US Environmental Protection Agency
Office of Pesticide Programs

BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Diallyl Sulfides (DADs) (PC Code 129087)

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U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
Diallyl Sulfides
(PC Code 129087)

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I. Executive Summary

A. IDENTITY

The Technical Grade Active Ingredient (TGAI) is a yellow liquid with a strong garlic odor. The end-use product, Alli-Up™ , is manufactured by an integrated process. The end-use product formulation consists of a new active ingredient (90% a.i.), diallyl sulfides (DADs), which is a mixture of 8.90% diallyl monosulfide, 86.90% diallyl disulfide, 3.90% diallyl trisulfide, and 0.30% diallyl tetrasulfide. These molecular substances contribute to the distinctive odor of garlic, onions and other *Allium* species.

The product chemistry data submitted by the registrant satisfies the requirements for product identity.

B. USE/USAGE

The end-use product Alli-Up™, is to be used to control white rot (*Sclerotium cepivorum*) in onions, garlic and leeks.

C. RISK ASSESSMENT

No unreasonable adverse effects to humans or the environment are anticipated from aggregate exposure to DADs. This includes all anticipated exposures for which there is reliable information.

1. Human Health Risk Assessment

a. Toxicological Endpoints

The Agency reviewed studies submitted by the registrant to identify toxic endpoints in the following studies: acute oral, acute dermal, eye and skin irritation, dermal sensitization, and mutagenicity (Ames assay). The results of the submitted studies placed DADs into the following Toxicity categories: Tox. II, acute oral; Tox II, acute dermal; Tox. III, eye irritation, Tox. II, dermal irritation. DADs was found to be a dermal sensitizer in guinea pigs, but was negative for mutagenicity. waivers were submitted and accepted by the Agency for the following studies: acute inhalation, mammalian mutagenicity, subchronic oral, dermal and inhalation, teratogenicity (1 species), chronic exposure and oncogenicity. This was based primarily on the low use rates (½ to 1 gallon per acre) and low exposure from the intended use of DADs.

b. Human Exposure

The most likely human exposure to DADs would be to agricultural applicators, and this is expected to be minimal because of the application method, which requires a shanking system to inject the product directly into the soil, combined with the 24 hours' worker reentry interval required by the

label. In addition, the volatility of the active ingredient is high and thus it does not persist in the environment. Thus, risks to humans are mitigated as long as the product is used according to label directions, and appropriate precautionary and first aid statements are heeded.

c. Risk Assessment

The Agency has considered DADs in light of the relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and has not identified any dietary or nondietary exposure issues as they may affect the U.S. population in general, including infants and children, and thereby determined that there is reasonable certainty that no harm will result from aggregate exposure to DADs residues, including all anticipated dietary exposures and all other exposures for which there is reliable information. Further, the Agency has also determined that, when used in accordance with widespread and commonly recognized practices, Alli-Up™ will perform its intended function without unreasonable adverse effects on the environment

2. Ecological Risk Assessment

a. Toxicity Endpoints

No toxic endpoints were identified. The data requirements for nontarget organisms were waived, in part due to the low use rate of the product, the low exposure (see below) due to the application methods and non-persistence of DADs in the environment when used as a pesticide. Moreover, the use of DADs as a pesticide

b. Ecological Exposure

DADs are naturally occurring compounds found in *Allium* crops, including onion and garlic, and are partially responsible for the distinctive odor of garlic which helps repel most nontarget organisms. The environmental exposure to DADs is significantly less than when a field is planted with garlic and onion crops. The application method of using a shanking system to inject the product directly into the soil at a low use rate and the rapid breakdown and volatility of the active ingredient will greatly reduce exposure from the pesticidal use of this product.

c. Risk Assessment

Risks to the environment and non-target organisms is expected to be minimal due to the low use rate of the product, application method resulting in low exposure, the target specificity and non-toxic mode of action for the target pest, and the rapid degradation in the soil and high volatility of DADs, resulting in non-persistence in the environment. Therefore, the Agency has determined that, when used in accordance with widespread and commonly recognized practice, Alli-Up™ will perform its intended function without unreasonable adverse effects on the environment.

