

US EPA ARCHIVE DOCUMENT



Reregistration Eligibility Decision for Aquashade

September 23, 2005

Reregistration Eligibility Decision

For

**Erioglaucine and Tartrazine
(Aquashade *)**

Case No. 4010

Reregistration Eligibility Decision (RED) Document
for Erioglaucine and Tartrazine (Aquashade*)

Approved by:

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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EPI-Suite	Estimation Programs Interface Suite TM
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
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
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
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration

$\mu\text{g/g}$	Micrograms Per Gram
$\mu\text{g/L}$	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1^*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

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 to the EPA. 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" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act (FQPA) was signed into law. This Act amends FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA) to require reassessment of all existing tolerances for pesticides in food. FQPA also requires that by August 3, 2006, EPA must review all tolerances in effect on the day before the enactment of the FQPA, which was August 2, 1996. FQPA also amends the FFDCA to require a safety finding in tolerance reassessment based on factors including aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. The existing exemption from tolerance for erioglaucine has been reassessed.

This document presents the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) decision regarding the reregistration eligibility of the registered uses of the aquatic algaecide/herbicide Aquashade* and other related end-use products containing the dyes erioglaucine and tartrazine as active ingredients. The Agency's reregistration eligibility determination is based on its review of required data and published scientific literature. The Agency has found that currently registered uses of erioglaucine/tartrazine are eligible for reregistration.

Use Profile

The dyes erioglaucine (Acid Blue 9 or FD&C Blue No. 1) and tartrazine (Acid Yellow 23 or FD&C Yellow No. 5), when combined, act as an aquatic algaecide/herbicide. This aquatic herbicide, commonly referred to by the trade name Aquashade*, will be referred to as erioglaucine/tartrazine or "the dyes" throughout the rest of the document. The mixture of erioglaucine and tartrazine control the wavelength range of the sunlight spectrum required for photosynthesis, thereby inhibiting growth of filamentous algae and submerged aquatic vegetation. It can be used in natural or manmade ponds, lakes, fountains, fish farms, and fish hatcheries, and may be applied by both professional applicators and homeowners. Application is recommended early in the growing season while growth is on the bottom of the water body, or later in the season after the killing

and/or removal of any existing growth. There are 4 registered end-use products containing the combination of erioglaucine and tartrazine; each product has a different ratio of the dyes, but in all the product formulations the percent of erioglaucine is higher than tartrazine.

Human Health Risk Assessment

Reference: “*Aquashade: HED Chapter of the Reregistration Eligibility Decision Document (RED)*,” W. Britton; 9/13/05.

Toxicology

This risk assessment takes a weight of the evidence approach and considers available data from a variety of sources, including the Food and Drug Administration (FDA) and the Joint Expert Committee on Food Additives of the Food and Agriculture Organization/World Health Organization (JECFA). This information is sufficient to evaluate the toxicity of erioglaucine/tartrazine and related compounds. Both erioglaucine and tartrazine are listed as safe for general use as food, drug, and cosmetic color additives by the Food and Drug Administration (FDA). The Agency is not aware of any adverse effects associated with exposure resulting from the FDA-approved uses of either tartrazine or erioglaucine. Based on the information available from these sources, the available toxicity database is complete and there are no data gaps.

Erioglaucine and tartrazine both have very low toxicity potentials. A definitive target organ has not been identified and clinical signs of toxicity were not observed in any study performed using these dyes. Both are rapidly metabolized and excreted in rats, rabbits, and dogs. Erioglaucine is poorly absorbed; this is not the case for tartrazine which can be found in bile. However, generally the parent compounds are excreted unchanged mainly in feces with a small amount excreted by the urine. Systemic toxicity was observed in one study in the toxicity database and was limited to a decrease in mean body weight following long-term dietary exposure to high doses in rats. There were no adverse effects observed in mice or dogs. All NOAELs were reported to be greater than or equal to 500 mg/kg/day with the exception of a non-guideline 21- day dermal study in rats. The NOAEL for this study was 5 mg/kg/day which was the highest dose tested.

The various end-use products each have a different ratio of the two dyes. A product containing 68% erioglaucine and 4.5% tartrazine was tested for acute toxicity. The product has low acute oral toxicity with no deaths occurring near the limit dose (category IV). It has a moderate acute dermal toxicity (category III). There were no clinical signs of systemic toxicity in the acute oral and dermal studies. Based on the use pattern, an acute inhalation study is not required. The product caused slight eye irritation (category III). It was negative for dermal irritation (category IV), but it was determined to be a dermal sensitizer.

