United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508C)

EPA 738-R-04-015
September 2004

Reregistration Eligibility Decision for Carboxin

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary risk assessments for the fungicide carboxin. The enclosed Reregistration Eligibility Decision (RED) document was approved on September 30, 2004. Public comments and additional data received were considered in this decision.

Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the environmental risks associated with the current use of carboxin. The tolerance reassessment was completed in December 2002. EPA is now publishing its Reregistration Eligibility Decision (RED) and risk management decision for carboxin and its associated human health and environmental risks. A Notice of Availability will be published in the *Federal Register* announcing a 60-day public comment period on the carboxin risk management decision. If substantive data or comments are received and indicate that any of the Agency's assumptions need to be refined and that alternate risk mitigation is warranted, EPA will make appropriate modifications at that time.

The RED and supporting risk assessments for carboxin are available to the public in EPA's Pesticide Docket **OPP-2004-0233** at: http://www.epa.gov/edockets. In addition, the Carboxin RED may be downloaded or viewed at: www.epa.gov/pesticides/reregistration/status.htm. Earlier information on carboxin, including public comments, can be found under docket **OPP-2004-0124**.

The Carboxin RED was developed through EPA's public participation process, published in the Federal Register on May 14, 2004, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. Developed in partnership with USDA and with input from EPA's advisory committees and others, the public participation process encourages robust public involvement starting early and continuing throughout the pesticide risk assessment and risk mitigation decision making process. The public participation process encompasses full, modified, and streamlined versions that enable the Agency to tailor the level of review to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern, and complexity associated with each pesticide. Using the public participation process, EPA is attaining its strong commitment to both involve the public and meet statutory deadlines.

Please note that the carboxin risk assessment and the attached RED document concern only this particular pesticide. This RED presents the Agency's conclusions on the dietary, drinking water, occupational and ecological risks posed by exposure to carboxin alone. This document also contains

both generic and product-specific data that the Agency intends to require in Data Call-Ins (DCIs). Note that DCIs, with all pertinent instructions, will be sent to registrants at a later date. Additionally, for product-specific DCIs, the first set of required responses will be due 90 days from the receipt of the DCI letter. The second set of required responses will be due eight months from the receipt of the DCI letter.

As part of the RED, the Agency has determined that carboxin will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. Sections IV and V of this RED document describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this document.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by carboxin. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, Lance Wormell, at (703) 603-0523. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Barbara Briscoe at (703) 308-8177.

Sincerely,

Debra Edwards, Ph. D.
Director, Special Review and
Reregistration Division

Attachment

REREGISTRATION ELIGIBILITY

DECISION

for

Carboxin

List A
CASE 0012

Approved By:

Debra Edwards, Ph.D.
Director, Special Review and
Reregistration Division

Date

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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC_{50}	Median Lethal Concentration. Statistically derived concentration of a substance expected to causing death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD_{50}	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day

MOE	Margin of Exposure
MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MRL	Maximum Residue Level
N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

EXECUTIVE SUMMARY

The Environmental Protection Agency (EPA or the Agency) has completed its review of public comments on the human health and environmental risk assessments for carboxin and is issuing its risk management decision. Carboxin is a member of the oxathiin class of systemic fungicides. It is applied to seed prior to planting for control of various fungi that cause seed and seedling diseases (smut, rot, and blight). Carboxin may be used to prevent the formation of these diseases or may be used to cure existing plant diseases. Its mode of action is to selectively concentrate in fungal cells, where it inhibits succinic dehydrogenase, a respiratory enzyme in the mitochondria. It is available in a variety of formulations including wettable powder, dust, flowable concentrate, emulsifiable concentrate, and ready-to-use liquid. Carboxin is applied both by commercial seed treaters and on-farm applicators. It currently has tolerances (40 CFR 180.301) in/on various commodities of the following crops: barley, beans, canola, corn, cotton, oats, onions, peanuts, rice, rye, safflower, sorghum, soybeans, triticale, and wheat (0.2 to 0.5 ppm). It also has tolerances for secondary residues in the meat, fat and meat by-products of cattle, goats, hogs, horses, poultry, and sheep (0.1 ppm), and in eggs and milk (0.01 ppm).

Based on available data, approximately 200,000 lbs a.i. are used annually throughout the U.S.; 140,000 for commercial seed treatment, and 60,000 for on-farm seed treatment. A screening level estimate of carboxin usage performed by the Agency indicates that less than 22,000 pounds of carboxin are used annually in California, with the highest usage on wheat seed crops.

Overall Risk Summary

The Agency's human heath risk assessment indicates no risks of concern. No toxicological endpoint attributable to a single oral dose was identified. Therefore, no acute dietary risk assessment was performed. Chronic risks from food are below the Agency's level of concern. Chronic dietary exposure from drinking water from ground water or surface water sources are low and not of concern. There are no residential uses for carboxin. For occupational workers who handle carboxin, the risks from exposure are low and below the Agency's level of concern.

The refined screening level ecological risk assessment for birds shows chronic risk quotients (RQs) that exceed levels of concern (LOCs) ranging from 2.5 to 27. For mammals, RQs for acute exposure range from 0.12 to 0.24 and for chronic exposure from 0.51 to 5.5. The Agency's initial assessment suggested that eight endangered species may potentially be impacted by carboxin; however, risk mitigation is required only for the Attwater's Prairie Chicken (*Tympanuchus cupido attwateri*).

Dietary Risk

Acute and chronic dietary (food) risks are below EPA's level of concern for the general U.S. population and all population subgroups. No toxicological endpoint attributable to a single oral dose was identified in the available toxicology studies on carboxin. Therefore, no acute dietary risk assessment was performed. The carboxin chronic dietary (food) risk does not exceed the Agency's level of concern for the U.S. population and all population subgroups using highly conservative assumptions in the risk assessment. Chronic dietary risks to all population subgroups are less than 36% of the cPAD. Therefore, no mitigation measures are necessary to reduce risks from dietary exposures.

The chronic dietary exposure/risk analysis for the carboxin seed treatment was a Tier 1 assessment assuming that residues are present at tolerance levels and that 100% of each crop was treated for all commodities with existing tolerances. Thus, the chronic dietary exposure/risk analysis for carboxin is a highly conservative assessment of exposure and potential food risk.

Drinking Water Risk

The use pattern selected for both the surface and groundwater assessment was the carboxin seed treatment use on peanuts as this is expected to represent a reasonable worst case situation. The surface water EEC (0.63 ppb) is less than the chronic DWLOC (26), indicating that chronic exposure to carboxin in food and drinking water from surface water sources is below the Agency's level of concern. The groundwater EEC (0.095 ppb) is less than the chronic DWLOC (26), indicating that chronic exposure to carboxin in food and drinking water from groundwater sources is below the Agency's level of concern. Therefore, no mitigation measures are necessary to reduce risks from drinking water exposure.

Residential Risk

There are no registered residential uses of carboxin; therefore, no residential risk assessment was performed.

Aggregate Risk

The aggregate risk assessment integrates the assessments conducted for dietary and drinking water exposure only since there are no registered residential uses of carboxin. As noted above, the average EECs for both surface water (0.63 ppb) and groundwater (0.095 ppb) are less than the most conservative chronic DWLOC (26) for children ages 1 to 2, indicating that aggregate chronic exposure to carboxin in food and drinking water is below the Agency's level of concern. Therefore, no mitigation measures are necessary to reduce risks from dietary or drinking water exposures.

Occupational Risk

The Agency calculated the potential exposure and risk to pesticide handlers from commercial and on-farm seed treatment and from loading and planting treated seed. Worker risk is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to the NOAEL taken from an animal study. A MOE of 100 or greater, for both the dermal and inhalation route is considered to be protective for carboxin. Only short- and intermediate-term exposures are expected and assessed based on label directed use patterns. All potential exposure scenarios result in MOEs greater than or equal to 100 for all routes of exposure (i.e., dermal, inhalation, and aggregate dermal and inhalation) at baseline levels of protection, for both on-farm and commercial seed treatment. Therefore, no carboxin-specific mitigation measures are necessary to reduce occupational risks for commercial or on-farm handlers. However, to reduce worker exposure, and to bring product labels into compliance with updated Worker Protection Standard (WPS) and other regulations, the Agency has determined that the following label changes are appropriate and required for reregistration eligibility:

Ecological Risk

The Agency conducted an ecological risk assessment to determine the potential impact of carboxin use on non-target terrestrial and aquatic organisms. The Agency used modeling to evaluate ecological risks for carboxin.

The Agency has determined that the risks posed by carboxin to most mammalian, avian, and aquatic species will be adequately mitigated by adhering to best management practices and covering or collecting spilled seeds treated with carboxin.

Birds. Carboxin is practically nontoxic to birds on an acute exposure basis and no acute LOCs are exceeded for birds species that are most likely to ingest seeds as part of their normal diet. However, chronic exposure can result in reproductive effects in birds such as reduced numbers of eggs hatched and reduced survival of hatchlings. Chronic LOCs (RQ $1.0) were exceeded for birds at the maximum seed treatment and maximum seed planting rates for all uses evaluated (RQ range: 2.5 to 27).

While the RQs exceed the chronic LOC by as much as 27-fold, there are a number of reasons why this is likely an overstatement of the risk. First, the LOEC (700 mg/kg of diet) is a factor of ten higher than the NOEC, and based on the type of experiment and data analysis done to estimate these values, the "true" LOEC likely lies somewhere between these values; RQ values based on the LOEC range from 0.3 to 2.7. Additionally, treated seed is available for consumption for only about 10 days before the seed germinates and becomes unavailable. Furthermore, carboxin should diffuse out of the seed coat and into the soil to some extent which will reduce the concentration. Carboxin parent degrades rather rapidly which will also reduce exposure. It is assumed but not known that the primary degradates, which are more persistent, have similar toxicity to the parent. While the chronic avian risk is above the level of concern in this screening assessment, risks may actually be lower if the duration of exposure is short as a result of dissipation processes and birds rely on other food sources in untreated areas. Usual planting practice is to plant the seed one-half to one inch deep in the soil. This practice reduces exposure, and thus risk. In addition, the RQs are based on the maximum seed treatment rates and maximum seed planting rates. Not all seeds are treated at the highest application rate nor are all seeds planted at the highest rate.

Mammals. Although carboxin is classified as practically nontoxic to mammals on an acute oral exposure basis, the acute restricted use LOC (RQ $0.2) is exceeded at maximum seed application rates used for onions (RQ=0.24) and the acute endangered species LOC (RQ $0.1) is exceeded for both cotton (RQ=0.12) and onions. However, similar to birds, the chronic risk level of concern (RQ $1.0) is exceeded with RQ values ranging from 0.51 to 5.5. The chronic mammalian LOEC (300 mg/Kg of diet) is only a factor of 1.5 higher than the NOEC and suggests the use of a NOEC in the risk calculation does not provide a large margin of safety. If risk quotients were based on the NOEC, the chronic risk LOC would only be exceeded for cotton (RQ=1.8), onions (RQ=3.7) and peanuts (RQ=1.4). The same mitigating factors that applied to the avian chronic assessment also apply to mammals and the assessment likely overstates the risk. In addition, while parent carboxin is not expected to be persistent, the carboxin sulfoxide degradate is much more persistent than the parent. Since the core structure of the molecule is intact, there is some basis for assuming the toxicity of this degradate could be similar to the parent.

Aquatic Organisms. Based on environmental concentrations in surface water, no acute LOCs are exceeded for aquatic animals or plants. No chronic toxicity data were available for the Agency to review and based on the use pattern, no chronic exposure for aquatic animals and plants is expected.

Endangered Species. The Agency's initial assessment suggested that eight endangered species may potentially be impacted by carboxin: the Delmarva fox squirrel (*Sciurus niger cinereus*), six species of kangaroo rat *(Dipodomys spp*.), and the Attwater's Prairie Chicken (*Tympanuchus cupido attwateri*). These species are known to consume seeds and may occur near field crops.

Based on the endangered species profiles for kangaroo rats, these animals are not expected in agricultural fields but may occur around them. The fox squirrel may venture into fields planted with treated seeds; however, information provided by the U.S. Fish and Wildlife Service indicates that the seed ingestion rate for the fox squirrel is lower than that calculated for mammals in the ecological risk assessment. Thus, the risk of either acute mortality or chronic effects to kangaroo rats or fox squirrels is not considered likely and no additional mitigation measures are required.

Based on information provided by the U.S. Fish and Wildlife Service, the endangered species profile, and communications with refuge managers, the Attwater's Prairie Chicken may be at risk for consuming unacceptable levels of carboxin treated seed. The seed foraging behavior of the Attwater's Prairie Chicken, combined with the fact that seed planted in the vicinity of this endangered species are typically incorporated at depths where the chicken is not likely to encounter the treated seed, reduces the likelihood of exposure and risk. To further mitigate risks posed to the Attwater's Prairie Chicken, the Agency will issue new or revised County Specific Bulletins in affected counties and require label and bag tag revisions.

Regulatory Decision

The Agency is issuing this RED for carboxin, as announced in a Notice of Availability published in the *Federal Register*. This RED document includes guidance and requested time frames for making any necessary label changes for products containing carboxin. The Agency is providing a final 60-day opportunity for stakeholders to respond to the carboxin risk management decision. If substantive information is received during the comment period, which indicates that any of the Agency's assumptions need to be refined and that alternate risk mitigation is warranted, appropriate modifications will be made at that time.

Summary of Mitigation Measures

EPA believes that carboxin is eligible for reregistration provided the following actions are implemented, combined with the general mitigation measures described in this document:

Dietary and Drinking Water Risk

No label changes are necessary, however, certain confirmatory data are required.

Occupational Risk

Label changes are necessary to comply with updated Worker Protection Standard and other regulations.

Ecological Risk

The Agency believes that the risks posed by carboxin to most mammalian, avian, and aquatic species will be adequately mitigated by adhering to best management practices and covering or collecting spilled seeds treated with carboxin. To be eligible for reregistration the following language must be added to the label and bag tags:

"Do not apply to water, 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 or by disposal of wastes. Treated seed exposed on soil surface may be hazardous to birds. Cover or collect spilled seeds."

To mitigate risks posed to endangered species, the Agency will issue new or revised County Specific Bulletins for the Attwater's Prairie Chicken in Austin, Colorado, and Galveston Counties in Texas. The bulletins will require minimum planting depths and subsequent discing for carboxin-treated seed planted within one mile of the U.S. Fish and Wildlife Service's Attwater Prairie Chicken National Wildlife Refuge and The Nature Conservancy's Texas City Preserve.

To be eligible for reregistration, the Agency requires that the following language be added to product labels:

"This product may have effects on federally listed threatened or endangered species or their critical habitat in some counties. It is a violation of federal law to kill, harm or harass listed animal species without authorization. To limit the potential for such impacts when using this product, consult and follow the instructions provided in the EPA Endangered Species Bulletin for the County or Parish in which you are applying the seed. To determine whether your County or Parish has a Bulletin consult http://www.epa.gov/espp before each season's use of this product."

"Seed that has been treated with this product that is then packaged or bagged for future use must contain the following labeling on the outside of the seed package or bag:

"This bag contains seed treated with carboxin. This product may have effects on federally listed threatened or endangered species or their critical habitat in some counties. It is a violation of federal law to kill, harm or harass listed animal species without authorization. To limit the potential for such impacts when using this product, consult and follow the instructions provided in the EPA Endangered Species Bulletin for the County or Parish in which you are applying the seed. To determine whether your County or Parish has a Bulletin consult http://www.epa.gov/espp before each season's use of this product."

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards 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 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 tolerance reassessment. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. The Act also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including consideration of cumulative effects of chemicals with a common mechanism of toxicity. This document presents the Agency's revised human health and ecological risk assessments; and the Reregistration Eligibility Decision (RED) for carboxin.

The implementation of FQPA has required the Agency to revisit some of its existing policies relating to the determination and regulation of dietary risk, and has also raised a number of new issues for which policies need to be created. These issues were refined and developed through collaboration between the Agency and the Tolerance Reassessment Advisory Committee (TRAC), which was later superceded by the Committee to Assist with Reassessment and Transition (CARAT). Both federal advisory committees were composed of representatives from industry, environmental groups, and other interested parties. Although FQPA significantly affects the Agency's reregistration process, it does not amend any of the existing reregistration deadlines. Therefore, the Agency is continuing its reregistration program while it resolves the remaining issues associated with the implementation of FQPA.

