BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Predator Urines:

Coyote Urine
(PC Code 029007)

Fox Urine
(PC Code 029008)

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

Predator urines, such as coyote and fox urine, are animal byproducts, considered naturally-occurring substances, and when used as a repellent have a "non-toxic" mode of action.

Coyote and fox urine are each a technical grade active ingredient (TGAI) which are to be used in the formulation of end-use products (EP) as repellents for various vertebrate animals. The specific component of predator urine which elicits the intended repellency response is unidentified, however, the main components of urine are water, urea, creatinine, sodium, potassium, chloride, phosphate, calcium, and magnesium.

Urine is commonly employed by certain vertebrate species as a part of animal behavior associated with indirectly asserting an animal's presence, such as in establishing a territorial area or in attracting members of the same species including potential mates. The scent of urine also allows competitors or potential prey species to respond by avoiding or at least in detecting the current or recent presence of the animal that has marked the area with their urine. This response to a specific scent associated with a species' urine is used by game hunters to mask the presence of the human scent. As such, masking human scent is not a pesticidal use. Trappers are also known to use coyote urine to attract coyotes to traps.

Based on the a review of data and information, including results of efficacy studies for the manufacturing processes designed to remove potential human health pathogens, the Agency has concluded that the registration of the non-food, end use products containing coyote and/or fox urine will pose no unreasonable adverse effects to humans or the environment.

II. Overview

A. ACTIVE INGREDIENT OVERVIEW

Common Name:	Coyote urine	Fox urine
Chemical Names:	Not applicable	Not applicable
CAS Registry Number:	None assigned	None assigned
OPP Chemical Code:	029007	029008
Basic Manufacturer:	Shake-Away 2330 Whitney Avenue Hamden, CT 06518	Shake-Away 2330 Whitney Avenue Hamden, CT 06518

B. USE PROFILE

Pesticide uses and application methods include the following:

Type of Pesticide: Biochemical pesticide; animal repellent

Use Sites: Residential gardens and yards (non-food)

Target Pests: repel armadillos, beavers, deer, domestic cats, elk, gophers, groundhogs, javalina (peccary or boar) and moles, possums, porcupines, rabbits, shrews, voles, and woodchucks

Formulation Type: Loose granules or granules inside a low density polyethylene (LDPE) bag

Method and Rates of Application: 1) Outdoors: loose granular formulations are shaken directly from the product container (bottle) along the ground, 2) Indoors: loose granular formulations are dispensed from the container onto a paper plate (with one paper plate placed to cover up to 80 square feet in attics, basements, garages, and sheds), and 3) the granular formulation in separate bags (called packs) are hung one pack for each 10 to 20 feet of the perimeter of the area to be protected.

Timing: Application of the loose granular formulation is made twice a week for the first two weeks and thereafter twice a month for maintenance and packs are replaced every 90 days.

Use Practice Limitations: Label instructions on formulations contained in packs state: "DO NOT OPEN OR DISPERSE CONTENTS."

C. ESTIMATED USAGE

Insufficient data are presently available since registered products have been in the market for a limited time.

D. DATA REQUIREMENTS

Data and/or accompanying information, submitted under Section 3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) in support of each predator urine registration have been reviewed by BPPD. Product Identity and analysis data as well as information in support of requests to waive testing requirements for both the toxicology and the non-target organisms and environmental fate data requirements set forth for the proposed use patterns. If label instructions are followed the Agency does not foresee any unreasonable adverse effects to humans and the environment from any of the uses of coyote or fox urine when used as directed by the product labeling.

E. REGULATORY HISTORY

1. Technical Grade Active Ingredients and Product Registrations

Shake Away submitted an application for the registration of an end use product (EP), EPA File Symbol 80917-R, containing the new active ingredient, coyote urine, on December 15, 2003. A notice of receipt of an application for registration of the EP containing coyote urine, was published in the Federal Register on December 15, 2004 (69 FR 75063) with a 30-day comment period. One comment was received following publication of the Federal Register notice (See 2. Dockets, Comments and Agency Responses). The primary issue raised to the Agency's attention is the potential for disease spread to both humans and domestic animals through wildlife urine. Supporting information was provided concerning potential contamination of predator urine products with microbial and viral pathogenic organisms. The Agency considered how the technical grade active ingredient (TGAI) was processed during manufacture and that the end-use product formulation is contained in a low density polyethylene (LDPE) bag. The pack (bag) reduces or eliminates the potential for exposure to any potential pathogenic organisms in the granules. The packs are sealed upon manufacture and not intended to be opened when distributed, marketed, in use, or when disposed after use.

Coyote urine is a new active ingredient for a pesticide formulation. The registered end-use product is intended as a non-food use, biochemical repellent against deer, elk, beavers, armadillos, javalina (peccary or boar) and domestic cats. A registration, under FIFRA 3(c)5, for this active ingredient was issued on March 31, 2005.

