



Reregistration Eligibility Decision (RED) for Mecoprop-p (mcpp)

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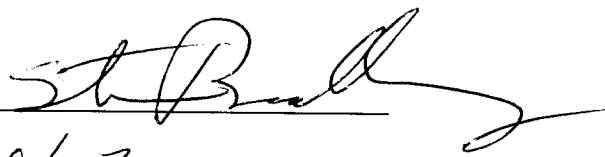
EPA 738-R-07-009

Reregistration Eligibility Decision for Mecoprop-p (MCP-P)

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Mecoprop-p (MCP-p)

List A

Case No. 0377

Approved by: 
Date: 8/28/07

Steven Bradbury, PhD., Director
Special Review and Reregistration Division

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EPA MCPP-p Team*Ecological Fate and Effects Division*

Christine Hartless

Holly Galavotti

Thuy Nguyen

James Lin

Health Effects Division

Timothy Dole

Kit Farwell

Whang Phang

Registration Division

Joanne Miller

Eugene Wilson

Special Review and Reregistration Division

Kevin Costello

Rosanna Louie

Patricia Moe

Biological Economics and Analysis Division

Jenna Carter

Bill Chism

Steve Jarboe

Andrew Lee

Bill Phillips

U.S. Department of Agriculture

Harold Coble

Glossary of Terms and Abbreviations

ae	Acid Equivalent
ai	Active Ingredient
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
DCI	Data Call-In
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
GENEEC	Tier I Surface Water Computer Model (Estimated Aquatic Environmental Concentrations)
LC ₅₀	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD ₅₀	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
N/A	Not Applicable
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
ppb	Parts per Billion
PPE	Personal Protective Equipment
ppm	Parts per Million
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RQ	Risk Quotient
TGAI	Technical Grade Active Ingredient
UV	Ultraviolet
WPS	Worker Protection Standard

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or “the Agency”). Reregistration involves a thorough review of the scientific database underlying a pesticide’s registration. The purpose of the Agency’s review is to reassess the potential risks arising from the currently registered uses of the pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the “no unreasonable adverse effects” criterion of FIFRA.

This document summarizes EPA’s human health and ecological risk assessments and reregistration eligibility decision (RED) for mecoprop-p (MCP-P), in the form of MCP-P acid, MCP-P dimethylamine salt (MCP-P DMAS), and MCP-P potassium salt. Because it is expected for these forms of MCP-P to quickly dissociate to the MCP-P acid, MCP-P will represent the acid form throughout this document. The document consists of six sections. Section I contains the regulatory framework for reregistration; Section II provides an overview of the chemical and a profile of its use and usage; Section III gives an overview of the human health and environmental effects risk assessments; Section IV presents the Agency’s decision on reregistration eligibility and risk management; and Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices list related information, supporting documents, and studies evaluated for the reregistration decision. The risk assessments for MCP-P and all other supporting documents are available in the Office of Pesticide Programs (OPP) public docket at www.regulations.gov under docket number EPA-HQ-OPP-2006-0943.

II. Chemical Overview

A. Regulatory History

A Registration Standard Guidance Document was issued in December 1988 on mecoprop acid, its salts, and ester forms, which summarized the regulatory conclusions based on available data, and specified the additional data required for reregistration purposes. The mecoprop case (0377) includes several forms of MCPP-p, of which only three forms are being supported for reregistration. The technical registrants, A.H. Marks and Company Limited, NuFarm UK Limited, and NuFarm Americas Incorporated, formed the MCPP-p Task Force to produce data needed for the reregistration review of MCPP-p.

Originally registered as an herbicide in the 1960s, the composition was a 50:50 ratio mixture of the dextro and levo (or R and S, respectively) isomers of MCPP. Subsequently, the dextro isomer was identified as the herbicidally active isomer, but no economic route was available to produce only the dextro isomer. In the 1980s, technologies were developed to produce the single enriched isomer form, MCPP-p, on a commercial scale, achieving approximately 93-95% purity of MCPP-p. Thus, the MCPP-p Task Force agreed to develop new data to fulfill guideline requirements for reregistration based on the enriched isomer, MCPP-p. Subsequently, data submissions have been received and evaluated since the Registration Standard Guidance Document was published.

In 1996, the technical manufacturers began to obtain EPA registrations for technical MCPP-p. Gradually, some end-use product (EUP) registrants began converting their formulations from the older racemic form to the single enriched isomer compositions. In September 2006, the Agency presented options to EUP registrants producing formulations that contained the racemic mecoprop: 1) convert their product formulations to contain the enriched isomer, MCPP-p; 2) produce data supporting the racemic mecoprop; or 3) submit voluntary cancellations for products they no longer wish to support. As of January 2007, EPA received voluntary cancellations or commitments to convert all product formulations to the enriched isomer, MCPP-p. Most products have been reformulated to the enriched isomer formulation and all reformulations are anticipated to be completed by the Fall of 2007. Table 1 lists all forms of MCPP-p included as part of the case and identifies active ingredients the MCPP-p Task Force is supporting.

Table 1. Summary of Mecoprop and Mecoprop-p Active Ingredients, Case No. 0377				
PC Code	CAS #	Name	Task Force Supported	Active Registrations
031501	7085-19-0	Mecoprop (and salts and esters)	No	Yes*
031503	1929-86-8	Mecoprop, potassium salt	No	No
031516	1432-14-0	Diethanolamine 2-(2-methyl-4-chlorophenoxy)propionate	No	No
031519	32351-70-5	Mecoprop, dimethylamine salt	No	Yes*
031520	66423-09-4	Propanoic acid, 2-(4-chloro-2-methylphenoxy)-, (R)-, compd. with N-methylmethanamine (MCPP-p DMAS)	Yes	Yes
031563	28473-03-2	Mecoprop, isooctyl ester	No	No
031564	861229-15-4	2-Ethylhexyl (R)-2-(2-methyl-4-chlorophenoxy)propionate	No	No
129046	16484-77-8	Mecoprop-p acid	Yes	Yes
119046	66423-05-0	(+)-(R)-2-(4-chloro-2-methylphenoxy) propanoic acid, potassium salt	Yes	Yes

*This indicates that products labels are currently transitioning from MCPP to MCPP-p as the active ingredient.

B. Chemical Identification

MCPP-p compounds are plant growth regulators that are part of the chlorophenoxy group of herbicides. Chemical information and structures for technical MCPP-p and its salts that are being supported are presented in Table 2. Table 3 presents the physical and chemical properties of MCPP-p acid.

Table 2. MCPP-p Chemical Information and Structures				
Compound Name	PC Code	CAS Number	Molecular Weight	Structure
MCPP-p; (+)-R-2-(4-chloro-2-methylphenoxy) propanoic acid (MCPP-p acid)	129046	16484-77-8	214.6 g/mol	
MCPP-p Dimethylamine Salt (DMAS)	031520	66423-09-4	259.7 g/mol	
MCPP-p potassium salt	119046	66423-05-0	252.7 g/mol	

Table 3. Physical and Chemical Properties of MCP-P acid	
Parameter	Value and Unit
Chemical Name	2-(4-chloro-2-methylphenoxy) propanoic acid
CAS Number	16484-77-8
Empirical Formula	C ₁₀ H ₁₁ ClO ₃
Molecular Weight	214.6 g/mole
Appearance	Colorless crystal
Odor	Odorless
Density	0.6 g/ml, dry uncompacted
Melting Point	94 - 95 °C
Organic Solvents Solubility	Readily soluble in benzene, acetone, chlorinated hydrocarbons
Vapor pressure (20 °C)	1.4 x 10 ⁻⁵ torr
Water Solubility (20 °C)	620 mg/L

C. Use Profile

Mecoprop-p (MCP-P) is a member of the chlorophenoxy class of herbicides. All technical product registrations now contain the MCP-P (R) isomer as the active ingredient. At the present, the MCP-P Task Force is supporting MCP-P acid, MCP-P DMAS, and MCP-P potassium salt. Henceforth, the MCP-P acid equivalent will be referred to as MCP-P.

Type of Pesticide: Herbicide

Target Pests: Annual and perennial broadleaf weeds.

Mode of Action: MCP-P is thought to increase cell-wall plasticity, biosynthesis of proteins, and the production of ethylene. The abnormal increase in these processes result in abnormal and excessive cell division and growth, damaging vascular tissue. The most susceptible tissues are those that are undergoing active cell division and growth.

Use Sites: Ornamental lawns, recreational turf, sports fields, sod farms, roadsides, industrial sites, and rights-of-ways.

Use Classification: General Use

Formulation Types: *Acid* - granular, emulsifiable concentrate, water-soluble concentrate dry, wettable powder.
DMAS - granular, water-soluble concentrate liquid, water soluble concentrate dry.
Potassium Salt - emulsifiable concentrate, soluble concentrate, Ready-to-Use solution.

Application Methods: Boom sprayers, handheld nozzle or wand sprayers, knapsack sprayers, granular spreaders.

Application Rates: Maximum application rate is 1.2 lbs acid equivalent of

MCP-P per acre (ae MCP-P/A), with a maximum of two applications per year. The Task Force indicated that the majority of typical use rates range from 0.20 to 0.78 lb ae MCP-P/A.

Application Timing: Post-emergence, when weeds are young and actively growing.

Registrants: A.H. Marks and Company Limited, NuFarm UK Limited, and NuFarm Americas Incorporated.

D. Estimated Usage of Pesticide

The majority of MCP-P use is associated with residential lawns, with smaller usage on other recreational turf and non-agricultural grassy areas. Based on usage information provided by the MCP-P Task Force (also referred to as the Task Force), total annual domestic usage of MCP-P is approximately 5 million pounds: >97% are applied to residential lawns, 2% is applied to golf courses, and <1% is applied to turf farms and other uncultivated non-agricultural land. According to the Task Force, geographical use areas for applications to turf in roughly descending order: Midwest, Northeast, South, Northwest, and West. MCP-P is often co-formulated with other chlorophenoxy herbicides, including 2,4-D and dicamba.

III. Summary of Mecoprop-p Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the RED. The human health and ecological risk assessments and supporting documents found in Appendix C were used to formulate the safety finding and regulatory decision for the pesticidal use of mecoprop-p and its related salts.

While the risk assessments and related addenda are not included in this document, they are available in the OPP Public Docket, docket number EPA-HQ-OPP-2006-0943, and may be accessed through the Agency's website at <http://www.regulations.gov/>. Hard copies of these documents may also be found in the OPP public docket under this same docket number.

- *MCPP-p acid, MCPP-p DMAS, & MCPP-p potassium salt: HED Human Health Risk Assessment. July 30, 2007.*
- *FQPA Drinking Water Assessment for Mecoprop-p. June 26, 2006.*
- *Environmental Fate and Effects Science Chapter for MCPP-p acid, MCPP-p DMAS, and MCPP-p potassium salt. August 28, 2007.*

A. Human Health Risk Assessment

The human health risk assessment addressed potential risks from all registered sources. Because MCPP-p is not registered on any food commodity in the U.S., the Agency assessed potential exposures via residues in drinking water, residential uses, and occupational applications. For the complete human health risk assessment, refer to *MCPP-p acid, MCPP-p DMAS, & MCPP-p potassium salt: HED Human Health Risk Assessment, July 30, 2007*, which is available in the public docket.

1. Toxicity of Mecoprop-p

The available toxicological data are sufficient for selecting toxicity endpoints for the risk assessment. A comparison of more recent conducted studies using the isomeric MCPP-p, with older studies conducted with the racemic MCPP, indicate that MCPP and MCPP-p produce similar toxicities. As available, the Agency relied on the newer MCPP-p studies. Because the racemic MCPP and MCPP-p are structurally similar and have comparable toxicities, the Agency is assuming equal toxicities from MCPP, MCPP-p, its salts, and any of its metabolites.

To date, there are no studies available to compare the relative toxicities between the DMA salt and the potassium salt forms of MCPP-p to the acid form. However, metabolism studies conducted with MCPP-p acid and MCPP-p DMAS showed similar pharmacokinetic parameters between both compounds. Furthermore, based on an *in vitro* dissociation/degradation study conducted with MCPP-p DMAS, the Agency concluded that in the *in vivo* environment, the DMAS form will completely dissociate to the MCPP-p acid. MCPP-p potassium salt is also expected to dissociate similarly to MCPP-p *in vivo*. Thus, the available toxicological studies are sufficient to select toxicity endpoints for the hazard assessment.

a. Toxicity Profile and Endpoint Selection

The available acute toxicity studies indicate that MCPP-p is of relatively low oral and dermal toxicity (Toxicity Category III). An available 21-day dermal toxicity study conducted on rabbits did not indicate any systemic toxicity at the highest tested dose level. As expected with acids, MCPP-p caused severe eye irritation (Toxicity Category I). Table 4 lists the acute toxicity profile of MCPP-p.

Table 4. Acute Toxicity Profile of MCPP-p				
Guideline	Study Type	MRID	Results	Toxicity Category
<i>MCPP-p Acid</i>				
870.1100	Acute oral (rat)	42947801	LD ₅₀ = 775 mg/kg	III
870.1200	Acute dermal (rat)	42947802	LD ₅₀ >2,000 mg/kg	III
870.1300	Acute inhalation (rat)	42947803	The study is unacceptable.	Unclassified
870.2400	Acute eye irritation (rabbit)	42947804	Opacity, redness, discharge for 72 hours.	I
870.2500	Acute dermal irritation (rabbit)	42947805	Redness and sloughing at 10 days.	III
870.2600	Skin sensitization	43749601	Non-sensitizer	N/A
<i>MCPP-p DMAS</i>				
870.1100	Acute oral (rat)	42614701	LD ₅₀ = 414 mg/kg	II
870.1200	Acute dermal (rabbit)	42614703	LD ₅₀ >2,000 mg/kg	III

LD₅₀ = 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) expressed in milligram per kilogram (mg/kg).

The Cancer Assessment Review Committee classified MCPP-p as "suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential." The No Observed Adverse Effects Level (NOAEL) of 24 milligram per kilogram per day (mg/kg/day) was used to measure dietary (drinking water only) risk. To account for any uncertainties in interspecies extrapolation (10X) and intraspecies variability (10X), a 100X uncertainty factor (UF) is applied in calculating the reference dose. The toxicological doses and endpoints used in the human health risk assessment for MCPP-p are listed in Table 5.

