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Reregistration Eligibility Decision for N-Octyl bicycloheptene dicarboximide (MGK-264)

List B

Case No. 2430

Reregistration Eligibility Decision (RED) Document

for

N-Octyl bicycloheptene dicarboximide (MGK-264)

Approved by: /S/
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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate

OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TCPSA	2,3,3-trichloroprop-2-ene sulfonic acid (nitrapyrin Metabolite)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

Executive Summary

EPA has completed its review of public comments on the human health and environmental risk assessments and is issuing its reregistration eligibility and tolerance reassessment decisions for MGK-264. There are currently 8 tolerances being reassessed for MGK-264. EPA will accept public comments on these decisions and the supporting documents for 60 days. The revised risk assessments and response documents are based on comments submitted, information from the technical registrant (MGK Company), and other information provided to EPA. After considering the risks identified in the revised risk assessments, comments and mitigation suggestions, EPA developed its risk management decision for uses of MGK-264 that posed risks of concern. As a result, the Agency has determined MGK-264-containing products are eligible for reregistration provided that risk mitigation measures are adopted, and labels are amended accordingly.

MGK-264 was first registered in the late 1940's and acts as a synergist. Synergists are chemicals that primarily enhance the pesticidal properties of other active ingredients, such as pyrethrins and synthetic pyrethroids. MGK-264 is a registered active ingredient in approximately 650 products used to control many different types of flying and crawling insects and arthropods, although there are no products that contain only MGK-264. It is registered for use in residential, commercial, and industrial sites. No agricultural crop uses of MGK-264 are being supported, and MGK-264 is not used in wide area mosquito abatement programs. Less than 300,000 pounds of MGK-264 are sold every year.

Overall Risk Summary

Dietary Risk (Food and Drinking Water)

Acute dietary (food only) risk does not exceed the Agency's level of concern; acute dietary risk estimates are 13% of the aPAD for females 13 to 49 years old, the only sub-population that needed to be assessed, because developmental toxicity was the sole endpoint attributable to a single dose in the available toxicology database.

The chronic dietary (food only) risk is below the Agency's level of concern; risk estimated are 19% cPAD for the general U.S. population, and 51% of the cPAD for children 1-2 years old, the most exposed sub-population.

The acute and chronic analyses were conducted using maximum and average residue levels, respectively, from applicable field trials and assumed all food commodities were treated.

Acute and chronic drinking water levels of concern (DWLOCs) were calculated based on dietary exposure estimates, default body weight and water consumption figures. The estimated drinking water concentrations (EDWCs) for both surface water and ground water are well below both the acute and chronic DWLOCs, indicating that combined exposure to MKG-264 in food and water is not a concern.

Residential

In the residential handler exposure assessment a number of scenarios were assessed to estimate the exposure to homeowners handling products containing MGK-264. The results from the assessed residential handler scenarios indicate there are no residential risks of concern when MGK-264 is mixed, loaded, applied, or handled by homeowners. Applying dips with MGK-264 to pets was not assessed because there were no application exposure data available. Based on high risk estimates from a pet shampoo study, there are no interim mitigation measures for applicators making dips to pets. However, confirmatory applicator exposure data will be required for pet dip applications.

A number of post-application residential scenarios were assessed for adults and children exposed to MGK-264 indirectly after application. There were post-application risk concerns for the following scenarios: 1) indoor spray applications; 2) broadcast dust applications to carpets; 3) aerosol space sprays indoors; 4) dust applications to pets; 5) insect repellents; and 6) applications from indoor metered release devices. To address the potential risks associated with these post-application scenarios, MGK Company has agreed to limit carpet dust applications to spot treatments only, conduct an aerosol space spray study with MGK-264 at the reduced label rate and amended application instructions, phase out all dust products applied to pets, and add additional label language and use restrictions to address potential by-stander risks from products used in metered release devices. The registrant is conducting a repeat 21-day dermal toxicity study to the limit dose which will be used to refine the dermal risk assessments. MGK Company has agreed to prohibit the use of metered release devices in residential indoor areas and remove the following use sites from their metered release device product labels: day care centers, nursing homes, schools, and hospitals. MGK Company is not supporting the use of residential misting systems and labels will be updated to prohibit the use of MGK-264 in these systems.

FQPA

After evaluating both the hazard and exposure data for MGK-264, EPA reduced the FQPA safety factor to 1X due to the low degree of concern for the fetal susceptibility effects and no evidence of residual uncertainties for pre- or post-natal toxicity. There were no residual uncertainties for potential exposures to infants and children.

Aggregate Risk

As noted above, acute and chronic aggregate risk assessments were conducted for exposure to MGK-264 in food and drinking water and did not indicate risks of concern. The short-term aggregate exposures from food, water, and residential (incidental oral) routes associated with application of PBO were also estimated since there is a common toxicity endpoint of slight decreases in pup body weight identified for these routes of exposure.

The short term aggregate risk for MGK-264 was estimated by comparing model based EDWCs to DWLOCs, where were determined by adding exposure estimates from food, drinking water, dermal, and incidental oral exposure pathways for the U.S. population and the highest

exposed sub-population, children 1-2 years old. The lowest short term DWLOC (38 µg/L) for children 1-2 years old is higher than the surface water EDWC (5.2 ppb) and the ground water EDWC (0.12 ppb), and therefore does not result in a risk of concern.

Cumulative

The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide and other substances that have a common mechanism of toxicity. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism finding as to MGK-264 and any other substances, and MGK-264 does not appear to produce a toxic metabolite produced by other chemicals. Therefore, for the purposes of this tolerance reassessment action, EPA has assumed that MGK-264 does not have a common mechanism of toxicity with other substances.

Occupational Risks

Occupational exposure assessments were completed by the Agency considering the use of baseline PPE and, if warranted, for handlers, increasing levels of PPE and engineering controls in order to estimate the potential impact on exposure and risk. The target MOE for MGK-264 is 1,000 for both dermal and inhalation exposures due to the lack of a no observable adverse effect level (NOAEL) in both studies selected for risk assessment. Of the handler scenarios assessed, two were potentially of concern assuming baseline clothing. These include: 1) applying MGK-264 with a handheld foggers indoors; and 2) applying dusts through power duster equipment. Pet dips and bulb duster applications were not assessed due to lack of data. Based on a shampoo scenario the Agency does not believe there will be risks of concern with applicators using pet dips, and exposure data will be required to confirm this assumption. The exposure from bulb dusters is not a concern for the Agency due to small amounts of dust used in this application method; the exposure is expected to be negligible. No additional data or risk assessments are required for bulb dusters.

There were potential post-application risks for products used in metered release devices which are commonly used in dairy barns and other sites. EPA believes that the potential post-application risks are lower for people working in these settings than for residential settings due to the fact that the occupational areas generally have a greater ventilation capacity. To better understand the risks from metered release devices in occupational settings the Agency is requesting additional usage information about the metered release device products.

Ecological Risks

In the ecological risk assessment for MGK-264, applications to turf, ornamentals, and lawns were considered the most likely use patterns that could lead to exposure to non-target organisms in the environment. The maximum use rate considered in the risk assessment was 2.2 lbs a.i./acre for lawn insect control. Since the ecological assessment was completed, MGK Company has reduced the outdoor spray application rate from 2.2 lbs a.i./acre to 0.3 lbs a.i./acre. This significant reduction in rate decreases the RQs predicted in the risk assessment, and results

in the majority of RQs for aquatic and terrestrial organisms being below the Agency's level of concern.

Summary of Mitigation Measures

EPA has determined that the currently registered uses of MGK-264 are eligible for reregistration provided the mitigation measures outlined in this document are implemented through label amendments. Mitigation measures include:

Residential

- Restrict carpet dust applications to only spot treatments.
- Reduce the rate for aerosol space sprays from 0.001 lb ai/1,000 ft^3 to 0.00015 lb ai/1,000 ft^3 and conduct an aerosol spray study with MGK-264 while following the label specifications that include a ventilation period of 15 minutes.
- Areas where sensitive populations are present, including day-care centers, nursing homes, schools and hospitals, will be removed from product labeled for use in metered release devices. In addition, the use of products in metered release devices in all other residential areas are prohibited unless required exposure data indicate risks are acceptable.
- Prohibit use of outdoor residential misting systems for MGK-264.
- Phase out all dust products used on pets.

Occupational

- Require applicators using handheld equipment such as handwand, backpack sprayers, or handgun equipment to wear gloves.
- Require applicators fogging indoors to wear double layers with a respirator.
- Prohibit power dusters as an application method.

Ecological

- Reduce the outdoor spray application rate from 2.2 lbs a.i./acre to 0.3 lbs a.i./acre.

Additional rate changes for MGK-264:

Use	Old maximum rate/formulation	New maximum rate/formulation
General outdoor spray applications	2.2 lb ai/A (0.05 lb ai/1,000 square feet)	0.3 lb ai/A
General crack and crevice or spot spray applications	1.6 lb ai/1,000 ft2	0.05 lb ai/1,000 ft2
Ready-to-use trigger pump spray applications	1.6 lb ai/1,000 ft2	0.1 lb ai/1,000 ft2 with the maximum concentration at 0.5%
General surface spray applications	0.4 lb ai/1,000 ft2	0.01 lb ai/1,000 ft2
Direct applications of solution to livestock	0.2 lb ai/gal	2 oz of 0.2% spray/animal (0.00025 lb ai/animal)
Ready-to-use wipe applications to horses	0.00018 lb ai/wipe	0.0000826 lb ai/wipe (~37.5 mg ai/wipe)

Use	Old maximum rate/formulation	New maximum rate/formulation
Indoor surface spray applications	0.4 lb ai/100 ft2	0.01 lb ai/1,000 ft2
Indoor space spray applications with aerosol can	0.006 lb ai/1,000 ft3	0.001 lb ai/1,000 ft3
Dust application to pets	10% product	Voluntary Cancel Use of Dusts on Pets
Application of insect repellants	8% product	5% product
Ready-to-use (RTU) pet collars	NA	0.0022 lb ai/per collar
RTU aerosol spray can applications	NA	0.0177 lb ai/16 oz can
Direct application to pets	NA	0.0028 lb ai/pet
RTU paste applications to horses	NA	0.0056 lbs ai per horse
Dust applied to carpeted and other indoor surfaces	NA	0.011 lb ai/100 ft2 (and restriction to spots 3 feet squared)
Metered release products	NA	1.77 mg ai/spray event and 0.002 lbs ai/1000 cubic feet / day
Surface sprays to pet premises	NA	0.01 lb ai/100 ft2
Aerosol Space Sprays	NA	0.00015 lb ai/1,000 ft3

I. Introduction

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

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require reassessment of all tolerances in effect on the day before it was enacted. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility among infants and children, and the cumulative effects of pesticides that have a common mechanism of toxicity. When the Agency determines that aggregate risks are not of concern and concludes that there is a reasonable certainty of no harm from aggregate exposure, the tolerances are considered reassessed. EPA decided that, for those chemicals that have tolerances and are undergoing reregistration, tolerance reassessment will be accomplished through the reregistration process.

The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to N-octyl bicycloheptene dicarboximide (MGK-264) and any other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that MGK-264 has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesicides/cumulative/.

The Agency made its reregistration eligibility determination based on the required data, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that currently registered uses of MGK-264 are eligible for reregistration provided the mitigation and labeling outlined in the RED are implemented. The document consists of six sections: Section I, the introduction, contains the

regulatory framework for reregistration/tolerance reassessment; Section II provides an overview of the chemical, including a profile of its use and usage; Section III gives an overview of the human health and environmental effects risk assessments; Section IV presents the Agency's reregistration eligibility, tolerance reassessment, and risk management decisions; Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV; and Section VI includes the appendices, related supporting documents and Data Call-In (DCI) information. The revised risk assessment documents and related addenda are not included in this document, but are available on the Agency's web page http://www.epa.gov/pesticides, and in the Public Docket under docket number EPA-HQ-OPP-2005-0040.

II. Chemical Overview

A. Regulatory History

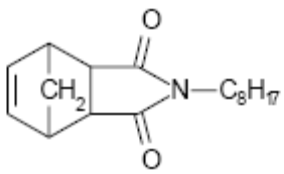
MGK-264 is a pesticide active ingredient that is classified as a synergist. Synergists are chemicals which, while lacking pesticidal properties of their own, enhance the pesticidal properties of other active ingredients. MGK-264 was first registered in the United States in the late 1940s. Currently there are approximately 650 end-use products registered in the United States containing MGK-264 as a synergist. There are 8 tolerances for MGK-264 listed in the Code of Federal Regulations. The reregistration of MGK-264 is being supported by the technical registrant, McLaughlin Gormely King Company.

MGK-264 is the only active ingredient in List B reregistration case 2430. A Phase IV Data Call-In was issued for MGK-264 in June of 1991. This DCI mainly required ecological and environmental fate data. An agricultural re-entry DCI was issued in October of 1995.

This Reregistration Eligibility Decision document evaluates risks from all currently registered uses of MGK-264.

B. Chemical Identification

MGK-264 is a FIFRA List B pesticide active ingredient classified as a synergist. As a synergist, MKG-264 works by inhibiting the detoxification of other pesticides by the insect pests.

Table 1: MGK-264 Nomenclature	
Chemical Structure	
Empirical Formula	$C_{17}H_{25}NO_2$

Common name	N-octylbicycloheptene dicarboximide, MGK-264
EPA PC Code	057001
IUPAC name	N-(2-ethylhexyl)-8,9,10-trinorborn-5-ene-2,3-dicarboximide
CAS name	4,7-Methano-1H-isoindole-1,3(2H)-dione, 2-(2-ethylhexyl)-3a,4,7,7a-tetrahydro-
CAS Registry Number	113-48-4
Chemical Class	Dicarboximide

Table 2: Physicochemical Properties of MGK-264

Parameter	Value	Reference
Melting point/range	N/A	Kenneth W. Dockter, 01/07/92: Reregistration of MGK-264. McLaughlin Gormley King Product Chemistry Considerations. CBRS # 8938; DP Barcode D171498.
Molecular Weight	275	
Boiling point/range	155-161EC at 1 mm Hg.	
pH	6.9; typical range of 6.8 to 7.2	
Density	1.049 ± 0.003 g/mL at 20°C	
Water solubility	15 ± 3 µg/mL at 25°C	
Solvent solubility	Miscible in: Acetone, Methanol, Isopropanol, Petroleum Ether, Concoco LPA (petroleum distillate), Ethyl Acetate, Toluene, Chloroform, Acetonitrile, Cyclo Solv 53 (aromatic petroleum distillate) and Isopar M (petroleum distillate)	
Vapor pressure	1.84 ± 0.49 x 10^{-5} mm Hg at 25°C	
Dissociation constant (pK_a)	N/A	
Octanol/water partition coefficient $Log(K_{OW})$	Log P = 3.61 & 3.80 for isomers 1 & 2, respectively, at 24°C	
UV/visible absorption spectrum	Data Gap	

C. Use Profile

MGK-264 comes in many chemical formulations and is found in numerous end-use products intended to be used in a wide range of use patterns. MGK-264 is used in combination with a variety of insecticides such as the natural pyrethrins and synthetic pyrethroids and is an ingredient in approximately 650 registered products. A Master Label including a list of all uses supported by the McLaughlin Gormely King Company is available at http://www.epa.gov/oppsrrd1/reregistration/piperonyl/ucm.pdf. The following is information on the currently registered uses including an overview of use sites and application methods. A detailed table of the uses of MGK-264 eligible for reregistration is contained in Appendix A.

1. MGK-264 Use Profile

Type of Pesticide: Synergist

Summary of Use: Commercial uses include application to non-food plants, applications in food and non-food handling commercial and agricultural structures and outdoor premises, housing for veterinary and farm animals, and direct application to veterinary and non-food animals. Residentially, it is used to control insects both inside the home, as well as outside on gardens, lawns and ornamentals, patios, and other outdoor structures. No agricultural crop uses of MGK-264 are being supported, and MGK-264 is not used in wide area mosquito abatement programs.

Target Organisms: MKG-264 is used with insecticides to target many types of pests, including various types of ants, worms, beetles, mites, flies, gnats, spiders, weevils, caterpillars, grubs, moths, ticks, lice, wasps, aphids, midges, and others.

Mode of Action: MGK-264 is known to inhibit microsomal enzymes in insects by binding directly to these enzymes and thereby inhibiting the breakdown of other pesticides such as pyrethrins and pyrethroids.

Tolerances: There are currently 8 tolerances established for MGK-264 including six (6) tolerances for residues in the fat of livestock commodities [40 CFR 180.367(a)(1)], one (1) food-processing use tolerance [40 CFR 180.367(a)(2)(i)], and one (1) exemption when applied to growing crops in accordance with good agricultural practice [40 CFR 180.905].

Use Classification: General Use

Formulation Types: Liquids, emulsifiable concentrate, dusts, ready-to-use formulations such as aerosol cans, foggers, trigger pump sprayers, shampoos, pastes, wipes, metered release devices, insect repellents, and others. MGK-264 is usually formulated with natural pyrethrins, piperonyl butoxide (PBO) [another synergist], or synthetic pyrethroids.

Application Methods: Applications to small areas may be made with handheld equipment, including low-pressure handwand sprayers, high pressure handwand sprayers, handgun sprayers, hose-end sprayers, thermal misters/foggers, and with ready-to-use application methods, including pump-trigger sprayers, foggers, aerosol cans, shampoos, dips, wipes, roll-ons, impregnated collars, and dust (puffer or shaker) cans.