Additional applications submitted by Shake Away were for registration of two EPs, with EPA File Symbols 80917-U and EPA File Symbol 80917-L. Both products are loose granular

formulations containing fox urine. The receipt of an application for fox urine as a new active ingredient was published in the Federal Register on December 15, 2004 (69 FR 75063) with a 30-day comment period. Comments submitted to the docket and the Agency's response is described below (See 2. Dockets, Comments and Agency Responses). The Agency's approval of registrations of any predator urine product, as a loose granular formulation, is subject to review and approval of the manufacturing process that is designed to significantly reduce the presence of potential human health pathogens.

Fox urine is a new active ingredient for a pesticide formulation. The registered end-use products are intended as a non-food use, biochemical repellent against armadillos, beavers, deer, domestic cats, elk, gophers, groundhogs, javalina (peccary or boar) and moles, possums, porcupines, rabbits, shrews, voles, and woodchucks. A registration , under FIFRA 3(c)5, for this active ingredient was issued on December 11, 2007.

2. Dockets, Comments and Agency Responses

Two Federal Register Notices announced receipt of two different applications for the registration of coyote urine as a new active ingredient (Federal Register: December 15, 2004 (69 FR 75063) and June 22, 2005 (70 FR 36153) each with a 30-day comment period. Corresponding dockets were opened with the docket numbers: OPP-2004-0389 and OPP-2005-0130. One comment was submitted to the first docket on behalf of the State of Iowa Department of Agriculture & Land Stewardship. This comment was accompanied by an attachment with scientific information from published literature on the potential for leptospirosis in urine. One of the sources supplied to the Agency states: "Leptospira are transmitted in the urine of chronically infected carrier animals."

To address the potential for the presence of any human health pathogens, viral or bacterial, in predator urines for use as TGAIs in pesticide products, the Agency requested sufficient information in the form of a laboratory protocol, data from laboratory studies, and the development of a manufacturing process that includes quality control and quality assurance (QA/QC) testing methods to significantly reduce the presence of viral or bacterial contaminants. These measures are especially important for the potential registration of liquid, powder, or granular formulations. Initially, only granular formulations, contained in a LDPE pack or as a loose granular formulation have been registered as end use products. Exposure to the loose granules is mitigated when contained inside an LDPE pack. Use of the QA/QC measures reviewed and approved by the Agency to reduce the potential for exposure to pathogens when products are registered for sale as loose granular formulations.

Comments were submitted to the second docket (OPP-2005-0130) by members of People for the Ethical Treatment of Animals (PETA), expressing concerns for potential inhumane treatment of the animals used as a source of the predator urine TGAI. A letter, dated July 9, 2005, from PETA, indicated that PETA supports "EPA's efforts, through the Office of Pesticide Program's (OPP) Biopesticides and Pollution Prevention Division (BPPD), to promote less hazardous and more ecologically sustainable alternatives to conventional pesticidal agents." Overall, PETA's main concern was an ethical issue related to the promotion of fur farms and trapping. This point was made in reference to some uses for predator urine (non-pesticidal) products which include

attracting the same animal species during hunting and trapping purposes. The docket received numerous comments containing similar concerns regarding use of animals for fur farms, hunting, trapping, animal testing and humane treatment of the animals used for urine collection. About 95 electronic mail messages were received by the docket.

In response to docket comments and to PETA's letter, BPPD met with PETA's Director of Science Policy. The Agency conveyed information to PETA concerning the manufacturer's ranch operations and the animals' sole use as the source of the predator urine TGAIs. Information provided to BPPD indicates coyotes and foxes are born, raised, and cared for, from birth to death, on the manufacturer's ranch and are not part of a fur farming practice. The animals are given veterinary care and housed only for the purpose of urine collection. The animals live in a contained environment, are neither wild not are trapped, and have no contact with wild animals. In addition to the manufacturing QA/QC measures required by the Agency, as described above, the Agency also requires that the ranch operators rabies vaccinate the animals at 12 to 16 weeks, receive a booster at three years of age, and thereafter boosters are given at three year intervals. The manufacturer of the TGAI predator urines maintains records for the life each animal and these records are to be made available to the Agency upon request. Any disease incidents are to be reported to the Agency under FIFRA 6(a)(2).

To access materials in the electronic docket referenced above: go to http://www.regulations.gov and under "Search" type the docket number EPA-HQ-OPP-2004-0389 or EPA-HQ-OPP-2005-0130 into the entry field, and then click on "Go>>."

F. CLASSIFICATION

On July 8, 2002, the Biochemical Classification Committee determined that predator urines can be classified as a biochemical pesticide due to their non-toxic mode of action as a repellent. The Committee recommended that all registrants be required to demonstrate that their product(s) derived from predator urine(s) are free of microbial and viral pathogens.

G. FOOD CLEARANCES/TOLERANCES

This end-use product registration is for non-food use and no food clearances or tolerances are required due to the non-food status of the current registered uses.

III. Science Assessment

A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for registration of predator urine end use products are satisfied.

