BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Calcium Acetate

PC Code: 011470

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

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BIOPESTICIDES REGISTRATION ACTION DOCUMENT TEAM

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I. EXECUTIVE SUMMARY:

The biochemical active ingredient Calcium Acetate is the calcium salt of acetic acid. It is an odorless white powder. It is intended for non-food outdoor use to attract eight species of yellow jackets in traps.

EPA granted waivers for all Tier I human health toxicity data requirements due to the fact that no significant human exposure by any route is anticipated from use of the trap containing this active ingredient. EPA also waived most ecological effects data requirements. All data waiver rationales are predicted on little exposure potential. An adequate efficacy study was submitted that also supported the finding that nontarget organisms are not attracted to traps baited with the attractant, when used according to label directions..

The Agency considered human exposure to calcium acetate in light of the relevant safety factors in FQPA and FIFRA. A determination has been made that there are no unreasonable adverse effects to the U.S. population in general, and to infants and children. No significant exposure via drinking water is expected from the use of the yellow jacket attractant.

Based on the information discussed above, the Agency has determined that the registered use of calcium acetate as an active ingredient will have **No Adverse Effects (NAE)** on threatened and/or endangered species. Exposure to endangered or threatened species is not expected since this is an attractant for yellow jackets and does not attract other nontarget insect species.

On October 1, 2009, EPA announced a new policy to provide a more meaningful opportunity for the public to participate on major registration decisions before they occur. According to this new policy, EPA intends to provide a public comment period prior to making a registration decision for, at minimum, the following types of applications: new active ingredients, first food use, first outdoor use, and first residential use.

Consistent with the new policy of making registration actions more transparent, Calcium Acetate has undergone a 30 day comment period as a “new active ingredient” whose registration would result in a “first outdoor use” and a “first residential use.” During this process, no comments were received. Accordingly, the preliminary decision to register Calcium Acetate stands. The basis for the preliminary decision can be found in the risk assessment for Calcium Acetate, which is characterized in this BRAD. As discussed above, acute toxicity data for demonstrate that it is toxicity category IV. Calcium Acetate does not demonstrate subchronic or developmental toxicity, and it is not mutagenic or genotoxic. EPA has no concerns for any non-target organisms exposed to Calcium Acetate in accordance with approved label directions. EPA has not identified any toxic endpoints for non-target mammals, birds, plants, aquatic, or soil organisms. Nor or there concerns for any threatened and endangered species. Thus, given that Calcium Acetate has very low toxicity and presents little if any risk to non-target organisms, and efficacy data confirm its effectiveness against target pests, EPA concludes that it is in the best interests of the public and the environment to issue the registration for Calcium Acetate.

The Environmental Protection Agency (EPA) considered information submitted for granting registration under Section 3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and determined that the information submitted in support of Calcium Acetate yellow

jacket attractant adequately satisfy current data requirements (refer to 40 CFR Subpart U § 158.2000).

II. ACTIVE INGREDIENT OVERVIEW

Common Names: Calcium Acetate
Calcium Ethanoate
Acetate of lime

Chemical Names: Calcium Acetate

Trade & Other Names: Calcium Acetate

CAS Registry Number: 62-54-4

OPP Chemical Code: 011470

Type of Pesticide: Attractant

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

III. REGULATORY BACKGROUND

On June 16, 2007, the Agency received an application filed by Bull Run Scientific, VBT, 7400 Beaufont Springs Drive, Suite 300, Richmond, Virginia 23225-5519. Bull Run retained Cynthia Smith of Conn & Smith as their agent. Bull Run wishes to register the product Disposable Bull Run Yellow jacket Trap E containing the new biochemical active ingredient Calcium Acetate at 19.8%. A notice of receipt of this application was published in the Federal Register March 16, 2009 (74 FR 49). No comments were received following the publication of this notice. In addition, on December 15, 2009, EPA provided the opportunity for a 30-day comment period on the Agency's draft risk assessment and intention to register this pesticide product. EPA has not received any comment on this proposed action.

A. Classification

The Biochemical Classification Committee determined that Calcium Acetate is a biochemical pesticide due to its apparent non-toxic mode of action and natural occurrence in the environment.

