



**BIOPESTICIDES REGISTRATION ACTION DOCUMENT**

Z-7-Tetradecen-2-one  
PC Code 127600

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

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## I. EXECUTIVE SUMMARY:

Z-7-Tetradecen-2-one (Oriental beetle pheromone) is a new active ingredient. This active ingredient is an arthropod pheromone used to attract adult male and female Oriental beetles (*Anomala orientalis* and *Exomala orientalis*). The Oriental beetle pheromone is housed in a cartridge. BPPD 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 or disposal of the cartridge or trap containing this active ingredient. An adequate efficacy study was submitted which also supported the non-target insect toxicity data requirements that demonstrated nontarget organisms including honey bees are not attracted to this arthropod pheromone. BPPD granted waivers for all ecological effects data requirements. All of the data waivers are based on the fact that exposure is not expected.

The Agency considered human exposure to Oriental beetle pheromone 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 Oriental beetle pheromone.

Based on the information discussed above, the Agency has determined that registered use of Oriental beetle pheromone 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 a pheromone that only attracts Oriental beetles.

The Biopesticides and Pollution Prevention Division (BPPD) considered data submitted for granting registration under Section 3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and determined that the data/information submitted in support of Oriental beetle pheromone adequately satisfy current guideline requirements (refer to 40 CFR Subpart U § 158.2000).

## II. ACTIVE INGREDIENT OVERVIEW

**Common Name:** Oriental Beetle Trap Attractant

**Chemical Names:** Z-7-tetradecen-2-one

**Trade & Other Names:** Bull Run Japanese & Oriental Beetle Trap Attractant

**CAS Registry Number:** 146955-45-5

**OPP Chemical Code:** 127600

**Type of Pesticide:** Biochemical pesticide (Pheromone).

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

## III. REGULATORY BACKGROUND

On October 10, 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 Bull Run Japanese & Oriental Beetle Trap Attractant containing the new biochemical active ingredient Z-7-tetradecen-2-one at 0.034%. A notice of receipt of this application was published in the Federal Register September 5, 2008 (73 FR 173).

### A. Classification

Since Z-7-tetradecen-2-one is a pheromone no formal biochemical classification is needed. Pheromones are naturally biochemicals.

### B. Food Clearances/Tolerances

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

## IV. RISK ASSESSMENT

### A. Active Ingredient Characterization

Z-7-tetradecen-2-one (Oriental beetle pheromone) is a new active ingredient which is intended for use to control Oriental and Japanese beetles. It is an arthropod pheromone consisting of an unbranched aliphatic carbon chain with one double bond which ends in a ketone functional group. Z-7-tetradecen-2-one is a volatile chemical produced by these of beetles to communicate with other beetles of the same species in order to alter their behavior. (MRID #s 47255026; 47255027)

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 Z-7-tetradecen-2-one have been satisfied.

<b>Guideline Reference No./Property</b>	<b>Description of Result</b>	<b>Methods/Source</b>
830.6302 Color	Colorless to pale yellow	47255029
830.6303 Physical State	Liquid	47255029
830.6304 Odor	Pheromone	47255030
830.6313 Stability	Stable for > 3 years in a cool, dark well-ventilated area in a tightly sealed container under inert gas	47255031
830.6315 Flammability	Flash point 230°F (110°C)	47255029
830.7000 pH	Not applicable – TGAI is insoluble in water	N/A
830.7220 Boiling Range	281.24°C	47255032
830.7300 Density	1.00900 to 1.01700 g/cm <sup>3</sup> at 25°C	47255021
	1.01 g/ml at 25°C	47255020
830.7840 Water Solubility	Insoluble	47255032
830.7050 UV/Visible light absorption	Max at 278 nm under neutral conditions	47317405
830.7950 Vapor pressure	0.00882 mmHg at 25 <sup>0</sup> C	47255032

## **B. Human Health Assessment**

### **1. Toxicology**

Since no significant human exposure by any route is anticipated from use of this active ingredient because it is confined to a cartridge, the active ingredient is not likely to result in adverse human health effects based upon available reports and information.

With regard to the Human Health Toxicity profile for Oriental beetle pheromone, all toxicity data requirements have been waived by BPPD.

#### **a. Acute Toxicity**

Data waivers 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 because it is a pheromone trap, and these data are not required. No repeated human oral exposure is anticipated.

### **c. Developmental Toxicity and Mutagenicity**

No developmental toxicity data were submitted with this application for registration because of little to no exposure, low toxicity, and this is a non-food use. Also, The Agency considered human exposure to Oriental beetle pheromone 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 reasonable adverse effect is 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**

The US Environmental Protection Agency (Agency) is required under the Federal Food, Drug, and Cosmetics Act (FFDCA), as amended by Food Quality Protection Act, 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). Based on the weight of the evidence of available data, no endocrine system-related effects have been identified for Oriental beetle pheromone and none is expected since this pheromone does not share any structural similarity to any known endocrine disruptor.

## **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. Drinking Water Exposure and Risk Characterization**

No significant drinking water exposure is expected from Oriental beetle pheromone because of its contained in a cartridge.

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

#### **a. Occupational Exposure and Risk Characterization**

Occupational exposure is not expected due to the fact that the end use product is a pheromone trap. Additionally, the product is not inhalable; therefore inhalation exposure is not likely to occur.

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

No indoor residential uses are currently approved for the product containing Oriental beetle pheromone. No exposure is anticipated to children at school or day care facilities because the pheromone is enclosed in a cartridge.

