Reregistration Eligibility Decision for Dikegulac sodium

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Agency

Prevention, Pesticides
and Toxic Substances
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Reregistration Eligibility Decision For Dikegulac Sodium

Reregistration Eligibility Decision (RED) for Dikegulac Sodium

List C

Case No. 3061

Approved by: Debra Edwards

Date: March 16, 2007

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TABLE OF CONTENTS

Glossary of Terms and Abbreviations

ai	Active Ingredient
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
DCI	Data Call-In
DNT	Developmental Neurotoxicity
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
GLN	Guideline Number
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
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts per Million
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RQ	Risk Quotient
SF	Safety Factor
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
UF	Uncertainty Factor
WPS	Worker Protection Standard

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Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for dikegulac sodium, a plant growth regulator, and is issuing its risk management decision. The risk assessments, which are summarized below, are based on the review of the required database supporting the use patterns of currently registered products and additional data provided by the technical registrant, PBI/Gordon Corporation. No toxicological endpoints were identified for the human health risk assessment; thus, only a qualitative assessment was conducted. Based on this assessment, there are no human health risks of concern (i.e., drinking water, occupational, residential). However, because of its acute toxicity level (eye irritation) additional personal protective equipment and restricted-entry interval measures are required. When completing the risk assessment, essential ecological fate studies were not yet submitted to the Agency and, therefore, the ecological fate characteristics of dikegulac sodium were based on upper-end assumptions and open literature. Despite these uncertainties, all potential risks to aquatic organisms and plants were below the Agency's level of concern (LOC). All potential risks to terrestrial organisms were also below the Agency's LOC, except for semi-aquatic non-listed and listed plants.

After considering the acute toxicity of dikegulac sodium identified in the human health assessment and the potential risks identified in the ecological risk assessment, the Agency developed its risk management decision for uses of dikegulac sodium. As a result of this review, EPA has determined that products containing dikegulac sodium are eligible for reregistration, provided that all protective measures are adopted and labels are amended accordingly. That decision is discussed fully in this document.

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" criteria of FIFRA.

This document presents EPA's human health and ecological risk assessments, and the reregistration eligibility decision for dikegulac sodium. The document consists of six sections. Section I contains the regulatory framework for reregistration. Section II provides a profile of the use and usage of the chemical. Section III gives an overview of the human health and environmental effects risk assessments based on data and other information received. Section IV presents the Agency's reregistration eligibility and risk management decisions. Section V summarizes label changes necessary outlined in Section IV. Section VI provides information on how to access related documents. Finally, the Appendices list related information and supporting documents. The risk assessments and other supporting documents for dikegulac sodium are available in the Public Docket, under docket number EPA-HQ-OPP-2006-0954, and on the Agency's web page, http://www.regulations.gov.

II. Chemical Overview

A. Regulatory History

Dikegulac sodium was first registered in the United States in 1978 to Maag Agrochemical. The first Generic Data Call-In (GDCI) was issued in January 1989 for product chemistry, ecological toxicology and fate, and acute and chronic toxicity data. In January 1992, PBI/Gordon Corporation acquired the label from Maag Agrochemical. As part of its phase 2 response to the GDCI, PBI/Gordon requested the Agency waive a number of data requirements due its limited productions and to the "low volume/minor use" of the chemical. "Minor use" is defined in part as the use of a pesticide on a commercial agricultural crop or site where the total United States production is fewer than 300,000 acres (see also FIFRA 2(ll)). The registrant provided the Agency projected sales and use data for 1992 and previous years, and anticipated sales of the formulated product would stay within the projected volume. As a result, the Agency accepted the low volume minor use waivers, contingent upon continued low production of dikegulac sodium. In order to retain the data waivers, the registrant was required to submit, and submitted, yearly sales data to the Agency demonstrating that dikegulac sodium production remained below specified levels.

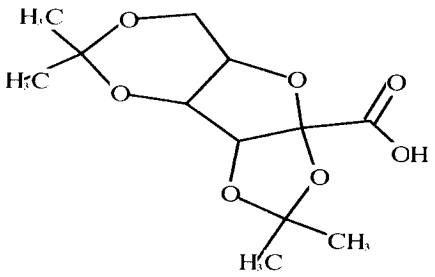
In October 2005, at a meeting with the Agency, the registrant petitioned the Agency to remove this condition, based on the low toxicity of the chemical. The Agency agreed to

consider the registrant's request during the reregistration process, and any additional data needs to support the removal of the production cap would be determined and identified in the RED.

There is no technical dikegulac sodium product registered in the United States. PBI/Gordon's formulated product, Atrinal Plant Growth Regulation (EPA registration number 2217-776), contains 18.5% active ingredient. There is also a Ready-to-Use (RTU) tree injection product, which also contains 18.5% active ingredient (EPA registration number 69117-7).

B. Chemical Identification

DIKEGULAC SODIUM:



Dikegulac sodium is structurally similar to natural products involved in synthesis, or biosynthesis, of L-ascorbic acid (vitamin C) and structurally similar to naturally occurring plant cell wall components.

Common Name:	Dikegulac Sodium
Trade Names:	Atrinal®, Pincher®
Chemical Name:	Sodium salt of 2,3:4,6-bis-O-(1-methylethylidene)-a-L-xylo-2-hexulofurano-sonic acid
Case Number:	3061
CAS Registry Number:	52508-35-7
OPP Chemical Code:	109601
Molecular Weight:	296.25 grams
Empirical Formula:	$C_{12}H_{17}NaO_7$

Basic End Use Producer: PBI/Gordon Corporation

C. Use Profile

The following information on the currently registered uses includes an overview of use sites and application methods. A detailed table of the uses of dikegulac sodium eligible for reregistration is contained in Appendix A.

Type of Pesticide: Plant Growth Regulator

Target Organism: Trees, plants, and shrubs

Mode of Action: Dikegulac sodium interferes with terminal growth areas by inhibiting DNA synthesis, which is required for new growth. The dominant growth points (apexes) of treated plants are suppressed, resulting in the breaking of "apical dominance" and the enhancing of the growth of lateral shoots.

Use Sites: Dikegulac sodium is used in greenhouses, nurseries, and on landscape trees, ornamentals, and plants. Landscape use sites include parks, school campuses, city streets, and similar recreational, institutional, or industrial areas. Although the labeled use sites do not preclude treatment of residential areas, residential applications made by homeowners are unlikely due to the high cost of the product, and according to the registrant, dikegulac sodium is not sold in the homeowner market.

Use Classification: Both dikegulac sodium products are designated as general use; however, the RTU product specifies use by professional arborists only.

