

Margery M. Exton
Consultant
Pesticide Regulatory Affairs

April 3, 2001

National Organic Standards Board
c/o Robert Pooler
Agricultural Marketing Specialist
USDA/AMS/TM/NOP
Room 2510-So.
Ag. Stop 0268
P.O. Box 96456
Washington, D.C. 20090-6456

Re: D-I-1-4, Inc. Petition to Add 1,4-Dimethylnaphthalene to National List of Substances Allowed in Organic Production and Handling

Dear Mr. Pooler:

On behalf of D-I-1-4 Inc., I am submitting a petition to add 1,4-Dimethylnaphthalene (1,4-DMN) to the National List of Substances Allowed in Organic Production and Handling. D-I-1-4 Inc. requests that 1,4-DMN be added to the synthetic substance list for use as a plant growth regulator. Products containing 1,4-DMN are being used on post-harvest potatoes to enhance dormancy and suppress sprouting. As potatoes are a major crop in the United States, 1,4-DMN use has the potential to affect a large number of organic growers.

As reflected in the attached petition, D-I-1-4's product, while synthesized, is chemically identical to 1,4-DMN naturally found in potatoes. As 1,4-DMN is efficacious at relatively low concentrations, it is correspondingly found in individual plants and tubers in small amounts. Thus, extraction of naturally occurring 1,4-DMN is not feasible in producing commercial quantities. The method of synthesizing 1,4-DMN is utilized solely to produce sufficient amounts of 1,4-DMN for commercialization; the molecule is unchanged from the naturally occurring molecule.

In support of this request, I am attaching the following documents:

- ▶ Justification for CBI claims;
- ▶ Petition, addressing the seven NOP evaluation criteria;
- ▶ Substance common name, CAS #, Manufacturer, Intended Use, & Crop;
- ▶ Description of Manufacturing Process;
- ▶ U.S. EPA Toxicity and Chemistry Reviews;
- ▶ Product Registrations and Sample Labels;
- ▶ EPA Decision Memo and Tolerance Exemption;
- ▶ Literature Review; and
- ▶ Petition Justification Statement.

Mr. Robert Pooler
D-I-1-4, Inc. Organic Petition
Substance: 1,4-Dimethylnaphthalene
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Please feel free to contact me on (703) 221-6639 if you have questions about the enclosed materials or need more information to perform your review. Thank you for your consideration of this request.

Sincerely,


Margery M. Exton
Pesticide Regulatory Consultant

enclosures

D-I-1-4 Inc. Organic Petition
Substance: 1,4-DMN
Attachment to cover letter

Justification for CBI Claims

D-I-1-4 Inc. claims two pieces of information within this petition as confidential business information. Both the identity (including address) of the manufacturer of 1,4-DMN, along with the actual description of the 1,4-DMN manufacturing process are considered confidential business information. The identity of the manufacturer is listed on page 5 of the petition, and the manufacturing process is described on page 6.

The identity of the manufacturer is commercial information of value to potential competitors in this market. Identification of a manufacturer who can or already has developed sophisticated synthesis techniques and is capable of producing high quality material takes an investing of time and resources. Knowledge of our existing source would enable competitors to more readily enter the market by gaining proprietary information.

The manufacturing process itself is also of great commercial value, in that potential competitors could enter the market by copying our exact production steps. Development of these techniques was resource intensive, and the knowledge of how to synthesize 1,4-DMN in a laboratory or manufacturing setting is considered confidential and proprietary.

Both pieces of information have been identified as "CBI" and a "CBI-Deleted Copy" has been included.

Petition for Listing 1,4-Dimethylnaphthalene on the National List of Allowed and Prohibited Substances

Introduction

The Organic Foods Production Act of 1990, as amended, requires that the Secretary of Agriculture establish a list of substances that may be used in organic production and handling operations. D-I-1-4, Inc. is petitioning the Secretary to list 1,4-dimethylnaphthalene (1,4-DMN) on the National List of Allowed Substances for use as a plant growth regulator. 1,4-DMN is a naturally occurring biochemical that is found in potatoes and in other vegetables. About fifty years ago scientists showed that potatoes produce this biochemical, which is involved in inhibiting sprouting during the plant's natural dormant stage.

1,4-DMN was first isolated via extraction from potatoes over forty years ago. Its biochemical action produced sprout suppressant activity at a level warranting development as a commercial sprout inhibitor. Today, products containing 1,4-DMN are used to enhance the dormancy stage of potatoes, thereby delaying sprouting. These products allow potatoes that might otherwise sprout and rot, to be held in storage and to delay sprouting during transportation of the potato crop. 1,4-DMN is the only alternative in the United States to a conventional (chlorinated) chemical, chlorpropham, which is also used to inhibit sprouting.

While 1,4-DMN naturally occurs in vegetables, the cost involved in extraction methods make it unfeasible to rely upon extraction to produce commercial quantities. As 1,4-DMN is efficacious at relatively low levels, it is correspondingly available in only small amounts in individual plants and tubers. Therefore, methods have been developed to produce 1,4-DMN in laboratory and manufacturing settings in sufficient quantities for commercialization. The synthesized 1,4-DMN is chemically identical to the compound as it naturally occurs. We believe 1,4-DMN meets all of the requirements for substances approved for use by the organic food industry, and appreciate your consideration of this petition.

Critical Supporting Information

Substance Category: Synthetic Substance Allowed for Use in Organic Crop Production

1,4-DMN is a biochemical that occurs naturally in potatoes and other crops. Natural substances can be used in organic farming without being included on the National List. Therefore, 1,4-DMN extracted from plants can be used by organic growers without need for a petition or listing. At this time, however, no one in the United States is extracting 1,4-DMN for sale for this use.

The synthetic method produces 1,4-DMN chemically identical to the isomer as found in nature, but in larger quantities. The substantially lower cost of producing synthesized material enables it to be highly competitive and attractive to growers for use as a potato sprout suppressant.

Use of the Substance: Plant Growth Regulator

At present, the grower of organic potatoes has no longer-term means for controlling sprouting during potato storage. A full 90% of the potatoes produced in the United States are harvested in the fall, with the remaining 10% of varieties reaching maturity during the winter, spring, or summer. Nearly half of all potatoes in the U.S. are placed in storage facilities, so that the potato crop can be released throughout the year to the fresh market and processed food industries. The time periods involved in storage range from several months to a year. Commercial sprout inhibitors enable this storage period by delaying sprouting and enhancing dormancy. Approximately 60% of all U.S. potatoes are aided by commercial sprout inhibitors either during storage, packaging, or in transportation.

The organic grower is limited to varieties with a few months natural dormancy period. The organic grower has no alternative to 1,4-DMN for maintaining potato dormancy for up to a year. Lowering the temperature of the storage facility (refrigeration) provides only an inefficient short-term means of control, and ultimately causes the potato to sweeten. Thus, to offer quality potatoes throughout the year they must continually harvest, which necessarily limits their market. Not having a consistent source of organic crop makes it harder for organic growers to enter the processed food markets. Using 1,4-DMN would enable organic potato growers to offer quality potatoes throughout the year and thus substantially increase their share of the potato market.

Correspondence with National Organic Standards Board Criteria

A recent Federal Register Notice identified the criteria that must be met for a substance to be listed on the National List of Approved Substances. D-I-1-4, Inc. has carefully examined the seven criteria and believes 1,4-DMN fits all of the criteria, as described below.

1. The potential of such substances for detrimental chemical interactions with other materials used in organic farming systems.

1,4-DMN is a colorless liquid. It has low chemical reactivity. 1,4-DMN is not used to treat growing crops in the field. Rather, it is applied to potatoes after they have been harvested and placed in a storage facility, to prevent sprouting. No other "chemicals" are used in the storage facility at about the time 1,4-DMN is applied so there would be no opportunity for a chemical interaction.

2. The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment.

1,4-DMN has relatively low mammalian toxicity. The acute oral LD₅₀ in rats is 2730 mg/kg and the dermal LD₅₀ in rabbits is greater than 2000 mg/kg. A guinea pig hypersensitization test showed that accidental human exposure to 1,4-DMN will not result in a sensitization (allergic) reaction. The biochemical was evaluated in three mutagenicity tests and was found to have no mutagenic or genotoxic activity. The inability of 1,4-DMN to enter the cell and interact with intracellular DNA further demonstrates the low chemical reactivity of

the substance. The lack of genotoxic activity indicates that 1,4-DMN is not a genotoxic carcinogen. Organizations such as the International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), the American College of Governmental

Industrial Hygienists (ACGIH), and the Occupational Safety and Health Administration (OSHA) publish lists of substances thought to be carcinogens. None of these lists contain 1,4-DMN and therefore none of the listing agencies believe that 1,4-DMN is a potential carcinogen. The chemical structure of 1,4-DMN is not similar to known reproductive toxins or teratogens.

The natural presence of 1,4-DMN in potatoes and the elevated concentration of 1,4-DMN during dormancy suggests that the substance functions as a growth regulator (sprout suppressant) within the potato. In fact, the available evidence indicates that 1,4-DMN suppresses the bud ("eye") from sprouting by directly repressing bud growth. In contrast, the chemical sprout inhibitor chlorpropham has a toxic mode of action. Chlorpropham does not block sprout growth. Rather, it selectively poisons the new sprout, turning it black.

Since 1,4-DMN is a natural substance, it can be found in the environment in small amounts, primarily as a result of decomposition of plants in which it occurs and the disposal of certain petroleum products. The use of 1,4-DMN for sprout suppression will not add a significant amount of the substance to the environment since it is applied inside a potato storage building. Various isomers of dimethylnaphthalene, including the 1,4-isomer, are found in petroleum and in various petroleum products. Most natural components of petroleum degrade in the environment with little persistence.

3. The probability of environmental contamination during manufacture, use, misuse, or disposal of such substance.

Initially 1,4-DMN was obtained from natural sources. When its commercial application became apparent, a synthetic process was developed to manufacture large quantities of the substance. The specific manufacturing process is patented and considered proprietary, thus 1,4-DMN is available from only one source. The manufacturer uses a closed process which minimizes any opportunity for release into the environment. As previously mentioned, the substance is applied to stored potatoes that are housed in a storage building. Since it is not used outdoors, there is very little opportunity for environmental contamination. Because 1,4-DMN has a biochemical mode of action, relatively small amounts of the substance are applied to the stored potatoes, minimizing the potential for misuse or contamination.

4. The effect of the substance on human health.

1,4-DMN has been used in the treatment of stored potatoes for several years without incident. D-I-1-4, Inc. is not aware of any adverse human health effects resulting from the manufacture, use, or disposal of the substance. The available animal toxicity test results and the presence of small amounts of naturally occurring 1,4-DMN in potatoes and in other vegetables support a conclusion that exposure to the substance during its application to organically grown potatoes or when ingested as a very small residue on the treated potatoes will have no adverse effect on human health.

5. The effects of the substance on biological and chemical interactions in the agroecosystem, including the substance's physiological effects on soil organisms (including the salt index and solubility of the soil), crops and livestock.

The use of 1,4-DMN by organic potato growers will have no impact on the agroecosystem because the substance is not used outdoors on crops, as are insecticides and herbicides. It is not applied to either living plants or to the soil so there would be no adverse physiological effects on soil organisms or on crops. Livestock are occasionally fed potatoes or potato process waste. The presence of a very low 1,4-DMN residue on potatoes or in potato process waste would not adversely effect the livestock.

6. The alternatives to using the substance in terms of practices and other materials.

At present, there is no sprout suppressant substance available to the organic potato grower. The organic grower must now store his potatoes at low temperature which makes the potatoes sweeten and thus far less desirable. These stored potatoes cannot be used for processing into potato chips or French fries because the excess sugars that were formed at the cold storage temperature cause the potato pulp to turn dark during processing. When removed from storage, organic potatoes very rapidly sprout on the grocer's shelf, resulting in a minimal shelf life. Organic growers are generally confined to relying on a few varieties which allow several months of storage, and then use physical means to detach sprouts when potatoes are removed from storage.

In contrast, potatoes treated with 1,4-DMN can be stored for up to one year with no change in quality. In the potato industry, processing plants prefer potatoes that have been suppressed with 1,4-DMN rather than with chlorpropham. The only other sprout suppressant available to the organic grower is chlorpropham, a chlorinated synthetic chemical which cannot be used by organic potato growers. If 1,4-DMN is made available to organic potato growers, they will be able to successfully compete with the general potato grower and will be able to offer high quality organically grown potatoes throughout the year.

7. It's compatibility with a system of sustainable agriculture.

Since 1,4-DMN is not used along with insecticides, herbicides, and other agrochemical products on growing crops prior to harvest, this criteria is not applicable.

D-I-1-4 is petitioning the Secretary of Agriculture to add 1,4-DMN to the National List and thus allow organic potato growers the opportunity to use 1,4-DMN to safely suppress sprouting of their stored potatoes. Since the organically grown potatoes will already contain small amounts of naturally formed 1,4-DMN, the use of this biochemical post-harvest to suppress sprouting would not result in a risk to human health or to the environment. D-I-1-4 thus requests favorable approval of this petition.

1. **Substance Common Name:** 1,4-Dimethylnaphthalene
2. **CAS Number:** 571-58-4
3. **Manufacturer:** [CBI-Deleted]
4. **Intended Use:** 1,4-DMN is used as a plant growth regulator, enhancing the dormancy of post-harvest potatoes and inhibiting sprouting. Products for this use containing 1,4-DMN are registered under FIFRA.
5. **Crops on which Substance will be Used:** Potatoes, post-harvest use only. 1,4-DMN will be used during storage and/or transportation. The rate and application methods are described on sample product labels in attachment 5.

D-I-1-4 Inc. Organic Petition
Substance: 1,4-DMN
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Manufacturing Process

[CBI-Deleted – *remaining text on entire page.*]



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

NOV 4 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

D-1-1-4, Inc.
c/o E.R. Butts International, Inc.
26 Sherman Court
P.O. Box 764
Fairfield, CT 06430

Gentlemen:

Subject: Application for Registration
1,4SIGHT
EPA File Symbol 67727-R
Pesticide Petition 4F4314
Your Submissions Dated December 21, 1993

Science Analysis Branch has completed review of the subject submission.

The toxicity profile based on 1,4SIGHT is as follows:

| | |
|---------------------------|--------------------------------------|
| Acute oral toxicity | III |
| Acute dermal toxicity → | IV - <i>III, per 3/18/94 letter.</i> |
| Acute inhalation toxicity | IV |
| Primary eye irritation | II |
| Primary skin irritation | IV |
| Dermal sensitization | negative |

Based on these studies, the precautionary labeling for the subject products should be revised as follows.

Submit five (5) draft labels with the following corrections:

1. The signal word is WARNING based on the primary eye irritation study. Change the signal word from CAUTION to WARNING everywhere it appears on the label.

2. The precautionary statements must state:

Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles, face shield or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove and wash contaminated clothing before reuse.



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3. The statements of practical treatment must read:

If in eyes: Call a physician. Hold eyelids open and flush with a steady gentle stream of water for 15 minutes.

If swallowed: Drink promptly a large quantity of milk, egg white, gelatin solution, or, if these are not available, large quantities of water. Avoid alcohol.

Refer to the Proposed Label Regulations published in the FEDERAL REGISTER on September 26, 1994 on page 37960.

4. We note that the Pesticide Disposal statements state that this pesticide is toxic. This language is not appropriate for this active ingredient. Use the following text from PR Notice 83-3:

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

For your assistance enclosed is a copy of the scientific review. This completes our review of the subject submissions. We await submission of the product chemistry data required by our October 20, 1994 letter and the revised labeling.

Sincerely yours,



Cynthia Giles-Parker
Product Manager (22)
Fungicide-Herbicide Branch
Registration Division (7505C)

Enclosure



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

MEMORANDUM

OCT 26 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: SAB Review of Toxicology Data Submitted by D-I-1-4, Inc.
(DP Barcode No.: D204774; Submission No.: S468617; ID
No.: 067727-R 1,4 Sight; Chemical ID No.: 055802).

