

**BIOPESTICIDES REGISTRATION ACTION DOCUMENT**

*(Pantoea agglomerans strain C9-1 )*  
**(Chemical PC Code 006470)**

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

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### **Environmental Fate and Effects Risk Assessment**

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## **I. EXECUTIVE SUMMARY**

*Pantoea agglomerans* strain C9-1, is a bacterium that was originally isolated from apple stem tissue. Subsequently, a natural spontaneous mutant derived from the original strain was obtained which had streptomycin and rifampicin resistance. This strain retained the designation C9-1 and was not derived through genetic engineering. When first isolated, this strain was identified as *Erwinia herbicola* based on gas chromatography-fatty acid methyl ester (GC-FAME) analysis and placed in GC subgroup B. Members of the group described as *E. herbicola/lathyri-Enterobacter agglomerans* are found in soil, water, air, and associated with plants and animals, including humans as commensal microbes. Following GC-FAME and substrate utilization analyses, and most importantly, a restructuring of the bacterial taxonomy of this group of microbes, this isolate is now considered a strain of *Pantoea agglomerans*.

The end use product BlightBan is used to control fire blight in apples and pears. *Pantoea agglomerans* strain C9-1 will be sprayed in apple and pear orchards only. This microbial pesticide is to be applied at 15-20 percent bloom followed by a second application at the first

petal fall-full bloom, and a third application will take place at rattail bloom for pear or post petal fall for apples. The percentage active ingredient is 71.

## II. OVERVIEW

### A. Use Profile

- ! **Active Ingredient:** *Pantoea agglomerans* strain C9-1
- ! **Trade and Other Names:** BlightBan
- ! **OPP Chemical Code:** 006470
- ! **Basic Manufacturer:** Nufarm, Inc.  
1333 Burr Ridge Parkway, Suite 125A  
Burr Ridge, IL 60527
- ! **Type of Pesticide:** Microbial
- ! **Use Sites:** Apples and Pears
- ! **Target Pest:** Fire blight

### B. Regulatory History

The company, Plant Health Technologies, first petitioned the Agency on August 18, 1997 for an experimental use permit (EUP) and temporary exemption from the requirement of a tolerance for the bacterium, *Pantoea agglomerans* strain C9-1, to control fire blight in apples and pears. The EUP was granted on May 20, 1998. The company under the new name, Nufarm, Inc. has applied for a full commercial use section 3 registration for *Pantoea agglomerans* strain C9-1 to control fire blight in apples and pears.

### III. SCIENCE ASSESSMENT

#### A. Physical and Chemical Properties Assessment

The data submitted in support of the product identity requirements for *Pantoea agglomerans* strain C9-1 microbial pesticide are sufficient for the proposed use patterns of the microbial pesticide.

##### 1. Product Identity and Mode of Action

*Pantoea agglomerans* strain C9-1 was originally isolated from apple stem tissue in an apple orchard in Michigan in 1981. Subsequently, a natural spontaneous mutant derived from the original strain was obtained which had streptomycin and rifampicin resistance. This strain retained the designation C9-1 and was not derived through genetic engineering. When first isolated, this strain was identified as *Erwinia herbicola* based on GC-FAME analysis and placed in GC subgroup B. Members of the group described as *E. herbicola/lathyri-Enterobacter agglomerans* are found in soil, water, air, and associated with plants and animals, including humans as commensal microbes.

As previously stated, the bacterial isolate from Michigan apple orchard was originally designated as *Erwinia herbicola*. Following GC-FAME and substrate utilization analyses, and most importantly, a restructuring of the bacterial taxonomy of this group of microbes, this isolate is now considered a strain of *Pantoea agglomerans*. No reports of plant pathogenicity exist for the *Pantoea agglomerans* species as such; however, strains once considered within the *E. herbicola* complex have been implicated in plant disease situations (i.e., pink fruit of pineapple, bacterial wilt of cassava, purple stain of papaya, bacterial leaf spot of *Dracaena sanderaria*, and black spot necrosis of beach pea). (MRID # 445405-01) Isolates designated as *E. agglomerans*, *E. herbicola* and *E. lathyri* have been loosely implicated as clinical isolates in several disease situations in humans. Evidence suggests, however, that the presence of these organisms in clinical pathology are as secondary colonizers especially in cases where an underlying pathology has compromised the immune system. Also in the literature an *E. agglomerans* isolate, before being renamed *Pantoea agglomerans*, was associated with hypersensitivity following pulmonary exposure through grain dust.

The target organism of *Pantoea agglomerans* strain C9-1 is the fire blight disease of pome fruit. Fire blight is caused by the phytopathogenic bacterium *Erwinia amylovora*. The pathogen may enter the tree through natural openings in the blossoms, leaves, or stem wounds. Usually the disease is caused by bacteria that, during the course of winter, survive in cankers of the main stem and branches or in infected twigs. In the spring, when the blossoms begin to open and there is sufficient moisture, the cankers resume growth and exude drops of bacterial ooze that are disseminated to the blossoms and young leaves principally by rain, heavy dew, or windblown mist. Fire blight may also be spread by pollinating insects such as bees, sucking, chewing, or boring insects, and unsanitary pruning tools. Warm temperatures and high humidity are the optimal conditions for infection and disease development.

The disease becomes apparent in the spring, when infected blossoms suddenly wilt and turn brown. Later, twigs and leaves also turn brown to black with twigs taking on a characteristic shepherd's crook appearance and the entire tree looks as if scorched by fire. The affected leaves usually remain on the tree well into the winter. Young infected fruits become watery or oily in appearance and exude droplets of clear, milky, or amber colored ooze. They later become leathery and turn brown, dark brown, or black. The shriveled fruit usually remains attached to the tree.

