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Prevention, Pesticides
And Toxic Substances
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Reregistration Eligibility Decision for Dodine

List A

Case No. 0161

Reregistration Eligibility Decision (RED) Document

for

Dodine

Approved by: /S/

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Director
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Date: 9/30/05

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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
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
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
μg/g	Micrograms Per Gram
μg/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)
TCPSA	2,3,3-trichloroprop-2-ene sulfonic acid (nitrapyrin Metabolite)
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

Executive Summary

EPA has completed preliminary risk assessments, error correction, and is now issuing its risk management decision for the fungicide dodine. EPA will accept public comments on this decision and the supporting documents for 60 days. The dodine risk assessments are based on review of the required database supporting the use patterns of the currently registered dodine products. EPA has elected to proceed with its risk management decision at this time due to the limited use and limited risks posed by this chemical. If during the comment period EPA receives new or additional information that substantively changes the risk assessment findings or the risk management decision, EPA will issue an amendment to this document.

Dodine is a fungicide used primarily on fruits and nuts. Approximately 70,000 pounds of dodine are applied annually, with the most use on apples and pears. The use of dodine has dropped from a 1992 high of approximately 265,000 pounds active ingredient. There are no registered residential uses of dodine. This document addresses the tolerance reassessment and reregistration eligibility decision for all the currently registered uses of dodine. Another active ingredient of similar chemical composition and properties, dodecylguanidine hydrochloride (DGH), is included with dodine in case no. 0161. DGH has only antimicrobial uses, some of which may occur in a residential environment, i.e. treatment of paper that comes into contact with food, paint additives, and anti-bacterial treatment of diapers. Because of the similarity of these compounds, EPA has considered the contribution to overall risk of the DGH uses in its aggregate assessment for dodine. However, the reregistration eligibility decision for the antimicrobial uses of DGH will be issued at a later date.

Dietary Risk (food and drinking water)

No acute dietary toxicity endpoint was identified in the dodine data base. Thus, no acute dietary assessments have been conducted.

An unrefined, screening level chronic dietary assessment indicates no risks of concern for the general population or any sub-population. Risk estimates are 3% of the cPAD for the general population and 16% of the cPAD for children 1-2 years old, the highest exposed sub-group. These estimates are considered very conservative because they were conducted using tolerance level values and assume treatment of all pome and stone fruits, not just those appearing on current registered labels.

Aggregate Risks

An acute aggregate assessment has not been conducted because no appropriate acute endpoint has been identified.

Short-term aggregate risks were conservatively estimated for adults taking into account dodine dietary exposures (food and water), as well as potential DGH exposure from treated paper that comes into contact with food (indirect food additive) and from applying paint containing DGH as a preservative. The short-term aggregate MOE for adults is 574 and does not exceed the Agency's level of concern.

Short-, intermediate-, and long-term aggregate risks were conservatively estimated for infants taking into account dodine dietary exposures (food and water), as well as potential DGH exposure from the paper (indirect food additive) use and from infants wearing DGH-impregnated diapers. The aggregate MOE for infants for all durations is 132, and does not exceed the Agency's level of concern.

Both of these aggregate assessments are considered to be conservative because the probability of repeated and simultaneous exposure to dodine/DGH from all sources for any given individual is small. Because risks are below EPA's level of concern and EPA is highly confident that actual risks will not exceed those estimated here, these screening level aggregate assessments have not been further refined.

Cumulative 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 for dodine and any other substances, and dodine does not appear to produce a toxic metabolite produced by other substances. Dodine and DGH are both salts of the same chemical. They dissociate similarly, are considered bioequivalents and toxicologically the same, as opposed to separate chemicals that share a common mechanism of toxicity. For the purposes of this action, therefore, EPA has assumed that dodine does not have a common mechanism of toxicity with other substances, but has considered the contribution of DGH in the aggregate assessment for dodine as noted above.

FQPA Finding

EPA has determined with reasonable certainty that no harm to the general population or any sub-population will result from exposure to dodine.

Occupational Risks

EPA has evaluated handler exposure for both liquid and wettable powder formulations and for groundboom and aerial spray applications. The majority of occupational handler scenarios assessed resulted in MOEs greater than 100, and thus are not of concern, either at baseline PPE or with the addition of gloves. Only two mixing/loading scenarios for the wettable powder formulations would require additional levels of protection to achieve MOEs of 100. An REI of 48 hours and a double notification requirement are adequate to address post-application worker risks.

Ecological Risks

EPA's screening level assessment for dodine indicate potential exceedences of levels of concern (LOCs) for some classes of organisms. Most of the potential exceedences are based on calculations that assume worst-case conditions, e.g., aerial application and maximum application rates. In practice, usage data indicate that aerial application is not common for dodine; it is used only when orchards floors are impassable for ground equipment. Orchard fungicides are most frequently applied with an airblast system to ensure complete coverage of the plant surface. Also, although the label for apples, for example, allows up to 1.95 lbs/ai/A to be applied at once, usage information indicates that only about 5% of all dodine applications to apples are made at rates higher than 1.75 lbs/ai/A. About 70% of all dodine applications to apples are made at rates less than 1.25 lbs/ai/A. Lower risk estimates are expected from these more typical use parameters.

In some cases specific data are lacking and risks are assumed based on data derived from related organisms. Data will be required to address these gaps and will allow further refinement of the assessments.

Fish

EPA screening level assessment indicates that acute and chronic risk quotients (RQs) are generally not of concern for fish, although there is a slight exceedence of the endangered species acute RQ for freshwater fish from aerial application to apples in Pennsylvania, with current label parameters.

Invertebrates

Some calculated RQs exceed LOCs for both freshwater and saltwater (marine/estuarine) invertebrates. Estimated RQs range from < LOC to 2.4. No chronic toxicity data are available to assess chronic risk to marine invertebrates.

Plants

The only data available indicate that dodine is highly toxic to green algae (an aquatic, non-vascular plant) and RQs exceed LOCs for most uses No data are available for aquatic vascular plants.

Tier 1 terrestrial plant toxicity studies indicate potential concern for phytotoxicity at the maximum current label rate (2.6 lbs/ai/A).

Birds

Calculated acute RQs exceed the LOC for birds consuming many types of food items, including short grass, tall grass, broadleaf plants, and small insects. Acute RQs range from 0-5.6. Chronic LOCs are exceeded for many modeled scenarios and application rates, with RQs ranging from 0.06 to 12.

Mammals

Calculated acute RQs exceed the LOC for mammals consuming many types of food items, including short grass, tall grass, broadleaf plants, and small insects, across most weight classes, with RQs ranging from 0 to 1. Chronic LOCs are exceeded for many modeled scenarios and application rates, with RQs ranging from 0.03 to 34.

Both the bird and mammal assessments assume that all of the animal's diet consists of dodine treated food items. Species specific information on behavior and dietary habits will permit refinement of these assessments.

Summary of Mitigation Measures

EPA has determined that the currently registered uses of dodine are eligible for reregistration provided the mitigation measures outlined in this document are implemented through label amendments. Mitigation measures include:

For Occupational Risk:

To address risk to mixers and loaders of dodine:

- Risk to workers from wettable powder formulations of dodine can be addressed by use of water-soluble packaging. However, registrants have chosen to voluntarily cancel wettable powder formulations.
- Retain gloves for handlers for mixing and loading dodine.

Post application exposure to dodine, a toxicity category I eye and skin irritant, can be addressed through the following measures:

- Require double notification; workers must be warned orally and by posting warning signs at entrances to treated areas regarding potential for eye and skin irritation.
- Require a 48 hour REI before workers can re-enter dodine treated fields.

For Ecological Risks:

Registrants have voluntarily agreed to numerous reductions in maximum application rates and increased application intervals that will lessen risks to all non-target species. These include:

- Reduce maximum single application rate on peaches, pecans and walnuts from 2.6 to 1.95 lbs/ai/A.
- Reduce maximum seasonal application rates on apples, cherries (sweet and sour), crab apples, peaches, pears, pecans, and walnuts.
- Increase application intervals for apples and pears from 5 to 7 days.
- Specify medium to coarse droplet size and other spray drift management practices.
- Specify erosion management practices to reduce runoff from vulnerable soils.

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 EPA review of all submitted data. 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 of 1996 (FQPA) was signed into law. This Act amends FIFRA to require reassessment of all tolerances in effect on the day before it was enacted. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility among infants and children, and the cumulative effects of pesticides that have a common mechanism of toxicity. When the Agency determines that aggregate risks are not of concern and concludes that there is a reasonable certainty of no harm from aggregate exposure, the tolerances are considered reassessed. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process.

The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. 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 for dodine and any other substances, and dodine does not appear to produce a toxic metabolite produced by other substances. As noted in this document dodine and DGH are both salts of the same chemical. They dissociate similarly, are considered bioequivalents and toxicologically the same, as opposed to separate chemicals that share a common mechanism of toxicity. As such, EPA has considered exposure to DGH in its aggregate exposure assessments for dodine. For the purposes of this action, therefore, EPA has not assumed that dodine has 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/pesicides/cumulative/.

This document addresses the tolerance reassessment and reregistration eligibility decisions for all the currently registered uses of dodine. Another active ingredient of similar chemical composition and properties, dodecylguanidine hydrochloride (DGH), is included with dodine in case no. 0161. DGH has only antimicrobial uses, some of which may occur in a residential environment, i.e. treatment of paper that comes into contact with food, paint additives, and anti-bacterial treatment of diapers. Because of the similarity of these compounds, EPA has considered the contribution to overall risk of these DGH uses in its aggregate assessment for dodine. However, the reregistration eligibility decision for the antimicrobial uses of DGH will be issued at a later date.

The Agency made its reregistration eligibility determination based on the required data, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that currently registered uses of dodine are eligible for reregistration provided the mitigation and labeling outlined in the RED are implemented. The document consists of six sections: Section I, the introduction, contains the regulatory framework for reregistration/tolerance reassessment; Section II provides an overview of the chemical, including a profile of its use and usage; Section III gives an overview of the human health and environmental effects risk assessments; Section IV presents the Agency's reregistration eligibility, tolerance reassessment, and risk management decisions; Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV; and Section VI includes the appendices, related supporting documents and Data Call-In (DCI) information. The revised risk assessment documents and related addenda are not included in this document, but are available on the Agency's web page http://www.epa.gov/pesticides, and in the Public Docket under docket number OPP-2005-0266.

II. Chemical Overview

A. Regulatory History

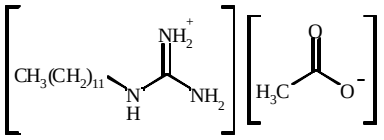
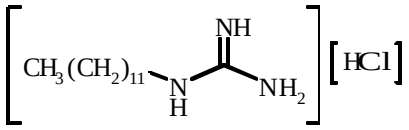
The Registration Standard and associated DCIs for the dodine case, which includes the three chemicals dodecylguanidine acetate (dodine), dodecylguanidine terephthalate (DGT), and dodecylguanidine hydrochloride (DGH) as listed below in table 1, were issued in February 1987 with the determination that data may be shared among the chemicals in this case when appropriate, due to their similar chemical properties. The last product for DGT was cancelled on October 10, 1989; therefore, this RED does not consider potential risks associated with DGT. This Reregistration Eligibility Decision (RED) reflects a reassessment of all the data reviewed to date on dodine.

Table 1: Ingredients in the Dodine Chemical Case (0161)

PC Code	Chemical Name	CAS Number	Status
044301	dodine, a.k.a. dodecylguanidine acetate (DGA)	2439-10-3	Agricultural uses being reregistered in this document.
044302	dodecylguanidine terephthalate (DGT)	19727-17-4	Last product cancelled 10/10/1989.
044303	dodecylguanidine hydrochloride (DGH)	13590-97-1	Preservative uses undergoing reregistration separately.

Dodine was first registered by American Cyanamid in 1956. American Cyanamid then transferred its DGH registrations to Cytec Industries. American Cyanamid sold the agricultural chemical division to BASF and they subsequently sold the dodine registration and supporting data to Shell Agror in 1988. In 2001, Chimac-Agriphar S.A. acquired the registrations of dodine and is currently the only technical dodine registrant. In February 2003, Chimac-Agriphar's new formulation, Syllit FL Fungicide, a liquid formulation, was registered and is presently replacing the wettable powder formulation, Dodine 65W. BASF has one active dodine end use product registration but is not currently marketing it. There are currently three DGH manufacturing-use product registrants: Chimac-Agriphar S.A., Verichem, Inc., and Cytec Industries, Inc. There are also three DGH end-use product registrants: Hercules, Inc., Nalco, and GE Betz, Inc. There are currently 20 registrations containing DGH as the active ingredient. There is no registered technical grade product for DGH.

B. Chemical Identification

Table 2: Dodine and DGH Nomenclature	
Chemical structure	
Common name	Dodine or n-dodecyl guanidine acetate
Molecular Formula	$C_{15}H_{33}N_3O_2$
Molecular Weight	287.4
IUPAC name	1-dodecylguanidinium acetate
CAS name	dodecylguanidine monoacetate
CAS #	2439-10-3
Basic Manufacturer	Chimac-Agriphar SA
Chemical structure	
Common name	Dodecylguanidine hydrochloride (DGH) or dodine hydrochloride
Molecular Formula	$C_{13}H_{30}N_3Cl$
Molecular Weight	263.9
IUPAC name	1-dodecylguanidinium hydrochloride
CAS name	dodecylguanidine hydrochloride
CAS #	13590-97-1 (guanidine, dodecyl-, monohydrate); 112-65-2 (guanidine, dodecyl-)
Basic Manufacturer	Chimac-Agriphar S.A., Verichem, Inc., and Cytec Industries, Inc.

C. Use Profiles

1. Dodine Use Profile

Type of Pesticide: Fungicide

Summary of Use: Dodine is registered for use on apple, cherry (sweet and tart), peach, pear, pecan, spinach, strawberry, and black walnut, and to control fungal diseases on ornamentals, including crab apples in the State of Oregon (SLN 24c).

Target Organisms: Dodine is registered for control of a range of pathogenic fungi that affect a number of agricultural and some ornamental crops.