TO: Leonard Cole/Cynthia Giles-Parker
Registration Division (H7505C)

FROM: Cindy Schaffer, Microbiologist *C. Schaffer*
Biological Pesticides Section
Science Analysis Branch
Health Effects Division (H7509C)

THROUGH: Roy Sjoblad, Ph.D, Section Head *Roy Sjoblad*
Biological Pesticides Section
Science Analysis Branch
Health Effects Division (H7509C)

DATA REVIEW RECORD

Product Name: 1,4 Sight
Trade Name: 1,4-Dimethylnapthalene
ID No: 067727-R
Chemical No.: 055802
MRID No.'s: 430825-10 Acute Oral Toxicity - Rat
430825-11 Acute Dermal Toxicity - Rabbit
430825-12 Acute Inhalation Toxicity - Rat
430825-13 Primary Eye Irritation - Rabbits
430825-14 Acute Dermal Irritation - Rabbits
430825-15 Dermal Sensitization - Guinea pig
430825-16 Mutagenicity - Ames Test
430825-17 Genotoxicity
430825-18 Mutagenicity - Mouse Micronucleus Assay

ACTION REQUESTED: SAB has been asked to review the toxicology data in support of the registration of 1,4 Sight, a potato sprout inhibitor. SAB has also been asked to review and comment on waiver requests for the 90-day feeding, immune response and teratogenicity studies.



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CONCLUSION: SAB finds the toxicity data acceptable to support the registration of 1,4 Slight. SAB also found the waiver requests for the 90-day feeding, immune response and teratogenicity studies acceptable based on the lack of significant toxicity demonstrated in the studies submitted, insignificant exposure for the proposed uses (see 10/7/94 memorandum from G. Jeffrey Herndon to Cynthia Giles-Parker/James Stone), and natural occurrence in food.

SUMMARY OF DATA SUBMITTED:

Acute Oral Toxicity:

The median oral LD₅₀ of 1,4-DMN was determined to be 2730 mg/kg of rat body weight.

CLASSIFICATION: ACCEPTABLE-TOX CATEGORY III

Acute Dermal Toxicity (Limit test):

1,4-DMN exhibited a dermal LD₅₀ of greater than 2 g/kg rabbit body weight.

CLASSIFICATION: ACCEPTABLE-TOX CATEGORY IV

Acute Inhalation Toxicity:

Rats exposed to a respirable dose of 1,4-DMN displayed an LC₅₀ greater than 4.16 mg/L.

CLASSIFICATION: ACCEPTABLE-TOX CATEGORY IV

Primary Eye Irritation:

1,4-DMN produced moderate ocular irritation in all rabbits at 24 hours post dose administration. Irritation dissipated by day 21.

CLASSIFICATION: ACCEPTABLE-TOX CATEGORY II

Acute Dermal Irritation:

1,4-DMN produced a moderate irritation when a single 0.5 ml dose was administered dermally. Dermal irritation dissipated by day 14.

CLASSIFICATION: ACCEPTABLE-TOX CATEGORY IV

Skin Sensitization:

Dermal sensitization was not apparent when 1,4-DMN was applied to guinea pigs when using the modified Bueller method.

CLASSIFICATION: ACCEPTABLE

Mutagenicity Assay (AMES):

Ninety-six point four percent pure 1,4-DMN, in the presence or absence of metabolic activation homogenate, is not a mutagen for any *S. typhimurium* strains tested.

CLASSIFICATION: ACCEPTABLE

Mutagenicity Assay (DNA Synthesis):

The test material did not appear to induce nuclear grain counts at the tested concentration range of 0.25 µg/ml to 10 µg/ml. 1,4-DMN is inactive in the *in vitro* test for unscheduled DNA synthesis in rat liver primary cell culture.

CLASSIFICATION: ACCEPTABLE

Mutagenicity Assay (In-Vivo Micronucleus Assay):

1,4-DMN did not increase the number of micronuclei per 1000 polychromatic erythrocytes in the bone marrow of the CD-1 mouse at doses of 225 mg/kg, 450 mg/kg and 900 mg/kg.

CLASSIFICATION: ACCEPTABLE

Hypersensitivity Incidents:

None reported. The registrant must notify the Agency of any hypersensitivity incidents.

DATA EVALUATION REPORT

Reviewed by: Cindy Schaffer, Microbiologist, SAB/HED^{CS}
Secondary Reviewer: Sheryl Reilly, Ph.D., Biologist, SAB/HED^{SR}

STUDY TYPE: Acute Oral Toxicity - Rat (152B-10)
MRID NO: 430825-10
TEST MATERIAL: 1,4-Dimethylnaphthalene
SYNONYMS: 1,4-DMN
PROJECT NO: L08456
STUDY NO.'S: 6, 7, 8
SPONSOR: D-I-1-4, Inc., Boise, ID
TESTING FACILITY: ITT Research Institute, Chicago, IL
TITLE OF REPORT: Acute Oral Toxicity Study of 1,4-Dimethylnaphthalene (1,4-DMN) in Rats.
AUTHOR(S): William D. Johnson, Ph.D., D.A.B.T.
STUDY COMPLETED: November 1993
CONCLUSION: The median oral LD₅₀ of 1,4-Dimethylnaphthalene was determined to be 2730 mg/kg of rat body weight.
CLASSIFICATION: ACCEPTABLE - TOX CATEGORY III

I. STUDY DESIGN

Test Material: The biochemical pest control agent is 1,4-Dimethylnaphthalene (1,4-DMN), lot no.: H5510. The nominal concentration was determined to be 94.7% 1,4-DMN by the sponsor. Stock solutions of the test material were prepared in corn oil at either a 25% w/v (study 6), 30% w/v (study 7) or 50% w/v (study 8) concentration: 750, 1000 or 2500 mg/kg respectively; and diluted to the appropriate dose concentration (see below).

| TABLE 1 | DOSE LEVEL OF 1,4-DMN MG/KG (5 RATS/SEX) | | |
|---------|--|------|------|
| STUDY 6 | 750 | 1000 | 2500 |
| STUDY 7 | 1300 | 1700 | 2100 |
| STUDY 8 | 2000 | 2300 | 2500 |

Test Animals: Forty five male and forty five female Sprague Dawley (Cr1:CD^RBR) rats were obtained from Charles River Laboratories, Portage, MI. The male rats weighed between 132g and 276g and female weights ranged from 129g to 195g at the beginning of all the studies.

Methods: Five male and five female rats were each treated orally, by gavage, (10ml/kg body weight) with the

test substance at the concentrations listed in table 1. The rats were randomly weighed before initial dosing, and weekly thereafter. Animals were observed for clinical signs and mortality at 1, 3 and 5 hours post dosing and twice daily for 14 days. All rats were examined by necropsy for any macroscopic abnormalities at the end of the study.

II. RESULTS

A. Body Weights: No abnormalities were noted in body weights or weight gain throughout the study.

B. Clinical Observations*:

| <u>Clinical Sign</u> | <u>Dose (mg/kg)</u> | <u>Incidence</u> |
|--------------------------------|---------------------|------------------|
| Discoloration around mouth: | 750 | 2 ♂, 1 ♀ |
| | 1000 | 2 ♂, 2 ♀ |
| | 1300 | 4 ♂, 4 ♀ |
| | 1700 | 4 ♂, 2 ♀ |
| | 2000 | 1 ♀ |
| | 2100 | 5 ♂, 4 ♀ |
| | 2300 | 3 ♂ |
| | 2500 | 7 ♂, 5 ♀ |
| Redness around nose fur: | 750 | 2 ♂ |
| | 1000 | 2 ♂, 4 ♀ |
| | 1300 | 2 ♂, 2 ♀ |
| | 1700 | 4 ♂, 5 ♀ |
| | 2000 | 3 ♂, 4 ♀ |
| | 2100 | 3 ♂, 4 ♀ |
| | 2300 | 2 ♂, 2 ♀ |
| | 2500 | 9 ♂, 7 ♀ |
| Salivation: | 750 | 1 ♂ |
| | 1000 | 1 ♀ |
| | 1300 | 4 ♂, 3 ♀ |
| | 1700 | 4 ♂, 2 ♀ |
| | 2000 | 2 ♂, 2 ♀ |
| | 2100 | 5 ♂, 3 ♀ |
| | 2300 | 4 ♂ |
| | 2500 | 5 ♂, 6 ♀ |
| Hunched posture: | 1000 | 2 ♂, 4 ♀ |
| | 1300 | 5 ♂, 5 ♀ |
| | 1700 | 5 ♂, 5 ♀ |
| | 2000 | 1 ♀ |
| | 2100 | 5 ♂, 5 ♀ |
| | 2300 | 1 ♀ |
| 2500 | 5 ♂, 4 ♀ | |

| | | | |
|--------------------------|------|------|-----|
| Lacrimation: | 1000 | | 2 ♀ |
| | 1300 | 3 ♂, | 4 ♀ |
| | 1700 | 5 ♂, | 5 ♀ |
| | 2000 | 2 ♂, | 3 ♀ |
| | 2100 | 4 ♂, | 3 ♀ |
| | 2300 | 2 ♂, | 4 ♀ |
| | 2500 | 6 ♂, | 8 ♀ |
| Clear nasal discharge: | 1000 | | 1 ♀ |
| | 1300 | | 1 ♀ |
| | 2000 | 1 ♂, | 1 ♀ |
| | 2100 | 1 ♂ | |
| | 2500 | 3 ♂, | 5 ♀ |
| Wet inguinal fur: | 1000 | | 1 ♀ |
| | 2000 | | 1 ♀ |
| | 2500 | 1 ♂, | 2 ♀ |
| Chromodacryorrhea: | 1300 | | 1 ♀ |
| Diarrhea: | 2100 | | 1 ♀ |
| Discolored inguinal fur: | 1700 | 2 ♂, | 1 ♀ |
| | 2000 | | 1 ♀ |
| | 2100 | | 1 ♀ |
| | 2300 | | 1 ♀ |
| | 2500 | | 2 ♀ |
| Discolored paws: | 2500 | 4 ♂, | 3 ♀ |
| Redness around eyes: | 1300 | | 1 ♀ |
| | 1700 | | 1 ♀ |
| | 2100 | | 1 ♀ |
| | 2500 | | 1 ♀ |
| Red nasal discharge: | 1300 | 1 ♂ | |
| | 1700 | | 1 ♀ |
| | 2500 | 1 ♂ | |
| Hair loss: | 2000 | | 1 ♀ |
| | 2500 | 1 ♂, | 1 ♀ |
| Irritability: | 2500 | | 1 ♀ |
| Hypoactivity: | 1300 | 3 ♂, | 3 ♀ |
| | 1700 | 5 ♂ | |
| | 2000 | 4 ♂, | 5 ♀ |
| | 2100 | 3 ♂, | 1 ♀ |
| | 2300 | 5 ♂, | 5 ♀ |
| | 2500 | 7 ♂, | 7 ♀ |
| Ataxia: | 2500 | 2 ♂, | 3 ♀ |

| | | |
|----------------|------|----------|
| Cold to touch: | 2300 | 1 ♂ |
| Coma: | 2500 | 2 ♂, 1 ♀ |
| Death: | 1700 | 1 ♀ |
| | 2000 | 1 ♂ |
| | 2100 | 1 ♀ |
| | 2300 | 1 ♂ |
| | 2500 | 7 ♂, 3 ♀ |

*NOTE: The actual time period for each clinical sign was not reported; except for death. All animals died within the first three days of testing.

C. Necropsy observations:

| <u>Observation</u> | <u>Dose (mg/kg)</u> | <u>Incidence</u> |
|-----------------------------|---------------------|------------------|
| Red Brain: | 2500 | 5 ♂, 6 ♀ |
| Red Lungs: | 2500 | 3 ♂, 2 ♀ |
| Pale Kidneys: | 2300 | 1 ♀ |
| | 2500 | 6 ♂, 2 ♀ |
| Tan/mottled Kidneys: | 1700 | 1 ♀ |
| | 2500 | 1 ♂ |
| Enlarged Adrenal Glands: | 2500 | 1 ♀ |
| Dark Adrenal Glands: | 1700 | 1 ♀ |
| Red Small Intestines: | 2100 | 1 ♀ |
| Small Testes: | 1300 | 1 ♂ |
| Pale Liver | 1700 | 1 ♀ |
| | 2500 | 5 ♂ |
| Tan/mottled Liver: | 1700 | 1 ♀ |
| Pale Spleen: | 2300 | 1 ♂ |
| | 2500 | 2 ♂ |
| Mottled/dark Thymus: | 2500 | 3 ♂, 3 ♀ |
| Dark fluid in Stomach: | 2500 | 2 ♂ |

| | | |
|-------------------------------|------|-----|
| Thin Stomach Mucosa: | 2500 | 1 ♀ |
| Compacted Cecum: | 2500 | 2 ♂ |
| Distended Urinary Bladder: | 2500 | 4 ♂ |

III. SAB DISCUSSION: All mortality occurred within the first three days; and clinical signs of the remaining animals diminished within the first week post dosing. The gross necropsy findings reportedly represent autolytic changes, not those related to the test substance. Overall, the median oral LD₅₀ was determined to be 2730 mg/kg rat body weight.

DATA EVALUATION REPORT

Reviewed by: Cindy Schaffer, Microbiologist, SAB/HED ^{CS}
Secondary Reviewer: Sheryl Reilly, Ph.D., Biologist, SAB/HED ^{SR}

STUDY TYPE: Acute Dermal Toxicity [limit test]-Rabbit
(152B-11)
MRID NO: 430825-11
TEST MATERIAL: 1,4-Dimethylnaphthalene
SYNONYMS: 1,4-DMN
PROJECT NO: L08456/Study #4
SPONSOR: D-I-1-4, Inc., Boise, ID
TESTING FACILITY: IIT Research Institute, Chicago, IL
TITLE OF REPORT: Acute Dermal Toxicity Study of 1,4-Dimethylnaphthalene (1,4-DMN) in Rabbits (Limit Test).
AUTHORS(S): William D. Johnson, Ph.D., D.A.B.T.
STUDY COMPLETED: October 1993
CONCLUSION: The dermal LD₅₀ of 1,4-DMN was determined to be greater than 2 g/kg rabbit body weight.
CLASSIFICATION: ACCEPTABLE - TOX CATEGORY IV

I. STUDY DESIGN

Test Material: The biochemical pest control agent (BPCA) is 1,4-Dimethylnaphthalene (1,4-DMN), batch number H5510. The nominal concentration was determined to be 94.7% 1,4-DMN (MRID #430825-05). The dose, 2 g/kg, was determined by volume (density of 1.016 g/ml per sponsor) but administered as received by weight.

Test Animals: Five male and five female New Zealand White rabbits, approximately 3 months old, were obtained from Kuiper Rabbit Ranch, Gary, IN. The rabbits weighed between 2.52 kg and 2.89 kg at the beginning of the study.

Methods: Twenty-four hours prior to testing, approximately 10% of the trunk fur was clipped. The BPCA was administered, undiluted as received, over the prepared skin followed by surgical dressing, plastic film, a lint-free cloth and an elastic adhesive bandage. All wrappings were removed 24 hours post dosing, the skin was wiped clean using a 0.9% saline moistened gauze pad and towel dried. The animals were observed for signs of toxicity frequently day 1 and daily thereafter. Body weights were recorded on day 1, day 8 and day 15. At the end of the study, all animals were sacrificed by anesthetic overdose and subjected to gross necropsy.

II. RESULTS

A. Body Weights:

One male rabbit failed to gain weight throughout the study and one female displayed a slight loss in body weight from week 1 to week 2.

B. Clinical Observations:

All animals displayed erythema, edema and eschar formation throughout the study and new or repaired skin by the end of the study.

C. Necropsy observations:

Two males and one female exhibited pale kidneys.

One male and one female had eschar formation upon necropsy.***

*** The clinical observations show two males and two females with eschar formation on the last day of the study.

III. SAB DISCUSSION:

Although all animals displayed eschar formation during the study, no mortality or unusual observations were made during necropsy. The LD₅₀ of 1,4-DMN was determined to be greater than 2 g/kg rabbit body weight.