Fire blight is considered one of the most destructive diseases of fruit trees in North America. It occurs sporadically and unpredictably and occasionally reaches epidemic levels. A severe outbreak can seriously damage or kill mature pear, apple, or crab apple trees in one season. Other ornamentals such as hawthorn, plum, chokecherry, Saskatoon berry, cotoneaster, and spirea may also be affected.

*Pantoea agglomerans* strain C9-1 is a bacterial antagonist of *Erwinia amylovora* on apples and pear trees. Following application to trees, *Pantoea agglomerans* strain C9-1 is able to reproduce on the blooms for several days, effectively colonizing the tree and competitively displacing the pathogen. Ishimaru et al. (1988) identified two antibiotics produced by strain C9-1, herbicolin O and herbicolin I, that may contribute to the protective effect.

As a streptomycin resistant isolate, *Pantoea agglomerans* strain C9-1 is compatible with the streptomycin-based control of fire blight in fruit orchards. Antibiotic treatments alone break down when exposed to light requiring frequent re-application for efficacy.

**Table 1: Product Identity & Manufacturing Process for *Pantoea agglomerans* strain C9-1**

<b>Guideline</b>	<b>Study</b>	<b>Result</b>	<b>MRID #</b>
151-10 *885.1100	Product Identity	<i>Pantoea agglomerans</i> strain C9-1 was isolated and identified	445405-01 (Acceptable)
151-11 *885.1300	Manufacturing Process	The manufacturing process includes quality control steps to prevent microbial contamination in the technical grade active ingredient and the batches.	442120-01, 442120-03 445405-01 (Acceptable)
151-12 *885.1300	Discussion of Formation of Unintentional Ingredients	Proper aseptic techniques are practiced throughout the manufacturing process. Cultures and the end-use product are examined and monitored for contamination. The registrant has defined sampling of the batches to quantify the antibiotic resistance expected from the active ingredient.	442120-05 (Acceptable)
151-13 *885.1400	Analysis of Samples	Analyses were performed on the end-use product	442120-05 (Upgradable)
151-15 *885.1500	Certification of limits	Certified limits are within OPPTS guidelines.	442120-03 Confidential Statement of Formula

\*OPPTS Harmonized Guidelines

## 2. Physical and Chemical Properties Assessment

**Table 2: Physical & Chemical Properties of *Pantoea agglomerans* strain C9-1 ( MRID 442120-03)**

Characteristic	Property
Color	Colorless
Physical State	Powder
Odor	Odorless
Density	0.4 g/cc
pH	6.7 (5% slurry)
Stability	Stable @ $\leq 70$ ° F; long-term storage @ -4 to 40 °F
Flammability	N/A
Storage Stability	Non-reactive
Viscosity	N/A
Miscibility	N/A
Corrosion Characteristics	Non-corrosive

### B. Human Health Assessment

#### 1. Food Clearances/Tolerances

An exemption from the requirement of a tolerance exists.

#### 2. Toxicology Assessment

##### a. Sensitivity of Detection of *Pantoea agglomerans* Strain C9-1 for Toxicity/Pathogenicity Testing in Rats (442120-01)

Trypticase soy agar (TSA) proved to be a suitable medium for enumeration of *Pantoea agglomerans* strain C9-1 from tissues and organs normally considered as clean, such as lungs. For tissues associated with the alimentary canal which is normally colonized by a significant microflora (e.g., caecum, intestine, and stomach), malt extract sucrose agar (mESA) proved to be a suitable medium for recovery of test bacterium. Blending of tissue samples had little effect on the test microbe regardless of presence of tissues.

CLASSIFICATION: ACCEPTABLE

**b. Tier I Acute Mammalian Toxicity Testing**

**Acute Oral Toxicity Study of *Pantoea agglomerans* Strain C9-1 in Rats (Limit Test) (442120-02)**

Sprague-Dawley Rats were dosed at 5g/kg with the test substance *Pantoea agglomerans* strain C9-1 and observed for 14 days. All animals gained weight during the study and no clinical manifestations of treatment were noted. Gross necropsy revealed no indications of treatment-related pathology or any unusual findings. It is concluded that *Pantoea agglomerans* strain C9-1 is not acutely toxic to rats following oral administration.

CLASSIFICATION: ACCEPTABLE B TOXICITY CATEGORY IV

**c. Toxicity/Pathogenicity Testing of *Pantoea agglomerans* Strain C9-1 (442120-03)**

Sprague-Dawley CD rats were challenged orally with *Pantoea agglomerans* strain C9-1 and heat-killed cells (heat-killed test substance) (KTS) as an additional control group. Nine female and nine male rats were also placed in a naïve control (NC) group (no dosing) and six rats of each sex were placed into a shelf-control (SC) group (placed adjacent to treated animals, but not dosed). Organs were sampled on days 0, 3 and 7. Since no bacteria were recovered from the samples, the study was terminated on day 10. No deaths of animals occurred during the course of this study and no significant clinical findings were noted.

CLASSIFICATION: ACCEPTABLE. TOXICITY CATEGORY IV

**d. Acute Dermal Irritation in Rabbits (442120-04)**

Approximately 2 g of test material were applied to the dorsal epidermis of 10 New Zealand White Rabbits and maintained there for 24 hours. All rabbits exhibited very slight to well-defined edema and three rabbits exhibited very slight edema. By day 10 all rabbits had cleared of any dermal irritation.

