CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION
PUBLIC REPORT 2003-5

Noviflumuron
Tracking ID Numbers CRR-193920 thru CCR-193923

DESCRIPTION OF ACTION

Dow AgroSciences LLC has submitted an application seeking California registration of Noviflumuron Technical (EPA Reg. No. 62719-452), Noviflumuron 50% Concentrate (EPA Reg. No. 62719-453), Recruit III (EPA Reg. No. 62719-454), and Recruit III AG (EPA Reg. No. 62719-478) to control subterranean termites. This product contains the new active ingredient noviflumuron.

The Department of Pesticide Regulation (DPR) evaluated the product labels and scientific data supporting registration of these products and found them to be acceptable to support registration. The acute health risks from exposure to noviflumuron are minimal due to its low mammalian toxicity. Precautionary and first aid statements on the product labels adequately mitigate potential health risks to persons who may come in contact with the pesticide. DPR does not expect significant adverse environmental impacts to result from registration of these products.

DPR accepted Dow's applications for registration concurrently with Dow's submission of applications to the United States Environmental Protection Agency (U.S. EPA) for federal registration. U.S. EPA registered Noviflumuron Technical, Noviflumuron 50% Concentrate, Recruit III, and Recruit III AG on May 13, 2003.

BACKGROUND

Registrant:	Dow AgroSciences LLC
Common name:	Noviflumuron
Chemical name:	(N{[[3,5-dichloro-2-fluro-4-(1,1,2,3,3,3-hexafuoropropoxy) phenyl]amino]carbonyl}-2,6-difluorobenzamide)
Brand names:	Noviflumuron Technical, Noviflumuron 50% Concentrate, Recruit III, and Recruit III AG
Uses:	To control subterranean termites
Pests controlled:	Termites
Type of registration:	Unconditional

Noviflumuron Technical and Noviflumuron 50% Concentrate are intended solely for use in the manufacturing of pesticide products. Both products are liquid concentrates with Noviflumuron Technical containing 98% noviflumuron, and Noviflumuron 50% Concentrate containing 50% noviflumuron. Recruit III and Recruit III AG are end-use pesticide products formulated with 0.5% noviflumuron impregnated in a cellulose matrix to form a solid bait. These products are intended to be used in a subterranean bait station or above the ground as a self contained bait block. Target sites include buildings, fences, utility poles, decking, and landscape plantings.

Noviflumuron is an insect growth regulator (IGR) that prevents the successful molting and development of subterranean termites. This disruption in termite growth and activity results in the decline of the colony to the point where the colony can no longer sustain itself and dies. Before using noviflumuron, subterranean termite activity is first determined through monitoring in and around the target site. When activity is detected, the 0.5% noviflumuron bait can be placed directly in the monitoring stations or applied in separate baitube devices or bait blocks. Termites can be collected from the monitoring device and added directly to the noviflumuron bait to hasten bait detection and feeding. The baitubes and bait stations are monitored and new bait is added as needed until feeding ceases. Under optimum conditions, termite colonies can be eliminated in three to three and one half months. When termite activity is no longer detected, monitoring only is resumed at the site to determine that the site remains free of new termite infestations.

The termite control program designed by Dow AgroSciences LLC virtually eliminates exposure to noviflumuron for the applicator and persons living at the treatment site. Since treatments are made only after termite activity is detected, the amount of pesticide used is greatly reduced compared to chemical barrier treatment programs. The application of noviflumuron with baitube and bait station devices protects wildlife from exposure.

SCIENTIFIC REVIEW

A. Chemistry

1. Product Chemistry: DPR evaluated the submitted chemistry studies for Noviflumuron Technical, Noviflumuron 50% Concentrate, Recruit III, and Recruit III AG and summarized the results in the following table.

Table I. Physical and Chemical Properties Using Technical Noviflumuron as the Test Substance

Properties	Values
Physical state	White powder
Density	1.88 g/cm^3
Partition Coefficient	4.94, $\log_{10}$ Kow 86200
Solubility (water)	1.94x10^{-4} g/L (20°C)
Vapor pressure	2.2 x 10^{-10} Pa (25°C)
Stability	Stable at normal + elevated temps.