This document consists of six sections. Section I contains the regulatory framework for reregistration/tolerance reassessment; Section II provides a profile of the use and usage of the chemical; Section III gives an overview of the human health and environmental effects risk assessments; Section IV presents the Agency's decision on reregistration eligibility and risk management; and Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices include Data Call-In (DCI) and other information. The revised risk assessments and related addenda are not included in this document, but are available in the public docket, at: http://www.epa.gov/edockets, and on the Office of Pesticide Programs web page at: http://www.epa.gov/pesticides/reregistration/.

II. Chemical Overview

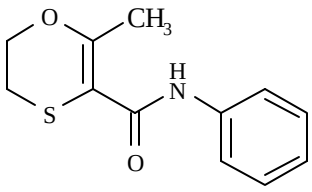
A. Regulatory History

Carboxin is a member of the oxathiin class of systemic fungicides. Carboxin is a List A reregistration pesticide. It has been registered in the U.S. since 1968. The Reregistration Standard for carboxin was issued in August, 1981. Carboxin Product and Residue Chemistry Reregistration Standard updates were issued in October, 1991. The Reregistration Standard and updates summarize the available data for each residue chemistry guideline and specify what additional data are required for reregistration purposes. Data Call-In (DCI) notices for carboxin were issued by the Agency in 1991, 1995 and 1997. In April, 2002, the Agency conducted a human health risk assessment for the use of carboxin as a seed treatment on onion and canola seeds in response to a petition from Uniroyal Chemical Company to establish a tolerance for carboxin (and its sulfoxide metabolite) in/on onions (dry bulb) at 0.2 ppm and from Gustafson LLC to establish a tolerance for carboxin (and its sulfoxide metabolite) in/on canola at 0.03 ppm. The tolerance reassessment decision for carboxin was completed in December 2002 [OPP-2002-0326; FRL-7282-1].

In an effort to promote transparency of the reregistration process and include the public in developing regulatory decisions, the Agency has developed a public participation process that is used for pesticide tolerance reassessment and reregistration. This public participation process was developed in partnership with USDA, based on EPA's and USDA's experiences with the pilot public participation process used for the organophosphate pesticides, comments received from Tolerance Reassessment Advisory Committee and the public during the public comment period on the proposed process and EPA's experience with the interim process used in developing decisions for a number of non-organophosphate pesticides during the past few years. The public participation process encompasses full and modified versions that enable EPA to tailor the level of review to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern and complexity associated with each pesticide.

B. Chemical Identification

Carboxin:



- Common Name: Carboxin
- Chemical Name: 5,6-dihydro-2-methyl-N-phenyl-1,4-oxathiin-3-carboxamide
- Chemical Family: Carboxin is a member of the oxathiin class of systemic fungicides.

- Case Number: 0012
- OPP Chemical Code: 090201
- Empirical Formula: $C_{12}H_{13}NO_2S$
- Molecular Weight: 235.31
- CAS Registry No.: 5234-68-4
- Common Trade Name: Vitavax, Vitaflo, Cotgard
- Basic Manufacturer: Crompton Corporation

Carboxin is an off-white crystalline solid with melting ranges of 91.5 to 92.5 and 98 to 101 C, reflecting two crystalline structures which revert to one in solution. Carboxin has a density of 1.70 g/mL, an octanol/water partition coefficient of 148.4, and a vapor pressure of 1.9×10^{-7} mm Hg at 25 C. Carboxin is slightly soluble in water (0.017 g/100 g at 25 C) and is soluble in a range of organic solvents including dimethyl sulfoxide (150 g/100 g), acetone (60 g/100 g), methanol (21 g/100 g), benzene (15 g/100 g), and ethanol (11 g/100 g). Carboxin is readily inactivated by ultraviolet light and sunlight. Carboxin is slightly soluble in water (0.017 grams solute/100 grams solvent at 25°C), its vapor pressure is low (< 1.0 mm Hg at 20°C), and its melting point is 91.5 to 92.5°C and 98.0 to 100°C.

C. Use Profile

Type of Pesticide

Carboxin is a member of the oxathiin class of systemic fungicides.

Summary of Use Sites

Carboxin is only registered for use as a commercial seed treatment and on-farm seed treatment. It is used on, and currently has tolerances (40 CFR 180.301) in/on various commodities of the following crops: barley, beans, canola, corn, cotton, oats, onions, peanuts, rice, rye, safflower, sorghum, soybeans, triticale, and wheat (0.2 to 0.5 ppm). It also has tolerances for secondary residues in the meat, fat and meat by-products of cattle, goats, hogs, horses, poultry, and sheep (0.1 ppm), and in eggs and milk (0.01 ppm).

There are no registered residential uses for carboxin.

Target Pests

Carboxin is applied to seed prior to planting for control of various fungi that cause seed and seedling diseases (smut, rot, and blight). Carboxin may be used to prevent the formation of these diseases or may be used to cure existing plant diseases. Its apparent mode of action is to selectively

concentrate in fungal cells, where it inhibits succinic dehydrogenase, a respiratory enzyme in the mitochondria.

Formulation Types Registered

Formulations include wettable powder, dust, flowable concentrate, emulsifiable concentrate, and ready-to-use liquid.

Methods of Application

Carboxin formulations are applied both commercially and by on-farm applicators. Most seeds are treated primarily in mechanical commercial operations. Based on information provided by the registrants, commodities currently treated on-farm include corn, cotton, soybean, and wheat. However, products labeled for on-farm treatment are available for most commodities.

Commercial applicators use automated machinery that mixes and applies carboxin to seeds as they are rotated through a metal drum or cylinder; these systems are used for both liquid and dust treatments. On-farm liquid applicators use a portable mechanical mixing system that applies carboxin to seeds as they are rotated through a metal cylinder. On-farm dust applicators pour carboxin into the seed chamber of the planter and mix the product by hand with a stick or paddle, just prior to planting. Carboxin is also used as a dip treatment for ornamental bulbs and corms.

Label Use Rates

Based on maximum treated seed application rates and maximum seed planting rates, the range is 0.01 to 0.4 lbs/ai/acre.

D. Estimated Usage of Carboxin

Based on available data, a total of approximately 200,000 lbs active ingredient (a.i.) are used annually throughout the U.S.; 140,000 for commercial seed treatment use, and 60,000 for on-farm seed treatment use. A screening level estimate of carboxin usage performed by the Agency indicates that less than 22,000 pounds of carboxin are used annually in California, with the highest usage on wheat seed crops. Approximately 10% of corn seed, 15% of cotton seed, 30% of onion seed, 90% of peanut seed, 5% of rice, and 5% of wheat seed planted in the U.S. is treated with carboxin.

III. Summary of Carboxin Risk Assessment

The purpose of this summary is to assist the reader by identifying the key features and findings of the human health and ecological risk assessments, and to enhance understanding of the conclusions reached in the assessments. The list of EPA's human health and ecological risk assessments, and supporting information that were used to formulate the findings and conclusions for the fungicide carboxin can be found in the OPP public docket, located in Room 119, Crystal Mall #2, 1801 Bell Street, Arlington, VA or viewed via the Internet at: http://www.epa.gov/edockets under the docket number **OPP-2004-0124**. In addition, documents may be downloaded or viewed via the Internet at: http://www.epa.gov/pesticides/reregistration/.

EPA issued its preliminary risk assessments on carboxin and made them available for public comment on April 28, 2004. The 60-day public comment period on the preliminary risk assessments ended June 28, 2004. Based on the comments received and additional information, the Agency revised the ecological effects risk assessment and is releasing it, along with this Carboxin RED for an additional 60-day public comment period.

A. Human Health Risk Assessment

1. Dietary Risk from Food

a. Toxicity and Carcinogenicity

(For a complete discussion, see section 3.1 of the Human Health Risk Assessment.)

The toxicology data base is adequate to characterize the toxicity of carboxin. Carboxin exhibits low acute toxicity via the oral (Toxicity Category III), inhalation (Toxicity Category IV), and dermal (Toxicity Category III) routes of exposure. It is a slight eye irritant (Toxicity Category III). It is not a skin irritant (Toxicity Category IV) and is negative for dermal sensitization.

Table 1. Acute Toxicity Data on Carboxin

Guideline	Study Type	MRID	Results[1]	Toxicity Category	Acceptable/ Unacceptable
870.1100	Acute Oral Rats	43171401	M: LD_{50} = 2588 mg/kg F: LD_{50} = 3080 mg/kg	III	Acceptable
870.1200	Acute Dermal Rabbits	43171402	M: LD_{50} > 4000 mg/kg F: LD_{50} > 4000 mg/kg	III	Acceptable
870.1300	Acute Inhalation Rats	43171403	M: LC_{50} > 4.7 mg/L F: LC_{50} > 4.7 mg/L	IV	Unacceptable
870.2400	Primary Eye Irritation Rabbits	43171404	Slightly Irritating	III	Acceptable
870.2500	Primary Skin Irritation Rabbits	43171405	Not Irritating	IV	Acceptable
870.2600	Dermal Sensitization Guinea Pigs	00105980	Negative for dermal sensitization	N/A	Unacceptable

[1] The acute toxicity values included in this table are for informational purposes only. The data supporting these values may or may not meet the current acceptance criteria.

In subchronic and chronic feeding studies in rats, the kidney was the primary target organ. In a

chronic feeding study in dogs, the primary target organ appeared to be the liver. In a carcinogenicity study in mice, dose-related increases in the incidence of liver centrilobular hypertrophy were observed in the mid- and high-dose males and high-dose females; however, this was considered to be an adaptive, rather, than an adverse response. In the female mice in this study, treatment-related increased mortality was observed at the mid- and high-dose, but not in the male mice at the high-dose.

In a developmental toxicity study in rats, no developmental toxicity was observed in the fetuses at the highest dose tested. Decreased body weight, decreased body weight gain, and decreased food consumption were noted in the dams in this study. In a developmental toxicity study in rabbits, a treatment-related increased incidence of abortions was observed. However, it could not be determined whether the abortions were due to maternal toxicity (e.g. the result of stress) or due to an effect on reproductive/developmental mechanisms. The dams (maternal toxicity) and fetuses (developmental toxicity) were considered to be equally sensitive to the test material. In a 2-generation reproduction study in rats, the endpoint for parental toxicity was based on decreased body weight gain and kidney damage. In the same study, the endpoint for reproductive toxicity was based on decreased fertility indices for the F_{1b} parents and the endpoint for offspring toxicity was based on decreased body weights for the F_{2b} male pups. The results in these two developmental toxicity studies and the reproduction study indicate no increased susceptibility of the fetuses or pups, as compared to adults, to carboxin.

Carboxin is rapidly and extensively absorbed, metabolized and excreted following oral administration, mostly within 24 hours. No significant residues remain after 72 hours.

In carcinogenicity studies in male and female rats and in male and female mice, carboxin did not demonstrate any biologically significant evidence of carcinogenic potential. Carboxin is classified as "not likely to be carcinogenic to humans."

b. FQPA Safety Factor

(For a complete discussion, see section 3.2 of the Human Health Risk Assessment.)

The FQPA Safety Factor was reduced to 1x for carboxin because there is a complete set of acceptable-guideline developmental and reproduction studies, as well as acute and subchronic neurotoxicity studies, there is no quantitative or qualitative evidence of increased susceptibility following in utero or postnatal exposure in any of the developmental or reproductive studies, and the toxicity endpoints selected are protective of pre/postnatal toxicity following acute and chronic exposures.

In addition, there are no major uncertainties identified in the exposure databases and there are no residential uses of carboxin. The dietary food exposure assessment conservatively assumes tolerance level residues and 100% crop treated. The dietary drinking water assessment utilizes water concentration values generated by models and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations which will not likely be exceeded in real-world settings. Use of these screening-level assessments ensures that actual exposures and risks will not be underestimated. Therefore, these assessments will not underestimate the potential exposure to infants and children resulting from the use of carboxin.

c. Population Adjusted Dose (PAD) & Reference Dose (RfD)

(For a complete discussion, see section 4.2 of the Human Health Risk Assessment.)

No toxicological endpoint attributable to a single oral dose was identified for carboxin, therefore, no acute dietary risk assessment was performed. Chronic dietary risk is calculated by using the average food consumption values for each population sub-group and average residue values in/on those foods over a 70-year lifetime to determine average exposure. A risk estimate that is less than 100% of the chronic population adjusted dose (cPAD), the dose at which an individual could be exposed over the course of a lifetime with no expected adverse health effect, does not exceed the Agency's level of concern. The cPAD is the chronic reference dose (cRfD) adjusted for the FQPA Safety Factor, which in the case of carboxin was reduced to (1X), therefore, the PAD and RfD are identical. Table 2 below summarizes the toxicological dose and endpoints used in the carboxin dietary risk assessment.

Table 2. Summary of Toxicological Dose and Endpoints for Carboxin for Use in Dietary Assessment

Exposure Scenario	Dose (mg/kg/day) & Total UF	FQPA Safety Factor	Study and Endpoint for Risk Assessment
Acute Dietary (All Populations)	No toxicological endpoint attributable to a single oral dose was identified in the available toxicology studies on carboxin that would be applicable to females (13 to 50 years) or to the general population (including infants and children).		
Chronic Dietary (All populations)	NOAEL= **0.8** mg/kg/day UF = **100** **Chronic RfD** = **0.008** mg/kg/day	FQPA SF = 1X **cPAD** = chronic RfD / FQPA SF = **0.008** mg/kg/day	Chronic feeding/ carcinogenicity study in rats. LOAEL = 9 mg/kg/day based on decreased body weight and body weight gain; kidney damage (including secondary effects)**.**
Cancer	**Classification:** not likely to be carcinogenic to humans.		

d. Exposure Assumptions

(For a complete discussion, see section 4.2 of the Human Health Risk Assessment.)

The carboxin chronic dietary exposure assessment was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 1.3), which incorporates consumption data from U.S. Department of Agriculture's (USDA) Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The 1994-96, 1998 data are based on the reported food consumption patterns of more than 20,000 individuals over two non-consecutive survey days. Consumption data are averaged for the entire U.S. population and within population subgroups for chronic exposure assessment, but are retained as individual consumption events for acute exposure assessment.

For chronic exposure and risk assessment, estimates of average residues for foods (e.g., orange) or food-forms (e.g., orange-juice) of interest are multiplied by the averaged consumption estimate of each

food/food-form of each population subgroup. Exposure estimates are expressed in mg/kg body weight/day and as a percent of the cPAD.

e. Acute Dietary (Food) Risk

(For a complete discussion, see section 4.2 of the Human Health Risk Assessment.)

For acute dietary exposure scenarios, no toxicological endpoint attributable to a single oral dose was identified in the available toxicology studies on carboxin that would be applicable to females (13 to 50 years) or to the general population (including infants and children). Therefore, an acute dietary exposure analysis was not required for this assessment.

f. Chronic Dietary (Food) Risk

(For a complete discussion, see section 4.2 of the Human Health Risk Assessment.)

The carboxin chronic dietary (food) risk does not exceed the Agency's level of concern for the U.S. population and all population subgroups using highly conservative assumptions in the risk assessment. The chronic dietary exposure analysis was conducted using the DEEM™ software. The exposure/risk analysis for the seed treatment used a conservative deterministic (Tier I) methodology. The Tier I analysis assumes that: 1) residues are present at published tolerances for registered uses and at recommended tolerances for proposed new uses; and 2) 100% crop treated (CT) for all commodities with existing and/or recommended tolerances. Tier I chronic dietary analyses were conducted for the general U.S. population and all population subgroups. Based on these analyses, chronic dietary risk associated with exposure to carboxin from existing and proposed uses are below the Agency's level of concern for the general US population and all population subgroups. The chronic exposure estimates were < 100% of the chronic PAD with the highest chronic exposure (mg/kg/day) occurring in children 1 to 2 years old (36% cPAD). Results of the chronic dietary exposure analysis are presented in Table 3.

