



US Environmental Protection Agency Office of Pesticide Programs

**BIOPESTICIDE REGISTRATION ACTION DOCUMENT
Puccinia thlaspeos 'strain woad' (PC Code 006489)**

June 2002

BIOPESTICIDES REGISTRATION ACTION DOCUMENT

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(PC Code 006489)

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
June 2002

BIOPESTICIDES REGISTRATION ACTION DOCUMENT TEAM

Office of Pesticide Programs

Biopesticides and Pollution Prevention Division

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I. ABSTRACT

Identification of microbe: *Puccinia thlaspeos* 'strain woad', also known as dyer's woad rust, is a rust fungus that will be used to control dyer's woad (*Isatis tinctoria*), a noxious weed in 8 western states. Woad Warrior, the only registered pesticide product containing this rust, consists of pieces of dyer's woad leaves infected with the rust.

Major scientific findings: Discovered in 1979 in southern Idaho, dyer's woad rust appears to be a new strain of a naturally occurring rust. Like many rusts, it can be grown only on its host plant. Despite extensive testing, the rust's only known host is dyer's woad, which grows in semi-arid regions in the western U.S. The rust's specificity and ease of application makes it especially suitable for controlling this weed.

Human health risk findings: No human health risks are expected. The rust is not toxic or infective to mammals, and does not develop at human body temperature. There have been no reports of health problems among workers who have handled the rust during the past ten years.

Ecological risk findings: No ecological risks are expected to animals in general, including mammals, birds, fish, and insects, or to non-target plants. Researchers have not found the rust on plants in the vicinity of infected woad, and have not been able to infect any of the numerous plants tested as potential hosts.

Risk mitigation and regulatory decisions: Workers are required to wear personal protective equipment to prevent dermal and inhalation exposure. The restricted entry interval (REI) is four hours.

II. OVERVIEW

A. Active Ingredient

- **Microbe Name:** *Puccinia thlaspeos* 'strain woad'
- **Trade and Other Names:** Woad Warrior; dyer's woad rust
- **OPP Chemical Code:** 006489
- **Basic Manufacturer:** Greenville Farms,
1689 N. 1200 E.
N. Logan, Utah 84341

B. Use Profile

Type of Pesticide: Microbial herbicide

Mechanism of action: Microbe infects first year plants in the spring and interferes with flower and seed formation the following year.

Use Sites: Farms, rangeland, waste areas, roadsides. Not for use on crops

Target Pests for Active Ingredient: *Isatis tinctoria* (dyer's woad)

Formulation Types Registered: The only registered product is an end product powder called Woad Warrior that is 100% active ingredient (7.6×10^9 teleospores/pound)

Method and Rates of Application:

Types of Treatment: Apply as a spray or powder directly to soil and young plants.

Equipment: Woad Warrior can be sprayed with most types of spray equipment. However, because particles are large, remove screens and spray orifice to prevent blockage. For dry application, use equipment that will shake or spread the product on soil and young plants. Better results are obtained if the spores are applied before or during a rain.

Timing : Apply in April or May when new plants are beginning their growth. One application is usually sufficient, since the rust spreads by itself. In areas heavily infested with dyer's woad, it may be necessary to repeat the application in subsequent years.

Rate of Application: Woad Warrior is applied at 7 lb/acre (1 lb/ 6000 sq.ft.)

Method of Application: The product can be diluted with water according to label directions and sprayed from the ground or air, or the powder can be spread directly.

C. Regulatory History

Greenville Farms was granted a one-year Experimental Use Permit (EUP) on March 1, 2001 for use of up to 83 pounds of Woad Warrior on a total of 12 acres of rangeland in the state of Utah (66 Federal Register 28487 (May 23, 2001). On November 14, 2001, the company submitted an application for full registration of Woad Warrior. The receipt of application was announced in 67 Federal Register, 10717-8 (March 8, 2002) with a 30-day comment period. No comments have been received. Because the registrant did not propose any food use, there was no need to consider a tolerance or exemption from a tolerance. On June 6, 2002, *Puccinia thlaspeos* ‘strain woad’ was unconditionally registered as a new active ingredient under Section 3(c)5 of FIFRA.

III. SCIENCE ASSESSMENT

A. Physical and Chemical Properties Assessment

1. Product Identity

Puccinia thlaspeos ‘strain woad’ (dyer’s woad rust) was discovered in 1979 in southern Idaho growing naturally on dyer’s woad, a plant recognized as a noxious weed in 8 western states. This rust is being registered to control the further spread of the weed.