Table II. Physical and Chemical Properties Using Noviflumuron 50% Concentrate as the Test Substance

Properties	Values
Physical state	White odorless liquid
Nominal Concentration	50% (w/w)
pH	8-9 at 20° C (10% dilution)
Density	1.289 g/ml at 20° C
Flammability	Flash point > 200° F or 93° C

DPR found the product chemistry data to be satisfactory to meet the regulatory data requirements to support the registration of these products.

2. Residues in Food and Animal Feed: The noviflumuron products are not intended for use on food or feed. Therefore, residue data are not required.

3. Environmental Fate: The environmental fate data reviewed included studies on soil adsorption/desorption, hydrolysis, and aerobic soil metabolism. The results indicate noviflumuron is stable to hydrolysis under acidic and neutral conditions; however it hydrolyzed to different degradation products under basic conditions. The estimated half-life is 19 days. Noviflumuron showed a tendency to absorb strongly to different soil types and metabolize slowly in sandy loam soil. The aerobic soil metabolism study observed a slow metabolism rate with a half-life of 232 or 368 days depending on where the radioactive label was placed on the noviflumuron molecule.

The submitted studies were found to be satisfactory and support registration of the subject products. The current proposed use of noviflumuron is expected to have minimal impact on the environment. When used in accordance with label directions, there is little potential for noviflumuron to accumulate or move into ground water. However, additional environmental fate studies may be required if use of this active ingredient is expanded in the future.

B. Toxicology

Dow AgroSciences LLC submitted adequate toxicology studies to conduct complete toxicological evaluations for Noviflumuron Technical, Noviflumuron 50% Concentrate, Recruit III, and Recruit III AG. DPR evaluated the submitted data to ascertain the potential for acute adverse health effects. The acute toxicity parameters for Noviflumuron Technical and Noviflumuron 50% Concentrate are summarized in the following tables.

Table III. Acute Toxicity of Technical Noviflumuron

Type of Study	Acute Toxicity Values	Acute Toxicity Category
Acute oral (rats)	>5000 mg/kg	IV
Acute dermal (rabbits)	>5000 mg/kg	IV
Acute inhalation (rats)	5.24 mg/L	IV
Primary eye irritation (rabbits)	Slight irritation	IV
Primary dermal irritation (rabbits)	Negative	IV
Dermal sensitization (guinea pigs)	N/A	Not a sensitizer

Table IV. Acute Toxicity of 50% Concentrate

Type of Study	Acute Toxicity Values	Acute Toxicity Category
Acute oral (rats)	>5000 mg/kg	IV
Acute dermal (rabbits)	>5000 mg/kg	IV
Acute inhalation (rats)	5.24 mg/L	III
Primary eye irritation (rabbits)	Slight irritation	IV
Primary dermal irritation (rabbits)	Negative	IV
Dermal sensitization (guinea pigs)	N/A	Not a sensitizer

DPR's evaluation indicates the studies are acceptable and Noviflumuron Technical, Noviflumuron 50% Concentrate, Recruit III, and Recruit III AG are low in mammalian toxicity. DPR toxicologists determined that the differences in formulations between the two end-use products and noviflumuron 50% concentrate were unlikely to be of toxicological concern. Acute toxicity studies conducted with noviflumuron 50% are suitable for bridging to the two end-use products. The precautionary language on the product labels adequately identifies the acute toxicity hazards noted in the studies.

DPR found the submitted toxicology studies sufficient to satisfy the data requirements of the Birth Defects Prevention Act (Food and Agricultural Code section 13121 *et.al*.). No adverse health effects were observed. The requested registrations are for termiticide bait products that will result in minimal exposure to the active ingredient. Based on the Code of Federal Regulations 40 (Protection of Environment) section 158.340, a full set of chronic toxicity studies are not required at this time. Any future registration submissions for other uses of noviflumuron will require reevaluation of the entire database.

At this time, noviflumuron has not been prioritized by DPR for risk assessment. DPR prioritizes pesticide active ingredients for risk assessment based on the nature of the potential adverse health effects, number of potential adverse effects, number of species affected, no effect levels (NOELs), potential for human exposure, use patterns and 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. The purpose of the risk assessment would be to appraise the potential for noviflumuron to cause adverse health effects in humans if exposed to the pesticide as the result of a legal use. The potential for exposure from eating food crops treated with noviflumuron will also be evaluated during the risk assessment. Further toxicity

information is available in DPR's Summary of Toxicology Data for noviflumuron, available on DPR public website at: http://www.cdpr.ca.gov/docs/toxsums/pdfs/5816.pdf.