Table 5. Summary of Toxicological Doses and Endpoints for MCP-p

Exposure Scenario	Point of Departure Uncertainty Factor RfD/Level of Concern	Study and Toxicological Effects
Acute Dietary (females age 13-49)	NOAEL = 50 mg/kg/day UF = 100 Acute RfD = 0.5 mg/kg/day	MCP-p developmental toxicity in rats. LOAEL = 100 mg/kg/day based on increased incidence of rudimentary cervical rib.
Acute Dietary (general population)	NOAEL = 175 mg/kg/day UF = 100 Acute RfD = 1.75 mg/kg/day	MCP-p acute neurotoxicity in rats. LOAEL = 350 mg/kg/day based on FOB changes (closed eyelids, prone body position, hypoactivity, ataxia, decreased number of rearings in females, increased landing foot splay in males, and decreased motor activity).
Chronic Dietary (all populations)	NOAEL = 4 mg/kg/day UF = 100 Chronic RfD = 0.04 mg/kg/day	MCP-p carcinogenicity study in mice. LOAEL = 46 mg/kg/day based on increased incidence of chronic nephropathy and increased absolute/relative kidney weights in females.
Incidental oral (short- and intermediate-term)	NOAEL = 35 mg/kg/day UF = 100 LOC = 100	MCP-p subchronic feeding/ subchronic neurotoxicity in rats. LOAEL = 189 mg/kg/day based on decreased body weight, increased water consumption, decreased hematological parameters, decreased adrenal weight, microscopic changes in adrenal gland, increased liver enzymes, increased liver weight and microscopic changes, and kidney transitional epithelial cells in urine of high-dose males.
Dermal (short- and intermediate-term)	Not applicable	No toxicity observed at 1,000 mg/kg/day and no developmental toxicity concerns by dermal route.
Inhalation (short- and intermediate-term)	NOAEL = 35 mg/kg/day UF = 100 LOC = 100	Subchronic feeding/subchronic neurotoxicity study in rats. LOAEL = 189 mg/kg/day based on decreased body weight, increased water consumption; decreased hematological parameters, decreased abs adrenal weight and lipid storage in adrenals, increased liver enzymes (females), increased absolute/relative liver weight and microscopic changes; kidney cells in urine of high-dose males.
Cancer	Classification: Suggestive Evidence of Carcinogenicity, but Not Sufficient to Assess Human Carcinogenic Potential.	

NOAEL = No Observed Adverse Effects Level
LOAEL = Lowest Observed Adverse Effects Level
LOC = Level of Concern
mg/kg/day = milligram per kilogram per day

cPAD = chronic Population Adjusted Dose
RfD = Reference Dose
UF = Uncertainty Factor
FOB = functional observation battery

b. Dietary Exposure (Drinking Water Only)

EPA assessed potential dietary exposure to MCP-P resulting only from drinking water exposure, based on the quick and complete dissociation of MCP-P DMAS and MCP-P potassium salt into MCP-P acid, DMAS, and potassium ions. Therefore, the drinking water assessment for MCP-P DMAS and MCP-P potassium salt is represented by the acid. Degradation products of MCP-P (4-chloro-2-methylphenol and CO₂) are presumed to be of equal or lesser toxicity than that of the parent. For more detail on the toxicological database and Agency's drinking water determination, refer to the *MCP-P acid, MCP-P DMAS, & MCP-P potassium salt: HED Human Health Risk Assessment*, dated July 30, 2007, and the *FQPA Drinking Water Assessment for Mecoprop-p (MCP-P)*, dated June 26, 2006.

Exposure to pesticides from drinking water can occur through surface and groundwater contamination. All forms of MCP-P are soluble in water and mobile in terrestrial and aquatic environments, giving it the potential to move in water and be transported in runoff from the application site. The Agency considers potential risks from both acute (one-day) and chronic (long-term) drinking water exposures and uses either modeling or actual monitoring data, if available. To model potential runoff concentrations from applications of MCP-P, EPA used the Tier II Pesticide Root Zone Model (PRZM), and Exposure Analysis Modeling System (EXAMS) models. EPA has assessed potential acute and chronic dietary risk from exposure to MCP-P in only surface water sources using screening-level model estimates. Because the estimated surface water residues are higher than those of groundwater, exposures to surface water residues are presented here and are considered to be protective of potential exposure to groundwater drinking sources.

Acute Drinking Water Assessment

The acute estimated drinking water concentration (EDWC) used to estimate MCP-P residues in surface water sources of drinking water were determined using the Tier II PRZM/EXAMS model. Conservative screening-level drinking water estimates were used in this assessment (i.e., the highest peak surface water level for a one-in-ten year concentration); therefore, the risk estimates were reported at the 95th percentile of exposure. The highest estimate resulted from the modeled Florida turf scenario, producing a concentration of 45 parts per billion (ppb). For the U.S. population, the exposure is 0.00236 mg/kg/day, which utilized <1% of the acute reference dose (aRfD). The exposure to infants, the most highly exposed population subgroup, is 0.00889 mg/kg/day, which occupies <1% of the aRfD at the 95th percentile. Thus, all potential acute exposures to MCP-P residues in drinking water are below the Agency's Level of Concern (LOC). Table 6 shows acute drinking water exposures and risks for all populations.

Chronic Drinking Water Assessment

The chronic EDWC used to estimate MCP-P residues in surface water sources of drinking water was determined using the Tier II PRZM/EXAMS model. A chronic drinking water analysis was performed based on the chronic EDWC value based on the Pennsylvania turf scenario, resulting in a concentration of 18.41 ppb. For the U.S. population, the exposure was

0.00039 mg/kg/day, which utilized 1.0% of the chronic reference dose (cRfD). The exposure for all infants, which was the most highly exposed population subgroup, was 0.00127 mg/kg/day, which used 3.2% of the cRfD. Thus, all potential chronic exposures to MCP-p residues in drinking water are below the Agency's LOC. Table 6 shows the chronic drinking water exposures and risks for all populations.

Table 6. Summary of Acute and Chronic Drinking Water Exposure and Risk for MCP-p						
Population Subgroup Age	Acute Drinking Water 95th Percentile			Chronic Drinking Water		
	aRfD (mg/kg/day)	Dietary Exposure (mg/kg/day)	% aRfD	cRfD (mg/kg/day)	Dietary Exposure (mg/kg/day)	% cRfD
General U.S. Population	1.75	0.00236	<1	0.04	0.00039	1.0
All Infants (<1 year)		0.00889	<1		0.00127	3.2
Children 1-2 years		0.00370	<1		0.00058	1.4
Children 3-5 years		0.00338	<1		0.00054	1.3
Females 13-49 years	0.5	0.00220	<1		0.00036	<1

aRfD = Acute Reference Dose mg/kg/day = milligram per kilogram per day cRfD = Chronic Reference Dose

2. Residential and Non-Occupational Exposure and Risk

Residential exposure assessments consider all potential non-occupational pesticide exposure, other than exposure due to residues in drinking water. For non-occupational exposure, EPA calculates a margin of exposure (MOE), which is then compared to a LOC to measure potential risk. The UF of 100X is applied to a particular toxicity study to account for interspecies extrapolation (10X) and intraspecies variability (10X). For MCP-p, any MOE greater than the target MOE of 100 would not pose any risks of concern to the Agency.

Homeowner exposures to MCP-p may result from outdoor residential applications to lawns and other turf areas. Residential products are typically co-formulated with other chlorophenoxy herbicides as dry weed and feed products or as liquid concentrates or Ready-to-Use (RTU) sprays. Both spot and broadcast treatments are currently permitted homeowner applications. Exposures are expected to be short-term in duration, as broadcast treatments are only permitted twice per year, and any repeat spot treatments would occur two to three weeks after the initial application. The majority of products are formulated and typically used at rates ranging from 0.25 - 0.78 lb ae MCP-p/A. There is a higher rate of 1.2 lbs ae MCP-p/A registered for spot treatments (less than 1,000 ft²/A). Because of the small amount of area treated and the specific and limited use pattern (i.e., weeds on non-agricultural, uncultivated land), the residential handler and applicator scenarios are considered to be protective for exposure from spot treatment uses in the risk assessment.

The Agency has determined that there is a potential for exposures in residential settings for those who handle (mix, load, and apply) products containing MCP-p and for potential oral and incidental ingestion exposures for toddlers playing on treated turf areas. Based on available dermal exposure studies, no systemic toxicity occurred at the limit dose of 1,000 mg/kg/day. Additionally, there is no evidence of developmental toxicity by dermal routes of exposure. Thus, a dermal exposure assessment was not conducted. For specific details, refer to the MCP-p:

Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision, dated August 13, 2007.

a. Residential Handler Exposure and Risk Assessment

The Agency has determined that there is a potential for short-term (up to 30 days) inhalation exposure in residential settings for those who handle (mix, load, and apply) products containing MCP-P. Because products containing MCP-P are only applied once or twice a year, with at least two to three weeks between applications for spot treatments, neither intermediate- or long-term exposure is expected. Thus, only short-term inhalation exposure was assessed. The maximum application rate assessed for residential handlers is 0.27 lb ae MCP-P/A, the highest typical rate that is used by homeowners. The MOEs for short-term residential handler exposure for all scenarios are greater than the target LOC of 100 and are not of concern to the Agency. Table 7 shows the MOEs for all residential handler exposure scenarios.

Table 7. MCP-P Short-term MOEs for Homeowner Applications to Lawns		
Exposure Scenario	Treated Area* (acre/day)	Inhalation MOE
1. Hand Application of Granules (spot treatment)	1,000 ft ² (0.023 acre)	190,000
2. Belly Grinder Application (spot treatment)		1,400,000
3. Load/Apply Granules with a Broadcast Spreader	0.5	4,500,000
4. Mix/Load/Apply with a Hose-end Sprayer (Mix your own)	0.5	260,000
5. Mix/Load/Apply with a Hose-end Sprayer (RTU)	0.5	370,000
6. Mix/Load/Apply with Hand Held Pump Sprayer	1,000 ft ² (0.023 acre)	9,900,000
7. Mix/Load/Apply with RTU Sprayer		1,300,000

MOE ≥ 100 = no risk of concern

*Area treated at the maximum application rate of 1.2 lbs ae MCP-P/A.

b. Residential Post-application (Turf) Exposure Assessment

After application of products containing MCP-P to turf, there is a potential for exposure to toddlers playing on treated lawns and other recreational areas. Because there are no risks of concern resulting from dermal exposure, only short-term incidental oral exposure and incidental granule ingestion exposure were assessed. The target MOE for residential post-application exposure is 100.

Short-term Incidental Oral Exposure Assessment

Children, namely toddlers, can be exposed to MCP-P while playing on treated lawns. EPA assessed various oral ingestion exposure scenarios that would occur repeatedly over a short-term (up to 30 days) duration. Because any one or all three of these exposures may occur within a short-term duration, combined exposures were also assessed. Based on exposures from transferable turf residues (TTR) applied at the maximum use rate, all MOEs are greater than the target LOC of 100 and pose no risks of concern to the Agency. A summary of the MOEs for each exposure scenario assessed is shown in Table 8.

Table 8. MCP-P MOEs for Short-term Incidental Oral Exposures to Toddlers		
Exposure Scenario	Dose (mg/kg/day)*	MOE
Hand-to-mouth Ingestion	0.018	1,900
Object-to-Mouth Ingestion	0.0048	7,800
Soil Ingestion	0.00006	580,000
Total of Above Exposures	0.023	1,600

*Based on the maximum application rate of 1.2 lbs ae MCP-P/A.

MOE $\geq$ 100 = no risk of concern

Granule Ingestion Exposure Assessment

The Agency also considered incidental oral ingestion of granular MCP-P products for toddlers playing on treated lawns or other turf areas. Granule ingestion was assessed separately because this scenario is considered a one-time (single acute episodic) exposure event, rather than a repeated exposures over a duration of up to 30 days. The incidental oral ingestion of granules MOE is greater than the target LOC of 100 and poses no risk of concern to the Agency. The summary of the MOE for the granular exposure scenario assessed is shown in Table 9.

Table 9. MCP-P MOEs for Incidental Oral Ingestion of Granules by Toddlers		
Scenario	Dose (mg/kg/day)*	MOE
Granule Ingestion	0.14	1,400

*Based on each granule containing 0.69% MCP-P (based on EPA Reg. #538-175).

3. Aggregate Exposure and Risk

Because the majority of MCP-P usage is applied annually to residential lawns, the Agency determined that aggregating the drinking water and residential exposures would be more representative of actual exposure. When aggregating risk from various sources, both the route and duration of exposure are considered. Because there are no registered food uses in the U.S. and dermal exposures are not expected to be a significant exposure route of concern, only MCP-P exposures via drinking water and residential post-application exposure routes are considered in the aggregate assessment.

To estimate residential handler aggregate risk, a hand application of granules was used to estimate the aggregate risk because this scenario results in the highest potential exposure among all assessed scenarios. For residential exposure in children, three subpopulation groups were examined: all infants (<1 year), the group which resulted in the highest potential exposure to drinking water; and children 1-2 and 3-5 years old who might exhibit hand-to-mouth, object-to-mouth, and soil ingestion behaviors. All aggregated exposure scenarios assessed result in MOEs greater than 100 and do not pose any risks of concerns to the Agency. A summary of exposures and their respective MOEs is shown in Table 10.

Table 10. MCPP-p MOEs for Aggregate Short-term Exposures (Drinking Water and Residential)				
Exposure Scenario	Drinking Water Exposure (mg/kg/day)	Residential Exposure (mg/kg/day)	Aggregate Exposure (mg/kg/day)	MOE
Residential Handler, hand application of granules	0.00036	0.00018	0.00054	66,000
Incidental Oral Exposure, <1 Year Old	0.0013	0.023	0.024	1,400
Incidental Oral Exposure, 1-2 Years Old	0.00058	0.023	0.024	1,500
Incidental Oral Exposure, 3-5 Years Old	0.00054	0.023	0.024	1,500

mg/kg/day = milligram per kilogram per day

4. Occupational Exposures Assessment

Workers can be exposed when mixing, loading, and applying MCPP-p, and there is also the potential for post-application exposure when re-entering a treated site. The Agency assessed risk to occupational handlers and workers in the same manner as it used to assess risks to residential users using the MOE approach. The target MOE of 100 reflects the ratio of the estimated exposure divided by the NOAEL. MOEs greater than 100 are not of concern to the Agency.

To assess the handler risks, the Agency used surrogate unit exposure data from the Pesticide Handler Exposure Database (PHED) and the Outdoor Residential Exposure Task Force (ORETF) studies. The PHED data were used to assess applications to residential and commercial turf and non-turf areas (i.e., roadsides and rights-of-way) and the ORETF data were used to assess exposures to professional lawn care operators. Short- and intermediate-term handler risks were assessed, with inhalation exposures being the exposure route of concern.

Because of low toxicity concerns with dermal exposures, only inhalation exposures were assessed. Only short- (up to 30 days) and intermediate-term (1 - 6 months) inhalation exposures were assessed, as long-term (>6 months) exposures are not expected based on the use pattern. Based on the assessed occupational exposure scenarios, all of the MOEs are greater than the LOC of 100 with baseline personal protective equipment (PPE). Thus, these exposures do not pose any risks of concern to the Agency. A summary of the MOEs is shown in Table 11.