Mode of Action: Dodine's mode of action is through disruption of cell membranes.

Tolerances: There are 11 tolerances established under 40 CFR §180.172 for dodine on apple, sweet cherry, tart cherry, peach, pear, strawberry, pecans, walnuts, milk, meat, and spinach.

Use Classification: General Use

Formulation Types: Current formulations for dodine include liquid flowable concentrate and wettable powder. The technical registrant has requested voluntary cancellation of the wettable powder formulation. A dust formulation had been registered but the registration was canceled for non-payment of maintenance fees in October 2004; therefore this formulation was not included in this assessment.

Application Methods: Most of the applications are by ground with an air blast sprayer (high or low volume). When rain persists in the growing season applications are made by aircraft.

Application Rates: The currently labeled maximum application rates range from 1.3 to 2.6 lbs. a.i./Acre/application. The minimum retreatment intervals range from 5-14 days and the pre-harvest intervals (PHIs) range from 5 to 15 days.

Application Timing: Dodine products can be applied at various stages of crop development including dormant, delayed dormant, prebloom, early bloom, bloom, foliar, petal fall, during mature fruit development, and postharvest (to the trees).

Usage of Dodine: Based on Agency data, the current average total annual domestic usage of dodine is approximately 70,000 pounds active ingredient (a.i.), which has dropped from a 1992 high of approximately 265,000 pounds active ingredient. The highest usage, in pounds a.i., is on pears (30%), apples

(30%), cherries (15%) and pecans (15%). Almonds, grapes, peaches, strawberries, and walnuts together account for about 10% of the total dodine applied.

2. DGH Use Profile

Type of Pesticide: Antimicrobial

Pesticide Category: Sanitizer, Bacteriostat, Microbiocide, Microbiostat, Fungicide, Algicide, Molluscicide

Use Sites: Water cooling towers, sewage disposal lagoons, additive to preserve finished paper and paperboard products (including food contact surfaces), brewery pasteurizer water, industrial disposal water, air washer water systems, waste water systems, sewage effluent water, sewage systems, industrial processing water, non-potable water, adhesives, glues, coatings, oil recovery drilling mud, secondary oil recovery injection water, polymers, latex, resin emulsions, latex emulsions, paper-making chemicals, alum solutions, printing pastes, evaporate condenser water, heat exchange water, disposable diapers, and slurries.

Target Pests: Algae, animal pathogenic bacteria, deterioration/spoilage bacteria, fouling organisms, fungal slime, fungi, mold, mollusks, slime-formulating bacteria, slime-formulating fungi, and yeasts.

III. Summary of Dodine and DGH Risk Assessments

The following is a summary of EPA's human health findings and conclusions for dodine as presented fully in the document, "Dodine: HED Chapter of the Reregistration Eligibility Decision Document," revised per 30-day error only registrant comments, dated 9/26/05.

A. Human Health Risk Assessment

The Agency has conducted a human health risk assessment for dodine for the purposes of making a reregistration eligibility decision. The Agency evaluated the toxicology, product and residue chemistry, and occupational/residential exposure studies submitted and determined that the data are adequate to support a reregistration decision. Details of the risk assessments and separate supporting disciplinary documents are available in the electronic docket. A summary of the human health risk assessment findings and conclusions are provided below.

The toxicological studies used in this risk assessment were all performed on dodine; the Agency considers dodine and DGH toxicologically equivalent. The database for dodine is complete and there are no data gaps. The available toxicity data are adequate to assess the chemical's hazard potential. The database for DGH contains a few toxicity studies, but they were all conducted with end-use product formulations which contain 35% DGH. The Agency

typically requires that studies submitted be conducted with the technical grade material. Therefore, all endpoints were selected from the dodine database.

1. Toxicity

Technical grade dodine has moderate acute toxicity via the oral, dermal and inhalation routes (Category III), is severely irritating to the skin and the eye (Category I), and is not a skin sensitizer. See table 3 below.

Table 3: Acute Toxicity Profile - Dodine

Guideline No.	Study Type	MRID	Results	Toxicity Category
870.1100	Acute oral [rat]	00124280	LC_{50} males =1931 mg/kg LC_{50} females =1171 mg/kg LC_{50} combined =1456 mg/kg	III
870.1200	Acute dermal [rabbit]	00124280	LD_{50} >2000 mg/kg	III
870.1300	Acute inhalation [rat]	00157300	LC_{50} = 1.05 mg/kg	III
870.2400	Acute eye irritation [rabbit]	00124280	Severe	I
870.2500	Primary dermal irritation [rabbit]	00124280	Primary Dermal Irritation Index, PDII - 7.5	I
870.2600	Skin sensitization [human]	00157386	Negative	Neg

The most common effects in intermediate- or long-term oral toxicity studies were a decrease in food consumption, body weight and/or body weight gain. There were some clinical signs noted including excessive salivation (dog and mice) and hunched posture/hypoactivity (rats), but only the dog showed a treatment-related dose response.

Carcinogenicity

Based on the weight of evidence it can be concluded that there is no evidence of carcinogenicity for dodine. In a mouse feeding study, females showed an increase in combined hepatocellular adenomas/carcinomas; however, when compared to historical controls the increase of incidence of combined tumors is marginal. In a rat feeding study there was no evidence of carcinogenicity. Dodine was negative in three studies for gene mutation.

Developmental Toxicity

There is no evidence of increased sensitivity in pups versus adults based on rat and rabbit developmental studies and the rat multi-generation reproduction study. In prenatal developmental studies in both rats and rabbits treated with dodine, there was no toxicity identified in the pups at the highest dose tested. In the two generation study, reduced body weight gain and decreased food consumption were seen in pups at the same dose at which maternal toxicity (decreased body weight, body weight gain and food consumption) was present. There is no concern for pre- or postnatal toxicity resulting from exposure to dodine.

Reproductive Toxicity

Dodine did not adversely affect reproductive parameters in rats over two generations. A decrease in parental body weight, body weight gain and food consumption was recorded in both generations of rats. The offspring of both generations demonstrated decreased body weight in the highest dose group. This continued through pre-mating of the parental animals.

Neurotoxicity

There is no evidence of neurotoxicity in the available studies. Based on the weight of evidence, a developmental neurotoxicity (DNT) study is not required for dodine.

Table 4 contains endpoints selected for the dietary and residential assessments.

Table 4: Summary of Toxicological Doses and Endpoints for Use in Human Risk Assessments

Exposure Scenario	**Dose Used in Risk Assessment, UF**	**Special FQPA SF* and Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Acute Dietary (females 13-49 and general population)	NA		No appropriate endpoint for females age 13-49 or for the general population attributable to a single exposure.
Chronic Dietary (all populations)	NOAEL = 2 mg/kg/day UF = 100 Chronic RfD = 0.02 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD / FQPA SF = 0.02 mg/kg/day	Chronic toxicity - dog LOAEL = 10 mg/kg/day (f) based on body weight loss in females.
Dermal Short-(1 - 30 days), Intermediate-(1 - 6 months), and Long-(> 6 months) Term	NOAEL = 200 mg/kg/day (highest dose tested)	Residential MOE =100 Occupational MOE = 100	28-Day Dermal Toxicity LOAEL = not identified* *Anticipated body weight effects based on weight of evidence from effects seen in acute dermal study and across the entire database (see explanation section 4.4.6 of the HED Chapter).
Inhalation Short-Term (1 - 30 days)	Developmental study NOAEL = 10 mg/kg/day (inhalation absorption rate assumed to be 100%)	Residential MOE =100 Occupational MOE = 100	Developmental toxicity study - rat LOAEL = 45 mg/kg/day based on decreased body weight gain and food consumption.
Cancer Classification: Carcinogenic potential; no evidence of carcinogenicity.			

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable

2. FQPA Safety Factor

After evaluating hazard and exposure data for dodine and DGH, EPA reduced the default 10X Food Quality Protection Act (FQPA) special safety factor to 1X. The toxicity database includes acceptable developmental and reproductive toxicity studies, and there is no evidence in the developmental toxicity study of susceptibility following *in utero* exposure. The Agency has a low level of concern and no residual uncertainties regarding exposure or concerns for the effects seen in the developmental toxicity studies after establishing toxicity endpoints and including the traditional uncertainty factors in the risk assessment. The dietary food exposure assessment utilizes tolerance level residues and percent crop treated information for all commodities. The drinking water assessment utilizes Estimated Drinking Water Concentrations (EDWCs) generated by models which are designed to provide conservative, health protective, high-end estimates of water concentrations. By using these conservative assumptions, exposures and risks will not be underestimated. Therefore, the 10X FQPA special safety factor was reduced to 1X. Thus the cPAD for dodine is the same as the cRfD of 0.02 mg/kg/day.

3. Acute Dietary Risk

No appropriate acute dietary endpoint was identified in any of the available toxicity studies. Therefore, no acute dietary exposure assessment (food + water) was performed.

4. Chronic Dietary Risk

A chronic dietary (food + water) risk assessment was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which uses food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. The chronic dietary exposure and risk analysis was conducted using tolerance values, DEEM default processing factors, percent crop treated for all commodities, and an Estimated Drinking Water Concentration (EDWC) point estimate value for drinking water contribution to exposure. This dietary assessment is conservative since the crop group tolerances for pome and stone fruits were included in the risk assessment, even though some of the crops within these groupings do not presently have registered uses. No monitoring data are available for dodine.

The chronic dietary assessment incorporates both exposure to and toxicity of dodine. The chronic dietary endpoint is decreased food consumption and decreased weight gain in a chronic toxicity dog study at the lowest observed adverse effect level (LOAEL) of 10 mg/kg/day. The no observed adverse effect level (NOAEL) was 2 mg/kg/day. An uncertainty factor of 100 (10X for inter-species extrapolation and 10X for intra-species variation and 1X FQPA) was applied to the NOAEL. The chronic Population Adjusted Dose (cPAD) is the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected. The cPAD was calculated as 2 mg/kg/day ÷ 100 = 0.02 mg/kg/day. Risk is expressed as a percentage of the cPAD. A risk estimate less than 100% of the cPAD does not exceed the Agency's level of concern.

Dietary risk estimates were calculated for the general U.S. population and various population subgroups. Dodine chronic dietary exposure estimates (food + water) for the U.S. population (3% of the cPAD) and for the most highly exposed population subgroups, non-nursing infants and children 1-2 years of age (16% of the cPAD), are below the Agency's level of concern. The highest contributors to estimated exposures were pome fruits (71% of total exposure) and water (24% of total exposure).

Table 5: Chronic Dietary (food + water) Exposure and Risk for Dodine

Population Subgroup	cPAD (mg/kg/day)	Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.02	0.000493	3
Children 1-2 years old		0.003152	16
Non-nursing Infants		0.003252	16

Chronic dietary risk from DGH used as an indirect food additive was also calculated using the same chronic dietary endpoint. DGH is used as a slimicide in food handling paper, as a preservative applied to paper, and in paper adhesives used in food packaging. None of these uses exceed the Agency's level of concern for the chronic exposure durations. This assessment is very conservative because it assumes 100% migration of DGH from the paper and packaging into the food. Data to refine the migration value have been submitted to the Agency and are under review.

Dietary risk estimates were calculated for the general U.S. population and various population subgroups for the individual uses and were also combined. Combined DGH chronic dietary exposure estimates for all paper and packaging uses were estimated for the U.S. population (13 % of the cPAD) and for children (45.5 % of the cPAD), and are below the Agency's level of concern. The large degree of difference between exposure to paper and packaging for children and adults is due to the smaller body weight assumption for kids (10 kg) compared to adults (70 kg) in the dietary risk calculation.

Table 5: Chronic Dietary Risks of DGH as an Indirect Food Additive

Use Site	cPAD (mg/kg/day)	Daily Dietary Dose (mg/kg bw/day)	% cPAD
Pulp/Paper-Slimicide	0.02	0.00080 (adult) 0.0028 (child)	4.0% (adult) 14.0% (child)
Paper Coating-Preservative		0.0015 (adult) 0.0053 (child)	7.5% (adult) 26.3% (child)
Paper Adhesive-Preservative		0.00030 (adult) 0.0011 (child)	1.5% (adult) 5.3% (child)
Combined Exposures		0.0026 (adult) 0.0091 (child)	13.0% (adult) 45.6% (child)

5. Drinking Water

(For a complete discussion, see the "Tier I Drinking Water Assessment for Dodine," dated 4/20/2005, and the "Drinking Water Exposure to DGH from Once-Through Cooling Uses" found in Appendix 4.0 of the HED Chapter.)

Drinking water exposure to pesticides can occur through ground and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. A separate DGH assessment was conducted to estimate potential contribution from the antimicrobial uses of DGH in drinking water. The PDM4 Model was used to estimate the concentration of DGH in receiving surface waters following application to once-through cooling systems, the application site considered to potentially contribute the highest amount of DGH to drinking water. The PDM4 model provided probabilities of exceeding various concentrations of concern (COCs) over time. The worst-case scenario in the model indicated the probability of exceeding the concentration of concern over a chronic (365 days) timeframe is negligible. Therefore, chronic drinking water concerns are not expected from the once-through cooling uses of DGH. See appendix 4.0 in the HED Chapter for further explanation.

The drinking water assessment for dodine considers contribution from dodine alone, due to the negligible estimated contribution from DGH. Since no monitoring data were available for dodine, EDWCs were calculated from models. The EDWCs were incorporated directly into the chronic dietary exposure assessment. The EDWCs were based on application methods, rates and use sites that would likely yield the highest drinking water concentrations.

Dodine is immobile and is generally not expected to persist in aerobic soils. Because of dodine's high partitioning coefficient, the potential to reach drinking water sources via runoff or leaching is limited. Based on a low estimated vapor pressure, volatilization is an unlikely route of dissipation. Dodine may, however, be transported off-site to drinking water sources as sediment or via spray drift during aerial, airblast or ground spray applications. Once in aquatic environments, dodine is resistant to hydrolysis and photolysis. In aerobic aquatic environments, dodine is likely to be moderately persistent. In anaerobic aquatic environments, dodine is likely to be very persistent. In the field, dodine was almost exclusively confined to the 0-6 inch depth of soils and is immobile in soil (sand, sandy loam, clay loam, and silt loam), regardless of organic matter content. With adsorption occurring in the upper layer of soil it is unlikely that toxicologically-important concentrations of either the parent compound or degradates will reach surface or ground water. Because of dodine's high partitioning coefficient, relative non-persistence in aerobic soils, and demonstrated fate and transport in the field, leaching to groundwater is not expected to be a major route of dissipation.