Table 3. Chronic Dietary (Food) Exposure Estimate and Percent of Chronic RfD - Tier 1 Exposure Analysis (Assumes Tolerance Level Residues and 100 %CT)

Subgroups	Mean Exposure (mg/kg/day)	% cPAD at Mean Exposure
General U.S. Population	0.0012	15
All Infants (< 1 year old)	0.0015	19
Children 1 to 2 years old	**0.0029**	**36**
Children 3 to 5 years old	0.0028	35
Children 6 to 12 years old	0.0019	24
Youth 13 to 19 years old	0.0012	16
Adults 20 to 49 years old	0.0010	12
Females 13 to 49 years old	0.0009	11

Subgroups	Mean Exposure (mg/kg/day)	% cPAD at Mean Exposure
Adults 50+ years old	0.0007	9

g. Cancer Dietary Risk Assessment

In carcinogenicity studies in male and female rats and in male and female mice, carboxin did not demonstrate any biologically significant evidence of carcinogenic potential. Carboxin is classified as "not likely to be carcinogenic to humans ." Therefore, no cancer risk assessment was conducted.

2. Dietary Risk from Drinking Water

(For a complete discussion, see section 4.3 of the Human Health Risk Assessment.)

Drinking water exposure to pesticides can occur through groundwater 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. To determine the maximum allowable contribution from water in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then calculates a drinking water level of comparison (DWLOC). The DWLOC represents the maximum contribution to the human diet (in ppb or ug/L) that may be attributed from residues of a pesticide in drinking water after dietary exposure is subtracted from the acute or chronic PAD. Risks from drinking water are assessed by comparing the DWLOC, to determine whether modeled or monitored estimated environmental concentrations (EECs) in both surface and groundwater exceed this level. EECs that are less than the DWLOC are not of concern.

The Agency has determined that the residues to evaluate in drinking water are carboxin and its sulfoxide degradate. Carboxin sulfoxide is significant because the sulfoxide forms quickly and is more persistent than the parent compound. Carboxin is very mobile and its sulfoxide degradate is expected to be more mobile and to be the predominant compound in the environment. Based on the structure of carboxin sulfoxide, the toxicity of the sulfoxide degradate is expected to be comparable to that of the parent compound. Aqueous photolysis is rapid with a half-life of 1.5 hours under a xenon arc lamp, which simulates natural sunlight. Additionally, there is some evidence that carboxin may degrade by oxidation in aqueous systems when dissolved oxygen is present.

The use pattern selected for both the surface and groundwater assessment was the carboxin seed treatment on peanuts from the Vitavax label (Reg. No.400-106) as this is expected to represent a reasonable worst case situation.

a. Surface Water

Monitoring data are not available to assess residues of carboxin and carboxin sulfoxide in drinking water. The Agency performed a Tier I drinking water assessment for carboxin using the FIRST model for estimating the upper bound concentrations that could occur in surface water used for drinking water. It is a single event model which assumes that a single run-off moves a maximum of 8% of the applied pesticide into the pond. The chronic surface water EEC (0.63 ppb) is less than the chronic

DWLOC (26), indicating that chronic exposure to carboxin in drinking water from surface water sources is below the Agency's level of concern.

b. Ground Water

Another model, SCI-GROW, was used to estimate the concentrations in ground water used for drinking water. It provides a groundwater screening concentration for use in determining potential risk to human health from drinking water contaminated with a pesticide. The groundwater concentration is estimated based on the maximum application rates in areas where groundwater is exceptionally vulnerable to contamination. These vulnerable areas are characterized by high rainfall, rapidly permeable soil, and shallow aquifer. The chronic groundwater EEC (0.095 ppb) is less than the chronic DWLOC (26), indicating that chronic exposure to carboxin in drinking water from groundwater sources is below the Agency's level of concern.

The modeled chronic drinking water EECs from surface and groundwater sources used for this risk assessment are presented in Table 4.

Table 4. Chronic Drinking Water EECs & DWLOC (Carboxin and Sulfoxide)

Drinking Water Source	Chronic EECs (ppb)	DWLOC (Children 1 to 2 years)
Surface Water	0.63	26
Groundwater	0.095	

3. Residential Risk

There are no registered residential uses of carboxin; therefore, no residential risk assessment was performed.

a. Aggregate Risk

(For a complete discussion, see section 5.0 of the Human Health Risk Assessment.)

The aggregate risk assessment integrates the assessments conducted for dietary and drinking water exposure only since there are no residential uses of carboxin. For aggregate exposure, the Agency calculates a DWLOC which represents the maximum allowable exposure through drinking water after considering the dietary exposure to carboxin. If the EECs are less than the DWLOCs, EPA does not have concern for aggregate exposure. The chronic EECs for both surface water (0.63 ppb) and groundwater (0.095 ppb) are less than the most conservative chronic DWLOC (26) for children ages 1 to 2; therefore, the Agency has determined that aggregate chronic exposure to carboxin in food and drinking water is below the Agency's level of concern.

4. Occupational Risk

(For a complete discussion, see section 7.0 of the Human Health Risk Assessment.)

There is potential exposure to workers who treat seed with carboxin in both commercial and on-farm settings. The Agency calculated the potential exposure and risk to workers from commercial and on-farm seed treatment and from loading and planting treated seed. Worker risk is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to the no observed adverse effect level (NOAEL) taken from an animal study. A MOE of 100 or greater, for both the dermal and inhalation route is considered to be adequately protective for carboxin. This is based on the conventional uncertainty factor of 100X (10X for intraspecies extrapolation and 10X for interspecies variation).

EPA has identified seven occupational exposure scenarios for carboxin. Because dermal and inhalation endpoints differ, separate dermal and inhalation exposure assessments have been conducted for each of the seven scenarios. Only short- and intermediate-term exposures are expected and assessed based on label directed use patterns. Dermal and inhalation unit exposure estimates (i.e., mg/lb a.i.) for each scenario are derived using the Agency's seed treatment Standard Operating Procedure (SOP for Seed Treatment, 6/1/03).

a. Toxicity

For short- and intermediate-term dermal exposures, the toxicology endpoint was selected from a 28-day dermal toxicity study in which the NOAEL was 400 mg/kg/day based on kidney histopathological effects such as tubular degeneration and mineralization at the LOAEL of 1000 mg/kg/day. The endpoint is appropriate for assessing short and intermediate-term dermal exposure based on both the route and duration of the study, and because the effects seen are consistent with the toxicity profile of carboxin.

For short- and intermediate-term inhalation exposure an oral NOAEL of 10 mg/kg/day was selected from a rat developmental gavage study which showed maternal treatment related decreased body weight, body weight gain, and food consumption, and increased hair loss at 90 mg/kg/day (LOAEL). These treatment-related effects were considered to be appropriate for assessing a short-term exposure scenario. An oral NOAEL was selected because there were no inhalation toxicity studies of any duration on carboxin available. In the absence of inhalation toxicity studies, the default value of 100% for inhalation absorption was used for route-to-route extrapolations.

b. Occupational Risk Assessment

Exposure data used for the carboxin assessment are taken primarily from the Agency's seed treatment SOP. The seed treatment SOP contains all scenarios for worker exposure from seed treatment and planting treated seed. The data contained in the SOP are mostly generated by industry sources. Exposure estimates are from actual seed treatment studies and are based on exposure factors associated with occupational handler scenarios (i.e., commercial seed treatment, on-farm seed treatment, planting of treated seed). Eight seed treatment studies were used in developing the SOP. Given the high level of variance in the data, multiple statistical analyses were undertaken to help ensure derivation of a statistically sound exposure value for the different scenarios evaluated. For all selected seed treatment studies, replicates were combined into sets of equivalent job functions. This process resulted in four categories of commercial seed treatment activities (loader/applicator, sewer, bagger, and multiple activities), and two categories for on-farm activities (treater and planter).

The Agency calculated the potential exposure and risk to workers from commercial and on-farm seed treatment and from loading and planting of treated seed. An MOE of 100 for the dermal and inhalation route is considered adequate for carboxin occupational exposure and risk assessment. Occupational handler exposure assessments are conducted by the Agency using different levels of protection. The Agency typically evaluates all exposures with minimal protection and then adds protective measures in a tiered approach to determine the level of protection necessary to obtain appropriate MOEs. The lowest level (baseline) of protection includes long sleeve shirts, long pants, shoes, and socks. The results of the worker exposure assessment indicate that all potential exposure scenarios result in MOEs greater than or equal to 100 for all routes of exposure, i.e., dermal, inhalation, and aggregate dermal and inhalation at baseline protection (i.e., with no added personal protective equipment). MOEs for on-farm seed treatment with dust formulation range from 100 to 460 for dermal exposure and $\geq$ 25,000 for inhalation exposure. MOEs for on-farm seed treatment with liquid formulation are $\geq$ 33,000 for dermal exposure and $\geq$ 3,300 for inhalation exposures. MOEs for loading and planting of treated seed are $\geq$ 2800 for dermal exposure and $\geq$ 1500 for inhalation exposure. MOEs for all categories of commercial seed treatment are $\geq$ 690 for dermal exposure and $\geq$ 460 for inhalation exposure.

c. Incident Reports

There are very few incidents due to carboxin, none of which were serious. There is no scientific literature on poisoning from carboxin exposure. There are no Incident Data System reports (6a2 reports to EPA). California had only one case reported from 1982 through 1996 of a possible skin injury. The Poison Center data shows a total of only 16 exposures from 1993 to 1998, too few to draw conclusions. Of the 16 cases, just four were seen in a health care facility and there was no consistent pattern in the symptoms reported.

B. Environmental Risk Assessment

1. Environmental Fate and Transport

Carboxin is a mobile compound that degrades rapidly in the environment. However, the primary metabolites formed, carboxin sulfoxide and carboxin sulfone, tend to be much more persistent than the parent and may have similar pesticidal activity.

Carboxin parent degrades rapidly in soil by aerobic metabolism with a mean half-life from two studies of 1.25 days. Carboxin degraded much more slowly in anaerobic soil with a half-life of 128 days. In both aerobic and anaerobic soil studies, the predominant degradate was carboxin sulfoxide. The degradates were otherwise similar, except that "-vinyl sulfinyl acetanilide is an additional degradate in the anaerobic soil metabolism study. There was no evidence of degradation by hydrolysis at any pH. Aqueous photolysis is rapid with a half-life of 1.5 hours under a xenon arc lamp. No soil photolysis data are available; however, photolysis is not expected to be a major route of dissipation in the field as planted seed is generally buried some depth below the surface. Photolysis may contribute to dissipation after it has entered surface water bodies. Degradation in the anaerobic phase of the anaerobic soil metabolism was much slower with a mean degradation half-life from two studies of 129 days. While a definitive statement cannot be made, there is some evidence that carboxin may degrade by direct oxidation in aqueous systems when dissolved oxygen is present. Limited information on aquatic metabolism show

slower degradation rates anaerobically (245 days) than aerobically (31 days). In two anaerobic soil metabolism studies conducted for carboxin sulfoxide the major degradate formed was carboxin, indicating that carboxin can reform from the sulfoxide under anaerobic conditions. Carboxin sulfoxide was the major degradate formed in all laboratory studies with oxo (phenylamino) acetic acid comprising up to 55% of the radioactivity in the aqueous photolysis study.

2. Ecological Effects (Toxicity) Assessment

Toxicity testing reported in this section does not represent all species of bird, mammal, or aquatic organism. Only a few surrogate species for both freshwater fish and birds are used to represent all freshwater fish (2000+) and bird (680+) species in the United States. For mammals, acute studies are usually limited to Norway rat or mice. Estuarine/marine testing is usually limited to a crustacean, a mollusk, and a fish. Also, neither reptiles nor amphibians are tested. The assessment of risk or hazard makes the assumption that avian and reptilian toxicities are similar. The same assumption is used for fish and amphibians.

Based on the ecological effect studies, carboxin is practically nontoxic to terrestrial animals (Table 5) and ranges from moderately to slightly toxic to aquatic animals (Table 6) on an acute exposure basis. No data were available to gauge the acute toxicity of carboxin to estuarine/marine fish. Following chronic exposure, mallard ducks (*Anas platyrhynchos*) exhibited reductions in the number of eggs laid, viable embryos, live 3-week embryos, normal hatchlings and 14-day survivors at 700 mg/kg/day. Chronic exposure to rats (*Rattus norvegicus*) resulted in reduced growth (decreased body weight) of offspring. No chronic toxicity data were available for aquatic animals.

Similar to technical grade carboxin, the formulated products Vitavax 75 W (38.7% carboxin plus 37.5% thiram) and Vitavax SP 38.7% carboxin plus 37.5% captan) were practically nontoxic to bobwhite quail with acute oral LD_{50} values of 2,410 mg/kg and greater than 10,000 mg/kg, respectively. Additionally, subacute dietary toxicity testing with Vitavax SP in bobwhite quail (LC_{50} >5,620 mg/kg of diet) and mallard ducks (LC_{50} >4,640 mg/kg of diet) indicated that the formulated product was practically nontoxic to birds.

Table 7 summarizes toxicity data on aquatic plants; both vascular (*Lemna gibba*) and nonvascular *(Pseudokirchneriella subcapitata*) plants were relatively sensitive to carboxin with EC_{50} values of 0.67 and 0.37 mg/L, respectively. No data were available on which to gauge either terrestrial or semiaquatic plant phytotoxicity.

OPP utilized the ECOTOX (Ecotoxicology Database System) database to supplement the registrant-submitted data. ECOTOX is a comprehensive computer-based system that provides single chemical toxic effect data for aquatic life, terrestrial plants and terrestrial wildlife derived predominately from peer-reviewed literature. There were approximately 40 carboxin related records; for a complete discussion, see the Ecological Risk Assessment.

Table 5. Summary of acute and chronic toxicity data for terrestrial organisms exposed to carboxin.

Species	Acute Toxicity				Chronic Toxicity	
	LD_{50} (ppm)	Acute Oral Toxicity (MRID)	5-day LC_{50} (ppm)	Subacute Dietary Toxicity (MRID)	NOAEC/LOAEC (ppm) (MRID)	Affected Endpoints
Bobwhite quail (*Colinus virginicus*)	>2,150	practically nontoxic (435823-01)	>4,110	practically nontoxic (435823-03)	--	--
Mallard duck (*Anas platyrhynchos*)	6094	--	--	--	70 / 700	reduced numbers of eggs hatched, reduced survival
Honey bee (*Apis meliferus*)	2 µg/bee	practically nontoxic (no MRID)	--	--	--	--
Laboratory rat (*Rattus norvegicus*)	2,588	practically nontoxic (431714-01)	--	--	200 / 300	reduced growth nephrititis

Table 6. Summary of acute aquatic animal toxicity estimates using technical grade carboxin.

Species	Acute Toxicity			Chronic Toxicity	
	96-hr LC_{50} (mg/L)	48-hr EC_{50} (mg/L)	Acute Toxicity (MRID)	NOAEC / LOAEC (mg/L)	Affected Endpoints (MRID)
Bluegill sunfish (*Lepomis macrochirus*)	1.2	--	moderately toxic (224935)	--	--
Water flea (*Daphnia magna*)	--	84.4	slightly toxic (235236)	--	--
Pink shrimp (*Panaeus duorarum*)	14	--	slightly toxic (165048A)	--	--

Table 7. Summary of acute phytotoxicity data for aquatic plants exposed to carboxin.

Species	Acute Toxicity	
	96-hr LC_{50} (mg/L)	Acute Toxicity (MRID)
Duckweed (*Lemna gibba*)	0.67	(414938-02)
Green algae (*Pseudokirchneriella subcapitata*)	0.37	(414938-01)

3. Ecological Risk Calculations

Risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects by using risk quotients (RQs). RQs are calculated by dividing exposure estimates by acute and chronic ecotoxicity values:

RQ = Exposure/Toxicity

RQs are then compared with OPP's levels of concern (LOCs). These LOCs are used by OPP to analyze potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. Risk presumptions, along with the corresponding LOCs are summarized in Table 8. The ecotoxicity test values (measurement endpoints) used in the acute and chronic risk quotients are derived from required studies.

Table 8. Risk Presumptions for Animals and Plants

Risk Presumption	LOC terrestrial animals	LOC aquatic animals	LOC plants
Acute Risk There is potential for acute risk; regulatory action may be warranted in addition to restricted use classification	0.5	0.5	1.0
Acute Restricted Use There is potential for acute risk, but may be mitigated through restricted use classification	0.2	0.1	NA
Acute Endangered Species Endangered species may be adversely affected; regulatory action may be warranted	0.1	0.05	1.0
Chronic Risk There is potential for chronic risk; regulatory action may be warranted	1	1	NA

4. Ecological Risk Profile

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. To evaluate the potential risk to nontarget organisms from the use of carboxin 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 chemical, when used as directed, has the potential to cause adverse effects on nontarget organisms. When the RQ exceeds the LOC for a particular category, the Agency presumes a risk of concern to that category of organisms.

a. Risk to Birds

(For a complete discussion, see the Ecological Risk Assessment.)