CLASSIFICATION: ACCEPTABLE: TOXICITY CATEGORY III

**e. Acute Intratracheal Testing in Rats (442120-05)**

No adverse clinical signs were recorded for any of the animals in this study. A definite pattern of clearance of test material recovered from Sprague-Dawley CD rat internal organs was established.

CLASSIFICATION ACCEPTABLE: TOXICITY CATEGORY IV

**f. Acute Intravenous Challenge in Rats (442120-06)**

No evidence of adverse clinical outcome or mortality for any of the study animals was recorded. Necropsy findings were normal for all animals. A definite pattern of clearance of test material recovered from Sprague-Dawley CD rat internal organs was established.

CLASSIFICATION: ACCEPTABLE

**g. Primary Eye Irritation Study (442120-07)**

Six New Zealand White Rabbits were administered 0.1 g of test substance into the right eyelid which was washed out after 24 hours. No mortality, corneal lesions or iridal effects were noted at any time during the study. *Pantoea agglomerans* strain C9-1 is considered to be a mild eye irritant.

CLASSIFICATION: ACCEPTABLE: TOXICITY CATEGORY III

**h. Hypersensitivity Study (Waived)**

The registrant has reported that there have been no hypersensitivity incidents during production and testing of *Pantoea agglomerans* strain C9-1. Additionally, the pathogenicity/toxicity studies discussed above have shown little toxicity or potential adverse effects of *Pantoea agglomerans* C9-1. The registrant is required to report any adverse incidents to the Agency under FIFRA Section 6(a)(2).

**i. Immune Response (Waived)**

All the infectivity tests demonstrated that the *Pantoea agglomerans* strain C9-1 was administered at a high dose, was recognized and cleared from the test animal. In addition, an acute oral toxicity study revealed no immunological response to *Pantoea agglomerans* strain C9-1. Treated animals displayed no significant clinical signs and gross necropsy revealed no unusual findings.

**j. Subchronic Toxicity, Chronic Toxicity and Oncogenicity**

Based on the data generated in accordance with the Tier I data requirements for acute oral toxicity, acute dermal irritation, intratracheal instillation, intravenous injection, and primary eye irritation; immune response, teratogenicity, virulence enhancement, and mammalian mutagenicity studies were not required. As a result, Tier III testing for chronic testing, oncogenicity testing, mutagenicity, and teratogenicity also were not required for *Pantoea agglomerans* strain C9-1.

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

The Agency is not requiring information on the endocrine effects of this active ingredient at this time. The Agency has considered, among other relevant factors, available information concerning whether the microorganism may have an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects. There is no known metabolite produced by this bacterium that acts as an endocrine disruptor. The submitted and cited toxicity/pathogenicity studies in rodents indicate that following injection and pulmonary routes of exposure, the immune system is still intact and able to process and clear the active ingredient. The Agency concludes that there will be no incremental adverse effects to the endocrine or immune systems.

**3. Occupational and Residential Exposure and Risk Characterization**

**a. Non-occupational Residential, School and Day Care Exposure and Risk Characterization**

The proposed product is an end-use product to be commercially used in apple and pear orchards. No mortality was observed at the dosing rate of  $2.1 \times 10^7$  cfu *Pantoea agglomerans* strain C9-1 per animal. No non-occupational residential, school or day care exposure is anticipated because of the use pattern of this product. The use of *Pantoea agglomerans* strain C9-1 should result in minimal to non-existent non-occupational risk. No indoor residential, school or daycare uses are permitted on the label of this product.

**b. Occupational Exposure and Risk**

The potential for exposure to the pesticide, *Pantoea agglomerans* strain C9-1, exists for the applicators and fruit harvesters. Because of the lack of mammalian toxicity, worker exposure data on *Pantoea agglomerans* strain C9-1 are not required. The A Caution@ Statement, hazard and first aid statements and worker protection equipment and re-entry intervals on the label are sufficient to protect from any reactions that may occur from exposure to *Pantoea agglomerans* strain C9-1.

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

No drinking water exposure is anticipated because of the use pattern and use sites. There are no aquatic use sites permitted for this pesticide, so exposure to drinking water is not expected. Further, there is no evidence of adverse effects from exposure to this organism. Exposure from the proposed use of *Pantoea agglomerans* strain C9-1 is not likely to pose any incremental risk via consumption of drinking water to adult humans, infants and children.

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

The potential aggregate exposure, derived from 1) dietary, oral exposure from treated food/feed commodities and from drinking water, potentially exposed secondary to treatment of orchards with this pesticide, and 2) dermal and inhalation non-occupational exposure of populations to *Pantoea agglomerans* strain C9-1, is not expected or should be adequately mitigated, as long as the pesticide is used in accordance with the labeling.

#### **6. Cumulative Effects**

The Agency has considered the potential for cumulative effects of *Pantoea agglomerans* strain C9-1 and other substances in relation to a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. As demonstrated in the toxicity assessment, *Pantoea agglomerans* strain C9-1 is non-toxic and non-pathogenic to mammals. Because no mechanism of pathogenicity or toxicity in mammals has been identified for this organism, no cumulative effects from the residues of this product with other related microbial pesticides are anticipated.

