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Reregistration Eligibility Decision for Triforine

Reregistration Eligibility Decision (RED) for Triforine

List B

Case No. 2720

Approved by: _____

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Director, Special Review and Reregistration Division

Date: 3/25/08

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Glossary of Terms and Abbreviations

ae	Acid Equivalent
ai	Active Ingredient
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
DCI	Data Call-In
ESTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
ESA	Endangered Species Act
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
GENEEC	Tier I Surface Water Computer Model (Estimated Aquatic Environmental Concentrations)
GRAS	Generally Recognized As Safe
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
N/A	Not Applicable
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
ppb	Parts per Billion
PPE	Personal Protective Equipment
ppm	Parts per Million
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RQ	Risk Quotient
TGAI	Technical Grade Active Ingredient
UV	Ultraviolet
WPS	Worker Protection Standard

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks arising from the currently registered uses of the pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

This document summarizes EPA's human health and ecological risk assessments and reregistration eligibility decision (RED) for triforine. The document consists of six sections. Section I contains the regulatory framework for reregistration; Section II provides an overview of the chemical and a profile of its use and usage; Section III gives an overview of the human health and environmental effects risk assessments; Section IV presents the Agency's decision on reregistration eligibility and risk management; and Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices list related information, supporting documents, and studies evaluated for the reregistration decision. The risk assessments for triforine and all other supporting documents are available in the Office of Pesticide Programs (OPP) public docket at http://www.regulations.gov under docket number EPA-HQ-OPP-2008-0196.

II. Chemical Overview

A. Regulatory History

Triforine was first registered in the United States by American Cyanamid in 1976 for use as a fungicide on ornamentals and a variety of food crops. All food uses were voluntarily cancelled in 1996 and the associated tolerances were revoked in a final rule published on July 23, 2004 (69 FR 43918) (FRL-7358-6). Outside the United States, triforine continues to be used on food crops, turf, and ornamentals. Summit Agro acquired the one technical product in May 2005.

A DCI was issued to the technical registrant in January 1991. Because of the many crop uses of triforine this DCI included data requirements for ecological, environmental fate, toxicology, and residue chemistry. In the registrant's response to the DCI, they indicated that they were no longer going to support the food uses of triforine and only maintain the non-food uses. All indoor food uses and terrestrial food uses were removed from their labels. In 1995, a DCI was mailed to the remaining registrants of triforine to allow them the opportunity to support these uses by submitting the required data. In subsequent responses to the DCI, all registrants removed food uses and only non-food uses now remain on the triforine labels. In October 1995 a DCI was mailed to the registrants which included data requirements for re-entry exposure.

There are currently four active Section 3 registrations for triforine. No tolerance exists for commodities treated with triforine. Table 1 presents the supported registrations that contain triforine as an active ingredient.

Table 1: Supported Registrations for Triforine

Registration #	Product Name	Active Ingredients (AI)	% AI
82534-1	Triforine Technical	Triforine	97
239-2435	Ortho Rose Disease Control	Triforine	6.5
239-2476	Ortho Systemic Rose & Floral Spray	Triforine Resmethrin Acephate	0.1 0.1 0.25
239-2594	Orthenex Insect & Disease Control Formula III	Triforine Fenbutatin-oxide Acephate	3.25 0.75 4

B. Chemical Identification

Triforine is a systemic fungicide with protectant, eradicant, and curative characteristics. Chemical information about the structure and physiochemical properties of triforine are presented in Tables 2 and 3.

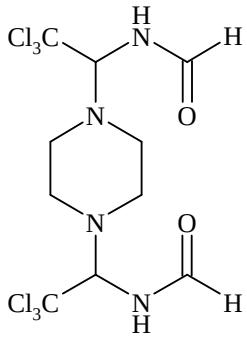
Table 2: Test Compound Nomenclature-Triforine	
Chemical Structure	
Empirical Formula	$C_{10}H_{14}Cl_6N_4O_2$
Common Name	Triforine
EPA PC Code	107901
IUPAC name	[piperazine-1,4-diylbis(2,2,2-trichloroethane-1,1-diyl)]diformamide
CAS Name	N,N'-[1,4-piperazinediylbis(2,2,2-trichloroethylidene)]bisformamide
CAS Registry Number	26644-46-2

Table 3: Physiochemical Properties		
Parameter	**Value**	**Reference**
Molecular Weight	434.98	MRIDs 42019601, -02, and 42172704
Melting point/range	151.3-154.1 °C, color change from white to light brown at 148.6 °C	
pH at 20 °C	An aqueous dispersion varied from pH 5.57-8.33	
Density (g/mL at 20-26 °C)	1.554	
Water solubility (g/L at 20°C)	Distilled water- 12.5×10^{-3} Water, pH 5- 11.3×10^{-3} Water, pH 7- 9.0×10^{-3} Water, pH 9- 8.7×10^{-3}	
Solvent solubility (g/100 mL at 19.5 °C)	Methanol- 4.69 Toluene- 0.011 Tetrahydrofuran- 16.8 Hexane, flask- $<0.47 \times 10^{-3}$ Hexane, colum- 0.26	
Vapor pressure (25°C)	8.0×10^{-2} Pa (6.0×10^{-4} mm Hg)	
Dissociation constant, pKa (20 °C)	2.4×10^{-11} (pKa = 10.6 ± 0.2)	
Octanol/water partition coefficient, $\log K_{OW}$ (25°C)	1.6×10^{2}, log K_{ow}= 2.2 in MeOH[HPLC ratio of equilibrium concentrations in a 2-phase system]	MRIDs 42795801, -02
UV/visible absorption spectrum	Not Available	

C. Use Profile

Type of Pesticide: Fungicide

Target Pests: Black spot, rust, and powdery mildew

Mode of Action: Inhibition of sterol biosynthesis in fungi membranes

Use Sites: Registered for use on ornamentals including roses, trees, herbaceous plants, woody shrubs and vines.

Formulation Type: Liquid concentrate (emulsifiable concentrate) and ready-to-use pressurized liquid (aerosol can)

Application Methods: Hose-end sprayers, low pressure handwand sprayers, sprinkling cans, backpack sprayers, and aerosol cans

Application Rates: 0.46 lb ai/acre for liquid sprays. Reapplication can be made as early as 3 days.

Application Timing: When first signs of disease appear.

Technical Registrant: Summit Agro (USA) Corporation

Uses Considered for Reregistration

Table 4 lists the labeled uses considered for reregistration.