1. Product Identity and Mode of Action

a. Product Identity

The end-use products contain coyote urine (from 3.5 to 5%) and/or fox urine (from 1.5 to 5%) as their active ingredient(s). Coyote and fox urine are a yellow liquid with an ammonia-like scent. Urine is collected from domesticated coyotes (*Canis latrans*) and foxes (*Vulpes fulva*) raised in enclosed areas on a ranch. The major urine constituents are water (95%), urea, creatinine, sodium, calcium, phosphate, chloride, potassium and magnesium.

The description of the product's production process and the formation of impurities were examined by the Agency and are acceptable to meet current guideline standards. A preliminary analysis of coyote urine was conducted using five batches of the technical grade active ingredient (TGAI) and was determined to be acceptable. The analytical results are used for quality control and quality assurance. The analytical method is a high performance liquid chromatography (HPLC) method that involves quantitation (that is, determining the presence and size) of a specific marker peak on a chromatogram. A specific link between the chosen marker peak and the product's animal repellency is as yet undetermined. The peak's consistent presence (at a given elution time and with a relative peak height) on chromatograms generated by product analyses provides a measure for relative consistency in the product when manufactured over time, from batch to batch.

The description above for coyote urine, as a TGAI, is likewise applicable to fox urine as a pesticide product TGAI.

b. Mode of Action

Predator urine end products are intended for use as animal repellents. The urine in each respective product formulation emits a scent that is associated with the presence of a coyote, fox, or both animal species which in turn mimics the presence of a coyote or fox in the area where the product is used. Target pests that detect the scent avoid the area where the product is placed.

2. Physical and Chemical Properties Assessment

The physical and chemical characteristics, for each predator urine, were submitted to support the registration of each end use product. The product chemistry requirements are summarized in Table 1. The physical and chemical properties of the technical grade active ingredient (TGAI)

and end-use product (EP), as applicable to Shake Away® end use products, are summarized in Table 2.

TABLE 1. Product Chemistry Data Requirements (40 CFR 158.2030)			
OPPTS GUIDELINE NO.	**STUDY**	**RESULTS**	**MRID NO.**
830.1550 to 830.1670	Product identity; Manufacturing process; Discussion of formation of unintentional ingredients	Submitted data satisfies the data requirements for product identity, manufacturing process, and discussion of formation of impurities	46312001
830.1700	Preliminary Analysis	Submitted data satisfy the data requirements for analysis of samples	46164701 46312001
830.1750	Certification of limits	Limits listed in the CSF are adequate / Acceptable	46312001
830.1800	Analytical Method	Acceptable	46164702 46312001

TABLE 2. Physical and Chemical Properties for TGAI (coyote and fox urines) and Shake Away® End Use Products (40 CFR 158.2030)	
OPPTS Guideline Reference No./Property	**Description of Result TGAI/EP[a]**
830.6302 Color	Yellow / White
830.6303 Physical State	Liquid / Granules
830.6304 Odor	Ammonia-like / Ammonia-like
830.6313 Stability	Stable when stored in sealed containers at ambient temperature / Not required for EP
830.6314 Oxidation/Reduction: Chemical incompatibility	TGAI and EP do not contain oxidizing or reducing agents
830.6315 Flammability	TGAI and EP do not contain combustible liquids
830.6316 Explodability	TGAI and EP are not potentially explosive and do not have explosion characteristics
830.6317 Storage Stability	Not required for TGAI / Storage stability assessed by scent detection of five samples every three months for a 12-month period of time
830.6319 Miscibility	Not required for TGAI / Product is not an emulsifiable liquid and is not to be diluted with petroleum solvents
830.6320 Corrosion Characteristics	Not required for TGAI / Corrosion characteristics assessed by visual inspection of the packaging material at each test period of the storage stability study
830.6321 Dielectric Breakdown Voltage	Not required for TGAI / Product is not a liquid and is not intended for use around electrical equipment

TABLE 2. Physical and Chemical Properties for TGAI (coyote and fox urines) and Shake Away® End Use Products (40 CFR 158.2030)	
OPPTS Guideline Reference No./Property	**Description of Result TGAI/EP[a]**
830.7000 pH	9.5-10.1 / Product is a solid and is not dispersible in water
830.7050 UV/Visible	Not applicable: photochemical degredation of the TGAI is not expected when used for manufacturing / Not required for EP
830.7100 Viscosity	1 centipoises at 25°C / Not required for EP: product is not a liquid
830.7200 Melting Range	Not required for TGAI: TGAI is a liquid / Not required for EP
830.7220 Boiling Range	100°C at 1 atm / Not required for EP
830.7300 Bulk Density/Specific Gravity	1.015-1.045 / 2.5-2.75 lb/ft3 at 25°C; 2.7 -2.75 lb/gal
830.7370 Dissociation Constant in Water	TGAI is not ionic and is used for manufacturing only / Not required for EP
830.7520 Particle Size/Distribution	Not available
830.7550 Partition Coefficient	Not available
830.7840 Water Solubility	Not available
830.7950 Vapor Pressure	23.756 mm Hg at 25°C at 1 atm

[a] Data from MRID 46312001 and 46591303.

