Extract of *Reynoutria sachalinensis* (Giant Knotweed) (055809) Biopesticide Registration Action Document

Issued: 11/00

I. Executive Summary

A. Identity

The technical grade active ingredient (TGAI) consists entirely of the dried and ground plant material from harvested *Reynoutria sachalinensis* (giant knotweed) plants grown for this purpose. The end-use product Milsana® Bioprotectant Concentrate (hereafter referred to as Milsana®) contains 5% of the ethanolic extract of *Reynoutria sachalinensis,* and is not manufactured by an integrated process. The product chemistry data submitted by the registrant satisfies the requirement for product identity.

B. Use/Usage

Milsana® is to be used as a spray on greenhouse grown ornamental plants for the purpose of boosting their natural defense mechanisms against certain fungal diseases. The product should be used as a preventive application mainly for the control of powdery mildew. The use is classified as a greenhouse, non-food crop application.

C. Risk Assessment

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

1. **Human Health Risk Assessment**

    a. **Toxicological Endpoints**

No toxicological endpoints were identified. Mammalian toxicology data requirements have been submitted and adequately satisfy data requirements to support the registration. Submitted data for the TGAI and the end-use product, indicate Toxicity Category IV for acute oral and acute inhalation toxicity. Acute dermal toxicity data indicated a Toxicity Category III. The data reported for primary eye

irritation studies showed that the test substance was moderately irritating, and was given a Toxicity Category III when the TGAI was used, and Toxicity Category II when the end use product Milsana® is used as a test material. Exposure to Milsana® produced very slight erythema in animal tests; as a result, a Toxicity Category IV was given for dermal irritation.

b. **Human Exposure**

Human exposure would be very low because the product is for use in greenhouses only. Moreover, for workers, the product is Toxicity Category IV for both inhalation and dermal irritation, and the label language will mitigate the eye irritation risks.

c. **Risk Assessment**

The Biopesticides and Pollution Prevention Division (BPPD) has not identified any subchronic, chronic, immune, endocrine, or nondietary exposure issues as they may affect children and the general U.S. population. The eye irritation risk to applicators is mitigated as long as the product is used according to label directions. No toxicological endpoints have been identified, and there is limited exposure to this product when used according to the label instructions. The Agency has considered the extract of *Reynoutria sachalinensis* in light of the relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and has determined that there will be no unreasonable adverse effects from the use of this product.

2. **Ecological Risk Assessment**

a. **Ecological Toxicity Endpoints**

No toxic endpoints were identified.

b. **Ecological Exposure**

The data requirements for nontarget organisms were waived based on the minimal environmental exposure to the extract of Reynoutria sachalinensis. The use of the end-use product in enclosed areas (greenhouses), minimize the chances of exposure for nontarget avian and aquatic organisms.

c. **Risk Assessment**

Risk to nontarget organisms is expected to be minimal, due to the low chances of exposure to the environment. Moreover, the active ingredient is a natural component of a commonly found plant. As a result, BPPD believes that the use of the extract of Reynoutria sachalinensis according to label use directions, should result in no significant adverse effects to wildlife.

D. Data Gaps / Labeling Restrictions

There are no data gaps or labeling restrictions. Because of Milsana®'s Toxicity Category II for eye irritation, some restrictions and precautionary labeling are required to mitigate risks associated with the proposed uses (see Labeling Rationale for details).

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III. Overview

A. Active Ingredient Overview

- **Common Name:** Giant Knotweed Plant Extract
- **Chemical Name:** Extract of Reynoutria sachalinensis
- **Trade and Other Names:** Milsana® Bioprotectant Cencentrate
- **OPP Chemical Code:** 055809

Basic Manufacturer:

KHH BioSci, Inc.
Centennial Campus/Venture II Building
920 Main Campus Drive, Suite 400 Raleigh, NC 27606

B. Use Profile

The following, is information on the proposed uses with an overview of use sites and application methods.

- **Type of Pesticide:** Growth Regulator
- **Use Sites:** Ornamental Species Grown in Greenhouses.
- **Target:** Fungal Diseases (Mainly Powdery Mildew and Gray Mold)
- **Formulation Types:** Suspension Concentrate (Liquid)

- **Method and Rates of Application:** Applications should be done using conventional ground or foliar application equipment. Mix Milsana® with water at a rate of 2 quarts (0.1 quart of the active ingredient) per 100 gallons of water.