Based on the lack of evidence of pre- and/or post-natal susceptibility following exposure to tartrazine or erioglaucine, and considering the lack of residual uncertainties and the

low level of concern for pre- and/or post-natal toxicity and exposure, no special FQPA safety factor is needed. The special FQPA safety factor was reduced to 1X.

There was no evidence of neurotoxicity in any study, and no evidence of carcinogenicity was observed in carcinogenicity studies in mice and rats with erioglaucine (Borzelleca and Hallagan, 1988a, 1988b) or tartrazine (Borzelleca et al, 1990).

An acute reference dose (aRfD) was not established since no appropriate endpoint could be attributed to a single exposure available from oral studies, including the developmental toxicity studies. A chronic reference dose (cRfD) of 5 mg/kg/day was established for erioglaucine/tartrazine based on a NOAEL of 500 mg/kg/day in a chronic oral toxicity study in dogs (tartrazine) and a combined chronic oral toxicity/carcinogenicity study in rats (erioglaucine), done by FDA. The NOAEL of 500 mg/kg/day was used as the dermal and inhalation exposure endpoint for residential and occupational risk assessments as well. The default assumption of 100% absorption was used for both dermal and inhalation assessments. Please refer to the human health risk assessment for a complete listing of studies and endpoints.

Dietary Risk from Food

Based on the consideration of anticipated exposure scenarios and risk, a dietary food exposure assessment was not conducted. Although water treated with the dyes may potentially be used for irrigation of food crops and livestock watering and the dyes are registered for use in fish farms and hatcheries, the Agency has not quantitatively assessed exposures and risks from food sources for several reasons:

- (1) Erioglaucine/tartrazine are used primarily in ornamental and/or recreational lakes and ponds with very little treated water expected to be used for agricultural purposes.
- (2) Erioglaucine and tartrazine are highly water soluble compounds and are not likely to accumulate in livestock or fish tissues.
- (3) Any residues of erioglaucine and tartrazine occurring in foods from the use of the dyes as an aquatic algaecide/herbicide would be negligible compared to residues in food from the common use of these dyes as food coloring additives, which are listed as safe for general use as food, drug and cosmetic color additives by the FDA.
- (4) The most significant route of exposure to erioglaucine and tartrazine from the use of the products is residential exposure, including residential handler and postapplication (swimming) exposure. The Agency believes that the conservative residential exposure and risk estimates discussed below are more than adequate to cover any food exposures that could potentially occur from the use of the combination of dyes as an aquatic algaecide/herbicide.

Dietary Risk from Drinking Water

Since the dyes are directly applied by hand to contained water bodies with little or no outflow and because none of the treated water bodies serve as a source of drinking water,

drinking water exposure is not expected and therefore a drinking water assessment was not conducted.

Residential Risk

Reference: *Aquashade: HED Chapter of the Reregistration Eligibility Decision Document* (09/13/05)

Aquatic herbicide products containing erioglaucine/tartrazine are labeled for consumer use to control aquatic algae and weeds in ponds and lakes. The anticipated use patterns and current labeling indicate several residential handler scenarios based on the types of equipment and techniques that can potentially be used to make dye applications. Residents or consumers applying erioglaucine/tartrazine products to ponds or lakes may be exposed for short-term (1 to 30 days) duration through skin contact or by inhalation. All residential handler scenarios assessed (dermal and inhalation) resulted in estimated MOEs greater than 100 and, therefore, are not of concern. Residential short-term dermal MOEs range from 1,930 (Liquids for Pouring Applications) to 16,000 (Liquids for LCO Handgun), and short-term inhalation MOEs range from 550,000 (Liquids for Garden Hose End Sprayer) to 6,600,000 (Liquids for Pouring Applications).

Postapplication exposures to children and adults that contact erioglaucine/tartrazine-treated swimming ponds are anticipated. To address the risk of such exposures, a screening tool called the Swimmer Exposure Assessment Model (SWIMODEL) was applied. The SWIMODEL uses well-accepted screening exposure assessment equations to calculate the total worst-case exposure for swimmers expressed as a mass-based intake value (mg/ event). Postapplication residential exposure durations are expected to be short- and intermediate-term (1 to 6 months) in duration. All residential postapplication scenarios assessed (dermal, ingestion, aural, buccal/sublingual, and nasal/orbital routes of exposure) resulted in estimated combined MOEs well above 100 (≥ 4900) and, therefore, are not of concern.

To better quantify residential erioglaucine/tartrazine hazard, results from residential handler and residential postapplication (i.e., swimmer) risk assessments were aggregated. Aggregate calculations of residential exposure were performed using worst-case MOEs resulting from each assessment. The residential aggregated exposure resulted in an estimated MOE of 1400 and, therefore, is not a risk of concern.