Birds in the field may be exposed to carboxin by ingesting treated seeds or by other routes, such as incidental ingestion of contaminated soil, dermal contact with treated seed surfaces and soil during activities in the treated areas, preening activities, inhalation of pesticide vapor and contaminated particulate, and ingestion of drinking water contaminated with the pesticide. In this assessment, only ingestion of the treated seed was considered because other routes are not expected to contribute significantly to exposure.

Carboxin is practically nontoxic to birds (LD_{50} >2,150 mg/kg) on an acute exposure basis and no acute LOCs are exceeded for birds species that are most likely to ingest seeds as part of their normal diet. However, chronic exposure can result in reproductive effects in birds. In a chronic mallard duck

feeding study, exposure to carboxin resulted in reduced numbers of eggs hatched and reduced survival of hatchlings with the no observable adverse effect concentration (NOAEC) of 70 mg Kg of diet. Chronic LOCs (RQ $1.0) were exceeded for birds at the maximum seed treatment and maximum seed planting rates for all uses evaluated (RQ range: 2.5 to 27).

While the RQs exceed the chronic level of concern LOC by as much as 27-fold, there are a number of reasons why this is likely an overstatement of the risk. First, the lowest observed effect concentration (LOEC) (700 mg/kg of diet) is a factor of ten higher than the NOEC, and based on the type of experiment and data analysis done to estimate these values, EPA can only say the "true" LOEC lies somewhere between these values; RQ values based on the LOEC range from 0.3 to 2.7. Additionally, treated seed is available for consumption for only about 10 days before the seed germinates and becomes unavailable. Furthermore, carboxin should diffuse out of the seed coat and into the soil to some extent which will reduce the concentration. Carboxin parent degrades rather rapidly which will also reduce exposure. It is assumed but not known that the primary degradates, which are more persistent, have similar toxicity to the parent. While the chronic avian risk is above the level of concern in this screening assessment, risks may be reduced if the duration of exposure is short as a result of dissipation processes and birds rely on other food sources in untreated areas. Usual planting practice is to plant the seed one-half to one inch deep in the soil. This practice further reduces exposure, and thus risk. In addition, the RQs are based on the maximum seed treatment rates and maximum seed planting rates. Not all seeds are treated at the highest application rate nor are all seeds planted at the highest rate.

For screening purposes, the Agency assessed acute risks to birds by considering the smallest birds that eat seeds, which weigh about 20 g. Small birds tend to eat more per unit body weight, so they will be the most vulnerable. Exposure is estimated from the concentration of carboxin on treated seed.

The chronic avian risk was estimated using the peak concentration on the seed used in method 1 (e.g., peanuts: 712 mg per kg bw day), as well as the NOAEC from the avian reproduction study (mallard duck NOAEC = 70 mg per kg of diet). Chronic RQ values (range 2.5 to 27) exceed the chronic risk LOC (RQ $1.0). If risk quotients were based on the lowest observed effect concentration (LOAEC = 700 mg/kg of diet) rather than the NOAEC, RQs would range from 0.25 to 2.7; only cotton (RQ=1.4), onion (RQ=2.7) and peanuts (RQ=1.0) would still exceed the chronic risk LOC.

Table 9. Summary of avian acute and chronic risk quotients for the major uses of carboxin based on an adjusted avian LD_{50} of 3,054 mg/kg of body weight and a chronic NOAEC of 70 mg/kg of diet.

Crop	mg a.i./kg day	Acute RQ[a]	mg a.i./kg seed	Chronic RQ[b]
Corn	344	<0.32	1360	4.9[c]
Cotton	956	<0.88	3778	14[c]
Onion	1907	<1.76	7533	27[c]
Peanuts	712	<0.66	2815	10[c]
Rice	190	<0.18	750	2.7[c]

Crop	mg a.i./kg day	Acute RQ[a]	mg a.i./kg seed	Chronic RQ[b]
Wheat	356	<0.33	1407	5.1[c]

[a] Acute RQ = mg•(kg•bw•day)$^{-1}$ /(adjusted LD_{50})
[b] Chronic RQ = mg•(kg•bw•day)$^{-1}$/ NOAEC
[c] Exceeds chronic risk (RQ $ 1.0) level of concern.

b. Risk to Mammals

(For a complete discussion, see the Ecological Risk Assessment.)

Mammals in the field may be exposed to carboxin by ingesting treated seeds or by other routes, such as incidental ingestion of contaminated soil, dermal contact with treated seed surfaces and soil during activities in the treated areas, inhalation of pesticide vapor and contaminated particulate, and ingestion of drinking water contaminated with the pesticide. In this assessment, only ingestion of the treated seed was considered because other routes are not expected to contribute significantly to exposure.

An approach similar to that used for birds was used for calculating exposure in mammals. Equations used for calculating the daily food intake and the adjusted toxicity value for a 35 g mammal are provided below (Nagy 1987; USEPA 1995). The analysis assumed that small mammals would weigh 35 g and would consume roughly 5.1 g of food per day. Also, similar to the approach used for birds, the LD_{50} was adjusted to reflect the differential in toxicity to a 35 g mammal versus the rough average weight (350 g) of the rats used in the acute oral toxicity study; the adjusted LD_{50} was determined to be 4,602 mg/kg.

Compared to the mammalian NOAEC (200 mg/Kg of diet), chronic risk LOCs are exceeded for cotton, oats, onion, peanuts, and wheat (RQ range 0.51 to 5.5) (Table 10). If chronic risk quotients were based on LOAEC (300 mg/kg of diet), RQ values would only be exceeded for cotton (RQ=1.8), onion (RQ=3.7), and peanuts (RQ=1.4).

Table 10. Summary of acute and chronic mammalian RQ values based on an adjusted mammalian acute LD_{50} and chronic NOAEC of 4602 mg/kg and 200 mg/kg of diet, respectively.

Crop	mg/kg day	Acute RQ[a]	mg a.i./kg seed	Chronic RQ[b]
Corn	45	0.04	1360	0.96
Cotton	125	0.12	3778	2.8[d]
Onion	249	0.24[c]	7533	5.5[d]
Peanuts	93	0.09	2815	2.1[d]
Rice	25	0.02	750	0.55

Crop	mg/kg day	Acute RQ[a]	mg a.i./kg seed	Chronic RQ[b]
Triticale	23	0.02	700	0.51
Wheat	47	0.04	1407	1.0[d]

[a] Acute RQ Method 1= mg•(kg•bw•day)$^{-1}$/(adjusted LD_{50})
[b] Chronic RQ = mg• (kg•bw•day)$^{-1}$/NOAEC
[c] Exceeds acute restricted use (RQ$0.2), and acute endangered species LOC (RQ$0.1)
[d] Exceeds chronic risk (RQ $ 1.0) level of concern.

c. Risk to Aquatic Animals

(For a complete discussion, see the Ecological Risk Assessment.)

Exposure to non-target aquatic animals may occur through runoff from adjacent treated sites. Based on environmental concentrations in surface water, no acute LOCs are exceeded for aquatic animals. No chronic toxicity data were available for the Agency to review and based on the use pattern, no chronic exposure for aquatic animals is expected.

The aquatic animal risk assessment used a single granular broadcast application, with no soil incorporation to represent the seed treatment application. Runoff is computed from environmental concentrations estimated using the model GENEEC 2.0. The peak concentration estimated using the model was 18.7 µg/L. Comparing this to the aquatic endpoints shows that there is no aquatic risk RQs exceed the Agency's level of concern (RQ $ 0.05).

d. Risk to Aquatic Plants

(For a complete discussion, see the Ecological Risk Assessment.)

Exposure to non-target aquatic plants may occur through runoff from adjacent treated sites. Based on environmental concentrations in surface water, no acute LOCs are exceeded for aquatic plants. No chronic toxicity data were available for the Agency to review and based on the use pattern, no chronic exposure for aquatic plants is expected.

The aquatic plant risk assessment was performed using the surrogate duckweed *Lemna gibba*. The non-vascular acute risk assessments uses either algae or a diatom, whichever is the most sensitive species. An aquatic plant risk assessment for acute- endangered species is usually made for aquatic vascular plants from the surrogate duckweed *Lemna gibba*. Runoff is computed from environmental concentrations estimated using the GENEEC 2.0 model. The risk quotient is determined by dividing the pesticide's initial or peak concentration in water by the plant EC_{50} value. Based on the results of this analysis, no acute levels of concern (RQ $1.0) are exceeded for aquatic plants. Additionally, when NOAEC values for green algae (NOAEC = 0.11 mg/L) and duckweed (NOAEC= 0.15 mg/L) were compared to estimated environmental concentrations, RQ values ranged from <0.01 to 0.17 for green algae and from <0.01 to 0.12 for duckweed. None of the RQ values exceed the endangered species LOC (RQ $1) for aquatic plants.

e. Risks to Endangered Species

(For a complete discussion, see the Ecological Risk Assessment.)

Acute risk LOCs for endangered/threatened mammals are exceeded for onions (RQ = 0.24) and cotton (RQ = 0.12) based on maximum seed application rate. Chronic risk LOCs have been exceeded for both avian (RQ range 2.5 to 27) and mammalian species (RQ range: 0.51 to 5.5).

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 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 to affect any particular species, EPA puts basic toxicity and exposure data developed for REDs into context for individual listed species and their locations by evaluating important ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. A determination that there is a likelihood of potential impact to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential impact, or consultations with the U.S. Fish and Wildlife Service and/or the National Marine Fisheries Service as necessary.

Carboxin is used primarily to treat seeds and its effects on endangered species are likely limited to seed-eating mammals and birds. EPA has identified eight species potentially impacted by ingesting carboxin-treated seeds: the Delmarva Peninsula fox squirrel, six species of kangaroo rat, and the Attwater's Prairie Chicken (Table 11).

Table 11. Endangered Species Potentially Impacted by Carboxin

Common Name	Scientific Name	Mammal/Bird	Mitigation Required
Delmarva Peninsula Fox Squirrel	*Sciurus niger cinereus*	Mammal	No
Kangaroo Rat[1]	*Dipodomys spp*.	Mammal	No
Attwater's Prairie Chicken	*Tympanuchus cupido attwateri*	Bird	Yes

[1] Six endangered species of kangaroo rats were identified as potentially impacted.

Based on the endangered species profiles for kangaroo rats, these animals are not expected in agricultural fields but may occur around them. The fox squirrel may venture into fields planted with treated seeds; however, information provided by the U.S. Fish and Wildlife Service indicates that the seed ingestion rate for the fox squirrel is lower than that calculated for mammals in the ecological risk assessment. Thus, the risk of either acute mortality or chronic effects to kangaroo rats or fox squirrels is not considered likely and no additional mitigation measures are required.

Based on information provided by the U.S. Fish and Wildlife Service, the endangered species profile, and communications with refuge managers, the Attwater's Prairie Chicken may be at risk for consuming unacceptable levels of carboxin treated seed. The seed foraging behavior of the Attwater's Prairie Chicken, combined with the fact that seed planted in the vicinity of this endangered species are typically incorporated at depths where the chicken is not likely to encounter the treated seed, reduces the likelihood of exposure and risk. To mitigate risks posed to the Attwater's Prairie Chicken, the Agency will issue new or revised County Specific Bulletins for the Attwater's Prairie Chicken in Austin, Colorado, and Galveston Counties in Texas. The bulletins will require minimum planting depths and subsequent discing for carboxin-treated seed planted within one mile of the U.S. Fish and Wildlife Service's Attwater Prairie Chicken National Wildlife Refuge and The Nature Conservancy's Texas City Preserve (see Section IV).

Attwater's Prairie Chicken The Attwater's Prairie Chicken prairie chicken was formerly located throughout Gulf Coast prairies of southwestern Louisiana and Texas, south to the Nueces River. Only two geographically separated small populations totaling approximately 62 individuals remain.

Properly managed coastal prairie grassland, characterized by diversity of vegetation, satisfies every known requirement of Attwater's prairie chicken. The bird uses shorter grasses for courtship and feeding, and tall grasses for nesting, feeding, and loafing. The chicken also uses fallow rice fields and other combinations of pasture and croplands. Courtship areas ("booming grounds") may be natural grassy flat with low vegetation, or artificially maintained surfaces such as little-used roads, airport runways, or oil well pads. The birds nest typically in tall grasses.

According to the U.S. Fish and Wildlife Service's recovery plan, the primary threat to the bird's existence is loss, fragmentation, and degradation of coastal prairie habitat, which has been converted to rice cultivation or over-grazed and invaded by brush. Residential and urban development, and oil and gas development also contributed to the habitat loss. Other possible threats include: increased predation as a result of habitat fragmentation, disease, catastrophic weather events, inbreeding, and red imported fire ants.

Although the Attwater's prairie chicken has been observed in sorghum, cotton, soybean and peanut crops on or near mating display sites during planting and in fallow rice fields; the birds were apparently not exposed to any of the pesticides typically used in their vicinity. Pesticides were not determined to affect the endangered prairie chicken in Texas since no mortalities of the chicken could be directly attributed to pesticides (in terms of tissue residues) during the three-year study period (1978 to 1980) .

Currently, the vast majority of Attwater Prairie Chickens are contained on two reserves in Texas, the Attwater Prairie Chicken National Wildlife Refuge (APCNWR) and The Nature Conservancy's Texas City Preserve (TCP). According to reserve managers in Texas (pers. comm: T. Rossignol, APCNWR manager, and B. Crawford, TCP reserve manager; 8/17/04), the ACPNWR contains approximately 40 birds and is directly surrounded by agricultural fields, mainly rice with a small amount of cotton. The birds are known to travel an average of three to four miles off of the refuge, with one occurrence of a chicken found ten miles away. Adult prairie chicken diets consist primarily of forb foliage, exceeding seeds and insects in all seasons. Greatest seed and insect consumption by adults occurs in autumn. Diets of young birds consist primarily of insects. The chickens weigh from one and a

half to two pounds. According to the reserve managers, the potential for the chickens to ingest treated seeds is present, however the potential would be greatly reduced if the birds had to dig for the seeds since the prairie chicken does not typically dig for seeds. The greatest risk of ingesting treated seeds would likely result from spilled seeds left on the ground's surface.

The Texas City Preserve is surrounded by grazing pastures and industry. Containing approximately 22 birds that are not known to venture far from the preserve, the risk of agricultural exposure is minimal. Therefore, the main concern would be for the birds contained on the APCNWR.

In Texas, rice is typically dry-seeded by drilling seeds to a depth of 0.5 to 1 inch. During wet years in Texas, rice is wet-seeded by broadcast aerial application of pre-germinated seeds to flooded rice fields containing 1 to 2 inches of water. However, since carboxin is mobile, it would readily dissociate from the treated seed into the water. Once the rice seed has settled onto the field, the water is immediately released from the field carrying with it the majority of carboxin. Thus, whether rice is dry seeded and incorporated to a minimum depth of 0.5 inches or is wet seeded to flooded fields which are eventually drained, the potential for the Attwater's Prairie Chicken to be exposed to carboxin is low based on the seeding practices.

As noted by the refuge managers, cotton is also grown to a limited extent in the vicinity of the reserves; however, treated cotton seed is incorporated to a depth of 1.5 to 2 inches. Based on seeding practices and the fact that the prairie chicken does not typically dig (scratch) for food, the likelihood of exposure to carboxin-treated seed is low.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

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

The Agency has completed its assessment of the dietary, occupational, residential, and ecological risk associated with the use of pesticide products containing the active ingredient carboxin. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient carboxin, the Agency has sufficient information on the human health and ecological effects of carboxin 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 carboxin containing products are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of carboxin that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of carboxin, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data

requirements that have not been satisfied with acceptable data.

Based on its evaluation of carboxin, the Agency has determined that carboxin products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of carboxin. If all changes outlined in this document are incorporated into the product labels, then all current risks for carboxin will be adequately mitigated for the purposes of this determination.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for carboxin. During the public comment period on the risk assessments, which closed on June 28, 2004, the Agency received comments from four commentors, Crompton Corporation, U.S. Fish and Wildlife Service, National Cotton Council, and a private citizen. These comments in their entirety are available in the public docket, http://www.epa.gov/edockets, (OPP-2004-0124). An individual response to these comments is being prepared by EPA and will be made available in the public docket, http://www.epa.gov/edockets, (OPP-2004-0233).