The rust fungi are a diverse group of Basidiomycetes that have complex life cycles. All the rusts are obligate parasites and are either difficult or impossible to culture in a laboratory. To complete their life cycles, many rusts alternate between two specific plant hosts. Other rusts, such as *Puccinia thlaspeos* and *P. holboellii*, have a simpler life cycle and require only a single host species. In either case, the rusts generally have narrow host ranges and infect only their host plant(s) or a few plant species that are closely related to their host plants. None of the rusts have been reported to infect organisms in the animal kingdom (e.g., mammals, insects).

Puccinia thlaspeos ‘strain woad’ appears to be a new rust strain, closely related taxonomically to the *P. monoica* complex of rusts. The woad rust was tested on likely and known hosts of the *P. monoica* complex of rusts, but the woad rust infected only *Isatis tinctoria* (dyer’s woad).

EPA has classified *Puccinia thlaspeos* ‘strain woad’ as a microbial pesticide active ingredient. The end product, Woad Warrior, contains living teleospores on ground-up leaf pieces of infected dyer’s woad. The only known way to grow and harvest the rust requires growing it on dyer’s woad. The rust teleospores produce infective basidiospores at 10 - 20 degrees C, with optimum production at 15 degrees C, and no production at 25 degrees C.

Product chemistry data that support the registration of *Puccinia thlaspeos* ‘strain woad’ are summarized in Table 1.

Table 1. Physical and Chemical Properties for Woad Warrior

| OPPTS GUIDELINE Number | STUDY | RESULT | MRID# |
|--|--|----------------|--------------|
| 885.1100 | Product Identity and Disclosure of Ingredients | Acceptable | 45550901 |
| 885.1200 | Manufacturing Process | Acceptable | 45550901 |
| 885.1300 | Formation of Unintentional Ingredients | Acceptable | 45550901 |
| 885.1400 | Analysis of Samples | Acceptable | 45550901 |
| 885.1500 | Certification of Limits | Acceptable | 45550901 |
| 830.6302, 830.6303, 830.6304, 830.7000, 885.7300 | Product Chemistry | Not applicable | |

B. Human Risk Assessment

There is a reasonable certainty that no harm will result from human exposure to *Puccinia thlaspeos* ‘strain woad’. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. All toxicity study requirements concerning human risk assessment were waived.

1. Human Toxicity Assessment

a. Acute Toxicity

EPA has examined available data on *Puccinia thlaspeos* ‘strain woad’ and has agreed to waive all the mammalian toxicology data requirements (See Table 2) for the following reasons:

1. Rust species infect only plants.
2. No evidence suggests any infectivity or toxicity to mammals.
3. Literature searches found no reports of rust toxicity or infectivity in mammals.

4. Although allergic (hypersensitivity) reactions are possible, no ill effects have been seen among the many individuals who have handled this rust in the past 10 years.
5. Spores of dyer's woad rust do not develop at or above 25 degrees C; therefore, the rust cannot survive at mammalian body temperatures.
6. Human exposure has already occurred and is continuing to increase with no reported human health effects.

Table 2. Human Toxicity Study Waivers Granted

| Guideline No. | Type of Study |
|----------------------|--|
| 152A-10 (885.3050) | Acute oral toxicity/pathogenicity |
| 152A-11 (885.3100) | Acute dermal toxicity/pathogenicity |
| 152A-12 (885.3150) | Acute pulmonary/toxicity/pathogenicity |
| 152A-13 (885.3200) | Acute injection toxicity/pathogenicity |
| 152A-14 (870.2400) | Eye irritation |
| 152A-15 (885.3400) | Hypersensitivity |
| 81-1 (870.1100) | Acute oral toxicity, rat |
| 81-3 (870.1300) | Acute inhalation, rat |
| 81-5 (870.2500) | Primary dermal irritation |

Note: Numbers in parentheses are current Microbial Pesticide Test Guidelines.

