MCPB and Salts RED

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Reregistration Eligibility Decision for MCPB, and Salts

(Case 2365)

Reregistration Eligibility Decision (RED) Document for

MCPB

List B

Case 2365

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Glossary of Terms and Abbreviations

ai	Active Ingredient
ae	Acid Equivalent
AR	Anticipated Residue
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GENEEC	Tier I Surface Water Computer Model
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking submitted studies.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Ambient Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data

PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted-Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLN	Special Local Need (Registrations Under Section 24©) of FIFRA)
TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
UF	Uncertainty Factor
WPS	Worker Protection Standard

Executive Summary

This document presents the Environmental Protection Agency's (hereafter referred to as the Agency or EPA) decision on the reregistration eligibility of the registered uses of MCPB [4-(2-methyl-4-chlorophenoxy) butyric acid]. MCPB is a phenoxy herbicide used for post-emergence weed control to protect pea crops from a variety of weeds including Canadian thistle, common lambsquarters, pigweed, smartweed, sowthistle, and morning glory.

The Agency made its reregistration eligibility determination based on the required data, and the current guidelines for conducting acceptable studies to generate such data. Confirmatory studies are required to fulfill some guideline data requirements. However, the Agency has found that currently registered uses of MCPB are eligible for reregistration. There is currently one MCPB tolerance, which is being reassessed at the current level.

Dietary Risk

Acute and chronic dietary risks for food and drinking water do not exceed the Agency's level of concern. No mitigation is required.

Occupational Risk

Short- and intermediate-term inhalation risks to occupational handlers are below the Agency's level of concern with baseline clothing (no respirator). Dermal risks associated with mixing and loading for groundboom and aerial application are above the Agency's level of concern with baseline clothing, but are below the Agency's level of concern when chemical-resistant gloves are added. Therefore, chemical-resistant gloves will be required on all MCPB product labels.

Residential Risk

There are no residential uses of MCPB. Thus, EPA did not conduct a residential assessment.

Aggregate Risk.

Short-term and chronic aggregate risks posed by the use of MCPB are below EPA's level of concern. No mitigation is required.

Cumulative Risk

EPA has not made a common mechanism of toxicity finding for MCPB, and therefore the Agency did not conduct a cumulative assessment.

Ecological Risk

EPA's level of concern is exceeded for acute risk to terrestrial plants, acute risk to small birds that consume short grass, and chronic risk to mammals. EPA has determined that the appropriate risk mitigation for environmental concerns at this time is to require medium or coarser droplet sizes to minimize the potential for spray drift.

Endangered Species

The screening level ecological risk assessment results in a determination that the use of MCPB will have no direct acute effects on freshwater fish, freshwater invertebrates, and insects, and no direct chronic effects to birds. However, the Agency's level of concern for direct acute effects to endangered and threatened birds, and terrestrial and semi-aquatic plants, and for direct acute and chronic effects to mammals, is exceeded for the use of MCPB. Potential risks to endangered species identified in the Environmental Fate and Ecological Risk Assessment and reflected in this Reregistration Eligibility Decision (RED) for MCPB are based solely on EPA's screening level ecological risk assessment and do not constitute "may effect" findings under the Endangered Species Act.

Next Steps

The Agency is issuing this Reregistration Eligibility Decision (RED) document for MCPB as announced in a Notice of Availability published in the *Federal Register*.

In the future, EPA will issue a generic DCI for additional data necessary to confirm the conclusions of this RED for the active ingredient MCPB. EPA will also issue a product-specific DCI for data necessary to complete product reregistration for products containing MCPB.

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 to the EPA. Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential risks arising from the currently registered uses of the pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

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

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

EPA followed a four-phase, modified public participation process for MCPB. Consistent with this process, EPA initiated Phase 1 of the process by transmitting the human health and ecological risk assessments to the technical registrants for a 30-day error-correction review. In Phase 2, EPA considered the errors that were identified by the registrants and made changes in the risk assessments as appropriate. To initiate Phase 3 of the process, EPA published a Federal Register notice announcing the availability of the revised risk assessments and supporting documents for a 60-day public review and comment period. During the 60-day public comment period, EPA received two comments, from the MCPB Task Force and a public citizen.

This document presents EPA's revised human health and environmental fate and effects

risk assessment, its progress toward tolerance reassessment, and the reregistration eligibility decision for MCPB. The document consists of six sections. Section I contains the regulatory framework for reregistration and tolerance reassessment. Section II provides a description of the chemical and a profile of the use and usage of the chemical. Section III provides a summary of the human health and ecological risk assessments which have been revised based on data, public comments, and other information received in response to the preliminary risk assessments. Section IV presents the Agency's risk management, reregistration eligibility, and tolerance reassessment decision. Section V summarizes any data requirements necessary to confirm the reregistration eligibility decision as well as label changes and language necessary to implement the risk mitigation measures outlined in Section IV. Section VI, the Appendices, provides related information and supporting documents. The preliminary and revised risk assessment for MCPB are available in the public docket EPA-HQ-2005-0263 located on-line in the Federal Docket Management System (FDMS) at http://www.regulations.gov.

II. Chemical Overview

A. Chemical Identification

MCPB was first registered by EPA in 1964. Currently, there are five products containing MCPB registered under Section 3 of FIFRA. There are two manufacturing use products (MCPB Technical Acid and MCPB Technical Grade) and the three end-use formulations (Sodium MCPB Herbicide, Thistrol Herbicide, and Sodium MCPB Solution). There are no Special Local Need (SLN) registrations.

MCPB (sodium)

Chemical Name: [Sodium 4-(2-methyl-4-chlorophenoxy)buytrate]

Chemical Structure:

CAS Registry Number: 6062-26-6

OPP Chemical Code: 019202

Case Number: 2365
Molecular Weight: 250.7 g/mol

Vapor Pressure: 4×10^{-7} (torr at 25 degrees Celsius)

Empirical Formula: $C_{11}H_{12}ClNaO_3$

Basic Manufacturers: A. H. Marks & Co. Ltd., Nufarm BV and Nufarm, Inc.

MCPB (acid)

Chemical Name: [4-(2-methyl-4-chlorophenoxy)butyric acid]

Chemical Structure:

CAS Registry Number: 94-81-5

OPP Chemical Code: 019201

Case Number: 2365

Molecular Weight: 228.6 g/mol

Vapor Pressure: 4×10^{-7} (torr at 25 degrees Celsius)

Empirical Formula: $C_{11}H_{13}ClO_3$

Basic Manufacturers: A. H. Marks & Co. Ltd., Nufarm BV and Nufarm, Inc.

B. Use Profile

The following is information on the currently registered MCPB use sites and application methods.

Type of Pesticide: MCPB is a phenoxy herbicide produced as a sodium salt and an acid.

Summary of Use: MCPB is registered for use on peas (both green and dry peas) before flowering. There are no residential uses of MCPB.

Target Organisms: Post-emergence control of Canadian thistle, buttercup, mustard, purslane, ragweed, common lambsquarters, pigweed, smartweed, sowthistle, morning glory and other broad leaf weeds

Use Classification: General Use

Formulation Types: Liquid

Application Methods: Methods of application include controlled droplet applicator, high volume ground sprayer, low volume ground sprayer, hand held sprayer, high volume spray (dilute), low volume spray (concentrate), aerial and ground broadcast, and spot treatment.

Application Rates: The maximum label application rate is 1.5 pounds acid equivalent/acre (lb ae/A), applied once per year.

Use Locations: MCPB is primarily used in Delaware, Idaho, Illinois, Maine, Maryland, Michigan, Minnesota, Montana, New Jersey, New York, Oregon, Pennsylvania, Washington and Wisconsin.

Tolerances: There is 1 tolerance, for peas.

Annual Pounds Used: Less than 15,000 pounds per year

Percent Crop Treated: Approximately 15 percent of green pea crops are treated with MCPB. Less than 2.5 percent of other types of pea crops are treated with MCPB.

III. Summary of MCPB Risk Assessments

This section summarizes EPA's human health and ecological risk findings and conclusions for MCPB. This information is presented in greater detail in the following documents: "MCPB: Revised Occupational and Residential Exposure (ORE) and Risk Assessments for the Reregistration Eligibility Decision RED Document" (Dole, 10/19/2005), "Revised Environmental Fate and Effects Division Preliminary Risk Assessment for MCPB" (Janson, 3/07/2006) and MCPB HED Chapter of the Reregistration Eligibility Decision (RED) Document" (Mendez, 10/24/2005).

The purpose of this section is to highlight the key features and findings of the risk assessments in order to help the reader better understand the risk management decisions reached by the Agency. While the risk assessments and related addenda are not included in this document, they are available in the OPP Public Docket http://www.regulations.gov/fdmspublic-rel11/component/main (docket number EPA-HQ-OPP-2005-0263).

A. Human Health Risk Assessment

Although data do not support and the Agency is not assuming a common mechanism of toxicity with other pesticides, MCPB is similar in its toxicity to the structurally related compound MCPA. Also, there are similarities in the metabolism of MCPB and MCPA. Thus, studies from the MCPA database were used as a surrogate for those lacking in the MCPB database.

1. Toxicity

MCPB has a low to moderate acute toxicity profile (Toxicity Category III to IV). The acute dermal toxicity test indicated low to moderate acute toxicity (Toxicity Category III to IV). The acute oral and inhalation toxicity studies showed moderate toxicity (Toxicity Category III). MCPB is not a dermal sensitizer nor is it irritating to the skin. However, it does cause moderate eye irritation. Please see Table 1, below, for the acute toxicity profile for MCPB.

Table 1. Acute Toxicity Profile for MCPB

Guideline No.	Study Type	MRID #	Results	Toxicity Category
870.1100	Acute oral - rat	116340	LD_{50} = 1570 mg/kg	III
870.1100	Acute oral - rat	144801	LD_{50} = 4300 mg/kg	III
870.1200	Acute dermal - rabbit	116342	LD_{50} > 10000 mg/kg	IV
870.1200	Acute dermal - rat	144799	LD_{50} > 2000 mg/kg	III
870.1300	Acute inhalation - rat	41630001	LC_{50} > 1.14 mg/L	III

Table 1. Acute Toxicity Profile for MCPB

Guideline No.	Study Type	MRID #	Results	Toxicity Category
870.2400	Acute eye irritation - rabbit	116343	Moderately irritating	III
870.2400	Acute eye irritation - rabbit	144797	Moderately irritating	III
870.2500	Acute dermal irritation - rabbit	144798	Non-irritating	IV
870.2600	Skin sensitization - guinea pig	144800	Negative	IV

Kidney and liver effects appear to be the most prevalent hazard concerns for MCPB, based on the effects seen throughout the MCPA database. Developmental and reproductive toxicity studies did not indicate an enhanced sensitivity or susceptibility to young animals. Neurotoxicity effects were noted in studies conducted on MCPA. Therefore, a developmental neurotoxicity study is required for MCPB.

