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EPA Reregistration Eligibility Document (RED)

Capsaicin

LIST D

CASE 4018

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WASHINGTON, D.C.

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GLOSSARY OF TERMS AND ABBREVIATIONS

CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GRAS	Generally Recognized As Safe
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the EPA.
ppm	Parts per Million
RED	Reregistration Eligibility Document

EXECUTIVE SUMMARY

Pesticide products containing capsaicin as an active ingredient have been registered since 1962. Currently, capsaicin is registered in ten products as an animal and insect repellent. It is used to repel dogs in the case of attack, and repel insects, birds, and a variety of other animals from crops, non-food plants, and specific residential areas. This document focuses only on the active ingredient capsaicin.

The Agency is basing its reregistration decision for capsaicin on a risk management decision. Precautionary label statements are required which should reduce potential environmental exposure. Further, the Agency has no significant concerns regarding capsaicin's toxicity to humans. Therefore, the Agency believes capsaicin can be used without causing unreasonable adverse effects in people or the environment and that all products containing capsaicin as an active ingredient are eligible for reregistration.

Before reregistering each product, the Agency is requiring product specific data to be submitted within eight months from the issuance of this document. After reviewing these data and the revised labels, EPA will determine whether or not the conditions of FIFRA Section 3(c)(5) have been met for each product. The product will be reregistered if its composition and labeling are acceptable, and its uses will not cause unreasonable adverse effects to humans or the environment. End-use products containing capsaicin in combination with other active ingredients will not be reregistered until the Reregistration Eligibility Documents for all active ingredients contained in that product are issued.

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 product-specific data, section 4(g)(2)(B), and either reregistering products or taking "other appropriate regulatory action," sections 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 capsaicin. The document consists of five sections. Section I is this introduction. Section II describes capsaicin, its uses and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV discusses the reregistration eligibility decision for capsaicin and Section V discusses product reregistration requirements. Additional details concerning the Agency 's 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. CASE OVERVIEW

A. Chemical Overview

Chemical Name: 8-methyl-n-vanillyl-6-non

Empirical Formula: $C_{18}H_{27}NO_3$

Common Name: Capsaicin

CAS Number: 404-86-4

Office of Pesticide Programs Chemical Code: 00611

Basic Sources: oleoresin extract of the Capsicum red pepper

B. Use Profile

The following is information on the registered use with specific use sites and application methods. A detailed table of eligible uses of capsaicin is in Appendix A.

Type of Pesticide: biochemical pesticide, animal and insect repellent

Pests Repelled: birds, moles, deer, dogs, insects, rabbits, squirrels

Registered Use Sites:
Terrestrial Food - fruits (including berries), vegetables, grains
Terrestrial Non-Food - ornamental plants, trees, and flowers (including roses) and shrubbery.

Residential Outdoor - ornamental plants, trees, and shrubs, garbage bags, lawns or gardens.
Residential Indoor - crack and crevice, ant trails carpets and upholstered furniture

Formulation Types Registered:
Dry powder, liquid formulation and liquid spray ground

Method and Rates of Application: Types Of Treatment: Rinse, aerial application, spray

Equipment: aircraft, ground boom, pump spray bottle, spray container, shaker can, hydraulic sprayer

Timing: As directed by product label

Rate of Application: From dose cannot be calculated to six pounds per acre.

Use Practices Limitations: Refer to precautionary label statements.

C. Regulatory History

The United States Department of Agriculture first registered a pesticide product with capsaicin as a single active ingredient in 1962. This product was a dog-attack repellent, a use that is still registered 30 years later. Currently, there are ten registered products containing the active ingredient capsaicin. These products are granular, liquid, and dust formulations, which are used for the control of birds, animals, and insects and arachnids in houses, gardens, crop lands, and forests. The Agency has also registered capsaicin in combination with garlic (Allium sativum) or oil of mustard (allyl isothiocyanate).

On November 26, 1991 the Agency classified capsaicin as a biochemical pesticide because it is a naturally occurring biological substance and because it has a non-toxic mode of action. The source of capsaicin derives from the oleoresin of pepper plants of the genus Capsicum.

III. SCIENCE ASSESSMENT OF CAPSAICIN

EPA has reviewed the scientific data base for capsaicin relying on information submitted by the registrants. These are cited in Appendix C.

A. Product chemistry Assessment

The active ingredient capsaicin (oleoresin of capsicum) is generally obtained by grinding dried ripe fruits of Capsicum frutescens L. (chili peppers) into a fine powder. The oleoresin may be obtained by distillation of the powder in an appropriate solvent, and evaporation of the solvent to yield the liquid oleoresin and associated fatty matter. The fatty

matter is removed by decanting or filtration. The resulting reddish-brown liquid is very thick; while little odor is associated with the oleoresin, the taste is extremely pungent (U.S. Dispensatory, 25th Edition).

The manufacturing process used by the primary supplier (Kalsec, Inc.) to obtain capsaicin powder and oleoresin has been described. Briefly, the peppers are ground, extracted with food grade hexane with the resulting extract being filtered through diatomaceous earth. Following distillation to remove the hexane (level will not exceed 25 ppm), the raw extract is analyzed for color intensity and capsaicinoid content, and then placed in storage for use in finished products. Batching operations are product-specific with sequential samples taken after the batching process to insure that the finished product conforms to specifications.

Upon final approval, the product is packaged and shipped. All operations are conducted according to Good Manufacturing Procedures.[2]

B. Human Health Assessment

1. Toxicology Data Base

The potential risks to humans from both dietary and occupational exposure are considered negligible due to the long history of use by humans as a food additive/component without any indication of deleterious health effects. Due to the nature of the subject compound it is unlikely that products containing capsaicin will have adverse effects on human health. Consequently, all toxicology data requirements have been satisfied. No additional generic data will be required.

2. Dietary Exposure

In the absence of toxicological concerns from ingestion of capsaicin because of its presence in the human diet, the Agency has waived the requirements for the submission of residue data. However, a tolerance exemption under Federal Food, Drug, and Cosmetic Act (FFDCA) Section 408 will be established for capsaicin for all currently registered food uses.

[2] See bibliography reference 1

3. Occupational and Residential Exposure

In Section II the Agency provides a brief description of the types of product formulations, application methods and sites. The ground formulation can be applied from the ground or by air as a dust to the foliage of growing crops or with a granular applicator (or shaker can). The labels require a minimum of 7 days between applications. Except for the ready-to-use pressurized product the liquid formulations are diluted with water and broadcast sprayed by aircraft, ground boom, hand-held garden hose, and airblast spray equipment.

Based on the application methods and formulation types, the potential for eye, dermal and inhalation exposure to mixers, loaders and applicators does exist. In addition, the potential for post-application exposure may be significant from the foliar treatments applied prior to harvest since pre-harvest intervals are being removed from the label.

Based on the lack of significant toxicological concerns for capsaicin, there are no additional exposure data required at this time.

4. Human Risk Assessment

The potential risks to humans from both dietary and occupational exposure are considered negligible due to the long history of use by humans as a food additive/component without any indication of deleterious health effects.

Due to the nature of the subject compound and the required precautionary statements on the label, EPA concludes that products containing capsaicin will not have adverse effects on human health.

C. Environmental Assessment

The basic data requirements for a biochemical pesticide consist of the Tier I ecological effects studies. Environmental fate (Tier II) and additional ecological effects (Tier III) studies are not required for biochemical pesticides unless adverse effects are observed in Tier I studies. As described below, the Tier I studies have been waived for capsaicin.

1. Ecological Effects Data

The Agency has no ecological effects or environmental fate data on capsaicin. As a biochemical pesticide, a reduced data set of four studies would normally be required: an acute avian oral study, a subacute avian dietary study, a 96-hour fish study, and a 48-hour aquatic invertebrate study (guideline requirements 154-6, 154-7, 154-8, and 154-9,

required: an acute avian oral study, a subacute avian dietary study, a 96-hour fish study, and a 48-hour aquatic invertebrate study (guideline requirements 154-6, 154-7, 154-8, and 154-9, respectively). In the case of capsaicin, the Agency believes that its unique repellent properties, in conjunction with appropriate label restrictions, can limit the exposure to non-target species so that waivers can be granted for these ecological effects studies.

The basis for the Agency's position is as follows. Capsaicin is a strong and immediately-acting irritant by both dietary and dermal routes of exposure. As such, one of the uses is as a bird repellent. Therefore, for birds and other terrestrial species, the Agency assumes that these animals will avoid excessive and prolonged exposure and thus minimize risk.

However, it should be noted that a bird feeding study (Blumberg, 1990) reported that capsaicin did not repel birds because birds do not recognize capsaicin as "hot" since they do not have capsaicin sensitive receptors, and a report of a second bird feeding study (letter of 6/2/82, from E. Schafer) states that ".... based on very limited data, I would expect that a bird repellent material composed of chili pepper and garlic or their powders would have minimal effectiveness in the field for its intended purpose on seed-eating birds."

EPA assumes that the product performance studies required by 40 CFR 158.640, footnote 1, showed that the product worked as a bird repellent. Although, for this type of product, these efficacy studies must be performed, they are not normally required to be submitted to the Agency unless, on a case-by-case basis, the Agency decides that review of the studies is necessary. In order to resolve this apparent discrepancy, the EPA will call in and review the product performance studies for birds. If these data support the Agency's rationale concerning exposure of terrestrial animals, avian study requirements will be waived.

EPA will also call in and review the product performance studies for the insect repellent labels since one label claims insecticidal activity for a mixture of this active ingredient and another pesticide. This call-in is necessary since both active ingredients were believed to have a non-toxic mode of action to the target pest; they have been classified as biochemical pesticides. If this is not the case, then product reclassification may be warranted.

With respect to aquatic exposure, *in lieu* of requiring the two aquatic studies, the amount of aquatic exposure can be minimized by restrictive label statements. In contrast to mobile terrestrial species, fish and aquatic species are not able to avoid chemicals that have become mixed with, or dispersed in, their habitat. Given the lack of information on toxicity to aquatic species and our inability to estimate exposure, there is great uncertainty about the risk to the aquatic species. However, the Agency has found no reports of adverse environmental effects from the previous use of this registered pesticide. As a precaution, the potential risk may be reduced by reducing the possibility of aquatic exposure. Therefore, the following statements will be required on the label under the general heading "Precautionary Statements" and under the subheading "Environmental Hazard": "This product may be toxic to aquatic organisms. Do not apply to or allow runoff to reach lakes, streams or ponds. Do

not contaminate water by cleaning of equipment or disposal of wastes." In addition, the Agency will require a maximum application rate on all labels.

2. Environmental Fate Data

Because capsaicin is a biochemical pesticide, the requirement for environmental fate data is contingent upon the results of Tier I ecological effects data requirements. Since the ecological effects studies have been waived contingent on labeling to reduce exposure, no environmental fate data will be required.

The Agency does not foresee the potential for significant risks associated with the specified use of capsaicin, given the labeling restrictions. No hazard or exposure issues have been identified that need to be addressed further. Therefore, no ecological effects or environmental fate data are required to support the reregistration of capsaicin.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION FOR CAPSAICIN

A. Determination Of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required or waived the submission of the generic (i.e., active ingredient specific) data required to support reregistration of products containing capsaicin as an active ingredient. The Agency has completed its review of these generic data and other relevant information and has determined that the data are sufficient to support reregistration of products containing capsaicin. Appendix B identifies the data requirements that the Agency considered as part of its determination of reregistration eligibility of capsaicin. Appendix C identifies references of information the Agency relied upon for its assessments.