In addition, workers who handle and apply the rusts are required to use appropriate protection to avoid dermal and inhalation exposure. A 4-hour Restriction Entry Interval (REI) was established to prevent inadvertent inhalation and dermal exposure.

b. Subchronic Toxicity and Chronic Toxicity

Subchronic and chronic toxicity studies were not required because there is no evidence for toxic endpoints, based on limited human exposure

2. Effects on the Immune and Endocrine Systems

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) “may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate.” Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen- and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC’s recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

Within the available scientific literature, there are no indications to suggest that *Puccinia thlaspeos* 'strain woad' has the potential to cause adverse effects on the endocrine or immune systems of humans or other organisms. When the appropriate screening and or testing protocols being considered under the Agency’s Endocrine Disruptor Screening Program have been developed, *Puccinia thlaspeos* 'strain woad' may be subjected to screening and/or testing to better characterize effects related to endocrine disruption. Based on the weight of the evidence of available data, no endocrine system-related effects have been identified for *Puccinia thlaspeos* 'strain woad'.

3. Dose Response Assessment

Although no specific studies were required, no toxicological endpoints have been identified, so no dose-response assessment is possible.

4. Dietary Exposure and Risk Characterization

Minimal to no dietary exposure is expected because the pesticide product will not be used on or near food crops. The rust does not infect any of the food crops tested, including canola, which is sometimes farmed in areas near dyer’s woad .

5a. Residential, School, and Daycare Exposure and Risk Characterization

Minimal to no exposure is expected in residential, school, and daycare sites. The product label limits uses to outdoor open rangeland and similar sites. There are no indoor or residential uses. The only known host for the rust is *Isatis tinctoria* (dyer's woad), a weed that grows in relatively dry and open areas in the western United States. Furthermore, no toxic endpoints have been detected with this rust based on known human exposure, so no adverse effects are expected if limited exposure occurs.

5b. Occupational Exposure and Risk Characterization

There have been no reports of adverse effects among workers who have handled the rust during the past 10 years. Nonetheless, to minimize dermal and inhalation exposure to workers, the Agency requires personal protective equipment (PPE) as described in **Section V** under **"Precautionary Labeling."**

6. Drinking Water Exposure and Risk Characterization

No exposure or risk from drinking water is expected because the rust is not likely to enter drinking water, would not survive treatment of drinking water, does not show any toxic endpoints for mammals, and is host-specific for dyer's woad.

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

FFDCA section 408 provides that EPA shall apply an additional ten-fold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database, unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. Based on all available information, the Agency concludes that *Puccinia thlaspeos* 'strain woad' has shown no evidence of toxicity or pathogenicity to mammals, including infants and children. Thus, because there are no threshold effects of concern, an additional margin of safety is not needed. As a result, the provision requiring an additional margin of exposure (safety) does not apply.

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

Because no toxic endpoints for mammals have been identified, and because no toxic effects have been reported from limited human exposure, no toxicity or pathogenicity is expected from aggregate exposure of the public via inhalation, dermal, and oral routes of exposure. Worker exposure via inhalation and dermal routes will be minimized by the use of personal protective equipment.

Based on the available information, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to the United States population, including infants and children, to residues of *Puccinia thlaspeos* 'strain woad'. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because *Puccinia thlaspeos* 'strain woad' shows no evidence of toxicity or infectivity in any animal, or even in any plant besides dyer's woad.

9. Cumulative Effects

No toxicologic or pathogenic endpoints in mammals have been found for *Puccinia thlaspeos* 'strain woad'. Therefore, no mechanism of toxicity in mammals has been identified, and no cumulative effects with related organisms are anticipated.

C. Environmental Assessment

1. Environmental Fate

Extensive studies indicate that *P. thlaspeos* 'strain woad' infects only dyer's woad. The rust occurs naturally on dyer's woad in several western states, and both the rust and the woad are dispersing naturally.

2. Ecological Toxicity

No non-target ecological toxicity has been detected or is expected. Deer eat rust-infected woad plants as readily as they eat uninfected plants. The rust occurs naturally, but has never been seen in other plants growing in the vicinity of infected woad. Waivers have been granted for the ecological guideline studies listed in Table 3 for the following reasons:

1. No evidence suggests that this woad rust is infective or toxic to any organism other than dyer’s woad.
2. Literature searches found no reports of rust toxicity or infectivity in animals in general, or in mammals, birds, fish, or insects specifically.
3. Spores of dyer’s woad rust do not develop above 25 degrees C; thus, the rust cannot survive at the body temperatures of mammals and birds.
4. Rusts are known to infect only plants.