Table 4: Summary of Registered Triforine Uses

Crop	Target	Formulations	Maximum Application Rate and Frequency of Application	Application Equipment
Ornamentals	Fungal diseases (powdery mildew, black spot, rust)	Liquid concentrates (3.25 & 6.5 percent) & Aerosol can (0.1%)	0.0021 lb triforine/gallon of finished spray or 0.46 lb ai/acre for liquid sprays & Aerosols are applied as needed Retreatments can be made at 3-4 or 7-10 days depending on the product	hose-end sprayers, low pressure handwand sprayers, sprinkling cans, backpacks (limited use expected), and aerosol cans

III. Summary of Triforine Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. While the risk assessments and related addenda are not included in this document they are available in the OPP Public Docket, docket number EPA-HQ-OPP-2008-0196, and may be accessed through http://www.regulations.gov/. Hard copies of these documents may also be found in the OPP public docket under this same docket number. The human health and ecological risk assessments and supporting documents listed below and referenced in Appendix C were used to formulate the regulatory decision for the pesticidal use of triforine.

- *Triforine: REVISED HED Chapter of the Reregistration Eligibility Decision Document.* Olinger, C. et al. Dated 3-11-08.
- *Revised Drinking Water Assessment for Reregistration of Triforine for Use on Ornamentals.* Moore, K. Dated 03-05-08.
- *Revised Level I Baseline Ecological Risk Assessment for the Reregistration of Triforine.* Moore, K., and Carey, S. Dated 03-05-08.

A. Human Health Risk Assessment

The human health risk assessment addressed potential exposure and risks from all registered uses. Triforine is not registered for use on any food commodities and risk is not expected from drinking water sources, due to its use pattern, its fate characteristics, the low potential for drinking water exposure given the small-scale residential nature of the labeled use and its toxicity profile. Triforine products are sold predominantly in the residential marketplace where it is used by gardeners to control various plant diseases primarily on roses but it can be used on other ornamental plants. For the complete human health risk assessment, refer to *Triforine: REVISED HED Chapter of the Reregistration Eligibility Decision Document* (Olinger, C. et al., Dated 3-11-08), which is available in the public docket.

1. Toxicity of Triforine

The toxicological database for triforine is sufficient for risk assessment purposes. Triforine has low to moderate (Category III) toxicity via the dermal route of exposure and is a minor eye irritant (Category III). It is not acutely toxic via the oral or inhalation routes of exposure (Category IV), it is not a dermal irritant (Category IV) and is negative for skin sensitization. Table 5 summarizes the acute toxicity profile of triforine.

Table 5: Acute Toxicity Profile - Triforine

Guideline No.	Study Type	MRID	Results	Toxicity Category
870.1100	Acute oral [rat]	42172701	LD_{50} > 5000 mg/kg	IV
870.1200	Acute dermal [rabbit]	42172702	LD_{50} = >2000 mg/kg	III
870.1300	Acute inhalation [rat]	42172703	LC_{50} = > 5.12 mg/L	IV

Table 5: Acute Toxicity Profile - Triforine				
Guideline No.	**Study Type**	**MRID**	**Results**	**Toxicity Category**
870.2400	Acute eye irritation [rabbit]	42380407	Conjunctival redness in 1 rabbit at 24 hrs. [score 1]; cleared by 48 hrs.	III
870.2500	Acute dermal irritation [rabbit]	42380408	Not an irritant	IV
870.2600	Skin sensitization [guinea pig]	42380409 43396901	Not a dermal sensitizer	Not Applicable

Effects observed in subchronic and chronic toxicity studies were generally not severe. Liver effects included increased liver weights, increased cholesterol levels, and increased alkaline phosphatase levels. A mild anemia was seen in several studies, apparently caused by damage to red blood cells because the bone marrow responded by increasing production of red blood cells.

No maternal or developmental toxicity was observed in the rat in the developmental toxicity study at significant dose levels. In the rabbit, decreased maternal body weight and food consumption and decreased fetal body weight were the only effects observed at the limit dose. Slight reproductive effects such as decrease in testes weight, were observed in the rat reproduction study at doses above the limit dose.

Developmental or reproductive toxic effects from triforine are not of concern. Some reproductive toxicity effects such as decreased testes weight, decreased male fertility, were observed at doses higher than the limit dose. No toxic reactions were observed in a 21-day dermal toxicity study at doses up to 1100 mg/kg/day which is higher than the limit dose. It is not a dermal sensitizer or dermal irritant. Triforine does not appear to be neurotoxic and there are no specific concerns for pre- and post-natal exposure to triforine. Therefore, no uncertainty factors specifically for children's pre- or post-natal exposures are included in the risk assessment.

Triforine has been classified as, "suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential." This was based on tumors seen in both sexes of one species (mice) only at the limit dose (liver tumors in male mice and lung tumors in female mice). Therefore, there is no quantification of cancer risk for triforine.

A point of departure is the data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with environmentally relevant human exposures. Table 6 contains selected points of departure for the triforine human health risk assessments.

Table 6: Summary of Toxicological Doses and Endpoints for Triforine for Use in Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure**	**Uncertainty Factors**	**Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
All Dietary Scenarios	No risk is expected from this exposure scenario as no hazard was identified in any toxicity study for this duration of exposure. Based on the use pattern for triforine, acute and chronic dietary exposure is not anticipated.			
Incidental Oral Short-Term (1-30 days) and Intermediate-Term (1-6 months)	Based on the use pattern for triforine, incidental oral exposure is not anticipated.			
Dermal Short- and Intermediate-Term	No risk is expected from this exposure scenario as no hazard was identified in a 21-day dermal toxicity study conducted at the limit dose.			
Inhalation Short-Term (1-30 days) and Intermediate-Term (1-6 months)	NOAEL = 23 mg/kg/day (inhalation and oral toxicity are assumed to be equivalent)	UF_A= 10x UF_H=10x	Occupational and Residential LOC for MOE < 100	Subchronic/chronic oral toxicity study – dog LOAEL = 120 mg/kg/day, based on decreased RBC, hematocrit, hemoglobin values, increased spleen weight, and siderosis in the liver, spleen, and bone marrow
Cancer (oral, dermal, inhalation)	Classification: "Suggestive Evidence of Carcinogenicity, but not sufficient to assess human carcinogenic potential" based on two adequate rodent carcinogenicity studies. Quantification of human carcinogenic risk is not required for triforine.			

POD = Point of Departure. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). MOE = margin of exposure. LOC = level of concern.

