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Office of Pesticide Programs

Reregistration Eligibility Decision for Prometon

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Reregistration Eligibility Decision for Prometon

Reregistration Eligibility Decision (RED) for Prometon

List B

Case No. 2545

Approved by: _____

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TABLE OF CONTENTS

GLOSSARY OF TERMS AND ABBREVIATIONS 4
I. INTRODUCTION 5
II. CHEMICAL OVERVIEW 6
A. Regulatory History 6
B. Chemical Identification 6
C. Use Profile 7
D. Estimated Usage of Pesticide 8
III. SUMMARY OF PROMETON RISK ASSESSMENTS 9
A. Human Health Risk Assessment 9
1. Toxicity of Prometon 9
2. Dietary Exposure (Drinking Water Only) 11
3. Residential and Occupational Assessment 13
a. Residential Assessment 13
b. Occupational Exposures and Risk 14
4. Aggregate Exposure and Risk 16
5. Incident Reports 16
B. Ecological Risk Assessment 17
1. Environmental Fate and Transport 17
2. Ecological Risk 18
a. Terrestrial Organisms 18
b. Aquatic Organisms Risk 23
IV. RISK MANAGEMENT AND REREGISTRATION DECISION 28
A. Determination of Reregistration Eligibility 28
B. Public Comments and Responses 28
C. Risk Mitigation and Regulatory Position 28
1. Human Health Risk Management 29
2. Ecological Risk Management 30
a. Terrestrial Organisms 30
b. Aquatic Organisms 32
c. Endangered Species 32
D. Labeling Requirements 33
V. WHAT REGISTRANTS NEED TO DO 34
A. Manufacturing-Use Products 34
1. Additional Generic Data Requirements 34
2. Labeling for Manufacturing-Use Products 35
B. End-Use Products 35
1. Additional Product-Specific Data Requirements 35
2. Labeling for End-Use Products 35
C. Labeling Changes Summary Table 35
APPENDIX A. PROMETON USE PATTERNS ELIGIBLE FOR REREGISTRATION 40
APPENDIX B. DATA SUPPORTING GUIDELINE REQUIREMENTS FOR PROMETON 41
APPENDIX C. TECHNICAL SUPPORT DOCUMENTS 43
APPENDIX D. BIBLIOGRAPHY 44
APPENDIX E. GENERIC DATA CALL-IN (GDCI) 48
APPENDIX F. PRODUCT-SPECIFIC DATA CALL-IN (PDCI) 49
APPENDIX G. EPA'S BATCHING OF PROMETON PRODUCTS 50

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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, hereon 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 prometon. 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 prometon and all other supporting documents are available in the Office of Pesticides Program (OPP) public docket at www.regulations.gov under docket number EPA-HQ-OPP-2007-1078.

II. Chemical Overview

A. Regulatory History

The prometon case (2545) contains only one ingredient, prometon, which was first registered as a pesticide in May 1959. Data call-ins (DCI) have been previously issued (January 1989, May 1991, September 1992, and March 1995) requiring data in support of reregistration, including several product chemistry studies, animal and ecological toxicity studies, environmental fate studies, spray drift studies, occupational exposure studies, and genotoxicity studies. Originally supported by Syngenta Crop Protection, prometon was then transferred to Makhteshim Agan of North America (MANA) in December 1998. MANA is the sole technical registrant to produce the generic data needed for the reregistration review of prometon.

B. Chemical Identification

Prometon is a non-selective herbicide that is part of the triazine group of herbicides. Chemical information and structure for prometon are presented in Table 1. Table 2 presents the physical and chemical properties of prometon.

Table 1. Prometon Chemical Information and Structure

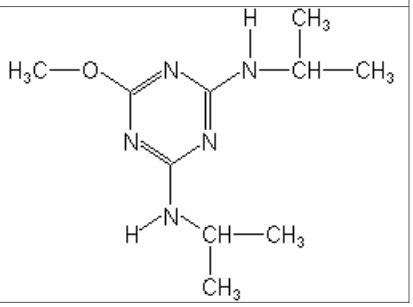
Compound Name	PC Code	CAS Number	Molecular Weight	Structure
Prometon; 1,3,5-Triazine-2,4-diamine, 6-methoxy-, N,N'-bis(1-methylethyl)-	080804	1610-18-0	225 g/mol	

Table 2. Physical and Chemical Properties of Prometon

Parameter	Value and Unit
CAS Chemical Name	6-methoxy-*N*,*N*′-bis(1-methylethyl)-1,3,5-triazine-2,4-diamine
CAS Number	1610-18-0
Empirical Formula	$C_{10}H_{19}N_5O$
Molecular Weight	225 g/mol
Appearance	White crystalline solid
Density	1.088 g/ml at 20 ºC
Melting Point	91-92°C
Vapor pressure (20 ºC)	3.1 x 10^{-6} mm Hg
Water Solubility (20 ºC)	620 ppm

C. Use Profile

Products containing prometon are labeled for use as a non-selective herbicide for pre- and post-emergence spot treatment applications where total vegetation control is desired, resulting in a bare ground site. Because of the persistence of prometon, weed control lasts generally for one year or longer.

Type of Pesticide:	Herbicide
Target Pests:	Annual and perennial grasses and broadleaf weeds
Mode of Action:	Prometon is a photosynthesis inhibitor, disrupting carbon dioxide fixation and production of the intermediary energy components. Prometon affects photosystem II, competing with plastoquinone and modifying electron transport processes.
Use Sites:	Prometon is registered for weed control for use as a spot treatment around the home, driveways, patios, buildings, storage areas, fences, pumps, machinery, fuel tanks, recreational areas, roadways, guard rails, airports, military installations, highway medians, pipelines, railroads, lumberyards, rights-of-way, and industrial sites (such as cross connects, pedestals, transformers, vaults, buried cable closures, telephone booths, fire plugs).
Use Classification:	General Use
Formulation Types:	Emulsifiable concentrate, ready-to-use, water-based flowable concentrate, and pelleted granule
Application Methods:	Boom sprayers, handheld nozzle or wand sprayers, knapsack sprayers, and granular spreaders
Application Rates:	The maximum supported application rate is 20 lbs of prometon active ingredient per acre (lbs ai/A), with typical application rates that range from 12 to 20 lbs ai/A.
Application Timing:	Pre-emergence direct soil application or post-emergence, when weeds are actively growing. Prometon has herbicidal activity from foliar contact, but it is most effective from root uptake in susceptible plants. Therefore, adequate rainfall or water is required to move the chemical into the root zone.
Technical Registrant:	Makhteshim Agan of North America, Inc. (MANA).

D. Estimated Usage of Pesticide

The majority of prometon use is associated with weed control along fencerows and building perimeters, with smaller usage on other industrial sites (i.e., pump stations, tanks, pipelines, pipe storage areas), rights-of-way areas (i.e., airports, railroads, and medians), and residential areas. Based on usage information provided by the registrant, total annual sales of prometon are approximately 550,000 - 600,000 pounds of ai: approximately 60% is applied to building perimeters or fencerows; 30% is applied to industrial sites; and <10% is applied to rights-of-way areas. According to the registrant, geographical use areas representing the greatest use include the following: Midwest, South, and Southeast, with lower demand in the Northwest and the Northeast. Use of prometon-containing products are restricted in Texas, Colorado, and Washington.

III. Summary of Prometon 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 listed below were used to formulate the safety finding and regulatory decision for the pesticidal use of prometon.

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-2007-1078, 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.

- *HED Chapter of the Reregistration Eligibility Decision Document (RED). Phase 4 Revisions*. March 17, 2008.
- *Prometon: Phase 4 Revisions for "Prometon: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision (Non-Food)*, March 13, 2008.
- *Response to Comments on the Ecological Risk Assessment in Support of the Re-registration Eligibility Decision for Prometon.* February 28, 2008.
- *Error Correction: Drinking Water Assessment and Ecological Risk Assessment for Prometon RED.* October 24, 2007.
- *Drinking Water Assessment for Prometon*, October 24, 2007.

A. Human Health Risk Assessment

The human health assessment addressed potential risks from all registered uses and sources. The Agency assessed exposures from both residential and occupational applications. Although prometon is not used on any food commodity in the U.S., potential dietary exposure via residues in drinking water was also assessed. For the complete human health risk assessment, refer to *HED Chapter of the Reregistration Eligibility Decision Document (RED). Phase 4 Revisions*, dated March 17, 2008, which is available in the public docket.

1. Toxicity of Prometon

The available toxicological data are adequate for selecting acute and chronic toxicity endpoints for the human health risk assessment. In the human health assessment, the Agency is presuming that the prometon parent compound and its respective degradates are of equal toxicity.

The Agency completed a cumulative risk assessment on certain triazine pesticides that met the criteria for being reviewed collectively; however, prometon did not meet those criteria. In the case of prometon, available studies did not demonstrate mammary gland tumors (refer to the document entitled "The Grouping of a Series of Triazine Pesticides Based on a Common Mechanism of Toxicity" prepared by U.S. EPA Office of Pesticide Programs Health Effects Division, dated March 2002). In addition to the lack of tumor formation, a clear structural difference between prometon and atrazine, simazine and propazine, the three triazine pesticides

that were considered in the cumulative assessment (refer to "Triazine Cumulative Risk Assessment," dated March 28, 2006). Prometon does not have chlorine substitutions on the triazine ring characteristic of the other three triazines. On these bases, prometon was not included in the cumulative risk assessment.

a. Toxicity Profile and Endpoint Selection

The available acute toxicity studies indicate that prometon is of relatively low oral and dermal toxicity. Prometon is not a dermal sensitizer and is a weak irritant to the skin, but is a moderate irritant to the eyes. It is classified as toxicity category III via the oral and dermal routes of exposure, and category II via the inhalation route of exposure. Table 3 lists the acute toxicity profile of prometon.

Table 3. Acute Toxicity Profile of Prometon

Study Type	MRID	Results	Toxicity Category
Acute oral - rat	42132103	LD_{50}= 4,345 mg/kg for males and 1,518 mg/kg for females.	III
Acute dermal - rabbit	41609112	>2,020 mg/kg	III
Acute inhalation - rat	42132104	LC_{50} = >0.52 mg/L	II
Acute eye irritation - rabbit	42144601	Conjunctivae redness and chemosis and discharge regressing by day 7	III
Acute dermal irritation - rabbit	41609113	Very slight erythema cleared by 24 hours	IV
Skin sensitization - guinea pig	41609114	Not a sensitizer	--

LD_{50} = 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).
LC_{50} = A statistically-derived single concentration 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 liter (mg/L).

Prometon is not classified as a carcinogen based on available animal studies. Prometon was negative in the mutagenicity/genetic toxicity studies including a bacterial mutagenicity (Ames) test, rat micronucleus test and an unscheduled DNA synthesis test. There were no indications of increased susceptibility to the fetuses or neonatal animals in either the rat or rabbit developmental toxicity studies or in the rat multi-generation reproduction study. Thus, prometon is classified as "Not likely to be Carcinogenic to Humans."

