



Reregistration Eligibility Decision (RED)

Agrobacterium radiobacter



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the biopesticide case *Agrobacterium radiobacter*. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base for this biopesticide, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED". This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **An Application for Reregistration is required to be submitted eight months from the date of this letter. Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.**

If you have questions about our decision or the requirements set forth in this document, please contact the reregistration representative for Biopesticides and Pollution Prevention Division, Richard King at (703) 308-8052.

Sincerely yours,

Janet L. Andersen, Acting Director
Biopesticides and Pollution
Prevention Division (7501W)

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-d below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

d. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA Form 8570-31 for each product.

4. COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. WHERE TO SEND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)

By U.S. Mail:

Document Processing Desk (**RED-BPPD**)
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk (**RED-BPPD**)
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

Agrobacterium radiobacter

LIST D

CASE 4101

TABLE OF CONTENTS

Agrobacterium radiobacter REREGISTRATION ELIGIBILITY DECISION TEAM . . .	i
EXECUTIVE SUMMARY	v
I. INTRODUCTION	1
II. CASE OVERVIEW	2
A. Chemical Overview	2
B. Use Profile	2
C. Estimated Usage of Pesticide	4
D. Data Requirements	4
E. Regulatory History	5
III. SCIENCE ASSESSMENT	5
A. Product Chemistry Assessment	5
B. Human Health Assessment	6
1. Acute Toxicity	6
2. Exposure and Risk Assessments	7
a. Dietary Exposure and Risk Assessment	7
b. Occupational Exposure and Risk Assessment	8
C. Environmental Assessment	8
IV. RISK MANAGEMENT AND REREGISTRATION DECISION	9
A. Determination of Eligibility	9
B. Determination of Eligibility	10
1. Eligibility Decision	10
2. Eligible and Ineligible Uses	10
C. Regulatory Position	10
1. Tolerance Reassessment	10
2. Endangered Species Statement	10
3. Labeling Rationale	10
V. ACTIONS REQUIRED BY REGISTRANTS	12
A. Manufacturing-Use Products	12
1. Additional Generic Data Requirements	12
2. Labeling Requirements for Manufacturing-Use Products	12
B. End-Use Products	13
1. Additional Product-Specific Data Requirements	13
2. Labeling Requirements for End-Use Products	13
C. Existing Stocks	14

VI. APPENDICES	15
APPENDIX A. Table of Use Patterns Subject to Reregistration	17
APPENDIX B. Table of the Generic Data Requirements and Studies Used to Make the Reregistration Decision	35
APPENDIX C. Citations Considered to be Part of the Data Base Supporting the Reregistration of 4101	41
APPENDIX D. List of Available Related Documents	47
APPENDIX E. FACT SHEET	51

Agrobacterium radiobacter **REREGISTRATION ELIGIBILITY DECISION TEAM**

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GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Acid Equivalent
a.i.	Active Ingredient
ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA) The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC ₅₀	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/L, mg/kg or ppm.
LD ₅₀	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD ₁₀	Lethal Dose-low. Lowest Dose at which lethality occurs
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MOE	Margin of Exposure
NOEC	No effect concentration
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OP	Organophosphate

GLOSSARY OF TERMS AND ABBREVIATIONS

OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PPE	Personal Protective Equipment
ppb	Parts Per Billion
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q ₁ *	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TMRC	Theoretical Maximum Residue Contribution
TLC	Thin Layer Chromatography
WP	Wettable Powder
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The Environmental Protection Agency has completed an assessment of the potential human health and environmental risks associated with the pesticidal use of *Agrobacterium radiobacter* in the United States.

Agrobacterium radiobacter is registered as a fungicide (microbial control agent) for the prevention of Crown Gall in certain non-bearing fruit, nut and ornamental nursery stock. This fungicide is target specific in mitigating the causative agent of Crown Gall, a bacterium *Agrobacterium tumefaciens*.

The Agency has determined that the uses of *A. radiobacter* as currently registered will not cause unreasonable risk to humans or the environment and that these uses are eligible for reregistration. The Agency is not requiring additional studies.

Before reregistering the products containing *A. radiobacter*, the Agency is requiring that product specific data; a revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain *A. radiobacter* in combination with other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of *A. radiobacter*. The document consists of six sections. Section I is the introduction. Section II describes *A. radiobacter*, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for *A. radiobacter*. Section V discusses the reregistration requirements for *A. radiobacter*. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Decision:

- **Common Name:** *Agrobacterium radiobacter*
- **Chemical Name:** *Agrobacterium radiobacter* (Strain Kerr-84)
- **Chemical Family:** Not applicable
- **CAS Registry Number:** Not applicable
- **OPP Chemical Code:** 114201
- **Empirical Formula:** Not applicable
- **Trade and Other Names:** Galltrol-A[®], Norbac 84-C[®]
- **Basic Manufacturer:**

AgBioChem, Inc.
New Bioproducts, Inc.

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of the use of *A. radiobacter* is in Appendix A.

Type of Pesticide: Fungicide (microbial control agent).

Use Sites: Terrestrial and Greenhouse Non-food Crops

Non-bearing Fruit and Nut Nursery Stock:

Almonds	Apples	Apricots
Blueberries	Caneberries *	Cranberries
Cherries	Kiwis	Nectarines
Peaches	Pears	Pecans
Plums	Prunes	Walnuts

* Caneberries include Blackberry, Boysenberry, Raspberry, and Youngberry

Ornamental Nursery Stock:

Euonymus	Rose	Weeping Cherry
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Target Pests: Aids in the control of Crown Gall disease (*A. tumefaciens*).

Formulation Types Registered: 2.25% Flowable concentrate
1.2% Solidified Agar

Method and Rates of Application:

Equipment - Hand-operated spray, drench and dip treatment equipment.

Method and Rate -

Dipping

Germinating Seed Application - 1 unit of product** /gallon of water.

Seedling Application - 1 unit of product** /gallon of water.

Cutting Application - 1 unit of product** /gallon of water.

Root and Stem Application - 1 unit of product** /gallon of water.

Spraying

Root and Stem Application - 1 unit of product** /gallon of water.

Soil Drench Application - 1 unit of product** / 5 gallons of water;
6-8 oz of suspension per 1 gallon container or 1 foot of plant row.

**1 unit of product equals 3×10^{12} and 1.2×10^{11} colony forming units per volume of product for the flowable concentrate and solidified agar formulations, respectively.

Timing - Preplant -- cutting, root and stem treatments; Immediately Prior to Planting -- germinating seed and seedling treatments; Postplant -- soil drench treatment.

Use Practice Limitations: Label limits use only to applications on certain non-food and non-bearing plants.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of *A. radiobacter*. The Agency estimates that less than 1000 lbs. a.i. are used annually. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources. The table below summarizes the pesticides use by site.

Annual Usage and Percent of Crop Treated in California^{a/} in 1990 with *A. radiobacter*

NAME OF SITE	ACRES GROWN/HARVESTED ^{b/} (1000)	PERCENT OF ACRES TREATED ^{c/}
Fruits and Nuts:		
Almond	404	< 1
Almond Seeds	NA	NA
Cherry	16	< 5
Walnuts	176	< 1
Prune	79	< 1
Nursery/Greenhouse:		
Greenhouse Cut Flowers or Greens	2	< 1
Greenhouse Grown Transplants	NA	NA
Outdoor Containers/Field Plants	27	< 1
Outdoor Grown Transplants	NA	NA

a/ National Usage data is not available.

b/ Three years average 1992 to 1994 (with some census data) are reported. For perennial crops, harvested acres are reported; for other crops, acres grown are reported. Sources: US Dept. of Commerce. 1992 Census of Agriculture, CA, Volume 1, Part 5, September 1994; US Dept. of Commerce. 1992 Census of Agriculture, Volume 1, Part 51, October 1994; USDA, Noncitrus Fruits and Nuts, 1994 Summary, January 1995.

c/ The relevant measure for percent of crop treated would be acres planted. Because annual estimates for planted acres are not available, percent of crop treated is based on annual harvested acres.