Table 11. MCPP-p MOEs for Occupational Handlers and Applicators Using Baseline PPE				
Scenario	Use Site	Application Rate (lb ae MCPP-p)	Daily Amount Treated or Applied	MOE
<i>Mixer/Loader</i>				
M/L WP for Turfgun Application (20 PCOs)	PCO Turf	1.2 lbs ae/A	100 acres	475
M/L WP for Groundboom	Golf Courses	1.2 lbs ae/A	40 acres	1,200
M/L DF for Turfgun (20 PCOs)	PCO Turf	1.2 lbs ae/A	100 acres	27,000
M/L DF for Groundboom	Golf Courses	1.2 lbs ae/A	40 acres	66,000
M/L Liquids for Turfgun (20 PCOs)	PCO Turf	1.2 lbs ae/A	100 acres	17,000
M/L Liquids for Groundboom	Sod Farms	1.2 lbs ae/A	80 acres	21,000
M/L Liquids for Groundboom	Golf Courses	1.2 lbs ae/A	40 acres	43,000
M/L Liquids for ROW Sprayer	Non-turf Areas*	0.0184 lb ae/gallon	1000 gallons	110,000
Load Granulars for Broadcast Spreader	Golf Courses	1.2 lbs ae/A	40 acres	30,000
<i>Applicator</i>				
Groundboom Application	Sod Farms	1.2 lbs ae/A	80 acres	35,000
Groundboom Application	Golf Courses	1.2 lbs ae/A	40 acres	69,000
ROW Sprayer Application	Non-turf Areas*	0.0184 lb ae/gallon	1000 gallons	34,000
Turfgun Application	PCO Turf	1.2 lbs ae/A	5 acres	410,000
Broadcast Spreader Application	Golf Courses	1.2 lbs ae/A	40 acres	43,000
<i>Mixer/Loader/Applicator</i>				
M/L/A Wettable Powder with Turfgun	PCO Turf	1.2 lbs ae/A	5 acres	6,600
M/L/A DF with Turfgun	PCO Turf	1.2 lbs ae/A	5 acres	190,000
M/L/A Liquid Flowables with Turfgun	PCO Turf	1.2 lbs ae/A	5 acres	210,000
M/L/A Liquids with Backpack Sprayer	Non-turf Areas*	0.038 lb ae/gallon	40 gallons	54,000
M/L/A Granules with Push Cyclone	PCO Turf	1.2 lbs ae/A	5 acres	54,000

M = mixer, L = loader, A = applicator
ae = acid equivalent

ROW = right-of-way PCO = Pest Control Operator

* use rate based on EPA Reg. #228-410

b. Occupational Post-application Exposures

There is potential for dermal and inhalation exposures to post-application workers who enter treated areas. However, the Agency determined that these exposures are minimal and are unlikely to pose any risks of concern. Occupational post-application dermal risks were not assessed because of the lack of any systemic toxicity via dermal exposures for all forms of MCPP-p. Occupational post-application inhalation exposures are not anticipated because MCPP-p has a low vapor pressure and, thus, will not readily volatilize, and because it is applied outdoors as a coarse spray. Because it is a severe eye irritant, the default Restricted Entry Interval (REI) for MCPP-p is 48 hours where the Worker Protection Standard applies.

Therefore, with the existing protective measures in place, the Agency has determined that any potential post-application exposures do not pose risks of concern to the Agency.

5. Incident Reports

The Agency reviews various databases to determine if any substantiated reported incidents warrant further investigation for effects not considered. Databases searched include the Office of Pesticides Program Incident Data System (IDS), Poison Control Center, California Department of Pesticide Regulation (CDPR), and the National Institute of Occupational safety and Health's Sentinel Event Notification system for Occupational Risks (NIOSH SENSOR). In the case of MCP-P, there were no human incident reports identified.

B. Environmental Risk Assessment

The ecological risk assessment evaluated three active ingredients: MCP-P acid, MCP-P DMAS, and MCP-P potassium salt. Because not all ecological studies conducted with each of the three MCP-P forms were available, the Agency developed a strategy to bridge the majority of fate and ecotoxicity data requirements for MCP-P acid, MCP-P DMAS, and MCP-P potassium salt. Likewise, this bridging strategy was used to reflect the most sensitive endpoint assessed. Based on available bridging data, which demonstrated that MCP-P DMAS rapidly dissociated to MCP-P acid and the dimethylamine ion, the Agency determined that acceptable studies conducted with the MCP-P acid, DMAS, or potassium salt form could be used as "surrogate" data, as appropriate, for the respective unavailable or deficient MCP-P studies. Assuming that MCP-P potassium salt will likewise completely and rapidly dissociate to MCP-P acid and the potassium ion, the Agency expects that the toxicity is similar to the MCP-P acid and MCP-P DMAS. A summary of the EPA's ecological fate and effects assessment is presented below. The full assessment, *Environmental Fate and Effects Science Chapter for MCP-P acid, MCP-P DMAS, and MCP-P potassium salt*, dated August 28, 2007, and response to public comments are available on the internet and in the public docket at www.regulations.gov (EPA-HQ-OPP-2006-0943).

1. Environmental Fate and Transport

Available environmental fate data indicates that MCP-P is generally non-persistent, but may be persistent in certain (acidic) terrestrial environments. The primary routes of dissipation appear to be photodegradation in water, microbial-mediated degradation, and leaching. MCP-P does not adsorb strongly to soils and, thus, is likely to be mobile in terrestrial and aquatic environments. MCP-P DMAS is expected to dissociate quickly, where the dimethylamine ion degrades by microbial-mediated processes. Aqueous photolysis data indicates that MCP-P photodegrades in aqueous environments, with reported half-lives ranging from 4.9 to 7.2 days. MCP-P acid is stable to abiotic hydrolysis in pH 5, 7, and 9 buffer solutions. Primary degradation products of MCP-P include 4-chloro-2-methylphenol, o-cresol, and carbon dioxide, depending on the type of degradation process. Although information on the toxicity of these degradates are not available, the Agency is assuming that degradates are of equal or less toxicity than the parent compound.

2. Ecological Exposure and Risk

The pesticide use profile, exposure data, and toxicity information are used to determine risk estimates to non-target aquatic and terrestrial organisms. As applicable, acute and chronic terrestrial toxicity studies are required to establish the potential toxicity (hazard) of MCP-P to non-target species. Estimated Environmental Concentrations (EECs) are estimates of potential residue concentrations from the maximum or typical application rate of MCP-P, to which an organism may be exposed. A risk quotient (RQ) is the ratio of the EECs to the organism's toxicity endpoint, which would yield the maximum exposure estimates. The RQ is then compared to the level of concern (LOC) to determine if that particular exposure scenario would pose a risk to the non-target organism. Table 12 outlines the Agency's LOCs and the corresponding risk presumptions.

Table 12. Agency's LOCs and Risk Presumptions			
Risk Presumption	LOC Terrestrial Animals	LOC Aquatic Animals	LOC Plants
Acute Risk - there is potential for acute risk; regulatory action may be warranted.	0.5	0.5	1
Acute Endangered Species – there is potential for endangered species risk; 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. Terrestrial Organisms

Terrestrial animals (birds, mammals, reptiles, and terrestrial-phase amphibians) that are nesting in or near the treated field may be exposed to MCP-P due to direct deposition from labeled uses of the pesticide, runoff, and from spray drift onto areas adjacent to treated sites. The Agency estimates exposures and potential risk to birds and mammals, which also serve as surrogates for exposures to terrestrial-phase amphibians and reptiles, and dryland and semi-aquatic plants. For exposure to terrestrial animals and plants, pesticide residues on food items are estimated based on the assumption that organisms are exposed to a single pesticide residue in a given exposure scenario.

The greatest MCP-P residues and exposure levels are likely to occur in the surface soil and on foliage (e.g., short and tall grasses, broadleaf plants), seeds, and insects on treated areas immediately following ground spraying and/or granular treatments. In addition to exposure through spray residues on and adjacent to the application area, direct terrestrial exposure is also expected through granular applications, as animals may ingest the granules. Bioaccumulation of MCP-P in the food chain is not expected to be a significant exposure source to non-target terrestrial organisms.

Residues of MCP-P from single and multiple applications are expected to occur on avian and mammalian food items. The Agency used the RQ method to determine potential risks of concern. Predicted maximum and mean concentrations of pesticide residues are based on the

nomogram by Hoerger and Kenaga (1972) as modified by Fletcher et al. (1994). The typical and maximum application rates are used to produce EECs and were used in the Agency's screening-level analyses. The Agency reviewed available acute and chronic terrestrial organism toxicity studies to establish the hazard of MCP-P to non-target species. With this information, each EEC is then divided by the corresponding acute and/or chronic toxicity value to produce the RQ, which is measured against the Agency's LOC to determine potential risk to that organism.

In estimating foliar residues for this screening-level assessment, the Agency assessed a maximum use scenario, based on the following assumptions:

- residues are based on a maximum application rate of 1.2 lbs ae MCP-P/A or the maximum typical rate assessed of 0.78 lb ae MCP-P/A, with 2 applications per year;
- a default residue degradation half-life of 35 days; and
- an interval of 30 days, the shortest timeframe between repeat applications.

Based on the above factors, EPA estimated several EECs for various food sources (grasses, fruit, seed, and insects) associated with the registered uses of MCP-P. Consumption-weighted EECs are determined for each food source to be more representative of actual exposures based on the size of the animal and its typical eating habits. The EECs on food items may be compared directly with dietary toxicity data or converted to a single oral dose. Single oral dose estimates represent an exposure scenario where absorption of the pesticide is maximized over a single ingestion event and represents a conservative estimate.

1. Avian and Mammalian Assessment

Residues of MCP-P from single and multiple application scenarios are expected to occur on avian and mammalian food items. Predicted maximum and typical EECs of pesticide residues from single and multiple applications of MCP-P were used in the screening-level ecological assessment. In estimating foliar residues from multiple applications, EPA used first order dissipation values, maximum application rates, minimum application intervals, and maximum number of applications.

The EECs were calculated using the T-REX model (Version 1.2.3) and corresponding avian acute and chronic RQs are based on the most sensitive acute and chronic endpoints, respectively, for birds. MCP-P appears to cause moderate acute oral toxicity to avian and mammalian species. Table 13 lists the toxicity endpoints used in the avian and mammalian assessments.

Table 13. Summary of Avian and Mammalian Toxicity Data Conducted with MCPP-p					
Species	LD ₅₀ (mg ae/kg bwt)	Acute Oral Toxicity, MRID	LC ₅₀ (mg ae/kg)	NOAEC/ LOAEC (mg/kg/day)	MRID
Northern Bobwhite quail	491	Moderately toxic, 42436701 (DMAS)	---	---	---
Mallard duck	---	---	>4,130	---	---
Japanese quail	---	---	---	NOAEC - 51.6 LOAEC - 174	44925501 (DMAS)
Laboratory rat	414	Moderately toxic 42614701 (DMAS)	---	NOAEC - 54 LOAEC - 83	46591804 (acid)

mg ae/kg bwt = milligrams of acid equivalent per kilogram body weight

Birds

For birds, the acute risk LOC is 0.5. Based on estimated avian acute dose-based RQs for both spray and granular applications, the LOC for non-endangered birds is exceeded for some scenarios. The acute endangered RQs exceeded the LOC (0.1) for birds. However, based on dietary-based acute RQs, the all scenarios are below the LOC. Tables 14 and 15 summarize the acute and chronic RQs for avian species, with acute non-endangered LOC exceedances identified in bold text.

Table 14. MCPP-p Acute Dose-based RQs for Birds at 1.2 lbs ae MCPP-p/A									
Body Weight	Spray Application								Granular Application
	Short grass		Tall Grass		Broadleaf plants/ small insects		Fruits/pods/seed/ large insects		LD ₅₀ /ft ²
	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	RQ
20 g	509	1.44	233	0.66	286	0.81	31	0.09	1.77
100 g	290	0.64	133	0.30	163	0.36	18	0.04	0.28
1,000 g	130	0.20	60	0.09	73	0.11	8	0.01	0.02

Acute non-endangered LOC for terrestrial animals ≥ 0.5 , endangered LOC ≥ 0.1 .

Bold = LOC exceedance.

The Agency also assessed potential acute and chronic risk to birds using dietary-based endpoints. The chronic risk LOC for birds is 1.0. Calculations for dietary-based RQs are not adjusted for bodyweight variations. Based on estimated avian acute dietary-based RQs for spray applications, the acute LOC is not exceeded. However, based on estimated chronic RQs, the LOC for non-endangered birds is exceeded for most food items. Table 15 summarizes the acute and chronic RQs for avian species.

Table 15. MCPP-p Acute and Chronic Dietary-based RQs for Birds, Spray Application at 1.2 lbs ae/A											
Short grass			Tall grass			Broadleaf plants/small insects			Fruits/pods/seed/large insects		
EEC	aRQ	cRQ	EEC	aRQ	cRQ	EEC	aRQ	cRQ	EEC	aRQ	cRQ
446.99	0.11	8.66	204.87	0.05	3.97	251.43	0.06	4.87	27.94	0.01	0.54

Acute non-endangered LOC for terrestrial animals ≥ 0.5 , endangered LOC ≥ 0.1 .
Chronic non-endangered and endangered LOC for terrestrial animals is ≥ 1.0
Bold = LOC exceedance.

aRQ = acute RQ
cRQ = chronic RQ

According to the MCPP-p Task Force, more than 95% of products containing MCPP-p are applied to residential lawns. The Agency assessed the maximum typical rate of 0.78 lb ae MCPP-p/A used by homeowners. Based on this typical use rate, some acute RQs and endangered species RQs still exceeded the acute LOC. The non-endangered LOC exceedances are identified in bold text. Acute RQs are shown in Table 16.

Table 16. MCPP-p Acute Dose-based RQs for Avian Species, 0.78 lb ae MCPP-p/A									
Body Weight	Spray Applications								Granular Application
	Short grass		Tall Grass		Broadleaf plants/small insects		Fruits/pods/seed/large insects		LD ₅₀ /ft ²
	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	RQ
20 g	330.90	0.94	151.66	0.43	186.13	0.53	20.68	0.06	1.15
100 g	188.69	0.42	86.48	0.19	106.14	0.24	11.79	0.03	0.18
1,000 g	84.48	0.13	38.72	0.06	47.52	0.07	5.28	0.01	0.01

Acute non-endangered LOC for terrestrial animals ≥ 0.5 , endangered LOC ≥ 0.1 .
Bold = LOC exceedance.

The Agency also assessed potential acute and chronic risk to birds using dietary-based endpoints. Calculations for dietary-based RQs are not adjusted for bodyweight variations. Based on estimated avian acute dietary-based RQs for spray applications, the acute LOC is not exceeded. However, based on estimated chronic RQs, the LOC for non-endangered birds is exceeded for most food items. Table 17 summarizes the acute and chronic RQs for avian species.

Table 17. MCPP-p Acute and Chronic Dietary-based RQs for Birds, Spray Application at 0.78 lb ae/A											
Short grass			Tall grass			Broadleaf plants/small insects			Fruits/pods/seed/large insects		
EEC	aRQ	cRQ	EEC	aRQ	cRQ	EEC	aRQ	cRQ	EEC	aRQ	cRQ
290.54	0.07	5.63	133.17	0.03	2.58	163.43	0.04	3.17	18.16	<0.01	0.35

Acute non-endangered LOC for terrestrial animals ≥ 0.5 , endangered LOC ≥ 0.1 .
Chronic non-endangered and endangered LOC for terrestrial animals is ≥ 1.0
Bold = LOC exceedance.

aRQ = acute RQ
cRQ = chronic RQ

Mammals

As with birds, EPA assesses acute and chronic risk to mammals based on an acute LOC of 0.5, acute endangered LOC of 0.1, and a chronic LOC of 1.0. Dose-based acute RQs for mammals exceed the acute LOC based on MCPP-p spray applications, but acute RQs exceed the

LOC of 0.1 for endangered mammals in both MCPP-p spray and granular applications. Based on the MCPP-p spray application, mammalian chronic dose-based RQs exceeds the LOC; however, dietary-based chronic RQs are below the Agency's LOC. The ranges of acute and chronic RQs are presented in Table 18 with LOC exceedances identified in bold text.

