considered in the final risk assessment.

0. **Ecological Effects Hazard Assessment**

All studies were conducted with the TGAI.

a. **Toxicity to Terrestrial Animals**

i. **Birds**

An avian oral pathogenicity and toxicity study using the northern bobwhite was submitted in fulfillment of Subdivision M Guideline 154-16. The study was classified as Invalid/Supplemental because the test substance was not

verified in the carrier. However, based on the lack of toxicological findings, enough information was provided to conclude that *Bacillus cereus* strain *BP01* when administered orally at an estimated dose of 4.44 x 107 cfu/g/day for five days is practically non-toxic to bobwhite quail.

ii. **Mammals**

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory studies, intended use pattern and other pertinent information. In most cases, rat or mouse toxicity/pathogenicity studies substitute for wild mammal testing. In this case, the Acute Oral Toxicity/Pathogenicity - Rat study, submitted in support of the human health risk assessment is considered an acceptable substitute for wild mammal testing. Risks to wild mammals are considered minimal to non-existent.

iii. **Insects**

Requirements for Non-target Insect Testing, Subdivision M Guideline 154-23, and Honeybee Toxicity Testing, Subdivision M Guideline 154-24 were waived. Data on post application die off and stability of *B.cereus* satisfied this requirement.

b. **Toxicity to Aquatic Animals**

A freshwater aquatic invertebrate toxicity test was required to establish the toxicity of *Bacillus cereus* Strain *BP01* to aquatic invertebrates. Two Freshwater Aquatic Invertebrate tests were submitted using *Daphnia magna*. Results from were classified as Inadequate/Invalid because 1) the actual exposure concentrations of *Bacillus cereus* Strain *BP01* were not verified and therefore were unknown and 2) percent mortality in the negative and sterile filtrate controls was greater than the maximum acceptable for guideline tests. The second freshwater aquatic invertebrate test was submitted and classified as acceptable (MRID# 441773-15). Results indicated *B. cereus BP01* was toxic to daphnids at concentrations ranging from 3.9 x 107 to 6.7 x 108 cfu/L. These concentrations represent 3000 - 6000 times the estimated environmental concentration and therefore the risk to non-target aquatic invertebrates is considered minimal.

i. **asdf**

A freshwater fish toxicity/pathogenicity study using the TGAI would usually be required to establish the toxicity of *Bacillus cereus* strain *BP01* to fish. In this however, a data waiver for this guideline requirement was granted. The data waiver is based on the rationale that 1) the freshwater invertebrate toxicity/pathogenicity test results indicated minimal toxicity to daphnids and 2) daphnids are considered to be the most sensitive aquatic test species especially to *Bacillus sp*. metabolites. In a worst case scenario, similar results would likely be expected from freshwater fish studies using *Bacillus cereus* strain *BP01*.

ii. **Toxicity to Plants**

Based on the information submitted, *Bacillus cereus BP01* does not induce phytotoxic responses in plants. No apparent effects were noted in germination of seeds and growth of soybean seedlings treated with BP01 at 0.2 g/A and 5.0 g/A when compared with control trays. Furthermore, no observable foliar phytotoxicity was reported in any of the treatment or control groups. No further testing is required.

1. **Environmental Fate and Ground Water Data**

Exposure assessments on this type of microbial pesticide are not performed unless significant human health or ecological effects issues arise in the Tier I studies (40 CFR 158.690 (c)). Since Tier II studies were not triggered, there is no requirement for environmental fate data.

2. **Ecological Exposure and Risk Characterization**

a. **Exposure and Risk to Nontarget Terrestrial Animals**

Toxicological studies indicated that there is no significant toxicity to rodents from acute oral testing at the maximum hazard dose. Therefore, risk to mammalian wildlife is expected to be minimal to nonexistent.

b. **Exposure and Risk to Aquatic Animals**

Exposure to aquatic invertebrates and vertebrates could occur based on current label use directions. However, results of atoxicity/pathogenicity study indicated *B.cereus BP01* was toxic to daphnids at concentrations ranging from 3.9 x 107 to 6.7 x 108 cfu/L. In addition, attenuated *B. cereus BP01* and the sterile filtrate of *B. cereus BP01* were toxic to daphnids at the 50 mg/L concentration. These concentrations represent 3000 - 6000 times the estimated environmental concentration and therefore risks to non-target aquatic invertebrates is considered minimal. As an additional risk mitigation measure, the appropriate aquatic mitigating label language is also required.

