**BIOPESTICIDES REGISTRATION ACTION DOCUMENT**

# PIPERINE
# (PC Code 043501)

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

**Piperine**
**(PC Code 043501)**
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## BIOPESTICIDES REGISTRATION ACTION DOCUMENT TEAM

**Office of Pesticide Programs:**

**Biopesticides and Pollution Prevention Division**

**Biochemical Pesticides Branch**

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## I. Executive Summary

Piperine, the technical grade active ingredient (TGAI), is naturally occurring in the black pepper plant, *Piper nigrum* L. The TGAI is derived by solvent extraction of the plant's fruit, which results in the oleoresin of black pepper. Approximately 40% of the oleoresin of black pepper is piperine. The end-use product (EP), Woodstream Corporation's Animal Repellent Granular, contains by weight 0.185% piperine, 0.480% oil of black pepper, and 0.032% capsaicin and related capsaicinoids as active ingredients. The registrant does not intend to register the TGAI, only the EP which is labeled as an animal repellant with indoor and outdoor non-food uses. The product is to be used indoors in "non-living" areas only such as attics, basements, storage areas, cellars, sheds, garages, and barns, and outdoors, but not on foliage of shrubs or on ornamental, soft-bodied plants or food/feed crops.

The Biopesticide and Pollution Prevention Division (BPPD) is making the risk management decision regarding the registration of piperine based on: 1) the TGAI is naturally occurring; 2) nontoxic mode of action; 3) the TGAI as used in the EP does not require a food tolerance; and 4) low concentration of piperine in the EP and its non-food use make it unlikely that any pre-existing dietary exposure of humans to piperine would be increased by the use of the end product as an animal repellent. Further, oleoresin of black pepper is recognized as GRAS, and piperine is approved as a direct food additive. Dermal exposure to piperine will also be negligible when the end-use product is used according to label directions.

The product chemistry data submitted by the registrant satisfy the requirements for product identity. Waivers from the requirement of data were requested for acute mammalian toxicity and skin and eye irritation and dermal sensitization studies on piperine as well as for the nontarget organism studies in support of the TGAI. The BPPD reviewed information submitted by the registrant to identify toxic endpoints for the EP in the following studies: acute oral, acute dermal, acute inhalation, primary eye irritation, primary dermal irritation, and dermal sensitization. No unreasonable adverse effects on humans or the environment are anticipated from aggregate exposure to piperine. Waivers were granted by the Agency for studies of mammalian mutagenicity and teratogenicity, 90-day oral and dermal toxicity, and immunotoxicity based on the low concentration of piperine in the product and its non-food use. Human exposure is expected to be minimal due to the use pattern and application methods. The risks to humans are mitigated as long as the product is used according to label directions and the appropriate precautionary and first aid statements are heeded.

The Agency considered piperine in light of the relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and has not identified any dietary or non-dietary exposure issues that may affect the U.S. population in general, including infants and children. The Agency has thereby determined that there is reasonable certainty that no harm will result from aggregate exposure to piperine residues, including dietary exposures and all other exposures for which there is reliable information.

No toxic endpoints were identified as part of the ecological risk assessment. Waivers were requested by the registrant for ecotoxicity/nontarget organism studies and granted by the BPPD based on the anticipated use pattern and the lack of adverse effects reported from the widespread non-pesticidal use of piperine.

## II. Overview

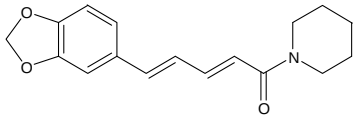
## A. ACTIVE INGREDIENT OVERVIEW

**Common Name:** Piperine

**Chemical Names:** Piperidine, 1-[(2E,4E)-5-(1,3-benzodioxol-5-yl)-1-oxo-2,4-pentadienyl]

**Chemical Formula:** $C_{17}\ H_{19}\ N\ O_3$

**Chemical Structure:**




**Trade and Other Names:** Animal Repellent Granular

**CAS Registry Number:** 94-62-2

**OPP Chemical Code:** 043501

**Basic Manufacturer:** Hill Tech Canada
249 Main Street East
Van Kleek Hill, Ontario, Canada K0B 1R0

## B. USE PROFILE

Proposed uses and application methods include the following:

**Type of Pesticide:** Biochemical pesticide; animal repellent.

**Use Sites:** Piperine in Animal Repellent Granular is labeled for use indoors in non-living areas only (attics, basements, cellars, storage areas, garages, sheds, and barns), and outdoors on lawns, garden paths, flower beds, ornamental plants, trees, shrubs, and garbage bags.

**Target Pests:** Dogs, cats, ground hogs, squirrels, skunks, and raccoons.

**Formulation Type:** Granules

**Method and Rates of Application:** For indoor application, Animal Repellent Granular is sprinkled directly from the container at a rate of 0.25 lbs/15 square feet (0.0005 lbs piperine/15 square feet). Outdoors, Animal Repellent Granular is sprinkled directly from the container or by using a spreader at a rate of 1 lb/40 square feet (0.0019 lbs piperine/40 square feet).

**Timing:** Both indoor and outdoor applications may be repeated after 30 days.

**Use Practice Limitations:** Outdoors: Apply on sunny, dry days. Do not apply to foliage of shrubs or to ornamental soft-bodied plants. Do not apply to food or feed crops.

## C. ESTIMATED USAGE

None used yet since this will be the first registered product.

## D. DATA REQUIREMENTS

The Biopesticides and Pollution Prevention Division (BPPD) reviewed data requirements for granting this registration under Section 3(c)(5) of FIFRA. Mammalian toxicology and ecological effects data requirements for the TGAI, piperine, were waived based on the submission of scientific rationales. No report of significant human health or ecological concerns from the use of this active ingredient were found in the open scientific literature, therefore an exposure assessment was not required. Neither Teir II toxicological studies nor Teir II environmental fate and groundwater were not triggered and therefore not required. Based on these reasons, the Agency foresees no unreasonable adverse effects to human health and the environment from the use of this animal repellent and no additional data are required.

Product analysis and toxicology data requirements are adequately satisfied by the data submitted by the registrant for the end product. These data were concurrently reviewed by U.S. EPA and the California Environmental Protection Agency. As a result of these reviews, the mammalian toxicology and ecological effects data requirements for piperine have been fulfilled.

## E. REGULATORY HISTORY

A notice of receipt of an application for registration of Animal Repellent Granular, containing piperine as an active ingredient, was published in the Federal Register on December 24, 2003 (68 FR 74576) with a 30-day comment period. No comments were received following this publication.

## F. CLASSIFICATION

On September 6, 2001, the Biochemical Classification Committee determined that piperine is classified as a biochemical pesticide due to its non-toxic mode of action.

## G. FOOD CLEARANCES/TOLERANCES

The present registration application is for non-food use. Piperine is approved as a direct food additive in 21 CFR §172.515.

# III. Science Assessment

## A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for registration of piperine, when formulated into the end-use product Animal Repellent Granular, have been satisfied.

### 1. Product Identity and Mode of Action

#### a. Product Identity:

Piperine, an alkaloid, is a pale yellow to yellow solid (crystals) with a slight odor. It is a solvent extract of the dried fruit of *Piper nigrum*. Piperine is an active ingredient in the end-use product Animal Repellent Granular, which is produced by an integrated system that involves the blending of 0.185% piperine, 0.480% oil of black pepper, and 0.032% capsaicin and related capsaicinoids with the inert ingredients.

#### b. Mode of Action:

Animal Repellent Granular repels animals by irritation upon touching or tasting the product.