DATA EVALUATION REPORT

Reviewed by: Cindy Schaffer, Microbiologist, SAB/HED ^{CS}
Secondary Reviewer: Sheryl Reilly, Ph.D., Biologist, SAB/HED ^{SR}

STUDY TYPE: Acute Inhalation Toxicity Study - Rat
MRID NO: 440825-12
TEST MATERIAL: 1,4-Dimethylnaphthalene
SYNONYMS: 1,4-DMN
PROJECT NO: L08456L001
SPONSOR: D-I-1-4, Inc., Biose, ID
TESTING FACILITY: ITT Research Institute, Chicago, IL
TITLE OF REPORT: Acute Inhalation Toxicity Study of 1,4-Dimethylnaphthalene (1,4-DMN) in rats.
AUTHOR(S): Narayanan Rajendran, Ph.D.
STUDY COMPLETED: October 1993
CONCLUSION: The LC₅₀ of 1,4-DMN, in a respirable dose, is greater than 4.16 mg/L in rats.
CLASSIFICATION: ACCEPTABLE - TOX CATEGORY IV

I. STUDY DESIGN

Test Material: The biochemical pest control agent is 1,4-Dimethylnaphthalene, batch number H5510. The test material purity was determined to be 94.7% by the sponsor. The test animals received a respirable aerosol dose of 4.16 mg/L.

Test Animals: Five male and five female Sprague-Dawley rats, were obtained from Charles River Laboratories, Kingston, NY. The male rat's weight ranged from 274 gm to 284 gm and the female's weight ranged from 187 gm to 225 gm at the beginning of the study.

Methods: The treated animals received a dose of 4.16mg/L in a respirable aerosol. A continuous supply of fresh test atmosphere was generated by a 'Laskin type' stainless-steel aspirator to produce a whole body exposure. To determine the test material concentration, filter samples were collected once each hour. To determine the amount of test substance, the samples were analyzed by a gas chromatograph. Particle size distribution was analyzed using an Anderson cascade impactor twice during exposure. A physical examination of the test animals was performed each hour during exposure, each half-hour after exposure (to 1.5 hours), and once daily, beginning the day after exposure, for 14 days. Body weights were recorded for both groups prior to exposure, day 7, day 14. Gross necropsy was performed on all animals at the end of the study.

II. RESULTS

A. Exposure Chamber:

The median aerodynamic diameter of particulates was 2.82 μm with a standard deviation of 1.67.

The air flow was reported to be 110 L/minute.

The %O₂ was determined to be 21%.

The relative humidity was 30%.

The chamber temperature was 25.9°C.

B. Clinical Observations:

One female rat was found dead day 1.

All animals experienced discoloration around the nose and wet inguinal fur during the day of dosing and the majority of animals displayed these symptoms on day 1 post dosing.

Discoloration around the mouth was observed in two males and 5 females the day of dosing. This continued in all females and one male through day 1 post dosing.

Ptosis was observed in three females the day of dosing and one male had ptosis on days 5 and 6.

Dyspnea and hypoactivity were noted in two females the day of dosing; and in four females and one male on day 1.

Two females demonstrated nasal discharge and one male and one female had a discharge from the eyes day 1. One male and one female exhibited nasal discharge and eye discharge on day 2.

One female was found prostrate the day of dosing and two females were found prone on day 1.

C. Animal Body Weights:

No abnormalities were noted in body weights or body weight gain during the study.

D. Necropsy Observations:

No abnormalities were noted upon necropsy.

III. SAB DISCUSSION:

The LC₅₀ of 1,4-DMN, in a respirable dose, is greater than 4.16 mg/L in rats.

DATA EVALUATION REPORT

Reviewed by: Cindy Schaffer, Microbiologist, SAB/HED *CS*
Secondary Reviewer: Sheryl Reilly, Ph.D., Biologist, SAB/HEDS *SR*

STUDY TYPE: Primary Eye Irritation-Rabbit (152B-13) *CR*
MRID NO: 430825-13
TEST MATERIAL: 1,4-Dimethylnaphthalene
SYNONYMS: 1,4-DMN
PROJECT NO: L08456 #1
SPONSOR: D-I-1-4, Inc., Boise, ID
TESTING FACILITY: ITT Research Institute, Chicago, IL
TITLE OF REPORT: Primary Eye Irritancy Study of 1,4-Dimethylnaphthalene (1,4-DMN) in Rabbits.
AUTHOR(S): William D. Johnson, Ph.D., D.A.B.T.
STUDY COMPLETED: October 1993
CONCLUSION: Moderate ocular irritation was observed in all rabbits at 24 hours post dose administration. Irritation dissipated by day 21.
CLASSIFICATION: ACCEPTABLE - TOX CATEGORY II

I. STUDY DESIGN

Test Material: The biochemical pest control agent (BPCA) is 1,4-Dimethylnaphthalene (1,4-DMN). ^{batch No. H 5510.} The purity was determined to be 94.7 by the sponsor. The BPCA was administered undiluted. 50

Test Animals: Three male and three female New Zealand White rabbits were obtained from Kuiper Rabbit Ranch, Gary, IN. The rabbits were approximately 3 months old and weighed between 2.3 kg and 2.7 kg at the beginning of the study.

Methods: Twenty-four hours prior to MPCA administration, a preliminary ocular screen using a 2% fluorescein solution to evaluate corneal lesions was performed.

A single dose of 0.1 ml of the BPCA was administered into the conjunctival sac of the right eye in each animal. The eye was gently held together for 2 seconds to prevent a loss of material. The left eye served as the control for each animal. The Draize Method was used to score ocular lesions at 1 hour, and 1, 2, 3, 7, 14 and 21 days post dosing. Body weights were recorded on day 1 prior to test material administration. All animals were observed daily for morbidity and mortality.

II. RESULTS

A. Clinical Observations:

Two rabbits vocalized immediately upon test substance instillation.

Three rabbits exhibited circumocular alopecia "during the study".

B. Eye Irritation Scoring:

| OBSERVATION | TIME | # RABBITS* | AVE. DRAIZE SCORE |
|-------------------|---------|------------|------------------------|
| <i>Erythema:</i> | 1 hr | 6/6 | 2.0 (moderate) |
| | 1 day | 6/6 | 2.0 (moderate) |
| | 2 days | 6/6 | 1.5 (mild to moderate) |
| | 3 days | 4/6 | 1.3 (mild) |
| | 7 days | 4/6 | 1.3 (mild) |
| | 14 days | 1/6 | 1.0 (mild) |
| <i>Chemosis:</i> | 1 hr | 6/6 | 1.8 (moderate) |
| | 1 day | 6/6 | 2.0 (moderate) |
| | 2 days | 6/6 | 2.0 (moderate) |
| | 3 days | 6/6 | 2.0 (moderate) |
| | 7 days | 6/6 | 1.3 (mild) |
| | 14 days | 2/6 | 1.5 (mild to moderate) |
| <i>Discharge:</i> | 1 day | 1/6 | 2.0 (moderate) |
| | 2 days | 2/6 | 1.5 (mild to moderate) |

III. **SAB DISCUSSION:** Moderate ocular irritation was observed in all rabbits at 24 hours post dose administration. Irritation dissipated by day 21.

DATA EVALUATION REPORT

Reviewed by: Cindy Schaffer, Microbiologist, SAB/HEDCS
Secondary Reviewer: Sheryl Reilly, Biologist, SAB/HED SR

STUDY TYPE: Primary Dermal Irritation-Rabbit (152-14)
MRID NO: 430825-14
TEST MATERIAL: 1,4-Dimethylnaphthalene
SYNONYMS: 1,4-DMN
PROJECT NO: L08456
SPONSOR: D-I-1-4, Inc., Boise, ID
TESTING FACILITY: IIT Research Institute, Chicago, IL
TITLE OF REPORT: Acute Dermal Irritancy/Corrosivity of 1,4-Dimethylnaphthalene (1,4-DMN) in Rabbits.
AUTHOR(S): William D. Johnson, Ph.D., D.A.B.T.
STUDY COMPLETED: October 1993
CONCLUSION: Overall, 1,4-DMN produced a moderate irritation in all rabbits averaged over a 72 hour period, when a single 0.5 ml dose was administered dermally for 4 hours. Slight erythema persisted in 3/6 rabbits for 7 days. Dermal irritation dissipated by day 14.
CLASSIFICATION: ACCEPTABLE - TOX CATEGORY IV

I. STUDY DESIGN

Test Material: The biochemical pest control agent (BPCA is 1,4-Dimethylnaphthalene, batch number H5510. The purity was determined to be 94.7%.

Test Animals: Three male and three female New Zealand White rabbits were obtained from Kuiper Rabbit Ranch, Gary, IN. Body weights ranged from 2.5 to 3.0 kg.

Methods: Approximately 24 hours prior to testing, no less than 240 cm² of rabbits' back fur was clipped. The BPCA (0.5 ml) was administered over the prepared skin followed by gauze, Dermiform tape and an elastic wrap used to secure the patch. Approximately 4 hours following application, the gauze patch removed and the site was wiped with 0.9% saline and gauze to remove residual test material. The animals were observed for dermal irritation and corrosivity at 1/2 to 1 hour, 1, 2, 3, 7, and 14 days post dosing. The animals were evaluated for dermal irritation using the Draize method. Body weights were recorded on prior to testing.

II. RESULTS

A. Dermal Irritation Scoring:

Erythema: All males and females displayed very slight to slight redness through day 3. Erythema was noted in all females on day 7.

Edema: All males and females had well-defined to moderate swelling within the first 24 hours post dosing. One male and one female showed signs of slight edema on day 3.

III. SAB DISCUSSION:

The primary irritation index for 1,4-DMN over a 72 hour period is 2.7, equivalent to a moderate irritant. Slight irritation was noted 72 hours post dose administration.

DATA EVALUATION REPORT

Reviewed by: Cindy Schaffer, Microbiologist, SAB/HED ^{CS}
Secondary Reviewer: Sheryl Reilly, Ph.D., Biologist SAB/HED ^{SR}

STUDY TYPE: Skin Sensitization Study-Guinea Pig (152B-15)
MRID NO: 430825-15
TEST MATERIAL: 1,4-Dimethylnaphthalene
SYNONYMS: 1,4-DMN
PROJECT NO: L08456
SPONSOR: D-I-1-4, Inc., Boise, ID
TESTING FACILITY: IIT Research Institute, Chicago, IL
TITLE OF REPORT: Dermal Sensitivity of 1,4-Dimethylnaphthalene
(1,4-DMN) in Guinea Pigs Using the Modified
Buehler Method.
AUTHOR(S): William D. Johnson, Ph.D., D.A.B.T.
STUDY COMPLETED: October 1993
CONCLUSION: Dermal sensitization was not apparent when
1,4-DMN was applied to Guinea Pigs.
CLASSIFICATION: ACCEPTABLE

I. STUDY DESIGN

Test Material: The Biochemical pest control agent is 1,4-Dimethylnaphthalene. The purity was determined to be 94.7%. A preliminary study was performed to determine the highest non-irritant concentration and threshold irritation concentration to be used for the dermal induction and challenge applications. Concentrations of 100%, 75%, 50% and 25% v/v test material in white mineral oil was applied to exposed test sites. Based on the results of this study, a concentration of 75% v/v of the test substance in white mineral oil was used for the epidermal induction, and the challenge application consisted of a 50% v/v 1,4-DMN solution in white mineral oil.

Test Animals: Twenty male albino Hartley guinea pigs were obtained from Sasco, Inc., Omaha, NE. The guinea pigs weighed between 375 and 453 grams at dosing.

Methods: The guinea pig maximization test consists of two stages. The induction phase, which consists of a three week series of topical dermal applications (0.3 ml @ 75% v/v dose in a hilltop chamber), on the upper left quadrant of ten guinea pigs backs, then wrapped with an elastic adhesive bandage. followed 14 days later by a challenge dose, of the test material (0.3 ml @ 50% v/v dose). Six hours post application, the bandages were removed. Ten guinea pigs in the control group received similar treatment with the omission of the test material

during the induction phase. The sham controls received the same challenge dose of the test material as the test group (0.3 ml of 50% v/v test material in white mineral oil). The skin reactions at the challenge site were assessed twenty four and forty eight hours after the dressings were removed and graded according to the following scale:

| <u>REACTION</u> | <u>VALUE</u> |
|--|--------------|
| No reaction | 0 |
| Slight erythema | 1 |
| Well defined erythema | 2 |
| Moderate to severe erythema | 3 |
| Severe erythema to slight eschar formation | 4 |

Each guinea pig was weighed once during the first week and weekly thereafter. The animals were observed daily for signs of toxicity and mortality.

II. RESULTS

A. Skin Reactions in Test Animals after induction:

Nine out of ten treated guinea pigs experienced very slight erythema within 24 hours; while seven guinea pigs showed signs of very slight erythema at 42 hours post induction.

B. Skin Reactions in Test Animals after challenge application:

Treated animals: Seven guinea pigs displayed signs of very slight erythema and three animals had well defined erythema within the first 24 hours post dosing. By 48 hours post dosing, very slight erythema was noted in 5/10 guinea pigs.

Sham control animals: Eight guinea pigs displayed signs of very slight erythema and two animals had well defined redness within the first 24 hours post dosing. By 48 hours post dosing, very slight erythema was noted in 5/10 guinea pigs.

C. Body Weights:

No abnormalities in body weight gain were noted.

E. Clinical signs/Mortality:

No signs of toxicity or mortality were noted during the study.

II. SAB DISCUSSION:

Since slight positive reactions were noted equally after the challenge dose in both the sham control and treated animals; 1,4-DMN is not considered a dermal sensitizer.

DATA EVALUATION REPORT

Reviewed by: Cindy Schaffer, Microbiologist, SAB/HED
Secondary Reviewer: Sheryl Reilly, Ph.D., Biologist, SAB/HED

STUDY TYPE: Mutagenicity Assay (Ames Assay) (84-2)
MRID NO: 430825-16
TEST MATERIAL: 1,4-Dimethylnaphthalene
SYNONYMS: 1,4-DMN
PROJECT NO: 15683-0-401
SPONSOR: D-I-1-4, Inc. Boise, ID
TESTING FACILITY: Hazelton Washington, Inc., Vienna, VA
TITLE OF REPORT: Mutagenicity Test on 1,4-Dimethylnaphthalene
in the Salmonella/Mammalian-Microsome Reverse
Mutation Assay (Ames Test).
AUTHORS(S): Timothy E. Lawlor, M.A.
STUDY COMPLETED: 21 September, 1993
CONCLUSION: Ninety-six point four percent pure 1,4-DMN, in
the presence or absence of metabolic
activation homogenate, is not a mutagen for
any *S. typhimurium* strains tested.
CLASSIFICATION: ACCEPTABLE

I. STUDY DESIGN

Test Material: 1,4-Dimethylnaphthalene (1,4-DMN), Batch H5510
(96.4% pure).

Salmonella typhimurium strains TA98, TA100, TA1535,
TA1537 and TA1538.

S-9 homogenate; prepared from livers of Sprague-
Dawley rats induced with Arochlor.

The following were utilized as positive controls:
The activated tester strains TA98, TA100, TA1535,
TA1537 and TA1538 used 2-aminoanthracene (2.5 μg);
The non-activated tester strains TA98 and TA1538
utilized 2-nitrofluorene (1.0 μg); Strains TA100
and TA1535 had sodium azide (2.0 μg); and TA1537
used ICR-191 (2.0 μg).

Methods: A preliminary study was performed to determine the
range of doses to be tested. The results of the
study indicate that in the presence of S9 mix, the
doses should range from 10 μg to 1000 μg per plate;
and in the absence of S9 mix, the dose range will
be 1 μg to 250 μg of the test material per plate.

The mutagenicity of 1,4-DMN to five strains of *S.*
typhimurium was evaluated using the test substance
at 10.0 μg , 50.0 μg , 100 μg , 250 μg , 500 μg and 1000 μg

per assay plate, when activated with rat liver microsomes; and at a concentration of 1.0 μ g, 5.0 μ g, 10 μ g, 25 μ g, 50 μ g and 250 μ g per assay plate, without the S-9 rat liver microsomes. The vehicle control was DMSO. Three individual studies were performed to evaluate the mutagenicity of the test material; with two of these assays specifically studying tester strain TA1538. Three plates per treatment were used for enumeration of revertant colonies.