Application Rates: Due to the varied number of use sites that MGK-264 is registered to treat, there is a wide range of application rates that are outlined in detail in the Use Closure Memo, which can be found at www.epa.gov/pesticides/reregistration/status.htm. Application rates range from 0.002 lbs ai/1,000 ft^3 for a space metered release spray to 1.6 lbs ai/1,000 ft^3 for crack, crevice, or spot surface treatments.

Usage of MGK-264: Less than 300,000 pounds of MGK-264 are sold every year in the U.S.

III. Summary of MGK-264 Risk Assessments

The following is a summary of EPA's human health and ecological risk findings conclusions for MGK-264. For more detail on the human health risk assessment, see the *Revised Memo to Incorporate Responses to Phase 5 Public Comments* (Donovan, March 20, 2006). For more detail on the environmental risk assessment, see the *Screening Ecological Risk Assessment for the Reregistration of MGK-264 Insecticide Synergist* (Eckel, September 29, 2004).

The purpose of this section is to summarize the key features and findings of the risk assessment in order to help the reader better understand the Agency's risk management decisions. The Agency has followed the full 6 phase reregistration public participation process for MGK-264. During this process, two 60-day public comment periods have been completed in order to allow interested stakeholders to provide feedback on the information and methods included in the Agency's risk assessments. Since the end of the last 60-day public comment period, the Agency has responded to the comments received, which are available on the public docket, along with all of the risk assessments and related addenda pertaining to MGK-264. These can be accessed through the website, www.regulations.gov, under docket number EPA-HQ-OPP-2005-0040.

A. Human Health Risk Assessment

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

The residues included in the tolerance expression are MGK-264 *per se*. For further information on the residue chemistry considerations, see the *Revised N-Octyl bicycloheptene dicarboximide (MGK-264) Product and Residue Chemistry Considerations*, (Donovan, September 9, 2005).

1. Toxicity Profile

MGK-264 is an insecticide synergist and is incorporated into insecticide formulations to prevent the breakdown of insecticides by the insect's mixed function oxidase (MFO) system so the toxic action of the insecticide will be more effective. Data are sufficient to assess all exposure scenarios and for FQPA evaluation.

Acute Toxicity Profile

MGK-264 is classified as Category IV for acute dermal irritation and Category III for acute dermal toxicity and eye irritation. No acute inhalation toxicity study or dermal sensitization study is available. An acute oral study was conducted that indicated toxicity

Category IV (MRID 41752305), but EPA found the study to be unacceptable because technical grade MGK-264 was not used (reviewed in memo from M. Lewis, June 16, 2004). See Table 3 below.

Table 3: Acute Toxicity Profile MGK-264

Guideline No.	Study Type	MRID(s)	Results	Toxicity Category
870.1100	Acute oral - rat	Study unacceptable.		
870.1200	Acute dermal - rabbit	41860601	LD_{50} > 2 g/kg	III
870.1300	Acute inhalation	Study not available.		
870.2400	Acute eye irritation - rabbit	41860602	Conjunctival irritation reversed by day 7	III
870.2500	Acute dermal irritation - rabbit	92122005	PDIS = 1.17	IV
870.2600	Skin sensitization	Study not available.		

Subchronic Dermal Toxicity

There was no systemic toxicity demonstrated in the 90-day rabbit dermal toxicity study at the highest dose tested of 100 mg/kg/day. This study was considered inadequate to establish a dermal endpoint because animals were not dosed at levels higher than 100 mg/kg/day. These higher doses might have elicited effects. Therefore, an endpoint for dermal risk assessment was selected from the 2-generation oral reproduction study in rats, based on offspring effects.

Dermal Absorption

A study with human volunteers indicated that the dermal absorption factor for MGK-264 is approximately 10% based on the combination of radiolabelled material in the urine (about 1%) and unaccounted for radioactivity (about 9%, assumed to be retained in the body). The dermal penetration factor of 10% based on this study with humans has been used for risk assessment instead of earlier data based on animal studies. EPA's use of a human dermal absorption study in the MGK-264 risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to the Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

Subchronic Inhalation Toxicity

A 90-day rat inhalation toxicity study demonstrated that at the lowest dose tested, there were indications of metaplasia/hyperplasia and changes in the larynx. At higher doses, histopathology of the larynx revealed additional changes and more intense changes in the epithelium and throat. Thus, inhalation exposure is capable of causing alterations in the respiratory tract.

Subchronic and Chronic Oral Toxicity

The liver is the target organ of MGK-264. Liver effects were noted in the adults in the rat chronic/oncogenicity study, the mouse chronic/oncogenicity study, the rat multi-generation reproduction study and subchronic and chronic dog studies. The dog appeared to be the most sensitive species for liver alterations but these alterations were limited to slight to moderate brown pigment and circulating enzyme changes. The dog study did not include histopathology of the liver to verify the presence of degenerative conditions. In the mouse, liver changes include bile duct histological changes including liver tumors, as well as kidney weight effects and brown pigment.

Carcinogenicity Evaluation

The Carcinogenicity Peer Review Committee (CPRC) classified MGK-264 as a Group C - Possible Human Carcinogen based on statistically significant increases mainly in benign liver adenomas in both sexes of mice at doses approaching the limit dose and on increases in benign thyroid follicular tumors in male rats at doses considered to be adequate to assess carcinogenic potential. The CPRC determined that a quantification of cancer risk is not required because the systemic NOAELs established in the chronic/cancer studies would be protective of any tumors seen at higher doses. Further, as discussed below, there is low concern for mutagenicity.

Developmental Toxicity

The rat and rabbit developmental toxicity studies did not demonstrate developmental toxicity for MGK-264. Maternal toxicity consisted of body weight and food consumption decreases. However, at higher doses, abortions, resorptions, and deaths were noted.

Reproductive Toxicity

There were no effects on the reproductive performance of either males or females in the multi-generation reproduction study. Systemic effects were related to body weight decrease as well as histopathological changes in the liver similar to those seen in the rat chronic feeding study. However, offspring for all generations indicated decreased body weight during lactation at a lower dose than parental systemic effects. The effect was reversible after weaning as pups regained weight and their weights were comparable to control animal weights after weaning. The lowest dose tested for the rat multi-generation reproduction study was determined to demonstrate the lowest LOAEL and was selected as the endpoint of concern for the chronic reference dose and other exposure scenarios. No NOAEL was established in the study.

Mutagenicity

Mutagenicity and genotoxicity were not evident in the Ames test for bacterial mutations, in the unscheduled DNA synthesis, or in a chromosome aberration studies. Although MGK-264 was considered weakly positive in the mouse lymphoma assay, there was a low concern for mutagenic or genetic toxicity.

Immunotoxicity and Neurotoxicity

There were no indications of immunotoxicity or specific neurotoxicity.

Metabolism

The metabolism and pharmacokinetics data for MGK-264 in rats demonstrated that MGK-264 is absorbed and excreted with little retention of metabolites.

Toxicity Endpoints

The toxicological endpoints used in the human health risk assessment for MGK-264 are listed below in Table 4.

Table 4: Summary of Toxicological Doses and Endpoints for MGK-264 for Use in Human Risk Assessments.

Exposure Scenario	Doses, Uncertainty Factors (UFs), and Safety Factors (SF)	Level of Concern: Population Adjusted Dose (PAD) or Target Margin of Exposure (MOE)	Study and Toxicological Effects
Acute Dietary (Females 13-49 years of age)	Maternal NOAEL = 100 mg/kg/day FQPA SF = 1X UF =100 Total UF = 100 Acute RfD = 1 mg/kg/day	aPAD = 1.0 mg/kg/day	Developmental toxicity study in rabbits LOAEL = 300 mg/kg/day based on maternal deaths, abortions and resorptions. (MRID: 40352301)
Acute Dietary (General population including infants and children)	An appropriate endpoint attributable to a single dose was not identified in the available toxicology database.		
Chronic Dietary (All populations)	Offspring LOAEL= 61 mg/kg/day FQPA SF = 1X UF =100 Lack of NOAEL UF = 10X Total UF = 1,000 Chronic RfD = 0.061 mg/kg/day	cPAD = 0.061 mg/kg/day	Multi generation reproduction-toxicity rat Offspring LOAEL= 61 mg/kg/day based on slight decreases in body weight in pups during lactation. (MRID: 42155701)
Short-Term (1-30 days) and Intermediate term (1-6 months) Incidental Oral	Offspring LOAEL = 61mg/kg/day FQPA SF = 1X UF =100 Lack of NOAEL UF = 10X Total UF = 1,000	Residential LOC: MOE = 1,000	
Dermal Exposures - all durations	Offspring LOAEL = 61mg/kg/day	Residential LOC: MOE = 1,000	Multi generation reproduction-toxicity rat Offspring LOAEL = 61mg/kg/day based on

Table 4: Summary of Toxicological Doses and Endpoints for MGK-264 for Use in Human Risk Assessments.			
Exposure Scenario	**Doses, Uncertainty Factors (UFs), and Safety Factors (SF)**	**Level of Concern: Population Adjusted Dose (PAD) or Target Margin of Exposure (MOE)**	**Study and Toxicological Effects**
	FQPA SF = 1X UF =100 Lack of NOAEL UF = 10X Total UF = 1,000 Used 10% dermal absorption	Occupational LOC: MOE = 1,000	slight decreases in body weight in pups during lactation. (MRID: 42155701) MGK-264 Human Dermal Absorption Study (MRID: 42976701, 42976702)
Inhalation - all durations	LOAEL = 0.01 mg/L converted to 1.9 mg/kg/day FQPA SF = 1X UF =100 Lack of NOAEL UF = 10X Total UF = 1,000	Residential LOC: MOE = 1,000 Occupational LOC: MOE = 1,000	90 day inhalation study - rat LOAEL = 0.01 mg/L (1.9 mg/kg/day) based on hyperplasia and metaplasia in larynx (MRID: 43309001)
Cancer (oral, dermal, inhalation)	Group C - Possible Human Carcinogen based on liver tumors in mice and thyroid tumors in rats. Quantification of cancer risk is not required.		

FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose

2. Safety and Uncertainty Factors

FQPA Safety Factor

The Food Quality Protection Act (FQPA) directs the Agency to use an additional tenfold (10X) safety factor to protect for special sensitivity of infants and children to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database. FQPA authorizes the Agency to modify the tenfold safety factor only if reliable data demonstrate that another factor would be appropriate. After evaluating hazard and exposure data for MGK-264, EPA reduced the 10X FQPA safety factor to 1X because there are no concerns and no residual uncertainties with regard to pre- and post-natal toxicity.

There are no residual uncertainties identified in the exposure databases relevant to potential exposure to infants and children. The dietary food exposure assessment assumes 100% treatment of all food handling establishments and warehouses. Additionally, the assessment assumes that all consumed foods have been treated and bear residues of MGK-264. By using these conservative assumptions, chronic exposures/risks will not be underestimated. The dietary drinking water assessment (Tier 1 estimates) utilizes values generated by models and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations. The residential exposure assumptions are conservative high-end estimates that are meant to be protective of potential exposure to MGK-264. Therefore,

these assessments will not underestimate the potential exposure to infants and children resulting from the use of MGK-264.

Other Uncertainty Factors

An additional 10X uncertainty factor was applied to the chronic dietary assessment and the incidental oral and dermal exposure scenarios because no NOAEL was identified in the multi-generation rat study. All inhalation exposure scenarios included an additional 10X because a NOAEL was not identified in the 90-day rat inhalation study either.

3. Endocrine Disruption

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

In the available toxicity studies on MGK-264, there was no estrogen or androgen mediated toxicity. It is noted, however, that the rat carcinogenicity study demonstrated increased thyroid tumors that may have been related to perturbation of the thyroid/liver/pituitary axis to alter thyroid hormone metabolism. EPA believes the endpoints and risk scenarios evaluated are protective of this potential endocrine effect. When additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, MGK-264 may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

2. Dietary Risk

The only MGK-264 food uses presently supported are in food handling establishments (FHEs) and warehouses. Because no agricultural crop uses or direct animal treatment uses are being supported, many residue chemistry data requirements are not applicable for the current uses of MGK-264. A summary of MGK-264 tolerance changes and data requirements is included in Section IV and V.

Acute and Chronic (Food Only)

Dietary risk assessment incorporates both exposure to and toxicity of a given pesticide. Dietary risk is expressed as a percentage of a level of concern. The level of concern is the dose predicted to result in no unreasonable adverse health effects to any human population subgroup, including sensitive members of such population subgroups. This level of concern is referred to as the population adjusted dose (PAD), which reflects the reference dose (RfD), either acute or chronic, adjusted to account for the FQPA safety factor.

Estimated risks that are less than 100% of the PAD are below EPA's level of concern. The acute PAD (aPAD) is the highest predicted dose to which a person could be exposed on any given day with no adverse health effects expected. The chronic PAD (cPAD) is the highest predicted dose to which a person could be exposed over the course of a lifetime with no adverse health effects expected.

The acute and chronic analyses were conducted using maximum and average residue levels, respectively, from applicable field trials and assumed all food commodities were treated. An acute analysis was conducted only for females 13-49 years old, because an appropriate endpoint for the general population was not identified. At the 99.9th percentile of exposure for the acute analysis for females 13-49 years old, the risk was at 13% of the acute population adjusted dose (aPAD). For the chronic analysis, the most highly exposed population subgroup was children 1-2 years old with a risk estimate at 51% of the chronic population adjusted dose (cPAD), while the estimate for the general population was at 19% of the cPAD. Acute and chronic analyses were conducted using both DEEM (Version 2.0) and Lifeline (Version 2.0). These analyses are conservative so the actual exposure is likely lower than the estimates provided.

Table 5: Acute and Chronic Dietary Exposure and Risk Estimates for MGK-264.

Population Subgroup	PAD, mg/kg/day	DEEM		Lifeline	
		Exposure, mg/kg/day	% PAD	Exposure, mg/kg/day	%PAD
Acute Dietary Estimates (99.9th Percentile of Exposure)					
Females 13-49 yrs	1	0.076	7.6	0.13	13
Chronic Dietary Estimates					
U.S. Population	0.061	0.012	19	0.011	19
All infants (< 1 yr)		0.016	26	0.015	24
Children 1-2 yrs		**0.031**	**51**	**0.029**	**48**

The values for the population subgroup with the highest predicted exposure are **bolded**.

3. Drinking Water

For more detail on the drinking water risk assessment, see the *Drinking Water Assessment for MGK-264 Insecticide Synergist: Surface Water Revision for Ground Spray* (Eckel, February 17, 2005).

Drinking water exposure to pesticides can occur through groundwater and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. To determine the maximum allowable contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a "drinking water level of comparison" (DWLOC) to ascertain whether modeled or monitored concentration levels exceed this level.

The Agency uses the DWLOC calculation to estimate risk associated with exposure from pesticides in drinking water. The DWLOCs represent the maximum contribution to the human diet (in ppb or μg/L) that may be attributed to residues of a pesticide in drinking water after dietary exposure is subtracted from the aPAD or the cPAD. Risks from drinking water are assessed by comparing the DWLOCs to the estimated drinking water concentrations (EDWC) in surface water and groundwater. EDWCs less than the DWLOC are below EPA's level of concern. Drinking water modeling is considered to be an unrefined assessment and generally provides high-end estimates.

The MGK-264 drinking water assessment for turf was based on a hypothetical Iowa corn scenario because no exposure model has been developed to estimate pesticide residue from applications in an outdoor urban setting. Since there are no agricultural or wide area mosquito abatement uses for MGK-264 and the most likely route of drinking water exposure is from residential turf use, this is a conservative drinking water risk assessment.

Surface Water

FIRST (FQPA Index Reservoir Screening Tool) was used to estimate surface water concentrations. FIRST is a Tier I screening level model used to provide high-end values on the concentrations that might be found in a small drinking water reservoir. FIRST is a single-event model (one run-off event), but can account for spray drift from multiple applications. FIRST makes adjustments for the percent-cropped area but makes conservative assumptions including modeling a runoff-prone watershed, the use of the maximum use rate, no buffer zone, and a single large rainfall. FIRST input parameters are based on weekly applications (52 per year) at the turf rate of 2.2 lb a.i. per acre (the Master Label is 0.05 lb active ingredient per 1,000 square feet) and a re-application interval of 7 days. These inputs were used to calculate an acute surface water concentration of 83 ppb and a chronic surface water concentration of 38 ppb.

During the Phase 5 public comment period, MGK Company, requested a rate reduction for outdoor application sites, which changes the application rate assumed in the drinking water assessment. Since there is a linear relationship between application rate and EDWCs, the calculated EDWCs were scaled to account for the rate reduction from 2.2 lb a.i. per acre to 0.3 lb a.i. per acre. When the application rate is reduced from 2.2 lbs a.i. per to 0.3 lbs a.i. per acre, the estimated acute surface water concentration is reduced to 11 ppb, and the chronic surface water concentration is reduced to 5.2 ppb.

Ground Water

The Screening Concentration in Ground Water (SCI-GROW) model was used to estimate ground water concentrations. The SCI-GROW screening model is a Tier I model that provides a high-end estimate. SCI-GROW model generates a single EDWC value of pesticide concentration in ground water used for drinking water and provides a screening concentration for use in determining potential risk to human health from drinking water contaminated with a pesticide. EPA used the Tier 1 SCI-GROW model and a hypothetical percent-cropped area of 87%, mean soil half-life of 430 days, and an Organic Carbon Partition coefficient (K_{oc}) of 899 mL/g, to predict a concentration of 0.86 ppb in ground water. When the application rate is reduced from 2.2 lbs a.i. per acre to 0.3 lbs a.i. per acre, the scaled ground water concentration is reduced to 0.12 ppb.