Surface Water - Tier 1 EDWCs in surface water were calculated using the FIFRA Index Reservoir Screening Tool (FIRST). As shown in table 6, the Agency calculated a chronic EDWC in surface water of 4.0 ppb, based on the use of dodine on pecans at a maximum annual application rate of 13 lbs/a.i./A/year.

Ground Water - Tier I EDWCs for ground water were calculated using the Screening Concentration In Ground Water (SCI-GROW) model. The Agency calculated a chronic EDWC in ground water of 0.08 ppb, based on the pecan use at the application rate of 13 lbs/a.i./A/year.

Table 6: Estimated Drinking Water Concentrations (EDWCs) for Dodine		
Duration of Exposure	**Surface Water EDWCs**	**Ground Water EDWCs**
Chronic	4 ppb	0.08 ppb

6. Residential Exposure

(For a complete discussion see, "Dodine: HED Chapter of the Reregistration Eligibility Decision Document (RED)," revised per 30-day error only registrant comments, dated 9/26/2005 and, "Dodecylguanidine hydrochloride (DGH) – Dietary and Non-dietary Exposures and Risks from Antimicrobial Uses," dated 6/21/2005.)

Residential risk is expressed as a Margin of Exposure (MOE), which measures how close the residential exposure comes to the NOAEL selected from toxicity studies. MOEs that are greater than 100 do not exceed the Agency's level of concern (the residential MOE incorporates the uncertainty factors of 10x for interspecies variability, 10x for intraspecies variability, and 1X for FQPA safety factor).

Dodine has no registered residential (non-occupational) uses and, therefore, no residential handler or postapplication exposures or risks are expected. However, the Agency determined that there are potential residential exposures to DGH because it is used as a preservative in paint and is impregnated in disposable diapers to inhibit the growth of fungus.

EPA assessed the short-, intermediate-, and long-term dermal risks using a NOAEL that is greater than 200 mg/kg/day from a 28-day dermal toxicity study in rats where no treatment related deaths or clinical signs of systemic toxicity were observed at the highest dose tested. A LOAEL from the study was not established. EPA assessed the short-term inhalation risks using a NOAEL of 10 mg/kg/day from a developmental toxicity study in rats in which decreased body weight gain and food consumption was observed at the LOAEL of 45 mg/kg/day.

Residential-Painter Exposure

The residential painter assessment considered both inhalation and dermal exposures of adults exposed to DGH while applying paint with a paint brush, with an airless sprayer, and with an aerosol can. Both inhalation and dermal exposures were considered to be short-term in duration (1-30 days). Since the toxicological effects from both the dermal and inhalation routes of exposure are the same, the Agency combined the margins of exposure (MOEs). All MOEs exceeded 100, and therefore are not of concern.

Post-application dermal contact with wet paint was not assessed because the paint is expected to dry within a short amount of time, so any potential exposure is expected to be negligible. DGH has a low vapor pressure, therefore it is not likely to generate sufficient vapor to cause an inhalation concern to residential populations performing post-application tasks or

occupying recently painted areas. Thus, although post-application exposures were not quantitatively evaluated, EPA has determined that any such risks would be below EPA's LOC.

Residential-Diaper Exposure

The impregnated disposable diaper assessment considered dermal exposure of infants (< 1 year old) wearing DGH treated diapers. DGH can be used as a bacteriostat in the manufacturing of the absorbent material used in disposable diapers. Since infants typically wear diapers on a continuous basis, short-, intermediate- and long-term dermal exposure durations were considered. However, because the same dermal toxicity NOAEL of 200 mg/kg/day was used for all durations, the risk estimates are the same. It was assumed that an infant wears 8 diapers per day.

The Agency calculated exposures using a value of 5% to estimate the potential transfer of DGH residues out of the absorbent material onto the skin. Using the 5% transfer value, which is based on the % transfer factor for pesticide residues migrating from carpets to skin surfaces (US EPA. 2001), resulted in risks that are not of concern to the Agency (MOE = 714). The registrants have submitted a residue migration study that is currently under review by the Agency to confirm the transfer value.

7. Aggregate Risk

In accordance with the FQPA, the Agency must consider pesticide exposures and risks from all potential sources. These usually include food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (e.g., a NOAEL or PAD), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, the Agency considers both the route and duration of exposure. Because dodine and DGH are considered bioequivalents having equal toxicity, and endpoints selected for dodine are used for DGH, their exposures can be aggregated. Therefore, EPA aggregated exposures from dodine in food and water with exposures to DGH in food and residential uses.

Acute Aggregate Risk

An acute aggregate risk assessment is not required, since no appropriate endpoint attributable to a single exposure was identified in the dodine database.

Short-, Intermediate-, and Long-Term Aggregate Risk

Short-term adult aggregate risk estimates were calculated based on dodine exposures from chronic dietary (food + water), DGH exposure from use as an indirect food additive, and exposure to homeowners using DGH-preserved paint products. Intermediate-, and long-term exposures to DGH in preserved paint products are not anticipated. The short-term aggregate MOE for adults was 574; therefore, the risk does not exceed the Agency's level of concern.

Short-, Intermediate-, and Long-term infant risk estimates were calculated based on contributions of dodine to exposure from chronic dietary (food + water), and contributions of DGH to exposure from use as an indirect food additive, and exposure to infants wearing DGH-impregnated diapers. MOEs were calculated for the impregnated disposable diapers using a 5% Transfer Factor. MOEs calculated using the 5% transfer factor (MOE = 132) do not exceed the Agency's level of concern.

The aggregate exposure assessment was conducted using tolerance values for commodities with registered uses and a conservative EDWC point estimate for drinking water contribution to exposure. In addition, it was assumed that 100% of the DGH would migrate out of the food handling paper products. The registrants have submitted a migration study that is currently under review by the Agency to confirm the DGH transfer factor.

Table 7: Short-, Intermediate-, and Long-Term Aggregate MOEs for Dodine and DGH

Target population	**Scenario**	**MOE Food + Water + indirect food additive**	**MOE Dermal**	**MOE Inhalation**	**MOE Total Target = 100**
Adults	Preserved Paint Products (Short-Term)	647	7,000	16,000	574
Infants	Impregnated Disposable Diapers 5% Transfer Factor (Short-, Intermediate-, Long-Term)	162	714	n/a	132

Both the adult and infant aggregate assessments are considered to be screening level because they do not take into account the probability of simultaneous exposure to dodine and DGH from all sources, which is likely to be low.

8. Cumulative Risk Assessment

The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. 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 for dodine and any other substances, and dodine does not appear to produce a toxic metabolite produced by other substances. As noted in this document, dodine and DGH are both salts of the same chemical. They dissociate similarly, are considered bioequivalents and toxicologically the same, as opposed to separate chemicals that share a common mechanism of toxicity. For the purposes of this action, therefore, EPA has not assumed that dodine has 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/pesicides/cumulative/.

9. Occupational Risk from Dodine

(For a complete discussion, see section 9.0 of the "Dodine: HED Chapter of the Reregistration Eligibility Decision Document (RED)," revised per 30-day error only registrant comments, dated 9/26/2005.)

Workers can be exposed to dodine through mixing, loading, applying a pesticide, or re-entering treated sites. Occupational handlers of dodine include mixers, loaders, and applicators in agricultural settings only. Occupational risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE). An MOE = 100 has been determined to be adequately protective for both short-term (1 to 30 days) and intermediate-term (1 to 6 months) exposures for dodine handlers based on the standard uncertainty factors of 10X for interspecies extrapolation and 10X for intraspecies variability. Long-term worker exposure to dodine is not expected.

a. Occupational Toxicity

The dodine dermal endpoint is based a toxicity study in rats in which no effects were seen at the highest dose tested, NOAEL = 200 mg/kg/day. No LOAEL was established.

The dodine inhalation endpoint is based on decreased body weight gain and food consumption in a developmental rat study at the LOAEL of 45 mg/kg/day. The NOAEL was 10 mg/kg/day.

Table 8: Occupational Doses and Endpoints for Dodine

Exposure Scenario	Dose Used in Risk Assessment	Level of Concern for Risk Assessment	Study and Toxicological Effects
Dermal Short-Term (1 - 30 days) and Intermediate-Term (1 - 6 months)	NOAEL = 200 mg/kg/day	Occupational MOE = 100	28-Day Dermal Toxicity-rat LOAEL = not identified
Inhalation Short-Term (1 - 30 days) and Intermediate-Term (1 - 6 months)	NOAEL = 10 mg/kg/day (inhalation absorption rate = 100%)	Occupational MOE = 100	Developmental toxicity study-rat LOAEL = 45 mg/kg/day Based on decreased body weight gain and food consumption.

NOAEL = no observed adverse effect level,
LOAEL = lowest observed adverse effect level,
MOE = margin of exposure

b. Occupational Handler Exposure

The Agency has determined that there are potential exposures to individuals who mix, load, apply, and otherwise handle dodine during the usual use associated with the pesticide. Based on the use patterns, the following major occupational handler exposure scenarios were identified and evaluated in the occupational risk assessment:

Mixer/ Loaders:

(1a) Liquids for Aerial Applications
(1b) Liquids for Groundboom Applications
(1c) Liquids for Airblast Applications
(2a) Wettable Powders for Aerial Applications
(2b) Wettable Powders for Airblast Applications

Applicators:

(3) Aerial Spray Applications
(4) Groundboom Spray Applications
(5) Airblast Spray Applications

Flaggers:

(6) Flagging for Aerial Spray Applications

Mixer/ Loader/ Applicators:

7a) Liquids for Low Pressure Handwand Applications
7b) Liquids for Backpack Sprayer Applications
7c) Liquids for High Pressure Handwand Applications

c. Occupational Handler Risk Summary

The majority of occupational handler exposure scenarios assessed had risks below the Agency's level of concern with MOEs greater than 100 with baseline attire and gloves. However, the following two wettable powder scenarios require additional engineering controls (water soluble packaging) to achieve an estimated risk which is above the Agency's target MOE:

(1) The mixer/ loader of wettable powders for aerial application to pecans with an application rate of 2.6 lb ai/acre.
(2) The mixer/ loader of wettable powders for aerial application to apples or pears with an application rate of 1.90 lb ai/acre.

Table 9: Summary of Short- and Intermediate-term Dodine Occupational MOEs

Exposure Scenario	App. rate (lb ai/ acre)	Area Treated (acres/ day)	MOEs Target MOE = 100								
			Baseline			Double Layers + Gloves + PF10 Respirator			Engineering Controls (water soluble packages)		
			Derm MOE	Inh MOE	Total	Derm MOE	Inh MOE	Total	Derm MOE	Inh MOE	Total
Wettable Powders for Mixer/ Loaders for Aerial application	2.60	350	4.2	18	3.4	120	180	71	1600	3200	**1100**
	1.90	350	6	24	4.6	160	250	97	2100	4400	**1400**

d. Occupational Postapplication Risk Summary

For workers entering a treated site, MOEs are calculated for each day after application to determine the minimum length of time required before workers can safely re-enter the treated site. Postapplication occupational risks were calculated for all crops and all postapplication tasks assessed and are below EPA's level of concern for dodine with MOEs that range from 99 to 57,509 approximately 24 hours after application. Based on dodine's classification as a category I eye irritant and skin irritant, the current restricted-entry interval (REI) of 48 hours is adequate for all postapplication workers. In addition, double notification for workers under the Worker Protection Standard is required when dodine is applied due to the potential for eye and skin irritation. Workers must be notified by warning them orally and by posting warning signs at entrances to treated areas.

10. Human Incident Data

In evaluating incidents to humans, the Agency reviewed reports from five sources including the OPP Incident Data System (IDS), Poison Control Centers, California Department of Pesticide Regulation, National Pesticide Telecommunications Network (NPTN), and National Institute of Occupational Safety and Health's Sentinel Event Notification System for Occupational Risks (NIOSH SENSOR). Of all poisoning incident data reported, there were 6 reports filed, but almost no reports of ill effects concerning human poisoning or other adverse effects from exposure to dodine and DGH. Of the reports that were filed, there were no known direct exposures to dodine or insufficient information to draw a conclusion from the reports.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment for dodine is presented below. More detailed information associated with the environmental risk from the use of dodine can be found in the "Review of the 30-day Error Correction Comments on the Draft Level 1 Screening Ecological Risk Assessment for the Reregistration of Dodine," dated September 23, 2005.

1. Environmental Fate and Transport

The environmental fate database is sufficient to characterize the environmental exposure and toxicity associated with dodine use. However, EPA does intend to issue a DCI as part of this RED to require submission of additional data for dodine to address areas of uncertainty. The following studies will help to refine the environmental risk assessments: aquatic plant toxicity data and chronic saltwater invertebrate toxicity data. These data are expected to confirm the conclusions of this environmental risk assessment.

The environmental fate and toxicity data for both dodine and DGH are considered as a combined data set because these compounds behave similarly under environmental conditions. Dodine and DGH are water soluble salts of the strong base dodecylguanidine, and are expected to dissociate to the same degree under normal environmental conditions. As strong bases, these compounds will be completely dissociated in aqueous solutions at normal environmental pHs and will be present as the dodecylguanidinium ion and either the acetate or chloride ion in the environment.

Dodine is likely to be immobile in soils based on its soil partition coefficient; therefore the potential to reach aquatic ecosystems via runoff or leaching is limited. Aerobic soil metabolism half-lives range between 17.5-22.3 days so dodine is generally not expected to persist in aerobic soils. Dodine is stable in anaerobic aquatic environments. Based on a low vapor pressure, volatilization is an unlikely route of dissipation.

