United States Environmental Protection Agency
Prevention, Pesticides And Toxic Substances (7508C)
EPA 738-R-03-003
September 23, 2003

# Reregistration Eligibility Decision (RED)

# Di-n-propyl isocinchomeronate (MGK® Repellent 326)

**[Revised: 03/11/05]**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

**CERTIFIED MAIL**

Dear Registrant:

This is to inform you that the U.S. Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the risk assessments for the insect repellent di-n-propyl isocinchomeronate (hereafter referred to as MGK® Repellent 326). Based on its review, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health risks associated with the current use of MGK® Repellent 326. EPA is now publishing its reregistration eligibility, risk management, and tolerance reassessment decisions for the current uses of MGK® Repellent 326 and its associated human health and environmental risks. The enclosed "Reregistration Eligibility Decision for Di-n-propyl isocinchomeronate (MGK® Repellent 326)" contains the Agency's decision on the individual chemical MGK® Repellent 326, which was approved on September 23, 2003.

A Notice of Availability for this Reregistration Eligibility Decision (RED) for MGK® Repellent 326 is being published in the *Federal Register*. To obtain a copy of the RED document, please contact the OPP Public Regulatory Docket at (703) 305-5805. Electronic copies of the RED and all supporting documents are available on the Internet at the following address: http//:www.epa.gov/edockets.

This document and the process used to develop it are the result of a process to facilitate greater public involvement and participation in the reregistration and/or tolerance reassessment decisions for pesticides. As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), the Agency is undertaking a special effort to maintain open public dockets and to engage the public in the reregistration and tolerance reassessment processes. Subsequently, the risk assessments for MGK® Repellent 326 were made available to the public for comment on May 23, 2003. This open process follows the guidance developed by the Tolerance Reassessment Advisory Committee (TRAC), a large multi-stakeholder advisory body that advised the Agency on implementing the new provisions of the FQPA. The Agency also conducted a close-out conference call on September 18, 2003 to discuss the risk management decisions and resultant changes to the MGK® Repellent 326 labels.

This document contains both generic or product-specific Data Call-Ins (DCIs) that outlines further data requirements for this chemical. Note that a complete DCI, with all pertinent instructions, is being sent to registrants under separate cover. Additionally, for product-specific DCIs, the first set of

required responses is due 90 days from receipt of the DCI letter. The second set of required responses is due eight months from the date of the DCI.

As part of the RED, the Agency has determined that MGK® Repellent is eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the RED document. The Agency believes that current uses of MGK® Repellent may pose unreasonable adverse effects to human health and that such effects can be mitigated with the risk management measures identified in the RED document. Accordingly, the Agency recommends that the registrants implement these risk mitigation measures immediately. Sections IV and V of the RED document describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by MGK® Repellent 326. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the proposed label changes, please contact the Chemical Review Manager for MGK® Repellent 326, Tawanda Spears at (703) 308-8050. For questions about product reregistration and/or the product-specific DCI that accompanies this document, please contact Barbara Briscoe at (703) 308-8177.

Sincerely,

*[signed 09/23/04]*

Betty Shackleford, Acting Director
Special Review and Reregistration Division

Attachment

# Reregistration Eligibility Decision

for

# Di-n-propyl isocinchomeronate
# (MGK® Repellent 326)

Chemical List B

Case No. 2215

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**MGK® REPELLENT 326 REREGISTRATION ELIGIBILITY DECISION TEAM**

**Office of Pesticide Programs:**

Health Effects Risk Assessment
Rebecca Daiss
David Jacquith
Abdallah Khasawinah
Jerry Stokes

Environmental Fate and Effects Assessment
Henry Craven
James Goodyear
John Jordan