Aggregate Risk

In accordance with the FQPA, EPA must consider and aggregate pesticide exposures and risks from three major sources: drinking water, food and residential exposures. Since the dyes are applied to contained water bodies with little or no outflow, and none of the treated water bodies serves as a source of drinking water, no drinking water exposure is expected. Also, no quantitative dietary assessment was deemed necessary for reasons listed above. The most significant route of exposure to erioglaucine and tartrazine is

residential exposure, including residential handler and postapplication (swimming) exposure. Estimated exposures (combined) for residential handlers and swimmers were well below the Agency's level of concern. Therefore, the Agency finds no risk concerns due to aggregate exposures to erioglaucine and tartrazine.

Cancer Risk

A cancer risk assessment was not conducted because there was no evidence of carcinogenicity in the toxicology studies submitted for the dyes.

Cumulative Risk Characterization/Assessment

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to erioglaucine and tartrazine and any other substances, and the dyes do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that the dyes do not share a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

Occupational Risk

The Agency determined that the potential for occupational exposure from erioglaucine/tartrazine exists in a variety of occupational environments. The anticipated use patterns and current labeling indicate several occupational exposure scenarios based on the types of equipment and techniques that can potentially be used for application of the dyes. These include the handling of erioglaucine/tartrazine during mixing, loading, and applying processes (i.e. mixer/loaders, and mixer/loader/applicators). As a result, a risk assessment has been completed for the occupational handler scenario. Short-term (1 to 30 days) and intermediate-term exposures (1 to 6 months) may occur; however, long-term exposures (greater than 6 months) are not expected.

The calculated occupational handler exposures for all scenarios resulted in estimated MOEs greater than 100 and, therefore, are not of concern. Short- and intermediate-term MOEs do not differ because they share the same toxicological endpoint. Short- and intermediate-term dermal MOEs range from 410 (Liquids for Pouring Applications) to 4,300 (Liquids for Garden Hose-End Sprayer). Short- and intermediate-term inhalation MOEs range from 120,000 (Liquids for Garden Hose End Sprayer) to 1,600,000 (Liquids for Pouring Applications). A summary of the short- and intermediate-term risks (dermal and inhalation) for each exposure scenario can be found in the occupational and residential exposure chapter referenced above.

Environmental Risk Assessment

Reference: “*Ecological Risk Assessment for the Re-registration of Tartrazine (“Acid Yellow 23”) and Erioglaucine (“Acid Blue 9”) Dyes in the End-use Products Aquashade, Admiral, and Algae Blocker;*” James Goodyear and Silvia Termes; 09/10/05.

The Agency has conducted an environmental assessment of erioglaucine/tartrazine for the purpose of making a reregistration eligibility decision. The Agency evaluated environmental fate and effects studies submitted for erioglaucine and tartrazine. Published literature on effects were obtained by EPA’s Office of Research and Development through their literature search conducted as part of the ECOTOX program. The Agency has determined that the data are adequate to support a reregistration decision.

More in depth details of the ecotoxicity and environmental fate used to develop the risk assessment and to support the requirements are provided in the environmental risk assessment referenced above.

Environmental Fate and Transport Properties

No environmental fate data were required for either dye based on the use pattern and toxicity studies. The environmental fate information in this assessment is qualitative, based mostly on data from the open literature on structurally related dyes. However, structure-activity relationship estimates do not adequately estimate physical and chemical properties of salts, particularly those of large anions such as in Acid Blue 9 and Acid Yellow 23.

Unlike the uses on food, drugs, and cosmetics, the dyes are exposed to an open aquatic environment when used as herbicides. Because the concentrated products are added directly to a water body, the dyes (which do not react chemically with each other) become diluted in the treated water. Neither runoff nor spray drift are routes of exposure because a specified amount of product is directly applied to the water body. End-product labeling recommends target concentrations of a product at either “1 ppm or 2 ppm”, depending on the weed to be controlled. To attain these target concentrations, the labels specify the volume of product to be added per volume of water to be treated. For this assessment, these maximum target concentrations were assumed to be maintained after treatment and no degradation was assumed.

The major route of dissipation of the dyes in an aquatic environment is likely indirect photolysis, which depends on the nature and concentration of natural photosensitizers as well as on the geographical location and season when the products are used. Biotransformation under anaerobic conditions may also contribute to the dissipation of each dye. The specific chemical nature of photoproducts and metabolites is not known.

The dyes are predominantly associated with the water column and have no potential to volatilize from water. Although the dyes are not applied to soils, data indicate they would be unlikely to volatilize from soils. Acid Blue 9 and Acid Yellow 23 do not have the potential to bioaccumulate in fish.