The No Observed Adverse Effects Level (NOAEL) of 5 milligrams per kilogram per day (mg/kg/day) derived from a dog chronic toxicity study was used to measure chronic dietary (drinking water only) risk and inhalation exposure risks. To account for any uncertainties in interspecies extrapolation (10X) and intraspecies variability (10X), a 100X uncertainty factor (UF) was applied in calculating the reference dose. To assess dermal short- and intermediate-term dermal exposures, the Agency relied on the Lowest Observed Adverse Effects Level (LOAEL) derived from a rabbit dermal toxicity study, with an additional 10X uncertainty factor, instead of using the available NOAEL of 25 mg/kg/day. At the LOAEL for the rabbit dermal toxicity study there is only a 10% to 12% decrease in body weight and there is little difference between the body weight effect at the high dose (12 to 13% decrease) of 1,050 mg/kg/day in

females. The Agency does not believe that there will be a decrease in body weight at a dose that is 10 times lower than the LOAEL established for this dermal toxicity study. Thus, the resulting Point of Departure (PoD) used in the dermal exposure assessment is 0.50 mg/kg/day. No indication of toxicity was apparent following a single dose of prometon; therefore, no acute toxicity endpoints were selected. The toxicological doses and endpoints used in the human health risk assessment for prometon are listed in Table 4.

Table 4. Summary of Toxicological Doses and Endpoints for Prometon

Exposure/Scenario	Point of Departure Uncertainty Factor RfD/Level of Concern	Study and Toxicological Effects
Acute Dietary (General population, including Infants and Children)	No toxicity endpoint for a single dose exposure was identified.	
Acute Dietary (Females 13-49 years of age)		
Chronic Dietary (All Populations)	NOAEL = 5 mg/kg/day Chronic RfD = 0.05 mg/kg/day UF = 100	Chronic study with dogs. LOAEL = 20 mg/kg/day based on emesis and body weight effects with three studies.
Dermal Short-Term and Intermediate	LOAEL = 500 mg/kg/day UF = 1000 LOC = 1000	21-day dermal toxicity study in rabbits with a NOAEL of 25 mg/kg/day and a LOAEL of 500 mg/kg/day based on decreased body weight and food consumption in females.
Inhalation - all durations	NOAEL= 5 mg/kg/day UF = 100 LOC = 100	Chronic study with dogs. LOAEL = 20 mg/kg/day based on emesis and body weight effects with three studies.
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.	

NOAEL = No Observed Adverse Effects Level
LOAEL = Lowest Observed Adverse Effects Level
LOC = Level of Concern
mg/kg/day = milligram per kilogram per day
RfD = Reference Dose
UF = Uncertainty Factor

2. Dietary Exposure (Drinking Water Only)

As there are no food use applications of prometon, the Agency assessed potential dietary exposure to prometon residues resulting only from drinking water exposure. Since there are no acute toxicity concerns, only chronic drinking water was assessed. For more details on the toxicological database and Agency's drinking water determination, refer to the *HED Chapter of the Reregistration Eligibility Decision Document (RED). Phase 4 Revisions*, dated March 17, 2008, and the *Drinking Water Assessment for Prometon*, dated October 24, 2007.

Exposure to pesticides from drinking water can occur through contamination in surface and groundwater sources. Prometon is persistent and highly mobile in soil, giving it the potential to move from the application site into adjacent terrestrial and aquatic environments. 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. There are no acute toxicity concerns; thus, only potential chronic exposures to prometon in drinking water exposures were assessed.

The Agency evaluated available non-targeted monitoring data taken from several data sources, including the United States Geological Survey National Water Quality Assessment Program (USGS NAWQA), USGS/EPA Pilot Reservoir Monitoring data for surface water occurrences, USGS Data Warehouse, Pesticide Data Program, and State of California surface water monitoring. Prometon was frequently detected (between 10% - 60%) in various monitoring programs with reported peak concentrations at 40 micrograms per liter (µg/L), or parts per billion (ppb), found in groundwater and 25.1 µg/L in surface water. The majority (99^{th} percentile of reported detections) of prometon concentrations range between 0.1 to 0.5 µg/L.

Estimated prometon concentrations were modeled for potential movement of prometon into groundwater and surface water. To estimate prometon concentrations in surface water, the Agency used the Tier II PRZM/EXAMS model. Because prometon is used to maintain smaller bare-ground areas, a percent crop area (PCA) factor was applied to drinking water concentrations estimated using PRZM/EXAMS, which more closely reflects a typical application to smaller treatment areas, rather than broadcast applications to an acre. The resulting EEC for surface water prometon residues is 24 ppb.

The Tier I Screening Concentration in Ground Water model (SCI-GROW, Version 2.3) model was used to estimate prometon residues in groundwater, which resulted in an estimated concentration of 236 ppb. Because the estimated screening-level model results for groundwater residues are higher than those of surface water (24 ppb) and reported concentrations from available monitoring data, only risk estimates to groundwater residues are presented here and are considered to be protective of potential exposure to drinking water from surface water sources. For details on the calculation of this PCA, refer to the *Drinking Water Assessment for Prometon*, October 24, 2007.

Chronic Drinking Water Assessment

Exposure estimates less than the chronic reference dose (cRfD) of 0.05 mg/kg/day are not of concern to the Agency. The exposure estimated for the U.S. population was 0.005 mg/kg/day, which is 10% of the (cRfD). The exposure for the most highly exposed population subgroup (infants), was 0.016 mg/kg/day, which is 33% of the cRfD. Thus, all potential chronic exposures to prometon residues in drinking water are below the Agency's level of concern (LOC). Table 5 includes the estimated chronic drinking water exposures and risks for all populations.

Table 5. Estimated Chronic Drinking Water (Groundwater) Exposure and Risk for Prometon

Population Subgroup	cRfD (mg/kg/day)	Dietary Exposure (mg/kg/day)	% cRfD
General U.S. Population	0.05	0.005	10
Infants (<1 year)		0.016	33
Children 1-2 years		0.007	15

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

3. Residential and Occupational Assessment

The residential (non-occupational) exposure assessment considered all potential exposures from applying pesticide products, other than those from residues in drinking water. Likewise, workers can be exposed when mixing, loading, and applying prometon, as well as post-application exposure when re-entering a treated site. To measure potential dermal or inhalation exposures from making pesticide applications, EPA calculates a margin of exposure (MOE), which is then compared to a LOC to measure potential risk. For both dermal and inhalation exposure, the UF of 100X is applied to the respective PoD of a particular toxicity study to account for interspecies extrapolation (10X) and intraspecies variability (10X). In addition to the 100X UF for dermal exposure only, an additional 10X UF was applied to account for using the LOAEL, which resulted in a target MOE of 1000 for dermal exposure. Since LOCs for dermal and inhalation routes of exposure are not the same (an MOE of 1000 defines dermal, while inhalation is defined by an MOE of 100), an aggregate risk index (ARI) was required to combine estimated MOEs. ARIs greater than 1 are not of concern to the Agency. ARIs were calculated using the formula below:

Aggregate Risk Index (ARI) = (1/(1/(Dermal MOE/ Dermal LOC))+(1/(Inhalation MOE/ Inhalation LOC))

In the preliminary occupational and residential assessment, the exposures were based on the previously supported maximum use rate of 20 lbs ai/A, which resulted in some exposure scenarios that were of potential risk concern to the Agency. In efforts to reduce potential exposures, the registrant voluntarily reduced their maximum supported rate to 18 lbs ai/A. This rate reduction was incorporated into this assessment and is reflected in the MOEs for the residential and occupational handler exposure and risk assessments.

To assess exposures from occupational applications, the risk assessment relied in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. EPA's use of occupational and residential exposure studies in the prometon risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26. For specific details, refer to the *Prometon: Phase 4 Revisions for "Prometon: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision (Non-Food)*, dated March 13, 2008.

a. Residential Assessment

The Agency determined that there is a potential for exposures to occur in residential settings (i.e., applications made to driveways and sidewalks) for those (i.e., homeowners) who handle (mix, load, and apply) products containing prometon. Exposures during applications of prometon are expected to be short-term in duration, as treatments are only permitted generally once a year.

Residential Handler Exposure and Risk Assessment

The Agency determined that there is a potential for short-term (up to 30 days) dermal and inhalation exposure in residential settings for those who handle (mix, load, and apply) products containing prometon. The scenarios, listed in Table 6, were selected based on all the possible application methods that would be available to a residential handler and the types of available formulations of products containing prometon. Because products containing prometon are generally only applied once a year, neither intermediate (1 - 6 months) or long-term (>6 months) exposures are expected. Thus, only short-term handler exposures were assessed. The maximum application rate and size treatment area assessed for residential handlers was 0.41 lb ai/1000 ft^2 (the equivalent to 18 lbs ai/A). Many of the residential short-term scenarios assessed do not pose any risk concerns. However, two residential scenarios result in ARIs less than 1 and, therefore, are of potential risk concern. Table 6 presents the MOEs for the individual dermal and inhalation exposures and the respective ARIs for all residential handler exposure scenarios.

Table 6. Prometon Short-Term Combined Residential Handler Exposures

Scenario	Dermal MOEs	Inhalation MOEs	ARI
Liquid: Mix/Load/Apply with a Hose-end Sprayer/ Sprinkling Can (Mix Your Own)	7800	50000	7.6
Liquid: Mix/Load/Apply with a Hose-end Sprayer (RTU)	33000	78000	32
Liquid: Mix/Load/Apply with a Low-Pressure Handwand	810	28000	2.2
Liquid: Mix/Load/Apply with a Hand Held Sprayer (Trigger Pump)	2200	320000	1.6
Granular: Hand Application	800	1800	0.76
Granular: Belly Grinder	780	14000	0.77
Granular: Push-type Spreader	130000	970000	130

MOE $\geq$ 100 = no risk of concern Aggregate Risk Index (ARI) $\geq$ 1 = no risk of concern

Residential Post-application Assessment

The Agency considered the potential for exposures to individuals that can occur as a result of entering into treated areas. In order to be efficacious, prometon needs to be watered into the soil to be available for plant root uptake. Based on these application instructions, significant post-application prometon exposures from previously treated areas would be unlikely as the prometon residues would predominantly be located below the soil surface. Further, since prometon is used as a spot/edging treatment along fences, curbs, pathways, etc., the likelihood of residential post-application contact is further minimized. Considering the current uses and the lack of potential significant exposures, the Agency concluded that a quantitative post-application assessment was not necessary and exposures would not pose any risk of concern.

b. Occupational Exposures and Risk

The Agency assessed exposure and risk to occupational handlers and workers in the same manner as is used to assess risks to residential users. The target MOE for potential inhalation

risk is 100 and the target MOE for potential dermal risk is 1000. LOCs for dermal and inhalation routes of exposure are not the same (an MOE of 1000 defines dermal, while inhalation is defined by an MOE of 100); thus, an aggregate risk index (ARI) was required to combine estimated MOEs. ARI estimates less than 1 are of potential concern to the Agency.