There are no anticipated major environmental degradates of dodine. Based on fate characteristics, dodine may be transported off-site to aquatic ecosystems adsorbed to eroded sediment or via spray drift during aerial, airblast or ground spray applications. Once in aquatic environments, dodine is resistant to hydrolysis and photolysis.

2. Ecological Risk

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to estimated environmental concentrations (EECs) based on environmental fate characteristics and pesticide use data. Since the use patterns of dodine are different and distinct from DGH, a separate ecological risk assessment is being completed to specifically address the environmental risk from DGH. To evaluate the potential risk to non-target organisms from the use of dodine products, the Agency calculates a Risk Quotient (RQ), which is the ratio of the EEC to the most sensitive toxicity endpoint values, such as the median lethal dose (LD_{50}) or the

median lethal concentration (LC_{50}). These RQ values are then compared to the Agency's levels of concern (LOCs), which indicate whether a pesticide, when used as directed, has the potential to cause adverse effects to non-target organisms. When the RQ exceeds the LOC for a particular category, the Agency presumes a risk of concern. These risks of concern may be addressed by further refinements of the risk assessment or mitigation measures. Use, toxicity, fate, and exposure are considered when characterizing the risk, as well as the levels of certainty and uncertainty in the assessment. EPA further characterizes ecological risk based on any reported incidents to non-target terrestrial or aquatic organisms in the field (e.g., fish or bird kills).

Table 10: EPA's Levels of Concern and Associated Risk Presumptions

Risk Presumption	**LOC Terrestrial Animals**	**LOC Aquatic Animals**	**LOC Plants**
Acute Risk - there is potential for acute risk	0.5	0.5	1
Acute Restricted Use - there is potential for acute risk, but may be mitigated through restricted use classification	0.2	0.1	N/A
Acute Endangered Species - endangered species may be adversely affected	0.1	0.05	1
Chronic Risk - there is potential for chronic risk	1	1	N/A

a. Risk to Aquatic Organisms

i. Fish and Invertebrate Exposure and Toxicity

For exposure to aquatic fish and invertebrates, EPA considers surface water only, since most aquatic organisms are not found in ground water. The aquatic exposure assessment for dodine has relied on Tier II models. The Pesticide Root Zone Model (PRZM version 3.12) simulates fate and transport on the agricultural field, while the water body is simulated with Exposure Analysis Modeling System (EXAMS version 2.98). Simulations are run for multiple (usually 30) years and the reported EECs represent the values that are expected once every ten years based on the thirty years of daily values generated during the simulation.

PRZM/EXAMS modeling of dodine was done for nine scenarios using the current maximum label rate, maximum number of applications per year and the minimum application interval, see table 11 below. All scenarios were assessed for aerial and ground applications. A complete listing of EECs, including those used for dodine RQ calculations included in this summary can be found in the risk tables in the EFED risk assessment, dated September 23, 2005.

Table 11: Estimated aquatic Estimated Environmental Concentrations (EEC) calculated with PRZM/EXAMS.

Dodine uses (EPA Reg. #)	**Scenario**	**Yearly Max. App. Rate (lbs. a.i./A)**	**1-in-10 Year Acute (μg/L)**	**1-in-10 Year 21-day Chronic (μg/L)**	**1-in-10 Year 60-day Chronic (μg/L)**
Apples (55260-5)	NC apple	11.7	7.5	3.1	2.8
	OR apple	11.7	6.4	2.7	2.4
	PA apple	11.7	43	8.7	7.8
Cherries (55260-6)	MI cherries	7.8	24	4.5	4.0
Peaches (55260-5)	GA peaches	13.0	16	3.2	2.9
Pears (55260-5)	CA fruit	11.7	6.0	2.4	2.1
Pecans (55260-5)	GA pecans	13.0	19	4.8	4.6
Strawberries (55260-5)	FL strawberry	6.5	0.80	0.28	0.26
Walnuts (55260-5)	CA almond (walnut)	13.0	7.8	2.6	2.4

The acute toxicity data, outlined in table 12 below, indicate that dodine is highly toxic to freshwater fish and moderately toxic to estuarine/marine fish on an acute exposure basis. Further, the available data show that dodine is highly toxic to estuarine/marine invertebrates and estuarine/marine mollusks, and very highly toxic to freshwater invertebrates.

Table 12: Summary of Acute Aquatic Toxicity Data for Dodine and DGH

Toxicity Study	**Test Species**	**LC_{50} or EC50 (ppb)**	**Toxicity Category**	**MRID/ Accession No.**
Freshwater Fish (96-hr)	Rainbow trout *Oncorhynchus mykiss* (TGAI)	570	Highly toxic	132149
Freshwater Invertebrate (48-hr)	Water flea *Daphnia magna* (TGAI)	17.8	Very highly toxic	42339601
Estuarine/ Marine Fish	Sheepshead minnow *Cyprinodon variegatus*	1782	Moderately toxic	43485506
Estuarine/ Marine Molluscs	Eastern oyster *Crassostrea virginica*	69.3	Highly toxic	43485508
Estuarine/ Marine Invertebrate	Mysid shrimp *Americamysis bahia*	59.4	Highly toxic	43485507

A freshwater fish early life-stage chronic toxicity test was used to evaluate the chronic toxicity of dodine. Results from the study indicated a NOAEL of 99 ppb and an associated LOAEL of 200 ppb. The basis of these effect levels was an observed decrease in both larval weight and larval length of dodine-exposed fish. An aquatic invertebrate life cycle test was conducted to evaluate the chronic toxicity of dodine to freshwater aquatic invertebrates. The most sensitive endpoint was the number of young produced with a NOAEC of 7.3 ppb and a LOAEC of 13 ppb. There were no chronic estuarine/marine invertebrate toxicity data available for this assessment.

Table 13: Summary of Chronic Aquatic Toxicity Data for Dodine

Toxicity Study	Test Species	NOAEC / LOAEC (ppb)	Effects at LOAEC	MRID
Freshwater Fish Early Life-Stage	Fathead Minnow *Pimephales promelas* (TGAI)	99/ 200	Larval length and weight	43876502
Freshwater Invertebrate	Water flea *Daphnia magna* (TGAI)	7.3/13	Number young produced	43876501

ii. Fish and Invertebrates Risk

Freshwater Fish

For freshwater fish all RQs are below the LOC, with the exception of the RQ for aerial applications to apples in Pennsylvania (RQ = 0.08). Modeled results in Pennsylvania are likely the result of higher erosion and subsequent off-site transport of dodine adsorbed to eroded sediment into water bodies adjacent to treated fields. Using the highest annual dodine use rates, as simulated for peaches, pecans and walnuts, did not produce EECs that resulted in LOC exceedences. Chronic risks of concern associated with freshwater fish exposed to dodine are not likely based on the RQs calculated, which range from 0.04 to 1.19.

Estuarine/Marine Fish

Acute risk to estuarine/marine fish is unlikely, given the lack of acute risks and the low chronic risks to freshwater fish species as a result of dodine use.

No chronic estuarine/marine fish toxicity data were submitted or located in the open literature for dodine; therefore, chronic risks associated with estuarine/marine fish exposure to dodine are unknown.

Freshwater Invertebrates

Most freshwater invertebrate RQs exceed the acute restricted use and endangered species LOCs. Acute LOCs are exceeded for aerial applications to Pennsylvania apples, Michigan

cherries, Georgia pecans, and Georgia peaches. See table 14 below for a complete list of RQs for invertebrates.

For freshwater invertebrates, the chronic LOC is exceeded based on aerial application of dodine to Pennsylvania apples only. Analysis based on one study of benthic invertebrates indicated that for benthic invertebrate species, the chronic risk LOC was not exceeded and risks are expected to be low.

Although the label rate for apples allows up to 1.95 lbs ai/A to be applied at once, Agency use information indicate that only 5% of all dodine applications to apples are made at rates higher than 1.75 lbs ai/A. About 70% of all dodine applications to apples are made at rates less than 1.25 lbs ai/A. Lower RQs are expected to result from these more typical use rates. See section IV, part D for further discussion on risk to freshwater invertebrates.

Estuarine/Marine Invertebrates

Endangered species acute risk LOCs for estuarine/marine invertebrates were exceeded for all uses of dodine except strawberries. The estuarine/marine invertebrate RQ based on apples exceeded the acute risk LOC.

No chronic estuarine/marine invertebrate toxicity data were available for dodine; therefore, chronic risks associated with estuarine/marine invertebrate exposure to dodine are unknown. The acute risks to estuarine/marine invertebrates suggest the potential for chronic risks as well. Also, given the sensitivity of freshwater invertebrates to dodine, studies on the chronic toxicity of dodine to estuarine/marine invertebrates are warranted.

Table 14: Acute RQs for Freshwater and Estuarine/Marine Invertebrates

Crop	Maximum Single Application Rate (lbs ai/A)	Peak EEC	Acute Invertebrates RQs	
			Freshwater (EC50=0.95 ppb)	Saltwater (EC50=59.4 ppb)
Apples (PA)	1.95	43	**2.42**	**0.72**
Cherries (MI)	1.3	24	**1.35**	**0.40**
Peaches (GA)	2.6	16	**0.90**	**0.27**
Pears (CA)	1.95	6.0	**0.34**	**0.10**
Pecans (GA)	2.6	19	**1.07**	**0.32**
Strawberries (FL)	1.3	0.80	0.04	0.00
Walnuts (CA)	2.6	7.8	**0.44**	**0.13**

Bold values indicate LOC exceedances.

Molluscs

For molluscs, acute restricted use and endangered species LOCs are exceeded for all modeled scenarios except strawberries. The effects of dodine on molluscs are not all together unexpected as DGH is used to control some invasive mollusc species.

iii. Non-target Aquatic Plants Exposure and Toxicity

Aquatic plant toxicity testing indicate that the non-vascular plant, *Selenastrum capricornutum* (green algae), is particularly sensitive to dodine at the concentrations tested. The estimated 120-hour EC50 was 0.95 ppb based on cell density effects. The corresponding 120-hour NOAEC for this effect was 0.082 ppb. Based on these results, dodine is classified as very highly toxic to green algae. A complete evaluation of the toxicity of a compound to aquatic plants requires at least one study on aquatic vascular plants. This study was not available for dodine, but will be required.

iv. Non-target Aquatic Plant Risk

For aquatic non-vascular plants, 1-in-10 year peak EECs were compared to acute EC_{50} values to derive acute non-listed species RQs. In addition, peak EECs were also compared to NOAEC values for non-vascular plants to derive listed species RQs for these taxonomic groups. RQs for aquatic non-vascular plants are summarized in table 15. Given the high toxicity of dodine to non-vascular aquatic plants and the lack of sufficient information on the toxicity of dodine to aquatic vascular plants, both non-vascular and vascular aquatic plants are considered together as "aquatic plants". The greatest contribution to predicted dodine exposure in water is from erosion, particularly at sites that are vulnerable to sediment loss. To reduce the potential for effects to aquatic plants, the Agency is requiring label language to limit the use of dodine on areas where erosion is high. This is further outlined in Section IV of this document.

Table 15: Acute RQs for Aquatic Non-vascular Plants

Crop	Maximum Single Application Rate (lbs ai/A)	Peak EEC	Acute Non-Vascular Plants	
			Aquatic Plants (EC50=0.95 ppb)	Aquatic End. Sp. (NOAEC=0.082 ppb)
Apples (PA)	1.95	43	**45.26**	**524**
Cherries (MI)	1.3	24	**25.26**	**293**
Peaches (GA)	2.6	16	**16.84**	**195**
Pears (CA)	1.95	6.0	**6.31**	**73**
Pecans (GA)	2.6	19	**20.00**	**232**
Strawberries (FL)	1.3	0.80	0.84	**10**
Walnuts (CA)	2.6	7.8	**8.21**	**95**

Bold values indicate LOC exceedences.

b. Risk to Terrestrial Organisms

i. Birds and Mammals Exposure and Toxicity

The Agency assessed exposure to terrestrial organisms by first predicting the amount of dodine residues found on animal food items and then using information on typical food consumption by various species of birds and mammals to determine the amount of pesticide consumed. The amount of residues on animal feed items is based on the Fletcher nomogram,

which is a model developed by Hoerger and Kenaga (1972) and modified by Fletcher (1994), and the current maximum application rates for dodine.

Estimated exposure concentrations for terrestrial receptors were determined using the standard screening-level exposure model, TREX (v.1.1), which is a simulation model that, in addition to incorporating the nomogram relationship, also includes pesticide degradation in the estimation of EECs. TREX considers exposure only in the area where dodine is applied. The underlying assumption is that most, if not all, of the applied pesticide will settle in the use area. However, depending on weather conditions and type of application, spray drift of pesticides may occur, increasing the likelihood of wildlife exposure outside the use area. Since dodine is applied via spray methods, spray drift is likely in some cases. Particularly for air blast applications, spray drift could be significant.

EPA's estimates of dodine residues on various wild animal food items are summarized in table 16. EPA used these EECs and standard food consumption values to estimate dietary exposure levels for dodine to birds and mammals.

Table 16: Maximum Residue EECs on Avian and Mammalian Food Items

Crop	**Application Rate lbs. a.i./A**	**# Apps / Interval (days)**	**Range of Maximum EECs for:** (1) Short grass, (2) Tall grass, (3) Broadleaf plants/small insects, and (4) Fruits, pods, seeds, and large insects **(mg/kg)**
Apples, Pears	1.95	(6 / 5)	139 - 2224
Cherries	1.3	(6 / 7)	85 - 1361
Crab Apples (OR only)	0.34	(6 / 5)	24 - 388
Ornamental Shade Trees (OR only)	0.85	(6 / 10)	49 - 789
Peaches	2.6	(5 / 7)	151 - 2410
Pecans, Walnuts	2.6	(5/ 10)	136 - 2183
Strawberries	1.3	(5 / 7)	75 - 1205

The acute toxicity of dodine to mammals was evaluated using the common laboratory rat to calculate an LD50 of 1056 mg/kg. Chronic studies in both dogs and rats show that the endpoint most sensitive to dodine exposure seems to be reduced body weight/growth in adults and/or offspring.

Table 17: Summary of Acute and Chronic Toxicity Data for Terrestrial Organisms Exposed to Dodine.