NA -- Not Available.

D. Data Requirements

Data requested in the Phase 3 of the Reregistration Process issued January 1989 and the DCI issued July 1993 include studies on product chemistry, ecological effects, environmental fate, and toxicology. These data were required to support the uses of products containing the active ingredient *A. radiobacter*. Appendix B includes all data requirements identified by the Agency for currently registered uses to support reregistration.

E. Regulatory History

The microbial control agent/bacterial inoculant, *A. radiobacter*, was initially registered in the United States in 1979 as Galltrol-A[®], EPA Reg. No 40230-1, for the prevention of Crown Gall infections in certain fruit, nut and ornamental nursery stock (non-bearing plants only). Later in 1979 another product containing *A. radiobacter*, Norbac 84-C[®], was registered for these uses.

During Phase 3 of the Reregistration Process, the toxicology data base for *A. radiobacter* was evaluated and determined to adequately satisfy most of the data requirements for microbial pest control agents. The acute pulmonary toxicity/pathogenicity, Guideline No. 152A-12, and acute intravenous toxicity/pathogenicity, Guideline No. 152A-13, were identified as outstanding data gaps and a Data Call-In was issued July 1993. Since the DCI, the Agency's initial position with respect to these guidelines was re-evaluated, and these data requirements were waived because it was determined that *A. radiobacter* was a soil saprophyte and was not known to be pathogenic to humans and animals.

This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the reregistration process.

III. SCIENCE ASSESSMENT

A. Product Chemistry Assessment

The Agency has determined that *A. radiobacter* meets the criteria for a select category of pesticide active ingredients (biopesticides) for which a reduced set of generic data requirements are appropriate for reregistration. Refer to §40 CFR 158.740 -- Guidelines for Microbial Control Agents -- Tier I -- for non-food/feed uses. Products in this select category of pesticides may also be exempt from certain generic data requirements for toxicology, residue chemistry, human exposure, ecological effects, and environmental fate on the active ingredient. In considering *A. radiobacter's* eligibility for reregistration, the Agency believes that it meets these criteria for the following reasons:

(1) Review of the available toxicology data and literature submitted in support of reregistration indicates that adequate information is available to characterize the risks to humans and animals; products containing *A. radiobacter* are not likely to produce unreasonable adverse effects on humans. *Agrobacterium radiobacter* is generally understood to be non-pathogenic to humans or animals. It has been registered and used since 1979 with no reports of adverse effects which would have been reported as required by section 6(a)(2) of FIFRA, if they had occurred. Although some strains of *Agrobacterium* have been identified in human clinical specimens, it appears that these were sampling contaminants or incidental non-pathogenic inhabitants of the patients. Moreover, these strains are distinguishable from the *A. radiobacter* Kerr 84 strain used in these products, which has never been identified in association with clinical specimens. Most *Agrobacterium* strains from clinical specimens have been identified as *A. radiobacter* biovar 1, which differs from the biovar 2 Kerr 84 strain used in these products by a number of

physiologically and metabolic factors such as the ability to grow at 35°C, and produce 3-ketolactose, acid from ethanol, H₂S, and oxidase (Kovacs method).

(2) The use patterns for *A. radiobacter*, applications to certain fruit, nut, and ornamental nursery stock are considered to be non-food/feed uses. Therefore, this microbial control agent does not require the establishment of tolerances or exemptions from tolerances under the provisions of FIFRA and FDCA Sections 408 and 409.

Agrobacterium radiobacter is a naturally occurring bacterium which is present in many soil types and plant rhizospheres. *Agrobacterium radiobacter* is one of the best examples of a successful microbial control agents that has been isolated from nature (first isolated from soil surrounding a peach tree in Australia in the early 1970's) and employed in agriculture. The use of *A. radiobacter* is targeted at mitigating pathogenic strains of another closely related bacteria, *A. tumefaciens*. *Agrobacterium tumefaciens* causes crown gall infections in certain fruit, nut, and ornamental nursery stock and is susceptible to Agrosin 84, the bacteriocin produced by *A. radiobacter*.

Agrobacterium radiobacter products range in color from cream for the technical grade active ingredient to light green for the end-use products. The physical state for *A. radiobacter* can be considered to be bacterial cells cultured on an agar medium. *Agrobacterium radiobacter* has a slight odor and a pH of 6.8-7.1 for both the technical grade active ingredient and the end-use products. These bacterial cultures are miscible in water and susceptible to drying at pH's greater than 9 and temperatures in excess of 35°C. The live bacteria cultures of *A. radiobacter* have a shelf-life of 120 days under refrigeration.

B. Human Health Assessment

Adequate toxicological effects data on *A. radiobacter* are available to support a Reregistration Eligibility Decision (RED).

1. Acute Toxicity

Certain acute toxicity studies for the technical grade active ingredient, *A. radiobacter*, have been submitted and adequately satisfy the requirements as set forth in §40 CFR 158.740 for non-food/feed use of microbial control agents.

GUIDELINE No.	STUDY	RESULTS	CATEGORY	MRID
152A-10	Acute Oral Toxicity/ Pathogenicity	LD ₅₀ > 5g/kg	IV	00060518
152A-11	Acute Dermal Toxicity	Slight erythema	IV	00064089

152A-12	Acute Pulmonary Toxicity/ Pathogenicity	Waived*	NA	NA
152A-13	Acute Intravenous Toxicity/ Pathogenicity	Waived*	NA	NA
152A-14	Primary Eye Irritation/ Infection	Irritation	III	00060518 00064089
152A-15	Hyper-sensitivity	None Reported**		41653304 41653305

Z* Literature submitted in support of reregistration indicated that *A. radiobacter* is not pathogenic to humans and animals.

** All incidents of hypersensitivity must be reported to the Agency.

In the Agency's initial evaluation of the primary eye irritation study (MRID 00060518 and 00064089), *A. radiobacter* was determined to be a Toxicity Category II eye irritant, based on persistent corneal effects in 1/6 rabbits over 21 days following the instillation of the test substance in the conjunctival sac of the eye. However, during a subsequent evaluation for the reregistration process it appeared that the toxicity category should be reconsidered, based on the fact that all eye irritation in 2 of the other 5 animals was resolved by 72 hours, and the remaining 3 animals by day seven. In addition, the affected animal reportedly had only slight irritation over the 21-day observation period. The actual ocular irritation in this animal was not described, but was scored 1 on a scale of 0-4. The eye irritation study was repeated with 4 more rabbits, and only 1 rabbit exhibited slight irritation of the cornea for 24 hours which was resolved within 48 hours. The Agency has reconsidered its initial position and has concluded that since there were no materials in the test substance (composed of an agar culture media dissolved in water) that would be likely to cause eye irritation, and only 1/10 animals tested exhibited very slight irritation beyond 7 days, the toxicity category is more appropriate classified as Toxicity Category III for eye irritation.

Agrobacterium radiobacter occurs naturally in the environment and does not appear to be pathogenic to humans and animals. For this reason and because of its low mammalian toxicity (oral, dermal, and ocular), the required acute pulmonary toxicity/pathogenicity and acute intravenous toxicity/pathogenicity guideline studies have been waived. Consequently, all of the toxicology data requirements for microbial control agents have been satisfied.