- **Use Practice Limitations:** For use only on ornamental non-food greenhouse crops. Make no more than 6 applications per year.

- **Timing:** Application should start at the 4-6 leaf stage. Repeat at 7 to 10 day intervals.

C. Estimated Usage

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

D. Data Requirements

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

E. Regulatory History

On May 6, 1999, the Agency received an application from KHH BioScience, Inc. to register Milsana® Bioprotectant Concentrate and the technical grade active ingredient, *Reynoutria sachalinensis* bioprotectant, containing 5% and 100% of dried and ground giant knotweed (*Reynoutria sachalinensis)* respectively .

A notice of receipt of the application for registration of *Reynoutria sachalinensis* as a new active ingredient was published in the Federal Register on December 28 1999 (64 FR 72658) with a 30-day comment period. No comments were received as a result of this publication.

F. Classification

In 1996, the Biochemical Classification Committee determined that Milsana® (alcoholic extract of *Reynoutria sachalinensis*) is a biochemical pesticide because it is naturally occurring and has a non-toxic, indirect mode of action.

G. Food Clearances/Tolerances

A numeric tolerance or exemption from the requirement of a tolerance is not needed because there are no food uses associated with the registration of Milsana®.

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V. Science Assessment

A. Physical/Chemical Properties Assessment

All product chemistry data requirements for the extract of *Reynoutria sachalinensis* are satisfied.

0. **Product Identity and Mode of Action**

a. **Product Identity:**

The technical grade active ingredient consists entirely of the dried and ground plant material from harvested *Reynoutria sachalinensis* (giant knotweed) plants grown for this purpose. The end-use product Milsana® Bioprotectant contains 5% of the ethanolic extract of *Reynoutria sachalinensis,* and is not manufactured by an integrated process.

b. **Mode of Action:**

Reynoutria sachalinensis extract, which is used as a preventive treatment, is believed to induce a non-specific resistance against certain fungal diseases. The active ingredient appears to be a natural elicitor of phytoalexins, which induce the plant's natural "immune system", providing resistance in the host plant.

c. **Food Clearances/Tolerances**

There are no food uses associated with this action. As a result, a tolerance establishment/exemption is not required.

d. **Physical And Chemical Properties Assessment**

The physical and chemical characteristics of the TGAI and the end-use product were submitted to support the registration. There are summarized in Table 1.

GUIDELINE NO.	STUDY	RESULTS	MRID NO.
151B-10 151B-11 151B-12	Product identity; Manufacturing process; Discussion of formulation of unintentional ingredients	TGAI consists of 100% dried and ground knotweed plant material. EU contains 5% of the ethanolic extracts of the TGAI and 95%	44821901

		impurities.	
151B-13	Analysis of samples	Since this a plant extract, a Bioassay Method (dose response) was used to demonstrate consistent activity in lieu of 5 batch analysis.	44857301
151B-15	Certification of limits	Limits listed in the CSF are adequate	44821901
151B-16	Analytical method	G C / F I D	44857301
151B-17	PHYSICAL / CHEMICAL PROPERTIES FOR THE TGAI and End-Use Product (EU)		
151B-17(a)	Color	TGAI: Olive green, brown and cream EU: Not Required	44821902
151B-17(b)	Physical State	TGAI: Non-uniform solid EU: Liquid	44821902
151B-17(C)	Odor	No odor	44821902
151B-17(d)	Melting point	Not Required TGAI is a solid plant extract	
151B-17(e)	Boiling point	Not Required; TGAI is a solid plant extract o	
151B-17(f)	Density/Specific gravity	TGAI: 0.135 g/ml EU: 1.394g/ml	44821903
151B-17(g)	Solubility	Not Required; TGAI is a solid plant extract o	
151B-17(h)	Vapor Pressure	Not Required; TGAI is a solid plant extract o	
151B-17(I)	pH	EU: 6.84 (@ " 0.03 for 1% solution	44821903
151B-17(j)	Stability	Not Required; TGAI is a solid plant extract o	
151B-17(k)	Flammability	Not Required; TGAI is a solid plant extract o EU: No flashpoint up to 101.8 EC	44821903

151B-17(l)	Storage stability	Not Required; TGAI is a solid plant extract o	
151B-17(m)	Viscosity	TGAI: Not Required; TGAI is a solid plant extract o EU: 79.4 cp at 20.1EC	44821903
151B-17(n)	Miscibility	TGAI: Not Required; TGAI is a solid plant extract o EU: Not emulsifiable	44821902
151B-17(o)	Corrosion characteristics	EU does not contain corrosive ingredients	44821902
151B-17(p)	Octanol/water partition coef.	Not Required; TGAI is a solid plant extract o	

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B. Human Health Assessment

The information submitted in support of the application for registration of Milsana® Bioprotectant Concentrate and the technical grade active ingredient *Reynoutria sachalinensis* bioprotectant adequately satisfies the requirements set forth in 40 CFR 158.690 (c) for biochemical pesticides for non-food indoor uses. The overall toxicological risk from human exposure to the extract of *Reynoutria sachalinensis* is considered negligible.