2. Exposure/Risk Pathway

Dietary Exposure

Because the use of triforine on roses and other plants is a non-food use and all tolerances from prior registrations have been revoked, there is no expectation of dietary exposures through food consumption. Therefore, the only dietary exposure considered in this assessment is from drinking water. There are Maximum Residue Limits established for triforine in other countries, and a list is included in the *Triforine Revised HED Chapter*, page 16.

Drinking Water

Triforine is moderately persistent in soil with a half-life of one to several months and it degrades rapidly in water through hydrolysis and photolysis with half-lives of several days.

Due to its rapid hydrolysis and aquatic photolysis, any triforine that reaches drinking water sources would not be long-lived so there is a low probability of exposure. Triforine is intended for small-scale use by individual homeowners; it is marketed as either 14 oz spray cans or in volumes of one pint to one quart, which can treat a maximum of 0.3 A. Use data from the California Department of Pesticide Regulation (CDPR) suggests that typical use by professional applicators is at rates of <0.05 lb a.i./application. No water monitoring data are available for triforine.

Tier I screening level models were used to quantify the upper bound for drinking water exposure by calculating estimated drinking water concentrations (EDWCs). EDWCs are based on the highly conservative assumption that an entire watershed has been treated with triforine at the maximum application rate, so these values likely overestimate potential exposure. The EDWC for annual average exposure (from surface or ground water sources) is less than one ppb. Considering the toxicity profile for triforine, the fate characteristics, the use pattern, and the very low EDWC, there is no concern from dietary exposure in drinking water.

Residential (Non-Occupational) Handler Exposure and Risk

Triforine is available as a consumer product used predominantly on roses for control of black spot, powdery mildew, and rust. Triforine can also be used on various ornamental and/or shade trees as well as ornamental herbaceous plants, woody shrubs and vines. The residential risk assessment addresses inhalation exposures that individuals receive through their use of consumer products that contain triforine and through inhalation exposures they could receive from frequenting areas that have been previously treated with triforine such as park or home ornamental gardens. No quantitative dermal assessment has been conducted because there were no systemic effects observed in the 21-day dermal toxicity study at the limit dose. Based on the use pattern no incidental oral exposure is expected.

Non-cancer risk estimates are expressed as a margin of exposure (MOE) which is a ratio of the dose from a toxicological study selected for risk assessment, typically a NOAEL, to the predicted exposure. Estimated MOEs are compared to a level of concern which reflects the dose selected for risk assessment and uncertainty factors (UFs) applied to that dose. The standard UF is 100X, which includes 10X for interspecies extrapolation (to account for differences between laboratory animals and humans) and 10X for intraspecies variation (to account for differences among humans). For triforine, MOEs greater than 100 for inhalation exposure do not exceed the Agency's level of concern.

The anticipated use patterns and current labeling indicate several residential exposure scenarios, based on the types of equipment and techniques, in which homeowners can be exposed to triforine during the application process. Intermediate- and long-term exposures are not expected and were not calculated for residential handlers, because of the sporadic nature of applications by homeowners.

The quantitative inhalation risk assessment developed for residential handlers is based on a number of scenarios that include handling liquid concentrates with various hand-held application equipment as well as application with aerosol cans. Although there is information

to suggest that triforine is not typically used in greenhouses, there is nothing on labels to prohibit this use. Since the rate of triforine used in greenhouses would be the same as the outdoor use of triforine, the estimated risk would be the same as well. All of the residential short-term handler inhalation scenarios have MOEs that are greater than the target MOE of 100 by a wide margin. MOEs are greater than 50,000; therefore, the risks are below EPA's level of concern. EPA evaluated both Pesticide Handlers Exposure Database (PHED) and Outdoor Residential Exposure Task Force (ORETF) data for several of the handler scenarios. Both sets of data result in a similar risk conclusion in that triforine risks are not of concern and by a similar wide margin.

Residential (Non-Occupational) Post-application Exposure Assessment

The term "post-application" describes exposure to individuals who enter areas previously treated with pesticides. For triforine, a quantitative post-application risk assessment was not conducted because (1) incidental oral exposure was not expected since the primary uses of triforine are for disease control on roses and other ornamental plants where children would not be expected to routinely contact treated plants and engage in mouthing behaviors; and (2) triforine is relatively not volatile which, coupled with the dilution expected outdoors and the small amounts of active ingredient used, diminish the possibility of post-application inhalation exposure. Therefore, there is no concern for post-application exposures to triforine.

Aggregate Exposure and Risk

There are no registered food uses for triforine and all tolerances for triforine have been revoked. Due to the use of triforine and its environmental fate properties, significant drinking water exposure is not expected. All the residential exposures do not exceed the Agency's level of concern. Therefore, there is no concern for aggregate exposure to triforine.

Cumulative Risk Characterizing/Assessment

EPA has not identified a common mechanism for triforine and any other substances. Triforine does not appear to produce a toxic metabolite produced by other substances.

Occupational Exposure and Risk

Although the primary marketplace for triforine is for residential gardeners, an occupational assessment was conducted to ensure that if use by professionals did occur that the anticipated higher daily use rates and frequency for occupational users would be considered. Occupational exposures can occur because people have contact with triforine residues while using commercial products containing triforine (handlers) or by being in areas that have been previously treated (post-application workers). The only occupational exposure route included in this risk assessment is the inhalation route. Effects from dermal exposures are not expected.

The scenarios associated with triforine use were classified as having short-term (from 1 to 30 days) and intermediate-term (from 30 days to several months) exposures. However, intermediate-term exposures for triforine are unlikely because of its limited use pattern, low

historic use, and low frequency of use by commercial applicators. Long-term exposures are also not expected to occur for the same reasons.

The quantitative inhalation risk assessment developed for occupational handlers is based on a number of scenarios that include handling liquid concentrates with various hand-held application equipment as well as application with aerosol cans. Although there is information to suggest that triforine is not typically used in greenhouses, there is nothing on labels to prohibit this use. Since the rate of triforine used in greenhouses would be the same as the outdoor use of triforine, the estimated risk would be the same as well. All of the occupational short- and intermediate-term handler inhalation scenarios have MOEs that are much greater than the target MOE of 100. Without the use of a respirator, MOEs were greater than 9,000; therefore, the risks are below EPA's level of concern. EPA evaluated both PHED and ORETF data for several of the handler scenarios. Both sets of data result in a similar risk conclusion in that triforine risks are not of concern and by a similar wide margin.