The data and information identified above are sufficient to allow the Agency to conduct a reasonable risk assessment for the registered uses of capsaicin. The Agency therefore finds that all products containing capsaicin as an active ingredient for the specified use patterns are eligible for reregistration (See Appendix A for use patterns). The reregistration of particular products is addressed in Section V of this document ("Product Reregistration").

Although the Agency has found that products containing capsaicin are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support reregistration of products containing capsaicin, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Tolerance Assessment

The Agency will propose a tolerance exemption for capsaicin under FFDCA Section 408 for all currently registered food uses.

V. ACTIONS REQUIRED BY REGISTRANTS OF END-USE PRODUCTS

A. Determination Of Eligibility

Based on consideration of information about the active ingredient capsaicin and the registered use patterns, the products containing this active ingredient 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 and determine whether to reregister individual products.

B. Product Specific Data Requirements

The product-specific data requirements are stated in Appendix D.

C. Labeling Requirements For End-Use Products

1. The 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.

2. The Agency in Section III above describes certain deficiencies regarding protection of workers and aquatic species and states that label changes are necessary to support the Agency's conclusion that the use of capsaicin products would not cause unreasonable risks. These label requirements are:

a. For products containing capsaicin as the only active ingredient the environmental precaution:

"This product may be toxic to aquatic organisms. Do not apply to or allow runoff to reach lakes, streams and ponds. Do not contaminate water by cleaning of equipment or disposal of wastes."

b. For labels with no maximum application limit of capsaicin on the label, registrants must include proposed maximum application rates for terrestrial food and terrestrial non-food uses.

c. Registrants must delete from their label a statement for a pre-harvest interval for products containing capsaicin since the Agency will propose a tolerance exemption for capsaicin under FFDCA Section 408 for all currently registered food uses.

APPENDIX A

Capsaicin Use Patterns Subject to Reregistration

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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: Allowed	Geographic Limitations: Disallowed	Use Limitations also see Abbreviations
USES ELIGIBLE FOR REREGISTRATION										
FOOD/FEED USES										
Apple Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
Broadcast, Foliar, Aircraft	D	na	6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	6 lb AI per A	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, 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.
Apricot Use Group: Terrestrial Food Crop										
Broadcast, Foliar, Aircraft	D	na	6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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 also see Abbreviations
								Allowed	Disallowed	
Apricot Use Group: Terrestrial Food 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.
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), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
High volume spray (dilute), Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
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 4018, [Capsaicin] Chemical 070701 [Capsaicin; In Oleoresin of Capsicum]

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: Allowed	Geographic Limitations: Disallowed	Use Limitations also see Abbreviations
Beans Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
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	na	2.4 lb AI per A	not spec	not spec	not spec	not spec			
Broadcast, Foliar, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Ground	D	na	3.6 lb AI per A	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			
Soil treatment, At planting, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			

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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 also see Abbreviations
								Allowed	Disallowed	
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.
Brussels Sprouts Use Groups: Terrestrial Food Crop										
High volume spray (dilute), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
High volume spray (dilute), Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Band treatment, At planting, Mechanical granule applicator	D	na	2.4 lb AI per A	not spec	not spec	not spec	not spec			

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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 also see Abbreviations
								Allowed	Disallowed	
Cabbage Use Group: Terrestrial Food Crop										
Broadcast, Foliar, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	3.6 lb per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Ground	D	na	3.6 lb per A	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			
Soil treatment, At planting, Shaker can	D	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
High volume spray (dilute), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
High volume spray (dilute), Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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 also see Abbreviations
								Allowed	Disallowed	
Carrot (including tops) Use Group: Terrestrial Food Crop										
Band treatment, At planting, Mechanical granule applicator	D	na	2.4 lb AI per A	not spec	not spec	not spec	not spec			
Broadcast, Foliar, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Ground	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preahrvest interval.
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.
High volume spray (dilute), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Cauliflower Use Group: Terrestrial Food Crop										

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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 also see Abbreviations
								Allowed	Disallowed	
Cauliflower Use Group: Terrestrial Food Crop										
High volume spray (dilute), Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
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.
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	na	6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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 also see Abbreviations
								Allowed	Disallowed	
Cherry Use Group: Terrestrial Food Crop										
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	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	na	2.4 lb AI per A	not spec	not spec	not spec	not spec			
Broadcast, Foliar, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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 also see Abbreviations
								Allowed	Disallowed	
Corn (Unspecified) Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
Broadcast, Seedling stage, Ground	D	na	3.6 lb AI per A	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			
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			
High volume spray (dilute), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
High volume spray (dilute), Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Cotton Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
High volume spray (dilute), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
High volume spray (dilute), Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray (concentrate), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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 also see Abbreviations
								Allowed	Disallowed	
Cotton Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray (concentrate), At emergence, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray (concentrate), Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Cucumber Use Group: Terrestrial Food Crop										
High volume spray (dilute), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
High volume spray (dilute), Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
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.

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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: Allowed	Geographic Limitations: Disallowed	Use Limitations also see Abbreviations
Cucumber Use Group: Terrestrial Food Crop										
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	na	2.4 lb AI per A	not spec	not spec	not spec	not spec			7 days preharvest interval.
Broadcast, Foliar, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Ground	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Fig Use Group: Terrestrial Food Crop										
Broadcast, Foliar, Aircraft	D	na	6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	6 lb AI per A	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	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.

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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 also see Abbreviations
								Allowed	Disallowed	
Grapes Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
Broadcast, Foliar, Ground	D	na	3.6 lb AI per A	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, 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.
Lettuce Use Group: Terrestrial Food Crop										
Band treatment, At planting, Mechanical granule applicator	D	na	2.4 lb AI per A	not spec	not spec	not spec	not spec			
Broadcast, Foliar, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Ground	D	na	3.6 lb AI per A	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			

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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: Allowed	Geographic Limitations: Disallowed	Use Limitations also see Abbreviations
Lettuce 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.
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										
High volume spray (dilute), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
High volume spray (dilute), Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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: Allowed	Geographic Limitations: Disallowed	Use Limitations also see Abbreviations
Melons Use Groups: Terrestrial Food Crop										
Band treatment, At planting, Mechanical granule applicator	D	na	2.4 lb AI per A	not spec	not spec	not spec	not spec			
Broadcast, Foliar, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Ground	D	na	3.6 lb AI per A	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			
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.

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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: Allowed	Geographic Limitations: Disallowed	Use Limitations also see Abbreviations
Melons Use Groups: Terrestrial Food Crop										
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										
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	na	6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Orchards (Unspecified) Use Group: Terrestrial Food Crop										
Broadcast, Foliar, Aircraft	D	na	6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.

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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 also see Abbreviations
								Allowed	Disallowed	
Orchards (Unspecified) Use Group: Terrestrial Food Crop										
Bark treatment, Dormant, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Bark treatment, Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Bark treatment, Postharvest, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Bark treatment, Dormant, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Bark treatment, Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Bark treatment, Postharvest, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Dormant, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Postharvest, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Dormant, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations / B
Low volume spray, Postharvest, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Dormant, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B

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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 also see Abbreviations
								Allowed	Disallowed	
Orchards (Unspecified) Use Group: Terrestrial Food Crop										
Low volume spray, Postharvest, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
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.
Spray, Petal fall, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.

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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 also see Abbreviations
								Allowed	Disallowed	
Peach **Use Group: Terrestrial Food Crop**										
Broadcast, Foliar, Aircraft	D	na	6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	6 lb AI per A	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, 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.
Peas (Unspecified) **Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop**										
High volume spray (dilute), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
High volume spray (dilute), Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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 also see Abbreviations
								Allowed	Disallowed	
Peas (Unspecified) Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
Low volume spray (concentrate), Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Peppers Use Group: Terrestrial Food Crop										
High volume spray (dilute), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
High volume spray (dilute), Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Plum Use Group: Terrestrial Food Crop										
Broadcast, Foliar, Aircraft	D	na	6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	6 lb AI per A	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, Petal fall, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	7	not spec			15 days preharvest interval.

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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 also see Abbreviations
								Allowed	Disallowed	
Plum Use Group: Terrestrial Food Crop										
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.
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			
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	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	3.6 lb AI per A	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.

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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 also see Abbreviations
								Allowed	Disallowed	
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.
Squash Use Group: Terrestrial Food Crop										
High volume spray (dilute), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
High volume spray (dilute), Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Sugar Maple Use Group: Terrestrial Food Crop										
Sap collection equipment treatment, When needed, By hand	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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 also see Abbreviations
								Allowed	Disallowed	
Sunflower Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
Band treatment, At planting, Mechanical granule applicator	D	na	2.4 lb AI per A	not spec	not spec	not spec	not spec			
Broadcast, Foliar, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Ground	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Tomato Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
High volume spray (dilute), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
High volume spray (dilute), Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), At emergence, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Low volume spray (concentrate), Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B, C
Broadcast, At planting, Mechanical granule applicator	D	na	2.4 lb AI per A	not spec	not spec	not spec	not spec			

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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 also see Abbreviations
								Allowed	Disallowed	
Tomato Use Groups: Terrestrial Food Crop and Terrestrial Feed Crop										
Broadcast, Foliar, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Ground	D	na	3.6 lb AI per A	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.

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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 also see Abbreviations
								Allowed	Disallowed	
Tree Nuts **Use Group: Terrestrial Food Crop**										
Broadcast, Foliar, Aircraft	D	na	6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Bark treatment, Dormant, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Bark treatment, Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Bark treatment, Postharvest, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Bark treatment, Dormant, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Bark treatment, Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Bark treatment, Postharvest, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Dormant, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Postharvest, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Dormant, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Postharvest, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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 also see Abbreviations
								Allowed	Disallowed	
Tree Nuts **Use Group: Terrestrial Food Crop**										
Low volume spray, Dormant, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Postharvest, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Vegetables (Unspecified) **Use Group: Terrestrial Food Crop**										
Band treatment, At planting, Mechanical granule applicator	D	na	2.4 lb AI per A	not spec	not spec	not spec	not spec			
Broadcast, Foliar, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Aircraft	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Foliar, Ground	D	na	3.6 lb AI per A	not spec	not spec	7	not spec			7 days preharvest interval.
Broadcast, Seedling stage, Ground	D	na	3.6 lb AI per A	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			

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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: Allowed	Geographic Limitations: Disallowed	Use Limitations also see Abbreviations
Vegetables (Unspecified) 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.
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.
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			
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										
Bark treatment, Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Bark treatment, Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Spray, Foliar, Ground	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			
Low volume spray, Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B

APPENDIX A - Case 4018, [Capsaicin] Chemical 070701 [Capsaicin, In Oleoresin of Capsicum]

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 also see Abbreviations
								Allowed	Disallowed	
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			
Ornametal and/or Shade Trees Use Groups: Terrestrial Non-Food Crop and Outdoor Residential										
Bark treatment, Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Bark treatment, Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Foliar, Aircraft	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Foliar, Hydraulic sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Low volume spray, Foliar, Low volume sprayer	SC/L	na	Dose cannot be calculated	not spec	not spec	not spec	not spec			Limitations A, B
Household/DomesticDwellings Contents Use Group: Indoor Residential										
Sprinkle, When needed, Equipment not on label	D	na	Dose cannot be calculated	not spec	not spec	1.5	not spec			
Household/DomesticDwellings Indoor Premises Use Group: Indoor Residential										
Contact and/or surface treatment, When needed, Pump spray bottle	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			
Household/DomesticDwellings Outdoor Premises Use Group: Outdoor Residential										
Outdoor general surface treatment, When needed, Pump spray bottle	SC/L	na	Dose cannot be calculated	not spec	not spec	As needed	not spec			
Humans (Animal Attack Preventative) (Vertebrate Pest Control) Use Group: Indoor Residential										
Directed spray, When needed, Aerosol can	PRL	na	Dose cannot be calculated	not spec	not spec	not spec	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 PRL=pressurized liquid
- **Rate:** ai=active ingredient; A=acre
- **Limitations:** Limitation A = Do not apply through any type of irrigation system
  Limitation B = Do not use treated foliage for animal bedding or feed.
  Limitation C = Do not apply after edible parts start to form.