Table 18. MCPP-p Acute and Chronic RQs for Mammals, 1.2 lbs ae MCPP-p/A											
Body Weight	Spray Applications										Granular Application
	Short grass		Tall grass		Broadleaf plants/small insects		Fruits/pods/large insects		Seeds (granivores)		LD ₅₀ /ft ²
	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	RQ
<i>Acute, dose-based</i>											
15 g	426	0.35	195	0.16	240	0.20	27	0.02	6	<0.01	0.69
35 g	295	0.30	135	0.14	166	0.17	31	0.02	4	<0.01	0.37
1,000 g	68	0.16	31	0.07	38	0.09	4	0.01	1	<0.01	0.03
<i>Chronic, dose-based</i>											
15 g	426	3.59	195	1.65	240	2.02	27	0.22	6	0.05	n/a
35 g	295	3.07	135	1.41	166	1.73	31	0.19	4	0.04	n/a
1,000 g	68	1.64	31	0.75	38	0.92	4	0.10	1	0.02	n/a
<i>Chronic, dietary-based</i>											
n/a	447	0.41	205	0.19	251	0.23	28	0.03	28	0.03	n/a

Acute LOCs for terrestrial animals for non-endangered ≥ 0.5 , endangered ≥ 0.1 .

n/a = not assessed

Chronic non-endangered and endangered LOC for terrestrial animals is ≥ 1.0 .

Bold = LOC exceedance.

As discussed above, according to the MCPP-p Task Force, more than 95% of products containing MCPP-p are applied to residential lawns by homeowners. The Agency assessed the maximum typical rate of 0.78 lb ae MCPP-p/A used by homeowners. Based on these typical use rates, RQs for chronic risk to mammals are lower and are presented in Table 19.

Table 19. MCPP-p Chronic Dose-based RQs for Mammals, 0.78 lb ae MCPP-p/A, Spray Applications										
Body Weight	Short grass		Tall grass		Broadleaf plants/small insects		Fruits/pods/large insects		Seeds (granivores)	
	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
15 g	277.01	2.33	126.96	1.07	155.82	1.31	17.31	0.15	3.85	0.03
35 g	191.45	1.99	87.75	0.91	107.69	1.12	11.97	0.12	2.66	0.03
1,000 g	44.39	1.07	107.69	0.49	24.97	0.60	2.77	0.07	0.62	0.01

Chronic non-endangered and endangered LOC for terrestrial animals is ≥ 1.0 .

Bold = LOC exceedance.

2. Terrestrial and Semi-aquatic Plant Assessment

Non-target terrestrial and semi-aquatic plants can be exposed to MCPP-p from spray drift and runoff moving to off-target field foliage and surface soil. Using TERRPLANT 1.2.1 modeling, EECs for terrestrial and semi-aquatic plants were derived for areas adjacent to the treatment site. Acute RQs for terrestrial plants are calculated by dividing the EEC by the EC₂₅

from available Tier II seedling emergence and vegetative vigor toxicity tests. To calculate acute RQs for endangered species, EECs are divided by the NOAEC value. Table 20 shows the toxicity data used to evaluate risks to terrestrial and semi-aquatic plants.

Table 20. Summary of Terrestrial Plant Toxicity Data Conducted with MCPP-p Acid.			
Species	Toxicity	Most Sensitive Endpoint	MRID
Seedling Emergence	Most sensitive monocot: Onion EC ₂₅ = 0.0051 lb ae/A NOAEC = 0.0014 lb ae/A	Dry Shoot Weight	43016601
	Most sensitive dicot: Cabbage EC ₂₅ = 0.0019 lb ae/A NOAEC = 0.0005 lb ae/A		
Vegetative Vigor	Most sensitive monocot: Corn EC ₂₅ = 0.006 lb ae/A NOAEC = 0.001 lb ae/A		43059301
	Most sensitive dicot: Cabbage EC ₂₅ = 0.011 lb ae/A NOAEC = 0.001 lb ae/A		

lb ae/A = pound of acid equivalent per acre

RQs are developed for terrestrial (dryland) plants are based on MCPP-p runoff and drift from one treated hectare moving to adjacent areas, whereas semi-aquatic areas (wetlands) are based on movement from a treated ten-hectare site. The difference in the model values (1 versus 10 hectares) are reflected in the ten-fold difference in resulting RQs, shown in Tables 20 and 21. Using EECs based on the maximum single application rate of 1.2 lbs ae MCPP-p/A, all RQs exceed the Agency's LOC of 1 for non-endangered and endangered plant species. Even based on the maximum typical rate of 0.78 lb ae MCPP-p/A, all RQs exceeded the LOC; LOC exceedances identified in bold text. Tables 21 and 22 summarize the EECs and RQs for terrestrial and semi-aquatic plants exposed to MCPP-p.

Table 21. Terrestrial Plant RQs for Ground Spray and Granular Applications, 1.2 lbs ae MCPP-p/A									
Application	Adjacent Areas			Semi-aquatic Areas			Drift Only		
	EEC (lb)	RQs		EEC (lb)	RQs		EEC (lb)	RQs	
		M	D		M	D		M	D
Non-Endangered, ground spray	0.072	14.12	37.89	0.612	120.00	322.11	0.12	2.35	6.32
Non-Endangered, granular	0.060	11.76	31.58	0.600	117.65	315.79	n/a		
Endangered, ground spray	0.072	51.43	144.00	0.612	437.14	1224.00	0.12	8.57	24.00
Endangered, granular	0.060	42.86	120.00	0.600	428.57	1200.00	n/a		

n/a = not applicable

M = monocot

D = dicot

EEC unit is ae MCPP-p/A.

Bold = LOC exceedance.

Table 22. Terrestrial Plant RQs for Ground Spray and Granular Applications, 0.78 lb ae MCPP-p/A									
Application	Adjacent Areas			Semi-aquatic Areas			Drift Only		
	EEC (lb)	RQs		EEC (lb)	RQs		EEC (lb)	RQs	
		M	D		M	D		M	D
Non-Endangered, ground spray	0.047	9.18	24.63	0.398	78.00	209.37	0.008	1.53	4.11
Non-Endangered, granular	0.039	7.65	20.53	0.390	76.47	205.26	n/a		
Endangered, ground spray	0.047	33.43	93.60	0.398	284.14	795.60	0.008	5.57	15.60
Endangered, granular	0.039	27.86	78.00	0.390	278.57	780.00	n/a		

n/a = not applicable

M = monocot

D = dicot

EEC unit = ae MCPP-p/A.

Bold = LOC exceedance.

b. Aquatic Organisms

Fish, amphibians, and aquatic invertebrates that live in aquatic environments are potentially exposed to MCPP-p residues in surface water by direct contact of their integument and via uptake through their gills or integument. Immediately following applications of MCPP-p, the highest residue levels are expected to be located in surface waters adjacent to treated fields due to spray drift at the time of application and/or from runoff after a rain event. MCPP-p has low persistence in some terrestrial environments; however, the likelihood of transport by runoff and leaching still exists. MCPP-p EECs for aquatic ecosystems were predicted using the Tier II PRZM/EXAMS models. PRZM is used to simulate pesticide transport as a result of runoff and erosion, and EXAMS considers the environmental data and transport of pesticides. The exposure values used in the ecological risk assessment are based on the “standard pond” scenario, intended to better represent the spatial and physical qualities of habitats relevant to risk assessment for aquatic non-target organisms in ponds or streams that may be in or adjacent to treated areas. The resulting EECs predict high-end values of pesticide concentrations that may be found in ecologically-sensitive environments following pesticide applications and, thus, represent conservative exposure estimates to which non-target organisms may be exposed. The EEC values determined for impact to non-target aquatic organisms are specific to ecological and fate properties in the respective turf scenarios assessed and, therefore, are different from those used to assess human health exposure in the drinking water assessment. The modeling scenarios for turf (i.e., sod farms) in Pennsylvania and Florida were selected for the assessment to represent applications to turf, lawns, and grass areas.

Currently, the Agency does not have a model with which to predict concentrations of MCPP-p in surface water from applications to home lawns, ornamental turf areas, or other grassy areas. Runoff from applications to these areas is expected to move over lawns and impervious surfaces to storm sewers and then to surface water. MCPP-p applications predicted by PRZM/EXAMS modeling are sufficiently conservative to be representative of applications to turf, lawns, and other grass sites. Application rates, number of applications and minimal retreatment intervals were based on the maximum values identified by the technical registrants in the MCPP-p Task Force. Estimated water concentrations of MCPP-p for representative turf scenarios are listed in Table 23.

Table 23. PRZM/EXAMS EECs of MCPP-p Acid in Water for Aquatic Exposure				
Crop Scenario	Application Rate	1-in-10 Year Peak Acute (µg/L)	1-in-10 Year 21 Day Chronic (µg/L)	1-in-10 Year 60 Day Chronic (µg/L)
Florida Turf				
Ground	- 1.2 lbs ae MCPP-p/A - 2 applications - 30 days apart	11.69	4.78	2.42
Granular		11.56	4.75	2.32
Pennsylvania Turf				
Ground	- 1.2 lbs ae MCPP-p/A - 2 applications - 30 days apart	6.66	3.19	1.99
Granular		6.66	2.97	1.84

lbs ae MCP-P/A = pounds of acid equivalent of MCP-P per acre.

1. Fish and Invertebrates

A limited number of acute aquatic toxicity studies were submitted for both freshwater and marine/estuarine fish and invertebrates. However, the registrant did not submit acute or chronic toxicity data for any marine/estuarine species. Table 24 is a summary of aquatic toxicity studies the Agency used in the ecological assessment.

Table 24. Summary of Fish and Invertebrate Toxicity Data for MCP-P					
Species	Acute Toxicity			Chronic Toxicity	
	96-hour LC ₅₀ (mg ae/L)	48-hour EC ₅₀ (mg ae/L)	MRID, Toxicity Category	NOAEC/LOAEC (mg ae/L)	MRID
Freshwater Fish: Bluegill sunfish	>93	---	42766901 (DMAS) Slightly toxic	---	---
Freshwater Fish: Rainbow trout	>93	---	42844801 (DMAS) Slightly toxic	---	---
Freshwater Invertebrate: Water flea	---	>91	45606104 (Acid) Slightly toxic	50.8/102.7	45606102 (Acid)

mg ae/L – milligrams of acid equivalent per liter

Freshwater Fish and Invertebrates

Similar to the way that RQs are calculated for terrestrial organisms, aquatic acute RQs are derived by dividing the peak EECs by the LC₅₀ to estimate acute hazard. Chronic RQs for freshwater invertebrates are derived by dividing the 21-day EECs by the NOAEC values. No data were available to assess chronic risks to freshwater fish. Based on predicted modeling assessing both ground spray and granular applications, all acute RQs are <0.01 for freshwater fish and invertebrates, and chronic exposures to freshwater invertebrates are less than 1 and do not exceed the Agency's LOCs.

Marine Fish and Invertebrates

Because there is insufficient chronic data to estimate potential hazard to marine/estuarine organisms, potential indirect acute and chronic effects to estuarine/marine fish and invertebrates cannot be precluded based on the available data. However, based on available chronic toxicity data conducted with 2,4-D, another chlorophenoxy herbicide, it is less likely that MCP-p will pose chronic effects to non-target marine animals.

2. Aquatic Plants

Likewise for non-target fish and invertebrates, surface water concentrations were predicted using PRZM/EXAMS modeling for MCP-p applications to turf scenarios, considering both ground spray and granular applications. Aquatic plants toxicity data were available to determine potential toxicity of MCP-p to non-target aquatic plants. Table 25 summarizes the toxicity studies used to calculate RQs for aquatic plants.

Table 25. Summary of Aquatic Plant Toxicity Data for MCP-p			
Species	Toxicity	Endpoint	MRID
Vascular plant, <i>Lemna gibba</i>	EC ₅₀ = 1.3 mg ae/L NOAEC <0.44 mg ae/L EC ₀₅ = 0.23 mg ae/L	Frond number	42486201
Nonvascular plant, <i>Skeletonema costatum</i>	EC ₅₀ = 0.014 mg ae/L NOAEC <0.009 mg ae/L EC ₀₅ = 0.0008 mg ae/L	Cell count density	42633902 43657303

mg ae/L – milligrams of acid equivalent per liter

For vascular and nonvascular plants, peak EECs were compared to acute EC₅₀ toxicity endpoints for the most sensitive plant species. RQs for endangered plants are calculated using the EC₀₅ toxicity endpoint, as NOAECs could not be determined from available submitted data. There were no exceedances at the non-endangered aquatic plant LOC of 1 for non-endangered plants. The only exceedance for endangered aquatic plants was for non-vascular plants; however, no non-vascular plants are listed threatened as or endangered. Table 26 summarizes the RQs for aquatic plants, with LOC exceedances identified in bold text.

Table 26. Aquatic Plant RQs for MCP-p					
Site	Application Method	Vascular		Non-vascular	
		Non-endangered	Endangered	Non-endangered	Endangered
Florida Turf	Ground Spray	0.01	0.05	0.83	14.61
	Granular	0.01	0.05	0.83	14.45
Pennsylvania Turf	Ground Spray	<0.01	0.03	0.48	8.32
	Granular	<0.01	0.03	0.48	8.32

Acute non-endangered and endangered LOC for aquatic plants ≥ 1.0 . Bold = LOC exceedance.

c. Spray Drift

Although it is expected that the highest concentrations of MCP-p would occur in directly treated areas, spray drift adjacent to treated areas may still present the potential for

exposures to non-target organisms. Potential exposures to non-target organisms include movement of MCP-p to off-target field surface soil, foliage, and insects. Spray drift into water bodies adjacent to treated areas can move to surface water, affecting sensitive aquatic organisms.

Because MCP-p is an herbicide, a more in-depth spray drift exposure assessment utilizing Tier I AgDRIFT® (version 2.01) modeling is also provided to better characterize potential exposure of terrestrial plants. The Agency used AgDRIFT to evaluate potential risk at several distances from the field, simulating typical applications with a low-boom sprayer. Based on the assessed turf scenario, predicted deposition away from the target area exceeded both non-endangered and endangered LOCs at the edge of the treated field (at zero feet). Based on available data, droplets were presumed to be fine to medium-coarse sizes. Table 27 shows the RQS for terrestrial and semi-aquatic plants, with non-endangered LOC exceedances identified in bold text.

Table 27. MCP-p Spray Drift EECs and RQs for Terrestrial and Semi-aquatic Plant RQs					
Exposure (EECs)		Non-Endangered, ground spray RQs		Endangered, ground spray RQs	
Distance from edge of field (feet)	Deposition (lbs/acre)	Monocot	Dicot	Monocot	Dicot
Toxicity endpoints (lb ae/acre)		0.0051	0.0019	0.0014	0.0005
<i>Maximum application rate of 1.2 lbs ae/A</i>					
0	1.21	237.25	636.84	864.29	2420.00
250	0.0026	0.51	1.37	1.86	5.20
500	0.0015	0.29	0.79	1.07	3.00
750	0.0010	0.20	0.53	0.71	2.00
<i>Typical application rate of 0.78 lbs ae/A</i>					
0	0.786	154.12	413.68	561.43	1572.00
250	0.0017	0.33	0.89	1.21	3.40
500	0.0009	0.18	0.47	0.64	1.80
750	0.0006	0.12	0.32	0.43	1.20

Acute non-endangered and endangered LOC for aquatic plants ≥ 1.0 . Bold = LOC exceedance.

d. Ecological Incidents

Ecological incidents are voluntarily reported to the Agency by local, state, other federal agencies, or at times, submitted under FIFRA section 6(a)2. A review of the EIIS database for ecological incidents involving MCP-p showed a reporting of six incidents. Five involved damage to grass on homeowner lawns and one involved a fish kill in a nearby pond. For all incidents, multiple active ingredients were used; therefore, it cannot be determined conclusively if MCP-p was responsible for these incidents. Results from these incidents do not necessarily determine direct effects from MCP-p only, as it is frequently co-formulated with other chlorophenoxy herbicides.