B. Environmental Risk Assessment

The Agency has conducted an environmental fate and effects risk assessment for triforine for the purpose of making a reregistration decision. The fate database for triforine is largely complete. The available data are sufficient to characterize the transport, mobility, and degradation of triforine in the environment. The ecological database for triforine is largely complete for terrestrial and aquatic animals. However, the ecological database for both aquatic and terrestrial plants is not complete and additional data is required. A summary of the environmental risk assessment findings and conclusions is provided below. For more detail on the ecological exposure and risk assessment, see the *Revised Level I Baseline Ecological Risk Assessment for the Reregistration of Triforine* (Moore, K., and Carey, S., Dated 03-05-08).

1. Environmental Fate and Transport

The environmental fate database for parent triforine is largely complete but there are gaps in identifying degradates and characterizing their fate. Triforine is a moderately mobile compound ($K_{oc}$is from 99 mL/g_{oc} to 199 mL/g_{oc}) that is moderately persistent in soil, with half-lives on the scale of weeks to months, and has rapid abiotic degradation in aquatic environments. Aquatic exposure may be to the degradates of triforine formed through hydrolysis and photolysis. No physical/chemical or environmental fate data are available for these degradates and ecological toxicity from these degradates are unknown. For the purposes of this assessment, aquatic degradates are assumed to be as persistent and to have equal toxicity as the parent.

2. Environmental Effects and Risk

To estimate potential ecological risk, EPA integrated the results of exposure and ecotoxicity studies using the risk quotient method. Risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic, for various wildlife species. RQs are then compared to the Agency's levels of concern (LOCs), indicating whether

a pesticide, when used as labeled, has the potential to cause adverse effects on non-target organisms (see Table 7 below). Generally, the higher the RQ, the greater the potential risk. Risk characterization provides further information on the likelihood of adverse effects occurring by considering the fate of the chemical in the environment, communities and species potentially at risk, their spatial and temporal distributions, and the nature of the effects observed in studies.

Table 7: EPA's Levels of Concern and Associated Risk Presumptions

Risk Presumption	LOC Terrestrial Animals	LOC Aquatic Animals	LOC Plants
Acute Risk - there is potential for acute risk	0.5	0.5	1
Acute Endangered Listed Species - endangered species may be adversely affected	0.1	0.05	1
Chronic Risk - there is potential for chronic risk	1	1	Not Assessed

Aquatic Organism Risk

The Agency used modeling to derive estimated environmental concentrations (EECs) for triforine in surface water to represent a variety of aquatic habitats, such as ponds adjacent to treated areas, which are relevant to risk assessment for aquatic animals.

Acute

Available acute toxicity data indicate that triforine is no more than slightly toxic to freshwater fish at the maximum solubility limit (LC_{50} >11 mg ai/L) and moderately toxic to freshwater invertebrates (EC_{50} = 8.95 mg ai/L). Since a definitive acute toxicity threshold could not be established for freshwater fish, RQs were not quantitatively estimated. Based on the available information there is no indication of risk for freshwater fish from acute exposure to triforine as a result of the labeled uses. For freshwater invertebrates, RQs were estimated based on the most conservative aquatic exposure scenario. The freshwater invertebrate RQ for acute exposure is 0.03 and does not exceed the acute listed species LOC of 0.05.

There is a potential for acute exposure to estuarine/marine fish and invertebrates, but acute risks were not estimated because toxicity data were not available. There are some uncertainty regarding the potential acute risks to estuarine/marine fish and invertebrates; however, given the limited residential use of triforine combined with the indication of minimal risk for freshwater animals, acute risks to estuarine/marine fish and invertebrates are likely minimal.

There is only one non-vascular plant study available for triforine. A Tier II toxicity study with green algae indicates that triforine adversely affects cell density. Based on the most conservative aquatic exposure scenario for triforine, which assumes 20 applications at a rate of 0.46 lbs. a.i./A, the peak EEC is 0.23 mg ai/L, the acute RQ for non-target plants is less than 0.01, which is well below the LOC of 1. Endangered species risk to aquatic non-vascular plants could not be calculated because the green algae NOAEC was below the lowest concentration

tested and an EC_{05} as a surrogate could not be calculated without the raw data of individual replicate measurements.

Data are not available to evaluate the risk of triforine to aquatic vascular plants (i.e., duckweed). The potential impact to aquatic vascular plants from exposure to triforine is unknown. However, data from the open literature and a history of phytotoxicity incidents to terrestrial vascular plants suggest that triforine may pose a risk to non-target aquatic vascular plants. Additional data are required in order to assess the potential risk of triforine to aquatic vascular plants.

Chronic

Data were not available to evaluate the chronic risk of triforine to freshwater fish and invertebrates or to estuarine/marine fish and invertebrates. Therefore, the potential risks to these organisms are unknown. There is some uncertainty regarding the potential chronic risk to these organisms. Given the limited residential use of triforine combined with the indication of minimal acute risk for freshwater animals, chronic risk to aquatic animals are likely minimal.

Terrestrial Organism Risk

Birds

Triforine is categorized as practically non-toxic to birds based on studies using upland game birds (bobwhite quail) and waterfowl (mallard duck) on an acute oral basis (LD_{50} >2000 mg ai/kg-bw) and subacute dietary route (LD_{50} >5000 mg ai/kg-diet). Since definitive acute oral toxicity thresholds were not established in the submitted toxicity studies, acute avian RQs were not estimated for birds. However, due to the high LD_{50}s, and relatively low potential for exposure, birds are not at risk to adverse effects of survival from acute oral exposure to triforine as a result of the labeled uses of triforine.

For chronic exposure, bird species are potentially at risk to adverse effects of growth and reproduction from chronic dietary exposure to triforine as a result of the labeled uses. Results of chronic studies with triforine indicate that waterfowl and upland game birds are equally sensitive with reproductive effects of eggshell thinning and cracked eggs being observed at 500 mg ai/kg-diet, resulting in a NOAEC of 100 mg ai/kg-diet. Based on the most conservative terrestrial scenario with multiple (20) applications of triforine and maximum predicted residue levels (upper bound EECs), chronic RQs range between 3.7 and 8. This exceeds the Chronic Risk LOC (LOC >1.0) for birds consuming short grass, tall grass, broadleaf forage/small insects. For a single application of triforine, the Chronic Risk and Endangered Species LOC of 1 is exceeded only for birds foraging short grass (RQ = 1.1). Although there are exceedances of the chronic LOC, the potential for risk of adverse effects to growth and reproduction is based on the assumption that birds are feeding exclusively within residential areas where roses, flowers, shrubs, and shady trees are grown. These exceedances to birds are based on the assumption that birds occupy, exclusively and permanently, the area of registered uses, and foraging feed items with triforine residues. To the extent that those birds

do not reside exclusively and permanently within the area, exposure will be less and risk is presumably less.