EPA has established an acute reference dose (RfD) of 0.2 mg/kg/day for MCPB, based on a No Observed Adverse Effect Level (NOAEL) of 200 mg/kg/day in an acute neurotoxicity study of MCPA in rats. The main effect observed at the Lowest Observed Adverse Effect Level (LOAEL) was gait impairment in male rats. The RfD was calculated by dividing the NOAEL by an uncertainty factor of 1,000 (10x for interspecies variability, 10x for intraspecies variability, and 10x FQPA database uncertainty to account for the lack of a developmental neurotoxicity study). The uncertainty factors are discussed in more detail below.

EPA has established a chronic RfD of 0.015 mg/kg/day for MCPB, based on a NOAEL of 4.4 mg/kg/day in a chronic toxicity study of MCPA in rats. Effects observed at the LOAEL were liver and kidney toxicity. The RfD was calculated by dividing the NOAEL by an uncertainty factor of 300 (10x for interspecies variability, 10x for intraspecies variability, and 3x database uncertainty to account for the lack of a developmental neurotoxicity study). The uncertainty factors are discussed in more detail, below.

There were no tumor effects observed in any MCPA or MCPB studies, and therefore EPA did not conduct a cancer assessment. Mutagenicity tests conducted with MCPB and MCPA were negative.

FQPA Safety Factor

FQPA directs EPA, in setting pesticide tolerances, to use an additional tenfold margin of safety to protect infants and children, taking into account the potential for pre- and post-natal toxicity and the completeness of the toxicology and exposure databases. The statute authorizes EPA to modify this tenfold FQPA safety factor only if reliable data demonstrate that the resulting level of exposure will be safe for infants and children.

The toxicity database for MCPB, which is bridged from MCPA, includes acceptable

developmental and reproductive toxicity studies. There is no evidence in the developmental (MCPB and MCPA) or reproductive (MCPA) toxicity studies of increased sensitivity or susceptibility to newborns. However, EPA has determined that all or part of the FQPA safety factor must be retained to account for database uncertainties.

Neurotoxicity was not seen in the MCPB subchronic studies (clinical signs of neurotoxicity in a rabbit developmental study occurred on the day of or day prior to death or moribund sacrifice and were attributed to agonal death). However, neurotoxicity was noted in an acute and subchronic MCPA rat study (decreased arousal, impaired coordination and gait, reduced motor activity, and reduced grip strength). Given that the MCPA database was used to evaluate MCPB, signs of neurotoxicity are expected with MCPB. A developmental neurotoxicity study is therefore necessary to further characterize the potential for pre- and post-natal neurotoxicity. The MCPB and MCPA databases do not include a DNT study, and therefore an FQPA database uncertainty factor must be retained for exposure scenarios through which exposure to children or pregnant women is expected.

The size of the FQPA database uncertainty factor is based on an analysis of DNT studies previously submitted to the Agency which suggests that NOAELs from a DNT study could be lower than the lowest dose tested in the studies currently used in the risk assessment. For MCPB, a 10x FQPA database uncertainty factor is retained for the acute dietary risk assessment because it is anticipated that the DNT may yield a NOAEL approximately ten times lower than the one currently used for the risk assessment. A 3x FQPA database uncertainty factor is retained for the chronic dietary risk assessment because it is expected that the DNT could yield a NOAEL approximately three times lower than the one currently used for this risk assessment.

The toxicological endpoints and uncertainty factors used in the human health risk assessment for MCPB are listed below in Table 2.

Table 2. Summary of Toxicological Doses and Endpoints for the MCPB Dietary Risk Assessment

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study	Uncertainty Factor	FQPA Safety Factor	PAD (mg/kg/day)
Acute Dietary (general population)	NOAEL = 200 mg/kg/day	Clinical signs of neurotoxicity	Acute neurotoxicity study (MCPA) in rats with a LOAEL of 400 mg/kg/day based on gait impairment in males [MRID No. 43562602]	100x (10x for intraspecies variation and 10x for interspecies extrapolation)	10x (for database uncertainty)	0.2
Chronic Dietary (general population)	NOAEL= 4.4 mg/kg/day	Hepatotoxicity and nephrotoxicity	Chronic toxicity study (MCPA) in rats with a LOAEL of 17.6 mg/kg/day [MRID No.	100x (10x for intraspecies variation and 10x for	3x (for database uncertainty)	0.015

Table 2. Summary of Toxicological Doses and Endpoints for the MCPB Dietary Risk Assessment

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study	Uncertainty Factor	FQPA Safety Factor	PAD (mg/kg/day)
			40634101]	interspecies extrapolation)		
Cancer	Classification: Not likely to be carcinogenic to humans					

2. Dietary Exposure and Risk from Food and Drinking Water

EPA conducted acute and chronic dietary (food and drinking water) risk assessments for MCPB using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03). To conduct the assessments, both food consumption data from USDA's Continuing Survey of Food Intakes by Individuals (CSFII), 1994-1996 and 1998, and screening-level model results for drinking water exposure were incorporated in the DEEM-FCID™ to estimate combined food and drinking water dietary risks.

a. *Dietary Exposure and Risk from Food*

The acute and chronic dietary (food only) risk assessments assumed 100% crop treated and tolerance-level residues for all commodities. This analysis is known as an unrefined (Tier 1) assessment, which provides an upper-bound estimate of potential risks.

The results of the dietary (food only) exposure and risk estimates for MCPB for the general population and the most highly-exposed population subgroup (all infants <1 year old) are summarized below in Table 3. The acute assessment shows that at the 95th percentile of exposure, the risk estimates are below the Agency's level of concern (<100% acute Population Adjusted Dose [aPAD]) for the general U.S. population and all population subgroups. The most highly exposed population subgroup was infants (<1 years old) at 2% of the aPAD. Note that for MCPB and other pesticides for which EPA conducts an unrefined Tier 1 analysis, the Agency presents acute dietary exposure results at the 95th percentile of exposure, which provides a more realistic though still high-end estimate of risk. The chronic risk estimates were also below the Agency's level of concern (<100% of the chronic Population Adjusted Dose [cPAD]) for the general U.S. population and all population subgroups. The most highly exposed population subgroup was infants (<1 years old) at <4% of the cPAD.

Table 3. Summary of dietary (food only) exposure and risk for MCPB

	Acute Dietary (95th Percentile)			Chronic Dietary		
Population Subgroup	**aPAD (mg/kg/day)**	**Exposure (mg/kg/day)**	**% aPAD***	**cPAD (mg/kg/day)**	**Exposure, mg/kg/day**	**% cPAD***
General U.S. Population	0.2	0.000754	0.4	0.015	0.000128	0.9
All Infants (< 1 yr)	0.2	0.003971	2	0.015	0.000568	3.8

* Risks > 100% of the aPAD or cPAD exceed EPA's level of concern.

b. *Dietary Exposure from Drinking Water*

Drinking water exposure to pesticides can occur through surface and ground water contamination. EPA considers acute (one day) and chronic (lifetime) drinking water risks and uses modeling (or monitoring data, if available and of sufficient quality) to estimate those exposures. For MCPB, EPA used modeling to calculate Estimated Drinking Water

Concentrations (EDWCs) for groundwater and surface water sources of drinking water for use in the human health risk assessment.

EPA used the Tier II screening model, Pesticide Root Zone Model and Exposure Analysis Modeling System (PRZM-EXAMS), to estimate MCPB residues in surface water. The Agency assumed MCPB would be applied once a year at 1.5 pounds of acid equivalent per acre (lb ae/A). EPA used the Tier I Screening Concentrations in Ground Water (SCI-GROW) model to estimate MCPB concentrations in ground water, assuming a maximum seasonal use rate of 1.5 lb ae/A. The EDWCs in surface water and ground water for MCPB are provided below, in Table 4. EPA used these EDWCs for the aggregate (food + water) risk assessments.

Table 4. Surface and Ground Water EDWCs for MCPB

Exposure Duration	Surface Water Concentration [a] (ppb)	Ground Water Concentration [b] (ppb)
Acute	54.7	0.86
Chronic (non-cancer)	13.5	0.86

[a] From the Tier II PRZM-EXAMS - Index Reservoir model. Input parameters are based on use of MCPB on pea crops once a year at the rate of 1.5 lbs ae/A.
[b] From the SCI-GROW model assuming a maximum seasonal use rate of 1.5 lbs ae/A

c. *Dietary Exposure and Risk from Food and Drinking Water*

MCPB concentrations are predicted to be higher in surface water than in ground water, and therefore EPA used the surface water EDWCs to calculate exposure and risk from combined dietary exposures from food and drinking water. The results of the acute and chronic dietary exposure analyses are summarized in Table 5, below.

At the 95th percentile of exposure, the acute risk estimates are below the Agency's level of concern (<100% aPAD) for the general U.S. population and all population subgroups. The most highly exposed population subgroup was infants (<1 years old) at approximately 6% of the aPAD. The chronic risk estimates were also below the Agency's level of concern (<100% cPAD) for the general U.S. population and all population subgroups. The highest exposed population subgroup was infants (<1 years old) at 10% of the cPAD.

Table 5. Acute and Chronic Dietary (food plus drinking water from surface water sources) Exposure and Risk Estimates for MCPB

	Acute (95th Percentile)		Chronic	
Population Subgroup	Exposure (mg/kg/day)	% aPAD*	Exposure (mg/kg/day)	% cPAD*
General U.S. Population	0.003356	1.7	0.00041	2.8

Table 5. Acute and Chronic Dietary (food plus drinking water from surface water sources) Exposure and Risk Estimates for MCPB

All Infants (< 1 year old)	0.011869	5.9	0.001501	10

* Risks > 100% of the aPAD or cPAD exceed EPA's level of concern.

3. Residential and Other Non-Occupational Exposure and Risk

There are no residential uses of MCPB, and therefore EPA did not conduct a residential risk assessment.