Species		Acute Toxicity				Chronic Toxicity	
		LD50 (mg/kg)	**Acute Oral Toxicity (MRID)**	**8-day LC50 (mg/kg diet)**	**Subacute Dietary Toxicity (MRID)**	**NOAEC/ LOAEC (mg/kg diet) (MRID)**	**Affected Endpoints**
Bird	Northern bobwhite quail *Colinus virginianus*	690	Slightly toxic (Acc.# 130888)	8413	Practically non-toxic (Acc.# 226855)	<75/75 (458197-24)	growth (14-day survivor weight); reproduction (eggs cracked)
	Mallard duck *Anas platyrhynchos*	2214	Practically non-toxic (Acc.# 131455)	>10000	Practically non-toxic (Acc.# 226855)	200/600 (432746-02)	multiple reproductive
Mammal	Dog *Canis familiaris*	--	--	--	--	2.0/10.0 Mg/kg/d (442461-01)	body weight
	Laboratory rat *Rattus norvegicus*	1056	Practically non-toxic (449224-01)	--	--	30.28 /60.5 (442460-01)	decreased pup body weights
Insect	Honey bee *Apis meliferus*	>200 (μg/bee contact)	Practically non-toxic (4013155-05)	--	--	--	--

ii. Birds and Mammals Risk

Risk quotients were calculated for both birds and mammals using the dose-based and dietary-based toxicity values. Generally dose-based RQs are higher than those calculated using the dietary-based values because the dose-based RQs are calculated with the assumption that a bird or mammal will experience a very short-term high intensity exposure from the pesticide. The dietary-based approach assumes that animals in the field are consuming food at a rate similar to that of confined laboratory animals despite the fact that energy content in food items differs between the field and the laboratory. There are benefits and uncertainties by considering both methods which are outlined in more detail in section 4.2.2 of the EFED Chapter. RQs calculated using both methods are included in the discussion below.

In addition, in order to bound the estimates of RQs, mean Kenega residue values were calculated along with upper-bound values. Log-normal distributions were generated that describe residue levels on the various food items. The analysis, demonstrates that mean Kenega values range from about 62-87 percent of the possible dodine residue values, indicating that 13 to 38 percent of the higher-end food item residue estimates are not captured in estimating exposure by using the mean Kenega values. For the upper-end Kenega residue estimates, about 3-13

percent of the upper-end residue estimates were not captured. Using the mean Kenaga residue values for calculating RQs would not protect birds and mammals that consume food items that have residues on the higher end of the residue distribution.

A range of RQs was calculated using dose and dietary based toxicity values and mean or upper-bounds Kenaga residue values. A summary of the high- and low-end RQs are outlined in the following tables; for a complete list of calculated RQs, refer to Section 4.1.2 of the EFED Chapter.

Birds

Using dose-based (LD_{50} = 690mg/kg-bw for bobwhite quail) toxicity values, acute, acute restricted use, and listed species LOCs are exceeded for birds that consume short grass, tall grass, broadleaf plants, and small insects for all modeled scenarios and application rates, with RQs ranging from 0.01 to 5.62 (see table 18 below for a range of RQs). Based on the dose-based endpoint, acute restricted use and listed species LOCs are also exceeded for birds that consume fruits, pods, seeds, and large insects at application rates for all modeled scenarios, except crab apples (2.04 lbs ai/A/yr), at the smallest weight class, and in some cases at the medium weight class.

Using the dietary-based (LC_{50} = 8413 mg/kg-diet for bobwhite quail) toxicity values, acute listed species LOCs are exceeded for only two scenarios, birds that consume broadleaf plants/small insects with the cherry scenario (RQ=0.11) and bird that consume short grass with the peach scenario (RQ=0.10).

Table 18: Acute RQs for Birds

Use	Maximum Single Application Rate (lbs ai/A)	# Applications / Retreatment Interval (days)	Acute RQ Ranges Based on Avian Diet	
			Dose –Based Upper Bound Kenaga Value	Dietary –Based Mean Kenaga Value
Apples (PA)	1.95	6/5	0.05 - **5.19**	0.01 - 0.09
Cherries (MI)	1.3	6/7	0.03 - **3.18**	0.01 - **0.11**
Crab Apples (OR)	0.34	6/5	0.01 - **0.90**	0.001 - 0.02
Ornamental Shade Tree (OR)	0.85	6/10	0.02 - **1.04**	0.003 - 0.03
Peaches (GA)	2.6	5/7	0.05 - **5.62**	0.01 - **0.10**
Pears (CA)	1.95	6/7	0.05 - **5.19**	0.01 - 0.09
Pecans (GA)	2.6	5/10	0.05 - **5.09**	0.01 - 0.09
Strawberries (FL)	1.3	5/7	0.02 - **2.81**	0.003 - 0.03
Walnuts (CA)	2.6	5/10	0.05 - **5.09**	0.01 - 0.09

Bold values indicate LOC exceedences.

Chronic RQs were calculated using both upper and mean Kenaga residue values. LOCs are exceeded for birds that consume short grass, tall grass, broadleaf plants, and small insects for many modeled scenarios and application rates, with RQs ranging from 0.12 to 12.05 when calculated with upper bound Kenaga values and ranging from 0.06 to 4.27 for mean Kenaga values. See table 19 below for a summary of RQs.

Table 19: Chronic RQs for Birds				
Use	**Maximum Single Application Rate (lbs ai/A)**	**# Applications / Retreatment Interval (days)**	**Chronic RQ Ranges Based on Avian Diet**	
			Dietary–Based Upper Bound Kenaga Value	**Dietary –Based Mean Kenaga Value**
Apples (PA)	1.95	6/5	0.69 - **11.12**	0.32 - **3.94**
Cherries (MI)	1.3	6/7	0.43 - **6.81**	0.20 - **2.41**
Crab Apples (OR)	0.34	6/5	0.12 - **1.94**	0.06 - 0.69
Ornamental Shade Tree (OR)	0.85	6/10	0.25 - **3.95**	0.12 - **1.40**
Peaches (GA)	2.6	5/7	0.75 - **12.05**	0.35 - **4.27**
Pears (CA)	1.95	6/7	0.69 - 11.12	0.32 - **3.94**
Pecans (GA)	2.6	5/10	0.68 - 10.91	0.32 - **3.87**
Strawberries (FL)	1.3	5/7	0.38 - **6.03**	0.18 - **2.13**
Walnuts (CA)	2.6	5/10	0.68 - 10.91	0.32 - **3.87**

Boldvalues indicate LOC exceedences.

Mammals

Acute, acute restricted use and listed species LOCs are exceeded for mammals that consume short grass, tall grass, broadleaf plants, and small insects across most weight classes for most modeled scenarios and application rates, with RQs ranging from 0 to 0.99. See Section 4.1.2.2 of the dodine EFED assessment for a complete list of the acute RQs for mammals.

Chronic RQs were calculated using mean and upper-bound Kenaga residue values, as well as considering both dose and dietary based toxicity values. LOCs are exceeded for wild mammals that consume short grass, tall grass, broadleaf plants, and small insects across most assessed weight classes for most modeled scenarios and application rates. RQs are summarized in table 20 below for two different RQ calculation values.

Table 20: Chronic RQs for Mammals				
Use	**Maximum Single Application Rate (lbs ai/A)**	**# Applications / Retreatment Interval (days)**	**Chronic RQ Ranges Based on Mammal Size and Diet**	
			Dose –Based Upper Bound Kenaga Value	**Dietary –Based Mean Kenaga Value**
Apples (PA)	1.95	6/5	0.18 - **31.74**	0.16 - **1.97**
Cherries (MI)	1.3	6/7	0.08 - **19.43**	0.10 - **1.21**
Crab Apples (OR)	0.34	6/5	0.03 - **5.53**	0.03 - 0.34
Ornamental Shade Tree (OR)	0.85	6/10	0.06 - **11.27**	0.06 - 0.70
Peaches (GA)	2.6	5/7	0.19 - **34.41**	0.18 - **2.14**
Pears (CA)	1.95	6/7	0.18 - **31.74**	0.16 - **1.97**
Pecans (GA)	2.6	5/10	0.18 - **31.16**	0.16 - **1.93**
Strawberries (FL)	1.3	5/7	0.10 - **17.20**	0.09 - **1.07**
Walnuts (CA)	2.6	5/10	0.18 - **31.16**	0.16 - **1.93**

Boldvalues indicate LOC exceedences.

iii. Non-target Terrestrial Plant Toxicity, Exposure, and Risk

Dodine exposure to terrestrial plants was estimated using the Terr Plant (v 1.0) model. The model produces EECs for plants residing near a use area that may be exposed to pesticides via runoff and/or spray drift. The EECs apply to plants that inhabit both dry and semi-aquatic (wetland) habitats.

Risk quotients could not be calculated for dodine because even though Tier I plant studies indicated between 20-25% effect, no Tier II studies which would give appropriate endpoints were submitted. The Agency indicated Tier II plant data would be required in the revised EFED chapter dated 9/23/2005, but upon further review this data is not being required because no major effects were observed in the tier one plant studies.

iv. Non-Target Insects Risks

Currently, the Agency does not estimate RQs for terrestrial non-target insects. However, based on acute toxicity studies on honeybees, dodine is classified as practically non-toxic to non-target insects. Therefore, no label statement is required.

3. Ecological Incidents

No incidents of wildlife or aquatic species poisonings associated with uses of dodine were found in the Ecological Incident Information System (EIIS) database.

4. Endangered Species Concerns

The Agency's screening level risk assessment indicates that uses of dodine will have no direct acute effects on estuarine/marine fish, no direct chronic risks on freshwater fish, and no effects on non-target insects. However, the screening-level risk assessment has identified potential concerns for direct effects on listed species taxa listed below in table 21. In addition to those effects expressed in table 21, there are no data with which to adequately assess the potential chronic risk to estuarine/marine fish and invertebrates, or risks to aquatic vascular plants. Therefore, potential risk to these species can not be precluded at the present time. Further, there could be indirect effects to any listed species dependent upon a species that may experience effects from the use of dodine. Finally, potential risks to reptiles and terrestrial phase amphibians are characterized by the risks to birds; and potential risks to aquatic phase amphibians is characterized by the risks to freshwater fish. Therefore, potential acute and chronic risks to reptiles and terrestrial phase amphibians, and potential acute risk to aquatic phase amphibians, can not be precluded based on the screening level assessment.

A preliminary analysis of the co-occurrence of listed species and proposed re-registration of dodine uses was conducted using the Agency's LOCATES database. In general, for all labeled uses of dodine there is at least one, and usually more, listed species that may potentially occur in or near a use area. This preliminary analysis indicates that there is a potential for dodine use to overlap with listed species and that a more refined assessment is warranted.

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 use and species-specific analysis. When conducted, this species-specific analysis will take into consideration any regulatory changes recommended in this RED that have been 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 dodine, other measure 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 use of dodine "may affect" listed species or adversely modify their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until that species specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to dodine at levels of concern.

Table 21: Summary of Direct Effects for Federally Listed Species Based on Screening Assessment

Listed Species Taxonomic Group of Concern	**Direct Effects**	**RQ Range**
Freshwater fish	Acute: mortality	<LOC - 0.08
Freshwater invertebrates	Acute: mortality/immobilization Chronic: growth/reproduction	<LOC - 2.42 <LOC - 1.19
Saltwater mollusc	Acute: shell deposition	< LOC - 0.62
Aquatic Plants: Non-vascular	Acute: reduced cell density	<LOC - 524
Birds	Acute: mortality/sublethal Chronic: reproduction	<LOC - 5.62 <LOC - 12
Mammals	Acute: mortality Chronic: reduced body weight/ growth	<LOC - 0.99 <LOC - 34
Terrestrial Plants: Monocots Dicots	 Acute: dry weight/ shoot height Acute: dry weight	Assumed Risks

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility and Tolerance Reassessment

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

The Agency has completed its assessment of the dietary, occupational and ecological risk associated with the use of dodine. Because of the similarity of dodine and DGH, EPA has also considered the contribution to overall exposure of the DGH uses that may occur in a residential environment, i.e. treated paper that comes into contact with food, paint additives, and antimicrobial treatment of diapers, in its aggregate assessment for dodine. Based on this assessment the Agency has sufficient information on dodine to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that dodine containing products are eligible for reregistration provided that label amendments are made as outlined in this RED. Note, however, that the RED for the antimicrobial uses of DGH will be issued later. Appendix A summarizes the uses of dodine that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility, and lists the submitted studies that the Agency found acceptable.

Based on its evaluation of dodine, the Agency has determined that dodine products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA and FQPA. Accordingly, should a registrant fail to implement any of the reregistration requirements identified in this document, the Agency may take regulatory action to address the risk concerns from the use of dodine. If all changes outlined in this document are incorporated into the product labels, then all current risks for dodine will be adequately mitigated for the purposes of this determination. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained under "Endangered Species Concerns" above.

B. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with dodine and DGH. EPA has determined that risk from dietary (food + water) exposure is within its own "risk cup." An aggregate assessment was conducted for dodine and DGH for exposures through dietary (food + water + indirect food additive) and residential (diaper and paint) exposures. The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In other words, EPA has concluded that the tolerances

for dodine meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food and residential sources.

b. Determination of Safety to U.S. Population

The Agency has determined that the established tolerances for dodine, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, as amended by FQPA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of dodine. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices, and the environmental behavior of dodine, as well as residential and dietary exposure to DGH. As discussed in Section III, aggregate short-, intermediate-, and long-term risks from food, drinking water, and residential exposures are below the Agency's LOC.

c. Determination of Safety to Infants and Children

EPA has determined that the established tolerances for dodine, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors on the toxicity, use practices and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of dodine residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of dodine, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and other information. The FQPA Safety Factor has been reduced to 1X, because there are no residual uncertainties for pre- and/or post-natal toxicity, exposure is not underestimated, and there is no evidence of increased susceptibility.

2. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." 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). In the available toxicity studies on dodine submitted for registration purposes, there was no estrogen, androgen, and/or thyroid mediated toxicity. When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, dodine may be subject to additional screening and/or testing.