Table 3. Ecological Guideline Waivers Granted

| Guideline No. | Name of Study |
|----------------------|--|
| 154A-16 (885.4050) | Avian oral toxicity-mallard duck |
| 154A-16 (885.4050) | Avian oral toxicity- bobwhite quail |
| 154A-19 (885.4020) | Freshwater fish toxicity-trout |
| 154A-19 (885.4020) | Freshwater fish toxicity-bluegill |
| 154A-20 (885.4240) | Freshwater invertebrate toxicity -daphnia |
| 154A-21 (885.4280) | Estuarine animal toxicity grass shrimp |
| 154A-21 (885.4280) | Estuarine animal toxicity- sheepshead minnow |
| 154A-23 (885.4340) | Non-target insect toxicity-green lacewing |
| 154A-23 (885.4340) | Non-target insect toxicity-parasitic hymenoptera |
| 154A-23 (885.4340) | Non-target insect toxicity-predaceous coleoptera |
| 154A-24 (885.4380) | Non-target insect toxicity-honey bee |

(Note: Numbers in parentheses are current Microbial Pesticide Test Guidelines)

a. Toxicity to Non-target Plant Species (Guideline # 885.4300)

Extensive testing (see Table 4) shows that *Puccinia thlaspeos* ‘strain woad’ appears specific for dyer’s woad as its host. The plants tested as potential rust hosts were in the family Brassicaceae, the taxonomic group containing all the known hosts of the *P. monoica* rust complex. The results below show that *Puccinia thlaspeos* ‘strain woad’ is not toxic or infective to any non-target plant species tested, including nine species that are known hosts of rusts in the *P. monoica* complex.

Table 3. Brassicaceae plants tested as potential hosts of dyer’s woad rust.

| Species tested (* indicates known susceptibility to <i>P. monoica</i> rust complex) | Susceptible to dyer’s woad rust? |
|--|----------------------------------|
| <i>Arabis breweri</i> * | No |
| <i>Arabis brownii</i> | No |
| <i>Arabis fecunda</i> | No |
| <i>Arabis gerardii</i> | No |
| <i>Arabis glabra</i> | No |
| <i>Arabis hirsuta</i> * | No |
| <i>Arabis holboellii</i> * | No |
| <i>Arabis turrita</i> | No |
| <i>Brassica napus</i> ‘Canola’ | No |
| <i>Brassica oleraceae</i> var. <i>capitata</i> ‘cabbage’ | No |
| <i>Descurainia pinnata</i> * | No |
| <i>Draba sp.</i> * | No |
| <i>Erysimum sp.</i> * | No |
| <i>Erysimum asperum</i> | No |
| <i>Erysimum crepidifidium</i> | No |
| <i>Erysimum inconspicuum</i> | No |
| <i>Erysimum cheiranthoides</i> | No |
| <i>Erysimum repandum</i> | No |
| <i>Hesperis matronallis</i> | No |
| <i>Lepidium sativum</i> | No |
| <i>Lepideum campestris</i> | No |
| <i>Lesquerella argyraea</i> | No |
| <i>Lesquerella gordonii</i> | No |
| <i>Lesquerella fendleri</i> | No |
| <i>Lesquerella perferata</i> | No |
| <i>Lunaria annua</i> | No |
| <i>Polyctenium fremontii</i> * | No |
| <i>Rhaphanus sastivus</i> ‘radish’ | No |
| <i>Sisymbrium austriacum</i> | No |
| <i>Sisymbrium altissimum</i> | No |
| <i>Smelowskia calycina</i> * | No |
| <i>Thlaspi arvense</i> | No |
| <i>Thlaspi montanum</i> (=alpestre)* | No |

b. Taxonomic Comparison of Rusts in the *P. monoica* Complex

As part of studies to determine whether *Puccinia thlaspeos* ‘strain woad’ is a new, native strain of *Puccinia* rust, the registrants compared spore characteristics of several rusts of the *P. monoica* complex with each other and with the only rust (*P. trabutii*) reported on dyer’s woad in Europe. The data in Table 5, and other information about *P. thlaspeos*, provide evidence that *Puccinia thlaspeos* ‘strain woad’ is a new rust strain, rather than a contaminant that came to the U.S. with the colonists. As further support for this hypothesis, studies have shown that the *Puccinia thlaspeos* ‘strain woad’ infects dyer’s woad grown from European seeds as readily as it infects dyer’s woad from the U.S., although the woad rust has never been reported in Europe.

