REREGISTRATION ELIGIBILITY DOCUMENT
ALLIUM SATIVUM
(GARLIC)

LIST D

CASE 4007

JUNE 1992

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION
WASHINGTON, D.C.

ALLIUM SATIVUM (GARLIC) REREGISTRATION ELIGIBILITY TEAM

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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
Agency	U.S. Environmental Protection Agency
CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
EP	End-Use Product
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GRAS	Generally Recognized As Safe
MP	Manufacturing Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
RED	Reregistration Eligibility Document

Executive Summary

The U.S. Environmental Protection Agency ("EPA" or "the Agency") first registered a pesticide product containing Allium sativum in 1983. Currently, there are a total of four registered products for this active ingredient. Three of these products also contain capsicum (red pepper) as an active ingredient. All currently registered products are repellents against birds and/or insects. The end- use products are either soluable concentrates applied by aerial application or dust formulations applied directly into furrows or by broadcast with ground applicators. These products prevent pests from attacking and damaging seeds and seedlings of vegetables, fruits, grains, ornamental plants and shrubbery.

Based on the results from the reregistration review, the EPA has determined that the data base for Allium sativum is sufficient to conduct a risk assessment. All product identity/chemistry data requirements have been satisfied. All applicable toxicology, residue chemistry, worker exposure, ecological and environmental effect data requirements have been waived for the subject compound. The potential risks, if any, to humans from both nondietary/dietary and occupational exposures are considered negligible because of the long history of use by humans as a food additive and or component. The potenial risks to the environment are considered negligible due to garlic's non-toxic mode of action and non-persistence in the environment.

Accordingly, EPA has determined that the registered uses of Allium sativum are eligible for reregistration. The decision to reregister specific products will be made after appropriate labeling are submitted and/or cited. After reviewing these labels the EPA will determine whether or not the conditions of FIFRA 3(c)(5) have been met, that is, whether product labeling are acceptable and their uses will not cause unreasonable adverse effects to humans or the environment. If these conditions are met, EPA will reregister the products. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

Section 4(g)(2)(A) of FIFRA states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products, section 4(g)(2)(B), and either reregistering products or taking "other appropriate regulatory action," under section 4(g)(2)(C) and (D). Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA, section 3(c)(5).

This document presents the Agency's decision regarding the reregistration eligibility of the active ingredient Allium sativum (garlic). The document consists of five sections. Section I is this introduction. Section II describes Allium sativum, its uses and regulatory history. Section III discusses the human health and environmental assessments based on the data available to the Agency. Section IV discusses the reregistration decision for Allium sativum and Section V discusses product reregistration. Additional details concerning the review of available data are available on request.[1]

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[1] EPA's reviews of specific reports and information on the set of registered uses considered for EPA's analyses may be obtained from: EPA, Freedom of Information, 401 M St. S.W., Washington, D.C. 20460.

II. ACTIVE INGREDIENTS COVERED BY THIS REREGISTRATION ELIGIBILITY DECISION DOCUMENT

A. IDENTIFICATION OF ACTIVE INGREDIENT

1. Chemical Name: Allium sativum (Garlic)

CAS Number: 8000-78-0

Office of Pesticide Programs Chemical Code Number: 128827

Empirical Formula: Not Applicable

B. USE PROFILE

Type of Pesticide: biochemical pesticide, insect and bird repellent

Pests Controlled: birds, mites and insects

Registered Use Groups: (See Appendix A for detailed specific use sites).

Terrestrial Food/Feed - vegetables, fruits, nuts and grains

Terrestrial Non-food - ornamental plants and shrubs

Indoor Residential - ornamental plants

Formulation Types Registered:

BIRDS -
Dust: 12% ground red pepper (Capsicum spp.)
5% ground garlic (Allium sativum)

INSECTS -
Soluble concentrate/liquid: 36% red pepper extract
24% garlic extract
Soluble concentrate/liquid: 100% garlic water

Methods and Rates of Applications

Dusts are applied as a banded furrow treatment at planting or applied broadcast to

foliage and fruit of plants. Product may be applied aerially or by ground equipment. There is no maximum rate on the label; a minimum rate is 20 to 50 lbs formulated material per acre (A). For seedlings, maturing produce and grains, the product is applied at a minimum rate of 30 lbs/A at 7 to 9 days before harvest.

Soluble concentrates are applied broadcast to foliage by air or ground equipment. There is no maximum rate for the 24% garlic: 36% capsaicin product.

100% garlic water product is applied up to 2 times per season at one gallon/A.

Use practice limitations: Application at bloom may repel pollinators.

C. REGULATORY HISTORY

The Agency first registered a product (EPA Reg. No. 47319-1) with garlic, on December 29, 1983, to the Sevana Company of Fresno, California. This product is used in combination with ground red peppers (Active Ingredient Code 070701; Case Name: Capsaicin; Reregistration Case No. 4018). The mode of action is that of a bird repellent. On July 2, 1985, the Agency registered a similar second bird repellent product (EPA Reg. No. 47319-2) to the Sevana Company.

The Agency registered a third repellent product to Sevana (EPA Reg. No. 47319-4) on November 4, 1988. This product also contains a combination of garlic and red pepper, however, it is an insect repellent, rather than bird, repellent and is a liquid formulation.

The most recent product was registered by the Agency on February 7, 1991 to the Guardian Spray Company of Lebec, California. This product contains a single active ingredient, garlic, and is a liquid formulation.

Until recently, Allium sativum was classified by the Agency as a conventional chemical pesticide. Since these four formulations consist of a food additive and/or component and cleared inert ingredients, the Agency only required minimal basic product and chemical identity data. Now the Agency has reclassified the subject compound as a biochemical pesticide because it is a naturally occurring biological substance and has a non-toxic mode of action.

III. AGENCY ASSESSMENT OF THE ACTIVE INGREDIENT

EPA has reviewed the scientific data base for Allium sativum, primarily relying on information from published literature submitted by the registrant. These are cited in Appendix C.

A. DESCRIPTION OF ACTIVE INGREDIENT AND SUMMARY OF PRODUCT CHEMISTRY

Garlic, as a pesticide active ingredient, consists of either a powder or a distilled extract from the fresh or dehydrated bulb or cloves obtained from Allium sativum. Natural derivatives of garlic include essential oils, oleoresins, and extracts. One such derivative is finely ground garlic bulbs (known as garlic powder).

When fresh garlic cloves are extracted and distilled, a range of color from a light orange to amber liquid color is observed. Fresh garlic has an extremely pungent and highly concentrated aroma and flavor. Garlic is dispersible in water (polar carriers) and oil (non-polar carriers) with agitation.

B. ENVIRONMENTAL AND HUMAN HEALTH ASSESSMENT

EPA has developed a normative set of data requirements, set forth in the regulations (40 CFR Part 158) and the Agency's Reregistration Phase 2 Technical Guidance Document to be addressed for pesticide reregistration. These regulations and the guidance document specify the necessary data based on factors including use sites, potential environmental and human (dietary and occupational) exposures, product formulation types, and product application methods. Due to the diverse nature and characteristics of pesticide products and their uses subject to reregistration, the Agency also recognizes the necessity to modify the data requirements for specific pesticides, including waiving certain data requirements because such requirements are inappropriate or unnecessary for reregistration.

The case-specific approach to waive individual data requirements has served to identify the appropriate data requirement sets for pesticide products. Further, the Agency believes there is a category of pesticide active ingredients for which a broadly reduced set of data requirements are appropriate for reregistration. Specifically, products in this category would be exempt from the generic data requirements for toxicology, residue chemistry, human exposure, ecological effects, and environmental fate on the active ingredient. The Agency believes there are considerations which, when taken together, can form the basis for a conclusion that such a reduction in data requirements is appropriate for a particular pesticide active ingredient, while not compromising human health or environmental safety.