c. **Exposure and Risk to Non-target Plants**

Exposure to non-target plants is unlikely based on the cotton only use pattern and the relatively low application rates of *Bacillus cereus* strain *BP01*. Furthermore, a plant study data indicated *Bacillus cereus BP01* does not induce phytotoxic responses in plants. No apparent effects were noted in germination of seeds and growth of soybean seedlings treated with BP01 at 0.2 g/A and 5.0 g/A when compared with untreated seedlings. No observable foliar phytotoxicity was reported in any of the treatment or control groups. Therefore, risks to non-target plants are considered minimal to non-existent.

d. **Exposure and Risk to Endangered and Threatened Species**

Endangered and threatened species commonly inhabit undisturbed ecosystems. Most agricultural areas are highly disturbed, cultivated lands. In the case of Bacillus cereus BP01 use on cotton, exposure to endangered and threatened species is unlikely as cotton is grown on intensely managed land. In addition, the low application rate of Bacillus cereus BP01 further reduces the possibility of exposure to endangered and threatened species. Risk to endangered and threatened species from exposure to Bacillus cereus BP01 are considered minimal to non-existent.

D. Efficacy Data

No efficacy data were required to be submitted to the Agency since no public health uses are involved.

IV. Risk Management Decision

A. Determination of Eligibility for Registration

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 criteria (A) above, *Bacillus cereus* strain *BP01* is not expected to cause unreasonable adverse effects when used according to label instructions. Criteria (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 an effective biological plant growth regulator and does provide protection as claimed satisfying Criteria (C). Criteria (D) is satisfied in that the toxicological properties of this product are less toxic than any other conventional pesticide product currently in use and the products are similar to other presently registered *Bacillus sp*. products.

Therefore, *Bacillus cereus* strain *BP01* TECHNICAL is eligible for registration. The only use is for terrestrial food crop. There are no ineligible uses issues.

B. Regulatory Position

0. Conditional / Unconditional Registration

Data requirements are fulfilled and the Biopesticides and Pollution Prevention Division recommends unconditional registration.

1. Tolerance Assessment

An exemption from tolerance is acceptable based upon the lack of mammalian toxicity of this product and the lack of exposure with the plant growth regulator use pattern.

2. CODEX Harmonization

There are no Codex harmonization considerations since there is currently no Codex tolerance for *Bacillus cereus* residues.

3. Nonfood Re/Registrations

There are no non-food issues at this time.

4. Risk Mitigation

Since there are no risk issues, no risk mitigation measures are required at this time for dietary risk, occupational and residential risk, risks to nontarget organisms (plants and wildlife), or ground and surface water contamination for these products.

5. Endangered Species Statement

The Agency has concerns about the exposure of threatened and endangered species. Currently, the Agency is developing a program (The Endangered Species Protection Program) to identify all pesticides whose use may cause potential adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program will require users to consult county-specific bulletins. These bulletins will provide information about specific use restrictions to protect endangered and threatened species in the county of specific pesticide use. Consultations with Fish and Wildlife Service will be necessary to assess risks to newly listed species or from proposed new uses. The Agency plans to publish a description of the Endangered Species Protection Program in the Federal Register and have enforceable county-specific bulletins. Because the Agency is taking this approach for protection of endangered and threatened species, it is not imposing label modifications at this time. To aid in the identification of threatened and endangered species and their habitats, several companies have formed an Endangered Species Task Force (EST) under the direction of the American Crop Protection Association (ACPA). Moreover, the EST will assist in providing species location information at the subcounty level, and particularly if an endangered species occurs in areas where pesticides would be used. This information will be useful once the Endangered Species Protection Program has been implemented.

Prior to the implementation of the Endangered Species Protection Program, the Agency will not impose specific labeling on those pesticides that pose risks to threatened and endangered species and their habitats but will defer imposing specific labeling language until the implementation of The Act. To

address this issue in the short term, the following language will be placed in the notice of pesticide registration:

"The Agency has concerns about the exposure of threatened and endangered species. Currently, the Agency is developing a program (The Endangered Species Protection Program) to identify all pesticides whose use may cause potential adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program will require users to consult county-specific bulletins. These bulletins will provide information about specific use restrictions to protect endangered and threatened species in the county of specific pesticide use. Consultations with Fish and Wildlife Service will be necessary to assess risks to newly listed species or from proposed new uses. The Agency plans to publish a description of the Endangered Species Protection Program in the Federal Register and have enforceable county-specific bulletins. Because the Agency is taking this approach for protection of endangered and threatened species, it is not imposing label modifications at this time. Rather, any requirement for product use modifications will occur in the future under the Endangered Species Program."