Table 6: Summary of Estimated Drinking Water Concentrations (EDWCs) for MGK-264.

Exposure Duration	Surface Water Concentration (ppb)	Ground Water Concentration (ppb)
Acute	83	0.86
Acute: Scaled [a]	11	0.12
Chronic	38	0.86
Chronic: Scaled [a]	5.2	0.12

[a] Scaled value based on assumption of direct relationship between application rate and surface or ground water concentration and a revised application rate of 0.30 lb ai/A.

The EDWCs listed above in Table 6 should be considered highly conservative because of the assumptions made in the modeling. The percent cropped area value used was 87% based on hypothetical corn use in Iowa. It is unlikely that a chemical with no crop uses and a treatment rate described in terms of lbs ai per 1,000 ft^2 would be used in 87% of a watershed. Use of the formulation modeled in the drinking water assessment is intended to be an "area" treatment rather than a watershed-scale treatment. Available monitoring data in raw ground water and surface water, and in finished drinking water from four cities, indicate that MGK-264 has not been found at the detectable limit of 0.1 ppb.

4. Residential Exposure and Risk

For more detail on the residential risk assessment, see the *MGK-264: REVISED Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document* (Weiss, March 10, 2006).

There is potential for residential exposure while applying and handling products containing MGK-264. There is also a potential for exposure of adults and children entering MGK-264 treated areas, such as lawns, golf courses, home gardens, and indoor surfaces (carpets and flooring) and through insect repellents and contact with treated pets. Risk assessments have been completed for both residential handler and post-application scenarios. Based on the Master Label provided by MGK Company, 11 residential handler exposure scenarios have been assessed for this RED.

Residential risk is expressed as a Margin of Exposure (MOE), which measures how close the residential exposure comes to a dose selected from toxicity studies. For MGK-264, MOEs greater than 1,000 are considered protective for all exposure durations (short-, intermediate-, and long-term) via all routes of exposure (incidental oral, dermal, and inhalation).

a. Toxicity

The toxicological endpoints used in the residential risk assessment for MGK-264 are listed in Table 7 and summarized below.

Table 7: Summary of Toxicological Doses and Endpoints for MGK-264 for Use in Residential Risk Assessment

Exposure Scenario	Doses, Uncertainty Factors (UFs), and Safety Factors (SF)	Target Level of Concern: Margin of Exposure (MOE)	Study and Toxicological Effects
Short-Term (1-30 days) and Intermediate term (1-6 months) Incidental Oral	Offspring LOAEL = 61 mg/kg/day FQPA SF = 1X UF =100 Lack of NOAEL UF = 10X Total UF = 1,000	Residential LOC: MOE = 1,000	Multi generation reproduction-toxicity rat Offspring LOAEL= 61 mg/kg/day based on slight decreases in body weight in pups during lactation. (MRID: 42155701)
Dermal Exposures - all durations	Offspring LOAEL = 61mg/kg/day Used 10% dermal absorption FQPA SF = 1X UF =100 Lack of NOAEL UF = 10X Total UF = 1,000	Residential LOC: MOE = 1,000	Multi generation reproduction-toxicity rat Offspring LOAEL = 61mg/kg/day based on slight decreases in body weight in pups during lactation. (MRID: 42155701) MGK-264 Human Dermal Absorption Study (MRID: 42976701, 42976702)
Inhalation - all durations	LOAEL = 0.01 mg/L converted to 1.9 mg/kg/day FQPA SF = 1X UF =100 Lack of NOAEL UF = 10X Total UF = 1,000	Residential LOC: MOE = 1,000	90 day inhalation study - rat LOAEL = 0.01 mg/L (1.9 mg/kg/day) based on hyperplasia and metaplasia in larynx (MRID: 43309001)

FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level

b. Residential Exposure Scenarios

The residential exposure assessment includes both handler and post-application residential exposure scenarios. The term "handler" applies to individuals who mix, load, and apply the pesticide product. The term "post-application" describes individuals who are exposed to pesticides after entering areas previously treated with pesticides. A post-application scenario was also assessed for the use of repellents containing MGK-264 that are applied directly to the skin. Based on information provided in the Master Label regarding current registrant supported uses, information provided by the registrants in public comments, and information gathered

through correspondences with the registrants, the Agency assessed the residential exposure scenarios for MGK-264.

i. Residential Handler Scenarios

The anticipated use patterns and current labeling indicate several residential handler exposure scenarios based on the types of equipment and techniques that can potentially be used to make MGK-264 applications. The quantitative residential handler exposure and risk assessment developed for residential handlers is based on these scenarios:

- Mixing/Loading/Applying liquid formulations with low pressure handwand (LPH)
- Mixing/Loading/Applying formulations with hose-end sprayer
- Applying ready-to-use dusts with shaker can
- Applying ready-to-use shampoos
- Applying ready-to-use mousse, soap, lotion, gel, comb, or roll-on products
- Applying ready-to-use wipes
- Applying ready-to-use formulations using trigger pump sprayer
- Applying ready-to-use aerosol cans
- Applying ready-to-use foggers
- Applying ready-to-use impregnated collars on dogs

Data were not available to assess applications of MGK-264 for dip applications. Based on high risk estimates from a pet shampoo study, there are no interim mitigation measures for applicators making dips to pets. Applicator pet dip exposure data may be required for this scenario pending the outcome of a 21-day dermal toxicity study.

ii. Residential Post Application Scenarios

The Agency uses the term "post-application" to describe exposures to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. MGK-264 can be used in many areas that can be frequented by the general population including residential areas (e.g., home lawns and gardens). As a result, individuals could be exposed by entering these areas if they have been previously treated. MGK-264 could also be used on pets, which can lead to exposures by contact with the treated animal, and through metered release devices. Products used in metered release devices are usually formulated in ready to use aerosol cans with a special nozzle that fits into the device. A battery-operated timer system allows a spray of MGK-264 to dispense regularly throughout a day. These systems are registered for use to control flying insects in food handling establishments, animal premises, and other areas.

c. Exposure Data and Assumptions

Handler and Post-application Exposure Data

Data from the Pesticide Handler Exposure Database (PHED), the Occupational Residential Exposure Task Force (ORETF) database, the Chemical Manufacturers Association

(CMA) Antimicrobial Exposure Assessment Study, and two proprietary studies (trigger pump spraying with propoxur and shampoo application with carbaryl) were used to assess residential handler exposures. With the exception of a dog shampoo study, no chemical-specific exposure data were submitted for MGK-264.

Standard default application assumptions regarding areas treated or amounts applied for residential handler scenarios were used. See the *MGK-264: REVISED Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document* (Weiss, March 10, 2006) for a complete list of all data and assumptions used in the residential risk assessment. Other residential exposure standard operating procedures (SOPs) may be viewed at the following website: http://www.epa.gov/oscpmont/sap/1997/september/sopindex.htm .

The Agricultural Re-entry Task Force (ARTF) database was used for re-entry dermal exposure to treated foliage. For post-application exposure following indoor treatments, surrogate data from the Non-Dietary Exposure Task Force (NDETF) and Residential Exposure Joint Venture (REJV) were used.

Exposure Parameters

The parameters and assumptions used in estimating risks from residential exposure to MGK-264 can be found in section 3.0 of the *MGK-264: Revised Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document* (Weiss, March 10, 2006). The information listed was used to assess all scenarios including incidental oral, aerosol space sprays, repellent use, and outdoor residential misting systems.

d. Residential Risk Estimates

Handler

It is likely that MGK-264 can be used in multiple ways that have not specifically been identified in the residential risk assessment. However, EPA believes that the scenarios assessed represent worse-case exposures and risks resulting from use of MGK-264 in residential environments.

All of the residential handler scenarios assessed had risks below the Agency's level of concern. That is, all MOEs calculated were above the target of 1,000. Dermal handler MOEs ranged from 1,800 (applying pet collars), to 260,000 (applying RTU trigger pump sprays outside). Handler inhalation MOEs ranged from 2,800 (applying aerosol sprays indoors), to well over a million (applying soap, hair mousse, lotion, or gel to pets).

Data were not available to assess applications of MGK-264 for dip applications. Based on relatively high MOEs from a pet shampoo study which would likely present similar exposure, no interim mitigation measures for residential applicators making dip application to pets will be required. Applicator pet dip exposure data may be required for this scenario pending the outcome of a 21-day dermal toxicity study.

Post-Application

Estimated MOEs for adults and toddlers were calculated for post-application risks following the application of MGK-264 to home lawns, indoor spaces/surfaces, repellent uses, and pets. The shampoo post-application dermal scenario is protective of post-application exposure to pets after dip applications since the dip rate is lower than the shampoo rate. Results of the post-application assessment are presented in Table 8. MOEs of less than 1,000 are described further below.

Toddlers

There were post-application dermal risk concerns for toddlers exposed to MGK-264 from indoor spray applications, indoor fogger applications, indoor dust applications, and from insect repellents. Aerosol space and metered release applications were a concern for post-application inhalation exposure. Dusts applied as a broadcast treatment to carpets were a concern for post-application incidental oral exposure.

Adults

For adults, there were post-application dermal risk concerns from exposure to indoor dust applications to carpets and from insect repellants. Indoor space and metered release applications were a concern for post-application inhalation exposure.

Table 8: Residential Post-Application MOEs

Exposure Scenario	Route of Exposure	Application Rate	MOEs	
			Adults	Toddlers
Outdoors				
Residential Turf (High Contact Activities)	Dermal	0.3 lb ai/acre	7,500	5,200
Residential Turf (Mowing)	Dermal	0.3 lb ai/acre	30,000	NA
Hand to Mouth Activity on Turf	Oral	0.3 lb ai/acre	NA	14,000
Object to Mouth Activity on Turf	Oral	0.3 lb ai/acre		54,000
Incidental Soil Ingestion	Oral	0.3 lb ai/acre		4,100,000
Indoors				
Hand to Mouth Activity on Indoor Surfaces (Spray applications to carpeted surfaces)	Oral	0.01 lb ai/1,000 ft^2	NA	4,700
Hand to Mouth Activity on Indoor Surfaces (Fogger applications to carpeted surfaces)	Oral	0.01 lb ai/1,000 ft^2		2,500
Hand to Mouth Activity on Indoor Surfaces (Fogger applications to hard surfaces)	Oral	0.01 lb ai/1,000 ft^2		7,900
Hand to Mouth Activity on Indoor Surfaces (dust applications to carpeted surfaces) 100% of surface residue available	Oral	0.011 lb ai/100 ft^2		**430**

Table 8: Residential Post-Application MOEs				
Exposure Scenario	Route of Exposure	Application Rate	MOEs	
			Adults	Toddlers
Hand to Mouth Activity on Indoor Surfaces (dust applications to carpeted surfaces) 50% of surface residue available	Oral	0.011 lb ai/100 ft^2		**850**
Hand to Mouth Activity on Indoor Surfaces (dust applications to carpeted surfaces) 25% of surface residue available	Oral	0.011 lb ai/100 ft^2		1700
Indoor Surfaces (Spray applications to carpeted/hard surfaces)	Dermal	0.01 lb ai/1,000 ft^2	1,000	**780**
Indoor Surfaces (Fogger applications to carpeted surfaces)	Dermal	0.01 lb ai/1,000 ft^2	1,200	**840**
Indoor Surfaces (Fogger applications to hard surfaces)	Dermal	0.01 lb ai/1,000 ft^2	4,700	3,300
Indoor Surfaces (dust applications to carpeted surfaces) 100% of surface residue available	Dermal	0.011 lb ai/100 ft^2	**100**	**70**
(dust applications to carpeted surfaces) 50% of surface residue available	Dermal	0.011 lb ai/100 ft^2	**210**	**140**
(dust applications to carpeted surfaces) 25% of surface residue available	Dermal	0.011 lb ai/100 ft^2	**290**	**410**
Inhalation Exposure from Space Sprays (aerosol cans)	Inhalation	0.001 lb ai/1,000 ft^3	**170**	**52**
Inhalation Exposure from Space Sprays in homes (metered release with 0.18 air changes per hour)	Inhalation	1.77 mg ai/spray event	**40**	**13**
Inhalation Exposure from Space Sprays (metered release with 2 air changes per hour)	Inhalation	1.77 mg ai/spray event	**440**	**140**
Pets				
Hand to Mouth Activity Following Pet Contact (Dust using Residential-Standard Operating Procedures)	Oral	0.00248 lb ai/animal	NA	**130**
Pet Contact (Dust using Residential-Standard Operating Procedures)	Dermal	0.05lb ai/animal		**61**
Hand to Mouth Activity Following Pet Contact (Shampoo using MGK-264 data)	Oral	0.00088 lb ai/animal		6,500
Hand to Mouth Activity Following Pet Contact (Mousse, Soap, Gel, Comb or roll-on using MGK-264 data)	Oral	0.00044 lb ai/animal		13,000
Pet Contact (Shampoo using MGK-264 data)	Dermal	0.00088 lb ai/animal		100,000
Pet Contact (Mousse, Soap, Gel, Comb or roll-on using MGK-264 data)	Dermal	0.00044lb ai/animal		50,000
Insect Repellents Applied to Skin				

Table 8: Residential Post-Application MOEs				
Exposure Scenario	Route of Exposure	Application Rate	MOEs	
			Adults	Toddlers
One Application to 25% of Body Surface Area Using 1 mg product per cm2 of skin	Dermal	8% ai formulation	**100**	**70**
	Oral		NA	1,100
One Application Based on REJV Survey Data	Dermal		**88**	**24**
One Application to 25% of Body Surface Area Using 1 mg product per cm2 of skin	Dermal	5% ai formulation	**160**	**110**
	Oral		NA	1,800
One Application Based on REJV Survey Data	Dermal		**140**	**38**

NA = Not Assessed
Bold indicates MOE is less than LOC of 1,000.

5. Aggregate Risk

In accordance with the FQPA, EPA must consider and aggregate (combine) pesticide exposures and risks from all sources. For pesticides, these usually include food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (e.g., a NOAEL or PAD), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, EPA considers both the route (oral, dermal, and inhalation) and duration (short-, intermediate-, or long-term) of exposure.

Model estimates have been used to estimate residues in drinking water (EDWCs). In order to determine if aggregate risks are of concern, EPA calculates drinking water levels of comparison, or DWLOCs. The DWLOC is the maximum amount of a pesticide in drinking water that would be acceptable in light of combined exposure from food and residential pathways. The calculated DWLOCs are then compared to the EDWCs; if model-derived EDWCs exceed the DWLOCs for surface or ground water, there may be a concern for dietary exposure to residues in drinking water, and monitoring data or other refinements may be required.

Acute Aggregate Risk (Food + Water)

An acute aggregate risk assessment was conducted for MGK-264. The acute assessment considered exposures from food and water only. Since adequate water monitoring data are not available to estimate levels of MGK-264 in drinking water, EPA calculated DWLOCs and compared them to the modeled EDWCs for surface and ground water to determine whether aggregate acute risks are of concern.

Table 9 summarizes the acute DWLOC calculated for the only population subgroup (females 13-49 years old) that was relevant based on effects seen in the toxicity database. Comparison of the acute DWLOC to the maximum EDWCs for surface and ground water shows that the acute DWLOC is greater than the EDWCs for acute exposure for females 13-49 years

old. Therefore, the acute aggregate exposures to MGK-264 result in risk estimates below the Agency's level of concern.

Table 9: Acute Aggregate Risk Assessment for MGK-264

Population Subgroup	Acute Scenario					
	aPAD mg/kg/day	Acute Food Exp mg/kg/day	Max Allowable Acute Water Exp mg/kg/day[1]	Ground Water EDWC (ppb)[2]	Surface Water EDWC (ppb)[2]	Acute DWLOC (ppb)[3]
Females 13-49 years old	1	0.128	0.872	0.12	11	26,160

[1] Maximum acute water exposure (mg/kg/day) = [(aPAD (mg/kg/day) - acute food exposure (mg/kg/day)]
[2] Based on extrapolation of the maximum single application outdoor use rate of 0.05 lb ai/1,000 ft2 to 87% of a watershed.
[3] Acute DWLOC(µg/L) = [maximum acute water exposure (mg/kg/day) x body weight (kg)] / [water consumption (L) x 10^{-3} mg/µg]

Short-Term Aggregate Risk (Food + Water + Dermal + Incidental Oral)

Short-term aggregate exposure takes into account residential exposure plus average exposure through food and water. Some MGK-264 residential uses represent short-term exposure scenarios. Toxicity endpoints were selected for short-term incidental oral, dermal, and inhalation exposures, and the acceptable MOE for short-term exposure was 1,000 for all exposures. Inhalation exposures were not included since the toxicological effects through the inhalation exposure route, changes in the larynx, are different from the toxicological effects through the oral and dermal routes, slight decreases in pup body weight. Indoor scenarios were selected because they could potentially lead to higher risk to adults and toddlers than outdoor scenarios.

This short-term aggregate risk assessment was conducted adding dermal, oral non-dietary exposure, and average food and water exposures as shown in Table 10. The aggregate MOE takes into account average food consumption values (calculated from the chronic dietary assessment), and oral and dermal exposures (from the indoor fogger scenario on hard floors at the rate of 0.01 lb ai/1,000 ft^2).