### **5. Risk Characterization**

The Agency considered human exposure to Oriental and Japanese beetle pheromone 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 Oriental beetle pheromone.

## **C. ENVIRONMENTAL ASSESSMENT**

### **1. Ecological Hazards**

Oriental beetle pheromone is contained in a cartridge. After Oriental beetle pheromone has been placed in the cartridge at the manufacturing facility, the cap is attached and sealed with eight spot welds. It cannot be opened without the use of a tool. The cartridge is for a single use and is not designed to be reused or refilled. When the product is assembled in the field, the attractant cartridge is attached to the trap using a plastic-coated wire that is used to attach the trap to a support, such as a fencepost. The cartridge is anticipated to stay attached to the trap, and the trap to the support. Due to the product's use pattern and the fact that Oriental beetle pheromone is contained in a sealed cartridge throughout use and disposal of the product, exposure to birds, aquatic organisms and plants is not expected. Efficacy data were submitted which demonstrated that nontarget organisms are not attracted to the Oriental beetle pheromone. (MRID 47255003)

### **2. Environmental Fate and Ground Water Data**

BPPD granted waivers for all environmental fate data. Oriental beetle pheromone is enclosed in a sealed cartridge, and there is no exposure to groundwater.

### **3. Ecological Exposure and Risk Characterization**

Based on BPPD's decision to grant waivers as discussed above, exposure and risk from the proposed use of Oriental beetle pheromone are not expected for nontarget organisms including honey bees.

### **4. Endangered Species Assessment**

The use of this product as a pheromone should result in no exposure and "no effect" to terrestrial or aquatic endangered species.

## **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](http://www.epa.gov/PR_Notices/pr2002-1.pdf)).

A report on the efficacy of the product was submitted. The test was conducted in three locations where significant damage from Oriental and Japanese beetles had been observed in previous years. Each of three field sites contained 18 traps (six traps with freshly produced attractant, six traps with attractant that had been stored in its commercial packaging for one year, and six control traps containing no active ingredient). Traps were placed according to label instructions. Traps were examined after four to nine days. Only Oriental and Japanese beetles were found in the traps. No nontarget insects were collected by any of the 54 traps. Oriental beetle pheromone poses no risks to nontarget insects.

## **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 Oriental beetle pheromone. This product is not expected to cause unreasonable adverse effects and is likely to act an Oriental and Japanese beetle attractant when used according to label instructions. Therefore, Oriental beetle pheromone is eligible for registration for the labeled uses.

## **B. Regulatory Decision**

The data submitted fulfill the requirements of registration for use of Oriental beetle pheromone to control Oriental and Japanese beetles. Refer to Appendix B for product-specific information.

### **Conditional/Unconditional Registration**

All data requirements are fulfilled and EPA has determined that unconditional registration of Oriental beetle pheromone 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. 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 Oriental beetle pheromone 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 Oriental beetle pheromone 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.

<b>Table 2. Human Toxicology Data Requirements for Oriental beetle pheromone (40 CFR § 158.2050)</b>				
<b><u>Study Type, Species, OPPTS Guideline</u></b>	<b><u>Regulatory Decision</u></b>	<b><u>LD<sub>50</sub>/LC<sub>50</sub>/LOAEL/NOAEL Results</u></b>	<b><u>Toxicity Category</u></b>	<b><u>MRID Review Date</u></b>
Acute Oral Toxicity, rat, OPPTS 870.1100	Acceptable Waiver	N/A	WAIVED	47255034
Acute Dermal Toxicity, rat, OPPTS 870.1200	Acceptable Waiver	N/A	WAIVED	47255034
Acute Inhalation Toxicity, rat, OPPTS 870.1300	Acceptable Waiver	N/A	WAIVED	47255034
Acute Eye Irritation, rabbit, OPPTS 870.2400	Acceptable Waiver	N/A	WAIVED	47255034
Acute Dermal Irritation, rabbit, OPPTS 870.2500	Acceptable Waiver	N/A	WAIVED	47255034
Skin Sensitization, guinea pig, OPPTS 870.2600	Acceptable Waiver	N/A	WAIVED	47255034

Table 3. Nontarget Organism, Fate and Expression Data Requirements for Oriental beetle pheromone (40 CFR § 158.2060)		
Study/OPPTS Guideline No.	Results	MRID #(s)
Avian acute oral toxicity (850.2100)	Waived	47255033
Nontarget plant toxicity (850.4150)	Waived	47255033
Nontarget insect toxicity (Honey bee) (850.3020)	Waived	47255033
Freshwater fish (850.1010)	Waived	47255033
Freshwater acute toxicity (850.4100)	Waived	47255033

### VIII. Appendix B.

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

### IX. Appendix C.

#### REFERENCES

**MRID 47255003.** Smith, C. October 1, 2007. Bull Run Japanese Beetle Trap Attractant: Field Bioassays to Evaluate Storage Stability and Effects on Non-Target Organisms and Laboratory Evaluation of Corrosion Characteristics

**MRID 47255026.** Smith, C. October 10, 2007. Z-7-Tetradecen-2-one Technical: Product Identity and Composition and Composition, Description of Starting Materials and Manufacturing Process, and Discussion of Formation of Impurities

**MRID 47255027.** Zhang, A., Facundo, H.T., Robbins, P.S., *et al.* 1994 Identity and Synthesis of Female Sex Pheromone of Oriental Beetle, *Anomala orientalis* (Coleoptera: Scarabaedae)