

***Candida oleophila* Strain O (021010) Fact Sheet**

Summary

Candida oleophila Strain O is a naturally occurring yeast that is found on various food commodities and was specifically isolated from golden delicious apples. Acting as an active ingredient in the microbial end-use product, NEXY, it is applied to apples and pears after harvest—but before storage—to control particular fungal pathogens. Use of *Candida oleophila* Strain O as an indoor post-harvest biofungicide on apples and pears is not expected to cause any unreasonable adverse effects on human health or the environment.

I. Description of the Active Ingredient

Candida oleophila Strain O is a single-celled yeast found naturally on plant tissues (fruits, flowers, and wood) and in water. It was originally isolated from golden delicious apples and is intended for use as an antagonist to control the fungal pathogens, gray mold (*Botrytis cinerea*) and blue mold (*Penicillium expansum*), which cause post-harvest decay on apples and pears. The mode of action for *Candida oleophila* Strain O is primarily through competition for nutrients and pre-colonization of plant wound sites, although information provided to the Agency suggests that production of beta-1,3-glucanases (i.e., hydrolytic enzymes that can degrade fungal phytopathogen cell walls) may also make a restricted contribution to its antagonistic activity.

II. Use Sites, Target Pests, and Application Methods

- **Use Sites:** Indoor use on apples and pears only.

- **Target Pests:** For post-harvest control of gray mold (*Botrytis cinerea*) and blue mold (*Penicillium expansum*).

- **Application Methods:** After harvest and prior to storage, one application is made to apples and pears either by dip (between 30 seconds and 2 minutes in duration) or drench (at least 30 seconds in duration).

0.9 ounces of the end-use product, NEXY, is diluted in 20 gallons of water and combined with 5.4 ounces of the NEXY ADDITIVE, a non-pesticidal component packaged with NEXY.

One ton of apples or pears is treated by 2.4–7.3 gallons of mixture (i.e., NEXY, NEXY ADDITIVE, and water).

III. Assessing Risks to Human Health

Based on the required toxicity and pathogenicity tests, no human health risks are expected when the product containing *Candida oleophila* Strain O is used according to the label directions. Because respiratory hypersensitivity incidents were reported by workers not wearing personal protective equipment during production involving large amounts of *Candida oleophila* Strain O, the label requires that mixers and loaders of the end-use product wear a dust/mist filtering respirator meeting National Institute for Occupational Safety and Health (NIOSH) standards of at least N-95, R-95, or P-95. Mixers, loaders, applicators, and individuals handling crates containing treated apples and pears are also required to wear the following personal protective equipment as a precaution based on exposure potential and toxicity categories assigned to the end-use product: long-sleeved shirt, long pants, shoes, socks, waterproof gloves, and protective eyewear.

IV. Assessing Risks to the Environment

No risks to non-target organisms (to include federally listed endangered and threatened species) or to the environment are anticipated as a result of the intended indoor uses of *Candida oleophila* Strain O. If future uses include outdoor uses where exposures of non-target organisms would be increased, additional data and/or information must be submitted to and reviewed by the Environmental Protection Agency (EPA). The label restricts use of the product to indoors and warns end users not to contaminate water when cleaning application equipment or disposing of application equipment washwaters or rinsate.

V. Regulatory Information

December 28, 2007 – SynTech Global, LLC, acting as the United States authorized agent for BioNext sprl, submitted an application to register NEXY (EPA File Symbol 84863-R) under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and a petition to establish an exemption from the requirement of a tolerance for *Candida oleophila* Strain O under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

March 28, 2008 – The Environmental Protection Agency announced receipt of the NEXY application, requesting to register a pesticide product containing a new active ingredient, and the filing of the petition to establish an exemption from the requirement of a tolerance for residues of the microbial pesticide, *Candida oleophila* Strain O, on apples and pears when used as a post-harvest biofungicide.

May 13, 2009 – The Environmental Protection Agency established a permanent exemption from the requirement of a tolerance for residues of the microbial pesticide, *Candida oleophila* Strain O, on apples and pears when applied/used as a post-harvest biofungicide [40 Code of Federal Regulations (CFR) § 180.1289].

June 1, 2009 – Pursuant to FIFRA section 3(c)(5), an unconditional registration was issued for the end-use product, NEXY (EPA Registration Number 84863-1).

VI. Producer Information

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B-5030 Gembloux
BELGIUM

BioNext sprl's United States Authorized Agent:

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VII. Additional Contact Information

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