B. HUMAN HEALTH ASSESSMENT

Data requirements for mammalian toxicity, to support the registration applications for the predator urine products, are satisfied by submission of information with appropriate rationales to justify granting requests for waivers from the requirement of guideline studies. The Agency determined that each of the biochemical pesticide products' use patterns qualifies as a non-food use.

1. Toxicology Assessment

Adequate mammalian toxicology data are available to support registration of each of the end use products containing the predator urine active ingredients. No additional toxicological data are required at this time.

a. Acute Toxicity

Acute toxicity waiver request rationales are summarized below. Each predator urine end use product is in Toxicity Category IV for acute oral, acute dermal, and acute inhalation toxicity and for primary eye and primary dermal irritation, and is not a dermal sensitizer. Based on the Agency's review of the information, rationale, submitted literature, and potential for exposure discussed in detail in this section of the BRAD, no additional toxicity data are required to support the non-food uses of these biochemical TGAIs.

Adequate waiver request rationales were presented in MRIDs 46311602 and 46622401 (see Appendix B: References for MRID volume titles) for all Tier I toxicity data requirements (40 CFR 158.690(c)). Mammalian carnivore urine chemical constituents are primarily the same and can vary depending on various factors including age, diet, and health. The major constituents include water, urea, potassium, chloride and sodium. (Ganong, 2003). A study discussing an analysis of urinary components of Alaskan sled dogs (Hinchcliff, 1997) was compared to an analysis of the technical grade active ingredient performed by the College of Veterinary Medicine of Cornell University (MRID 46311602). The urines were very similar in composition, containing the same constituents with the exception of the coyote urine, which contained magnesium, which was not mentioned in the Hinchcliff study. Coyote urine osmolality was approximately ten percent that of the dog urine. Consequently the coyote urine was more dilute, containing less solutes than the dog urine. Urine is ubiquitous in nature, and all of the identified components naturally occur in the environment. Urea is on the Agency's list of ingredients of minimal concern – Inert Ingredients Eligible for FIFRA 25(b) Pesticide Products.

Exposure to the active ingredient is not likely when granules are contained in a LDPE bag during storage, use and disposal. End products sold as loose granular formulations without the LDPE pack, are granted a registration only for formulations that are manufactured with a TGAI(s) that have been processed to significantly reduce the presence of potential human health pathogens.

b. Mutagenicity and Developmental Toxicity

Requested waivers of the mammalian mutagenicity and teratogenicity data requirements were granted by the Agency because of the low toxicity of the active ingredients and intermittent and low exposure. The components of the technical grade active ingredient are not structurally related to any known mutagen or belong to any chemical class of compounds containing known mutagens.

c. Subchronic Toxicity and Immunotoxicity

Waivers requested for the subchronic and immunotoxicity study requirements were granted by the Agency because of the low toxicity of the active ingredients and intermittent to low exposure. The subchronic studies (90-day feeding (OPPTS 870.3100), 90-day dermal (OPPTS 870.3250), and 90-day inhalation (OPPTS 870.3465)) are not required.

d. Chronic Exposure and Oncogenicity Assessment

Repeated dose studies are conditionally required if the potential for adverse chronic effects are indicated based on: 1) the subchronic effect levels established in Tier I subchronic oral, inhalation, or dermal studies, 2) the pesticide use pattern, or 3) the frequency and the level of repeated human exposure that is expected. Oncogenicity studies are required only if the active ingredient or any of its metabolites, degradation products, or impurities produces in Tier I studies a morphologic effects in any organ that potentially could lead to neoplastic changes. None of the submitted information triggered the need for chronic exposure or oncogenicity testing.

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."

Endocrine system-related effects from use of coyote or fox urine are not expected: 1) due to the containment of the formulation inside of the product's packaging, when in a 'product pack,' and thus reducing the potential for exposure, and 2) coyote urine is not a known endocrine disruptor nor is it, or any of its components, related to any known endocrine disruptors.

f. Elimination of Microorganisms

Exposure to the end-use product's granules, containing coyote or fox urine, when contained inside of the sealed LDPE bag (product pack) is not likely. The manufacturer is required to demonstrate that manufacturing methods are sufficient in eliminating potential human health pathogens significantly below the threshold that would be of concern to the Agency. Based on the manufacturing process data reviewed by BPPD, there are no concerns at this time with regard to

human health pathogens and therefore, the Agency believes that there is little to no human health risk due to exposure to the end use product.

The manufacturing process and associated quality control and quality assurance methods to be used in routine manufacturing operations was reviewed and approved by BPPD (MRIDs 46591302, 46727201, 46727202, 46997102, 47016101, 47075901, 47075902, 47075903, and 47091401) and is considered to be confidential business information. Records are to be maintained for routine QA/QC testing during batch manufacturing of the predator urine TGAIs and these records are to be made available to EPA upon request.