Occupational Handler Exposure and Risk Assessment

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 larger industrial and commercial areas (i.e., roadsides and rights-of-way), which are more representative of the total amount of applications a professional applicator may make. The ORETF data were used to assess exposures to professional applicators that apply to smaller areas, such as sidewalks and building perimeters. The exposure scenarios, listed in Table 7, were selected based on all the possible occupational uses and the types of available formulations of products containing prometon. The Agency assumed that a treatment area equal to one acre would represent an upper-bound exposure estimate from applications made with mechanical application (vehicle-driven) equipment. For applications made manually (with a backpack sprayer or push-type granular spreader), EPA assumed a smaller treatment area equal to 0.25 acre.

Only short- and intermediate-term exposures were assessed because long-term (>6 months) exposures are not expected based on the use pattern. Based on the assessed exposure scenarios, all of the ARIs are greater than 1 with baseline personal protective equipment (PPE), except for mixers and loaders of liquid applications using rights-of-way equipment, which require baseline PPE with gloves. With the respective PPE in place, these exposures do not pose any risks of concern to the Agency. A summary of the MOEs and its respective ARIs are listed in Table 7.

Table 7. Prometon Exposures for Occupational Handlers and Applicators

Scenario		Area Treated (acre)	Dermal MOEs	Inhalation MOEs	ARIs	Level of PPE
M/L	Liquids: Rights of Way Equipment	1	670	16000	0.7	Baseline
			85000	16000	56	SL/GL/NR
	Granular: Tractor Drawn Spreader		600000	29000	200	Baseline
A	Liquids: Rights of Way Equipment	1	1500	5000	1.5	Baseline
	Granular: Tractor Drawn Spreader		510000	42000	230	Baseline
M/L/A	Liquid: Backpack Sprayer	0.25	3100	2600	2.8	Baseline
	Granular: Push Type Spreader		57000	27000	47	Baseline

SL/GL/NR = single layer PPE (long pants, long-sleeved shirt, shoes, and socks), gloves, no respirator
MOE = margin of exposure PPE = personal protective equipment
M/L/A = mixer, loader, applicator Aggregate Risk Index (ARI) ≥ 1 = no risk of concern
Baseline = long pants, long-sleeved shirt, shoes, and socks

Occupational Post-application Exposures

The Agency determined that post-application exposures to workers are minimal and are unlikely to pose any risks of concern. Because prometon residues would predominantly be located below the soil surface, significant post-application exposures to these residues from reentering previously treated areas would be unlikely. Additionally, the types of applications of prometon (i.e., fencerows, rights-of-ways, building perimeters) do not warrant the need for workers to re-enter the application site. Based on these factors, the Agency does not anticipate significant post-application exposure. Thus, the Agency concluded that a quantitative assessment was not necessary and all potential post-application exposures do not pose any risks of concern.

4. Aggregate Exposure and Risk

The Agency considered the potential for aggregate exposures and whether there is a concern for these combined exposure and risk concerns. Although an aggregate risk assessment is not required under current Agency policies for non-food use chemicals, to ensure that the public health is adequately protected, a screening-level aggregate risk assessment to consider combined dietary and non-occupational or residential exposures was conducted for prometon. For chronic aggregate risks, the only potential exposure is from drinking water. The dietary exposures (drinking water only) do not exceed 10% of the cRfD for adults and 33% of the cRfD for children. For short-term aggregate risks, no aggregate assessment is needed for children since there are no expected residential (post-application or handler) exposures to children. For short-term aggregate risk for adults when considering the dietary exposure (drinking water only) as a background exposure, the level of dietary exposure (0.005 mg/kg/day) is small and considered negligible when compared to the maximum residential handler exposure (0.64 mg/kg/day) from belly grinder application of granules. No intermediate-term residential post-application or residential handler exposure scenarios were identified.

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 (PCC), 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). A relatively large number of incidents including prometon were identified in the PCC Database and in IDS. The symptoms were concentrated in five areas as follows:

1. Gastrointestinal: nausea, vomiting and throat irritation
2. Neurological: headache and dizziness/vertigo
3. Respiratory: dyspnea and cough/choke
4. Ocular: eye irritation/pain, lacrimation, and corneal abrasion
5. Dermal: skin irritation/pain

The frequency and severity of events reported to PCC (data available 1993 - 2005) is comparable in magnitude to the composite average of all pesticides for occupational and childhood exposures. Although a higher than average number of non-occupational incidents was seen at a health care facility, the severity of outcome was comparable to the composite average of all pesticides. A total of 86 IDS (1999 - present) individual prometon human incident reports were reviewed. A descriptive tally of the types of exposures showed: 30 dermal exposure cases, 4 eye exposures, 12 inhalation exposure cases, 2 ingestion cases, with 1 being a possible suicide but not so designated in the reporting (known suicides are excluded), 29 systemic multiple organ system effects cases by multiple routes of exposure, and 11 systemic cases with unknown routes of exposure, and 1 possible misuse. The NIOSH SENSOR (1998 - 2003) database only reported 3 incidents involving prometon, with symptoms as described above. A large number of incidents involve irritation as a symptom, which is not seen in animal studies with prometon. Thus, these incidents could be due to another component of the pesticide formulation, either another active ingredient or an inert ingredient. CDPR (1999 - 2004) provided a summary report of 33 incidents for the above period of record. Many incidents are old and only 2 were reported since 2000. Skin and eye exposures predominate with 14 systemic symptoms cases.

Based on the reported information, there are a number of uncertainties of whether it is prometon active ingredient that is the direct cause of these reported incidents. Some of the uncertainties include determining which component of the product caused irritation incidents (i.e., irritation from exposure to a product's inert ingredient), the scenario in which exposure had occurred (i.e., misuse or inappropriate use of product), and if there were other products that the person had been exposed to.

B. Ecological Risk Assessment

The ecological risk assessment on prometon addressed potential exposures and risks from all registered uses in the U.S. The full assessment, *Response to Comments on the Ecological Risk Assessment in Support of the Re-registration Eligibility Decision for Prometon (080804),* dated February 28, 2008, and the *Error Correction: Drinking Water Assessment and Ecological Risk Assessment for Prometon RED,* dated October 24, 2007, and response to public comments is available on the internet and in the public docket at www.regulations.gov (EPA-HQ-OPP-2007-1078).

1. Environmental Fate and Transport

Available environmental fate data indicates that prometon is persistent and mobile in both soil and aquatic environments. The likely routes of movement from the application site are through runoff into surface water and leaching into groundwater. Prometon is resistant to abiotic hydrolysis, photodegradation in water, aerobic soil metabolism, and anaerobic soil metabolism, where half-lives range from 462 to 932 days in aerobic soil. In anaerobic soil the half-life is 557 days. Major degradation products of prometon include 2 amino-4-(isopropylamino)-6-methyoxy-s-triazine (GS-14626), 2,4-diamino-6-methoxy-s-triazine (GS-12853), and 2-hydroxy-4,6 bis (isopropylamino)-s-triazine (GS-11526). Although information on the toxicity of these degradates are not available, the Agency is assuming that degradates are of equal or lesser toxicity to that of the parent compound.

2. Ecological 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 used to establish the potential toxicity (hazard) of prometon to non-target species. Estimated Environmental Concentrations (EECs) measure the potential residue concentrations from the maximum or typical application rate of prometon 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 8 lists the Agency's LOCs and the corresponding risk presumptions.

Table 8. 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, insects, and terrestrial-phase amphibians) that are located in or near the treated area may be exposed to prometon by feeding on food items with prometon residues from overspray, 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 to 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.

EPA estimated EECs of prometon residues that may occur on avian and mammalian food items. Although prometon is a "bare ground" herbicide, animals can be exposed to prometon residues that are available on plant foliage surfaces shortly after application and prior to plant death. The greatest prometon residues and exposure levels are likely to occur in the surface soil and on plant foliage (e.g., grasses and broadleaf plants), seeds, and insects on treated areas immediately following applications. 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 on soil surfaces. Bioaccumulation of prometon in the food chain is not expected to be a significant exposure source to non-target terrestrial organisms.

In estimating foliar residues for this screening-level assessment, the Agency assessed a maximum exposure scenario based on the maximum application rate and prometon fate

properties. These upper-bound estimates result in higher EECs that represent dose-based exposures to various food sources (grasses, fruit, seed, and insects). Dietary-based EECs can be more representative of actual exposures, and typically indicate lower residue estimates, as EECs are adjusted based on the size of the animal and its typical eating habits (i.e., amount of a certain food item). 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 there is complete absorption of the pesticide in the animal over a single ingestion event and represents a conservative estimate.

i. Avian and Mammalian Assessment

Residues of prometon from single application scenarios are expected to occur on avian and mammalian food items. Predicted maximum EECs of pesticide residues from a single application of prometon were used in the screening-level ecological assessment. Exposures are estimated using the Terrestrial Exposure Model (TREX, version 1.2.3). The TREX model uses the Kenaga nomogram to determine the amount of pesticide residues on food items and corresponding avian acute and chronic RQs are based on the most sensitive acute and chronic endpoints, respectively, for birds. Dose estimates are based on the upper bound dose and the assumptions that the organism exclusively eats one type of food item and forages only in the treated and/or overspray areas, whereas dietary-based EECs are an estimation of actual deposition on the food item. On an acute basis, prometon is practically non-toxic to slightly toxic to birds and mammals. On a chronic basis, it can cause weight reduction in both parent and offspring at concentrations of 175-500 mg/kg for these organisms. Table 9 lists the toxicity endpoints used in the avian and mammalian assessments.

Table 9. Summary of Avian and Mammalian Toxicity Data Conducted with Prometon

Assessment Endpoint	Species	Toxicity Value Used	MRID	Effects
Vertebrates				
Acute Risk to Mammals	Rat (Sprague-Dawley)	LD_{50}=1,518 mg/kg bw (Females)	42132103	Males are less sensitive
Chronic Risk to Mammals	Rat	NOAEC=20 mg/kg/day LOAEC=500 mg/kg/day	40361501	Changes in body weight gain for both parents and pups.
Acute Risk to Birds, Terrestrial-phase Amphibians, and Reptiles	Bobwhite quail (oral dose)	LD_{50}>2,264 mg/kg bw	41609104	Ruffled appearance and lethargy at lowest dose (294 mg/kg bw)
	Bobwhite quail (dietary)	LD_{50}>5,620 mg/kg	41609105	Sublethal effects include lethargy, ruffled appearance, and reduced weight gain

Table 9. Summary of Avian and Mammalian Toxicity Data Conducted with Prometon				
Chronic Risk to Birds, Terrestrial phase Amphibians, and Reptiles	Mallard duck	NOAEC=50 mg/kg diet LOAEC=175 mg/kg diet	42132102	Eggshell thickness most sensitive endpoint; reduced female body weight post-treatment.
Invertebrates				
Acute Risk to Invertebrates	Honey bee (acute contact)	LD_{50}= 36 µg/bee 95% CI=31-45 µg/bee	41609115	None

mg/kg bw = milligrams of active ingredient per kilogram body weight, dose-based
mg/kg diet = milligrams of active ingredient per kilogram body weight, dietary-based
NOAEC = no observed adverse effect concentration LOAEC = lowest observed adverse effect concentration
LD_{50} = a statistically derived single dose that can be expected to cause death in 50% of the test animals

Birds

Dose-based RQs for the respective different-sized birds were calculated for both spray and granular applications. Although a granular pesticide does not deposit on plant surfaces in the same fashion as a liquid spray does, the granules may be ingested by organisms foraging in the treated area. For birds the acute risk LOC is 0.5, the endangered species risk LOC is 0.1, and the chronic risk LOC for birds is 1.0. Calculations for dietary-based RQs are not adjusted for body weight variations. The chronic LOCs for non-endangered birds are exceeded for many of the scenarios, where chronic RQs range from 6 to 96. Although the acute dose-based avian RQs range from 0.1 to 3.4 and acute dietary RQs range from 0.1 to 1.1, the significance of these values presents an uncertainty as to the potential acute risk because the toxicity studies did not indicate any mortality at the highest test dose. Because the median lethal dose (LD_{50}) values only established as greater than (>) a particular concentration, RQs are reported as less than (<) values. Table 10 summarizes the acute and chronic RQs for avian species.