II. RESULTS: The effect of 1,4-Dimethylnaphthalene to induce reverse mutations in *S. typhimurium* test strains (average of all three studies):

| Compound Vehicle | Mean number of revertant colonies formed with strains: | | | | | | | | | | | |
|--------------------------|--|-----|-------|-----|--------|-----|--------|----|--------|-----|---------|---|
| | TA98 | | TA100 | | TA1535 | | TA1537 | | TA1538 | | TA1538* | |
| Dose level (ug/plate) | + | - | + | - | + | - | + | - | + | - | + | - |
| 50µl | 33 | 12 | 133 | 97 | 14 | 11 | 10 | 4 | 16 | 14 | | |
| 1,4-Dimethyl-naphthalene | | | | | | | | | | | | |
| 1.0µg | - | 12 | - | 89 | - | 8 | - | 7 | - | 15 | | |
| 5.0µg | - | 14 | - | 114 | - | 10 | - | 5 | - | 12 | | |
| 10.0µg | 26 | 13 | 173 | 107 | 13 | 12 | 6 | 5 | 15 | 11 | | |
| 25.0µg | - | 11 | - | 93 | - | 4 | - | 3 | - | 11 | | |
| 50.0µg | 24 | 11 | 184 | 90 | 12 | 9 | 9 | 5 | 17 | 11 | | |
| 100.0µg | 26 | - | 190 | - | 11 | - | 9 | - | 20 | - | | |
| 250.0µg | 30 | 5 | 142 | 54 | 11 | 5 | 5 | 4 | 27 | 1 | | |
| 500.0µg | 31 | - | 93 | - | 13 | - | 2 | - | 0 | - | | |
| 1000.0µg | 9 | - | 13 | - | 3 | - | 0 | - | 0 | - | | |
| Positive controls | | | | | | | | | | | | |
| 2-nitrofluorene | - | 138 | - | - | - | - | - | - | - | 241 | | |
| 2-aminoanthracine | 677 | - | 452 | - | 323 | - | 234 | - | 989 | - | | |
| Sodium azide | - | - | - | 776 | - | 129 | - | - | - | - | | |
| ICR-191 | - | - | - | - | - | - | - | 96 | - | - | | |

* (+) = activated; (-) = non-activated ; = Concentration in µl/plate

III. SAB DISCUSSION:

The test material did not appear to induce mutagenicity or dose related bacterial toxicity in any *S. typhimurium* test strain during this study.

DATA EVALUATION REPORT

Reviewed by: Cindy Schaffer, Microbiologist, SAB/HEDCS
Secondary Reviewer: Sheryl Reilly, Ph.D., Biologist, SAB/HEDS^{SR}

STUDY TYPE: Mutagenicity Assay (In-vivo Micronucleus Assay) (84-2)
MRID NO: 430825-18
TEST MATERIAL: 1,4-Dimethylnaphthalene
SYNONYMS: 1,4-DMN
PROJECT NO: 15683-0-455
SPONSOR: D-I-1-4, Inc. Boise, ID
TESTING FACILITY: Hazelton Washington, Inc., Vienna, VA
TITLE OF REPORT: Mutagenicity Test on 1,4-Dimethylnaphthalene In Vivo Mouse Micronucleus Assay.
AUTHORS(S): Hemalatha Murli, Ph.D.
STUDY COMPLETED: 24 August, 1993
CONCLUSION: Although the test material did not increase the number of micronuclei per 1000 polychromatic erythrocytes in the bone marrow of the CD-1 mouse at doses of 225 mg/kg, 450 mg/kg and 900 mg/kg, the PCE:NCE ratio decreases with an increased dose of 1,4-DMN. This may indicate a suppressive effect on the bone marrow.
CLASSIFICATION: ACCEPTABLE

I. STUDY DESIGN

Test Material: 1,4-Dimethylnaphthalene (1,4-DMN), Batch H5510 (96.4% pure) solubilized in corn oil.

Positive control: Cyclophosphamide solubilized in deionized water.

Vehicle control: Corn oil.

Test Animals: Sixty male and sixty female CD-1 mice were obtained from Charles River Laboratories, Raleigh, NC..

Methods: *Dose Selection:* Two preliminary studies were performed to determine the range of doses to be tested. In the first study, three animals of each sex received either 500mg/kg, 1625 mg/kg, 2750 mg/kg, 3875 mg/kg, or 5000 mg/kg of 1,4-DMN by oral gavage. All but one animal died when given a dose of 1625 mg/kg or higher. Since these results were not sufficient to select a dose range, an additional study was conducted testing dose levels of 900 and 1300 mg/kg. One out of six animals died when treated with 900 mg/kg while 2/6 mice died when dosed with 1300 mg/kg of the test material.

The results of this study indicate that the maximum tolerated dose (MTD) was 900 mg/kg 1,4-DMN. The doses selected for this assay were 225, 450 and 900 mg/kg body weight.

The test substance, diluted in corn oil, was administered by oral gavage, to five mice of each sex per treatment group at a volume of 10 ml/kg. An additional five males and five females were orally dosed with either 80 mg/kg of the positive control; or 10 ml/kg of the vehicle control. The treated animals were terminated 24, 48 or 72 hours post dosing; while the control mice were euthanized with CO₂ within 24 hours after dose administration. The bone marrow was aspirated from the tibia of the mice, and mixed with 0.1 ml fetal bovine serum (FBS). The cells were placed on a slide, air dried, fixed in methanol, and stained with May-Grunwald solution and Giemsa. A coverslip was mounted on each slide with Depex mounting medium. Each slide was scored for micronuclei as well as the polychromatic (PCE) to normochromatic (NCE) cell ratio. One thousand PCE's were counted. The frequency of micronucleated cells was based on the percent of micronucleated cells per total PCE's present in the optic field. The normal range of micronuclei in CD-1 mice is 0.0% to 0.4%. The frequency of PCE's versus NCE's was determined by grading the number of PCE's and NCE's observed in the optic fields while counting the first 1000 erythrocytes.

II. RESULTS: The effect of 1,4-Dimethylnaphthalene to induce an increase the frequency of micronuclei per 1000 polychromatic erythrocytes in mouse bone marrow; average of five animals per sex:

| <u>Compound</u> | <u>Dose (mg/kg)</u> | <u>% mean</u> | | <u>Ratio PCE:NCE mean</u> | |
|------------------|---------------------|---------------------|----------|---------------------------|----------|
| | | <u>PCE's (1000)</u> | | | |
| | | <u>σ</u> | <u>♀</u> | <u>σ</u> | <u>♀</u> |
| Vehicle control | 10 ml/kg | 0.02 | 0.04 | 0.77 | 0.92 |
| Positive control | 80 | 0.82 | 1.16 | 0.96 | 0.97 |
| 1,4-DMN @ 24 hrs | 225 | 0.12 | 0.02 | 0.71 | 1.00 |
| | 450 | 0.04 | 0.04 | 0.84 | 0.92 |
| | 900 | 0.14 | 0.00 | 0.87 | 0.94 |
| 1,4-DMN @ 48 hrs | 225 | 0.06 | 0.20 | 0.54 | 0.48 |
| | 450 | 0.06 | 0.06 | 0.54 | 0.37 |
| | 900 | 0.10 | 0.02 | 0.56 | 0.44 |

| | | | | | |
|------------------|-----|------|------|------|------|
| 1,4-DMN @ 72 hrs | 225 | 0.10 | 0.02 | 0.58 | 0.32 |
| | 450 | 0.06 | 0.00 | 0.54 | 0.45 |
| | 900 | 0.04 | 0.02 | 0.48 | 0.38 |

III. SAB DISCUSSION:

Although the test material did not increase the number of micronuclei per 1000 polychromatic erythrocytes in the bone marrow of the CD-1 mouse at doses of 225 mg/kg, 450 mg/kg and 900 mg/kg, the PCE:NCE ratio decreases with an increased dose of 1,4-DMN. This may indicate a suppressive effect on the bone marrow.

DATA EVALUATION REPORT

Reviewed by: Cindy Schaffer, Microbiologist, SAB/HED (C)
Secondary Reviewer: Sheryl Reilly, Ph.D., Biologist, SAB/HED SR

STUDY TYPE: Genotoxicity Test (DNA synthesis) [84-2(3)(i)(c)]
MRID NO: 430825-17
TEST MATERIAL: 1,4-Dimethylnaphthalene
SYNONYMS: 1,4-DMN
PROJECT NO: 15683-0-447
SPONSOR: D-I-1-4, Inc. Boise, ID
TESTING FACILITY: Hazelton Washington, Inc., Vienna, VA
TITLE OF REPORT: Genotoxicity Test on 1,4-Dimethylnaphthalene In the Assay for Unscheduled DNA Synthesis in Rat Liver Primary Cell Cultures.
AUTHORS(S): Andrea L. Ham, B.S.
STUDY COMPLETED: 28 September, 1993
CONCLUSION: The test material did not appear to induce nuclear grain counts at the tested concentration range of 0.250 µg/ml to 10 µg/ml. 1,4-Dimethylnaphthalene is inactive in the *in vitro* test for unscheduled DNA synthesis in rat liver primary cell culture.
CLASSIFICATION: ACCEPTABLE

I. STUDY DESIGN

Test Material: 1,4-Dimethylnaphthalene (1,4-DMN), Batch H5510 (96.4% pure).

Indicator cells: Hepatocytes, obtained from a single adult male Fischer 344 rat, cultured in monolayers in Williams' Medium E supplemented with 2 mM L-glutamine, 100 µg/ml streptomycin sulfate, 150 µg/ml gentamycin, and with [WME+] or without 10% fetal bovine serum (FBS) [WMEI], depending upon the phase of growth. The latter phase was cultured in WMEI. The treatment phase of the study contained 10 µCi/ml ³HTdr (46 Ci/mMole) [WME-treat].

Solvent control: Dimethylsulfoxide (DMSO).

Positive control: 2-Acetylaminofluorene (2-AAF).

Stock solution: Fresh preparations of the test material in DMSO were prepared at the highest desired concentration and serially diluted with DMSO; then diluted 1:100 into WME-treat.

Methods:

Indicator cells were prepared by perfusion of rat livers *in situ* with Hanks balanced salt solution (HBSS), and subsequently with collagenase/HBSS. The hepatocytes were obtained by a mechanical extraction. After shaking the plates, the cellular debris was allowed to settle and the supernatant was spun down in a centrifuge and reconstituted with WME+. The cells were counted and at least 5 aliquots (of 0.5×10^6 viable cells in 3 ml of WME+ per dose level) were placed in 35mm culture dishes. The culture dishes used for unscheduled DNA synthesis (UDS) contained coverslips; the others utilized for attachment efficiency and cytotoxicity evaluation did not.

To establish cell cultures, the plates were initially incubated at $37^\circ\text{C}/5\% \text{CO}_2$ for 1.8 hours then washed and refed with WMEI. The media was replaced 2.1 hours later with 2.5 ml WMEI + $10\mu\text{Ci/ml } ^3\text{HTdr}$ (46Ci/Mmole) + the test material [or positive or negative control] at the following concentrations: $10\mu\text{g/ml}$, $5\mu\text{g/ml}$, $2.5\mu\text{g/ml}$, $1\mu\text{g/ml}$, $0.5\mu\text{g/ml}$, and $0.25\mu\text{g/ml}$. The cultures incubated for an additional 18.6 hours. The assay was terminated by washing the cultures twice with WMEI. Three cultures had an additional wash of WMEI + 1Mm Thymidine. The other two cultures were refed with WMEI, incubated for an additional 20.3 hours and viable cell counts relative to the negative control were obtained through trypan blue exclusion.

An addition of one percent sodium citrate to the coverslips for 10 minutes allowed swelling of the cell nuclei. The cells were then fixed with a 1:3 ratio of acetic acid:ethanol and dried for at least 24 hours. The coverslips were then mounted onto glass slides, coated with an emulsion of Kodak NTB2 and deionized water, then dried. The slides were stored in a light tight box containing dessicant for seven days, developed in D19, fixed and stained using Williams' modified hematoxylin and eosin method.

UDS (or net nuclear grain count) was measured by examining the cells, at 1500X magnification, counting the nuclear grains on at least 50 randomly selected cells from each coverslip, and subtracting the background count of grains in a three nuclear-sized area adjacent to each nucleus.

II. RESULTS: The effect of 1,4-Dimethylnaphthalene to induce an increase of net nuclear grain (NNG) counts in rat liver primary cell cultures:

| <u>Compound</u> | <u>Dose level</u> <u>(μg/ml)</u> | <u>Mean NNG</u> | <u>% Survival @ 20 hrs</u> |
|------------------|--|-----------------|----------------------------|
| Solvent control | 1% | -2.68 | 100.0 |
| Positive control | 0.1 | 7.35 | 89.4 |
| 1,4-DMN | 10.0 | 0.01 | 58.2 |
| | 5.0 | -1.38 | 95.8 |
| | 2.5 | -2.77 | 108.9 |
| | 1.0 | -1.18 | 106.8 |
| | 0.5 | -1.37 | 103.2 |
| | 0.25 | -1.65 | 103.0 |

III. SAB DISCUSSION:

The test material did not appear to induce nuclear grain counts at any tested concentration. 1,4-Dimethylnaphthalene is inactive in the *in vitro* test for unscheduled DNA synthesis in rat liver primary cell culture.



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

OCT 7 1994 .

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: PP#4F04314. Product Chemistry Review and Request for Exemption from a Tolerance for the Biochemical Active Ingredient 1,4-Dimethylnaphthalene. The End-Use Product 1,4-SIGHT® Is Intended to Inhibit Sprouting in Stored Potatoes.

MRID#s 430825-01 thru -09 and 432668-01 thru -03
(13 vols.).

DP Barcodes#: D204771, D204773, D207820.

CBTS#s: 13930, 13931, 14444.

From: G. Jeffrey Herndon, Chemist
Tolerance Petition Section II
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

G. Jeffrey Herndon

Through: Elizabeth T. Haebeler, Section Head
Tolerance Petition Section II
Chemistry Branch I - Tolerance Support
Health Effects Division (H7509C)

Elizabeth T. Haebeler
10/6/94

To: Cynthia Giles-Parker/James Stone, PM Team 22
Fungicide-Herbicide Branch
Registration Division (H7505C)

and

Sheryl Reilly, Ph.D.
Science Analysis Branch
Health Effects Division (H7509C)

E.R. Butts International, Inc., acting as the agent and regulatory consultant for the registrant, D-I-1-4, Inc., has submitted product and residue chemistry data to support the registration of the biochemical sprouting inhibitor 1,4-dimethylnaphthalene for use on potatoes.

Background

1,4-dimethylnaphthalene was classified as a biochemical 3/23/93. The classification was based on 1,4-dimethylnaphthalene's natural occurrence and its acting as a plant growth regulator (in this case as a sprouting inhibitor). The registrant provided information to show that 1,4-dimethylnaphthalene occurs naturally in potatoes at levels between 1 and 10 ppm. When conditions are right for sprouting, the potato metabolizes the 1,4-dimethylnaphthalene to low enough levels that sprouting can occur. 1,4-dimethylnaphthalene is intended to be a safer replacement for chlorpropham.

Proposed Use

The end-use product, 1,4SIGHT will be applied to stored potatoes using a fogging system similar to the way chlorpropham can be applied. One gallon of 1,4SIGHT contains 8 lbs of active ingredient and will treat 400,000 lbs of potatoes (2.5 ppm). Up to 4 applications may be made during the storage season, which generally runs from October to August. No minimum time period between treatment and consumption was explicitly specified, but the label contains language that the product will not be sprayed on stored potatoes during the retail packing process.