Formulation Types: Soluble Concentrate/Liquid
Ready-to-Use (RTU)

A technical formulation of dikegulac sodium active ingredient is not registered in the United States. Therefore, Table 1 lists the current end-use formulations.

Table 1. Formulations of Dikegulac Sodium

Formulation	Registration No.	% Active Ingredient	% Acid Equivalent[1]
Soluble Concentrate/Liquid	2217-776	18.5%	17%
RTU	69117-7	18.5%	17%

[1]Acid equivalent (ae) is defined as that portion of a formulation that can be converted back to the corresponding parent acid. The percentage ae is specified on the product labels, and the application rates are given in ae.

Application Methods: Dikegulac sodium is applied either as a foliar spray or by pressure injection.

Application Rates: As a sodium salt, dikegulac sodium will rapidly dissociate into dikegulac acid and sodium ions in water. Therefore, the rates on the dikegulac sodium product labels are expressed as acid equivalent (ae). The product contains 1.67 pounds of ae per gallon (lbs ae/gal). The maximum application rates (lbs ae/gal) per use are as follows.

- Greenhouse and Nursery Ornamentals (chemical pinching): 0.048 lb ae/gal
- Landscape Ornamentals (growth control): 0.07 lb ae/gal
- Broadleaf Trees (plant growth retardant): 0.77 lb ae/gal
- Fruiting Landscape Trees and Shrubs (suppression of flower and fruit formation): 0.060 lb ae/gal

The label does not specify the application rate per acre because, according to the registrant, the applications are to individual trees or plants with a hand held spray wand and not a broadcast type application. Therefore, the applicator will usually only be spraying one tree in a residential setting and possibly multiple trees in a park or street setting. However, for the purpose of this risk assessment, the Agency calculated the maximum application rate of 5.68 lbs ae/acre[1]. This is based on the landscape ornamental (growth control) application rate.

D. Estimated Usage of Pesticide

Dikegulac sodium has been designated a low volume/minor use pesticide (< 300,000 acres of crop treated per year) by EPA. However, since there is a single manufacturer, identification of the amount produced or used per year would disclose the amount that manufacturer produces per year – information the manufacturer considers to be confidential business information (CBI). However, the manufacturer has provided the Agency with annual sales information to support the low volume/minor use designation and the use assumptions used in risk assessments.

III. Summary of Dikegulac Sodium 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. The human health and ecological risk assessment documents, and supporting information listed in Appendix C, were used to formulate the safety finding and regulatory decision for dikegulac sodium.

While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket, docket number OPP-2006-0954, and may

[1] Based on directions for use specified on the label, the Agency used the following calculation to determine the lbs ae/A: 1.67 lbs ae/gal * 4 fl oz/128 fl oz * 1 gal/400 sq ft * 43,560 sq ft/acre = 5.68 lbs ae/acre.

also be accessed through the Agency's website at https://www.regulations.gov. Hard copies of these documents may be found in the OPP public docket under this same docket number.

- *Dikegulac Sodium. Human Health Considerations for the Reregistration Eligibility Decision, October 31, 2006*
- *Drinking Water Assessment for Dikegulac sodium Reregistration Eligibility Decision (RED), February 9, 2007*
- *EFED Risk Assessment for the Reregistration of Dikegulac sodium, October 6, 2006*

A. Human Health Risk Assessment

The human health risk assessment incorporates potential exposure and risk from all sources, which for dikegulac sodium are limited. The growth regulator uses of dikegulac sodium do not involve use on food commodities. Further, given the extremely limited annual production of dikegulac sodium currently permissible, any drinking water exposure as a result of the use of dikegulac sodium is expected to be infrequent and not significant on a national scale. Additionally, based on the available toxicity data for dikegulac sodium, a low hazard concern is indicated via the oral, dermal, and inhalation routes of exposures (i.e., there is very low systemic toxicity). Therefore, the Agency has concluded that a qualitative human health risk assessment to evaluate potential drinking water, occupational, and non-occupational (residential) exposures is appropriate for dikegulac sodium and will be protective of all U.S. populations, including infants and young children. For the complete health risk assessment, refer to *Dikegulac Sodium. Human Health Considerations for the Reregistration Eligibility Decision, October 31, 2006*, which is available in the public docket.

1. Toxicity of Dikegulac Sodium

The available toxicological data for dikegulac sodium are sufficient for hazard assessment. The database consists of acute toxicity, irritation, inhalation, and sensitization studies. In addition, there are developmental rat and rabbit (oral) toxicity studies, subchronic dog and rat (oral) toxicity studies, and a 21-day (dermal) rabbit study. Mutagenicity studies available include *Salmonella typhimurium*, micronucleus, and gene mutation assays. The available combination of published literature and submitted toxicity studies are sufficient to assess the toxicity of dikegulac sodium. Based on the very low hazard concern *via* the oral, dermal, and inhalation routes of exposure, a qualitative hazard assessment is appropriate for dikegulac sodium.

The available acute toxicity studies indicate that dikegulac sodium is of low oral, dermal and inhalation toxicity (all Toxicity Categories IV). A primary eye irritation study resulted in moderate ocular irritation and iridial changes, subsiding in all test animal eyes by 7 days, and conjunctival changes subsiding by 10 days (Toxicity Category II). Dikegulac sodium did not produce dermal sensitization in tests with guinea pigs. Table 2 summarizes the acute toxicity profile of dikegulac sodium.

Table 2. Acute Toxicity Profile for Dikegulac Sodium			
Study	**MRID**	**Results**	**Toxicity Category**
81-1 Acute Oral - Rat 870.1000	44093901 43064604 43064605 43064606 43064608	No death, no clinical signs LD50>5000 mg/kg	IV
81-2 Acute Dermal - Rabbit 870.1200	44093902	No deaths, no clinical signs LD50 >5000 mg/kg	IV
81-3 Acute Inhalation - Rat 870.1300	44093903	No deaths. LC50>2.09 mg/L	IV
81-4 Eye Irritation - Rabbit 870.2400	44093904	No corneal effects were observed. Iridial changes subsided in all eyes by 7 days and conjunctival changes subsided by 10 days	II
81-5 Skin Irritation - Rabbit 870.2500	44093905	Slight erythema and edema observed.	IV
81-6 Dermal Sensitization 870.2600	43064616 44093906	All animals survived. No adverse clinical signs. Not a dermal sensitizer	N/A

There is currently no long-term rodent information regarding the carcinogenic potential of dikegulac sodium. However, limited usage and use patterns preclude the need for such long-term chronic studies. Also, neurotoxicity information is currently not available. However, there were no clinical signs in any of the acute, subchronic, or developmental toxicity studies to suggest that dikegulac sodium elicits a neurotoxic effect.

