BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Yeast
PC Code 100054

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division

(Last updated May 26, 2009)

This document is for informational purposes only and is representative of the Agency's justification in registering products containing this active ingredient. This is not a legal document.

TABLE OF CONTENTS

BIOPESTICIDES REGISTRATION ACTION DOCUMENT TEAM

Office of Pesticide Programs:

Biopesticides and Pollution Prevention Division

Biochemical Pesticides Branch (BPB)

Branch Chief
Linda A. Hollis, M.S.

Health Effects/Nontarget Organisms
Clara Fuentes, PhD

Regulatory Action Leader
John Fournier, M.S.

I. EXECUTIVE SUMMARY:

Yeast (*Saccharomyces cerevisiae*), a new active ingredient, is one of the many single-celled eukaryotic microorganisms in the kingdom Fungi. *Saccharomyces cerevisiae*, commonly known as baker's or brewer's yeast, has been used in the baking of bread and brewing of wine, beer, and other alcoholic beverages for thousands of years. Yeast is ubiquitous in the environment, can be easily obtained at any grocery store, and is commonly found as an ingredient in many foods.

Yeast is commonly used as food or as a food ingredient and there is a vast field of data available to support the registration of products containing it. Acceptable waivers for mammalian toxicology data were submitted to Biopesticides and Pollution Prevention Division (BPPD) on yeast. Adequate data and justification for waivers were submitted to address the non-target data requirements. There is no reason to believe that yeast would have any adverse effects on non-target organisms, including beneficial insects or endangered species. Used as an attractant, it has a non-toxic mode of action, is naturally occurring in the environment, breaks down naturally, and is not expected to accumulate.

Guideline toxicity and non-target organism studies were not submitted in support of the registrant's application. In lieu of studies, the registrant requested data waivers from the requirements for all guideline studies and submitted a compendium of information sources – regarding the use of yeast in food products – in support of the data waivers. Therefore, the Agency believes that products containing yeast can be used without causing unreasonable adverse effects to humans or the environment.

Based on data and acceptable waivers submitted by the registrant, there is no reason to believe that any non-target organisms, including honeybees and other beneficial insects, would be attracted to or adversely affected by the use of yeast.

Based on the negligible risk concerns and a prior history of safe use as a food, yeast meets the criteria as specified in §3(c)(5) of FIFRA, as amended, and is thus eligible for unconditional registration. No additional data are needed.

II. ACTIVE INGREDIENT OVERVIEW

Common Name: Yeast

Chemical Names: Saccharomyces cerevisiae

Trade & Other Names: Baker's Yeast, Brewer's Yeast

CAS Registry Number: 68876-77-7

OPP Chemical Code: 100054

Type of Pesticide: Biochemical pesticide, attractant.

Application rates and methods vary depending on the product. For specific information regarding the product*(s)* refer to Appendix B.

III. REGULATORY BACKGROUND

On April 4, 2008, the Agency received an application from Bull Run Scientific, VBT to register yeast as an active ingredient in an end-use product (EP) containing 5.5% yeast. A notice of receipt of the application for registration for yeast as a new active ingredient was published in the Federal Register on March 11, 2009, with a 30 day comment period. No comments were received as a result of this publication.

A. Classification

Yeast is a known microbial organism and, as such, did not require classification by the Biochemical Classification Committee. Yeast has a non-toxic mode of action, naturally occurs in the environment, and there is a history of exposure to humans and the environment demonstrating minimal toxicity.

B. Food Clearances/Tolerances

Currently, this active ingredient is not registered for use on food or feed commodities. A tolerance or exemption from the requirement of a tolerance is not relevant.

IV. RISK ASSESSMENT

A. Active Ingredient Characterization

The new active ingredient, yeast, will be formulated as an EP for use as an attractant for filth flies. The technical grade active ingredient (TGAI) is a tan to pale beige colored powder that has a mild yeast odor.

The mode of action of yeast, when activated, is to produce odors that attract filth flies. As part of a water-soluble attractant insert in a disposable or re-useable trap, it draws filth flies into the apparatus where they are trapped.

The product chemistry data submitted by the registrant, including manufacturing process, discussion of formation of impurities, analysis of samples, and certified ingredients limits satisfied the requirement for product identity. Refer to Table 1 in Appendix A for a summary of product chemistry data requirements. Refer to Table 2 in Appendix A for the summary of physical and chemical characteristics for yeast.

All product chemistry data requirements for registration of yeast have been **satisfied.**

B. Human Health Assessment

1. Toxicology

For acute toxicity data requirements, toxicity categories are assigned based on the hazard(s) identified from studies and/or information on file with the Agency. The active ingredient is classified into Toxicity Category I, II, III or IV where Toxicity Category I indicates the highest toxicity and Toxicity Category IV indicates the lowest toxicity. For more information, refer to 40 CFR § 156.62.