Table 5. Spore characteristics of the *P. monoica* group in U.S. compared with *P. trabutii* from Europe.

| Species | Spermatia | Aecia | Uredia | Telia | Basidia | Alternate host required (grass) |
|-----------------------------------|-----------|-------------|--------|-------------|---------|---------------------------------|
| <i>P. trabutii</i> | + | + | + | + | + | + |
| <i>P. monoica</i> | + | +(systemic) | + | + | + | + |
| <i>P. consimilis</i> | + | +(systemic) | - | + | + | ? |
| <i>P. holboellii</i> | - | - | - | +(systemic) | + | - |
| <i>P. thlaspeos</i> | +/- | - | - | +(systemic) | + | - |
| <i>P. thlaspeos</i> ‘strain woad’ | + | - | - | +(systemic) | + | - |

IV. RISK MANAGEMENT AND REGISTRATION DECISION

A. Determination of Eligibility

-

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

To satisfy criterion "A" above, *P. thlaspeos* 'strain woad' has well known properties. The Agency has no knowledge that would contradict the claims made on the label of this product. Criterion "B" is satisfied by the current label and by the data presented in this document. It is believed that this new pesticidal active ingredient will not cause any unreasonable adverse effects, is a specific herbicide for a noxious weed, and does provide protection as claimed, satisfying criterion "C". Criterion "D" is satisfied in that *P. thlaspeos* 'strain woad' is not expected to cause unreasonable adverse effects when used according to label instructions.

Therefore, *P. thlaspeos* 'strain woad' is eligible for registration. The uses are listed in the Section II, B. Use Profile. These eligible uses are limited to outdoor terrestrial non-food sites. There are no ineligible uses for *P. thlaspeos* 'woad strain'.

B. Regulatory Position

1. Unconditional Registration

All data requirements have been fulfilled or waived and the Biopesticides and Pollution Prevention Division recommends unconditional registration of products that contain *P. thlaspeos* 'woad strain' as the sole Active Ingredient (Woad Warrior).

2. Tolerances for Food Uses and /or Exemptions from Tolerances

Puccinia thlaspeos 'strain woad' is not registered for use on foods, and therefore does not need either a tolerance or an exemption from a tolerance.

3. CODEX Harmonization

There are no CODEX values for *Puccinia thlaspeos* ‘strain woad’.

4. Risk Mitigation

Except for workers, as specified below, no risk mitigation measures are required.

5. Endangered Species Statement

Given the specificity of this microbial pesticide, and based on the intended use pattern, toxicity data, and exposure information, the Agency has determined that this registration action will have no adverse effects on currently listed endangered and threatened species. The registrant was unable to obtain seeds or field samples of threatened or endangered Brassicaceae species with habitat requirements similar to those of dyer’s woad. However, when closely-related brassicaceous plants were tested as hosts, none of the plants were susceptible to *P. thlaspeos* ‘strain woad’.

C. Labeling Rational

1. Human Health Hazards (WPS and non-WPS)

Puccinia thlaspeos ‘strain woad’ products with commercial use sites are subject to the Worker Protection Standard. Because certain acute toxicity studies were waived, and there is no indication of mammalian toxicity or pathogenicity for *P. thlaspeos* ‘strain woad’, the Restricted Entry Interval for uses within the scope of WPS is 4 hours. Precautionary statements and personal protective equipment as specified below are required to ensure adequate worker protection.

2. Environmental Hazards

Precautionary labeling is required as indicated below.

V. ACTIONS REQUIRED BY REGISTRANTS

A. Precautionary Labeling

Puccinia thlaspeos ‘strain woad’ products must state the following under the heading “Precautionary Statements”:

Personal Protective Equipment required for applicators and other handlers:

Long sleeved shirt and long pants. Waterproof gloves. Shoes plus socks. Dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any N, P, R, or HE filter.

WPS labels must state the following under the heading "User Safety Recommendations"

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. If gloves are worn, wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

B. Environmental Hazards Labeling

Provided the following statement is placed into the environmental hazards statement, the risk of *Puccinia thlaspeos* 'strain woad' is minimal to nonexistent to non-target organisms, including endangered species.

1. End-Use Product Environmental Hazards Labeling

"Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of equipment washwaters. "

2. Application Rate

It is the Agency's position that the labeling for the pesticide products containing *Puccinia thlaspeos* 'strain woad' as the active ingredient complies with the current pesticide labeling requirements. The Agency has not required a maximum number of applications per season of this active ingredient.