2. Dose Response Assessment

No toxicological endpoints were identified. A dose response assessment is not required.

3. Dietary Exposure and Risk Characterization

There will be no dietary exposure when end use products are used according to label directions.

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

a. Occupational Exposure and Risk Characterization

The end use products are intended for residential use only. No occupational exposures are expected for the registered product.

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

The end use products containing predator urines are intended for use in a residential setting. Because the active ingredients are naturally occurring, possess a non-toxic mode of action, and are processed to significantly reduce the presence of potential human health pathogens, the Agency is not concerned about the potential exposure to children when the end-use product is used according to label directions.

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

Drinking water exposure will not occur if the end-use product is used according to label instructions.

6. Risk Characterization

The Agency considered human exposure to predator urines 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 predator urine end use products when label instructions are followed.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment

To satisfy the data requirements at 40 CFR 158.2060, the registrant submitted waiver requests supported by information presented in MRIDs 46311602 and 46622401. This information is similar to what was submitted as part of the rationale for waiving the mammalian toxicity requirements.

Adequate data waiver requests and supporting rationales were presented for all Tier I ecotoxicity data requirements (40 CFR 158.690(b). A study discussing an analysis of urinary components of Alaskan sled dogs (Hinchcliff, 1997) was compared to an analysis of the technical grade active ingredient as performed by the College of Veterinary Medicine of Cornell University (MRID 46311602). The urines were very similar in composition, containing the same constituents with the exception of the coyote urine, which contained magnesium, which was not mentioned in the Hinchcliff study. Coyote urine osmolality was approximately ten percent that of the dog urine. Consequently the coyote urine was more dilute, containing less solute than the dog urine. Urine is ubiquitous in nature and all of the identified components naturally occur in the environment. Urea is on the Agency's listof ingredients of minimal concern – Inert Ingredients Eligible for FIFRA 25(b) Pesticide Products.

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data was not triggered. Risk to non-target species is minimal due to the precautions taken during manufacturing to reduce the presence of viral and bacterial pathogens, the end product use pattern, application methods, and lack of toxicity.

3. Ecological Exposure and Risk Characterization

The potential for risk to non-target wildlife is unlikely because the active ingredients are naturally occurring, possess a non-toxic mode of action, and are processed to significantly reduce the presence of potential pathogens. However, it is noted that coyotes or foxes might be attracted to areas where the product is used.

D. EFFICACY DATA

Efficacy data were not submitted and are not required.

IV. 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 Biopesticides and Pollution Prevention Division (BPPD) risk management decision regarding the registration of predator urines is based on each TGAI: A) is naturally occurring, B) is applied for "non-food uses and is used in the end-use product does not require a tolerance, C) is not likely to be toxic to mammals or the environment when used according to label instructions, and D) exposure to the product formulation is unlikely due to the design of the end-use product when contained in a product pack or the TGAI is processed to remove potential human health pathogens in end use products with loose granular formulations. Therefore, predator urines are eligible for registration.

B. REGULATORY POSITION

1. Unconditional Registration

All of the data requirements are fulfilled and EPA granted a registration, under FIFRA 3(c)5, for each of the active ingredients: coyote and fox urine.

Tolerance Establishment

The uses of predator urines are determined to be "non-food" uses and therefore do not require the establishment of a food tolerance or an exemption from the requirements of a tolerance.

2. CODEX Harmonization

Not applicable because all of the uses have been determined to be non-food.

3. Nonfood Registrations

There are no issues at this time.

4. Risk Mitigation

There are no significant risk issues identified for dietary risk, residential risk, or ground and surface water contamination.

5. Endangered Species Statement

Based on the information discussed above, the Agency has determined that end-use products containing coyote urine (from 3.5 to 5%) and/or fox urine (from 1.5 to 5%) as their active ingredient(s), will **Not Adversely Affect (NAA)** threatened and/or endangered species. When a product is used according to label use directions, there are no concerns for any non-target organisms. The product acts as a repellent to most mammalian species, does not affect insects or plants, is not used on aquatic sites, and is only attractive to other coyotes and other canine species.

C. LABELING RATIONALE

The Agency's position is that the labeling for the Shake Away® end use products, containing coyote or fox urine as the active ingredient(s), complies with current pesticide labeling requirements imposed under FIFRA and 40 CFR ' 156.10.

1. Human Health Hazard

a. Worker Protection Standard

The end use products do not come under the provisions of the Worker Protection Standards (WPS).

b. Non-Worker Protection Standard

There are no non-worker (non-mixer/loader/applicator) human health hazard issues.

c. Precautionary Labeling

The Agency has examined the toxicological data base for coyote or fox urine and concludes that the precautionary labeling (i.e., Signal Word, First Aid statement, and other label statements) listed on the label (See Appendix A - Product Label) adequately mitigate the risks associated with the currently registered uses.

d. Spray Drift Advisory

No spray drift advisory statement is necessary for this use pattern.

2. Environmental Hazards Labeling

For terrestrial uses: Do not apply directly to water. Do not contaminate water when disposing of equipment washwater or rinsate.