Ecological Risk Assessment

To estimate potential ecological risk, EPA usually integrates the results of exposure and ecological ecotoxicity using the risk quotient method. RQs are then compared to levels of concern (LOCs), which represent the threshold of potentially significant risk in the environment. Generally, the higher the RQ is above the LOC, the higher the risks. The ecotoxicity studies submitted for the dyes included an avian oral, two avian dietary, two fish acute toxicity, and an aquatic invertebrate acute toxicity. All studies indicated very low toxicity. All of the ecological toxicity studies were conducted with the Aquashade* end-use product containing 23.63% Acid Blue 9 and 2.39% Acid Yellow 23 as the test substance, whereas the mammalian toxicity study was conducted with the Admiral WSP end-use product which contains 49.72% Acid Blue 9 and 3.27% Acid Yellow 23.

1. Risk to Aquatic Animals

Review of aquatic toxicity studies on bluegill fish, rainbow trout, and daphnia studies showed erioglaucine/tartrazine to be “slightly toxic” to aquatic animals and aquatic invertebrate. The calculated RQs were less than 0.01, and no risks of concern were observed for any aquatic animal.

2. Risk to Terrestrial Animals

The avian oral acute toxicity studies for both the bobwhite quail and the mallard duck found LD₅₀s and NOAELs greater than or equal to 5,620 ppm. The dyes are considered to be practically nontoxic to birds. Two rat studies reviewed for the human health risk assessment showed that the dyes are practically non-toxic to mammals. Since the dyes are applied directly applied to water, there are unlikely to be any pesticide residues on terrestrial food items, which forms the basis of EPA’s standard terrestrial animal risk assessment. Therefore, acute RQs for birds and mammals exposed to the dyes via consumption of contaminated water were calculated for each of three body weight classes using the daily exposure value expressed as milligrams of erioglaucine/tartrazine and the toxicity value expressed in terms of milligrams of the dye combination. RQs are below all levels of concern with RQs less than 0.01 and the dyes are not expected to harm terrestrial animals that drink treated water, or harm freshwater animals and invertebrates dwelling in treated, confined water bodies.

3. Risk to aquatic plants

The combination of erioglaucine/tartrazine in water bodies kills non-target plants by depriving them of light necessary for photosynthesis. Because submerged aquatic plants are the target species and it is assumed that all submerged plants will be killed, no aquatic

plant studies were required. Because the dyes are only applied to contained ponds with little or no outflow, and since the runoff water is generally not used for irrigation, it is not expected to come into contact with non-target aquatic organisms outside of the target pond. All submerged plants in a treated pond are considered to be targets; therefore, RQs were not calculated for aquatic plants.

4. Risk to terrestrial plants

Terrestrial plants growing in dry-land and semi-aquatic environments are not exposed because the products containing erioglaucine/tartrazine are applied to confined water bodies with little or no outflow. Therefore, a terrestrial plant risk characterization was not performed.

5. Endangered Species

Based on EPA's screening level assessment, erioglaucine/tartrazine will have no effect on endangered species of aquatic animals, terrestrial animals, or terrestrial plants. The Agency concludes that the only potential risks are direct effects to aquatic plants that may be present in treated ponds and lakes, and indirect effects to aquatic or terrestrial animals that depend on the vegetation in the treated water bodies.

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 developed for the REDs and considers it in relation to individual species and their locations by evaluating important ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species, as part of a refined species-specific analysis. When conducted this species-specific analysis will take into consideration any regulatory changes recommended in this RED that are being implemented at that time.

Following this future species-specific analysis, a determination that there is a likelihood of potential impact to a listed species or its critical habitat may result in: limitations on the use of herbicide products containing erioglaucine/tartrazine, other measures to mitigate any potential impact, or consultations with the Fish and Wildlife Service and/or the National Marine Fisheries Service as necessary. If the Agency determines the use of erioglaucine/tartrazine "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). EPA is not requiring specific label language at the present time relative to threatened and endangered species. If, in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

Tolerance Reassessment

The Agency has determined that the existing exemption from a tolerance for erioglaucine is adequate and is considered reassessed. However, the Agency will propose to establish an additional tolerance exemption for the FD&C Yellow No. 5 dye tartrazine.

Active ingredient	Current Tolerance	Tolerance Reassessment	Comment
Tolerance Exemption Listed Under 40 CFR §180.1074:			
F.D.&C. Blue No. 1	Exempted from the requirement of a tolerance when used as an aquatic plant control agent.	Exempted from the requirement of a tolerance when used as an aquatic plant control agent.	In 1982, based on Aquashade's low toxicity profile, EPA waived residue chemistry data requirements and established an exemption from the requirement of a tolerance for erioglaucine (F.D.&C. Blue No. 1) when used as an aquatic plant control agent.
F.D.&C. Yellow No. 5	No current exemptions	Proposed to add Exemption from the requirement of a tolerance when used as an aquatic plant control agent.	