Conclusions and Recommendations

As noted in the main body of this memo, additional data are necessary in order to fulfill the following guidelines:

- | | |
|--------|--|
| 151-12 | Discussion of the Formation of Unintentional Ingredients |
| 151-13 | Analysis of Samples |
| 151-15 | Certification of Ingredient Limits |
| 151-16 | Analytical Methods for Certified Limits |
| 151-17 | Physical and Chemical Properties |

However, based on the nature of the product, CBTS does not believe that the outstanding data necessitate a delay in the registration of the product. Therefore, TOX considerations permitting (as noted in section 151-12), CBTS can recommend that RD issue a conditional registration for 1,4-dimethylnaphthalene provided that the additional data are supplied at a later date (to be determined by RD).

Note to PM:

CBTS defers the review of end-use products to the Registration Division (RD).

Detailed Considerations

Product Chemistry

Note: Some of the confidential material in this petition have been photocopied and placed in a Confidential Appendix. However our conclusions on each guideline number appear below in the non-confidential portion of the review.

151-10 Product Identity and Disclosure of Ingredients

Product Identity

1,4SIGHT contains the active ingredient 1,4-dimethylnaphthalene.

Confidential Statement of Formula

Data for the Confidential Statement of Formula (CSF) for 1,4-dimethylnaphthalene were submitted and are found in Confidential Appendix Part A, which was photocopied directly from the petition.

Information on Ingredients

Information on the active ingredient is listed in Table 1 below. Information on the impurities are in Table 2 under section 151-10 of the Confidential Appendix.

Table 1

Supplied Information on Active Ingredient

| | |
|-----------------------|---------------------------------|
| Name | 1,4-dimethylnaphthalene |
| CAS# | 571-58-4 |
| Empirical Formula | C ₁₂ H ₁₂ |
| Molecular Weight | 156.2 |
| % in Product (weight) | 94.7% |

Information on the starting materials for the manufacturing processes were submitted and are found in Confidential Appendix Part B, which was photocopied directly from the petition.

CBTS Response to 151-10

CBTS considers the CSF and information on the active ingredient and impurities adequate to fulfill the requirements of 151-10.

151-11 Manufacturing Process

Descriptions of the manufacturing processes for 1,4-dimethylnaphthalene are provided in the Confidential Appendix Part C, which was photocopied directly from the petition.

CBTS Response to 151-11

CBTS considers the descriptions of the manufacturing processes adequate to fulfill the requirements of 151-10.

151-12 Discussion of the Formation of Unintentional Ingredients

The discussion on the formation of unintentional ingredients associated with the manufacture of 1,4-dimethylnaphthalene are provided in the Confidential Appendix Part D, which was photocopied directly from the petition.

CBTS Response to 151-12

Based on our review of the manufacturing processes provided by the petitioner (see CBTS response to 151-11) and the discussion on the formation of unintentional ingredients provided by the petitioner, CBTS does not expect that nitrosamines, HCBs, dioxins, or other trace, toxicologically significant impurities will be produced in the manufacture of 1,4-dimethylnaphthalene. However, CBTS defers any judgement on the toxicity of any impurities in the product to TOX and the toxicology tests performed using the technical product. Additional discussion is needed on the newly identified impurity (see CBTS Response to 151-13 in the Confidential Appendix of this memo).

151-13 Analysis of Samples

The petitioner provided the results from the analysis of the 1,4-dimethylnaphthalene technical product for levels of active ingredient and impurities. These are found in Confidential Appendix Part E.

The analytical methods for the analysis of the active ingredient and impurities in the 1,4-dimethylnaphthalene technical product were provided and are found in Confidential Appendix Part F.

CBTS Response to 151-13

See CBTS Response to 151-13 in the Confidential Appendix of this memo.

151-15 Certification of Ingredient Limits

The petitioner provided proposed upper and lower certified limits for the active ingredient, and upper certified limits for the impurities in the 1,4-dimethylnaphthalene technical product (see CSF in Confidential Appendix Part A).

CBTS Response to 151-15

See CBTS Response to 151-13 in the Confidential Appendix of this memo.

151-16 Analytical Methods for Certified Limits

The analytical methods for the analysis of the active ingredient and impurities in the technical product were submitted and are found in Confidential Appendix Part F (see CBTS Response to 151-13).

CBTS Response to 151-16

See CBTS Response to 151-13 in the Confidential Appendix of this memo. Other than the lack of an analytical method for the analysis of the newly identified impurity, CBTS considers the submitted methods adequate to fulfill the requirements of 151-16.

151-17 Physical and Chemical Properties

The registrant submitted a list of the physical and chemical properties for the 1,4-dimethylnaphthalene technical product, which are contained in Table 3 below.

Table 3

Physical and Chemical Properties of 1,4-Dimethylnaphthalene

| Requirement | Guideline | Data |
|-------------------------------------|-----------|--|
| color | 63-2 | pale yellow |
| physical state | 63-3 | liquid |
| odor | 63-4 | petroleum distillates |
| melting point | 63-5 | N/A |
| boiling point | 63-6 | 264°C @ 744 mm Hg. |
| specific gravity | 63-7 | 1.014 @ 25°C |
| solubility | 63-8 | 5.1 ppm in water |
| vapor pressure | 63-9 | 1.88x10 ⁻² @ 25°C 3.64x10 ⁻² @ 35°C 8.75x10 ⁻² @ 45°C |
| dissociation constant | 63-10 | N/A |
| ethanol/water partition coefficient | 63-11 | no data submitted |
| pH | 63-12 | 6.3 (inert atmosphere), 5.9 (ambient atmosphere) for a 1% solution @ 25°C |
| stability | 63-13 | accelerated storage: test was negative (14 days @ 55°C) light stability: 13.7% decrease in weight (14 days @ 55°C) thermal stability: up to 7% loss at up to 150°C in both air and inert environments sensitivity to metals: no decomposition @ 100°C for 1 hour in the presence of aluminum, iron, and tin powders |
| flammability | 63-15 | 122°C @ 760 mm Hg |
| explodability | 63-16 | test was negative (drop height of 32.25 inches) |
| storage stability | 63-17 | no data submitted |
| viscosity | 63-18 | 6 cps at both 12 and 30 rpm |
| miscibility | 63-19 | N/A |
| corrosion characteristics | 63-20 | test was negative (conducted on both HDPE and tin containers @ 50°C for 92 days) |
| dielectric breakdown voltage | 63-21 | N/A |

CBTS Response to 151-17

The following 151-17 data are outstanding:

octanol/water partition coefficient (63-11)
storage stability (63-17)

The petitioner is referred to the Pesticide Assessment Guidelines, Subdivision M Section 151-17, and Subdivision D Sections 63-2 thru 63-21 for more guidance on these and other physical and chemical property requirements.

Attachment I : Confidential Appendix, including:

- Part A - Confidential Statement of Formula (1 page)
- Part B - Information on the Starting Materials (8 pages)
- Part C - Manufacturing Processes (8 pages)
- Part D - Discussion of the Formation of Unintentional Ingredients (2 pages)
- Part E - Certification of Ingredient Limits (2 pages)
- Part F - Analytical Methods for Certified Limits (8 pages)

cc (without attachments): circu., E. Haeberer (section head).

cc (with attachments): RF, SF (1,4 Dimethylnaphthalene),
G.J. Herndon.

RDI: Section Head: E. Haeberer: 10/4/94,
Acting Branch Chief: R. Loranger: 10/5/94.

H7509C: CBTS: G.J. Herndon: 305-6362: CM#2, Rm. 804C: 10/4/94.

EFED BIOTECHNOLOGY REVIEW

Pesticide Name 1,4-Dimethylnaphthalene

Reviewed By:

David Bays, PhD
Microbiologist
EFED Biotechnology Team

David Bays
8/31/94

Approved By:

Robert Pilsucki, PhD
Microbiologist
EFED Biotechnology Team

Robert Pilsucki
8/31/94

Elizabeth Leovey
Team Leader
EFED Biotechnology Team

Elizabeth Leovey
8/31/94

100.0.0 Submission Purpose and Label Information

100.1.0 Submission Purpose and Pesticide Use

D-I-1-4, Inc. has requested a Section 3 Registration for 1,4-dimethylnaphthalene. This product is used as an aerosol to control sprouting of potatoes during the storage phase.

100.2.0 Formulation Information

1,4SIGHT

Aerosol Grade-Potato Sprout Inhibitor

| | By Weight |
|---|-----------|
| ACTIVE INGREDIENT: 1,4-Dimethylnaphthalene* | 94.7% |
| Inert Ingredients | 3.6% |
| TOTAL | 100.00% |

*Contains 7.9 pounds active ingredient per gallon.

100.3.0 Application Methods, Directions, Rates

See attached label.

100.4.0 Target Organisms

Not Applicable, because this product acts as a sprout inhibitor in potatoes.

100.5.0 Precautionary Labeling

The label contains the following precautions:

KEEP OUT OF REACH OF CHILDREN

CAUTION

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS): (adequate)

(Pesticide and container disposal directions are adequate)

Environmental Hazards

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 by disposal of equipment wash waters.

101.0.0 Hazard Assessment

101.1.0 Discussion

The studies supplied with this submission will be considered core and fulfill EPA Guideline requirements. The results indicate that Naphthalene is highly toxic to freshwater invertebrates and fish, and practically nontoxic to birds (on an acute basis). Therefore, Naphthalene should not pose an adverse risk to birds, but may pose an adverse risk to aquatic organisms.

101.2.0 Likelihood at Adverse Effects to Nontarget Organisms

Avian Studies

Submitted study entitled "An Acute LD₅₀ Study, Species: Northern Bobwhite Quail (*Colinus virginianus*)" (MRID #430825-19) shows that the acute oral LD₅₀ value for northern bobwhite exposed to Naphthalene was greater than 2,000 mg a.i./kg (practically nontoxic). The no observed effect dosage was 2,000 mg a.i./kg.

The results of this study indicates that Naphthalene should not cause any adverse effects to avian wildlife.

Fish Studies

Submitted study entitled "1,4-dimethylnaphthalene - Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*)" (MRID #430825-20) demonstrated the 96 hour LC₅₀ was 0.67

mg a.i./L. The 96 hour NOEL was 0.19 mg a.i./L.

The above data indicate that Naphthalene is highly toxic to freshwater fish species and could potentially cause adverse effects to nontarget freshwater fish.

Mammalian Wildlife

The data submitted to the toxicology branch indicate that there is no significant toxicity to rodents from acute oral testing at the maximum hazard dose. In light of the above results, risk to mammalian wildlife is expected to be minimal to nonexistent.

Aquatic Invertebrate Studies

In a study entitled "1,4-Dimethylnaphthalene-Acute toxicity to daphnids (*Daphnia magna*) under flow-through conditions" (MRID #430825-21) the 48-hour EC₅₀ was determined to be 0.54 mg a.i./L. The NOEL was considered to be 0.10 mg a.i./L.

The above data indicates that Naphthalene is highly toxic to aquatic invertebrate species and could potentially cause adverse effects to this species.

Nontarget Plant Studies

None submitted. Plant testing of biochemical pest control agents is conditionally required when there is published evidence that the compound is toxic to plants. To the best of our knowledge, this compound is not known to be toxic to plants.

Honey Bee Studies

None submitted. These studies are conditionally required and will not be required for this product.

Endangered Species Considerations

No risk to endangered species is expected from the use of this product.

101.4.0 Adequacy of Toxicity Data

(See the Generic Data Table)

The registrant has addressed the data requirements outlined in the Pesticide Assessment Guidelines, Subdivision M.

Generic Data Requirements For Naphthalene

| Data Requirement | Test ¹ Substance | Use ² Patterns | Does EPA Have Data? | Bibliographic Citation | Must Additional Data Be Submitted? |
|---|--------------------------------|------------------------------|------------------------|---------------------------|---------------------------------------|
| <u>§158.740 Microbial Pesticide Nontarget Organism - Tier I</u> | | | | | |
| <u>Avian Testing</u> | | | | | |
| 154-6 Avian Acute Oral | | | | | |
| - upland gamebird | TGAI | A,I | Yes | 430825-19 | No |
| 154-7 Avian Dietary | | | | | |
| - upland gamebird | TGAI | A,I | No | --- | No ⁴ |
| <u>Aquatic Organism Testing</u> | | | | | |
| 154-8 Freshwater Fish LC ₅₀ | | | | | |
| - rainbow trout | TGAI | A,I | Yes | 430825-20 | No |
| 154-9 Freshwater Invertebrate | | | | | |
| - <u>Daphnia magna</u> | TGAI | A,I | Yes | 430825-21 | No |
| <u>Additional Testing</u> | | | | | |
| 154-10 Nontarget plant studies | | | | | |
| - terrestrial | TGAI | A,I | No | --- | No ⁴ |
| - aquatic | TGAI | A,I | No | --- | No ⁴ |
| 154-11 Nontarget insect testing | | | | | |
| - honey bee | TGAI | A,I | No | --- | No ⁵ |

¹TGAI = Technical Grade of the Active Ingredient; TEP = Typical End-Use Product.

²The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic, Outdoor; I = Indoor.

³This data requirement is not required if the pesticide is highly volatile. In this case, Naphthalene is applied to stored potatoes as a highly volatile aerosol.

⁴Not required for this use pattern.

⁵Conditionally required for biochemicals. Not required in this case.

101.5.0 Adequacy of Labeling

The precautionary labeling (see sec. 100.5.0) is adequate except that the following statement will need to be added as the first sentence in the Environmental Hazards portion of the label: This product is highly toxic to freshwater fish and aquatic invertebrates.

102.0.0 Classification N/A

103.0.0 Conclusions

EEB has reviewed the proposed Section 3 Registration of Naphthalene by D-I-1-4, Inc. for the control of sprouting of potatoes during storage.

The studies supplied with this submission indicate that Naphthalene is practically nontoxic to avian species using an acute route of exposure, and did not demonstrate any toxicity to rodents in studies submitted to the Healthy Effects Division of OPP. However, the compound is highly toxic to freshwater fish and aquatic invertebrates. Even though this product is highly toxic to these aquatic species, it should not pose a risk to these organisms based on a lack of exposure due to its use pattern. Naphthalene is applied as an aerosol to potato tubers in storage buildings.

However, to better document this risk to aquatic organisms, the registrant should add the following statement to the Environmental Hazards Section of its label: This product is highly toxic to freshwater fish and aquatic invertebrates.

Therefore, Naphthalene should not cause any adverse effects to nontarget wildlife as long as exposure to aquatic organisms is minimized through the restricted use pattern. If the use pattern changes, then a second risk assessment will need to be completed.

DATA EVALUATION REPORT

1. Chemical: 1,4-Dimethylnaphthalene
2. Test Material: Technical
3. Study/Action Type: An Acute LD₅₀ Study, Species: Northern Bobwhite Quail (Colinus virginianus) (154B-6)
4. Study Identification: Acute Oral LD₅₀ with Bobwhite Quail (Colinus virginianus), By Md. Sayed Ahmed, PhD. Prepared By Genesis Laboratories, Inc. October 1993. Project No. 93004. Submitted By D-I-1-4, Inc., Boise, Idaho. EPA Acc. No. 430825-19.

5. Reviewed By: David C. Bays, PhD.
Biotech Review Team
EFED

Signature: 

Date: 8/31/94

Robert Pilsucki
Biotech Review Team
EFED

Signature: 

Date: 8/31/94

6. Conclusions:

The study is scientifically sound and demonstrated an LD₅₀ > 2,000 mg a.i./kg and the no observed effect level of 2,000 mg a.i./kg. This indicates that Naphthalene is practically non-toxic to birds on an acute basis.

7. Recommendations: N/A

8. Background:

This study was submitted to support the request for a Section 3 Registration of the biochemical pesticide 1,4-dimethylnaphthalene.

9. Materials and Methods:

- A. Test Organisms: Healthy northern bobwhite quail, 17 weeks of age and phenotypically indistinguishable from wild birds, were obtained from Barrett's Quail Farm. The quail were distributed into one test group and one control group of 10 birds each, 5 males and 5 females, for a limit dose test. The test birds were acclimated to the facilities for 15 days prior to the beginning of the study. Tap water and feed, Purina Game Bird Maintenance Chow, were provided ad libitum during the acclimation and testing periods.
- B. Dosage Form: The test substance, a colorless liquid (reported purity of 96.4%), was administered as an oral dose by capsule. The control birds received blank capsules.