3. Application Rate

The end-use product, in LDPE packs, comes with twist ties and four packs in the end-use product retail package. Each pack is hung every 10 to 20 feet around the area, such as a garden or yard, to be protected by the repellent product. The label instructs the user to suspend each pack approximately 2 to 4 feet above the ground. For continued use, the packs are to be replaced every 90 days.

Loose granular products are sold in plastic "shaker" bottles used to directly apply the loose granular formulation from the bottle. Granules are dispensed in a 'line' along the ground at the perimeter of the areas to be protected.

D. LABELING

The label language requirements listed below apply to the named product. Other label language requirements may apply on a product-by-product basis. A list of other registered end use products appears in Table 3.

Product name: **Shake Away® Deer Repellent Granules**

Active Ingredient:

Coyote Urine.....5.0%

Other Ingredients.....95.0%

Total 100.00%

Signal word is "CAUTION".

The product shall contain the following information:

- Product Name
- Ingredient Statement
- Registration Number
- Signal Word (CAUTION)

Similar labeling requirements apply to the other currently registered end use products (see table listing below).

Table 3: Registered End Use Products Containing Predator Urine as Active Ingredient		
EPA Registration Number	Product Name	Company
80917-4	Shake Away® Critter Repellent Granules	Shake Away
80917-5	Shake Away® All Purpose Repellent Granules	Shake Away

Images of the labels for products referred to in Table 3 are available for viewing by use of the EPA online Pesticide Product Label System (http://oaspub.epa.gov/pestlab/ppls.home)

V. Actions Required by Registrants

There are no data requirements, label changes or other responses necessary for the reregistration of the end-use product since the product is being registered after November 1984 and is, therefore, not subject to reregistration. There are also no existing stocks provisions at this time.

The Agency evaluated all of the data submitted in connection the initial registration of coyote urine and determined that these data are sufficient to satisfy current registration guideline requirements. Therefore, the product, Shake Away® Deer Repellent Granules, EPA Registration Number 80917-1, is eligible for registration. No additional data are required to be submitted to the Agency at this time.

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 humans or domestic animals (including both suspected and confirmed incidents) 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 158.690(c), guideline reference number 152-16.

VI. Appendix A

Table 5 lists the use sites for the product. The label for the product is also attached (see **Appendix B)**.

Table 4. Use Sites	
Shake Away Deer Repellent Granules Residential: gardens and yards	**Official date registered:**

Label Language Requirements

The following labeling language as listed below is required for Federal registration.

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals. Caution. Harmful if swallowed. Avoid contact with mouth, skin, or eyes. Wash hands before eating, drinking, chewing gum, using tobacco, or using bathroom facilities.

Environmental Hazards: For terrestrial uses: Do not apply directly to water. Do not contaminate water when disposing of equipment washwater or rinsate.

FIRST AID:

If inhaled:
Call a poison control center or doctor for further treatment advice.
Have person sip a glass of water if able to swallow.
Do not induce vomiting unless told to do so by the poison control center or doctor.
Do not give anything by mouth to an unconscious person.

If on skin or clothing
Take off contaminated clothing.
Rinse skin immediately with plenty of water for 15-20 minutes.
Call a poison control center or doctor for treatment advice.

If in eyes:
Hold eye open and rinse slowly and gently with water for 15-20 minutes.
Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
Call a poison control center or doctor for treatment advice.

The following statement must accompany the First Aid text block: "Have the product container or label with you when calling a poison control center or doctor, or going for treatment." The

Appendix B

REFERENCES

General References

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References Related to Potential Human Health Pathogens

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Agency guidance also suggests including a contact telephone number for additional emergency medical treatment information.

Use Directions:

The Directions for Use pertaining to hanging the end-use product packs states the following:

"DO NOT OPEN PACKS OR DISPERSE CONTENTS."