4. Aggregate Exposure and Risk

The FQPA amendments to the FFDCA (Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure. In the case of MCPB, the aggregate risk estimates are the same as those presented in the dietary (combined food and drinking water) risk section of this document (see Table 5), because there are no registered residential uses and no residential exposures are expected to occur.

While the Agency has concluded that MCPB converts to MCPA in the environment, and that MCPA may be present in crops, residues of MCPA resulting from MCPB use are expected to be negligible, and significantly below analytical method limits of detection. These residues will not contribute significantly to the aggregate exposure to MCPA from other sources, and therefore EPA did not conduct an aggregate assessment combining MCPA exposures from MCPA and MCPB uses.

5. Occupational Exposure and Risk Assessment

Workers may be exposed to MCPB while handling, mixing, loading, or applying MCPB, and when entering treated sites. Handler and worker risks are measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) taken from animal studies. Generally, MOEs greater than 100 do not exceed the Agency's level of concern.

For MCPB, only short- and intermediate-term occupational exposures are expected based on label-specified use patterns. The Agency determined that pesticide handlers and applicators are likely to be exposed during MCPB use resulting in short- (one day to one month) and intermediate-term (one to six month) exposures. Chronic exposures (longer than six months) are not expected because MCPB is used only once a year.

For the occupational assessment, the short- and intermediate-term dermal endpoint was selected from an MCPA 21-day dermal toxicity study in rabbits. The short- and intermediate-term inhalation endpoint was selected from an MCPB developmental toxicity in rabbits. Table 6, below, provides a listing of the toxicological endpoints used in the MCPB occupational risk assessment.

Table 6. MCPB Toxicological Endpoints Used for Occupational Risk Assessment

Exposure Scenario	Dose (mg/kg/day)	Endpoint	Study	Uncertainty Factor	Level of Concern
Dermal (Short- and Intermediate-term)	Dermal NOAEL = 100 mg/kg/day	Kidney toxicity and decreased body weight gain	21-day dermal toxicity study (MCPA) in rats with a LOAEL of 1,000 mg/kg/day [MRID No. 42715001]	100x (10x for intraspecies variation and 10x for interspecies extrapolation)	100
Inhalation (Short- and Intermediate-Term)	Oral NOAEL = 5 mg/kg/day*	Maternal mortality	Developmental toxicity study in rabbits (MCPB) with a LOAEL of 20 mg/kg/day [MRID No. 40865401]	100x (10x for intraspecies variation and 10x for interspecies extrapolation)	100

* Inhalation absorption is assumed to be equivalent to oral absorption (100 percent default value).

a. *Short- and Intermediate-Term Handler Risk*

EPA has determined that there are potential short- and intermediate-term exposures to workers who handle MCPB. The four major occupational handler exposure scenarios are as follows:

2. Mixing/loading liquid formulations;
3. Performing aerial applications;
4. Performing groundboom applications; and
5. Flagging for aerial applications.

For MCPB, the target MOE for occupational exposures is 100, which includes the default uncertainty factors for interspecies extrapolation and intraspecies variation. The MOEs for handlers are summarized in Table 7. All of the MOEs for dermal exposure are greater than 100 (and therefore do not exceed the Agency's level of concern) if single layer PPE (*i.e.*, baseline clothing with chemical resistant gloves) is worn. All inhalation MOEs are greater than 100 at baseline (*i.e.*, respirators not needed), and therefore do not exceed the Agency's level of concern.

Table 7. MCPB MOEs for Handlers

Exposure Scenario	Application Rate (lb ae/acre)	Acres/Day	Dermal MOE (Single Layer PPE)	Inhalation MOE (Baseline)
Mixing and Loading Liquids for Aerial Application	1.5	350	580	560
Mixing and Loading Liquids for Groundboom Application	1.5	200	1000	970

Table 7. MCPB MOEs for Handlers

Exposure Scenario	Application Rate (lb ae/acre)	Acres/Day	Dermal MOE (Single Layer PPE)	Inhalation MOE (Baseline)
Applying Aerially	1.5	350	N/A	9800
Applying via Groundboom Equipment	1.5	200	1700	1600
Flagging for Aerial Applications	1.5	350	1100	1900

b. *Short- and Intermediate-Term Postapplication Risk*

Post-application exposures to MCPB can occur when workers enter pea fields recently treated with MCPB to conduct tasks such as scouting and irrigation.

Since no chemical-specific data were available for MCPB, standard values and assumptions were used to evaluate post-application risks (*e.g.*, maximum application rates, default dislodgeable foliar residue value of 20 percent).

A summary of worker risks for post-application exposures is presented in Table 8. All of the MOEs are above 100 on Day 0 (12 hours after application) for all activities which indicates that the risks are below the Agency's level of concern.

Table 8. MCPB Post-Application Worker Risks

Crop	Application Rate (lb ae/acre)	Task	Transfer Coefficient (cm^2/hr)	Day 0 Dermal MOE
Peas	1.5	Irrigation, scouting, immature plants	100	2600

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment for MCPB is presented below. The complete environmental risk assessment may be accessed in the OPP Public Docket (EPA-HQ-OPP-2005-0263) at www.regulations.gov and on the Agency's website at www.epa.gov/pesticides/reregistration/status.htm.

MCPB is a phenoxy herbicide that disrupts hormone (auxin) and protein synthesis within various sites in sensitive plants to cause growth abnormalities in addition to non-lethal effects (such as brown leaf tips, necrosis, decrease in size, leaf curling, chlorosis, and stem tumors). The use of MCPB produces potential risks to non-target plants within close proximity to target areas

and along streams and/or ponds near sprayed fields.

The environmental fate database is sufficient to characterize the environmental exposure associated with MCPB use. However, EPA does intend to issue a DCI as part of this RED to require submission of additional data for the parent compound to address areas of uncertainty. Studies on environmental fate, aquatic invertebrates, and marine/estuarine fish will help provide the Agency with data to refine the environmental risk assessments and to confirm the conclusions reached in this RED. As previously discussed, MCPB has similiar effects as MCPA. Therefore, EPA took into consideration both MCPB and MCPA data for the purpose of this environmental assessment.

1. Environmental Exposure

a. *Environmental Fate and Transport*

MCPA and the CHPA-hexose conjugate are byproducts of MCPB detected in fate studies. MCPA, MCPB, and the CHPA-hexose conjugate have similar fate characteristics as evidenced by fate studies and chemical structure. The inclusion or exclusion of these metabolites had little influence on the overall risk assessment because of their relatively minor presence and lack of persistence. However, the Agency has included both metabolites in combination with parent MCPB as total toxic residues with a combined half-life of 26 days. The Agency assumed that the toxicity and environmental fate properties for the two metabolites are equivalent to parent MCPB.

Based on laboratory studies and physicochemical properties, MCPB is not volatile, not persistent, and not likely to bioconcentrate. Its acidic/anionic nature, physicochemical properties, and relatively low sorption to soil (average soil sorption coefficient of 0.85 mL/g) indicate that MCPB is prone to leaching and runoff.

MCPB is essentially stable to hydrolysis, but photolyzed in laboratory water under optimal light exposure conditions with half-lives of approximately 2 to 3 days. Phototransformation products included 4 -(4-hydroxy-o-tolyloxy)butyric acid, 2,4-dihyroxyphenyl formate, o-cresol, benzoic acid, and 2-hydroxyphenyl formate. Specific study information is not available concerning the fate of these products, and the Agency has not included any potential effects of aqueous photolysis products in the risk assessment based on their expected toxicity and persistence.

b. *Aquatic Organism Exposure*

EPA used the PRZM 3.12 and EXAMS 2.98 models in tandem to estimate aquatic exposure concentrations for MCPB. PRZM/EXAMS is a Tier II screening model designed to estimate pesticide concentrations found in water at the edge of a treated field. As such, it provides high-end values of the pesticide concentrations that might be found in ecologically sensitive environments following pesticide application. The acute risk assessments were performed using 1-in-10-year peak estimated environmental concentration

(EEC) values for single applications of MCPB. EPA performed chronic risk assessments for aquatic invertebrates and fish using the average 21-day and 60-day EECs, respectively.

To simulate field application of MCPB to peas, EPA selected a California lettuce scenario and an Oregon snap bean scenario based on similarity in agricultural practices and usage areas. The EECs from the two scenarios are provided in Table 9. The Oregon scenario represents the typical use of MCPB application to peas, and the California scenario represents a reasonable upper bound estimate.

Table 9. Estimated Environmental Concentrations (µg ae/L) of MCPB + Metabolites (MCPA and CHPA/CHPA-hexose) in Surface Water (PRZM-EXAMS)

Simulation Scenario			Concentration (µg ae/L)		
Crop and Location	**Rate**	**Application Method**	**Peak**	**21-Day Average**	**60-Day Average**
Lettuce (CA) (Surrogate for Peas)	1.5 lbs ae/acre (1.68 kg ae/ha)	Ground spray Aerial spray	40.4 43.2	39.0 41.7	36.4 38.9
Snap Beans (OR) (Surrogate for Peas)	1.5 lbs ae/acre (1.68 kg ae/ha)	Ground spray Aerial spray	29.5 33.1	29.0 32.5	28.1 31.5

Surface water and groundwater monitoring data were not available for evaluation in this risk assessment.

c. *Terrestrial Organism Exposure*

(1) *Exposure to Terrestrial Birds and Mammals*

EPA estimated exposure to birds and mammals by first predicting the amount of MCPB residues found on animal food items, and then using information on typical food consumption by various species of birds and mammals to determine the amount of pesticide consumed. The amount of residues on animal feed items are based on the Fletcher nomogram, which is a model developed by Hoerger and Kenaga (1972) and modified by Fletcher (1994), and the current maximum application rate for MCPB (1.5 lb ae/acre).

EPA used the terrestrial exposure (T-REX) model Ver. 1.1 to predict mean EECs from a single application of MCPB. The predicted EECs are provided in Table 10, below. EPA calculated acute and chronic RQs using these EECs and appropriate toxicity data.

Table 10. Mean EECs on Terrestrial Food Items from Use of MCPB on Peas

Simulation Scenario		Concentration (ppm ae)
Crop	**Food item**	**Mean**

Table 10. Mean EECs on Terrestrial Food Items from Use of MCPB on Peas

Simulation Scenario		Concentration (ppm ae)
Crop	**Food item**	**Mean**
Peas	Short Grass	127.5
	Tall Grass	54
	Broadleaf Plants/Small Insects	67.5
	Fruits/Pods/Seeds/Large Insects	10.5

(2) *Exposure to Non-target Insects*

There is a potential for exposure to non-target insects as a result of spray drift from aerial and ground applications of the liquid formulation.