Furthermore, based on the low hazard concern from the available studies, no endpoints of toxicological concern have been identified for risk assessment purposes. Finally, given the extremely limited annual production of dikegulac sodium currently allowed, and that it is unlikely to be used in a significant portion of any given watershed, the Agency concludes that human drinking water exposure to this compound is negligible. For more detail on the toxicological data base and Agency's drinking water determination, refer to the *Dikegulac Sodium. Human Health Considerations for the Reregistration Eligibility Decision, October 31, 2006,* and the *Drinking Water Assessment for Dikegulac sodium Reregistration Eligibility Decision (RED), February 9, 2007.*

2. Human Incident Data

In evaluating incidents to humans, the Agency reviewed reports from the National Poison Control Centers (PCC), the Agency's Office of Pesticide Program's Incident Data System (IDS), the California Pesticide Illness Surveillance Program, National Pesticide Information Center, and the National Institute for Occupational Safety and Health's (NIOSH) Sentinel Event Notification System for Occupational Risk (SENSOR) program. There are no reported cases of reactions or illness to workers or others, due to dikegulac sodium, in any of the databases.

B. Environmental Risk Assessment

On a nationwide basis, dikegulac sodium use is relatively limited. Therefore, ecological exposure and risks will be relatively localized to specific use sites. Dikegulac sodium application methods include spraying of foliage (nursery, greenhouse and landscape plants), tree injection to retard growth, spray banding of tree trunks to suppress flowering and fruiting, and spraying of individual tree crowns. Based on these use patterns, the Agency believes the most likely exposure scenario involves spray drift or runoff from a large outdoor nursery or landscape maintenance to nearby terrestrial or aquatic habitats. Tree injection is not considered to be a major route of environmental exposure and, therefore, was not assessed in the ecological risk assessment. For the complete ecological risk assessment, refer to *EFED Risk Assessment for the Reregistration of Dikegulac Sodium, October 6, 2006*, which is available in the public docket.

1. Environmental Fate and Transport

As of this writing, no guideline environmental fate studies for dikegulac sodium had been submitted. However, dikegulac sodium is a sugar derivative, and its intermediate breakdown products include ascorbic acid (vitamin C). Therefore, it is expected that dikegulac sodium will be fully mineralized to carbon dioxide and water, with no persistent degradates. An unreviewed soil metabolism study suggests that the soil metabolism half-life of dikegulac sodium is 15 days. Once the epoxide bridges are removed, the remaining molecule should be metabolized by natural pathways. As a sodium salt, dikegulac sodium will dissociate into dikegulac-acid and sodium ions in water. Thus, dikegulac-acid is the form that organisms will be exposed to in water. As a free acid, dikegulac is semi-volatile; however, the very low Henry's Law constant makes exposure by volatilization unlikely.

On site, liquid formulations of dikegulac sodium applied using spray banding of trunks, and spray application to foliage (hand applicator) will be directly applied to target plants with the potential for incidental exposure to invertebrates inhabiting the foliage at the time of application. Applied as foliar spray, dikegulac sodium is also expected to result in residues on the soil, non-target ground foliage, and invertebrates on the soil. Dikegulac sodium residues on vegetation will be absorbed through the leaves and translocated to the shoot tips. After dikegulac sodium reaches the soil, it is available for uptake by vegetation and soil invertebrates. Terrestrial wildlife exposure could result from the following actions or behaviours: incidental inhalation of spray; ingestion of residues on or in food items (i.e., plants and insects); deliberate or incidental ingestion of pesticide-treated soil when foraging or preening; dermal uptake via direct contact of skin with treated vegetation; soil or spray; contaminated puddles or surface water; and ingestion of water from contaminated surface water, puddles, or dew.

Dikegulac sodium may also reach offsite soil, terrestrial vegetation, and insects from spray drift, or it may reach offsite soils via runoff and erosion. Dikegulac sodium applied to trees in urban/suburban parking lots and similar areas will tend to run off from impervious surfaces with rainfall and be transported to surface water bodies. Direct aquatic organism exposure could result from direct contact with contaminated water or pore water.

2. Toxicity and Risk Characterization

The pesticide use profile, exposure data, and toxicity information are used to determine risk estimates to non-target aquatic and terrestrial organisms. Estimated Environmental Concentrations (EECs) are used to calculate risk quotients (RQs). An RQ is the estimated ratio of exposure concentration to the toxicity endpoint. The calculated RQs use the EECs that are based on the maximum single application rate of dikegulac sodium, which would yield the maximum exposure estimates. The RQ is then compared to the level of concern (LOC) to determine if exposure to dikegulac sodium would pose a risk to non-target organisms. Table 3 outlines the Agency's LOCs and the corresponding risk presumptions.

Table 3. Agency's LOCs and Risk Presumptions

Risk Presumption	LOC Terrestrial Animals	LOC Aquatic Animals	LOC Plants
Acute Risk - there is potential for acute risk; regulatory action may be warranted in addition to restricted use classification.	0.5	0.5	1
Acute Endangered Species - endangered species may be adversely affected; regulatory action may be warranted.	0.1	0.05	1
Chronic Risk - there is potential for chronic risk; regulatory action may be warranted.	1	1	N/A

3. Non-target Aquatic Exposure and Risk

Fish and aquatic invertebrates in surface water or sediment adjacent to treated ornamentals and fruiting trees (nurseries and/or urban use sites) may be exposed to dikegulac sodium residues through spray drift alone or in concert with run-off from labeled use of the pesticide. For exposure to fish and aquatic invertebrates, EPA generally considers residues in both surface water and sediment. However, based on environmental fate data on dikegulac sodium, the Agency believes that dikegulac sodium will be predominantly in the water column in an aquatic system; therefore, exposure estimates for aquatic organisms used in the ecological risk assessment focused on surface water, not sediment. Aquatic plants in surface water adjacent to treated ornamentals and fruiting trees (nurseries and/or urban use sites) may also be exposed to dikegulac sodium residues through spray drift alone or in concert with run-off from labeled use of the pesticide.

