UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND
TOXIC SUBSTANCES

March 14, 1989

MEMORANDUM

SUBJECT: Biological Evaluation of Public Interest Documentation Submitted by Griffin Corporation in Support of Sulfluramid Ant Bait Stations (Raid® Ant Controller II).

FROM: David W. Brassard, Senior Entomologist DWB
Biological Analysis Branch
Biological and Economic Analysis Division (H 7503-C)

TO: Phil Hutton, Product Manager
PM 17
Insecticide/Rodenticide Branch
Registration Division (H 7505-C)

THRU: E. David Thomas, PhD
Chief, Entomology Section
Biological Analysis Branch
Biological and Economic Analysis Division (H 7503-C)

I have reviewed the Public Interest Documentation submitted by Griffin Corporation in support of sulfluramid ant bait stations (Raid® Ant Controller II) and am offering the following discussion and conclusions for your consideration.

Sulfluramid is a delayed action toxicant that belongs to a new class of insecticides known as the flouroaliphatic sulfonamides. Sulfluramid kills insects by interfering with cellular respiration via the uncoupling of oxidative phosphorylation. The applicant is proposing conditional registration of a 0.5 percent sulfluramid bait station for control of ants in homes.

The applicant makes a variety of claims for this formulation including:

-most advanced ant killing agent
-faster acting than IGR's or hydramethylnon
-the most effective ant bait you can buy
-kills the queen; kills the colony
-kills a variety of household ants (black carpenter ants, argentine ants, cornfield ants, pharaoh ants, etc.)

In support of these claims the applicant has submitted one laboratory study on the subject formulation, several laboratory and field studies on a [redacted] and a great deal of creative narrative which attempts to demonstrate efficacy using deductive reasoning.

In the first study Owens and Szymczak (1988) evaluated the efficacy of sulfluramid, hydramethylnon, and propoxur ant bait stations against laboratory colonies of pharaoh ants. In this study, only the sulfluramid bait stations successfully eliminated colonies. Exposure to hydramethylnon and propoxur bait stations only resulted in population reductions in the range of 66 to 77%. In a test of hydramethylnon (Combat®) baits, without the bait station, pharaoh ant colonies were completely eliminated suggesting that Combat's bait station may inhibit feeding. The results of this study are summarized in Table 1.

Table 1. Mean population reductions within pharaoh ant colonies following treatment with bait toxicants. Percentages given are the mean of three replicates after a 42 day exposure to the bait.

Toxicant (% ai)	Percent Population Reduction		
	Workers	Brood	Queens
Sulfluramid (0.51%)	100*	100**	100*
Hydramethylnon (0.9%) (Combat®)	77	77	67
Propoxur (0.25%) (Black flag)	66	70	0
Hydramethylnon (0.9%) (Combat w/o station)	100	100	100
Control	+107***	+20***	+100***

* eliminated within 28 days
** eliminated within 21 days
***represents percentage population increase

Although this study was fairly well designed (replicated, included controls and comparison treatments, and was free choice) it is not useful for evaluating product performance under actual use conditions because it fails to evaluate how the bait competes with natural food sources. Ants are the most plastic (i.e. adaptable) insects known to man and can be conditioned in the laboratory to feed on food items they would not normally find attractive. According to the Product Performance Guidelines (Section 95-11 (c) (3)) laboratory tests are only useful in establishing the proper dosage and intrinsic attractancy of a formulation. The utility of the product should be evaluated under actual use conditions (EPA, 1982). I have not seen any data demonstrating the attractiveness of the combination of inert [redacted] (Brassard, 1989).

157

[redacted]

The narrative justification accompanying this documentation (Hainze, 1988) contains many unsupported (no references or data cited to support) assertions. For example the applicant mentions field testing for bait acceptability by Argentine ants, harvester ants, and odorous house ants but includes no data explaining the results. The applicant then reasons that because the bait was well accepted in these tests we can assume product efficacy against these species. The applicant also includes an unsupported assertion that residual sprays are ineffective in killing the ant colony. My investigations into the efficacy of various ant control methods (in support of my direct testimony used in the Sodium arsenate hearings) convinced me that nest treatment with residual insecticides is the most effective control strategy for ants (Brassard, 1989). The inclusion of unsupported biased assertions of this type raises serious doubts that any of the other claims have been made in good faith.

There were no data included in this documentation to support the claims that sulfluramid ant baits are effective against the black carpenter ant, Argentine ant, or cornfield ant. My investigations have shown that insecticidal baits are not effective in controlling carpenter ants and that baits containing [redacted] found in this sulfluramid bait have not demonstrated satisfactory control against Argentine ants which generally prefer sweet liquid baits (Brassard, 1989). In fact, a personal communication between myself and John Owens of S.C. Johnson indicated that, in a laboratory efficacy test conducted by Mike Rust at the University of California, Argentine ant colonies were not eliminated by treatments with sulfluramid baits.