There are, however, certain data requirements which are essential and not likely to be waived. Basic product identity/chemistry information on the active ingredient and formulated products is required for pesticides in this category so that the Agency has reasonable certainty of the pesticide's identity and chemical and physical characteristics. Also, acute toxicology studies for formulated and manufacturing-use

products are required for the Agency to determine appropriate product labeling for potential hazards to those who handle or apply such products. However, these toxicology studies may be waived if an assessment of the product formulation, including the inert ingredients, indicates that such studies are unnecessary to prescribe appropriate labeling.

In considering garlic for reregistration eligibility the Agency believes it is an active ingredient that should be considered for this broad waiver of the generic data requirements. The considerations that lead the Agency to this conclusion are as follows.

Garlic is widely distributed and commercially available for flavoring and seasoning throughout the United States for nonpesticidal uses. Garlic is generally recognized as safe (GRAS) under 21 CFR 182.10 (spices and other natural seasonings and flavorings) and 182.20 (ssential oils, oleoresins [solvent-free] and natural extractives [including distillates]) as affirmed in 184.1317 ([garlic and its derivatives]).

Garlic is formulated as either a powder or a distilled extract from garlic cloves and is used to repel birds and insects in certain fruit, nut, and citrus trees, vegetables, vine crops, berries, grains, roses, flowers, and shrubs. This active ingredient has a non-toxic mode of action for target pests. Moreover, garlic can be presumed to be non-persistent based on knowledge of its composition; e.g., organic material known to be rapidly degraded in the environment to elemental constituents by normal biological, physical, and/or chemical processes that can be reasonably expected to exist where the pesticide is applied.

No reports of adverse effects have been submitted to the Agency for this active ingredient and EPA has not identified any indication of significant adverse effects from garlic to humans or the environment associated with its use as a pesticide. This includes consideration of information in the literature, or in any incident reports by the registrant or the public.

Based on these factors the Agency does not believe generic data, beyond those data required to satisfy basic product identity and chemistry questions (refer to Appendix B), are necessary to determine whether the current registered uses of this active ingredient pose unreasonable risks to humans or the environment.

Therefore, the Agency has waived all generic data requirements except basic product identity and chemistry data. The Agency believes that, based on the above factors, the registered uses of garlic do not pose unreasonable risks to humans or the environment.

IV. REREGISTRATION DECISION FOR ALLIUM SATIVUM

A. DETERMINATION OF ELIGIBILITY

Section 4(g)(2)(A) of FIFRA requires the Agency to determine, after consideration of relevant data concerning an active ingredient whether products containing the active ingredient are eligible for reregistration. For products containing garlic as an active ingredient the Agency has waived all generic data requirements except for certain basic product identity and chemistry. In addition to these data the Agency has considered the factors discussed above in Section III regarding the natural occurrence of garlic, common use as a food item, and the lack of reported adverse effects information. The Agency has completed its consideration of these data and other factors and has determined this information is sufficient to support reregistration of products containing garlic as an active ingredient. The reregistration of particular products is addressed in Section V. of this document.

Although the Agency has concluded that products containing garlic are eligible for reregistration, the Agency may take regulatory actions in the future that would affect the continued registration of garlic-containing products if new and/or significant information about this active ingredient and/or its products comes to the Agency's attention. Such regulatory action could include requiring the submission of additional data if the data requirements for registration (or the guidelines for generating such data) change.

B. ADDITIONAL GENERIC DATA REQUIREMENTS

The generic data base supporting the reregistration of products containing Allium sativum and the registered use patterns, has been reviewed and determined to be substantially complete for reregistration.

C. TOLERANCE ASSESSMENT

End-use products are registered for application to a variety of food crops however, no finite residues for tolerance or exemption from tolerances have been established in 40 CFR Part 180. As discussed above in Section III, the Agency does not believe any dietary exposure to residues on crop commodities from the application of these products would present a health concern and as such has waived toxicology and residue chemistry data requirements on the active ingredient. However, to meet tolerance requirements in the regulations, the Agency will propose a tolerance exemption for Allium sativum under 40 CFR Part 180 for all currently registered uses on food/feed crops.

D. LABELLING REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS OF ALLIUM SATIVUM

No manufacturing-use products are registered.

V. PRODUCT REREGISTRATION

A. DETERMINATION OF ELIGIBILITY

Based on the reviews of the generic data for the active ingredient, Allium sativum, the products containing them are eligible for reregistration. Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Agency will review these data when they have been submitted and/or cited and determine whether to reregister individual products.

B. PRODUCT SPECIFIC DATA REQUIREMENTS

The product-specific data requirements are listed in Appendix D, Attachment D. These requirements include product chemistry, acute toxicology, and efficacy studies.

C. LABELING REQUIREMENTS FOR END-USE PRODUCTS CONTAINING ALLIUM SATIVUM

The labels and labeling of all products must comply with EPA's current regulations and requirements. Follow the instructions in the Product Reregistration

Handbook with respect to labels and labeling.

Based on the lack of toxicological concerns the Agency has no product precautionary labeling concerns at this time.

However, certain products lack directions for application of maximum rates. In reponse to this RED, registrants must submit draft amended product labels in which minimum and maximum application rates are proposed. The Agency will evaluate these proposals and determine where each label is satisfactory.

APPENDIX A

USE PATTERNS SUBJECT TO REREGISTRATION FOR *ALLIUM SATIVUM* (GARLIC)

APPENDIX A - Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
FOOD/FEED USES										
Almond Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb ai/A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb ai/A	2 per Cycle	not spec	not spec	not spec			
Apple Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
Broadcast, Foliar, Aircraft	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spray, Petal fall, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spray, Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spray, Petal fall, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.

APPENDIX A - Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Apricot Use Group: Terrestrial Food Crop										
Broadcast, Foliar, Aircraft	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spray, Petal fall, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spray, Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spray, Petal fall, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Beans Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
High volume spray (dilute), Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			

APPENDIX A - Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Beets (Unspecified) Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
Band treatment, At planting, Mechanical granule applicator	D	1 lb AI per A	not spec	not spec	not spec	not spec	not spec			
Broadcast, Foliar, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	1.5 lb per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Ground	D	1.5 lb per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Postemergence, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Soil band treatment, At planting, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			

APPENDIX A - Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Soil treatment, At planting, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Broccoli Use Group: Terrestrial Food Crop										
High volume spray, Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling stage, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling stage, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Cabbage Use Group: Terrestrial Food Crop										
Band treatment, At planting, Mechanical granule applicator	D	1 lb AI per A	not spec	not spec	not spec	not spec	not spec			
Broadcast, Foliar, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Ground	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.

APPENDIX A - **Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]**										
SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Broadcast, Postemergence, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Soil band treatment, At planting, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Soil treatment, At planting, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Carrot (including tops) Use Group: Terrestrial Food Crop										
Band treatment, At planting, Mechanical granule applicator	D	1 lb AI per A	not spec	not spec	not spec	not spec	not spec			
Broadcast, Foliar, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Ground	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preahrvest interval.

APPENDIX A - **Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]**

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Cauliflower Use Group: Terrestrial Food Crop										
High volume spray (dilute), Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling stage, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling stage, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Celery Use Group: Terrestrial Food Crop										
High volume spray (dilute), Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling stage, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.

APPENDIX A - Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Spray, Seedling stage, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Cherry Use Group: Terrestrial Food Crop										
Broadcast, Foliar, Aircraft	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	7	not spec			2 days preharvest interval.
Spray, Foliar, Aiorcraft	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spray, Petal fall, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spray, Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spray, Petal fall, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Corn (Unspecified) Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
Band treatment, At planting, Mechanical granule applicator	D	1 lb AI per A	not spec	not spec	not spec	not spec	not spec			

APPENDIX A - **Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]**										
SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Broadcast, Foliar, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Ground	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Shaker can, Postemergence	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Soil band treatment, At planting, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Soil treatment, At planting, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Cucumber Use Group: Terrestrial Food Crop										
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.

APPENDIX A - **Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]**

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Spray, Seedling stage, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling stage, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Cereal Grains Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
Band treatment, At planting, Mechanical granule applicator	D	1 lb AI per A	not spec	not spec	not spec	not spec	not spec			7 days preharvest interval.
Broadcast, Foliar, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Ground	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Fig Use Group: Terrestrial Food Crop										
Broadcast, Foliar, Aircraft	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.