2. Exposure and Risk Assessments

a. Dietary Exposure and Risk Assessment

Although *A. radiobacter* is applied to certain fruit and nut crops, the Agency considers these applications to be non-food uses because they are made only to non-bearing nursery stock. Thus, neither a tolerance or an exemption from tolerance is required. Additionally, the Agency has

concluded that the dietary exposure from consuming commodities which were treated with *A. radiobacter* as nursery stock are not expected.

b. Occupational Exposure and Risk Assessment

Based on the application methods (dipping of plants by hand and spraying with a hand-held sprayer) listed on the product label, the potential for eye, dermal and inhalation exposure to handlers and post application nursery workers exists. Because of a lack of human toxicity concern, worker exposure data are not required. Moreover, it is the Agency's opinion that these occupational exposures and subsequent risks are negligible because: (1) the proposed precautionary product labeling stipulated in Section V will adequately mitigate the risks to applicators and related nursery workers; and (2) the organism has been determined not to be pathogenic to humans and animals.

C. Environmental Assessment

Agrobacterium radiobacter is a well-characterized bacterium which has been in continuous use since 1979. The Agency is unaware of any cases where it or related bacteria have been found in association with diseases of birds, fish, insects or other non-target species. *Agrobacterium radiobacter*'s mechanism of action to control the target plant pathogen, *A. tumefaciens*, the causal agent of crown gall, is well-understood. It involves direct competition with *A. tumefaciens* and is enhanced by the production of a specific bacteriocin (Agrosin 84).

No ecological toxicity data requirements were required for *A. radiobacter* because there are mitigating factors that support the conclusion that exposure to non-target terrestrial and aquatic organisms is extremely minimal. The major mitigating factor is that the registered use of *A. radiobacter* being supported for reregistration is the treatment of certain nursery stock in a contained environment (indoor use). Thus, there is little or no exposure to the environment when used according to label directions. Because there is little or no exposure, the risk to non-target terrestrial and aquatic organisms is expected to be minimal

Based on the previously mentioned rationale, the Agency has waived the following Environmental and Ecological Guidelines (Tier I) for *A. radiobacter*.

Guideline No.	Description	Conclusion
154A-16	Avian pathogenicity/toxicity	Waived
154A-19	Freshwater Fish pathogenicity/toxicity	Waived
154A-20	Freshwater invertebrate	Waived
154A-22	Nontarget plant testing	Waived
154A-23	Nontarget insect testing	Waived
154A-24	Honeybee toxicity/pathogenicity	Waived

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing the bacterium, *A. radiobacter* as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing *A. radiobacter*. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of *A. radiobacter*, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of *A. radiobacter* and to determine that *A. radiobacter* can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that all products containing *A. radiobacter* as the active ingredients are eligible for reregistration. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of *A. radiobacter* are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing *A. radiobacter*, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility

1. Eligibility Decision

Based on the reviews of the generic data for the active ingredient *A. radiobacter*, the Agency has sufficient information on the health effects of *A. radiobacter* and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that *A. radiobacter* products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that products containing *A. radiobacter* for all currently registered uses are eligible for reregistration.

2. Eligible and Ineligible Uses

The Agency has determined that all currently registered uses of *A. radiobacter* are eligible for reregistration.

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for *A. radiobacter*. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Tolerance Reassessment

Although *A. radiobacter* is applied to certain fruit and nut crops, the Agency considers these applications to be non-food uses, because they are only made to non-bearing nursery stock. Therefore, neither a tolerance nor an exemption from tolerance is required. Should one be needed in the future, the data available are adequate to support an exemption from the requirement of a tolerance.

2. Endangered Species Statement

Based on the current use patterns, the potential for adverse effects to plant and animal (avian and aquatic) endangered species from applications of *A. radiobacter* is not expected.

3. Labeling Rationale

Precautionary Labeling:

In the evaluation of the toxicology data base for the reregistration eligibility decision for *A. radiobacter*, the Agency reexamined the acute toxicity study -- primary eye irritation (MRID 00060518 and 00064089), and concluded that the eye

irritation potential is more appropriately reclassified Toxicity Category III. This reduction in potential hazard prompts the revision of the precautionary labeling statements (Signal word, Statement of Practical Treatment, and other associated label statements mitigating risks) for all *A. radiobacter* products. The Agency is now requiring that these revised precautionary labeling statements be placed on the label/labeling of all *A. radiobacter* products as specified in Section V.

Worker Protection Requirements:

The 1992 Worker Protection Standards for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turf grasses, flowers, shrubs, ornamental, and seedlings). Uses within the scope include not only uses on plants, but also uses on soil or planting medium the plants are (or will be) grown in. At this time all currently registered uses of *A. radiobacter* are within the scope of the Worker Protection Standards for Agricultural Pesticides (WPS).

Any product whose labeling reasonably permits use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS), and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

After April 21, 1994, except as otherwise provided in PR Notice 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 the primary registrant or any supplementally registered distributor.

After October 23, 1995, except as otherwise 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.

On April 26, 1995, the Agency established a policy which allows registrants to reduce the interim WPS restricted entry interval (REI) from 12 hours to 4 hours for certain low risk pesticides. This policy identifies *A. radiobacter* as a candidate eligible for a reduced WPS REI. The procedures for requesting a reduction in the REI are outlined in Section V.

Personal Protective Equipment (PPE):

All PPE labeling requirements for products containing *A. radiobacter* were established using the process described in PR Notice 93-7 or more recent EPA guidelines. This RED will not impose any changes to the PPE WPS labeling requirements established in PR Notices 93-7 and 93-11.

Restricted-Entry Interval (REI):

Under the Worker Protection Standard (WPS), interim restricted entry intervals (REI) for all uses within the scope of the WPS were established on the basis of the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential were used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. The interim WPS REI for *A. radiobacter* is 12 hours, since all of the acute toxicity categories are either III or IV.

V. ACTIONS REQUIRED BY REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of *A. radiobacter* for the above eligible uses has been reviewed and determined to be substantially complete. At this time, no additional data are being required.

2. Labeling Requirements for Manufacturing-Use Products

Precautionary Labeling

The product labeling of each product containing *A. radiobacter* as an active ingredient must bear the following revised precautionary label statements. Refer to 40 CFR 156.10 -- Labeling Requirements for Pesticides and Devices, for additional information regarding proper placement and type size requirements for these statement.

CAUTION

Keep out of Reach of Children

Avoid contact with skin, eyes or clothing

STATEMENT OF PRACTICAL TREATMENT:

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

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. However, the data base supporting the reregistration for the above eligible end-uses of *A. radiobacter* products is substantially complete and no additional product specific data is being required at this time.

2. Labeling Requirements for End-Use Products

Precautionary Labeling

Refer to subsection A. above for labeling requirements for precautionary labeling.

Worker Protection Standard Labeling:

If registrants of *A. radiobacter* wish their products to be considered for a REI reduction from 12 hours to 4 hours, they must notify EPA. For each product, the following information must be submitted:

1. An Application for Registration (EPA Form 8570-1).
2. One copy of the current product label, clearly marked to highlight the interim WPS REI.
3. Two copies of the revised label, clearly marked to highlight the revised WPS REI.
4. The following certification statement:

"I certify that this notification is complete in accordance with the provisions of EPA's reduced REI policy and that no other changes have been made to the labeling or confidential statement of formula of this product. I further

understand that if this notification does not comply with the terms of EPA's reduced REI Policy, this product may be in violation of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. I understand that the Agency may direct a change in the REI of a product subject to this notice if the Agency determines that a change is appropriate, and that products may be subject to regulatory and enforcement action if the appropriate changes are not made."