C. 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 carboxin. The Agency has concluded that the tolerances for carboxin meet the FQPA safety standards and that the risk from dietary (food sources only) exposure is within the "risk cup." An aggregate assessment was conducted for exposures through food and drinking water. A residential assessment was not conducted or included in the aggregate assessment because there are currently no registered residential uses for carboxin. The Agency has determined that the human health risks from these combined exposures are within acceptable levels. 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 water.

b. Determination of Safety to U.S. Population

The Agency has determined that the established tolerances for carboxin, 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, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of carboxin. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of carboxin. As discussed in Chapter 3, the total acute dietary (food alone) risk was not assessed as no acute oral endpoint was observed. Further, the chronic dietary (food alone) risk from carboxin is not of concern.

Acute and chronic risks from drinking water exposures are not of concern. Models have been used to estimate ground and surface water concentrations. The DWLOC calculated to assess the surface

water contribution to chronic (noncancer) dietary exposure is a range of less than 0.07 to less than 3.5 for the U.S. general population (all population subgroups). The surface water EEC (0.63 ppb) is less than the chronic DWLOC (26), indicating that chronic exposure to carboxin in food and drinking water from surface water sources is below the Agency's level of concern. The groundwater EEC (0.095 ppb) is less than the chronic DWLOC (26), indicating that chronic exposure to carboxin in food and drinking water from groundwater sources is below the Agency's level of concern. Since the model-based estimates for concentrations in surface water and groundwater are below the calculated chronic DWLOC, the Agency concludes with reasonable certainty that aggregate exposure to food and drinking water will not result in an unacceptable chronic risk.

There are no registered residential uses for carboxin.

c. Determination of Safety to Infants and Children

EPA has determined that the established tolerances for carboxin, 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 carboxin residues in this population subgroup.

No Special FQPA Safety Factor is necessary to protect the safety of infants and children. In determining whether or not infants and children are particularly susceptible to toxic effects from carboxin residues, the Agency considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. The FQPA Safety Factor has been removed (i.e., reduced to 1X) for carboxin because: 1) there is no quantitative or qualitative evidence of increased susceptibility following in utero or postnatal exposure in any of the developmental or reproductive studies; (2) the toxicity endpoints selected are protective of pre/postnatal toxicity following acute and chronic exposures; and (3) there are no major uncertainties identified in the exposure databases and there are no residential uses of carboxin..

d. 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).

When the appropriate screening and/or testing protocols being considered under the EDSP have

been developed, carboxin may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

e. Cumulative Risks

Risks summarized in this document are those that result only from the use of carboxin. 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 carboxin. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

2. Tolerance Summary

Tolerances are established for the combined residues of the fungicide carboxin (5,6-dihydro-2-methyl-1,4-oxathiin-3- carboxanilide) and its metabolite 5,6-dihydro-3-carboxanilide-2-methyl- 1,4-oxathiin-4-oxide (calculated as carboxin) (from treatment of seed prior to planting) in or on raw agricultural commodities (RACs): barley, beans, canola, corn, cotton, oats, onions, peanuts, rice, rye, safflower, sorghum, soybeans, triticale, and wheat (0.2 to 0.5 ppm). It also has tolerances for secondary residues in the meat, fat and meat by-products of cattle, goats, hogs, horses, poultry, and sheep (0.1 ppm), and in eggs and milk (0.01 ppm).

The Agency intends to change the tolerance expression to "combined residues of carboxin [5,6-dihydro-2-methyl-1,4-oxathiin-3-carboxanilide] and its metabolites determined as aniline and expressed as parent compound".

a. Tolerances Currently Listed Under 40 CFR §180.301

Pending label revisions for some commodities, adequate residue data are available to support the established carboxin tolerances on the following raw agricultural commodities: barley grain and straw; bean, dry and succulent; canola seed; field corn grain, forage, and stover; pop corn grain and stover; sweet corn, kernel plus cob with husks removed and forage; cottonseed; oat grain, forage, and straw; onion (dry bulb); peanut; peanut hay; rice grain and straw; safflower seed; soybean; and wheat grain, forage, and straw.

Adequate residue data are also available to support the established carboxin tolerances on the following animal commodities: egg; milk; fat, meat, and meat byproducts of cattle, goat, hog, horse, and sheep; and the fat, meat, and meat byproducts of poultry. The established tolerances for fat and the meat of cattle, goat, hog, horse, and sheep should be lowered from 0.1 ppm to 0.01 ppm and from 0.1 ppm to 0.05 ppm, respectively, based on the re-examination of a dairy cattle feeding study relative to the maximum theoretical dietary burden.

The established carboxin tolerances on sorghum grain, forage, and fodder will be revoked unless an interested party proposes uses and submits supporting residue data. In addition, the established tolerances on bean forage, hay, and straw should be revoked because these commodities are no longer considered significant livestock feedstuffs and have been deleted from Table 1 of OPPTS 860.1000.

As a result of changes to Table 1 of OPPTS 860.1000, Residue Chemistry Test Guidelines, the Agency has determined that tolerances on the following commodities are warranted (Table 12). Following submission of data by the registrant, EPA intends to evaluate the data and, if adequate, set appropriate tolerances for barley hay, cotton gin byproducts, oat hay, and wheat hay. The registrant may request that the available data for wheat be translated to rye provided the use patterns of the crops are identical.

Table 12. Tolerance Reassessment Summary for Carboxin

Commodity	Current Tolerance (ppm)	Tolerance Reassessment [1] (ppm)	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR §180.301 (a)			
Barley, grain	0.2	0.20	
Barley, straw	0.2	0.20	
Bean, dry, seed	0.2	0.20	
Bean, forage	0.5	Revoke	These commodities are no longer considered significant livestock feedstuffs and have been deleted from Table 1 (OPPTS 860.1000).
Bean, hay	0.5	Revoke	
Bean, straw	0.5	Revoke	
Bean, succulent	0.2	0.20	
Canola, seed	0.03	0.03	
Cattle, fat	0.1	0.05	
Cattle, meat	0.1	0.05	
Cattle, meat byproducts	0.1	0.10	
Corn, fodder	0.2	0.20	[*Corn, field, stover*] [*Corn, pop, stover*] [*Corn, sweet, stover*]
Corn, forage	0.2	0.20	[*Corn, field, forage*] [*Corn, sweet, forage*]
Corn, fresh, including sweet corn, kernel plus cob with husks removed	0.2	0.20	[*Corn, sweet, kernel plus cob with husks removed*]
Corn, grain	0.2	0.20	[*Corn, field, grain*] [*Corn, pop, grain*]
Cotton, undelinted seed	0.2	0.20	
Egg	0.01	0.05	
Goat, fat	0.1	0.05	
Goat, meat	0.1	0.05	
Goat, meat byproducts	0.1	0.10	
Hog, fat	0.1	0.05	
Hog, meat	0.1	0.05	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment [1] (ppm)	Comment/ *[Correct Commodity Definition]*
Hog, meat byproducts	0.1	0.10	
Horse, fat	0.1	0.05	
Horse, meat	0.1	0.05	
Horse, meat byproducts	0.1	0.10	
Milk	0.01	0.05	
Oat, forage	0.5	0.50	
Oat, seed	0.2	0.20	[*Oat, grain*]
Oat, straw	0.2	0.20	
Onion, dry bulb	0.2	0.20	
Peanut	0.2	0.20	
Peanut, hay	0.2	0.20	Alternatively, the established tolerance for peanut hay may be revoked since the registered seed treatment use of carboxin on peanut prohibits the grazing or feeding of livestock on hay grown from treated seed.
Poultry, fat	0.1	0.10	
Poultry, meat	0.1	0.10	
Poultry, meat byproducts	0.1	0.10	
Rice, grain	0.2	0.20	
Rice, straw	0.2	0.20	
Safflower, seed	0.2	0.20	
Sheep, fat	0.1	0.05	
Sheep, meat	0.1	0.05	
Sheep, meat byproducts	0.1	0.10	
Sorghum, forage	0.2	Revoke	Carboxin is presently not registered for use on sorghum. Tolerances should be revoked unless registrants other than the basic producers intend to support carboxin use on sorghum and submit additional data.
Sorghum, grain	0.2	Revoke	
Sorghum, grain, stover	0.2	Revoke	
Soybean	0.2	0.20	[*Soybean, seed*]
Wheat, forage	0.5	0.50	
Wheat, grain	0.2	0.20	
Wheat, straw	0.2	0.20	
Tolerances That Need To Be Proposed Under 40 CFR §180.301 (a)			
Barley, hay	None	TBD	Additional data are required for barley hay.
Cotton gin byproducts	None	TBD	Additional data are required for cotton gin byproducts.
Oat, hay	None	TBD	Additional data are required for oat hay.
Rye, forage	None	TBD	The available data for wheat may be translated to rye if the registered uses are identical.
Rye, grain	None	TBD	
Rye, straw	None	TBD	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment [1] (ppm)	Comment/ *[Correct Commodity Definition]*
Wheat, hay	None	TBD	Additional data are required for wheat hay.

TBD = To be determined.

b. Codex Harmonization

No Codex MRLs have been established for carboxin; therefore, issues of compatibility between Codex MRLs and U.S. tolerances do not exist. No Canadian or Mexican MRLs have been established for carboxin.

D. Regulatory Rationale

The Agency has determined that carboxin is eligible for reregistration provided that additional required data confirm this decision and that the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures.

The following is a summary of the rationale for managing risks associated with the use of carboxin. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

For all supported commodities, the chronic dietary exposure estimates are below the Agency's level of concern. Therefore, no risk mitigation measures are required to address exposure to carboxin residues in food.

No toxicological endpoint attributable to a single oral dose and applicable to females (13 to 50) or to the general population was identified in the available toxicology studies for carboxin, and all effects observed were due to multiple exposures; therefore, an acute dietary analysis was not performed. The chronic dietary exposure estimate for the highest exposed population subgroup, children 1 to 2 years of age, is 0.0029 mg/kg/day or 36% of the cPAD. No cancer dietary exposure assessment was performed because carboxin is classified as "not likely to be carcinogenic to humans."

b. Drinking Water Risk Mitigation

The chronic DWLOC is 26 ppb based on the food exposure from the most highly exposed subgroup (children 1 to 2 years). The Agency's model based estimates for average concentrations of carboxin in surface and ground water are 0.63 and 0.095 ppb, respectively. Since the model-based estimates for concentrations in surface water and groundwater are below the calculated chronic DWLOC, no mitigation is needed for drinking water.

c. Residential Risk Mitigation

There are currently no registered residential uses for carboxin and no risk mitigation is needed.

d. Occupational Risk Mitigation

1) Handler exposure

Occupational exposure and risk estimates were conducted using maximum application rates and high-end assumptions for amount of seed treated and planted. A target Margin of Exposure (MOE) of 100 is considered adequate for occupational exposure via dermal and inhalation routes. The results of the worker exposure assessment indicate that all potential exposure scenarios result in MOEs $\geq$ the target MOE of 100 for dermal and inhalation for all of the seed crops treated with carboxin products being actively sold in the U.S.

MOEs for dermal exposure from on-farm seed treatment with dust formulation range from 100 to 460. MOEs for on-farm seed treatment with liquid formulation are $\geq$ 33,000 for dermal exposure and $\geq$ 3,300 for inhalation exposures. MOEs for loading and planting of treated seed are $\geq$ 2,800 for dermal exposure and $\geq$ 1,500 for inhalation exposure. MOEs for all categories of commercial seed treatment are $\geq$ 690 for dermal exposure and $\geq$ 460 for inhalation exposure.

However, to reduce worker exposure, and to bring product labels into compliance with updated Worker Protection Standard (WPS) and other regulations, the Agency has determined that the following label changes are appropriate and required for reregistration eligibility:

- Mixers/loaders/applicators/other handlers (general): wear long sleeved shirt and long pants; socks plus shoes; chemical resistant gloves except when bagging or sewing bags of treated seeds; chemical resistant aprons when mixing and participating in dip treatments.
- Mixers/loaders/applicators/other handlers (bulbs or corms): When opening this packaging or loading/pouring the treated {bulbs or corms}, wear long-sleeved shirt, long pants, shoes, socks, and chemical resistant gloves.
- Mixers/loaders/applicators/other handlers (packaged seed): seed that has been treated with this product that is then packaged or bagged for future use must bear labeling that contains the restricted-entry interval (REI) information and the following text on the outside of the seed package or bag: "When opening this bag or loading/pouring the treated seed, wear long-sleeved shirt, long pants, shoes, socks, and chemical resistant gloves." "Treated Seed - Do Not Use for Food, Feed, or Oil Purposes."

2) Post-Application Risk Mitigation

EPA has determined that the minimum 12 hour REI is appropriate, and labels must contain the following language to be eligible for reregistration:

"After the seeds/bulbs/corms have been planted, do not enter or allow worker entry into treated areas during the REI of 12 hours. Exception: Once the seeds/bulbs/corms are planted in soil or other planting media, the Worker Protection Standard allows workers to enter the treated area without restriction if there will be no worker contact with the soil/media subsurface. Personal protective equipment (PPE) required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, or treated seed, is coveralls, shoes plus socks, and chemical-resistant gloves made of any waterproof material."

2. Environmental Risk Mitigation

Carboxin is a mobile compound (Kd = 0.78 L per kg-soil) that degrades rapidly in the environment; however, its primary degradates, i.e., carboxin sulfoxide and carboxin sulfone, are more likely to persist. The primary routes of degradation of carboxin are via aerobic soil metabolism (mean half life (T½) = 1.25 days) and aqueous photolysis (T½ = 1.5 hours).
The only exceedance of acute risk levels of concern (LOCs) involve seed-eating mammals at maximum seed application rates used for onions and cotton (RQ range: 0.12 - 0.24). Chronic risk LOCs for birds (range 2.5 - 27) are exceeded for all of the uses evaluated; however chronic risk LOCs for mammals are only exceeded on barley, cotton, oats, onion, peanuts and wheat. Based on environmental concentrations in surface water, no acute LOCs are exceeded for aquatic animals or plants.

To mitigate risks to ecosystems as well as mammalian, avian, and aquatic species, the Agency requires the following language to be added to the label: "Do not apply to water, 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 or by disposal of wastes. Treated seed exposed on soil surface may be hazardous to birds. Cover or collect spilled seeds."

No further mitigation is needed at this time. Considering the conservative assumptions used in the assessment models (highest rates with multiple applications) the risks to non-target organisms are considered to be within an acceptable range.

3. Other Labeling Requirements

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

4. Endangered Species Considerations

a. The Endangered Species Program

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 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 ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. This analysis will consider the risk mitigation measures that are being implemented as a result of this RED.

A determination that there is a likelihood of potential impact to a listed species may result in limitations on use of the pesticide, other measures to mitigate any potential impact, or consultations with the U.S. Fish and Wildlife Service and/or the National Marine Fisheries Service as necessary.

The Endangered Species Protection Program as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim

program, the Agency has developed County Specific Bulletins that articulate many of the specific measures outlined in the Biological Opinions issued to date. The Pamphlets are available for voluntary use by pesticide applicators on EPA's website at www.epa.gov/espp.

b. General Risk Mitigation

The endangered species risk mitigation strategies described in this document address risks associated with carboxin as a sole active ingredient. Carboxin end use products (EPs) may also contain other registered pesticides. To address the risks posed by these end use products, the Agency requires that users adopt all endangered species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting endangered species risk mitigation measures, the more stringent measure(s) should be adopted.

The Agency believes that the risks posed by carboxin to most endangered species will be adequately mitigated by adhering to best management practices and covering or collecting spilled seeds treated with carboxin. To be eligible for reregistration the following language must be added to the label:

"Do not apply to water, 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 or by disposal of wastes. Treated seed exposed on soil surface may be hazardous to birds. Cover or collect spilled seeds."

c. Species-Specific Risk Mitigation

The Agency's initial assessment suggested that eight endangered species may potentially be impacted by carboxin: the Delmarva fox squirrel (*Sciurus niger cinereus*), six species of kangaroo rat *(Dipodomys spp*.), and the Attwater's Prairie Chicken (*Tympanuchus cupido attwateri*). These species are known to consume seeds and may occur near field crops.