C. Labeling

The attached label for Woad Warrior (EPA File # 73417-R) conforms with the labeling requirements for *Puccinia thlaspeos* 'strain woad'. Signal word is "Caution," based on Toxicity Category III. Some of the essential label requirements are listed below:

- Product Name
- Ingredient Statement
- Registration Number
- "Keep Out of Reach of Children"
- Signal Word (CAUTION)
- First Aid Statement
- Personal Protective Equipment (PPE) Requirements
- Environmental Hazards Statement
- Storage and Disposal Statement
- Agricultural Use Requirements
- Directions for Use

BIBLIOGRAPHY:

A. OPP Guideline and MRID numbers for studies submitted to support the registration of *P. thlaspeos* 'strain woad'

Guideline: 151-10 Product Identity and Disclosure of Ingredients

MRID: 45236701

Citation: Thomson, S. (1999) Product Identity: (Woad Warrior). Unpublished study prepared by Utah State University. 8 p.

Guideline: 151-11 Manufacturing Process

MRID: 45236701

Citation: Thomson, S. (1999) Product Identity: (Woad Warrior). Unpublished study prepared by Utah State University. 8 p.

Guideline: 151-12 Discussion of Formation of Unintentional Ingredients

MRID: 45236701

Citation: Thomson, S. (1999) Product Identity: (Woad Warrior). Unpublished study prepared by Utah State University. 8 p.

Guideline: 151-13 Analysis of Samples

MRID: 45236701

Citation: Thomson, S. (1999) Product Identity: (Woad Warrior). Unpublished study prepared by Utah State University. 8 p.

Guideline: 151-15 Certification of Ingredient Limits

MRID: 45236701

Citation: Thomson, S. (1999) Product Identity: (Woad Warrior). Unpublished study prepared by Utah State University. 8 p.

Guideline: 151-20 Product Identity and Disclosure of Ingredients

MRID: 45550901

Citation: Thomson, S. (2001) Product Identity: (Woad Warrior). Unpublished study prepared by Greenville Farms. 9 p.

Guideline: 151-21 Manufacturing Process

MRID: 45550901

Citation: Thomson, S. (2001) Product Identity: (Woad Warrior). Unpublished study prepared by Greenville Farms. 9 p.

Guideline: 151-22 Discussion of Formation of Unintentional Ingredients

MRID: 45550901

Citation: Thomson, S. (2001) Product Identity: (Woad Warrior). Unpublished study prepared by Greenville Farms. 9 p.

Guideline: 151-23 Analysis of Samples

MRID: 45550901

Citation: Thomson, S. (2001) Product Identity: (Woad Warrior). Unpublished study prepared by Greenville Farms. 9 p.

Guideline: 151-25 Analytical Methods for Certified Limits

MRID: 45550901

Citation: Thomson, S. (2001) Product Identity: (Woad Warrior). Unpublished study prepared by Greenville Farms. 9 p.

Guideline: 154-22 Non-Target Plant Studies

MRID: 45550902

Citation: Thomson, S. (2001) Plant Toxicity Data Requirements: Woad Warrior. Unpublished study prepared by Greenville Farms. 23 p. {OPPTS 885.4300}

Guideline: 61-2 Description of Beginning Materials and Manufacturing Proces

MRID: 45236708

Citation: Kropp, B.; Hooper, G.; Hansen, D. et al. (1999) Initial events in the colonizatin of Dyer's Woad by Pucinninia thlaspeos. Can. J. Bot. 77:843-849.

Guideline: 62-1 Preliminary Analysis [of product samples]

MRID: 45236707

Citation: Kropp, B.; Albee, S.; Flint, M. et al. (1995) Early detection of systemic rust infections of Dyers Woad (*Isatis tinctoria*) using the Polymerase Chain Reaction. Weed Science 43:6-12.

Non-Guideline Studies

MRID: 45236700

Citation: Utah State University Extension (1999) Submission of Efficacy, Toxicity, and Product Chemistry Data in Support of the Experimental Use Permit for Woad. Transmittal of 8 Studies.

MRID: 45236702

Citation: Thomson, S. (1999) Plant Toxicity Data Requirements: (Woad Warrior). Unpublished study prepared by Utah State University Ag. Extension. 19 p.

MRID: 45236703

Citation: Thomson, S.; Dewey, S.; Kropp, B. (1995) One for the Woad: Rust as biocontrol. Utah Science 56:2-5.