B. Food Clearances/Tolerances

Currently, this active ingredient is not registered for use on food or feed commodities because applications are for non-food outdoor use. Therefore a tolerance or exemption from the requirement of a tolerance is not required.

IV. RISK ASSESSMENT

A. Active Ingredient Characterization

The new active ingredient calcium acetate will be formulated as an EP for use as an attractant for yellow jackets. The technical grade active ingredient (TGAI) is a white odorless powder.

Calcium acetate occurs naturally as the calcium salt of acetic acid, and has a non-toxic mode of action.

The descriptions of the product formulation and production process as well as the formation of impurities were examined by BPPD and found to be acceptable in meeting current guideline standards.

All product chemistry data requirements for registration of the new active ingredient Calcium Acetate have been satisfied.

Guideline Reference No./Property		Description of Result
830.6302	Color	White
830.6303	Physical State	Powder
830.6304	Odor	Odorless
830.6313	Stability	Stable **Not addressed for metals and metal ions**
830.6314	Oxidation/Reduction: Chemical Incompatibility	Not required for TGAI
830.6315	Flammability	Autoignition temperature = 680-730°C
830.6316	Explodability	Not required for TGAI
830.6317	Storage Stability	Not required for TGAI
830.6319	Miscibility	Not required for TGAI
830.6320	Corrosion Characteristics	Not required for TGAI
830.6321	Dielectric Breakdown Voltage	Not required for TGAI
830.7000	pH	7.2 ± 0.1 at 21°Cb
830.7100	Viscosity	Not applicable, the ingredient is a solid
830.7200	Melting Range	Decomposes to acetone at 160°C
830.7220	Boiling Range	Not applicable, the ingredient is a solid
830.7300	Density/Relative Density/Bulk Density	Approximately 30 lb/ft^3
830.7370	Dissociation Constant in Water	pKa = 4.76 at 25°C
830.7550	Partition Coefficient	Log Kow = -1.3774
830.7840	Water Solubility	400 g/L
830.7950	Vapor Pressure	0.00548 mm Hg

B. Human Health Assessment

1. Toxicology

No significant human exposure by any route is anticipated from use of this active ingredient because it is confined to a water soluble pouch inside the trap via the securely attached entrance structure. Therefore, based upon the relevant data and information, we conclude that the active ingredient is not likely to result in adverse human health effects. With regard to the Human Health Toxicity profile for Calcium Acetate, all toxicity data requirements have been waived by EPA.

a. Acute Toxicity

Data waiver rationales were granted by BPPD for all Tier I data requirements. This includes the Acute Oral Toxicity, Acute Dermal Toxicity, Acute Inhalation Toxicity, Acute Eye Irritation, Acute Dermal Irritation, Dermal Sensitization, Prenatal Developmental Toxicity, Bacterial Reverse Mutation Test, and the In Vitro Mammalian Cell Gene Mutagenicity. No additional toxicity data are required to support the nonfood use registration of this active ingredient.

b. Subchronic Toxicity

No subchronic toxicity data were submitted with this application for registration of this new active ingredient . No repeated human oral exposure is anticipated.

c. Developmental Toxicity and Mutaenicity

No developmental toxicity data were submitted with this application for registration because of little to no exposure, low toxicity, and the use pattern as a non-food use. In addition, Calcium Acetate is a naturally-occurring substance that is also approved for food-use by FDA under 40 CFR 184.1185. Also, The Agency considered human exposure to calcium acetate in light of the relevant safety factors in FIFRA. It is not expected that use of the product would result in significant human exposure when the product is used as directed. No unreasonable adverse effects are expected from exposure to this active ingredient when the product is used according to label instructions.

d. Chronic exposure and oncogenicity assessment

No chronic exposure and oncogenicity data were submitted with this application for registration because these data are not required.

e. Effects on the Endocrine System

EPA is in the process of issuing test orders for endocrine effects. The schedule for issuance of test orders, and details regarding status is available at http://www.epa.gov/endo/. EPA has also established a docket for the test orders in www.regulations.gov under docket number EPA-HQ-OPP-2009-0634.