APPENDIX A - **Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]**										
SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Broadcast, Foliar, Ground	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Grapes Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
Broadcast, Foliar, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	7	not spec			2 days preharvest interval.
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Spray, Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Kiwi Use Group: Terrestrial Food Crop										
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray, Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Lemon Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			

APPENDIX A - Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Lettuce Use Group: Terrestrial Food Crop										
Band treatment, At planting, Mechanical granule applicator	D	1 lb AI per A	not spec	not spec	not spec	not spec	not spec			
Broadcast, Foliar, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Ground	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Postemergence, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
High volume spray (dilute), Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			

APPENDIX A - Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Soil band treatment, At planting, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Soil treatment, At planting, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling stage, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling stage, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Melons Use Groups: Terrestrial Food Crop										
Band treatment, At planting, Mechanical granule applicator	D	1 lb AI per A	not spec	not spec	not spec	not spec	not spec			
Broadcast, Foliar, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Ground	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Postemergence, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			

APPENDIX A - Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Low volume spray (concentrate), Prebloom, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Soil band treatment, At planting, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Soil treatment, At planting, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling stage, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling stage, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Melons, Cantaloupe Use Group: Terrestrial Food Crop										
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			

APPENDIX A - Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling stage, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling stage, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Nectarine Use Group: Terrestrial Food Crop										
Broadcast, Foliar, Aircraft	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Onion Use Group: Terrestrial Food Crop										
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Orchards (Unspecified) Use Group: Terrestrial Food Crop										

APPENDIX A - Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Broadcast, Foliar, Aircraft	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	7	not spec			2 days preharvest interval.
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			15 days preharvest interval.
Spray, Petal fall, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			15 days preharvest interval.
Spray, Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			15 days preharvest interval.
Spray, Petal fall, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			15 days preharvest interval.
Orange Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spray, Petal fall, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spray, Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.

APPENDIX A - Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Spray, Petal fall, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Peach Use Group: Terrestrial Food Crop										
Broadcast, Foliar, Aircraft	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concetrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spray, Petal fall, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spray, Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spray, Petal fall, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Pear Use Group: Terrestrial Food Crop										

APPENDIX A - Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Peas (Unspecified) Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Plum Use Group: Terrestrial Food Crop										
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Broadcast, Foliar, Aircraft	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spray, Petal fall, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.

APPENDIX A - Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Spray, Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spray, Petal fall, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Potato, White/Irish Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Pumpkin Use Group: Terrestrial Food Crop										
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Prebloom, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Radish Use Group: Terrestrial Food Crop										
Broadcast, Postemergence, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Soil treatment, At planting, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			

APPENDIX A - **Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]**

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Soil band treatment, At planting, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Small Fruits Use Group: Terrestrial Food Crop										
Broadcast, Foliar, Aircraft	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spray, Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.
Spinach Use Group: Terrestrial Food Crop										
High volume spray (dilute), Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling stage, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling stage, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Sunflower Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										

APPENDIX A - Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Band treatment, At planting, Mechanical granule applicator	D	1 lb AI per A	not spec	not spec	not spec	not spec	not spec			
Broadcast, Foliar, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Ground	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Tomato Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
Broadcast, At planting, Mechanical granule applicator	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Ground	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Postemergence, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
High volume spray (dilute), Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.

APPENDIX A - Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Soil band treatment, At planting, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Soil treatment, At planting, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling stage, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling stage, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Tree Nuts Use Group: Terrestrial Food Crop										
Broadcast, Foliar, Aircraft	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	2.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Vegetables (Unspecified) Use Group: Terrestrial Food Crop										
Band treatment, At planting, Mechanical granule applicator	D	1 lb AI per A	not spec	not spec	not spec	not spec	not spec			
Broadcast, Foliar, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.

APPENDIX A - Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]

SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Broadcast, Seedling stage, Ground	D	1.5 lb AI per A	not spec	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Postemergence, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
High volume spray (dilute), Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Soil band treatment, At planting, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Soil treatment, At planting, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling stage, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Spray, Seedling stage, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			15 days preharvest interval.
Walnut (English/Black) Use Group: Terrestrial Food Crop										
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
Low volume spray (concentrate), Foliar, Low volume ground	SC/L	na	.825 lb AI per A	2 per Cycle	not spec	not spec	not spec			
NONFOOD/NONFEED USES										
Ornamental Herbaceous Plants Use Groups: Terrestrial Non-Food Crop and Outdoor Residential										
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			

APPENDIX A - **Case 4007, [Allium sativum] Chemical 128827 [Allium sativum]**										
SITE Application Type, Application Timing, Application Equipment	Form	Minimum Application Rate	Maximum Application Rate	Max. # Apps.	Max. # Apps. @ Max. Rate	Min. Interval Between Apps. @ Max. Rate (Days)	Restricted Entry Interval (Days)	Geographic Limitations		Use Limitations
								Allowed	Disallowed	
Spray, Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			
Ornamental Woody Shrubs and Vines Use Groups: Terrestrial Non-Food Crop and Outdoor Residential										
Spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			
Spray, Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			

Abbreviations used

Header: max=maximum; min=minimum; apps=applications; not spec=not specified; na=not applicable

Form: D=dust; SC/L=soluble concentrate/liquid

Rate: ai=active ingredient; A=acre

APPENDIX B

Generic Data Requirements for Reregistration of *Allium Sativum* (Garlic) and Data Citations Supporting Reregistration

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for the pesticide covered by this Reregistration Eligibility Document.

Appendix B contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

The data table are generally organized according to the following format:

1. Data Requirements (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Use Pattern (Column 2). This column indicates the use patterns to which the data requirement applies. The following letter designations are used for use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
K	Residential

Any other designations will be defined in a footnote to the table.

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF ALLIUM SATIVUM AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Product Chemistry			
61-1	Product Identity	ABCK	470028026
61-2(a)	Begin. Mat. and Mfg.Process	ABCK	satisfied
61-2(b)	Discussion of Impurities	ABCK	satisfied
62-1	Preliminary Analysis	ABCK	satisfied
62-3	Analytical Method	ABCK	satisfied
63-2	Color	ABCK	satisfied
63-3	Physical State	ABCK	satisfied
63-4	Odor	ABCK	satisfied
63-5	Melting Point	ABCK	satisfied
63-7	Density	ABCK	satisfied
63-8	Solubility	ABCK	satisfied

63-10	Dissociation Constant	ABCK	satisfied
63-12	pH	ABCK	satisfied
63-13	Stability	ABCK	satisfied

Ecological Effects:

EPA waived all of these guidelines as discussed in sections III and IV.

Toxicology:

EPA waived all of these guidelines as discussed in sections III and IV.

Environmental Fate:

EPA waived all of these guidelines as discussed in section III and IV.

Residue Chemistry:

EPA waived all of these guidelines as discussed in section III and IV.

Occupational Exposure:

EPA waived all of these guidelines as discussed in section III and IV.

APPENDIX C

ALLIM SATIVUM (GARLIC)

Citations Considered to be Part of the
Data Base Supporting Reregistration

GUIDE TO APPENDIX C

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or MRID number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REREGISTRATION ELIGIBILITY DOCUMENT
BIBLIOGRAPHY

470028026 Supplementary To The List Of Data Requirements. Unpublished study submitted by Sevana Company.

APPENDIX D

PR NOTICE 91-2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 2

PR NOTICE 91-2

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products.