(3) *Exposure to Non-target Terrestrial Plants*

Exposure to non-target terrestrial plants is most likely to occur as a result of spray drift from aerial and ground applications of the liquid formulation. Spray drift is an important factor in characterizing the risk of MCPB to non-target plants. EPA used the TerrPlant model (Ver.1.0) to predict EECs for terrestrial plants located adjacent to the treated field. MCPB applied according to label directions as a liquid for ground or aerial applications may impact non-target plants for some distance from the application site depending on droplet size, wind speed, and other factors. In addition, the Agency used the AgDrift model (Ver. 2.0.1) to estimate drift dispersion and deposition as a result of ground and aerial spray droplet and nozzle size, wind speed, and distance from the treated field.

2. Environmental Effects (Hazard)

a. *Toxicity to Aquatic Organisms*

(1) *Freshwater and Estuarine/Marine Fish*

Available acute toxicity data, listed below in Table 11, indicate that MCPB is slightly to moderately toxic to freshwater fish. The median lethal concentration (LC_{50}) value from the rainbow trout study (the more sensitive species) was used to evaluate acute risk to freshwater fish.

Table 11. Freshwater Fish Acute Toxicity for MCPB Sodium

Species	96-hour LC_{50} (mg ae/L) (nominal)	Toxicity Category	MRID Number
Bluegill sunfish *(Lepomis macrochirus)*	12.7	Slightly toxic	42532601
Rainbow trout *(Oncorhynchus mykiss)*	3.9	Moderately toxic	42532608

No chronic data for freshwater fish are available. These studies were not previously required by the Agency.

No acute or chronic data for estuarine/marine fish are available. These studies were not previously required by the Agency. A study with the degradate MCPA indicates that MCPA is practically non-toxic to estuarine/marine fish for acute exposures. However, a comparison between freshwater fish acute exposure studies with MCPB and MCPA indicates that MCPB is potentially more toxic to fish than MCPA.

(2) *Freshwater and Estuarine/Marine Invertebrates*

A toxicity study with the test species *Daphnia magna* demonstrated that MCPB is slightly toxic to freshwater invertebrates under acute exposure. The study results are provided below, in Table 12.

Table 12. Freshwater Invertebrate Acute Toxicity for MCPB Sodium

Species	48-hour EC_{50} (mg ae/L)	Toxicity category	MRID Number
Waterflea (*Daphnia magna*)	50	Slightly toxic	42532602

No freshwater aquatic invertebrate life-cycle studies or estuarine/marine invertebrate toxicity studies are available. These studies were not previously required by the Agency.

Studies with the degradate MCPA indicate that MCPA is practically non-toxic to freshwater and estuarine/marine invertebrates. However, a comparison between freshwater invertebrate acute exposure studies with MCPB and MCPA indicates that MCPB is potentially more toxic to aquatic invertebrates than MCPA.

(3) *Aquatic Plants*

EPA has reviewed several aquatic plant toxicity studies to establish the toxicity of MCPB to aquatic plants. The results of these studies are provided in Table 13, below.

Table 13. Non-target Aquatic Plant Toxicity for MCPB

Species [Study Type]	EC_{50}/NOEC (mg ae/L)	Endpoints Affected	MRID Number
Duckweed (*Lemna gibba*) [Tier I]	0.21/<0.01 1.55/0.15	Frond production Frond biomass	42532604
Green Algae (*Selenastrum capricornutum*) [Tier I]	0.38/<0.31	Cell density	42532605
Blue-green Algae (*Anabaena flos-aquae*) [Tier I]	>1.9/1.9	Cell density	42532603
Diatom (*Navicula pelliculosa*) [Tier I & II]	0.65/0.044	Cell density	42532609
Diatom (*Skeletonema costatum*) [Tier I & II]	1.36/0.10	Cell density	42532606

b. *Toxicity to Terrestrial Organisms*

(1) *Birds*

MCPB is classified as moderately toxic to birds on an acute oral basis, based on a gavage study with bobwhite quail with a median lethal dose (LD_{50}) of 257 mg ae/kg. MCPB is classified as practically non-toxic to avian species on an acute dietary basis, based on an 8-day acute dietary LD_{50} of greater than 4,550 ppm ae for both mallard duck and bobwhite quail. Table 14, below, summarizes the data that support the acute toxicity endpoints used in assessing acute risks to birds.

Table 14. Avian Toxicity Studies for MCPB

Acute Oral Gavage			
Species	**LD_{50} (mg ae/kg)**	**Toxicity Category**	**MRID No.**
Northern bobwhite quail *(Colinus virginianus)*	257	Moderately toxic	42560801
Acute Dietary			
Species	**8-Day LD_{50} (ppm ae)**	**Toxicity Category**	**MRID No.**
Northern bobwhite quail *(Colinus virginianus)*	> 4,550	Practically non-toxic	42560802
		Practically non-	

Acute Dietary			
Species	**8-Day LD_{50} (ppm ae)**	**Toxicity Category**	**MRID No.**
Mallard duck *(Anas platyrhynchos)*	> 4,550	toxic	42560803

No chronic avian data on MCPB are available. These data were not previously required by the Agency. A chronic avian reproduction study with the degradate MCPA resulted in a no observed adverse effect concentration (NOAEC) of 1,000 mg ae/kg-diet (the highest dose tested). No negative effects were observed in that study. EPA used the MCPA chronic avian study to estimate chronic avian risks from MCPB. The MCPA study is an appropriate surrogate because MCPB is expected to rapidly dissociate to MCPA in a bird's gut due to the chemical properties of MCPB. Further, a comparison of the MCPB and MCPA avian acute toxicity studies with bobwhite quail indicates that the two compounds have an approximately equivalent acute toxic potential to birds.

(2) *Mammals*

MCPB is classified as slightly toxic to practically non-toxic to small mammals on an acute oral basis (LD_{50} values range from 912 to 7,400 mg ai/kg/day). However, adverse effects were demonstrated in the mammalian subchronic and developmental toxicity studies. See Table 15, below, for a summary of the data.

Table 15. Summary of Mammalian Toxicity Endpoints for MCPB

Species	**Purity**	**Test Type**	**Dose**	**Affected Endpoints**	**MRID No.**
Rat	Technical	Acute oral	LD_{50} = 912-2700 mg/kg/day (males) LD_{50} = 969-2981 mg/kg/day (females)	Mortality	116340
Rabbit	97.6%	Developmental	NOAEL = 5 mg/kg/day LOAEL = 20 mg/kg/day	Maternal toxicity; developmental effects	40865401

(3) *Non-Target Insects*

There is a potential for exposure to non-target insects from the use of MCPB. In particular, MCPB's foliar application will result in honey bee exposure. Available data from a honey bee acute toxicity study indicated that technical MCPB is practically non-toxic to the honey bee (with an LD_{50} greater than 23 micrograms per bee).

(4) *Non-target Terrestrial Plants*

MCPB is an herbicide, and therefore plant toxicity is expected. Terrestrial plant toxicity studies indicate that the most sensitive monocot species in seedling emergence tests is the onion with the lowest EC_{25} of 0.02 lb ae/acre based on shoot length. This value represents 0.093% of the maximum application rate for MCPB. The most sensitive dicot species is cabbage with an EC_{25} of 0.016 lb ae/acre in the seedling emergence study based on shoot length. The most sensitive monocot in the vegetative vigor test is onion, with an EC_{25} of 0.016 lb ae/acre based on shoot weight. The most sensitive dicot species in the seedling emergence study is tomato with an extrapolated EC_{25} of 0.0017 lb ae/acre based on shoot weight. The observed non-lethal effects included brown leaf tips in cabbage, corn, onion, ryegrass, radish, and soybean; necrosis in corn, radish, onion, and soybean; chlorosis in onion, cucumber, and lettuce; stem tumors in soybean and tomato; leaf curl in tomato, and decreased size in cabbage, cucumber, lettuce, onion, and ryegrass.

3. Ecological Risk Estimation (RQs)

The Agency's ecological risk assessment compares toxicity endpoints from ecological toxicity studies to EECs which are based on environmental fate characteristics and pesticide use data. To evaluate the potential risk to non-target organisms from the use of MCPB 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), shown in Table 16, which indicate whether a pesticide, when used as directed, has the potential to cause adverse effects to non-target organisms. When the RQ exceeds the LOC for a particular category, the Agency presumes a risk of concern to that category. These risks of concern may be addressed by further refinements of the risk assessment or mitigation. Use, toxicity, fate, and exposure are considered when characterizing the risk, as well as the levels of certainty and uncertainty in the assessment. EPA further characterizes ecological risk based on any reported incidents to non-target terrestrial or aquatic organisms in the field (e.g., fish or bird kills).

Table 16. EPA's Levels of Concern and Associated Risk Presumptions

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

a. *Risk to Aquatic Organisms*

(1) *Fish and Aquatic Invertebrates*

No acute risks are predicted for freshwater fish and invertebrates at the maximum predicted estimated concentration of MCPB in water bodies. All acute freshwater fish and invertebrate RQs are less than 0.01.

There are no LOC exceedences for acute risks to estuarine/marine fish and chronic risks to freshwater fish, freshwater invertebrates, and estuarine/marine fish for MCPB based on RQ values calculated using acute-to-chronic ratios derived from MCPA data.

(2) *Aquatic Plants*

For MCPB acid runoff/drift, there are no exceedances of the acute risk LOCs for the pea scenarios that were modeled. The RQs range from 0.08 to 0.21.

b. *Risk to Non-target Terrestrial Organisms*

(1) *Birds*

Assuming mean predicted residues at the maximum application rate (1.5 lb ae/A), there are potential acute risks to small (20 gram) birds that consume short grass (RQ is 0.80). All other avian RQs are below the Agency's level of concern. The avian acute risk quotients are presented in Table 17, below.

No chronic avian risks are predicted for MCPB. Chronic RQs for MCPB were calculated using the NOEC of 1,000 mg/kg-diet from an MCPA avian reproduction study. The chronic RQs range from 0.02 to 0.36, which is below EPA's level of concern.

