

Overview of the MGK 264 Risk Assessments

May 3, 2005

Introduction

This document summarizes EPA's human health and ecological risk findings and conclusions for the synergist N-Octyl bicycloheptene dicarboximide (MGK-264), as presented fully in the documents, "N-Octyl bicycloheptene dicarboximide (MGK-264): HED Chapter of the Reregistration Eligibility Decision Document (RED)," dated October 5, 2004, and the "Screening Ecological Risk Assessment for the Reregistration of MGK-264 Insecticide Synergist," dated September 29, 2004. The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments and conclusions reached in the assessments. This overview was developed in response to comments and requests from the public which indicated that the risk assessments were difficult to understand, that they were too lengthy, and that it was not easy to compare the assessments for different chemicals due to the use of different formats.

These MGK-264 risk assessments and additional supporting documents are posted on EPA's Internet website (<http://www.epa.gov/edocket>) and are available in the Pesticide Docket for public viewing and comment. This feedback will be used to complete the Reregistration Eligibility Decision (RED) document, which will include the resulting risk management decisions. The Agency plans to conduct a close-out conference call with interested stakeholders to describe the regulatory decisions to be presented in the RED.

Risks summarized in this document are those that result only from the use of MGK-264. 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 and MGK-264 does not appear to produce a toxic metabolite produced by other substances. For the purposes of this 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/pesticides/cumulative/>.

Use Profile

- **Synergist:** MGK 264 is an insecticide synergist. Synergists are chemicals that lack pesticidal effects of their own but enhance the pesticidal properties of other chemicals. 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, and outside on gardens, lawns and ornamentals, patios, and other outdoor structures, and is directly applied to pets. No agricultural crop uses of MGK-264 are being supported.
- **Tolerances:** There are 8 tolerances for MGK 264. These include 1 tolerance for all food items to cover the food handling use and one inert exemption now in 40 CFR 180.905.
- **Formulations:** MGK-264 is formulated as an emulsifiable concentrate, as well as a number of ready to use formulations such as aerosol cans, foggers, trigger pump sprayers, shampoos, pastes, wipes, dusts, etc. MGK-264 is usually formulated with natural pyrethrins, piperonyl butoxide (PBO) [another synergist], or synthetic pyrethroids.
- **Method of Application:** aerial, groundboom, and truck-mounted ULV sprayer applications. Applications to smaller areas may be made with handheld equipment, including low-pressure handwand sprayers, high pressure handwand sprayers, handgun sprayers, hose-end sprayers, and 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.
- **Use Rates:** Due 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. Rates range from 0.002 lbs ai/1000 ft³ for a space metered release spray to 1.6 lbs ai/1000 ft³ for crack, crevice, or spot surface treatments.
- **Annual Poundage:** Less than 300,000 pounds of MGK-264 are sold every year.
- **Technical Registrant:** McLaughlin Gormley King Company and Valent Biosciences Corporation.

Human Health Risk Assessment

Acute Dietary (Food) Risk

(For a complete discussion, see section 6.1 of the Human Health Risk Assessment)

Acute dietary risk is calculated considering what is consumed in one day and maximum, or high-end residue values in food. A risk estimate that is less than 100% of the acute Population Adjusted Dose (aPAD), the dose at which an individual could be exposed on any given day and no adverse health effects would be expected, does not exceed the Agency's level of concern. The aPAD is the acute reference dose (aRfD) adjusted for the FQPA Safety Factor.

- An acute analysis was conducted only for females 13-49 years old because an appropriate endpoint for the general population was not identified.
- The acute analysis was conducted with both DEEM (Version 2.0) and Lifeline (Version 2.0). The results were consistent with each other.
- Acute dietary food risk is less than the Agency's level of concern for females 13-49 years old (aPAD = 13% at the 99.9th percentile).
- The acute dietary assessment was conducted using maximum and average residue levels, from applicable field trials and assumed all food commodities could be treated in food handling establishments.
- The acute dietary toxicological endpoint, as seen at the lowest observed adverse effect level (LOAEL) of 300 mg/kg/day, is based on deaths, abortions, and resorptions in female rabbits from a developmental toxicity study. The no observed adverse effect level (NOAEL) is 100 mg/kg/day.
- The special FQPA uncertainty factor for sensitivity in infants and children was reduced to 1x.

