CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION
PUBLIC REPORT 2008-1

Active Ingredient: Metaflumizone
Tracking ID Number 215646

DESCRIPTION OF ACTION

BASF Corporation submitted an application for California registration of Siesta Insecticide Fire Ant Bait, EPA Reg. No. 7969-232. Siesta Insecticide Fire Ant Bait is intended for use in the control of imported and native fire ants on lawns, landscaped areas, golf courses, industrial and municipal sites, and other non-crop/non-grazed areas. The product contains the active ingredient metaflumizone. The U.S. Environmental Protection Agency (U.S. EPA) conditionally registered Siesta Insecticide Fire Ant Bait on August 3, 2007. Under the federal conditions of registration, the registrant is required to submit storage stability and corrosion characteristics data for Siesta Insecticide Fire Ant Bait.

The Department of Pesticide Regulation (DPR) evaluated the product label and scientific data for Siesta Insecticide Fire Ant Bait and found them acceptable to support conditional registration in California. Precautionary and first aid statements, and other protective measures on the product label, adequately mitigate the potential health risks to users. DPR does not expect significant adverse environmental impacts to result from registration of Siesta Insecticide Fire Ant Bait. The data adequately substantiates Siesta Insecticide Fire Ant Bait as an effective control for imported and native fire ants.

Note on other metaflumizone products: DPR registered two other pesticide products containing metaflumizone, Promeris for Cats, EPA Reg. No. 80490-3, and Promeris for Dogs, EPA Reg. No. 80490-2, prior to registering Siesta Insecticide Fire Ant Bait. DPR conditionally registered Fort Dodge Animal Health's product Promeris for Cats, containing 18.53% metaflumizone, on May 10, 2007. Promeris for Cats is labeled to control fleas on cats, and is available only from licensed veterinary professionals. The conditional registration was contingent upon submission of an acceptable one-year storage stability and corrosion characteristics study. Fort Dodge Animal Health submitted the requested data and DPR granted Promeris for Cats full registration on August 17, 2007. On August 20, 2007, DPR registered Fort Dodge Animal Health's product Promeris for Dogs, which contains 14.34% metaflumizone and 14.34% amitraz. Promeris for Dogs is labeled for control of fleas, mites, and ticks on dogs and is also available only from licensed veterinary professionals. This public report only summarizes data submitted to support the Siesta Insecticide Fire Ant Bait use pattern. It does not cover data submitted to support the Promeris products.

BACKGROUND

Registrant:	BASF Corporation
Common name:	Metaflumizone
Chemical name:	E-isomer (8.4%): 4-{(2E)-2-({[4-(trifluoromethoxy)anilino]carbonyl} hydrozono)-2-[3-(trifluoromethyl)phenyl]ethyl}benzonitrile Z-isomer (91.6%): 4-{(2Z)-2-({[4-(trifloromethoxy)anilino]carbonyl} hydrazono)-2-[3-(trifluoromethyl)phenyl]ethyl}benzonitrile
Brand name:	Siesta Insecticide Fire Ant Bait
Uses:	Control of imported fire ants and native fire ants
Pests controlled:	Fire ants
Type of registration:	Conditional Registration

Siesta Insecticide Fire Ant Bait is a yellowish granular material containing 0.063% metaflumizone. Metaflumizone is in the semicarbazone class of chemicals. Efficacy testing has proven metaflumizone to be an effective insecticide for treatment of existing fire ant infestations. Metaflumizone's mode of action blocks the sodium channel of the nervous system causing paralysis of the insect. Imported and native fire ants are strongly attracted to Siesta Insecticide Fire Ant Bait. Because of the strong attraction, the ants readily carry the bait into the mound as food, where they eat it, destroying the colony.

SCIENTIFIC REVIEW

A. Chemistry

BASF Corporation submitted chemistry studies for BAS 320 I Pro Fire Ant Bait, which is identical to Siesta Insecticide Fire Ant Bait. DPR evaluated the submitted studies, and determined that the product chemistry and environmental fate data support conditional registration of Siesta Insecticide Fire Ant Bait. The conditional registration is contingent upon the submission of an acceptable 12-month storage stability and corrosion characteristics study for Siesta Insecticide Fire Ant Bait. BASF Corporation did not submit data addressing residue in food and animal feed. In accordance with California Notice 2004-7, DPR no longer requires these data.