Table 17. Avian Acute Risk Quotients (RQs)

Food type	Weight class (g)	RQs at Predicted Mean Residues
short grass	20	0.8
	100	0.36
	1000	0.11
tall grass	20	0.34
	100	0.15
	1000	0.05
broadleaf forage, small insects	20	0.42
	100	0.19
	1000	0.06
fruit, pods, seeds, large insects	20	0.07
	100	0.03
	1000	0.01

(2) *Mammals*

Assuming mean residue levels at the maximum MCPB application rate of 1.5 lb ae/A, there are no exceedances of any acute LOCs for mammals (RQs range from <0.01 to 0.07). However, chronic LOCs are exceeded for mammals of all weight classes that

consume grasses, broadleaf forage, and small insects (RQs range from 1.23 to 6.44). Table 18, below, provides the mammalian chronic RQs.

Table 18. Mammalian Chronic Risk Quotients (RQs) based on NOAEC of 91.2 mg/kg-diet

Food type	Weight class (g)	RQs at Predicted Mean Residues
Short grass	15	6.44
	35	5.53
	1000	2.91
Tall grass	15	2.73
	35	2.34
	1000	1.23
Broadleaf forage, small insects	15	3.41
	35	2.93
	1000	1.54
Fruit, large insects	15	0.53
	35	0.46
	100	0.24
Seeds, pods	15	0.12
	35	0.1
	1000	0.08

(3) *Non-Target Insects*

EPA does not currently quantify risks to terrestrial non-target insects. RQs are therefore not calculated for these organisms. Since MCPB is practically non-toxic to bees on a contact exposure basis (LD_{50} of >23 µg/bee), the potential for MCPB to have adverse effects on pollinators and other beneficial insects is low.

(4) *Non-Target Terrestrial Plants*

EPA used the most sensitive seedling emergence values (0.02 and 0.016 lb ae/acre, respectively) for monocots and dicots, to calculate RQs for exposure to terrestrial plants near MCPB-treated fields. Exposure is expected due to runoff and spray drift. The acute LOCs for non-target terrestrial plants are exceeded for non-endangered monocots and dicots in dryland and semi-aquatic areas located near treated areas. Acute LOCs are also exceeded for monocots and dicots due to exposure from spray drift. Table 19, below, provides the terrestrial plant risk quotients.

Table 19. Terrestrial Plant Risk Quotients (RQs)

Scenario	Acute Non-Endangered RQs			Acute Endangered RQs		
	Adjacent to treated sites	Semi-Aquatic areas	Drift	Adjacent to treated sites	Semi-Aquatic areas	Drift
Ground spray application (1.5 lbs ae/acre)						
Monocot	4.50	38.25	0.94	9.00	76.50	--
Dicot	5.63	47.81	2.08	9.00	76.50	--
Aerial spray application (1.5 lbs ae/acre)						
Monocot	6.00	26.25	4.69	12.00	52.50	--
Dicot	7.50	32.81	10.42	12.00	52.50	–

4. Ecological Incidents

The Agency has not received any ecological incident reports for MCPB.

5. Endangered Species Concerns

The screening level ecological risk assessment results in a determination that the use of MCPB will have no direct acute effects on freshwater fish, freshwater invertebrates, and insects, and no direct chronic effect to birds. However, the Agency's level of concern for direct acute effects to endangered and threatened birds, and terrestrial and semi-aquatic plants, and for direct acute and chronic effects to mammals, is exceeded for the use of MCPB. Further, potential indirect effects to any species dependent upon a species that experiences effects from use of MCPB can not be precluded based on the screening level ecological risk assessment.

a. *Risk to Endangered Species*

The screening level risk assessment for listed species indicates that MCPB exceeds the acute endangered species LOCs for birds that feed on grasses, broadleaf forage, and small insects (RQs range up to 2.26 at maximum predicted residues) and terrestrial and semi-aquatic plants (RQs range up to 77). Also, the chronic LOC of 1.0 is exceeded for mammals foraging on grasses, broadleaf forage, small insects, fruit, and large insects (RQs range up to 20 at maximum predicted residues). In addition to

potential direct effects, there may be potential for indirect effects to listed species that are dependent upon a taxa that may experience effects from the use of this pesticide.

The Agency can not quantitatively predict potential acute direct effects to endangered and threatened estuarine/marine fish or aquatic vascular and non-vascular plants; nor direct chronic effects to endangerd and threatened fresh water fish and invertebrates, and estuarine/marine fish and invertebrates and therefore the potential for effects can not be precluded based on EPA's screening level ecological risk assessment. In the case of the current lack of effects thresholds for listed aquatic plants, the potential for indirect effects on listed species with obligate relationships on a given species of aquatic plant cannot be discounted because definitive RQs for comparison to the listed species LOCs are unavailable. Potential risks to endangered species identified in the Environmental Fate and Ecological Risk Assessment and reflected in this RED for MCPB are based solely on EPA's screening level ecological risk assessment and do not constitute "may effect" findings under the Endangered Species Act.

6. Risk Characterization

The risk assessment for MCPB is a conservative, screening-level assessment conducted with the maximum application rate of 1.5 lb ae/A.

Freshwater and estuarine/marine fish and aquatic invertebrates do not appear to be at acute risk from exposure to MCPB, and there are no risk concerns for non-endangered aquatic plants for the pea scenarios that were modeled.

EPA's level of concern is exceeded for chronic risk to mammals that consume grasses, broadleaf plants, and small insects, although the exceedances are relatively small (RQs range from 1.23 to 6.44; chronic LOC is exceeded if RQ > 1.0). This screening-level assessment assumes that 100 percent of the diet is comprised of single food types foraged only from treated fields. The assumption of 100 percent diet from a single food type may not be realistic for chronic exposures from the single annual application of MCPB to peas because diets are likely to be more variable over longer periods of time depending on size and forage range of animals.

EPA's level of concern is also exceeded for acute risk to small birds that consume short grasses, although the exceedances are relatively small (RQs range from 0.34 to 0.80). The screening-level assessment assumes that 100 percent of the diet is comprised of single food types. This assumption may be more realistic for acute risks than chronic risks. MCPB is categorized as moderately toxic to avian species on an acute oral basis, but it is practically non-toxic to avian species on an acute dietary basis. Based on these acute toxicity data, there is a large differential in the acute lethality when MCPB is administered as a single gavage for acute oral studies, as compared to when MCPB is mixed in the feed for acute dietary studies. There are limitations to both the dose-based and dietary-based method of calculating risk quotients; however, for many compounds a gavage dose represents a very short-term, high-intensity exposure, whereas dietary exposure may be of a more prolonged nature. The disparity in mortality between the two types of

studies suggests that the dietary matrix may have a lowering effect for the toxicity of MCPB.

EPA's level of concern is exceeded for terrestrial plants, which is expected based on MCPB's herbicidal properties. Risks are expected if exposure occurs, but there is very limited use of MCPB. It is only registered for use on pea crops, and it is approved for use only once per year, at a maximum rate of 1.5 lb ae/acre. Total annual use is less than 15,000 pounds.

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 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 to support reregistration of products containing MCPB as an active ingredient.

The Agency has completed its review of submitted data and its assessment of the human and ecological risks associated with the use of pesticide products containing the active ingredient MCPB. Based on a review of these data, the Agency has sufficient information on the human health and ecological effects of MCPB to make decisions as part of the tolerance reassessment process under FFDCA and the reregistration process under FIFRA, as amended by FQPA. The Agency has determined that MCPB-containing products are eligible for reregistration provided that: (i) required product-specific data are submitted; (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 MCPB that are eligible for reregistration. Appendix B identifies the generic data that the Agency reviewed as part of its determination for reregistration eligibility of MCPB, and lists the submitted studies that the Agency found acceptable.

Based on its evaluation of MCPB, the Agency has determined that MCPB products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA and FFDCA. 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 MCPB. If all changes outlined in this document are incorporated into the product labels, then all current risks for MCPB will be adequately mitigated for the purposes of this determination under FIFRA. Once the Endangered Species assessment is completed, further changes to these registrations may be necessary as explained in Section IV.D.3.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked extensively with stakeholders and the public to reach the regulatory decisions for MCPB. During the public comment period on the risk assessments, which closed on January 3, 2006, the Agency received comments from one private citizen, and the MCPB Task Force. These comments in their entirety are available in the public docket (EPA-HQ-OPP-2005-0263) at http://www.regulations.gov. A detailed Response to Comments document is available in the public docket as well.

The RED and technical supporting documents for MCPB are available to the public through EPA's electronic public docket and comment system, EPA Dockets, under docket identification (ID) number EPA-HQ-OPP-2005-0263. The public may access EPA Dockets at http://www.regulations.gov/fdmspublic-rel11/component/main. In addition, the MCPB RED may be downloaded or viewed through the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

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 MCPB. An aggregate assessment was conducted for exposures through food and drinking water. (Residential exposures were not aggregated because MCPB is not registered for residential use.) EPA has determined that risk from dietary (food and water sources) exposure to MCPB is within its own "risk cup." The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In other words, EPA has concluded that the tolerances for MCPB meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food and water.

b. *Determination of Safety to the U.S. Population*

The Agency has determined that the established tolerances for MCPB 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 other population from the use of MCPB. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of MCPB. As discussed in Chapter 3, the total acute and chronic dietary (food plus water) risks are below the Agency's level of concern (< 100% of the PAD) for the general population and all subgroups. The highest exposed population subgroup was infants (<1 years old) at < 4% of the aPAD and 10% of the cPAD.

c. *Determination of Safety to Infants and children*

The Agency has determined that the established tolerances for MCPB meet the safety standards under the FQPA amendments to Section 408(b)(2)(C) of the FFDCA, and that there is a reasonable certainty that no harm will result to infants and children. The safety determination for infants and children considers 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 MCPB residues in this population subgroup.

In determining whether infants and children are particularly susceptible to toxic effects from MCPB 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 for MCPB has been retained for acute exposures and partially retained for chronic exposures due to uncertainty in the toxicology database (lack of a DNT study). However, the toxicity database for MCPB, which is bridged from MCPA, includes acceptable developmental and reproductive toxicity studies and there is no evidence in the developmental or reproductive toxicity studies of sensitivity or susceptibility to newborns.

As discussed in Chapter 3, the total acute and chronic dietary (food plus water) risks are below the Agency's level of concern (< 100% of the PAD) for the general population and all subgroups. The highest exposed population subgroup was infants (<1 years old) at < 4% of the aPAD and 10% of the cPAD.