Further, as explained in the environmental fate and transport section above, dikegulac-acid is the form that organisms will be exposed to in water. Therefore, the Tier 1 aquatic model GENEEC was used to estimate surface water concentrations of dikegulac-acid. This model was also used to derive EECs to measure potential exposures to freshwater organisms in surface water. The maximum single application rate of 5.68 lb acid equivalent (ae)/acre[2] to fruiting trees and ornamentals in nurseries, greenhouses, urban and suburban

[2] Based on the use directions on the label, the Agency used the following calculation to establish the maximum rate of 5.68 lbs ae/A: 1.67 lbs/gal * 4 fl oz/128 fl oz * 1 gal/400 sq ft * 43,560 sq ft/acre.

areas is the highest application rate that would yield the maximum EECs. Table 4 lists the EECs for dikegulac acid in surface water using the GENEEC model.

Table 4. Dissolved dikegulac-acid surface water EECs using the GENEEC model

EECs (ug ae/L) in a small surface water body		
Average Peak	Average 21-day	Average 60-day
663	663	662

Due to the lack of complete dikegulac sodium or dikegulac acid environmental fate data, the exposure assessment is based partly on literature data, quantitative structure-activity relationship (QSAR) estimates, and conservative assumptions. The Agency made the very conservative assumption that the dikegulac acid is highly stable in the environment and does not degrade in the soil, water, or when exposed to light. The effect of this is that exposure estimates are likely to be higher than they would be with data on fate properties.

a. Fish and Aquatic Invertebrates

Dikegulac sodium has little to no toxic effect on freshwater fish and invertebrates. For these taxa, there was no mortality at the highest concentrations tested in the laboratory, and the EECs were all well below these concentrations. Therefore, the Agency determined that there is no acute risk (listed or non-listed) to freshwater fish or invertebrates; the RQs are below the Agency's LOC.

Acute toxicity data was only submitted for one marine/estuarine species, which is the brown shrimp. The test was conducted only for 48 hours rather than the guideline 96 hours. This value was selected for calculating RQs for marine/estuarine invertebrates. Acute risk may potentially be underestimated because it is only a 48-h LC_{50} and not the guideline 96-h LC_{50}. No 96-h LC_{50} study was submitted by the registrant or found in the literature for marine/estuarine fish. Based on similar sensitivity between freshwater fish and invertebrates for the range tested, it is assumed that marine/estuarine fish would be at least as sensitive as the brown shrimp. However, the 48-hr EC_{50} for brown shrimp, representing estuarine/marine invertebrates and fish is 9,129,000 ppb which results in an acute RQ of <0.0001. Therefore, there are no listed or non-listed LOC exceedances for marine/estuarine fish and invertebrates.

Chronic toxicity data were not submitted for any aquatic animals; the Agency is unable to quantitatively assess possible chronic effects to aquatic animals. However, chronic risks are considered unlikely for the given labeled uses, based on consideration of the magnitude of the acute-to-chronic ratio. Based on the acute fish and invertebrate data, the Agency determined that the chronic toxicity would have to be between 7,000 to 15,000 times greater than the acute toxicity to result in an chronic RQ > 1, which is the chronic LOC. This is highly unlikely, based on the Agency's experience interpreting ecotoxicology data for many other pesticide chemicals. For more detailed information, refer to the *EFED Risk Assessment for the Reregistration of Dikegulac Sodium, October 6, 2006*, which is available in the public docket.

b. Aquatic Plants

Despite the use of dikegulac sodium as a plant growth regulator, no risks to aquatic plants (listed or non-listed) have been identified. Average peak EECs for dikegulac-acid are compared to the acute EC_{50} toxicity endpoints for duckweed (a vascular plant), green alga (non-vascular plant), freshwater diatom, and marine diatom to calculate RQs to non-listed aquatic plant species. There are no exceedances of LOCs for non-listed or listed aquatic plants.

4. Non-target Terrestrial Exposure and Risk

Terrestrial vertebrates (birds, mammals, reptiles, terrestrial phase amphibians) may be exposed to dikegulac sodium residues on seeds, insects, and foliage on treated ornamentals and fruiting trees due to direct deposition or overspray from labeled use of the pesticide on these media. Spray drift and long-range aerial transport would result in lower residue levels for these media than on target plants; therefore, this risk hypothesis provides an upper bound for risks to terrestrial vertebrates from dietary exposure.

Upland plants adjacent to treated ornamentals and fruiting trees (nurseries and/or urban use sites) may be exposed to dikegulac sodium residues in soil or on foliage due to spray drift from labeled use of the pesticide. Furthermore, riparian/wetland plants adjacent to treated ornamentals and fruiting trees (nurseries and/or urban use sites) may be exposed to dikegulac sodium residues on foliage due to spray drift from labeled use of pesticide.

The Agency used the maximum single application rate of 5.68 lbs ae/acre[3] to fruiting trees and ornamentals in nurseries, greenhouses, urban and suburban areas, which is the highest application rate that would yield the maximum EECs for terrestrial organisms in tables 5 and 6 below.

Table 5. Upper Kenaga dietary and dose-based EECs of dikegulac acid equivalents (ae) for avian food items

Use Site	Food Item	Dietary EECs (ppm ae)	Dose-based EECs (mg ae/kg-bw) by Avian Body Weight		
			Small (20g)	Medium (100g)	Large (1000g)
Nurseries, greenhouses, urban and suburban areas with fruiting trees and ornamentals	short grass	2481.48	2826.16	1611.60	721.53
	tall grass	1137.35	1295.32	738.65	330.70
	broadleaf plants/sm insects	1395.83	1589.71	906.52	405.86
	fruits/pods/seeds/lg insects	155.09	176.63	100.72	45.10

[3] Based on the use directions on the label, the Agency used the following calculation to establish the maximum rate of 5.68 lbs ae/A: 1.67 lbs/gal * 4 fl oz/128 fl oz * 1 gal/400 sq ft * 43,560 sq ft/acre.