SUBJECT: Accuracy of Stated Percentages for Ingredients Statement

I. PURPOSE:

The purpose of this notice is to clarify the Office of Pesticide Program's policy with respect to the statement of percentages in a pesticide's label's ingredient statement. Specifically, the amount (percent by weight) of ingredient(s) specified in the ingredient statement on the label must be stated as the nominal concentration of such ingredient(s), as that term is defined in 40 CFR 158.153(i). Accordingly, the Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

II. BACKGROUND

For some time the Agency has accepted two different methods of identifying on the label what percentage is claimed for the ingredient(s) contained in a pesticide. Some applicants claimed a percentage which represented a level between the upper and the lower certified limits. This was referred to as the nominal concentration. Other applicants claimed the lower limit as the percentage of the ingredient(s) that would be expected to be present in their product at the end of the product's shelf-life. Unfortunately, this led to a great deal of confusion among the regulated industry, the regulators, and the consumers as to exactly how much of a given ingredient was in a given product. The Agency has established the nominal concentration as the only acceptable label claim for the amount of active ingredient in the product.

Current regulations require that the percentage listed in the active ingredient statement be as precise as possible reflecting good manufacturing practices 40 CFR 156.10(g)(5). The certified limits required for each active ingredient are intended to encompass any such "good manufacturing practice" variations 40 CFR 158.175(c)(3).

IV. PRODUCTS THAT REQUIRE EFFICACY DATA

All pesticides are required to be efficacious. Therefore, the certified lower limits may not be lower then the minimum level to achieve efficacy. This is extremely important for products which are intended to control pests which threaten the public health, e.g., certain antimicrobial and rodenticide products. Refer to 40 CFR 158.640.

In those cases where efficacy limits have been established, the Agency will not accept certified lower limits which are below that level for the shelf life of the product.

V. COMPLIANCE SCHEDULE

As described earlier, the purpose of this Notice is to make the registration process more uniform and more manageable for both the agency and the regulated community. It is the Agency's intention to implement the requirements of this notice as smoothly as possible so as not to disrupt or delay the Agency's high priority programs, i.e., reregistration, new chemical, or fast track (FIFRA section 3(c)(3)(B). Therefore, applicants/registrants are expected to comply with the requirements of this Notice as follows:

(1) Beginning July 1, 1991, all new product registrations submitted to the Agency are to comply with the requirements of this Notice.

(2) Registrants having products subject to reregistration under FIFRA section 4(a) are to comply with the requirements of this Notice when specific products are called in by the Agency under Phase V of the Reregistration Program.

(3) All other products/applications that are not subject to (1) and (2) above will have until July 1, 1997, to comply with this Notice. Such applications should note "Conversion to Nominal Concentration" on the application form. These types of amendments will not be handled as "Fast Track" applications but will be handled as routine requests.

VI. FOR FURTHER INFORMATION

Contact Tyrone Aiken for information or questions concerning this notice on (703) 557-5024.

Anne E. Lindsay

Anne E. Lindsay, Director
Registration Division (H-7505

APPENDIX E

DATA CALL-IN

Product Specific data call-in and attachments

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DATA CALL-IN NOTICE

CERTIFIED MAIL

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments A through G; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment C, Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment B, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment F).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 (expiration date 12-31-92).

This Notice is divided into six sections and seven Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You Are Receiving This Notice
Section II - Data Required By This Notice
Section III - Compliance With Requirements Of This Notice
Section IV - Consequences Of Failure To Comply With This Notice
Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

A - Data Call-In Chemical Status Sheet
B - Data Call-In Response Form
C - Requirements Status and Registrant's Response Form
D - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
E - EPA Acceptance Criteria
F - List of Registrants Receiving This Notice
G - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment C, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment C, Requirements Status and Registrant's Response Form, within the timeframes provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue N.W., Washington, D.C. 20006.

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting

your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this Notice or (c) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment B and Attachment C. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment B). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment A.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice. There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose this option, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified timeframe (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2. Agree to Share in Cost to Develop Data --Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3. Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been

unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment G. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a costsharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4. Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " '[r]aw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5. Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment A. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6. Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable

toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, as appropriate.

III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency will grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol if such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study if required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer either to:

a. Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;

b. Fulfill the commitment to develop and submit the data as required by this Notice; or

c. Otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for

issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2. EPA requirements regarding the submission of protocols (if applicable), including the incorporation of any changes required by the Agency following review.

3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with

all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on a case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment A, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment B and Attachment C) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment A. If the voluntary cancellation option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Daniel M. Barolo, Director
Special Review and
Reregistration Division

Attachments

A - Data Call-In Chemical Status Sheet
B - Data Call-In Response Form
C - Requirements Status and Registrant's Response Form
D - EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
E - EPA Acceptance Criteria
F - List of Registrants Receiving This Notice
G - Cost Share and Data Compensation Forms, and Product Specific Data Report Form

ATTACHMENT A

DATA CALL-IN CHEMICAL STATUS SHEET

ATTACHMENT A

ALLIUM SATIVUM: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Data Call-In Notice because you have products containing Allium sativum.

This attachment, the Data Call-in Chemical Status Sheet, contains a point of contact for inquiries. This attachment is to be used in conjunction with (1) the Data Call-In Notice, (2) Attachment B, the Data Call-In Response Form, (3) Attachment C, the Requirement Status and Registrant's Response Form for product specific data, (4) Attachment D, EPA Grouping of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration, (5) Attachment E, EPA Acceptance Criteria, (6) Attachment F, List of All Registrant(s) sent this Data Call-In Notice, and (7) Attachment G, the Cost Share and Data Compensation Forms for product specific data, and Product Specific Data Report Form for use in replying to this Allium sativum Data Call-In. Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for Allium sativum are listed in the Requirements Status and Registrant's Response Form, Attachment C.

The Agency has concluded that product specific data are needed for Allium sativum. The required additional data are listed in Attachment C.

Depending on the results of the studies required in this Notice, additional testing may be required.

INQUIRES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Rob Forrest at (703) 305-6600. All responses to this Notice should be submitted to:

Document Processing Desk (RED/RD/PM-14)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460

RE: Allium sativum

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Margarita Collantes at (703) 308-8583. All responses to this Notice should be submitted to:

Chemical Review Manager Margarita Collantes
Accelerated Reregistration Branch (H7508W)
Special Review and Reregistration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460

RE: Allium sativum

ATTACHMENT B

PRODUCT SPECIFIC DATA CALL-IN RESPONSE FORM

SPECIFIC INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORM

Product Specific Data

This form is designed to be used to respond to call-ins for generic and product specific data for the purpose of reregistering pesticides under the Federal Insecticide Fungicide and Rodenticide Act. Fill out this form each time you are responding to a data call-in for which EPA has sent you the form entitled "Requirements Status and Registrant's Response."

Items 1-4 will have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

INSTRUCTIONS FOR COMPLETING THE "DATA CALL-IN RESPONSE" FORM FOR PRODUCT SPECIFIC DATA

Item 1-4. Already completed by EPA.

Item 5. If you wish to voluntarily cancel your product, answer "yes." If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).

Item 6. Not applicable since this form calls in product specific data only. However, if your product is identical to another product and you qualify for a data exemption, you must respond with "yes" to Item 7a (MP) or 7b (EP) on this form, provide the EPA registration numbers of your source(s) and complete and submit the "Generic Data Exemption" form; you would not complete the "Requirements Status and Registrant's Response" form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

Item 7a. For each manufacturing use product (MP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b. For each end use product (EP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes." If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with Option 7 (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.

Items 8-11. Self-explanatory.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	4007 Allium sativum	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
62998-1		N.A.	N.A.		

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	4007 Allium sativum	PRODUCT SPECIFIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily.	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is a MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
47319-4 47319-2		N.A.	N.A.		

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

ATTACHMENT C

PRODUCT SPECIFIC REQUIREMENT STATUS AND REGISTRANT'S RESPONSE FORM

SPECIFIC INSTRUCTIONS FOR COMPLETING THE REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM

Product Specific Data

This form is designed to be used for registrants to respond to call-ins for generic and product-specific data as part of EPA's reregistration program under the Federal Insecticide Fungicide and Rodenticide Act. Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. These instructions are for completion of product specific data requirements.

EPA has developed this form individually for each data call-in addressed to each registrant, and has preprinted this form with a number of items. DO NOT use this form for any other active ingredient.