Table 10. Avian Acute and Chronic RQ Summary for Spray and Granular Prometon Applications									
Body Weight	Spray								Granular
	Short grass		Tall grass		Broadleaf plants/small insects		Fruits/pods/ large insects		LD_{50}/ft^2
	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	RQ
Acute, dose-based									
20 g	5478	<3.4	2511	<1.5	3081	<1.9	342	<0.2	<6.4
100 g	3124	<1.5	1432	<0.7	1757	<0.9	195	<0.1	<1.0
1,000 g	1398	<0.5	641	<0.2	786	<0.3	87	<0.1	<0.1
Acute, dietary-based									
All birds	4810	<1.1	2204	<0.5	2705	<0.6	301	<0.1	n/a
Chronic, dietary-based									
All birds	4810	96	2204	33	2705	54	301	6	n/a

Acute non-endangered LOC for terrestrial animals ≥ 0.5, endangered LOC ≥ 0.1. RQ = risk quotient
Chronic non-endangered and endangered LOC for terrestrial animals is ≥ 1.0 n/a = not assessed
LD_{50} = a statistically derived single dose that can be expected to cause death in 50% of the test animals
EEC = estimated environmental concentration

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, ranging from 0.1 to 4.2, exceed the LOC for some of the scenarios based on prometon spray applications. For both the prometon granular and spray applications, mammalian chronic dietary- (RQs ranging from 15 to 241) and dose-based RQs (ranging from 13 to 2,086) exceed the LOC. The acute and chronic RQs are presented in Table 11 with LOC exceedances identified.

Table 11. Mammalian Acute and Chronic RQ Summary for Spray and Granular Prometon Applications

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
Acute, dose-based											
15 g	4586	1.4	2102	0.6	2579	0.8	287	0.1	64	<0.1	4.2
35 g	3170	1.2	337	0.5	413	0.7	46	0.1	44	<0.1	2.2
1,000 g	735	0.6	667	0.3	413	0.4	46	<0.1	10	<0.1	0.2
Chronic, dietary-based											
All mammals	4810	241	2204	110	2705	135	301	15	n/a	n/a	n/a
Chronic, dose-based											
15 g	4586	2086	2102	956	2579	1174	287	130	64	29	n/a
35 g	3170	1782	337	817	413	1002	46	111	44	25	
1,000 g	735	955	667	438	413	537	46	60	10	13	

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.
LD_{50} = a statistically derived single dose that can be expected to cause death in 50% of the test animals
EEC = estimated environmental concentration

ii. Terrestrial and Semi-Aquatic Plant Assessment

Non-target terrestrial and semi-aquatic plants can be exposed to prometon 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 that may receive that runoff. The Agency also estimated potential EECs from overspray or drift from ground spray applications. The AgDrift model considers the method of application and droplet size to estimate potential spray drift deposition to areas outside of the treatment area. The acute RQs for terrestrial plants are calculated by dividing the EEC by the toxicity value (EC_{25}) 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. In the case of prometon, submitted studies indicate that dicots appear to be slightly more

sensitive than monocots. Table 12 lists the toxicity data used to evaluate risks to terrestrial and semi-aquatic plants.

Table 12. Summary of Terrestrial Plant Toxicity Data Conducted with Prometon.			
Species	Toxicity (lb ai/A)	Most Sensitive Endpoint	MRID
Seedling Emergence	Most sensitive monocot: Oat EC_{25} = 0.027 NOAEC = 0.005	Radicle length	41725303
	Most sensitive dicot: Lettuce EC_{25} = 0.010 NOAEC = 0.009		
Vegetative Vigor	Most sensitive monocot: Oat EC_{25} = 0.016 NOAEC = 0.012		
	Most sensitive dicot: Lettuce EC_{25} = 0.008 NOAEC = 0.005		

Lb ai/A = pound of active ingredient per acre NOAEC = no observed adverse effect concentration
EC_{25} = effective concentration that can be expected to cause death in 25% of the test plants

RQs were calculated for terrestrial (dryland) plants based on prometon runoff and drift from one treated hectare moving to adjacent areas, whereas semi-aquatic areas were based on movement from a treated ten-hectare site. The difference in the model values (1 versus 10 hectares) were reflected in the ten-fold difference in resulting RQs, presented in Table 13. As expected with an herbicide, all RQs exceeded the Agency's LOC of 1 for non-endangered and endangered plant species, where RQs for non-endangered plants range from 37 to 1,022 and from 107 to 2,175 for endangered plants. Table 13 is a summary of the RQs for terrestrial and semi-aquatic plants exposed to prometon.

Table 13. Terrestrial Plant RQs for Ground Spray and Granular Applications of Prometon						
Application	Adjacent Areas			Semi-aquatic Areas		
	lbs ai/A	RQs		lbs ai/A	RQs	
		M	D		M	D
Non-Endangered, ground spray	1.2	45	120	10.2	379	1022
Non-Endangered, granular	1.0	37	100	10.0	371	1002
Endangered, ground spray	1.2	256	128	10.2	2175	1087
Endangered, granular	1.0	213	107	10.0	2132	1066

n/a = not applicable M = monocot D = dicot

iii. Spray Drift

Although it is expected that the highest concentrations of prometon would occur in directly treated areas, spray drift from liquid applications to adjacent non-treated areas may still present the potential for exposures to non-target organisms. Potential exposures to non-target

organisms include movement of prometon to off-target surface soil, foliage, and insects. Spray drift into water bodies adjacent to treated areas can also affect sensitive aquatic organisms.

The Agency used Tier I AgDRIFT (version 2.01) modeling to evaluate potential risk at several distances from the field, simulating typical applications with a ground sprayer. Using estimated point deposition of prometon, plant RQs were calculated based on the more sensitive vegetative vigor endpoint. To estimate EECs from spray drift, EPA assumed that spray applications were made using a high boom sprayer and nozzles that produce spray droplets ranging in fine to medium-coarse sizes. Using the most sensitive endpoint (vegetative vigor EC_{25}) for the most sensitive monocot (0.016 lb ai/A), all RQs exceed the LOC of 1, with RQs ranging from 13 to 43. Based on this AgDRIFT analysis, effects could occur at greater than 995 feet away from the use site, which is the maximum distance that the model can estimate. However, this may be an overestimate of typical applications of products containing prometon, as most applications are spot treatments. Table 14 presents the RQs for terrestrial and semi-aquatic plants from estimated spray drift exposure.

Table 14. Terrestrial Plant RQs for Spray Drift Exposure

Plant Type	Non-endangered Plants		Endangered Plants		Clearance Distance (ft)	
	EEC	RQ	EEC	RQ	Acute LOC	Endangered Species LOC
Monocot	0.2 lb ai/A	13	0.2 lb ai/A	17	>995	>995
Dicot		25		43	>995	>995

Acute non-endangered and endangered LOC for aquatic plants ≥ 1.

b. Aquatic Organisms Risk

Fish, amphibians, and aquatic invertebrates in aquatic environments can be exposed to prometon in surface water by direct residue contact with their integument and via uptake through their gills or integument. Immediately following applications of prometon, the highest residue levels are expected to be located in surface waters adjacent to treated areas due to spray drift at the time of application and/or from runoff after a rain event. With the persistence of prometon residues in some terrestrial environments, there is also the likelihood of transport by runoff and leaching.

Prometon EECs for aquatic ecosystems were predicted using the Tier II PRZM/EXAMS models. PRZM uses the chemical's physical and environmental fate properties and the site characteristics to predict the concentration of pesticide in runoff and entrained sediment from the field. 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 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 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 scenarios assessed and, therefore, are different from those used to assess human

exposures in the drinking water assessment. To simulate runoff in a mixed grass and shrub environment to represent the range of application scenarios, the Agency modeled the following scenarios:

- rights-of-way in Texas and California;
- rangeland/hay in Texas and California; and
- turf in Florida and Pennsylvania.

One of the assumptions of the PRZM/EXAMs modeling is that EECs are estimated based on the maximum application rate and movement of the pesticide from a 10-hectare application site. Because prometon is used to maintain a bare ground on smaller areas, a PCA factor 2.6% of an acre was applied to water concentrations estimated using PRZM/EXAMS, which more closely reflects typical spot treatment applications, rather than broadcast applications over an acre. Estimated water concentrations of prometon for assessing ecological exposures are listed in Table 15.

Table 15. PRZM/EXAMS EECs of Prometon in Water for Aquatic Exposure

Application Scenario	Application Rate (lbs ai/A)	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)
California Rangeland/Hay				
Ground Spray	20	1179	1178	1157
Granular		1079	1078	1057
California Rights-of-Way				
Ground Spray	20	1549	1539	1527
Granular		1440	1439	1426
California Turf (no irrigation)				
Ground Spray	20	1408	1399	1399
Granular		1058	1058	1049
Florida Turf				
Ground Spray	20	423	422	420
Granular		333	332	330
Pennsylvania Turf				
Ground Spray	20	539	537	534
Granular		404	403	401
Texas Range				
Ground Spray	20	2468	2458	2447
Granular		2397	2387	2368
Texas Rangeland				
Ground Spray	20	726	724	719
Granular		644	641	637

Lbs ai/A = pounds of active ingredient per acre EEC = estimated environmental concentration

1. Aquatic Organisms Assessment

Prometon is slightly toxic to both freshwater and saltwater fish and invertebrates. The LC_{50} for freshwater non-vascular aquatic plants (represented by a green alga) is 0.098 mg/L. Based on available data, freshwater vascular aquatic plants and saltwater non-vascular aquatic plants (represented by a diatom) appear to be less sensitive than non-vascular freshwater plants. Table 16 is a summary of aquatic toxicity studies the Agency used in the ecological assessment.