Table 6. Dikegulac-acid EECs for non-target vascular plants in off-site upland and semi-aquatic lowland areas using upper and lower bound label application rates

Use Site	Application Rate (lbs ae/acre)	Application Method	EECs (lbs ae/acre)		
			Adjacent upland	Semi-aquatic lowland	Drift
Nurseries, greenhouses, urban and suburban areas with fruiting trees and ornamentals	5.68 (lower bound)	Ground	0.3408	2.8968	0.0568

As stated above, due to a lack of available environmental fate data for dikegulac sodium, the exposure assessment is based on literature, quantitative structure-activity relationship (QSAR) estimates, and conservative assumptions. Therefore, the exposure estimates above are likely to be higher than they would be with data on fate properties.

a. Birds

Dikegulac-sodium is classified as being practically non-toxic to avian species. The Agency's avian acute LOCs (listed or non-listed) were not exceeded for any proposed use. Therefore, no acute risks to birds (or reptiles) are expected. In addition, since dikegulac sodium is not acutely toxic to birds at doses many times higher than expected exposure, and is not chronically toxic to mammals (see section below), the Agency does not expect a chronic risk to birds, and will not require chronic avian toxicity studies.

b. Mammals

Dikegulac sodium has little to no toxic effect on mammals; there were no mortalities at the highest level tested (5000 ppm). Considering estimated exposures are below this level, the Agency determined there is no acute risk to mammals. No mammalian reproductive data are available. However, a rabbit development toxicity study was reviewed in which no fetal parameters such as litter size, litter weight or viability were significantly affected compared with the controls. Therefore, the Agency determined there were no chronic risks of concern to non-listed or listed mammals.

c. Beneficial Insects

Dikegulac sodium is non-toxic to honey bees (no mortality at 81 ug/bee). Therefore, the Agency determined there are no risks to beneficial insects.

d. Non-target Terrestrial Plants

The TERR-PLANT model was used to estimate risk to terrestrial plants in areas adjacent to the treated field (sheet runoff), wetland areas (channelized runoff), and from spray drift. Table 7 contains the acute RQs for terrestrial plants using the TERR-PLANT exposure model for the maximum application rate of 5.68 lb ae/A.

Table 7. Acute RQs for terrestrial plants

Application Rate	Application Method	Runoff Plus Drift RQs Adjacent Areas		Runoff Plus Drift RQs Semi-Aquatic Areas		Spray Drift RQs Vegetative Vigor	
		Non listed	Listed	Non listed	Listed	Non listed	Listed
USE SITE: NURSERIES, GREENHOUSES, URBAN & SUBURBAN AREAS							
5.68 lbs ae/A	Ground	0.09	0.1	0.8	**1.2**	<0.1	0.3

The TERR-PLANT exposure model calculates RQs for terrestrial plants for a single pesticide application only. Since dikegulac sodium labels allow for up to two foliar applications per year to several plants, the magnitude of the risk to plants is uncertain, and potentially underestimated. In order to compensate for this uncertainty, the Agency considered the upper bound to the magnitude of the RQs for terrestrial plants, which would be to sum the exposures from each application as if the effect to non-target plants were additive. The resulting RQs for two applications, or a maximum yearly application rate of 11.36 lbs ae/A indicate a potential risk to both non-endangered and endangered semi-aquatic plants. However, the Agency believes that this is an upper bound and highly conservative exposure scenario; thus, these risk estimates were not presented in Table 7 above. The RQs for a single application of dikegulac sodium (5.68 lbs ae/A) do not indicate a potential risk for non-endangered terrestrial plants.

However, additional information on the effect of dikegulac sodium on terrestrial plants would be needed to evaluate the uncertainty in multiple application terrestrial plant RQs. The effects of multiple applications could only be additive if the affected plants could not recover from the effects of successive applications. If the plants could recover over time, the effect of multiple applications could be greater for plants which are treated at the shortest application intervals.

The magnitude of effect of dikegulac sodium on terrestrial plants from multiple applications is uncertain. The effects of multiple applications could only be additive if the affected plants could not recover from the effects of successive applications. If the plants could recover over time, the effect of multiple applications could be greater for plants which are treated at the shortest application intervals.

The uncertainty in the magnitude of exposure to multiple applications of dikegulac sodium is even greater. The RQs for terrestrial plants assume exposure both through spray drift and runoff from a treated site after a heavy rain event. The likelihood of co-occurrence of such events is uncertain, especially for multiple applications, and as a result the estimated exposure values are conservative. In addition, while the likelihood of exposure to non-target plants through drift alone is significantly higher, the same plants may not be exposed to spray drift from each application since wind speed and direction could be different at the time of each application.

5. Adverse Ecological Incidents

There are currently no adverse ecological incidents listed in the Ecological Incident Information System (EIIS) that are associated with the dikegulac sodium.

6. Endangered Species Considerations

Based upon the screening-level assessment conducted on dikegulac sodium, the RQ for non-target semi-aquatic terrestrial plants exceeds the endangered species LOC. Acute RQs did not exceed endangered species LOCs for birds, mammals, aquatic plants, freshwater fish and invertebrates, or estuarine/marine fish and invertebrates. Chronic data were not available for any aquatic species or birds. Additionally, no mammalian reproductive study was available, although a developmental study was available.

As described above, the Agency believes that the low toxicity in available acute toxicity studies for freshwater and marine/estuarine animals suggests that chronic risk to freshwater and estuarine/marine animals is unlikely. Similarly, since dikegulac sodium is not acutely toxic to birds at doses many times higher than expected exposure, and is not chronically toxic to mammals, the Agency does not expect a chronic risk to birds. However, because the toxicity data are not available, the Agency cannot completely preclude chronic risks to birds, terrestrial phase amphibians, reptiles, freshwater fish and crustaceans, and estuarine/marine fish, invertebrates, and crustaceans at this time.

Additionally, because the screening-level assessment identified exceedences of the endangered species LOC for listed semi-aquatic terrestrial plants, the Agency cannot preclude indirect effects on listed species which rely on a specific or multiple plant species. However, as stated above, the Agency believes the RQs used in this assessment were conservative because 1) the use scenario assumes application of a full acre of tress, shrubs, and/or ornamental plants, which the registrant stated is a highly unlikely to occur due to the intended use of the product, as well as the high cost of the product, and 2) the model used to generate the RQs assumes co-exposure from spray drift and a large run-off event.

Table 8 provides a matrix that depicts the potential for direct and indirect effects to listed species resulting from the use of dikegulac sodium. Details regarding these effects are provided in the sections below.

Table 8. Listed species potential risk associated with direct or indirect effects due to applications of dikegulac sodium

Listed Taxon	Direct Effects		Indirect Effects
	Acute	Chronic	
Terrestrial plants	Yes	N/A	No
Terrestrial invertebrates	No	N/A	Yes
Birds	No	No available data	Yes
Terrestrial phase amphibians	No	No available data	Yes
Reptiles	No	No available data	Yes

Listed Taxon	Direct Effects		Indirect Effects
	Acute	Chronic	
Mammals	No	No	Yes
Aquatic non-vascular plants	No	N/A	No
Aquatic vascular plants	No	N/A	No
Freshwater fish	No	No available data	Yes
Aquatic phase amphibians	No	N/A	Yes
Freshwater crustaceans	No	No available data	Yes
Mollusks	No	N/A	Yes
Marine/estuarine fish	No available data	No available data	Yes
Marine/Estuarine invertebrates	No	No available data	Yes
Marine/estuarine crustaceans	No	No available data	Yes

N/A is not applicable since guidelines for these studies do not exist.