Adequate mammalian toxicology data/information are available to support registration of yeast. All toxicology data requirements for yeast have been **satisfied.**

a. Acute Toxicity

Acute toxicity testing is required to 1) determine systemic toxicity from acute exposure via the dermal, inhalation and oral routes, 2) determine irritant effects from exposure to the eyes and 3) determine the potential for skin sensitization (allergic contact dermatitis). All required toxicology data for yeast are waived. No additional toxicological data are needed. The decision to waive these data is based on: 1) the product is naturally occurring, 2) possesses a non-toxic mode of action, 3) is commonly used as a food ingredient, and 4) due to the design of the trap, there is no anticipated exposure to the attractant pouch ingredients. For more information regarding the acute toxicity data requirements, refer to Table 3 in Appendix A.

b. Subchronic Toxicity

Subchronic data is required to determine a no-observed-effect-level (NOEL) and toxic effects (if any) associated with repeated or continuous exposure to a test substance for a period of 90 days. The request submitted by the registrant to waive subchronic mammalian toxicity data was determined to be acceptable. For more information regarding the subchronic data requirements, refer to Table 3 in Appendix A.

c. Developmental Toxicity and Mutagenicity

The Agency waived data requirements for developmental toxicity and mutagenicity of yeast based on 1) its long history of use as a food ingredient 2) its natural occurrence in the environment, and 3) little to no potential for exposure to humans based on the EP attractant packet and fly trap designs. For more information regarding these data requirements, refer to Table 3 in Appendix A.

e. Effects on the Endocrine System

EPA is required under the Federal Food, Drug, and Cosmetics Act (FFDCA), as amended by the Food Quality Protection Act (FQPA), to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, the Agency will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The Agency is not requiring information on the endocrine effects of yeast at this time. The Agency has considered, among other relevant factors, available information concerning whether the active ingredient may have an effect on humans similar to an effect produced by naturally-occurring estrogen or other endocrine effects. There is no known metabolite that acts as an endocrine disrupter produced by this active ingredient. Based on the low potential exposure level associated with the proposed use, the Agency expects no incremental adverse effects to the endocrine or immune systems.

2. Dose Response Assessment

No toxicological endpoints were identified; therefore, a dose response assessment was not required.

3. Drinking Water Exposure and Risk Characterization

Based on use patterns, no significant exposure is expected from use of yeast in the environment when used according to label instructions.

4. Occupational, Residential, School and Day Care Exposure and Risk Characterization

a. Occupational Exposure and Risk Characterization

Occupational exposures are not a concern based on the use pattern, low potential for exposure due to trap design, and because yeast is naturally occurring in the environment and possesses a non-toxic mode of action. The application method of yeast inside a water-soluble pouch that is placed within a trap poses no significant concern for dermal, eye, and inhalation exposures. Based on the non-toxicity of yeast, worker exposure data on yeast are not required. Based on the nature, use pattern, non-toxic mode of action, and relative safety of yeast, including the battery of information from the open scientific literature, the toxicity category has been characterized as IV

and the product label will bear the signal word "Caution." No reentry interval is required in conjunction with the use of the EP.

b. Residential, School and Day Care Exposure and Risk Characterization

The end use product containing yeast is intended for use in a residential or agricultural setting. Again, because trimethylamine is naturally occurring, possesses a non-toxic mode of action, and the trap design will result in low to no potential for exposure, the Agency is not concerned about the potential exposure to children.

5. Risk Characterization

The Agency has considered human exposure to yeast in light of the relevant safety factors in FIFRA. A determination has been made that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result from the use of yeast when label instructions are followed.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Hazards

Based on the common food-grade nature of yeast and the fact that yeast is not expected to cause adverse effects on non-target organisms, adequate rationales for waiving non-target toxicology data were submitted to support registration of yeast. All non-target toxicology data requirements for yeast have been **satisfied.**

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data was not triggered because results of the acute toxicity studies did not trigger any additional Tier I studies.

3. Ecological Exposure and Risk Characterization

The end use product, Bull Run Fly Attractant, is intended for residential use. When used according to the proposed label directions, no direct exposures are expected for non-target organisms. Moreover, the active ingredient is naturally occurring, has a non-toxic mode of action, and, as noted previously, is a documented food ingredient. Given these characteristics of yeast, non-target exposure and ecological effects studies were waived for the use of yeast in the fly trap.