3. Cumulative Risks

The FFDCA, as amended by the FQPA, requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. 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 for dodine and any other substances, and dodine does not appear to produce a toxic metabolite produced by other substances. As noted in this document dodine and DGH are both salts of the same chemical. They dissociate similarly, are considered bioequivalents and toxicologically the same, as opposed to separate chemicals that share a common mechanism of toxicity. For the purposes of this action, therefore, EPA has not assumed that dodine has 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/pesicides/cumulative/.

C. Tolerance Reassessment Summary

Table 22: Tolerance Reassessment Summary for Dodine (40 CFR §180.172)

Commodity	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments (correct commodity definition)
Apple	5	5	--
Pear	5	5	--
Peach	5	5	--
--	--	5	Plum
Cherry, Sweet	5	3	See Codex MRL comment regarding cherries below.
Cherry, Tart	5	3	
Strawberry	5	TBD[1]	Insufficient data were available to determine if the residue data support the established tolerance of 5 ppm.

Table 22: Tolerance Reassessment Summary for Dodine (40 CFR §180.172)			
Commodity	**Established Tolerance (ppm)**	**Recommended Tolerance (ppm)**	**Comments (correct commodity definition)**
Pecans	0.3	0.3	Change to Pecan. The data submitted were for nutmeat and shells combined. The Agency previously determined that a tolerance of 0.3 ppm is appropriate and data for nutmeats only are not required (SF0655; 12/22/67; J. Iverson and R.S. Quick)
Walnut, Black	0.3	0.3	The correct commodity name should be: "Walnut".
Spinach	12.0 (Regional)	Revoke tolerance	The use of dodine on spinach is not supported by the registrant.
Milk	0	Revoke tolerance	HED concludes that there is no reasonable expectation of residues 180.6(a)(3) in milk.
Meat	0	Revoke Tolerance	HED concludes that there is no reasonable expectation of residues 180.6(a)(3) in any livestock or poultry tissue.
Apple, Wet Pomace	--	15	A tolerance of 15 ppm is required for dodine residues in apple pomace based upon the 5.13X concentration factor and HAFT residue of 2.36 ppm in/on apples (RAC).

[1] TBD = To be determined. Tolerances cannot be determined at this time because additional data are required. Conservative exposure assumptions were used in the dietary risk assessment to ensure that risks are not underestimated.

Codex maximum residue limits (MRLs) for dodine currently exist on apples, grapes, peaches, pears, and strawberries at 5 ppm and on cherries at 2 ppm. The MRLs are in agreement with the U.S. tolerances for apples, pears, and strawberries. There are no Codex MRLs for milk, meat, pecans, spinach, walnuts, or apple pomace. For cherries, the current U.S. tolerance of 5 ppm is higher than Codex MRL of 2 ppm. According to the Residue and Analytical Aspects of Dodine, evaluated within the Periodic Review Programme of the Codex Committee on Pesticide Residues (http://www.fao.org/DOCREP/006/Y5221E/y5221e0d.htm) the committee is recommending the withdrawal of the current CXL of 2 mg/kg for cherries to be replaced by 3 mg/kg, which will be consistent with the reassessed US tolerance.

D. Regulatory Rationale

The Agency has determined that dodine is eligible for reregistration provided that the risk mitigation measures and label amendments specified in this RED are implemented. The following is a summary of the rationale for managing risks associated with the use of dodine.

1. Human Health Risk

There are no dodine dietary (food + drinking water) residential, or aggregate risks that exceed the Agency's level of concern. Moreover, this assessment is protective of the general U.S. population and all population subgroups, including infants and young children. Therefore, no mitigation is necessary for these scenarios.

There are mitigation measures necessary to address occupational risks that exceed the Agency's level of concern.

Risk to workers from mixing and loading the wettable powder formulations of dodine can be addressed by use of water-soluble packaging. However, technical registrants have chosen to voluntarily cancel wettable powder formulations. If wettable powder formulations are registered in the future, water soluble packages would be needed to protect these workers from risks associated with dodine.

There are some concerns to workers when mixing and loading both liquid and wettable powder formulations of dodine. All mixers and loaders handling dodine, including potential future water soluble bag formulations, are required to wear chemical resistant gloves for dermal protection.

Dodine is classified as a category I for eye and skin irritation which requires double notification. Workers must be notified by warning them orally and by posting warning signs at entrances to treated areas.

A 48 hour REI is also required to protect workers re-entering treated fields after dodine applications. In addition, workers who want to enter a dodine treated field before the REI has expired must wear coveralls over long-sleeve shirt and long pants, chemical-resistant gloves made of any waterproof material, chemical-resistant footwear plus socks, protective eyewear, and chemical-resistant headgear if overhead exposure occurs.

2. Environmental Risk

The Agency has conducted a screening-level ecological and environmental risk assessment for the registered uses of dodine. Based on the available data, the Agency has identified potential acute and chronic risks of concern to freshwater and estuarine/marine invertebrates, birds, mammals, and non-vascular plants. However, the screening-level risk assessment does not indicate a risk concern for freshwater fish.

While there are slight estimated exceedences of the LOC for some terrestrial and aquatic species, the ecological risks associated with the use of dodine are expected to be limited based on its use pattern and usage information. Dodine is used on apples, cherries, peaches, pears, pecans, strawberries, walnuts, ornamentals, and crab apples. The use of dodine has dropped to approximately 70,000 pounds active ingredient used per year from a 1992 high of approximately 265,000 pounds active ingredient used per year. Of the estimated 70,000 pounds of dodine used, 57% or 40,000 pounds are used on apples and pears and 28 % or 20,000 pounds are used on cherries and pecans. The remaining 5 crops account for 15% or 10,000 pounds of use per year of dodine.

The registrant for dodine has agreed to decrease the maximum single application rate for 3 of the 7 food crops and decrease the maximum seasonal rates for 6 of the 7 food crops. Also, for apples and pears, the minimum retreatment interval will be increased from 5 days to 7 days. All other crops already have a minimum retreatment interval of at least 7 days.

For peaches, peacans, and walnuts the maximum single application rate will be reduced by approximately 25%. The single application rate will be decreased from 2.6 lbs ai/A to 1.95 lbs ai/A. The maximum seasonal rate will be reduced by approximately 60 % from 13 lbs ai/A/year to 7.8 lbs. ai/A/year.

For apples, even though the maximum single application rate will remain at 1.95 lbs ai/A for a rescue treatment (post-infection), the maximum seasonal rate will be reduced at least 20% from 11.7 lbs ai/A/year to 9.1 lbs ai/a/year. For apples, the modeled rate is the 1.95 lbs ai/A. However, typical use rates range between 0.25 and 1.25 lbs ai/A and approximately 70% of apple applications are made between these rates. Only 5% of applications to apples occur at the higher rate.

For pears, the maximum single application rate will remain at 1.95 lbs ai/A. However, the maximum seasonal rate will be reduced at least 20% from 11.7 lbs ai/A/year to 9.1 lbs ai/a/year.

For cherries, the modeled maximum single application rate will remain at 1.3 lbs ai/A. However, the maximum seasonal rate will be reduced approximately 40% from 7.8 lbs ai/A/year to 5.2 lbs ai/a/year. For cherries, the typical use rates range between 0.25 and 1.25 lbs ai/A and approximately 70% of cherry applications are made between these rates. Approximately 30% of applications to cherries occur at the higher rates.

Many orchard fungicides are applied with airblast systems to ensure complete coverage of plant surfaces. Since dodine is a fungicide applied mostly to fruit and nut orchard crops, the Agency does not anticipate large numbers of applications are made with aerial equipment. In discussions with the registrant, it appears that aerial applications are only made as a rescue treatment when substantial rainfall prevents ground applications of dodine. The use of ground equipment reduces the potential for off-site drift.

The following summary of ecological concerns does not reflect the mitigation measures mentioned above. Thus, the actual exposure to dodine will be less for all non-target species than current estimates reflect. See table 23 for a list of new and original dodine use rates.

a. Fish and Aquatic Invertebrate Risk

Acute and Chronic Freshwater and Estuarine/Marine Fish

For freshwater fish and aquatic-phase amphibians the acute RQ value of 0.08 based on aerial application of dodine to Pennsylvania apples (1.95 lb ai/A) with a 5 day retreatment interval exceeds the listed species acute risk LOC (RQ $\geq$ 0.05). The acute RQ values associated with all other modeled scenarios are less than the LOC.

For estuarine/marine fish acute RQ values calculated for all modeled scenarios are less than the LOCs (RQs < 0.05).

Chronic Freshwater and Estuarine/Marine Fish

For freshwater fish and aquatic-phase amphibians, the chronic RQ values associated with all modeled scenarios are less than the chronic risk LOC (RQ < 1).

Chronic RQ values were not derived for estuarine/marine fish because data on the chronic toxicity of dodine are not available. However, since acute risks to fresh and saltwater fish are minimal and there were no chronic risks to freshwater fish, chronic risks to saltwater fish is not likely.

A fish bioconcentration (BCF) study was not available so this is a source of uncertainty in this assessment. However, the Hazardous Substances Data Bank (HSDB, 2005) reports an estimated BCF for dodine of 16 suggesting that the potential for bioaccumulation in aquatic organisms is low.

Acute and Chronic Freshwater Invertebrates

Acute LOCs for all modeled scenarios, except Florida strawberry, were exceeded for freshwater invertebrates (RQs = 0.34 - 2.4) and estuarine/marine invertebrates LOCs (RQs = 0.10 – 0.72).

For freshwater invertebrates, the chronic RQ value based on aerial application of dodine to Pennsylvania apples (1.95 lb ai/A) exceeds the chronic LOC (RQ = 1.2).

Chronic RQ values were not derived for estuarine/marine invertebrates because data on the chronic toxicity of dodine are not available.

b. Avian Risk

Terresterial Birds

Acute risk LOCs are slightly exceeded for birds that consume short grass, tall grass, broadleaf plants, and small insects across most weight classes for all modeled scenarios and application rates, with acute RQs ranging from 0.06 to 5.6. In addition, acute RQ values also exceed acute risk LOCs for birds that consume fruits, pods, seeds, and large insects at application rates for all modeled scenarios, except crab apples, at the smallest weight class, and in some cases at the medium weight class (RQs that represent exceedances = 0.12 - 0.35).

For avian chronic risk, LOCs are exceeded for birds that consume short grass, tall grass (in most cases), broadleaf plants, and small insects for all modeled scenarios and application rates, with chronic RQs that represent exceedances ranging from 1.09 to 12.

c. Mammalian Risk

Terrestrial Mammals

Acute risk LOCs are exceeded for mammals that consume short grass, tall grass, broadleaf plants, and small insects across all weight classes for all modeled scenarios and application rates, except crab apples and ornamentals, with acute RQs that represent LOC exceedences ranging from 0.10 to 0.99.

The chronic mammalian dose-based RQs exceed the LOC for mammals that consume short grass, tall grass, and broadleaf plants and small insects across all weight classes for all modeled scenarios and application rates, with chronic RQs that represent exceedances ranging from 1.0 to 34. For mammals that consume fruits, pods, and/or large insects, RQs exceeded the chronic LOCs for all uses with the exception of 1000 kg mammals in most cases. For seed eating mammals, no RQs exceeded the chronic LOC for any use.

Exposure estimates for terrestrial birds and mammals are generated assuming these species feed exclusively on the treated field soon after application of the pesticide. Moreover, the assumption is that these organisms will consume at a particular daily ingestion rate while on the treated field. Although some individuals at particular times may feed exclusively on a treated field, the actual frequency and duration of this type of behavior is a source of uncertainty. While the current approach may overestimate exposure for some individuals, it does capture the potential exposures that may occur.

d. Non-Target Terrestrial and Aquatic Plant Risk

For non-listed non-vascular plants, the acute RQs for all modeled scenarios, except Florida strawberry, exceed the acute risk LOC (RQs = 6.3 - 45). Similarly, for listed non-vascular plants, RQs for all scenarios exceed the listed species acute risk LOC (RQs = 10 - 524). Risk to aquatic vascular plants cannot be assessed since there are no available toxicity data. Although there are no listed endangered nonvascular plant species, indirect effects on a number of aquatic listed species are possible. The most obvious indirect effects would likely relate directly to reductions in food availability or habitat alterations associated with reduced aquatic plant and invertebrate biomass. The Endangered Species Protection Program will further explore the risk of endangered species from dodine use in the future.

e. Non-Target Insects

Currently, the Agency does not estimate RQs for terrestrial non-target insects. However, based on acute toxicity studies on honeybees, dodine is classified as practically non-toxic to non-target insects. Therefore, no label statement is required.

Table 23: Original and New Dodine Usage Information

Crop	Original Maximum Application Rate (lbs a.i./A/app)	New Max. Typical Application Rate (lbs a.i./acre)	New Maximum/Rescue Application Rate (lbs a.i./acre)	Original Yearly Maximum App Rates (lbs a.i./A/yr)	New Yearly Maximum App Rates (lbs a.i./A/yr)	Maximum Number of Applications	New Minimum Retreatment Interval
Apples	1.95	1.3 (max 4 apps/yr)	1.95 (max 2 apps. per year)	11.7	9.1	6 per year	7 days (originally 5)
Cherries (sour and sweet)	1.3	0.65 (max 4 apps/yr)	1.3 (max 2 apps. per year)	7.8	5.2	6 per year	7 days
Crab Apples(SLN OR)	0.35	0.35	0.35	2.10	1.4	6 per year	7 days (originally 5)
Ornamental Shade Trees (SLN OR)	0.85	0.85	0.85	5.1	5.1	6 per year	10 days
Peaches	2.6	1.3 (max 3 apps/yr)	1.95 (max 2 apps. per year)	13.0	7.8	5 per year	7 days
Pears	1.95	1.3 (max 4 apps/yr)	1.95 (max 2 apps. per year)	11.7	9.1	6 per year	7 days (originally 5)
Pecans	2.6	1.3 (max 4 apps/yr)	1.95 (max 2 apps. per year)	13.0	7.8	6 per year (originally 5)	10 days
Strawberries[1]	1.3	1.3	1.3	6.5	6.5	5 per year	7 days
Walnuts	2.6	1.3 (max 3 apps/yr)	1.95 (max 2 apps. per year)	13.0	7.8	5 per year	10 days

[1] Stawberries are the only crop with no aerial application supported.
NA = Not Applicable

V. What Registrants Need to Do

The Agency has determined that dodine is eligible for reregistration provided that the mitigation measures and label changes identified in this RED are implemented. Registrants will need to amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table (table 25). The Agency intends to issue Data Call-Ins (DCIs) requiring generic and product specific data. Generally, the registrant will have 90 days from receipt of a DCI to complete and submit response forms or request time extensions and/or waivers with a full written justification. For product-specific data, the registrant will have eight months to submit data and amended labels.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of dodine for currently registered uses has been reviewed and determined to be substantially complete. However, the data listed below are necessary to confirm the reregistration eligibility decision documented in this RED.