0. Toxicology Assessment

Adequate mammalian toxicology data are available and support registration of the product containing the active ingredient *Reynoutria sachalinensis* plant extract.

a. Acute Toxicity

The registrant submitted acceptable acute toxicity studies. Based on a lack of mortality observed in albino rats, the oral LD_{50} of the liquid end-use product Milsana®, was >5000 mg/kg; Toxicity Category IV. Based on a lack of mortality observed in albino rabbits dermally dosed with 2000 mg/kg of liquid product, the LD_{50} was >2000 mg/kg; Toxicity Category III. All the animals exposed to the product for 4 hours, lived and gained weight during the study. The LC_{50} is >2.6 mg/L; making inhalation a Toxicity Category IV. With a dose of

0.1 ml of liquid Milsana®, the highest Average Ocular Irritation Index was 23.3, recorded one hour after initiation. This classifies Milsana® as moderately irritating with a Toxicity Category II. However, when the TGAI was used as a test material, the highest average ocular irritation recorded was 12.2. As a result, the primary eye imitation for the extract of *Reynoutria sachalinensis* could be classified as Toxicity Category III. Therefore, it may be safe to believe that product Milsana® contains an eye irritant inert. Dermal application of 0.5 g of liquid product did not cause any dermal irritation symptoms up to 72 hours postdosing; Toxicity Category IV. Based on the data submitted for dermal sensitization, the test substance is not considered to be a contact sensitizer in guinea pigs by the Buehler method.

b. **Mutagenicity, Developmental Toxicity, and Immune Response**

Studies to detect genotoxicity are only conditionally required for terrestrial, non-food use biochemical pesticides. 40 CFR 158.690(c)(v) indicates that these studies are required if use is likely to result in significant human exposure, or if the active ingredient or its metabolites are structurally related to a known mutagen or belong to a class of chemical compounds which contains known mutagens. Human exposure to the active ingredient when used in accordance with label instructions in greenhouses on ornamental plants is anticipated to be very low due to the low application rate, re-entry restrictions, and protective wear requirements for greenhouse workers. In addition, the active ingredient is not structurally related to a known mutagen, nor does it belong to a class of known mutagens. Since *Reynoutria sachalinensis* is found in food and in medicines, and there have been no reports of adverse effects over many years of significant human exposure, these studies were waived.

Although immune response studies are required under 40 CFR 158.690(c), the test compound did not cause dermal sensitization in guinea pigs when tested by the Buehler method. Thus, along with the low anticipated human exposure from the labeled uses, the presence of the active ingredient as food, animal feed, and medicine in other parts of the world, and no reports of adverse effects in humans after many years of significant human exposure, the immune response study was waived. Any incidents resulting from the

labeled uses must be reported in accordance with section 6(a)(2) of FIFRA. If such reports occur, this data may be required at that time.

Mammalian toxicity data for the extract of *Reynoutria sachalinensis*, are summarized in Table 2.

Table 2. Toxicity data requirements

GUIDELINE NO.	STUDY	RESULTS	MRID NO.
		TIER I	
152-10	Acute oral toxicity in rats	LD_{50} is > 5000 mg/Kg Toxicity Category IV	44821905
152-11	Acute dermal toxicity in rabbits	Both TGAI and EU: LC_{50} is >2000 mg/Kg Toxicity Category III	44821907
152-12	Acute inhalation toxicity in rats	Both TGAI and EU: LC50 is >2.6 mg/L Toxicity Category IV	44821908
152-13	Primary eye irritation in rabbits	TGAI: Average ocular irritation index recorded was 12.2 Toxicity Category III EU: Average Ocular Irritation Index was 23.3, recorded one hour after initiation Toxicity Category II	4482190
152-14	Primary dermal irritation in rabbits	Dermal application of 0.5 g of liquid product did not cause any dermal irritation symptoms up to 72 hours postdosing Toxicity Category IV	44821911
152-15	Dermal sensitization in guinea pigs	Both TGAI and EU are not considered to be a contact sensitizer in guinea pigs by the	44821914