D. DATA GAPS / LABELING RESTRICTIONS

There are no data gaps. Labeling restrictions include: “Do not apply to the soil surface.” In addition, precautionary labeling are required to mitigate risks that may be associated with proposed uses (see labeling rationale section of this document for details).

II. Overview

A. ACTIVE INGREDIENT OVERVIEW

Common Name: Diallyl Sulfides
DADs

Chemical Name: Diallyl Monosulfide, Diallyl Disulfide, Diallyl Trisulfide, and Diallyl Tetrasulfide

Chemical Family: Diallyl Sulfides

Trade and Other Names: Alli-Up™

CAS Registry Number:
Diallyl Monosulfide: 592-88-1
Diallyl Disulfide: 2179-59-9
Diallyl Trisulfide: 2050-87-5
Diallyl Tetrasulfide: 2444-49-7

OPP Chemical Code: 129087

Basic Manufacturer: Platte Chemical Co.
P.O. Box 667
Greeley, CO 8o832

B. USE PROFILE

Proposed uses, sites and application methods include:

Type of Pesticide: Biochemical pesticide

Use Sites: Fields intended for growing *Allium* crops (such as onions, garlic and leeks), which has been infected with *Sclerotia cepivorum.*

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Target Pest: White rot (*Sclerotia cepivorum*)

Formulation Type: Liquid

Method and Rates of Application: Alli-Up™ will injected directly into the soil at a rate of ½ to 1 gallon of product per acre using an enclosed shanking system.

Use Practice Limitations: Alli-Up™ has to be injected into the soil to be effective. Do not apply to the soil surface; the product also has a very strong garlic odor.

Timing: Alli-Up™ is recommended for use as a preventative control method, therefore, the timing of application should occur prior to planting. No *Allium* species should be in the field when the product is applied.

C. ESTIMATED USAGE

None used yet since this will be the first registered product.

D. DATA REQUIREMENTS

The data requirements for granting this registration under Section 3(c)(5) of FIFRA have been reviewed by BPPD. The mammalian toxicology and ecological effects data requirements for DADs have been fulfilled. Product analysis data requirements are adequately satisfied.

E. REGULATORY HISTORY

On September 17, 2001, the Agency received an application from Platte Chemical Company to register Alli-Up™ containing 90% of DADs, as a soil fumigant. A notice of receipt of the application for registration of DADs as a new active ingredient was published in the Federal Register on November 1, 2001 (66 FR 55174), with a 30-day comment period. No comments were received as a result of this publication. EPA issued a notice pursuant to section 408(d)(3) of the FFDCA (21 USC 346a(d)(3)), announcing the filing of a pesticide tolerance petition (PP 1F6316) by Platte Chemical Company, requesting an exemption from the requirement of a tolerance for residues of diallyl sulfides (66 FR 58481). No comments were received during the 30-day comment period following the publication of this petition.

F. CLASSIFICATION

On November 3, 1998, the Biochemical Classification Committee determined that DADs are volatile sulfur compounds found naturally in garlic and onions, that induce the germination of the target pest, *Sclerotium cepivorum*. DADs were classified as biochemical pesticides due to their natural occurrence and non-toxic mode of action on the target species.

G. FOOD CLEARANCES/TOLERANCES

An Exemption from the requirement of a tolerance was established for residues of Diallyl Sulfides when used in/on garlic, leeks, onions, and shallots, on July 9, 2003 **(68 FR 40803)**.

III. Science Assessment

A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for registration of the end-use product, Alli-Up™, containing the new pesticide active ingredient, DADs, have been satisfied.

1. Product Identity and Mode of Action

a. Product Identity:

Alli-Up™ is produced by an integrated system which involves the blending of 8.9% diallyl monosulfide, 86.9% diallyl disulfide, 3.90% diallyl trisulfide, and 0.30% diallyl tetrasulfide collectively known as diallyl sulfides (DADs). The total active ingredient comprises 90% of the product by weight. The TGAI is a yellow liquid with a strong garlic odor.

b. Mode of Action:

Under natural conditions, the diallyl sulfides in *Allium* species stimulate the germination of *Sclerotia cepivorum*, which subsequently infects the growing plants. This results in a fungal disease, called white rot, that ultimately causes crops failure. When applied to infected fields, the diallyl sulfides in Alli-Up™ mimic the presence of *Allium* crop, and stimulates the spores to germinate. However, finding no host plants in the field, the fungal pathogen eventually dies.