### **C. Environmental Assessment**

#### **1. Environmental Fate, Ecological Exposure, and Environmental Expression Risk Characterization**

No studies were submitted to address the environmental fate and behaviour of *Pantoea agglomerans* strain C9-1. Environmental fate data (Tier II/III) are not required, due to the absence of significant toxicological effects in non-target organisms in Tier I testing. Environmental fate testing is intended to demonstrate whether a Microbial Pesticide Control Agent (MPCA) is capable of surviving or replicating in the environment to which it is applied, and could provide an indication of which non-target organisms may be exposed to the MPCA as well as provide an indication of the extent of exposure. Some information on the environmental fate of *Pantoea agglomerans* strain C9-1 is available in the published literature.

Johnson et al. (2000) investigated the spread of *Pantoea agglomerans* strain C9-1, from inoculated to non-inoculated pear and apple trees, by applying the MPCA to the three central rows of trees in an orchard block, and sampling blossoms from inoculated and non-inoculated trees for the presence and population density of the MPCA. Immediately post-inoculation, the MPCA was detected on blossoms from inoculated trees, but not on non-inoculated trees. As bloom progressed, the size of the population on inoculated trees increased, and non-inoculated trees up to 18 meters from the nearest inoculated tree had high proportions of blossoms colonized by *Pantoea agglomerans* strain C9-1. The colonization of inoculated blossoms with the MPCA as well as the dissipation of the organism to non-inoculated blossoms was favoured by periods of warm, dry weather, and limited by periods of cooler, wet weather. The authors hypothesized that warm weather favoured colonization and dissipation because of a higher bacterial growth rate on inoculated trees and on non-inoculated trees following dissipation from the treated row. Warm, dry weather also favoured increased insect activity, and this appeared to favour dissipation, as bees were important vectors for transfer of the MPCA between blossoms of the inoculated and non-inoculated trees.

The ubiquity and diversity of habitats employed by *Pantoea agglomerans* suggests that it will survive under field conditions. The organism is best understood as an epiphyte of plants. It occurs in many parts of the plant, for example in the phyllosphere of *Rosa rugosa* (Hashidoki et al. 2002), salad vegetables (Brocklehurst et al. 1987, Hamilton-Miller and Shah, 2001), and herbs (Golec et al. 2004), on the stem of sweet potato (Asis and Adachi 2003), on buckwheat seeds (Imura and Hosono 1996) and in the rhizosphere of oilseed rape (Berg et al. 2002). It has also been isolated from aquatic environments (as *Enterobacter agglomerans*; Brown and Leff (1996), and from recirculated water in industrial settings. As a facultative anaerobe, it has also been isolated as an iron-reducing bacterium from the anaerobic sediments of a marine coastal basin (Francis et al., 2000). Costa et al. (2002) investigated the growth requirements of a biocontrol strain, *Pantoea agglomerans* strain CPA-2, and delimited its growth range with respect to water availability ( $a_w$  0.95–0.96), temperature (34–107° F), and pH (5–8.6).

## **2. Ecological Effects Hazard Assessment**

### **Birds**

The acute oral toxicity of *Pantoea agglomerans* strain C9-1 to 28-day-old Northern Bobwhite quail (*Colinus virginianus*) was assessed over 14 days in accordance with U.S. EPA OPPTS guideline 850.2100. *Pantoea agglomerans* strain C9-1 was administered to a group of 10 birds (5/sex) by oral intubation at 2250 mg/kg bw in a limit test (equivalent to a nominal concentration of  $3.85 \times 10^8$  CFU/kg bw based on a certificate of analysis submitted with the study report). The test substance was not assessed for MPCA viability. Ten birds received the same volume of a negative control dose containing only dilution water.

There were no mortalities and no treatment-related clinical signs or findings. No necropsies were performed. The 14-day oral LD50 was >2250 mg/kg bw ( $>3.85 \times 10^8$  CFU/kg bw, nominal). The 14-day oral NOEL for *Pantoea agglomerans* strain C9-1 to Northern Bobwhite quail based on body weight gain and feed consumption was 2250 mg/kg bw ( $3.85 \times 10^8$  CFU/kg bw, nominal).

This toxicity study is classified as acceptable and satisfies the U.S. EPA OPPTS 850.2100 guideline requirements for an acute oral toxicity study in avian species. (MRID 466503-01)

### **Wild mammals**

No additional testing is required to further assess the risks of *Pantoea agglomerans* strain C9-1 to wild mammals, as no significant adverse effects were noted in the published literature or in any of the acute oral, dermal toxicity, and dermal and eye irritation studies. *Pantoea agglomerans* strain C9-1 was not infective. (WAIVED)

### **Effects on bees and other arthropod species**

In a 7-day dietary toxicity study, honey bees (*Apis mellifera*) were exposed to *Pantoea agglomerans* strain C9-1 at nominal concentrations of  $1.35 \times 10^8$  CFU/ml, and  $5.42 \times 10^8$  CFU/ml, in accordance with U.S. EPA OPPTS guideline 885.4380. A negative control group (sugar water diet alone) and an attenuated (heat-killed) control group were maintained concurrently. Diets were provided *ad libitum* throughout the test period. The viability of the MPCA in the diets was not measured; therefore, the LC50 was based on nominal concentrations.

The test was terminated on Day 7 when mortality in the negative control group exceeded 20%. A similar pattern of mortality was observed in treatment and control groups. There was no apparent dose response. The 7-day dietary LC50 was  $>5.42 \times 10^8$  CFU/ml, the highest concentration tested, and the NOEC, based on immobility, was  $5.42 \times 10^8$  CFU/ml.