Chronic Dietary (Food) Risk

(For a complete discussion, see section 6.1 of the Human Health Risk Assessment)

Chronic dietary risk is calculated by using the average consumption values for food residue values averaged over a 70-year lifetime. A risk estimate that is less than 100% of the chronic PAD (the dose at which an individual could be exposed over the course of a lifetime and not expect an adverse health effect) does not exceed the Agency's level of concern.

- The chronic dietary risk (food) for MGK 264 does not exceed the Agency's level of concern (i.e., less than 100% of the chronic PAD is utilized).
- The chronic dietary analyses were conducted for the general U.S. population and all population subgroups.
- The chronic analysis was conducted with both DEEM (Version 2.0) and Lifeline (Version 2.0). The results were consistent with each other.
- The exposure estimate for the US population is 19% of the chronic Population Adjusted Dose (% cPAD) and 51% for the highest exposed population, children (1-2 years of age).

Chronic risk estimates could be refined with additional information on percent of food handling establishments treated with PBO.

- For all populations the chronic dietary toxicological endpoint, as seen at the lowest observed adverse effect level (LOAEL) of 61 mg/kg/day, is based on a slight decrease in body weight of rat pups during lactation, from a multi-generation reproduction study. An additional 10x uncertainty factor was applied because a NOAEL was not identified in this study
- The chronic dietary assessment was conducted using maximum and average residue levels from applicable field trials and assumed all food commodities were treated.

Drinking Water Dietary Exposure

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 ug/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 not of concern. Drinking water modeling is considered to be an unrefined assessment and generally provides high-end estimates.

- 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 input parameters are based on a single application at 2.18 lb ai/A based on extrapolation of the maximum label rate of 0.05 lb ai per 1000 ft² for “ornamentals, lawns, and groundcovers” to calculate an acute surface water concentration of 87 ppb and a chronic surface water concentration of 41 ppb.
- 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 assessment that provides a high-end estimate. SCI-GROW model generates a single EEC value of pesticide concentration in ground water used for drinking water and provides a ground water 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 assumed a maximum seasonal use rate of 2.18 lb ai/A, a mobility constant of 636 mL/g, and a half-life of 341 days to predict a concentration of 0.86 ppb in ground water.

- The EDWCs listed below should be considered highly conservative because of the high percent cropped area value assumption made in the modeling.

Summary of Estimated Surface and Ground Water Concentrations for MGK-264.		
Exposure Duration	MGK-264	
	Surface Water Conc., ppb	Ground Water Conc., ppb
Acute	87	0.86
Chronic	41	0.86

Cancer Risk

(For a complete discussion, see section 7.4 of the Human Health Risk Assessment.)

MGK-264 is classified as a Group C - possible human carcinogen with no cancer quantification required for MGK-264 risk assessments.

Dermal, Inhalation Toxicity and Incidental Oral Toxicity

- The following endpoints were used to determine residential, aggregate, and occupational risk.

Dermal Toxicity

- The short-, intermediate-, and long-term dermal exposure endpoint is extrapolated from an oral study based on decrease in body weight in rat pups during lactation in a multi generation reproduction-toxicity study at the lowest observed adverse effect level (LOAEL) of 61 mg/kg/day.
- An additional 10X uncertainty factor is added to account for a lack of a NOAEL in the oral study.
- A dermal rat study was not used because at the highest dose tested there was no effect. However, a dermal absorption factor of 10 percent was selected to extrapolate from the oral to the dermal route, based on a study using human volunteers.

Inhalation Toxicity

- The short-, intermediate-, and long-term inhalation exposure endpoint is based on the presence of metaplasia and hyperplasia in the larynx at the lowest observed adverse effect level (LOAEL) of 0.01 mg/L, from a subchronic inhalation study in rats.
- An additional 10X uncertainty factor is added to account for a lack of a NOAEL in the inhalation study.

Incidental Oral Toxicity

- The multi-generation reproduction study in rats was selected to set doses and endpoints for this exposure scenario. Because no NOAEL was identified in this study, the appropriate MOE for the corresponding risk assessment is 1000. The endpoint of concern is appropriate for the population (infants and children) of concern and appropriate for both short and intermediate term durations since the decrease in pup body weight was seen during the lactation period.

Residential Risk

(For a complete discussion, see section 6.3 of the Human Health Risk Assessment)

There is also potential for residential exposure from entering MGK-264-treated areas, such as lawns, golf courses, home gardens, and indoor surfaces (carpets and flooring) that could lead to exposures to adults and children. Risk assessments have been completed for both residential handler and postapplication scenarios.