Table 16. Summary of Aquatic Organism Toxicity Data for Prometon

Assessment Endpoint	Species	Toxicity Value Used	Source Citation
Freshwater			
Acute Toxicity to Fish and Aquatic-phase Amphibians	Rainbow trout	LC_{50} = 12 mg/L	ECOTOX 546
		LC_{50} =19.6 mg/L	MRID 41609108
Chronic Toxicity Fish and Aquatic-phase Amphibians	Fathead minnow	NOAEC = 9.5 mg/L LOAEC = 19.7 mg/L	MRID 41810902
Acute Toxicity to Aquatic Invertebrates	Water flea	LC_{50} = 25.7 mg/L	MRID 41609109
Chronic Toxicity Aquatic Invertebrates	Water flea	NOAEC = 3.5 mg/L LOAEC = 6.8 mg/L	MRID 41810903
Acute Toxicity to Aquatic Plants (non-vascular)	Green alga	LC_{50} = 0.098 mg/L NOAEC=0.032 mg/L	MRID 41725305
Acute Toxicity to Aquatic Plants (vascular)	Duckweed	LC_{20} = 0.246 mg/L LC_{50} = 0.624 mg/L	ECOTOX 81431
Saltwater			
Acute Toxicity to Fish	Sheepshead minnow	LC_{50} =47.3 mg/L	MRID 41725301
Chronic Toxicity to Fish	Based on ACR of 4.0 (Rainbow/ fathead)	NOAEC = <11.8 mg/L*	ACR
Acute Toxicity to Aquatic Invertebrates	Mysid shrimp	LC_{50} = 18.0 mg/L	MRID 41810910
Chronic Toxicity Aquatic Invertebrates	Based on ACR of 7.34 (Water flea/ water flea)	(18.0 mg/L/7.34) NOAEC = 2.5 mg/L	ACR
Acute Toxicity to Aquatic Plants	SW diatom	LC_{50} = 0.25 mg/L	ECOTOX 9211

mg/L = milligrams per liter ACR = acute-to-chronic ratio

LC_{50} = Lethal Concentration: a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals

*Endpoint expressed as "less than" value because freshwater endpoint was non-definitive.

Freshwater Fish and Invertebrates

Similar to the way that RQs are calculated for terrestrial organisms, aquatic acute RQs were derived by dividing the peak EECs by the LC_{50}. Chronic RQs for freshwater invertebrates

were derived by dividing the 21-day EECs by the NOAEC values. For prometon, the peak modeled aquatic concentrations ranged from 2,468 µg/L (TX BSS Right of Way scenario, ground spray) to 333 µg/L (FL Turf scenario, granular). These two scenarios were used as upper- and lower-bound estimates to calculate the range of RQs.

Based on predicted modeling, which assessed both ground spray and granular applications, neither the acute LOC (0.5) nor the chronic LOC (1.0) was exceeded for any aquatic animal in the scenarios modeled. However, the endangered species acute risk LOC (0.05) was exceeded for both freshwater and marine/estuarine animals in all but one of the scenarios modeled based on the highest EEC modeled. Acute RQs for fish and invertebrates ranged from 0.01 to 0.09. Chronic RQs for both freshwater and saltwater fish and invertebrates ranged from 0.02 to 0.67. The aquatic animal LOC was not exceeded for any animal in any scenario modeled. Table 17 summarizes the acute and chronic RQs for freshwater and saltwater animals.

Table 17. Summary of Fish and Invertebrate Acute and Chronic RQs

Species	Acute RQ	Chronic RQ
Texas BSS Right of Way Ground Spray (highest EEC)		
FW Aquatic Invertebrates	0.06	0.48
FW Fish	0.09	0.34
SW Aquatic Invertebrates	0.05	0.67
SW Fish	0.04	0.14
Florida Turf Granular (lowest EEC)		
FW Aquatic Invertebrates	0.01	0.10
FW Fish	0.02	0.07
SW Aquatic Invertebrates	0.02	0.02
SW Fish	0.01	0.33

FW - freshwater SW - saltwater EEC - estimated environmental concentration RQ = Risk Quotient

2. Aquatic Plants

Surface water concentrations were predicted using PRZM/EXAMS modeling for prometon applications to surrogate turf scenarios, which considered both ground spray and granular applications. Aquatic plants toxicity data were available to determine potential toxicity of prometon to non-target aquatic plants. For vascular and nonvascular plants, peak EECs were compared to acute EC_{50} toxicity endpoints for the most sensitive plant species. For prometon, RQs for endangered plants were calculated using the EC_{05} toxicity endpoint, as NOAECs could not be determined from available submitted data.

For aquatic plants, both the acute risk and endangered species acute risk LOC is 1. The endangered species RQ is calculated based on the NOAEC instead of the LC_{50}, which is used for the acute risk RQ. In all cases modeled, RQs for both freshwater and saltwater non-vascular plants exceeded both the acute and endangered species risk LOCs. RQs for freshwater vascular plants exceeded the endangered species LOC in all scenarios, and exceeded the acute risk LOC in 10 out of 14 scenarios modeled. Acute RQs ranged from 0.53 to 17, whereas endangered plant RQs range from 1.6 to 52. Table 18 summarizes the RQs for aquatic plants.

Table 18. Summary of Aquatic Plant RQs		
Species	Acute RQ	Endangered Species RQ
TX BSS Right of Way Ground Spray (highest EEC)		
FW Algae	17.0	52.2
FW Vascular Plants	2.7	8.2
SW Algae	6.7	20.4
FL Turf Granular (lowest EEC)		
FW Algae	3.40	10.4
FW Vascular Plants	0.53	1.6
SW Algae	1.33	4.1

FW - freshwater SW - saltwater EEC - estimated environmental concentration
Acute non-endangered and endangered LOC for aquatic plants ≥ 1.0.

c. 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. EPA's incident database contained only two incidents related to prometon. Based on information reported, one of these incidents (Incident ID I014409-078) appears to have been a case of misuse, where a paving contractor used prometon on a roadway and the resulting runoff killed trees and lawn plants near the road. The report notes that the application was not in accordance with the label. The second incident (Incident ID I005895-355) was a fish kill. The magnitude of the kill is listed as unknown, and the kill is attributed to an accidental spill of a prometon product into a contained pond. EPA's incident database contains information regarding adverse effects associated with particular pesticide applications that are reported to the manufacturer/distributor of the chemical. While the registrant is required by law to report adverse effects to the Agency, reporting of incidents by the public and/or state and local agencies is largely voluntary. Thus, there may be incidents that are not reported to the Agency. Generally, a large number of reported incidents may indicate a high degree of hazard for non-target species exposed to the pesticide. However, the converse is not necessarily true, and a small number of reported incidents should not be interpreted as implying any degree of "safety" for non-target species.

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 prometon 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 prometon.

The Agency has determined that prometon-containing products are eligible for reregistration provided that the required risk mitigation measures, which are outlined below in Section C, are adopted and label amendments are made to implement these mitigation measures, as outlined in Chapter V. Appendix A summarizes the uses of prometon 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 prometon, 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 also worked with stakeholders and the public to reach the regulatory decisions for prometon. During the public comment period, which closed on January 7, 2008, the Agency received comments from interested stakeholders. These comments in their entirety are available in the public docket (EPA-HQ-OPP-2007-1078) at www.regulations.gov. The RED document, supporting documents for prometon, and the Agency's response to received comments are also available in the docket. In addition, the prometon 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

With the exception of granule applications that may be applied by hand or a belly grinder, currently registered products containing prometon are eligible for reregistration provided that the risk mitigation measures and label amendments are adopted as outlined in Table 20 (Label Table) and mitigated use patterns in Appendix A. The following is a summary of the rationale for mitigation measures necessary for managing risks associated with the use of prometon products to be eligible for reregistration. Table 19 summarizes the human and ecological risks of concern and the respective mitigation measure.

Table 19. Prometon Human and Ecological Risk Mitigation Measures	
Risk of Concern	Mitigation Measure
Dermal exposure risks from residential applications for hand application of granules and belly grinder application of granules.	These two application methods, as well as all other residential sites (i.e., patios, driveways, and areas around the home), are no longer supported by the registrant and will be prohibited on all labels.
Dermal exposure risks for occupational mixers and loaders of liquid formulations intended for applications using rights-of-way spray equipment.	The requirement to use gloves in addition to baseline PPE.
Non-target terrestrial exposures to animals and plants, including spray drift.	The maximum use rate is reduced to the equivalent to 16 lbs ai/A for applications under block or solid paving.
	The maximum use rate is reduced to the equivalent of 18 lbs ai/A for all other industrial sites.
	End-use product labels will include language requiring that weeds greater than 4 inches must be mowed, removed, or hoed into the soil prior to application.
	End-use product labels will include language requiring that immediately after application, treatment areas must be watered in with at least 1/4" of water or treatments will be made just prior to a rain event.
	Applications must be made using medium- to coarse-sized droplets.
	Applications must not be made to sloped areas where desirable vegetation or adjacent water bodies are located downhill of the treatment area.
	Products containing prometon are limited to one application per year.

1. Human Health Risk Management

The Agency determined that all potential exposures (dietary and handlers) and risks are not of concern. The only potential dietary exposure to prometon residues were chronic exposures drinking water, which are below EPA's LOC for all populations. All currently registered assessed residential and occupational uses of prometon, with the exception of some residential applications (handler exposures), do not pose risks of concern. In the preliminary occupational and residential risk assessments, all exposure values were based on the originally supported maximum rate of 20 lbs ai/A. The Agency identified two residential scenarios where there are dermal exposure concerns: for granules applications applied by hand and granule applications made with a belly grinder. Even with the reduction of the maximum use rate to 18 lbs ai/A, both application scenarios are of risk concern to the Agency (i.e., ARIs < 1).

To reduce exposures from these application methods, the registrant voluntarily and agreed to cancel these application methods. Additionally, the registrant also agreed to cancel all other residential use sites, including, but not limited to, "areas around the home," patios, play areas, and driveways. Although there are some uncertainties of whether prometon was the direct cause of the various effects identified in the incident reports, the cancellation of all residential uses of these products will significantly reduce potential exposures to adults, as well as to

children. For spray applications made with rights-of-way equipment, the requirement for mixers and loaders to use gloves in addition to baseline PPE mitigates any remaining occupational risks of concern. Thus, there are no additional human health risk concerns from using prometon-containing products.