MRID: 45236704

Citation: Flint, K.; Thomson, S. (2000) Seasonal infection of the weed Dyer's Woad by a *Puccinia* sp. rust used for biocontrol, and effects of temperature on Basidiospore production. *Plant Disease* 84:753-759.

MRID: 45236705

Citation: Kropp, B.; Hansen, D.; Wolf, P. et al. (1997) A study on the Phylogeny of the Dyer's Woad rust fungus and other species of *Puccinia* from Crucifers. *Phytopathology* 87:565-571.

MRID: 45236706

Citation: Kropp, B.; Hansen, K.; Flint, K. et al. (1996) Artificial inoculation and colonization of Dyer's Woad (*Isatis tinctoria*) by the systemic rust fungus *Puccinia thlaspeos*. *Phytopathology* 86:891-896.

MRID: 45550900

Citation: Greenville Farms (2001) Submission of Product Chemistry, Efficacy, Environmental Fate, Risk and Exposure Data in Support of the Application for Registration of Woad Warrior. Transmittal of 4 Studies.

MRID: 45550903

Citation: Thomson, S.; Hansen, D.; Kropp, B. (1999) Preparation of Rust Inoculum for Biological Control of Dyer's Woad (*Isatis tinctoria*). Unpublished study prepared by Greenville Farms. 3 p.

MRID: 45550904

Citation: Thomson, S.; Hansen, D.; Kropp, B. (1999) Inoculation and Subsequent Dispersal of Dyer's Woad Rust in Field Populations. Unpublished study prepared by Greenville Farms. 3 p.

B. Literature Cited

- Arthur, J.C. and G.B. Cummins. 1962. *Manual of the rusts in the United States and Canada*. Hafner Publishing Co. New York. 438 pp.
- Arthur, J. C. 1934. *Manual of the Rusts in the United States and Canada*. The Science Press Printing Co., Lancaster, PA.
- Callihan, R.H., Dewey, S. A., Patton, J.E., and D.C. Thill. 1984. Distribution, biology and habitat of dyer's woad (*Isatis tinctoria* L.) in Idaho. *J. Idaho Acad. Sci.* 20:18-32.

- Dewey, S. A., Price, K. P., and Ramsey, D. 1991. Satellite remote sensing to predict potential distribution of dyer's woad (*Isatis tinctoria*). *Weed Technology* 5:479-484.
- Farr, D. F., Bills, G.F., Chamuris, G. P., and A.Y. Rossman. 1989. *Fungi on Plants and Plant Products in the United States*. The American Phytopathological Society, St. Paul MN.
- Gaumann, E. 1959. *Die Rospilze Mitteleuropas*. Buchler, Bern Switzerland, p. 751-755.
- Kok, L. T., Abad, R. G., and A. B. Baudoin. 1996. Effects of *Puccinia carduorum* on musk thistle herbivores. *Biological Control* 6:123-129 (abstract).
- Roy, B.A., D.R. Vogler, T.D.Bruns and T.M. Szaro. 1998. Cryptic species in the *Puccinia monoica* complex. *Mycologia* 90:846-853.
- Saccardo, P.A. *Sylloge Fungorum omnium hucusque cognitorum*. 1899. Vol 7. Gasteromyceteeae, Phycomyceteeae, Myxomyceteeae, Ustilagineae et Uredineae. Published by the author, Pavia.
- Viennot-Bourgin, G. 1956. Mildious, oïdiums, caries, charbons, rouilles des plantes de France. *Encyclopédie mycologique XXVI-XXVII*. Ed. Paul Lechevalier, Paris.
- Shaw, C.G. 1973. *Host Fungus Index for the Pacific Northwest*. Bulletin 766. Washington Agricultural Experiment Station.
- Tinney, G. W., Hatcher, P. E., Ayres, P. G., Paul, N. D., and J.B.Whittaker. 1998. Inter- and intra- species differences in plants as hosts to *Tyria jacobaeae*. *Entomologia Experimentalis et Applicata* 88:137-145
- Varga, W. A., and J.O.Evans 1978. Dyer's woad: From cultivated to cursed. *Utah Science* 39:87-89.
- Wan, J. Z., Lin, D., and M.Lin. 1994. Preliminary experimental study on the etiology of wheat harvest dermatitis. *Zhonghua Pifuke Zazhi* 27:337-338 (abstract).
- Wilson, M. and D.M. Henderson. 1966. *British rust fungi*. Cambridge; Cambridge University Press.