Residue values from water monitoring data were not available for MGK-264; therefore, as with the acute dietary aggregate risk estimate, DWLOCs were calculated for comparison with EDWCs. For the U.S. population and children 1-2 years old, the estimated ground (0.12 ppb) and surface water (0.2 ppb) EDWC values do not exceed the DWLOC value for the U.S. population (1,261 ppb) or children 1-2 years old (38 ppb), the highest exposed subpopulation. Therefore, short-term aggregate risk does not exceed the Agency's level of concern.

Many of the indoor residential post-application use scenarios resulted in predicted risk levels that exceeded the Agency's level of concern by themselves (*i.e.,* without aggregating).

Thus, the following scenarios were not included in the aggregate assessment indoor spray applications, fogger applications to carpets, dust applications to pets, insect repellents applied to humans, aerosol space sprays, metered release applications, and dusts applied as a broadcast treatment to carpets.

In general, the potential exposure to MGK-264 from residential scenarios exceeds that expected from food and water sources. Because the exposure contributions from food and water sources are relatively low in the aggregate risk assessment, mitigation adequate to address residential exposure scenarios of potential concern will also be protective for the short-term aggregate risk from MGK-264. Further, there are several conservative assumptions in the dermal risk assessment, including the use of 10% as the dermal absorption factor, and reliance on an oral study with a 10X uncertainty factor for lack of a NOAEL, which tend to overstate the dermal component of the aggregate calculation. For more details and data required to refine dermal estimates, see discussion in Section IV, under Insect Repellents.

Table 10: Short-Term Aggregate Risk and DWLOC Calculations for MGK-264

Population Subgroup	Short-Term Scenario					
	Aggregate MOE (food and residential)[1]	**MOE Water[2]**	**Allowable water exposure[3] (mg/kg/day)**	**Ground Water EDWC[4] (ppb)**	**Surface Water EDWC[4] (ppb)**	**Short-term DWLOC[5] (µg/L)**
U.S. Population	2,442	1,693	0.036	0.12	5.2	1,261
Children 1-2 years old	1,066	16,152	0.0038	0.12	0.2	38

[1] Aggregate MOE (food and residential) = 1÷[(1÷MOE food) + (1÷MOE oral) + (1÷MOE dermal)]
[2] Water MOE = 1÷ [(1÷ Target Aggregate MOE) - (1÷Aggregate MOE (food and residential)]
[3] Allowable water exposure = Short Term Oral NOAEL ÷ MOE Water
[4] The highest label rate for outdoor area treatments was extrapolated to a watershed area for modeling purposes.
[5] DWLOC(µg/L) = [allowable water exposure (mg/kg/day) x body weight (kg)] / [water consumption (L) x 10^{-3} mg/µg]

Chronic Aggregate Risk (Food + Water)

A long-term (chronic) aggregate risk assessment was conducted for MGK-264. The chronic assessment considered exposures from food and water only because there were no residential uses expected to contribute to chronic exposures for this chemical. DWLOCs were calculated and compared to the modelled EDWCs for surface and ground water to determine whether aggregate chronic risks are of concern.

The results of the dietary exposure assessment indicate that chronic dietary exposures to MGK-264 in food are below the Agency's level of concern (100% of the cPAD). MGK-264 food exposure was estimated at 0.012 mg/kg/day for the U.S. population (19% of the cPAD) and 0.031 mg/kg/day (51% of the cPAD) for the most highly exposed population subgroup (children

1-2 years old) based on the most conservative estimates for each population subgroup from the LifeLine and DEEM-FCID models. The calculated DWLOCs ranged from 1800 ppb for adults to 300 ppb for children. The Tier 1 chronic surface water EDWC (5.2 ppb) was below the Agency's calculated DWLOCs for chronic exposure to MGK-264 for the U.S. population and each population subgroup. The Tier 1 ground water EDWC (0.12 ppb) is also less than the Agency's calculated chronic DWLOCs for all population subgroups. The chronic aggregate risk associated with the use of MGK-264 does not exceed the Agency's level of concern for any population subgroup.

Table 11: Aggregate Risk Assessment for Chronic Exposure to MGK-264

Population Subgroup[1]	Chronic Scenario					
	cPAD mg/kg/day	Chronic Food Exp mg/kg/day	Max Chronic Water Exp mg/kg/day[2]	Ground Water EDWC (ppb)[3]	Surface Water EDWC (ppb)[3]	Chronic DWLOC (ppb)[4]
U.S. Population	0.061	0.0118	0.0492	0.12	5.2	1,722
All Infants (<1 year old)	0.061	0.0161	0.0449			449
Children 1-2 years	0.061	0.0309	0.0301			301
Children 3-5 years	0.061	0.0289	0.0321			321
Children 6-12	0.061	0.0196	0.0414			414
Youth 13-19	0.061	0.0126	0.0484			1,452
Adults 20-49	0.061	0.00953	0.05147			1,801
Females 13+	0.061	0.0111	0.0499			1,497
Adults 50+ years	0.061	0.0089	0.0521			1,824

[1] DWLOC values calculated assuming standard body weights (70 kg adult male; 60 kg adult female; 10 kg child).
[2]Maximum Chronic Water Exposure (mg/kg/day) = [Chronic PAD (mg/kg/day) - Chronic Dietary Exposure (mg/kg/day)]
[3] Based on extrapolation of the maximum single application outdoor use rate of 0.05 lb ai/1,000 ft2 to 87% of a watershed.
[4] Chronic DWLOC(µg/L) = [maximum chronic water exposure (mg/kg/day) x body weight (kg)] / [water consumption (L) x 10^{-3} mg/µg]

6. Occupational Risk

For more detail on the occupational risk assessment, see section 2.0 of the *MGK-264: REVISED Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document* (Weiss, March 10, 2006).

a. Occupational Toxicity

Table 12 provides a listing of the toxicological endpoints used in the MGK-264 occupational risk assessment.

Table 12: Summary of Toxicological Doses and Endpoints for MGK-264 for Use in Occupational Risk Assessment

Exposure Scenario	Doses, Uncertainty Factors (UFs), and Safety Factors (SF)	Level of Concern: Target Margin of Exposure (MOE)	Study and Toxicological Effects
Dermal Exposures - all durations	Offspring LOAEL = 61mg/kg/day UF =100 Lack of NOAEL UF = 10X Total UF = 1,000 Used 10% dermal absorption	Occupational LOC: MOE = 1,000	Multi generation reproduction-toxicity rat Offspring LOAEL = 61mg/kg/day based on slight decreases in body weight in pups during lactation (MRID: 42155701) MGK-264 Human Dermal Absorption Study (MRID: 42976701, 42976702)
Inhalation - all durations	LOAEL = 0.01 mg/L converted to 1.9 mg/kg/day UF =100 Lack of NOAEL UF = 10X Total UF = 1,000	Occupational LOC: MOE = 1,000	90 day inhalation study - rat LOAEL = 0.01 mg/L (1.9 mg/kg/day) based on hyperplasia and metaplasia in larynx (MRID: 43309001)

NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level

The level of concern MOEs for occupational exposure include the conventional uncertainty factor of 100X (10X for interspecies extrapolation and 10X for intraspecies variation) and an additional 10X for the use of a LOAEL (i.e, lack of a NOAEL in the selected study) for dermal and inhalation exposure risk assessments for all durations.

Workers can be exposed to a pesticide through mixing, loading, or applying the pesticide, and through reentering a treated site. Worker risk is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to the NOAEL taken from animal studies. In the case of MGK-264, MOEs greater than 1,000 for short- and intermediate-term exposures are not a concern. No long term exposures (> 6 months) are expected.

b. Occupational Handler Exposure

The quantitative exposure and risk assessment developed for occupational handlers is based on the following scenarios:

Mixing/Loading/Applying (M/L/A):

- M/L/A liquids with low pressure hand-wand (LPH)
- M/L/A liquids with backpack sprayer
- M/L/A liquid with handgun
- M/L/A liquids with high pressure hand-wand (HPH)

Applying:

- Applying ready-to-use (RTU) paste
- Applying RTU wipes
- Applying pour-on or spot-on
- Applying RTU formulations via trigger-pump sprayer
- Applying RTU formulations to pet via hair mousse, soap, lotion, gel, comb, or roll-on
- Applying RTU shampoo
- Applying RTU formulations with aerosol cans
- Applying RTU formulations with fogger cans
- Applying fogs with hand-held equipment
- Applying liquid formulations for handheld fogger application

Due to lack of applicator exposure data, MOEs were not calculated for handlers applying liquids for dip applications. Based on high MOEs from a pet shampoo study which likely pose similar exposure, there are no interim mitigation measures for applicators making dips to pets. Applicator pet dip exposure data may be required for this scenario pending the outcome of a confirmatory 21-day dermal toxicity study.

c. Occupational Handler Risk Summary

With the exception of the four occupational handler scenarios in Table 13 below, estimated MOEs were below EPA's level of concern for most scenarios at baseline protection, which includes a single layer of clothes plus shoes and socks, with no gloves, and no respirator. Dermal MOEs ranged from 1,400 (applying paste or shampoo to animals) to over a million (mixing and loading for dip applications) for most scenarios. Possible dermal risks were identified for four scenarios. The addition of gloves elevated the estimated MOEs to greater than 1,000 for mixer, loader, and applicator scenarios using handheld equipment, such as handwand, backpack, or handgun spray equipment. There were additional concerns for applicators using hand-held fogging equipment, which is further explained below.

Most occupational handler scenarios did not required additional inhalation protection with a respirator. Inhalation MOEs for most scenarios ranged from 1,900 (applying dusts with shaker can) to over a million (applying shampoo to pets).

Table 13: MGK-264 Occupational Handler Scenarios of Concern

Exposure Scenario	Application Rate	Area Treated	Baseline Dermal MOE	Baseline Inhalation MOE	PPE-Gloves Dermal MOE
M/L/A Liquids w/ LPH	0.00005 lb ai/ft^2	11,200 ft^2	**654**	7,800	150,000

Table 13: MGK-264 Occupational Handler Scenarios of Concern					
Exposure Scenario	**Application Rate**	**Area Treated**	**Baseline Dermal MOE**	**Baseline Inhalation MOE**	**PPE-Gloves Dermal MOE**
M/L/A Liquids w/ Backpack	0.00005 lb ai/ft^2	11,200 ft^2	No data	7,800	26,000
	0.3 lb ai/A	1 A	No data	14,000	49,000
	0.00025 lb ai/ animal	25 animals	No data	690,000	2,300,000
M/L/A Liquids w/ Backpack	0.07 lb ai/A	5 A	No data	12,000	42,000
M/L/A Liquid w/ Handgun	0.3 lb ai/A	5 A	No data	46,000	90,000
	0.00005 lb ai/ft^2	11,200 ft^2	No data	120,000	240,000
	0.00025 lb ai/ animal	25 animals	No data	> 1,000,000	> 1,000,000

Indoor Handheld Fogging

The Agency does not have data to estimate risk to applicators fogging with hand-held equipment indoors. Due to insufficient information, two different handheld fogging studies that were submitted for other chemicals were used for inhalation and dermal risk assessment for MGK-264.

The exposure values estimated from the two studies differ greatly depending on the type of equipment, duration of application, size of fogging area, and air flow. One study with the pyrethroid prallethrin (MRID 45869301) was conducted to estimate exposure from a short (6 minute) fogging application in a small space. Another study conducted in a Florida greenhouse (MRID 40350501) may be more appropriate to estimate exposure for greenhouse and warehouse applications. The estimated MOE from inhalation exposure using the prallethrin study was 12, while the MOE was 5,700 using the Florida greenhouse study. Additional information is needed to assess handheld fogging exposure for MGK-264. Until data are submitted that satisfy the Agency's concerns for applicators using handheld foggers, additional PPE, including double layers and a respirator, are required.

d. Occupational Post-Application Summary

The Agency uses the term "post-application" to describe exposures to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. MGK-264 uses that may result in foliar contact were identified in the following crop groupings based on EPA's review of current MGK-264 uses:

- Floriculture crops grown for cutting;
- Floriculture crops not grown for cutting;
- Evergreen trees (Christmas trees);
- Turf/sod (e.g., golf courses, sod farms); and
- Nursery crops (e.g., container and balled and burlapped ornamentals).

For MGK-264, the exposure durations for post-application risk assessment were short-term (up to 30 days) and intermediate-term (greater than 30 days up to several months).

However, since the dermal toxicological endpoint was the same for short- and intermediate-term exposures, the short- and intermediate-term post-application risks are the same.

Inhalation exposures are thought to be negligible in outdoor post-application scenarios, since MGK-264 has low vapor pressure and the dilution with outdoor air is considered infinite. For indoor scenarios, under the Worker Protection Standard (WPS) for Agricultural Pesticides (40 CFR 170) greenhouses must be appropriately ventilated following pesticide applications so that post-application inhalation exposures are minimal. As a result, post-application inhalation exposures from outdoor applications were not considered in this assessment and ventilation requirements will be in place for greenhouse applications.

None of the scenarios assessed have a risk concern on day 0, or 12 hours after application. Transplanting many crops, including in the ornamental and forestry industry and various operations with Christmas trees, such as pruning or balling, do not involve substantial foliar contact; therefore they have not been evaluated in this risk assessment. Post-application risk at the current reentry interval (REI) of 12 hours is below EPA's level of concern for all post-application scenarios that fall under the Worker Protection Standard. This REI does not apply to occupational handlers that are not covered by the WPS.

III. MGK-264 Ecological Fate and Effects Risk Assessment

The Agency has conducted an environmental assessment for MKG-264 for the purposes of making a reregistration decision. The Agency evaluated environmental fate, wildlife, and aquatic organism toxicity studies submitted for MGK-264 and determined that the data are adequate to support a reregistration decision. More in depth details of the toxicity to aquatic and terrestrial organisms, as well as fate and persistence studies used to develop the risk assessments are provided in the *Screening Ecological Risk Assessment for the Reregistration of MGK-264 Insecticide Synergist* (Lee, September, 29, 2004). A summary of the environmental risk assessment findings and conclusions is provided below.

1. Environmental Fate and Transport Properties

The physical properties and fate characteristics of MGK-264 indicate that it is a persistent compound, and that it will be mobile in coarse soils (K_{oc}=636 in sand). MGK-264 is immobile in clay soils (K_{oc}=3106 in clay loam), which may serve as a sink. MGK-264 may partition to particulate matter in water. MGK-264 is stable to hydrolysis, direct photolysis, and soil photolysis. Aerobic and anaerobic soil metabolism are very slow (mean aerobic half-life was 341 days). The expected half-life in air is short (half-life = 1.4 hours), so long-range transport is not expected, and it is expected to be an aerosol rather than a gas. The combined persistence and mobility would predict MGK-264 being found in surface and ground water, however, limited monitoring shows no detections above the limit of detection (LOD) of 0.1 ppb.

2. Ecological Risk Assessment

To estimate potential ecological risk, EPA integrated the results of exposure and ecotoxicity studies using the risk quotient method. Risk quotients (RQs) are calculated by

dividing exposure estimates by ecotoxicity values, both acute and chronic, for various wildlife species. RQs are then compared to the Agency's levels of concern (LOCs), which are listed below in Table 14. Generally, the higher the RQ, the greater the potential risk. Risk characterization provides further information on the likelihood of adverse effects occurring by considering the fate of the chemical in the environment, communities and species potentially at risk, their spatial and temporal distributions, and the nature of the effects observed in studies.

Table 14: EPA's Levels of Concern and Associated Risk Presumptions

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

According to use information available to the Agency and information provided by the technical registrant, most of the use of MGK-264 is for residential insect control, direct application to animals, and veterinary use. Since there are no agricultural or wide area mosquito abatement uses for MGK-264, applications to turf, ornamentals, and lawns were considered the most likely uses that could lead to exposure to non-target organisms in the environment. Two turf scenarios were used in the ecological risk assessment. There were no frequency or reapplication directions on the MGK-264 Master Label, so for the risk assessment it was assumed that MGK-264 was applied up to 20 times at 7-day intervals. The maximum use rate considered was 2.2 lbs a.i./acre for lawn insect control. The registrant has since agreed to reduce the outdoor spray application rate from 2.2 lbs a.i./acre to 0.3 lbs a.i./acre, which will decrease the RQs estimated in this risk assessment.

3. Risk to Aquatic Animals

Freshwater

MGK-264 is considered to be "moderately toxic" to freshwater fish and invertebrates on an acute basis. The median lethal concentrations (LC_{50}) for freshwater fish range from 1.4 to 2.4 ppm and the effects concentration level (EC_{50}) is 2.3 ppm for freshwater invertebrates. There were screening level endangered species risk exceedences for listed freshwater fish with RQs ranging up to 0.40 and listed freshwater invertebrates with RQs ranging up to 0.24 at an application rate of 2.2 lbs a.i./acre.

There were no aquatic chronic studies available for this risk assessment.

Estuarine/Marine

There were no data available to complete a risk assessment for estuarine/marine species; however, the possible risk to freshwater species the rate of 2.2 lbs a.i./acre suggests a potential risk concern for estuarine/marine species at this rate as well.

4. Risk to Terrestrial Animals

Birds

For birds, MGK-264 is practically nontoxic on an acute basis as no deaths were observed at any dose level. Therefore, no risk assessment was conducted for birds.