Notifications should be sent to:

By U.S. Mail:

Document Processing Desk (WPS:95-1)(BPPD)
Office of Pesticide Programs (7504C)
Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460-0001

By express:

Document Processing Desk (WPS:95-1) (BPPD)
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell *A. radiobacter* products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

SITE Application Type, Application Timing, Application Equipment - Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Rate (AI Tex. @ Max. Dose cycle)	# Apps @ Max. Rate /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Limitations Disallowed	Use Limitations Codes
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USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

APPLE (con't)

Use Group: GREENHOUSE NON-FOOD CROP (con't)

Seed treatment., Preplant., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA		UC	*	NS	NS	NS	NS	NS	NS
Spray., Bare root., Sprayer.	FlC	NA		UC	*	NS	NS	NS	NS	NS	NS

Use Group: TERRESTRIAL NON-FOOD CROP

Dip treatment., Bare root., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS	NS
Seed treatment., Preplant., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA		UC	*	NS	NS	NS	NS	NS	NS
Spray., Bare root., Sprayer.	FlC	NA		UC	*	NS	NS	NS	NS	NS	NS

APRICOT

Use Group: GREENHOUSE NON-FOOD CROP

Dip treatment., Bare root., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS	NS
Dip treatment., Cutting., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS	NS
Dip treatment., Seedling stage., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS	NS
Seed treatment., Preplant., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA		UC	*	NS	NS	NS	NS	NS	NS
Spray., Bare root., Sprayer.	FlC	NA		UC	*	NS	NS	NS	NS	NS	NS

Use Group: TERRESTRIAL NON-FOOD CROP

Dip treatment., Bare root., By hand.	FlC	NA	.6614 lb 1K plant	UC	*	NS	NS	NS	NS	NS	0.5
	FlC	NA		UC	*	NS	NS	NS	NS	NS	NS
Dip treatment., Cutting., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS	0.5
	FlC	NA		UC	*	NS	NS	NS	NS	NS	NS

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SITE Application Type, Application      Form(s)  Min. Appl.      Max. Appl. Soil Max. # Apps Max. Dose [(AI  Min. Restr.   Geographic Limitations  Use
Timing, Application Equipment -        Rate (AI un-    Rate (AI Tex. @ Max. Rate unless noted  Interv Entry   Allowed           Disallowed           Limitations
Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)  otherwise)    unless noted Max. /crop /year otherwise)/A] (days) Interv [day(s)]
                                otherwise)    otherwise) Dose cycle /crop /year cycle
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USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

APRICOT (con't)										
Use Group: TERRESTRIAL NON-FOOD CROP (con't)										
Dip treatment., Nonbearing nurserystock., By hand.	FlC	NA	.6614 lb 1K plant	* NS	NS	NS	NS	NS	NS	0.5
Dip treatment., Seedling stage., By hand.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Seed treatment., Preplant., By hand.	FlC	NA	1.47 lb cwt	* NS	NS	NS	NS	NS	NS	0.5
	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., By hand.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Spray., Bare root., Sprayer.	FlC	NA	.6614 lb 1K plant	* NS	NS	NS	NS	NS	NS	0.5
	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Spray., Nonbearing nurserystock., Sprayer.	FlC	NA	.6614 lb 1K plant	* NS	NS	NS	NS	NS	NS	0.5
BLACKBERRY										
Use Group: GREENHOUSE NON-FOOD CROP										
Dip treatment., Bare root., By hand.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Dip treatment., Cutting., By hand.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Dip treatment., Seedling stage., By hand.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., By hand.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Spray., Bare root., Sprayer.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Use Group: TERRESTRIAL NON-FOOD CROP										
Dip treatment., Bare root., By hand.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Dip treatment., Cutting., By hand.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Dip treatment., Seedling stage., By hand.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., By hand.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Spray., Bare root., Sprayer.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS


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SITE Application Type, Application      Form(s)  Min. Appl.      Max. Appl. Soil Max. # Apps Max. Dose [(AI  Min. Restr.   Geographic Limitations  Use
Timing, Application Equipment -        Rate (AI un-    Rate (AI Tex. @ Max. Rate unless noted  Interv Entry   Allowed           Disallowed           Limitations
Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)  otherwise)    unless noted Max. /crop /year otherwise)/A] (days) Interv [day(s)]
                                             otherwise)    otherwise) Dose cycle /crop /year cycle
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USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

CANE BERRIES										
Use Group: TERRESTRIAL NON-FOOD CROP										
Dip treatment., Bare root., By hand.	FlC	NA	.6614 lb 1K plant	* NS	NS	NS	NS	NS	NS	0.5
Dip treatment., Cutting., By hand.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	0.5
Dip treatment., Nonbearing nurserystock., By hand.	FlC	NA	.6614 lb 1K plant	* NS	NS	NS	NS	NS	NS	0.5
Spray., Bare root., Sprayer.	FlC	NA	.6614 lb 1K plant	* NS	NS	NS	NS	NS	NS	0.5
Spray., Nonbearing nurserystock., Sprayer.	FlC	NA	.6614 lb 1K plant	* NS	NS	NS	NS	NS	NS	0.5
CHERRY										
Use Group: GREENHOUSE NON-FOOD CROP										
Dip treatment., Bare root., By hand.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Dip treatment., Cutting., By hand.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Dip treatment., Seedling stage., By hand.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Seed treatment., Preplant., By hand.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., By hand.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Spray., Bare root., Sprayer.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Use Group: TERRESTRIAL NON-FOOD CROP										
Dip treatment., Bare root., By hand.	FlC	NA	.6614 lb 1K plant	* NS	NS	NS	NS	NS	NS	0.5
	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Dip treatment., Cutting., By hand.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	0.5
	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Dip treatment., Nonbearing nurserystock., By hand.	FlC	NA	.6614 lb 1K plant	* NS	NS	NS	NS	NS	NS	0.5
Dip treatment., Seedling stage., By hand.	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS
Seed treatment., Preplant., By hand.	FlC	NA	1.47 lb cwt	* NS	NS	NS	NS	NS	NS	0.5
	FlC	NA	UC	* NS	NS	NS	NS	NS	NS	NS

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SITE Application Type, Application      Form(s)  Min. Appl.      Max. Appl. Soil Max. # Apps Max. Dose [(AI  Min. Restr.   Geographic Limitations   Use
Timing, Application Equipment -        Rate (AI un-    Rate (AI Tex. @ Max. Rate unless noted  Interv Entry   Allowed           Disallowed           Limitations
Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)  otherwise)      unless noted Max. /crop /year otherwise)/A] (days) Interv [day(s)]
                                otherwise)      otherwise) Dose cycle /crop /year
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USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

CHERRY (con't) Use Group: TERRESTRIAL NON-FOOD CROP (con't)

Application	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Rate (AI Tex. @ Max. /crop /year)	# Apps /year	Max. Dose [(AI unless noted otherwise)/A]	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Limitations Allowed	Limitations Disallowed	Use Limitations Codes
Soil drench treatment., Postplant., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS			NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS			NS
Spray., Bare root., Sprayer.	FlC	NA	.6614 lb 1K plant	UC	* NS NS	NS NS NS	NS	NS			0.5
	FlC	NA		UC	* NS NS	NS NS NS	NS	NS			NS
Spray., Nonbearing nurserystock., Sprayer.	FlC	NA	.6614 lb 1K plant	UC	* NS NS	NS NS NS	NS	NS			0.5