IV. Risk Management and Reregistration

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 completed its review of available generic data (i.e., active ingredient-specific), and has determined that the data are sufficient to support reregistration of all products containing dikegulac sodium.

The Agency has completed its assessment of the occupational, residential, drinking water, and ecological risk associated with the use of pesticide products containing the active ingredient dikegulac sodium. The Agency has determined that dikegulac sodium-containing products are eligible for reregistration provided that label amendments are made as outlined in Chapter V. Appendix A summarizes the uses of dikegulac sodium that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of dikegulac sodium, and lists the submitted studies that the Agency found acceptable.

Based on its evaluation of dikegulac sodium, the Agency has determined that dikegulac sodium does not present risks to human health or the environment. However, in order to comply with the Worker Protection Standards, the Agency is requiring additional PPE for tree injection applications, as well as for early entry, and an increased REI for agricultural uses. Additionally, to mitigate potential ecological risks to semi-aquatic plants, the Agency is requiring the implementation of spray drift language on all end use labels with foliar applications. Should a registrant fail to implement any of the reregistration requirements identified in this document, or should the Agency identify any risks inconsistent with FIFRA at a later date, the Agency may take regulatory action.

B. Public Comments and Responses

Because the risks associated with the use of dikegulac sodium were low and did not warrant significant mitigation measures, the Agency determined an expedited one phase RED process was appropriate for dikegulac sodium. Therefore, a public comment period was not conducted. However, a 60-day public comment period will be conducted after the RED is issued, and will be announced in the Federal Register. Comments may be submitted under Docket number EPA-HQ-OPP-2006-0954 at http://www.regulations.gov. The RED document and technical supporting documents for dikegulac sodium are also available to the public through EPA's electronic public docket and comment system, at http://www.regulations.gov under docket identification (ID) number EPA-HQ-OPP-2006-0954. In addition, the dikegulac sodium RED document may be downloaded or viewed through the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

C. Regulatory Position

1. Regulatory Rationale

The Agency has determined that dikegulac sodium is eligible for reregistration provided that specified label amendments are made. The following is a summary of the rationale for managing risks associated with the use of dikegulac sodium.

a. Human Health Risk Management

There are no human health risks of concern for dikegulac sodium. However, the Agency is updating the Restricted Entry Interval (REI) and Personal Protective Equipment (PPE) requirements for dikegulac sodium. Dikegulac sodium is an acute toxicity category II eye irritant; therefore, pursuant to the Worker Protection Standard (WPS) and according to the OPPTS Label Review Manual 3rd Edition, products with agricultural uses must require a 24 hour REI and the following PPE for early entry: coveralls, chemical-resistant gloves made of any water proof material, shoes plus socks, and protective eyewear. The RTU product is registered for tree injection only; therefore, there would be little to no post-application exposure and a REI and early entry PPE are unnecessary.

Protective eye equipment must also be worn by occupational handlers making direct injection applications to trees due to the nature of the application and the possibility of backsplash. Further, additional personal protective equipment may be required, if appropriate based on the acute toxicity categories of each end-use product.

b. Ecological Risk Management

All ecological risks are below the Agency's LOC, except for potential risks to non-endangered and listed semi-aquatic plants as a result of two applications of dikegulac sodium on an acre of trees, plants, and/or shrubs, and exposure from both run-off and spray drift. As stated in Section III, the Agency believes the RQs are overly conservative because: 1) the EECs are based on conservative assumptions of stability, and not chemical specific fate data,

2) the use scenario assumes an application on an acre of trees, shrubs, and/or ornamental plants, which the registrant stated is highly unlikely to occur due to the intended use of the product, as well as the high cost of the product, and 3) the model assumes exposure both through spray drift and run-off from a treated site after a heavy rain event, the Agency believes the likelihood of co-occurrence for multiple applications is unlikely.

Additionally, while the likelihood of exposure to non-target plants through drift alone is significantly higher than simultaneous exposure from spray drift and run-off from a heavy rain event, the same plants may not be exposed to spray drift from each application since wind speed and direction could be different at the time of each application. However, in order to mitigate the potential for exposure through drift, the Agency is requiring the addition of spray drift language on all labels with foliar applications. Section V, Table 9 contains the required spray drift language.

c. Data Waivers Based Upon Low-Volume Minor-Use Status

As stated in the Regulatory History in Section I above, the Agency agreed to waive certain data requirements in light of the low volume of production of dikegulac sodium. PBI/Gordon has recently requested that the Agency remove the linkage between production and the data waivers based upon the low toxicity and low potential for human health or ecological risk associated with the use of dikegulac sodium. The Agency has considered this request and has determined that an increase in the production and use of dikegulac sodium would not impact either the human health or ecological risk assessments. The Agency determined that the maximum production amount estimated by the registrant, which is considered by the registrant to be CBI, would not be great enough to be used in a significant portion of a single watershed and, therefore, the increase in production would not impact the drinking water assessment. Finally, the Agency determined that an increase in production would not require any additional data, other than the product chemistry data listed in Section V of this document. Therefore, the requirement to report annual sales information and the linkage between such information and the data waivers will no longer be required for these registrations, provided that the Agency receives acceptable generic product chemistry data.

2. Endocrine Disruptor Effects

Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, dikegulac sodium may be subject to additional screening and/or testing.

3. Endangered Species

The Endangered Species Act required federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on federally listed endangered and threatened species, and to implement mitigation measures that address these impacts. To assess the potential of registered pesticide uses that may affect any particular species, EPA puts basic toxicity and exposure data developed for the REDs into context for individual listed species and considers ecological parameters, pesticide use information, the 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. 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 dikegulac sodium "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402).

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. That assessment refines the screening-level assessment to take into account such things as the geographic area of pesticide use in relation to the listed species, the habits and habitat requirements of the listed species, etc. If the Agency's specific assessments for dikegulac sodium 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.

D. Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing dikegulac sodium. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

Because of the potential risks to non-listed and listed semi-aquatic plants, as summarized in this document, the Agency is requiring spray drift mitigation as part of the reregistration eligibility determination. Section V, Table 9 contains the required spray drift label language.

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray. As part of the reregistration process, the EPA will continue to work with all interested parties on this important issue.