Use and Usage Analysis
Stephen Smearman

Registration Support
Ann Sibold
Joseph Tavano

Risk Management
Neil Anderson
Tawanda Spears

## GLOSSARY OF TERMS AND ABBREVIATIONS

| | |
|---|---|
| ai | Active Ingredient |
| CSF | Confidential Statement of Formula |
| CFR | Code of Federal Regulations |
| DCI | Data Call-In |
| $EC_{50}$ | Effective Concentration for aquatic plants and invertebrates. The concentration of a chemical in water at which an effect is observed that is 50% of the maximum effect. |
| EP | End-Use Product |
| EPA | U.S. Environmental Protection Agency |
| FAO | Food and Agriculture Organization |
| FDA | Food and Drug Administration |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| FQPA | Food Quality Protection Act |
| GLN | Guideline Number |
| $LC_{50}$ | Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm. |
| $LD_{50}$ | Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg. |
| LOC | Level of Concern |
| LOAEL | Lowest Observed Adverse Effect Level |
| mg/kg/day | Milligram Per Kilogram Per Day |
| mg/L | Milligrams Per Liter |
| MOE | Margin of Exposure |
| MP | Manufacturing-Use Product |
| MRID | Master Record Identification (number). EPA's system of recording and tracking studies submitted. |
| NA | Not Applicable |
| N/A | Not Applicable |
| NAFTA | North American Free Trade Agreement |
| NOEC | No Observed Effect Concentration |
| NOEL | No Observed Effect Level |
| NOAEL | No Observed Adverse Effect Level |
| NR | Not Required |
| OPP | (EPA) Office of Pesticide Programs |
| OPPTS | (EPA) Office of Prevention, Pesticides and Toxic Substances |
| PAM | Pesticide Analytical Method |
| ppb | Parts Per Billion |
| ppm | Parts Per Million |
| PRN | Pesticide Registration Notice |
| $Q_1^*$ | The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model |

| | |
|---|---|
| RED | Reregistration Eligibility Decision |
| SF | Safety Factor |
| SLN | Special Local Need (Registrations Under Section 24(c) of FIFRA) |
| TGAI | Technical Grade Active Ingredient |
| UF | Uncertainty Factor |
| µg/g | Micrograms Per Gram |
| µg/L | Micrograms Per Liter |
| USDA | United States Department of Agriculture |
| UV | Ultraviolet |

## EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (EPA or the Agency) has completed its reregistration eligibility decision (RED) for the insect repellent di-n-propyl isocinchomeronate (hereafter referred to as MGK® Repellent 326). The Agency has determined that MGK® Repellent 326 products, labeled and used as specified in this Reregistration Eligibility Decision (RED) document, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency has determined that MGK® Repellent 326 is eligible for reregistration under the conditions specified in this RED document.

MGK® Repellent 326 was initially registered by the USDA in 1957 as an insect repellent for livestock. Tolerances were established for meat and milk and are found in 40 CFR § 180.143. However, in 1993, McLaughlin Gormley and King Company, the technical registrant, elected to voluntarily cancel use on livestock intended for slaughter, which resulted in MGK® Repellent 326 being limited to indoor non-food (i.e., pet living/sleeping quarters) and residential use (i.e., repellents for humans and companion animals). In addition, in light of the fact that there are no active food uses, the Agency is recommending that all existing tolerances for MGK® Repellent 326 be revoked. Because food uses have been cancelled and the Agency is revoking all tolerances, EPA did not perform the standard FFDCA analyses in this reregistration.

MGK® Repellent 326 is never used as the sole active ingredient (a.i). Rather, it is used to expand the spectrum of repellency of other formulation components. For instance, when found in products intended for use on humans, MGK® Repellent 326 is always combined with DEET (N,N-diethyl-m-toluamide) and MGK® 264. According to current marketing data, the total amount of MGK® Repellent 326 sold to customers with pesticide labels for use as "personal insect repellents" is approximately 15,000 to 20,000 pounds (lbs) of a.i. Whereas use on dogs/cats and horses average 2,100 and 14,000 lbs of a.i., respectively.

*Overall Risk Summary*

The Agency's human health risk assessment for MGK® Repellent 326 indicates some risk concerns. Dietary risk from both food and drinking water are not of concern due to the current use pattern. Also, individual and combined non-cancer residential risks are not of concern because the Margin of Exposures (MOEs) are all above the Agency's level of concern (target MOE 100). The human health risk assessment indicates there is a marginal cancer residential risk of concern, based on direct application of MGK® Repellent 326 to individuals over a lifetime. However, the Agency's risk assessment is highly conservative and is believed to overestimate actual risk. The Agency did not conduct an environmental risk assessment because MGK® Repellent 326 is an "indoor residential" use pesticide and MGK® Repellent 326 is not likely to result in exposures and risks to non-target organisms.