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. Furthermore, as the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP) and MCPB may be subject to additional screening.

e. *Cumulative Risks*

Risks summarized in this document are those that result only from the use of MCPB. 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 MCPB. 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 Reassessment Summary

a. *Tolerances Currently Listed Under 40 CFR § 180.318*

Tolerances are currently established under 40 CFR §180.318 for residues of MCPB [4-(2-methyl-4-chlorophenoxy)butyric acid)] *per se* in/on peas at 0.1 ppm. The Agency has concluded that the residue of concern for both tolerance enforcement and for dietary risk analysis consists of MCPB and MCPA, free and conjugated. The tolerance expression will be revised accordingly, once all data have been submitted (see Table 20). EPA notes that although additional data are required, there are no dietary risks associated with the tolerance for peas and EPA considers it reassessed at the current level.

No maximum residue limits (MRLs) for MCPB have been established by Codex for any agricultural commodity. Additionally, no Canadian or Mexican MRLs have been established for MCPB.

Table 20. Tolerance Reassessment Summary for Registered MCPB Uses

Commodity	Current Tolerance (ppm)	Range of Residues (ppm)	Tolerance Reassessment (ppm)	Comment
Tolerances Listed Under 40 CFR §180.318				
Pea	0.1(N)*	<0.05	0.1	Residue studies must be submitted depicting the magnitude of both MCPB and MCPA residues in/on peas.

* The "(N)" designation indicates negligible residues and EPA will propose to remove the "(N)" designation from all entries to conform to current Agency administrative practice.

D. Regulatory Rationale

The Agency has determined that MCPB is eligible for reregistration provided that 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 MCPB. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Mitigation

a. *Dietary (Food) Risk Mitigation*

The Agency's unrefined Tier 1 (100% crop treated) acute and chronic dietary (food only) risk assessments for MCPB indicated that acute and chronic risk estimates are below the Agency's level of concern. Therefore, no dietary risk reduction measures are required.

b. *Drinking Water Risk Mitigation*

Estimated environmental concentrations (EECs) of MCPB and its degradates for both ground water and surface water sources of drinking water are below the Agency's level of concern. Therefore, no mitigation is needed for drinking water.

c. *Aggregate Risk Mitigation*

EPA must consider and aggregate (add) pesticide exposures and risks from three major sources: food, drinking water, and residential. MCPB has no residential uses. Therefore, the aggregate exposure risk assessments for MCPB only incorporate exposures and risks from food and drinking water.

(1) *Acute Aggregate Risk*

The Agency's acute dietary (food plus water) risk assessment indicated that acute dietary risks are below the Agency's level of concern. Therefore, no mitigation is required.

(2) *Chronic Aggregate Risk*

The Agency's chronic dietary (food plus water) risk assessment indicated that chronic dietary risks are below the Agency's level of concern. Therefore, no mitigation is required.

d. *Occupational Risk Mitigation*

(1) *Handler Exposure*

EPA completes handler exposure assessments by using a baseline (long-sleeved shirt and long pants) exposure scenario and, if required, increasing levels of mitigation such as Personal Protective Equipment (PPE) or engineering controls to achieve an adequate margin of exposure (MOE). For MCPB, short- and intermediate-term inhalation risks to occupational handlers are below the Agency's level of concern (i.e., MOE ≥100) at baseline (i.e., no respirator) for mixers, loaders, and applicators. For dermal risks associated with mixing and loading for groundboom and aerial application, MOEs are above the Agency's level of concern (i.e., MOE < 100) at baseline, but are below EPA's level of concern (i.e., MOE ≥100) when chemical-resistant gloves

are added. To mitigate the potential dermal risks to mixers and loaders, chemical-resistant gloves will be required.

(2) *Post-Application Risk Mitigation*

EPA assessed short/intermediate-term post-application risks to workers who enter pea fields recently treated with MCPB to conduct tasks such as scouting and irrigation. EPA did not assess long-term post-application exposure risks because MCPB is used only once per season. Using the maximum application rate of 1.5 lb ae/A and the default dislodgeable foliar residue value of 20 percent, post-application risks are below the Agency's level of concern (i.e., MOEs ≥100) on day zero, or 12 hours after application. EPA has determined that a 12-hour restricted entry interval is appropriate for MCPB.

2. Environmental Risk Mitigation

EPA's levels of concern are exceeded for acute risk to small-sized birds and terrestrial plants, and chronic risk to mammals. EPA has determined that the risk mitigation that is appropriate for environmental concerns at this time is to require medium or coarser droplet sizes to minimize the potential for spray drift.

3. Endangered Species Considerations

From the screening-level assessment, RQs exceeded the LOCs for endangered species for some of the exposure scenarios. Chronic RQs exceed the LOCs for endangered mammals (RQs range from 2 to 20 at maximum residue levels), acute RQs exceed LOCs for endangered birds (RQs range from 0.2 to 2.26 at maximum residue levels), and acute RQs exceed the endangered terrestrial plant LOCs for monocots and dicots (RQs range from 9 to 77).

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. The Endangered Species Act (ESA) requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers it in relation to individual species and their locations by evaluating important ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species, as part of a refined species-specific analysis. When conducted, this species-specific analysis will take into consideration any regulatory changes recommended in this RED that are being implemented at that time.

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

4. Spray Drift Management

The Agency has been working with the Spray Drift Task Force, EPA Regional Offices, State Lead Agencies for pesticide regulation, and other parties to develop the best spray drift management practices. The Agency has completed its evaluation of the new database submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast, and ground hydraulic methods. After the policy is in place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application methods where appropriate.

Spray drift is a potential source of MCPB non-target exposure near spraying operations. This is particularly the case with aerial application, but spray drift exposure may also result from ground application of MCPB. To minimize the potential for spray drift, the Agency is requiring medium or coarser droplet sizes for all MCPB end-use products. Additionally, the Agency encourages the inclusion of best management practices on labels to reduce spray drift. In the future, MCPB labels may need to be revised to include additional or different drift label statements.

V. What Registrants Need to Do

The Agency has determined that MCPB is eligible for reregistration provided that product-specific data are submitted and the mitigation measures stated in this document are included in upcoming label submissions. In the near future, the Agency intends to issue Data Call-In (DCI) notices requiring product-specific data and generic confirmatory data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extensions and/or waivers with a full written justification. For product-specific data,

the registrant will have eight months to submit data and amended labels. For generic data, due dates can vary depending on the specific studies being required. Listed below are the additional generic data that the Agency intends to require.

F. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of MCPB for the above eligible use has been reviewed and determined to be substantially complete based on bridging from MCPA data. However, the data listed below, in Tables 21 and 22, are necessary to confirm the reregistration eligibility decision documented in this RED.

Table 21. Toxicology and Residue Chemistry Data Requirements

Study Required	Guideline Number	Comment
Confined Accumulation in Rotational Crops Study	860.1850	Must be conducted with MCPB
Magnitude of Residues in Plants	860.1300	Must be conducted with MCPB and MCPA
Enforcement Analytical Methods	860.1340	Must be conducted with MCPB and MCPA
Developmental neurotoxicity study in rats *[Reserved]*	870.6300	Reserved pending outcome of developmental neurotoxicity study in rats with MCPA 2-EHE
28-day Inhalation Study (abbreviated 90-day protocol) *[Reserved]*	870.3465	Reserved pending outcome of 28-day Inhalation Study with MCPA

Table 22. Environmental Fate and Ecological Toxicity Data Requirements

Study Required	Guideline Number	Comment
Terrestrial Field Dissipation	835.1600	
Estuarine/marine invertebrate acute EC_{50} (eastern oyster)	850.1025	
Estuarine/marine fish acute LC_{50} (sheepshead minnow)	850.1075	
Freshwater fish early life stage (fathead minnow)	850.1400	
Freshwater invertebrate life cycle (daphnia) *[Reserved]*	850.1300	Reserved pending the outcome of acute estuarine/marine fish and invertebrate studies.
Estuarine/marine life cycle (mysid) *[Reserved]*	850.1350	Reserved pending the outcome of acute estuarine/marine fish and invertebrate studies.
Estuarine/marine life cycle (fish) *[Reserved]*	850.1400	Reserved pending the outcome of acute estuarine/marine fish and invertebrate studies.
		Reserved pending the outcome of acute

Study Required	Guideline Number	Comment
Freshwater fish full life cycle *[Reserved]*	850.1500	estuarine/marine fish and invertebrate studies.

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 23 at the end of this section.

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 they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrations Response Form provided for each product. The Agency intends to issue a separate product-specific Data Call-In outlining specific data requirements.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. The specific changes and language required are presented in Table 23 below.

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. Please refer to "Existing Stocks of Pesticide Products; Statement of Policy," Federal Register, Volume 56, No. 123, June 26, 1991.

C. Labeling Changes Summary Table

In order to be eligible for reregistration, registrants must 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 23: Summary of Labeling Changes for MCPB		
Description	**Amended Labeling Language**	**Placement on Label**
Manufacturing Use Products		
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	"Only for formulation into an ***herbicide*** for use on peas."	Directions for Use
	"This product may be used to formulate products for specific use(s) not listed on the MUP 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 waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency."	Precautionary Statements
End Use Products Intended for Occupational Use (WPS)		
PPE Requirements Established by the RED[1]	"Personal Protective Equipment (PPE)	Immediately following/below

for liquid formulations	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. Mixers, loaders, and other handlers must wear: · Long-sleeved shirt · Long pants · Shoes plus socks · Chemical-resistant gloves when mixing, loading or exposed to the concentrate. ”	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	“Follow manufacturer’s instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.”	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
Engineering Controls	“Engineering Controls: Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(6)].”	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
User Safety Recommendations	“User Safety Recommendations Users should wash with plenty of soap and water 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	“Environmental Hazards	Precautionary Statements immediately

	Avoid spray drift as this product may injure susceptible crops and plants such as cotton, beans, grapes, tomatoes and ornamentals. (Course sprays are less likely to drift.) Do not use same spray equipment for other purposes unless thoroughly cleaned prior to use. Do not apply this product through any type of irrigation system."	following the User Safety Recommendations
Restricted-Entry Interval	"Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours."	Directions for Use, Agricultural Use Requirements Box
Early Re-entry Personal Protective Equipment established by the RED.	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: Coveralls, Shoes plus socks, Chemical-resistant gloves made of any waterproof material"	
General Application Restrictions	"It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read entire label before using this product." "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirement specific to your State or Tribe, consult the agency responsible for pesticide regulations."	Place in the Direction for Use directly above the Agricultural Use Box.
Spray Drift Label Language for Products Applied as a Spray	"Apply only as a medium or coarser spray (ASAE standard 572) or a volume mean diameter of 300 microns or greater for spinning atomizer nozzles." "A variety of factors including weather conditions (e.g., wind direction, wind speed, temperature, relative humidity) and method of application (e.g., ground, aerial, airblast, chemigation) can influence pesticide drift. The applicator and grower must evaluate all factors and make appropriate adjustments when applying this product. WIND SPEED: Do not apply at wind speeds greater than 10 mph at the application site." DROPLET SIZE: "Apply as a medium or coarser spray (ASAE standard 572)." RELEASE HEIGHT (GROUND APPLICATION):	Directions for Use under General Precaution and Restrictions

	"Apply using a nozzle height of no more than 4 feet above the ground or crop canopy." RELEASE HEIGHT (AERIAL APPLICATION): "Do not release spray at a height greater than 10 feet above the ground or crop canopy."	