Table 24. Guideline Requirements for Dodine

Data Requirement	Old Guideline Number	New OPPTS Guideline No.
Mysid Chronic Toxicity Test	72-4c	850.1350
Aquatic Plant Toxicity Test using Lemna spp. - Tiers I and II	123-2	850.4400
Crop Field Trials - Strawberry An adequate set of field trials on strawberry is required. Only a minimal number of the trials using a PHI of 14 days were conducted and no trials were conducted using an application rate of 1.3 lb ai/A/application (the maximum application rate); therefore, insufficient data were available to support or reassess the established tolerance of 5 ppm The geographic locations of the crop field trials for strawberry are not adequate based on the current recommended locations provided in OPPTS Guideline 860.1500. These field trials will need to be supported by appropriate storage stability data, and labels will need to be amended as appropriate following the results of these field trials	171-4k	860.1500
Crop Field Trials using the flowable concentrate formulation. No crop field trials were conducted using the flowable concentrate formulation. According to the OPPTS Guideline 860.1500, side-by-side studies are required for the flowable concentrate formulation because foliar applications are allowable in the mid-to-late season. Such side-by-side trials must be submitted.	171-4k	860.1500
Confined Accumulation in Rotational Crops	165-1	860.1850

Table 24. Guideline Requirements for Dodine		
Data Requirement	**Old Guideline Number**	**New OPPTS Guideline No.**
Confined rotational studies are needed to support the strawberry use.		

Additional Residue Chemistry Clarifications

A maximum number of applications per season was not provided on the labels for the following commodities: apple, peach, cherry, pecan, walnut, and strawberry. The labels need to be amended to specify the maximum number of applications and the maximum seasonal application rate and as necessary to be made consistent with application rates used in the field trials.

2. Labeling Requirements

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

3. Spray Drift Management

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

Specific spray drift language for dodine is outlined in the "spray drift management" section of table 25. Due to concerns with risk to non-target species the following spray drift language will be required on all dodine labels:
- Droplet size restricted to medium or coarse sprays.
- Wind speeds must not exceed 10 mph at the application site.
- Release heights for airblast and ground applications must not exceed 4 feet above the crop canopy, and must not exceed 10 feet above the crop canopy for aerial applications.

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. For any questions regarding the PDCI, please contact Veronica Dutch at (703) 308-8585.

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 25. 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.

Labeling Changes Summary Table

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

Table 25: Summary of Labeling Changes for Dodine

Description	Dodine Amended Labeling Language for Manufacturing Use Products	Placement on Label
For all Manufacturing Use Products	AOnly for formulation into a fungicide for the following use(s) [fill blank only with those uses that are being supported by MP registrant].@ AWettable powder end use product formulations must be packaged in water soluble packaging.@	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	AThis 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).@ AThis 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	"This product is toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements

Labeling for Dodine End Use Products Intended for Occupational Use (WPS and Non-WPS Uses)		
PPE Requirements Established by the RED[1] for Liquid and Wettable Powder Formulations in Water Soluble Packaging	APersonal Protective Equipment (PPE)@ ASome materials that are chemical-resistant to this product are@ (*registrant inserts correct chemical-resistant material*). AIf you want more options, follow the instructions for category@ *[registrant inserts A,B,C,D,E,F,G,or H*] Aon an EPA chemical-resistance category selection chart.@ AAll mixers, loaders, applicators, and other handlers must wear: - long sleeved shirt and long pants, - socks plus shoes . In addition, mixers and loaders must wear: - chemical-resistant apron, and - chemical-resistant gloves. See engineering controls for additional requirements.@	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	AFollow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.@	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
Engineering Controls for Wettable Powder Formulations	AEngineering Controls Water-soluble packaging when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4)]. Mixers and loaders using water soluble packets must: B wear the personal protective equipment on this labeling for mixers/loaders, B be provided and have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown: chemical-resistant footwear.@	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
Engineering Controls for Enclosed Cockpits	Enclosed Cockpits AEngineering Controls: Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety

Labeling for Dodine End Use Products Intended for Occupational Use (WPS and Non-WPS Uses)		
	Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]. @	Requirements.)
User Safety Recommendations	AUser 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.)
Environmental Hazards	"This pesticide is toxic to aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas." Surface Water and Erosion Control Statement: "A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, steams, and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours. Sound erosion control practices will reduce this product's contribution to surface water contamination."	Precautionary Statements immediately following the User Safety Recommendations
Restricted-Entry Interval	ADo not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours for all crops.@	Directions for Use, Under Agricultural Use Requirements Box
Early Entry Personal Protective Equipment established by the RED.	APPE 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 plants, soil, or water, is: B coveralls worn over long-sleeve shirt and long pants, B chemical-resistant gloves made of any waterproof material, B chemical-resistant footwear plus socks, B protective eyewear, and B chemical-resistant headgear (if overhead exposure).@	Direction for Use Agricultural Use Requirements box

Labeling for Dodine End Use Products Intended for Occupational Use (WPS and Non-WPS Uses)		
Double Notification Requirement	ANotify workers of the application by warning them orally and by posting warning signs at entrances to treated areas.@	Directions for Use, Agricultural Use Requirements Box
General Application Restrictions	ADo 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.@	Place in the Direction for Use directly above the Agricultural Use Box.
Application Restrictions	ADo not apply this product through any type of irrigation system.@ ADo not apply in greenhouses.@	Directions for Use
Use-Specific Application Restrictions (Note: the maximum allowable application rate and maximum allowable rate per year must be listed as pounds or gallons of formulated products per acres, not just as pounds active ingredient per acre.)	Apples "Do not apply more than 9.1 lbs ai/acre/year." ADo not apply more than 2 applications per year at a rate of 1.95 lbs ai/acre/application." ADo not apply more than 4 applications per year at a rate of 1.3 lbs ai/acre/application.@ ADo not apply less than 7 days from the last application.@ ADo not apply within 7 days of harvest.@ Cherries (sour and sweet) "Do not apply more than 5.2 ai/acre/year." ADo not apply more than 2 applications per year at a rate of 1.3 lbs ai/acre/application." ADo not apply more than 4 applications per year at a rate of 0.65 lbs ai/acre/application.@ ADo not apply less than 7 days from the last application.@ ADo not apply within 7 days of harvest.@ Crab apples (SLN in Oregon) ADo not apply more than 0.35 lbs ai/acre/application.@ ADo not apply more than 6 times per year.@ ADo not apply less than 7 days from the last application.@	Directions for Use

Labeling for Dodine End Use Products Intended for Occupational Use (WPS and Non-WPS Uses)		
	Ornamental Shade Trees (SLN in Oregon) ADo not apply more than 0.85 lbs ai/acre/application.@ ADo not apply more than 6 times per year.@ ADo not apply less than 10 days from the last application.@ Peaches “Do not apply more than 7.8 lbs ai/acre/year.” ADo not apply more than 2 applications per year at a rate of 1.95 lbs ai/acre/application.” ADo not apply more than 3 applications per year at a rate of 1.3 lbs ai/acre/application.@ ADo not apply less than 7 days from the last application.@ ADo not apply within 15 days of harvest.@ Pears “Do not apply more than 9.1 lbs ai/acre/year.” ADo not apply more than 2 applications per year at a rate of 1.95 lbs ai/acre/application.” ADo not apply more than 4 applications per year at a rate of 1.3 lbs ai/acre/application.@ ADo not apply less than 7 days from the last application.@ ADo not apply within 7 days of harvest.@ Pecans “Do not apply more than 7.8 lbs ai/acre/year.” ADo not apply more than 2 applications per year at a rate of 1.95 lbs ai/acre/application.” ADo not apply more than 4 applications per year at a rate of 1.3 lbs ai/acre/application.@ ADo not apply less than 10 days from the last application.@ ADo not apply after shucks have started to open.@	

Labeling for Dodine End Use Products Intended for Occupational Use (WPS and Non-WPS Uses)		
	Strawberries ADo not apply more than 1.3 lbs ai/acre/application.@ ADo not apply more than 5 times per year.@ ADo not apply less than 7 days from the last application.@ ADo not apply within 14 days of harvest.@ "Do not apply aerially to strawberries." Walnuts "Do not apply more than 7.8 lbs ai/acre/year." ADo not apply more than 2 applications per year at a rate of 1.95 lbs ai/acre/application." ADo not apply more than 3 applications per year at a rate of 1.3 lbs ai/acre/application.@ ADo not apply less than 10 days from the last application.@ ADo not apply within 7 days of harvest.@	
Spray Drift Label Language for ALL Products Applied as a Spray	SPRAY DRIFT MANAGEMENT: "A variety of factors including weather conditions (e.g., wind direction, wind speed, temperature, relative humidity) and method of application (e.g., ground, aerial, airblast) can influence pesticide drift. The applicator and grower must evaluate all factors and make appropriate adjustments when applying this product. WIND SPEED: Do not apply at wind speeds greater than 10 mph at the application site. DROPLET SIZE: Apply as a medium or coarser spray (ASAE standard 572)."	Directions for Use under General Precautions and Restrictions
Spray Drift Label Language for Products Applied as a Spray through ground equipment	RELEASE HEIGHT: "Apply using a nozzle height of no more than 4 feet above the ground or crop canopy." AIRBLAST: "Sprays must be directed into the crop canopy." "Outward pointing nozzles should be turned off at row ends and when spraying outer rows."	Directions for Use under General Precautions and Restrictions

Labeling for Dodine End Use Products Intended for Occupational Use (WPS and Non-WPS Uses)		
Spray Drift Label Language for Products Applied as an Aerial Spray	RELEASE HEIGHT: ADo not release spray at a height greater than 10 feet above the ground or crop canopy.@ BOOM LENGTH: AThe boom length must not exceed 75% of the wingspan or 90% of the rotor blade diameter.@ SWATH ADJUSTMENT: AWhen applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind. Leave at least one swath unsprayed at the downwind edge of the treated field.@	Directions for Use under General Precautions and Restrictions

[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.

VI. Dodine Appendices

Appendix A. Uses of Dodine Eligible for Reregistration

Crop	Typical Application Rate (lbs a.i./acre)	Maximum/Rescue Application Rate(lbs a.i./acre)	Maximum Total Pounds A.I. Applied Per Acre Per Year	MaximumNumber of Applications	Minimum Retreatment Interval	Application Method	REI	Pre Harvest Interval (PHI)
Apples	1.3	1.95 (max 2 apps. per year)	9.1	6 per year	7 days	aerial & ground	48 hours	7 days
Cherries (sour and sweet)	0.65	1.3 (max 2 apps. per year)	5.2	6 per year	7 days	aerial & ground	48 hours	7 days
Crab Apples(SLN OR)	0.17	0.35	1.4	6 per year	7 days	aerial & ground	48 hours	Not applicable
Ornamental Shade Trees (SLN OR)	0.85	0.85	5.1	6 per year	10 days	aerial & ground	48 hours	Not applicable
Peaches	1.3	1.95 (max 2 apps. per year)	7.8	5 per year	7 days	aerial & ground	48 hours	15 days
Pears	1.3	1.95 (max 2 apps. per year)	9.1	6 per year	7 days	aerial & ground	48 hours	7 days
Pecans	1.3	1.95 (max 2 apps. per year)	9.1	6 per year	10 days	aerial & ground	48 hours	Do not apply after shucks have opened.
Strawberries	0.975	1.3	6.5	5 per year	7 days	ground only	48 hours	14 days
Walnuts	1.3	1.95 (max 2 apps. per year)	7.8	5 per year	10 days	aerial & ground	48 hours	7 days

Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision for Dodine (PC 044301)

GUIDE TO APPENDIX B

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

The data table is organized in the following formats:

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

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

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

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

Data Requirement			Use Patterns	Citations
New Guideline Number	Old Guideline Number	Description		
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition	All	40315501, 45322701, 46165601
830.1600	61-2A	Description of materials used to produce the product	All	40315501, 45322701, 46165601
830.1620	61-2B	Description of production process	Al	40315501, 45322701, 46165601
830.1670	61-2B	Formation of Impurities	All	40315501, 45322701, 46165601
830.1700	62-1	Preliminary Analysis	All	40315502, 45322702, 46146501 , 46165602
830.1750	62-0	Certification of Limits	All	40315502, 45322703, 46165601
830.1800	62-3	Analytical Method	All	40315502, 45322702, 46165601
830.6302	63-2	Color	All	40315503, 45322704
830.6303	63-3	Physical State	All	40315503, 45322704
830.6304	63-4	Odor	All	40315503, 45322704
830.6313	63-13	Stability to normal and elevated temperatures, metals, and metal ions	All	40315503, 40975701, 45322708,
830.6314	63-14	Oxidation/reduction: chemical incompatibility	All	45322704
830.6316	63-16	Explodability	All	45322704
830.6317	63-17	Storage stability	All	45322708
830.6320	63-20	Corrosion characteristics	All	45322708
830.7000	63-12	pH	All	45322705, 40315503
830.7050	None	UV/Visible Absorption	All	40975701, 46621301
830.7200	63-5	Melting Point	All	40315503
830.7300	63-7	Density	All	40315503, 45322704
830.7370	63-10	Dissociation Constants in Water	All	40315503, 45322705
830.7550	63-11	Partition coefficient, shake flask method	All	40315503, 45322707
830.7840	63-8	Solubility	All	40315503, 45322706,
830.7950	63-9	Vapor Pressure	All	45322709
ECOLOGICAL EFFECTS				
850.2100	71-1A	Avian Acute Oral Toxicity	A, B, D	Acc. 130888, Acc. 131455, 41671001 (under review), 41671003 (under review)
850.2200	71-2A	Avian Dietary Toxicity – Quail	A, B, D	Acc. 226855, 41671002 (under review)
850.2200	71-2B	Avian Dietary Toxicity – Duck	A, B, D	Acc. 226855, 41671004 (under review)