1. Product Chemistry**:** The product chemistry results are summarized in Table 1 on page 3.

2. Environmental Fate**:** The metaflumizone environmental fate data included hydrolysis, aquatic photolysis, aerobic soil metabolism, and soil adsorption/desorption coefficient. DPR found the studies to be satisfactory. Comparison of the metaflumizone environmental fate data to the U.S. EPA and California Environmental Protection Agency (Cal/EPA) ground water leaching criteria indicate that metaflumizone has the potential to leach. However, metaflumizone has very low water solubility, it photolyzes rapidly in water, and is immobile

in soil. Consequently, it would not be expected to leach to ground water. The potential to leach is summarized in Table 2.

Table 1. Physical and Chemical Properties of BAS 320 I Pro Fire Ant Bait

Properties	Values
Physical state	Granular/yellow
Density (20 ^{o}C)	1.21 grams (g)/centimeter^3 (cm^3)
pH (1% solution)	5.24 @ 25 °C
Boiling point	334 °C
Melting point	-54 °C
Viscosity (20 °C)	19.3 mm^2/sec
Partition coefficient (K_{ow})	E-isomer 1.1 x 10^3 (Log_p = 5.0) Z-isomer 9.4 x 10^4 (Log_p = 5.0)
Water solubility	E-isomer 0.67 mg/L @ (20°C) Z-isomer 0.50 mg/L @ (20°C)
Vapor pressure	9.47 x 10^{-4} Pa (7.10 x 10^{-6}mmHg)
Storage stability /corrosion	Stable and non-corrosive after 3 months in HDPE bottles at 5°C

Table 2. Comparison of U.S. EPA and Cal/EPA Ground Water Leaching Criteria with Environmental Fate Study Results for Metaflumizone

Parameter	Potential to Leach Value (U.S. EPA)	Potential to Leach Value (Cal/EPA)	Experimental Value	Criteria Exceeded
Water solubility	> 30 ppm	> 3 ppm	0.67 ppm E-isomer 0.50 ppm Z-isomer	No
Soil adsorption coefficient (K_d)	< 5 ml/g		1030 ml/gm (loam) 623 ml/gm (sandy loam)	No No
K_{oc}		<1,900 ml/g	28,000 ml/gm (loam) 51,000 ml/gm (sandy loam)	No No
Hydrolytic half-life	> 30 days	> 14 days	Stable	Yes
Aerobic soil metabolic half-life	> 21 days	> 3 days	198 days (sandy loam)	Yes

B. Toxicology

BASF Corporation submitted adequate toxicology studies to conduct complete toxicological evaluations of Siesta Insecticide Fire Ant Bait. DPR evaluated the submitted data to determine the potential for adverse health effects. The product label adequately identifies the potential acute toxicity hazards indicated by the data reviewed. The first aid statements and personal protective equipment (PPE) requirements are adequate for the indicated acute toxicity hazards. The acute toxicity parameters for metaflumizone are summarized in Table 3.

Table 3. Summary of Acute Toxicity of Metaflumizone

Type of Study	Acute Toxicity Values*	Acute Toxicity Category
Acute oral	LD_{50} > 2000 mg/kg	III
Acute dermal	LD_{50} > 2000 mg/kg	III
Acute inhalation	LC_{50} 1080 mg/m^3 to 1960 mg/m^3	III
Acute eye irritation	N/A	IV
Primary dermal irritation	N/A	IV
Dermal sensitization	N/A	Not a Sensitizer
Signal word	N/A	CAUTION

*Acute Toxicity Values expressed as:
LD_{50} = Lethal dose that kills 50% of the test population
LC_{50} = Lethal environmental concentration that kills 50% of the test population
N/A = Not applicable

DPR found the submitted toxicology studies for metaflumizone sufficient to satisfy the data requirements of the Birth Defects Prevention Act (Food and Agricultural Code section 13121, et al.). Two chromosomal effects studies were submitted, and are acceptable with one of the studies indicating a possible adverse effect.

DPR prioritizes pesticide active ingredients for risk assessment based on of the nature the potential adverse health effects, the number of potential adverse effects, the number of species affected, no observable effect levels (NOELs), the potential for human exposure, use patterns, and other similar factors. Based on these criteria, pesticides with the greatest potential for health problems are placed in high priority, with other chemicals being in moderate or low priority. DPR placed metaflumizone into moderate priority for risk assessment. The purpose of the risk

assessment would be to appraise the potential for metaflumizone to cause adverse health effects in humans if exposed to the pesticide through legal use. A summary of all metaflumizone toxicology data is available on DPR's website at:
http://www.cdpr.ca.gov/docs/risk/toxsums/pdfs/5935.pdf.