The Agency has determined that the risk of either acute mortality or chronic effects to kangaroo rats or fox squirrels is not considered likely and no additional mitigation measures are required. The Attwater's Prairie Chicken may be at risk for consuming unacceptable levels of carboxin treated seed and, to be eligible for reregistration, the Agency requires that additional risk mitigation measures be implemented.

Attwater's Prairie Chicken In addition to the general risk mitigation measures discussed above, the Agency will issue new or revised County Specific Bulletins for the Attwater's Prairie Chicken in Austin, Colorado, and Galveston Counties in Texas. These bulletins will allow the Agency to communicate to users the species-specific mitigation measures discussed in this document as well as any additional or updated measures as necessary. Specifically, the bulletins will require minimum planting depths and subsequent discing for carboxin-treated seed planted within one mile of the U.S. Fish and Wildlife Service's Attwater Prairie Chicken National Wildlife Refuge and The Nature Conservancy's Texas City Preserve.

County Specific Bulletins currently exist for Austin and Colorado Counties in Texas. These bulletins address use limitations for aerial and granular pesticide applications, and will be revised to address seed treatments. A County Specific Bulletin does not exist for Galveston County in Texas and

will be created. The Agency will ensure that the new or revised bulletins for these three counties include carboxin endangered species information before the updated product labels are issued.

To be eligible for reregistration, the Agency requires that the following language be added to product labels:

"This product may have effects on federally listed threatened or endangered species or their critical habitat in some counties. It is a violation of federal law to kill, harm or harass listed animal species without authorization. To limit the potential for such impacts when using this product, consult and follow the instructions provided in the EPA Endangered Species Bulletin for the County or Parish in which you are applying the seed. To determine whether your County or Parish has a Bulletin consult http://www.epa.gov/espp before each season's use of this product."

"Seed that has been treated with this product that is then packaged or bagged for future use must contain the following labeling on the outside of the seed package or bag:"

"This bag contains seed treated with carboxin. This product may have effects on federally listed threatened or endangered species or their critical habitat in some counties. It is a violation of federal law to kill, harm or harass listed animal species without authorization. To limit the potential for such impacts when using this product, consult and follow the instructions provided in the EPA Endangered Species Bulletin for the County or Parish in which you are applying the seed. To determine whether your County or Parish has a Bulletin consult http://www.epa.gov/espp before each season's use of this product."

EPA plans to require carboxin registrants to implement the measures specified above to mitigate the potential risks to Attwater's prairie chicken, an endangered species. As discussed in the Federal Register notice describing EPA's proposed Endangered Species Protection Program (ESPP), 67 FR 71,549 (December 2, 2002), such risk mitigation measures would be implemented through changes to pesticide product labeling and county bulletins. Under the ESPP, registrants would amend their labeling to include a statement requiring users to obtain and follow requirements set forth in a bulletin developed for affected counties. The restrictions contained in the bulletin would be designed to protect threatened and endangered species to the extent necessary in each affected county. County bulletins would be available through EPA's website, as well as through local distribution sources. EPA expects to finalize its ESPP in the near future, and the risk mitigation measures described in this RED will be implemented consistent with the provisions of the final ESPP.

d. Endangered Species Determination

Based on the ecological risk assessment conducted for carboxin and the implementation of the risk mitigation measures described above, EPA has determined that carboxin will have no effect on any endangered or threatened species or their critical habitat, with the possible exception of the Attwater's prairie chicken. With regard to the Attwater's prairie chicken, EPA concludes that there is very little likelihood carboxin will have any impact on this species. The Agency, however, wishes to collect and analyze additional information before making a determination under the Endangered Species Act whether carboxin either has "no effect" or is "not likely to adversely affect" the Attwater's prairie chicken. EPA intends to make such determinations prior to completing the product specific reregistration for carboxin. If EPA determines that carboxin "may affect," e.g., is not likely to adversely affect, the Attwater's prairie chicken, EPA will comply with the requirements in the consultation regulations promulgated by the U.S. Fish & Wildlife Service and the National Marine Fisheries Service in 50 CFR Part 402.

V. What Registrants Need to Do

The Agency has determined that carboxin is eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision; and (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants must amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table in Section B below (Table 14). The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For carboxin technical grade active ingredient products, the registrant needs to submit the following items:

Within 90 days from receipt of the generic data call in (DCI):

1. completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and
2. submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

1. cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Lance Wormell at (703) 603-0523 with questions regarding generic reregistration.

By US mail:
Document Processing Desk (DCI/SRRD)
Lance Wormell
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Lance Wormell
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1801 S. Bell Street
Arlington, VA 22202

For end use products containing the active ingredient carboxin, the registrant needs to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

1. completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and
2. submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. two copies of the confidential statement of formula (EPA Form 8570-4);
2. a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";
3. five copies of the draft label incorporating all label amendments outlined in Table 14 of this document;
4. a completed form certifying compliance with data compensation requirements (EPA Form 8570-34); and
5. if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and
6. the product-specific data responding to the PDCI.

Please contact Barbara Briscoe at (703) 308-8177 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk (PDCI/PRB)
Barbara Briscoe
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (PDCI/PRB)
Barbara Briscoe
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of carboxin for the above eligible uses has been reviewed and determined to be substantially complete. However, the following data requirements listed in Table 13 are necessary to confirm the reregistration eligibility decision documented in this RED.

Table 13. Data Requirements for the Reregistration Eligibility Decision on Carboxin

Guideline	Study Title
830.1620	Description of Production Process
830.7050	UV/Visible Absorption
835.1230	Sediment and Soil Adsorption/Desorption for Parent and Degradates
835.1240	Soil Column Leaching
835.2410	Photodegradation of Parent and Degradates in Soil
850.1035	Acute Toxicity Test for Estuarine and Marine Organisms
850.1400	Fish Early-Life Stage Toxicity Test
850.1300	Daphnid Chronic Toxicity Test
860.1340	Residue Analytical Method
860.1500	Crop Field Trials
870.3465	28-Day Inhalation Toxicity

2. Labeling for Technical and Manufacturing-Use Products

To ensure compliance with FIFRA, technical and manufacturing use product (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The Technical and MP labeling should bear the labeling contained in Table 14, Label Changes Summary Table.

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 meed 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.

A product-specific data call-in, outlining specific data requirements, accompanies this RED.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 14.

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 52 months from the approval of labels reflecting the mitigation described in this RED. However, 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. Refer to "Existing Stocks of Pesticide Products; Statement of Policy,"*Federal Register*, Volume 56, No. 123, June 26, 1991.

a. Label Changes Summary Table

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

Table 14. Carboxin Label Changes Summary Table

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

Description	Amended Labeling Language	Placement on Label
End Use Products Intended for Occupational Use (WPS and Non-WPS)		
PPE Requirements Established by the RED[1] for wettable powders, dry flowables, and liquid concentrates	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators, and other handlers must wear: - long sleeved shirt and long pants, - socks plus shoes, - chemical resistant gloves, *except* when bagging or sewing bags of treated seeds, - chemical resistant aprons when mixing, loading, or participating in dip treatments."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED[1] for dust formulations	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart." "All loaders, applicators, and other handlers must wear: - long sleeved shirt and long pants, - socks plus shoes, - chemical resistant gloves, *except* when bagging or sewing bags of treated seeds, - chemical resistant aprons when loading."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED[1] for ready-to-use formulations	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators, and other handlers must wear: - long sleeved shirt and long pants, - socks plus shoes, - chemical resistant gloves, *except* when bagging or sewing bags of treated seeds, - chemical resistant aprons when loading or participating in dip treatments."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

Description	Amended Labeling Language	Placement on Label
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not apply to water, 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 or by disposal of wastes. Treated seed exposed on soil surface may be hazardous to birds. Cover or collect spilled seeds."	Precautionary Statements immediately following the User Safety Recommendations
Environmental Hazards Statements Required by the RED and Agency Label Policies	Endangered Species "This bag contains seed treated with carboxin. This product may have effects on federally listed threatened or endangered species or their critical habitat in some counties. It is a violation of federal law to kill, harm or harass listed animal species without authorization. To limit the potential for such impacts when using this product, consult and follow the instructions provided in the EPA Endangered Species Bulletin for the County or Parish in which you are applying the seed. To determine whether your County or Parish has a Bulletin consult http://www.epa.gov/espp before each season's use of this product."	Precautionary Statements immediately following the User Safety Recommendations

Description	Amended Labeling Language	Placement on Label
Restricted-Entry Interval for products that contain uses within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) (on-farm planter box or hopper box treatments and on-nursery bulb or corm dipping) NOTE: if the pesticide label doesn't have directions for use on bulbs or corms, those words can be dropped from the exception statement.	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours. Exception: Once the seeds, corms, or bulbs are planted in soil or other planting media, the Worker Protection Standard allows workers to enter the treated area without restriction if there will be no worker contact with the soil/media subsurface."	Directions for Use, Under Agricultural Use Requirements Box
Early Entry Personal Protective Equipment for products with directions for use within the scope of the WPS	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, or treated seed, is: * coveralls, * shoes plus socks, * chemical-resistant gloves made of any waterproof material."	Direction for Use Agricultural Use Requirements Box
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons. Only protected handlers may be in the area during application."	Place in the Direction for Use directly above the Agricultural Use Box

Description	Amended Labeling Language	Placement on Label
Environmental Hazards Statements Required by the RED and Agency Label Policies for seed that has been treated with this product that is then packed or bagged for future use	"Seed that has been treated with this product that is then packaged or bagged for future use must contain the following labeling on the outside of the seed package or bag:" "This bag contains seed treated with carboxin. This product may have effects on federally listed threatened or endangered species or their critical habitat in some counties. It is a violation of federal law to kill, harm or harass listed animal species without authorization. To limit the potential for such impacts when using this product, consult and follow the instructions provided in the EPA Endangered Species Bulletin for the County or Parish in which you are applying the seed. To determine whether your County or Parish has a Bulletin consult http://www.epa.gov/espp before each season's use of this product." "Treated seed exposed on soil surface may be hazardous to birds. Cover or collect spilled seeds."	Directions for Use
Application Restrictions for seed that has been treated with this product that is then packaged or bagged for future use	"Seed that has been treated with this product that is then packaged or bagged for future use must contain the following labeling on the outside of the seed package or bag:" "When opening this bag or loading/pouring the treated seed, wear long-sleeved shirt, long pants, shoes, socks, and chemical resistant gloves." "Treated Seed - Do Not Use for Food, Feed, or Oil Purposes. "After the seeds have been planted, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours. Exception: Once the seeds are planted in soil or other planting media, the Worker Protection Standard allows workers to enter the treated area without restriction if there will be no worker contact with the soil/media subsurface."	Directions for Use
Application Restrictions for seed that has been treated with this product that is then packaged or bagged for future use	All grazing or feeding restrictions currently mandated on the pesticide labeling must be retained and placed on the label of the seed package or bag.	Directions for Use

Description	Amended Labeling Language	Placement on Label
Application Restrictions for bulbs and corms that have been treated with this product that is then packaged or bagged for future use	"Seed that has been treated with this product that is then packaged or bagged for future use must contain the following labeling on the outside of the seed package or bag:" "This package contains {bulbs or corms} treated with carboxin. When opening this packaging or loading/pouring the treated {bulbs or corms}, wear long-sleeved shirt, long pants, shoes, socks, and chemical resistant gloves." "Treated {Bulbs or Corms} - Do Not Use for Food, Feed, or Oil Purposes." "After the {bulbs or corms} have been planted, do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours. Exception: Once the {bulbs or corms} are planted in soil or other planting media, the Worker Protection Standard allows workers to enter the treated area without restriction if there will be no worker contact with the soil/media subsurface."	Directions for Use
Engineering controls for all formulations, except dusts	"Engineering Controls" "When handlers use closed systems designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people AND the system is functioning properly and is used and maintained in accordance with the manufacturer's written operating instructions, the handlers need not wear the chemical-resistant apron. However, the chemical-resistant gloves must be immediately available for use in an emergency, such as a spill or equipment breakdown."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements)

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

Appendix A. Food/Feed Use Patterns Subject to Reregistration for Carboxin

Appendix A. Food/Feed Use Patterns Subject to Reregistration for Carboxin

SITE NAME	Product/Site Limitations				
Application Type (for any Reg.# at any rate) (aggregate) **Application Timing (for any Reg.# at any rate)** Application Equipment (for any Reg.# at any rate) (aggregate)	Max. Single Appl. Rate (AI unless noted otherwise) Inconvertible Label (L) Dosages Also Present	Max. Seasonal Rate (L) Dosages Also Present	Max. No. of Apps Per Crop Cycle (cc) and Year (at any rate)	Min. Retmt. Interv. (days)	PHI/PGI/PSI Use Limitations (at any rate) (May not apply to all Reg. #s within group)
BARLEY	42 day(s) prefeeding interval. 42 day(s) pregrazing interval. Do not graze or feed livestock on treated areas for 42 days after planting. Do not use treated seed for feed, food or oil purposes. Treated seed must not be used for or mixed with food or animal feed or processing oil.				
Seed treatment **At planting** Drill box/Planter/seed box/Seed treater	.1875 lb cwt	NS	NS NS	NS	
Seed treatment **Preplant** Seed treater/Slurry-type seed treater	.07828 lb cwt	NS	NS NS	NS	
Seed treatment **Seed** Liquid seed treater/Mist-type seed treater/Slurry-type seed treater	.1875 lb cwt	NS	NS NS	NS	
BEANS	Do not allow livestock to graze or feed on bean forage until 60 days after treated seed is planted. Do not graze or feed livestock on hay grown from treated seed. Do not graze or feed livestock on treated areas for 42 days after planting. Do not use treated seed for feed, food or oil purposes. Treated seed must not be used for or mixed with food or animal feed or processing oil.				
Seed treatment **At planting** Planter/seed box/Seed treater	.075 lb cwt	NS	NS NS	NS	

SITE NAME	Product/Site Limitations				
Application Type (for any Reg.# at any rate) (aggregate) **Application Timing (for any Reg.# at any rate)** Application Equipment (for any Reg.# at any rate) (aggregate)	Max. Single Appl. Rate (AI unless noted otherwise) Inconvertible Label (L) Dosages Also Present	Max. Seasonal Rate (L) Dosages Also Present	Max. No. of Apps Per Crop Cycle (cc) and Year (at any rate)	Min. Retmt. Interv. (days)	PHI/PGI/PSI Use Limitations (at any rate) (May not apply to all Reg. #s within group)
Seed treatment **Preplant** Slurry-type seed treater	.1044 lb cwt	NS	NS NS	NS	

SITE NAME	Product/Site Limitations				
Application Type (for any Reg.# at any rate) (aggregate) **Application Timing (for any Reg.# at any rate)** Application Equipment (for any Reg.# at any rate) (aggregate)	Max. Single Appl. Rate (AI unless noted otherwise) Inconvertible Label (L) Dosages Also Present	Max. Seasonal Rate (L) Dosages Also Present	Max. No. of Apps Per Crop Cycle (cc) and Year (at any rate)	Min. Retmt. Interv. (days)	PHI/PGI/PSI Use Limitations (at any rate) (May not apply to all Reg. #s within group)
CORN (UNSPECIFIED)	42 day(s) pregrazing interval. Do not graze or feed livestock on treated areas for 42 days after planting. Do not use treated seed for feed, food or oil purposes. Treated seed must not be used for or mixed with food or animal feed or processing oil.				
Seed treatment **At planting** Drill box/Planter/seed box/Seed treater	.0375 lb bu .09375 lb cwt	NS	NS NS	NS	
Seed treatment **Preplant** Seed treater/Slurry-type seed treater	.0175 lb bu .1044 lb cwt	NS	NS NS	NS	
CORN, FIELD	42 day(s) prefeeding interval. 42 day(s) pregrazing interval. Do not use treated seed for feed, food or oil purposes. Rotational/plant back crop restriction.				
Seed treatment **Seed** Planter/seed box	.03125 lb cwt	NS	NS NS	NS	
CORN, POP	42 day(s) prefeeding interval. 42 day(s) pregrazing interval. Do not use treated seed for feed, food or oil purposes. Rotational/plant back crop restriction.				
Seed treatment **Seed** Planter/seed box	.03125 lb cwt	NS	NS NS	NS	