*Regulatory Decision*

The Agency has concluded, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), that MGK® Repellent 326 products, when labeled and used as specified in this document, will not cause unreasonable adverse effects on human health or the environment. Therefore, MGK® Repellent 326 products are eligible for reregistration.

*Risk Mitigation*

For the potential residential cancer risks associated with use of MGK® Repellent 326 over a lifetime, the Agency is limiting production and distribution of MGK® Repellent 326 for personal insect repellents to 20,000 lbs of a.i. per year. Additionally, the Agency is limiting and reducing the maximum concentration of a.i. to 2.5% for end-use products containing MGK® Repellent 326 intended for use on humans. The Agency believes these steps are necessary to provide assurance that human exposure to MGK® Repellent 326 in the U.S. will not increase beyond current levels. Further, to limit potential overexposure to young children, no more than 3 applications per day of MGK® Repellent 326 are allowed on children ages twelve and under.

## I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the EPA. Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards 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 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 tolerance reassessment during reregistration. The Act also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA, which was August 3, 1996. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity.

With respect to tolerances for MGK® Repellent 326, the technical registrant voluntarily cancelled all livestock food uses in a Data Call In (DCI) response dated April 24, 1994. Therefore, the end-use registrants removed the livestock uses from their labels, either through product cancellations or label amendments. Because these uses are no longer active, the Agency is proposing to revoke tolerances for the following commodities: meat, fat, meat byproducts of cattle, goats, hogs, horses, and sheep; and milk. Upon revocation and removal of these tolerances for combined residues of MGK® Repellent 326 and its metabolites from 40 CFR 180.143, this insect repellent will no longer fall under the scope of FQPA with respect to tolerance reassessment. As such, the Agency did not conduct an aggregate assessment of risk from dietary and residential exposures as a part of this reregistration eligibility decision (RED).

At this time, the Agency has not made a decision as to whether MGK® Repellent 326 shares a common mechanism of toxicity with other pyridine carboxylic acids or any other pesticides. Nevertheless, a thorough review of the available data is still required before a formal decision is made on the common mechanism of toxicity. Therefore, for purposes of this RED, the Agency assumes that MGK® Repellent 326 does not share a common mechanism of toxicity with other pesticides. After a decision is made regarding common mechanism of toxicity, if it is determined that a cumulative assessment is necessary, then the Agency will re-evaluate risks posed by MGK® Repellent 326 and address any outstanding risk concerns at that time.

This document for MGK® Repellent 326 presents the Agency's human health and environmental risk conclusions, tolerance reassessment, and risk management decision for MGK® Repellent 326, and consists of five sections. Section I contains the regulatory authority and framework

for reregistration/tolerance reassessment. Section II provides a profile of the use and usage of the chemical. 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 identifies label changes necessary to implement the risk mitigation measures. Finally, among the Appendices is a description of the revised use patterns, generic and product-specific DCI, and other reference information. The risk assessments and supporting documents are not included in this document, but are available in the public docket and the electronic docket at www.epa.gov/edockets.

## II. CHEMICAL OVERVIEW

### II. A. Regulatory History

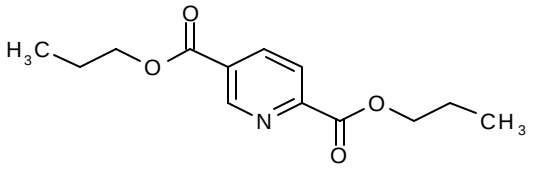
MGK® Repellent 326 was first registered in the United States in 1957 by McLaughlin Gormley King Company (MGK). The chemical was formulated as di-n-propyl isocinchomeronate (EPA Reg No. 1021-461), a manufacturing-use product to be further formulated into insect repellents for use in barns or on livestock commodities (i.e., cattle, goats, hogs, horses, sheep). MGK® Repellent 326 works to broaden the spectrum of repellency of other formulation components, such as DEET (N,N-diethyl-m-toluamide) or pyrethrins, to repel flies, gnats, and other flying and biting insects.