The test birds were fasted for at least 17 hours before dosing. The test substance concentration was adjusted to provide a constant volume to body weight dosage for all test birds (mg/test substance per kg/body weight), but was not adjusted for the purity of the test substance. The nominal dosage used in this limit dose study was 2000 mg a.i./kg of body weight.

- C. Referenced Protocol: The dosages used in the study were established using known toxicity data. The birds were given a single oral dose of the test substance by capsule at the beginning of the study. The control consisted of birds given blank capsules.

All birds were tested in pens (90x60x45 cm) assigned by random draw and housed indoors. Average ambient room temperature for the study varied from 74F to 65F with an average relative humidity between 66% and 52%. The photoperiod (monitored by a time clock) was 10 hours of light per day during acclimation and throughout the study. Housing and husbandry practices were based upon the "Guide for the Care and Use of Laboratory Animals", NIH Publication No. 85-23, 1985.

All birds were observed daily during acclimation and any exhibiting abnormal behavior or physical injury were not used. After test initiation and continuing until termination, all birds were observed at least twice daily with all mortality, signs of toxicity or abnormal behavior being recorded. Body weights of the test birds were recorded individually prior to dosing, on Day 3, Day 7, and Day 14. Average estimated feed consumption was measured daily.

- D. Statistical Analysis: The test data in this study was not statistically analyzed because of a lack of mortalities.

12. Reported Results:

| <u>Dosage</u> | <u>mg/kg</u> | <u>Number Dead/Number Exposed</u> <u>(At 14 Days After Dosing)</u> |
|-------------------------------------|--------------|---|
| Control | | 0/12 |
| Treatment | 2000 | 0/12 |
| LD ₅₀ < 2,000 mg a.i./kg | | |

No mortalities occurred with any of the control or treated birds.

13. Study Author's Conclusions/Quality Assurance Measures:

LD₅₀ < 2,000 mg a.i./kg

"This study contained herein, 93004, was conducted in accordance with the requirements of Title 40, Code of Federal Regulations, Part 160, Good Laboratory Practice Standards. The raw data have been reviewed by the study Director who certifies that the information contained in this report is consistent with the data within the context of the study design and evaluation criteria." Signed by study director, Md. Sayed Ahmed, PhD.

14. Reviewer's Discussion and Interpretation of the Study:

- A. Test Procedures: The procedures used followed those recommended by EPA in Section 154-6 of the EPA Registration Guidelines (Pesticide Assessment Guidelines, FIFRA Subdivision M, Microbial and Biochemical Pest Control Agents).
- B. Statistical Analysis: No Statistical analysis was performed due to a lack of mortalities.
- C. Discussion/Results: An LD₅₀ < 2,000 mg a.i./kg indicates that Naphthalene is practically non-toxic to birds on an acute basis.
- D. Adequacy of the Study:
1. Validation Category: Core
 2. Rationale: The study meets guideline requirements

15. Completion of the One-liner:

DATA EVALUATION REPORT

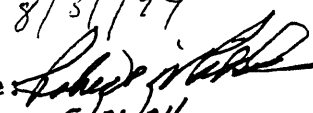
1. Chemical: 1,4-Dimethlynaphthalene
2. Test Material: Technical.
3. Study/Action Type: Freshwater Fish LC₅₀ (154-8)
4. Study Identification: 1,4-Dimethlynaphthalene - Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Under Flow-Through Conditions. By Michael J. Bettencourt, Study Director. Prepared By Springborn Laboratories, Inc., October 8, 1993. Project ID. #13117.0693.6101.108. Submitted By D-I-1-4, Inc., Boise, Idaho, EPA Acc. No. 430825-20.

5. Reviewed By: David C. Bays, PhD.
Biotech Review Team
EFED

Signature: 

Date: 8/31/94

Bob Pilsucki, PhD.
Biotech Review Team
EFED

Signature: 

Date: 8/31/94

6. Conclusions:

The study is scientifically sound and demonstrated an LC₅₀ = 0.67 mg a.i./L. This indicates that Naphthalene is highly toxic to freshwater fish. The no-effect concentration at 96 hours was found to be 0.19 mg a.i./L. The 95% confidence limits were 0.57 and 0.80 mg a.i./L. The study fulfills EPA Guideline requirements for an acute toxicity test for freshwater fish.

7. Recommendations: N/A

8. Background:

This study was submitted for a Section 3 registration of the biochemical pesticide Naphthalene.

10. Materials and Methods:

- A. Test Organisms: The rainbow trout used in this study were obtained from Mt. Lassen Trout Farm in Red Bluff, California. The fish (mean weight 1.5 g [0.8 to 2.8] and a mean length of 50 [42 to 63] mm) were reared and maintained at Springborn Labs in water with a total hardness that ranged from 26 to 28 mg/l - as CaCO₃. The fish were fed salmon a dry commercial pelleted food mash, *ad libitum*, during holding, but were not fed 48 hours before test initiation or during the test.

B. Dosage Form: The test material, a clear liquid, (96.4% active ingredient) was mixed with acetone for a concentration of 5.0 mg a.i./ml. The nominal concentration regime was 0.32, 0.54, 0.90, 1.5, and 2.5 mg a.i./L. The regime was determined using preliminary static tests. The mean measured test concentrations from samples collected at 0 and 96 hours were 0.19, 0.22, 0.41, 0.75 and 1.2 mg a.i./L. The low recovery level of test material was most likely due to the limited water solubility of Naphthalene.

C. Referenced Protocol: A proportional diluter was used to provide the proper concentration of test substance to each of the test chambers (6.6 volume changes every 24 hours). The study was initiated after the test solutions had been flowing through the test chambers (glass 39X20X25 cm aquaria filled with 15 L of test solution) for several days. At this time, 10 rainbow trout were impartially distributed to each chamber, which was positioned in a temperature-controlled water bath (12±1 C). The treatments included 2 replications (each containing 10 trout) of the 5 concentrations of the test material, and a dilution water control.

The water quality parameters of temperature, dissolved oxygen and Ph were measured at 0-, 48- and 96- hours and were determined to be within acceptable limits (Temp. = 11-12C; pH = 7.1-7.7; Dissolved oxygen = 8.4-9.8 mg/L). Observations for mortality and sub-lethal responses were made once every 24 hours during the 96 hour test period.

D. Statistical Analysis: The LC₅₀ values and 95% confidence limits were calculated using the computer program of C.E. Stephan, which uses probit analysis, the moving average-angle method, or binomial probability method with nonlinear interpolation.

12. Reported Results:

| <u>Dosage(mg/l)</u> | | <u>Number Dead/Number Exposed</u> <u>(At 96 hours After Dosing)</u> |
|---------------------|---|--|
| Negative Control | A | 0/10 |
| | B | 0/10 |
| Solvent Control | A | 0/10 |
| | B | 0/10 |
| 0.19 | A | 0/10 |
| | B | 0/10 |
| 0.22 | A | 1/10 |
| | B | 0/10 |

| | | |
|------|---|-------|
| 0.41 | A | 0/10 |
| | B | 1/10 |
| 0.75 | A | 5/10 |
| | B | 4/10 |
| 1.2 | A | 10/10 |
| | B | 10/10 |

$LC_{50} = 0.67$ mg a.i./L

The 95% confidence limits were 0.57 and 0.80 mg a.i./L and the no effects concentration was 0.19 mg a.i./L.

13. Study Author's Conclusions/Quality Assurance Measures:

$LC_{50} = 0.67$ mg a.i./L

"The data and report presented for 1,4-Dimethylnaphthalene - Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Under Flow-Through Conditions were produced and compiled in accordance with all pertinent EPA Good Laboratory Practice regulations (40 CFR, Part 160) with only minor exceptions which were not significant enough to affect the integrity of the study or the interpretation of the test results."

Signed by study director: Michael J. Bettencourt

14. Reviewer's Discussion and Interpretation of the Study:

- A. Test Procedures: The procedures used followed those recommended by EPA in Section 154-8 of the EPA Registration Guidelines (Pesticide Assessment Guidelines, FIFRA Subdivision M, Microbial and Biochemical Pest Control Agents).
- B. Statistical Analysis: Binomial probability with nonlinear interpolation using the computer program of C. E. Stephan.
- C. Discussion/Results: An $LC_{50} = 0.67$ mg a.i./L indicates that Naphthalene is highly toxic, on an acute basis, to rainbow trout.
- D. Adequacy of the Study:
 1. Validation Category: Core
 2. Rationale: Meets EPA Guideline requirements

15. Completion of the One-Liner:

DATA EVALUATION REPORT

1. Chemical: Naphthalene
2. Test Material: Technical
3. Study/Action Type: Freshwater Invertebrate Acute EC₅₀ (154-9)
4. Study Identification: 1,4-Dimethylnaphthalene-Acute Toxicity to daphnids (*Daphnia magna*) under flow-through conditions. By Arthur E. Putt, Study Director. Prepared By Springborn Laboratories, Inc., October 8, 1993 Study ID.#: 13117.0693.6102.115. Submitted By Springborn Laboratories, Wareham, Massachusetts, EPA Acc. No. 430825-21.

5. Reviewed By: David C. Bays, PhD
Biotech Review Team
EFED

Robert Pilsucki, PhD.
Biotech Review Team
EFED

Signature: 

Date: 8/31/94

Signature: 

Date: 8/31/94

6. Conclusions:

The study is scientifically sound and demonstrated an EC₅₀ = 0.54 mg/L. This indicates that Naphthalene is highly toxic to freshwater invertebrates. The no-effect concentration at 48 hours was found to be 0.10 mg/L. The study fulfills EPA Guideline requirements for an acute toxicity test for freshwater invertebrates.

7. Recommendations: N/A

8. Background:

This study was submitted to support the request for the registration of the biochemical pesticide 1,4-dimethylnaphthalene.

10. Materials and Methods:

- A. Test Organisms: Test specimens of *Daphnia magna* were obtained from in-house cultures maintained by Springborn Laboratories. During a holding period, the daphnids were fed a mixture of trout food suspension and a unicellular green algae (*Ankistrodesmus falcatus*) once daily.
- B. Dosage Form: The test material, a clear liquid, was characterized as 96.4% active ingredient and having negligible solubility in water.
- C. Referenced Protocol: The test system employed a diluter

which was calibrated to inject a stock solution into a mixing chamber which continuously stirred the solution. A mechanical injector delivered the proper amount of stock solution to each 1.6 L glass battery jar that corresponded to each test concentration. Ten daphnids/beaker (<24 hours old) were used and were added to each beaker within 30 minutes of test solution preparation. Preliminary experiments were conducted using the following exposure concentrations: 0.10, 0.50, 1.0, 5.0 mg a.i./L; 0.16, 0.26, 0.43, 0.72 and 1.2 mg a.i./L; and 0.65, 1.1, 1.8, 3.0, 5.0 mg a.i./L. Based on these results, the mean measured concentrations of 0.21, 0.33, 0.56, 0.94 and 2.2 mg a.i./L were used in this study.

The water quality parameters of temperature, dissolved oxygen and pH were measured at 0- and 48- hours and were determined to be within acceptable limits (Temp. = $20 \pm 2^\circ\text{C}$; pH = 7.9-8.3; Dissolved oxygen = 8.3-8.8 mg/L). Observations for mortality and sub-lethal responses were made at 0, 24, and 48 hours.

- D. Statistical Analysis: The EC_{50} values and 95% confidence limits were calculated using the computer program of C.E. Stephan, which uses probit analysis, the moving average-angle method, or binomial probability method with nonlinear interpolation.

12. Reported Results:

| <u>Dosage(mg/l)</u> | <u>Replicate</u> | <u>Number Dead/Number Exposed (At 48 hours After Dosing)</u> |
|---------------------|------------------|--|
| Control | A | 0/10 |
| | B | 0/10 |
| Solvent Control | A | 0/10 |
| | B | 0/10 |
| 0.056 | A | 0/10 |
| | B | 0/10 |
| 0.10 | A | 0/10 |
| | B | 0/10 |
| 0.18 | A | 0/10 |
| | B | 10/10 |
| 0.31 | A | 0/10 |
| | B | 10/10 |
| 0.48 | A | 10/10 |
| | B | 10/10 |

$EC_{50} = 0.54$ mg a.i./L (95% confidence levels=0.33 to 0.94 mg a.i./L-calculated by binomial probability)

13. Study Author's Conclusions/Quality Assurance Measures:

$EC_{50} = 0.54$ mg a.i./L

"The data and report prepared for 1,4-Dimethylnaphthalene-Acute Toxicity To Daphnids (*Daphnia magna*) Under Flow-Through Conditions were produced and compiled in accordance with all pertinent U.S. EPA Good Laboratory Practice Standards; Pesticide Programs (40 CFR 160) with only minor exceptions which did not affect the integrity of the study or the interpretation of the test results. "

Signed by study director: Arthur E. Putt, Study Director

14. Reviewer's Discussion and Interpretation of the Study:

- A. Test Procedures: The procedures used followed those recommended by EPA in Section 154-9 of the EPA Registration Guidelines (Pesticide Assessment Guidelines, FIFRA Subdivision M, Microbial and Biochemical Pest Control Agents).
- B. Statistical Analysis: Computer program of C. E. Stephan.
- C. Discussion/Results: An $EC_{50} = 0.54$ mg a.i./L indicates that Naphthalene is highly toxic, on an acute basis, to daphnids.
- D. Adequacy of the Study:
1. Validation Category: Core
 2. Rationale: Meets EPA Guideline requirements

15. Completion of the One-Liner:

Master Label

1,4SIGHT®

Aerosol Grade - Potato Dormancy Enhancer

Product Benefits:

- Naturally occurring plant biochemical delays sprouting, so smaller buds on potatoes; [and/or]
- Enhances the potato's ability to heal cuts and bruises; [and/or]
- Reduces respiration, resulting in less water loss; [and/or]
- Reduces refrigeration and ventilation needs; [and/or]
- Reduces pressure bruising; [and/or]
- Firmer potatoes with improved visual appearance.

| | |
|---|-----------|
| Active Ingredient: 1,4-Dimethylnaphthalene* | By Weight |
| Inert Ingredients: | 97.4% |
| TOTAL | 2.6% |
| | 100.0% |

* Contains 8.2 pounds active ingredient per gallon.

Keep Out of Reach of Children

WARNING

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

First Aid

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

| | |
|-------------------------------|---|
| If in eyes | <ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.• Call a poison control center or doctor for treatment advice. |
| If swallowed | <ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person. |
| If on skin or clothing | <ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice. |

Emergency Information

For spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300.

Environmental Hazards

This product is highly toxic to freshwater fish and aquatic invertebrates. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

Net Contents _____

Manufactured For:
D-I-1-4, Inc.
P.O. Box 860
Meridian, ID 83680 USA

EPA Reg. Number 67727-1
EPA Est. Number 68738-JPN-001
Made in Japan
Revision D-3-S

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE

- Keep container closed. This product temporarily inhibits germination of seed potatoes.

PESTICIDE DISPOSAL

- Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

- Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Do not reuse empty container.

Continue Directions for Use on Reverse

NOTICE

- 1,4SIGHT® is used as an aerosol to enhance the dormancy of potatoes during the storage phase.
- Applicators and other handlers must wear: long-sleeved shirt, long pants, shoes, socks, protective eyewear (goggles or face shield), and chemical resistant (such as nitrile or butyl) gloves.
- For reentry into treated areas during application and prior to ventilation or settling of aerosol fog, workers must wear: coveralls over long-sleeved shirt, long pants, shoes plus socks, and chemical resistant (such as nitrile or butyl) gloves; face-sealing goggles, unless a full-face respirator is worn; and a respirator with an organic vapor-removing cartridge with a pre-filter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G) or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P or HE prefilter.
- 1,4SIGHT® must not be applied to potatoes in the field.
- 1,4SIGHT® may be applied anytime after the potatoes are placed into the storage area.
- 1,4SIGHT® is a short term dormancy enhancer which should not adversely affect eventual germination of seed potatoes.
- Let 60 days elapse before using a treated storage area as a temporary holding area for seed potatoes. Air system components (including ducts) and building must be thoroughly ventilated before area is used for storage of seed potatoes to prevent dormancy effects.
- Do not allow vapors to come in contact with storage areas used for seed potatoes within 60 days of their planting.