In addition to homeowner uses in residential settings, MGK-264 is labeled for wide-area broadcast use for insect control, which is applied by occupational applicators, but may result in postapplication exposures in residential settings. These potential postapplication exposures to homeowners have also been considered in this assessment.

Residential Applicator (Handler)

- The overall uncertainty factor applied to MGK-264 for residential handler risk assessments is 1000, which is based on the FQPA safety factor of 1X along with the 10X for inter-species extrapolation, 10X for intra-species sensitivity, and 10X for the use of a LOAEL, rather than a NOAEL.
- Residential handler exposure scenarios are considered to be short-term only, due to the infrequent use patterns associated with the homeowner products.
- Only the dermal and inhalation scenarios of concern for the residential handler and residential postapplication are listed in the following tables.

Residential Handler Exposure Scenarios of Concern	Site	Application Rate	Daily Area Treated	Dermal MOEs of concern (Target = 1000)	Inhalation MOEs of concern (Target = 1000)
Mixing/Loading/Applying Emulsifiable Concentrates with Low Pressure Handwand	Indoor Surfaces – crack and crevice or spot	0.0016 lb ai/ sq ft	1000 sq ft	410	Not a concern

Residential Handler Exposure Scenarios of Concern	Site	Application Rate	Daily Area Treated	Dermal MOEs of concern (Target = 1000)	Inhalation MOEs of concern (Target = 1000)
	Pet Premises – crack and crevice	0.00075 lb ai/sq ft	1000 sq ft	870	Not a concern
Mixing/Loading/Applying Dusts with a Shaker Can	Indoor Surfaces – Master Label	0.7 lb ai/lb dust	0.5 lb of dust	700	600
	Indoor Surfaces – label	0.0025 lb ai/sq ft	1,000 sq ft	98	84
			100 sq ft	980	840
Applying Ready to Use Formulations with Fogger	Pet Premises	0.5 lb ai/1000 cubic feet	12,000 cubic feet	28	9
	Indoor Spaces	0.006 lb ai/1000 cubic feet	12,000 cubic feet	Not a concern	750
	Indoor Ornamental	0.005 lb ai/1000 cubic feet	12,000 cubic feet	Not a concern	900

Residential Post Application

Adult Residential Risk Estimates of Concern for Postapplication Exposure to MGK-264			
Exposure Scenario	Route of Exposure	Application Rate	MOE at Day 0 (Target = 1000)
Indoors			
Indoor Surfaces (High Contact Activities) - Spray (Carpet)	Dermal	0.0004 lb ai/sq ft	28
		0.000042 lb ai/sq ft	270
Indoor Surfaces (High Contact Activities) - Spray (Vinyl)	Dermal	0.0004 lb ai/sq ft	28
		0.000042 lb ai/sq ft	270
Indoor Surfaces (High Contact Activities) - Fogger (Carpet)	Dermal	0.016 lb ai/5 oz fogger	190
		0.008 lb ai/5 oz fogger	390
Indoor Surfaces (High Contact Activities) - Fogger (Vinyl)	Dermal	0.016 lb ai/5 oz fogger	790

Toddler (3 year old)

Risks (MOEs) to toddlers were calculated for postapplication risks following the application of MGK-264 to home lawns, indoor surfaces, and pets. Short-term MOEs from incidental oral exposures were greater than 1,000 on the day of application and are not of concern for treated turf following spray applications, to treated indoor surfaces following fogger application at the lowest percent active ingredient per fogger, and inhalation exposures to ULV truck fogger mosquito treatments.

The following toddler scenarios indicate postapplication risks potentially of concern (MOE < 1,000) on the day of application