APPENDIX B

Generic Data Requirements for Reregistration of Capsaicin
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 Requirement (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 the given use patterns:

A	Terrestrial food
K	Residential outdoor
O	Residential indoor

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 CAPSAICIN AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Product Chemistry			
151B-10	Product Identification	AKO	Data were obtained from the most recent confidential statements of formula for registered products.
151B-11	Manufacturing Process	AKO	1
151B-12	Discussion of Formulation of Unintentional Ingredients	AKO	1
151B-13	Analysis of Samples	AKO	1
151B-15	Certification of Limits	AKO	1
151B-16	Analytical Methods	AKO	1

1 Information was obtained from internal files and documents.

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF CAPSAICIN AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Product Chemistry (continued)			
151B-17(a)	Color	AKO	1
151B-17(b)	Physical State	AKO	1
151B-17(c)	Odor	AKO	1
151B-17(e)	Boiling Point	AKO	1
151B-17(f)	Density or Specific Gravity	AKO	1
151B-17(g)	Solubility	AKO	1
151B-17(h)	Vapor Pressure	AKO	1
151B-17(i)	Ph	AKO	1
151B-17(j)	Stability	AKO	1
151B-17(k)	Flammability	AKO	Not applicable
151B-17(l)	Storage Stability	AKO	1
151B-17(m)	Viscosity	AKO	Waived

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF CAPSAICIN AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
151B-17(n)	Miscibility	AKO	Waived
151B-17(o)	Corrosion Characteristics	AKO	Waived
151B-17(p)	Octanol/H_20 Partition Coefficient	AKO	Waived

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF CAPSAICIN AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Ecological Effects			
154-6	Avian Acute Oral	AKO	Waived
154-7	Avian Dietary	AKO	Waived
154-8	Freshwater Fish LC50	AKO	Waived
154-9	Freshwater Invertebrate LC50	AKO	Waived

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF CAPSAICIN AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Environmental Fate			
Data requirements do not apply since ecological effects data are waived.			

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF CAPSAICIN AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
Toxicology:			
152B-10	Acute Oral Toxicity	AKO	Waived
152B-11	Acute Dermal Toxicity	AKO	Waived
152B-12	Acute Inhalation	AKO	Waived
152B-13	Primary Eye Irritation	AKO	Waived
152B-14	Primary Dermal Irritation	AKO	Waived
152B-15	Dermal Sensitization	AKO	Waived
152B-16	Hypersensitivity*	AKO	Waived
152B-18	Immunotoxicity	AKO	Waived

APPENDIX B

GENERIC DATA REQUIREMENTS FOR REREGISTRATION OF CAPSAICIN AND DATA CITATIONS SUPPORTING REREGISTRATION

GUIDELINE CITATION	TITLE OF STUDY	USE PATTERNS	BIBLIOGRAPHIC CITATION
152B-20	90-Day Feeding (1 Species)	AKO	Waived
152B-21	90-Day Dermal-Rat	AKO	Waived
152B-22	90-Day Inhalation-Rat	AKO	Waived
152B-23	Teratogenicity (1 Species)	AKO	Waived
152B-17	Mutagenicity (Ames)	AKO	Waived

APPENDIX C

Citations Considered to be Part of the Data Base Supporting the Reregistration of Capsaicin

OFFICE OF PESTICIDE PROGRAMS
REREGISTRATION ELIGIBILITY DOCUMENT
BIBLIOGRAPHY

Chemical Name: Capsaicin

1. Letter from J. Gordon Dixon, ARI, dated December 1991, providing a description of the manufacturing process, including composition and purity of starting and intermediate materials; a complete list of the names and amounts of ingredients in the products; physical and chemical properties, descriptions of analytical methods used to determine the identity and concentrations of active ingredients and impurities, in sufficient detail to permit repetition and validation of those methods; results o analytical procedures including raw data; and a theoretical discussion of the impurities which may be sent in the product--e.g., unreacted starting materials or products formed by degradation of the active ingredient and the reasons why such impurities might not be present in the product.

APPENDIX D

PR Notice 91-2

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

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).

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The upper and lower certified limits, which must be proposed in connection with a product's registration, represent the amounts of an ingredient that may legally be present 40 CFR 158.175. The lower certified limit is used as the enforceable lower limit for the product composition according to FIFRA section 12(a)(1)(C), while the nominal concentration appearing on the label would be the routinely achieved concentration used for calculation of dosages and dilutions.

The nominal concentration would in fact state the greatest degree of accuracy that is warranted with respect to actual product composition because the nominal concentration would be the amount of active ingredient typically found in the product.

It is important for registrants to note that certified limits for active ingredients are not considered to be trade secret information under FIFRA section 10(b). In this respect the certified limits will be routinely provided by EPA to States for enforcement purposes, since the nominal concentration appearing on the label may not represent the enforceable composition for purposes of section 12(a)(1)(C).

III. REQUIREMENTS

As described below under Unit V. " **COMPLIANCE SCHEDULE**," all currently registered products as well as all applications for new registration must comply with this Notice by specifying the nominal concentration expressed as a percentage by weight as the label claim in the ingredient(s) statement and equivalence statements if applicable (e.g., elemental arsenic, metallic zinc, salt of an acid). In addition, the requirement for performing sample analyses of five or more representative samples must be fulfilled. Copies of the raw analytical data must be submitted with the nominal ingredient label claim. Further information about the analysis requirement may be found in the 40 CFR 158.170. All products are required to provide certified limits for each active, inert ingredient, impurities of toxicological significance(i.e., upper limit(s) only) and on a case by case basis as specified by EPA. These limits are to be set based on representative sampling and chemical analysis(i.e., quality control) of the product.

The format of the ingredient statement must conform to 40 CFR 156-Labeling Requirements For Pesticides and Devices.

After July 1, 1997, all pesticide ingredient statements must be changed to nominal concentration.

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

Pesticide Reregistration Handbook

APPENDIX F

Product Specific Data Call-In

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
ARI, INC. BOX 999 GRIFFIN GA 30224	4018 Capsaicin	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 claimimg 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."
7754-38		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

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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

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1. Company name and Address
ARI, INC.
BOX 999
GRIFFIN GA 30224

2. Case # and Name
4018 Capsaicin

EPA Reg. No. 7754-38

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 7754-RD-2292

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	K	O	EP	8 mos.	
151B-11	Manufacturing process	(1)					ABC	K	O	EP	8 mos.	
151B-12	Discussion of formation of unintentional ingrdients	(2)					ABC	K	O	EP	8 mos.	
151B-13	Analysis of samples	(3)					ABC	K	O	EP	8 mos.	
151B-15	Certification of limits						ABC	K	O	EP	8 mos.	
151B-16	Analytical methods						ABC	K	O	EP	8 mos.	
151B-17(b)	Physical state						ABC	K	O	EP	8 mos.	
151B-17(f)	Density						ABC	K	O	EP	8 mos.	
151B-17(i)	pH	(6)					ABC	K	O	EP	8 mos.	
151B-17(l)	Storage stability						ABC	K	O	EP	8 mos.	
151B-17(m)	Viscosity	(8)					ABC	K	O	EP	8 mos.	
151B-17(n)	Miscibility	(9)					ABC	K	O	EP	8 mos.	
151B-17(o)	Corrosion characteristics						ABC	K	O	EP	8 mos.	

10. Certification
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11. Date

12. Name of Company Contact

13. Phone Number

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

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

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ARI, INC. BOX 999 GRIFFIN GA 30224	4018 Capsaicin EPA Reg. No. 7754-38	PRODUCT SPECIFIC ID# 7754-RD-2292

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
	Acute Toxic - Biochemical								
152B-13	Primary eye irritation					ABC K O	EP	8 mos.	
152B-14	Primary dermal irritation					ABC K O	EP	8 mos.	
152B-16	Hypersensitivity incidents (5)					ABC K O	EP	8 mos.	
	Efficacy - Invertebrate Control Agents								
	Premises Treatments								
95-11	Laboratory efficacy evaluation (1,56)					K M O	EP	8 mos.	
	Efficacy - Vertebrate Control Agents								
96-6	Avian repellents (1)					ABC K	EP	8 mos.	
96-11	Rodenticides in orchards (1)					ABC K	EP	8 mos.	
96-18	Domestic dog and cat repellents (1)					ABC K	EP	8 mos.	
96-19	Browsing animal repellents (1)					ABC JK	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: 4018 Capsaicin

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

1 If an experimental use permit is being sought, a schematic diagram and/or description of the manufacturing process will suffice if the pesticide is not already under full scale production.

2 If the product is not already under full scale production and an experimental use permit is being sought, a discussion of impurities shall be submitted to the extent this information is available.

3 Required to support registration of each manufacturing-use product and end use products produced by an integrated formulation system. Data on other end-use products will be required on a case-by-case basis. For pesticides in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.

6 Required if test substance is dispersible with water.

8 Required if product is a liquid.

9 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.

Acute Toxic - Biochemical

5 Incidents must be reported, if they occur.

Efficacy - Invertebrate Control Agents

1 The agency has waived all requirements to submit efficacy data for invertebrate control agents for nonpublic health uses. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly 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.

56 Available data on the insecticidal properties of products containing Capsaicin indicates that these products repell. Registrants that make label claims of "killing" will need to submit or cite data. In lieu of submitting or citing data registrants have the option to change the label claim from killing" to "repelling".

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4018 Capsaicin

Footnotes (cont.):

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 commonly 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.
   The Agency has determined that submission of efficacy data is required to support the claims made for products claimed to repel vertebrate animals.

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
CHAMPON'S 100% NATURAL PRODUCTS, INC
2706 N.W. 91ST AVE
CORAL SPRINGS FL 33065

2. Case # and Name
4018 Capsaicin

3. Date and Type of DCI
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."
61966-2		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

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Washington, D. C. 20460

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CHAMPON'S 100% NATURAL PRODUCTS, INC
2706 N.W. 91ST AVE
CORAL SPRINGS FL 33065

2. Case # and Name
4018 Capsaicin

EPA Reg. No. 61966-2

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 61966-RD-2298

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 K O	EP	8 mos.	
151B-11	Manufacturing process	(1)					ABC K O	EP	8 mos.	
151B-12	Discussion of formation of ununtentional ingrdients	(2)					ABC K O	EP	8 mos.	
151B-13	Analysis of samples	(3)					ABC K O	EP	8 mos.	
151B-15	Certification of limits						ABC K O	EP	8 mos.	
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151B-17(b)	Physical state						ABC K O	EP	8 mos.	
151B-17(f)	Density						ABC K O	EP	8 mos.	
151B-17(i)	pH	(6)					ABC K O	EP	8 mos.	
151B-17(l)	Storage stability						ABC K O	EP	8 mos.	
151B-17(m)	Viscosity	(8)					ABC K O	EP	8 mos.	
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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
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United States Environmental Protection Agency
Washington, D. C. 20460

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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

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3 Required to support registration of each manufacturing-use product and end use products produced by an integrated formulation system. Data on other end-use products will be required on a case-by-case basis. For pesticides in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.
6 Required if test substance is dispersible with water.
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9 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.