FORCED AIR DISTRIBUTION METHOD

1. Prepare aerosol generating equipment. The discharge from the vaporizer should be located to provide optimum distribution in the storage area. Take precautions to prevent the spray from coming into direct contact with the potatoes.
2. Running fans during the application may aid disbursement of vapors, but is not required.
3. It is advantageous to keep the storage area closed as long as practical to allow for maximum absorption into the potatoes.

TREATMENT OF STORAGE AREAS THAT DO NOT HAVE RECIRCULATING AIR SYSTEMS

These storage areas are more difficult to treat. Additional steps must be taken to treat these storage areas.

1. Prepare aerosol generating equipment. The discharge from the vaporizer should be located to provide optimum distribution in the storage area. Take precautions to prevent the spray from coming into direct contact with the potatoes.
2. Completely close off the area to be treated. This may include vent doors in the attic and walk doors around the perimeter. The large truck doors may need to be sealed to prevent excess leakage.
3. Begin treatment by following the listed steps:
 - A. Start the aerosol generator.
 - B. Adjust the location of the vaporizer so all the storage area receives an equal amount of aerosol fog. It may be necessary to move the vaporizer during the application or make the application in multiple phases. For reentry into treated areas during application and prior to ventilation or settling of the

aerosol fog, workers must wear: coveralls over long-sleeved shirt, long pants, shoes plus socks, and chemical resistant (such as nitrile or butyl) gloves; face-sealing goggles, unless a full-face respirator is worn; and a respirator with an organic vapor-removing cartridge with a pre-filter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G) or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P or HE prefilter.

4. Wait at least 12 hours before fresh air is introduced into the storage area, then return the storage area to "normal" operation.
5. It is advantageous to keep the storage area closed as long as practical to allow for maximum absorption into the potatoes.

APPLICATION TIMING AND RATES

Application of 1,4SIGHT® can be made anytime after the potatoes are placed in the storage area.

1. Apply at rates of up to 1 pound of active ingredient per 50,000 lbs (500 cwt), which is equivalent to 20 ppm on a product to potato basis or 1 gallon per 4,000 cwt.
2. While potatoes may be retreated as necessary for effective control, do not exceed the maximum application of 80 ppm during the storage season.

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| 1 cwt. = 100 lbs = 2.5 cubic feet; 1 ton = 20 cwt. |
|--|

CONDITIONS OF SALE

D-I-1-4, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.

Master Label

1,4SEED™

Aerosol Grade - Seed Potato Dormancy Enhancer

Product Benefits:

- Naturally occurring plant biochemical delays sprouting, resulting in more vigorous seed growth; [and/or]
- Enhances the potato's ability to heal cuts and bruises; [and/or]
- Reduces respiration, resulting in less water loss; [and/or]
- Reduces Refrigeration and ventilation needs; [and/or]
- Reduces pressure bruising; [and/or]
- Firmer potatoes with improved visual appearance.

| | |
|---|-----------|
| Active Ingredient: 1,4-Dimethylnaphthalene* | By Weight |
| Inert Ingredients: | 98.4% |
| TOTAL | 1.6% |
| | 100.0% |

* Contains 8.3 pounds active ingredient per gallon.

Keep Out of Reach of Children

WARNING

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

First Aid

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

| | |
|-------------------------------|---|
| If in eyes | <ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.• Call a poison control center or doctor for treatment advice. |
| If swallowed | <ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person. |
| If on skin or clothing | <ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice. |

Emergency Information

For spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300.

Environmental Hazards

This product is highly toxic to freshwater fish and aquatic invertebrates. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

Net Contents _____

Manufactured For:
D-I-1-4, Inc.
P.O. Box 860
Meridian, ID 83680 USA

EPA Reg. Number 67727-3
EPA Est. Number 68738-JPN-001
Made in Japan
Revision 1

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE

- Keep container closed. This product temporarily inhibits germination of seed potatoes.

PESTICIDE DISPOSAL

- Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

- Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. Do not reuse empty container.

Continue Directions for Use on Reverse

NOTICE

- 1,4SEED™ is used as an aerosol to enhance the dormancy of seed potatoes prior to germination.
- Applicators and other handlers must wear: long-sleeved shirt, long pants, shoes, socks, protective eyewear (goggles or face shield), and chemical resistant (such as nitrile or butyl) gloves.
- For reentry into treated areas during application and prior to ventilation or settling of aerosol fog, workers must wear: coveralls over long-sleeved shirt, long pants, shoes plus socks, and chemical resistant (such as nitrile or butyl) gloves; face-sealing goggles, unless a full-face respirator is worn; and a respirator with an organic vapor-removing cartridge with a pre-filter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G) or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P or HE prefilter.
- 1,4SEED™ must not be applied to potatoes in the field.
- 1,4SEED™ may be applied anytime after the potatoes are placed into the storage area.
- Do not allow vapors to come in contact with storage areas used for seed potatoes within 60 days of their planting.

FORCED AIR DISTRIBUTION METHOD

1. Prepare aerosol generating equipment. The discharge from the vaporizer should be located to provide optimum distribution in the storage area. Take precautions to prevent the spray from coming into direct contact with the potatoes.
2. Running fans during the application may aid disbursement of vapors, but is not required.
3. It is advantageous to keep the storage area closed as long as practical to allow for maximum absorption into the potatoes.

TREATMENT OF STORAGE AREAS THAT DO NOT HAVE RECIRCULATING AIR SYSTEMS

These storage areas are more difficult to treat. Additional steps must be taken to treat these storage areas.

1. Prepare aerosol generating equipment. The discharge from the vaporizer should be located to provide optimum distribution in the storage area. Take precautions to prevent the spray from coming into direct contact with the potatoes.
2. Completely close off the area to be treated. This may include vent doors in the attic and walk doors around the perimeter. The large truck doors may need to be sealed to prevent excess leakage.
3. Begin treatment by following the listed steps;
 - A. Start the aerosol generator.
 - B. Adjust the location of the vaporizer so all the storage area receives an equal amount of aerosol fog. It may be necessary to move the vaporizer during the application or make the application in multiple phases. For

reentry into treated areas during application and prior to ventilation or settling of the aerosol fog, workers must wear: coveralls over long-sleeved shirt, long pants, shoes plus socks, and chemical resistant (such as nitrile or butyl) gloves; face-sealing goggles, unless a full-face respirator is worn; and a respirator with an organic vapor-removing cartridge with a pre-filter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P or HE prefilter.

4. Wait at least 12 hours before fresh air is introduced into the storage area, then return the storage area to "normal" operation.
5. It is advantageous to keep the storage area closed as long as practical to allow for maximum absorption into the potatoes.

APPLICATION TIMING AND RATES

Application of 1,4SEED™ can be made anytime after the potatoes are placed in the storage area.

1. Apply at rates of up to 1 pound of active ingredient per 50,000 lbs (500 cwt), which is equivalent to 20 ppm on a product to potato basis or 1 gallon per 4,000 cwt.
2. While potatoes may be retreated as necessary for effective control, do not exceed the maximum application of 80 ppm during the storage season.

| |
|--|
| 1 cwt. = 100 lbs = 2.5 cubic feet; 1 ton = 20 cwt. |
|--|

CONDITIONS OF SALE

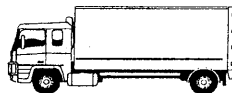
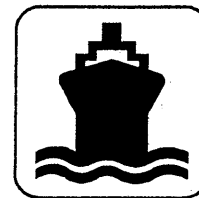
D-I-1-4, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.



Labeling To Be On Outer Box

1,4SHIP™

Ready-To-Use Aerosol Potato Dormancy Enhancer



For Use on Potatoes Prepared for Transportation

| | |
|---|--------------------|
| Active ingredient: 1,4-Dimethylnaphthalene* | By Weight 63.8% |
| Other ingredients: | 36.2% |
| TOTAL | 100% |

* Contains 3.83 ounces active ingredient per can.

Keep Out of Reach of Children

WARNING

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Causes substantial but temporary eye injury. Harmful if swallowed or absorbed through skin. May be harmful if inhaled. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Avoid contact with skin. Avoid breathing spray mist or vapor. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

First Aid

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If Swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

If on Skin or Clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Emergency Information

For spill, leak, fire, exposure, or accident call CHEMTREC 1-800-424-9300.

Physical or Chemical Hazards

Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130 °F may cause bursting. This product contains a highly flammable ingredient. It may cause a fire or explosion if not used properly. Follow the "Directions for Use" on this label very carefully.



HIGHLY FLAMMABLE INGREDIENT INGREDIENTE ALTAMENTE INFLAMABLE

Do Not Smoke During Application or Near Treated Area!
Net Contents 6 ounces

Manufactured For:
D-I-1-4, Inc.
P.O. Box 860
Meridian, ID 83680-0860 USA

EPA Reg. Number 67727-
EPA Est. Number 11623-GA-1
Revision 1

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE

- Store product in unopened, labeled packaging. Do not store product near or expose product to sources of heat, including open flame, sparks, welding operations, etc.

PESTICIDE DISPOSAL

- Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

- Do not puncture or incinerate. Discard container in trash.

NOTICE

- 1,4SHIP™ is a ready-to-use aerosol which enhances the dormancy of potatoes prepared for transportation.
- During and for 30 minutes after the application, do not smoke, weld, cut metal, or allow open flame, high temperature surfaces, or other ignition sources to be near the treated area.
- Applicators and other handlers must wear: long-sleeved shirt, long pants, shoes, socks, protective eyewear (goggles or face shield), and chemical resistant (such as nitrile or butyl) gloves.
- When either a rail car or cold storage room is treated with more than one can, applicators and other handlers must additionally wear a respirator. Refer to the reentry statement below for acceptable respirator type.
- For reentry into treated areas during application or within 30 minutes post-application, for **emergencies** only, workers must wear: coveralls over long-sleeved shirt, long pants, shoes plus socks, and chemical resistant (such as nitrile or butyl) gloves; face-sealing goggles, unless a full-face respirator is worn; and a respirator with an organic vapor-removing cartridge with a pre-filter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G) or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P or HE prefilter.
- 1,4SHIP™ is a short term dormancy enhancer which will not adversely affect eventual germination of seed potatoes.
- Let 60 days elapse before using a treated area as storage of seed potatoes. Air system and building must be thoroughly ventilated before area is used for storage of seed potatoes.
- Do not allow vapors to come in contact with storage areas used for seed potatoes within 60 days of their planting.

APPLICATION OF 1,4SHIP™

(Can graphic to be inserted here - See attached image.)

1. Fill the area to be treated (truck, rail car, shipping container, or cold storage room) with potatoes and close all but the exit door.
2. Turn off all electrical equipment (air circulators, refrigeration, etc.) in the treatment area prior to application. Turn off lighting in treatment area, and allow to cool prior to application.
3. Remove top portion of box by pulling the separator at the arrow symbol. Take out the enclosed 1,4SHIP™ tag and note the date and time of application on the space provided.
4. Position the box(es) containing the can(s) in opposite corners of the treatment area, so vapors will be dispersed throughout the area. In trucks, place box(es) at the end farthest away from the refrigeration unit (near doors).
5. Remove the back side of the double-sided tape and adhere the box containing the can to an inside cargo wall, in an area with some open volume of air around it.
6. Without removing the can from the box, remove the can cap and depress the trigger until it locks.
7. Immediately leave the area and close the exit door.
8. Feed a door seal through the 1,4SHIP™ tag and affix the seal to the exit door.
9. Do not open or enter treated area for at least 30 minutes. Do not start any electrical system within the cargo

area for at least 30 minutes.

10. It is advantageous to keep the treated area closed as long as practical to allow for maximum product absorption into the potatoes.

APPLICATION TIMING AND RATE

Application of 1,4SHIP™ can be made anytime after the potatoes are removed from storage, prepared for shipment, and placed either in a truck, sea-going shipping container, rail car, or a cold storage room. Do not exceed recommended maximum number of cans. At the maximum use rate, this can will treat 20,000 lbs (200 cwt) of potatoes.

1. In trucks and shipping containers, apply at the rate of up to 2 cans per 40,000 lbs (400 cwt) of potatoes.
2. In rail cars, apply at the rate of up to 6 cans per 120,000 lbs (1200 cwt) of potatoes.
3. In cold storage rooms, apply at a maximum rate of 1 can per 1500 cubic feet and 20,000 lbs (200 cwt) of potatoes.

| |
|--|
| 1 cwt. = 100 lbs = 2.5 cubic feet; 1 ton = 20 cwt. |
|--|

CONDITIONS OF SALE

D-I-1-4, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.

D-I-1-4 Inc. Organic Petition
Substance: 1,4-DMN
Page 7

U.S. Environmental Protection Agency Reviews of 1,4-DMN

Attached are the reviews (both toxicity and chemistry) from the Environmental Protection Agency in assessing 1,4-DMN under FIFRA.

Product Registrations and Labels

D-I-1-4 Inc. offers three products for sale containing 1,4-DMN which can be used on post-harvest potatoes. All three products are registered under FIFRA. Sample labels under which the product would be sold are attached. The products are as follows:

1,4Sight, EPA Reg. No. 67727-1

1,4Seed, EPA Reg. No. 67727-3

1,4Ship, EPA Reg. No. 67727-4

D-I-1-4 Inc. Organic Petition
Substance: 1,4-DMN
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Other Scientific and Regulatory Information Relating to 1,4-DMN

We have enclosed a copy the Decision Memo from the EPA, signed by a Program Director at the time 1,4-DMN was registered under FIFRA. This document provides an overview of the chemical from EPA's perspective, supporting their decision to register the product.

In addition, there is an exemption from the requirement of a tolerance for 1,4-DMN under FFDCA. Attached is the Federal Register Notice announcing this decision.

JAN 26 1995

BRIEFING MEMORANDUM

SUBJECT: Registration of 1,4-Dimethylnaphthalene, "1,4SIGHT"
 FROM: Stephen L. Johnson, Director
 Registration Division (7505C)
 TO: Daniel M. Barolo, Director
 Office of Pesticides Programs (7501C)

BACKGROUND

On January 19, 1994, D-I-1-4, Inc, 15401 Cartwright Road, Boise, ID 83703 submitted an application for registration of the product, "1,4SIGHT", as a potato sprout inhibitor, and a pesticide petition (PP 4F4314) requesting that EPA establish an exemption from the requirement of a tolerance for the plant growth regulator, 1,4-Dimethylnaphthalene, for use on potatoes (post harvest).

"1,4SIGHT", a 94.7% pure liquid, is applied to potatoes as an aerosol in storage buildings to inhibit sprout formation at an application rate of 1 pound active ingredient per 50,000 pounds (lbs) (500 Cubic Weight Tons [CWT]) of potatoes, or 20 ppm on a product to potato basis, or 1 gallon of product per 4,000 CWT of potatoes.

Adequate chemistry, toxicological, and ecological effects data have been submitted and reviewed to support the unconditional registration of 1,4-Dimethylnaphthalene, for use on potatoes to inhibit sprouting.

SCIENTIFIC FINDINGS

Toxicological Characteristics

1,4-Dimethylnaphthalene is classified in toxicity categories II [WARNING] based on an eye irritation study and Toxicity category III or IV for the acute oral, acute dermal, acute inhalation, and skin irritation studies. ~~The dermal sensitization study was~~

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| DATE | 1/17/95 | 1/24/95 | 1/24/95 | 1/26/95 | | | |

An Ames mutagenicity study, an in-vitro test for unscheduled DNA synthesis, and a in-vivo Micronucleus Assay were negative. No hypersensitivity Incidents were reported.

Waiver requests of the 90-day feeding, immune response and teratogenicity studies were accepted based on the lack of significant toxicity demonstrated by the studies submitted, insignificant exposure from the proposed use, and natural occurrence in food.