IV. Risk Management and Reregistration Decision

A. Determination of Reregistration Eligibility

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

The Agency has determined that MCP-P-containing products are eligible for reregistration provided that the risk mitigation measures outlined in Section C of this document are adopted and label amendments are made to implement these mitigation measures, as outlined in Chapter V. Appendix A summarizes the uses of MCP-P that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of MCP-P, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data. Should a registrant fail to implement any of the reregistration requirements identified in this document, the Agency may take regulatory action to address these concerns.

B. Public Comments and Responses

When making its reregistration decision, the Agency considered all comments received in the docket during the public participation phase, EPA worked with stakeholders and the public to reach the regulatory decisions for MCP-P. During the public comment period, which closed on June 25, 2007, the Agency received comments from interested stakeholders. These comments in their entirety are available in the public docket (EPA-HQ-OPP-2006-0943) at www.regulations.gov. The RED document, supporting documents for MCP-P, and the Agency's response to received comments are also available in the docket. In addition, the MCP-P RED document may be downloaded or viewed through the Agency's website at <http://www.epa.gov/pesticides/reregistration/status.htm>.

C. Risk Mitigation and Regulatory Position

Products containing MCP-P are eligible for reregistration provided that the following risk mitigation measures and label amendments are adopted accordingly. Table 28 summarizes the human and ecological risks of concern and the respective mitigation measure.

Table 28. MCPP-p Human and Ecological Risk Mitigation Measures	
Risk of Concern	Mitigation Measures
Acute eye irritation (Toxicity Category I).	For any use (e.g., sod farms) for which the WPS applies, a 48-hour REI is required after applications of MCPP-p.
	For early entry workers, protective eyewear must be worn in addition to baseline PPE.
Non-target terrestrial exposures to animals and plants, including spray drift.	The maximum application rate for broadcast treatments is 0.75 lb ae MCPP-p/A.
	For spot treatments only, the maximum use rate permitted is the equivalent to 1.2 lbs ae MCPP-p/A, to be applied to areas no larger than 1,000 ft ² per acre.
	Applications must be made using medium- to coarse-sized droplets.

lbs ae MCPP-p/A = pounds of acid equivalent MCPP-p per acre.

REI = restricted entry interval

The following is a summary of the rationale for managing risks associated with the use of MCPP-p.

1. Human Health Risk Management

The Agency has determined that based on the currently registered residential uses of MCPP-p, there are no risks of concern (drinking water, handler, and post-application exposures). As is expected of an acid, MCPP-p acid is an acute severe eye irritant (Toxicity Category I). In the absence of available acute eye toxicity data conducted with MCPP-p DMAS, the Agency assumes a default Toxicity Category I. To address this concern, uses of MCPP-p where the Worker Protection Standard applies, will require a 48-hour REI after applications of MCPP-p. Early entry workers must wear goggles in addition to the baseline PPE.

2. Ecological Risk Management

Based on available toxicological data and refined use information, the ecological risk assessment identified some exposure scenarios with MCPP-p that may pose ecological risks of concern to the Agency, including effects on endangered species. However, considering the conservative assumptions made in the ecological assessment and the refined usage information provided by the Task Force, the risks can be sufficiently mitigated with the adoption of the proposed labeling mitigation measures. Therefore, the Agency has determined that the current use patterns, as specified in Appendix A, are eligible for reregistration. The following section is a summary for each respective affected organism identified earlier in Chapter III, as well as characterization of the actual usage of MCPP-p versus the screening-level modeling estimates.

a. Terrestrial Organisms

Avian and Mammalian Species

The ecological assessment identified potential risk to some non-target terrestrial animals. When considering the upper-bound residues on treated food items, even at the highest assessed typical rate (0.78 lb ae MCPP-p/A), EPA's avian assessment shows that there are some acute and chronic LOC exceedances based on granular and spray application scenarios. Exceedances were

also identified for acute and chronic exposures based on the assessed food items for mammals. As expected, estimates for both acute and chronic RQs are greater when assessing spot treatments at the highest application rate of 1.2 lbs ae MCP-P/A. There are some conservative assumptions made in the acute and chronic risk assessments that may have overestimated potential terrestrial risks. First, both the dose-based and dietary-based assessments presumed that the animal's diet is comprised of 100% of treated foodstuff (i.e., plant foliage, insects, fruit, and seeds) with upper-bound residues. Typically, wildlife organisms consume a variety of foodstuff from various locations, rather than from a single location. Assuming mean residues, many of the acute and chronic RQs no longer exceeded the LOCs, with the exception of some small-sized birds or mammals. Also, due to the lack of a foliar dissipation study, the Agency used the default foliar dissipation half-life of 35 days, resulting in the greatest MCP-P residues on food items.

To reduce the amount of MCP-P residues in a given area, application rates have been reduced and the highest concentration rate has been further restricted to specific types of applications (spot treatments). For broadcast treatments (primarily to residential lawns and other ornamental turf), with the exception of spot treatment use, the maximum supported application rate permitted is 0.75 lb ae MCP-P/A (used during greater weed infestation). Typical application rates range from 0.25 - 0.50 lb ae MCP-P/A, which further reduces the amount of residues in a treated area. The application rate for spot treatments has been reduced to 1.2 lbs ae MCP-P/A and is restricted to application areas no greater than 1,000 ft² per acre. These reduced rates and more restrictive use patterns effectively reduce the amount of residues available to birds and mammals. Reducing the area treated in spot treatments also decreases the likelihood of animals consuming 100% of foodstuff from a treated area, as the model assumes. Refer to Table 29 for additional specific labeling language.

Terrestrial Plants

Typically with a terrestrial herbicide, there are some risks of concern to the Agency for effects to non-target terrestrial plants. The highest RQ estimates for effects to terrestrial plants resulted from combined runoff and drift; however, the majority of RQs exceeded the LOC even for drift alone at the highest typical rate (0.78 lb ae MCP-P/A) assessed. As conservative assumptions were made in the assessment, some RQ estimates may be overestimating potential risks. The majority of MCP-P usage is applied to residential lawns, which are typically adjacent to other lawns, rather than wetlands or other habitats of non-target plants that are used in the models. Because the predominant use of MCP-P products are on residential turf, MCP-P from a treated area is more likely to move onto adjacent hard surfaces (i.e., sidewalks and streets) and into storm sewers or receiving water bodies, rather than to an adjacent wetland or wild habitat as presumed in the model. Additional assumptions that may overestimate the potential amount of MCP-P transported via runoff and drift are as follows: a maximum use rate of 1.2 lbs ae MCP-P/A and the highest typical application rate assessed of 0.78 ae MCP-P/A; a default half-life of 35 days in the modeling; assuming exposure to terrestrial plants from an application applied to one hectare; and exposure to semi-aquatic plants based on a 10 hectare application.

Specific to spray drift, risk is estimated in two ways: the amount of pesticide that could be deposited onto non-target plant surfaces and the distance from the target application area where pesticide drift could occur. Droplet size can influence the distance a pesticide drifts from the target area. Spray drift was assessed based on fine to medium-coarse droplet sizes that can occur from applications made using a high ground boom (four feet above the canopy). Most applications are made using handheld or broadcast sprayers, such as hand-wand sprayers, Ready-to-Use, and hose-end liquid products. These application methods produce a coarser droplet size and are applied closer (15 - 30 inches) to the ground, rather than applications made with a high boom sprayer. Applications made to a residential lawn are more likely to drift to adjacent lawns, rather than onto a wetland or wild habitat as presumed in the model. Because the majority of MCPP-p usage is applied to ornamental turf, the likelihood of the drift movement is to similar turf areas. Likewise in the runoff assessment, the reduction in rates and restricting droplet size to medium- to coarse-sized droplets will reduce the amount of MCPP-p deposited via spray drift.

Even considering all these factors that could over-estimate movement of runoff and drift onto non-target areas, there are still risks of concern for non-target plants, specifically in or next to golf courses, adjacent to sod farms, and forests. To reduce the potential for non-target exposures, the Agency is imposing rate reductions to a maximum of 0.75 lb ae MCPP-p for broadcast treatments. Spot treatments will be restricted to applications no greater than 1,000 ft²/A at the maximum rate of 1.2 lbs ae MCPP-p/A. Thus, the 1.2 lbs ae MCPP-p/A rate would not be applied to an entire acre. Because spot treatments are expected to be small treatment areas (no greater than 100 ft² per 5,000 ft²), concentrated products (liquid and soluble) will have dilution directions for the respective broadcast or spot treatments that specify the quantity (volume) of diluted solution for the respective size of the treatment area. Applying liquid products using medium-to-coarse droplets reduces the amount of spray drift from target areas. With the implementation of these mitigation measures and labeling requirements, movement of MCPP-p to non-target areas will be reduced. The Agency has conducted this assessment with the available vegetative vigor and seedling emergence studies that were conducted using the technical product. To confirm the Agency's assumption that the toxicity of the end-use product is the same as the technical product, EPA is requiring additional seedling emergence and vegetative vigor studies conducted with the end-use product containing MCPP-p. Refer to Table 28 for the mitigation measures required respective to the risks of concern and Table 29 for specific labeling language.

b. Aquatic Organisms

Fish and Aquatic Invertebrates

Based on available acute toxicity data, there are no risks of concern to the Agency, as MCPP-p exhibits low acute toxicity potential of MCPP-p to fish and other aquatic animals. Although no data were available to assess potential chronic risks to fish and aquatic invertebrates, the Agency compared potential chronic effects to aquatic animals based on available data conducted with other chlorophenoxy compounds. Based on chronic toxicity data conducted with another chlorophenoxy, 2,4-D, on fish and invertebrates in freshwater and marine/estuarine environments, 2,4-D poses low potential for chronic toxicity. The Agency believes that it is unlikely that MCPP-p would pose risks to fish and aquatic invertebrates,

considering its low acute toxicity and low chronic toxicity posed by other chlorophenoxy compounds. Based on the current use patterns, no additional data is needed at this time to assess potential chronic toxicity.

Aquatic Plants

Based on available data for aquatic plants, there are no risks of concern to the Agency, with the exception of exceedances identified for endangered non-vascular plants. Although there was indication for potential effects to non-target endangered non-vascular plants, there are no non-vascular plants listed as endangered species. Thus, no mitigation for aquatic plants is needed at this time.

c. Endangered Species

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 and considers ecological parameters, pesticide use information, geographic relationship between specific pesticide uses and species locations, and biological requirements and behavioral aspects of the particular species. When conducted, these analyses take into consideration any regulatory changes recommended in this RED being implemented at that time.

The ecological assessment that EPA conducted for this RED does not, in itself, constitute a determination as to whether specific species or critical habitat may be harmed by the pesticide. Rather, this assessment serves as a screen to determine the need for any species-specific assessment that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. The species-specific assessment refines the screening-level assessment to take into account information such as the geographic area of pesticide use in relation to the listed species and the habits and habitat requirements of the listed species. If the Agency's specific assessments for MCPP-p result in the need to modify use of the pesticide, any geographically specific changes to the pesticide's registration will be implemented through the process described in the Agency's *Federal Register* Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

Based on EPA's screening level assessment for MCPP-p, RQs exceed the LOCs for mammals, birds, and terrestrial plants. Additionally, chronic effects to fish and aquatic invertebrates cannot be precluded from concern for potentially affected endangered species. However, these findings are based solely on EPA's screening-level assessment and do not constitute "may affect" findings under the ESA. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, and/or consultations with the Fish and Wildlife Service or National Marine Fisheries Service, as necessary. If the Agency determines use of MCPP-p "may affect" listed species or their designated critical habitat, EPA will employ the

provisions in the Services regulations (50 CFR Part 402). To reduce potential effects to non-target endangered species, EPA is requiring various mitigation measures, including rate reductions as well as additional labeling language to reduce the movement of pesticide away from target application areas. Additionally, the Agency is requiring additional data to further characterize and refine its ecological and endangered species risk assessments.

D. Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing MCPP-p. For the specific labeling statements, refer to Table 29 of this RED document.

E. Import Tolerance

MCPP-p is not registered for any food uses in the United States. The Agency is aware of the use of MCPP-p on food commodities, specifically on grains, in Europe and Canada. The MCPP-p Task Force provided data to the Pest Management Regulatory Agency (PMRA) in Canada that showed all grain samples collected at normal crop maturity showed no detectable residues (<0.005 ppm) of MCPP-p. Therefore, no import tolerance is required.

F. Endocrine Disruption

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 such endocrine effects as the Administrator may designate.”* Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC’s recommendation that the Program include evaluations of potential effects in wildlife. When the appropriate screening and/or testing protocols being considered under the Agency’s Endocrine Disruptor Screening Program (EDSP) have been developed and vetted, MCPP-p may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

V. What Registrants Need to Do

For MCPP-p technical-grade active ingredient products, registrants need to submit the following items.

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

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

Within the time limit specified in the GDCI, cite any existing generic data which addresses data requirements or submit new generic data responding to the GDCI. Please contact Rosanna Louie at (703) 308-0037 with questions regarding generic reregistration and/or the DCI. All materials submitted in response to the GDCI should be addressed:

By U.S. mail:

Document Processing Desk (DCI/SRRD)
Rosanna Louie
U.S. EPA (7508P)
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

By express or courier service:

Document Processing Desk (DCI/SRRD)
Rosanna Louie
U.S. EPA (7508P)
2777 South Crystal Drive
Arlington, VA 22202

For end-use products containing the active ingredient MCPP-p, registrants need to submit the following items for each product.

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

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

Within eight months from receipt of the PDCI:

- (1) submit two copies of the confidential statement of formula, EPA form 8570-4;
- (2) a completed original application for reregistration (EPA form 8570-1). Indicate on the form that it is an "application for reregistration";
- (3) five copies of the draft label incorporating all label amendments outlined in Table 27 of this document;
- (4) a completed form certifying compliance with data compensation requirements (EPA Form 8570-34);

- (5) if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and
- (6) the product-specific data responding to the PDCI.

Please contact Julia Stokes at 703-347-8966 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed:

By U.S. mail:

Document Processing Desk (DCI/SRRD)
Julia Stokes
U.S. EPA (7508P)
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

By express or courier service:

Document Processing Desk (DCI/SRRD)
Julia Stokes
U.S. EPA (7508P)
2777 South Crystal Drive
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of MCPP-p for currently registered uses has been reviewed and determined to be substantially complete. However, confirmatory data is required in some instances. The Agency has conducted this assessment with the available vegetative vigor and seedling emergence studies that were conducted using the technical product. To confirm the Agency's assumption that the toxicity of the end-use product is the same as the technical product, EPA is requiring additional seedling emergence and vegetative vigor studies conducted with the end-use product containing MCPP-p, and these are listed below.

<u>OPPTS Guideline Number</u>		<u>Study, Test Species</u>
(old)	(new)	
Not available	830.7050	UV/Visible Absorption
123-1(a)	850.4225	Seedling germination/seedling emergence (Tier II)
123-1(b)	850.4250	Vegetative Vigor (Tier II)

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 29.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements. For any questions regarding the PDCI, please contact Julia Stokes at 703-347-8966.

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 28. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

C. Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to comply with the following table. Table 29 describes how language on the labels should be amended.