4. Endangered Species Assessment

Adverse effects on threatened and endangered species are not expected based on available information about the use pattern of the product, product performance data, and habitat of Diptera species currently listed as threatened or endangered.

D. PRODUCT PERFORMANCE DATA (EFFICACY)

Submission of product performance data (OPPTS 810.3000) is listed as a requirement for all pesticide products. Customarily, the Agency requires efficacy data to be submitted for review only in connection with the registration of products directly pertaining to the mitigation of disease bearing human health organisms and certain designated quarantine pests, i.e., ticks, mosquitoes, fleas, Mediterranean fruit flies, gypsy moths, Japanese beetles, etc. For a list of organisms considered by the Agency as "public health pests", please refer to Pesticide Registration Notice 2002-1 (http://www.epa.gov/PR_Notices/pr2002-1.pdf).

Based on the data submitted by the registrant, the Agency determined that product performance data were acceptable.

V. Risk Management Decision

A. Determination of Eligibility for Registration

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The four criteria of the Eligibility Determination for Pesticidal Active Ingredients are satisfied by the science assessments supporting products containing yeast. Such products are not expected to cause unreasonable adverse effects, and are likely to provide protection as claimed when used according to label instructions. Therefore, yeast is eligible for registration for the labeled uses.

B. Regulatory Decision

The data submitted fulfill the requirements of registration for use as an ingredient in a water-soluble fly attractant packet inside an insect trap. Refer to Appendix B for product-specific information.

1. Conditional/Unconditional Registration

All data requirements are fulfilled and EPA has determined that unconditional registration of yeast is appropriate.

C. Environmental Justice

EPA seeks to achieve environmental justice - the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income - in the development, implementation, and enforcement of environmental laws, regulations, and policies. At this time EPA does not believe that use of pesticide products containing yeast will cause harm or a

disproportionate impact on at-risk communities.

For additional information regarding environmental justice issues, please visit EPA's website at: http://www.epa.gov/compliance/environmentaljustice/index.html.

VI. ACTIONS REQUIRED BY REGISTRANTS

The Agency evaluated all of the data submitted in connection with the initial registration of yeast and determined that these data are sufficient to satisfy current registration data requirements. No additional data are required to be submitted to the Agency at this time. For new uses and/or changes to existing uses, additional data may be required.

Not withstanding the information stated in the previous paragraph, it should be clearly understood that certain, specific, data are required to be reported to the Agency as a requirement for maintaining the Federal registration for a pesticide product. A brief summary of these types of data are listed below.

A. Reporting of Adverse Effects

Reports of all incidents of adverse effects to the environment must be submitted to the Agency under the provisions stated in FIFRA, Section 6(a)(2).

B. Reporting of Hypersensitivity Incidents

Additionally, all incidents of hypersensitivity (including both suspected and confirmed incidents) must be reported to the Agency under the provisions of 40 CFR Part 158.2050(d).

VII. Appendix A. Data Requirements (40 CFR Part 158-Subpart U)

*NOTE: MRID numbers listed in the following tables are representative of supporting data for the original registration of the product containing this active ingredient. Subsequent to this registration, there may be additional MRIDs that support registration of other products containing this active ingredient.

TABLE 1. Product Chemistry Data Requirements for Yeast (40 CFR § 158.2030)

OPPTS Guideline No.	Study	Results	MRID
830.1550 to 830.1670	Product identity; Manufacturing process; Discussion of formation of unintentional ingredients	Submitted data satisfy the requirements for product identity, manufacturing process, and discussion of formation of impurities.	473969-34
830.1700	Analysis of samples	Submitted data satisfy the requirements for analysis of samples.	473969-34
830.1750	Certification of limits	Limits listed in the CSF are adequate / acceptable.	473969-34
830.1800	Analytical method	Acceptable.	473969-34

TABLE 2. Physical and Chemical Properties of Yeast (40 CFR § 158.2030)

OPPTS Guideline No.	Property	Description of Result	MRID
830.6302	Color	tan to pale beige	473969-35
830.6303	Physical State	powder	473969-35
830.6304	Odor	mild yeast odor	473969-35
830.6313	Stability to Normal and Elevated Temperatures, Metals and Metal Ions	Stable for 2 years in unopened package stored at $\leq$ 75° F	473969-35
830.6315	Flammability	Not applicable	
830.6317	Storage Stability	Stable for 2 years in unopened package stored at $\leq$ 75° F	473969-35
830.6319	Miscibility	Not applicable	N/A
830.6320	Corrosion Characteristics	Not required for EP	N/A
830.7000	pH	6.4	473969-36
830.7050	UV/Visible Light Absorption	Not required for EP	N/A
830.7100	Viscosity	Not applicable	N/A
830.7200	Melting Point/Range	Not required for EP	N/A
830.7220	Boiling Point/Range	Not required for EP	N/A
830.7300	Density	0.7 g/cm^3	473969-36
830.7520	Particle Size, Fiber Length and Diameter Distribution	Not required for EP	N/A
830.7550 830.7560 830.7570	Partition Coefficient (n-Octanol/Water)	Not required for EP	N/A
830.7840	Water Solubility	Not required for EP	N/A
830.7950	Vapor Pressure	Not required for EP	N/A