C. Health & Safety

DPR compared the results of the acute toxicity study evaluations with the medical management information on the Siesta Insecticide Fire Ant Bait label. DPR determined that the product label bears all of the required statements and warnings regarding safety to handlers and other persons who may be exposed to the pesticide. The product label bears an adequate First Aid statement and the PPE requirements are adequate for the indicated acute toxicity hazards. The product label requires applicators or other handlers to wear long-sleeved shirt and long pants, chemical-resistant gloves, and shoes plus socks. Additionally, the label directs users to wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet, to remove clothing or PPE immediately if pesticide gets inside, and also to wash thoroughly and put on clean clothing.

D. Efficacy

Submitted efficacy studies indicate that Siesta Insecticide Fire Ant Bait provides effective control of imported and native fire ants. The label recommends both individual mound treatment and broadcast treatment. The recommended use rate for individual mound treatment is 1.0-2.0 ounces per mound with re-treatment after 4-8 weeks if needed. Broadcast treatment is recommended only in areas having a mound density of at least 1 mound per 2000 square foot area. The recommended use rate for broadcast treatment is 1.0-1.5 pounds per acre (lbs./acre), not to exceed 6 lbs./acre total or 4 applications in a one-year period.

E. Fish & Wildlife

The registrant submitted fish and wildlife toxicity studies, including studies on rainbow trout, *Daphnia magna*, zebrafish, eastern oyster, mysid shrimp, bluegill sunfish, carp, channel catfish, sheepshead minnow, fresh water and marine amphipod, earthworm, bobwhite quail, mallard duck, midge, and honeybee**.** The submitted data are adequate to characterize the toxicity to wildlife and aquatic animals from an environmental exposure**.** Table 4 summarizes the results of these studies.

Table 4. Summary of Fish & Wildlife Toxicity Values*

Test Animal	Type of Study	Acute Toxicity Value**	Relative Acute Toxicity
Rainbow trout	Water exposure (96 hrs)	0.343 mg/l LC_{50} 0.0174 mg/l NOEC	Highly toxic
Rainbow trout	Early life stage (93 day)	1.47 µg/l NOEC	N/A
Daphnia magna	Water exposure (48 hrs)	2.56 mg/l EC_{50} 1.10 mg/l NOEC	Moderately toxic
Daphnia magna	Chronic toxicity (21 day)	>1.47 µg/l NOEC	N/A
Zebrafish	Static full life (148 day)	15.0 µg/l NOEC	N/A
Eastern oyster	Water exposure (96 hrs)	136.0 µg/l EC_{50} 3.52 µg/l NOEC	Highly toxic
Mysid shrimp	Water exposure (96 hrs)	>289.0 µg/l LC_{50} <19.0 µg/l NOEC	Highly toxic
Mysid shrimp	Life cycle (28 day)	>0.645 µg/l LC_{50}	N/A
Bluegill sunfish	Water exposure (96 hrs)	>349.0 µg/l LC_{50} 75.8 µg/l NOEC	Highly toxic
Carp	Water exposure (96 hrs)	295 µg/l NOEC	N/A
Channel catfish	Water exposure (96 hrs)	271 µg/l NOEC	N/A
Sheepshead minnow	Water exposure (96 hrs)	>257 µg/l LC_{50} 28.1 µg/l NOEC	Highly toxic
Sheepshead minnow	Early life stage (41 day)	1.15 µg/l NOEC	N/A
Fresh water amphipod	Static sediment exposure (10 day)	>995 mg/dry kg LC_{50} 105 mg/dry kg NOEC	N/A
Marine amphipod	Static sediment exposure (10 day)	>935 mg/dry kg LC_{50} 397 mg/dry kg NOEC	N/A
Earthworm	Soil exposure (14 day)	>1000 mg/kg LC_{50} 1000 mg/kg NOEC	Relatively non-toxic
Bobwhite quail	Feeding (8 day)	997 ppm LC_{50} 51 ppm NOEC	Moderately toxic
Bobwhite quail	Feeding (14 day)	>2025 mg/l LD_{50} 2025 mg/l LOEC	Relatively non-toxic
Bobwhite quail	Reproduction (8 weeks)	40 ppm LOEC	N/A
Mallard duck	Feeding (14 day)	>2025 mg/l LD_{50} 2025 mg/l LOEC	Relatively non-toxic
Mallard duck	Feeding (8 day)	1281 ppm LC_{50}	Slightly toxic
Mallard duck	Reproduction (8 weeks)	35 ppm LOEC	N/A