Mammals

The acute LD_{50} (>5000 mg ai/kg bw) for mammals is greater than the highest concentration tested, suggesting that triforine is practically non-toxic to mammals on an acute oral basis. Since a definitive acute toxicity threshold was not established, acute mammalian RQs were not estimated; however, mammals are not likely to be at risk from acute oral exposure to triforine as a result of the labeled uses.

Results of chronic toxicity studies with rats indicated an NOAEC of 3000 mg ai/kg-diet for reproductive and offspring effects. Based on the maximum application rate of triforine at 0.46 lb ai/A and maximum predicted residue levels (upper bound EECs), the chronic risk and endangered species LOC (LOC >1.0) is exceeded for 15 and 35 g mammals consuming short grass at 7 and 8 applications, respectively. Although there is an exceedance of the chronic LOC, the potential for risk of adverse effects to growth and reproduction is based on the assumption that mammals are feeding exclusively within residential areas where roses, flowers, shrubs, and shady trees are grown and treated with triforine. The exceedance to mammals that weigh 15 and 35 grams is based on the assumption that small and medium sized mammals occupy, exclusively and permanently, the area of registered uses, and foraging feed items with triforine residues. To the extent that those mammals do not reside exclusively and permanently within the area, exposure will be less and risk is presumably less. In addition, the RQs calculated from average estimated environmental concentrations did not exceed LOCs.

Non-target insects

Acute contact honeybee studies indicate that triforine is practically non-toxic to honey bees (LD_{50} >100 µg/bee).

Terrestrial Plants

Open literature and approximately nine incidents reported impacts to terrestrial plants from the approved non-crop uses of triforine. Given the available information the potential risk to non-target terrestrial plants cannot be precluded at this time and there are assumed to be direct effects from triforine. Additional data are required in order to assess the potential risk of triforine to terrestrial plants.

IV. Risk Management and Reregistration Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration

of products containing triforine as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing triforine.

The Agency has completed its assessment of the human health and ecological risks associated with the use of pesticide products containing triforine. The Agency has determined that triforine products are eligible for reregistration provided label amendments are made to implement these mitigation measures, as outlined in Chapter V. Appendix A summarizes the uses of triforine that are eligible for reregistration. Appendix B identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility of triforine, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data. Should a registrant fail to implement any of the reregistration requirements identified in this document, the Agency may take regulatory action to address these concerns.

B. Requirements for Reregistration

Triforine products are eligible for reregistration provided that registrants comply with the requirements outlined in this document including the following: (1) submit required data and (2) implement label changes.

1. Required Data

Triforine products are eligible for reregistration provided that registrants submit data as required by the product-specific data call-ins that EPA intends to issue as a result of this RED (see Section V). The generic database supporting the reregistration of triforine uses has been reviewed and determined to be adequate to support a reregistration eligibility decision, except for data deficiencies in plant toxicity data. Additional plant toxicity data are required to better characterize risk to non-target plants.

2. Risk Mitigation

Products containing triforine are eligible for reregistration provided the specific labeling requirements required in Table 9 are reflected on the triforine labels.

C. Regulatory Rationale

The Agency has determined that triforine is eligible for reregistration provided that the requirements for reregistration outlined in this document are implemented. Provided that registrants comply with the requirements of this RED, EPA believes that triforine will not present risks inconsistent with FIFRA.

1. Human Health and Ecological Risk

EPA has conducted human health and ecological risk assessments for triforine to support the reregistration eligibility decision. EPA concluded that there are no outstanding

human health risks due to the use of triforine as a pesticide product that are below the Agency's level of concern.

In EPA's ecological risk assessment, a number of exceedances were estimated from use of triforine, specifically concerning chronic risk to mammals and birds, as well as potential risk for plants. Although there are exceedances of the chronic LOC for birds and mammals, the potential for risk is based on the assumption that birds and mammals are feeding exclusively within residential areas where roses, flowers, shrubs, and shady trees are grown. To the extent that those birds and mammals do not reside exclusively and permanently within the area, exposure will be less and risk is presumably less.

Since there is currently no limit on the number of times triforine may be used in a year, a statement will be added to all labels limiting the number of applications per year to 20 for all triforine use sites. The following statement is also required for all triforine labels in order to reduce the opportunity for ecological exposure of triforine:

> "Do not apply directly to or near water, storm drains, gutters, sewers, or drainage ditches. Do not apply when windy. To prevent product run-off, do not over water the treated area(s) to the point of runoff or apply when raining or when rain is expected that day. Rinse application equipment over lawn or garden area only."

Additional required label changes for triforine are included in Table 9.

2. Endocrine Screening

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 were scientific bases for including, as part of the program, 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 extend that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupter Screening Program (EDSP) have been developed and vetted, there may be additional screening and/or testing required for the pesticidal use of triforine.

3. Endangered Species

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that address these impacts. The Endangered Species Act (ESA) requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide

uses that may affect any particular species, EPA uses basic toxicity and exposure data and considers ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. When conducted, these analyses take into consideration any regulatory changes recommended in this RED being implemented at that time.

The ecological assessment that EPA conducted for this RED does not, in itself, constitute a determination as to whether specific species or critical habitat may be harmed by the pesticide. Rather, this assessment serves as a screen to determine the need for any species-specific assessment that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. The species-specific assessment refines the screening-level assessment to take into account information such as the geographic area of pesticide use in relation to the listed species and the habits and habitat requirements of the listed species. If the Agency's specific assessments for the pesticidal use of triforine result in the need to modify use of the pesticide, any geographically specific changes to the pesticide's registration will be implemented through the process described in the Agency's *Federal Register* Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

Risk findings are based solely on EPA's qualitative assessment for triforine and do not constitute "may affect" findings under the ESA. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, and/or consultations with the Fish and Wildlife Service or National Marine Fisheries Service, as necessary. If the Agency determines use of triforine "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402).

