

subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP-30521. Electronic comments may also be filed online at many Federal Depository Libraries.

*D. How Should I Handle CBI that I Want to Submit to the Agency?*

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT.**

*E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the registration activity.
7. Make sure to submit your comments by the deadline in this notice.
8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

**II. Registration Applications**

EPA received an application as follows to register a pesticide product containing an active ingredient not included in any previously registered product pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of this application does not imply a decision by the Agency on the application.

*Product Containing an Active Ingredient not Included in any Previously Registered Product*

*File Symbol:* 73417-R. *Applicant:* Greenville Farms, 6189 N. 1200 E., Logan, UT 84341. *Product Name:* Woad Warrior. Fungal Herbicide. *Active ingredients:* *Puccinia thlaspeos* "woad strain" on rust-infected pieces of dyer's woad at 100% and contains at least 7.6 x 10<sup>9</sup> teliospores/pound of Woad Warrior. *Proposed Classification/Use:* None. For control of *Isatis tinctoria* (dyer's woad).

**List of Subjects**

Environmental protection, Pesticides and pest.

Dated: February 25, 2002.

**Janet L. Andersen,**

*Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.*

[FR Doc. 02-5444 Filed 3-7-02; 8:45 am]

**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

[OPP-00761; FRL-6825-5]

**Reclassification of Certain Inert Ingredients and Rhodamine B**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA intends to reclassify eight inert ingredients from List 2, "Potentially Toxic Inerts/High Priority for Testing" to List 1 "Inerts of Toxicological Concern." These eight inert ingredients have been determined to be animal carcinogens, thus meeting one of the criteria for reclassification. EPA also intends to reclassify the inert ingredient, Rhodamine B, from List 1 to List 4B, "inerts for which EPA has sufficient information to reasonably conclude that the current use pattern in pesticide products will not adversely affect public health or the environment." This reclassification is based on the Agency's determination that Rhodamine B when used as a dye in seed treatment is not likely to result in residues in food or feed; thus, meeting the criteria of List 4B.

**DATES:** Comments, identified by docket control number OPP-00761, must be received on or before May 7, 2002.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. under

**SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-00761 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-6304; fax number: (703) 305-0599; e-mail address: boyle.kathryn@epa.gov.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

This action is directed to the public in general. This action may, however, be of interest to "those persons who use pesticide products and those who formulate pesticide products and therefore are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide

Act (FIFRA).” Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select “Laws and Regulations,” “Regulations and Proposed Rules,” and then look up the entry for this document under the “**Federal Register—Environmental Documents.**” You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

The Agency has established an official record for this action under docket control number OPP-00761. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

*C. How and to Whom Do I Submit Comments?*

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5. Provide specific examples to illustrate your concerns.

6. Offer alternative ways to improve the notice or collection activity.

7. Make sure to submit your comments by the deadline in this notice.

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**II. Reclassification of Eight Inert Ingredients from List 2 to List 1**

*A. Background*

On April 22, 1987 (52 FR 13305), EPA announced certain policies designed to reduce the potential for adverse effects from the use of pesticide products containing toxic inert ingredients. In developing the policy, the Agency reviewed the available data on chemicals used as inert ingredients, and concluded that some inert ingredients had potentially significant long-term health and environmental hazards associated with their use in pesticide products. The 1987 Notice categorized all of the then existing inert ingredients into four lists, according to the available information regarding toxicity, i.e., the hazard of the chemical. List 1 inert ingredients, described as “inerts of toxicological concern” were so categorized on the basis of toxicological or adverse ecological effects which had been documented in studies subject to peer review. The Agency’s criteria for placing an inert ingredient on List 1 were reviewed by the FIFRA Scientific Advisory Panel (SAP).

One of the criteria for being considered a List 1 inert ingredient is to be “...characterized by the National Toxicology Program (NTP) as an animal carcinogen in at least one species and one sex.” (Inert ingredients in Pesticide Products; Policy Statement; Revision and Modification of Lists at <http://www.epa.gov/oppd001/inerts/fr54.htm>). NTP Technical Reports describe the results of individual experiments on a chemical agent and note the strength of evidence for conclusions regarding each study.