Mammals

For mammals, MGK-264 is practically nontoxic on an acute basis as no deaths were observed at any dose level. No risk assessment was conducted for acute risk to mammals.

For chronic exposure in mammals, the multi-generation rat study produced a LOAEL of 1,250 mg/kg diet, with an endpoint of reduced body weight gain in the pups. A NOAEL was not observed.

A range of applications from 1 to 20 per year, with an application interval of 7 days was assessed at a rate of 2.2 lbs a.i./acre. There were chronic risk exceedences depending on the number of applications made in a year. For mammals feeding on short grass, RQs range from 0.42 (1 application) to 3.03 (20 applications), for tall grass RQs range from 0.19 (1 application) to 1.39 (20 applications), and for broadleaf plants/small insects RQs range from 0.24 (1 application) to 1.7 (20 application). There were no chronic LOC exceedences for mammals feeding on fruits/pods/large insects. Many of these RQs are expected to be substantially reduced when labels are amended to reflect a maximum application rate of 0.3 lbs a.i./acre.

5. Risk to Plants

No data were required for plants; therefore, no assessment was conducted to evaluate risks to terrestrial or aquatic plants. It is unlikely that MGK-264 would cause phytotoxicity in plants.

6. Endangered Species

The Agency's screening level assessment indicated that MGK-264 is practically nontoxic to birds and mammals on an acute basis. No deaths were observed at any dose level and no risk assessments were conducted for acute risk to mammals or birds. These results suggest that MGK-264 will have no direct acute effects on threatened and endangered mammals or birds. There are no data or reported incidents on plant effects from MGK-264. The preliminary risk assessment for endangered species indicates that RQs exceed endangered species LOCs for

aquatic organisms. However, this preliminary assessment will be modified as proposed label changes limiting applications to 0.3 lbs a.i./acre are implemented. Further, potential indirect effects to any species dependent upon a species that experiences effects from use of MGK-264 can not be precluded based on the screening level ecological risk assessment. These findings are based solely on EPA's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility and Tolerance Reassessment

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic data to support reregistration of products containing MGK-264. 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 MGK-264.

The Agency has completed its assessment of the dietary, occupational, residential, and ecological risk associated with the use of pesticide products containing the active ingredient MGK-264. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient MGK-264, the Agency has sufficient information on the human health and ecological effects to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that products containing MGK-264 are eligible for reregistration provided that: (i) the risk mitigation measures outlined in this document are adopted, and (ii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of MGK-264 that are eligible for reregistration. Appendix B identifies the generic data that the Agency reviewed as part of its determination of reregistration eligibility of MGK-264, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of MGK-264, the Agency has determined that MGK-264 products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA and FQPA. Accordingly, should a registrant fail to implement any of the reregistration requirements identified in this document, the Agency may take regulatory action to address the risk concerns from the use of MGK-264. If all changes outlined in this document are incorporated into the product labels, and all required data are acceptable, then all current risks for MGK-264 will be adequately mitigated for the purposes of this determination. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained under "Endangered Species Concerns" above.

B. Regulatory Position

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for MGK-264. EPA released its MGK-264

preliminary risk assessments for public comment on April 27, 2005, for a 60-day public comment period (Phase 3 of the 6 Phase public participation process). Where appropriate, the MGK-264 risk assessments were revised in response to the comments received, and the assessments were released for an additional 60 day public comment period on September 21, 2005 (Phase 5 of the 6 Phase public participation process). During both public comment periods, the Agency received comments from MGK Company, stakeholder groups such as the State and Local government entities in California, California Water Boards, and Publicly Owned Treatment Works. The comments included concerns about synergistic effects with MGK-264, water quality concerns with urban runoff, and other water quality concerns from residential uses including pet shampoos. All of the preliminary and revised MGK-264 risk assessments, public comments, response to comments, and this RED document are available in the public docket (OPP-2005-0040) at EPA's docket and in the EPA's electronic docket at www.regulations.gov.

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with MGK-264. EPA has determined that risk from dietary (food + water) exposure is within its own "risk cup." An aggregate assessment was conducted for MGK-264 for exposures through dietary and residential exposures. The Agency has determined that with the mitigation measures outlined below the human health risks from these combined exposures are within acceptable levels. In other words, EPA has concluded that the tolerances for MGK-264 meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food, drinking water, and residential sources.

b. Determination of Safety to U.S. Population

The Agency has determined that the established tolerances for MGK-264, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, as amended by FQPA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of MGK-264. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices, and the environmental behavior of MGK-264. The acute, chronic, short-term, intermediate-term, and long-term risks from food, drinking water, and residential exposures do not exceed the Agency's level of concern either individually or aggregated, after mitigation measures outlined below are considered.

c. Determination of Safety to Infants and Children

EPA has determined that the established tolerances for MGK-264, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors on the toxicity, use practices and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption

patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of MGK-264 residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of MGK-264, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and other information. The FQPA Safety Factor has been reduced to 1X because there are no residual uncertainties for pre- and/or post-natal toxicity, exposure is not underestimated, and there is no evidence of increased susceptibility.

2. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

In the available toxicity studies on MGK-264, there was no estrogen or androgen mediated toxicity. It is noted, however, that the rat carcinogenicity study demonstrated increased thyroid tumors that may have been related to perturbation of the thyroid/liver/pituitary axis to alter thyroid hormone metabolism. EPA believes the endpoints and risk scenarios evaluated are protective of this potential endocrine effect. When additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, MGK-264 may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

3. Cumulative Risks

The Food Quality Protection Act (FQPA) requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for MGK-264 and any other substances. Therefore, for purpose of this decision, EPA has not assemmed

that MGK-264 shares a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

C. Tolerance Reassessment Summary

Table 16 provides a summary of the MGK-264 tolerance reassessment decision. Further tolerance explanation is provided after the table.

All references that indicate use in combination with another active ingredient, such as pyrethrins or PBO, are removed, or decoupled from the tolerance expressions for MGK-264. EPA will propose to update 40 CFR part 180 to reflect all of these changes as summarized in Table 15 below.

Table 15: 40 CFR Changes for MGK-264

Current 40 CFR Citation	Action	Comment
§180.367(a)(2)(i)	Remove	This section refers MGK-264 being used in conjunction with pyrethrins and piperonyl butoxide in food-processing areas. All references to use with multiple chemicals will be removed from the CFR.
§180. 367 (a)(2)(ii)	Retain	This tolerance for food areas will be retained as specified in Table 16 below. Recodify under §180. 367(a)(1)
§180.127(a)(2)(iii)	Remove	Old language not used in the CFR currently.

Table 16: Tolerance Reassessment Summary for MGK-264

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment
Tolerances Listed Under 40 CFR §180. 367(a)(1)			
Cattle, fat	0.3	Revoke	Direct dermal uses are no longer being supported for uses on livestock intended for food uses.
Goat, fat	0.3	Revoke	Direct dermal uses are no longer being supported for uses on livestock intended for food uses.
Hog, fat	0.3	Revoke	Direct dermal uses are no longer being supported for uses on livestock intended for food uses.
Horse, fat	0.3	Revoke	Direct dermal uses are no longer being supported for uses on livestock intended for food uses.

Table 16: Tolerance Reassessment Summary for MGK-264			
Commodity	**Current Tolerance (ppm)**	**Tolerance Reassessment (ppm)**	**Comment**
Milk, fat	0.3	Revoke	Direct dermal uses are no longer being supported for uses on livestock intended for food uses.
Sheep, fat	0.3	Revoke	Direct dermal uses are no longer being supported for uses on livestock intended for food uses.
Tolerances Listed Under 40 CFR §180.905(a)(6)			
Raw Agricultural Commodities	Exemption	Revoke	Formerly established under 180.1001 (b). The registrant has agreed to drop all agricultural uses of MGK-264 on growing crops
Tolerances Listed Under 40 CFR §180. 367(a)(2)(ii)			
Processed Food (food handling establishments)	10	5	Decouple MGK-264 tolerance from pyrethrins and PBO. The new tolerance should be stated as: "A tolerance of 5 ppm is established for residues of the insecticide synergist MGK-264 in or on all food items in food handling establishments where food and food products are held, processed, prepared and/or served."

Tolerance exemption under CFR §180.1001(b)(2)

MGK-264 is currently exempt from the requirement of a tolerance when applied to growing crops in accordance with good agricultural practice [40 CFR §180.1001(b)(2)]. Based on the decision of the registrant to drop all agricultural uses of MGK-264 on growing crops, EPA will propose to revoke this tolerance exemption.

Tolerances Established Under CFR §180.367

Tolerances are established in 40 CFR §180.367(a)(1) for residues of n-octyl bicycloheptene dicarboximide (MGK-264) *per se,* resulting from dermal applications to livestock, in/on the fat of cattle, goat, sheep, hog, horse, and milk at 0.3 ppm. Because direct dermal uses are no longer being supported for uses on livestock intended for food uses, EPA will propose to revoke these tolerances.

The remainder of tolerances and tolerance exemptions established in CFR §180.367 pertain to uses of MGK-264 in food handling establishments and warehouses.

- According to 40 CFR §180.367(a)(2)(i), MGK-264 may be safely used in combination with piperonyl butoxide (PBO) and pyrethrins for control of insects in food-processing and food-storage areas, provided that the food is removed or covered prior to such use.

- According to 40 CFR §180.367(a)(2)(ii), residues in food resulting from the use described in the preceding paragraph shall not exceed 10 ppm of MGK-264, 10 ppm of PBO, and 1 ppm of pyrethrins.

- According to 40 CFR §180.367(a)(2)(iii), to assure the safe use of MGK-264, the label and labeling shall conform to that registered with the U.S. EPA, and MGK-264 shall be used in accordance with such label and labeling.

EPA will propose that the tolerance level of 10 ppm for MGK-264 in all foods be reduced to 5.0 ppm to better reflect the likely residue levels expected based on the residue data and use pattern. Presently, 40 CFR §180.367(a)(2)(i) specifies that MGK-264 may be used in combination with PBO and pyrethrins for insect control in food-processing and food-storage areas, provided that the food is removed or covered prior to such use.

However, MGK Company plans to market use of MGK-264-containing products in warehouses without removing or covering food items which are packaged in cloth, paper, or foil bags. Adequate residue data were submitted for MGK-264 reflecting residue levels based on this use pattern. Consequently, EPA will propose that a paragraph be added to 40 CFR §180.367 specifying that bagged foods in warehouse storage need not be removed or covered prior to applications of formulations containing MGK-264. The residue data indicate that these uncovered bagged foods in warehouse storage are likely to exhibit finite levels of MGK-264 residues (<5.0 ppm) following treatment. In contrast, the covered or removed foods in food processing/handling establishments are not likely to have detectable residue levels. This determination does not apply to piperonyl butoxide and pyrethrins because the labels for these pesticide chemicals were not examined in this decision, but are considered in separate Reregistration Eligibility Decision documents. Products containing multiple active ingredients will need to be labeled in accordance with the most protective provisions of any single component active ingredient.

Codex/International Harmonization

There are no Codex, Canadian, or Mexican tolerances/MRLs for MGK-264.

Updated 40 CFR

The 40 CFR should be updated to incorporate all the changes specified above. Once these changes are made the CFR should be in the format listed below.

> **§180.367 *n*-Octyl bicycloheptenedicarboximide; tolerances for residues.**
>
> (a)*General.*
>
> (1) A tolerance of 5 ppm is established for residues of the insecticide synergist *n*-octyl bicycloheptene-dicarboximide in or on all food items in food handling establishments where food and food products are held, processed, prepared and/or served.
>
> (b) *Section 18 emergency exemptions.*
> [Reserved]

(c) *Tolerances with regional registrations.*
[Reserved]
(d) *Indirect or inadvertent residues.*
[Reserved]

D. Regulatory Rationale

The Agency has determined that MGK-264 is eligible for reregistration provided that the risk mitigation measures and label amendments specified in this RED are implemented. The following is a summary of the rationale for managing risks associated with the use of MGK-264. Additional label restrictions that were assumed in the risk assessments for MGK-264 are included in the label changes summary table (Table 17).

1. Human Health Risk

a. Dietary (Food Only) Risk Mitigation

Acute Risk

Acute dietary (food only) risk does not exceed the Agency's level of concern; acute dietary risk estimates are 13% of the aPAD for females 13 to 49 years old, the only sub-population that needed to be assessed. Therefore, no mitigation is necessary for this scenario.

Chronic Risk

The chronic dietary (food only) risk is below the Agency's level of concern; risk estimated are 19% cPAD for the general U.S. population, and 51% of the cPAD for children 1-2 years old, the most highly exposed subpopulation. Therefore, no mitigation is necessary for this scenario.

b. Residential Risk Mitigation

i. Handler

In the residential handler exposure assessment a number of scenarios were assessed to estimate the exposure to homeowners handling products containing MGK-264. The results from the assessed residential handler scenarios indicate there are no residential risks of concern when MGK-264 is mixed, loaded, applied, or handled by homeowners. Therefore, no mitigation is necessary for these scenarios.

There were no dermal or inhalation handler data available for handlers applying liquids for dip applications to pets. However, a scenario was assessed for residential handlers applying shampoos to pets, which resulted in risks well above the Agency's level of concern for both dermal (MOE is about 2,300) and inhalation (MOE is well over a million) exposures. Since the

MOEs in the shampoo scenario are high, no additional steps are necessary to address risk from dips while confirmatory data are being developed.

The dermal exposure from dips is expected to be higher than inhalation exposure. The dermal risk assessment contains several conservative assumptions, as described below in the insect repellent section, which may exaggerate the possible dermal risk from dips. The registrant has agreed to conduct a 21 day dermal toxicity study in rats with MGK-264 up to the limit dose of 1,000 milligrams per kilogram per day to confirm the Agency's assumption that risk from dips are not above the Agency's level of concern. Exposure data for applicators using dips will be held in reserve pending the outcome of the dermal toxicity study.

ii. Post-Application

A number of post-application residential scenarios were assessed for adults and children exposed to MGK-264 indirectly after application. There were post-application dermal risk concerns for toddlers exposed to MGK-264 from indoor spray applications, indoor fogger applications, indoor dust applications, and from application of insect repellents. Aerosol space and metered release applications were potentially a concern for post-application inhalation exposure. Dusts applied as a broadcast treatment to carpets were potentially a concern for post-application incidental oral exposure. For adults, there were post-application dermal risk concerns from exposure to indoor dust applications to carpets and from use of insect repellants. Indoor space and metered release applications were a concern for post-application inhalation exposure.

Indoor Spray Applications – Surface and Fogger Applications

There are potential post-application dermal concerns for toddlers exposed to MGK-264 after indoor surface spray to both carpeted and hard surfaces (MOE is 780) and fogger applications to carpeted surfaces (MOE is 840). The toxicity studies selected for the dermal risk assessment contain several conservative assumptions which may exaggerate the toddler dermal risk estimated for post-application exposure from indoor surface and fogger applications. These assumptions, which are described further under the insect repellent section below, include selecting an oral study instead of a route-specific dermal study for the risk assessment, adding an additional 10X safety factor to the target MOE due to lack of a NOAEL in the oral study, plus a conservative dermal absorption factor. Considering all of these factors together, the Agency does not believe there is a post-application dermal risk of concern from use of surface or fogging sprays indoors. The registrant has agreed to conduct a 21 day dermal toxicity study in rats with MGK-264 up to the limit dose of 1,000 milligrams per kilogram per day to confirm this conclusion. This study will allow the Agency to assess any possible dermal effects from MGK-264 through a route-specific study more appropriate for dermal risk assessment.

Dusts - Broadcast Applications to Carpets

Applying dusts to carpets over a wide area can lead to exposure to children through incidental oral exposures. Most of the labels containing this type of application indicate the dust needs to be vacuumed after application. Since there is no information to determine how much

MGK-264 is removed from the carpet while vacuuming, there is an unknown amount of dust available for exposure to children. Using various assumptions in the assessment, the MOEs range from 70 to 410. The Agency has concerns from the potential incidental oral exposure children could have from this type of broadcast application to large carpeted areas. To reduce exposure to children from broadcast dust applications to carpets, the registrants have agreed to restrict carpet applications to spot treatments no greater than 3 feet by 3 feet in area.

In addition to the use on carpets, MGK-264 is also used on turf, and so an incidental oral assessment was conducted for use on turf which is considered a conservative risk estimate for oral exposures. This assessment includes 3 separate incidental oral exposure activities and assumes the exposures occur simultaneously. The turf scenario methodology, which has been peer reviewed and is better understood than the carpet dust scenario, includes incidental oral exposure to pesticide on turf from (1) hand to mouth activities, (2) object to mouth activities, and (3) ingesting soil particles. MOEs from all three of these incidental oral turf scenarios are greater than the Agency's target MOE of 1,000 with MOEs ranging from 14,000 to 4 million. Given the conservative nature of the turf exposure scenario, it is unlikely that the magnitude and frequency of exposure to small spot treatments (3 sq ft) of dust formulations of MGK-264 would result in exposure estimates equal to or greater than those estimated for the residential lawns. Since there are no incidental oral risks of concern from the turf scenario, and the registrants have agreed to reduce the amount of potential exposure to children by restricting applications to spots only, the Agency is not requiring any additional data at this time.