Based on the data submitted, the Agency recommends that Bacillus cereus strain BP01 TECHNICAL be registered under Section 3(c)(5) of FIFRA for use in growing crops.

There are no Codex harmonization, risk mitigation, or endangered species considerations. While there are food uses, the residues are exempt from the requirement of a tolerance per 40 CFR 180.1011. The use is not expected to impact endangered species and there are no risks to mitigate.

C. Labeling Rationale

0. **Human Health Hazard**

a. **Worker Protection Standard**

Any product whose labeling reasonably permits use in the production of an agricultural plant after April 21, 1994, except as provided in PR

Notices 93-7 and 93-11, are subject to the Worker Protection Standard. All products within the scope of those notices must bear WPS complying labeling when they are distributed or sold by the primary registrant or any supplementally registered distributor.

After October 23, 1995, except as provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person.

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR 156.10 and other applicable notices. Labeling also conforms to Worker Protection Safety standards where re-entry into sprayed fields must not take place until sprays have dried unless protective clothing is employed. Agricultural worker entry is not permitted during the restricted entry interval (REI) of 12 hours for Mepichlor/BP01 4-2.

b. **Non-Worker Protection Standard**

There are no non-WPS human health hazard issues.

c. **Precautionary Labeling**

The Agency has examined the toxicological data base for *Bacillus cereus* Strain *BP01* TECHNICAL and Mepichlor/BP01 4-2 and concluded that the proposed labeling Signal Word 'CAUTION' is appropriate.

For *Bacillus cereus* Strain *BP01* TECHNICAL and Mephichlor/BP01 4-2, IF IN EYES: Flush eyes with plenty of water. Call a physician if irritation persists; and IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

For both *Bacillus cereus* STRAIN *BP01* TECHNICAL and Mepichlor/BP01 4-2, CAUTION, "Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling." Occupational and residential exposure is expected to be minimal since the label directs that personal protective equipment (long-sleeved shirt, long pants and shoes plus socks) must be worn.

d. **Spray Drift Advisory**

An advisory statement is contained in the DIRECTIONS FOR USE statement for the end-product. "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."

1. **Environmental Hazards Labeling**

Provided the following statement is placed into the environmental hazards statement, the risk of Mepichlor/BP01 4-2 and Bacillus cereus STRAIN BP01 TECHNICAL is minimal to nonexistent to nontarget organisms including endangered species.

a. **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."

b. **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."

2. **Application Rate**

It is the Agency's position, that the labeling for the pesticide products containing *Bacillus cereus BP01* complies with the current pesticide labeling requirements. The Agency has required a maximum number of six (6) applications for the active ingredient. A specified maximum of product per application per acre is being required.

D. Labeling

Product name: Bacillus cereus STRAIN BP01 TECHNICAL

Active Ingredient: Bacillus cereus strain BP01	100.0%

Total	100.0%

Signal word is ACAUTION@ based upon the acute dermal and primary eye toxicity of Bacillus cereus STRAIN BP01. Eye and skin irritation warnings are appropriate. The product shall contain the following information:

- Product Name
- Ingredient Statement
- Registration Number
- AKeep Out of Reach of Children@
- Signal Word (CAUTION)

Product name: Mepichlor/BP01 4-2

Active Ingredients: Bacillus cereus strain BP01	.0.05%
Mepiquat Chloride	4.20%
Inert Ingredients	95.75%
Total	100.000%

Signal word is ACAUTION@ based upon the acute toxicity of the end use product. Eye and skin irritation warnings are appropriate. The product shall contain the following information:

- Product Name
- Ingredient Statement
- Registration Number
- AKeep Out of Reach of Children@
- Signal Word (CAUTION)

V. Actions Required by Registrants

Reports of incidences of adverse effects to humans or domestic animals under FIFRA, Section 6(a)2 and incidents of hypersensitivity under 40 CFR Part 158.690(c), guideline reference number 152-16. There are no data requirements and responses necessary for the reregistration of the manufacturing and end-use products since the products are being registered after November 1984. The registrant has agreed to provide information on antibiotic susceptibility which would serve as supplemental information.

VI. Appendices

Table 4 lists the use sites for each product.

TABLE # 4: Food and Nonfood Use Site Registrations/Reregistration
Bacillus cereus STRAIN BP01 TECHNICAL

Food and Nonfood Use Sites -
cotton

Mepichlor/BP01 4-2

Food Use Sites -
cotton

Official Date:
registered,