



New Pesticide Fact Sheet

Bifenazate

Description of the Chemical

Generic Name: Hydrazine carboxylic acid, 2-(4-methoxy-[1,1-biphenyl]-3-yl)-1-methylethyl ester
Common Name: Bifenazate
Molecular Formula: C₁₇H₂₀N₂O₃
Molecular Weight: 300.36
Trade Name: Floramite
Chemical Family: Carbazate
EPA Shaughnessy Code (OPP Chemical Code): 000586
Chemical Abstracts Service (CAS) Number: 149877-41-8
Year of Initial Registration: 1999
Pesticide Type: Acaricide
Manufacturer: Uniroyal Chemical Company, Inc.

Use Patterns and Formulations

Application Sites: Floramite is registered for control of mite pests on greenhouse, shadehouse, nursery, field, landscape and interiorscape grown ornamentals.

Types of Formulation: 91.7% technical product; 50% wettable powder end use product packaged in water soluble bags

**Types and Methods
of Application:** Ground application using standard commercial sprayers

Application Rates: Application rates 2 to 4 oz.(1 to 2 oz. active ingredient) in 100 gallons of water, applied as a full coverage spray using a minimum volume of 1-2 qts. of final solution per 100 sq. ft. Residual control of up to 21 days. Not to be used in successive applications, only between applications of at least two products of alternative chemical classes.

Carrier: Water

Science Findings

Summary Statement:

Bifenazate possesses low acute toxicity by all routes of exposure (Category IV) with no evidence of dermal sensitization potential. It is non-irritating to skin and minimally irritating to eyes. Bifenazate is negative for mutagenic potential in a battery of required mutagenicity studies. Bifenazate has not yet received a human

carcinogen classification since bifenazate is being considered as a non-food use pesticide and both the mouse and rat chronic toxicity/carcinogenicity studies are not required at this time. Occupational exposure to those working in a nursery or greenhouse environment is the primary source for human exposure. The MOE for post-application exposures is 114. Since bifenazate has no dietary or residential uses, an aggregate risk assessment was not required. Based on expected use pattern information bifenazate is neither mobile or persistent in the aquatic and soil environment. Bifenazate would be expected to exhibit low potential to contaminate ground and surface waters.

Chemical Characteristics	Technical Grade	
	PROPERTY	TECHNICAL
Physical State	Solid Crystalline	Wettable Powder
Color	Beige	Beige
Odor	Slight Aromatic	N/A
Melting Point	120-124°C	N/A
Density	1.31 g/cc @ 25°C	0.21 g/cc @ 25°C
Solubility (Water)	3.8 mg/L @ 20°C	N/A
Vapor Pressure	<1x10 ⁻⁷ torr @ 25°C	N/A
Octanol/Water Partition Coefficient	Log Pow=3.4 @ 25°C	N/A
pH	6.78	4.6

Human Health Assessment TOXICOLOGY CHARACTERISTICS

Acute Toxicity

- * Acute Oral Toxicity- Rats- LD50>5000 mg/kg; Toxicity Category IV
- * Acute Dermal Toxicity- Rats-LD50>5000 mg/kg; Toxicity Category IV
- * Acute Inhalation Toxicity- Rats-LC50>4.4 mg/L; Toxicity Category IV
- * Primary Eye Irritation-Rabbits- Slight eye irritant; Toxicity Category IV
- * Primary Dermal Irritation-Rabbits-Slight irritant; Toxicity Category IV
- * Primary Dermal Sensitization-Guinea Pigs-Not a skin sensitizer.

[NOTE: For acute oral, dietary, mammalian:

- Category I = very highly or highly toxic
- Category II = moderately toxic
- Category III = slightly toxic

Category IV = practically non-toxic]

Subchronic Toxicity

* A 90 day subchronic oral toxicity study of bifenazate was performed in rats at dose levels of 0, 40, 200, or 400 ppm (equivalent to 0, 2.7, 13.8 or 27.7 mg/kg/day in males and 0, 3.2, 16.3, or 32.6 mg/kg/day in females). There were no deaths or adverse clinical signs. Decreased absolute liver weight and liver weight relative to brain weight were observed in high dosed males. Histologic findings in the liver included minimal to slight hepatocellular hypertrophy and minimal cell necrosis. The systemic NOAELs for the study were 40 ppm in females (3.2 mg/kg/day) and 200 ppm in males (13.8 mg/kg/day). The LOAEL was 400 ppm in males (27.7 mg/kg/day) and 200 ppm in females (16.3 mg/kg/day) based on decreased BWG, increased liver weight in males and spleen weight in females, and the histopathology of the liver in both males and females.