Since then the technical registrant voluntarily cancelled all outdoor and livestock food uses in response to DCIs issued in June 1991 and August 1993, respectively. Accordingly, MGK® Repellent 326 technical formulation products have been revised to include the statement "for use in manufacturing of pesticide products for use in indoor non-food and residential areas only." Based on these actions by the technical registrant, all end-use registrants were given the option in a DCI issued April 24,1994 of providing supporting data, amending their labels to include language to prohibit the use of these products on horses intended for slaughter, or deleting the use on livestock commodities entirely.

In response to the DCI, end-use registrants agreed to delete all livestock food uses from MGK® Repellent 326 product labels. Therefore, residue chemistry data requirements to support livestock food uses are no longer applicable and the Agency is proposing to revoke all di-n-propyl isocinchomeronate tolerances for the following commodities: meat, fat and meat byproducts of cattle, goats, hogs, horses, and sheep; and milk.

At the present time, EPA's records show there are ninety-one MGK® Repellent 326 products with active registrations. There is one technical product, six formulation intermediates, and the rest are end-use products. There are no active special local need state registrations (24(c)s).

## II. B. Chemical Identification

- Common Name: Dipropyl isocinchomeronate
- Chemical Name: Di-n-propyl isocinchomeronate
- Chemical Structure: 
- Chemical Family: Pyridine carboxylic acid
- Case Number: 2215
- CAS Registry Number: 136-45-8
- OPP Chemical Code: 047201
- Empirical Formula: $C_{13}H_{17}NO_4$
- Molecular Weight: 251.3
- Common Trade Name: MGK® Repellent 326
- Basic Manufacturer: McLaughlin Gormley King Company (MGK)

Technical MGK® Repellent 326 is an amber liquid with a vapor pressure of $4.92 \times 10^{-7}$ mm Hg at 25 °C. The melting point is not applicable, because the technical is a liquid at room temperature. MGK® Repellent 326 is soluble in petroleum distillates such as kerosene, toluene, xylene, methanol, ethanol, and isopropanol, and practically insoluble in water.

## II. C. Use Profile

**Type of Pesticide:**

- Insect Repellent

**Summary of Use:**

- Indoor Residential: Cats (adults/kittens), dogs/canines(adults/puppies), human body/clothing, horses (not intended for food), pet living/sleeping quarters

- Public Health: MGK® Repellent 326 is used to expand the spectrum of repellency of DEET for biting flies and ticks, but the Centers for Disease Control and Prevention (CDC) did not indicate that MGK® Repellent 326 has any significant use in public health programs.

**Target Pests:**

- On Humans: Biting flies (i.e., black flies, deer flies, stable flies), chiggers, fleas, gnats, house flies, no-see-ums, mosquitos, and ticks.

- On Companion Animals/Premises: Biting flies (i.e., black flies, bot flies, deer flies, face flies, horn flies, stable flies, horse flies), chiggers, fleas, gnats, house flies, lice, mosquitos, and ticks.

**Formulation Types Registered:**

- Technical Grade
  Active Ingredient: 97.00%

- Manufacturing Use
  Active Ingredient: 7.70 to 50.00%

- End-Use Products:

  For Humans: MGK® Repellent 326 is always co-formulated with DEET and MGK® 264 when intended for use on humans. Aerosol products range from 1.0-2.5% a.i. The other products for use on humans are lotions, pump sprays or liquids, which range from 1.76-4.0% MGK® Repellent 326.

  For Companion Animals/Premises: Products used for dip applications to dogs and cats contain 4.0% MGK® Repellent 326. There are also spray and towelette products with 0.2% and 1.0% a.i., respectively, that are applied to horses. The concentrate products contain a maximum of 5.0% a.i. for use as surface sprays to the interior of kennels, barns and other animal premises.

**Methods and Rates of Application**

- For Use on Humans: Aerosol product labels specify to "apply to cover exposed skin or clothing." The other labels for liquid and lotion products direct the user to "apply to cover exposed skin."

- For Use on Companion Animals: Products used for dip applications to dogs and cats direct users to dilute at the rate of 1 fl. oz. of product in 1 gallon of water. The concentrate products directions are to apply undiluted material with a mist applicator at the rate of 1 fl. oz. of product per 1000 sq. ft. of space in animal premises.

- Timing: All products are applied on an "as needed" basis for both humans and companion animals.

**Use Classification:** General Use

## II. D. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of MGK® Repellent 326. Because of a lack of available use data, a Quantitative Use Assessment was not conducted for MGK® Repellent 326. Rather, the Agency relied on estimates derived from the technical registrant. The data reported reflect annual fluctuations in use patterns.