Aerosol Space Sprays

There are potential inhalation risks from post-application exposure to MGK-264 from aerosol space sprays. This scenario was evaluated with data from a Non-Dietary Exposure Task Force (NDETF) study that measured the air concentration after an aerosol application of a pyrethrins and piperonyl butoxide product assuming no deposition and no ventilation. The study application rate was adjusted to reflect the MGK-264 application rate of 0.001 lb ai/1,000 ft^3. With these assumptions the MOE for inhalation post-application exposure to MKG-264 was estimated to be 170 for adults and 52 for children. MGK Company has agreed to reduce the rate for aerosol space sprays from 0.001 lb ai/1,000 ft3 to 0.00015 lb ai/1,000 ft3. Using this new application rate the MOEs are expected to be about 10 times higher.

In addition, there are currently label statements on some MGK-264 products that contain the instructions: "When using indoors, do not remain in treated area. Ventilate the area for 15 minutes following treatment. Allow treated surfaces to thoroughly dry before use." Since ventilation was not factored into the assessment, it can be expected that requiring a ventilation period before entering a treated area would further reduce the potential exposure to adults and children. Therefore, all MGK-264 aerosol space spray products will be required to include a 15 minute ventilation reentry restriction. In addition, MGK Company has agreed to conduct a repeat aerosol study with MGK-264 with the lower rate and to follow the specific label directions for ventilation periods in the study.

Pet Applications with Dusts

There are both incidental oral (MOE is 130) and dermal (MOE is 61) risk concerns with post-application exposure for toddlers exposed to pets treated with dust products. Therefore, MGK Company has agreed to phase out all dust products used on pets.

Insect Repellents

There are potential dermal concerns for MGK-264 products applied to both adults and children as insect repellents with MOEs ranging from 24 to 160. The toxicity studies selected for the dermal risk assessment contain several conservative assumptions which may exaggerate the dermal risk from repellents. A dermal toxicity study in rabbits was conducted for MGK-264, but was not selected for risk calculation because the highest dose tested (100 mg/kg/day) did not elicit systemic toxicity. Since animals were not dosed at levels above 100 mg/kg/day in the dermal study an oral study was selected for the dermal risk assessment.

The dermal risk assessment for MGK-264 is based on a LOAEL of 61 mg/kg/day from a multi-generation reproduction study in rats. The LOAEL was based on slight decreases in maternal body weight. An additional 10X safety factor was added to the LOAEL, because a NOAEL was not reached in this study. In addition, a dermal absorption factor of 10 percent from a study using human volunteers was factored into the dermal calculation. The dermal absorption factor of 10% that was factored into the dermal assessment includes the portion of radioactive material that was not recovered in the human dermal absorption study (MRID: 42976701, -02). About 1% of the radiolabelled material was recovered in the human volunteers, with about 9% assumed to be retained in the body. It is an upper bound assumption to include all of the unaccounted for radioactivity in the dermal absorption factor.

Considering all of these factors together and that no systemic effects were observed in the rabbit dermal study at 100 milligrams per kilogram per day, the Agency does not believe there is a risk of concern from use of repellents with MGK-264. MGK Company has agreed to conduct a 21-day dermal toxicity study in rats with MGK-264 up to the limit dose of 1,000 milligrams per kilogram per day to confirm this conclusion. This study will allow the Agency to assess any possible dermal effects from MGK-264 insect repellents through a route-specific study more appropriate for dermal risk assessment. Depending on the results of this study, further mitigation could be required in the future for insect repellents.

Indoor Metered Release Devices - Residential

There are potential risk concerns for post-application short- and intermediate-term exposures following indoor applications with metered release devices. The MOEs range from 13 to 440 and are less than the target MOE of 1,000. The risk calculations for the metered release scenarios are conservative because it was assumed that the aerosol sprays would remain airborne until they were removed by ventilation and the effect of aerosol spray settling was not considered. Aerosol spray settling could be a major factor depending upon the aerosol droplet size and rate of evaporation. Information regarding the aerosol droplet size and evaporation rate

could be used to refine the risks, particularly for the residential scenarios where the ventilation removal rate is probably slower than the settling rate.

In the absence of such data, to reduce the risks to potentially sensitive bystander populations, MGK Company has agreed to remove use sites where sensitive populations could be present from their metered release device product labels including day care centers, nursing homes, schools, and hospitals. In addition, EPA is requiring air concentration and particle size data for indoor metered release devices. Use of metered release device in residential areas will be prohibited unless acceptable data are submitted that show there are no risks of concern to residential populations.

Outdoor Residential Misting Systems

MGK Company is not supporting the use of MGK-264 in outdoor residential misting systems, and has agreed to include a statement on all technical labels prohibiting use in these systems. All end-use product labels will also be required to include a label statement prohibiting use in outdoor residential misting systems. Table 17 contains a list of all label statements required for the reregistration of MGK-264.

c. Aggregate Risk Mitigation

Food and drinking water exposures were aggregated for acute (one day) and chronic (one year or more) durations. A short-term aggregate assessment was also completed since some MGK-264 residential uses represent short-term exposure scenarios. The short-term aggregate risk assessment added dermal, oral non-dietary exposure, and average food and water exposures since there was a common toxicity endpoint of decreased pup body weight for these routes of exposure.

i. Acute and Chronic Aggregate Risk (Food + Water)

Acute DWLOC

Acute DWLOCs were calculated based on acute dietary exposure estimates and default body weights and water consumption figures. The EDWCs for both surface water (EDWC = 11) and groundwater (EDWC = 0.12) are well below the acute DWLOCs (DWLOC = 26,160) for the only population subgroup (females 13-49 years old) that was relevant from the toxicity endpoints selected, indicating that acute aggregate exposure to MGK-264 in food and water is not a concern. Therefore, no mitigation is necessary for this scenario.

Chronic DWLOC

Chronic DWLOCs were calculated based on the chronic dietary exposure estimates and default body weights and water consumption figures. The EDWCs for both surface water (EDWC = 5.2) and groundwater (EDWC = 0.12) are well below the chronic DWLOCs for the general U.S. population (DWLOC = 1,722) and the most highly exposed sub-population, Children 1 to 2 years old (DWLOC Children 1-2 years = 301), indicating that chronic aggregate

exposure to MGK-264 in food and water is below the Agency's level of concern for these populations. Therefore, no mitigation is necessary for this scenario.

ii. Short-Term Aggregate (Food + Water + Residential)

The short term aggregate risk for MGK-264 was calculated by adding exposure estimates from food, drinking water, dermal, and incidental oral exposure pathways for the U.S. population and the highest exposed sub-population, children 1-2 years old, and comparing them with model based EDWCs. The aggregate MOE takes into account average food consumption values (calculated from the chronic dietary assessment), and oral and dermal exposures (from the indoor fogger scenario on hard floors at the rate of 0.01 lb ai/1,000 ft^2). The lowest short term DWLOC (38 ppb) for children 1-2 years old is higher than the surface water EDWC (0.2 ppb) and the ground water EDWC (0.12 ppb), and therefore does not result in a risk of concern for this scenario (indoor fogging to hard surfaces). Therefore, no mitigation is necessary.

Many of the indoor residential post-application use scenarios resulted in predicted risk levels that exceeded the Agency's level of concern by themselves (*i.e.,* without aggregating). Thus, the following scenarios were not included in the aggregate assessment indoor spray applications, fogger applications to carpets, dust applications to pets, insect repellents applied to humans, aerosol space sprays, metered release applications, and dusts applied as a broadcast treatment to carpets.

In general, the potential exposure to MGK-264 from residential scenarios exceeds that expected from food and water sources. Because the exposure contributions from food and water sources are relatively low in the aggregate risk assessment, mitigation for residential exposure scenarios of potential concern will be protective for the short-term aggregate risk from MGK-264.

d. Occupational Risk Mitigation

Occupational exposure assessments were completed by the Agency considering the use of baseline PPE and, if warranted, for handlers, increasing levels of PPE and engineering controls in order to estimate the potential impact on exposure and risk. The target MOE for MGK-264 is 1,000 for both dermal and inhalation exposures.

i. Handler Risk Mitigation

<u>Handheld Equipment</u>

There are possible dermal risk concerns for occupational applicators mixing, loading, and applying MGK-264 for scenarios using handheld equipment such as handwands, backpack, or handgun spray equipment. The addition of gloves while using handheld equipment increases the estimated MOEs to greater than 1,000. Therefore, MGK Company has agreed to add gloves to the baseline PPE requirement which includes long pants, long sleeved shirt, shoes and socks for all scenarios that involve occupational handlers applying MGK-264 with handheld equipment.

Handheld Foggers Applied Indoors (including thermal, cold, and ULV foggers)

The Agency does not have data to estimate risk to applicators fogging with hand-held equipment indoors. Due to insufficient information, two different handheld fogging studies that were submitted for other chemicals were used for inhalation and dermal risk calculation for MGK-264 that resulted in MOE estimates that ranged from 12 to 5711 for inhalation risk, and 2179 for dermal risk. Due to the great uncertainty in fogging practices with MGK-264, the Agency is requiring use and usage information to determine if the existing data are appropriate to calculate exposure values for fogging with MGK-264. Based on review of these use and usage data, the Agency will determine if further fogging exposure data are needed.

To mitigate potential inhalation and dermal risks to applicators using handheld fogging equipment, a dust-mist respirator (PF10) will be required in the interim to address inhalation risk concerns. Double layers, including gloves, coveralls over long-pants and a long sleeved shirt, shoes and socks, are required to address the dermal risk concerns. Based on review of the use/usage data the Agency may require additional exposure data in the future.

Dusts Applied through Power Dusters - Agricultural and Pest Control Operator (PCO) Handlers

The Agency was not able to assess scenarios involving dust applications with power dusters because there are no exposure data to represent this application method. Power dusters could potentially create a significant inhalation risk. Due to a lack of data on this exposure scenario and no interest in supporting this application method from MGK Company, labels will be amended to prohibit power dusters as an application method for MGK-264 for agricultural or PCO handlers. If there is interest in supporting this application method, acceptable handler exposure data with power dusters need to be submitted to the Agency.

Dusts Applied through Bulb Dusters

The Agency was not able to assess scenarios involving dust applications with bulb dusters because of a lack of data. Bulb dusters are only used for crack and crevice treatments, which reduces the possible exposure to an applicator. Due to small amounts of dust used in this application method, the exposure is expected to be negligible. Therefore, no mitigation or data are required for this scenario.

Pet Dip Applications

As stated above under the residential handler section, there is a data gap for handlers making dip applications to pets. There were no dermal or inhalation handler data available for handlers mixing/loading/applying liquids for dip applications. Based on high MOEs from a pet shampoo study, there are no interim mitigation measures for applicators making dips to pets. The dermal exposure from dips is expected to be higher than inhalation exposure; therefore, applicator pet dip exposure data may be required for this scenario pending the outcome of a 21-day dermal toxicity study that could change the dermal risk assessment for MGK-264.

ii. Post-Application Worker Risk Mitigation

Metered Release Devices – Occupational Settings

The Agency has similar concerns for post-application short- and intermediate- term exposures from these systems as described in the residential post-application section on this chapter. The risk estimates from these occupational uses are expected to be less of a concern due to the fact that occupational areas where these devices are installed generally have a greater ventilation capacity.

Therefore, to better understand the risks from metered release devices in occupational settings the Agency is requiring air concentration and particle size data for these products, as well as requiring the label changes included in Section V. Some products labeled for use in occupational areas are also labeled for use in residential settings and areas where children may be present. Therefore, as mentioned in the residential metered release device section above, MGK Company will remove the following use sites where potentially sensitive populations may be present from their metered release device product labels: day-care centers, nursing homes, and schools. Use of metered release device in residential areas will be prohibited unless acceptable data are submitted that show there are no risks of concern to residential populations.

2. Non-Target Organism (Ecological) Risk Management

For aquatic organisms, there were slight exceedences for endangered species for freshwater fish (maximum RQ = 0.40) and freshwater invertebrates (maximum RQ = 0.24). There were no data available for estuarine/marine species; however, the risk to freshwater species suggests a potential risk concern for estuarine/marine species as well. The maximum use rate considered in the assessment was 2.2 lbs a.i./acre for lawn insect control. The registrant has since agreed to reduce the outdoor spray application rate from 2.2 lbs a.i./acre to 0.3 lbs a.i./acre, which will decrease the RQs approximately 7 fold. This will also decrease the potential loading and exposure to aquatic organisms. The majority of RQs for aquatic organisms will be below the Agency's level of concern, with the highest RQ for freshwater fish about 0.06.

For terrestrial organisms, there were chronic risk exceedences for most mammals with RQs ranging up to 3.03. Again, the maximum use rate considered in the assessment was 2.2 lbs a.i./acre for lawn insect control. The registrant has since agreed to reduce the outdoor spray application rate from 2.2 lbs a.i./acre to 0.3 lbs a.i./acre, which will decrease the potential the RQs approximately 7 fold. As a result, all of the chronic RQs for terrestrial organisms are expected to fall below the Agency's level of concern at the rate of 0.3 lbs a.i./acre.

Other Urban Uses

In the MGK-264 ecological risk assessment two turf scenarios were used to estimate the potential risk from MGK-264 to the environment and resulted in slight potential risk exceedances for aquatic organisms. Although MGK-264 is registered for use on turf, it is also used on other sites including outdoor residential areas and a wide variety of indoor sites. The

Agency does not currently have a model available to assess the urban contribution to the residues of MGK-264 in the environment, but EPA is working to develop a model for this scenario. Comments from a variety of stakeholders and recent studies focusing on the contribution of pyrethroid residues used in urban settings to the estimated environmental concentration of pesticides have lead to further exploration of this area of pesticide contribution.

Development of a screening model which could simulate the fate and transport of pesticides applied in an urban setting would require a large body of data which is currently unavailable. For instance, an urban landscape cannot be simulated as easily as an agricultural field. The PRZM model simulates runoff from a field using readily available data describing surface soil characteristics and laboratory data detailing the persistence and mobility of pesticides in these soils. The field simulated is homogenously planted to a single crop, and soil and water are transported from the field to an adjacent receiving water body with dimensions consistent with USDA farm-pond construction guidelines.

By contrast, an urban landscape or suburban housing development consists of impervious surfaces such as streets and sidewalks, and permeable surfaces such as lawns and parkland. One could expect much greater mobility for pesticides applied to impervious surfaces, but laboratory soil metabolism studies may not provide an accurate measure of the persistence of pesticides on these surfaces. The path runoff water and eroded sediment might take is less obvious for an urban setting than an agricultural field. First, an urban landscape cannot be considered homogeneous, as the proportion of impervious and pervious surfaces varies for different locations. In addition, the flow path of runoff water and sediment is not necessarily a direct path over land, but can pass below ground through storm sewer networks, or be directed or slowed by pumping stations or temporary holding ponds.

The timing and magnitude of urban applications is less well defined than turf uses. While turf uses could occur within a predictable window during the growing season, the need for urban uses could occur at different times for different locations each year, and might occur at different times within the same watershed. In addition, since records of how and to what extent MGK-264 is applied by homeowners are less well defined than for professional applications, it is harder to estimate the total load to model.

Monitoring Data

The Agency considers surface water monitoring data in addition to modeling results when they are available. Available monitoring data in raw ground water and surface water, and in finished drinking water from four cities, indicate that MGK-264 has not been found at the detectable limit of 0.1 ppb.

There has been limited monitoring for the pyrethroids, but recently researchers from the University of California- Berkeley have published studies which reported transport of pyrethroids to stream bed sediment as a result of urban uses. In 2004, Weston, et al. collected sediment from creeks draining a residential area in Rosedale, California. The sediments were analyzed for 7 pyrethroids (including two currently in the reregistration process), as well as for other insecticides. All of the pyrethroids were detected in the bed sediment from at least one

sampling location. The researchers exposed the aquatic amphipod *Hyalella azteca* to the 21 sediment samples they collected; pesticide concentrations in 9 of these samples were sufficient to cause 90% mortality in the amphipods after a 10-day exposure. The concentrations of pyrethroids detected in the sediments were above the level expected to cause 50% mortality in *H. azteca*, suggesting that the pyrethroids were responsible for the observed toxicity.

In a subsequent study, Weston, et al. collected samples from 15 urban creeks in California and 12 in Tennessee. Toxicity to *H. azteca* was observed at least once with sediments taken from 12 of the 15 California sampling sites. In most cases, the toxicity could be accounted for by the concentrations of pyrethroids detected in the sediment. Pyrethroids were rarely detected in the Tennessee sediment samples, and exposure to the Tennessee sediments did not prove to be toxic to *H. azteca*. The Weston studies did not sample for MGK-264.

The Weston, et al. studies indicate that urban uses of pesticides can lead to surface-water contamination, including contamination by pesticides that would bind almost completely to soil in an agricultural setting. In general MGK-264 is more mobile in soils than the pyrethrins or the pyrethroids. Since MGK-264 is commonly formulated with these types of insecticides, efforts to better understand the conditions under which pyrethroids and pyrethrins might be transported to surface water would help improve our assessment of the scenarios in which MGK-264 might contribute to increased risk to aquatic organisms.

The results of the Weston, et al. studies have led a number of organizations, such as the California State Water Resources Control Board (SWRCB) to submit comments to the Agency calling for mitigation measures to prevent surface-water contamination. However, the lack of data and information to develop an urban pesticide transport model also makes it difficult to identify whether risks may exceed some LOCs, and appropriate mitigation at this time. The Agency is committed to develop mitigation options during the reregistration process, and to identify steps which can be taken to allow a greater understanding of potential ecological risk from urban use of pesticides.