2. Physical And Chemical Properties Assessment

The data requirements for physical and chemical characteristics that support the registration of Alli-Up™ are summarized in Table 1.

Table 1. Product chemistry data requirements:

GUIDELINE NO.	STUDY	RESULTS	MRID NO.
151B-10 151B-11 151B-12	Product identity; Manufacturing process; Discussion of formulation of unintentional ingredients	The product is a mixture of 8.9% diallyl monosulfide, 86.9% diallyl disulfide, 3.90% diallyl trisulfide, and 0.30% diallyl tetrasulfide collectively known as diallyl sulfides (DADs). The total active ingredient comprises 90% of the product by weight	454229-01 454229-02
~~151B-13~~	Analysis of samples **CBI**	Acceptable data submitted to the Agency	454229-02 and 03

GUIDELINE NO.	STUDY	RESULTS	MRID NO.
~~151B-15~~	Certification of limits **CBI**	Limits listed in the CSF are adequate	454229-02 and 03
151B-17	PHYSICAL / CHEMICAL PROPERTIES OF DADs		
151B-17(a)	Color	Yellow	454229-04, 05, 06
151B-17(b)	Physical State	Liquid	454229-04, 05, 06
151B-17©	Odor	garlic	454229-04, 05, 06
151B-17(d)	Melting point	Not Applicable (liquid)	
151B-17(e)	Boiling point	176 ˚C	454229-04, 05, 06
151B-17(f)	Density/Specific gravity	1.03 at 25 ˚C	454229-04, 05, 06
151B-17(g)	Solubility	Water: 0.006 % at 25 ˚C 2- Propanol: 7.01 at 25 ˚C Acetone: 100% 25 ˚C Isooctane 1.86% 25 ˚C	454229-04, 05, 06
151B-17(h)	Vapor Pressure	9 mm Hg at 20 ˚C 12 mm Hg at 20 ˚C	454229-04, 05, 06
151B-17(I)	pH	6.34 at 22 ˚C	454499-01
151B-17(j)	Stability	Heat will result in a loss of diallyl disulfide and an increase in diallyl monosulfide; presence of ferric chloride will result in a loss of diallyl disulfide and an increase in diallyl mono-, tri-, and tetrasulfide; no change in presence of UV light, aluminum, aluminum nitrate, zinc, zinc nitrate hexahydrate, and iron.	454499-01
151B-17(k)	Flammability	52.7 ± 0.6 ˚C	454499-01

GUIDELINE NO.	STUDY	RESULTS	MRID NO.
151B-17(l)	Storage stability	Not Required	
151B-17(m)	Viscosity	Not Required	
151B-17(n)	Miscibility	Not Required	
151B-17(o)	Corrosion characteristics	Not Required	
151B-17(p)	Octanol/water partition coef.	Not Applicable; not used around electrical equipment	

B. HUMAN HEALTH ASSESSMENT

Mammalian toxicity studies and waivers submitted in support of the registration and the tolerance exemption petition for DADs adequately satisfy the requirements to register a new biochemical pesticide, intended for use on food commodities.

1. Toxicology Assessment

a. Acute Toxicology

1. Acute oral toxicity (OPPTS 870.1100; 152-10; MRID 454229-07). Male and female rats (5 per sex) were dosed with 200, 600, and 1000 mg/kg, and 10 of each sex were dosed with 5000 mg/kg. Treated rats displayed a number of effects including breathing abnormalities, wobbly gait, decreased defecation, decreased activity, and pilo-erection. The abnormalities are attributed to hemolytic anemia in rodents fed diets rich in sulfures derived from onion and garlic. The acute oral LD50 was 346 mg/kg. The study was acceptable and placed the test material in Toxicity Category II for acute oral toxicity.