This study is classified as acceptable as it satisfies the U.S. EPA OPPTS 885.4380 guideline requirements for oral/dietary pathogenicity/toxicity testing for honey bees. (MRID 466503-04)

As part of a waiver rationale, also submitted with the arthropod test data, the applicant provided evidence that bees used as a vector for *Erwinia herbicola* strain Eh318 (Vanneste, 1996), and ladybird beetles experimentally fed *Erwinia herbicola* strain 265G-2 as an ice-nucleating bacterium (Strong-Gunderson et al., 1990) experienced no reported adverse effects. It should be noted, however, that adverse effects were not the experimental outcome of interest in either of these studies, so only effects severe enough to compromise the results of the study would likely have been reported.

Reports in the literature also identify *Pantoea agglomerans* in the normal gut microflora of insects. *Enterobacter agglomerans* was reported to be symbiotically associated with the apple maggot fly (Lauzon et al. 2003), in that the bacterium detoxifies a plant defense chemical (phloridzin), which would otherwise kill the fly. *Pantoea agglomerans* is also associated with the gut of locusts, and has recently been reported to release guaiacol and phenol, components of the locust cohesion pheromone not produced in germ-free locusts (Dillon et al., 2002).

(WAIVED)

### **Effects on earthworms and other soil macro-organisms**

No study was submitted to address the risks of *Pantoea agglomerans* strain C9-1 to earthworms or other nonarthropod invertebrates. Effects data are not required because the product is not intended to control pest nonarthropod invertebrates or soil macroorganisms, and proposed use patterns do not indicate a potential for adverse effects.

### **Effects on soil micro-organisms**

No study was submitted to address the risks of *Pantoea agglomerans* strain C9-1 to soil microorganisms. Effects data are not required although the product is intended to control pest microorganisms, as *Pantoea agglomerans* is a normal component of the soil, and the organism is not expected to affect environmentally or economically important microbial species or microbiologically-mediated biogeochemical processes.

### **Effects on vascular plants**

No study was submitted to address the risks of *Pantoea agglomerans* strain C9-1 to plants. The applicant stated that in over 15 years of laboratory and field research, *Pantoea agglomerans* strain C9-1 was not implicated in any adverse effect on plants. *Pantoea agglomerans* strain C9-1 does not exhibit pectinolytic activity (Feistner and Ishimaru, 1996) and is negative in a pear fruit assay (Ishimaru et al., 1988). In the scientific literature, *Erwinia herbicola* has been implicated, though rarely, in infections of several plant species, including cotton (Ashworth et al., 1970), onion (Kritzman and Zutra, 1984), garlic (Koch et al., 1996), beach pea (pathogen identified as *Pantoea agglomerans*; Khetmalas et al., 1996) and Douglas-fir (DeYoung et al., 1998). In the Douglas-fir study, *Erwinia herbicola*, isolated from a slow-growing, smooth-surfaced circular gall on Douglas-fir, induced gall formation on stab inoculation of several conifer species (*Abies amabilis*, *A. grandis*, *A. lasiocarpa*, *Chamaecyparis nootkatensis*, *Larix occidentalis*, *Picea engelmannii*, *P. glauca*, *P. stichenensis*, *Pinus contorta*, *P. monticola*, *P. ponderosa*, *Thuja plicata*, *Tsuga heterophylla*), all economically-important softwood lumber species. Douglas-fir remained the most susceptible host. The presence of these galls affected

the health and structural integrity of the host tree. Death of the inoculated branch or branch tips occurred 2–4 months after gall formation. Galls on the main stem of young Douglas-fir seedlings (<6 months old) often killed the seedlings. Trees greater than one year old did not appear to be significantly affected. (WAIVED)

### **Summary of effects on terrestrial organisms**

*Pantoea agglomerans* strain C9-1 was found not to be toxic or infective in birds exposed by the oral route, or in bees exposed to *Pantoea agglomerans* strain C9-1 in the diet. Neither were adverse effects noted in bees used experimentally as vectors for the *Erwinia herbicola* as a biocontrol agent or in ladybird beetles exposed to *Erwinia herbicola* in the diet. Adverse effects in mammals were assessed in studies described Human Health Assessment. With the exception of transient inflammatory responses to large quantities of aerosolized bacterial endotoxin, adverse effects are not anticipated in terrestrial animals. In the published literature, *Pantoea agglomerans* (often as *Erwinia herbicola*) has been associated with necrotic infections in plants, but incidents of disease attributable to *Pantoea agglomerans* appear to be rare. Because of the economic importance of softwood lumber, a study showing gall formation due to *Erwinia herbicola* in Douglas-fir and other Western conifer species is of some concern. Precautionary labeling should be sufficient to mitigate the risk to newly planted seedlings, which might be susceptible to galls induced by the MPCA.

**Table 1. Summary of effects on terrestrial organisms**

ORGANISM	EXPOSURE	TEST SUBSTANCE	END POINT VALUE	SIGNIFICANT EFFECTS, COMMENTS
<b>Vertebrates</b>				
Birds	Oral	<i>Pantoea agglomerans</i> strain C9-1	$>3.85 \times 10^8$ CFU/kg bw	Northern bobwhite quail, 5/sex. No mortalities, treatment-related clinical signs. Necropsy not performed.
	Pulmonary	No study or waiver submitted. Based on mammal studies reviewed under Human Health and Safety, pulmonary inflammation, but not infectivity, can be expected in birds inhaling <i>Pantoea agglomerans</i> strain C9-1 spray		
	Injection	No study or waiver submitted. Based on mammal studies, reviewed under Human Health and Safety, <i>Pantoea agglomerans</i> strain C9-1 is not expected to infect birds.		
Wild mammals	No study submitted. Testing in laboratory mammals indicates that acute inflammatory effects, which are transient (based on a single exposure) are expected, most probably due to the endotoxic properties of <i>Pantoea agglomerans</i> strain C9-1 lipopolysaccharide.			