Table 3. Human Toxicology Data Requirements for Yeast (40 CFR § 158.2050)			
Study/OPPTS Guideline No.	**Results**	**Toxicity Category/Description**	**MRID**
Acute oral toxicity (rat) (870.1100)	Waiver requested*	Acceptable	474060-01
Acute dermal toxicity (rat) (870.1200)	Waiver requested*	Acceptable	473696-11
Acute inhalation toxicity (rat) (870.1300)	Waiver requested*	Acceptable	473696-11
Primary eye irritation (rabbit) (870.2400)	Waiver requested*	Acceptable	473696-11
Primary dermal irritation (rabbit) (870.2500)	Waiver requested*	Acceptable	473696-11
Dermal sensitization (guinea pig) (870.2600)	Waiver requested*	Acceptable	473696-11
Hypersensitivity incidents (885.3400)	Waiver requested*	Acceptable	473969-38
90-Day oral toxicity (870.3100)	Waived due to lack of exposure	N/A	
90-Day dermal toxicity (870.3250)	Waived due to lack of exposure	N/A	
90-Day inhalation toxicity (870.3465)	Waived due to lack of exposure	N/A	
Mutagenicity (870.5100, 5300 and 5375)	Waived due to lack of exposure	N/A	
Developmental toxicity (870.3700)	Waived due to lack of exposure	N/A	

* Due to the fact that no significant human exposure is expected, the Agency did not require human health data on the Technical Grade Active Ingredient (TGAI). This is due to the fact that the active ingredient is enclosed in a water-soluble vapor barrier packet which is placed inside the fly trap, resulting in no exposure to the product handler. The Agency did, however, require data for the EP.

TABLE 4. Non-Target Organism Toxicity Requirements for Yeast (40 CFR § 158.2060)			
Study/OPPTS Guideline No. /MRID No.	**Results**	**Toxicity Category/Description**	**MRID**
Avian acute oral toxicity *Colinus virginianus* (850.2100)	Waived only for the proposed use pattern of the EP contained within a water-soluble vapor barrier packet inside the fly trap	Acceptable	473969-09
Avian dietary toxicity *Colinus virginianus* (850.2200)	Waived only for the proposed use pattern of the EP contained within a water-soluble vapor barrier packet inside the fly trap	Acceptable	473969-09
Avian dietary toxicity *Anas platyrhynchos* (850.2200)	Waived only for the proposed use pattern of the EP contained within a water-soluble vapor barrier packet inside the fly trap	Acceptable	473969-09
Aquatic invertebrate acute toxicity (*Daphnia magna*) (850.1010)	Waived only for the proposed use pattern of the EP contained within a water-soluble vapor barrier packet inside the fly trap	Acceptable	473969-09
Freshwater fish LC_{50} (*Oncorhynchus mykiss*) (850.1075)	Waived only for the proposed use pattern of the EP contained within a water-soluble vapor barrier packet inside the fly trap	Acceptable	473969-09
Non-target plant studies (850.4000-4800, as applicable)	Waived only for the proposed use pattern of the EP contained within a water-soluble vapor barrier packet inside the fly trap	Acceptable	473969-09
Non-target insect testing (880.4350)	The study, Product performance data indicated no evidence that the product attracts non-target insects.	Acceptable	473696-03

VIII. Appendix B.

For product specific information, please refer to http://www.epa.gov/pesticides/pestlabels/

IX. Appendix C.

REFERENCES

Mulla M.S., Hwang Yih-Shen, Loomis E.C., Axelrod H., 1978, Product of Putrefaction and Brewing Odors that Attract Synanthropic Flies. Proceedings and Papers of the Forty-sixth Annual Conference of the California Mosquito and Vector Control Association, Inc., pp. 70-73.

Mulla, M.S., Hwang Yih-Shen, Axelrod H., 1977, Attractants for Synanthropic Flies: Chemical Attractants for Domestic Flies. Journal of Economic Entomology Vol. 70, No. 5. pp. 644-648.

TOXNET, 2009. http://toxnet.nlm.nih.gov

Wikipedia, 2009. http://en.wikipedia.org/wiki/Yeast