		Buehler method.	
152-16	Hypersensitivity incidents	No hypersensitivity incidents observed	44821914
152-17	Genotoxicity - *Salmonella typhimurium* gene mutation assay	Waived	
152-18	Cellular immune response	Waived	
152-19	Mutagenicity: * Mouse Lymphoma forward mutation * In vivo mouse micronucleus assay	Waived	

c. **Subchronic Toxicity**

A 90 - day feeding study was not required because of the non-food use of Milsana®. Moreover, the 90 - day dermal and inhalation toxicity studies are not required because the proposed use pattern does not result in prolonged exposure at concentrations that are likely to be toxic. The immunotoxicity study (cellular immune response study) was waived based on the minimal potential for exposure and the low toxicity of the extract of *Reynoutria sachalinensis* shown in the studies submitted.

d. **Chronic Exposure and Oncogenicity Assessment**

Chronic exposure studies are conditionally required to support non-food uses only if the potential for adverse chronic effects are indicated based on 1) the subchronic effect levels established in Tier I subchronic oral, inhalation, or dermal studies, 2) the pesticide use pattern, or 3) the frequency and the level of repeated human exposure that is expected. Oncogenicity studies are required to support non-food uses only if the active ingredient or any of its metabolites, degradation products, or impurities produce in Tier I studies morphologic effects in any organ that potentially could lead to neoplastic changes. The triggers for chronic exposure and oncogenicity studies were not met.

e. **Effects on the 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).

Based on the weight of the evidence of available data, no endocrine system-related effects have been identified for the extract of *Reynoutria sachalinensis*.

1. **Dose Response Assessment**

No toxicological endpoints are identified.

2. **Dietary Exposure and Risk Characterization**

Dietary exposure is unlikely to occur because of the non-food use of Milsana®. In the absence of any toxicological endpoints, risk from the consumption of residues is not expected for the general population including infants and children.

3. **Occupational, Residential, School and Day Care Exposure and Risk Characterization**

Significant human exposure to Milsana® is not expected in residential, school and day care areas.

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a. **Occupational Exposure**

Based on its low toxicity and its use on ornamentals intended for aesthetic purposes, Milsana® is not subject to the Worker Protection Standards (WPS). Moreover, the possibility for dermal, eye and inhalation exposure, is mitigated as long as the product is used according to label directions, which requires the use of protective equipment, the restricted entry interval into treated areas, and allowing proper ventilation time before permitting human activity in the treated areas.

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

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

4. **Drinking Water Exposure**

Exposure to Milsana® in drinking water is not expected.

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

There are no food uses associated with the proposed use of the Milsana®. Therefore, the acute dietary risks should be negligible based on the lack of exposure.

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

Aggregate exposure would primarily occur to the applicators via dermal and inhalation routes. Risks associated with dermal and inhalation aggregate exposure are measured via the acute toxicity studies submitted to support registration. Because the inhalation toxicity studies for Milsana® showed no toxicity (Toxicity Category IV), the risks anticipated for this route of exposure are considered minimal. Results of the acute dermal study indicated low toxicity (Toxicity Category III) and no significant dermal irritation (Toxicity Category IV). Based on these results, the anticipated risks from dermal exposure are also considered minimal. Therefore, the risks from aggregate exposure via dermal and inhalation exposure are a compilation of two low risk exposure scenarios and are considered negligible. Temporary

eye irritation and injury may occur, because the primary eye irritation study for Milsana7 is Toxicity Category II. However, this risk is mitigated as long as the product is used according to label directions, which requires the use of protective equipment by users, restricted re-entry interval into treated areas, and proper ventilation time before permitting human activity in the treated areas.

7. **Cumulative Effects**

The extract of *Reynoutria sachalinensis* is not toxic and therefore there would be no expected cumulative effects from common mechanisms of toxicity.

8. **Risk Characterization**

The Agency has considered the extract of *Reynoutria sachalinensis* in light of the relevant safety factors in FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U. S. population in general, and to infants and children in particular, will result from the use of Milsana7

when label instructions are followed.