Based on pesticide usage information from 1997 to 2001, the average total annual domestic usage of MGK® Repellent 326 was approximately 26,000 lbs of a.i. According to more recent marketing data provided by the technical registrant, approximately 15,000 to 20,000 lbs of a.i. was sold to customers with pesticide labels for use as "personal insect repellents," 14,000 lbs a.i for use on horses, and 2,100 lbs a.i. for use on dogs and cats.

## III. SUMMARY OF MGK® REPELLENT 326 RISK ASSESSMENT

The purpose of this section of the RED document is to summarize the key features and findings of the risk assessments and to enhance the reader's understanding of the conclusions reached in the assessments. EPA's human health assessment, environmental risk findings and conclusions for the pesticide MGK® Repellent 326 are fully presented in the human health risk assessment document *MGK® Repellent 326 (di-n-propyl isocinchomeronate) HED Risk Assessment for Reregistration Eligibility Decision (RED),* dated April 7, 2003; and the environmental fate and effects document, *MGK 326/Disopropyl isochinomerate [sic] RED,* dated December 24, 2002.

Risks summarized in this RED document are those that result only from the use of MGK® Repellent 326. While the risk assessments and supporting documents are not included in this RED document, they are available in the electronic docket at http://www.epa.gov/edocket/.

## III. A. Human Health Risk Assessment

EPA issued its risk assessments for MGK® Repellent 326 on May 23, 2003. These risk assessments were made available for comment and to solicit risk management ideas for this insect repellent. There is a discussion of these comments in Section IV of this document. Following is a list of supporting information that was used to formulate the human health risk assessment for MGK® Repellent 326:

- *MGK® Repellent 326: HED Toxicology Chapter for the Reregistration Eligibility Decision Document (RED) by Abdallah Khasawinah (04/07/03)*
- *Exposure Assessment for MGK 326 (Dipropyl isocinchomerate) by David Jaquith (04/07/03)*
- *Di-N-propyl isocinchomerate (MGK® Repellent 326) Use Closure Memo by Tawanda Spears (01/16/03)*
- *MGK® Repellent 326 - Revised Report of the Hazard Identification Assessment Review Committee by Abdallah Khasawinah (12/20/02)*
- *Drinking water concentration for Di-N-Propyl isocinchomerate (MGK 326) by Henry Craven (11/22/02)*
- *Carcinogenicity Peer Review of MGK® Repellent 326 by Whang Phang and Esther Rinde (07/21/93)*

### III. A. 1. Dietary Risk from Food

Dietary food risk assessments are conducted by comparing the inherent toxicity of a pesticide to the amount of pesticide to which an individual is exposed to in food on a single day (acute) and over a lifetime (chronic). Estimates of dietary food exposure are derived from the amount of pesticide residue that is present in and on a food (i.e., the residue level) and the types and amounts of food that people eat (i.e., food consumption).

For MGK® Repellent 326, there are no proposed or registered food uses. Therefore, there are no potential dietary (food) exposures from the use of MGK® Repellent 326, and a dietary (food) risk assessment was not conducted. Further, the Agency proposes to revoke all the following established tolerances found at 40 CFR § 180.143, because the livestock commodity uses have been deleted: meat, fat and meat byproducts of cattle, goats, hogs, horses, and sheep; and milk.

### III. A. 2. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through surface and/or ground water exposure. To assess potential exposures from drinking water, the Agency evaluates the use patterns of a pesticide to determine its potential to reach ground and surface water against levels of concern to human health that are computed by the Agency.

When considering the use of products containing MGK® Repellent 326 as a personal repellent, the Agency assumes that products directed to this market are washed off the human body and released in household wastewater into a treatment plant. Similarly, those products that are used as surface sprays of animal premises and pet dips would be discharged as wastewater, often to septic systems or sewage treatment plants.

Yet, the Agency assumes the amount of MGK® Repellent 326 reaching drinking water sources from disposal of personal use, surface sprays and pet dip products would be negligible due to low overall volume of the chemical used and dilution of the compound in water systems. Therefore, the Agency did not conduct a quantitative assessment and does not expect products containing MGK® Repellent 326 to contaminate drinking water because of the low potential for MGK® Repellent 326 to reach drinking water sources in significant concentrations.