Study Information Submitted For Product Registrations for Shake-Away

MRID	Study Title
46164700	Shake Away (2003) Submission of Product Chemistry Data in Support of the Application for Registrations of SA Deer Repellent Granules, SA Deer Repellent 90-Day Packs, SA Cat Deterrent Granules, SA Small Critter Granules, SA Rodent Repellent Granules, SA Squirrel Repellent 90-Day Packs and SA All Purpose Repellent Granules. Transmittal of 2 Studies.
46164701	Askins, C. (2003) Predator Urine Active Ingredient Characterization HPLC Fingerprint: Project Number: 0313110, SAMPLE/PREDATOR, SA2003/01. Unpublished study prepared by Life Sciences Labs., Inc. 55 p.
46164702	Askins, C. (2003) Active Ingredient - Shake-Away Products, HPLC Fingerprint Analytical & Enforcement Methods. Project Number: 314823, SA2003/02, SAMPLE/PREDATOR/LIQ. Unpublished study prepared by Life Sciences Labs Inc. 36 p.
46221600	Shake-Away (2004) Submission of Product Chemistry Data in Support of the Applications for Registrations of Deer Repellent Granules, Deer Repellent 90-Day Packs, Cat Deterrent Granules, Small Critter Granules, Rodent Repellent Granules, Squirrel Repellent 90-Day Packs, and All Purpose Repellent Granules. Transmittal of 1 Study.
46221601	Askins, C. (2003) 30 Day Product Stability & Container Corrosivity Study: Shake Away Animal Repellent Products. Project Number: 314823, 316070. Unpublished study prepared by Life Sciences Laboratories, Inc. 54 p.
46311600	Shake Away (2004) Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Shake-Away Critter Repellent Granules. Transmittal of 2 Studies.
46311601	Roberts, A. (2004) Product Chemistry for Shake-Away Critter Repellent Granules. Unpublished study prepared by Shake-Away. 42 p.
46311602	Mileson, B. (2004) Response to Tier 1 Biochemical Pesticide Data Requirements for Shake-Away Critter Repellent Granules. Unpublished study prepared by Technology Sciences Group, Inc. 73 p.
46311900	Shake-Away (2004) Submission of Product Chemistry Data in Support of the Application for Registration of Shake-Away All Purpose Repellent Granules. Transmittal of 1 Study.
46311901	Roberts, A. (2004) Product Chemistry for Shake-Away All Purpose Repellent Granules. Unpublished study prepared by Technology Sciences Group, Inc. 42 p.
46312000	Shake-Away (2004) Submission of Product Chemistry Data in Support of the Application for Registration of Shake-Away Deer Repellent Granules. Transmittal of 1 Study.

46312001 Roberts, A. (2004) Product Chemistry for Shake-Away Deer Repellent Granules. Unpublished study prepared by SHAKE-AWAY. 42 p.

46409500 Shake-Away (2004) Submission of Product Chemistry Data in Support of the Application for Registrations of Shake-Away Deer Repellent Granules, Shake-Away Critter Repellent Granules and Shake-Away All Purpose Repellent Granules. Transmittal of 1 Study.

46409501 Askins, C. (2004) Product Stability and Container Corrosivity of Shake-Away Animal Repellant Products. Project Number: 316071, 316074. Unpublished study prepared by Life Sciences Laboratories, Inc. 87 p.

46591300 Shake-Away (2005) Submission of Product Chemistry and Safety Data in Support of the Applications for Registration of Shake-Away Deer Repellent Granules, Shake-Away Critter Repellent Granules and Shake-Away All Purpose Repellent Granules. Transmittal of 4 Studies.

46591301 Askins, C. (2005) Granule Size Analysis for Shake-Away Animal Repellent End-Use Formulations. Project Number: RFA4761, SA2005/01. Unpublished study prepared by Pittsburgh Mineral & Environmental Technology, Inc. and A.G. Environmental Services, Inc. 12 p.

46591302 Askins, C. (2005) Microbiological Effectiveness of Predator Urine Pasteurization & Pathogen Presence in Shake-Away Animal Repellent End-Use Formulations. Project Number: 0505720, 0506075, SA2005/02. Unpublished study prepared by Life Sciences Laboratories, Inc. and A.G. Environmental Services, Inc. 30 p.

46591303 Roberts, A. (2005) Supplemental Product Chemistry Information for Shake-Away Animal Repellent End-Use Formulations. Unpublished study prepared by Technology Sciences Group, Inc. 23 p.

46591304 Askins, C. (2005) Supplemental Data on the Product Stability of Shake-Away Animal Repellent Products. Project Number: 316071, 316074. Unpublished study prepared by Life Sciences Laboratories, Inc. and A.G. Environmental Services, Inc. 15 p.

46622400 Shake-Away (2005) Submission of Product Chemistry Data in Support of the Application for Registrations of Shake-Away Deer Repellent Granules, Shake-Away Critter Repellent Granules and Shake-Away All Purpose Repellent Granules. Transmittal of 1 Study.

46622401 Mileson, B. (2005) Supplemental Product Identity and Composition Information for Shake-Away Animal Repellent End-Use Formulations. Unpublished study prepared by Cornell University and Technology Sciences Group, Inc. 54 p.

46727200 Shake-Away (2005) Submission of Efficacy, Pesticide Fate and Fate Data in Support of the Application for Registration of Shake-Away Critter Repellent Granules. Transmittal of 2 Studies.

46727201 Mileson, B. (2005) Discussion on the Effectiveness of Pasteurization of Shake-Away Animal Repellent End-Use Formulations. Unpublished study prepared by Technology Sciences Group, Inc. 62 p.

46727202 Mileson, B. (2005) Discussion on the Potential for Phytotoxicity From Use of Shake-Away Animal Repellent End-Use Formulations. Unpublished study prepared by Technology Sciences Group, Inc. 10 p.

46997100 Shake-Away Products (2006) Submission of Product Chemistry and Efficacy Data in Support of the Application for Registration of Deer Repellent Granules, Critter Repellent Granules and All Purpose Repellent Granules. Transmittal of 2 Studies.