KIWI FRUIT Use Group: GREENHOUSE NON-FOOD CROP

Dip treatment., Bare root., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS			NS
Dip treatment., Cutting., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS			NS
Dip treatment., Seedling stage., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS			NS
Seed treatment., Preplant., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS			NS
Soil drench treatment., Postplant., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS			NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS			NS
Spray., Bare root., Sprayer.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS			NS

Use Group: TERRESTRIAL NON-FOOD CROP

Dip treatment., Bare root., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS			NS
Dip treatment., Cutting., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS			NS
Dip treatment., Seedling stage., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS			NS
Seed treatment., Preplant., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS			NS
Soil drench treatment., Postplant., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS			NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS			NS
Spray., Bare root., Sprayer.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS			NS

NECTARINE Use Group: GREENHOUSE NON-FOOD CROP

Dip treatment., Bare root., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS			NS
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SITE Application Type, Application      Form(s)  Min. Appl.      Max. Appl. Soil Max. # Apps Max. Dose [(AI  Min. Restr.   Geographic Limitations  Use
Timing, Application Equipment -        Rate (AI un-    Rate (AI Tex. @ Max. Rate unless noted  Interv Entry   Allowed           Disallowed           Limitations
Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)  less noted    unless noted Max. /crop /year otherwise)/A] (days) Interv  [day(s)]
                                             otherwise)    otherwise) Dose cycle /crop /year cycle
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USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

NECTARINE (con't) Use Group: GREENHOUSE NON-FOOD CROP (con't)

Application	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Rate (AI Tex. @ Max. /crop /year)	# Apps /year	Max. Dose [(AI unless noted otherwise)/A]	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
Dip treatment., Cutting., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS	NS	NS	NS
Dip treatment., Seedling stage., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS	NS	NS	NS
Seed treatment., Preplant., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS	NS	NS	NS
Spray., Bare root., Sprayer.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS	NS	NS	NS

Use Group: TERRESTRIAL NON-FOOD CROP

Dip treatment., Bare root., By hand.	FlC	NA	.6614 lb 1K plant	UC	* NS NS	NS NS NS	NS	NS	NS	0.5	
	FlC	NA		UC	* NS NS	NS NS NS	NS	NS	NS	NS	
Dip treatment., Cutting., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS	NS	0.5	
	FlC	NA		UC	* NS NS	NS NS NS	NS	NS	NS	NS	
Dip treatment., Nonbearing nurserystock., By hand.	FlC	NA	.6614 lb 1K plant	UC	* NS NS	NS NS NS	NS	NS	NS	0.5	
Dip treatment., Seedling stage., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS	NS	NS	
Seed treatment., Preplant., By hand.	FlC	NA	1.47 lb cwt	UC	* NS NS	NS NS NS	NS	NS	NS	0.5	
	FlC	NA		UC	* NS NS	NS NS NS	NS	NS	NS	NS	
Soil drench treatment., Postplant., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS	NS	NS	
Soil drench treatment., Postplant., Sprayer.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS	NS	NS	
Spray., Bare root., Sprayer.	FlC	NA	.6614 lb 1K plant	UC	* NS NS	NS NS NS	NS	NS	NS	0.5	
	FlC	NA		UC	* NS NS	NS NS NS	NS	NS	NS	NS	
Spray., Nonbearing nurserystock., Sprayer.	FlC	NA	.6614 lb 1K plant	UC	* NS NS	NS NS NS	NS	NS	NS	0.5	

ORNAMENTAL AND/OR SHADE TREES Use Group: GREENHOUSE NON-FOOD CROP

Dip treatment., Bare root., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS	NS	NS	
Dip treatment., Cutting., By hand.	FlC	NA		UC	* NS NS	NS NS NS	NS	NS	NS	NS	

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SITE Application Type, Application      Form(s)  Min. Appl.      Max. Appl. Soil Max. # Apps Max. Dose [(AI  Min. Restr.   Geographic Limitations   Use
Timing, Application Equipment -        Rate (AI un-    Rate (AI Tex. @ Max. Rate unless noted  Interv Entry   Allowed           Disallowed           Limitations
Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only) otherwise) unless noted Max. /crop /year otherwise)/A] (days) Interv [day(s)]
                                         otherwise) Dose cycle /crop /year
  
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USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

ORNAMENTAL AND/OR SHADE TREES (con't) Use Group: GREENHOUSE NON-FOOD CROP (con't)

Application	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Rate @ Max. Dose /crop /year	# Apps /year	Max. Dose [(AI unless noted otherwise)/A]	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
Dip treatment., Seedling stage., By hand.	FlC	NA			NS	NS	NS	NS			NS
Seed treatment., Preplant., By hand.	FlC	NA			NS	NS	NS	NS			NS
Soil drench treatment., Postplant., By hand.	FlC	NA			NS	NS	NS	NS			NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA			NS	NS	NS	NS			NS
Spray., Bare root., Sprayer.	FlC	NA			NS	NS	NS	NS			NS

Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL

Dip treatment., Bare root., By hand.	FlC	NA	3.307 lb 5K plants		* NS	NS	NS	NS			0.5
	FlC	NA			* NS	NS	NS	NS			NS
Dip treatment., Cutting., By hand.	FlC	NA			* NS	NS	NS	NS			0.5
	FlC	NA			* NS	NS	NS	NS			NS
Dip treatment., Nonbearing nurserystock., By hand.	FlC	NA	3.307 lb 5K plants		* NS	NS	NS	NS			0.5
Dip treatment., Seedling stage., By hand.	FlC	NA			* NS	NS	NS	NS			NS
Seed treatment., Preplant., By hand.	FlC	NA	1.102 lb 75 lb seed		* NS	NS	NS	NS			0.5
	FlC	NA			* NS	NS	NS	NS			NS
Soil drench treatment., Postplant., By hand.	FlC	NA			* NS	NS	NS	NS			NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA			* NS	NS	NS	NS			NS
Spray., Bare root., Sprayer.	FlC	NA	3.307 lb 5K plants		* NS	NS	NS	NS			0.5
	FlC	NA			* NS	NS	NS	NS			NS
Spray., Nonbearing nurserystock., Sprayer.	FlC	NA	3.307 lb 5K plants		* NS	NS	NS	NS			0.5