Table 29. MCPP-p Labeling Requirements Table		
Description	Mecoprop-p (MCPP-p): Required Labeling Language	Placement on Label
<i>Manufacturing-Use Products</i>		
For all Manufacturing Use Products	“Only for formulation as an herbicide for the following use(s) [fill blank only with those uses that are being supported by MP registrant].” “Only for formulation into end-products with directions for use that prohibit aerial application.” “Only for formulation into end-products with directions for use that prohibit broadcast applications greater than 0.75 lb ae MCPP-p/A.” “Only for formulation into end-use products with directions for use that prohibit spot treatment applications greater than 1.2 lbs ae MCPP-p/A.” Must only be formulated into Ready-to-Use spray containers that produce droplets that are Medium or coarse in size according to the ASAE (S572) definition for standard nozzles.	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group.	“This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).” “This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	“Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.”	Precautionary Statements
<i>End-Use Products Intended for Occupational Use (WPS and Non-WPS)</i>		

PPE Requirements Established by the RED for all formulations except for granular and Ready-to-Use formulations	“Personal Protective Equipment (PPE)” All mixers, loaders, applicators, and other handlers must wear the following PPE: - long-sleeved shirt and long pants, and - shoes plus socks.”	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED for granular formulations	“Personal Protective Equipment (PPE)” All loaders, applicators, and other handlers must wear the following PPE: - long-sleeved shirt and long pants, and - shoes plus socks.”	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED for Ready-to-Use formulations	“Personal Protective Equipment (PPE)” All applicators and other handlers must wear the following PPE: - long-sleeved shirt and long pants, and - shoes plus socks.”	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
Restricted Entry Interval for products with WPS uses	“Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours.”	Directions for Use, Agricultural Use Requirements Box
Early Entry Personal Protective Equipment for products with WPS uses	“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 as follows: - coveralls, - shoes plus socks, - chemical-resistant gloves made of any waterproof material, and - protective eyewear.”	Directions for Use, Agricultural Use Requirements Box
General Application Restrictions	“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.”	Place in the Direction for Use directly above the Agricultural Use Box.
Entry Restrictions for Non-WPS Uses for Products Applied as a Spray	“Do not enter or allow entry until sprays have dried.”	Directions for Use Under General Precautions and Restrictions. If the product also contains WPS uses, then create a Non-Agricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.

Entry Restrictions for Non-WPS Uses for Granular Products	If the product does not have instructions for watering in, include the following statement: “Do not enter or allow entry to the treated area until dusts have settled.” If the product has instructions for watering in, include the following statement: “Do not enter or allow entry to the treated areas (except those involved in the watering) until the watering in is complete and the surface is dry.”	Directions for Use Under General Precautions and Restrictions. If the product also contains WPS uses, then create a Non-Agricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.
User Safety Requirement	“Follow manufacturer’s instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.” “Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product’s concentrate. Do not reuse them.”	Precautionary Statements: Hazards to Humans and Domestic Animals Immediately following the PPE requirements
User Safety Recommendations	“USER SAFETY RECOMMENDATIONS” “Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.” “Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.” “Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazard Statement	“This pesticide may adversely affect non-target plants. Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash waters or rinsate. This chemical has properties and characteristics associated with chemicals detected in groundwater. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination. Application around a cistern or well may result in contamination of drinking water or groundwater.”	Precautionary Statements immediately following the User Safety Recommendations

Other Application Restrictions (Risk Mitigation) (Note: The maximum allowable application rate and maximum allowable rate per year must be listed as pounds or gallons of formulated product per acre or per 1,000 square feet, not just as pounds acid equivalent per acre.)	For broadcast treatments, include the following: “Limited to 2 applications per year. Maximum of 0.75 lb ae MCP-P-p/A per application (or the respective lb ae MCP-P-p/1,000 ft²). Minimum of 30 days between applications.” For spot treatments for all use sites, include the following statements: “Limited to 2 applications per year. Maximum of 1.2 lbs ae MCP-P-p/A per application (or the respective lb ae MCP-P-p/1,000 ft²). Minimum of 30 days between applications. Broadcast application is prohibited at this use rate.” Spot treatment is defined as a treatment area no greater than 1,000 ft² per acre.	Directions for Use Associated with the Specific Use Pattern
General Application Restrictions	“Do not use this product on or near desirable plants, including within the dripline of the roots of desirable trees and shrubs, since injury may result.”	Directions for Use under Other Use Precautions

Spray Drift Management	“SPRAY DRIFT MANAGEMENT” “A variety of factors including weather conditions (e.g. wind direction, wind speed, temperature, relative humidity) and method of application (e.g. groundboom, sprayer) can influence pesticide drift. The applicator must evaluate all factors and make appropriate adjustments when applying this product.” Droplet Size “Use only Medium or coarser spray nozzles according to ASAE (S572) definition for standard nozzles.” Wind Speed “Do not apply at wind speeds greater than 10 mph.” Temperature Inversions “If applying at wind speeds less than 3 mph, the applicator must determine if 1) conditions of temperature inversion exist, or 2) stable atmospheric conditions exist at or below nozzle height. Do not make applications into areas of temperature inversions or stable atmospheric conditions.” Additional Requirements for groundboom application: “Do not apply with a nozzle height greater than four feet above the target site.”	Directions for Use under Use Precautions
<i>End Use Products Intended for Residential Use</i>		
Application Restrictions	“Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application.”	Directions for use under General Precautions and Restrictions
Entry Restrictions for products applied as a spray	“Do not allow people or pets to enter the treated area until sprays have dried.”	Directions for use under General Precautions and Restrictions

Entry Restrictions for granular formulations	If the product does not have instructions for watering in, include the following statement: “Do not allow people or pets to enter the treated area until dusts have settled.” If the product has instructions for watering in, include the following statement: “Do not enter or allow others (including children or pets) to enter the treated areas (except those involved in the watering) until the watering-in is complete and the surface is dry.”	Directions for use under General Precautions and Restrictions
Environmental Hazard Statement for Residential Use labels	“This pesticide may adversely affect non-target plants. Do not apply directly to water. Do not contaminate water when disposing of equipment wash waters or rinsate.”	Precautionary Statements immediately following the User Safety Recommendations
Other Application Restrictions	See the “General Application Restrictions” listed above for requirement for all products. In addition also add the following statement: “Do not apply as a fine mist because of potential injury to desirable plants.”	Directions for Use under Other Use Precautions

Other Application Restrictions	Requirements for Granular Formulations, include the following statement: “Do not apply directly to or near water, storm drains, gutters, sewers, or drainage ditches. Do not apply within 25 feet of rivers, fish ponds, lakes, streams, reservoirs, marshes, estuaries, bays, and oceans. Do not apply when windy. Apply this product directly to your lawn or garden, and sweep any product landing on the driveway, sidewalk, gutter, or street, back onto the treated area. To prevent product run-off, do not over water the treated area to the point of runoff or apply when raining or when rain is expected that day.” Requirements for Liquid and Dust products (excludes Ready-to-Use Products), include the following statement: “Do not apply directly to or near water, storm drains, gutters, sewers, or drainage ditches. Do not apply within 25 feet of rivers, fish ponds, lakes, streams, reservoirs, marshes, estuaries, bays, and oceans. Do not apply when windy. To prevent product run-off, do not over water the treated area(s) to the point of runoff or apply when raining or when rain is expected that day. Rinse applicator over lawn or garden area only.” Requirements for Ready-to-Use Formulations labeled or intended for outdoor use, include the following statement: “Do not apply directly to or near water, storm drains, gutters, sewers, or drainage ditches. Do not apply within 25 feet of rivers, fish ponds, lakes, streams, reservoirs, marshes, estuaries, bays, and oceans. Do not apply when windy. To prevent product run-off, do not over water to the point of runoff, or apply when raining or when rain is expected that day.”	Directions for Use under Other Use Precautions
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APPENDIX A. Use Patterns Eligible for Reregistration

Table of MCPP-p Use Patterns Eligible for Reregistration (Case #0377)							
Use Site	Formulation	Typical Application Rate	Maximum Application Rate	Restrictions	Timing	Restricted Entry Interval	Application Equipment
Ground Broadcast Treatments in: residential turf, ornamental turf (e.g., golf courses, cemeteries, parks, sports fields, and turfgrass), sod farms, and uncultivated non-agricultural areas (e.g., roadsides, fencerows, and rights-of-ways)	MCPP-p acid: granular, emulsifiable concentrate, water-soluble dry concentrate, and wettable powder MCPP-p DMAS: granular, water-soluble liquid concentrate, and water-soluble concentrate dry	0.20 - 0.75 lb ae/A	0.75 lb ae/A	Maximum of 2 applications per year	Post-emergence	48 hours	Low boom sprayer, handheld nozzle sprayer, wand sprayer, knapsack sprayer, and granular spreader
Spot Treatments (for woody plants management) in uncultivated non-agricultural areas (e.g., utility power lines, hedgerows, industrial sites, ditches, airports, and fence rows)		Not applicable	Concentration equivalent up to 1.2 lbs ae/A	- Treatment areas no greater than 100 feet (linear or square feet)/A - Maximum of 2 applications per year			Handheld nozzle sprayer, wand sprayer, knapsack sprayer, and granular spreader

lb ae/A = pound of acid equivalent per acre

APPENDIX B. Data Supporting Guideline Requirements for MCPP-p

Data Supporting Guideline Requirements for the Reregistration of Mecoprop-p (MCPP-p)				
PRODUCT CHEMISTRY				
New Guideline Number	Old Guideline Number	Study Description	Use Pattern	Citation(s)
830.1550	61-1	Product Identity and Composition	All	
830.1600	61-2a	Starting Materials & Manufacturing Process	All	
830.1670	61-2b	Formation of Impurities	All	
830.1700	62-1	Preliminary Analysis	All	
830.1750	62-2	Certification of limits	All	
830.1800	62-3	Analytical Method	All	
830.6302	63-2	Color	All	
830.6303	63-3	Physical State	All	
830.6304	63-4	Odor	All	
830.7050	None	UV/Visible Absorption	All	
830.7200	63-5	Melting Point	All	
830.7220	63-6	Boiling Point	All	
830.7300	63-7	Density	All	
830.7840 830.7860	63-8	Solubility	All	
830.7950	63-9	Vapor Pressure	All	
830.7370	63-10	Dissociation Constant	All	
830.7550	63-11	Octanol/Water Partition Coefficient	All	
830.7000	63-12	pH	All	
830.6313	63-13	Stability	All	
830.6314	63-14	Oxidizing/Reducing Action	All	
830.6315	63-15	Flammability	All	
830.6316	63-16	Explosibility	All	
830.6317	63-17	Storage Stability	All	
830.7100	63-18	Viscosity	All	
830.6319	63-19	Miscibility	All	
830.6320	63-20	Corrosion characteristics	All	
ECOLOGICAL EFFECTS				
850.2100	71-1a	Avian Acute Oral Toxicity - Quail	All	41013912 42436701 43810201
850.2200	71-2a	Avian Dietary Toxicity - Quail	All	42435601
850.2200	71-2b	Avian Dietary Toxicity - Duck	All	44030401
850.2300	71-4a	Avian Reproduction - Quail	All	44925501 - supplemental
850.1075	72-1a	Fish Toxicity Bluegill	All	42766901 43810202
850.1075	72-1c	Fish Toxicity Rainbow Trout	All	42844801

Data Supporting Guideline Requirements for the Reregistration of Mecoprop-p (MCP-p)				
850.1010	72-2a	Invertebrate Toxicity - Water flea	All	42971301 43372301 45606102 - supplemental 45606104 - supplemental
850.1300	72-4	Daphnid Chronic Toxicity	All	45606102 - supplemental
850.4400	122-2	Aquatic Plant Toxicity	All	42486201 46591807
850.4225	123-1a	Seed Germ./ Seedling Emergence	All	42845501 - supplemental 43016601 - supplemental 43385901
850.4250	123-1b	Vegetative Vigor	All	42775401 - supplemental 43059301 - supplemental
850.4400	123-2	Aquatic Plant Growth	All	42486201 42633902 43657303
850.5400	123-2	Algal Toxicity	All	42633901 42666201 42698601 - supplemental 43048901 43657301 43657302 44294401 46591808 - supplemental
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity-Rat	All	42614701 42947801
870.1200	81-2	Acute Dermal Toxicity-Rabbit	All	42916401
870.1300	81-3	Acute Inhalation Toxicity-Rat	All	
870.2400	81-4	Primary Eye Irritation-Rabbit	All	42947804
870.2500	81-5	Primary Skin Irritation	All	42947805
870.2600	81-6	Dermal Sensitization	All	43749601
870.6200	81-8-SS	Acute Neurotoxicity Screen	All	43770801
870.3100	82-1a	Repeated dose 28-day/ 90-Day Feeding - Rodent	All	00158359 41013910 43059201 43908201
870.3200	82-2	21-Day Dermal - Rabbit/Rat	All	42916401 43638101 43638102
870.3550	None	Reproduction/development Toxicity Screening Test	All	46591804
870.6200	82-7	Neurotoxicity Screening Battery	All	43908201
870.4100	83-1a	Chronic Feeding Toxicity - Rodent	All	40937501 44895501 44953601
870.4100	83-1b	Chronic Feeding Toxicity - Non-Rodent	All	44642401
870.4200	83-2a	Oncogenicity - Rat	All	40937501 46591801

Data Supporting Guideline Requirements for the Reregistration of Mecoprop-p (MCP-p)				
870.4200	83-2b	Oncogenicity - Mouse	All	44895501 44953601 46591802
870.3700	83-3a	Developmental Toxicity - Rat	All	00164569 42815302
870.3700	83-3b	Developmental Toxicity - Rabbit	All	42815301
870.5140	84-2a	Gene Mutation (Ames Test)	All	00158361 41013909 42860801 42936802 42947807 42980101 43113401 46614001
870.5375	84-2b	Structural Chromosomal Aberration	All	00158362 00158363 41013908 42860804 42936803 42947808 43189501 46614001
None	84-4	Other Genotoxic Effects	All	44895502
870.7485	85-1	Metabolism and Pharmacokinetics	All	43717201 44362701 44362702
875.2100	132-1	Foliar Dislodgeable Residue Dissipation	All	44655702 44655703 45033101
875.2400	132-3	Dermal Exposure	All	44459801
875.2500	132-4	Inhalation Exposure	All	44459801
ENVIRONMENTAL FATE				
835.2110	161-1	Hydrolysis as a function of pH	All	44110901
835.2240	161-2	Photodegradation - Water	All	44110901
835.2410	161-3	Photodegradation - Soil	All	44147001
835.4100	162-1	Aerobic Soil Metabolism	All	44281301
	162-4	Aerobic Aquatic Metabolism	All	42845301
835.1240	163-1	Leaching/Adsorption/Desorption	All	42845302 44205701
835.6100	164-1	Terrestrial Field Dissipation	All	43909701 43909702 43909703 43909704 43909705 43943201
OTHER				
850.3020	141-1	Honey Bee Acute Contact		42159701 46591810

APPENDIX C. Technical Support Documents

Additional documentation in support of the MCPP-p RED is maintained in the OPP Regulatory Public Docket, located in Room S-4400 One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 a.m. to 4:00 p.m. All documents may be viewed in the OPP Docket room or viewed and/or downloaded via the Internet at <http://www.regulations.gov>. The Agency's documents in support of this RED include the following:

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2. Dole, T. MCPP-p: 2nd Revised Occupational and Residential Exposure and Risk Assessment for the Reregistration Eligibility Decision (RED). July 27, 2007.
3. Hetrick, J. FQPA Drinking Water Assessment for Mecoprop-p. June 26, 2007.
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5. Phillips, W., Lee, A. A Preliminary evaluation of Mecoprop (MCPP-p) and Dichlorprop (2,4-DP-p) Use and Potential Alternatives. August 21, 2007.

