# *Pasteuria* spp. (*Rotylenchulus reniformis* nematode) – Pr3 (016456) 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* spp. (*Rotylenchulus reniformis* nematode) – Pr3, Pasteuria Bioscience, Inc. proposed to register a manufacturing-use pesticide product, NAVIVA Tech, and two end-use pesticide products, NAVIVA ST and NAVIVA LF, containing this bacterium. NAVIVA ST and NAVIVA LF will be applied to several food and nonfood crops, primarily as seed or soil treatments, to control the reniform nematode. Use of *Pasteuria* spp. (*Rotylenchulus reniformis* nematode) – Pr3 as a nematicide and in accordance with label directions is not expected to cause any unreasonable adverse effects on human health or the environment.

## I. Description of the Active Ingredient

*Pasteuria* spp. (*Rotylenchulus reniformis* nematode) – Pr3 was isolated from soil samples collected in the southeastern United States. Endospores of *Pasteuria* spp. (*Rotylenchulus reniformis* nematode) – Pr3 attach to *Rotylenchulus* species nematodes at all life stages, except eggs. After an endospore attaches to the cuticle of a nematode host, a germ tube penetrates the cuticle, and growth and sporogenesis begin in the pseudocoelom of the nematode. The nematode is eventually filled with cells, mycelial hyphae, and sporangia, which leads to its death.

## II. Use Sites, Target Pests, and Application Methods

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| **Use Sites:** | Various food (e.g., soybean & lettuce) and nonfood (e.g., zinnia) crops |
| **Target Pests:** | Reniform nematode (*Rotylenchulus reniformis*) |
| **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* spp. (*Rotylenchulus reniformis* nematode) – Pr3's specificity for the reniform nematode, and the absence of occurrences of hypersensitivity incidents during testing and production of *Pasteuria* spp. (*Rotylenchulus reniformis* nematode) – Pr3, no human health risks are expected when pesticides products containing *Pasteuria* spp. (*Rotylenchulus reniformis* nematode) – Pr3 are used according to their respective label directions. Despite the low toxicological profile of *Pasteuria* spp. (*Rotylenchulus reniformis* nematode) – Pr3, 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* spp. (*Rotylenchulus reniformis* nematode) – Pr3 in agricultural and/or commercial settings must wear a long-sleeved shirt, long pants, waterproof gloves, 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. For future products, EPA may require additional PPE (e.g., protective eyewear), other than the standard described above, 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* spp. (*Rotylenchulus reniformis* nematode) – Pr3. 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 June 13, 2012, EPA registered the first pesticide products containing *Pasteuria* spp. (*Rotylenchulus reniformis* nematode) – Pr3 as an active ingredient (NAVIVA Tech, EPA Reg. No. 85004-4; NAVIVA ST, EPA Reg. No. 85004-5; NAVIVA LF, EPA Reg. No. 85004-8). 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* spp. (*Rotylenchulus reniformis* nematode) – Pr3 and accordingly established a tolerance exemption (40 CFR § 180.1316).

## VI. Registrant Information

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## VII. Additional Contact Information

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