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56 Available data on the insecticidal properties of products containing Capsaicin indicates that these products repell. Registrants that make label claims of "killing" will need to submit or cite data. In lieu of submitting or citing data registrants have the option to change the label claim from killing" to "repelling".

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FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4018 Capsaicin

Footnotes (cont.):

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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
CHAMPON'S 100% NATURAL PRODUCTS, INC 2706 N.W. 91ST AVE CORAL SPRINGS FL 33065	4018 Capsaicin	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."
61966-1		N.A.	N.A.		

8. Certification

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Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

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Washington, D. C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

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CHAMPON'S 100% NATURAL PRODUCTS, INC
2706 N.W. 91ST AVE
CORAL SPRINGS FL 33065

2. Case # and Name
4018 Capsaicin

EPA Reg. No. 61966-1

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 61966-RD-2297

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	K	O	EP	8 mos.	
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151B-17(b)	Physical state						ABC	K	O	EP	8 mos.	
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151B-17(n)	Miscibility	(9)					ABC	K	O	EP	8 mos.	
151B-17(o)	Corrosion characteristics						ABC	K	O	EP	8 mos.	

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2706 N.W. 91ST AVE
CORAL SPRINGS FL 33065

2. Case # and Name
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EPA Reg. No. 61966-1

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PRODUCT SPECIFIC
ID# 61966-RD-2297

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
	Acute Toxic - Biochemical								
152B-13	Primary eye irritation					ABC K O	EP	8 mos.	
152B-14	Primary dermal irritation					ABC K O	EP	8 mos.	
152B-16	Hypersensitivity incidents (5)					ABC K O	EP	8 mos.	
	Efficacy - Invertebrate Control Agents								
	Premises Treatments								
95-11	Laboratory efficacy evaluation (1,56)					K M O	EP	8 mos.	
	Efficacy - Vertebrate Control Agents								
96-6	Avian repellents (1)					ABC K	EP	8 mos.	
96-11	Rodenticides in orchards (1)					ABC K	EP	8 mos.	
96-18	Domestic dog and cat repellents (1)					ABC K	EP	8 mos.	
96-19	Browsing animal repellents (1)					ABC JK	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: 4018 Capsaicin

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

1 If an experimental use permit is being sought, a schematic diagram and/or description of the manufacturing process will suffice if the pesticide is not already under full scale production.

2 If the product is not already under full scale production and an experimental use permit is being sought, a discussion of impurities shall be submitted to the extent this information is available.

3 Required to support registration of each manufacturing-use product and end use products produced by an integrated formulation system. Data on other end-use products will be required on a case-by-case basis. For pesticides in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.

6 Required if test substance is dispersible with water.

8 Required if product is a liquid.

9 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.

Acute Toxic - Biochemical

5 Incidents must be reported, if they occur.

Efficacy - Invertebrate Control Agents

1 The agency has waived all requirements to submit efficacy data for invertebrate control agents for nonpublic health uses. 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.

56 Available data on the insecticidal properties of products containing Capsaicin indicates that these products repell. Registrants that make label claims of "killing" will need to submit or cite data. In lieu of submitting or citing data registrants have the option to change the label claim from killing" to "repelling".

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4018 Capsaicin

Footnotes (cont.):

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.
The Agency has determined that submission of efficacy data is required to support the claims made for products claimed to repel vertebrate animals.

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
MILLER CHEMICAL AND FERTILIZER CORPO BOX 333 HANOVER, PA 17331	4018 Capsaicin	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."
72-574		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

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	2. Case # and Name	3. Date and Type of DCI
MILLER CHEMICAL AND FERTILIZER CORPO BOX 333 HANOVER, PA 17331	4018 Capsaicin EPA Reg. No. 72-574	PRODUCT SPECIFIC ID# 72-RD-2289

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 K O	EP	8 mos.	
151B-11	Manufacturing process (1)					ABC K O	EP	8 mos.	
151B-12	Discussion of formation of ununtentional ingrdients (2)					ABC K O	EP	8 mos.	
151B-13	Analysis of samples (3)					ABC K O	EP	8 mos.	
151B-15	Certification of limits					ABC K O	EP	8 mos.	
151B-16	Analytical methods					ABC K O	EP	8 mos.	
151B-17(b)	Physical state					ABC K O	EP	8 mos.	
151B-17(f)	Density					ABC K O	EP	8 mos.	
151B-17(i)	pH (6)					ABC K O	EP	8 mos.	
151B-17(l)	Storage stability					ABC K O	EP	8 mos.	
151B-17(m)	Viscosity (8)					ABC K O	EP	8 mos.	
151B-17(n)	Miscibility (9)					ABC K O	EP	8 mos.	
151B-17(o)	Corrosion characteristics					ABC K 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

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	2. Case # and Name	3. Date and Type of DCI
MILLER CHEMICAL AND FERTILIZER CORPO BOX 333 HANOVER, PA 17331	4018 Capsaicin EPA Reg. No. 72-574	PRODUCT SPECIFIC ID# 72-RD-2289

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
	Acute Toxic - Biochemical								
152B-13	Primary eye irritation					ABC K O	EP	8 mos.	
152B-14	Primary dermal irritation					ABC K O	EP	8 mos.	
152B-16	Hypersensitivity incidents (5)					ABC K O	EP	8 mos.	
	Efficacy - Invertebrate Control Agents								
	Premises Treatments								
95-11	Laboratory efficacy evaluation (1,56)					K M O	EP	8 mos.	
	Efficacy - Vertebrate Control Agents								
96-6	Avian repellents (1)					ABC K	EP	8 mos.	
96-11	Rodenticides in orchards (1)					ABC K	EP	8 mos.	
96-18	Domestic dog and cat repellents (1)					ABC K	EP	8 mos.	
96-19	Browsing animal repellents (1)					ABC JK	EP	8 mos.	

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Date

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4018 Capsaicin

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

1 If an experimental use permit is being sought, a schematic diagram and/or description of the manufacturing process will suffice if the pesticide is not already under full scale production.

2 If the product is not already under full scale production and an experimental use permit is being sought, a discussion of impurities shall be submitted to the extent this information is available.

3 Required to support registration of each manufacturing-use product and end use products produced by an integrated formulation system. Data on other end-use products will be required on a case-by-case basis. For pesticides in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.

6 Required if test substance is dispersible with water.

8 Required if product is a liquid.

9 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.

Acute Toxic - Biochemical

5 Incidents must be reported, if they occur.

Efficacy - Invertebrate Control Agents

1 The agency has waived all requirements to submit efficacy data for invertebrate control agents for nonpublic health uses. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly 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.

56 Available data on the insecticidal properties of products containing Capsaicin indicates that these products repell. Registrants that make label claims of "killing" will need to submit or cite data. In lieu of submitting or citing data registrants have the option to change the label claim from killing" to "repelling".

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4018 Capsaicin

Footnotes (cont.):

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 commonly 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. The Agency has determined that submission of efficacy data is required to support the claims made for products claimed to repel vertebrate animals.

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
NORTH HEALTH CARE
1515 ELMWOOD ROAD
ROCKFORD IL 61101

2. Case # and Name
4018 Capsaicin

3. Date and Type of DCI
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."
8668-1		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

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
NORTH HEALTH CARE
1515 ELMWOOD ROAD
ROCKFORD IL 61101

2. Case # and Name
4018 Capsaicin

EPA Reg. No. 8668-1

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 8668-RD-2293

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 K O	EP	8 mos.	
151B-11	Manufacturing process	(1)					ABC K O	EP	8 mos.	
151B-12	Discussion of formation of ununtentional ingrdients	(2)					ABC K O	EP	8 mos.	
151B-13	Analysis of samples	(3)					ABC K O	EP	8 mos.	
151B-15	Certification of limits						ABC K O	EP	8 mos.	
151B-16	Analytical methods						ABC K O	EP	8 mos.	
151B-17(b)	Physical state						ABC K O	EP	8 mos.	
151B-17(f)	Density						ABC K O	EP	8 mos.	
151B-17(i)	pH	(6)					ABC K O	EP	8 mos.	
151B-17(l)	Storage stability						ABC K O	EP	8 mos.	
151B-17(m)	Viscosity	(8)					ABC K O	EP	8 mos.	
151B-17(n)	Miscibility	(9)					ABC K O	EP	8 mos.	
151B-17(o)	Corrosion characteristics						ABC K 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

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

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1. Company name and Address
NORTH HEALTH CARE
1515 ELMWOOD ROAD
ROCKFORD IL 61101

2. Case # and Name
4018 Capsaicin

EPA Reg. No. 8668-1

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 8668-RD-2293

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
	Acute Toxic - Biochemical								
152B-13	Primary eye irritation					ABC K O	EP	8 mos.	
152B-14	Primary dermal irritation					ABC K O	EP	8 mos.	
152B-16	Hypersensitivity incidents (5)					ABC K O	EP	8 mos.	
	Efficacy - Invertebrate Control Agents								
	Premises Treatments								
95-11	Laboratory efficacy evaluation (1,56)					K M O	EP	8 mos.	
	Efficacy - Vertebrate Control Agents								
96-6	Avian repellents (1)					ABC K	EP	8 mos.	
96-11	Rodenticides in orchards (1)					ABC K	EP	8 mos.	
96-18	Domestic dog and cat repellents (1)					ABC K	EP	8 mos.	
96-19	Browsing animal repellents (1)					ABC JK	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

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
XTTRIUM LABS INC
415 W PERSHING RD
CHICAGO IL 60609

2. Case # and Name
4018 Capsaicin

EPA Reg. No. 5464-6

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 5464-RD-2290

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 K O	EP	8 mos.	
151B-11	Manufacturing process	(1)					ABC K O	EP	8 mos.	
151B-12	Discussion of formation of ununtentional ingrdients	(2)					ABC K O	EP	8 mos.	
151B-13	Analysis of samples	(3)					ABC K O	EP	8 mos.	
151B-15	Certification of limits						ABC K O	EP	8 mos.	
151B-16	Analytical methods						ABC K O	EP	8 mos.	
151B-17(b)	Physical state						ABC K O	EP	8 mos.	
151B-17(f)	Density						ABC K O	EP	8 mos.	
151B-17(i)	pH	(6)					ABC K O	EP	8 mos.	
151B-17(l)	Storage stability						ABC K O	EP	8 mos.	
151B-17(m)	Viscosity	(8)					ABC K O	EP	8 mos.	
151B-17(n)	Miscibility	(9)					ABC K O	EP	8 mos.	
151B-17(o)	Corrosion characteristics						ABC K 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

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
XTTRIUM LABS INC
415 W PERSHING RD
CHICAGO IL 60609

2. Case # and Name
4018 Capsaicin

EPA Reg. No. 5464-6

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 5464-RD-2290

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
	Acute Toxic - Biochemical								
152B-13	Primary eye irritation					ABC K O	EP	8 mos.	
152B-14	Primary dermal irritation					ABC K O	EP	8 mos.	
152B-16	Hypersensitivity incidents (5)					ABC K O	EP	8 mos.	
	Efficacy - Invertebrate Control Agents								
	Premises Treatments								
95-11	Laboratory efficacy evaluation (1,56)					K M O	EP	8 mos.	
	Efficacy - Vertebrate Control Agents								
96-6	Avian repellents (1)					ABC K	EP	8 mos.	
96-11	Rodenticides in orchards (1)					ABC K	EP	8 mos.	
96-18	Domestic dog and cat repellents (1)					ABC K	EP	8 mos.	
96-19	Browsing animal repellents (1)					ABC JK	EP	8 mos.	