In their technical reports, NTP uses five categories of evidence of carcinogenic activity to summarize the strength of the evidence observed in

each experiment. These categories (“no evidence,” “equivocal evidence,” “some evidence,” “clear evidence,” and “inadequate study”) have been used by NTP since the 1980s. Two of the categories are for positive results, which demonstrate that a chemical is carcinogenic for laboratory animals under the conditions of the study and indicate that exposure to the chemical has the potential for hazard to humans. “Clear evidence” of carcinogenic activity is demonstrated by studies that are interpreted as showing a dose-related increase of malignant neoplasms or of a combination of malignant and

benign neoplasms, or a marked increase of benign neoplasms if there is an indication from this or other studies of the ability of such tumors to progress to malignancy. “Some evidence” of carcinogenicity is demonstrated by studies that are interpreted as showing a chemically-related increased incidence of neoplasms (malignant, benign, or combined) in which the strength of the response is less than that required for clear evidence.

#### *B. NTP Technical Reports for the Eight Inert Ingredients*

For the purpose of reclassifying a List 2 inert ingredient to a List 1 inert

ingredient the two categories (described above) for positive results (“clear evidence” and “some evidence,”) meet the List 1 placement criteria of being characterized by NTP as an animal carcinogen in at least one species and one sex. The data in the NTP Technical Reports as described in the table and summaries below fully support a reclassification to List 1 for the following inert ingredients. The complete reports are available at <http://ntp-server.niehs.nih.gov/>.

NTP Report Number	Category	Inert Ingredient	CAS Reg. No.
TR-424	Some evidence	2-Benzyl-4-chlorophenol	120-32-1
TR-484	Some evidence	2-Butoxyethanol (ethylene glycol monobutyl ether)	111-76-2
TR-213 TR-458	Some evidence	Butyl benzyl Phthalate	85-68-7
TR-478	Clear evidence	Diethanolamine	11-42-2
TR-466	Clear evidence Some evidence	Ethylbenzene	100-41-14
TR-329	Clear evidence	1,2-Epoxybutane(butylene oxide)	106-88-7
TR-332	Some evidence	2-Mercaptobenzothiazole	149-30-4
TR-461	Clear evidence	Nitromethane	75-52-5

1. *2-Benzyl-4-chlorophenol*. There were two chronic toxicity/carcinogenicity gavage studies performed on 2-benzyl-4-chlorophenol, which is also known as o-benzyl-p-chlorophenol. Under the conditions of the 2-year rat study, there was no evidence of carcinogenic activity in male rats and there was equivocal evidence of carcinogenic activity in female rats based on the occurrence of two rare renal transitional cell carcinomas. Under the conditions of the 2-year study, in mice there was some evidence of carcinogenic activity in male mice based on increased incidences of renal tubule adenoma and renal tubule adenoma or carcinoma (combined) and there was no evidence of carcinogenic activity in female mice.

2. *Butyl benzyl phthalate*. There was a 2-year chronic toxicity/carcinogenicity study in rats performed using butyl benzyl phthalate. As evaluated in 1997, under the conditions of this study, there was some evidence of carcinogenic activity in male rats based on increased incidences of pancreatic acinar cell adenoma and of acinar cell adenoma or carcinoma

(combined) and there was equivocal evidence of carcinogenic activity in female rats based on the marginally increased incidences of pancreatic acinar cell adenoma and of transitional epithelial papilloma of the urinary bladder. Results of mutagenicity testing, a mouse bone marrow sister chromatid exchange test were positive at sample times of 23 and 42 hours. Chromosomal aberrations were induced in bone marrow cells of male mice sampled 17 hours after intraperitoneal injection of butyl benzyl phthalate.

3. *2-Butoxyethanol*. There were two inhalation chronic toxicity/carcinogenicity studies performed on 2-butoxyethanol. Under the conditions of these studies, there was no evidence of carcinogenic activity in male rats. There was equivocal evidence of carcinogenic activity in female rats based on the increased combined incidences of benign or malignant pheochromocytoma (mainly benign) of the adrenal medulla. There was some evidence of carcinogenic activity in male mice based on increased incidences of hemangiosarcoma of the liver. There was some evidence of carcinogenic

activity in female mice based on increased incidences of fore stomach squamous cell papilloma or carcinoma (mainly papilloma).