What Registrants Need to Do

The Agency has determined that the dye combination of erioglaucine/tartrazine is eligible for reregistration. In the near future, the Agency intends to issue Data Call-In Notices (DCIs) requiring product specific data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product specific data, the registrant will have 8 months to submit data and amended labels.

Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of the dyes for the eligible uses has been reviewed and determined to be complete. No additional data are required.

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.

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

Currently, there are no required labeling changes for erioglaucine/tartrazine.

Appendices

Appendix A. Food/Feed Use Patterns Subject to Reregistration for Aquashade (Case)						
Site	Application Timing Application Type Application Equipment	Maximum Single Application Rate (lb a.i./A)	Maximum Number of Applications Per Year	Maximum Yearly Rate (lb a.i./A)	Min. App Interval (days)	Use Directions and Limitations
Commercial Fishery Water Systems				Do not apply directly to water except as specified on the product label. Do not contaminate water intended for irrigation or domestic purposes. Do not contaminate water, food, or feed by storage or disposal.		
Preemergence Water treatment Package applicator		0.68365 lb A-ft	NS	NS	AN	
When needed Water treatment Measuring container/Not on label/Product container/Squeeze applicator	(L) 0.004165 lb 1K gal 0.6897 lb A-ft	NS	NS	AN		
Lakes/Ponds/Reservoirs (with Human or Wildlife Use)				Do not apply directly to water except as specified on the product label. Do not contaminate water intended for irrigation or domestic purposes. Do not contaminate water, food, or feed by storage or disposal.		
Preemergence Water treatment Package applicator		0.68365 lb A-ft	NS	NS	AN	
When needed Water treatment Measuring container/Not on label/Product container/Squeeze applicator	(L) 0.004165 lb K gal 0.6897 lb A-ft	NS	NS	AN		

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 case dicamba covered by this RED. It contains generic data requirements that apply dicamba 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 if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Dicamba

New Guideline Number	Old Guideline Number	Description	Use Patterns	Citations
PRODUCT CHEMISTRY				
	63-0	Reports of multiple physical/chemical characteristics	D,E,G	43503401, 43503402
ECOLOGICAL EFFECTS				
850.2100	71-1A	Avian Acute Oral Toxicity	D,E,G	4336701
	71-1B	Avian Acute Oral -Duck	D,E,G	4336702
850.2200	71-2A	Avian Dietary Toxicity – Quail	D,E,G	43503403
850.2200	71-2B	Avian Dietary Toxicity – Duck	D,E,G	43503404
850.2300	71-4A	Avian Reproduction - Quail	D,E,G	¹
850.2300	71-4B	Avian Reproduction – Duck	D,E,G	¹
	71.3	Acute Wild Mammal Toxicity-Rat	D,E,G	45281101
850.1075	72-1A	Fish Toxicity Bluegill	D,E,G	43297502
850.1075	72-1C	Freshwater Fish Toxicity Rainbow Trout	D,E,G	43297501
850.1075	72-1D	Freshwater Fish Toxicity Rainbow Trout – TEP	D,E,G	
850.1010	72-2A	Freshwater Invertebrate Toxicity	D,E,G	43297503
850.5400	122-2	Aquatic Plant Growth	D,E,G	
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity - Rat	D,E,G	45281101
870.1200	81-2	Acute Dermal Toxicity – Rabbit/Rat	D,E,G	45144401
870.2400	81-4	Primary Eye Irritation - Rabbit	D,E,G	44902902
870.2500	81-5	Primary Skin Irritation	D,E,G	45086102
870.2600	81-6	Dermal Sensitization	D,E,G	44902904
870.3100	82-1A	Subchronic Oral Toxicity: 90-Day Study Rodent	D,E,G	Satisfied ²
870.3150	82-1B	Subchronic Oral Toxicity: 90-Day Study Non-rodent	D,E,G	Satisfied ²
870.3200	82-2	21-Day Dermal – Rabbit/Rat	D,E,G	43410101
870.3700	83-3A	Developmental Toxicity – Rat	D,E,G	43408101
870.3700	83-3B	Developmental Toxicity – Rabbit	D,E,G	Satisfied ²
870.3800	83-4	2-Generation Reproduction – Rat	D,E,G	43410901
870.4100	83-1A	Chronic Feeding Toxicity – Rat	D,E,G	Satisfied ²
870.4100	83-1B	Chronic Feeding Toxicity - Non-rodent	D,E,G	Satisfied ²
870.4200a	83-2A	Oncogenicity Rat	D,E,G	Satisfied ²
870.4200	83-2B	Carcinogenicity Mice	D,E,G	Satisfied ²
870.4300	83-5	Combined Chronic Toxicity/Carcinogenicity: Rats	D,E,G	Satisfied ²
870.5100	84-2	Bacterial Reverse Gene Mutation	D,E,G	Satisfied ²
870.7485	85-1	General Metabolism	D,E,G	Satisfied ²
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	D,E,G	Waived ³
835.2240	161-2	Photodegradation - Water	D,E,G	Waived ³
835.4400	162-3	Anaerobic Aquatic Metabolism	D,E,G	Waived ³
835.4300	162-4	Aerobic Aquatic Metabolism	D,E,G	Waived ³
835.1240	163-1	Leaching/Adsorption/Desorption	D,E,G	Waived ³
835.1410	163-2	Laboratory Volatilization	D,E,G	Waived ³