C. Health & Safety

An evaluation of the medical management information on the Recruit III and Recruit III AG labels and the acute toxicity study results indicate the product labels bear all of the required statements and warnings regarding safety to handlers and other persons who may be exposed to the pesticide.

D. Fish & Wildlife

The registrant submitted fish and wildlife toxicity studies, including studies on northern bobwhite, mallard duck, rainbow trout, bluegill sunfish and daphnia magna. The submitted data are adequate to characterize the toxicity to wildlife and aquatic animals from an environmental exposure. Table V summarizes the results of these studies.

Table V. Summary of Toxicity Studies for Wildlife

Test Animal	Type of Study	Acute Toxicity Value[a]	Relative Toxicity
Rat (male, female)	Single acute oral dose	>5000 mg/kg(LD_{50})	Relatively non-toxic
Bluegill sunfish	Water exposure (96 hrs.)	>1.63 mg a.i./l (LC_{50})	Moderately toxic
Rainbow trout	Water exposure (96 hrs.)	>1.77 mg a.i./l (LC_{50})	Moderately toxic
Daphnia magna	Water exposure (48 hrs.)	311 ng a.i./l (EC_{50})	Highly toxic
Bobwhite quail	Single oral acute dose	>2000 mg/kg (LD_{50})	Relatively non-toxic
Bobwhite quail	Feeding study (8 days)	4100 mg/kg (LC_{50})	Slightly toxic
Mallard duck	Feeding study (8 days)	>5300 mg/kg (LC_{50})	Relatively non-toxic

a. Values expressed as: 1. LD_{50}= lethal dose that will kill 50% of test population; and 2. LC_{50}= lethal environmental concentration that will kill 50% of test population. The test substance used for the studies was technical noviflumuron.

The data indicate that noviflumuron is relatively non-toxic to vertebrate animals, birds, moderately toxic to fish and highly toxic to freshwater invertebrates. The proposed label does bear precautionary statements regarding the high toxicity to freshwater invertebrates. The environmental fate data indicates noviflumuron is strongly bound to soil and has low water solubility indicating a low potential for soil leaching. The proposed use for noviflumuron as a self contained bait to control termites around structures, fence posts, utility poles and landscape plantings is not expected to pose a treat to wildlife.

E. Efficacy

The submitted efficacy studies were developed using the proposed application rates and methods on the Recruit III label. The data were developed from different locations including California. The studies entailed various aspects of termite control such as impact on termite populations, deterrence of bait, and time to eliminate the

target colony. The data indicate IG007 (Recruit III) provided effective control of subterranean termites.

ALTERNATIVES

Noviflumuron is a structural analog of the pesticide active ingredient hexaflumuron. Pesticide products containing hexaflumuron are currently registered for use in California for termite control. However, recent research indicates noviflumuron is more efficacious than hexaflumuron and Dow AgroSciences LLC plans to eventually replace it with noviflumuron. As an insect growth regulator (IGR), noviflumuron prevents the successful molting and development of subterranean termites and eventually eliminates the colony. Products formulated with noviflumuron are intended for use only when termite activity is detected. Noviflumuron is a safer alternative to termite control products formulated with chlorpyrifos, imidacloprid, fipronil or synthetic pyrethroids. These products are generally more toxic and are applied to the soil on a preventive basis to create a chemical barrier in the soil between a structure and foraging subterranean termites. These products are applied at much higher rates than noviflumuron and have a greater potential for exposure to the applicator and the environment.

CONCLUSION

DPR evaluated the product labels and scientific data submitted to support the registration of Noviflumuron Technical, Noviflumuron 50% Concentrate, Recruit III, and Recruit III AG and found them acceptable to support registration. The acute health risks to humans from exposure to noviflumuron are minimal due in part to its mode of action that is specific to insects. The end-use products are formulated with 0.5% active ingredient in a cellulose bait which virtually eliminates exposure to the applicator, the homeowner and the environment. If a risk assessment is conducted and DPR determines that exposure to noviflumuron may result in unacceptable margins of exposure, further restrictions will be placed on the use of noviflumuron at that time. The submitted data also indicate significant adverse environmental impacts are not expected to occur from the use of Noviflumuron Technical, Noviflumuron 50% Concentrate, Recruit III and Recruit III AG. When used in accordance with label directions, these products should be effective for their intended use.