It would be useful, as some commenters have suggested, performing a risk assessment for all of the pyrethrins, pyrethroids, and synergists at the same time. The Weston papers indicated that the sediments which proved toxic to the tested aquatic invertebrate were contaminated not only with the chemicals undergoing reregistration, but also pyrethroids such as bifenthrin and lambda-cyhalothrin.

The Agency will also continue in its efforts to develop a screening model for urban pesticide uses. Advances in the resolution of GIS databases may allow better representation of the impervious and pervious portions of a typical urban landscape. As it becomes clearer which uses are most likely to lead to transport of MGK-264 to surface water, the conceptual model of how urban transport should be simulated will be more focused.

The Agency plans to evaluate available published literature and call-in data to resolve data gaps to ensure a robust comparison of the potential ecological risk of all the pyrethrins, pyrethroids, and synergists during Registration Review. Toxicity data cited by several commenters from published literature are included in the Agency's ECOTOX database. The

Agency will evaluate the quality of studies to identify those to be included in the risk assessments during Registration Review.

V. What Registrants Need to Do

The Agency has determined that MGK-264 is eligible for reregistration provided that the mitigation measures and label changes identified in this RED are implemented. Registrants will need to amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table (Table 17). The Agency intends to issue Data Call-Ins (DCIs) requiring generic and product specific data. Generally, the registrant will have 90 days from receipt of a DCI to complete and submit response forms or request time extensions and/or waivers with a full written justification. For product-specific data, the registrant will have eight months to submit data and amended labels.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of MGK-264 for currently registered uses has been reviewed and determined to be substantially complete. However, the data listed below are necessary to confirm the reregistration eligibility decision documented in this RED.

Human Health Data Requirements

Toxicity Data

- 870.1100: Acute oral toxicity data on the technical grade product.
- 870.1300: Acute inhalation data on the technical grade product.
- 870.2600: Skin sensitization data on the technical grade product.
- 870.3200: 21-day dermal toxicity study in rats up to the limit dose of 1,000 mg/kg/day.

Chemistry

- 830.7050: UV/Vis data on the technical grade product.

Occupational and Residential Data

- 875.1700: Metered release devices. Use and usage information, as well as air concentration and particle size data.
- 875.1700: Applicators using handheld fogging equipment. Use and usage data on application practices.
- 875.1400: Aerosol Space Sprays. A repeat aerosol study with MGK-264 with ventilation periods included in the study.
- 875.2400 & 875.2500: Exposure data for pet dip applications.
- 875.2400 & 875.2500: Shampoo application exposure data (used carbaryl study in risk assessment).

- 875.2400 & 875.2500: Trigger pump spray exposure data (used propoxur study in risk assessment).

Environmental Fate and Ecological Effects Data

The following ecological studies are required for MGK-264:

- 850.2300: Avian reproduction study.
  The potential chronic risks to birds would be clearer if a study on avian reproductive effects was available. Chronic risk to birds may exist because the chronic RQ for mammals exceeds the Level of Concern. The avian reproduction study is required to remove or confirm the presumption of risk to birds.

- 850.1035 (mysid shrimp), 805.1025 (oyster), 850.1075 (fish) Acute toxicity studies.
  Acute toxicity data on estuarine/marine fish, invertebrates, and mollusks are required to clarify the potential ecological risks to aquatic estuarine/marine organisms. In the risk assessment uncertainty exists regarding risk to estuarine/marine species because of the presumed risk to freshwater species. These studies will remove uncertainty regarding the presumption of risk.

The following studies are reserved and may be required to refine the Environmental Fate and Ecological Effects assessment of MGK-264:

- 835.4300: Aerobic aquatic metabolism.
  The Agency's understanding of the exposure of aquatic and estuarine/marine organisms would be improved by submission of data on aerobic aquatic metabolism. This study will allow refinement of the modeled aquatic EECs, and possibly remove the presumption of risk to aquatic estuarine/marine organisms.

- 850.1730: Fish bioaccumulation study.
  The measured log K_{ow} value (3.70) indicates a potential for bioaccumulation in fish. Since fish are expected to be exposed to MGK-264, a fish bioaccumulation study (guideline 165-4) will indicate if there is any potential for food-chain effects in species that consume fish.

In addition to the ecological and fate data requirements listed above for MGK-264, there may be uncertainties about how the synergists effects from chemicals like MGK-264 and piperonyl butoxide could impact the risk to certain non-target organisms, specifically aquatic invertebrates, fish, and non-target insects. Since products formulated with piperonyl butoxide are registered for use in more outdoor areas than products containing MGK-264, additional confirmatory data for typical end-use products formulated with piperonyl butoxide will be required in the piperonyl butoxide RED and Data Call-In. Some of the data required for the piperonyl butoxide products will include products containing MGK-264.

2. Labeling Requirements

To ensure compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 17.

3. Spray Drift Management

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

Specific spray drift language for ground applications of MGK-264 are outlined in the "spray drift management" section of Table 17.

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 Bonnie Adler at (703) 308-8523.

In addition, efficacy data for all applications that target public health pests must be submitted, including data for insect repellents and metered release devices. Additional information on the efficacy data can be found in the Series 810 Product Performance Test Guidelines on the Agency's website.
(http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/810_Product_Performance_Test_Guidelines/index.html)

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 17. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

Labeling Changes Summary Table 17

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

Description	MGK-264 Required Labeling Language	Placement on Label
	Manufacturing-Use Products	
Required on all MUPs	"Only for formulation into a synergist for the following use(s) [fill blank only with those uses that are being supported by MP registrants]." "Not for formulation into an end use product with directions for use permitting use in power dusters." "Not for formulation into a dust end use product for use on pets." **Outdoor Residential Misting Systems** The following statement must appear on the MUP label of all liquid products that could feasibly be formulated into end-use products (e.g. liquid concentrates) for use in outdoor residential misting systems: "Not for formulation into an end use product for use in outdoor residential misting systems." **Pet Care** <u>Ready-to-use formulated products for use on pets eligible for reregistration must not contain a percentage of a.i. that exceeds the following</u>: Shampoos – 1.0 % ai Sprays – 2.5% ai Spot-on or Pour-on – 1.0 % ai Mousse, soap, lotion, roll-on, or gel – 0.5 % ai Comb – 0.5 % ai Wipe or rub – 1.5 % ai	Directions for Use

Description	MGK-264 Required Labeling Language	Placement on Label
	Towelettes-2% ai In addition for collars and dips, products must not contain a percentage of a.i. of MGK-264 that exceeds the following: Collar – 0.0022 lbs ai/collar Dip – 0.3 % ai per ounce of dip **Direct Application to Non-domestic Animals (non-food livestock only, i.e. donkeys, horses, ponies, mules)** Formulated products must not contain a percentage of a.i. that exceeds the following: Towelettes for application to horses– 37.5 mg ai/ towelette (or 0.0000826 lbs ai/wipe) **Repellent Applied to Humans** Formulated products eligible for reregistration must not contain a percentage of a.i. that exceeds the following: On skin or clothing – 5.0 % ai	
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 Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product 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. Do not contaminate water when disposing of equipment wash-waters."	Directions for Use

Description	MGK-264 Required Labeling Language	Placement on Label
End-Use Products Intended for Occupational Use (WPS and non-WPS)		
Handler PPE Requirements[1] for Liquid Products that are registered for use in handheld fogging equipment or could potentially be used in handheld fogging equipment. [including: microencapsulated concentrates and liquid concentrates] Notes: (1) If the use of handheld equipment such as handwands, backpack sprayers, or foggers is not feasible or is prohibited on the label, the statement requiring gloves for those uses may be omitted. (2) If dip applications are not feasible or are prohibited on the label, the statement requiring gloves and aprons for those uses may be omitted.	"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." "Applicators using hand held foggers in an enclosed area must wear: - coveralls over long-sleeved shirt and long pants, - chemical-resistant footwear plus socks, - chemical-resistant gloves, - chemical-resistant headgear, and - a half-face, full-face, or hood-style NIOSH-approved respirator with: -- a dust/mist filtering cartridge (MSHA/NIOSH approval number prefix TC-21C), or -- a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or -- a cartridge or canister with any N, R, P or HE filter." "All other mixers, loaders, applicators, and other handlers must wear the following: - long-sleeve shirt, - long pants, - shoes plus socks, - chemical-resistant gloves for applicators using handheld equipment (other than handheld foggers) or participating in dip treatments, and - chemical-resistant apron when participating in dip treatments." ***Instruction to Registrant:*** Drop the "N" type filter from the respirator statement, if the pesticide product contains, or is used with, oil.	Precautionary Statements: Hazards to Humans and Domestic Animals
Handler PPE Requirements[1] for Liquid Formulations	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are (*registrant inserts correct chemical-*	Precautionary Statements: Hazards to

Description	MGK-264 Required Labeling Language	Placement on Label
that prohibit the use of handheld fogging equipment or for products that could **NOT** feasibly be used in handheld fogging devices [including: total release foggers, or ready to use products such as foams, aerosols, gels, pastes, and pressurized liquids] Notes: (1) This entire statement may be omitted if the end-use product is labeled only for use on pets or humans. (2) If the use of handheld equipment such as handwands, backpack sprayers, or foggers is not feasible or is prohibited on the label, the statement requiring gloves for those uses may be omitted. (3) If dip applications are not feasible or are prohibited on the label, the statement requiring gloves and aprons for those uses may be omitted.	*resistant material*). If you want more options, follow the instructions for category *[registrant inserts A,B,C,D,E,F,G,or H]* on an EPA chemical-resistance category selection chart." "Mixers, loaders, applicators, and other handlers must wear the following: - long-sleeve shirt, - long pants, - shoes plus socks, - chemical-resistant gloves for applicators using handheld equipment or participating in dip treatments, and - chemical-resistant apron when participating in dip treatments."	Humans and Domestic Animals

Description	MGK-264 Required Labeling Language	Placement on Label
Handler PPE Requirements for Dusts [1]	"Personal Protective Equipment (PPE)" "Loaders, applicators, and other handlers must wear the following: - long-sleeve shirt, - long pants, - shoes plus socks."	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "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 for all products	"USER SAFETY RECOMMENDATIONS" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
User Safety Recommendations for all products EXCEPT those labeled solely for use on pets and humans.	"USER SAFETY RECOMMENDATIONS" "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards Statements for products labeled for outdoor	"ENVIRONMENTAL HAZARDS" "This product may contaminate water through runoff. This product has a potential for runoff for	Precautionary Statements under Environmental Hazards

Description	MGK-264 Required Labeling Language	Placement on Label
uses	several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product. 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."	
Environmental Hazards for Products labeled only for Indoor Use EXCEPT ready to use impregnated materials (e.g. flea collars, ear tags, coils, mats) (Note: Products used on domestic animals like flea collars and ear tags, generally do not require an Environmental Hazards statement.)	"ENVIRONMENTAL HAZARDS" "Do not contaminate water when disposing of equipment, washwater, or rinsate. See Directions for Use for additional precautions and requirements." **For indoor products packaged in containers equal to or greater than 5 gallons or 50 lbs add the following statement:** "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 under Environmental Hazards
Restricted-Entry Interval for products with WPS uses	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours."	Directions for Use, Agricultural Use Requirements Box
Early Entry Personal Protective Equipment for products with WPS uses	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as soil or water, is: - coveralls, - chemical-resistant gloves made of any waterproof material, and - shoes plus socks."	Directions for Use, Agricultural Use Requirements Box
Entry Restrictions for products with non-WPS uses on the label Note: This excludes products labeled for use when people are permitted	**Entry Restriction for products applied as a spray (does not apply to products applied directly to humans or domestic animals or applied when people are permitted to be present):** "Do not enter or allow others to enter until sprays have dried." **Entry Restriction for products applied dry:**	If no WPS uses on the product label, place the appropriate statement in the Directions for Use Under General Precautions and Restrictions. If the

Description	MGK-264 Required Labeling Language	Placement on Label
to be present (e.g. metered release devices, pet applications, and repellents applied to humans)	"Do not enter or allow others to enter until dusts have settled." **Entry Restriction for total release foggers or products applied as a space spray:** "Do not allow adults, children, or pets to enter the treated area for at least 15 minutes, until vapors, mists, and aerosols have dispersed, and the treated area has been thoroughly ventilated."	product also contains WPS uses, then create a Non-Agricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.
Entry Restrictions for products labeled solely for use when people are present (e.g. metered release devices, applications to pets, and repellents applied to humans)	**Note to Registrants:** No entry restrictions are required. See below under Use Restrictions for further requirements.	
Entry Restrictions for products labeled for use when people are present (e.g. metered release devices, applications to pets, and repellents applied to humans) and for use on other sites as a directed or space spray.	**Products labeled for use as a directed spray (does not apply to products applied directly to domestic animals):** "Except when (insert application method or site that allows people to be present), do not enter or allow others to enter until sprays have dried." **Products labeled for use as a space spray:** "Except when (insert application method or site that allows people to be present), do not enter or allow others to enter until vapors, mists, and aerosols have dispersed, and the treated area has been thoroughly ventilated." Note to Registrant: An example is as follows: Except when applying in a metered release system, do not enter or allow others to enter until sprays have dried.	If no WPS uses on the product label, place the appropriate statement in the Directions for Use Under General Precautions and Restrictions. If the product also contains WPS uses, then create a Non-Agricultural Use Requirements box as directed in PR Notice 93-7 and place the appropriate statement inside that box.
General Application Restrictions for products with WPS or non-WPS uses on the label	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift."	Place in the Direction for Use.

Description	MGK-264 Required Labeling Language	Placement on Label
Note: This excludes products that contain any directions for uses when people are permitted to be present in the treated area (e.g. metered release devices, applications to pets, and repellents applied to humans)	"Only protected handlers may be in the area during application."	
General Application Restrictions for Ready-to-use (RTU) Total Release Fogger products	"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." "Do not remain in treated area. Exit area immediately and remain outside the treated area until aerosols, vapors, and/or mists have dispersed."	Place in the Direction for Use.
General Application Restrictions for products with WPS and non-WPS uses on the label AND contain directions for uses when people are permitted to be present in the treated area (e.g. metered release devices, applications to pets, and repellents applied to humans)	"Except when" (insert application method or site that allows people to be present) "do not apply this product in a way that will contact workers or other persons, either directly or through drift." "Except when" (insert application method or site that allows people to be present) "only protected handlers may be in the area during application."	Place in the Direction for Use.
General Application Restrictions for products labeled for use solely when	**Note to Registrants:** No entry restrictions are required. See below under Use Restrictions for further requirements.	Place in the Direction for Use.

Description	MGK-264 Required Labeling Language	Placement on Label
people are permitted to be present in the treated area (e.g. metered-release devices, applications to pets, and repellents applied to humans)		
Other Application Restrictions	**Note to Registrants:** Delete any reference to tolerance exemptions on labels. In addition add the following restrictions depending on the registered product uses and formulation: **Dust formulations:** "Aerial applications are prohibited." "Applications with power duster equipment are prohibited." "Applications to pets are prohibited." **Products labeled for spray applications to plants:** "Do not wet plants to point of runoff or drip." **Products labeled for spray applications to articles:** "Do not wet articles to point of runoff or drip." "Do not use treated article until spray has dried." **Products labeled for applications to clothing articles:** "Dry clean treated clothes before wearing." **Products labeled for dip applications to articles:** "Do not use treated article before it is dry." **Products labeled for crack and crevice, surface or space spray, fogging or dust applications indoors:** "Remove or cover exposed food and drinking water before application."	Directions for Use under General Precautions and Restrictions and/or Application Instructions

Description	MGK-264 Required Labeling Language	Placement on Label
	"Remove or cover dishes, utensils, food processing equipment, and food preparation surfaces, or wash them before use." **Products labeled for applications to non-residential indoor sites:** "Do not use in aircraft cabins except in compliance with PR Notice 96-3." "When used in dairy barns or facilities: Close milk bulk tank lids to prevent contamination from spray and from dead or falling insects. Remove or cover milking utensils before application. Wash teats of animals before milking." **Products labeled for use in food handling and processing facilities:** "Do not make space spray applications when facility is in operation." "Prior to space spray applications, cover or remove food." "Prior to space spray applications, cover food processing surfaces or clean after treatment with a suitable detergent and rinse with potable water before use." **Products labeled for applications to indoor areas including pet areas:** "Remove or cover exposed food and water before application." "Remove or cover dishes, utensils, food processing equipment, and food preparation surfaces, or wash them thoroughly before use."	
Use Restrictions [2] (Note: The maximum application rate and maximum seasonal rates specified in this table must be listed as pounds or gallons of formulated product per acre/square ft/ppm/cubic feet etc., not just as pounds active ingredient)	**Trigger Pump Sprayers** <u>Products must be formulated to deliver no more than this maximum rate when used according to directions:</u> All trigger pump sprayers - 0.1 lbs ai/1000 square feet (maximum concentration is 0.5 % ai) **Indoor Aerosol Space Sprays (Residential Areas)** <u>Products must be formulated to deliver no more than this maximum rate when used according to directions:</u> All aerosol pump sprayers used in residential areas- 0.00015 lbs ai/1000 cubic foot **Non-food (ornamentals, flowering, and foliage plants) plants in Commercial Greenhouses** <u>Maximum application rates:</u> Greenhouse surface spray – 0.01 lbs per 1000 square feet	Directions for Use under General Precautions and Restrictions and/or Application Instructions