### 2. Physical and Chemical Properties Assessment

The physical and chemical characteristics of Animal Repellent Granular and piperine were submitted to support the registration. They are summarized in Tables 1 and 2, respectively.

| TABLE 1. Product chemistry data requirements | | | |
|---|---|---|---|
| **GUIDELINE NO.** | **STUDY** | **RESULTS** | **MRID NO.** |
| 830.1550<br><br>to<br><br>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 | 457977-01<br>457977-06 |
| 830.1700 | Analysis of samples | Submitted data satisfy the data requirements for analysis of samples | 457977-03 |
| 830.1750 | Certification of limits | Limits listed in the CSF are adequate / Acceptable | 457977-06 |
| 830.1800 | Analytical Method | Acceptable | 457977-03 |

| TABLE 2A: Physical and Chemical Properties for the Active Ingredient Piperine | | | |
|---|---|---|---|
| **GUIDELINE NO.** | **STUDY** | **RESULTS** | **MRID NO.** |
| 830.6302 | Color | Pale yellow to yellow | 457977-05 |
| 830.6303 | Physical State | Solid (crystals) | 457977-05 |
| 830.6304 | Odor | Slight odor | 457977-05 |
| 830.7200 | Melting Point | 131-134°C | 457977-05 |
| 830.7220 | Boiling Point | N/A | 457977-05 |
| 830.7300 | Specific Gravity | 1.28 @ 22.3°C | see note 1 below |
| 830.7840 | Solubility | Soluble in chloroform and ether; practically insoluble in water (40 mg/L) | 457977-05 |
| 830.7950 | Vapor Pressure | Not Applicable | 457977-05 |
| 830.7000 | pH | Neutral to litmus (pka = 12.2) | 457977-05 |
| 830.6313 | Stability | Stable at room temperature | 457977-05 |
| 830.6319 | Miscibility | Not Applicable | 457977-05 |
| 830.6320 | Corrosion Characteristics | Not Corrosive | 457977-05 |
| 830.7570 | Octanol/Water Partition Coefficient | Practically insoluble in water | 457977-05 |

1) requirement satisfied by registrant's submission by letter, dated December 3, 2003.

| TABLE 2B: Physical and Chemical Properties for Animal Repellent Granular | | | |
|---|---|---|---|
| 830.6302 | Color | Multi-colored, mainly black/brown | see note 1 below |
| 830.6303 | Physical State | Solid (granules) | |
| 830.6304 | Odor | Rancid and peppery | see note 1 below |
| 830.7300 | Density/Specific gravity | 1.39 g/mL @ 23°C | 457977-07 |
| 830.7000 | pH | 5.10 @ 25°C (1% w/v in deionized water) | 457977-07 |
| 830.6315 | Flammability | Not applicable | |
| 830.6317 | Storage Stability | To be submitted on Agency request | |
| 830.6320 | Corrosion Characteristics | Acceptable | 457977-07 |

1) requirement satisfied by registrant's submission by letter, dated December 3, 2003.

## B. HUMAN HEALTH ASSESSMENT

The mammalian toxicity studies and scientific rationales in support of data waiver requests submitted to support the registration application for Animal Repellent Granular adequately satisfy the requirements to register a new biochemical pesticide intended for use on non-food commodities.

### 1. Toxicology Assessment

Adequate mammalian toxicology data are available to support registration of Animal Repellent Granular, containing the new active ingredient piperine (Table 3). No additional toxicological data are needed.

Piperine is currently approved as a direct food additive (21 CFR §172.515), and is reported in foods at concentrations ranging from 0.4 to 6 ppm in candy up to 640 ppm in baked goods. The registrant provided One study an estimate for human dietary consumption of piperine as 0.3 to 0.54 mg/kg/person/day (based on Fenaroli's Handbook of Flavor Ingredients, 2nd edition, 1974. The values for piperine are calculated based on data showing that the oleoresin of black pepper is 40% piperine.) Piperine works through an irritant, rather than toxic, mode of action. Information submitted by the registrant indicates there is already widespread exposure to piperine without any reported adverse effects to human health. No risks to human health are expected from the use of piperine, based on its already-wide usage and the expected low exposure to humans resulting from label-directed use rates of Animal Repellent Granular.