Conclusions

The documentation presented here does not, in my opinion, contain enough data to support the basic efficacy data requirements for registration. Although the laboratory study included in this documentation did show complete control of pharaoh ants colonies in a laboratory setting, it did not evaluate how the bait competes with natural food sources. The Product Performance Guidelines specify that the utility of the product should be evaluated under actual use conditions. [redacted] Additionally the justification accompanying this documentation contains many unsupported and biased assertions and raises serious doubts that any of the claims have been made in good faith. Lastly there were no data included in this documentation to support the claim that this bait is effective against the black carpenter ant, Argentine ant, or cornfield ant.

I do not believe that the sulfluramid ant baits satisfy the basic criteria for a Public Interest Finding. Specifically I do not believe, with the exception of pharaoh ants, that there is a need for a new chemical that is not being met by other currently registered pesticides. My investigations have shown that Drax ant kil gel is the only product currently marketed to consumers that has been demonstrated to be efficacious against pharaoh ants. For other ant species there are many effective alternative ant bait products containing active ingre-

dients such as bendiocarb, borax, boric acid, chlorpyrifos, hydramethylnon, and propoxur. Of these, only hydramethylnon has been demonstrated to be a delayed action toxicant over a wide range of concentrations. Refer to Table 3 for a complete list of registered ant bait products.

Except for the lack of convincing efficacy data, I believe that a IV A 2 Presumption of Public Interest (see attached FR notice) would be appropriate because of the sodium arsenate Notice of Intent to Cancel and subsequent Administrative Hearing.

References

Banks, W.A. 1987. Control of Imported Fire Ants with New Insect Growth Regulator and Fluorocarbon baits. Origin Unknown. pp 76 to 82.

Brassard, D.W. 1989. Direct Testimony of David W. Brassard. In the Matter of Protexall et al., FIFRA Docket Nos. 625 et al.. Environmental Protection Agency, Washington, DC 20460 60 pp plus tables and exhibits.

Hainze, J. 1988. Label Claim Support for Raid Ant Controller II. Internal Document, S.C. Johnson & Son, Inc., Racine, WI 53403, 8 pp.

Owens, J.M. and J. Szymczak. 1988. Efficacy Data/ Ant Baits/ Pharaoh Ants. Unpublished efficacy study, S.C. Johnson & Son, Inc., Racine, WI 53403, 4 pp.

EPA. 1982. Pesticide Assessment Guidelines: Subdivision G: Product Performance. Office of Pesticide Programs, Environmental Protection Agency, Washington, DC 20460, p. 270-271.

Vander Meer, R.K., C. Lofgren, and D. Williams. 1986. Control of Solenopsis invicta with Delayed Action Fluorinated Toxicants. Pesticide Science, Vol. 17, p. 449-455.

PRODUCT PERFORMANCE DATA REQUIREMENTS (§ 158.160)—Continued

	Guideline reference	Time generally allowed for conducting study (months)
Actual Washing Machine Test		6
Self-Sanitizing Laundry Additives (residual):		
AOAC (Bacteriostatic) Activity of Laundry Additives		6
AATCC Committee RA31, Test Method 100-1974		6
Actual Washing Machine Test		6
Carpet Sanitizers:		
Sanitizer Carpet RD, EPA		6
Air Sanitizers—No Std. Test (for products w/o glycols)	*91-6	9
Products for Control of Microbial Pests Associated With Human and Animal Wastes; Treatments for Toilet Bowl and Urinal Surfaces	91-7	
Disinfectants:		
AOAC Use-Dilution Method		6
AOAC Germicidal Spray Products Test		6
Sanitizers:		
Sanitizers—Non Food contact surfaces		6
Sanitizers for Toilet and Urinal Bowl Water:		
Test in toilet/urinal		6
Products for Treating Water Systems	91-8	
Potable Water Treatment Units:		
No standard test		6
Swimming Pool Water:		
AOAC Method for Water Disinfectants for Swimming Pools		6
Actual Swimming Pool Test		9
Efficacy of Fungicides and Nematicides		
Products for Control of Organisms Producing Mycotoxins	93-16	27
Efficacy of Vertebrate Control Agents:		
Avian toxicants	96-5	
TOX tests		9
LAB acceptance tests		9
LAB efficacy tests		9
Field tests		9
Avian Repellents	96-6	
TOX tests		9
LAB acceptance tests		9
LAB efficacy tests		9
Field tests		9
Avian frightening agents	96-7	
TOX tests		9
LAB acceptance tests		9
LAB efficacy tests		9
Field tests		9
Bat toxicants and repellents	96-9	
TOX tests		9
LAB efficacy tests		9
Field tests		9
Commensal rodenticides	96-10	
TOX tests		9
LAB efficacy tests		9
Field tests		9
Rodenticides on Farm and Rangelands	96-12	
TOX tests		9
LAB efficacy tests		9
Field tests		9
Rodent fumigants	96-13	
TOX tests		9
LAB efficacy tests		9
Field tests		9
Rodent reproductive inhibitors	96-16	
TOX tests		9
LAB efficacy tests		9
LAB breeding tests		12
Field tests		27
Mammalian predacides	96-17	
TOX tests		9
BAIT acceptance tests		9
LAB efficacy tests		9
Field tests		12