Items 1 through 8 (inclusive) will have been preprinted on the form. You must complete all other items on this form by typing or printing legibly.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE" FORM FOR PRODUCT SPECIFIC DATA

Item 1-3 Completed by EPA. Note the unique identifier number assigned by EPA in Item 3. This number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.

Item 5. The study title associated with the guideline reference number is identified.

Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.

Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.

Item 8. The due date for submission of each study is identified. It is normally based on 8 months after issuance of the Reregistration Eligibility Document unless EPA determines that a longer time period is necessary.

Item 9. Enter <u>only one</u> of the following response codes <u>for each data requirement</u> to show how you intend to comply with the data requirements listed in this table. Fuller descriptions of each option are contained in the Data Call-In Notice.

1. I will generate and submit data by the specified due date (Developing Data). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice.

2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing). I am submitting a copy of this agreement and a completed "Certification With Respect To Data Compensation Requirements" form. I understand that this option is available only for acute toxicity or certain efficacy

data and only if EPA indicates in an attachment to this Notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

3. I have made offers to share in the cost to develop data (Offers to Cost Share). I understand that this option is available only for acute toxicity or certain efficacy data and only if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed "Certification of Offer to Cost Share in the Development Data" form. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well.

4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice.

5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (Upgrading a Study). I will submit evidence of the Agency's review indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study). If I am citing

another registrant's study, I understand that this option is available only for acute toxicity or certain efficacy data and only if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number(s) for the cited data on a "Product Specific Data Report" form or in a similar format. If I cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

7. I request a waiver for this study because it is inappropriate for my product (Waiver Request). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change.

Items 10-13. Self-explanatory.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

DRAFT COPY

United States Environmental Protection Agency
Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
Approval Expires 12-31-92

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address
SAMPLE COMPANY
NO STREET ADDRESS
NO CITY, XX 00000

2. Case # and Name
4007 Allium sativum

EPA Reg. No. NNNNNN-NNNNN

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern		7. Test Substance	8. Time Frame	9. Registrant Response
	Prod Chem - Biochemical										
151B-10	Product identity						ABC	O	EP	8 mos.	
151B-11	Manufacturing process	(50)					ABC	O	EP	8 mos.	
151B-12	Discussion of formation of ununtentional ingrdients	(51)					ABC	O	EP	8 mos.	
151B-15	Certification of limits						ABC	O	EP	8 mos.	
151B-16	Analytical methods	(52)					ABC	O	EP	8 mos.	
151B-17(b)	Physical state						ABC	O	EP	8 mos.	
151B-17(f)	Density						ABC	O	EP	8 mos.	
151B-17(i)	pH	(6)					ABC	O	EP	8 mos.	
151B-17(m)	Viscosity	(8)					ABC	O	EP	8 mos.	
	Acute Toxic - Biochemical										
152B-13	Primary eye irritation	(53)					ABC	O	EP	8 mos.	
152B-14	Primary dermal irritation	(53)					ABC	O	EP	8 mos.	

10. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D. C. 20460

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1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	4007 Allium sativum EPA Reg. No. NNNNNN-NNNNN	PRODUCT SPECIFIC ID# NNNNNN-RD-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
	Efficacy - Vertebrate Control Agents								
96-6	Avian repellents (1,54)					ABC O	EP	8 mos.	

Initial to indicate certification as to information on this page (full text of certification is on page one).

Date

United States Environmental Protection Agency
Washington, D. C. 20460

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4007 Allium sativum

Key: MP = manufacturing-use product; EP = end-use product; provided formulators purchase their active ingredient(s) from a registered source, they need not submit or cite data pertaining to the purchased product.[NOTE: If a product is a 100 percent repackage of another registered product that is purchased, and any use for the product does not differ from those of the purchased and registered source, users are not subject to any data requirements identified in the tables.]; TEP = typical end-use product; TGAI = technical grade of the active ingredient; PAI = "pure" active ingredient; PAIRA = "pure" active ingredient, radiolabeled.

Use Categories Key:

A - Terrestrial food crop	B - Terrestrial food feed crop	C - Terrestrial nonfood crop	D - Aquatic food crop	E - Aquatic nonfood outdoor
F - Aquatic nonfood Industrial	G - Aquatic nonfood residential	H - Greenhouse food crop	I - Greenhouse nonfood crop	J - Forestry
K - Residential outdoor	L - Indoor food	M - Indoor nonfood	N - Indoor Medical	O - Indoor residential

Footnotes: [The following notes are referenced in column two (5. Study Title) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

Prod Chem - Biochemical

6 Required if test substance is dispersible with water.
8 Required if product is a liquid.

50
51
52

Acute Toxic - Biochemical

53

Efficacy - Vertebrate Control Agents

1 The agency has waived all requirements to submit efficacy data for vertebrate control agents unless the pesticide product bears a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commenly accepted pest control practices. The registrant must develop and maintain the relevant data upon which the determination of efficacy is based. The Agency reserves the right to require, on a case-by-case basis (e.g., significant new uses or benefits data in cases of special reviews) submission of efficacy data for any pesticide product, registered or proposed for registration when necessary.

54

Footnotes for Garlic Product Specific Data Tables (6/10/92)

[50]The description of the manufacturing process must include the steps taken to insure the integrity of the starting materials and to limit extraneous contamination during manufacturing. Also, the description must include the quality control methods used to insure a uniform product.

[51]The applicant must provide a discussion of the unintentional ingredients that may be present in the product and why they may be present. Examples of such ingredients might include residues of contaminants that remain following the extraction or purification process. If these contaminants are not of toxicological significance (e.g., small quantities of dirt retained on garlic bulbs after washing), there is no need for further discussion.

[52]The Agency recognizes the difficulty of establishing methods for analysis and verification of the certified limits of naturally occurring products. Such methods could include analytical, bio-assay, microscopic, or any other method that would allow the Agency to verify the limits.

[53]These tests are required for products that combine garlic and red peper (Capsaicin). They are not required for products that contain only garlic.

[54]The data currently available to the Agency on the effectiveness of these products as bird repellents are either inconclusive or have suggested a lack of effectiveness. Therefore, registrants of bird control products must establish those claims during reregistration through citation or submission of data. If registrants develop new data, they must submit their protocols to the Agency with the 90 day response.

If tests suggest that efficacy is highly variable, the registrant will need to develop methods for quantifying the biological activity of the active ingredients so that consistent results can be obtained.

ATTACHMENT D

EPA GROUPING OF END-USE PRODUCTS FOR MEETING DATA REQUIREMENTS FOR REREGISTRATION

EPA'S BATCHING OF ALLIUM SATIVUM (GARLIC) END-USE PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of end-use products containing the active ingredient Allium sativum (Garlic), the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Batching has been accomplished using the readily available information described above, and frequently acute toxicity data on individual end-use products has been found to be incomplete. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual end-use product should the need arise.

Registrants of end-use products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Table I shows one batch which of two products. Table II shows the remaining two products which could not be batched as they were not considered similar for purposes of acute toxicity. The registrants of these products are responsible for meeting the acute toxicity data requirements specified in the data matrix for end-use products.

Table I.

EPA REG. NO.	% of Garlic & Other Active Ingredients	Formulation Type
47319-1	5.0% - Garlic 12.0% - Red Pepper	Dust
47319-2	5.0% - Garlic 12.0% - Red Pepper	Dust

Table II.