2-Butoxyethanol has also been reviewed by a team of Agency health scientists. The results of this recent review on (December 31, 1999) can be located on the Agency's website at <http://www.epa.gov/ngispgm3/iris/subst/0500.htm>. In accordance with the 1996 proposed Guidelines for Carcinogen Risk Assessment, 2-butoxyethanol has been classified as a chemical whose carcinogenic potential for humans cannot be determined, but for which there is suggestive evidence that raises concern for carcinogenic effects. This classification was based on the reviews of the NTP studies, the fact that 2-butoxyethanol is generally negative in genotoxicity tests and the uncertainty of the relevance of these tumors to humans. Thus, while 2-butoxyethanol has not been classified as a known/likely human carcinogen, it also cannot be classified as not likely to be a human carcinogen. Indeed, it was clearly stated that there was “suggestive evidence that raises concern for carcinogenic effects.”

Under the Agency's 1986 Guideline, 2-butoxyethanol would be judged as Group C, possible human carcinogen. Based on the evidence of carcinogenicity in mice, 2-butoxyethanol meets the criteria for inclusion on List 1 of being an animal carcinogen in at least one species and one sex.

4. *Diethanolamine*. There were two dermal chronic toxicity/carcinogenicity studies performed on diethanolamine. Under the conditions of these 2-year studies, there was no evidence of carcinogenic activity of diethanolamine in male or female rats. There was clear evidence of carcinogenic activity of diethanolamine in male and female mice based on increased incidences of liver neoplasms in males and females and increased incidences of renal tubule neoplasms in males.

5. *Ethylbenzene*. There were two inhalation chronic toxicity/carcinogenicity studies performed on ethylbenzene. Under the conditions of the 2-year rat study, there was clear evidence of carcinogenic activity in male rats based on increased incidences of renal tubule neoplasms. The incidences of testicular adenomas were also increased. There was some evidence of carcinogenic activity in female rats based on increased incidences of renal tubule adenomas. There was some evidence of carcinogenic activity in male mice based on increased incidences of alveolar/bronchiolar neoplasms and in female mice based on increased incidences of hepatocellular neoplasms.

6. *1,2-Epoxybutane*. There were two inhalation chronic toxicity/carcinogenicity studies performed on 1,2-epoxybutane. Under the conditions of these studies, there was clear evidence of carcinogenic activity in male rats based on an increased incidence of papillary adenomas of the nasal cavity, alveolar/bronchiolar carcinomas, and alveolar/bronchiolar adenomas and carcinomas (combined). There was equivocal evidence of carcinogenic activity for female rats based on papillary adenomas of the nasal cavity. There was no evidence of carcinogenic activity in male or female mice. 1,2-Epoxybutane was mutagenic in *Salmonella typhimurium* strains, induced forward mutations in mouse lymphoma cells, and induced chromosomal aberrations and sister chromatid exchanges in chinese hamster ovary (CHO) cells.

7. *2-Mercaptobenzothiazole*. There were two gavage chronic toxicity/carcinogenicity studies performed on 2-mercaptobenzothiazole. Under the conditions of the studies, there was some evidence of carcinogenic activity

in male rats indicated by increased incidences of mononuclear cell leukemia, pancreatic acinar cell adenomas, adrenal gland pheochromocytomas, and preputial gland adenomas or carcinomas (combined), and in female rats, based on increased incidences of adrenal gland pheochromocytomas and pituitary gland adenomas. There was no evidence of carcinogenic activity in male mice. There was equivocal evidence of carcinogenic activity for female mice based on increased incidences of hepatocellular adenomas or carcinomas (combined).

8. *Nitromethane*. There were two inhalation chronic toxicity/carcinogenicity studies performed on nitromethane. Under the conditions of these studies, there was no evidence of carcinogenic activity in male rats. There was clear evidence of carcinogenic activity in female rats based on increased incidences of mammary gland fibroadenomas and carcinomas, in male mice based on increased incidences of harderian gland adenomas and carcinomas, and in female mice based on increased incidences of liver neoplasms (primarily adenomas) and harderian gland adenomas and carcinomas. Increased incidences of alveolar/bronchiolar adenomas and carcinomas in male and female mice exposed to nitromethane were also considered to be related to administration of nitromethane.

#### C. Future Actions

EPA solicits comments upon the conclusions set forth in this Notice. The Agency will review and evaluate any submitted comments, and will then publish a final Notice in the **Federal Register** to complete the reclassification of these chemicals. After the publication of that Notice, as an immediate step to inform users and the general public of the presence of an inert of toxicological concern, EPA anticipates requiring that the presence of the reclassified List 1 inert ingredient be disclosed on the label. Registrants of a product that contains one or more inert ingredients that are the subject of this notice will receive correspondence from the Agency concerning the procedures for label disclosure.