### a. Acute Toxicity

Waivers from data requirements were requested for acute mammalian toxicity and skin and eye irritation and dermal sensitization studies on piperine as well as for the nontarget organism studies in support of the TGAI. The BPPD reviewed information submitted by the registrant to identify toxic endpoints for the EP as indicated in Table 3.

**TABLE 3. Toxicity Data (Tier I)**

| GUIDELINE NO. | STUDY | RESULTS TGAI | RESULTS EP | MRID NO. |
|---|---|---|---|---|
| 870.1100 | Acute oral toxicity | Waiver granted for TGAI | $LD_{50}$ >5000 mg/kg Toxicity Category IV | 457977-09 |
| 870.1200 | Acute dermal toxicity | Waiver granted for TGAI | $LD_{50}$ >5000 mg/kg Toxicity Category IV | 457977-10 |
| 870.1300 | Acute inhalation toxicity | Waiver granted for TGAI | $LC_{50}$ >2.04 mg/L Toxicity Category IV | 457977-11 |
| 870.2400 | Primary eye irritation | Waiver granted for TGAI | Mildly irritating. Toxicity Category III | 457977-12 |
| 870.2500 | Primary dermal irritation | Waiver granted for TGAI | Slightly irritating. Toxicity Category IV | 457977-13 |
| 870.2600 | Skin Sensitization | Waiver granted for TGAI | Not a sensitizer | 457977-14 |

### b. Mutagenicity and Developmental Toxicity

Waivers from the requirement of data for mammalian mutagenicity and teratogenicity studies were granted by the Biopesticides and Pollution Prevention Division (BPPD) based on the low concentration of piperine in the product and the non-food use, which would make it unlikely that the pre-existing dietary exposure of humans to piperine would be increased by the use of the end-use product as an animal repellent.

### c. Subchronic Toxicity and Immunotoxicity

Waivers requested for 90-day oral and dermal toxicity and immunotoxicity studies were granted by the Biopesticides and Pollution Prevention Division (BPPD) based on the low concentration of piperine in the product and the non-food use, which would make it unlikely that the pre-existing dietary exposure of humans to piperine would be increased by the use of the end product as an animal repellent. Dermal exposure would be negligible when the end-use product is applied according to label directions. A waiver for a 90-day inhalation toxicity study was granted

by the Agency based on minimal inhalation exposure expected from the application method and the lack of toxicity in the acute inhalation study.

### d. Chronic Exposure and Oncogenicity Assessment

Repeated dose studies are conditionally required if the potential for adverse chronic effects is 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 produce in Tier I studies any morphologic effects in any organ that potentially could lead to neoplastic changes. None of the results of the submitted studies 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 FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen- and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, the Agency will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

Based on the weight of the evidence of available data, no endocrine system-related effects have been identified for piperine and none is expected since it does not share any structural similarity to any known endocrine disruptor.

## 2. Dose Response Assessment

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

## 3. Dietary Exposure and Risk Characterization

Current dietary exposure to piperine is from its use as a flavoring agent in foods. Dietary exposure from its proposed non-food use in Animal Repellent Granular is expected to be insignificant.

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

### a. Occupational Exposure and Risk Characterization

Occupational exposure to piperine is mitigated as long as the end-use product Animal Repellent Granular is used according to label directions. Occupational exposures are not included under the FFDCA in the assessment of aggregate exposures for the purpose of establishing tolerances and exemptions from tolerance. The signal word on the EP label is Caution and precautionary statements include "Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco." for routes of exposure. The product is being registered for residential use and no reentry interval is required.

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

Animal Repellent Granular, when used indoors, is intended for use only in non-living areas. Although accidental non-dietary exposure may occur, the health risk is expected to be minimal due to the low concentration of piperine in the product, the lack of oral, inhalation, and dermal toxicity endpoints, and minimum potential for eye and dermal irritation. Significant human exposure to piperine is not expected in residential, school and day care areas.