2. Acute dermal toxicity (OPPTS 870.1200; 152.11; MRID 454229-08). Rats (5/sex/dose) treated with a single acute dose of DADs at male and five female rats were dosed with 1500, 1750, and 2000 mg/kg, observed daily and weighed weekly. The acute dermal LD50 of DADs in male rats was determined to be 1826 mg/kg, in female 2009 mg/kg, and in sexes combined 1967 mg/kg. The study was acceptable and placed the test material in Toxicity Category II for acute dermal toxicity.

3. Primary eye irritation (OPPTS 870.2400; 152-13; MRID 454229-09). Six rabbits were administered DADs in the right eye with the left eye serving as an untreated control. Exposure of the test article produced corneal opacity in 3/6 test eyes at the 1 or 24 hour scoring interval. Conjunctivitis was noted in 6/6 test eyes at the 1 hour testing interval. The conjunctival irritation resolved completely in all animals by study day 14. Under the conditions of the test, DADs are considered a moderate eye irritant, The study was acceptable and placed the test material in Toxicity Category III for eye irritation.

4. Primary dermal irritation (OPPTS 870.2500: 152-14; MRID 454229-10). Rabbits were administered on shaved, unabraded skin for 24 hours. Severe skin reactions, with evident erythema grade 2 and 1 at 1 hour post-exposure, were observed. The study was acceptable and placed the test material in Toxicity Category II for dermal irritation.

5. Dermal sensitization (OPPTS 870.2600; 152-15; MRID 454229-11). A dermal sensitization potential test for DADs was evaluated in guinea pigs, using the Buehler method. The test material was found to cause contact dermal sensitization in guinea pigs. The study was acceptable.

6. Acute Inhalation Toxicity (OPPTS 870.1300; 152-12): The registrant submitted a data waiver for this requirement, based on low exposure (due to application via closed shanking system, low use rate). The waiver was accepted by the Agency.

b. Mutagenicity and Developmental Toxicity

1. Bacterial reverse mutation assay (OPPTS 870.5195; MRID 454229-12).

A Salmonella reverse mutation assay (Ames Test) was done using DADs. The assay evaluated the test article for its ability to induce reverse mutations at the histidine locus in the genome of specific *Salmonella typhimurium* tester strains in the presence and absence of a metabolic activation system of mammalian microsomal enzymes derived from ArocolrTM-induced rat liver. The results of the assay indicate that under the conditions of the study, DADs did not cause a positive increase in the number of histidine revertants per plate of any of the tester strains either in the presence or absence of the microsomal enzymes prepared from the ArocolrTM-induced rat liver. As a result, diallyl disulfide, the main component of DADs, is not considered mutagenic. The study was acceptable.

2. Data waivers were requested by Platte Chemical Company, and granted for the following studies: Mammalian mutagenicity tests(OPPTS 870.5300), and Teratogenicity (1 species) (OPPTS 870.3700), based upon low exposure due to the agricultural application method (closed shanking system) and low use rate. The waiver was accepted by the Agency.

c. Subchronic Toxicity, Immunotoxicity

Data waivers were submitted for the following studies, based upon low exposure due to the agricultural application method (closed shanking system) and low use rate. The waivers were accepted by the Agency.

90-Day feeding (1 species) (OPPTS 870.3100).
90-Day dermal (1 species) (OPPTS 870.3250).
90-Day inhalation (1 species) (OPPTS 870.3465).
Immunotoxicity (OPPTS 870.7600)

Given the application method and low use rate of Alli-Up™, very low levels of human exposure are expected to DADs from its use as a biochemical pesticide. Further, DADs are naturally present in garlic and other *Allium* crops, and in fields planted with these crops, and there is a long history and prevalence of *Allium* food crops in human diets. No toxic induced dysfunction or inappropriate suppressive or stimulatory responses in components of the immune system of humans or test animals have been reported, nor any developmental effects. No adverse toxicological effects are anticipated due to the low exposure to DADs from this use. As a result, the Agency considered waivers of the above studies, and determined that for the present registration action, these studies could be waived.

References for acute toxicity end-points for DADs are summarized in Table 2 below.