Data required under the test orders will provide information to help EPA identify whether chemicals have the potential to interact with the estrogen, androgen, and/or thyroid hormone systems, which regulate growth, metabolism, development, and reproduction. The data generated from the screens will provide robust and systematic scientific information that will help EPA identify whether additional testing is necessary.

Calcium Acetate is a naturally occurring substance. To date, there is no evidence to suggest that our natural exposure to Calcium Acetate affects the immune system, functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor. Moreover, the use of Calcium Acetate is not expected to result in any significant exposures, effectively obviating any opportunity for negative effects on humans or the environment. Therefore, it is unlikely that Calcium Acetate will have estrogenic or endocrine effects.

2. Dose Response Assessment

A dose response assessment was not conducted because based on the proposed use of the product, human exposure is not expected.

3. Dietary Exposure and Risk Characterization

The active ingredient Calcium Acetate is intended for non-food uses. Accordingly, it is not expected to pose any direct dietary risk to humans.

With regard to any incidental exposure, all routes of exposure associated with the active ingredient's use as an attractant are negligible. Additionally, the active ingredient occurs naturally in fruit and is a well-recognized flavor agent in food additives. Its regular consumption in a human diet is not associated with any hazards. Finally, the acute toxicity information on file indicates that the risks associated with even incidental exposures would be negligible.

4. Drinking Water Exposure Risk Characterization

No significant drinking water exposure is expected from Calcium Acetate because of its contained in a water soluble pouch inside the trap.

5. Acute and Chronic Dietary Exposure and Risks for Sensitive Subpopulations, Particularly Infants and Children

Based on the non-food use pattern, the limited potential for even incidental exposure, and the dietary toxicity information discussed above, EPA concludes that there is a reasonable certainty that no harm will result to the United States population, including infants and children, from

aggregate exposure to any incidental residues of Calcium Acetate.

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

a. Occupational Exposure and Risk Characterization

There is little likelihood of occupational exposure via oral, dermal, or ocular routes due to the fact that the end product is in a trap. Inhalation exposure is minimal and not likely to occur at levels that would be toxic due to the low concentration of Calcium Acetate in the end-use product (19.8%).

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

No indoor residential uses are currently approved. No exposure is anticipated to children at school or day care facilities because the pesticide is enclosed in a water soluble pouch inside a trap.

7. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

The potential for aggregate exposure is expected to be insignificant. Calcium Acetate is not expected to be present in quantities greater than 2.466×10^{9} g/liter air/week, and limited only to those times when yellow jackets, hornets and wasps are active. Given a lack of acute toxicological endpoints for Calcium Acetate, the aggregate exposure scenario presents no significant concerns for risk.

8. Cumulative Effects

Calcium Acetate is intended for non-food uses as an attractant in a trap. No dietary exposures are expected. To the degree that there might be any incidental dietary exposure, Calcium Acetate does not share any known common mechanism of toxicity with other substances.

9. Risk Characterization

The Agency considered human exposure to Calcium Acetate in light of the relevant safety factors in FQPA and 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 the calcium acetate insecticide

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Hazards (Relative to the Biochemical Pesticides Nontarget Organisms and Environmental Fate Data Requirements- 40 CFR§158.2060)

Calcium Acetate is contained in a water soluble pouch in a trap. The user must cut open the trap entrance structure, add the appropriate amount of water to activate the attractant, and hang the trap. The trap is for a single use and is not designed to be reused or refilled. The used trap is disposed via trash collection. Efficacy data were submitted that demonstrated that nontarget organisms are not attracted to the Calcium Acetate trap. (MRID 47255003)

2. Environmental Fate and Ground Water Data

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

3. Ecological Exposure and Risk Characterization

The active ingredient is intended for formulation of end use products that are placed in insect traps for residential or agricultural use. When used according to the proposed label directions, no direct exposures are expected for nontarget organisms. Moreover, the active ingredient is used at a low concentration as an attractant, and is not expected to accumulate in the environment. Given these characteristics of Calcium Acetate, nontarget exposure and ecological effects studies were waived.