ORNAMENTAL WOODY SHRUBS AND VINES Use Group: GREENHOUSE NON-FOOD CROP

Dip treatment., Bare root., By hand.	FlC	NA			* NS	NS	NS	NS			NS
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=====
SITE Application Type, Application      Form(s)  Min. Appl.      Max. Appl. Soil Max. # Apps Max. Dose [(AI  Min. Restr.   Geographic Limitations   Use
Timing, Application Equipment -        Rate (AI un-    Rate (AI Tex. @ Max. Rate unless noted  Interv Entry   Allowed           Disallowed           Limitations
Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)  otherwise)    unless noted Max. /crop /year otherwise)/A] (days) Interv [day(s)]          Codes
                                                    otherwise) Dose cycle /crop /year
=====
  
```

USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

ORNAMENTAL WOODY SHRUBS AND VINES (con't) Use Group: GREENHOUSE NON-FOOD CROP (con't)

Application	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Rate (AI Tex. @ Max. /crop /year)	# Apps /year	Max. Dose [(AI unless noted otherwise)/A]	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
Dip treatment., Cutting., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Dip treatment., Seedling stage., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Soil drench treatment., Postplant., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Soil drench treatment., Postplant., Sprayer.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Spray., Bare root., Sprayer.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	

Use Group: TERRESTRIAL NON-FOOD+OUTDOOR RESIDENTIAL

Dip treatment., Bare root., By hand.	FlC	NA	3.307 lb 5K plants	UC	* NS NS	NS NS	NS	NS	NS	0.5	
	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Dip treatment., Cutting., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	0.5	
	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Dip treatment., Nonbearing nurserystock., By hand.	FlC	NA	3.307 lb 5K plants	UC	* NS NS	NS NS	NS	NS	NS	0.5	
Dip treatment., Seedling stage., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Soil drench treatment., Postplant., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Soil drench treatment., Postplant., Sprayer.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Spray., Bare root., Sprayer.	FlC	NA	3.307 lb 5K plants	UC	* NS NS	NS NS	NS	NS	NS	0.5	
	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Spray., Nonbearing nurserystock., Sprayer.	FlC	NA	3.307 lb 5K plants	UC	* NS NS	NS NS	NS	NS	NS	0.5	

PEACH Use Group: GREENHOUSE NON-FOOD CROP

Dip treatment., Bare root., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Dip treatment., Cutting., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Dip treatment., Seedling stage., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	


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=====
SITE Application Type, Application      Form(s)  Min. Appl.  Max. Appl. Soil Max. # Apps Max. Dose [(AI  Min. Restr.  Geographic Limitations  Use
Timing, Application Equipment -       Rate (AI un-   Rate (AI Tex. @ Max. Rate unless noted  Interv Entry  Allowed          Disallowed          Limitations
Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)  less noted    unless noted Max. /crop /year otherwise)/A] (days) Interv [day(s)]  Codes
otherwise)    otherwise) Dose cycle  /crop /year cycle
=====
  
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USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

PEAR (con't) Use Group: GREENHOUSE NON-FOOD CROP (con't)

Application	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Rate (AI Tex. otherwise)	Max. # Apps @ Max. Rate /crop /year	Max. Dose [(AI unless noted otherwise)/A] /crop /year cycle	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
Soil drench treatment., Postplant., Sprayer.	FlC	NA			NS	NS	NS	NS			NS
Spray., Bare root., Sprayer.	FlC	NA			NS	NS	NS	NS			NS

Use Group: TERRESTRIAL NON-FOOD CROP

Dip treatment., Bare root., By hand.	FlC	NA			NS	NS	NS	NS			NS
Dip treatment., Seedling stage., By hand.	FlC	NA			NS	NS	NS	NS			NS
Seed treatment., Preplant., By hand.	FlC	NA			NS	NS	NS	NS			NS
Soil drench treatment., Postplant., By hand.	FlC	NA			NS	NS	NS	NS			NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA			NS	NS	NS	NS			NS
Spray., Bare root., Sprayer.	FlC	NA			NS	NS	NS	NS			NS

PECAN Use Group: GREENHOUSE NON-FOOD CROP

Dip treatment., Bare root., By hand.	FlC	NA			NS	NS	NS	NS			NS
Soil drench treatment., Postplant., By hand.	FlC	NA			NS	NS	NS	NS			NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA			NS	NS	NS	NS			NS
Spray., Bare root., Sprayer.	FlC	NA			NS	NS	NS	NS			NS

Use Group: TERRESTRIAL NON-FOOD CROP

Dip treatment., Bare root., By hand.	FlC	NA			NS	NS	NS	NS			NS
Soil drench treatment., Postplant., By hand.	FlC	NA			NS	NS	NS	NS			NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA			NS	NS	NS	NS			NS
Spray., Bare root., Sprayer.	FlC	NA			NS	NS	NS	NS			NS

PLUM Use Group: GREENHOUSE NON-FOOD CROP

Dip treatment., Bare root., By hand.	FlC	NA			NS	NS	NS	NS			NS
Dip treatment., Cutting., By hand.	FlC	NA			NS	NS	NS	NS			NS
Dip treatment., Seedling stage., By hand.	FlC	NA			NS	NS	NS	NS			NS


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SITE Application Type, Application      Form(s)  Min. Appl.      Max. Appl. Soil Max. # Apps Max. Dose [(AI  Min. Restr.   Geographic Limitations   Use
Timing, Application Equipment -        Rate (AI un-    Rate (AI Tex. @ Max. Rate unless noted  Interv Entry   Allowed           Disallowed           Limitations
Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)  otherwise)      otherwise) Dose cycle /crop /year otherwise)/A] (days) Interv [day(s)]          Codes
  cycle /crop /year
=====
  
```

USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

RASPBERRY (BLACK, RED) (con't)

Use Group: TERRESTRIAL NON-FOOD CROP

Application	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Rate (AI Tex. @ Max. Dose cycle)	# Apps /crop /year	Max. Dose [(AI unless noted otherwise)/A]	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
Dip treatment., Bare root., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Dip treatment., Cutting., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Dip treatment., Seedling stage., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Soil drench treatment., Postplant., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Soil drench treatment., Postplant., Sprayer.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Spray., Bare root., Sprayer.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	

WALNUT (ENGLISH/BLACK)

Use Group: GREENHOUSE NON-FOOD CROP

Application	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Rate (AI Tex. @ Max. Dose cycle)	# Apps /crop /year	Max. Dose [(AI unless noted otherwise)/A]	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
Dip treatment., Bare root., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Dip treatment., Cutting., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Dip treatment., Seedling stage., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Seed treatment., Preplant., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Soil drench treatment., Postplant., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Soil drench treatment., Postplant., Sprayer.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Spray., Bare root., Sprayer.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	

Use Group: TERRESTRIAL NON-FOOD CROP

Application	Form(s)	Min. Appl. Rate (AI unless noted otherwise)	Max. Appl. Rate (AI unless noted otherwise)	Soil Max. Rate (AI Tex. @ Max. Dose cycle)	# Apps /crop /year	Max. Dose [(AI unless noted otherwise)/A]	Min. Interv (days)	Restr. Entry Interv [day(s)]	Geographic Allowed	Limitations Disallowed	Use Limitations Codes
Dip treatment., Bare root., By hand.	FlC	NA	.6614 lb 1K plant	UC	* NS NS	NS NS	NS	NS	NS	NS	0.5
	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Dip treatment., Cutting., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	0.5
	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Dip treatment., Nonbearing nurserystock., By hand.	FlC	NA	.6614 lb 1K plant	UC	* NS NS	NS NS	NS	NS	NS	NS	0.5
Dip treatment., Seedling stage., By hand.	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	
Seed treatment., Preplant., By hand.	FlC	NA	1.47 lb cwt	UC	* NS NS	NS NS	NS	NS	NS	NS	0.5
	FlC	NA		UC	* NS NS	NS NS	NS	NS	NS	NS	

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=====
SITE Application Type, Application      Form(s)  Min. Appl.      Max. Appl. Soil Max. # Apps Max. Dose [(AI  Min. Restr.   Geographic Limitations  Use
Timing, Application Equipment -        Rate (AI un-    Rate (AI Tex. @ Max. Rate unless noted  Interv Entry   Allowed           Disallowed           Limitations
Surface Type (Antimicrobial only) & Efficacy Influencing Factor (Antimicrobial only)  otherwise)      unless noted Max. /crop /year otherwise)/A] (days) Interv [day(s)]
                                                                                               /crop /year
                                                                                               cycle
=====
  
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USES ELIGIBLE FOR REREGISTRATION

NON-FOOD/NON-FEED (con't)

 WALNUT (ENGLISH/BLACK) (con't) Use Group: TERRESTRIAL NON-FOOD CROP (con't)

