

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:

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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

Dy.

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 9.5 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 and a great deal of creative marrative 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

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

sard, 1989).

(Bras-

^{**} eliminated within 21 days

^{***}represents percentage population increase

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 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.

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 <u>Solenopsis</u> invicta with Delayed Action Fluorinated Toxicants. Pesticide Science, Vol. 17, p. 449-455.

PRODUCT PERFORMANCE DATA REQUIREMENTS (8 158 160)—Continued

(§ 158.160)—Contin	wed	
-	Guide- tre refer- ence	Time general- ly atowed for conduct- eng study (months)
Actual Washing Machine Test		6
Sell-Senitong Laundry Additives fre- aduals:		
AOAC (Bectenostatic) Activity of		
AATOC Committee RA31. Test		
Method 100-1974 Actual Westing Machine Test		•
Carpet Servitzers: Servitzer Carpet RO, EPA		6
Air Senemers-No Std. Teel (for prod-	*91-6	
ucts w/o glycols) Products for Control of Microbial Peets Associated With Human and Animal Wastes; Treatments for Tollet Bowl and I time! Surfaces	91-7	-
Dentectants:		4
AOAC Use-Dilution Method AOAC Germodel Spray Products Test		. •
Sentizers—Non Food contact sur-		
Senitzers for Tolet and Urinel Bowl Water:		6
Test in toilet/urnel	91-8	
No standard test Swimming Pool Water: AOAC Method for Water Disinfectants for Swimming Pools		
Actual Swittening Pool Test		•
Efficacy of Fungicides and Nemeticides		
Products for Control of Organisms Pro- ducing Mycolosins Efficacy of Vertebrate Control Agents Avian toxicants	93-16 96-5	27
TOX tests	}	9
LAB acceptance tests	ļ	
Field lests	96-6	
TOX tests	ļ	
LAB efficacy tests	<u> </u>	
Avian Inginierung agents	96-7	-
LAS acceptance lests	 	
Field tests		1 .
Bal toucants and repetients	96-0	
LAB efficacy tests	1	
Commensai odenecides	96-10	-
LAB afficacy wets	 	} :
Field tests Rodenscides on Farm and Rangelands	96-12	
TOX tests	1	
Field tests Rodent furnigents	96-13	
TOX tests		- :
Feld lests	96-16	•
Rodent reproductive inhibitors		
LAB efficacy tests	1	12
Field tests Mammelan predecides	96-17	27
TOX tests	1	-
SAIT acceptance tests	1	
LAB efficacy tests	- 3] 12

The timeframes in the tables will serve as the basis for determining whether sufficient time has slapsed 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 ILC 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.

으로 Active Coloredient 다	Registra- tion Number	Percent AI	Product type	Product Name	Registrant Name
Arsenic trioxide	1663-15	0.46%	Impregnated stake	Grants ant control	Grant Laboratories, Inc.
HAvermectin B ₁ O Z	618-93 618-94	0.011% 0.011%	Fire ant bait Fire ant bait	Affirm fire ant bait Affirm fire ant insecticide	Merck Merck
თ Bendiocarb	506-143	0.0312%	Bait station	Tat-l ant trap	Walco-Link Co.
GREDIENT BOLEX	149-8 358-169 395-33 3095-24 5887-134 9086-3	5.4% 5.0% 5.4% 5.0% 5.4%	Bait station Bait station Bait station Bait station	Terro California ant killer Nott ant-x-trap Magi-kil jelly Pic ant trap Black leaf ant trap Magi-kil ant trap	Senoret Chem. Co. Nott Mfg. Co. Lethelin products Co.Inc. Pic Corporation Black Leaf Products Co. Roxo International
NE N	60-3 475-237 3314-92 4972-23 4972-50 44313-6 44313-13 47056-4 49315-4	4.5% 2.0% 5.0% 9.5% 12.0% 5.0% 51.0% 6.0%	Granular Bait station	Gator ant bait Antrol ant killer formula II Pharaoh ant piper Protexall ant-kil Hide ant trap Drax ant kil gel Drax ant kil PF Superior roach and ant gel Bug wizard ant bait	H.R. MccLane, Inc Boyle-Midway Colonial Products Inc. Protexall Products Inc. Protexall Products Inc. R Value, Inc. R Value, Inc. H. R. McLane & Co. Inc. Integrated Pest Mgt. Syst
Ochlorpyrifos H H H	475-254 10370-4457 34149-3545 47006-5	0.5% 0.5% 0.5% 0.5%	Bait station Granular Granular Granular	Black flag ant control system Ford's roach and ant bait Bug house roach & ant bait Orlick big red ant bait	Boyle-Midway Ford's Chemical & Srvc Co Bug house Chemical Store Phaeton Corp.
ZFenoxycarb O H	35977 - 4 35977-27	1.0%	Fire ant bait Fire ant bait	Logic fire ant bait Maag Logic fire ant bait	Maag Agrochem. R & D Maag Agrochem. R & D
Hydramethylnon H H U U U U U U U U U U U U U U U U U	241-260 241-261 241-304 1730-65 1730-68 1730-72 1730-73	0.88% 0.88% 0.9% 0.88% 0.9% 0.9%	Fire ant bait Fire ant bait Fire ant bait Fire ant bait Bait station Bait station Bait Station	Amdro fire ant insecticide Amdro fire ant insecticide Amdro ant control stations Combat fire ant killer Combat ant control system Maxforce pharaoh ant killer 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
M H C H H H H H H H H H H H H H H H H H H	358-163 475-173 475-213 506-136 506-137 506-138 1663-26 1663-27 1663-27 1663-29 3095-17	1.0% 2.0% 0.25% 0.25% 0.25% 0.25% 1.7% 1.7% 0.25%	Bait station Timpregnated stake Bait station	Nott ant trap Antrol ant trap Black flag ant trap form II Antcheck ant trap Tat ant trap E-Z ant trap Grants ant control gel Grants ant trap Grants ant control Pic ant trap	Nott Mfg. Co. Boyle-Midway Boyle-Midway Walco-Link Co. Walco-Link Co. Grant Laboratories Grant Laboratories Grant Laboratories Pic Corporation
FORMATION	3941-24 8730-35 52115-3	2.0% 10.0% 0.25%	Bait station Bait station Bait station	Echols roach and ant killer Lure & kill roach & ant bait Curex ant trap	Athena corporation
ZTrichlorfon H	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.