4. Threatened and Endangered Species Assessment

Based on the available data, a No Effects (NE) determination was made Calcium Acetate on threatened and endangered species when the product is used according to label use directions. Specifically, in MRID 47451404, efficacy testing showed no honeybees or other non-target insect species were attracted or caught by the Calcium Acetate product. Since the active ingredient in contained in a trap, there is no exposure to birds, fish, aquatic invertebrates, or other non-target organisms.

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).

A report on the efficacy of the product was submitted because the yellow jacket wasp is a public health pest. The study consisted of 7 field trials conducted on different dates and at different locations representing different habitats. Traps were emptied and rebaited periodically. Traps were rotated independently of replenishment, to avoid possible positional effects. Insects were collected for identification. Data was analyzed on mean number of insects per trap per day. Treatment means were compared to control means using a Paired t-Test with P set 0.05 significance level. Replicates with no recorded catch were omitted from the analyses. Data was summarized by average species caught per trap per treatment, and by average species per trap across all the treatment pooled together. The study results showed statistically significant difference between treatment and control traps in number of catches for all wasps.

V. Risk Management Decision

A. Determination of Eligibility for Registration

Section 3(c)(5) of FIFRA provides for the registration of a new active ingredient 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 the product containing Calcium Acetate. This product is not expected to cause unreasonable adverse effects and is likely to act as a yellow jacket attractant when used according to label instructions. Therefore, EPA concludes that Calcium Acetate is eligible for registration for the labeled uses.

B. Regulatory Decision

On October 1, 2009, EPA announced a new policy to provide a more meaningful opportunity for the public to comment on major registration decisions before they occur. According to this new policy, EPA intends to provide a public comment period prior to making a registration decision for, at minimum, the following types of applications: new active ingredients; first food use; first outdoor use; and first residential use. Accordingly, this pesticide was subject to a 30-day comment period as a new active ingredient with both outdoor uses and residential uses. No comments were received during that comment period.

At this time, EPA believes, the data submitted fulfill the requirements of registration for products containing Calcium Acetate for use to attract yellow jackets, wasps and hornets. Acute toxicity data for Calcium Acetate demonstrate that it is toxicity category IV for all routes of exposure. Calcium Acetate does not demonstrate subchronic or developmental toxicity, and it is not mutagenic or genotoxic. EPA has no concerns for any non-target organisms exposed to Calcium Acetate in accordance with approved label directions. EPA has not identified any toxic endpoints for non-target mammals, birds, plants, aquatic, or soil organisms. Nor are there concerns for any threatened and endangered species. Given the non-toxic character of Calcium Acetate, EPA supports its registration under Section 3(c) (5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Refer to Appendix B for product-specific information.

1. Conditional/Unconditional Registration

All data requirements are fulfilled and EPA has determined that an unconditional registration for Calcium Acetate is warranted under Section 3(C) (5) of FIFRA.

C. Labeling

Before releasing pesticide products containing Calcium Acetate for shipment, the applicant is required to provide appropriate labels.

D. 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. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to calcium acetate compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.

VI. ACTIONS REQUIRED BY REGISTRANTS

The Agency evaluated all of the data submitted in connection with the initial registration of Calcium Acetate 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.

Notwithstanding 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 2. Human Toxicology Data Requirements for Calcium Acetate (40 CFR § 158.2050)

Study Type, Species, OPPTS Guideline	Regulatory Decision	LD_{50}/LC_{50}/LOAEL/NOAEL Results	Toxicity Category	MRID Review Date
Acute Oral Toxicity, rat, OPPTS 870.1100	Acceptable Waiver	N/A	WAIVED	47451405

Acute Dermal Toxicity, rat, OPPTS 870.1200	Acceptable Waiver	N/A	WAIVED	47451405
Acute Inhalation Toxicity, rat, OPPTS 870.1300	Acceptable Waiver	N/A	WAIVED	47451405
Acute Eye Irritation, rabbit, OPPTS 870.2400	Acceptable Waiver	N/A	WAIVED	47451405
Acute Dermal Irritation, rabbit, OPPTS 870.2500	Acceptable Waiver	N/A	WAIVED	47451405
Dermal Sensitization OPPTS 870.2600	Acceptable Waiver	N/A	WAIVED	47451405
Prenatal Development OPPTS 870.3700	Acceptable Waiver	N/A	WAIVED	47451405
Reproductive Toxicity OPPTS 870.3800	Acceptable Waiver	N/A	WAIVED	47451405