Soil drench treatment., Postplant., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA		UC	*	NS	NS	NS	NS	NS
Spray., Bare root., Sprayer.	FlC	NA	.6614 lb 1K plant	UC	*	NS	NS	NS	NS	0.5
	FlC	NA		UC	*	NS	NS	NS	NS	NS
Spray., Nonbearing nurserystock., Sprayer.	FlC	NA	.6614 lb 1K plant	UC	*	NS	NS	NS	NS	0.5

YOUNGBERRY Use Group: GREENHOUSE NON-FOOD CROP

Dip treatment., Bare root., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS
Dip treatment., Cutting., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS
Dip treatment., Seedling stage., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA		UC	*	NS	NS	NS	NS	NS
Spray., Bare root., Sprayer.	FlC	NA		UC	*	NS	NS	NS	NS	NS

Use Group: TERRESTRIAL NON-FOOD CROP

Dip treatment., Bare root., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS
Dip treatment., Cutting., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS
Dip treatment., Seedling stage., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., By hand.	FlC	NA		UC	*	NS	NS	NS	NS	NS
Soil drench treatment., Postplant., Sprayer.	FlC	NA		UC	*	NS	NS	NS	NS	NS
Spray., Bare root., Sprayer.	FlC	NA		UC	*	NS	NS	NS	NS	NS

=====

LEGEND

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HEADER ABBREVIATIONS

Min. Appl. Rate (AI unless : Minimum dose for a single application to a single site. System calculated. Microbial claims only.
noted otherwise)
Max. Appl. Rate (AI unless : Maximum dose for a single application to a single site. System calculated.
noted otherwise)
Soil Tex. Max. Dose : Maximum dose for a single application to a single site as related to soil texture (Herbicide claims only).
Max. # Apps @ Max. Rate : Maximum number of Applications at Maximum Dosage Rate. Example: "4 applications per year" is expressed as "4/1 yr"; "4 applications per 3
years" is expressed as "4/3 yr"
Max. Dose [(AI unless : Maximum dose applied to a site over a single crop cycle or year. System calculated.
noted otherwise)/A]
Min. Interv (days) : Minimum Interval between Applications (days)
Restr. Entry Interv (days) : Restricted Entry Interval (days)
PRD Report Date : LUIS contains all products that were active or suspended (and that were available from OPP Document Center) as of this date. Some products
registered after this date may have data included in this report, but LUIS does not guarantee that all products registered after this date have
data that has been captured.

SOIL TEXTURE FOR MAX APP. RATE

* : Non-specific
C : Coarse
M : Medium
F : Fine
O : Others

FORMULATION CODES

FLC : FLOWABLE CONCENTRATE

ABBREVIATIONS

AN : As Needed
NA : Not Applicable
NS : Not Specified (on label)
UC : Unconverted due to lack of data (on label), or with one of following units: bag, bait, bait block, bait pack, bait station, bait station(s), block, briquet,
briquets, bursts, cake, can, canister, capsule, cartridges, coil, collar, container, dispenser, drop, eartag, grains, lure, pack, packet, packets, pad, part,
parts, pellets, piece, pieces, pill, pumps, sec, sec burst, sheet, spike, stake, stick, strip, tab, tablet, tablets, tag, tape, towelette, tray, unit, --

APPLICATION RATE

DCNC : Dosage Can Not be Calculated
No Calc : No Calculation can be made
W : PPM calculated by weight
V : PPM Calculated by volume
U : Unknown whether PPM is given by weight or by volume
cwt : Hundred Weight
nnE-xx : nn times (10 power -xx); for instance, "1.234E-04" is equivalent to ".0001234"

**APPENDIX B. Table of the Generic Data Requirements
and Studies Used to Make the Reregistration Decision**

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 4101 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 4101 in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of *Agrobacterium radiobacter*

REQUIREMENT	USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY:		
151A-10	Chemical Identity	CI 41653301
151A-11	Start. Mat. & Mnfg. Process	CI 41653302
151A-12	Discussion of Formation of Unintention Ingredients	CI 41653302
151A-15	Certification of limits	CI 41653303
151A-16	PHYSICAL AND CHEMICAL PROPERTIES:	
(a)	Color	CI 41653303
(b)	Physical State	CI 41653303
(c)	Odor	CI 41653303
(d)	Density	CI 41653303
(e)	pH	CI 41653303
(f)	Stability	CI 41653303
(g)	Storage Stability	CI 41653303
TOXICITY TIER I:		
152A-10	Acute Oral Tox/Path	CI 00060517, 00060518, 00060519, 41653304 41653305
152A-11	Acute Dermal Toxicity	CI 00064089, 41653304, 41653305
152A-12	Acute Pulmonary/Tox/Path	CI WAIVED
152A-13	Acute Intravenous Tox/Path	CI WAIVED

Data Supporting Guideline Requirements for the Reregistration of *Agrobacterium radiobacter*

REQUIREMENT	USE PATTERN	CITATION(S)
152A-14 Primary Eye Irritation	CI	00060517, 00060518, 00060519, 41653304, 41653305
152A-15 Hypersensitivity Incidents	CI	00060517, 00060518, 00060519, 41653304, 41653305

ECOLOGICAL EFFECTS (Tier I):

All Ecological Effects data requirements have been waived.

OCCUPATIONAL EXPOSURE:

All Occupational Exposure data requirements have been waived.

ENVIRONMENTAL FATE:

All Environmental Fate data requirements have been waived.

**APPENDIX C. Citations Considered to be Part of the Data
Base Supporting the Reregistration of 4101**

GUIDE TO APPENDIX C

1. **CONTENTS OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
 - a. **Author.** Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
 - b. **Document date.** The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears

as (19??), the Agency was unable to determine or estimate the date of the document.

- c. **Title.** In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. **Trailing parentheses.** For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
 - (1) **Submission date.** The date of the earliest known submission appears immediately following the word "received."
 - (2) **Administrative number.** The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
 - (3) **Submitter.** The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
 - (4) **Volume Identification (Accession Numbers).** The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

BIBLIOGRAPHY

MRID

CITATION

- 00060517 Nortell Laboratories (1977?) Introduction: Crown Gall Disease. (Unpublished study received Jan 24, 1978 under 38087-EX-1; CDL:232741-B)
- 00060518 Nortell Laboratories (1977?) Toxicology Studies for *Agrobacterium radiobacter*, Isolate 84, Used for Biological Control of Crown Gall. (Unpublished study received Jan 24, 1978 under 38087-EX-1; CDL:232741-C)
- 00060519 Patton, N.M. (1976) Letter sent to Nortell Laboratories, Inc. dated Mar 25, 1976: Determination of LD₅₀ in mice for Norbac 84C (*Agrobacterium radiobacter*) a plant bacteria. (Unpublished study received Jan 24, 1978 under 38087-EX-1; prepared by Oregon State Univ., Laboratory Animal Resource Center, submitted by Nortell Laboratories, Corvallis, Ore.; CDL:232741-D)
- 00064089 Baltezare, M. (1978) Product Culture and Skin and Eye Irritation: Laboratory Nos. 9861, 10056. (Technical report; unpublished study received Jun 8, 1978 under 40230-1; prepared by Unilab Research, submitted by Agbiochem, Inc., Orinda, Calif.; CDL: 234064-A)
- 41653301 Moore, L. (1990) *Agrobacterium radiobacter* Strain K84: Product Identity: Lab Project Number: L.W.M.-1. Unpublished study prepared by Oregon State University. 209 p.
- 41653302 Moore, L. (1990) *Agrobacterium radiobacter* Strain K84: Manufacturing Process; Discussion of Formation of Unintentional Ingredient; Analysis of Samples: Lab Project Number: L.M.W.-2. Unpublished study prepared by New BioProducts Laboratory, Inc. 48 p.
- 41653303 Moore, L. (1990) Norbac 84C (*A. radiobacter* strain K84): Physical and Chemical Properties: Lab Project Number: L.W.M.-3. Unpublished study prepared by New BioProducts Laboratory, Inc. 3 p.
- 41653304 Moore, L. (1990) *Agrobacterium radiobacter* Strain K84: Tier 1 Toxicology: Lab Project Number: L.W.M.-4. Unpublished study prepared by Oregon State University. 14 p.
- 41653305 Moore, L. (1990) *Agrobacterium radiobacter* Strain K84: Tier 1 Tox, Nontarget Organisms: Lab Project Number: L.W.M.-5. Unpublished study

BIBLIOGRAPHY

MRID

CITATION

prepared by Oregon State University. 74 p.