### III. A. 3. Residential Risk

### III. A. 3. a. Toxicity Assessment

Toxicity assessments are designed to determine if a pesticide causes adverse health effects (including short-term or acute effects such as skin or eye damage; and lifetime or chronic effects such as cancer, development and reproduction deficiencies, etc.) and the level or dose at which the effects occur. The Agency has reviewed all toxicity studies submitted and has determined that the toxicity database is complete.

For more details on the toxicity and carcinogenicity of MGK® Repellent 326, beyond what is found in the *MGK® Repellent 326 (Di-N-propyl isocinchomeronate) HED Risk Assessment for Reregistration Eligibility Document (RED)*, dated April 7, 2003, see particularly the *MGK® Repellent 326: HED Toxicology Chapter for the Reregistration Eligibility Decision Document (RED)* dated April 7, 2003 and the *MGK® Repellent 326 - Revised Report of the Hazard Identification Assessment Review Committee*, dated December 20, 2002.

### III. A. 3. a. i. Acute Toxicity

MGK® Repellent 326 demonstrates low acute toxicity via the oral (Toxicity Category III), dermal (Toxicity Category III), and inhalation (Toxicity Category IV) routes of exposure.

Because MGK® Repellent 326 is not irritating to the eyes or the skin, it is in Toxicity Categories III and IV, respectively. Also, it is not a dermal sensitizer. The acute toxicity profile for MGK® Repellent 326 is summarized in Table 1.

**TABLE 1. ACUTE TOXICITY FOR MGK® REPELLENT 326 (TECHNICAL)**

| Guideline No. | Study Type | MRID | Results | Toxicity Category |
|---|---|---|---|---|
| 870.1100 | Acute Oral | 00155068 | $LD_{50}$* = 5850 mg/kg, male<br>$LD_{50}$ = 4270 mg/kg female<br>$LD_{50}$ = 5120 mg/kg male & female | III<br>based on female toxicity |
| 870.1200 | Acute Dermal | 41648601 | $LD_{50}$ = > 2000 mg/kg | III |
| 870.1300 | Acute Inhalation | 41571501 | $LC_{50}$*= > 6.09 mg/L | IV |
| 870.2400 | Eye Irritation | 41800501 | Not irritating | III |
| 870.2500 | Skin Irritation | 41826505 | Not irritating | IV |
| 870.2600 | Dermal Sensitization | 41648602 | Negative | NA |

* LD50 or LC50 = Median Lethal Dose or Concentration. A statistically derived single dose or concentration that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation).

### III. A. 3. a. ii. Toxicological Endpoints

In determining the toxicological endpoints for a chemical, a NOAEL (No Observed Adverse Effect Level) is identified and/or selected from a study that best approximates the duration and route of exposure. The NOAEL is the highest dose at which no adverse health effects are observed in animal studies. The selected toxicological endpoint and NOAEL form the basis of the hazard component of the risk assessment for each route of human exposure (i.e., oral, dermal, and inhalation).

Residential exposure is the only relevant exposure scenario for MGK® Repellent 326 based on the current use patterns. Therefore, toxicological doses and endpoints for dietary (food and drinking water) exposure were not established. However, short- (1-30 days) and intermediate- (1-6 months) term endpoints for incidental oral, dermal, and inhalation exposures were selected. Because MGK® Repellent 326 is used seasonally, a long-term (>6 months) exposure endpoint was not selected.

For both incidental oral and dermal routes of exposure, 65 mg/kg/day was selected as the NOAEL from a two generation reproductive study in the rat based on decreased pup body weight occurring on lactation days 14-21 at a LOAEL (Lowest Observed Adverse Effect Level) of 250 mg/kg/day. Due to lack of toxicity at the highest dose from a 90-day inhalation rat toxicity study, the NOAEL was identified as 60 mg/kg/day, which was the highest dose tested for the inhalation route of

exposure. The cancer endpoint was selected based on a combined chronic toxicity/carcinogenicity study in rats and a carcinogenicity study in mice. Toxicological endpoints used in the residential risk assessment are summarized in Table 2.