V. What Registrants Need to Do

The Agency has determined that the products containing triforine (PC 107901) are eligible for reregistration provided that the mitigation measures and label changes identified in this RED are implemented. Registrants will need to amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table 9. The Agency intends to issue a Data Call-In (DCI) requiring generic and product-specific data. Generally, the registrant will have 90 days from receipt of a DCI to complete and submit response forms or request time extensions and/or waivers with a full written justification. For product-specific data, the registrant will have eight months to submit data and amended labels.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

No fate data is required. However, ecological toxicity data for plants is required as listed below.

Table 8: Generic Data Requirements for Triforine		
Guideline #		**Data Requirement**
850.4100	122-1(a)	Seedling Emergence – Tier I
850.4150	122-1(b)	Vegetative Vigor - Tier I
850.4400	123-2	Aquatic plant acute EC_{50} (duckweed)

Data Justification

Data are not available to evaluate the risk of triforine to aquatic vascular plants (i.e., duckweed) or terrestrial plants. The potential impacts to these plants from exposure to triforine are unknown. However, data from the open literature and a history of phytotoxicity incidents to terrestrial vascular plants suggest that triforine may pose a risk to non-target aquatic vascular and terrestrial plants.

Due to the potential for surface run-off or spray drift, EPA has expanded the seedling emergence and vegetative vigor data requirements to terrestrial food and feed crops, aquatic food crops, and residential outdoor uses. These factors trigger a data requirement for submission of plant studies for the triforine.

During the triforine RED process, the Agency has finalized its update to the data requirements in 40 CFR part 158. These updated data requirements were promulgated on October 26, 2007. Tier I seedling emergence, vegetative vigor, and aquatic vascular studies are required for terrestrial and aquatic nonfood uses. These phytotoxicity data are needed to evaluate the level of pesticide exposure to non-target terrestrial and aquatic plants and to assess the impact of pesticides on endangered and threatened plants.

A solid understanding of the potential risks to terrestrial plants is essential for sound environmental management because plants form the basis of most habitats and significantly contribute to overall environmental quality. Without plant growth data for triforine, the Agency cannot determine the levels of triforine that result in effects to terrestrial and aquatic plants.

The Agency now requires that seedling emergence and vegetative vigor studies be conducted using the typical end use product (TEP). The TEP that contains the highest percentage of active ingredient, and/or is the most commonly used, would be required. In addition, the Agency recommends the seedling emergence and vegetative vigor toxicity tests include one of the ten lettuce cultivars (Avondefiance, Deciso, Kares, Lobjoits cos, Plucos, Vigar, All the Year Round, Romano, Valmaine or Winter Density) that may be susceptible to triforine.

Since EPA was unable to evaluate the potential risks to terrestrial plants in dry and semi-aquatic areas and aquatic vascular plants in water bodies associated with the proposed uses of triforine, risks are presumed for terrestrial and aquatic vascular plants. Data from Tier I terrestrial and aquatic vascular plant toxicity studies will be used to estimate potential risks to plants associated with uses of triforine. The data will reduce uncertainties associated with the

current risk assessment for terrestrial and aquatic plants and will improve our understanding of the potential effects of triforine on plants.

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 9.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements.

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 9. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

C. Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to comply with the following table. Table 9 describes how language on the labels should be amended.

Table 9: Summary of Labeling Changes for Triforine –

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 9. Summary of Labeling Changes for Triforine		
Description	Amended Labeling Language	Placement on Label
Manufacturing Use Products		
For all Manufacturing Use Products	"Only for formulation into a *fungicide* for the following use(s) [fill blank only with those uses that are being supported by MP registrant]."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements

End Use Products		
PPE Requirements Established by the RED	"All mixers, loaders, applicators, and other handlers must wear the following PPE: - long-sleeved shirt and long pants, and - shoes plus socks."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Application Restrictions	"Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application."	Directions for Use under General Precautions and Restrictions
Entry Restrictions for liquids and aerosol formulations	"Do not allow people or pets to enter the treated area until sprays have dried."	Directions for use under General Precautions and Restrictions
Environmental Hazard Statement	"Do not apply directly to water. Do not contaminate water when disposing of equipment wash waters or rinsate."	Precautionary Statements immediately following the User Safety Recommendations
Other Application Restrictions	"Do not apply directly to or near water, storm drains, gutters, sewers, or drainage ditches. Do not apply when windy. To prevent product run-off, do not over water the treated area(s) to the point of runoff or apply when raining or when rain is expected that day. Rinse application equipment over lawn or garden area only.*" * **Note**: Do not include the last sentence for ready-to-use products. For all uses of triforine: The maximum number of applications allowed per year is 20.	Directions for Use under Other Use Precautions

Appendix A: Use Patterns Subject to Reregistration

Use Site	Maximum Application Rate	Formulation[2]	Maximum Number of Applications per Year	Minimum Application Interval	Application Equipment //Type
TERRESTRIAL NON-FOOD & OUTDOOR RESIDENTIAL USES					
ornamental and/or shade trees	0.46 lb. ai/acre	EC	20	7 days	Hose-end sprayer/ Tank-type sprayer //Spray
	Formulated as 0.1% ai per can	PRL	20	7 days	Aerosol can //Spray
ornamental herbaceous plants	0.46 lb. ai/acre	EC	20	3 days	Hose-end sprayer/ Tank-type sprayer //Spray
	Formulated as 0.1% ai per can	PRL	20	7 days	Aerosol can //Spray
ornamental woody shrubs and vines	0.46 lb. ai/acre	EC	20	3 days	Hose-end sprayer/ Tank-type sprayer //Spray
	Formulated as 0.1% ai per can	PRL	20	7 days	Aerosol can //Spray

[1] Current product labels for products containing triforine express maximum application rates equivalent to 0.0021 pounds active ingredient per gallon. At EPA's request, the registrant converted pounds active ingredient per gallon to pounds active ingredient per acre. The assumptions used to calculate this rate are presented in the June 20, 2007 email from Carrie Daniels to Lance Wormell.

[2] EC: Emulsifiable Concentrate; PRL: Pressurized Liquid.

Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains a listing of data requirements which support the reregistration for active ingredients within the 4-AP case covered by this RED. It contains generic data requirements that apply 4-AP in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which is available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

   A. Terrestrial food
   B. Terrestrial feed
   C. Terrestrial non-food
   D. Aquatic food
   E. Aquatic non-food outdoor
   F. Aquatic non-food industrial
   G. Aquatic non-food residential
   H. Greenhouse food
   I. Greenhouse non-food
   J. Forestry
   K. Residential
   L. Indoor food
   M. Indoor non-food
   N. Indoor medical
   O. Indoor residential

3. Bibliographic Citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number is no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B.