New Guideline Number	Old Guideline Number	Description	Use Patterns	Citations
None	165-4	Bioaccumulation in Fish	D,E,G	Waived ³

1. Aquashade* is acutely non-toxic to birds. Long-term exposures are unlikely and chronic risks are not expected; therefore, no avian reproduction data are required.

2. Information from open literature are included to supplement the submitted studies. No additional data are required.

3. All Environmental Fate Data Requirements were placed under “reserved” in 1993, depending on the results of the required ecological toxicity studies. Because the risk assessment did not identify risks to fish, aquatic invertebrates, or mammals, the environmental fate studies may be waived.

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall 2, 1801 S. Bell Street, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 AM to 4:30 PM.

The nitrapyrin docket initially contained preliminary risk assessments and related documents as of October 27, 2004. Sixty days later, the comment period closed. The Agency considered the comments and added the formal “Response to Comments” documents to the docket. All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following website:

<http://www.epa.gov/pesticides/reregistration/status.htm>.

These documents include:

HED Documents:

Aquashade: Revised HED Chapter of the Reregistration Eligibility Decision Document. (Wade Britton and Kim Morgan. 9/27/2005)

Aquashade: Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document. (Wade Britton. 9/27/2005)

EFED Documents:

Ecological Risk Assessment. Reregistration: “Acid Blue 9” (Erioglaucine) and “Acid Yellow we” (Tartrazine) Dyes Used Together in the End- Use Products Aquashade, Aquashade OA, Admiral Liquid, Admiral WSP and Pond Care Algae Blocker for Control of Algal Growth and Other Undesirable Aquatic Plants

Appendix D. Citations Considered to be Part of the Database Supporting the Reregistration Eligibility Decision (Bibliography)

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selection from other sources, including published literature, in those instances where they have been considered, are included.
2. UNITS OF ENTRY. The unit of entry in this bibliography is called a “study.” In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting “studies” generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as single studies.
3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or “MRID” number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit “Accession Number”, which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also used whenever specific reference is needed.
4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
 - a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

- b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.
- c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
 - (1) Submission date. The date of the earliest known submission appears immediately following the word “received.”
 - (2) Administrative number. The next element immediately following the word “under” is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
 - (3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
 - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol “CDL,” which stands for “Company Data Library.” This accession number is in turn followed by an alphabetic suffix, which shows the relative position of the study within the volume.

Open Literature

Books

Lynch, D.G. "Estimating the Properties of Synthetic Organic Dyes", in **Handbook of Property Estimation Methods for Chemicals- Environmental Health Sciences**, Edited by Robert S. Boethling and Donald Mackay. Published by Lewis Publishers, Boca Raton, FL; Pages 447- 467. And pertinent references therein.

Marmion, D.M. **Handbook of U.S. Colorants- Food, Drugs, and Medical Devices**, Third Edition., 1991. Published by John Wiley and Sons, New York

Helz, G.R., Zepp, R.G., and Crosby, D.G, Editors. 1994. **Aquatic and surface photochemistry**. Lewis Publishers, Boca Raton, Florida.

Journal Articles

Jank. M., Köser, H., Lücking, F., Martienssen, M., and Wittchen, S. 1998, "*Decolorization and Degradation of Erioglaucine (Acid Blue 9) Dye in Wastewater,*" *Environmental Technology*, v.19(7), pp.741-747.

Weber, E.J. and Adams, R.L. 1995. "*Chemical and Sediment-Mediated Reduction of the Azo Dye Disperse Blue 79,*" *Environ. Sci. Technol.* v.29, pp. 1163-1170.

Baughman, G.L. 1995. "*Fate of azo dyes in aquatic systems. Part 3: The role of suspended sediments in adsorption and reaction of acid and direct dyes,*" *Dyes and Pigments*, v.27, pp. 197-210.