SITE NAME	Product/Site Limitations				
Application Type (for any Reg.# at any rate) (aggregate) **Application Timing (for any Reg.# at any rate)** Application Equipment (for any Reg.# at any rate) (aggregate)	Max. Single Appl. Rate (AI unless noted otherwise) Inconvertible Label (L) Dosages Also Present	Max. Seasonal Rate (L) Dosages Also Present	Max. No. of Apps Per Crop Cycle (cc) and Year (at any rate)	Min. Retmt. Interv. (days)	PHI/PGI/PSI Use Limitations (at any rate) (May not apply to all Reg. #s within group)
CORN, SWEET	42 day(s) prefeeding interval. 42 day(s) pregrazing interval. Do not use treated seed for feed, food or oil purposes. Rotational/plant back crop restriction.				
Seed treatment **Seed** Planter/seed box	.03125 lb cwt	NS	NS NS	NS	
COTTON (UNSPECIFIED)	49 day(s) pregrazing interval. Do not graze or feed livestock on hay grown from treated seed. Do not graze or feed livestock on treated areas for 42 days after planting. Do not graze or feed livestock on treated areas or on hay grown from treated seed. Do not use treated seed for feed, food or oil purposes. Seed treatment only. Treated seed must not be used for or mixed with food or animal feed or processing oil.				
Seed treatment **At planting** Planter/seed box/Seed treater	.375 lb cwt	NS	NS NS	NS	
Seed treatment **Preplant** Slurry-type seed treater	.20875 lb cwt	NS	NS NS	NS	
Seed treatment **Seed** Liquid seed treater/Mist-type seed treater/Seed treater/Slurry-type seed treater	.375 lb cwt	NS	NS NS	NS	

SITE NAME	Product/Site Limitations				
Application Type (for any Reg.# at any rate) (aggregate) **Application Timing (for any Reg.# at any rate)** Application Equipment (for any Reg.# at any rate) (aggregate)	Max. Single Appl. Rate (AI unless noted otherwise) Inconvertible Label (L) Dosages Also Present	Max. Seasonal Rate (L) Dosages Also Present	Max. No. of Apps Per Crop Cycle (cc) and Year (at any rate)	Min. Retmt. Interv. (days)	PHI/PGI/PSI Use Limitations (at any rate) (May not apply to all Reg. #s within group)
OATS	42 day(s) prefeeding interval. 42 day(s) pregrazing interval. Do not graze or feed livestock on treated areas for 42 days after planting. Do not use treated seed for feed, food or oil purposes. Treated seed must not be used for or mixed with food or animal feed or processing oil.				
Seed treatment **At planting** Drill box/Planter/seed box/Seed treater	.09375 lb cwt	NS	NS NS	NS	
Seed treatment **Preplant** Seed treater/Slurry-type seed treater	.07828 lb cwt	NS	NS NS	NS	
Seed treatment **Seed** Liquid seed treater/Mist-type seed treater/Slurry-type seed treater	.09375 lb cwt	NS	NS NS	NS	
ONION	Seed treatment only. Geographic allowable: NJ				
Seed treatment Seed treater	.75 lb cwt	NS	NS NS	NS	
PEANUTS (UNSPECIFIED)	Do not graze or feed livestock on hay grown from treated seed. Do not graze or feed livestock on treated areas or on hay grown from treated seed. Do not hog down treated fields. Do not use seed for food, feed or oil purposes. Do not use treated seed for feed, food or oil purposes. Do not use treated seed pieces for food or feed purposes.				

SITE NAME	Product/Site Limitations				
Application Type (for any Reg.# at any rate) (aggregate) **Application Timing (for any Reg.# at any rate)** Application Equipment (for any Reg.# at any rate) (aggregate)	Max. Single Appl. Rate (AI unless noted otherwise) Inconvertible Label (L) Dosages Also Present	Max. Seasonal Rate (L) Dosages Also Present	Max. No. of Apps Per Crop Cycle (cc) and Year (at any rate)	Min. Retmt. Interv. (days)	PHI/PGI/PSI Use Limitations (at any rate) (May not apply to all Reg. #s within group)
Seed treatment **At planting** Planter/seed box/Seed treater	.28125 lb cwt	NS	NS NS	NS	
Seed treatment **Seed** Liquid seed treater/Mist-type seed treater/Not on label/Seed treater/Slurry-type seed treater	.28125 lb cwt	NS	NS NS	NS	
RICE	42 day(s) prefeeding interval. 49 day(s) pregrazing interval. Do not use treated seed for feed, food or oil purposes. Seed treatment only.				
Seed treatment **At planting** Planter/seed box/Seed treater	.08325 lb cwt	NS	NS NS	NS	
Seed treatment **Seed** Mist-type seed treater/Slurry-type seed treater	.06054 lb cwt	NS	NS NS	NS	
SAFFLOWER (UNSPECIFIED)	Do not apply through any type of irrigation system. Do not graze or feed livestock on treated areas for 42 days after planting. Treated seed must not be used for or mixed with food or animal feed or processing oil.				
Seed treatment **Preplant** Slurry-type seed treater	.05219 lb cwt	NS	NS NS	NS	

SITE NAME	Product/Site Limitations				
Application Type (for any Reg.# at any rate) (aggregate) **Application Timing (for any Reg.# at any rate)** Application Equipment (for any Reg.# at any rate) (aggregate)	Max. Single Appl. Rate (AI unless noted otherwise) Inconvertible Label (L) Dosages Also Present	Max. Seasonal Rate (L) Dosages Also Present	Max. No. of Apps Per Crop Cycle (cc) and Year (at any rate)	Min. Retmt. Interv. (days)	PHI/PGI/PSI Use Limitations (at any rate) (May not apply to all Reg. #s within group)
SOYBEANS (UNSPECIFIED)	42 day(s) prefeeding interval. 42 day(s) pregrazing interval. Do not graze or feed forage or hay from treated areas to livestock. Do not graze or feed livestock on hay grown from treated seed. Do not graze or feed livestock on treated areas for 42 days after planting. Do not use treated seed for feed, food or oil purposes. Rotational/plant back crop restriction. Seed treatment only. Treated seed must not be used for or mixed with food or animal feed or processing oil.				
Seed treatment **At planting** Planter/seed box/Seed treater	.06263 lb cwt	NS	NS NS	NS	
Seed treatment **Preplant** Planter/seed box/Seed treater/Slurry-type seed treater	.1044 lb cwt	NS	NS NS	NS	
Seed treatment **Seed** Planter/seed box/Slurry-type seed treater	.0525 lb cwt	NS	NS NS	NS	
TRITICALE	Do not apply through any type of irrigation system. Do not graze or feed livestock on treated areas for 42 days after planting. Treated seed must not be used for or mixed with food or animal feed or processing oil.				
Seed treatment **Preplant** Slurry-type seed treater	.07828 lb cwt	NS	NS NS	NS	
WHEAT	42 day(s) prefeeding interval.				

SITE NAME	Product/Site Limitations				
Application Type (for any Reg.# at any rate) (aggregate) **Application Timing (for any Reg.# at any rate)** Application Equipment (for any Reg.# at any rate) (aggregate)	Max. Single Appl. Rate (AI unless noted otherwise) Inconvertible Label (L) Dosages Also Present	Max. Seasonal Rate (L) Dosages Also Present	Max. No. of Apps Per Crop Cycle (cc) and Year (at any rate)	Min. Retmt. Interv. (days)	PHI/PGI/PSI Use Limitations (at any rate) (May not apply to all Reg. #s within group)
	42 day(s) pregrazing interval. Do not contaminate water, food or feed. Do not contaminate water, food, or feed by storage or disposal. Do not graze or feed livestock on treated areas for 42 days after planting. Do not use treated seed for feed, food or oil purposes. Treated seed must not be used for or mixed with food or animal feed or processing oil.				
Seed treatment **At planting** Drill box/Planter/seed box/Seed treater	.02813 lb bu .1875 lb cwt	NS	NS NS	NS	
Seed treatment **Preplant** Seed treater/Slurry-type seed treater	.07828 lb cwt	NS	NS NS	NS	
Seed treatment **Seed** Liquid seed treater/Mist-type seed treater/Seed treater/Slurry-type seed treater	.1875 lb cwt	NS	NS NS	NS	
Product Number(s) Contained in this Report : 000400-00080 000400-00106 000400-00107 000400-00113 000400-00115 000400-00124 000400-00152 000400-00438 000400-00439 007501-00036 007501-00037 007501-00043 007501-00087 007501-00112 007501-00139 007501-00145 007501-00152 007501-00166 007501-00189 042056-00021 042056-00024 NJ94000100					

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

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

REQUIREMENT			USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY				
New Guideline Number	**Old Guideline Number**	**Requirement**	**Use Pattern**	**Citation(s)**
830.1550	**61-1**	**Product Identity and Composition**	All	Data gap for 75% FI, 42877204, 43515401
830.1600	**61-2A**	**Description of Materials Used to Produce the Product**	All	Data gap for 75% FI, 42877201
830.1620	**61-2B**	**Description of Production Process**	All	Data gap, 42877201
830.1650	**158.165**	**Description of Formulation Process**	All	Data gap for 75% FI
830.1670	**61-2B**	**Formation of Impurities**	All	Data gap for 75% FI, 42877202
830.1700	**62-1**	**Preliminary Analysis**	All	42877203, 42877204
830.1750	**62-2**	**Certification of Limits**	All	Data gap for 75% FI, 42877204, 43515401
830.1800	**62-3**	**Analytical Method**	All	Data gap for 75% FI, 42493701, 42877203
830.6302	**63-2**	**Color**	All	Data gap for 75% FI, 00005859
830.6303	**63-3**	**Physical State**	All	00005859
830.6304	**63-4**	**Odor**	All	Data gap for 75% FI, 42493702
830.6313	**63-13**	**Stability to Normal and Elevated Temperatures, Metals, and Metal Ions**	All	42709001, 42709002, 42709003
830.6314	**63-14**	**Oxidation/Reduction: Chemical Incompatibility**	All	Data gap for 75% FI, 42493707
830.6316	**63-16**	**Explodability**	All	Data gap for 75% FI, 42493708
830.6317	**63-17**	**Storage Stability**	All	Data gap for 75% FI, 43040301
830.6320	**63-20**	**Corrosion Characteristics**	All	Data gap for 75% FI, 43040302

REQUIREMENT			USE PATTERN	CITATION(S)
830.7000	**63-12**	**pH**	All	Data gap for 75% FI, 42493706
830.7050	**None**	**UV/Visible Absorption**	All	Data gap
830.7200	**63-5**	**Melting Point**	All	00005859
830.7300	**63-7**	**Density**	All	00005859
830.7370	**63-10**	**Dissociation Constants in Water**	All	42493704
830.7550	**63-11**	**Partition Coefficient, Shake Flask Method**	All	42493705
830.7840	**63-8**	**Solubility**	All	00005859
830.7950	**63-9**	**Vapor Pressure**	All	42493703
ECOLOGICAL EFFECTS				
850.2100	**71-1A**	**Avian Acute Oral Toxicity**	A, B	43582301
850.2200	**71-2**	**Avian Dietary Toxicity**	A, B	43582303, 43582302, 00003037, 00029175, 00003139
850.1075	**72-1A**	**Fish Toxicity Bluegill**	A, B	43582304, Acc. No. 224935
850.1075	**72-1C**	**Fish Toxicity Rainbow Trout**	A, B	43582305, Acc. No. 224935
850.1010	**72-2A**	**Invertebrate Toxicity**	A, B	Acc. No. 235236, 43582306
850.1035	**72-3**	**Acute Toxicity Test for Estuarine and Marine Organisms**	A, B	Data gap, 165048A
850.1300	**72-4**	**Freshwater Invertebrate Life Cycle**	A, B	Data gap
850.1400	**72-4**	**Freshwater Fish- Acute Toxicity**	A, B	Data gap
850.2300	**71-4**	**Avian Reproduction Test**	A, B	44240102, 44240101
850.4400	**122-2, 123-2**	**Aquatic Plant Toxicity Test Using *Lemna* spp., Tiers I and II**	A, B	41493802
850.5400	**122-2**	**Algal Toxicity Test, Tiers I and II**	A, B	41317801, 41493801
TOXICOLOGY				

REQUIREMENT			USE PATTERN	CITATION(S)
870.1100	**81-1**	**Acute Oral Toxicity-Rat**	All	43171401
870.1200	**81-2**	**Acute Dermal Toxicity-Rabbit/Rat**	All	43171402
870.1300	**81-3**	**Acute Inhalation Toxicity-Rat**	All	43171403
870.2400	**81-4**	**Primary Eye Irritation-Rabbit**	All	43171404
870.2500	**81-5**	**Primary Skin Irritation**	All	43171405
870.2600	**81-6**	**Dermal Sensitization**	All	00105980
870.3100	**82-1A**	**Subchronic Oral Toxicity: 90-Day Study Rodent**	A, B	45695501, 42391106
870.3200	**82-2**	**21-Day Dermal - Rabbit/Rat**	A, B	45695503
870.3465	**82-4**	**90-Day Inhalation-Rat**	A, B	Data gap for 28-day inhalation
870.3700	**83-3A**	**Developmental Toxicity - Rat**	A, B	45261401
870.3700	**83-3B**	**Developmental Toxicity - Rabbit**	A, B	00086054, 42391104, 42391105
870.3800	**83-4**	**2-Generation Reproduction - Rat**	A, B	41922601, 42391107
870.4300	**83-5**	**Combined Chronic Toxicity/ Carcinogenicity: Rats**	A, B	41882902, 42391101, 42391102, 42391106
870.4100	**83-1**	**Chronic Toxicity in Dogs**	A, B	41882901, 42391103
870.4200	**83-2B**	**Carcinogenicity Mice**	A, B	00114139, 42533301, 42533302
870.5100	**84-2**	**Bacterial Reverse Gene Mutation**	A, B	00132453
870.5375	**84-2B**	**Cytogenetics**	A, B	45541102
870.5385	**84-2**	***In Vivo* Mammalian Chromosome Aberration Test (CHO cells)**	A, B	00152339, 45541101
870.5550	**84-2**	**UDS in Primary Rat Hepatocytes**	A, B	00132454
870.7485	**85-1**	**General Metabolism**	A, B	42656501, 42656502

REQUIREMENT			USE PATTERN	CITATION(S)
ENVIRONMENTAL FATE				
835.2120	**161-1**	**Hydrolysis**	A, B	Acc. No. 254339
835.2240	**161-2**	**Photodegradation - Water**	A, B	42192801
835.2410	**161-3**	**Photodegradation - Soil**	A, B	Data gap
835.4100	**162-1**	**Aerobic Soil Metabolism**	A, B	41242503, 41242504, 41252501, 41224501, 41224502
835.4200	**162-2**	**Anaerobic Soil Metabolism**	A, B	41224507, 41286601, 41224508, 41314303, 41725501
835.4400	**162-3**	**Anaerobic Aquatic Metabolism**	A, B	42600803
835.4300	**162-4**	**Aerobic Aquatic Metabolism**	A, B	42600801
835.1230	**163-1**	**Sediment and Soil Adsorption/Desorption for Parent and Degradates**	A, B	Data gap
835.1240	**163-1**	**Leaching/Adsorption/Desorption**	A, B	Data gap, 00005541, 00003227, 00003229
835.6100	**164-1**	**Terrestrial Field Dissipation**	A, B	41259401-A
RESIDUE CHEMISTRY				
860.1300	**171-4A**	**Nature of Residue - Plants**	A, B	00002941, 00003044, 00125661, 05001172, 05001302, 05001304, 05002177, 05002793, 05002886, 05003663, 05003664, 05003673, 05006363, 05013368, 42977501, 43356601, 43356602, 43736402, 43736403, 43736404, 43736405
860.1340	**171-4C**	**Residue Analytical Method - Plants**	A, B	Data gap, 00002905, 00002919, 00002940, 00003054, 00003058, 00003335, 00025467, 00025468, 00025483, 05002737, 44485903
860.1340	**171-4C**	**Residue Analytical Method - Animals**	A, B	Data gap, 00002857, 00003058, 44485904
860.1360	**171-4M**	**Multiresidue Method**	A, B	43370901

REQUIREMENT			USE PATTERN	CITATION(S)
860.1380	**171-4E**	**Storage Stability - Plants**	A, B	00025466, GS001201, 42782801, 45788001, 45788002, 45788003, 45788004
860.1480	**171-4J**	**Magnitude of the Residue - Meat, Milk, Poultry, Eggs**	A, B	00002945
860.1500	**171-K**	**Crop Field Trials (Bulb Vegetables)**	A, B	41032701
860.1500	**171-K**	**Crop Field Trials (Legume Vegetables)**	A, B	00096675, 00128613
860.1500	**171-K**	**Crop Field Trials (Cereal Grains)**	A, B	00003158, 00003221, 00025468, 00003356, 00005852, 00025483, 00003220, 00003054, 00002961, 00003045, 00003218, 00003219
860.1500	**171-K**	**Crop Field Trials (Forage, Fodder, and Straw of Cereal Grains)**	A, B	Data gap for barley, oat, and wheat hay, 00003158, 00003221, 00025468, 00003220, 00003045, 00003054, 00002961, 00003045, 00003218, 00003219
860.1500	**171-4K**	**Crop Field Trials (Miscellaneous Commodity)**	A, B	Data gap for cotton gin byproducts, 44875601, 00003129, 00003185, 00025468, 00002903, 00002905, 00003045, 00003300, 00165338
860.1520	**171-4L**	**Processed Food/Feed**	A, B	44875601, 44957401, 44485901, 44485902, 00002938, 00003300, 00125661, 45205402, 44721001, 45205401
860.1900	**165-2**	**Field Accumulation in Rotational Crop Study**	A, B	40500901, 00003114

Appendix C. Technical Support Documents

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 Bell St., Arlington, VA 22202. It is open Monday through Friday, excluding legal holidays, from 8:30 AM to 4:00 PM..