Table 2. Human Toxicology Data Requirements for Calcium Acetate (40 CFR § 158.2050)

Study Type, Species, OPPTS Guideline	**Regulatory Decision**	**LD_{50}/LC_{50}/LOAEL/NOAEL Results**	**Toxicity Category**	**MRID Review Date**
Bacterial Reverse Mutation Test OPPTS 870.5100	Acceptable Waiver	N/A	WAIVED	47451405
In vitro Mammalian Cell Gene Mutation Assay OPPTS 870.5300	Acceptable Waiver	N/A	WAIVED	47451405
Acute Neurotoxicity OPPTS 870.6200	Acceptable Waiver	N/A	WAIVED	47451405

Table 3. Nontarget Organism, Fate and Expression Data Requirements for Calcium Acetate (40 CFR § 158.2060)		
Study/OPPTS Guideline No.	**Results**	MRID #(s)
Avian acute oral toxicity (850.2100)	Waived	47451404
Vegetative Vigor (850.4150)	Waived	47451404
Nontarget insect toxicity (Honey bee) (850.3020)	Waived	47451404
Aquatic Invertebrate Acute Toxicity (850.1010)	Waived	47451404
Seeding Emergence (850.4100)	Waived	47451404
Oyster Acute Toxicity (850.1025)	Waived	47451404
Fish Acute Toxicity, Freshwater (850.1075)	Waived	47451404
Daphnid Chronic Toxicity (850.1300)	Waived	47451404
Fish Early-Life Stage Toxicity (850.1400)	Waived	47451404
Avian Dietary Toxicity (850.2200)	Waived	47451404
Avian Reproduction (850.2300)	Waived	47451404
Aquatic Plant Toxicity (850.4400)	Waived	47451404
Algal Toxicity (850.5400)	Waived	47451404
Nontarget insect testing (850.4350)	Waived	47451404

VIII. GLOSSARY OF ACRONYMS AND ABBREVIATIONS

BPPD	Biopesticides and Pollution Prevention Division
BRAD	Biopesticide Registration Action Document
CFR	Code of Federal Regulations
cm^3	cubic centimeter
CSF	Confidential Statement of Formula
°C	degrees Celsius
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EPA	Environmental Protection Agency (the “Agency”)
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
FR	Federal Register
g	gram
kg	kilogram
L	liter

LD_{50}	median lethal dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, or inhalation). It is expressed as a weight of substance per unit weight of animal (e.g., mg/kg).
MRID No.	Master Record Identification Number
mg	milligram
mL	milliliter
MP	manufacturing-use product
MPCA	microbial pest control agent
NE	"No Effect"
NIOSH	National Institute for Occupational Safety and Health
OPP	Office of Pesticide Programs
OPPTS	Office of Prevention, Pesticides, and Toxic Substances
PCR	polymerase chain reaction
PPE	personal protective equipment
TGAI	technical grade of the active ingredient

IX. Appendix B.

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

X. Appendix C.

REFERENCES

MRID 47451401. Smith, C. June 13, 2008. Calcium Acetate: Product Identity, Composition and Analysis.

MRID 47451402. Smith, C. June 13, 2008. Calcium Acetate: Color, Physical, State, Odor, Stability, UV/Visible Lights Absorption, Melting Point, Density, Dissociation Constant, Partition Coefficient, Water Solubility and Vapor

MRID 47451403. Smith, C. June 13, 2008. Calcium Acetate: pH.

MRID 47451404. Smith, C. June 13, 2008. Calcium Acetate (TGAI) & Disposable Bull Run Yellow jacket Trap E. Environmental Fate & Effects on Non target organisms.

MRID 47451405. Smith, C. June 13, 2008. Calcium Acetate (TGAI) Mammalian Toxicology.