2. Ecological Risk Management

Based on available toxicological data and mitigated use rates, the ecological risk assessment identified some exposure scenarios with prometon that may pose ecological risks of concern to the Agency, including potential effects on endangered species. The registrant agreed to decrease the maximum application rate from 20 lbs ai/A to 18 lbs ai/A for bare-ground areas, a decrease in the application rate by 10%. Specific to soil applications made under solid or block paving, the supported maximum rate has been further decreased to 16 lbs ai/A. Even with these reductions, there were still exceedances identified in the terrestrial assessment, described in further detail below. However, considering the conservative assumptions made in the ecological assessment, the mitigation measures adopted, and the nature of the weed control activity of this herbicide, the risks can be significantly reduced with the adoption of the proposed modifications to label use directions. The following sections summarize the risks identified for each respective affected organism identified earlier in Chapter III, as well as a presentation of refined risk estimates based on use rate reductions, and characterization of the actual usage of prometon.

a. Terrestrial Organisms

Birds and Mammals

The ecological assessment identified potential risk to some non-target terrestrial animals. Based on the originally maximum supported rate of 20 lbs ai/A, EPA's avian and mammalian assessments showed that there were acute and chronic LOC exceedances for certain food items from both granular and liquid application scenarios. In the avian and mammalian assessments, EECs based on granular applications are significantly lower than those based on liquid applications. When the Agency considered the use rate reduction of approximately 10% to 18 lbs ai/A, the resulting acute avian RQs ranged from 0.03 to 2.92, and chronic RQs ranged from 5.2 to 83.6. For mammalian exposures, the 10% reduction in application rate resulted in acute RQs ranging from 0.01 to 1.2 and chronic RQs ranging from 11.5 to 1,814. Based on prometon residues that drift from the application area, even with the application rate reduction of 10%, modeling a spray application using a low boom (30 inches above the target area), and fitted with nozzles to produce a very coarse spray, spray drift models estimated chronic effects on mammals that can occur up to 500 feet from the application site.

In addition, there are some conservative assumptions made in the bird and mammalian assessments that may overestimate potential risks. To estimate upper-bound exposures, the Agency assumes that the animal's diet is comprised solely of food (i.e., plant foliage, insects, fruit, and seeds) from potential forage areas that may contain residues from recent prometon applications. However, wildlife organisms typically consume a variety of foodstuff from multiple locations, rather than from a single location. Second, because prometon is a non-selective herbicide intended to maintain a treatment area devoid of any forage plants or other

vegetation, it is expected that there should be minimal-to-no plants available for animals to forage on much longer after an application of prometon. Although at a likely lesser exposure, animals that may encounter a treated area, namely birds, can still be exposed to prometon residues that feed on remaining seeds or insects.

Some limitations of the modeling may have overestimated prometon exposures. Although the acute dose-based avian RQs (based on 20 lbs ai/A) range from 0.1 to 3.4 and acute dietary RQs range from 0.1 to 1.1, the significance of these values presents an uncertainty as to the potential acute risk because the toxicity studies did not indicate any mortality at the highest test dose. Thus, this may be an overestimate of potential acute risk to birds. The chronic assessment assumes that the animal repeatedly returns to the treated area to feed or forage. Considering that prometon is intended for spot treatments and maintaining bare ground areas, rather than reliance on prometon as a knock-down herbicide, there should be limited food availability in treated areas that would be attractive for animals to feed. There is some uncertainty as to how long plants in treated areas may survive from the time of application. The sensitivity of the target weed to prometon can vary, resulting in differing rates of plant death from the time of treatment. Since these times and efficacy on different weed species are variable, the models used to assess exposures cannot consider these factors. As prometon is used to maintain barren grounds, the model does not account for any timeframe duration as forage supplies decrease.

To reduce the amount of available prometon granules or residues from spray applications in treated areas on food items that animals may consume in treated areas, additional measures must be adopted to reduce the remaining residues on plant surfaces. In order for prometon to be the most efficacious, it must be taken up by plant roots from the soil. The requirement of watering the treated area after an application of prometon-containing products will reduce the amount of prometon residues remaining on plant surfaces immediately after liquid applications or dissolving granules after application. For areas that have more dense vegetation with plants that are taller than four inches, labeling will include requirements to mechanically remove or mow the area to better ensure that prometon applications reach the soil. Adopting these measures will substantially reduce the amount of prometon residues on plants available to animals.

Terrestrial Plants

As expected with a terrestrial herbicide, there are some risks of concern for effects to non-target terrestrial plants. Specific to semi-aquatic areas, RQs estimated for terrestrial (dryland) plants are significantly higher based on prometon runoff and drift from one treated hectare moving to adjacent areas, whereas semi-aquatic areas (wetlands) are based on movement from a treated 10 acre site. The highest RQ estimates for terrestrial plants effects resulted from combined runoff and drift; however, the majority of RQs exceeded the LOC even for drift alone at the highest originally supported maximum rate (20 lbs ai/A) assessed. With the persistence and solubility of prometon, non-target plants in the immediate area surrounding the application site may also be affected.

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. Depending on the type of application equipment and the type of nozzles used, finer droplets may be produced. Droplet size can influence the distance a pesticide drifts from the application area. In Chapter III, RQs for spray drift was assessed based on the originally supported maximum use rate of 20 lbs ai/A, a range of fine to medium-coarse droplet sizes that can occur from spray applications made using a high ground boom (four feet above the treatment area), and spray applications made with a high ground boom. Because of the very small dose needed to adversely affect plants, spray drift models estimated potential effects that can occur as far as over 1,000 feet away from the application site.

The sensitivity of the non-target plant's exposure to prometon can vary, resulting in varying severity of effects on plants. The registrant indicated that although there is some foliar activity when prometon is applied, the majority of herbicidal activity is by root uptake from prometon in the soil. Because the predominant use of prometon is for smaller areas, typically around building perimeters or along fence lines, liquid applications are more likely to be made using handheld equipment (i.e., backpack sprayer or sprinkling can) or other application equipment that would be lower to the ground and closer to the target area. Because prometon is intended as a soil sterilant that works primarily via plant root uptake, nozzles that produce larger droplets would move more readily into the soil and the prometon would be available for plant root uptake. Thus, in order for prometon to be available for plant root uptake, spray applications using nozzles to produce larger droplets will produce less fine droplets that can potentially drift off-site.

b. Aquatic Organisms

Although prometon products are not registered for use in aquatic settings, the high persistence and solubility of prometon can result in its movement into adjacent aquatic areas via runoff from treated areas. Spray drift droplets can also deposit prometon into nearby aquatic areas. Based on the originally maximum supported use rates, estimated exposures to fish and aquatic invertebrates do not pose any risks of concern. Based on both the modeled highest and lowest EECs, prometon residues can affect both vascular and non-vascular aquatic plants. The Agency believes that the modeling represents an upper bound assessment, as the modeling includes the assumption that the receiving water body and the application site are adjacent to each other. This is apparent when comparing modeling results with the monitoring data, where estimated peak exposures are approximately 1 - 2 orders of magnitude above the highest reported detections in the monitoring data. To further reduce inadvertent movement of prometon into water bodies, labeling language will include recommendations to avoid applications made to sloped areas where desirable vegetation or nearby water bodies may be located downhill of the application area.

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 prometon 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 prometon, RQs exceed the LOCs for mammals, birds, and terrestrial and aquatic plants. 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 that the use of prometon "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 and additional labeling language to reduce the movement of pesticide away from target application areas.

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 prometon. For the specific labeling statements, refer to Table 20 of this RED document.

V. What Registrants Need to Do

For end-use products containing the active ingredient prometon, 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 20 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 Karen Jones at 703-308-8047 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)
Karen Jones
U.S. EPA (7508P)
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Karen Jones
U.S. EPA (7508P)
2777 South Crystal Drive
Arlington, VA 22202

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

Within the scope of the uses and currently registered products subject to reregistration, the generic database supporting the reregistration of prometon has been reviewed and determined

to be substantially complete. At this time, no additional studies are required for reregistration of currently approved products containing prometon.

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 20.

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 Karen Jones at 703-308-8047.

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 20. 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 required language show in the following table. Table 20 describes how language on the labels should be amended.

Table 20. Prometon Labeling Requirements Table		
Description	Prometon: Required Labeling Language	Placement on Label
Manufacturing-Use Products		
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-use liquid products with directions for use that prohibit aerial application." "Only for formulation into end-use granular products with directions for use that prohibit application by hand or with belly grinder (rotary spreader) equipment." "Only for formulation into end-use products with directions for use that prohibit application in residential settings." "Only for formulation into end-products with directions for use that prohibit applications greater than the equivalent of 18 lbs of prometon per acre, or 0.2 lb of prometon per 500 ft^2."	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
End-Use Products Intended for Occupational Use (Non-WPS)		

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 liquid formulations	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H*] "on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators, and other handlers must wear: - long-sleeved shirt and long pants, and - shoes plus socks. In addition, mixers and loaders supporting motorized ground equipment and handlers cleaning up spill or equipment must wear chemical-resistant gloves, such as (*registrant insert correct chemical-resistant materials)*."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
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 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.
Entry Restrictions for Granular Products	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.
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 (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)	For treatments made under solid or block paving , include the following: "Limited to 1 application per year. The maximum use rate is 0.18 lb ai/500 ft^2, or the equivalent to a maximum of 16 lbs ai/A." For all other applications to industrial sites: "Limited to 1 application per year. The maximum use rate is 0.20 lb ai/500 ft^2, or the equivalent to a maximum of 18 lbs ai/A."	Directions for Use Associated with the Specific Use Pattern
Other Application Restrictions (Risk Mitigation)	"Do not apply this product in a residential setting."	Directions for Use under Other Use Precautions

General Application Restrictions	Include the following instructions for treatment areas with greater weed density: "Weeds greater than 4 inches must be mowed, removed, or hoed into the soil prior to application."	Directions for Use under Other Use Precautions
General Application Restrictions	Include the following instructions for watering-in requirement: "This product will not provide herbicidal action in the treated area unless application is immediately followed by watering the area with at least ¼" of water or application of the product just prior to a rain event sufficient to penetrate to the root system of the target vegetation."	Directions for Use under Other Use Precautions
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 to desirable plants and other vegetation may result."	Directions for Use under Other Use Precautions
General Application Restrictions	"Do not use this product to sloped areas where desirable vegetation or nearby water bodies may be located downhill of the application area, since injury to desirable plants and other vegetation may result."	Directions for Use under Other Use Precautions
Spray Drift Management for spray applications	"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."	Directions for Use under Use Precautions