## 5. Drinking Water Exposure and Risk Characterization

No significant exposure is expected from an accumulation of piperine in the aquatic environment when Animal Repellent Granular is used according to the product label directions.

## 6. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children

FFDCA section 408 provides that the US Environmental Protection Agency (Agency) shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless the Agency determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, the Agency has concluded that there is reasonable certainty that no harm to infants and children or adults will result from the use of piperine in Animal Repellent Granular.

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

There is reasonable certainty that no harm to the U.S. population will result from aggregate exposure to residues of piperine. This includes all exposures for which there is reliable information. The Agency arrived at this conclusion based on the low level of toxicity and already widespread exposure to piperine without any reported adverse effects on human health. The risks from aggregate exposure via oral, dermal and inhalation exposure are a compilation of three low-risk exposure scenarios and are negligible. Since there are no threshold effects of concern, the provision requiring an additional margin of safety does not apply. Therefore, the Agency has not used a margin of exposure (safety) approach to assess the safety of piperine.

### 8. Cumulative Effects

When used as labeled, Animal Repellent Granular is not expected to result in piperine residues at levels that are of toxicological concern. The information submitted indicates there is already widespread exposure to piperine without any reported adverse effects to human health. Because of its low inherent toxicity and low use rates, no cumulative effect with other toxins is anticipated.

### 9. Risk Characterization

The Agency considered human exposure to piperine 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 Animal Repellent Granular when label instructions are followed.

## C. ENVIRONMENTAL ASSESSMENT

### 1. Ecological Effects Hazard Assessment

In an acute oral toxicity study (OPPTS 850.2100, MRID 457977-08), mallard ducks received a single oral dose of Animal Repellent Granular in capsules. The test material caused no mortality and did not affect body weight gains or feed consumption over 14 days. The acute oral $LD_{50}$ was >2250 mg/kg.

The registrant requested a waiver for avian dietary toxicity. The BPPD granted the waiver based on the low avian acute oral toxicity and the likelihood that Animal Repellent Granular would repel birds since one of the active ingredients, capsaicin, is a known bird repellent. Waivers were also requested for freshwater fish toxicity, freshwater invertebrate toxicity, and nontarget insect toxicity data requirements. The BPPD granted these waivers based on the anticipated lack of aquatic exposure from the proposed use, and the lack of adverse effects reported from the widespread non-pesticidal uses of piperine.

### 2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data (Tier II, (40 CFR Section 158.690(d)(2)(vii through xv)) was not triggered because of practically non-toxic results indicated in the Tier I studies. Risk to non-target species is minimal due to the use pattern, application methods, and lack of toxicity.

### 3. Ecological Exposure and Risk Characterization

The potential for exposure to non-target wildlife is minimal due to the use pattern and low toxicity.

## D. EFFICACY DATA

Efficacy data (MRID 461199-01) were submitted in support of label claims and product performance.

## 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.

To satisfy criterion "A" above, piperine in Animal Repellent Granular is not expected to cause unreasonable adverse effects when used according to label instructions. Criterion "B" is satisfied by the current label and by the data presented in this document. It is believed that piperine, the new pesticidal active ingredient, will not cause any unreasonable adverse effects and will help to repel dogs, cats, ground hogs, squirrels, skunks, and raccoons, satisfying Criterion "C". Criterion "D" is satisfied by the data submitted and the low exposure to piperine in the product when used according to the label directions.

Therefore, piperine as used in the end-use product Animal Repellent Granular is eligible for registration. The uses are listed in Section VI, Table 4.

## B. REGULATORY POSITION

### 1. Conditional Registration

Based on data submitted, the Agency recommends that Animal Repellent Granular is eligible for conditional registration under Section 3(c)(7)(A) of FIFRA. The Agency foresees no adverse effects to human health or the environment from the use of piperine in this product when the product is used in accordance with the label directions.