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Date

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
SEVANA CO.
5336 E. EASTERBY DR.
FRESNO CA 93727

2. Case # and Name
4018 Capsaicin

EPA Reg. No. 47319-1

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 47319-RD-2294

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 K O	EP	8 mos.	
151B-11	Manufacturing process (1)					ABC K O	EP	8 mos.	
151B-12	Discussion of formation of ununtentional ingrdients (2)					ABC K O	EP	8 mos.	
151B-13	Analysis of samples (3)					ABC K O	EP	8 mos.	
151B-15	Certification of limits					ABC K O	EP	8 mos.	
151B-16	Analytical methods					ABC K O	EP	8 mos.	
151B-17(b)	Physical state					ABC K O	EP	8 mos.	
151B-17(f)	Density					ABC K O	EP	8 mos.	
151B-17(i)	pH (6)					ABC K O	EP	8 mos.	
151B-17(l)	Storage stability					ABC K O	EP	8 mos.	
151B-17(m)	Viscosity (8)					ABC K O	EP	8 mos.	
151B-17(n)	Miscibility (9)					ABC K O	EP	8 mos.	
151B-17(o)	Corrosion characteristics					ABC K O	EP	8 mos.	

10. Certification

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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

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	2. Case # and Name	3. Date and Type of DCI
SEVANA CO. 5336 E. EASTERBY DR. FRESNO CA 93727	4018 Capsaicin EPA Reg. No. 47319-1	PRODUCT SPECIFIC ID# 47319-RD-2294

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
	Acute Toxic - Biochemical								
152B-13	Primary eye irritation					ABC K O	EP	8 mos.	
152B-14	Primary dermal irritation					ABC K O	EP	8 mos.	
152B-16	Hypersensitivity incidents (5)					ABC K O	EP	8 mos.	
	Efficacy - Invertebrate Control Agents								
	Premises Treatments								
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	Efficacy - Vertebrate Control Agents								
96-6	Avian repellents (1)					ABC K	EP	8 mos.	
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96-18	Domestic dog and cat repellents (1)					ABC K	EP	8 mos.	
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Approval Expires 12-31-92

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1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
SEVANA CO. 5336 E. EASTERBY DR. FRESNO CA 93727	4018 Capsaicin	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		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

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
SEVANA CO.
5336 E. EASTERBY DR.
FRESNO CA 93727

2. Case # and Name
4018 Capsaicin

EPA Reg. No. 47319-4

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 47319-RD-2296

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 K O	EP	8 mos.	
151B-11	Manufacturing process	(1)					ABC K O	EP	8 mos.	
151B-12	Discussion of formation of ununtentional ingrdients	(2)					ABC K O	EP	8 mos.	
151B-13	Analysis of samples	(3)					ABC K O	EP	8 mos.	
151B-15	Certification of limits						ABC K O	EP	8 mos.	
151B-16	Analytical methods						ABC K O	EP	8 mos.	
151B-17(b)	Physical state						ABC K O	EP	8 mos.	
151B-17(f)	Density						ABC K O	EP	8 mos.	
151B-17(i)	pH	(6)					ABC K O	EP	8 mos.	
151B-17(l)	Storage stability						ABC K O	EP	8 mos.	
151B-17(m)	Viscosity	(8)					ABC K O	EP	8 mos.	
151B-17(n)	Miscibility	(9)					ABC K O	EP	8 mos.	
151B-17(o)	Corrosion characteristics						ABC K 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

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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
SEVANA CO.
5336 E. EASTERBY DR.
FRESNO CA 93727

2. Case # and Name
4018 Capsaicin

EPA Reg. No. 47319-4

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 47319-RD-2296

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
	Acute Toxic - Biochemical								
152B-13	Primary eye irritation					ABC K O	EP	8 mos.	
152B-14	Primary dermal irritation					ABC K O	EP	8 mos.	
152B-16	Hypersensitivity incidents (5)					ABC K O	EP	8 mos.	
	Efficacy - Invertebrate Control Agents								
	Premises Treatments								
95-11	Laboratory efficacy evaluation (1,56)					K M O	EP	8 mos.	
	Efficacy - Vertebrate Control Agents								
96-6	Avian repellents (1)					ABC K	EP	8 mos.	
96-11	Rodenticides in orchards (1)					ABC K	EP	8 mos.	
96-18	Domestic dog and cat repellents (1)					ABC K	EP	8 mos.	
96-19	Browsing animal repellents (1)					ABC JK	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: 4018 Capsaicin

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

1 If an experimental use permit is being sought, a schematic diagram and/or description of the manufacturing process will suffice if the pesticide is not already under full scale production.

2 If the product is not already under full scale production and an experimental use permit is being sought, a discussion of impurities shall be submitted to the extent this information is available.

3 Required to support registration of each manufacturing-use product and end use products produced by an integrated formulation system. Data on other end-use products will be required on a case-by-case basis. For pesticides in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.

6 Required if test substance is dispersible with water.

8 Required if product is a liquid.

9 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.

Acute Toxic - Biochemical

5 Incidents must be reported, if they occur.

Efficacy - Invertebrate Control Agents

1 The agency has waived all requirements to submit efficacy data for invertebrate control agents for nonpublic health uses. 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.

56 Available data on the insecticidal properties of products containing Capsaicin indicates that these products repell. Registrants that make label claims of "killing" will need to submit or cite data. In lieu of submitting or citing data registrants have the option to change the label claim from killing" to "repelling".

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4018 Capsaicin

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

1 If an experimental use permit is being sought, a schematic diagram and/or description of the manufacturing process will suffice if the pesticide is not already under full scale production.

2 If the product is not already under full scale production and an experimental use permit is being sought, a discussion of impurities shall be submitted to the extent this information is available.

3 Required to support registration of each manufacturing-use product and end use products produced by an integrated formulation system. Data on other end-use products will be required on a case-by-case basis. For pesticides in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.

6 Required if test substance is dispersible with water.

8 Required if product is a liquid.

9 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.

Acute Toxic - Biochemical

5 Incidents must be reported, if they occur.

Efficacy - Invertebrate Control Agents

1 The agency has waived all requirements to submit efficacy data for invertebrate control agents for nonpublic health uses. 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.

56 Available data on the insecticidal properties of products containing Capsaicin indicates that these products repell. Registrants that make label claims of "killing" will need to submit or cite data. In lieu of submitting or citing data registrants have the option to change the label claim from killing" to "repelling".

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4018 Capsaicin

Footnotes (cont.):

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. The Agency has determined th t submission of efficacy data is required to support the claims made for products claimed to repel vertebrate animals.

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
SEVANA CO. 5336 E. EASTERBY DR. FRESNO CA 93727	4018 Capsaicin	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."
47319-2		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

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	2. Case # and Name	3. Date and Type of DCI
SEVANA CO. 5336 E. EASTERBY DR. FRESNO CA 93727	4018 Capsaicin EPA Reg. No. 47319-2	PRODUCT SPECIFIC ID# 47319-RD-2295

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 K O	EP	8 mos.	
151B-11	Manufacturing process (1)					ABC K O	EP	8 mos.	
151B-12	Discussion of formation of ununtentional ingrdients (2)					ABC K O	EP	8 mos.	
151B-13	Analysis of samples (3)					ABC K O	EP	8 mos.	
151B-15	Certification of limits					ABC K O	EP	8 mos.	
151B-16	Analytical methods					ABC K O	EP	8 mos.	
151B-17(b)	Physical state					ABC K O	EP	8 mos.	
151B-17(f)	Density					ABC K O	EP	8 mos.	
151B-17(i)	pH (6)					ABC K O	EP	8 mos.	
151B-17(l)	Storage stability					ABC K O	EP	8 mos.	
151B-17(m)	Viscosity (8)					ABC K O	EP	8 mos.	
151B-17(n)	Miscibility (9)					ABC K O	EP	8 mos.	
151B-17(o)	Corrosion characteristics					ABC K 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

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
SEVANA CO.
5336 E. EASTERBY DR.
FRESNO CA 93727

2. Case # and Name
4018 Capsaicin

EPA Reg. No. 47319-2

3. Date and Type of DCI
PRODUCT SPECIFIC
ID# 47319-RD-2295

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
	Acute Toxic - Biochemical								
152B-13	Primary eye irritation					ABC K O	EP	8 mos.	
152B-14	Primary dermal irritation					ABC K O	EP	8 mos.	
152B-16	Hypersensitivity incidents (5)					ABC K O	EP	8 mos.	
	Efficacy - Invertebrate Control Agents								
	Premises Treatments								
95-11	Laboratory efficacy evaluation (1,56)					K M O	EP	8 mos.	
	Efficacy - Vertebrate Control Agents								
96-6	Avian repellents (1)					ABC K	EP	8 mos.	
96-11	Rodenticides in orchards (1)					ABC K	EP	8 mos.	
96-18	Domestic dog and cat repellents (1)					ABC K	EP	8 mos.	
96-19	Browsing animal repellents (1)					ABC JK	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: 4018 Capsaicin

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

1 If an experimental use permit is being sought, a schematic diagram and/or description of the manufacturing process will suffice if the pesticide is not already under full scale production.

2 If the product is not already under full scale production and an experimental use permit is being sought, a discussion of impurities shall be submitted to the extent this information is available.

3 Required to support registration of each manufacturing-use product and end use products produced by an integrated formulation system. Data on other end-use products will be required on a case by-case basis. For pesticides in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.

6 Required if test substance is dispersible with water.

8 Required if product is a liquid.

9 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.

Acute Toxic - Biochemical

5 Incidents must be reported, if they occur.

Efficacy - Invertebrate Control Agents

1 The agency has waived all requirements to submit efficacy data for invertebrate control agents for nonpublic health uses. 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.

56 Available data on the insecticidal properties of products containing Capsaicin indicates that these products repell. Registrants that make label claims of "killing" will need to submit or cite data. In lieu of submitting or citing data registrants have the option to change the label claim from killing" to "repelling".

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4018 Capsaicin

Footnotes (cont.):

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.
The Agency has determined that submission of efficacy data is required to support the claims made for products claimed to repel vertebrate animals.

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
XTTRIUM LABS INC
415 W PERSHING RD
CHICAGO IL 60609

2. Case # and Name
4018 Capsaicin

3. Date and Type of DCI
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."
5464-6		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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4018 Capsaicin

Footnotes (cont.):

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 commonly 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. The Agency has determined that submission of efficacy data is required to support the claims made for products claimed to repel vertebrate animals.