Data Requirement			Use Patterns	Citations
New Guideline Number	Old Guideline Number	Description		
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition	All	42019601, 42019602, 42172704
830.7560	63-11	Octanol Water Partition coefficient	All	42795802, 42795801
830.7000	63-12	pH	All	42019601, 42019602, 42172704
830.7200	63-5	Melting Point	All	42019601, 42019602, 42172704
830.7300	63-7	Density	All	42019601, 42019602, 42172704
830.7370	63-10	Dissociation Constants in Water	All	42019601, 42019602, 42172704
830.7840	63-8	Solubility	All	42172704, 42019601, 42019602
830.7860	63-8	Water solubility, generator column method	All	42019601, 42019602, 42172704
830.7950	63-9	Vapor Pressure	All	42019601, 42019602, 42172704
ECOLOGICAL EFFECTS				
850.2100	71-1A	Avian Acute Oral Toxicity	C	232695, 122589, 42428401, 42380401
850.2200	71-2A	Avian Dietary Toxicity – Quail	C	42380403
850.2200	71-2B	Avian Dietary Toxicity – Duck	C	42380402,
850.2300	71-4A	Avian Reproduction - Quail	C	43231901
850.2300	71-4B	Avian Reproduction – Duck	C	43231902
850.1010	72-2	Freshwater Invertebrate Toxicity	C	42380406, 44388302
850.1075	72-1	Freshwater Fish Toxicity Rainbow Trout	C	42380404, 42380405, 44388301
850.3020	141-1	Honey bee acute contact LD50	C	42453101
850.4100	122-1A	Seedling Emergence – Tier I	C	**Data Gap**
850.4150	122-1B	Vegetative Vigor - Tier I	C	**Data Gap**
850.4400	123-2	Aquatic Plant Toxicity	C	**Data Gap**
850.5400	122-2	Aquatic Plant Growth	C	42879901, 42879902
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity - Rat	All	42172701
870.1200	81-2	Acute Dermal Toxicity – Rabbit/Rat	All	42172702
870.1300	81-3	Acute Inhalation Toxicity – Rat	All	42172703
870.2400	81-4	Primary Eye Irritation - Rabbit	All	42380407
870.2500	81-5	Primary Skin Irritation	All	42380408
870.2600	81-6	Dermal Sensitization	All	42380409, 43396901

Data Requirement			Use Patterns	Citations
New Guideline Number	Old Guideline Number	Description		
870.3100	82-1A	Subchronic Oral Toxicity: 90-Day Study Rodent	C	00091341
870.3150	82-1B	Subchronic Oral Toxicity: 90-Day Study Non-rodent	C	00068936, 00122575
870.3200	82-2	21-Day Dermal – Rabbit/Rat	C	42395201, 00091338, 00122576
870.3700A	83-3A	Developmental Toxicity – Rat	C	42889201, 43222101
870.3700B	83-3B	Developmental Toxicity – Rabbit	C	43664901, 43664902, 42889202
870.3800	83-4	2-Generation Reproduction – Rat	C	42371801, 43323301
870.4100A	83-1A	Chronic Toxicity Study - Rodent	C	42412001
870.4100B	83-1B	Chronic Feeding Toxicity Study - Non-rodent	C	42380410, 43222102
870.4200	83-2B	Carcinogenicity Mice	C	42412001
870.4300	83-5	Combined Chronic Toxicity/Carcinogenicity: Rats	C	42454001
870.5375	84-2	Cytogenics- Human Lymphocytes Chromosome Aberration Test	C	43508101, 42251703
870.5395	84-2	In Vitro Mammalian Cytogenetics Tests	C	43508101
870.5550	84-2	Unscheduled DNA Synthesis in Mammalian Cells in Culture	C	42251702
870.7485	85-1	General Metabolism	C	42428402, 00071991, 00071992, 123000, 123001
ENVIRONMENTAL FATE				
835.1240	163-1	Leaching/Adsorption/Desorption	C	42304101
835.2120	161-1	Hydrolysis	C	42647703, 42647702
835.2240	161-2	Photodegradation - Water	C	42647701
835.2410	161-3	Photodegradation - Soil	C	42380411
835.4100	162-1	Aerobic Soil Metabolism	C	43231903, 43231904
835.6100	164-1	Terrestrial Field Dissipation	C	42331501

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, EPA-HQ-OPP-2008-0196

It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:www.epa.gov/pesticides/reregistration

These documents include:

HED Document:

Triforine: Revised HED Chapter of the Reregistration Eligibility Decision Document (RED). PC Code 107901, DP 339610. Olinger, C., Taylor, L., Goodlow, T., and Dawson, J. Dated 03-11-08.

Triforine: Response to Registrant Error-only Comments on HED Risk Assessment. PC Code 107901, DP 339628. Olinger, C., Taylor, L., and Dawson, J. Dated 03-11-08.

EFED Documents:

Revised Drinking Water Assessment for Reregistration of Triforine for Use on Ornamentals. PC Code 107901, DP339605. Moore, K. Dated 03-05-08.

Revised Level I Baseline Ecological Risk Assessment for the Reregistration of Triforine. PC Code 107901, DP339607. Moore, K., and Carey, S. Dated 03-05-08.

EFED Responses to Triforine Phase 1 Error-Only Comments. PC 107901, DP 339629. Carey, S., and Moore, K. Dated 02-26-08.