<b>Invertebrates</b>				
Bees	Oral (Dietary)	<i>Pantoea agglomerans</i> strain C9-1	$>5.42 \times 10^8$ CFU/ml in diet	The test was terminated on Day 7 when mortality in controls exceeded 20%.
	Contact	No study submitted. A waiver request cited the experimental use of bees as vectors for the <i>Erwinia herbicola</i> strain Eh 318, without reported adverse effects as evidence of the safety of <i>Pantoea agglomerans</i> strain C9-1 to bees.		
	Brood or hive			
Other arthropods	Dietary	No study submitted. In a waiver request, a study showing <i>Erwinia herbicola</i> strain 265G-2 administered without adverse effect in the diet of ladybird beetle, and in the published literature, studies identifying <i>Enterobacter agglomerans/Pantoea agglomerans</i> as a gut-associated symbiont of apple maggot fly and locust suggest that <i>Pantoea agglomerans</i> strain C9-1 is not pathogenic to terrestrial arthropods.		
Earthworms	Acute	No study or waiver submitted. Data is not required for <i>Pantoea agglomerans</i> strain C9-1.		
Soil microbes	Acute	No study or waiver submitted. Data is not required for <i>Pantoea agglomerans</i> strain C9-1.		

<b>Vascular plants</b>		
Vascular plants		A waiver was submitted based on the absence of observed adverse effects in 15 years of laboratory and field research on <i>Pantoea agglomerans</i> strain C9-1. A review of the literature indicated that cases of <i>Erwinia herbicola</i> / <i>Pantoea agglomerans</i> infection occurred in plants, albeit rarely. Gall formation due to <i>Erwinia herbicola</i> infection of conifers, especially Douglas-fir, may be of concern where newly planted forestry blocks abut treated apple or pear orchards.

## Effects on aquatic species

### Freshwater Fish

In a 30-day acute toxicity study, rainbow trout (*Oncorhynchus mykiss*) were exposed to *Pantoea agglomerans* strain C9-1 in the diet and by aqueous exposure under semi-static conditions. The study followed U.S. EPA OPPTS guideline 885.4200. The mean measured test concentrations for aqueous exposure were  $5.1 \times 10^6$ ,  $1.0 \times 10^7$ ,  $3.0 \times 10^7$ ,  $4.3 \times 10^7$  and  $9.2 \times 10^7$  CFU/ml. The highest mean measured concentration fell slightly below the maximum hazard concentration of  $10^{11}$  CFU/ml. Exposure by the dietary route was achieved by feeding a treated diet containing *Pantoea agglomerans* strain C9-1 at nominal concentrations of  $4.6 \times 10^5$ ,  $9.1 \times 10^5$ ,  $1.8 \times 10^6$ ,  $3.7 \times 10^6$  and  $7.3 \times 10^6$  CFU/g. The diets were not measured for MPCA viability. A negative control group, in which saline was added to the test water and the diet consisted of unsupplemented feed, and a heat-killed test substance control group, in which heat-killed *Pantoea agglomerans* strain C9-1 was added to the test water and to the diet at concentrations equivalent to the highest test concentrations, were also included in the study.

With the exception of fish in the highest-concentration treatment group, fish from all treatment groups appeared normal throughout the test period, with no mortalities or clinical signs of toxicity. There were no mortalities in fish exposed to the highest test concentrations (aquatic:  $9.2 \times 10^7$  CFU/ml; dietary:  $7.3 \times 10^6$  CFU/g), but several fish were described as “small” in relation to the negative control fish at the study termination. Gross necropsies performed on three representative fish from each treatment group and control showed no evidence of pathogenic or toxic lesions. Infectivity (clearance of the MPCA) was not assessed.

The 30-day LC50 was  $>9.2 \times 10^7$  CFU/ml (mean measured aquatic)/ $7.3 \times 10^6$  CFU/g (nominal dietary, the highest concentrations tested). The 30-day NOEC value, based on reduction in growth rate was  $4.3 \times 10^7$  CFU/ml (mean measured aquatic)/ $3.7 \times 10^6$  CFU/g (nominal dietary).

This toxicity study is classified as acceptable and satisfies the U.S. EPA OPPTS 885.4200 guideline requirement for Tier I freshwater fish testing in rainbow trout. (MRID 466503-03)

### Estuarine or Marine

No study on estuarine or marine fish was submitted. Marine and estuarine fish are not expected to be exposed to the *Pantoea agglomerans* strain C9-1, based on the proposed use pattern, so test data are not required for *Pantoea agglomerans* strain C9-1.

## Effects on Invertebrates

### Arthropods

The effect of *Pantoea agglomerans* strain C9-1 on daphnid (*Daphnia magna*) mortality, reproduction and growth was assessed over 21 days following guidelines outlined in U.S. EPA OPPTS guideline 885.4240.

Twenty neonate daphnids were exposed to a geometric series of five test concentrations of *Pantoea agglomerans* strain C9-1 under semi-static conditions. The mean measured test concentrations were  $4.8 \times 10^5$ ,  $9.8 \times 10^5$ ,  $1.8 \times 10^6$ ,  $4.6 \times 10^6$  and  $1.1 \times 10^7$  CFU/ml. The highest nominal concentration and the highest mean measured concentration were less than the maximum hazard concentration of  $10^{11}$  CFU/ml, calculated as  $1000 \times$  the expected environmental concentration (EEC) following application at the maximum label rate to a 15 cm depth of water.