The timeframes in the tables will serve as the basis for determining whether sufficient time has elapsed for a study to have been generated. Based on the date of imposition of data requirements given in Unit II.A. and the timeframes needed for generation of data given in Unit II.C. an applicant seeking conditional registration of a new chemical must satisfy the Agency that he has had insufficient time to generate a particular study that he is unable to submit at the time of application. Prospective applicants should note that, based on the 1982 date of imposition which the Agency presumes to apply in the majority of situations, sufficient time to conduct a large number of the listed studies has already passed. If the timeframes for all required studies have elapsed, the Agency cannot grant conditional registration if any of those studies are missing at the time of application.

If conditional registration is approved, the timeframes in Unit II.C will be used to determine the duration of the conditional registration. Conditional registration will be granted to coincide with the timeframe for generation of the longest study conditionally required. If the results of the conditionally required study trigger a requirement for another (tiered) study, the conditional registration may be extended.

III. Risk Assessment for New Chemicals

The second criterion that must be met for approval of conditional registration is a risk criterion. The Agency must determine that use of the pesticide for the limited period while the required studies are conducted will not cause unreasonable adverse effects on human health or the environment.

Risk assessment for a new chemical will focus on the potential risks from use of the pesticide for the limited time period while required studies are being generated. Since the data base for a new chemical must be virtually complete at the time of application (lacking only those studies recently imposed, or those that the applicant could not reasonably ascertain were required), the Agency should be able to adequately characterize the risks likely in the short term. Approval will be based on the Agency's determination that the data base as a whole provides reasonable assurance of acceptable human and environmental risk during the limited time while studies are being generated.

IV. Public Interest Finding

Finally, the Agency must determine that use of the new chemical during the period of the conditional registration will be in the public interest. In deciding whether this public interest criterion has been satisfied, EPA will consider a number of factors, enumerated in this unit. However, neither the applicant's desire to market the pesticide nor a user's desire to have the product available is sufficient grounds for a public interest finding.

A. Presumption of Public Interest

In certain circumstances, EPA will presume that the use of a pesticide is in the public interest. In these instances, the applicant need not substantiate the public interest finding. Registration of a new pesticide is presumed to be in the public interest for the following uses:

1. A minor crop use. The Agency intends to issue in the Federal Register a notice of its minor crop policies.

2. A replacement for another pesticide that is of continuing concern to the Agency. These pesticides are those which have been determined, through the special review process, to present relatively high risk, but whose registration has been continued because the benefits are also relatively high (often because of a lack of alternatives).

3. A use for which an exemption under FIFRA sec. 18 has been granted, if the basis for the exemption was the lack of a registered alternative product.

4. A use against a pest of public health significance.

B. Factors Affecting a Public Interest Finding

For all other new chemicals, EPA will consider a variety of factors pertaining to the need for the chemical, its comparative benefits, risks, and costs. The Agency must determine that (1) there is a need for the new chemical that is not being met by other currently registered pesticides or on-pesticidal alternatives; (2) the new pesticide is comparatively less risky to health or the environment than currently registered pesticides; or (3) the benefits (including economic benefits) from use of the new chemical exceed those of alternative registered pesticides and other available non-chemical techniques.

The Agency may consider any or all of the factors listed below to determine whether the public interest finding can be made. The list is intended to provide guidance to applicants on the considerations that may influence the Agency's decision. In many cases, the data required by Part 158 as part of the application will suffice to support the public interest finding and no information need be submitted by the applicant; however, the burden rests with the applicant to provide additional

Table 3. Product Data on Alternative Ant Bait Formulations to Sodium Arsenate.