APPENDIX D. Bibliography

In addition to the studies listed in Appendix B, this bibliography contains additional citations considered to be part of the database supporting the reregistration decision for MCP-p.

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APPENDIX E. Generic Data Call-in (GDCI)

United States Environmental Protection
Agency Washington, D.C. 20460
DATA CALL-IN RESPONSE

OMB Approval 2070-0107
OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000		2. Case # and Name 0377 MCPP Chemical # and Name 129046 Mecoprop-P		3. Date and Type of DCI and Number DD-MMM-YYYY GENERIC ID # GDCI-129046-NNNNN	
4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
NNNNNNN-NNNNN				N.A.	N.A.
8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.				9. Entry Date	
Signature and Title of Company's Authorized Representative					
10. Name of Company				11. Phone Number	

United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000		2. Case # and Name 0377 MCPP Chemical # and Name Mecoprop-P		3. Date and Type of DCI and Number DD-MMM-YYYY GENERIC ID # GDCI-129046-NNNNN						
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response			
								1	2	3
				<u>Nontarget Plant Protection Data Requirements (Conventional Chemical)</u>						
850.4225	Seedling emergence, Tier II		(1, 2, 3, 4)		C, HH, II, K, Q, R, T, U	TEP	12			
850.4250	Vegetative vigor, Tier II		(5, 6, 7, 8, 9)		C, HH, II, K, Q, R, T, U	TEP	12			
	<u>Product Chemistry Data Requirements (Conventional Chemical)</u>									
830.7050	UV/Visible absorption				C, HH, II, K, Q, R, T, U	TGA/PAI	8			
10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law						11. Date				
Signature and Title of Company's Authorized Representative _____						13. Phone Number				
12. Name of Company										

United States Environmental Protection
Agency Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0377 MCP
DCI Number: GDCI-129046-NNNN

Key: TEP = Typical End Use Product [TEP]; TGA/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Use Categories Key:

C - Terrestrial nonfood crop	R - Agricultural premises and equipr	HH - Occupational Use Conventional
K - Residential	T - Commercial, institutional and inc	II - Residential Use Conventional C
Q - Residential outdoor use	U - Residential and public access pr	

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANTS RESPONSE form.]

- 1 Not required for contained pesticide treatments such as bait boxes and pheromone traps unless adverse effects reports are received by the Agency.
- 2 Reserved for aquatic residential uses.
- 3 Required if a terrestrial species exhibits a 25 percent or greater detrimental effect in Tier 1.
- 4 Required for known phytotoxicants such as herbicides, desiccants, defoliants, and plant growth regulators.
- 5 Not required for contained pesticide treatments such as bait boxes and pheromone traps unless adverse effects reports are received by the Agency.
- 6 Reserved for aquatic residential uses.
- 7 Generally not required for granular formulations. May be requested on a case-by-case basis.
- 8 Required if a terrestrial species exhibits a 25 percent or greater detrimental effect in Tier 1.
- 9 Required for known phytotoxicants such as herbicides, desiccants, defoliants, and plant growth regulators.

United States Environmental Protection
Agency Washington, D.C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 0377,MCPP

Co. Nr.	Company Name	Agent For	Address	City & State	Zip
264	BAYER CROPSCIENCE LP		2 T.W. ALEXANDER DRIVE	RESEARCH TRIANGLE PARK	NC 27709
2217	PBI/GORDON CORP		PO Box 014090 1217 WEST 12TH STREET	KANSAS CITY	MO 641010090
15440	A H MARKS & CO LTD	REGISTRATION AND REGULATORY SERVICES	PMB 239, 7474 CREEDMOOR ROAD	RALEIGH	NC 27613
70596	NUFARM BV	NUFRAM BV	PO Box 13439	RTP	NC 27709

United States Environmental Protection
Agency Washington, D.C. 20460
DATA CALL-IN RESPONSE

OMB Approval 2070-0107
OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000		2. Case # and Name 0377 MCPP Chemical # and Name 031520 Propanoic acid, 2-(4-chloro-2-methylphenoxy)-, (R)-, compd. with N-methylmethanamine (1:1)		3. Date and Type of DCI and Number DD-MMM-YYYY GENERIC ID # GDCI-031520-NNNNN	
4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
NNNNNNN-NNNNN				N.A.	N.A.
8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.				9. Entry Date	
Signature and Title of Company's Authorized Representative					
10. Name of Company				11. Phone Number	

United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000		2. Case # and Name 0377 MCPP Chemical # and Name 031520 Propanoic acid, 2-(4-chloro-2-methylphenoxy)-, (R)-, compd. with N-methylmethanamine (1:1)		3. Date and Type of DCI and Number DD-MMM-YYYY GENERIC ID # GDCI-031520-NNNNN						
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response			
								1	2	3
	Nontarget Plant Protection Data Requirements (Conventional Chemical)									
850.4225	Seedling emergence, Tier II				A, C, HH, II, K, Q, R, T, U TEP	12				
850.4250	Vegetative vigor, Tier II				A, C, HH, II, K, Q, R, T, U TEP	12				
	Product Chemistry Data Requirements (Conventional Chemical)									
830.7050	UV/Visible absorption				A, C, HH, II, K, Q, R, T, U TGAI/PAI	8				
10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law						11. Date				
Signature and Title of Company's Authorized Representative _____						13. Phone Number				
12. Name of Company										

United States Environmental Protection
Agency Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0377 MCP
DCI Number: GDCI-031520-NNNN

Key: TEP = Typical End Use Product [TEP]; TGA/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Use Categories Key:

A -	Terrestrial food crop	Q -	Residential outdoor use	U -	Residential and public access pr
C -	Terrestrial nonfood crop	R -	Agricultural premises and equipr	HH -	Occupational Use Conventional
K -	Residential	T -	Commercial, institutional and inc	II -	Residential Use Conventional C

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANTS RESPONSE form.]

- 1 Not required for contained pesticide treatments such as bait boxes and pheromone traps unless adverse effects reports are received by the Agency.
- 2 Reserved for aquatic residential uses.
- 3 Required if a terrestrial species exhibits a 25 percent or greater detrimental effect in Tier 1.
- 4 Required for known phytotoxicants such as herbicides, desiccants, defoliants, and plant growth regulators.
- 5 Not required for contained pesticide treatments such as bait boxes and pheromone traps unless adverse effects reports are received by the Agency.
- 6 Reserved for aquatic residential uses.
- 7 Generally not required for granular formulations. May be requested on a case-by-case basis.
- 8 Required if a terrestrial species exhibits a 25 percent or greater detrimental effect in Tier 1.
- 9 Required for known phytotoxicants such as herbicides, desiccants, defoliants, and plant growth regulators.

United States Environmental Protection
Agency Washington, D.C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 0377,MCPP

Co. Nr.	Company Name	Agent For	Address	City & State	Zip
15440	A H MARKS & CO LTD	REGISTRATION AND REGULATORY SERVICES	PMB 239, 7474 CREEDMOOR ROAD	RALEIGH	NC 27613
70596	NUFARM BV	NUFRAM BV	PO Box 13439	RTP	NC 27709

APPENDIX F. Product-specific Data Call-in (PDCI)

As previously stated in Section II of this RED, most products have been reformulated from the racemic mixture (MCP) to the enriched isomer formulation (MCP-p) and all reformulations are anticipated to be completed by the Fall of 2007. Although the technical registrants are supporting only the enriched isomeric forms of MCP-p, the remaining reformulations and respective labeling updates were still being processed at the time this RED was issued. To ensure that all companies affected by this data call-in receive the PDCI, PDCIs were generated for all current registrations that reflect either MCP (racemic) or MCP-p (enriched isomer) forms as an active ingredient.

United States Environmental Protection
Agency Washington, D.C. 20460
DATA CALL-IN RESPONSE

OMB Approval 2070-0107
OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000		2. Case # and Name Chemical # and Name 119046 MCPP-P-potassium		3. Date and Type of DCI and Number DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-119046-NNNN	
4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below. N.A.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response." N.A.	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
NNNNNNN-NNNNN					
8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.					
Signature and Title of Company's Authorized Representative				11. Date	
10. Name of Company				11. Phone Number	

**United States Environmental Protection
Agency Washington, D.C. 20460
DATA CALL-IN RESPONSE**

OMB Approval 2070-0107
OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000		2. Case # and Name 0377 MCPP Chemical # and Name 129046 Mecoprop-P		3. Date and Type of DCI and Number DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-129046-NNNN	
4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
NNNNNNN-NNNNN		N.A.	N.A.		
8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.					
Signature and Title of Company's Authorized Representative _____					11. Date _____
10. Name of Company _____					11. Phone Number _____

United States Environmental Protection
Agency Washington, D.C. 20460
DATA CALL-IN RESPONSE

OMB Approval 2070-0107
OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000		2. Case # and Name 0377 MCPP Chemical # and Name 031501 Mecoprop (and salts and esters)		3. Date and Type of DCI and Number DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-031501-NNNN	
4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
NNNNNNN-NNNNN		N.A.	N.A.		
8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.					
Signature and Title of Company's Authorized Representative					11. Date
10. Name of Company					11. Phone Number

**United States Environmental Protection
Agency Washington, D.C. 20460
DATA CALL-IN RESPONSE**

OMB Approval 2070-0107
OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000		2. Case # and Name 0377 MCPP Chemical # and Name 031519 Mecoprop, dimethylamine salt		3. Date and Type of DCI and Number DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-031519-NNNN	
4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
NNNNNNN-NNNNN		N.A.	N.A.		
8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.					
Signature and Title of Company's Authorized Representative _____					11. Date _____
10. Name of Company _____					11. Phone Number _____

**United States Environmental Protection
Agency Washington, D.C. 20460
DATA CALL-IN RESPONSE**

OMB Approval 2070-0107
OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000		2. Case # and Name 0377 MCPP Chemical # and Name 031520 Propanoic acid, 2-(4-chloro-2-methylphenoxy)-, (R)-, compd. with N-methylmethanamine (1:1)		3. Date and Type of DCI and Number DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-031520-NNNN	
4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
NNNNNNN-NNNNN		N.A.	N.A.		
8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.					
Signature and Title of Company's Authorized Representative _____					11. Date _____
10. Name of Company _____					11. Phone Number _____

United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000		2. Case # and Name EPA Reg. No. NNNNNN-NNNNN			3. Date and Type of DCI and Number DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-119046-NNNN				
4. Guideline Requirement Number	5. Study Title	P R O D U C T I O N C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	Product Chemistry Data Requirements (Conventional Chemical								
830.1550	Product Identity and composition	(1)				C, HH, II, K, Q, R, T, U	TGA/MP/EP	8	
830.1600	Description of materials used to produce the product	(2)				C, HH, II, K, Q, R, T, U	TGA/MP/EP	8	
830.1620	Description of production process	(3)				C, HH, II, K, Q, R, T, U	TGA/MP/EP	8	
830.1650	Description of formulation process	(4)				C, HH, II, K, Q, R, T, U	MP/EP	8	
830.1670	Discussion of formation of impurities	(5)				C, HH, II, K, Q, R, T, U	TGA/MP/EP	8	
830.1700	Preliminary analysis	(6, 7, 8)				C, HH, II, K, Q, R, T, U	TGA/MP/EP	8	
830.1750	Certified limits	(9, 10)				C, HH, II, K, Q, R, T, U	TGA/MP/EP	8	
830.1800	Enforcement analytical method	(11)				C, HH, II, K, Q, R, T, U	TGA/MP/EP	8	
830.6302	Color	(12)				C, HH, II, K, Q, R, T, U	TGA/MP/EP	8	
830.6303	Physical state	(13)				C, HH, II, K, Q, R, T, U	TGA/MP/EP	8	
830.6304	Odor	(14)				C, HH, II, K, Q, R, T, U	TGA/MP/EP	8	
830.6313	Stability to sunlight, normal and elevated temperatures; (15, 16) metals, and metal ions					C, HH, II, K, Q, R, T, U	TGA/MP/EP	8	
10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law									
Signature and Title of Company's Authorized Representative								11. Date	
12. Name of Company								13. Phone Number	

United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000		2. Case # and Name EPA Reg. No. NNNNNN-NNNNN			3. Date and Type of DCI and Number DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-119046-NNNN				
4. Guideline Requirement Number	5. Study Title	P R O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
830.6314	Oxidizing or reducing action	(17)				C, HH, II, K, Q, R, T, U	MP/EP	8	
830.6315	Flammability	(18)				C, HH, II, K, Q, R, T, U	MP/EP	8	
830.6316	Explosibility	(19)				C, HH, II, K, Q, R, T, U	MP/EP	8	
830.6317	Storage stability of product	(20)				C, HH, II, K, Q, R, T, U	MP/EP	8	
830.6319	Miscibility	(21)				C, HH, II, K, Q, R, T, U	MP/EP	8	
830.6320	Corrosion characteristics	(22)				C, HH, II, K, Q, R, T, U	MP/EP	8	
830.6321	Dielectric breakdown voltage	(23)				C, HH, II, K, Q, R, T, U	MP/EP	8	
830.7000	pH of water solutions or suspensions	(24, 25)				C, HH, II, K, Q, R, T, U	TGAI/MP/EP	8	
830.7050	UV/Visible absorption					C, HH, II, K, Q, R, T, U	TGAI/PAI	8	
830.7100	Viscosity	(26)				C, HH, II, K, Q, R, T, U	MP/EP	8	
830.7200	Melting point/melting range	(27, 28)				C, HH, II, K, Q, R, T, U	TGAI	8	
830.7220	Boiling point/boiling range	(29, 30)				C, HH, II, K, Q, R, T, U	TGAI	8	
830.7300	Density/relative density	(31, 32)				C, HH, II, K, Q, R, T, U	TGAI/MP/EP	8	
Initial to indicate certification as to information on this page (full text of certification is on page one).									
Date									

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Agency Washington, D.C. 20460

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000		2. Case # and Name EPA Reg. No. NNNNNN-NNNNN			3. Date and Type of DCI and Number DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-119046-NNNN				
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
830.7370	Dissociation constant in water					C, HH, II, K, Q, R, T, U	TGAI or PAI	8	
830.7550	Partition coefficient (n-octanol/water), shake flask method					C, HH, II, K, Q, R, T, U	TGAI/PAI	8	
830.7570	Partition coefficient (n-octanol/water), estimation by liquid chromatography					C, HH, II, K, Q, R, T, U	TGAI/PAI	8	
830.7840	Water solubility: Column elution method, shake flask method					C, HH, II, K, Q, R, T, U	TGAI or PAI	8	
830.7860	Water solubility, generator column method					C, HH, II, K, Q, R, T, U	TGAI or PAI	8	
830.7950	Vapor pressure					C, HH, II, K, Q, R, T, U	TGAI or PAI	8	
	Toxicology Data Requirements (Conventional Chemical)								
870.1100	Acute Oral Toxicity					C, HH, II, K, Q, R, T, U	TGAI, EP, dilute EP?	8	
870.1200	Acute dermal toxicity					C, HH, II, K, Q, R, T, U	TGAI, EP, dilute EP?	8	
870.1300	Acute inhalation toxicity					C, HH, II, K, Q, R, T, U	TGAI & EP	8	
870.2400	Acute eye irritation					C, HH, II, K, Q, R, T, U	TGAI & EP	8	
870.2500	Acute dermal irritation					C, HH, II, K, Q, R, T, U	TGAI & EP	8	
870.2600	Skin sensitization					C, HH, II, K, Q, R, T, U	TGAI & EP	8	
Initial to indicate certification as to information on this page (full text of certification is on page one).							Date		