C. Environmental Assessment

0. **Ecological Effects Hazard Assessment**

The end use product Milsana® is intended for use in non-food enclosed areas. When applied according to the proposed label, no direct exposure of birds, aquatic organisms and non-target insects to Milsana® is expected to occur. Moreover, the active ingredient is a naturally abundant plant species. Therefore, Milsana®'s potential environmental/ecological effects are likely to be negligible. As a result, non-target organism/ecological effects studies were not required for this particular use of Milsana®.

1. **Environmental Fate and Ground Water Data**

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

2. **Ecological Exposure and Risk Characterization**

Minimal potential for exposure exists to nontarget wildlife as a result of Milsana®'s use.

D. Efficay Data

No efficacy data are required, because no public health uses are involved.

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VII. Risk Management Decision

A. Determination of Eligibility for Registration

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

To satisfy criteria "A" above, the extract of *Reynoutria sachalinensis* is not expected to cause unreasonable adverse effects when used according to label instructions. Criteria "B" is satisfied by the current label and by the data presented in this document. It is believed that this new pesticidal active ingredient will not cause any unreasonable adverse effects, will extend the life and usefulness of ornamentals as claimed satisfying Criteria "C". Criteria "D" is satisfied by the data submitted and the low exposure to the product when used according to label directions.

Therefore, the extract of *Reynoutria sachalinensis* is eligible for registration. Registered use is listed in Table 4, Appendix A.

B. Regulatory Position

0. **Conditional / Unconditional Registration**

All data requirements are fulfilled and BPPD recommends unconditional registration of the extract of *Reynoutria sachalinensis*.

1. **CODEX Harmonization**

There are no Codex harmonization consideration since there is no food use associated with this registration.

2. **Nonfood Re/Registrations**

There are no non-food issues at this time. The nonfood uses are listed in Appendix A, Table 4.

3. **Risk Mitigation**

There are no significant risk issues. Risks to greenhouse workers are mitigated by protective clothing requirements and re-entry restrictions.

4. **Endangered Species Statement**

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

Prior to the implementation of the Endangered Species Protection Program, the Agency will not impose specific labeling on those pesticides that may pose risks to threatened and endangered species and their habitats but will defer imposing specific labeling language until implementation of the Program.

C. Labeling Rational

It is the Agency's position that the labeling for Milsana® Bioprotectant Concentrate and the technical grade active ingredient *Reynoutria sachalinensis* bioprotectant containing, respectively, 5% and 100% of dried and ground giant knotweed (*Reynoutria sachalinensis)* complies with the current pesticide labeling requirements.

0. **Human Health Hazard**

   a. **Human Health Hazard**

This product does not come under the provisions of the Worker Protection Standards (WPS).

b. **Non-Worker Protection Standard**

There are no non-WPS human health hazard issues.

c. **Precautionary Labeling**

The Agency has examined the toxicological data base for Milsana® product and concluded that the proposed precautionary labeling (i.e. Signal Word, Statement of Practical Treatment and other label statements) adequately mitigates any risks associated with the proposed uses.

End-Use product Precautionary Labeling: For Milsana®, "WARNING". Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses) Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of twenty four (24) hours.

d. **Spray Drift Advisory**

No spray drift advisory statement is necessary for this use

1. **Environmental Hazards Labeling**

End-Use Product Environmental Hazards Labeling: Because Milsana® is exclusively intended for greenhouse use, the environmental hazard statement is not required on the end-use product's label.

2. **Application Rate**

t is the Agency's position that the labeling for the pesticide product containing Milsana® complies with the current pesticide labeling requirements. The Agency has not stipulated a maximum number of applications for the active ingredient. Applications should be done using conventional ground or foliar application equipments. Mix Milsana® with

water at a rate of 2 quarts per 100 gallons of water. Begin applications at 4-6 leaf stage at 7 to 10 day intervals.

D. Labeling

0. Product name: **Milsana7 Bioprotectant Concentrate**

   Active Ingredient: Extract of Reynoutria sachalinensis 5.00%

   Other Ingredients 95.57%

   Total 100.00%

1. Product name: ***Reynoutria sachalinensis* bioprotectant**

   Active Ingredient: Extract of Reynoutria sachalinensis 100 %

   Other Ingredients 0 %

   Total 100.00%

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

F. The product shall contain the following information:

G. - Product Name

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

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VIII. Actions Required by Registrants

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

IX. Appendix A

Milsana® Bioprotectant Concentrate Use Site	Official date registered:
Greenhouse grown ornamental plants	