Table 4. Summary of Fish & Wildlife Toxicity Values*

Midge larvae	Sediment exposure (10 day)	1.8 mg/dry kg LC_{50} 0.26 mg/dry kg NOEC	N/A
Honeybee	Acute contact	>106 µg a.i./bee LD_{50} 25 µg a.i./bee NOEC	Slightly toxic

* The test substance used for the studies was the technical active ingredient.
** Acute Toxicity Values expressed as:
LD_{50} = Lethal dose that kills 50% of the test population
LC_{50} = Lethal environmental concentration that kills 50% of the test population
EC_{50} = Concentration of a toxicant causing a defined non-lethal effect in 50% of the test population
NOEC = No observed effect concentration
LOEC= Lowest observed effect concentration

The data indicate that metaflumizone is relatively non-toxic to earthworms, slightly toxic to mallard ducks and honeybees, moderately toxic to bobwhite quail and *Daphnia magna*, and highly toxic to fish, oysters, and mysid shrimp. To mitigate the hazards to aquatic organisms the Siesta Insecticide Fire Ant Bait label contains the following environmental hazards statements:

- This pesticide is toxic to fish and aquatic invertebrates. DO NOT apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Cover, incorporate, or clean up granules that are spilled. DO NOT apply this product directly to bodies of water such as lakes, reservoirs, rivers, permanent streams, marshes or natural ponds, estuaries, or commercial fishponds. DO NOT contaminate water when disposing of equipment washwaters.

- FOR BROADCAST APPLICATIONS: DO NOT make broadcast application within 15 feet of perennial fresh water bodies: including lakes, reservoirs, rivers, permanent streams, marshes, natural ponds, and commercial fishponds. When it is necessary to treat active fire ant mounds within the 15-foot buffer zone, make individual mound treatments as described in the application instructions.

- DO NOT make broadcast application within 60 feet of estuarine water bodies (brackish water), including tidal water such as bays, mouths of rivers, salt marshes, and lagoons. When it is necessary to treat active fire ant mounds within the 60-foot buffer zone, make individual mound treatments as described in the application instructions.

When used as directed, DPR does not expect metaflumizone to be released into soil or waterways.

ALTERNATIVES

Imported fire ants were first reported in Alabama in the 1930's. The imported fire ant is an extremely aggressive, economically and environmentally destructive stinging ant. Despite various federal quarantine measures, the imported fire ant has spread over much of the southern United States. Texas estimates an economic loss due to fire ants of over $300 million annually. In 1998, imported fire ants were discovered in California in an Orange County commercial nursery. Since the first California discovery, they have also been found in Los Angeles, Riverside, San Bernardino, San Diego, Kern, Fresno, Madera, Stanislaus, and Sacramento counties.

Siesta Insecticide Fire Ant Bait effectively controls both imported and native fire ants. Imported and native fire ants are strongly attracted to Siesta Insecticide Fire Ant Bait and carry it into the nest as food, destroying the colony as they feed upon the bait. The mode of action of metaflumizone, as well as the strong bait acceptance, make Siesta Insecticide Fire Ant Bait very effective and fast acting. Siesta Insecticide Fire Ant Bait can also be used in conjunction with a follow up application of a conventional contact insecticide. The Siesta Insecticide Fire Ant Bait label recommends allowing 7 days between the bait application and the use of a contact insecticide on the bait treated area. A number of baits with other active ingredients and contact insecticides are currently registered in California for control of fire ants. However, an effective integrated pest management strategy requires the flexibility of a large number of comparable, but not exactly equivalent, pesticides in order to reduce the development of resistance.

CONCLUSION

DPR evaluated the product label and scientific data submitted to support the registration of Siesta Insecticide Fire Ant Bait. The label and data were found acceptable to support conditional registration. The acute health risks to humans from exposure to metaflumizone are minimal due to its low mammalian toxicity. The precautionary and first aid statements on the product label, and the recommended protective measures mitigate potential health risks to persons who may be exposed to these pesticides. If a risk assessment conducted by DPR determines that exposure to metaflumizone may result in unacceptable margins of exposure, further restrictions will be placed on the use of metaflumizone at that time. Conditional registration of Siesta Insecticide Fire Ant Bait is recommended for one year pending the submission of an acceptable 12-month storage stability and corrosion characteristics study. If BASF Corporation does not submit the required data within one year, the registration for Siesta Insecticide Fire Ant Bait will not be renewed.