EPA REG. NO.	% of Garlic & Other Active Ingredients	Formulation Type
47319-4	24.0% - Garlic 36.0% - Red Pepper	Liquid
62998-1	5.0% - Garlic	Liquid

ATTACHMENT E

EPA ACCEPTANCE CRITERIA

SUBDIVISION D

61 Product Identity and Composition

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ___ Name of technical material tested (include product name and trade name, if appropriate)
2. ___ Name, nominal concentration, and certified limits (upper and lower) for each active ingredient and each intentionally-added inert ingredient
3. ___ Name and upper certified limit for each impurity or each group of impurities present at ≥ 0.1% by weight and for certain toxicologically significant impurities (e.g., dioxins, nitrosamines) present at <0.1%
4. ___ Purpose of each active ingredient and each intentionally-added inert
5. ___ Chemical name from Chemical Abstracts Index of Nomenclature and Chemical Abstracts Service (CAS) Registry Number for each active ingredient and, if available, for each intentionally-added inert
6. ___ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient
7. ___ Description of each beginning material in the manufacturing process
   - ___ EPA Registration Number if registered; for othe. beginning materials, the following:
   - ___ Name and address of manufacturer or supplier
   - ___ Brand name, trade name or commercial designation
   - ___ Technical specifications or data sheets by which manufacturer or supplier describes composition, properties or toxicity
8. ___ Description of manufacturing process
   - ___ Statement of whether batch or continuous process
   - ___ Relative amounts of beginning materials and order in which they are added
   - ___ Description of equipment
   - ___ Description of physical conditions (temperature, pressure, humidity) controlled in each step and the parameters that are maintained
   - ___ Statement of whether process involves intended chemical reactions
   - ___ Flow chart with chemical equations for each intended chemical reaction
   - ___ Duration of each step of process
   - ___ Description of purification procedures
   - ___ Description of measures taken to assure quality of final product
9. ___ Discussion of formation of impurities based on established chemical theory addressing (1) each impurity which may be present at ≥ 0.1% or was found at ≥ 0.1% by product analyses and (2) certain toxicologically significant impurities (see #3)

Criteria marked with a * are supplemental and may not be required for every study.

61 Product Identity and Composition

GUIDANCE FOR SUMMARIZING STUDIES

The following criteria apply to the technical grade of the active ingredient being reregistered. Items 1, 2, 3, and 5 can be satisfied for most registered products by submission of the Certified Statement of Formula Ingredients Page (EPA Form 8570-4). Items 7 and 8 can be satisfied for most technical grade active ingredients (TGAIs) by submission of a flow chart with chemical equations for each intended chemical reaction. The flow chart should include complete chemical structures and names for each reactant and product of all the reactions.

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. Name of technical material (include product name and trade name, if appropriate).
2. Description of each active and intentionally-added inert ingredient, including name, concentration, and certified limits.
3. Name and upper limit for all impurities present at ≥ 0.1% and those toxicologically significant impurities present at <0.1%.
4. The purpose of each active and intentionally-added inert ingredient.
5. Chemical name and Registry Number for each active and intentionally-added inert ingredient (if available).
6. Molecular, structural, and empirical formulas, molecular weight, and any experimental or internal code number for each active ingredient.
7. Description of each beginning material in the manufacturing process.
8. Description of manufacturing process.
9. Discussion of formation of impurities based on established chemical theory.

62 Analysis and Certification of Product Ingredients

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered. Use a table to present the information in items 6, 7, and 8.

Does your study meet the following acceptance criteria?

1. ___ Five or more representative samples (batches in case of batch process) analyzed for each active ingredient and all impurities present at ≥ 0.1%
2. ___ Degree of accountability or closure ≥ ~~≤~~ 98%
3. ___ Analyses conducted for certain trace toxic impurities at lower than 0.1% (examples, nitrosamines in the case of products containing dinitroanilines or containing secondary or tertiary amines/alkanolamines plus nitrites; polyhalogenated dibenzodioxins and dibenzofurans) [Note that in the case of nitrosamines both fresh and stored samples must be analyzed.]
4. ___ Complete and detailed description of each step in analytical method used to analyze above samples
5. ___ Statement of precision and accuracy of analytical method used to analyze above samples
6. ___ Identities and quantities (including mean and standard deviation) provided for each analyzed ingredient
7. ___ Upper and lower certified limits proposed for each active ingredient and intentionally added inert along with explanation of how the limits were determined
8. ___ Upper certified limit proposed for each impurity present at ≥ 0.1% and for certain toxicologically significant impurities at <0.1% along with explanation of how limit determined
9. ___ Analytical methods to verify certified limits of each active ingredient and impurities (latter not required if exempt from requirement of tolerance or if generally recognized as safe by FDA) are fully described
10. ___ Analytical methods (as discussed in #9) to verify certified limits validated as to their precision and accuracy

Criteria marked with a * are supplemental and may not be required for every study.

62 Analysis and Certification of Product Ingredients

GUIDANCE FOR SUMMARIZING STUDIES

The following criteria apply to the technical grade of the active ingredient being reregistered.

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. Number of representative samples analyzed for all active ingredients and all impurities present at ≥ 0.1%.

2. Degree of accountability or closure in analyses in item #1.

3. Chemical names of toxic impurities which were analyzed for levels <0.1%.

4. Brief description(s) of analytical method(s) used to measure active ingredients and impurities in items #1 and #3.

5. Statement of precision and accuracy of method(s) in item #4.

6. Chemical name and quantities observed (range, mean, standard deviation) for each ingredient (actives and impurities) analyzed in item #1.

7. Proposed upper and lower certified limits for each active ingredient and intentionally added inert with brief explanation of how limits were determined.

8. Proposed upper certified limit for each impurity present at >=0.1% and certain toxicologically significant impurities at <0.1% with brief explanation of how limits were determined.

9. Brief description of analytical method(s) used to verify certified limits (if same methods as item #4, may reference latter).

10. Statement of precision and accuracy of method(s) in item #9 (may reference item #5 if applicable).

63 Physical and Chemical Characteristics

ACCEPTANCE CRITERIA

The following criteria apply to the technical grade of the active ingredient being reregistered.

Does your study meet the following acceptance criteria?

63-2 Color

___ Verbal description of coloration (or lack of it)
___ Any intentional coloration also reported in terms of Munsell color system

63-3 Physical State

___ Verbal description of physical state provided using terms such as "solid, granular, volatile liquid"
___ Based on visual inspection at about 20-25°C

63-4 Odor

___ Verbal description of odor (or lack of it) using terms such as "garlic-like, characteristic of aromatic compounds"
___ Observed at room temperature

63-5 Melting Point

___ Reported in °C
___ Any observed decomposition reported

63-6 Boiling Point

___ Reported in °C
___ Pressure under which B.P. measured reported
___ Any observed decomposition reported

63-7 Density, Bulk Density, Specific Gravity

___ Measured at about 20-25°C
___ Density of technical grade active ingredient reported in g/ml or the specific gravity of liquids reported with reference to water at 20°C. [Note: Bulk density of registered products may be reported in lbs/ft^3 or lbs/gallon.]

63-8 Solubility

___ Determined in distilled water and representative polar and non-polar solvents, including those used in formulations and analytical methods for the pesticide
___ Measured at about 20-25°C
___ Reported in g/100ml (other units like ppm acceptable if sparingly soluble)

Criteria marked with a * are supplemental and may not be required for every study.

63-9 Vapor Pressure

___ Measured at ≈25°C (or calculated by extrapolation from measurements made at higher temperature if pressure too low to measure at 25°C)
___ Experimental procedure described
___ Reported in mm Hg (torr) or other conventional units

63-10 Dissociation Constant

___ Experimental method described
___ Temperature of measurement specified (preferably about 20-25°C)

63-11 Octanol/water Partition Coefficient

___ Measured at about 20-25°C
___ Experimentally determined and description of procedure provided (preferred method-45 Fed. Register 77350)
___ Data supporting reported value provided

63-12 pH

___ Measured at about 20-25°C
___ Measured following dilution or dispersion in distilled water

63-13 Stability

___ Sensitivity to metal ions and metal determined
___ Stability at normal and elevated temperatures
___ Sensitivity to sunlight determined

Criteria marked with a * are supplemental and may not be required for every study.

63 Physical and Chemical Characteristics

GUIDANCE FOR SUMMARIZING STUDIES

The following criteria apply to the technical grade of the active ingredient being reregistered.