An attenuated (heat-killed) control, and a negative (dilution water) control were tested concurrently. First-generation daphnids were observed daily for mortality, clinical signs of toxicity, and the onset of reproduction. At the end of the exposure period the body lengths and dry weights of the surviving daphnids were measured to determine the effect on growth. Following the onset of reproduction, the number of second-generation daphnids was counted to determine the effect of the test substance on reproduction.

At the end of the exposure period, survival in the negative control group and in the heat-killed control group was 95% and 90%, respectively, while survival in the  $4.8 \times 10^5$ ,  $9.8 \times 10^5$ ,  $1.8 \times 10^6$ ,  $4.6 \times 10^6$  and  $1.1 \times 10^7$  treatment groups were 85%, 95%, 95%, 100% and 75%, respectively. These results showed no significant difference in survival between the test and control groups. There was no apparent delay in the onset of brood production for the first-generation treated or heat-killed control daphnids as compared with negative controls. A statistically significant ( $p < 0.05$ ) decrease in fecundity, and in mean length of daphnids was reported for the heat-killed control group and for the  $4.6 \times 10^6$ , and the  $1.1 \times 10^7$  CFU/ml treatment groups, compared with negative controls.

Based on these results, the 21-day LC50 for aquatic exposure was  $>1.1 \times 10^7$  CFU/ml. Based on fecundity and growth, the NOEC was  $1.8 \times 10^6$  CFU/ml, and the LOEC was  $4.6 \times 10^6$ . This study is classified as acceptable as a measure of toxicity for freshwater aquatic invertebrates. (MRID 466503-02)

### Effects on other aquatic macro-organisms

No other aquatic macroorganisms were tested for adverse effects on exposure to *Pantoea agglomerans* strain C9-1. Given the proposed terrestrial use pattern for BlightBan, and the known sensitivity of daphnids, the study summarized above is considered to be sufficient to

assess adverse effects in aquatic organisms.

## **Plants**

No study testing for adverse effects on the exposure of aquatic plants to *Pantoea agglomerans* strain C9-1 was submitted. Given that effects in terrestrial plants are rare, and the proposed terrestrial use pattern of BlightBan, no nontarget aquatic plant data are required.

## **Summary of effects on aquatic organisms**

Two studies were submitted to address the adverse effects of *Pantoea agglomerans* strain C9-1 in aquatic organisms. The MPCA affected the size of rainbow trout at the highest tested dose in a combined aquatic and dietary exposure study. Fecundity and growth rate were affected in daphnids at the two highest aquatic concentrations tested. The tested concentrations did not meet the maximum challenge concentration of 1000 times the EEC on direct application of the product to a 15 cm depth of water, or  $10^{11}$  CFU/L. This is nevertheless acceptable, because effects were seen at the tested concentrations. The LOEC based on fecundity and growth in *Daphnia magna*, and the NOEC based on growth in rainbow trout were less than or equal to the EEC on direct application to a 15 cm depth of water. Although the product is not intended for direct application to water, spray drift and surface water runoff may result in contamination of aquatic ecosystems. Several strains of *Enterobacter agglomerans* have been isolated from aquatic habitats (Brown and Leff 1996), suggesting that *Pantoea agglomerans* strain C9-1 could survive in aquatic ecosystems. To ensure that harmful concentrations of the MPCA do not accumulate, precautionary labeling should be required on the product label to reduce drift and runoff.

**Table 2. Summary of effects on aquatic organisms**

ORGANISM	EXPOSURE	TEST SUBSTANCE	END POINT VALUE	SIGNIFICANT EFFECTS, COMMENTS
<b>Vertebrates</b>				
Freshwater fish	Acute	<i>Pantoea agglomerans</i> strain C9-1	30-day LC50: $>9.2 \times 10^7$ CFU/ml (aquatic); $>7.3 \times 10^6$ CFU/g (dietary)  30-day NOEC based on growth: $4.3 \times 10^7$ CFU/ml (aquatic); $3.7 \times 10^6$ CFU/g (dietary).	Rainbow trout ( <i>Oncorhynchus mykiss</i> ) in the highest-concentration treatment group were described as “small” in relation to negative control fish. No other effects were noted.
Estuarine/ marine fish	Acute	No study submitted		

<b>Invertebrates</b>				
Freshwater Arthropods	Acute	<i>Pantoea agglomerans</i> strain C9-1	21-day LC50: $>1.1 \times 10^7$ CFU/ml  21-day NOEC for fecundity and growth: $1.8 \times 10^6$ CFU/ml  21-day LOEC: $4.6 \times 10^6$ CFU/ml	A statistically significant (p. 0.05) decrease in fecundity and in mean length was observed in the daphnid, <i>Daphnia magna</i> , in heat-killed test substance control and in groups dosed with $4.6 \times 10^6$ CFU/ml and $1.1 \times 10^7$ CFU/ml.
Estuarine/ Marine arthropods	Acute	No study or waiver request submitted. Estuarine and marine arthropods are not expected to be exposed to the MPCA.		
Non-arthropod invertebrates	Acute	No study or waiver request submitted. The daphnid study summarized above is considered to be sufficient to assess adverse effects in aquatic organisms.		
<b>Plants</b>				
Algae	Acute	No study or waiver request submitted. Data requirements were waived based on the terrestrial use pattern and lack of significant effects in terrestrial plants.		
Vascular plants				

