United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7504C) | EPA-738-F-95-020 June 1995

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. It's primary eye irritation/infection toxicity places it in Toxicity Category III (the second lowest of four categories). *Agrobacterium radiobacter's* oral toxicity is $LD_{50} > 5g/Kg$, 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.