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. Description of color.
2. Description of physical state.
3. Description of odor.
4. Indication of melting point (in °C).
5. Indication of boiling point (in °C).
6. Indication of density, bulk density, and specific gravity.
7. Indication of solubility.
8. Indication of vapor pressure.
9. Indication of dissociation constant.
10. Indication of octanol/water partition coefficient.
11. Indication of pH.
12. Description of stability.

SUBDIVISION F

81-1 Acute Oral Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ___ Technical form of the active ingredient tested. (for reregistration only)
2.* ___ At least 5 young adult rats/sex/group
3. ___ Dosing, single oral may be administered over 24 hrs.
4.* ___ Vehicle control if other than water.
5. ___ Doses tested, sufficient to determine a toxicity category or a limit dose (5000 mg/kg).
6. ___ Individual observations at least once a day.
7. ___ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
8. ___ Individual daily observations.
9.* ___ Individual body weights.
10.* ___ Gross necropsy on all animals.

Criteria marked with a * are supplemental and may not be required for every study.

81-1 Acute Oral Toxicity in the Rat

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g. solid, liquid, percent AI in technical, etc.
2. The number of animals/dose/sex tested.
3. Dosing route and regimen.
4. Vehicle used
5. Doses tested and results
6. Individual observations on day of dosing.
7. Individual observations on day of dosing and for at least 14 days or until all animals appear normal (whichever is longer).
8. See items 6 and 7
9. Summarization of body weights
10. Summarization of gross necropsy
11. Significance of changes from the Acceptance Criteria

81-2 Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2.* ____ At least 5 animals/sex/group
3.* ____ Rats 200-300 gm, rabbits 2.0-3.0 kg or guinea pigs 350-450 gm.
4. ____ Dosing, single dermal.
5. ____ Dosing duration at least 24 hours.
6.* ____ Vehicle control, only if toxicity of vehicle is unknown.
7. ____ Doses tested, sufficient to determine a toxicity category or a limit dose (2000 mg/kg).
8. ____ Application site clipped or shaved at least 24 hours before dosing
9. ____ Application site at least 10% of body surface area.
10. ____ Application site covered with a porous nonirritating cover to retain test material and to prevent ingestion.
11. ____ Individual observations at least once a day.
12. ____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
13. ____ Individual daily observations.
14.* ____ Individual body weights.
15.* ____ Gross necropsy on all animals.

Criteria marked with a * are supplemental and may not be required for every study.

81-2 Acute Dermal Toxicity in the Rat, Rabbit or Guinea Pig

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, etc.
2. The number of animals/sex/dose
3. Weight range of animals
4. Verification of single, dermal exposure
5. Duration of dermal exposure
6. Statement of vehicle control
7. Doses tested and results
8. Preparation of application site
9. Area of application site (percent body surface)
10. Occlusion of test material on application site
11. Individual observations on day of dosing
12. Individual observations on day of dosing and for at least 14 days or until all animals appear normal (whichever is longer)
13. See items 11 and 12
14. Summarization of body weights
15. Summarization of gross necropsy
16. Significance of changes from Acceptance Criteria

81-3 Acute Inhalation Toxicity in the Rat

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2. ____ Product is a gas, a solid which may produce a significant vapor hazard based on toxicity and expected use or contains particles of inhalable size for man (aerodynamic diameter 15 um or less).
3.* ____ At least 5 young adult rats/sex/group
4.* ____ Dosing, at least 4 hours by inhalation.
5.* ____ Chamber air flow dynamic, at least 10 air changes/hour, at least 19% oxygen content.
6. ____ Chamber temperature, 22° C (±2°), relative humidity 40-60%.
7. ____ Monitor rate of air flow
8. ____ Monitor actual concentrations of test material in breathing zone.
9. ____ Monitor aerodynamic particle size for aerosols.
10. ____ Doses tested, sufficient to determine a toxicity catagory or a limit dose (5 mg/L actual concentration of respirable substance).
11. ____ Individual observations at least once a day.
12. ____ Observation period to last at least 14 days, or until all test animals appear normal whichever is longer.
13. ____ Individual daily observations.
14.* ____ Individual body weights.
15.* ____ Gross necropsy on all animals.

Criteria marked with a * are supplemental and may not be required for every study.

81-3 Acute Inhalation Toxicity in the Rat

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, etc.
2. Statement of the inhalability of test substance
3. The number of animals/sex/dose
4. Duration of inhalation exposure
5. Number of chamber air changes/hour and the percent oxygen content of chamber air
6. Ranges for chamber air temperature and relative humidity
7. Air flow rate
8. Analytical concentrations of test material in breathing zone
9. Results of aerosol particle-size determination
10. Doses tested (or limit dose of 5mg/L or highest attainable)
11. Individual observations on day of dosing
12. Individual observations on day of dosing and for at least 14 days or until all animals appear normal (whichever is longer)
13. See items 11 and 12
14. Summarization of body weights
15. Summarization of gross necropsy
16. Significance of changes from Acceptance Criteria

81-4 Primary Eye Irritation in the Rabbit

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2. ____ Study not required if material is corrosive, causes severe dermal irritation or has a pH of $\leq$ 2 or $\geq$ 11.5.
3.* ____ 6 adult rabbits
4. ____ Dosing, instillation into the conjunctival sac of one eye per animal.
5.* ____ Dose, 0.1 ml if a liquid; 0.1 ml or not more than 100 mg if a solid, paste or particulate substance.
6. ____ Solid or granular test material ground to a fine dust.
7. ____ Eyes not washed for at least 24 hours.
8. ____ Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hr, then daily until eyes are normal or 21 days (whichever is shorter).
9.* ____ Individual observations for the entire day of dosing.
10.* ____ Individual daily observations.

Criteria marked with a * are supplemental and may not be required for every study.

81-4 Primary Eye Irritation in the Rabbit

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, etc.
2. State of material is corrosive, cause severe dermal irritation or has a pH of <2 or >11.5
3. Number of adult rabbits tested
4. State method of dosing, i.e., instillation into the conjunctival sac of one eye per animal
5. Dose administered
6. Note whether solid or granular test material has been ground to a fine dust
7. State whether eyes were washed and at what time post instillation (not less than 24 hours)
8. State whether eyes were examined and graded for irritation before dosing and at what periods after dosing
9. Individual observations for entire day of dosing
10. Individual observations for entire day of dosing and individual daily observations afterwards, until eyes are normal or for 21 days
11. Significance of changes from Acceptance Criteria

81-5 Primary Dermal Irritation Study

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Technical form of the active ingredient tested. (for reregistration only)
2. ____ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3.* ____ 6 adult animals.
4. ____ Dosing, single dermal.
5. ____ Dosing duration 4 hours.
6. ____ Application site shaved or clipped at least 24 hour prior to dosing.
7. ____ Application site approximately 6 cm^2.
8. ____ Application site covered with a gauze patch held in place with nonirritating tape
9. ____ Material removed, washed with water, without trauma to application site
10. ____ Application site examined and graded for irritation at 1, 24, 48 and 72 hr, then daily until normal or 14 days (whichever is shorter).
11.* ____ Individual observations for the entire day of dosing.
12.* ____ Individual daily observations.

Criteria marked with a * are supplemental and may not be required for every study.

81-5 Primary Dermal Irritation Study

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, etc.
2. State if material is corrosive, has a pH <2 or >11.5, or has a dermal LD-50 <200 mg/kg
3. Number of adult animals tested
4. Amount applied
5. Duration of dermal exposure
6. Preparation of application site (shaved or clipped at specified time before dosing)
7. Area of application site
8. Method for occlusion of application site
9. Note removal of test material and if skin was washed with water
10. State times post application when site was graded for irritation
11. Individual observations for entire day of dosing.
12. Individual observations for entire day of dosing and individual daily observations thereafter
13. Significance of changes from Acceptance Criteria.