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4018 Capsaicin

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

1 If an experimental use permit is being sought, a schematic diagram and/or description of the manufacturing process will suffice if the pesticide is not already under full scale production..
2 If the product is not already under full scale production and an experimental use permit is being sought, a discussion of impurities shall be submitted to the extent this information is available.
3 Required to support registration of each manufacturing-use product and end use products produced by an integrated formulation system. Data on other end-use products will be required on a case-by-case basis. For pesticides in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.
6 Required if test substance is dispersible with water.
8 Required if product is a liquid.
9 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.

Acute Toxic - Biochemical

5 Incidents must be reported, if they occur.

Efficacy - Invertebrate Control Agents

1 The agency has waived all requirements to submit efficacy data for invertebrate control agents for nonpublic health uses. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly 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.

56 Available data on the insecticidal properties of products containing Capsaicin indicates that these products repell. Registrants that make label claims of "killing" will need to submit or cite data. In lieu of submitting or citing data registrants have the option to change the label claim from killing" to "repelling".

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
SEVANA CO. 5336 E. EASTERBY DR. FRESNO CA 93727	4018 Capsaicin	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."
47319-1		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

DRAFT COPY

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4018 Capsaicin

Footnotes (cont.):

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 commonly 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. The Agency has determined that submission of efficacy data is required to support the claims made for products claimed to repel vertebrate animals.

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4018 Capsaicin

Footnotes (cont.):

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. The Agency has determined that submission of efficacy data is required to support the claims made for products claimed to repel vertebrate animals.

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

FOOTNOTES AND KEY DEFINATIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 4018 Capsaicin

Key: (TP = 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

1 If an experimental use permit is being sought, a schematic diagram and/or description of the manufacturing process will suffice if the pesticide is not already under full scale production.

2 If the product is not already under full scale production and an experimental use permit is being sought, a discussion of impurities shall be submitted to the extent this information is available.

3 Required to support registration of each manufacturing-use product and end use products produced by an integrated formulation system. Data on other end-use products will be required on a case-by-case basis. For pesticides in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.

6 Required if test substance is dispersible with water.

8 Required if product is a liquid.

9 Required if product is an emulsifiable liquid and is to be diluted with petroleum solvents.

Acute Toxic - Biochemical

5 Incidents must be reported, if they occur.

Efficacy - Invertebrate Control Agents

1 The agency has waived all requirements to submit efficacy data for invertebrate control agents for nonpublic health uses. 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.

56 Available data on the insecticidal properties of products containing Capsaicin indicates that these products repell. Registrants that make label claims of "killing" will need to submit or cite data. In lieu of submitting or citing data registrants have the option to change the label claim from killing" to "repelling".

ATTACHMENT B

PRODUCT SPECIFIC DATA CALL-IN RESPONSE FORMS (Form A)
PLUS INSTRUCTIONS

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 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.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

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 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 requirement 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 make 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 antoher 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.

ATTACHMENT A

Chemical Status Sheet

ATTACHMENT A

CAPSAICIN: DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

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

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 capsaicin Data Call-In. Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

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

The Agency has concluded that product specific data are needed for capsaicin. 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.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the product specific data requirements and procedures established by this Notice, please contact Robert 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: Capsaicin

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Ernestine Dobbins at (703) 308-8071. All responses to this Notice should be submitted to:

Chemical Review Manager Ernestine Dobbins
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: Capsaicin

ATTACHMENT C

PRODUCT SPECIFIC REQUIREMENT STATUS AND REGISTRANT'S RESPONSE
(FORMS B) PLUS INSTRUCTIONS
AND
PR NOTICE 86-5

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

JUL 29 1986

PR NOTICE 86-5

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

NOTICE TO PRODUCERS, FORMULATORS, DISTRIBUTORS AND REGISTRANTS

Attention: Persons responsible for Federal registration of pesticides.

Subject: Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and certain provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Purpose

To require data to be submitted to the Environmental Protection Agency (EPA) in a standard format. This Notice also provides additional guidance about, and illustrations of, the required formats.

II. Applicability

This PR Notice applies to all data that are submitted to EPA to satisfy data requirements for granting or maintaining pesticide registrations, experimental use permits, tolerances, and related approvals under certain provisions of FIFRA and FFDCA. These data are defined in FIFRA §10(d)(1). This Notice does not apply to commercial, financial, or production information, which are, and must continue to be, submitted differently under separate cover.

III. Effective Date

This notice is effective on November 1, 1986. Data formatted according to this notice may be submitted prior to the effective date. As of the effective date, submitted data packages that do not conform to these requirements may be returned to the submitter for necessary revision.

IV. Background

On September 26, 1984, EPA published proposed regulations in the Federal Register (49 FR 37956) which include Requirements for Data Submission (40 CFR §158.32), and Procedures for Claims of Confidentiality of Data (40 CFR §158.33). These regulations

specify the format for data submitted to EPA under Section 3 of FIFRA and Sections 408 and 409 of FFDCA, and procedures which must be followed to make and substantiate claims of confidentiality. No entitlements to data confidentiality are changed, either by the proposed regulation or by this notice.

OPP is making these requirements mandatory through this Notice to gain resource-saving benefits from their use before the entire proposed regulation becomes final. Adequate lead time is being provided for submitters to comply with the new requirements.

V. Relationship of this Notice to Other OPP Policy and Guidance

While this Notice contains requirements for organizing and formatting submittals of supporting data, it does not address the substance of test reports themselves. "Data reporting" guidance is now under development in OPP, and will specify how the study objectives, protocol, observations, findings, and conclusions are organized and presented within the study report. The data reporting guidance will be compatible with submittal format requirements described in this Notice.

OPP has also promulgated a policy (PR Notice 86-4 dated April 15, 1986) that provides for early screening of certain applications for registration under FIFRA §3. The objective of the screen is to avoid the additional costs and prolonged delays associated with handling significantly incomplete application packages. As of the effective date of this Notice, the screen will include in its criteria for acceptance of application packages the data formatting requirements described herein.

OPP has also established a public docket which imposes deadlines for inserting into the docket documents submitted in connection with Special Reviews and Registration Standards (see 40 CFR §154.15 and §155.32). To meet these deadlines, OPP is requiring an additional copy of any data submitted to the docket. Please refer to Page 10 for more information about this requirement.

For several years, OPP has required that each application for registration or other action include a list of all applicable data requirements and an indication of how each is satisfied--the statement of the method of support for the application. Typically, many requirements are satisfied by reference to data previously submitted--either by the applicant or by another party. That requirement is not altered by this notice, which applies only to data submitted with an application.

VI. Format Requirements

A more detailed discussion of these format requirements follows the index on the next page, and samples of some of the requirements are attached. Except for the language of the two alternative forms of the Statement of Data Confidentiality Claims (shown in Attachment 3) which cannot be altered, these samples are illustrative. As long as the required information is included and clearly identifiable, the form of the samples may be altered to reflect the submitter's preference.

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A. Organization of Submittal Package

A 'submittal package' consists of all studies submitted at the same time for review in support of a single regulatory action, along with a transmittal document and other related administrative material (e.g. the method of support statement, EPA Forms 8570-1, 8570-4, 8570-20, etc.) as appropriate.

Data submitters must organize each submittal package as described in this notice. The transmittal and any other administrative material must be grouped together in the first physical volume. Each study included in the submittal package must then be bound separately.

Submitters sometimes provide additional materials that are intended to clarify, emphasize, or otherwise comment to help Product Managers and reviewers better understand the submittal.

- If such materials relate to <u>one</u> study, they should be included as an appendix to that study.
- If such materials relate to <u>more than one</u> study (as for example a summary of all studies in a discipline) or to the submittal in general, they must be included in the submittal package as a separate study (with title page and statement of confidentiality claims).

B. Transmittal Document

The first item in each submittal package must be a transmittal document. This document identifies the submitter or all joint submitters; the regulatory action in support of which the package is being submitted--i.e., a registration application, petition, experimental use permit (EUP), §3(c)(2)(B) data call-in, §6(a)(2) submittal, or a special review; the transmittal date; and a list of all individual studies included in the package in the order of their appearance, showing (usually by Guideline reference number) the data requirement(s) addressed by each one. The EPA-assigned number for the regulatory action (e.g. the registration, EUP, or tolerance petition number) should be included in the transmittal document as well, if it is known to the submitter. See Attachment 1 for an example of an acceptable transmittal document.

The list of included studies in the transmittal of a data submittal package supporting a registration application should be subdivided by discipline, reflecting the order in which data requirements appear in 40 CFR 158.

The list of included studies in the transmittal of a data submittal package supporting a petition for tolerance or an application for an EUP should be subdivided into sections A, B, C,.... of the petition or application, as defined in 40 CFR 180.7 and 158.125, (petitions) or Pesticide Assessment Guidelines, Subdivision I (EUPs) as appropriate.

When a submittal package supports a tolerance petition and an application for a registration or an EUP, list the petition studies first, then the balance of the studies. Within these two groups of studies follow the instructions above.

C. Individual Studies

A study is the report of a single scientific investigation, including all supporting analyses required for logical completeness. A study should be identifiable and distinguishable by a conventional bibliographic citation including author, date, and title. Studies generally correspond in scope to a single Guideline requirement for supporting data, with some exceptions discussed in section C.1. Each study included in a submittal package must be bound as a separate entity. (See comments on binding studies on page 9.)

Each study must be consecutively paginated, beginning from the title page as page 1. The total number of pages in the complete study must be shown on the study title page. In addition (to ensure that inadvertently separated pages can be reassociated with the proper study during handling or review) use either of the following:

- Include the total number of pages in the complete study on each page (ie., 1 of 250, 2 of 250, ...250 of 250).

- Include a company name or mark and study number on each page of the study, e.g., Company Name-1986-23. Never reuse a study number for marking the pages of subsequent studies.

When a single study is extremely long, binding it in multiple volumes is permissible so long as the entire study is paginated in a single series, and each volume is plainly identified by the study title and its position in the multi-volume sequence.

C.1 Special Considerations for Identifying Studies

Some studies raise special problems in study identification, because they address Guidelines of broader than normal scope or for other reasons.

a. Safety Studies. Several Guidelines require testing for safety in more than one species. In these cases each species tested should be reported as a separate study, and bound separately.

Extensive supplemental reports of pathology reviews, feed analyses, historical control data, and the like are often associated with safety studies. Whenever possible these should be submitted with primary reports of the study, and bound with the primary study as appendices. When such supplemental reports are submitted independently of the primary report, take care to fully identify the primary report to which they pertain.

Batteries of acute toxicity tests, performed on the same end use product and covered by a single title page, may be bound together and reported as a single study,

b. Product Chemistry Studies. All product chemistry data within a submittal package submitted in support of an end-use product produced from registered manufacturing-use products should be bound as a single study under a single title page.

Product chemistry data submitted in support of a technical product, other manufacturing-use product, an experimental use permit, an import tolerance petition, or an end-use product produced from unregistered source ingredients, should be bound as a single study for each Guideline series (61, 62, and 63) for conventional pesticides, or for the equivalent subject range for biorational pesticides. The first of the three studies in a complete product chemistry submittal for a biochemical pesticide would cover Guidelines 151-10, 151-11, and 151-12; the second would cover Guidelines 151-13, 151-15, and 151-16; the third would cover Guideline 151-17. The first study for a microbial pesticide would cover Guidelines 151-20, 151-21, and 151-22; the second would cover Guidelines 151-23 and 151-25; the third would cover Guideline 151-26.