Toddler (3 yrs old) Residential Risk Estimates of Concern for Postapplication Exposure to MGK-264			
Exposure Scenario	Route of Exposure	Application Rate	MOE at Day 0 (Target = 1000)
Outdoors			
Residential Turf (High Contact Activities)	Dermal	2.2 lb ai/acre	710
Indoors			
Hand to Mouth Activity on Indoor Surfaces (Spray - Carpet)	Oral	0.0004 lb ai/sq ft	120
Hand to Mouth Activity on Indoor Surfaces (Spray - Hard Flooring)	Oral	0.0004 lb ai/sq ft	120
Hand to Mouth Activity on Indoor Surfaces (Fogger - Carpet)	Oral	0.016 lb ai/5 oz fogger	400
		0.008 lb ai/5 oz fogger	800
Indoor Surfaces (High Contact Activities) - Spray (Carpet)	Dermal	0.0004 lb ai/sq ft	19
		0.000042 lb ai/sq ft	190
Indoor Surfaces (High Contact Activities) - Spray (Vinyl)	Dermal	0.0004 lb ai/sq ft	19
		0.000042 lb ai/sq ft	190
Indoor Surfaces (High Contact Activities) - Spray (Carpet)	Dermal	0.008 lb ai/5 oz fogger	270
		0.003 lb ai/5 oz fogger	810
Indoor Surfaces (High Contact Activities) - Fogger (Vinyl)	Dermal	0.016 lb ai/5 oz fogger	530
Pet Hug			
Hand to Mouth Activity Following Pet Contact (Dust)	Oral	0.05lb ai/animal	3
Hand to Mouth Activity Following Pet Contact (Shampoo)	Oral	0.00088 lb ai/animal	170
Hand to Mouth Activity Following Pet Contact (Mousse, Gel)	Oral	0.00044 lb ai/animal	340
Pet Contact (Dust)	Dermal	0.05lb ai/animal	6
Pet Contact (Shampoo)	Dermal	0.00088 lb ai/animal	370
Pet Contact (Mousse, Gel)	Dermal	0.00044lb ai/animal	730

Aggregate Risk

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

Aggregate risk looks at the combined risk from exposure through food, drinking water, and residential uses of a pesticide.

Acute (one-day) and Chronic (lifetime) Aggregate Risk

- For MGK-264 only food and water were aggregated for acute (one-day), and chronic (lifetime) exposures to pesticides. The chronic assessment considered exposures from food and water only, because there are no residential uses expected to contribute to chronic exposures for this chemical. Risks from acute and chronic aggregate exposures are not a concern for the Agency. Those risk assessment conclusions are included under the acute dietary, chronic dietary, and drinking water sections of this Overview document.

Short-Term(1-30 days) Aggregate Risk

- Short-term aggregate exposure takes into account residential exposure plus average exposure levels to food and water (considered to be a background exposure level).
- MGK-264 residential uses constitute short-term exposure scenarios; endpoints have been selected for short-term incidental oral, dermal, and inhalation exposures.
- Since the toxicological effects through the inhalation exposure route are different from the toxicological effects through the oral and dermal routes, this aggregate risk assessment was conducted adding dermal, oral non-dietary exposure, and average food and water exposure, but did not include an inhalation component.
- Most of the indoor residential postapplication use scenarios result in predicted exposure levels that exceed the Agency's level of concern and were not aggregated.
- The lowest use rate for the fogger application to indoor vinyl surfaces does not exceed the Agency's level of concern and was selected for aggregate analysis.
- For the US population, the computed ground and surface water EDWC values do not exceed the DWLOC value. Thus, short-term aggregate risk does not exceed the Agency's level of concern for the following residential exposure scenario: adult postapplication dermal exposure resulting from use of the 0.003 lb ai/5 oz fogger application to indoor vinyl surfaces.
- For children 1-2 years old, the computed surface water EDWC value does exceed the DWLOC value. Thus, short-term aggregate risk does exceed the Agency's level of concern for the following residential exposure scenario: toddler postapplication oral and dermal exposure resulting from use of the 0.003 lb ai/5 oz fogger application to indoor vinyl surfaces. However, it must be noted that because the DWLOC and EDWC values are close, and in light of the conservative assumptions in the Tier 1 drinking water analysis, it is likely that refinement of the EDWC value would likely result in a risk level below the Agency's level of concern for this aggregate exposure scenario.

Occupational Risk

(For a complete discussion, see section 9.0 of the Human Health Risk Assessment)

It has been determined that exposure to pesticide handlers is likely during the occupational use of MGK-264. MGK-264 uses are extremely varied as it can be used on ornamentals, turf, agricultural animals (livestock), and in a variety of other indoor and outdoor occupational settings. 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. Dermal and inhalation exposures have been assessed for each of the occupational scenarios. MOEs that are greater than 1000 for short and intermediate term dermal and inhalation exposures are not a concern for the Agency.

- Twenty-seven occupational exposure scenarios have been assessed for MGK-264. The scenarios with exposures potentially of concern are listed below.

There are only a few occupational handler scenarios for MGK-264 that have risks above the Agency's level of concern. However, there are many occupational handler scenarios for MGK-264 that have data gaps.