EPA also anticipates that products containing one or more of these reclassified List 1 inert ingredients will be subject to a Data-Call-In (DCI) Notice. This DCI (expected to be issued in the near future) would require the submission of an extensive data set to support the continued use of these List 1 inert ingredients in pesticide products. The Agency would also

provide in the DCI a list of all registrants or designated agents whose products contain one or more of these List 1 inert ingredients, which will allow registrants to form groups for the purposes of data generation and submission.

### III. Reclassification of Rhodamine B from List 1 to List 4B

#### A. Background

The previously described **Federal Register** notice published on April 22, 1987 (52 FR 13305), also established List 4 inert ingredients "inerts of minimal concern." On November 22, 1989 (54 FR 48314), List 4 was further subdivided into List 4A and 4B. List 4B inert ingredients are "inerts for which EPA has sufficient information to reasonably conclude that the current use pattern in pesticide products will not adversely affect public health or the environment."

Rhodamine B's current classification as a List 1 inert ingredient is due to its carcinogenicity. A Rhodamine B DCI Notice was issued in February 1993 that required registrants of products containing Rhodamine B to generate additional toxicity data (to further define the hazard) and exposure data to support the continued registration of their products. If submitted, these data would have been used to perform a risk assessment to support all uses of Rhodamine B. However, as a result of the issuance of the DCI, most of the existing uses of Rhodamine B as an inert ingredient were not supported. Registrants of non-seed treatment pesticide products either reformulated their products to use substitutes for Rhodamine B or voluntarily canceled those products containing Rhodamine B rather than generate data to support the use of Rhodamine B as a food-use. However, several registrants wished to retain the use of Rhodamine B as a dye in seed treatment pesticide formulations. They submitted to the Agency a radiolabeled magnitude of the residue study in which Rhodamine B was used to dye seeds that were then planted and grown to harvest.

In the **Federal Register** of August 2, 2001 (66 FR 40170) (FRL-6598-4), EPA issued a proposal pursuant to section 408 of the FFDCFA, 21 U.S.C. 346a as amended by the Food Quality Protection Act (FQPA) (Public Law 104-170) to limit the uses of Rhodamine B as a dye in seed treatment only. As explained in the proposed rule, based on its review and evaluation of the submitted data, EPA concluded that use of Rhodamine B as a dye in seed treatment is a non-food use, because the use is not likely to result in residues in food or feed.

Therefore, neither a tolerance nor a tolerance exemption is needed for the use of Rhodamine B as a dye in seed treatment pesticide products.

The final rule was published on December 27, 2001 (66 FR 66769) (FRL-6813-6). The Rhodamine B use pattern is now limited to use as a dye in seed treatment, and for a period of 3 years Rhodamine B can also be used as a dye in animal ear tag pesticide products. This 3-year time frame is needed to allow those pesticide ear tag products containing Rhodamine B to clear the channels of trade.

*B. Future Actions*

Rhodamine B's classification as a carcinogen remains unchanged. However, the Agency no longer considers List 1 classification for Rhodamine B for its use as a dye in seed treatment pesticide products to be appropriate. List 1 classifications are made according to hazard criteria only. However, the December 27, 2001 **Federal Register** limited the use of Rhodamine B to a specified use pattern. A List 4B inert ingredient is considered to be an inert ingredient for which the available toxicity (hazard) information when paired with the available exposure information indicates no reasonable expectation of adverse effects. Rhodamine B now meets the definition of a List 4B, and will be reclassified as such.

Those persons desiring to register products containing Rhodamine B as an inert ingredient for any uses other than as a dye in seed treatment would need to submit an extensive data set similar to that required in the 1993 Rhodamine B DCI. These data would be used by the Agency in a risk assessment on the proposed use. If, the risk assessment supports the required safety finding, then the use would be approved.

**List of Subjects**

Environmental protection, pesticides and pests.

Dated: February 26, 2002.

**Peter Caulkins,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

[FR Doc. 02-5445 Filed 3-7-02; 8:45 am]

**BILLING CODE 6560-50-S**

**ENVIRONMENTAL PROTECTION AGENCY**

[PF-1072; FRL-6825-8]

**Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

**DATES:** Comments, identified by docket control number PF-1072, must be received on or before April 8, 2002.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-1072 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: James A. Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5697; e-mail address: tompkins.jim@epa.gov.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311  32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American

Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

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2. *In person.* The Agency has established an official record for this action under docket control number PF-1072. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as, the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

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