United States Environmental Protection
Agency Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name:

DCI Number: PDCL-119046-NNNN

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGA = Technical Grade Active Ingredient [TGA]; TGA & EP = Technical Grade of the Active Ingredient and End-Use Product; TGA or P. Technical Grade of the Active Ingredient or Pure Active Ingredient; TGA, EP, dilute EP? = Technical Grade of the Active Ingredient, End Use Product, and possibly diluted End Use Product; TGA/MP/E Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGA/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Use Categories Key:

C -	Terrestrial nonfood crop	R -	Agricultural premises and equipr	HH -	Occupational Use Conventional
K -	Residential	T -	Commercial, institutional and inc	II -	Residential Use Conventional C
Q -	Residential outdoor use	U -	Residential and public access pr		

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

- 1 Data must be provided in accordance with the "Product Composition" Section.(158.155)
- 2 Data must be provided in accordance with the "Description of Materials used to Produce the Product" Section.(158.160)
- 3 Data must be provided in accordance with the "Description of Production Process" Section.(158.162)
- 4 Data must be provided in accordance with the "Description of Formulation Process" Section.(158.165)
- 5 Data must be provided in accordance with the "Description of Formation of Impurities" Section(158.167)
- 6 Data must be provided in accordance with the "Preliminary Analysis" Section.(158.170)
- 7 Required for TGAs and products produced by an integrated system.
- 8 If the TGA cannot be isolated, data are required on the practical equivalent of the TGA (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 9 Data must be provided in accordance with the "Certified Limits" Section(158.175)

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Agency Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name:

DCI Number: PDCI-119046-NNNN

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGA/EP = Technical Grade Active Ingredient [TGA/EP = Technical Grade of the Active Ingredient and End-Use Product; TGA/EP = Technical Grade of the Active Ingredient or Pure Active Ingredient; TGA/EP, dilute EP? = Technical Grade of the Active Ingredient, End Use Product, and possibly diluted End Use Product; TGA/MP/EP = Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGA/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANTS RESPONSE form.]

- 10 If the TGA/EP cannot be isolated, data are required on the practical equivalent of the TGA/EP (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 11 Data must be provided in accordance with the "Enforcement Analytical Method" Section (158.180)
- 12 If the TGA/EP cannot be isolated, data are required on the practical equivalent of the TGA/EP (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 13 If the TGA/EP cannot be isolated, data are required on the practical equivalent of the TGA/EP (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 14 If the TGA/EP cannot be isolated, data are required on the practical equivalent of the TGA/EP (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 15 If the TGA/EP cannot be isolated, data are required on the practical equivalent of the TGA/EP (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 16 Data on the stability to metals and metal ions is required only if the active ingredient is expected to come in contact with either material during storage.
- 17 Required if the product contains an oxidizing or reducing agent

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name:

DCI Number: PDCI-119046-NNNN

Key: MP/EP = Manufacturing-Use Product; Pure Active Ingredient; TGA I = Technical Grade Active Ingredient [TGA I]; TGA I & EP = Technical Grade of the Active Ingredient and End-Use Product; TGA I or P. Technical Grade of the Active Ingredient or Pure Active Ingredient; TGA I, EP, dilute EP? = Technical Grade of the Active Ingredient, End Use Product, and possibly diluted End Use Product; TGA I/MP/EP Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGA I/PA I = Technical Grade Active Ingredient; Pure Active Ingredient

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANTS RESPONSE form.]

- 18 Required when the product contains combustible liquids.
- 19 Required when the product is potentially explosive.
- 20 Please see attached "Additional Information and Requirements Pertaining to Storage Stability (OPPTS 830.6317) and Corrosion Characteristics (OPPTS 830.6320) Data Requirements of the Pro Specific Data Call-Ins issued under the Reregistration Eligibility Decision (RED)/Interim Reregistration Eligibility Decision (IREDD) Documents."
- 21 Required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.
- 22 Please see attached "Additional Information and Requirements Pertaining to Storage Stability (OPPTS 830.6317) and Corrosion Characteristics (OPPTS 830.6320) Data Requirements of the Pro Specific Data Call-Ins issued under the Reregistration Eligibility Decision (RED)/Interim Reregistration Eligibility Decision (IREDD) Documents."
- 23 Required if the end-use product is a liquid and is to be used around electrical equipment.
- 24 If the TGA I cannot be isolated, data are required on the practical equivalent of the TGA I (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 25 Required if the product is dispersible with water.
- 26 Required if the product is a liquid.

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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name:

DCI Number: PDCL-119046-NNNN

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGA = Technical Grade Active Ingredient [TGA]; TGA & EP = Technical Grade of the Active Ingredient and End-Use Product; TGA or P. Technical Grade of the Active Ingredient or Pure Active Ingredient; TGA, EP, dilute EP? = Technical Grade of the Active Ingredient, End Use Product, and possibly diluted End Use Product; TGA/MP/E Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGA/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

- 27 If the TGA cannot be isolated, data are required on the practical equivalent of the TGA (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 28 Required when the TGA is solid at room temperature.
- 29 If the TGA cannot be isolated, data are required on the practical equivalent of the TGA (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 30 Required if the TGA is liquid at room temperature.
- 31 If the TGA cannot be isolated, data are required on the practical equivalent of the TGA (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 32 True density or specific density are required for all test substances. Data on bulk density is required for MPs that are solid at room temperature.
- 33 If the TGA cannot be isolated, data are required on the practical equivalent of the TGA (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 34 Required when the test substance contains an acid or base functionality (organic or inorganic) or an alcoholic functionality (organic).

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Agency Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name:

DCI Number: PDCI-119046-NNNN

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGAI = Technical Grade Active Ingredient [TGAI]; TGAI & EP = Technical Grade of the Active Ingredient and End-Use Product; TGAI or P. Technical Grade of the Active Ingredient or Pure Active Ingredient; TGAI, EP, dilute EP? = Technical Grade of the Active Ingredient, End Use Product, and possibly diluted End Use Product; TGAI/MP/EP Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGAI/PAI = Technical Grade Active Ingredient, Pure Active Ingredient

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE form.]

- 35 Required if the TGAI or PAI is organic and non-polar.
- 36 Required if the TGAI or PAI is organic and non-polar.
- 37 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 38 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 39 If the TGAI cannot be isolated, data are required on the practical equivalent of the TGAI (i.e., if the active ingredient is either an acid, base or ionic form, and it is formulated into salts or esters, the concentration of the active ingredient in these products must be expressed in acid equivalent or active equivalent).
- 40 Not required for salts.
- 41 Not required if test material is a gas or a highly volatile liquid.
- 42 Not required if test material is a gas or a highly volatile liquid.
- 43 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

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Agency Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name:

DCI Number: PDCI-119046-NNNN

Key: MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGA/ = Technical Grade Active Ingredient [TGA/]; TGA/ & EP = Technical Grade of the Active Ingredient and End-Use Product; TGA/ or P. Technical Grade of the Active Ingredient or Pure Active Ingredient; TGA/EP,dilute EP? = Technical Grade of the Active Ingredient, End Use Product, and possibly diluted End Use Product; TGA/MP/EP Manufacturing-Use Product, Pure Active Ingredient and Technical Grade Active Ingredient; TGA/PA/ = Technical Grade Active Ingredient, Pure Active Ingredient

Footnotes: [The following notes are referenced in column two (5. Study File) of the REQUIREMENTS STATUS AND REGISTRANTS RESPONSE form.]

- 44 Required if the product consists of, or under conditions of use will result in, a respirable material (e.g., gas, vapor, aerosol, or particulate).
- 45 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.
- 46 Not required if test material is a gas or a highly volatile liquid.
- 47 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.
- 48 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.
- 49 Required if repeated dermal exposure is likely to occur under conditions of use.

**United States Environmental Protection
Agency Washington, D.C. 20460**

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 0377,MCPP

Co. Nr.	Company Name	Agent For	Address	City & State	Zip
4	BONIDE PRODUCTS, INC.		6301 SUTLIFF ROAD	ORISKANY	NY 13424
228	NUFARM AMERICAS INC.		150 HARVESTER DRIVE, SUITE 200	BURR RIDGE	IL 60527
239	THE ORTHO BUSINESS GROUP		PO Box 190	MARYSVILLE	OH 43040
478	REALEX		PO Box 142642	ST LOUIS	MO 631140642
802	CENTRAL GARDEN & PET D/B/A LILLY MILLER BRANDS/EXCEL GARDEN	REGISTRATIONS BY DESIGN, INC.	1181/2 EAST MAIN ST., SUITE 1	SALEM	VA 241533805
869	GREEN LIGHT COMPANY		PO Box 17985	SAN ANTONIO	TX 78217
2217	PBI/GORDON CORP		PO Box 014090 1217 WEST 12TH STREET	KANSAS CITY	MO 641010090
3862	ABC COMPOUNDING CO., INC		PO Box 16247	ATLANTA	GA 303210247
8378	KNOX FERTILIZER CO INC	TOTAL TURF CONSULTING LLC	300 W. FIFTH ST., #411	CHARLOTTE	NC 28202
9198	THE ANDERSONS LAWN FERTILIZER DIVISION, INC.		PO Box 119	MAUMEE	OH 43537
9688	CHEMSICO		PO Box 142642	ST LOUIS	MO 631140642
10088	ATHEA LABORATORIES INC		PO Box 240014	MILWAUKEE	WI 53224
10404	LESCO INC		1301 EAST 9TH STREET, SUITE 1300	CLEVELAND	OH 441141849
14774	WINFIELD SOLUTIONS, LLC		PO Box 64589	ST. PAUL	MN 551640589
15440	A H MARKS & CO LTD	REGISTRATION AND REGULATORY SERVICES	PMB 239, 7474 CREEDMOOR ROAD	RALEIGH	NC 27613
32802	HOWARD JOHNSON'S ENTERPRISES INC		700 W. VIRGINIA ST STE 222	MILWAUKEE	WI 532041548
34704	LOVELAND PRODUCTS, INC.		PO Box 1286	GREELEY	CO 806321286
35512	HOWARD FERTILIZER & CHEMICAL CO., INC	REGISTRATIONS BY DESIGN, INC.	118 1/2 E MAIN ST, SUITE 1	SALEM	VA 24153
70596	NUFARM BV	NUFRAM BV	PO Box 13439	RTP	NC 27709
72155	BAYER ADVANCED		PO Box 12014 2 T.W. ALEXANDER DRIVE	RESEARCH TRIANGLE PARK	NC 27709

United States Environmental Protection
Agency Washington, D.C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 0377,MCPP

Co. Nr.	Company Name	Agent For	Address	City & State	Zip
192	VALUE GARDENS SUPPLY, LLC		PO Box 585	SAINT JOSEPH	MO 64502
228	NUFARM AMERICAS INC.		150 HARVESTER DRIVE, SUITE 200	BURR RIDGE	IL 60527
239	THE ORTHO BUSINESS GROUP		PO Box 190	MARYSVILLE	OH 43040
769	VALUE GARDENS SUPPLY, LLC		PO Box 585	SAINT JOSEPH	MO 64502
802	CENTRAL GARDEN & PET D/B/A LILLY MILLER BRANDS/EXCEL GARDEN	REGISTRATIONS BY DESIGN, INC.	1181/2 EAST MAIN ST., SUITE 1	SALEM	VA 241533805
9688	CHEMSICO		PO Box 142642	ST LOUIS	MO 631140642
10807	AMREP, INC		990 INDUSTRIAL DR	MARIETTA	GA 30062
59144	GRO TEC INC	REGWEST COMPANY	30856 ROCKY ROAD	GREELEY	CO 806319375
72155	BAYER ADVANCED		PO Box 12014 2 T.W. ALEXANDER DRIVE	RESEARCH TRIANGLE PARK	NC 27709

United States Environmental Protection
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Case # and Name: 0377,MCPP

Co. Nr.	Company Name	Agent For	Address	City & State	Zip
538	SCOTTS COMPANY, THE		14111 SCOTTSLAWN RD	MARYSVILLE	OH 43041
2217	PBI/GORDON CORP		PO Box 014090 1217 WEST 12TH STREET	KANSAS CITY	MO 641010090

United States Environmental Protection
Agency Washington, D.C. 20460

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Case # and Name: 0377,MCPP

Co. Nr.	Company Name	Agent For	Address	City & State	Zip
228	NUFARM AMERICAS INC.		150 HARVESTER DRIVE, SUITE 200	BURR RIDGE	IL 60527
239	THE ORTHO BUSINESS GROUP		PO Box 190	MARYSVILLE	OH 43040
264	BAYER CROPSCIENCE LP		2 T.W. ALEXANDER DRIVE	RESEARCH TRIANGLE PARK	NC 27709
538	SCOTTS COMPANY, THE		14111 SCOTTSLAWN RD	MARYSVILLE	OH 43041
802	CENTRAL GARDEN & PET D/B/A LILLY MILLER BRANDS/EXCEL GARDEN	REGISTRATIONS BY DESIGN, INC.	1181/2 EAST MAIN ST., SUITE 1	SALEM	VA 241533805
2217	PBI/GORDON CORP		PO Box 014090 1217 WEST 12TH STREET	KANSAS CITY	MO 641010090
15440	A H MARKS & CO LTD	REGISTRATION AND REGULATORY SERVICES	PMB 239, 7474 CREEDMOOR ROAD	RALEIGH	NC 27613
32802	HOWARD JOHNSON'S ENTERPRISES INC		700 W. VIRGINIA ST STE 222	MILWAUKEE	WI 532041548
70596	NUFARM BV	NUFRAM BV	PO Box 13439	RTP	NC 27709
71995	MONSANTO	MONSANTO	1300 I STREET, NW,SUITE 450 EAST	WASHINGTON	DC 20005
72155	BAYER ADVANCED		PO Box 12014 2 T.W. ALEXANDER DRIVE	RESEARCH TRIANGLE PARK	NC 27709

United States Environmental Protection
Agency Washington, D.C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name:

Co. Nr.	Company Name	Agent For	Address	City & State	Zip
1769	NCH CORP		2727 CHEMSEARCH BLVD.	IRVING	TX 75062
2217	PBI/GORDON CORP		PO Box 014090 1217 WEST 12TH STREET	KANSAS CITY	MO 641010090
11474	SUNGRO CHEMICALS, INC.		PO Box 24632	LOS ANGELES	CA 90024
33955	PBI/GORDON CORP		PO Box 014090 1217 WEST 12TH STREET	KANSAS CITY	MO 641010090
34704	LOVELAND PRODUCTS, INC.		PO Box 1286	GREELEY	CO 806321286
62719	DOW AGROSCIENCES LLC		9330 ZIONSVILLE RD 308/2E	INDIANAPOLIS	IN 462681054
72155	BAYER ADVANCED		PO Box 12014 2 T.W. ALEXANDER DRIVE	RESEARCH TRIANGLE PARK	NC 27709

APPENDIX G. EPA's Batching of MCPP-p 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 MCPP-p 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.

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.

Because of the extensive number of products to consider in this batching process, the batching report will be made available at a later date and posted on-line in the Public Docket.