[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.

Instructions in the Labeling section appearing in quotations represent the exact language that should appear on the label.
Instructions in the Labeling section not in quotes represents actions that the registrant should take to amend their labels or product registrations.

VI. Related Documents and How to Access Them

This interim Reregistration Eligibility Document is supported by documents that are presently maintained in the OPP docket under docket number EPA-HQ-2005-0263. The OPP docket is located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding legal holidays from 8:30 am to 4 pm. The documents are also available on-line in the Federal Docket Management System (FDMS) at http://www.regulations.gov.

The docket initially contained preliminary risk assessments and related documents as of November 2, 2005. Sixty days later, on January 3, 2006, the public comment period closed. The EPA then considered the comments received, revised the risk assessments as necessary. EPA then added formal "Response to Comments" documents, the Reregistration Eligibility Decision (RED) document, and the revised risk assessments to the docket on July 21, 2006.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at http://www.regulations.gov.

Appendix A:
Use Patterns Eligible for Reregistration for use on Peas

Table 1. MCPB use on Peas

Application Type, Equipment	Formulation	Max. Single App. Rate (lbs ae/A)	Seasonal Max. (lbs ae/A/Yr)	PHII (Days)	REI (Hours)	Restrictions/Comments
Spray/ground and Aerial	Thistrol Herbicide (71368-5) and Sodium MCPB Solution (71368-7)	1.5	1.5	1	24	Use single layer PPE

Appendix B:
Data Supporting Guideline Requirements of the Reregistration of MCPB

Table 1. Product Chemistry

New Guideline Number	Old Guideline Number	Requirement	Use	Citation(s)
860.1400	171-4H	Magnitude of Residue in Irrigated Crops	Peas	44754101

Table 2. Ecological Effects

New Guideline Number	Old Guideline Number	Requirement	Use	Citation(s)
850.2100	71-1	Bobwhite Quail	Peas	42560801
850.2200	71-2A	Avian Acute Dietary Toxicity Test, Bobwhite quail	Peas	42560802
850.2200	71-2B	Avian Acute Dietary Toxicity Test, Mallard	Peas	42560803
850.1075	72-1C	Fish Acute Toxicity Test Rainbow Trout	Peas	42532608
850.1075	72-1A	Fish Acute Toxicity Test, Bluegill Sunfish	Peas	42532601
850.1010	72-2A	Invertebrate Acute Toxicity Test, Freshwater Daphnids	Peas	42532602
850.1100	82-1	Acute Oral Toxicity Test, Rat	Peas	144801, 116340
870.3100	82-1A	Subchronic Oral Toxicity Test, (90-day Feeding, rodent)	Peas	42883602, 42883601
870.3150	82-1B	Subchronic Oral Toxicity Test, (90day - Feeding, non-rodent)	Peas	116345, 116344, 42883603
870.3700	83-3A	Prenatal Developmental Toxicity (Teratogenicity), RAP	Peas	40865402
870.3700	83-3B	Prenatal Developmental Toxicity (Teratogenicity), Rabbit	Peas	40865401
870.3800	83-4A (MCPA)	2-generation Reprodution and Fertility	Peas	40041701
850.4150	122-1B	Terrestrail Plant, Tier 1 (Vegetative Vigor)	Peas	42560804, 43083205 (MCPA)
850.5400	122-2A	Algal Toxicity, Tier 1	Peas	42532605,42532603,42532609, 42532606
850.5400	122-2B	Algal Toxicity, Tier 2	Peas	42532605, 42532609, 42532603, 42532606

850.4225	123-1A	Seedling Germination and Seedling Emergence, Tier 2	Peas	42560804
850.4250	123-1B	Vegetative Vigor, Tier 2	Peas	42560804
850.4400	123-2	Aquatic Plant Toxicity Test Using Duckweed Lemma	Peas	42532604
850.3020	141-1	Honey Bee Acute Contact Toxicity	Peas	42532607

Table 3. Toxicology

New Guideline Number	Old Guideline Number	Requirement	Use	Citation(s)
870.1100	81-1	Acute Oral Toxicity-Rat	Peas	116340, 144801
870.1200	81-2	Acute Dermal Toxicity-Rabbit/Rat	Peas	116342, 144799
870.1300	81-3	Acute Inhalation Toxicity-Rat	Peas	41630001
870.2400	81-4	Primary Eye Irritation- Rabbit	Peas	116343, 144797
870.2500	81-5	Primary Skin Irritation - Rabbit	Peas	144798
870.2600	81-6	Dermal Sensitization, Guinea Pig	Peas	144800
870.3100	82-1A	Subchronic Oral Toxicity Test (90 Day Feeding - Rodent)	Peas	42883602
870.3150	81-1B	Subchronic Oral Toxicity Test (90 Day Feeding - Non-Rodent)	Peas	42883603
870.3200	82-3	Repeated Dose Dermal Toxicity Test (21 Day), Rabbit	Peas	116346
870.3700a	83-3A	Prenatal Developmental Toxicity, (Teratogenicity), Rat	Peas	40865402
870.3700b	83-3B	Prenatal Developmental Toxicity, (Teratogenicity), Rabbit	Peas	40865401
870.5100	84-2	Bacterial (Escherichia Coll Wp2 and Wp2 uvrA) Reverse Gene Mutation Assay Test	Peas	40564302, 40564303
870.5375	84-2B	In Vitro Mammalian Cytogenetics Tests (Structural Chromosomal Aberration Test)	Peas	40564301
870.5550	84-2	Unscheduled DNA synthesis in Mammalian Cells in Culture	Peas	40564304
870.7485	85-1	Metabolism and Pharmacokinetics (General Metabolism)	Peas	44818101

Table 4. Environmental Fate

New Guideline Number	Old Guideline Number	Requirement	Use	Citation(s)
835.2120	161-1	Hydrolysis of Parent and Degradates as a Function of pH at 25°C (Hydrolysis)	Peas	42574301
835.2240	161-2	Direct Photolysis Rate of Parent and Degradates in Water (Photodegradation in water)	Peas	42574302
835.2410	161-3	Photodegradation of Parent and Degradates in Soil (Photodegradation in soil)	Peas	43829901
835.4100	162-1	Aerobic Soil Metabolism Study	Peas	43247601
835.4200	162-2	Anaerobic Soil Metabolism Study	Peas	43015501
835.1230	163-1	Sediment (Leaching) and Soil Absorption/desorption for Parent and Degradates	Peas	42693701, 43466401

Appendix C:
Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in 2777 Crystal Drive (One Potomac Yard) Arlington, VA 22202. It is open Monday through Friday, excluding legal holidays, from 8:30 AM to 4:30 PM.

The docket initially contained preliminary human health and ecological effects risk assessments and related documents that were published November 2, 2005. The public comment period closed sixty days later, on January 3, 2006. The EPA then considered the comments received and revised the risk assessments where appropriate. Revised ecological risk assessments, as well as additional supporting documents will be published in the docket with this RED.

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

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40564301	SanSebastian, J. (1987) 2-Methyl-4-chlorophenoxybutyric Acid (MCPB Acid): In vitro Chromosome Aberration Analysis in Chinese Hamster Ovary (CHO) Cells: Laboratory Project ID PH 320-RP-001- 87. Unpublished study prepared by Pharmakon Research Interna- tional, Inc. 34 p.

40564302	Stankowski, L. (1987) 2-Methyl-4-chlorophenoxybutyric Acid (MCPB Acid): Ames/Salmonella Plate Incorporation Assay: Laboratory Project ID PH 301-RP-001-87. Unpublished study prepared by Pharmakon Research International, Inc. 22 p.
40564303	Stankowski, L. (1988) @-Methyl-4-chlorophenoxybutyric.acid (MCPB Acid): CHO/HPRT Mammalian Cell Forward Gene Mutation Assay: Laboratory Project ID PH 317-RP-001-87. Unpublished study pre- pared by Pharmakon Research International, Inc. 67 p.
40564604	Barfknecht, T. (1987) @-Methyl-4-chlorophenoxybutyric Acid (MCPB Acid): Rat Hepatocyte Primary Culture/DNA Repair Test: Laboratory Project ID PH 311-RP-001-87. Unpublished study pre- pared by Pharmakon Research International, Inc. 68 p.
40865401	Tyl, R.; Neeper-Bradley, T. (1988) Developmental Toxicity Evaluati- on of MCPB Administered by Gavage to New Zealand White Rabbits: Laboratory Project ID 51-547. Unpublished study prepared by Bu- shy Run Research Center. 241 p.
40865402	Tyl, R. (1988) Development Toxicity Evaluation of MCPB Administe- red by Gavage to CD (Sprague Dawley) Rats: Laboratory Project ID 51-532. Unpublished study prepared by Bushy Run Research Cente- r. 299 p.
41630001	Jackson, G.; Hardy, C.; Lewis, D.; et al. (1985) MCPB Technical Acid Acute Inhalation Toxicity Study in Rats 4-Hour Exposure: Lab Project Number: AHM17/85188. Unpublished study prepared by Hungtindon Research Centre, Ltd. 47 p.
42574301	Das, Y. (1992) Hydrolysis of (carbon 14)MCPB in Aqueous Solutions Buffered at pH 5, 7 and 9: Lab Project Number: 92010: 92-06. Unpublished study prepared by Innovative Scientific Services, Inc. 77 p.
42574302	Das, Y. (1992) Photodegradation of (carbon 14)MCPB in Aqueous Solutions Buffered at pH 5, 7 and 9 under Artificial Sunlight: Lab Project Number: 92011: 92-07. Unpublished study prepared by Innovative Scientific Services, Inc. 174 p.
42693701	Robson, M. (1993) Determination of Adsorption/Desorption Characteristics of 4-(2-Methyl,4-Chlorophenoxy) Butyric Acid (MCPB) in Soil: Final Report: Lab Project Number: 68/127: 7414. Unpublished study prepared by