Brown, D. and Laboureur, P. 1983, "*The Degradation of Dyestuffs: Part I- Primary biodegradation under anaerobic conditions,*" *Chemosphere*, v.122, pp. 397-404.

Baran,W., Makowski, A., Wardas, W. 2003. "*The influence of FeCl₃ on the photocatalytic degradation of dissolved azo dyes in aqueous TiO₂ suspensions,*" *Chemosphere*, v.53, pp 82-95.

Tai, W.T., Chang, C.Y, Ing, C.H., and Chang,C.F. 2004. "*Adsorption of acid dyes from aqueous solutions on activated bleaching earth,*" *J. Colloid and Interface Science*, vol. 275, pp 72-78.

Mon, J., Flury, M., and Harsh, J.B. 2005 . "*Sorption of four triarylmethane dyes in a sandy soil determined by batch and column experiments,*" *Geoderma*. in press.

Mon, J., Flury. M., and Harsh. 2005 "A quantitative structure-activity relationship (OSAR) analysis of triarylmethane dye tracers," *Journal of Hydrology*, in press.

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- 43297501 Graves, W.; Swigert, J. (1994) Aquashade: A 96-Hour Static Acute Toxicity Test with the Rainbow Trout (*Oncorhynchus mykiss*): Final Report: Lab Project Number: 196A/107A. Unpublished study prepared by Wildlife International Ltd. 39 p.
- 43297502 Graves, W.; Swigert, J. (1994) Aquashade: A 96-Hour Static Acute Toxicity Test with the Bluegill (*Lepomis macrochirus*): Final Report: Lab Project Number: 196A/108. Unpublished study prepared by Wildlife International Ltd. 38 p.
- 43297503 Graves, W.; Swigert, J. (1994) Aquashade: A 48-Hour Static Acute Toxicity Test with the Cladoceran (*Daphnia magna*): Final Report: Lab Project Number: 196A/109. Unpublished study prepared by Wildlife International Ltd. 38 p.
- 43336701 Campbell, S.; Beavers, J. (1994) Aquashade: An Acute Oral Toxicity Study with the Northern Bobwhite: Lab Project Number: 196/103A. Unpublished study prepared by Wildlife International Ltd. 24 p.
- 43336702 Campbell, S.; Beavers, J. (1994) Aquashade: An Acute Oral Toxicity Study with the Mallard: Lab Project Number: 196/104. Unpublished study prepared by Wildlife International Ltd. 23 p.
- 43410101 Wolven, A. (1962) Acid Blue 9--The Safety Evaluation of FD&C Blue #1 on the Skin of Rabbits: Lab Project Number: 20729. Unpublished study prepared by Leberco Laboratories. 106 p.
- 43503401 Ellison, F. (1994) Physical and Chemical Characteristics of Aqua Shade Blue 9: Color, Physical State, Odor, Boiling Point, Specific Gravity, Solubility, Vapor Pressure, pH and Stability: Lab Project Numbers: 140-11: 2398: DTI 2398. Unpublished study prepared by Case Consulting Labs, Inc. 19 p.
- 43503403 Campbell, S.; Beavers, J. (1994) Aquashade: A Dietary LC50 Study With the Northern Bobwhite: Lab Project Number: 196-101. Unpublished study prepared by Wildlife Int'l, Ltd. 36 p.
- 43503404 Campbell, S.; Beavers, J. (1994) Aquashade: A Dietary LC50 Study With the Mallard: Lab Project Number: 196-102. Unpublished study prepared by Wildlife Int'l, Ltd. 35 p.
- 44902902 Fitzgerald, G. (1992) Primary Eye Irritation Study: Lake Colorant II: (in Rabbits): Lab Project Number: 92G-0511. Unpublished study prepared by Toxikon Corporation. 22 p.
- 44902904 Fitzgerald, G. (1992) Buehler Sensitization Test: Lake Colorant II: (in Guinea Pigs): Lab Project Number: 92G-0512. Unpublished study prepared by Toxikon Corporation. 23 p.
- 45086102 Tay, C. (2000) Acute Dermal Irritation (in Rabbits): Admiral WSP: Final Report: Lab Project Number: 00-0661-G2. Unpublished study prepared by Toxikon Corp. 19 p. {OPPTS 870.2500}
- 45144401 Cerven, D. (2000) Acute Dermal Toxicity in Rabbits/LD50 in Rabbits: Admiral WSP: Lab Project Number: 1100: MB 00-8314.02. Unpublished study prepared by MB Research Labs. 14 p. {OPPTS 870.1200}
- 45281101 Graver, K. (2000) Acute Oral Toxicity/LD 50 in Rats: Admiral WSP: Lab Project

Number: MB 00-8731.01:1000. Unpublished study prepared by MB Research Laboratories. 13 p. {OPPTS 870.1100}