Note particularly that product chemistry studies are likely to contain Confidential Business Information as defined in FIFRA §10(d)(1)(A), (B), or (C), and if so must be handled as described in section D.3. of this notice.

C. Residue Chemistry Studies. Guidelines 171-4, 153-3, and 153-4 are extremely broad in scope; studies addressing residue chemistry requirements must thus be defined at a level below that of the Guideline code. The general principle, however, of limiting a study to the report of a single investigation still applies fully. Data should be treated as a single study and bound separately for each analytical method, each report of the nature of the residue in a single crop or animal species, and for each report of the magnitude of residues resulting from treatment of a single crop or from processing a single crop. When more than one commodity is derived from a single crop (such as beet tops and beet roots) residue data on all such commodities should be reported as a single study. When multiple field trials are associated with a single crop, all such trials should be reported as a single study.

D. Organization of Each Study Volume

Each complete study must include all applicable elements in the list below, in the order indicated. (Also see Page 17.) Several of these elements are further explained in the following paragraphs. Entries in the column headed 'example' cite the page number of this notice where the element is illustrated.

Element	When Required	Example
Study Title Page	Always	Page 12
Statement of Data Confidentiality Claims	One of the two alternative forms of this statement is always required.	Page 13
Certification of Good Laboratory Practice	If study reports laboratory work subject to GLP requirements	Page 16
Flagging statements	For certain toxicology studies. (When flagging requirements are finalized.)	
Body of Study	Always - with an English language translation if required.	
Study Appendices	At submitter's option	
Cover Sheet to Confidential Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	
CBI Attachment	If CBI is claimed under FIFRA §10(d)(1)(A), (B), or (C)	Page 15
Supplemental Statement of Data Confidentiality Claims	Only if confidentiality is claimed on a basis other than FIFRA §10(d)(1)(A), (B), or (C)	Page 14

D.1 Title Page

A title page is always required for each submitted study, published or unpublished. The title page must always be freely releasable to requestors; DO NOT INCLUDE CBI ON THE TITLE PAGE. An example of an acceptable title page is on page 12 of this notice. The following information must appear on the title page:

a. Study title. The study title should be as descriptive as possible. It must clearly identify the substance(s) tested and correspond to the name of the data requirement as it appears in the Guidelines.

b. Data requirement addressed. Include on the title page the Guideline number(s) of the specific requirement(s) addressed by the study.

c. Author(s). Cite only individuals with primary intellectual responsibility for the content of the study. Identify them plainly as authors, to distinguish them from the performing laboratory, study sponsor, or other names that may also appear on the title page.

d. Study Date. The title page must include a single date for the study. If parts of the study were performed at different times, use only the date of the latest element in the study.

e. Performing Laboratory Identification. If the study reports work done by one or more laboratories, include on the title page the name and address of the performing laboratory or laboratories, and the laboratory's internal project number(s) for the work. Clearly distinguish the laboratory's project identifier from any other reference numbers provided by the study sponsor or submitter.

f. Supplemental Submissions. If the study is a commentary on or supplement to another previously submitted study, or if it responds to EPA questions raised with respect to an earlier study, include on the title page elements a. through d. for the previously submitted study, along with the EPA Master Record Identifier (MRID) or Accession number of the earlier study if you know these numbers. (Supplements submitted in the same submittal package as the primary study should be appended to and bound with the primary study. Do not include supplements to more than one study under a single title page).

g. Facts of Publication. If the study is a reprint of a published document, identify on the title page all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and publication date.

D.2. Statements of Data Confidentiality Claims Under FIFRA §10(d)(1).

Each submitted study must be accompanied by one of the two alternative forms of the Statement of Data Confidentiality Claims specified in the proposed regulation in §158.33 (b) and (c). (See Attachment 3) These statements apply only to claims of data confidentiality based on FIFRA §10(d)(1)(A), (B), or (C). Use the appropriate alternative form of the statement either to assert a claim of §10(d)(1) data confidentiality (§158.33(b)) or to waive such a claim (§158.33(c)). In either case, the statement must be signed and dated, and must include the typed name and title of the official who signs it. Do not make CBI claims with respect to analytical methods associated with petitions for tolerances or emergency exemptions (see NOTE Pg 13).

D.3. Confidential Attachment

If the claim is made that a study includes confidential business information as defined by the criteria of FIFRA §10(d)(1)(A), (B), or (C) (as described in D.2. above) all such information must be excised from the body of the study and confined to a separate study-specific Confidential Attachment. Each passage of CBI so isolated must be identified by a reference number cited within the body of the study at the point from which the passage was excised (See Attachment 5).

The Confidential Attachment to a study must be identified by a cover sheet fully identifying the parent study, and must be clearly marked 'Confidential Attachment.' An appropriately annotated photocopy of the parent study title page may be used as this cover sheet. Paginate the Confidential Attachment separately from the body of the study, beginning with page 1 of X on the title page. Each passage confined to the Confidential Attachment must be associated with a specific cross reference to the page(s) in the main body of the study on which it is cited, and with a reference to the applicable passage(s) of FIFRA §10(d)(1) on which the confidentiality claim is based.

D.4. Supplemental Statement of Data Confidentiality Claims (See Attachment 4)

If you wish to make a claim of confidentiality for any portion of a submitted study other than described by FIFRA §10(d)(1)(A), (B), or (C), the following provisions apply:

- The specific information to which the claim applies must be clearly marked in the body of the study as subject to a claim of confidentiality.

- A Supplemental Statement of Data Confidentiality Claims must be submitted, identifying each passage claimed confidential and describing in detail the basis for the claim. A list of the points to address in such a statement is included in Attachment 4 on Pg 14.

- The Supplemental Statement of Data Confidentiality Claims must be signed and dated and must include the typed name and title of the official who signed it.

D.5 Good Laboratory Practice Compliance Statement

This statement is required if the study contains laboratory work subject to GLP requirements specified in 40 CFR 160. Samples of these statements are shown in Attachment 6.

E. Reference to Previously Submitted Data

DO NOT RESUBMIT A STUDY THAT HAS PREVIOUSLY BEEN SUBMITTED FOR ANOTHER PURPOSE unless EPA specifically requests it. A copy of the title page plus the MRID number (if known) is sufficient to allow us to retrieve the study immediately for review. This prevents duplicate entries in the Agency files, and saves you the cost of sending more copies of the study. References to previously submitted studies should not be included in the transmittal document, but should be incorporated into the statement of the method of support for the application.

F. Physical Format Requirements

All elements in the data submittal package must be on uniform 8 1/2 by 11 inch white paper, printed on one side only in black ink, with high contrast and good resolution. Bindings for individual studies must be secure, but easily removable to permit disassembly for microfilming. Check with EPA for special instructions before submitting data in any medium other than paper, such as film or magnetic media.

Please be particularly attentive to the following points:

- Do not include frayed or torn pages.
- Do not include carbon copies, or copies in other than black ink.
- Make sure that photocopies are clear, complete, and fully readable.
- Do not include oversize computer printouts or fold-out pages.
- Do not bind any documents with glue or binding tapes.
- Make sure that all pages of each study, including any attachments or appendices, are present and in correct sequence.

Number of Copies Required - All submittal packages except those associated with a Registration Standard or Special Review (see Part G below) must be provided in three complete, identical copies. (The proposed regulations specified two copies; three are now being required to expedite and reduce the cost of processing data into the OPP Pesticide Document Management System and getting it into review.)

G. Special Requirements for Submitting Data to the Docket

Data submittal packages associated with a Registration Standard or Special Review must be provided in four copies, from one of which all material claimed as CBI has been excised. This fourth copy will become part of the public docket for the RS or SR case. If no claims of confidentiality are made for the study, the fourth copy should be identical to the other three. When portions of a study submitted in support of an RS or SR are claimed as CBI, the first three copies will include the CBI material as provided in section D of this notice. The following special preparation is required for the fourth copy.

- Remove the 'Supplemental Statement of Data Confidentiality Claims'.
- Remove the 'Confidential Attachment'.
- Excise from the body of the study any information you claim as confidential, even if it does not fall within the scope of FIFRA §10(d)(1)(A), (B), or (C). Do not close up or paraphrase text remaining after this excision.
- Mark the fourth copy plainly on both its cover and its title page with the phrase "Public Docket Material - contains no information claimed as confidential".

V. For Further Information

For further information contact William C. Grosse, Chief, Information Services Branch, Program Management and Support Division, (703-557-2613).

James W. Akerman
Acting Director,
Registration Division

Attachment 1. Sample Transmittal Document
Attachment 2. Sample Title Page for a Newly Submitted Study
Attachment 3. Statements of Data Confidentiality Claims
Attachment 4. Supplemental Statement of Data Confidentiality Claims
Attachment 5. Samples of Confidential Attachments
Attachment 6. Sample Good Laboratory Practice Statements
Attachment 7. Format Diagrams for Submittal Packages and Studies

ATTACHMENT 1.

ELEMENTS TO BE INCLUDED IN THE TRANSMITTAL DOCUMENT*

1. Name and address of submitter (or all joint submitters**)

†Smith Chemical Corporation
1234 West Smith Street
Cincinnati, OH 98765

-and-

Jones Chemical Company
5678 Wilson Blvd
Covington, KY 56789

†Smith Chemical Corp. will act as sole agent for all submitters.

2. Regulatory action in support of which this package is submitted

Use the EPA identification number (e.g. 359-EUP-67) if you know it Otherwise describe the type of request (e.g. experimental use permit, data call-in - of xx-xx-xx date).

3. Transmittal date

4. List of submitted studies

Vol 1. Administrative materials - forms, previous correspondence with Project Managers, and so forth.

Vol 2. Title of first study in the submittal (Guideline No.)

.
.
.

Vol n. Title of nth study in the submittal (Guideline No.)

* Applicants commonly provide this information in a transmittal letter. This remains an acceptable practice so long as all four elements are included.

** Indicate which of the joint submitters is empowered to act on behalf of all joint submitters in any matter concerning data compensation or subsequent use or release of the data.

Company Official: _____ _____
Name Signature

Company Name: _____

Company Contact: _____ _____
Name Phone

ATTACHMENT 2.

SAMPLE STUDY TITLE PAGE FOR A NEWLY SUBMITTED STUDY

Study Title

(Chemical name) - Magnitude of Residue on Corn

Data Requirement

Guideline 171-4

Author

John C. Davis

Study Completed On

January 5, 1979

Performing Laboratory

ABC Agricultural Laboratories
940 West Bay Drive
Wilmington, CA 39897

Laboratory Project ID

ABC 47-79

Page 1 of X
(X is the total number of pages in the study)

ATTACHMENT 3.

STATEMENTS OF DATA CONFIDENTIALITY CLAIMS

1. No claim of confidentiality under FIFRA §10(d)(1)(A),(B), or (C)

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C).

Company _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

2. Claim of confidentiality under FIFRA §10(d)(1)(A), (B), or (C).

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

Information claimed confidential on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: _____

Company Agent: _____ Typed Name _____ Date: _____

_____ Title _____ _____ Signature _____

NOTE: Applicants for permanent or temporary tolerances should note that it is OPP policy that no permanent tolerance, temporary tolerance, or request for an emergency exemption incorporating an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Pesticide Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods, for which which confidentiality claims have been made, to the submitter, to obtain the confidentiality waiver before they can be processed.

ATTACHMENT 4.