1,4-Dimethylnaphthalene has been classified as a biochemical since 1,4-Dimethylnaphthalene is naturally occurring in potatoes at levels between 1 and 10 ppm and it is intended to be used as a plant growth regulator. When conditions are right for sprouting, the potato metabolizes the 1,4-Dimethylnaphthalene to low enough levels that sprouting can occur. Preliminary results demonstrate adequate sprout inhibition at levels of 3-6 mg/cubic meter.

ECOLOGICAL CHARACTERISTICS

1,4-Dimethylnaphthalene was shown to be practically non-toxic to avian species, and highly toxic to fish and fresh water invertebrates.

Based on the toxicity data, low application rate, and use indoors, 1,4-Dimethylnaphthalene will cause minimal risk to mammalian, avian, and aquatic fish and invertebrate life. The following environmental hazard precautionary statements are required to appear on the "1,4SIGHT" label to mitigate any risk:

Environmental Hazards Statements

This product is highly toxic to freshwater fish and aquatic invertebrates. Do not contaminate water when disposing of equipment washwaters.

TOLERANCE ASSESSMENT

Acceptable daily intake (ADI) and maximum permissible intake (MPI) considerations are not relevant to this action. No enforcement proceedings are expected. Therefore, the requirement for an analytical method for enforcement purposes is not applicable to this exemption request. It is appropriate to establish an exemption from the requirement of a tolerance for residues of the plant growth regulator, 1,4-Dimethylnaphthalene, when applied post harvest to potatoes in accordance with good agricultural practices.

BENEFITS

1,4-Dimethylnaphthalene is intended to be a safer replacement for chlorpropham.

RECOMMENDATION

I recommend that you concur with the Section 3(c)(5) registration of 1,4-Dimethylnaphthalene.

CONCUR:



DO NOT CONCUR:

DATE:

JAN 27 1995

OHIO—OZONE—Continued

| Designated area | Designation | | Classification | |
|---|----------------------|-------------|-------------------|------|
| | Date ¹ | Type | Date ¹ | Type |
| Staubenville Area, Jefferson County | March 10, 1995 | Attainment. | | |

¹ This date is November 15, 1990, unless otherwise noted.

* * * * *
 [FR Doc. 95-3072 Filed 2-7-95; 8:45 am]
 BILLING CODE 6560-50-P

40 CFR Part 180
 [PP 4F4314/R2104; FRL-4932-4]
 RIN 2070-AB78

1,4-Dimethylnaphthalene; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).
 ACTION: Final rule.

SUMMARY: EPA establishes an exemption from the requirement of a tolerance for residues of the potato sprout inhibitor 1,4-dimethylnaphthalene from the postharvest application to potatoes. D-I-1-4, Inc., requested this exemption.
EFFECTIVE DATE: This regulation becomes effective February 8, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 4F4314/R2104], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing request filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington DC 20450. In Person, bring copy of objections and hearing request to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 277M, Pittsburgh, PA 15251.

FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Product Manager (PM) 22, Registration Division, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Office location and telephone number: Rm. 229, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703) 305-5540.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the Federal Register of March 30, 1994 (59 FR 14854), which announced that D-I-1-4, Inc., 15401 Cartwright Rd., Boise, ID 83703, had submitted pesticide petition (PP) 4F4314 to EPA requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), establish an exemption from the requirement of a tolerance for the plant growth regulator 1,4-dimethylnaphthalene for use on potatoes (post-harvest).

There were no comments received in response to this notice of filing. The data submitted in the petition and all other relevant material have been evaluated. The toxicological data considered in support of the exemption from the requirement of a tolerance include:

1. A rat acute oral study with an LD₅₀ of 2,730 milligrams (mg)/kilogram (kg).
2. A rabbit acute dermal study with an LD₅₀ greater than 2 grams (g)/kg.
3. A rat acute inhalation study with an LD₅₀ greater than 4.16 mg/Liter (L).
4. A rabbit primary eye irritation study with moderate irritation that dissipated by day 14.
5. A rabbit primary dermal irritation study with moderate irritation that dissipated by day 14.
6. A guinea pig dermal sensitization study with no apparent sensitization.
7. An Ames mutagenicity study that was negative in the presence and absence of metabolic activation homogenate.
8. An in vitro test for unscheduled DNA synthesis in rat liver primary cell culture that was negative.
9. A in vivo micronucleus assay that was negative.
10. No hypersensitivity incidents were reported.

1,4-Dimethylnaphthalene has been classified as a biochemical as defined by 40 CFR 158.65. Biochemical pesticides

are distinguished by their unique nontoxic mode of action, low use volume, target specificity, and natural occurrence. 1,4-Dimethylnaphthalene is naturally occurring in potatoes at levels between 1 and 10 ppm. When conditions are right for sprouting, the potato metabolizes 1,4-dimethylnaphthalene to a low enough level so that sprouting can occur. 1,4-Dimethylnaphthalene is applied to potatoes at a 2.5 ppm level up to 4 applications as a plant growth regulator during the storage season, which generally runs from October to August, to keep 1,4-dimethylnaphthalene at a sufficient concentration in the potato to continue to inhibit sprouting.

The results of the toxicity studies provided, the low-volume use pattern, and the fact that use of the product will not increase levels of 1,4-dimethylnaphthalene above levels normally found in potatoes are sufficient to demonstrate that there are no foreseeable human health hazards likely to arise from the use of the product as a potato sprout inhibitor. Because no enforcement residue level is established by this exemption, the requirement for an analytical method for enforcement purposes is not applicable to this exemption request.

1,4-Dimethylnaphthalene is considered useful for the purposes for which the exemption is sought. Based on the information and data considered, the Agency concludes that the establishment of a tolerance is not necessary to protect the public health. Therefore, the exemption from requirement of a tolerance is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections and/or request a hearing with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the

regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fees provided by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, and the requestor's contentions on each such issue, and a summary of the evidence relied upon by the objection (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: there is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve on or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in

the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recording and recordkeeping requirements.

Dated: January 27, 1995.

Daniel M. Barolo,
Director, Office of Pesticide Programs.

Therefore, 40 CFR Part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In subpart D, by adding new § 180.1142, to read as follows:

§ 180.1142 1,4-Dimethylnaphthalene; exemption from the requirement of tolerance.

An exemption from the requirement of a tolerance is established for residues of the plant growth regulator 1,4-dimethylnaphthalene when applied post harvest to potatoes in accordance with good agricultural practices.

[FR Doc. 95-2821 Filed 2-7-95; 8:45 am]
BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[PP 5F3188/R2107; FRL-4933-6]

RIN 2070-AB78

Pesticide Tolerances for Paraquat

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes tolerances for residues of the dessicant, defoliant, and herbicide paraquat (1,1'-dimethyl-4,4'-bipyridinium ion) derived from the application of either the bis(methyl sulfate) or dichloride salt (both calculated as the cation) in or on the raw agricultural commodities (RACs) rice grain and rice straw. Zeneca Agricultural Products requested the establishment of these maximum permissible residues of the herbicide.

EFFECTIVE DATE: This regulation becomes effective February 8, 1995.

ADDRESSES: Written objections, identified by the document control number, [PP 5F3188/R2107], may be

submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OIP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

FOR FURTHER INFORMATION CONTACT: By mail: Robert J. Taylor, Product Manager (PM 25), Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 241, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6027.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 21, 1994 (59 FR 65744), EPA issued a proposed rule that gave notice that Zeneca Agricultural Products, 1800 Concord Pike, Wilmington, DE 19897, had submitted to EPA a pesticide petition, PP 5F3188, under section 408 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a, to establish tolerances for the desiccant, defoliant, and herbicide paraquat (1,1'-dimethyl-4,4'-bipyridinium ion) derived from the application of either the bis(methyl sulfate) or dichloride salt (both calculated as the cation) in or on the raw agricultural commodities rice grain at 0.05 part per million (ppm) and rice straw at 0.06 ppm.

There were no comments or requests for referral to an advisory committee received in response to the proposed rule.

The data submitted in the petition and other relevant material have been evaluated and discussed in the proposed rule. Based on the data and information considered, the Agency concludes that the tolerances will protect the public health. Therefore, the tolerances are established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections and/or request a hearing with the Hearing Clerk, at the address given

D-I-1-4 Inc. Organic Petition
Substance: 1,4-DMN
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Peer-Reviewed Literature Summary

Attached is a summary document of the peer-reviewed literature addressing the efficacy of 1,4-DMN in suppressing potato sprouting. Referenced articles can be supplied upon request.

Summary of Literature Regarding Use of 1,4-DMN as a Potato Sprout Inhibitor

It has been known for many years that potato dormancy is a naturally occurring event that is triggered by endogenous biochemicals found within the tuber. As early as 1952, scientists observed that stored potatoes contain "volatile chemicals" capable of inhibiting sprout growth (1, 2). Since then, more than twenty naturally occurring volatile biochemicals have been identified as evolving from stored potatoes. These biochemicals include citral, coumarin, limonene, methyl salicylate, and the 1,4-, 1,6-, and 2,3- isomers of dimethylnaphthalene (3).

When the volatile biochemicals were tested for sprout suppressing activity, the 1,4- and 1,6-dimethylnaphthalene isomers showed the greatest potency (4). Since then, several other laboratories have independently examined the sprout inhibiting properties of chemicals derived from potato tubers, and have confirmed the efficacy of 1,4-dimethylnaphthalene. In 1981, John Beveridge and his associates examined the sprout suppressant properties of twenty volatile substances that they isolated from potatoes and concluded that only benzothiazole and 1,4-dimethylnaphthalene had sprout suppressant activity sufficient for development as a commercial pesticide (3). 1,4-Dimethylnaphthalene was reported to be as efficacious as chlorpropham (5).

In 1985, Filmer and Rhodes confirmed the earlier studies by independently evaluating volatile biochemicals that they isolated from potatoes (6). Sprout inhibition was measured in a very sensitive bioassay using excised potato shoot tips. Diphenylamine, 3-methyl diphenylamine, and 1,4-dimethylnaphthalene exhibited the greatest sprout suppression. Thus, Filmer and Rhodes confirmed both the natural occurrence of 1,4-dimethylnaphthalene in potatoes and its efficacious sprout suppression activity.

Other independent scientists have continued to examine the sprout suppressing (potato dormancy enhancing) ability of the biochemical. As recently as 1997, the efficacy of chlorpropham and 1,4-dimethylnaphthalene was again compared by the National Potato Council at the Idaho Experimental Station. This study once again showed that 1,4-dimethylnaphthalene has sprout suppressant activity comparable to that of chlorpropham (7).

In addition to the many independently conducted studies described above which provide repeated confirmation of the efficacious sprout suppression activity of 1,4-dimethylnaphthalene, in 1994 a new study was undertaken by the University of Tasmania in collaboration with the Australian Horticultural Research & Development Corporation to test the efficacy of alternative potato sprout suppressants (8). The project was initiated because the continued use of chlorpropham in Australia was uncertain due to outstanding product safety issues. The efficacy of several naturally occurring and synthetic sprout suppressants was simultaneously evaluated. When the two year study was completed and the resulting data carefully reviewed, the project scientists concluded that "The most promising new sprout suppressant is the single isomer of DMN which has recently been registered with the EPA" as a commercial alternative to chlorpropham. The project report once again confirms the efficacy of 1,4-dimethylnaphthalene by stating "1-4 Sight was shown to be a potent sprout inhibitor."

References

1. Burton, W.G. 1952. Studies on the Dormancy and Sprouting of Potatoes. III. The effect upon sprouting of volatile metabolic products other than carbon dioxide. *New Phytologist* 51:154-162.
2. Burton, W.G. and Meigh, D.F. 1971. The Production of Growth Suppressing Volatile Substances by Stored Potatoes. *Potato Research* 14:96-101.
3. Beveridge, J.L., Dalziel, J. and Duncan, H.J. 1981. The Assessment of Some Volatile Organic Compounds as Sprout Suppressants for Ware and Seed Potatoes. *Potato Research* 24:61-76.
4. Meigh, D.F., Filmer, A.A., and Self, R. 1973. Growth Inhibitory Volatile Aromatic Compounds Produced by *Solanum tuberosum* Tubers. *Phytochemistry* 12:987-993.
5. Beveridge, J.L., Dalziel, J. and Duncan, H.J. 1981. Dimethylnaphthalene as a Sprout Suppressant for Seed and Ware Potatoes. *Potato Research* 24:77-88.
6. Filmer, A.A. and Rhodes, J.C. 1985. Investigation of Sprout-Growth-Inhibitory Compounds in the Volatile Fraction of Potato Tubers. *Potato Research* 28:361-377.
7. Lewis, M.D., Kleinkopf, G.E. and Shetty, K.K. 1997. Dimethylnaphthalene and Diisopropylnaphthalene for Potato Sprout Control in Storage. *American Potato Jnl.* 74:183-188.
8. Baker, A. 1995. Use of Natural Sprouting Inhibitors for Potato Storage. Final report from the Horticultural Research & Development Corporation, Australia.

Petition Justification Statement

1,4-DMN is a naturally occurring biochemical that is found in potatoes and in other vegetables. About fifty years ago scientists showed that potatoes produce this biochemical, which is involved in inhibiting sprouting during the plant's natural dormant stage.

1,4-DMN was first isolated via extraction from potatoes over forty years ago. Its biochemical action produced sprout suppressant activity at a level warranting development as a commercial sprout inhibitor. Today, products containing 1,4-DMN are used to enhance the dormancy stage of potatoes, thereby delaying sprouting. These products allow potatoes that might otherwise sprout and rot, to be held in storage and to delay sprouting during transportation of the potato crop. 1,4-DMN is the only alternative in the United States to a conventional (chlorinated) chemical, chlorpropham, which is also used to inhibit sprouting.

While 1,4-DMN naturally occurs in vegetables, the cost involved in extraction methods make it unfeasible to rely upon extraction to produce commercial quantities. As 1,4-DMN is efficacious at relatively low levels, it is correspondingly available in only small amounts in individual plants and tubers. Therefore, methods have been developed to produce 1,4-DMN in laboratory and manufacturing settings in sufficient quantities for commercialization.

The synthesized 1,4-DMN is chemically identical to the compound as it naturally occurs. The substantially lower cost of producing synthesized material enables it to be highly competitive and attractive to growers for use as a potato sprout suppressant.

At present, the grower of organic potatoes has no longer-term means for controlling sprouting during potato storage. A full 90% of the potatoes produced in the United States are harvested in the fall, with the remaining 10% of varieties reaching maturity during the winter, spring, or summer. Nearly half of all potatoes in the U.S. are placed in storage facilities, so that the potato crop can be released throughout the year to the fresh market and processed food industries. The time periods involved in storage range from several months to a year. Commercial sprout inhibitors enable this storage period by delaying sprouting and enhancing dormancy. Approximately 60% of all U.S. potatoes are aided by commercial sprout inhibitors either during storage, packaging, or in transportation.

The organic grower is limited to varieties with a few months natural dormancy period. The organic grower has no alternative to 1,4-DMN for maintaining potato

dormancy for up to a year. Lowering the temperature of the storage facility (refrigeration) provides only an inefficient short-term means of control, and ultimately causes the potato to sweeten. These stored potatoes cannot be used for processing into potato chips or French fries because the excess sugars that were formed at the cold storage temperature cause the potato pulp to turn dark during processing. When removed from storage, organic potatoes very rapidly sprout on the grocer's shelf, resulting in a minimal shelf life. Organic growers are thus confined to relying on a few varieties which allow limited storage, and then use physical means to detach sprouts when potatoes are removed from storage.

In contrast, potatoes treated with 1,4-DMN can be stored for up to one year with no change in quality. The only other sprout inhibitor on the market, chlorpropham, is a chlorinated chemical not available to the organic grower. Between the two, however, processing plants prefer potatoes that have been suppressed with 1,4-DMN rather than with chlorpropham. If 1,4-DMN is made available to organic potato growers, they will not only be able to penetrate the processed food market, they will be able to successfully compete with the general potato grower by offering high quality organically-produced potatoes throughout the year.