Active Ingredient	Registration Number	Percent AI	Product type	Product Name	Registrant Name
Arsenic trioxide	1663-15	0.46%	Impregnated stake	Grants ant control	Grant Laboratories, Inc.
Avermectin B_1	618-93	0.011%	Fire ant bait	Affirm fire ant bait	Merck
	618-94	0.011%	Fire ant bait	Affirm fire ant insecticide	Merck
Bendiocarb	506-143	0.0312%	Bait station	Tat-1 ant trap	Walco-Link Co.
Borax	149-8	5.4%	[redacted]	Terro California ant killer	Senoret Chem. Co.
	358-169	5.0%	Bait station	Nott ant-x-trap	Nott Mfg. Co.
	395-33	5.4%	[redacted]	Magi-kil jelly	Lethelin products Co.Inc.
	3095-24	5.0%	Bait station	Pic ant trap	Pic Corporation
	5887-134	5.4%	Bait station	Black leaf ant trap	Black Leaf Products Co.
	9086-3	5.4%	Bait station	Magi-kil ant trap	Roxo International
Boric acid	60-3	4.5%	[redacted]	Gator ant bait	H.R. McClane, Inc
	475-237	2.0%		Antrol ant killer formula II	Boyle-Midway
	3314-92	5.0%	Granular	Pharaoh ant piper	Colonial Products Inc.
	4972-23	9.5%	[redacted]	Protexall ant-kil	Protexall Products Inc.
	4972-50	12.0%	Bait station	Hide ant trap	Protexall Products Inc.
	44313-6	5.0%	[redacted]	Drax ant kil gel	R Value, Inc.
	44313-13	5.0%		Drax ant kil PF	R Value, Inc.
	47056-4	51.0%		Superior roach and ant gel	H. R. McLane & Co. Inc.
	49315-4	6.0%		Bug wizard ant bait	Integrated Pest Mgt. Syst
Chlorpyrifos	475-254	0.5%	Bait station	Black flag ant control system	Boyle-Midway
	10370-4457	0.5%	Granular	Ford's roach and ant bait	Ford's Chemical & Srvc Co
	34149-3545	0.5%	Granular	Bug house roach & ant bait	Bug house Chemical Store
	47006-5	0.5%	Granular	Orlick big red ant bait	Phaeton Corp.
Fenoxycarb	35977-4	1.0%	Fire ant bait	Logic fire ant bait	Maag Agrochem. R & D
	35977-27	1.0%	Fire ant bait	Maag Logic fire ant bait	Maag Agrochem. R & D
Hydramethylnon	241-260	0.88%	Fire ant bait	Amdro fire ant insecticide	American Cyanamid Co.
	241-261	0.88%	Fire ant bait	Amdro fire ant insecticide	American Cyanamid Co.
	241-304	0.9%	Fire ant bait	Amdro ant control stations	American Cyanamid Co.
	1730-65	0.88%	Fire ant bait	Combat fire ant killer	American Cyanamid Co.
	1730-68	0.9%	Bait station	Combat ant control system	American Cyanamid Co.
	1730-72	0.9%	Bait station	Maxforce pharaoh ant killer	American Cyanamid Co.
	1730-73	0.9%	Bait Station	Combat ant control system II	American Cyanamid Co.
Methoprene	20954-109 1/	10.0%	Liquid concentrate	Pharorid ant growth regulator	Zoecon Prof. Pest Mgt D
Propoxur	358-163	1.0%	Bait station	Nott ant trap	Nott Mfg. Co.
	475-173	2.0%	Bait station	Antrol ant trap	Boyle-Midway
	475-213	0.25%	Bait station	Black flag ant trap form II	Boyle-Midway
	506-136	0.25%	Bait station	Antcheck ant trap	Walco-Link Co.
	506-137	0.25%	Bait station	Tat ant trap	Walco-Link Co.
	506-138	0.25%	Bait station	E-Z ant trap	Walco-Link Co.
	1663-26	1.7%	[redacted]	Grants ant control gel	Grant Laboratories
	1663-27	1.7%	Bait station	Grants ant trap	Grant Laboratories
	1663-29	1.7%	Impregnated stake	Grants ant control	Grant Laboratories
	3095-17	0.25%	Bait station	Pic ant trap	Pic Corporation
	3941-24	2.0%	Bait station	Echols roach and ant killer	Athena corporation
	8730-35	10.0%	Bait station	Lure & kill roach & ant bait	Hercon Laboratories Corp.
	52115-3	0.25%	Bait station	Curex ant trap	Columbia Specialty Co.
Trichlorfon	8612-105	5.0%	Granular bait	B & G ban bug bait	B & G Company

1/ transferred to 2724-386 on September 25, 1986.

Exhibits 217, 260, 288, 295, and 296.