Description	MGK-264 Required Labeling Language	Placement on Label
	Greenhouse space sprays - 0.001 lbs ai/1000 cubic feet Use restrictions: "Do not apply more than 1 time per day." **Direct Application to Non-domestic Animals (non-food livestock only, i.e. donkeys, horses, ponies, mules)** Products must be formulated to deliver no more than this maximum rate when used according to directions: Application to non-food livestock– 0.00025 lbs ai/animal (or 2 oz of 0.2% spray/animal) Ready-to-use paste applications to horses – 0.0056 lbs ai/horse Use restrictions: "Do not apply more than 1 time per day." **Indoor Agricultural Premises and Commercial Animal Housing and Equipment (animals not present)** Products must be formulated to deliver no more than this maximum rate when used according to directions: Crack/crevice or spot– 0.05 lbs ai/1000 square feet Surface applications – 0.01 lbs ai/1000 square feet Space sprays – 0.001 lbs ai/1000 cubic feet Metered release device sprays – 0.002 lbs ai/ 1000 cubic feet per day and 1.77 mg ai/spray event Use Restrictions: "Do not apply more than 1 time per day." **Indoor Food Handling/Processing Facilities** Products must be formulated to deliver no more than the maximum rate when used according to directions:	

Description	MGK-264 Required Labeling Language	Placement on Label
	Surface applications – 0.01 lbs ai/1000 square feet Crack/crevice or spot – 0.05 lbs ai/1000 square feet Space sprays– 0.001 lbs ai/1000 cubic feet Metered release device space sprays – 0.002 lbs ai/1000 cubic feet/day and 1.77 mg ai/spray event Use Restrictions: "Do not apply more than 1 time per day." In addition, these label statements should be deleted from all products registered for **food handling and processing facilities:** "Except in Federally inspected meat and poultry plants, food processing operations may continue when the product is applied as a general surface spray with care and in accordance with the directions and precautions on the label, at a maximum rate of 0.01 pounds of MGK-264 per 1000 square feet." "Except in Federally inspected meat and poultry plants, food processing operations may continue when the product is applied as a crack and crevice treatment with care and in accordance with the directions and precautions on the label, at a maximum rate of 0.05 pounds of MGK-264 per 1000 square feet." **Outdoor Agriculture Premises and Equipment** Products must be formulated to deliver no more than this maximum rate when used according to directions: Surface applications – 0.01 lbs ai/1000 square feet Crack/crevice or spot– 0.05 lbs ai/1000 square feet Use Restrictions: "Do not apply more than 1 time per day." **Pet Care** Products must be formulated to deliver no more than this maximum rate when used according to directions:	

Description	MGK-264 Required Labeling Language	Placement on Label
	The use directions must not allow more than 0.0028 lbs ai/pet for all pet applications, including those listed above. Use restrictions: "Do not apply to pets less than 12 weeks old." "Consult a veterinarian before applying this product on medicated, debilitated, aged, pregnant, or nursing animals." "Sensitivities may occur after using any pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately." ***Registrant Note:*** Follow instructions in PR Notice 96-6, Pet Pesticide Product Label Statements, for including reapplication restrictions on the end-use product label. **Pet Premise Treatment (pets are not present)** Products must be formulated to deliver no more than this maximum rate when used according to directions: Surface – 0.01 lbs per 100 square feet Space spray – 0.001 lbs per 1000 square feet **Outdoor Residential Ornamental and Lawns** Maximum application rates: Surface applications – 0.3 lbs ai/A User Restrictions: "Do not apply more than 1 time per day." **Residential Dwellings and Commercial, Institutional Indoor Sites** Products must be formulated to deliver no more than this maximum rate when used according to directions: Surface applications –0.01 lbs ai/1000 square feet Crack/crevice or spot – 0.05 lbs ai/1000 square feet Space sprays– 0.001 lbs ai/1000 cubic feet	

Description	MGK-264 Required Labeling Language	Placement on Label
	Metered release device space sprays (except for residential dwellings which are prohibited)– 0.002 lbs ai/1000 cubic feet/day and 1.77 mg ai/spray event **Residential Indoor Dust Applications to Carpet and Other Indoor Surfaces** Products must be formulated to deliver no more than this maximum rate when used according to directions: Dust – 0.011 lbs ai/100 square feet User Restrictions: "Do not apply more than once a day." "Only apply as a spot treatment to areas no greater than 3 feet by 3 feet per room." **General Outdoor Sites (including non-agricultural rights-of-way, commercial/institutional/industrial premises, residential sites, and outdoor eating establishments)** Products must be formulated to deliver no more than this maximum rate when used according to directions: Surface applications – 0.01 lbs ai/1000 square feet Crack/crevice or spot – 0.05 lbs ai/1000 square feet Metered release device space sprays (except for residential sites which are prohibited) – 0.002 lbs ai/1000 cubic feet/day and 1.77 mg ai/spray event **Manholes** Products must be formulated to deliver no more than this maximum rate when used according to directions: Surface applications to manholes – 0.07 lbs ai per manhole over a length of 200 feet Use restrictions: "Do not apply more than 1 time per day." **Food Stored in Bags**	

Description	MGK-264 Required Labeling Language	Placement on Label
	Products must be formulated to deliver no more than this maximum rate when used according to directions: Space sprays may be made to the surfaces of bags of stored food products at the rate of 0.001 lbs ai/1000 cubic foot. Use restrictions: "Direct application to food contact surfaces is prohibited."	
Application Restrictions for products used in Metered Release Devices	**Note to Registrants:** Delete nurseries, day care centers, schools, hospitals, and nursing homes as registered use sites on all product labels for this use pattern. Add the following statements: "Not for use in residential areas." "Do not use in nurseries or rooms where infants, ill, or aged persons are present." "Do not place metering device directly over or within 8 feet of exposed food, dishes, utensils, food processing equipment, and food handling or preparation." "Do not install within 3 feet of air vents." "Carefully follow directions for the dispenser unit when installing the dispenser and replacing cans or conducting maintenance."	Directions for Use under General Precautions and Restrictions and/or Application Instructions
Use-Specific Application Restrictions for all liquid products that could feasibly be used in an outdoor residential misting system ***Note to registrants:*** No products for use in outdoor residential misting systems will be eligible for reregistration	**Outdoor Residential Misting Systems** **Products that could be feasibly used in outdoor residential misting systems (e.g., liquid concentrates) must contain the following statement:** "Not for use in outdoor residential misting systems."	Directions for Use under General Precautions and Restrictions and/or Application Instructions

Description	MGK-264 Required Labeling Language	Placement on Label
	Products Primarily Used by Consumers/Homeowners	
Application Restrictions for products applied as a space spray or by a fogger	"Do not remain in treated area. Exit area immediately and remain outside the treated area until aerosols, vapors, and/or mists have dispersed."	Place in the Direction for Use.
Entry Restrictions for products except those products that contain any directions for uses when people are permitted to be present in the treated area (e.g. pet applications and repellents)	**Entry Restriction for products applied as a surface or crack and crevice spray except for sprays applied directly to domestic animals:** "Do not allow adults, children, or pets to enter the treated area until sprays have dried." **Entry Restriction for products applied dry:** "Do not allow adults, children, or pets to enter the treated area until dusts have settled." **Entry Restriction for products applied as a space spray or by fogger:** "Do not allow adults, children, or pets to enter the treated area for at least 15 minutes, until vapors, mists, and aerosols have dispersed, and the treated area has been thoroughly ventilated."	Directions for use under General Precautions and Restrictions
Entry Restrictions for products products that only contain directions for uses when people are permitted to be present (e.g. pet applications and repellents)	**Note to Registrants:** No entry restrictions are required. See below under Use Restrictions for further requirements.	Directions for use under General Precautions and Restrictions
Entry Restrictions for products that contain directions for uses when people are permitted to be present in the treated area (e.g. applications to pets and repellents) AND for use on other sites as a surface and/or crack and crevice spray.	**Products labeled for use as a surface spray (does not apply to products applied directly to domestic animals):** "Except when applying directly to pets, do not allow adults, children, or pets to enter until sprays have dried."	Directions for use under General Precautions and Restrictions

Description	MGK-264 Required Labeling Language	Placement on Label
General Application Restrictions for all products except those products that contain any directions for uses when people are permitted to be present in the treated area (e.g. pet applications and repellents)	"Do not apply this product in a way that will contact adults, children, or pets, either directly or through drift." "Remove pets, birds, and cover fish aquariums before spraying."	Place in the Direction for Use
General Application Restrictions for products that only contain directions for uses when people are permitted to be present (e.g. pet applications and repellents)	**Note to Registrants:** No entry restrictions are required. See below under Use Restrictions for further requirements.	Place in the Direction for Use
General Application Restrictions for products that contain directions for uses when people are permitted to be present in the treated area (e.g. pet applications) AND for use on other sites.	"Except when applying directly to pets, do not apply this product in a way that will contact adults, children, or pets, either directly or through drift. Remove pets, birds, and cover fish aquariums before spraying."	Place in the Direction for Use
Homeowner User Safety Recommendations Statements	"User Safety Recommendations Users should wash hands with plenty of soap and water before eating, drinking, chewing gum, using tobacco, or using the toilet."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Homeowner User Safety Recommendations	"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."	Precautionary Statements under:

Description	MGK-264 Required Labeling Language	Placement on Label
for all products EXCEPT those labeled solely for use on pets and humans.		Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Residential Use Restrictions (Note: The maximum allowable application rate and maximum allowable seasonal rate must be listed as pounds or gallons of formulated product per acre or per square feet or per cubic feet, not just as pounds active ingredient per unit area.)	**Trigger Pump Sprayers** <u>Products must be formulated to deliver no more than this maximum rate when used according to directions:</u> All trigger pump sprayers - 0.1 lbs ai/1000 square feet (maximum concentration is 0.5 % ai MGK-264) **Indoor Aerosol Space Sprays (Residential Areas)** <u>Products must be formulated to deliver no more than this maximum rate when used according to directions:</u> All aerosol pump sprayers used in residential areas- 0.00015 lbs ai/1000 cubic foot **Non-food (ornamentals, flowering, and foliage plants) plants in Residential Greenhouses** <u>Maximum application rates:</u> Greenhouse surface spray – 0.01 lbs per 1000 square feet Greenhouse space sprays - 0.001 lbs ai/1000 cubic feet <u>Use restrictions:</u> "Do not apply more than 1 time per day." **Pet Premise Treatment (pets are not present)** <u>Products must be formulated to deliver no more than this maximum rate when used according to directions:</u> Surface – 0.01 lbs per 100 square feet Space spray – 0.001 lbs per 1000 square feet	Directions for Use under General Precautions and Restrictions and/or Application Instructions

Description	MGK-264 Required Labeling Language	Placement on Label
	Outdoor Residential Ornamental and Lawns Maximum application rates: Surface applications – 0.3 lbs ai/acre User Restrictions: "Do not apply more than once a day." **Indoor Residential Dwellings** Products must be formulated to deliver no more than this maximum rate when used according to directions: Surface applications – 0.01 lbs ai/1000 square feet Crack/crevice or spot– 0.05 lbs ai/1000 square feet Space sprays– 0.001 lbs ai/1000 cubic feet **Residential Indoor Dust Applications to Carpet and other indoor surfaces** Products must be formulated to deliver no more than this maximum rate when used according to directions: Dust– 0.011 lbs ai/100 square feet User Restrictions: "Do not apply more than once a day." "Do not apply as a broad carpet treatment. Only spots less than 3 feet by 3 feet per room may be applied with this product." **Repellent Applied to Humans** Use restrictions: "Do not use under clothing." "Avoid over application." "Do not apply over cuts, wounds, or irritated skin." "Do not spray directly on face."	

Description	MGK-264 Required Labeling Language	Placement on Label
	"To apply to face, spray into hands first and then apply sparingly and avoid eyes." "Do not apply near eyes and mouth." "Apply sparingly around ears." "Do not allow children to handle product." "Do not apply to children's hands." "When using on children, apply to your own hands first and then put it on a child." **Pet Care** Products must be formulated to deliver no more than this maximum rate when used according to directions: The use directions must not allow more than 0.0028 lbs ai/pet for all pet applications, including those listed above. Use restrictions: "Do not apply to pets less than 12 weeks old." "Consult a veterinarian before applying this product on medicated, debilitated, aged, pregnant, or nursing animals." "Sensitivities may occur after using any pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately." ***Registrant Note:*** Follow instructions in PR Notice 96-6, Pet Pesticide Product Label Statements, for including reapplication restrictions on the end-use product label. **General Outdoor Sites (including outdoor residential sites, automobiles, and manure)** Products must be formulated to deliver no more than this maximum rate when used according to directions: Surface applications – 0.01 lbs ai/1000 square feet Crack/crevice or spot– 0.05 lbs ai/1000 square feet	
Use-Specific Application Restrictions	**Requirement for Liquid Formulations (except for Ready to Use) with outdoor uses:** "Do not apply directly to or near water, storm drains, or drainage ditches. Do not apply when	Directions for Use under General Precautions and Restrictions and/or

Description	MGK-264 Required Labeling Language	Placement on Label
For products with directions for residential uses	windy. To prevent product run-off, do not over water the treated area(s) or apply when heavy rain is expected. Rinse applicator over lawn or garden area only." **Requirement for Ready to Use Liquid or Dust Formulations with outdoor uses:** "Do not apply directly to or near water, storm drains, or drainage ditches. Do not apply when windy. To prevent product run-off, do not over water the treated area(s) or apply prior to heavy rainfall."	Application Instructions
Use-Specific Application Restrictions for all liquid labels that could feasibly be used in an outdoor residential misting system ***Note to registrants:*** No products for use in outdoor residential misting systems will be eligible for reregistration	**Outdoor Residential Misting Systems** **Products that could be feasibly used in outdoor residential misting systems (e.g., liquid concentrates) must contain the following statement:** "Not for use in outdoor residential misting systems."	Directions for Use under General Precautions and Restrictions and/or Application Instructions

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

[2] All references to the active ingredient (a.i.) in this table refer to MGK-264.

Appendix: Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in room S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

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

These documents include:

HED Documents:

Revised Memo to Incorporate Reponses to Phase 5 Public Comments. N-Octyl bicycloheptene dicarboximide (MGK-264): HED Chapter of the Reregistration Eligibility Decision Document (RED). Donovan, W.; D327167; March 20, 2006.

MGK-264 Indoor Handheld Fogger Applicator Scenario: Comparison of Prallethrin Inhalation Study and Florida Greenhouse Study. Weiss, S.; D327961; July 5, 2006.

MGK-264: REVISED Occupational and Residential Exposure Assessment for the Reregistration Eligibility Decision Document. Weiss, S.; D324674; March 10, 2006.

Revised Memo to Incorporate Responses to Phase 3 Public Comments. N-Octyl bicycloheptene dicarboximide (MGK-264) RED – Reregistration Eligibility Decision. Product and Residue Chemistry Considerations. Donovan, W.; D318874; September 9, 2005.

Review of MGK-264 Incident Reports. Blondell, J.; D306591; October 6, 2004.

N-Octyl bicycloheptene dicarboximide (MGK-264) Acute and Chronic Dietary Exposure Assessments for the Reregistration Eligibility Decision. Donovan, W.; D295639; September 21, 2004.

MGK-264: First Report of the Hazard Identification Assessment Review Committee. Eiden, C.; TXR No. 0052650; June 25, 2004.

HED Response to Comments Documents:

MGK-264. Health Effects Division (HED) Phase 6 Response to Phase 5 Comments on the MGK-264 Preliminary Reregistration Eligibility Decision (RED) and Supporting Memos. Donovan, W., Doherty, J., Weiss, S.; D324672; May 11, 2006.

MGK-264. Health Effects Division (HED) Phase 4 Response to Phase 3 Public Comments on the MGK-264 Preliminary Reregistration Eligibility Decision (RED) and

Supporting Memos. Donovan, W., Doherty, J., Weiss, S.; D321193; September 15, 2005.

Piperonyl Butoxide (PBO), Pyrethrins and MGK-264: Health Effects Division's response to the Registrant's concerns for using metaplasia seen in the larynx in subchronic inhalation studies as an endpoint for inhalation risk assessment. Ramasamy, S., et al.; D319913, D319914, and D320298; September 8, 2005.

MGK-264. HED Response to Error-Only Registrant Comments on the MGK-264 Preliminary RED. Donovan, W., Doherty, J., Weiss, S.; D311280; March 2, 2005.

EFED Documents:

Revised Screening Ecological Risk Assessment for the Reregistration of MGK-264 Insecticide Synergist. Eckel, W.; D329617; July 14, 2006.

Drinking Water Assessment for MGK-264 Insecticide Synergist: Surface Water Revision for Ground Spray. Eckel, W.; D305104; February 17, 2005.

EFED Response to Comments Documents:

Response to Comments of Phase 5 Period About Water Quality, and Other Issues on the Revised Draft EFED RED Chapters for Pyrethrins, PBO and MGK-264. Davy, M., et al.; D324663, D324664, D324667, D324662, D324671, and D324673; January 30, 2006.

Response to Pubic Comments on Drinking Water Assessment for MGK-264 Insecticide Synergist. Eckel, W.; D318870; August 31, 2005.

Response to Public Comments on Ecological Risk Assessment for MGK-264 Insecticide Synergist. Eckel, W., and Lee, R.; D318871; August 31, 2005.

Response to Error-Only Review of Ecological Risk Assessment and Drinking Water Assessment for MGK-264 Insecticide Synergist. Eckel, W.; D295633; February 17, 2005.