APPENDIX D. List of Available Related Documents

The following is a list of available documents related to 4101. It's purpose is to provide a path to more detailed information if it is needed. These accompanying documents are part of the Administrative Record for 4101 and are included in the EPA's Office of Pesticide Programs Public Docket.

1. Health and Environmental Effects Science Chapters
2. Detailed Label Usage Information System (LUIS) Report
3. 4101 RED Fact Sheet

APPENDIX E. FACT SHEET



R.E.D. FACTS

Agrobacterium radiobacter

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 4101, *Agrobacterium radiobacter*, also referred to as *A. radiobacter*.

Use Profile

Agrobacterium radiobacter is a fungicide (microbial control agent) used to control Crown Gall in certain non-bearing fruit, nut and ornamental nursery stock.

Non-bearing Fruit and Nut Nursery Stock:

Almonds	Apples	Apricots
Blueberries	Caneberries*	Cranberries
Cherries	Kiwis	Nectarines
Peaches	Pears	Pecans
Plums	Prunes	Walnuts

* Caneberries include Blackberries, Boysenberries, Raspberries, and Youngberries.

Ornamental Nursery Stock:

Euonymus Rose Weeping Cherry

Formulations include a 2.25% flowable concentrate product and a 1.2 % solidified agar product.

Agrobacterium radiobacter is applied by hand operated spray, drench and dip treatment equipment.

Method and Rate -

Dipping

Germinating Seed Application - 1 unit of product**/gallon of water.

Seedling Application - 1 unit of product**/gallon of water.

Cutting Application - 1 unit of product**/gallon of water.

Root and Stem Application - 1 unit of product**/gallon of water.

Spraying

Root and Stem Application - 1 unit of product**/gallon of water.

Soil Drench Application - 1 unit of product**/ 5 gallons of water; 6-8 oz of suspension per 1 gallon container or 1 foot of plant row.

**1 unit of product equals 3×10^{12} and 1.2×10^{11} colony forming units per volume

of product for the flowable concentrate and solidified agar formulations, respectively.

Timing - Preplant -- cutting, root and stem treatments; Immediately Prior to Planting -- germinating seed and seedling treatments; Postplant -- soil drench treatment.

Amount- Less than 1,000 pounds of this active ingredient (a.i.) are used annually.

Use practice limitations: Label limits use only to applications on certain non-food and non-bearing plants.

**Regulatory
History**

Agrobacterium radiobacter was first registered as a pesticide in the U.S. in 1979. During Phase 3 of the Reregistration Process, the toxicology data base for *A. radiobacter* was evaluated and determined to adequately satisfy most of the data requirements for microbial pest control agents. Acute pulmonary toxicity/pathogenicity studies, and acute intravenous

toxicity/pathogenicity studies were identified as outstanding data gaps and a Data Call-In was issued July 1993. Since the DCI, the Agency's initial position with respect to these guidelines was re-evaluated, and these data requirements were waived because it was determined that *A. radiobacter* was a soil saprophyte and was not known to be pathogenic to humans and animals.

Currently, two *A. radiobacter* products are registered: Galltrol-A and Norbac 84-C.

Human Health Assessment

Toxicity

In studies using laboratory animals, *A. radiobacter* generally has been shown to be of very low acute toxicity. Its primary eye irritation/infection toxicity places it in Toxicity Category III (the second lowest of four categories). *Agrobacterium radiobacter's* oral toxicity is LD₅₀ > 5g/Kg, which places it in Toxicity Category IV (the lowest of four categories). Likewise, *A. radiobacter's* acute dermal toxicity is in Toxicity Category IV.

Dietary Exposure

Although *A. radiobacter* is applied to certain fruit and nut crops, the Agency considers these applications to be non-food uses because they are made only to non-bearing nursery stock. Thus, neither a tolerance nor an exemption from a tolerance is required. Additionally, the Agency has concluded that dietary exposure from consuming commodities which were treated with *A. radiobacter* as nursery stock not expected.

Occupational and Residential Exposure

Based on the application methods (dipping of plants by hand and spraying with a hand-held sprayer) listed on the product label, the potential for eye, dermal and inhalation exposure to handlers and post application nursery workers exists. Because of a lack of human toxicity concern, worker exposure data are not required. Moreover, it is the Agency's opinion that these occupational exposures and subsequent risks are negligible because: (1) the proposed precautionary product labeling stipulated in the RED for *A. radiobacter* will adequately mitigate the risks to applicators and related nursery workers; and (2) the organism has been determined not to be pathogenic to humans and animals.

Human Risk Assessment

Since exposures and subsequent risks from *A. radiobacter* applications are not expected, any potential risks from exposure to treated plants will be mitigated by the use of PPE required by the WPS, supplemented by specific precautionary labeling required by this RED. Post-application reentry workers will be required to observe a 12-hour Restricted Entry Interval. Because of *A. radiobacter's* ubiquitous nature and low toxicity, it is a candidate for a reduced reentry interval: from 12 hours to 4 hours.

Environmental Assessment

No environmental or ecological toxicity data requirements are being required for *A. radiobacter* in this RED, because mitigating factors support the conclusion that exposure to non-target terrestrial and aquatic organisms is extremely minimal. The major mitigating factor is that the registered use of *A. radiobacter* being supported for reregistration is the treatment of certain nursery stock in a contained environment (indoor use). Thus, little or no exposure to the environment results from use according to label directions. Because there is little or no exposure, the risk to non-target terrestrial and aquatic organisms is expected to be minimal.

Additional Data Required

EPA is requiring the following information for reregistration *A. radiobacter*: revised Confidential Statements of Formula (CSFs), and revised product labeling.

Product Labeling Changes Required

In the evaluation of the toxicology data base for *A. radiobacter*, an acute toxicity study -- primary eye irritation was re-evaluated. It was determined that the eye irritation potential is more appropriately reclassified, Toxicity Category III. This reduction in potential hazard prompts revision of the precautionary labeling statements (Signal Word -- Caution vs Warning and Statement of Practical Treatment) for end-use products. For a comprehensive list of labeling requirements, please see the *A. radiobacter* RED document.

Regulatory Conclusion

The use of currently registered products containing *A. radiobacter* in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Agrobacterium radiobacter products will be reregistered once the revised Confidential Statements of Formula and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for *A. radiobacter* during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the *A. radiobacter* RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the *A. radiobacter* RED, or reregistration of individual products containing *A. radiobacter*, please contact the Biopesticides and Pollution Prevention Division (7504C), OPP, US EPA, Washington, DC 20460, telephone 703-308-8712.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 8:00 am and 8:00 pm Eastern Standard Time, Monday through Friday.