Pasteuria nishizawae - Pn1 (016455) Fact Sheet

Summary

Pasteuria, a genus of bacteria, includes several species that have shown potential in controlling plant-parasitic nematodes that attack and cause significant damage to many valuable agricultural crops. These gram-positive, mycelial, endospore-forming bacteria are mainly obligate parasites (i.e., organisms that depend on particular hosts to complete their own life cycle) of nematodes, although one species, Pasteuria ramosa, is known to parasitize water fleas. Pasteuria species are ubiquitous in most environments and are found in nematodes in at least 80 countries on 5 continents, as well as on islands in the Atlantic, Pacific, and Indian Oceans. In light of the demonstrated nematicidal capabilities and host specificity of Pasteuria nishizawae – Pn1, Pasteuria Bioscience, Inc. proposed to register a manufacturing-use pesticide product, Soyacyst Tech, and two end-use pesticide products, Soyacyst Tech+ and Soyacyst LF, containing this bacterium. Soyacyst Tech+ and Soyacyst LF will be applied to soybean or its seed to control the soybean cyst nematode. Use of Pasteuria nishizawae – Pn1 as a nematicide and in accordance with label directions is not expected to cause any unreasonable adverse effects on human health or the environment.

Description of the Active Ingredient

Pasteuria nishizawae – Pn1 was isolated from an Illinois soybean field in the mid-2000s. Although endospores of Pasteuria nishizawae have been observed to attach to the cuticle of three nematodes of the genus Heterodera and one nematode of the genus Globodera, it is known only to infect and complete its life cycle within the female soybean cyst nematode (Heterodera glycines). In the following manner, Pasteuria nishizawae – Pn1 exerts a pesticidal effect on the soybean cyst nematode through parasitism that ultimately results in the death of infected females:

- (1) Endospores attach to the cuticle of a juvenile soybean cyst nematode female.
- (2) Once a soybean cyst nematode female invades soybean roots, *Pasteuria nishizawae* Pn1 produces a germ tube that penetrates the body of the nematode.
- (3) Primary and secondary microcolonies of *Pasteuria nishizawae* Pn1 develop and proliferate within the body of the nematode, causing its death.

II. Use Sites, Target Pests, and Application Methods

Use Sites: Soybean

Target Pests: Soybean cyst nematode (*Heterodera glycines*)

Application Methods: For specific details, see Appendix B of the associated Biopesticides

Registration Action Document or the accepted pesticide product labels

available through EPA's Pesticide Product Label System.

III. Assessing Risks to Human Health

Given the results of required toxicity/pathogenicity testing, *Pasteuria nishizawae* – Pn1's specificity for the soybean cyst nematode, and the absence of occurrences of hypersensitivity incidents during testing and production of *Pasteuria nishizawae* – Pn1, no human health risks are expected when pesticides products containing *Pasteuria nishizawae* – Pn1 are used according to their respective label directions. Despite the low toxicological profile of *Pasteuria nishizawae* – Pn1, baseline personal protective equipment is required for handlers that may be exposed to the active ingredient for prolonged periods or numerous times. Handlers working with *Pasteuria nishizawae* – Pn1 in agricultural and/or commercial settings must wear a long-sleeved shirt, long pants, socks, shoes, and a dust/mist filtering respirator meeting National Institute for Occupational Safety and Health standards of at least N-95, R-95, or P-95. EPA may require additional PPE on a product-specific basis.

IV. Assessing Risks to the Environment

EPA performed an environmental risk assessment, based on data and other information (e.g., scientific literature) provided by the applicant, and determined that adverse effects to nontarget organisms are not anticipated from the proposed pesticidal uses of *Pasteuria nishizawae* – Pn1. Moreover, EPA made a "No Effect" determination for direct and indirect effects to listed species and their designated critical habitats resulting from these same proposed pesticidal uses.

V. Regulatory Information

On February 2, 2012, EPA registered the first pesticide products containing *Pasteuria nishizawae* – Pn1 as an active ingredient (Soyacyst Tech, EPA Reg. No. 85004-6; Soyacyst Tech+, EPA Reg. No. 85004-7; Soyacyst LF, EPA Reg. No. 85004-9). EPA also concluded that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Pasteuria nishizawae* – Pn1 and accordingly established a tolerance exemption (40 CFR § 180.1311).

VI. Registrant Information

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VII. Additional Contact Information

Communications and Registration Liaison Biopesticides and Pollution Prevention Division (7511P) Office of Pesticide Programs Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, D.C. 20460