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Eligibility Decision

MRID	Citation Reference
68936	Leuschner, F.; Leuschner, A.; Schwerdtfeger, W.; et al. (1971) 13 Weeks Oral Toxicity Study in Beagle Dogs with W-524. (Unpub- lished study received Mar 28, 1975 under 239-2435; prepared by Laboratorium fur Pharmakologie und Toxikologie, W. Germany, sub- mitted by Chevron Chemical Co., Richmond, Calif.; CDL:232696-B)
71991	Darda, S. (1971) Biochemical Investigations with W 524 (^3IH) in Rats. (Unpublished study received Feb 8, 1977 under 21137-4; prepared by C.H. Boehringer Sohn, West Germany, submitted by EM Laboratories, Inc., Elmsford, N.Y.; CDL:095808-C)
71992	Darda, S. (1974) The Pharmacokinetics of the Systemic Fungicide Triforine (W 524) in the Rat. (Unpublished study received Feb 8, 1977 under 21137-4; prepared by C.H. Boehringer Sohn, West Germany, submitted by EM Laboratories, Inc., Elmsford, N.Y.; CDL:095808-D)
91338	Leuschner, F.; Leuschner, A.; Schwerdtfeger, W.; et al. (1973) 21- day Toxicity Tests with the Compound W-524 in Sprague-Dawley- rats Using Dermal Application. (Translation; unpublished study received Mar 28, 1975 under 239-2435; prepared by Celamerck, GmbH & Co., KG, West Germany, submitted by Chevron Chemical Co., Richmond, Calif.; CDL:232698-K)
91341	Stotzer, H.; Herbst, M.; Kollmer, H.; et al. (1971) Testing of the Subacute Toxicity of the Substance W524 in Rats following Oral Administration: Document No. T15. (Translation; unpublished study received Mar 28, 1975 under 239-2435; prepared by C.H. Boehringer Sohn, West Germany, submitted by Chevron Chemical Co., Richmond, Calif.; CDL:232698-N)
122575	Leuschner, F.; Leuschner, A.; Schwerdtfeger, W.; et al. (1971) 13 Weeks Oral Toxicity Study in Beagle Dogs with W-524. (Un- published study received Feb 8, 1977 under 21137-4; prepared by Laboratorium fur Pharmakologie und Toxikologie, W. Ger., submitted by EM Laboratories, Inc., Elmsford, NY; CDL:095805-B)
122576	Leuschner, F.; Leuschner, A.; Schwerdtfeger, W.; et al. (1973) 21-day Toxicity Tests with the Compound W-524 in Sprague-Dawley Rats Using Dermal Application. (Translation; unpublished study received Feb 8, 1977 under 21137-4; prepared by Laboratorium fur Pharmakologie und Toxikologie, W. Ger., submitted by EM Laboratories, Inc., Elmsford, NY; CDL:095805-C)
122589	Reno, F.; Moore, S. (1979) Acute Oral LD50 in Bobwhite Quail: Triforine Technical: Project No. 920-102. Final rept. (Un- published study received Jan 15, 1979 under 21137-4; prepared by Hazleton Laboratories America, Inc., submitted by EM Labo- ratories, Inc., Elmsford, NY; CDL:236746-A)
123000	Darda, S. (1974) Excretion and Metabolism of Triforine ... in the Rat. Interim rept. (Unpublished study received Mar 28, 1975 under 239-2435; prepared by C.H. Boehringer Sohn, W. Ger., sub- mitted by Chevron Chemical Co., Richmond, CA; CDL:232064-L)
123001	Darda, S. (1975) Pharmacokinetics of the Systemic Fungicide Trifor- ine ... in Rats. (Translation; unpublished study received Mar 28, 1975 under 239-2435; prepared by C.H. Boehringer Sohn, W. Ger., submitted by Chevron Chemical Co., Richmond, CA; CDL: 232064-M)
42019601	Jungblut, H.; Mladenovic, P.; Van't Klooster-Cornelissen, A. (1990) Product Identity and Composition: Triforine: Lab Project Number: 102AX184002. Unpublished study prepared by Shell Agar. 97 p.
42019602	Van't Klooster-Cornelissen, A.; Jungblut, H. (1990) Analysis and Certification of Product Ingredients: Triforine: Lab Project Number: 102AX137002. Unpublished study prepared by Shell Agar. 54 p.
42172701	Ullman, L. (1986) Acute Oral Toxicity Study with Triforine Technical in Rats: Lab Project Number: 076151. Unpublished study prepared by Research & Consulting Co. Ag. 29 p.

42172702 Ullman, L.; Althaus, P.; Janiak, T.; et al. (1986) Acute Dermal Toxicity Study with Triforine Technical in Rats: Lab Project Number: 278774. Unpublished study prepared by Research & Consulting Co. Ag. 37 p.

42172703 Ullman, L. (1986) 4-Hour Acute Inhalation Toxicity Study with Triforine Technical in Rats: Lab Project Number: 076162. Un- published study prepared by Research & Consulting Co. Ag. 34 p.

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Appendix E. List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available via the Agency's website at *http://www.epa.gov/opprd001/forms/*.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed).

2. The completed form(s) should be submitted in hard copy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at *williams.nicole@epa.gov*.

The following Agency Pesticide Registration Forms are currently available via the Internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	*http://www.epa.gov/opprd001/forms/8570-1.pdf*
8570-4	Confidential Statement of Formula	*http://www.epa.gov/opprd001/forms/8570-4.pdf*
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	*http://www.epa.gov/opprd001/forms/8570-5.pdf*
8570-17	Application for an Experimental Use Permit	*http://www.epa.gov/opprd001/forms/8570-17.pdf*
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	*http://www.epa.gov/opprd001/forms/8570-25.pdf*
8570-27	Formulator's Exemption Statement	*http://www.epa.gov/opprd001/forms/8570-27.pdf*
8570-28	Certification of Compliance with Data Gap Procedures	*http://www.epa.gov/opprd001/forms/8570-28.pdf*
8570-30	Pesticide Registration Maintenance Fee Filing	*http://www.epa.gov/opprd001/forms/8570-30.pdf*
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	*http://www.epa.gov/opprd001/forms/8570-32.pdf*
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	*http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf*
8570-35	Data Matrix (PR Notice 98-5)	*http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf*
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	*http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf*
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	*http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf*

Pesticide Registration Kit *http://www.epa.gov/pesticides/registrationkit/*

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

a. 83-3 Label Improvement Program--Storage and Disposal Statements
b. 84-1 Clarification of Label Improvement Program
c. 86-5 Standard Format for Data Submitted under FIFRA
d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at *http://www.epa.gov/opppmsd1/PR Notices*

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).

a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
b. EPA Form No. 8570-4, Confidential Statement of Formula
c. EPA Form No. 8570-27, Formulator's Exemption Statement
d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).

a. Registration Division Personnel Contact List
b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
c. Antimicrobials Division Organizational Structure/Contact List
d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
e. 40 CFR §156, Labeling Requirements for Pesticides and Devices (PDF format)
f. 40 CFR §158, Data Requirements for Registration (PDF format)
g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' website.

2. The booklet "General Information on Applying for Registration of Pesticides in the United States," PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161-0002

The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.

4. The National Pesticide Information Center (NPIC) can provide information on active ingredients, uses, toxicology and chemistry of pesticides. You can contact NPIC by telephone at (800) 858-7378 or through their website at *http://www.ncis.orst.edu*.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

- Date of receipt;
- EPA identifying number; and
- Product Manager assignment.

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying file symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.