SUPPLEMENTAL STATEMENT OF DATA CONFIDENTIALITY CLAIMS

For any portion of a submitted study that is not described by FIFRA §10(d)(1)(A), (B), or (C), but for which you claim confidential treatment on another basis, the following information must be included within a Supplemental Statement of Data Confidentiality Claims:

- Identify specifically by page and line number(s) each portion of the study for which you claim confidentiality.
- Cite the reasons why the cited passage qualifies for confidential treatment.
- Indicate the length of time--until a specific date or event, or permanently--for which the information should be treated as confidential.
- Identify the measures taken to guard against undesired disclosure of this information.
- Describe the extent to which the information has been disclosed, and what precautions have been taken in connection with those disclosures.
- Enclose copies of any pertinent determinations of confidentiality made by EPA, other Federal agencies, or courts concerning this information.
- If you assert that disclosure of this information would be likely to result in substantial harmful effects to you, describe those harmful effects and explain why they should be viewed as substantial.
- If you assert that the information is voluntarily submitted, indicate whether you believe disclosure of this information might tend to lessen the availability to EPA of similar information in the future, and if so, how.

ATTACHMENT 5.

EXAMPLES OF SEVERAL CONFIDENTIAL ATTACHMENTS

Example 1 (Confidential word or phrase that has been deleted from the study)

CROSS REFERENCE NUMBER 1 — This cross reference number is used in the study in place of the following words or phrase at the indicated volume and page references.

DELETED WORDS OR PHRASE: Ethylene Glycol

PAGE	LINE	REASON FOR THE DELETION	FIFRA REFERENCE
6	14	Identity of Inert Ingredient	§10(d)(1)(C)
28	25	"	"
100	19	"	"

Example 2 (Confidential paragraph(s) that have been deleted from the study)

CROSS REFERENCE NUMBER 5 — This cross reference number is used in the study in place of the following paragraph(s) at the indicated volume and page references.

DELETED PARAGRAPH(S):

(Reproduce the deleted paragraph(s) here)

PAGE	LINES	REASON FOR THE DELETION	FIFRA REFERENCE
20	8-17	Description of the quality control process	§10(d)(1)(C)

Example 3 (Confidential pages that have been deleted from the study)

CROSS REFERENCE NUMBER 7 — This cross reference number noted on a place-holder page is used in place of the following whole pages at the indicated volume and page references.

DELETED PAGE(S): are attached immediately behind this page.

PAGE(S)	REASON FOR THE DELETION	FIFRA REFERENCE
33-41	Description of product manufacturing process	§10(d)(1)(A)

ATTACHMENT 6.

SAMPLE GOOD LABORATORY PRACTICE STATEMENTS

Example 1.

This study meets the requirements for 40 CFR Part 160

Submitter _____

Sponsor _____

Study Director _____

Example 2.

This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:

1. _____

2. _____

3. _____

Submitter _____

Sponsor _____

Study Director _____

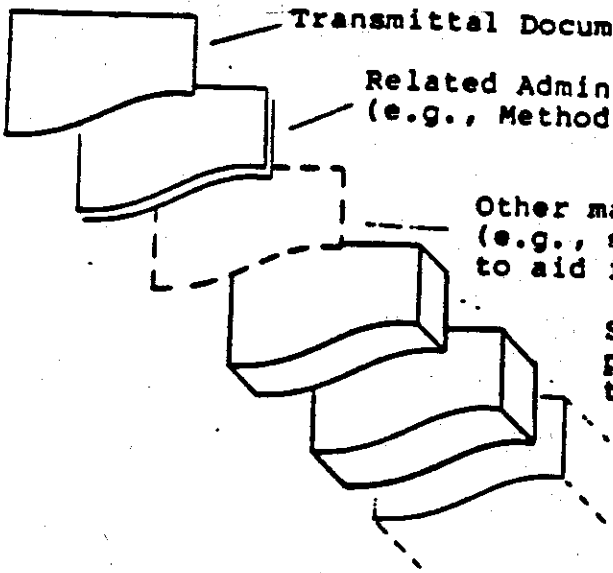
Example 3.

The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160.

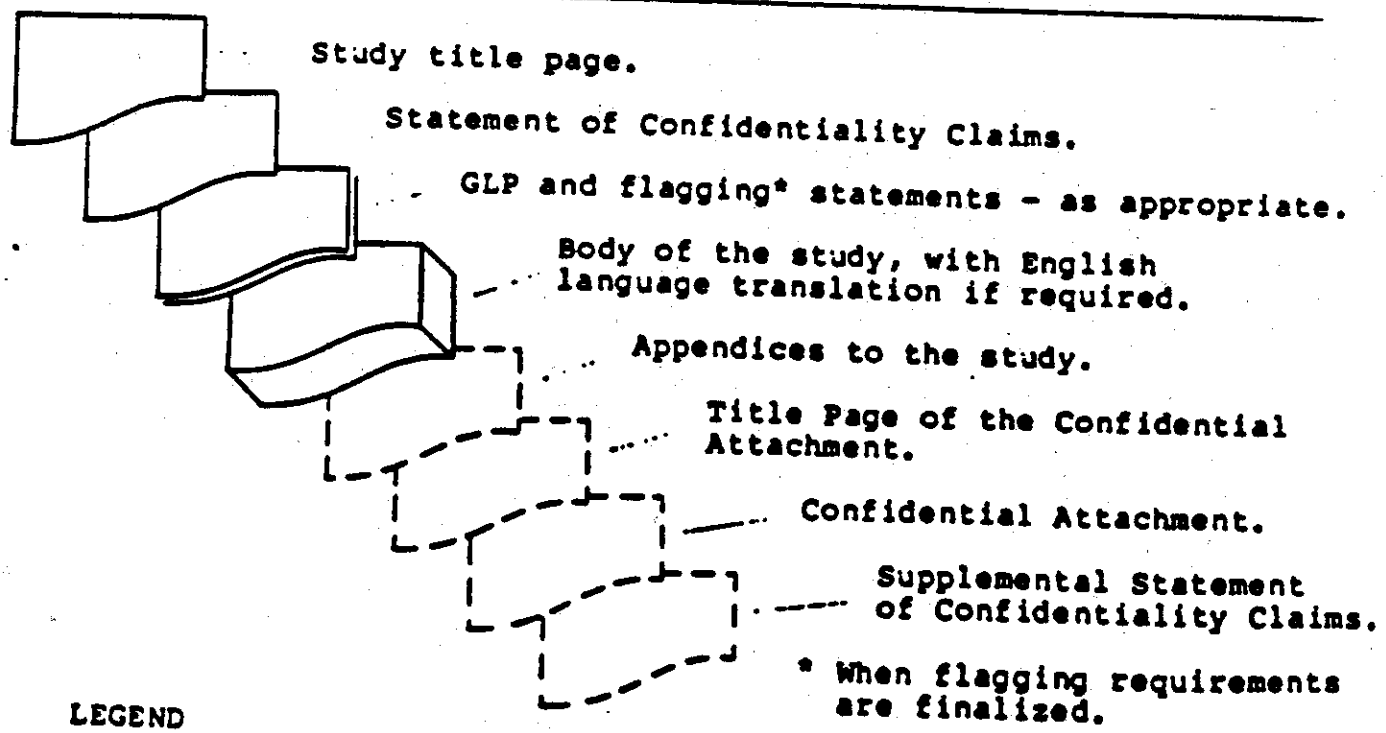
Submitter _____

ATTACHMENT 7.

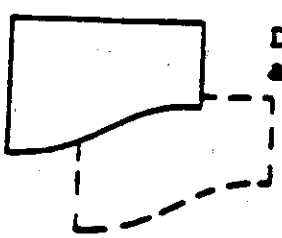
FORMAT OF THE SUBMITTAL PACKAGE



FORMAT OF SUBMITTED STUDIES



LEGEND



ATTACHMENT D

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

EPA'S BATCHING OF CAPSAICIN 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 capsaicin, 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 two batches. Batch 1 contains two products and batch 2 contains five products.

Table I.

Batch Number	EPA REG. NO.	% of Capsaicin & Other Active Ingredients	Formulation Type
1	47319-1	12.0% - Capsaicin 5.0% - Garlic	Dust
	47319-2	12.0% - Capsaicin 5.0% - Garlic	Dust
2	5464-6	0.35% - Capsaicin	Pressurized spray liquid
	7754-37	0.35% - Capsaicin	Pressurized spray liquid
	7754-38	1.0% - Capsaicin	Pressurized spray liquid
	8668-1	1.0% - Capsaicin	Pressurized spray liquid
	61966-1	0.625% - Capsaicin 0.216% - Allyl Isothiocyanate	Pump spray liquid

Table II lists the products which could not be batched. These products 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 II.

EPA REG. NO.	% of Capsaicin & Other Active Ingredients	Formulation Type
72-574	2.5% - Capsaicin	Liquid
47319-4	36.0% - Capsaicin 24.0% - Garlic	Liquid
61966-2	0.625% - Capsaicin 0.216% - Ally Isothiocyanate	Dust

ATTACHMENT E

EPA ACCEPTANCE CRITERIA

151B-10 Product Identity

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Product name and trade name (if different)
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., microbial toxins, 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. ____ Product name, trade name, and common name (if established) for each active ingredient
7. ____ Molecular, structural, and empirical formulas, molecular weight or weight range, and any company assigned experimental or internal code numbers for each active ingredient
8. ____ Description of each beginning material in the manufacturing process
   - ____ EPA Registration Number if registered; for other 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
9. ____ Genus and species (and strain, subspecies, isolate, etc., if applicable) from which the biochemical was isolated or with which it is commonly associated
10. ____ Specificity of biochemical activity, the mode of action, and field rates at which the biochemical is active/proposed (units ai/A, etc.)
11. ____ Similarity to the naturally-occurring biochemical, if not derived from a biological entity.
12. ____ An updated Confidential Statement of Formula must be provided (EPA Form 8570-4 rev. 9/87).
13. ____ Any known or suspected hazards of the biochemical to man, the environment, or nontarget species.

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

151B-11 Manufacturing Process

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ Description of manufacturing process or extraction/isolation steps if obtained from a biological entity.
2. ____ Statement of whether batch or continuous process, if applicable
3. ____ Relative amount of beginning materials and order in which they are added
4. ____ Description of equipment
5. ____ Description of physical conditions (temperature, pH, pressure, humidity) controlled in each step and the parameters that are maintained
6. ____ Statement of whether process involves intended chemical reactions
7. ____ Flow chart with chemical equations for each intended chemical reaction
8. ____ Duration of each step of process
9. ____ Description of purification procedures
10. ____ Description of measures taken to assure quality of final product including identity of the biological source, if applicable
11. ____ A clear presentation of the stage at which inerts are intentionally added, if and when any concentration is effected, the material to be used as the manufacturing use product (MP), whether MP registration is sought, and whether a TGAI/MP is sold and/or shipped.

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

151B-12 Discussion of Formation of Unintended Ingredients

ACCEPTANCE CRITERIA

Does your study meet the following acceptance criteria?

1. ____ 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 present at < 0.1% by weight

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

151B-13 Analysis of Samples

ACCEPTANCE CRITERIA

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 ≥ ca 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 should 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. ____ The test material is to be the purest pesticidal grade commercially produced prior to intentional addition of inerts. Generally, this test material is the same as that used for certain nontarget and human hazard testing and is identical to, or equivalent to the technical grade. Any differences from the test substance used for hazard testing should be noted.

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