Data Requirement			Use Patterns	Citations
New Guideline Number	Old Guideline Number	Description		
850.2300	71-4A	Avian Reproduction - Quail	A, B, D	43274601, 44985805
850.2300	71-4B	Avian Reproduction – Duck	A, B, D	44985705
850.1075	72-1A	Fish Toxicity Bluegill	A, B, D	Acc. 132149, 41900301 (under review)
850.1075	72-1C	Freshwater Fish Toxicity Rainbow Trout	A, B, D	Acc. 132149, 43485505, 41900302 (under review)
850.1010	72-2A	Freshwater Invertebrate Toxicity	A, B, D	42339601,42653501, Acc. 226855, 40756805, 46621305 (under review), 46621307 (under review)
850.1075	72-3A	Estuarine/Marine Toxicity – Fish	A, B, D	42653502, 43485506, 42501501 (under review)
850.1025	72-3B	Estuarine/Marine Toxicity – Mollusk	A, B, D	42653503, 43485508, 42501502 (under review)
850.1035	72-3C	Estuarine/Marine Toxicity – Shrimp	A, B, D	42653504, 43485507, 42501503 (under review)
850.1045	72-3	Panaeid Acute Toxicity Test	A, B, D	40940802
850.1300	72-4A	Daphnid Chronic Toxicity Test	A, B, D	43876501
850.1350	72-4B	Estuarine/Marine Invertebrate Life Cycle	A, B, D	Data Gap
850.1400	72-4C	Early-life Stage Freshwater Fish	A, B, D	43876502
850.4225	123-1A	Seedling Germination and Seedling Emergence, Tier 2	A, B, D	42695102
850.4250	123-1C	Vegetative Vigor, Tier 2	A, B, D	42695103
850.4400	123-2	Aquatic Plant Toxicity	A, B, D	42695101, Data Gap
850.5400	122-2B	Aquatic Plant Growth, Tier 2	A, B, D	46621308 (under review), 46621309 (under review)
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity - Rat	All	44922401, 00124280
870.1200	81-2	Acute Dermal Toxicity – Rabbit/Rat	All	00124280
870.1300	81-3	Acute Inhalation Toxicity – Rat	All	00157300
870.2400	81-4	Primary Eye Irritation - Rabbit	All	00124280
870.2500	81-5	Primary Skin Irritation	All	00124280
870.2600	81-6	Dermal Sensitization	All	00157386
870.3100	82-1A	Subchronic Oral Toxicity: 90-Day Study Rodent	A, B, D	44704401, 46585001
870.3150	82-1B	Subchronic Oral Toxicity: 90-Day Study Non-rodent	A, B, D	41316903 (DGH)
870.3200	82-2	21-Day Dermal – Rabbit/Rat	A, B, D	46420701, 41316901 (DGH)

Data Requirement			Use Patterns	Citations
New Guideline Number	Old Guideline Number	Description		
870.3700A	83-3A	Developmental Toxicity – Rat	A, B, D	41900304, 41316902 (DGH)
870.3700B	83-3B	Developmental Toxicity – Rabbit	A, B, D	41900303
870.3800	83-4	2-Generation Reproduction – Rat	A, B, D	44246001
870.4100B	83-1B	Chronic Feeding Toxicity Study - Non-rodent	A, B, D	44246101
870.4200	83-2B	Carcinogenicity Mice	A, B, D	44703201
870.4300	83-5	Combined Chronic Toxicity/Carcinogenicity: Rats	A, B, D	44704401
870.5100	84-2	Bacterial Reverse Gene Mutation	A, B, D	40315504
870.5300		Gene Mutation (CHO)	A, B, D	41711002
870.5375		Cytogenics - Human Lymphocytes Chromosome Aberration Test	A, B, D	41711001
870.5385		Mammalian Bone Marrow Chromosomal Aberration Test	A, B, D	42311601
870. 5395	84-2	In Vitro Mammalian Cytogenetics Tests	A, B, D	41418901 (DGH), 41418902 (DGH)
870.5550	84-2	Unscheduled DNA Synthesis in Mammalian Cells in Culture	A, B, D	41418903 (DGH)
870.7485	85-1	General Metabolism	A, B, D	42479001
870.7600		Dermal Penetration (Rat)	A, B, D	46621303, 46621304 (under review)
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	A, B, D	42242601, 00101402, 00134831, 00144366, 42242601
835.2240	161-2	Photodegradation - Water	A, B, D	42419001, 46438203
835.2410	161-3	Photodegradation - Soil	A, B, D	46438204, 43506401
835.4100	162-1	Aerobic Soil Metabolism	A, B, D	43945201, 00058169, 40894801
835.4400	162-3	Anaerobic Aquatic Metabolism	A, B, D	42763001, 00058169, 42763002
835.4300	162-4	Aerobic Aquatic Metabolism	A, B, D	42327401, 46438202, 4394520, 42327401, 42414601
835.1240	163-1	Leaching/Adsorption/Desorption	A, B, D	42148901, 5001190
835.6100	164-1	Terrestrial Field Dissipation	A, B, D	44985701, 44985702, 00094615, 00101375
RESIDUE CHEMISTRY				
860.1300	171-4A	Nature of Residue – Strawberry	A, B, D	42703001
860.1300	171-4A	Nature of Residue – Apple	A, B, D	58170, 42553201
860.1300	171-4A	Nature of Residue – Pecan	A, B, D	44717601
860.1300	171-4B	Nature of Residue – Livestock (Goat)	A, B, D	44146401
860.1340	171-4C	Residue Analytical Method – Plants	A, B, D	34562, 89415, 90258, 94615, 101357, 101358, 101371, 101385, 101393,

Data Requirement			Use Patterns	Citations
New Guideline Number	Old Guideline Number	Description		
				43945202, 44146402, 44176402, 44176401
860.1380	171-4E	Plant commodities	A, B, D	44985704, Data Gap
860.1500	171-4K	Crop Field Trials		
		Apple	A, B, D	34962, 35127, 35128, 89415, 96154, 97630 101360, 101380, 101391, 101393, 44182801, Data Gap
		Pear	A, B, D	34562, 44182802, Data Gap
		Peach	A, B, D	35128, 29036, 93588, 101357,90258 44171801, Data Gap
		Plum	A, B, D	46438205, Data Gap
		Cherry	A, B, D	89417, 101357, 29036, 90111, 44171802, Data Gap
		Strawberry	A, B, D	89881, Data Gap
		Pecan	A, B, D	101358, Data Gap
		Spinach	A, B, D	101371, 101373, Data Gap
		Walnut	A, B, D	Data Gap
860.1850	165-1	Confined Accumulation in Rotational Crops	A, B, D	699066, Data Gap
860.1520	171-4L	Magnitude of Residue in Processed Food/Feed – Apple (juice and wet pomace)	A, B, D	44176401
OTHER				
885.4380	154A-24	Honey Bee Testing, Tier 1	A, B, D	401315505
875.2100	132-1	Foliar Dislodgeable Reside Dissipation	A, B, D	45192201
Non-guideline Study	Non-guideline Study	Acute Toxicity Study in Daphnia Magna	A, B, D	46621306 (under review)

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 South Bell Street, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:

www.epa.gov/pesticides/reregistration

These documents include:

HED Documents:

1. "Corrections to *Phase III - Revised as per 30-day Error Only Registrant Comments.* Dodine: HED Chapter of the Reregistration Eligibility Decision Document (RED)." 11/15/2005
2. "Dodine and Salts. Revised Reregistration Eligibility Decision (RED). Summary of Analytical Chemistry and Residue Data." 9/14/2005
3. "Dodine RED - Revised Reregistration Eligibility Decision. Product Chemistry Considerations. Case No. 0161" 9/14/2005
4. "Review of Dodine and Dodecylguanidine hydrochloride Incident Reports." 5/10/2005
5. "Dodine. Chronic Dietary Exposure Assessment for the Reregistration Eligibility Decision." 6/30/2005
6. "Dodecylguanidine hydrochloride (DGH) – Dietary and Non-dietary Exposures and Risks from Antimicrobial Uses" 6/21/2005
7. "Tier I Drinking Water Assessment for Dodine." 4/20/2005
8. "Dodine: Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document." 6/29/2005

EFED Documents:

1. "Correction to the 'Review of the 30-day Error Correction Comments on the Draft Level 1 Screening Ecological Risk Assessment for the Reregistration of Dodine'." 11/15/2005
2. "Review of the 30-day Error Correction Comments on the Draft Level 1 Screening Ecological Risk Assessment for the Reregistration of Dodine." 9/23/2005
3. "Ecological Risk Assessment in Support of the Reregistration Eligibility Decision on Dodine." 6/30/2005
4. "Level I Screening Ecological Risk Assessment for the Reregistration of Dodine." Attached to the Cover Memo dated 9/23/2005

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

MRID	Citation
00034562	American Cyanamid Company (1958) Cyprex, Dodecylguanidine acetate Residues from Pears. (Unpublished study received Mar 17, 1968 under 241-51; CDL:001692-E)
00035127	American Cyanamid Company (1958) Dodecylguanidine acetate Residues from Apples. (Unpublished study received Nov 25, 1959 under 241-51; CDL:001688-D)
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00089415	American Cyanamid Company (1958) Dodecylguanidine Acetate Residues from Apples. (Unpublished study received Oct 17, 1958 under PP0211; CDL:090237-A)
00089417	American Cyanamid Company (1958) Dodecylguanidine Acetate Residues from Sour Cherries: Summary. (Compilation; unpublished study received Oct 17, 1958 under PP0211; CDL:090237-D)
00089881	American Cyanamid Company (1960) Results of Tests on the Amount of Residue Remaining, Including a Description of the Analytical Method Used: ?Cyprex 65-W|. Includes method D 20 e dated Jul 2, 1958. (Compilation; unpublished study received Aug 7, 1960 under PP0324; CDL:-090352-A)
00090258	American Cyanamid Company (1964) Results of Tests on the Amount of Residue Remaining, Including a Description of the Analytical Method Used: ?Cyprex|. (Compilation; unpublished study received May 5, 1964 under PP0416; CDL:090450-B)
00093588	Orloski, E.J.; Caruso, M. (1965) Cyprex^(R)I Dodine Residues in Peaches: Report No. C-101. (Unpublished study received Jan 26, 1967 under 7F0577; submitted by American Cyanamid Co., Princeton, N.J.; CDL:090739-B)
00094615	Larsen, D.J. (1979) Spinach Foliar Fungicide Study. Includes method dated Apr 17, 1978. (Unpublished study, including letter dated Sep 25, 1979 from R.W. Vetro to C.F. Niven, Jr., received Feb 9, 1982 under 4E1474; submitted by Interregional Research Project No. 4, New Brunswick, N.J.; CDL:070669-H)
00096154	Terriere, L.C.; Kiigemagi, U. (1960) Cyprex Residues on Apples. (Unpublished study received Feb 24, 1961 under 241-12; prepared by Oregon State Univ., Agricultural Experiment Station, Dept. of Agricultural Chemistry, submitted by American Cyanamid Co., Princeton, N.J.; CDL:026957-C)
00101357	American Cyanamid Co. (1962) ?Residues of Cyprex in Peaches and Cherries|. (Compilation; unpublished study received Nov 29, 1962 under 241-51; CDL:026949-A)
00101358	American Cyanamid Co. (1967) ?Residues of Dodine in Pecans and Peanuts|. (Compilation; unpublished study received Oct 12, 1967 under 8F0655; CDL:091143-A)

00101371 Interregional Research Project No. 4 (1974) The Results of Tests on the Amount of Dodine Residue Remaining in or on Spinach, Including a Description of the Analytical Method Used. (Compi- lation; unpublished study received Feb 28, 1974 under 4E1474; CDL:093922-A)

00101385 Steller, W.; Klotsas, K.; Kuchar, E. (1960) Colorimetric esti- mation of dodecylquanidine acetate residues. Agricultural and Food Chemistry 8(6):460-464. (Also In unpublished sub- mission received on unknown date under unknown admin. no.; sub- mitted by American Cyanamid Co., Princeton, NJ; CDL:125047-A)

00101393 American Cyanamid Co. (1958) Results of Tests on the Amounts of Residues of Cyprex Dodine Remaining on Apples. (Compilation; unpublished study received Feb 8, 1960 under unknown admin. no.; CDL:125134-B)

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40315501 Haefele, L. comp. (1987) Drexel Dodine Technical: Product Identity and Composition. Unpublished compilation. 83 p.

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41418902 Ivett, J. (1990) Mutagenicity Test on CT-334-87 in vivo Mouse Mi- cronucleus Assay: Lab Project Number: 11071-0-455: 20996. Unpublished study prepared by Hazleton Laboratories America, Inc. 22 p.

41418903 Cifone, Maria A. (1990). Mutagenicity Test on CT-334-87 in the In Vitro Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay. Hazleton Laboratories America, Inc.

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Appendix E. EPA's Batching of Dodine Products for Meeting Acute Toxicity Data Requirements for Reregistration

In deciding how to meet the product-specific data requirements, registrants must follow the directions given in the Data Call-In notice (DCI) and its attachments appended to the dodine RED document. 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. End-use product batching was not performed for dodine; therefore, acute toxicity data requirements should be addressed for each product individually.

EPA Reg. No.	% Active Ingredient
241-51	65
55260-4	98
55260-6	39.6

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

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

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

Instructions

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

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

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

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

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

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

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

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

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

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

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

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

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

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

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

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

1. The Office of Pesticide Programs' website.

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

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

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

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

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

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

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

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

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