Table 2. Acute Mammalian Toxicity: Tier I **DADs**

OPPTS Guideline Number	*OPPTS Guideline Name*	*Results*
870.1100	*Acute Oral Toxicity - Rat*	*Tox. Cat. II*
870.1200	*Acute Dermal Toxicity - Rabbit*	*Tox. Cat. II*
870.1300	*Acute Inhalation Toxicity - Rat*	*Waived; not likely to be a major route of exposure.*
870.2400	*Primary Eye Irritation - Rabbit*	*Tox. Cat. III*
870.2500	*Primary Dermal Irritation - Rabbit*	*Tox. Cat. II*
870.2600	*Dermal Sensitization - Guinea Pig*	*Contact dermal sensitizer in guinea pigs*
870.3100, 3250, 3465	*90-Day Oral, Dermal, and Inhalation*	*Waived, low exposure*
870.3700	*Developmental Toxicity (1 species)*	*Waived, low exposure*

870.5100	*Genotoxicity*	*Not genotoxic (Ames Assay); mammalian cell assay waived due to low exposures from the registered use.*
870.5300	*Mammalian cell gene mutation*	*Waived; low exposure, negative Ames study*
870.7600	*Immunotoxicity*	*Waived; low exposure*

d. Chronic Exposure and Oncogenicity Assessment

Data waivers were submitted for the following studies, based upon low exposure due to the agricultural application method (closed shanking system) and low use rate. The waivers were accepted by the Agency.

90-Day feeding (1 species) (OPPTS 870.3100).
90-Day dermal (1 species) (OPPTS 870.3250).
90-Day inhalation (1 species) (OPPTS 870.3465).
Immunotoxicity (OPPTS 870.7600)

The Agency has granted waivers for subchronic and chronic repeated dose studies and oncogenicity. Repeated dose studies are conditionally required if the potential for adverse, chronic effects are indicated based on 1) the subchronic effect levels established in Tier I subchronic oral, inhalation, or dermal studies, 2) the pesticide use pattern, or 3) the frequency and the level of repeated human exposure that is expected. Oncogenicity studies are required only if the active ingredient or any of its metabolites, degradation products, or impurities produce in Tier I studies any morphologic effects in any organ that potentially could lead to neoplastic changes. None of the results of the submitted studies triggered the need for chronic exposure and oncogenicity tests.

e. Effects on the Endocrine Systems

Based on available data, no endocrine system-related effects have been identified with consumption of DADs. In addition, DADs does not share any structural similarity to any known endocrine disruptive chemical.

2. Dose Response Assessment

No toxicological endpoints were identified; therefore, a dose-response assessment was not required.

3. Dietary Exposure and Risk Characterization

The primary source for human exposure to DADs would occur through the consumption of garlic, onions, leeks, and other *Allium* crops. The Agency does not believe that the use of Alli-Up on fallow fields will result in levels of DADs that exceed the normal levels found in foods that are commonly consumed in the human diet. There have been no reports of adverse reactions in humans from the consumption of *Allium* crops and derived products.

4. Occupational, Residential, School and Day Care Exposure and Risk Characterization

Significant human exposure to Alli-Up™ is expected to be minimal to non-existent in residential, school and day care areas, due to its agricultural use.

a. Occupational Exposure

The possibility for occupational exposure to Alli-Up™ is mitigated as long as the product is used according to label directions, which requires the use of protective equipment and restricted entry interval into fumigated areas

b. Residential, School and Day Care Exposure and Risk Characterization

No indoor residential, school, or day care uses currently appear on proposed labels. Human exposure to Alli-Up™ should not occur in these areas.

5. Drinking Water Exposure and Risk Characterization

Since Alli-Up® will be used as a soil fumigant, and degrades in the soil or dissipates into the atmosphere at very low rates, there is little if any, potential for drinking water exposure from pesticide drift in the surface water. Therefore, the level of residues that might get into the ground or surface water would most likely be negligible.

6. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, and the use pattern of Alli-Up™ as a soil fumigant in agricultural settings, EPA has concluded there is reasonable certainty that no harm to infants and children, or adult will result from the use of Alli-Up™. Thus there are no threshold effects of concern and, as a result the provision requiring an additional margin of safety does not apply. Further, the provisions of consumption patterns, special susceptibility, and cumulative effects do not apply.

7. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

There is reasonable certainty that no harm will result from aggregate exposure to residues of Diallyl Sulfides to the U.S. population. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the low levels of toxicity, the long history of safe consumption of onions and garlic which naturally contain Diallyl Sulfides, and the lack of exposure. Levels of exposure resulting from use of Diallyl Sulfides would be significantly lower than those found in the U.S. population's consumption of onion and garlic foods (raw, cooked and processed). Moreover, the Agency concludes that Diallyl Sulfides is non-toxic to humans, including infants and children. Thus, there is no threshold effects of concern and, as a result the provision requiring an additional margin of safety does not apply. Further, the provisions of consumption patterns, special susceptibility, and cumulative effects do not apply. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of Diallyl Sulfides.

8. Cumulative Effects

EPA does not have, at this time, available data to determine whether DADs have a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, DADs do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that DADs have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

9. Risk Characterization

The Agency has considered human exposure to DADs in light of the relevant safety factors in FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U. S. population in general, and to infants and children in particular, will result from the use of human exposure to Alli-Up™ when label instructions are followed.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment

The applicant has requested waivers for avian oral toxicity, avian dietary toxicity, fish toxicity, aquatic invertebrate toxicity, nontarget plant toxicity, nontarget insect toxicity and honeybee toxicity data requirements. The Agency has granted waivers of these data requirements due to the lack of exposure of non-target organisms, and rapid microbial degradation in the soil. Moreover, DADs are naturally occurring compounds found in *Allium* crops, so these non-target species would likely be exposed to these active ingredient, at a higher level than by the labeled use of Alli-Up™.

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data (Tier II, (40 CFR Section 158.690(d)(2)(vii through xv)) was not triggered because of practically non-toxic results indicated in Tier I studies. Risk to nontarget species is minimal due to the lack of toxicity, use pattern, and application methods.

3. Ecological Exposure and Risk Characterization

A potential for exposure to nontarget wildlife is minimal because of the application method (soil fumigation), and the rapid dissipation or breakdown of DADs in the soil. The environmental risk may be characterized as minimal when the product is used in accordance with the label directions that mitigate risks by decreasing exposure due to the application of Alli-Up™ by soil fumigation.

D. EFFICACY DATA

No efficacy data were requested to be submitted to the Agency, since the product does not claim public health uses. Registrants are required to have product performance data available, in the event the performance of the product comes into question and the Agency must review the data.

IV. Risk Management Decision

A. DETERMINATION OF ELIGIBILITY FOR REGISTRATION

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment; and (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

To satisfy criteria "A" above, DADs *is not expected to cause unreasonable adverse effects when used according to label instructions. Criteria "B" is satisfied by the current label and by the data presented in this document. It is believed that DADs will not cause any unreasonable adverse effects, is an effective biochemical fungicide for plant diseases, and does provide protection as claimed to satisfy criteria "C." Criteria "D" is satisfied in that the toxicological properties of this active ingredient are less toxic than other products currently in use, and the exposure to the active ingredient* resulting from use of Alli-Up™ would be significantly lower than those found in the U.S. population's consumption of onion and garlic foods (raw, cooked and processed). *Therefore,* DADs *is eligible for registration.*

B. REGULATORY POSITION

1. Unconditional Registration

Based on eligible data submitted, the Agency concludes that DADs is eligible for unconditional registration under Section 3(c)(5) of FIFRA. The Agency foresees no adverse effects to human health or the environment from the use of this active ingredient in accordance with the label directions for use.

2. CODEX Harmonization

No Codex maximum residue levels are established for residues of DADs in or on any food or feed crop. An Exemption from the requirement of a tolerance is established for residues of Diallyl Sulfides when used in/on onions, garlic, shallots and leeks **(68 FR 40803; July 09, 2003).**

3. Nonfood Registrations

There are no nonfood uses for DADs.