The Agency also concludes that future products using piperine as active ingredient at a percentages above that considered here may trigger additional data requirements. The scope of the information submitted in support of the registration of Animal Repellent Granular is appropriate for low level use of piperine in the end-use product.

### 2. CODEX Harmonization

There are no CODEX maximum residue levels for piperine.

### 3. Nonfood Registrations

The active ingredient and end use product are intended only for nonfood use.

### 4. Risk Mitigation

There are no significant risk issues, and as such, mitigation measures for dietary risk, occupational and residential risk, or ground and surface water contamination are not required. Risk to nontarget organisms will be mitigated by appropriate label precautions.

### 5. Endangered Species Statement

Currently, the Agency is developing a program (The Endangered Species Protection Program) to identify all pesticides whose use may cause potential adverse impacts on endangered and threatened species and their habitats. To aid in the identification of threatened and endangered species and their habitats, several companies have formed an Endangered Species Task Force (EST) under the direction of the American Crop Protection Association (ACPA). Moreover, the EST will assist in providing species location information at the subcounty level, and particularly if an endangered species occurs in areas where pesticides would be used. This information will be useful once the Endangered Species Protection Program has been implemented.

The Agency currently has no evidence indicating that any endangered or threatened species will be adversely affected by products containing piperine when used according to the product label directions. In this regard, label language specific for endangered or threatened species is not imposed at this time for such products.

## C. LABELING RATIONALE

It is the Agency's position that the labeling of Animal Repellent Granular complies with current pesticide labeling requirements.

### 1. Human Health Hazard

#### a. Worker Protection Standard

Any product whose labeling reasonably permits its use on an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, ''Labeling Revisions required by the Worker Protection Standard (WPS),'' and PR Notice 93-11 "Supplemental Guidance for PR Notice 93-7," which reflect the requirements of EPA's labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in PR Notices 93-7 and 93-11. Unless otherwise specifically directed, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those Notices.

After October 23, 1995, except as provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person. The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR 156.10 and other applicable notices. Labeling must also conform to Worker Protection Safety standards concerning re-entry into sprayed fields.

This product does not come under the provisions of the Worker Protection Standard.

**b. Non-Worker Protection Standard**

There are no non-WPS human health hazard issues.

**c. Precautionary Labeling**

The Agency has examined the toxicological data base for piperine and concluded that the proposed precautionary labeling (i.e. Signal Word, First Aid, and other label statements) adequately mitigates any risks associated with the proposed uses. Precautionary labeling for end-use products containing this active ingredient is:

> **"CAUTION. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling** *and before eating, drinking, chewing gum, or using tobacco.***"**

**d. Spray Drift Advisory**

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

**2. Environmental Hazards Labeling**

No environmental hazards statement is necessary for this proposed use.

**3. Application Rate**

The end-use product is applied in indoor non-living areas at a rate of 0.25 lbs/15 square feet, and outdoors at a rate of 1 lb/40 square feet.

## D. LABELING

Product name: **Animal Repellent Granular**

Active Ingredients:

| | |
|---|---|
| Piperine | 0.185% |
| Oil of Black Pepper | 0.480% |
| Capsaicin and related capsaicinoids | 0.032% |
| Other Ingredients | 99.303% |
| Total | 100.00% |

Signal word is "CAUTION".

The product shall contain the following information:
- Product Name
- Ingredient Statement
- Registration Number
- Signal Word (CAUTION)

## 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.

## VI. Appendix A

Table 4 lists the use sites for the product. The label for the product is also attached.

**Table 4. Use Sites**

| | |
|---|---|
| **Animal Repellent Granular**<br><br>Use Sites: Indoors - attics, basements, cellars, storage areas, garages, sheds, and barns. Outdoors - lawns, garden paths, flowerbeds, garbage bags, ornamental plants, trees, shrubs. | **Official date registered**: |