* A 90 day subchronic oral toxicity study was performed in beagle dogs at dose levels of 0, 40, 400, or 1,000 ppm (equivalent to 0, 0.9, 10.4, or 25 mg/kg/day in males and 0, 1.3, 10.7, or 28.2 mg/kg/day in females) resulted in no deaths or adverse clinical signs. The systemic NOAEL was considered to be the low dose of 40 ppm in both sexes (0.9 mg/kg/day in males and 1.3 mg/kg/day in females). The LOAEL was 400 ppm (10.4 mg/kg/day in males, 10.7 mg/kg/day in females) based on hematological findings, increased liver weight, and microscopic changes in the liver.

* In a 21 day dermal toxicity study conducted at dose levels of 0, 80, 400, and 1,000 mg/kg in rats of both sexes, the systemic non observed adverse effect level (NOAEL) was considered to be the lowest dose of 80 mg/kg/day for both sexes. The lowest observed adverse effect level (LOAEL) was 400 mg/kg/day based on decreased body weight (BW), food consumption (FC), clinical pathology findings, and extramedullary hematopoiesis in the spleen.

Chronic Toxicity and Carcinogenicity

A determination of cancer potential was not made since there are no chronic studies for MNDA (As far as toxicology data requirements, the Agency is treating this proposed registration as a non-food use). If the use pattern changes, additional data will be required to satisfy these guideline requirements.

Developmental Toxicity

* A developmental toxicity study was conducted in rats at doses of 0, 10, 100, or 500 mg/kg/day on gestation days (GD) 6-15. At the high dose, treatment-related clinical signs of toxicity included pale extremities, dried red material on the forelimbs or around the nose, dried brown vaginal discharge, and decreased

defecation. Body weights, body weight gains, and food consumptions by dams in the low-dose group were similar to the controls throughout the study. Mean maternal body weights were significantly lower than the controls for the mid and high dose groups beginning on GD 8 and 7, respectively, and continuing until termination. No treatment-related differences were observed between the treated and control groups for the corpora lutea/dam, implantations/dam, preimplantation loss, resorptions/dam, fetal body weights, or fetal sex ratios. No treatment-related external, visceral, or skeletal malformations/variation were observed in any fetuses. The maternal toxicity NOAEL was considered to be 10 mg/kg/day and the maternal LOAEL was considered to be 100 mg/kg/day based on decreased BW, BWG, and food consumption. The developmental toxicity NOAEL was greater than 500 mg/kg/day and no developmental LOAEL was identified..

* In a developmental toxicity study with pregnant New Zealand white rabbits, bifenazate (92.5% a.i.) administered by gavage at doses of 0, 10, 50, or 200 mg/kg/day on gestation days 7-19, yielded no treatment-related clinical signs of toxicity observed in any animal in any treated group. No treatment related differences were observed between the treated and control groups for number of corpora lutea/doe, implantations/doe, pre- or postimplantation loss, resorptions/doe, fetal body weights, or fetal sex ratios. Both the maternal and developmental toxicity NOAELs were 200 mg/kg/day. A maternal and developmental LOAEL were not identified.

Mutagenicity

* Based on the available mutagenicity studies, there are no concerns for mutagenicity at this time.

OCCUPATIONAL EXPOSURE

Handler

Greenhouse and nursery (field grown crops) scenarios were chosen as representative of worst case scenarios for mixer/loaders and applicators. The risk estimates indicate that the short term dermal MOEs ranged from 2200 (high pressure handwand application to field grown ornamentals) to 17,000 (groundboom application to field grown ornamentals). The short term inhalation MOEs ranged from 5600 (high pressure handwand application to field grown ornamentals) to 100,000 (groundboom application to field grown ornamentals). The risk estimates indicate that the potential risk for mixer/loader/applicator for short term exposure from the proposed Section 3 uses of bifenazate on ornamentals do not exceed the Agency's level of concern.

Post Application

There are potential post-application exposures to workers entering treated areas for routine crop maintenance tasks and for workers cutting and sorting treated plants. A risk assessment was conducted using the following assumptions: application rate of 0.27 lb ai/A, 20% of the application rate available as dislodgeable residues, a dermal transfer coefficient of 10,000 ug/cm² (generic value, based on the Transfer Coefficients Surrogate Table developed by the HED Exposure SAC), a work day of 8 hours, and reentry on day 0. The short and intermediate term dermal MOE was 114. The risk estimates indicate that the potential post application risks for workers from short and intermediate term dermal exposures from the proposed Section 3 uses of bifenazate on ornamentals do not exceed the Agency's level of concern.

Restricted Entry Interval (REI)

The proposed interim REI is 12 hours based on bifenazate acute toxicity classification.

AGGREGATE RISK ASSESSMENT AND RISK CHARACTERIZATION

Bifenazate has no anticipated dietary exposures. Therefore, an aggregate risk assessment is not warranted.