4. Risk Mitigation

There are no significant risk issue, and as such mitigation measures for dietary risk, occupational and residential risk or ground and surface water contamination are not required. Risk to nontarget organisms will be mitigated by appropriate label precautions.

5. Endangered Species Statement

Currently, the Agency is developing a program (The Endangered Species Protection Program) to identify all pesticides whose use may cause potential adverse impacts on endangered and threatened species and their habitats. To aid in the identification of threatened and endangered species and their habitats, several companies have formed an Endangered Species Task Force (EST) under the direction of the American Crop Protection Association (ACPA). Moreover, the EST will assist in providing species location information at the subcounty level, and particularly if an endangered species occurs in areas where pesticides would be used. This information will be useful once the Endangered Species Protection Program has been implemented.

The Agency has no evidence to believe that any endangered or threatened species will be adversely affected by products containing DADs, when used as labeled. In this regard, label language specific for endangered or threatened species is not imposed at this time for these products.

C. LABELING RATIONALE

It is the Agency's position that the labeling for Alli-Up™ complies with the current pesticide labeling requirements.

1. Human Health Hazard

a. Worker Protection Standard

Any product whose labeling reasonably permits its use in an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions required by the Worker Protection Standard (WPS)," and PR Notice 93-11 "Supplemental Guidance for PR Notice 93-7," which reflect the requirements of EPA's labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in PR Notices 93-7 and 93-11. Unless otherwise specifically directed, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those Notices. After October 23, 1995, except as provided in PR Notices 93-7 and 93-11, all products within the scope of those notices must bear WPS PR Notice complying labeling when they are distributed or sold by any person. The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR 156.10 and other applicable notices. Labeling must also conform to Worker Protection Safety standards concerning re-entry into sprayed fields.

End-use products containing DADs must comply with WPS, and as such have the appropriate language as required by the standard.

b. Non-Worker Protection Standard

There are no non-WPS human health hazard issues.

c. Precautionary Labeling

The Agency has examined the toxicological database for DADs and concluded that the proposed precautionary labeling (i.e. Signal Word, First Aid Statement and other label statements) adequately mitigates the risks associated with the proposed uses. Precautionary labeling for end-use products containing this active ingredient are:

> *"WARNING. Harmful if swallowed. Causes skin irritation and moderate eye irritation. Do not get on skin or clothing. Avoid contact with eyes and avoid breathing vapor. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash thoroughly with soap and water after handling."*

d. Spray Drift Advisory

An advisory statement is contained in the DIRECTIONS FOR USE statement: "Do not apply this product in a way that will contact workers or other persons, either directly or through drift."

2. Environmental Hazards Labeling

The precautionary labeling for end-use products containing DADs is:

> *"Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters. Do not contaminate irrigation ditches or water used for irrigation or domestic purposes. Do not apply when conditions favor drift from treated areas."*

3. Application Rate

Alli-Up™ *will be used as a soil fumigant at a rate of one half (□) to* one *gallon* per acre using an enclosed shanking system.

D. LABELING

(1) Product name: **Alli-Up™ White Rot Control Soil Fumigant**

Active Ingredient:
Diallyl Sulfides..... . . . . 90 %
Other Ingredients 10%

Total 100.00%

Signal word is "WARNING". Eye irritation warning is appropriate.

The product shall contain the following information:

- Product Name
- Ingredient Statement
- Registration Number
- "Keep Out of Reach of Children"
- Signal Word (WARNING)

V. Actions Required by Registrants

Reports of incidences of adverse effects to humans or domestic animals under FIFRA, Section 6(a)2 and incidents of hypersensitivity under 40 CFR Part 158.690(c), guideline reference number 152-16. There are no data requirements, label changes and other responses necessary for the reregistration of the end-use product since the product is being registered after November 1984 and is, therefore, not subject to reregistration. There are also no existing stocks provisions at this time.

VI. Appendix A

Table 4 lists the use sites for the product. The label for the product is also attached.

Table 4. Use Sites

Alli-Up™ White Rot Control Soil Fumigant	*Official date registered:*
Food use sites *Onions, Garlic and leeks*	*June 20, 2003*