The short- and intermediate-term dermal and inhalation handler risk assessment for MGK-264 indicates potential risk concerns for a few handler scenarios. All of these scenarios are mixer/loader/applicator scenarios that have relatively high application rates or relatively high amounts treated daily. These scenarios include:

- mixing/loading/applying emulsifiable concentrates with a low pressure handwand sprayer (using PHED data) for spot treatments to manholes, sewers, and drains assuming 0.0016 pounds active ingredient per square foot (master label rate) and 40,000 square feet (equivalent to 40 gallons) treated per day;
- mixing/loading/applying emulsifiable concentrates with a high pressure handwand sprayer (using PHED data) for treatments to indoor and outdoor ornamentals assuming 0.058 pounds active ingredient per gallon (label rate) and 1000 gallons applied per day;
- applying emulsifiable concentrates with backpack ULV sprayer (using PHED backpack data) for treating outdoor spaces assuming 0.7 pounds active ingredient per gallon (label rate) and 40 gallons applied per day;
- applying ready-to-use wipes (using CMA data) to treat horses assuming 0.01 pounds active ingredient per wipe and 400 wipes applied per day;
- applying ready-to-use wipes (using CMA data) to treat pets assuming 0.015 pounds active ingredient per wipe and 8 wipes applied per day; and
- applying impregnated collars (using R-SOPs) to treat pets assuming 0.03 pounds active ingredient per collar and 8 collars applied per day.

Several data gaps were identified for MGK-264 including:

- dip treatments to animals,
- truck-mounted fogger treatments, and
- thermal fogger/mist generator treatments.

Occupational Post Application Exposures and Risk

MGK-264 can be used on a variety of sites including ornamentals, turf, agricultural animals (livestock), and in a variety of other indoor and outdoor occupational settings. As a result, a wide array of individuals can potentially be exposed by working in areas that have been previously treated. MGK-264 is applied to:

- sodfarms with aerial (liquid formulation) and groundboom equipment; and
- smaller areas (indoor and outdoor settings, indoor and outdoor use on ornamentals, applications to animals, etc.), which may be made with handheld equipment (e.g., low-pressure handwand sprayers, backpack sprayers, hose-end sprayers, and handgun sprayers) and ready-to-use applications (e.g., pump-trigger sprayers, aerosols, foggers, shaker cans, shampoos, combs, and collars).

Summary of MGK-264 Postapplication Worker Risks					
Crop	Activity	TC cm²/hr	Maximum Application Rate (lb ia/A)	Short/ Intermediate- Term MOE (Target = 1000)	DAT (days)
Field grown- Christmas trees	hand harvesting, thinning	3000	2.2	310	0
				1100	12
	hand-pruning	1500		620	0
				1000	5
	hand-weeding, scouting, irrigating	1000		930	0
				1000	1
Ornamentals – floriculture	hand-pruning	400	2.2	2300	0
	hand-pinching	175		5300	0
Ornamentals - nursery grown	irrigating, scouting (all at medium development)	500	2.2	1900	0
Cut flowers	Old Brouwer data - for comparative purposes only	7000	2.2	130	0
				1100	20
	cut roses	2600		360	0
				1000	10
all other cut flowers	500	1900	0		
Turf	transplanting, hand weeding, hand or mechanical harvesting	16500	2.2	220	0
				1100	15
	mowing, scouting, irrigating	500		7400	0

For Christmas trees, roses grown for cutting, and sodfarms, postapplication risks are potentially a concern for several days following application. For all other crops, risks are not a concern on day 0 (12 hours following application).

Ecological Risk

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity 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 levels of concern (LOCs). 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.

Environmental Fate and Transport

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

MGK-264 is stable to hydrolysis, direct aqueous photolysis, and soil photolysis. Aerobic and anaerobic soil metabolism are very slow (mean aerobic half-life was 341 days). MGK-264 was very mobile to moderately mobile in sand and sandy loam soils ($K_{oc} = 636$ in sand) and essentially immobile in silt loam and clay loam soils ($K_{oc} = 3106$ in clay loam). Adsorption increased with increasing organic matter content, as expected for a neutral organic molecule. MGK-264 aerosols in air are expected to be rapidly degraded (half-life ~ 1.4 hr) by reaction with ozone and hydroxyl radical based on structure-activity relationships. Free radical reactions may also degrade MGK-264 in natural waters.