V. What Registrants Need to Do

The Agency has determined that dikegulac sodium is eligible for reregistration provided that the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants will be required to amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table (Table 9) below. The Agency intends to issue Data Call-In Notices (DCIs) requiring product-specific data and additional generic (technical grade) 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 eight months to submit data. For generic data, due dates can vary depending on the specific studies being required. Below are the additional generic data and label amendments that the Agency intends to require for dikegulac sodium to be eligible for reregistration.

A. Generic Data Requirements

The generic data base supporting the reregistration of dikegulac sodium has been reviewed and determined to be substantially complete. However, there are a few data gaps remaining, and these are listed below. In addition, updated Confidential Statements of Formula (CSFs) are required.

Product Chemistry

830.1750	Certified Limits
830.1800	Enforcement Analytical Methods
830.1900	Submittal of Samples
830.7050	UV/VIS Absorption

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.

C. Labeling Changes Summary Table

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

1. Labeling for Manufacturing-Use Products

There are currently no Manufacturing-Use Products of dikegulac sodium registered with in the United States. However, should any MUP products be registered at a later date, labeling must comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 9.

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.

Table 9. Dikegulac Sodium Labeling Changes Summary Table		
Description	**Amended Labeling Language for Manufacturing Use Products**	**Placement on Label**
Required on all MUPs	"Only for formulation into a growth regulator for the following use(s) [fill blank only with those uses that are being supported by MP registrants]."	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."	
Description	**End-Use Products Intended for Occupational Use (WPS and non-WPS)**	**Placement on Label**
Handler PPE Requirements for liquids included soluble concentrates and RTU liquid formulations [1]	"Mixers, loaders, applicators, and other handlers must wear: -long-sleeve shirt, -long pants, -shoes and socks. -When making direct injections to trees, applicators must wear protective eyewear."	Precautionary Statements: Hazards to Humans and Domestic Animals
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." "Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Table 9. Dikegulac Sodium Labeling Changes Summary Table		
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. Wash the outside of gloves before removing. 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.)
Restricted-entry Interval for WPS products as required by Supplement Three of PR Notice 93-7 Note: this statement is not necessary for end-use products labeled solely for direct injection	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours."	Directions for Use, Agricultural Use Requirements Box
Early Reentry Personal Protective Equipment for Products subject to WPS as required by Supplement Three of PR Notice of 93-7	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as soil or water, is: For all end-use products, except those labeled solely for direct injection: -coveralls, -chemical-resistant gloves made of any waterproof material, -shoes plus socks, and -chemical-resistant eyewear."	Directions for Use, Agricultural Use Requirements Box

Table 9. Dikegulac Sodium Labeling Changes Summary Table		
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application." "For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation." For Products with Spray Applications: "Do not apply through any type of irrigation system" or include directions in compliance with PR Notice 87-1.	Place in the Directions for Use directly above the Agricultural Box, if there is one, otherwise place in the Directions for Use under General Precautions and Restrictions.
General Directions for Use	*Note to registrant:* *Include specific instructions for calculating Tree Row Volume for application to tree crowns.*	Directions for Use, Application Instructions
Environmental Hazards Statements Required by the RED and Agency Label Policies	"For terrestrial uses: Do not apply directly to water, or to areas where water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate."	Precautionary Statements: Hazards to Humans and Domestic Animals
Spray Drift Label Language for Products Applied as a Spray	**"SPRAY DRIFT MANAGEMENT"** "Non-target terrestrial plants can be adversely affected when exposure to this product. Avoid spray drift to non-target terrestrial plants during application. Do not apply when wind velocity exceeds 15 mph, or when wind gusts approach 15 mph. Do not apply this product if the wind direction does not favor on-target deposition. Use only spray equipment with medium or coarser spray nozzles according to ASABE (S572) definition for standard nozzles. In conditions of low humidity and high temperatures, applicators must use a coarser droplet size."	Directions for Use under General Precautions or Restrictions and/or Application Instructions

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Appendix A

Use Patterns Subject to Reregistration for Dikegulac Sodium

Appendix A. Use Patterns Subject to Reregistration for Dikegulac Sodium							
Application Timing Application Type Application Equipment	**Formulation EPA Reg. No.**	**Maximum Single Application Rate[1]**	**Maximum No. of Applications per Year**	**Maximum Seasonal Rate**	**Application Interval (days)**	**Reentry Interval**	**Limitations**
Greenhouse and Nursery Ornamentals (chemical pinching)							
Foliar Spray Handheld Sprayer	SC [2217-776]	0.048 lb ae/gal	1	0.048 lb ae/gal	NA	24 hours	
Landscape Ornamentals - Shrubs, Hedges, Trees, and Groundcover (growth control)							
Foliar Spray Handheld Sprayer	SC [2217-776]	0.035 lb ae/gal	2	0.07 lb ae/gal	10-14 days	24 hours	
Fruiting Landscape Trees and Shrubs (suppression of flower and fruit formation)							
Pre-bloom, Foliar Spray Handheld Sprayer	SC [2217-776]	0.060 lb ae/gal	1	0.060 lb ae/gal	NA	24 hours	Treat healthy, vigorously growing trees only.
Broadleaf Trees (plant growth retardant)							
Tree Injection Tree Injection Systems	SC [2217-776] RTU [69117-7]	0.77 lb ae/gal	1	0.77 lb ae/gal	NA	NA	Do not inject into drought stressed trees or trees that do not appear healthy. Do not inject into bearing fruit or nut trees or sugar maple trees tapped for sugar.

[1]Maximum application rate identified from product label review. Rates are in acid equivalent (ae).

Appendix B

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case 2510 covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to 2510 in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are 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 Dikegulac Sodium				
REQUIREMENT			**Use Patterns**	**CITATION(S)**
PRODUCT CHEMISTRY				
New Guideline Number	**Old Guideline Number**	**Study Description**	**Use Patterns**	**CITATION(S)**
830.1550	61-1	Product Identity and Composition	All	43225901 43225902 43225903
830.1600	61-2A	Description of materials used to produce the product	All	43225901 43225902 43225903
830.1620	61-2B	Description of production process	All	43225901 43225902 43225903
830.1650		Description of Formulation Process	All	43225901 43225902 43225903
830.1670	61-2B	Formation of Impurities	All	43225901 43225902 43225903
830.1700	62-1	Preliminary Analysis	All	43225901 43225902 43225903
830.1750	62-2	Certification of limits	All	**Data Gap**
830.1800	62-3	Analytical Method	All	**Data Gap**
830.1900		Submission of Samples	All	**Data Gap**
830.6302	63-2	Color	All	Waived/ Material Safety Data Sheet (MSDS)
830.6303	63-3	Physical State	All	Waived/Farm Chemical Handbook (FCH)
830.6304	63-4	Odor	All	Waived/MSDS
830.6313	63-13	Stability to normal and elevated temperatures, metals, and metal ions	All	Waived/MSDS
830.7000	63-12	pH	All	Waived/MSDS
830.7050	None	UV/Visible Absorption	All	**Data Gap**
830.7200	63-5	Melting Point	All	Waived/FCH