APPENDIX A. Prometon Use Patterns Eligible for Reregistration

Table of Prometon Use Patterns Eligible for Reregistration (Case #2545)					
Use Site	Formulation	Maximum Application Rate	Restrictions	Timing	Application Equipment
Treatment to soil prior to/ under solid or block paving	- Granular (pelleted), - Emulsifiable concentrate - liquid, - Ready-to-use - Water-soluble flowable concentrate	16 lbs ai/A (0.18 lb/500 ft^2)	Maximum of 1 application per year	- pre-emergence - post-emergence	- Low boom sprayer - low-pressure handwand sprayer - high pressure hose-end sprayer - backpack sprayer - push-type granular spreader
Spot treatments in industrial areas including around buildings, storage areas, fences, pumps, machinery, fuel tanks, recreational areas, roadways, guard rails, airports, military installations, highway medians, pipelines, railroads, lumberyards, rights-of-way, and industrial sites (such as cross connects, pedestals, transformers, vaults, buried cable closures, telephone booths, fire plugs).	- Granular (pelleted), - liquid, - Ready-to-use - Water-soluble flowable concentrate	18 lbs ai/A (0.20 lb/500 ft^2)	Maximum of 1 application per year	- pre-emergence - post-emergence	- Low boom sprayer - low-pressure handwand sprayer - handheld nozzle sprayer - knapsack sprayer - push-type granular spreader

lbs ai/A or 500 ft^2 = pounds of active ingredient per acre or 500 ft^2

APPENDIX B. Data Supporting Guideline Requirements for Prometon

Data Supporting Guideline Requirements for the Reregistration of Prometon				
New Guideline Number	**Old Guideline Number**	**Study Description**	**Use Pattern**	**Citation(s)**
ECOLOGICAL EFFECTS				
850.2100	71-1a	Avian Acute Oral Toxicity - Quail	All	41609104
850.2200	71-2a	Avian Dietary Toxicity - Quail	All	41609105
850.2300	71-4B	Avian Reproduction - Duck	All	42132102
850.1075	72-1a	Fish Toxicity Bluegill	All	ECOTOX 546
850.1075	72-1c	Fish Toxicity Rainbow Trout	All	ECOTOX 546 41609108
850.1010	72-2a	Invertebrate Toxicity - Water flea	All	41609109
850.1300	72-4	Invertebrate Chronic Toxicity	All	41810903
850.1075	72-3A	Estuarine/Marine Toxicity - Fish		41725301
850.1035 850.1045	72-3C	Estuarine/Marine Toxicity - Shrimp	All	41810910
850.1400	72-4A	Fish- Early Life Stage	All	41810902
850.4400	122-2	Aquatic Plant Toxicity	All	ECOTOX 9211
850.4225	123-1a	Seed Germ./ Seedling Emergence	All	41725302-3
850.4250	123-1b	Vegetative Vigor	All	41725304
850.4400	123-2	Aquatic Plant Growth	All	41725305
850.5400	123-2	Algal Toxicity	All	ECOTOX 81431
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity-Rat	All	42132103
870.1200	81-2	Acute Dermal Toxicity-Rabbit	All	41609112
870.1300	81-3	Acute Inhalation Toxicity-Rat	All	42132104
870.2400	81-4	Primary Eye Irritation-Rabbit	All	42144601
870.2500	81-5	Primary Skin Irritation	All	41609113
870.2600	81-6	Dermal Sensitization	All	41609114
870.3100	82-1a	Repeated dose 90-Day Feeding - Rodent	All	00129985 - Supplemental
870.3200	82-2	21-Day Dermal - Rabbit	All	42144602
870.4300	82-4	Combined chronic feeding/carcinogenicity	All	40488101 40488102
870.4100	83-1a	Chronic Feeding Toxicity - Rodent	All	40361501
870.4100	83-1b	Chronic Feeding Toxicity - Non-Rodent	All	40097901 42581201
870.3800	83-4	Multi-generation Reproduction, Rat	All	40361501
ENVIRONMENTAL FATE				
835.2110	161-1	Hydrolysis as a function of pH	All	41114801
835.2240	161-2	Photodegradation - Water	All	40225801
835.2410	161-3	Photodegradation - Soil	All	41114802
835.4100	162-1	Aerobic Soil Metabolism	All	40145501 42313501

Data Supporting Guideline Requirements for the Reregistration of Prometon				
835.4400	162-3	Anaerobic Aquatic Metabolism	All	40145501
835.1240	163-1	Leaching/Adsorption/Desorption	All	40225803
835.6100	164-1	Terrestrial Field Dissipation	All	00162534 - 36
OTHER				
850.3020	141-1	Honey Bee Acute Contact	All	41609115

APPENDIX C. Technical Support Documents

Additional documentation in support of the Prometon 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:

1. US EPA. HED Chapter of the Reregistration Eligibility Decision Document (RED). Phase 4 Revisions. March 17, 2008.

2. US EPA. Prometon: Phase 4 Revisions for "Prometon: Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision (Non-Food), March 13, 2008.

3. US EPA. Response to Comments on the Ecological Risk Assessment in Support of the Re-registration Eligibility Decision for Prometon (080804), February 28, 2008.

4. US EPA. Error Correction: Drinking Water Assessment and Ecological Risk Assessment for Prometon RED, dated October 24, 2007.

4. US EPA. Drinking Water Assessment for Prometon, October 24, 2007.

APPENDIX D. Bibliography

In addition to the MRID study references listed in Appendix B, this bibliography contains the expanded study citations as well as additional literature citations considered to be part of the database supporting the reregistration decision for prometon.

MRID	Citation Reference
129983	Florek, C.; Christian, M.; Christian, G.; et al. (1981) Teratogenicity Study of Prometon Technical in Pregnant Rats: Argus Project 203-003. (Unpublished study received Aug 4, 1983 under 100-544; prepared by Argus Research Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:250917-B)
129984	Lightkep, G.; Christian, M.; Christian, G.; et al. (1982) Teratogenic Potential of Prometon Technical in New Zealand White Rabbits (Segment II Evaluation): Project No. 203-002. Final rept. (Unpublished study received Aug 4, 1983 under 100-544; prepared by Argus Research Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:250917-C)
129985	Johnson, W.; Becci, P. (1982) 90-Day Subchronic Feeding Study with Prometon Technical in Sprague-Dawley Rats: FDRL Study No. 6805. (Unpublished study received Aug 4, 1983 under 100-544; prepared by Food and Drug Research Laboratories, Inc., submitted by Ciba-Geigy Corp., Greensboro, NC; CDL:250917-D; 250918)
148609	Ciba-Geigy Corp. (1985) Ciba-Geigy's Response to EPA Toxicology Branch Review Dated March 26, 1984, on Prometon Rat and Rabbit Teratology Studies and 90-Day Rat Feeding Study. Unpublished compilation. 52 p.
40097901	Breckenridge, C.; Green, J. (1986) Prometon: Chronic Study in Dogs: Laboratory Study No. 100-84. Unpublished study prepared by Ciba-Geigy Corp. 540 p.
40361501	Salamon, C. (1987) Prometon Technical: Two-generation Reproduction Study in Rats: Laboratory Study No. 450-2208. Unpublished study prepared by American Biogenics Corp. 901 p.
40488101	Osheroff, M. (1988) Lifetime Oncogenicity Study in Mice with Prometon Technical: Final Report: Study Number 483-234. Unpublished study performed by Hazleton Laboratories America, Inc. 2778 p.
40488102	O'Connor, D.; McCormick, G.; Green, J. (1988) Prometon Technical: Combined Chronic Toxicity/Oncogenicity Study in Rats: Study Number 852003. Unpublished study performed by Ciba-Geigy Corporation. 2094 p.
40636401	Giknis, M. (1986) Prometon Technical: Salmonella/Mammalian - Microsome Mutagenicity Assay: Laboratory Study No. 852196. Unpublished study prepared by Ciba-Geigy Corp. 19 p.
40636402	Strasser, F. (1988) Prometon Technical: Micronucleus Test (Rat): Laboratory Study No. 871355. Unpublished study prepared by Ciba-Geigy Limited. 32 p.
40636403	Hertner, T. (1987) Prometon Technical: Autoradiographic DNA-repair Test on Rat Hepatocytes: Laboratory Study No. 871354. Unpublished study prepared by Ciba-Geigy Ltd. 95 p.

41609104 Campbell, S. (1990) Prometon: An Acute Toxicity Study with the Northern Bobwhite: Lab Project Number: 108-326. Unpublished study prepared by Wildlife International Ltd. 22 p.

41609105 Long, R. (1990) Prometon: A Dietary LC_{50} Study with the Northern Bobwhite: Lab Project Number: 108-324. Unpublished study prepared by Wildlife International Ltd. 52 p.

41609108 Murphy, D. (1990) Prometon: A 96-hour Static Acute Toxicity Test with the Rainbow Trout (Oncorhyncus mykiss): Lab Project Number: 108A-102B. Unpublished study prepared by Wildlife International Ltd. 49 p.

41609109 Bellantoni, D. (1990) Prometon: A 48-hour Static Acute Toxicity Test with the Cladoceran (Daphnia magna): Lab Project Number: 108A-101. Unpublished study prepared by Wildlife International Ltd. 50 p.

41609112 Kuhn, J. (1989) Acute Dermal Toxicity Study in Rabbits: Lab Project Number: 6658-89. Unpublished study prepared by Ciba-Geigy Corp. 13 p.

41609113 Kuhn, J. (1990) Prometon Technical FL 892529: Primary Dermal Irritation Study in Rabbits: Lab Project Number: 6659-89. Unpublished study prepared by Stillmeadow, Inc. 13 p.

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41725302 Chetram, R. (1990) Tier 2 Seed Germination Nontarget Phytotoxicity Study Using Prometon Technical: Lab Project Number: LR90-04. Unpublished study prepared by Pan-Agriculutural Laboratories. 149 p.

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41725304 Chetram, R. (1990) Tier 2 Vegetative Vigor Nontarget Phytotoxicity Study Using Prometon Technical: Lab Project Number: LR90-03. Unpublished study prepared by Pan-Agricultural Laboratories, Inc. 224 p.

41725305 Hughes, J. (1990) The Toxicity of Prometon to Selenastrum capricornutum: Lab Project Number: B267-47-1. Unpublished study pre- pared by Malcolm Pirnie, Inc. 33 p.

41810901 Ward, T. (1991) Acute Flow Through Mollusc Shell Deposition Test with Prometon: Lab Project Number: 9113-CG. Unpublished study prepared by Resource Analysts, Inc., Envirosystems Div. 36 p.

41810902 Peters, G. (1991) An Early Life-Stage Toxicity Test with the Fathead Minnow (Pimephales promelas): Lab Project No: 108A-115A. Unpublished study prepared by Wildlife International Ltd. 47 p.

41810903 Peters, G. (1991) A Flow-through Life-cycle Toxicity Test with the Cladoceran (Daphnia magna): Lab Project Number: 108A-114E. Unpublished study prepared by Wildlife International Ltd. 49 p.

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APPENDIX E. Generic Data Call-in (GDCI)

With respect to the current uses and registered products containing prometon subject to reregistration, the generic database supporting the reregistration of prometon has been reviewed and determined to be substantially complete. At this time, no additional studies are required for reregistration of currently approved products containing prometon and no GDCI will be issued for this pesticide.

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

The following pages include the list of product-specific data that are required for reregistration that will be sent to all registrants that have currently registered end-use products containing prometon.