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 (sand and sandy loam). MGK-264 is immobile in clay soils, which may serve as a sink. MGK-264 may partition to particulate matter in water. Volatilization from soil or water is not expected to be important. MGK-264 is expected to be an aerosol rather than in the gas phase (as a result of spraying). The expected half-life in air is short, so long-range transport is not expected. The combined persistence and mobility may result in MGK-264 being found in surface and ground water. The low K_{ow} value of 3.70 indicates a potential for bioconcentration in aquatic organisms.

Non-target Species Risk

Identifiable risks of concern include acute risks to freshwater fish (RQs range from 0.062 to 0.40) and invertebrates (RQs range from 0.10 to 0.24) when three or more weekly applications are made at the maximum application rate for turf and ornamental plants. The RQ of 1.1 for chronic risks to mammals (decreased pup weight gain) after three or more applications of PBO exceed the LOC for mammals consuming short grass food items. RQs ranging from 1.11 to 3.03

for chronic risks to mammals exceed the LOCs for all food items except fruits/pods/large insects after ten applications.

Risks to estuarine/marine species, and terrestrial and aquatic plants, and reproductive effects in birds could not be quantitatively assessed due to lack of data. However, estuarine/marine organisms are presumed to be at acute risk due to the exceedence of the Level of Concern in freshwater fish and invertebrates. Likewise, birds are presumed to be at risk of reproductive effects, based on exceedence of the Level of Concern in mammals.

Endangered Species

Federally-listed (endangered and threatened) freshwater aquatic organisms may be at acute risk from exposure to contaminated water bodies receiving run-off and spray drift from MGK-264 treated sites. Listed mammals are also at chronic risk of reproductive effects if present in treated areas. We presume that estuarine/marine organisms may also be at acute risk, based on the identified risk to freshwater organisms. We also presume that birds may be at risk of reproductive effects, based on the identified risk to mammals.

The Agency cannot determine which species might be affected, because the endangered species data bases are based on co-occurrence of the species with agricultural crops by county. Non-agricultural use sites such as lawns and ornamental plants have not been specifically associated with any listed species. Because the lawn and ornamental plants use pattern may be geographically widespread, exposure of listed species cannot be ruled out.

To be meaningful, an endangered species assessment for MGK-264 would have to consider simultaneous exposure to the insecticides it is used to synergize, including pyrethrins, pyrethroids, and rotenone, as well as the co-synergist piperonyl butoxide.

Summary of Data Needs

Environmental Fate and Ecological Effects Data Needs

The following studies and information would be useful to refine the preliminary Environmental Fate and Ecological Effects assessment of MGK-264:

Our understanding of the exposure of aquatic and estuarine/marine organisms would be improved by submission of data on aerobic aquatic metabolism (guideline 162-4), anaerobic aquatic metabolism (guideline 162-3), and indirect aqueous photolysis. These three studies would allow refinement of the modeled aquatic EECs, and possibly remove the presumption of risk to aquatic and estuarine/marine organisms.

Potential ecological risks would be clarified by submission of acute toxicity data on estuarine/marine fish, invertebrates, and mollusks (guideline 72-3). Presently, we presume that

there is a risk to estuarine/marine species because of the presumed risk to freshwater species. The guideline 72-3 studies will either confirm or deny the presumption of risk.

The measured log Kow value (3.70) indicates a potential for bioaccumulation in fish. Since we expect fish to be exposed to MGK-264, a fish bioaccumulation study (guideline 165-4) would indicate if there is any potential for food-chain effects in fish consumers.

The exposure of birds and mammals would be better understood if data on the dissipation of total foliar residues (guideline 132-1a) were submitted. Due to lack of this data, a default half-life of 35 days on foliage has been assumed. A measured foliar dissipation rate, if shorter than 35 days, might remove the presumption of chronic risk to mammals.

The potential chronic risks to birds would be clearer if a study on avian reproductive effects (guideline 71-4) was submitted. Presently, we presume a chronic risk to birds because the chronic RQ for mammals exceeds the Level of Concern. The avian reproduction study would allow confirmation or removal of the presumption of risk to birds.

Human Health Data Requirements

The following data are being requested to support the reregistration of MGK 264:

Occupational and Residential Exposure

- For the “metered release” uses, the registrant should correct the label rate to read 0.0001 lb/1000 ft³/day, as this rate is supported by the available residue data. Alternatively, a new study depicting MGK-264 residue levels at the current label rate may be submitted.
- Chemical specific information on MGK-264 to permit a refined analysis of exposure scenarios that exceed the Agency’s level of concern when using default exposure assumptions for occupational and residential exposures.