830.7220	63-6	Boiling Point/Boiling Point Range	All	Waived/MSDS
830.7300	63-7	Density	All	Waived/MSDS
830.7840	63-8	Solubility	All	Waived/FCH
830.7950	63-9	Vapor Pressure	All	Waived/MSDS
830.7370	63-10	Dissociation constants in water	All	Waived
830.7550	63-11	Partition coefficient, shake flask method	All	Waived/MSDS
ECOLOGICAL DATA				
850.2100	71-1A	Avian Acute Oral Toxicity	C, I	Waived/ 46547302
850.2200	71-2A	Avian Dietary Toxicity - Quail	C, I	Waived/ 46547303 45631702
850.2200	71-2B	Avian Dietary Toxicity – Duck	C, I	Waived
850.1075	72-1A	Fish Toxicity Bluegill	C, I	Waived/ 45631702
850.1075	72-1C	Fish Toxicity Rainbow Trout	C, I	Waived/ 46547301
850.1010	72-2A	Invertebrate Toxicity	C, I	Waived/ 45631702
850.1075	72-3A	Estuarine/Marine Toxicity - Fish	C, I	45631702
850.4100	122-1A	Terrestrial Plant Toxicity, Seedling Emergence	C, I	46547305
850.4150	122-1B	Terrestrial Plant Toxicity, Vegetative Vigor	C, I	46547306
850.4400	122-2	Aquatic Plant Growth	C, I	46547307
850.3020	141-1	Honey Bee Acute Contact	C, I	44093910
ACUTE AND CHRONIC TOXICITY				
870.1100	81-1	Acute Oral Toxicity-Rat	C, I	44093901 43064604 43064605 43064606 43064607 43064608
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	C, I	43064612 43064610 44093902
870.1300	81-3	Acute Inhalation Toxicity-Rat	C, I	43064613 44093903
870.2400	81-4	Primary Eye Irritation-Rabbit	C, I	43064614 44093904

870.2500	81-5	Primary Skin Irritation	C, I	43064615 44093905
870.2600	81-6	Dermal Sensitization	C, I	43064616 44093906
	81-7	Acute Delayed Neurotoxicity	C, I	Waived
870.3100	82-1A	Subchronic Oral Toxicity: 90-Day Study Rodent	C, I	Waived/ 42957701
870.3150	82-1B	Subchronic Oral Toxicity: 90-Day Study Non-rodent	C, I	Waived/ 42957702
870.3200	82-2	21-Day Dermal - Rabbit/Rat	C, I	Waived/ 42957703
	82-3	90-Day Dermal - Rodent	C, I	Waived
	82-4	90-Day Inhalation - Rat	C, I	Waived
	82-5A	90-Day Neurotox - Hen	C, I	Waived
	82-5B	90-Day Neurotox - Mammal	C, I	Waived
870.3700	83-1A	Chronic Feeding Toxicity - Rat	C, I	Waived/ 43064617 43064618
870.4100	83-1B	Chronic Feeding Toxicity - Non-Rodent	C, I	Waived
870.4200	83-2A	Carcinogenicity – Rat	C, I	Waived
870.4200	83-2B	Carcinogenicity – Mouse	C, I	Waived
870.3700	83-3A	Developmental Toxicity - Rat	C, I	43064618
870.3700	83-3B	Developmental Toxicity - Rabbit	C, I	43612801 43064601
870.3800	83-4	2-Generation Reproduction - Rat	C, I	Waived
870.5100	84-2A	Bacterial Reverse Gene Mutation	C, I	44093907
870. 5300	84-2B	HGPRT Forward Mutation Assay/V79 Cell Line	C, I	44093908
870.5395	84-2	Micronucleus	C, I	44093909
	84-4	Other genotoxic effect	C, I	44093909
870.7485	85-1	General Metabolism	C, I	Waived
870.7600	85-2	Dermal Penetration and Absorption	C, I	Waived
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2400	133-3	Dermal Passive Dosimetry Exposure	C, I	Waived
875.2500	133-4	Inhalation Passive Dosimetry Exposure	C, I	Waived
ENVIRONMENTAL FATE				

835.2120	161-1	Hydrolysis	C, I	Waived/ 46932401
835.2240	161-2	Photodegradation - Water	C, I	Waived
835.2410	161-3	Photodegradation - Soil	C, I	Waived
835.4100	162-1	Aerobic Soil Metabolism	C, I	Waived/ 46932402
835.4200	162-2	Anaerobic Soil Metabolism	C, I	Waived
835.4400	162-3	Anaerobic Aquatic Metabolism	C, I	Waived
835.1240	163-1	Leaching/Adsorption/Desorption	C, I	Waived
835.1410	163-2	Laboratory Volatilization	C, I	Waived
835.8100	163-3	Field Volatilization	C, I	Waived
835.6100	164-1	Terrestrial Field Dissipation	C, I	Waived
	165-1	Confined Rotational Crop	C, I	Waived
	165-2	Field Rotational Crop	C, I	Waived
850.1730	165-4	Bioaccumulation in Fish	C, I	Waived
	165-5			Waived

Appendix C

Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room S-4400, One Potomac Yard (South Building), 1777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The risk assessments and other supporting documents for dikegulac sodium are available in the Public Docket, under docket number EPA-HQ-OPP-2006-0954, and on the Agency's web page, http://www.regulations.gov. The docket contains risk assessments and related documents as of February 2007.

Technical support documents for the Dikegulac Sodium RED include the following:

Health Effects Documents

1. *Dikegulac Sodium. Human Health Consideration for the Reregistration Eligibility Decision.* October 31, 2006.
2. *Dikegulac Sodium. Addendum to the HED Risk Assessment.* February 6, 2007.

Ecological Fate and Effects Documents

3. *EFED Risk Assessment for the Reregistration of Dikegulac Sodium.* October 6, 2006.
4. *Drinking Water Assessment for Dikegulac-Sodium Reregistration Eligibility Decision (RED).* February 9, 2007.

Appendix D

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43064601	Wipf, H. (1974) Na-DAG (Ro 07-6145/001): Stability in Aqueous Solution. Unpublished study prepared by Roche Corporate Lab. 8 p.
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