81-6 Dermal Sensitization in the Guinea Pig

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ___ Technical form of the active ingredient tested. (for reregistration only)
2. ___ Study not required if material is corrosive or has a pH of ≤ 2 or ≥ 11.5.
3. ___ One of the following methods is utilized;
   - ___ Freund's complete adjuvant test
   - ___ Guinea pig maximization test
   - ___ Split adjuvant technique
   - ___ Buehler test
   - ___ Open epicutaneous test
   - ___ Mauer optimization test
   - ___ Footpad technique in guinea pig
   - ___ Other test accepted by OECD (specify)_____
4. ___ Complete description of test
5. *___ Reference for test.
6. ___ Test followed essentially as described in reference document.
7. *___ Positive control included.

Criteria marked with a * are supplemental and may not be required for every study.

81-6 Dermal Sensitization in the Guinea Pig

GUIDANCE FOR SUMMARIZING STUDIES

Items in summary should include the items discussed in Chapter 2 of this package and the specific items listed below.

1. The form of pesticide tested, e.g., solid, liquid, percent AI in technical, etc.
2. State if material is corrosive or has pH <2 or >11.5).
3. State specific method utilized
4. Complete description of specific method
5. Reference for the specific method employed
6. Note adherence of the protocol to that in the reference for the specific method utilized
7. State the positive control tested
8. Significance of changes from Acceptance Criteria

81-7 Acute Neurotoxicity in the Hen

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Study performed on an organophosphate cholinesterase inhibiting compound.
2. ____ Technical form of the active ingredient tested.
3.* ____ Positive control utilized.
4. ____ Species utilized, domestic laying hen 8-14 months of age.
5. ____ Dosing oral by gavage or capsule (dermal or inhalation may be used).
6. ____ An acute oral LD_{50} is determined.
7. ____ Dose tested equal to an acute oral LD_{50} or a limit test of 5000 mg/kg.
8.* ____ Dosed animals may be protected with atropine and/or 2-PAM.
9. ____ Sufficient test animals so that at least 6 survive.
10. ____ Negative (vehicle) control group of at least 6 hens
11.* ____ Positive control of at least 4 hens. (if used)
12. ____ Test dose repeated if no signs of delayed neurotoxicity observed by 21 days after dosing.
13. ____ Observation period 21 days after each dose.
14. ____ Individual daily observations.
15. ____ Individual body weights.
16.* ____ Individual necropsy not required.
17. ____ Histopathology performed on all animals. Tissue to be fixed *in situ* preferably using whole animal perfusion techniques. At least three sections of each of the following tissues:
    - ____brain, including medulla oblongata
    - ____spinal cord; upper cervical, mid-thoracic and lumbro-sacral regions
    - ____tibial nerve; proximal regions and branches
    - ____sciatic nerve

Criteria marked with a * are supplemental and may not be required for every study.

ATTACHMENT F

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

ATTACHMENT F

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case Number and Name

4007 Allium sativum (Garlic)

COMPANY NUMBER	COMPANY NAME	ADDRESS, CITY AND STATE ZIP
	Sevana	5336 East Easterby Drive Fresno, California 93727
	Guardian Spray	900 Lancer Way Lebec, California 93242

ATTACHMENT G

COST SHARE AND DATA COMPENSATION FORMS

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Form Approved
OMB No. 2070-0106
Approval Expires 12-31-92

Please fill in blanks below.

Company Name	
Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(D) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are:

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form."

3. That I have previously complied with section 3(c)(1)(D) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date
Name and Title (Please Type or Print)	

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D).

Signature	Date
Name and Title (Please Type or Print)	

EPA

United States Environmental Protection Agency
Washington, DC 20460

CERTIFICATION OF OFFER TO COST SHARE IN THE DEVELOPMENT OF DATA

Form Approved
OMB No. 2070-0106
Approval Expires 12-31-92

Please fill in blanks below.

Company Name	
Product Name	EPA Reg. No.

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

US Environmental Protection Agency
Washington, DC 20460

EPA Product Specific Data Report

Registration Standard for:	EPA Registration Number	Form Approved OMB #2070-0057 Expires 11-30-89

Registration Guideline No.	Name of Test	Testing not required for my product listed above (Check below)	I am complying with Data Requirements by -		(For EPA Use Only) Accession numbers assigned
			Citing MR ID No.	Submitting Data (Attached) (Check below)	
Sec. 158.120 Product Chemistry					
61-1	Identity of ingredients				
61-2 (a)	Statement of composition				
61-2 (b)	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion Characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.135 Toxicology					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit /rat/g.pig				
81-3	Acute inhalation toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Typed Name and Title	Signature	Date

EPA RED FACTS

ALLIUM SATIVUM (GARLIC)

PESTICIDE REREGISTRATION

All pesticides sold or used in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered years ago be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, showing the human health and environmental effects of each pesticide. The Agency imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing undue hazards to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Document, or RED. This fact sheet summarizes the information in the RED for Allium sativum (garlic).

USE PROFILE

Allium sativum or garlic, formulated as a powder or a distilled extract from garlic cloves, is an active ingredient in four registered pesticide products; three of these products also contain the active ingredient capsaicin (red pepper). The garlic pesticides are applied aerially or by ground equipment, and are used to repel birds and/or insects and thus prevent them from damaging seeds and seedlings of vegetable plants, fruit trees, grain crops, ornamental plants and shrubbery.

REGULATORY HISTORY

EPA registered the first two pesticide products containing garlic as an active ingredient in 1983 and 1985. Both products also contain red pepper, and are used to repel birds. A third garlic and red pepper product, used to repel insects, was registered in 1988. The fourth product, which contains garlic as a single active ingredient, was registered in February 1991, also to control insects.

EPA previously classified garlic as a conventional chemical pesticide. However, the Agency now is reclassifying garlic as a biochemical pesticide since it is a naturally-occurring substance and has a non-toxic mode of action.

HUMAN HEALTH AND ENVIRONMENTAL ASSESSMENT

Although EPA has developed a set of data requirements for reregistration, the Agency believes there is a category of pesticides for which a greatly reduced set of data requirements are appropriate. Such pesticides may be exempt from the usual generic data requirements for toxicology, residue chemistry, human exposure, ecological effects and environmental fate, without compromising human health or environmental safety. However, some data requirements (such as basic product identity and product chemistry data and acute toxicology studies) usually are essential, and generally will not be waived.

Garlic is in this category of pesticides, and EPA is waiving most of the generic data requirements for its reregistration. The bulb of a plant, its primary use in the United States is non-pesticidal; it is used widely to flavor and season foods. Garlic is "generally recognized as safe," or GRAS, as a natural seasoning or flavoring (see 21 CFR 182.10, 182.20 and 184.1317).

Used as a pesticide, garlic has a non-toxic mode of action for repelling target birds and insects. Garlic is presumed to be non-persistent since it is material known to rapidly degrade in the environment. EPA has received no reports of adverse effects resulting from its use. The Agency believes that no significant adverse effects to humans or the environment are associated with the use of garlic as a pesticide.

ADDITIONAL DATA REQUIRED

EPA has waived all generic data requirements for garlic except basic product identity and product chemistry studies. These are being required now, through the RED.

PRODUCT LABELING CHANGES REQUIRED

The labels of the four registered garlic pesticide products must comply with EPA's current pesticide labeling requirements. No other labeling changes are being required at this time.

REGULATORY CONCLUSION

- The registered bird and insect repellent uses of garlic are not likely to cause unreasonable adverse effects in people or the environment, and are eligible for reregistration.

- The registered product that contains garlic as its only active ingredient will be reregistered once product-specific data and amended labeling are received and accepted by EPA.

- The other three registered products that contain both garlic and red pepper as active ingredients will be reregistered after red pepper also is determined to be eligible for reregistration.

FOR MORE INFORMATION

EPA is requesting public comments on the Reregistration Eligibility Document (RED) for garlic during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED or to submit written comments, please contact the Public Response and Program Resources Branch, Field Operations Division (H-7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

In the future, the garlic RED will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about garlic or about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (H-7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000. For information about reregistration of individual garlic products, please contact the Registration Division (H-7505C), OPP, US EPA, Washington, DC 20460, telephone 703-305-5447.

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, 24 hours a day, seven days a week, or Fax your inquiry to 806-743-3094.