46997101 Mileson, B. (2006) Supplemental Product Chemistry Information for Shake-Away Animal Repellent End-Use Formulations. Unpublished study prepared by Technology Sciences Group, Inc. 39 p.

46997102 Bowman, D. (2006) Inactivation of Parasites, Viruses, and Bacteria by Heat. Unpublished study prepared by Cornell Univ. 89 p.

47016100 Shake-Away (2006) Submission of Product Chemistry Data in Support of the Applications for Registration of Shake-Away Critter Repellent Granules, Shake-Away All Purpose Repellent Granules and the Registration of Deer Repellent Granules. Transmittal of 1 Study.

47016101 Roberts, A. (2006) Supplemental Manufacturing Process Description for Shake-Away Animal Repellent End-Use Formulations. Unpublished study prepared by Technology Sciences Group, Inc. 183 p.

47075900 Shake-Away Products (2006) Submission of Product Chemistry Data in Support of the Applications for Registration of Critter Repellent Granules and All Purpose Repellent Granules. Transmittal of 3 Studies.

47075901 Roberts, A. (2007) QC Bacterial Assay on Shake-Away Products: (Critter Repellent Granules and All Purpose Repellent Granules). Unpublished study prepared by Shake-Away. 16 p.

47075902 Dubovi, E. (2007) Virus Inactivation Assay (Critter Repellent Granules and All Purpose Repellent Granules). Unpublished study prepared by College of Veterinary Medicine, Cornell University. 13 p.

47075903 Dubovi, E. (2007) Viral Detection Assay: (Critter Repellent Granules and All Purpose Repellent Granules). Unpublished study prepared by College of Veterinary Medicine, Cornell University. 15 p.

47091400 Shake-Away (2006) Submission of Product Chemistry Data in Support of the Registrations of Rodent Repellent Granules and Small Critter Granules. Transmittal of 1 Study.

47091401 Pillai, S. (2007) Supplemental Information on the QC Bacterial Assay on Shake-Away Products. Unpublished study prepared by Shake-Away. 62 p.

Appendix C

Product Label
Text pesticide label without graphics, pictures or illustrations

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Shake-Away® Deer Repellent Granules

(Alternate Brand Names: Shake-Away® Deer Repellent 90-Day Packs)

Active Ingredient:
Coyote Urine..... 5.00%
Other Ingredients: 95.00%
Total: 100.0%

Keep Out of Reach of Children

CAUTION

See (back panel) (insert label) (insert instructions) for (additional) Precautionary Statements and Directions for Use.

EPA Reg. No.: (pending as File Symbol 80917-R)
EPA Est. No.:

Net Contents: XX oz. (XX grams).

Manufactured by:
Shake-Away
2330 Whitney Avenue
Hamden, CT 06518
www.shake-away.com
toll-free: 1-800-517-9207

FIRST AID	
If swallowed	• Call poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If on skin or clothing	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 – 20 minutes. • Call a poison control center or doctor for treatment advice.
If in eyes	• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. (In the U.S.) You may also contact 1-800-222-1222 for emergency medical treatment information.	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals. Caution: Harmful if swallowed. Avoid contact of mouth, skin, or eyes. Wash hands before eating, drinking, chewing gum, using tobacco or using bathroom facilities.

ENVIRONMENTAL HAZARDS

Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

General:

Animals use urine to communicate in the wild. When they repeatedly smell a predator's odor, animals conclude it's a "dangerous" place and choose instead to move elsewhere. Shake-Away® Deer Repellent Granules uses the same laws of nature to protect your yard and garden. Shake-Away® Deer Repellent Granules creates the illusion that coyotes are present in your lawn or garden.

Use Shake-Away® Deer Repellent Granules to repel:

Deer
Elk
Beavers
Armadillos
Javalina
Domestic Cats

Application Directions:

- One application lasts 90 days.

- Shake-Away® Deer Repellent 90-Day Packs kit contains: Four Shake-Away® Deer Repellent 90-Day Packs, two twist ties for hanging.

Use Restrictions – This product is not for direct application to plants intended for human consumption (i.e. food plants). Apply only to the perimeter of where food plants are grown.

Hanging -
Hang one pack every 10 to 20 feet around your garden or flowerbed perimeter, ensuring there is a pack on every outside corner. Suspend each pack approximately 2 to 4 feet above ground. For best results on isolated trees and bushes, consider hanging one or two packs on each bush or tree. DO NOT OPEN PACKS OR DISPERSE CONTENTS.

Replacing -
Replace each pack 90-Day Pack after 90 days. When replacing, hang the new pack in the same location.

Allow up to two to three weeks for Shake-Away® Deer Repellent 90-Day Packs to take full effect.

Helpful Hints -
Better results will be experienced if the pack is squeezed a few times when first applying, and then every four to six weeks thereafter.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Storage: Store in a cool, dry place
Disposal: Dispose of sealed pack by placing in the trash. Do not reuse pack.

(Warranty Statement)