	Hazleton UK. 81 p.
42883601	Trutter, J. (1993) Range-Finding Dietary Toxicity Study with MCPB in Rats: Final Report: Lab Project Number: HWA 656-173. Unpublished study prepared by Hazleton Washington, Inc. 275 p.
42883602	Trutter, J. (1993) 13-Week Dietary Toxicity Study with MCPB in Rats: Final Report: Lab Project Number: HWA 656-174. Unpublished study prepared by Hazleton Washington, Inc. 439 p.
42883603	Dalgard, D. (1993) 13-Week Dietary Toxicity Study with MCPB in Dogs: Final Report: Lab Project Number: HWA 656-172. Unpublished study prepared by Hazleton Washington, Inc. 406 p.
43015501	Goodyear, A. (1993) Carbon 14-MCPB: Anaerobic Soil Metabolism: Final Report: Lab Project Number: 68/131-1015: 68/131: 200352. Unpublished study prepared by Hazleton UK. 90 p.
43247601	John, A.; Jones, M.; Lowden, P.; et al. (1994) MCPB: Aerobic Soil Metabolism: Lab Project Number: P/93/194. Unpublished study prepared by Rhone-Poulenc Agriculture Ltd. 108 p.
43466401	John, A.; Jones, M.; Lowden, P. (1994) MCPB: Fresh and Aged Leaching Study in Five Soils: Lab Project Number: P 92/333: 200724: RPAL P92/333. Unpublished study prepared by Rhone-Poulenc Agriculture Ltd. 142 p.
43829901	Ferreira, E.; John, A.; Lowden, P.; et al. (1995) MCPB Soil Photolysis Study: Amended Report: Lab Project Number: P92/126 Unpublished study prepared by Rhone-Poulenc Agriculture Ltd. 75 p. (Amended version of 42519101).
44754101	Corley, J.; Kunkel, D. (1999) MCPB: Magnitude of Residue on Pea (Reregistration): Lab Project Number: 05470.94-CAR23: 05470.94-CA52: 05470.94-NY17. Unpublished study prepared by University of California. 423 p.
44818101	Thornley, K. (1998) (Carbon-14)-MCPB: A Study of Adsorption, Distribution, Metabolism, and Excretion Following Oral Administration to the Rat: Final Report: Lab Project Number: 785/10-D1141. Unpublished study prepared by Covance. 195 p.

PC Code: 019202

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42532601	Bettencourt, M. (1992) MCPB Sodium--Acute Toxicity to Bluegill Sunfish (Lepomis macrochirus) under Flow-through Conditions: Final Report: Lab Project Number: 92-8-4363: 10566.0392.6226.105. Unpublished study prepared by Springborn Labs, Inc. 64 p.
42532602	Putt, A. (1992) MCPB Sodium--Acute Toxicity to Daphnids (Daphnia magna) under Flow-through Conditions: Final Report: Lab Project Number: 92-7-4351: 10566. 0392. 6228. 115. Unpublished study prepared by Springborn Labs, Inc. 2 p.
42532603	Hoberg, J. (1992) MCPB Sodium--Toxicity to the Freshwater Blue-green Alga, Anabaena flos-aquae: Final Report: Lab Project Number: 92-8-4381: 10566.0392.6230.420. Unpublished study prepared by Springborn Labs, Inc. 54 p.
42532604	Hoberg, J. (1992) MCPB Sodium--Toxicity to the Duckweed Lemna gibba: Final Report: Lab Project Number: 92-8-5368: 10566. 0392.6229.410. Unpublished study prepared by Springborn Labs, Inc. 61 p.
42532605	Hoberg, J. (1992) MCPB Sodium--Toxicity to the Freshwater Green Alga, Selenastrum capricornutum: Final Report: Lab Project Number: 92-8-4361: 10566.0392.6232.430. Unpublished study prepared by Springborn Labs, Inc. 58 p.
42532606	Hoberg, J. (1992) MCPB Sodium--Toxicity to the Marine Diatom, Skeletonema costatum: Final Report: Lab Project Number: 92-8-4372: 10566.0392.6233.450. Unpublished study prepared by Springborn Labs, Inc. 59 p.
42532607	Maggi, V. (1992) Acute Contact Toxicity of MCPB Sodium Salt to Honey Bees (Apis mellifiora L.): Lab Project Number: CAR 169-92. Unpublished study prepared by California Agricultural Research, Inc. 22 p.
42532608	Bettancourt, M. (1992) MCPB Sodium--Acute Toxicity to Rainbow Trout (Oncorrhynchus mykiss) under Flow-through Conditions: Final Report:

	Lab Project Number: 92-7-4338: 10566.0392.6227. 108. Unpublished study prepared by Springborn Labs, Inc. 64 p.
42532609	Hoberg, J. (1992) MCPB Sodium--Toxicity to the Freshwater Diatom, Navicula pelliculosa: Final Report: Lab Project Number: 92-10-4448: 10566.0392.6231.440. Unpublished study prepared by Springborn Labs, Inc. 60 p.
42560801	Pedersen, C.; Helsten, B. (1992) MCPB Sodium: 14-day Acute Oral LD50 Study in Bobwhite Quail: Lab Project Number: 108-016-03. Unpublished study prepared by Bio-Life Associates, Ltd. 59 p.
42560802	Pedersen, C.; Helsten, B. (1992) MCPB Sodium: 8-day Acute Dietary LC50 Study in Bobwhite Quail: Lab Project Number: 108-014-01. Unpublished study prepared by Bio-Life Associates, Ltd. 103 p.
42560803	Pedersen, C.; Helsten, B. (1992) MCPB Sodium: 8-day Acute Dietary LC50 Study in Mallard Ducklings: Lab Project Number: 108-015-02. Unpublished study prepared by Bio-Life Associates, Ltd. 103 p.
42560804	Christensen, K. (1992) MCPB Sodium; Determination of Effects on Seed Germination, Seedling Emergence and Vegetative Vigor of Ten Plant Species: Final Report: Lab Project Number: 92-8-4377. Unpublished study prepared by Springborn Labs, Inc. 208 p.
44754101	Corley, J.; Kunkel, D. (1999) MCPB: Magnitude of Residue on Pea (Reregistration): Lab Project Number: 05470.94-CAR23: 05470.94-CA52: 05470.94-NY17. Unpublished study prepared by University of California. 423 p.

PC Code: 030501

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40041701	MacKenzie, K. (1986) Two-Generation Reproduction Study with MCPA in Rats: Final Report: Study No. 6148-100. Unpublished study pre- pared by Hazleton Laboratories America, Inc. 1304 p.
43083205	Hoberg, J. (1993) MCPA Acid--Determination of Effects on Seed Germination, Seedling Emergence and Vegetative Vigor of Ten Plant

	Species: Final Report: Lab Project Number: 10566.0493. 6280.610: 93-8-4888. Unpublished study prepared by Springborn Laboratories, Inc. 246 p.
106595	Reuzel, P.; Hendriksen, C.; Feron, V.; et al. (1980) Subchronic (13-week) Oral Toxicity Study of MCPA in Beagle Dogs: Report No. R 6478. Final rept. (Unpublished study received Jul 6, 1982 under unknown admin. no.; prepared by Centraal Instituut Voor Voedingsonderzoek, TNO, Neth., submitted by Diamond Shamrock Agricultural Chemicals, Cleveland, OH; CDL:247854-A; 247855; 247856)
165471	Kirsch, P. (1985) Report on the Study of the Toxicity of MCPA in Rats after 3 Months Administration in the Diet: [Range-finding Study for 2-year Oncogenicity Study in Rats]: Project No. 31S0046/8302. Unpublished study prepared by BASF Ag. 381 p.
42723801	Hellwig, J.; Hildebrand, B. (1993) Study of the Prenatal Toxicity of MCPA-Acid in Rats after Oral Administration (Gavage): Lab Project Number: 30R0374/91096. Unpublished study prepared by BASF Aktiengesellshaft. 302 p.
42723802	Hellwig, J.; Hildebrand, B. (1993) Study of the Prenatal Toxicity of MCPA-Acid in Rabbits after Oral Administration (Gavage): Lab Project No. 40R0374/91095. Unpublished study prepared by BASF Aktiengesellshaft. 230 p.
43562601	Mellert, W.; Deckardt, K.; Kaufmann, W.; et al. (1994) MCPA-Acid--Subchronic Oral Dietary Toxicity and Neurotoxicity Study in Wistar Rats: Lab Project Number: 50C0374/91133. Unpublished study prepared by BASF Aktiengesellschaft. 723 p.

Appendix E:
Generic Data Call-In

The Generic Data Call-In will be posted at a later date. See Chapter V of the MCPB RED for a list of studies required.

Appendix F:
Product Specific Data Call-In

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

Appendix G:
EPA's Batching of MCPB Products for Meeting Acute Toxicity Data Requirements for Reregistration

EPA'S BATCHING OF MCPB 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 MCPB as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

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

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In

Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

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

Batching Instructions:

No Batch: Each product in this Batch should have its own data generated.

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

Batch 1	EPA Reg. No.	% Active Ingredient
	15440-28	95.5
	71368-8	97

No Batch	EPA Reg. No.	% Active Ingredient
	15440-38	23.5
	71368-5	23.5

No Batch	EPA Reg. No.	% Active Ingredient
	71368-7	43.85

Appendix H:
List of Registrants Sent This Data Call-In

A list of registrants sent this Data Call-In will be posted at a later date

A H MARKS & CO LTD
Richard J. Otten
Official Address:
PMB 239, 7474 Creedmoor Road
Raleigh, North Carolina 27613
United States
Agent Phone: (919) 846-7860

NUFARM, INC.
Theodore D. Head
Official Address
150 Harvester Drive Suite 200
Burr Ridge, Illinois 60527
United States
Agent Phone: (630) 455-2000

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

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

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

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

Instructions

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

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

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

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

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

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

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-2	Application for/Notification of	http://www.epa.gov/opprd001/forms/857

5	State Registration of a Pesticide To Meet a Special Local Need	0-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit 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' website.

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

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

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

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

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

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

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

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

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

Documents Associated with this RED

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

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