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	2. Case # and Name	3. Date and Type of DCI and Number
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	2545 Prometon Chemical # and Name 080804 Prometon	DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-080804-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."
NNNNNN-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_____

9. Date

10. Name of Company

11. Phone Number

F - 1

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

REQUIREMENTS STATUS AND REGISTRANT'S 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	2. Case # and Name	3. Date and Type of DCI and Number
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	2545 Prometon EPA Reg. No. NNNNNN-NNNNN	DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-080804-NNNN

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
	Product Chemistry Data Requirements (Conventional Chemical									
830.1550	Product Identity and composition	(1)					HH, II, K, Q, R, T, U	TGAI/MP/EP	8	
830.1600	Description of materials used to produce the product	(2)					HH, II, K, Q, R, T, U	TGAI/MP/EP	8	
830.1620	Description of production process	(3)					HH, II, K, Q, R, T, U	TGAI	8	
830.1650	Description of formulation process	(4)					HH, II, K, Q, R, T, U	MP/EP	8	
830.1670	Discussion of formation of impurities	(5)					HH, II, K, Q, R, T, U	TGAI/MP/EP	8	
830.1700	Preliminary analysis	(6 ,7 ,8)					HH, II, K, Q, R, T, U	TGAI	8	
830.1750	Certified limits	(9 ,10)					HH, II, K, Q, R, T, U	TGAI/MP/EP	8	
830.1800	Enforcement analytical method	(11)					HH, II, K, Q, R, T, U	TGAI/MP/EP	8	
830.1900	Submittal of samples	(12 ,13)					HH, II, K, Q, R, T, U	EP, PAI & TGAI	8	
830.6302	Color	(14)					HH, II, K, Q, R, T, U	TGAI/MP/EP	8	
830.6303	Physical state	(15)					HH, II, K, Q, R, T, U	TGAI/MP/EP	8	
830.6304	Odor	(16)					HH, II, K, Q, R, T, U	TGAI/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

REQUIREMENTS STATUS AND REGISTRANT'S 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	2. Case # and Name	3. Date and Type of DCI and Number
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	2545 Prometon EPA Reg. No. NNNNNN-NNNNN	DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-080804-NNNN

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
830.6313	Stability to sunlight, normal and elevated temperatures metals, and metal ions (17 ,18)					HH, II, K, Q, R, T, U	TGAI	8	
830.6314	Oxidizing or reducing action (19)					HH, II, K, Q, R, T, U	MP/EP	8	
830.6315	Flammability (20)					HH, II, K, Q, R, T, U	MP/EP	8	
830.6316	Explodability (21)					HH, II, K, Q, R, T, U	MP/EP	8	
830.6317	Storage stability of product (22)					HH, II, K, Q, R, T, U	MP/EP	8	
830.6319	Miscibility (23)					HH, II, K, Q, R, T, U	MP/EP	8	
830.6320	Corrosion characteristics (24)					HH, II, K, Q, R, T, U	MP/EP	8	
830.6321	Dielectric breakdown voltage (25)					HH, II, K, Q, R, T, U	MP/EP	8	
830.7000	pH of water solutions or suspensions (26 ,27)					HH, II, K, Q, R, T, U	TGAI/MP/EP	8	
830.7050	UV/Visible absorption					HH, II, K, Q, R, T, U	TGAI/PAI	8	
830.7100	Viscosity (28)					HH, II, K, Q, R, T, U	MP/EP	8	
830.7200	Melting point/melting range (29 ,30)					HH, II, K, Q, R, T, U	TGAI	8	
830.7220	Boiling point/boiling range (31 ,32)					HH, II, K, Q, R, T, U	TGAI	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

REQUIREMENTS STATUS AND REGISTRANT'S 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	2. Case # and Name	3. Date and Type of DCI and Number
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	2545 Prometon EPA Reg. No. NNNNNN-NNNNN	DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-080804-NNNN

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
830.7300	Density/relative density	(33 ,34)					HH, II, K, Q, R, T, U	TGAI/MP/EP	8	
830.7370	Dissociation constant in water	(35 ,36)					HH, II, K, Q, R, T, U	TGAI or PAI	8	
830.7520	Particle size, fiber length, and diameter distribution	(37)					HH, II, K, Q, R, T, U	TGAI or PAI	8	
830.7550	Partition coefficient (n-octanol/water), shake flask method	(38)					HH, II, K, Q, R, T, U	TGAI/PAI	8	
830.7560	Partition coefficient (n-octanol/water), generator colum method	(39)					HH, II, K, Q, R, T, U	TGAI/PAI	8	
830.7570	Partition coefficient (n-octanol/water), estimation by liquid chromatography	(40)					HH, II, K, Q, R, T, U	TGAI/PAI	8	
830.7840	Water solubility: Column elution method, shake flask method	(41)					HH, II, K, Q, R, T, U	TGAI or PAI	8	
830.7860	Water solubility, generator column method	(42)					HH, II, K, Q, R, T, U	TGAI or PAI	8	
830.7950	Vapor pressure	(43 ,44)					HH, II, K, Q, R, T, U	TGAI or PAI	8	
	Toxicology Data Requirements (Conventional Chemical)									
870.1100	Acute Oral Toxicity	(45)					HH, II, K, Q, R, T, U	TGAI,EP,dilute EP?	8	
870.1200	Acute dermal toxicity	(46 ,47)					HH, II, K, Q, R, T, U	TGAI,EP,dilute EP?	8	
870.1300	Acute inhalation toxicity	(48)					HH, II, K, Q, R, T, U	TGAI & EP	8	

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Date

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	2. Case # and Name	3. Date and Type of DCI and Number
SAMPLE COMPANY NO STREET ADDRESS NO CITY, XX 00000	2545 Prometon EPA Reg. No. NNNNNN-NNNNN	DD-MMM-YYYY PRODUCT SPECIFIC ID # PDCI-080804-NNNN

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
870.2400	Acute eye irritation	(49)					HH, II, K, Q, R, T, U	TGAI & EP	8	
870.2500	Acute dermal irritation	(50 ,51)					HH, II, K, Q, R, T, U	TGAI & EP	8	
870.2600	Skin sensitization	(52 ,53)					HH, II, K, Q, R, T, U	TGAI & EP	8	
830.1000	Background for product properties test guidelines						HH, II, K, Q, R, T, U			

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Date

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

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2545 Prometon

DCI Number: PDCI-080804-NNNN

Key: EP, PAI & TGAI = End-Use Product, Pure Active Ingredient, and Technical Grade Active Ingredient; MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGAI = Technical Grade Active Ingrec [TGAI]; TGAI & EP = Technical Grade of the Active Ingredient and End-Use Product; TGAI or PAI = 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; TGA = Technical Grade Active Ingredient, Pure Active Ingredient

Use Categories Key:

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

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 TGAIs and products produced by an integrated system.

8 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).

9 Data must be provided in accordance with the "Certified Limits" Section(158.175)

10 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).

11 Data must be provided in accordance with the "Enforcement Analytical Method" Section.(158.180)

12 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).

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

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2545 Prometon

DCI Number: PDCI-080804-NNNN

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

13 Basic manufacturers are required to provide the Agency with a sample of each TGAI used to formulate a product produced by an integrated system when the new TGAI is first used as a formulati ingredient in products registered under FIFRA. A sample of the active ingredient (PAI) suitable for use as an analytical standard is also required at this time. Samples of end-use products produc an integrated system must be submitted on a case-by-case basis.

14 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).

15 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).

16 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).

17 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).

18 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.

19 Required if the product contains an oxidizing or reducing agent

20 Required when the product contains combustible liquids.

21 Required when the product is potentially explosive.

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 (IRED) Documents."

23 Required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.

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

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 2545 Prometon

DCI Number: PDCI-080804-NNNN

Key: EP, PAI & TGAI = End-Use Product, Pure Active Ingredient, and Technical Grade Active Ingredient; MP/EP = Manufacturing-Use Product, Pure Active Ingredient; TGAI = Technical Grade Active Ingrec [TGAI]; TGAI & EP = Technical Grade of the Active Ingredient and End-Use Product; TGAI or PAI = 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; TGA = 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.]**

24 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 (IRED) Documents."

25 Required if the end-use product is a liquid and is to be used around electrical equipment.

26 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).

27 Required if the product is dispersible with water.

28 Required if the product is a liquid.

29 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).

30 Required when the TGAI is solid at room temperature.

31 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).

32 Required if the TGAI is liquid at room temperature.

33 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).

34 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.

35 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).

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

36 Required when the test substance contains an acid or base functionality (organic or inorganic) or an alcoholic functionality (organic).

37 Required for water insoluble test substances (<0.000010 g/l) and fibrous test substances with diameter >= 0.1 m.

38 Required if the TGAI or PAI is organic and non-polar.

39 Required if the TGAI or PAI is organic and non-polar.

40 Required if the TGAI or PAI is organic and non-polar.

41 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).

42 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).

43 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).

44 Not required for salts.

45 Not required if test material is a gas or a highly volatile liquid.

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.

United States Environmental Protection
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FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

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

48 Required if the product consists of, or under conditions of use will result in, a respirable material (e.g., gas, vapor, aerosol, or particulate).

49 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

50 Not required if test material is a gas or a highly volatile liquid.

51 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

52 Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

53 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: 2545,Prometon

Co. Nr.	Company Name	Agent For	Address	City & State	Zip
4	BONIDE PRODUCTS, INC.		6301 SUTLIFF ROAD	ORISKANY	NY 13424
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
869	GREEN LIGHT COMPANY		PO Box 17985	SAN ANTONIO	TX 78217
1459	THE BULLEN COMPANIES		PO Box 37	FOLCROFT	PA 19032
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
4170	BETCO CORP LTD		PO Box 3127	TOLEDO	OH 43607
6186	DAMON INDUSTRIES INC		PO Box 2120	ALLIANCE	OH 446010120
9688	CHEMSICO		PO Box 142642	ST LOUIS	MO 631140642
10088	ATHEA LABORATORIES INC		PO Box 240014	MILWAUKEE	WI 53224
10807	AMREP, INC		990 INDUSTRIAL PARK DRIVE	MARIETTA	GA 30062
11603	AGAN CHEM MFG, LTD	MAKHTESHIM-AGAN OF NORTH AMERICA INC	4515 FALLS OF NEUSE RD STE 300	RALEIGH	NC 27609
33955	PBI/GORDON CORP		PO Box 014090 1217 WEST 12TH STREET	KANSAS CITY	MO 641010090
40849	ENFORCER PRODUCTS		1420 SEABOARD INDUSTRIAL BOULEVARD	ATLANTA	GA 30318
46515	CELEX, DIVISION OF UNITED INDUSTRIES CORP		PO Box 142642	ST LOUIS	MO 631140642
53883	CONTROL SOLUTIONS, INC.		5903 GENOA-RED BLUFF	PASADENA	TX 775071041
66222	MAKHTESHIM-AGAN OF NORTH AMERICA INC		4515 FALLS OF NEUSE RD, SUITE 300	RALEIGH	NC 27609
69204	TOPAZ TURF CORP	ADAMS TECHNOLOGY SYSTEMS	5145 FOREST RUN TRACE - SUITE B	ALPHARETTA	GA 300224504
70799	STATE INDUSTRIAL PRODUCTS		3100 HAMILTON AVE	CLEVELAND	OH 44114
84396	SUNGRO PRODUCTS, LLC		810 E. 18TH STREET	LOS ANGELES	CA 90021

APPENDIX G. EPA's Batching of Prometon 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 prometon 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, ready-to-use, 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 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.