### **Integrated environmental risk summary**

*Pantoea agglomerans* strain C9-1 was found not to be toxic or infective in birds exposed by the oral route, or in bees exposed to *Pantoea agglomerans* strain C9-1 in the diet. Neither were notable adverse effects noted in bees used experimentally as vectors for the *Erwinia herbicola* strain Eh318 as a biocontrol agent or in ladybird beetles exposed to *Erwinia herbicola* 265G-2 in the diet. With the exception of transient inflammatory responses to large quantities of aerosolized bacterial endotoxin, adverse effects are not anticipated in terrestrial animals. In the published literature, *Pantoea agglomerans* (often as *Erwinia herbicola*) has been associated with necrotic infections in plants, but incidents of disease attributable to *Pantoea agglomerans* appear to be rare. Because of the economic importance of softwood lumber, a study showing gall

formation due to *Erwinia herbicola* in Douglas-fir and other Western conifer species is of some concern. Precautionary labeling warning applicators not to spray BlightBan near newly-planted forestry blocks should be sufficient to prevent the inoculation and possible galling of young seedlings through wounds inflicted during planting.

Two studies were submitted to address the adverse effects of *Pantoea agglomerans* strain C9-1 in aquatic organisms. The MPCA affected the size of rainbow trout at the highest tested dose in a combined aquatic and dietary exposure study ( $4.3 \times 10^7$  CFU/ml aquatic;  $3.7 \times 10^6$  CFU/ml dietary). Fecundity and growth rate were affected in *Daphnia magna* at the two highest aquatic concentrations tested ( $1.8 \times 10^6$  CFU/ml and  $4.6 \times 10^6$  CFU/ml). The LOEC for fecundity and growth in *Daphnia magna*, and the NOEC for rainbow trout were less than or equal to the EEC on direct application to a 15 cm depth of water ( $10^8$  CFU/L). Although the product is not intended for direct application to water, spray drift and surface water runoff from treated orchards may result in contamination of aquatic ecosystems. Several strains of *Enterobacter agglomerans* have been isolated from aquatic habitats (Brown and Leff, 1996), suggesting that *Pantoea agglomerans* strain C9-1 could survive in aquatic ecosystems. To ensure that potentially harmful concentrations of the MPCA do not accumulate, precautionary labeling should be required on the product label to reduce drift and runoff.

#### **D. Efficacy Data**

Efficacy data were not reviewed by the Agency because this product is intended for control of fire blight in apples and pears, and it will not be formulated into products for control of public health pests.

#### **E. Endangered Species Assessment**

An environmental risk assessment was performed on non-target birds, wild mammals, plants, freshwater fish, aquatic invertebrates, estuarine and marine animals, honeybees and non-target insects using information as submitted by the registrant. The information and data regarding product identity and characterization support a risk characterization and a conclusion of a reasonable certainty that there are no incremental hazards to non-target organisms, including endangered and threatened species, as a result of the intended uses of *Pantoea agglomerans* strain C9-1.

This opinion is based on a general rationale based on the biology and ecology of the MPCA from the open literature, data from host range studies, and the lack of exposures to non-target organisms. Requests to waive wild mammal toxicity/pathogenicity studies were reviewed and determined acceptable based on associative rationale substantiating a reasonable certainty that wild mammals will not be exposed to intended applications of the MPCA. In addition, direct

testing of rodent species for human health assessment purposes did not reveal any hazards. A determination of reasonable certainty was made that no exposure will take place to avian species, freshwater fish, aquatic invertebrates, or estuarine and marine animals and plants from the intended application method and the fate of the MPCA in the environment.

#### **IV. RISK MANAGEMENT AND REGISTRATION DECISION**

##### **A. Determination of Eligibility**

Section 3(c)(5) of FIFRA provides for the registration of a new active ingredient 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, *Pantoea agglomerans* strain C9-1 has well known physical and chemical properties. The Agency has no knowledge that would contradict the claims made on the label of this product and the active ingredient is not expected to cause unreasonable adverse effects when used according to label instructions. Criterion B is satisfied by the current label and by the data submitted by the registrant, reviewed and presented in this document. It is believed that this new microbial pesticide active ingredient will not cause any unreasonable adverse effects, and is likely to provide protection to apples and pears as claimed, satisfying Criterion C. Criterion D is satisfied in that *Pantoea agglomerans* strain C9-1 is not expected to cause unreasonable adverse effects when used according to label instructions.

##### **B. Regulatory Position**

###### **Unconditional Registration**

The data requirements are fulfilled and BPPD recommends the unconditional registration of the product (BlightBan) that contains *Pantoea agglomerans* strain C9-1 as a new active ingredient.

#### **V. ACTIONS REQUIRED BY REGISTRANT**

This is an unconditional registration under FIFRA 3(c)(5). Reports of incidents of adverse effects to humans or domestic animals are required 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, label changes, and other responses necessary for the reregistration of the end-use product because the product is being registered after November 1984 and is,

therefore, not subject to reregistration. For the same reason, there are also no existing stocks provisions at this time. Before releasing these products for shipment, the registrant is required to provide appropriate labels and other Agency requirements as discussed in this Biopesticide Registration Action Document. The registrant must provide the Agency an upgraded analysis of samples.

## VI. APPENDICES

### APPENDIX A - Use sites

**Table 5** lists the use sites for the product. The registrant must comply with the appropriate labeling requirements before releasing products containing *Pantoea agglomerans* strain C9-1 as the active ingredient for shipment.

**Table 5: Use Site Unconditional Registration**

<b>BlightBan®</b>  <u>Use Sites</u> The end-use product is intended for spraying apple and pear orchards only to control the disease fire blight.	<b>Official date registered:</b>
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