FQPA Considerations

The uses proposed for bifenazate are non-food uses and there are no expected dietary exposures. Therefore FQPA safety factor considerations do not apply.

Dose Response Assessment

Since the current application is for non-food uses, no acute or chronic dietary RfDs for bifenazate were selected. Since Bifenazate is being considered as a non-food use pesticide and no chronic exposures are expected, chronic toxicity/carcinogenic studies are not required at this time. Accordingly, bifenazate has not been classified for carcinogenic potential.

Short and intermediate term dermal and inhalation risk assessments are required. The HIARC determined that inhalation exposure should be converted to oral equivalents and compared to the short or intermediate oral NOAEL. Dermal exposure should be compared with the NOAEL from the 21 day dermal toxicity in rats for systemic effects. The HIARC recommended that the level of concern for MOEs estimated by the inhalation and dermal routes is 100. The HIARC did not select long term dermal and inhalation endpoints since long term exposures are not expected from the proposed use.

**Environmental Fate
and Ecological
Effects
Characteristics**

STUDY TYPE	HALF-LIFE/OTHER
Hydrolysis	6.34 days at pH 4 2.68 days at pH 5 7.7 hours at pH 7 0.45 hours at pH 9
Photolysis in Water	16.20 hours at pH 5
Photolysis on Soil	<0.5 hour
Aerobic Soil Metabolism	7.3 hours
Anaerobic Aquatic Metabolism	77.9 days
Mobility-Column Leaching	Low mobility in sandy loam Immobile in silt loam and clay loam soils
Mobility-batch equilibrium	K_{ads} of 5 for a CA sandy loam 38 for an Ohio sandy loam 77 for a silty loam 84 for a silt loam 246 for a loam sediment The K_{oc} values ranged from 3011 to 6189
Terrestrial Field Dissipation	5 days

ENVIRONMENTAL FATE

Bifenazate is considered to be neither mobile or persistent in the aquatic and soil environment. Bifenazate would be expected to exhibit low potential to contaminate ground and surface waters.

Drinking Water Assessment

Based on a preliminary evaluation of submitted environmental fate data and expected use patterns, EFED has concluded that parent bifenazate has a very low potential to contaminate ground and surface water drinking supplies. The concentration of parent bifenazate in drinking water from the labeled uses can be considered as negligible. This evaluation is based on information indicating that bifenazate is neither mobile or persistent in the environment.

Ecological Risk Characterization

The available data indicate that bifenazate is categorized as highly toxic to freshwater fish ($LC50=0.58\text{--}76$ ppm) and aquatic invertebrates ($LC50/EC50=0.50$ ppm) on an acute basis. Bifenazate is categorized as slightly toxic to avian species on an acute oral basis ($LD50=1032$ mg/kg) and as moderately toxic to avian species on a subacute dietary basis ($LC50=656\text{--}1862$ ppm). Bifenazate is categorized as practically nontoxic to small mammals on an acute oral basis ($LD50>5000$ mg/kg).

An analysis of the results indicate that bifenazate is categorized as moderately toxic to bees on an acute contact basis (LD₅₀=7.5 ug/bee).

Endangered Species Concerns

A single application of Floramite at 0.25 lbs ai/A would not be expected to trigger endangered species risk presumptions for avian, aquatic or mammalian species.

Data Gaps Toxicology

Available data provide adequate information to support the unconditional registrations of Bifenazate Technical and Floramite, a 50% ai wettable powder formulation packaged in water soluble bags, for use on greenhouse, shadehouse, nursery, field, landscape, and interiorscape grown ornamentals.

Confirmatory Data for Ecological Effects:

- * Avian Reproduction Quail 71-4(a)
- * Avian Reproduction Duck 71-4(b)

These studies were required to support outdoor uses since the label permits multiple applications. A study to support these data requirements (MRID No. 447796-01) has been submitted and is in review.

Regulatory Use Directions-General Precautions

Conclusion Do not apply this product through any type of irrigation system.

Do not use Floramite in successive applications. Apply only one application of Floramite before rotating to products of an alternative chemical class. Use at least two alternative products between treatments of Floramite.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

Manufacturing Use Products: This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

End Use Products: This pesticide is toxic to fish. Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of equipment washwater or rinsate. This product is toxic to bees exposed to direct treatment or residues on

blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

For More CONTACT PERSON:
Information George J. Tompkins
Insecticide/Rodenticide Branch
Registration Division (7505C)
Office of Pesticide Programs
Environmental Protection Agency
401 M. Street, SW
Washington, DC 20460

Room 210, Crystal Mall Building #2
1921 Jefferson Davis Highway
Arlington, VA 22202
(703) 308-9397

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For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, from 6:30 a.m. to 4:30 p.m. Pacific Time, or 9:30 a.m. to 7:30 p.m. Eastern Standard Time, seven days a week.