The docket initially contained preliminary risk assessments and related documents as of April 28, 2004. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket.

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

http://www.epa.gov/edockets

These documents include:

1. Environmental Fate and Ecological Risk Assessment for the Registration of Carboxin (Revised). 19-Aug-2004.
2. Carboxin HED Risk Assessment for Reregistration Eligibility Document (RED). 17-Dec-2003.
3. Carboxin Chronic Dietary Exposure Assessment for the Reregistration Eligibility Decision Document. 07-Aug-2003.
4. CARBOXIN - Report of the Hazard Identification Assessment Review Committee. 05-Jun-2003.
5. Occupational Exposure Assessment And Recommendations For The Reregistration Eligibility Decision (RED) for Carboxin. 07-Aug-2003.
6. Tolerance Reassessment Eligibility Document (TRED) of Carboxin (PC Code 090201): Product and Residue Chemistry Considerations. 07-Aug-2003.

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

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MRID	Citation
00002857	Uniroyal Chemical (1973) Enforcement Method for Vitavax in Animal Tissue, Milk and Eggs. Method dated Sep 17, 1973. (Unpub- lished study received on unknown date under 3F1318; CDL:093547-D)
00002903	Uniroyal Chemical (1974) Residue Analysis of Peanut Hulls for Vitavax^(R)I. (Unpublished study received on unknown date under 4F1499; CDL:093979-C)
00002905	Uniroyal Chemical (1974) The Effects of EPA Tolerance Pesticides upon the Recovery of Vitavax^(R)I Residues from Peanuts. (Un- published study received on unknown date under 4F1499; prepared in cooperation with Morse Laboratories, Inc.; CDL:093979-F)
00002919	Uniroyal Chemical (1975) The Effects of EPA Tolerance Pesticides upon the Recovery of Vitavax^(R)I Residues from Soybeans. (Un- published study including summary, received Jun 9, 1975 under 5F1637; prepared in cooperation with Morse Laboratories, Inc.; CDL:094947-K)
00002938	Sisken, H.R. (1970) Determination of Residual Vitavax^(R)I in Meal and Oil from Cotton and Peanut Seed. (Unpublished study received Jul 28, 1972 under 0F0939; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:091603-A)
00002940	Uniroyal Chemical (1972) Summary of Vitavax Residue Data in Corn and Small Grains. Includes method dated Nov 1, 1968. (Unpub- lished study including report, received Oct 9, 1973 under 3F1318; CDL:092254-E)
00002941	Chin, W.T.; Kucharczyk, N.; Smith, A.E. (1972) Nature of Vitavax^(R)I-Derived Bound Residues in Plants. (Unpublished study received Oct 9, 1973 under 3F1318; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:092254-F)
00002945	Kennedy, G.; Jenkins, D.H. (1971) Report to Uniroyal Chemical, Div- ision of Uniroyal, Inc.: Milk and Meat Residue Study in Dairy Cows Treated with 14C-Labeled Vitavax: IBT No. J294. (Unpub- lished study received Oct 9, 1973 under 3F1318; prepared by Industrial Bio-Test Laboratories, Inc., submitted by Uniroyal Chemical, Bethany, Conn.; CDL:092254-J)
00002961	Uniroyal Chemical (1972) ?Residue Data: Vitavax|. (Unpublished study received on unknown date under 2F1191; prepared in cooperation with Morse Laboratories and Harris Laboratories; CDL:091003-A)
00003037	Weir, R.J. (1967) Final Report: Acute Dietary Toxicity--Bobwhite Quail: Project No. 798-100. (Unpublished study received Jun 14, 1969 under 9G0819; prepared by Hazleton Laboratories, Inc., sub- mitted by Uniroyal Chemical, Bethany, Conn.; CDL:091420-O)
00003044	Chin, W.T.; Stone, G.M.; Smith, A.E. (1969) 14C-Vitavax Studies on Barley, Wheat and Cotton Plants. (Unpublished study received Jun 14, 1969 under 9G0819; Uniroyal Chemical, Bethany, Conn.; CDL:091420-W)
00003045	Uniroyal Chemical (1969) Disappearance Studies: Wheat and Barley; ?Peanut; Sorghum: Vitavax|. (Unpublished study received Jun 14, 1969 under 9G0819; CDL:091420-X)
00003054	Uniroyal Chemical (1975) The Effects of EPA Tolerance Pesticides upon the Recovery of Vitavax^(R)I Residues from Sorghum: (1) Grain, (2) Fodder and Forage. (Unpublished study including summary, received Jun 9, 1975 under 5F1638; prepared in cooper- ation with Morse Laboratories, Inc.; CDL:094948-G)
00003058	Lane, J.R. (1966) Residue Analysis for D-735 and/or F-461. Method dated May 16, 1966. (Unpublished study received Jan 25, 1967 under 400-81; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:121531-A)
00003114	Dannals, L.E.; Campbell, C.R.; Cardona, R.A. (1976) Environmental Fate Studies on Vitavax^(R)I: Status Report II on PR 70-15. Includes three undated methods. (Unpublished study received Mar 17, 1976 under 400-80; submitted by Uniroyal Chemical, Beth- any, Conn.; CDL:223866-A)
00003129	Uniroyal Chemical (1973) Residues in PPM. (Unpublished study received May 16, 1973 under 400-107; prepared in cooperation with Morse Laboratories, Inc.; CDL:003284-P)
00003139	Fink, R. (1974) Final Report: Eight-Day Dietary LCI50^--Mallard Ducks: Project No. 117-102. (Unpublished study including offi- cial analytical report, received Mar 11, 1974 under 400-106; prepared by Truslow Farms, Inc., submitted by Uniroyal Chemical, Bethany, Conn.; CDL:128723-A)
00003158	Uniroyal, Incorporated (1974) Summary of Corn and Rice Residue Data. (Unpublished study received Jun 17, 1974 under 5F1525; prepared in cooperation with Morse Laboratories, Inc. and State Univ. College of New York--Oswego, Lake Ontario Environmental Laboratory; CDL:094043-H)

00003185 Uniroyal Chemical (1967) Residue Analysis of Cotton Seedlings from Vitavax-Treated Cotton Seeds. (Unpublished study received Nov 29, 1967 under 400-EX-28; CDL:123430-A)

00003218 Uniroyal Chemical (1978) Residues in PPM: Wheat: Vitavax 25DB: Grain & Straw. (Unpublished study received May 10, 1978 under 400-115; prepared in cooperation with Morse Laboratories, Inc.; CDL:235653-B)

00003219 Uniroyal Chemical (1978) Residues in PPM: Wheat: Vitavax 25DB: Forage. (Unpublished study received May 10, 1978 under 400-115; prepared in cooperation with Morse Laboratories, Inc.; CDL: 235653-C)

00003220 Uniroyal Chemical (1978) Residues in PPM: Oats: Vitavax 25DB: Grain & Straw. (Unpublished study received May 10, 1978 under 400- 115; prepared in cooperation with Morse Laboratories, Inc.; CDL:235653-D)

00003221 Uniroyal Chemical (1977) Residues in PPM: Barley: Vitavax 25DB: Grain & Straw. (Unpublished study received May 10, 1978 under 400-115; prepared in cooperation with Morse Laboratories, Inc.; CDL:235653-E)

00003227 Lacadie, J.A.; Gerecke, D.R.; Cardona, R.A. (1978) Vitavax^(R)I- 14C Laboratory Column Leaching Study in Clay Loam: Project No. 7758. (Unpublished study received Dec 27, 1978 under 400-80;submitted by Uniroyal Chemical, Bethany, Conn.; CDL:236662-H)

00003229 Lacadie, J.A.; Dzialo, D.G.; Dannals, L.E. (1978) Vitavax^(R)I- 14C Aged Laboratory Column Leaching in Sandy Soil: Project No. 7832. (Unpublished study received Dec 27, 1978 under 400-80; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:236662-J)

00003300 Collier, Y.J.; Womer, J.M.; Stone, G.M.; Kucharczyk, N. (1974) Data of Vitavax^(R)I-14C Derived Residues in Peanut Hulls, Seed, Oil and Meal. (Unpublished study received on unknown date under 4F1499; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:093979-E)

00003335 Sisken, H.R.; Newell, J.E. (1971) Determination of residues of Vitavax and its sulfoxide in seeds. Journal of Agricultural and Food Chemistry 19(4):738-741. (Also~In~unpublished submission received Apr 21, 1977 under unknown admin. no.; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:229370-P)

00003356 Uniroyal Chemical (1975) Residues of Vitavax^(R)I--EVS Concen- trate in Corn. (Unpublished study received Jun 10, 1975 under 400-124; prepared in cooperation with Morse Laboratories, Inc.; CDL:235928-C)

00005541 Smyser, B.P. (1979) Adsorption-Desorption of Vitavax^(R)I-14C by Manchester Sandy Loam: Project No. 7859. (Unpublished study received Mar 28, 1979 under 400-81; submitted by Uniroyal Chem- ical, Bethany, Conn.; CDL:098029-B)

00005852 Uniroyal Chemical (1973) Residues in PPM: Corn: UNI-1088. (Unpub- lished study received Mar 28, 1977 under 400-107; prepared in cooperation with New York State Univ.--Oswego, Lake Ontario Environmental Laboratory and Morse Laboratories, Inc.; CDL: 238083-A)

00005859 Uniroyal Chemical (1977) Vitavax^(R)I Fungicide: Technical Data Sheet. (Unpublished study received Feb 6, 1979 under 400-EX-58; CDL:237329-A)

00018842 STUDY ADP RECORD DELETED. STUDY IS A DUPLICATE OF MRID 9181

00025466 Sisken, H.R.; Lane, J.R. (1970) Storage Stability Studies of Vita- vax^(R)IResidue in Grain. (Unpublished study received Jan 12, 1970 under 0F0939; submitted by Uniroyal Chemical, Bethany, Conn.; CDL:091604-E) Author: Sisken, H.R.

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Appendix E. Batching of Carboxin Products for Meeting Acute Toxicity Data Requirements for Reregistration

Appendix E. Batching of Carboxin Products for Meeting Acute Toxicity Data Requirements for Reregistration

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

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-in Response, " asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If the registrant supplies the data to support a batch of products, he/she must select the one of the following options: Developing data (Option 1), Submitting an existing Study (Option 4), Upgrading an existing Study (Option 5), or Citing an Existing Study (Option). If a registrant depends on another's data, he/she must choose among: Cost sharing (Option 2), Offers to Cost Share (Option

3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does

not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Thirty three products were found which contain ***Carboxin*** as the active ingredient. These products have been placed into ***two batches and a No batch*** in accordance with the active and inert ingredients and type of formulation.

Batch 1	EPA Reg. No.	Percent active ingredient	Formulation Type
	400-107	34.0	Liquid
	400-152	34.0	Liquid

Batch 2	EPA Reg. No.	Percent active ingredients	Formulation Type
	400-112	Carboxin-17.0 Thiram- 17.0	Liquid
	400-116	Carboxin-17.0 Thiram- 17.0	Liquid

No Batch	EPA Reg. No.	Percent active ingredient(s)	Formulation Type
	400-80	Carboxin-75.0	Solid
	400-81	Carboxin-97.9	Solid
	400-92	Carboxin - 37.0 Thiram - 37.0	Solid
	400-106	Carboxin - 75.0	Solid
	400-111	Carboxin - 97.0	Solid
	400-113	Carboxin - 17.1	Liquid
	400 - 115	Carboxin - 25.00	Solid
	400- 124	Carboxin - 29.52	Solid
	400-144	Carboxin - 75.0	Solid
	400-156	Carboxin-5.7 Thiram- 5.7	Liquid

No Batch	EPA Reg. No.	Percent active ingredient(s)	Formulation Type
	400- 435	Carboxin - 30.0 Thiram - 50.0	Solid
	400 - 438	Carboxin - 27.8 Imazalil - 2.0 Thiabendazole - 2.5	Liquid
	400-439	Carboxin - 32.6 Thiabendazole - 2.7	Liquid
	7501-36	Carboxin - 20.0 Captan - 20.0	Solid
	7501-43	Carboxin - 12.5 Captan - 24.4	Solid
	7501-87	Carboxin - 17.0 PCNB - 17.0	Liquid
	7501-114	Carboxin - 10.0 Thiram - 10.0	Solid
	7501-133	Carboxin - 14.9 Thiram 13.2	Liquid
	7501-139	Carboxin - 10.0 PCNB - 15.0 Captan - 46.0	Solid
	7501-141	Carboxin - 14.0 Thiram - 12.0 Lindane - 8.0	Liquid
	7501-145	Carboxin - 15.0 PCNB - 15.0 Metalaxyl - 1.56	Solid
	7501-187	Carboxin - 3.5 Thiram - 7.0 Imidacloprid - 21.0	Liquid
	7501-189	Carboxin - 14.35 TCMTB - 5.0 Metalaxyl - 2.40	Liquid

No Batch	EPA Reg. No.	Percent active ingredient(s)	Formulation Type
	7501-190	Carboxin - 4.43 Thiram - 9.49 Clothianidin - 9.49 Metalaxyl - 0.316	Liquid
	7501-194	Carboxin - 10.0 Thiram - 10.0 Metalaxyl - 28.35	Liquid
	7501-198	Carboxin - 14.00 Imidacloprid - 25.0 Metalaxyl - 1.0	Solid
	42056-21	Carboxin - 14.00 Permithrin - 10.42	Solid
	42056- 24	Carboxin - 12.50 Captan - 25.0 Metalaxyl - 3.75	Solid
	42056- 23	Carboxin - 10.0 Thiram - 10.0 Metalaxyl - 1.62	Liquid

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

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

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

http://www.epa.gov/opprd001/forms/.

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

Instructions

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

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

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

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

   If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.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 (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf.
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf.

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

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

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

2. Pesticide Registration (PR) Notices

    a. 83-3 Label Improvement Program--Storage and Disposal Statements
    b. 84-1 Clarification of Label Improvement Program
    c. 86-5 Standard Format for Data Submitted under FIFRA
    d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
    e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
    f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
    g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
    h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires 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 Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
    f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
    g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of

information. These include:

1. The Office of Pesticide Programs' Web Site

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

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

   The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

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 Web site.

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

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

   Date of receipt
   EPA identifying number
   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 CAS number if one has been assigned.

Documents Associated with this RED

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

1. Revised Environmental Fate and Effects Division Chapter.
2. Health Effects Division Chapter.

Appendix G. Generic Data Call-In

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

Appendix H. Product Specific Data Call-In

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A Product Specific Data Call-In will be posted at a later date.

Appendix I. List of All Registrants Sent this Data Call-In

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A list of registrants sent this data call-in will be posted at a later date.