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PC Code: 110302

- 43297501 Graves, W.; Swigert, J. (1994) Aquashade: A 96-Hour Static Acute Toxicity Test with the Rainbow Trout (*Oncorhynchus mykiss*): Final Report: Lab Project Number: 196A/107A. Unpublished study prepared by Wildlife International Ltd. 39 p.
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- 43408101 Smith, J. (1972) Acid Yellow 23--Rat Teratology Study: Lab Project Numbers: 71R-719A; 71R-721A. Unpublished study prepared by Bio-dynamics, Inc. 142 p.
- 43410901 Smith, J. (1973) Acid Yellow 23: Three Generation Reproduction Study of FD&C Yellow 5: Lab Project Number: 71R/735. Unpublished study prepared by Bio-dynamics Inc. 212 p.
- 43503402 Ellison, F. (1994) Physical and Chemical Characteristics of Aqua Shade Yellow 23: Color, Physical State, Odor, Boiling Point, Specific Gravity, Solubility, Vapor Pressure, pH and Stability: Lab Project Number: 140-13: 2398: DTI 2398. Unpublished study prepared by Case Consulting Labs, Inc. 20 p.
- 43503403 Campbell, S.; Beavers, J. (1994) Aquashade: A Dietary LC50 Study With the Northern Bobwhite: Lab Project Number: 196-101. Unpublished study prepared by Wildlife Int'l, Ltd. 36 p.
- 43503404 Campbell, S.; Beavers, J. (1994) Aquashade: A Dietary LC50 Study With the Mallard: Lab Project Number: 196-102. Unpublished study prepared by Wildlife Int'l, Ltd. 35 p.
- 44902902 Fitzgerald, G. (1992) Primary Eye Irritation Study: Lake Colorant II: (in Rabbits): Lab Project Number: 92G-0511. Unpublished study prepared by Toxikon Corporation. 22 p.
- 44902904 Fitzgerald, G. (1992) Buehler Sensitization Test: Lake Colorant II: (in Guinea Pigs): Lab Project Number: 92G-0512. Unpublished study prepared by Toxikon Corporation. 23 p.
- 45086102 Tay, C. (2000) Acute Dermal Irritation (in Rabbits): Admiral WSP: Final Report: Lab Project Number: 00-0661-G2. Unpublished study prepared by Toxikon Corp. 19 p. {OPPTS 870.2500}
- 45144401 Cerven, D. (2000) Acute Dermal Toxicity in Rabbits/LD50 in Rabbits: Admiral WSP: Lab Project Number: 1100: MB 00-8314.02. Unpublished study prepared by MB Research Labs. 14 p. {OPPTS 870.1200}

45281101 Graver, K. (2000) Acute Oral Toxicity/LD 50 in Rats: Admiral WSP: Lab Project Number: MB 00-8731.01:1000. Unpublished study prepared by MB Research Laboratories. 13 p. {OPPTS 870.1100}

Appendix E. Generic Data Call-In

The Generic Data Call-In will be posted at a later date.

Appendix F. Product Specific Data Call-In

Please insert Product Specific Data Call- In here.

Appendix G

EPA'S BATCHING OF AQUASHADE PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing AQUASHADE as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide

the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Four products were found which contain Aquashade as the active ingredient. These products have been placed in a no batch group in accordance with the active and inert ingredients and type of formulation.

Batching Instructions:

No Batch: Each product in this Batch should generate their own data.

NOTE: The technical acute toxicity values included in this document are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

No Batch	EPA Reg. No.	Percent Active Ingredient
	33068-1	Acid Blue #9: 23.63 Acid Yellow # 23: 2.39
	33068-2	Acid Blue #9: 2.36 Acid Yellow # 23: 0.24
	67064-1	Acid Blue #9: 49.72 Acid Yellow # 23: 3.27
	67064-2	Acid Blue #9: 15.31 Acid Yellow # 23: 1.00

Appendix H. List of Registrants sent this DCI.

Aquashade
W175 N11163 Stonewood Dr.
Ste 234
Germantown, Wi 53022

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

Pesticide Registration Forms are available at the following EPA internet site:

<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 hardcopy 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/oppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/oppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/oppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/oppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit 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 Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices 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 Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
 - f. 40 CFR Part 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

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 Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their website: ace.orst.edu/info/nptn.

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:

1. Date of receipt;
2. EPA identifying number; and
3. 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.

Documents Associated with this RED

The following documents are part of the Administrative Record for this RED document and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

1. Health Effects Division and Environmental Fate and Effects Division Science Chapters, which include the complete risk assessments and supporting documents.
2. Detailed Label Usage Information System (LUIS) Report.