**TABLE 2. SUMMARY OF DOSES AND ENDPOINTS SELECTED FOR MGK® REPELLENT 326 RESIDENTIAL RISK ASSESSMENT**

| Route and Duration of Exposure | Dose (mg/kg/day) & Uncertainty Factor (UF) | Toxicological Endpoint | Study Type (MRID) |
|---|---|---|---|
| **Incidental Oral** Short- and Intermediate- Term (1 day to 6 months) | NOAEL= 65<br>LOAEL= 250<br>UF = 100 | Decreased pup body weight on lactation days 14-21. | 2-Generation reproductive study in the rat (41547801) |
| **Dermal** Short- and Intermediate-Term (1 day to 6 months) | Oral* NOAEL=65<br>LOAEL=250<br>UF = 100 | | |
| **Inhalation** Short- and Intermediate-Term (1 day to 6 months) | NOAEL = 60<br>LOAEL >60<br>UF = 100 | Lack of toxic effects at highest dose tested | 90-day inhalation toxicity study in the rat (42990201) |
| **Cancer** | Classification: B2; Probable human carcinogen<br>$Q_1$* = $1.6x10^{-3}$ $(mg/kg/day)^{-1}$ | | |

* A 5% dermal absorption factor was applied for conversion from oral to dermal.

Since the dermal exposure endpoint was selected from an oral toxicity study, a dermal absorption factor (DAF) was required to convert an oral dose to an equivalent dermal dose. Accordingly, the Agency selected a 5% DAF based on two human dermal absorption studies with a 1% MGK® Repellent 326 product (MRIDs 42974602 and 42732101).

### III. A. 3. a. iii. Carcinogenicity

In assessing the carcinogenicity of pesticides, the Agency first evaluates evidence that the pesticide is a carcinogen. If there is evidence, such as tumor formation and the pesticide is classified as a carcinogen, a quantitative assessment is conducted using a $Q_1$* (non-threshold) or a Margin of Exposure (threshold) approach. The mechanism of the tumor formation determines whether or not a threshold or non-threshold assessment is conducted.

Since 1993, MGK® Repellent 326 has been classified as a probable human carcinogen or group "B2", based on findings in both the rat and mouse studies during carcinogenicity testing, under the Agency's 1986 cancer risk assessment guidelines. In light of the findings, the Agency quantified the cancer risk using a non-threshold approach. The $Q_1$* value for MGK® Repellent 326 is $1.6x10^{-3}$

$(mg/kg/day)^{-1}$ based on combined liver tumors in rats. It should be noted that the carcinogenic effects were seen at the limit dose (1000 mg/kg/day) for the rats and twice the limit dose for the mice.

### III. A. 3. a. iv. FQPA Safety Factor Considerations

Determination of the FQPA safety factor is based on an analysis of all the toxicology data following the approach described in the Agency's 2002 guidance document, *Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment*, dated February 28, 2002. Because all MGK® Repellent 326 registrations for use in/on foods have been cancelled and EPA is proposing to revoke the tolerances, a FQPA safety factor is not applicable for this pesticide. However, although the FQPA safety factor does not apply, the toxicity and exposure databases were examined to determine if any special concerns exist for infants and children. Based on low evidence of increased susceptibility, the Agency determined that the traditional uncertainty factors (UFs) for MGK® Repellent 326 are adequately protective of all population subgroups, including infants and children. The traditional UFs account for differences between test animals and humans (10x for interspecies extrapolation) and the differences among different human sub-populations (10x for intraspecies variation).

### III. A. 3. b. Residential Assessment

The Agency looks at residential exposure by assessing how a person may come in contact with a pesticide by using the pesticide in and around the home. Accordingly, a residential exposure assessment was conducted for MGK® Repellent 326 because there is potential exposure and risk due to direct application of insect repellents containing MGK® Repellent 326 to humans, pets and their premises. It is assumed that direct application to human skin would result in the highest level of potential exposures to adults and children, and would exceed those from transfer of residues from any animal applications. Moreover, the majority of human personal use products contain 2.5% or less of the a.i., whereas animal products contain 1% a.i. or less. Therefore, the residential risk assessment was conducted only on exposures resulting from direct application of MGK® Repellent 326 to humans, since it is considered to be the scenario of greatest potential concern. For a detailed discussion, see the *Exposure Assessment for MGK 326 (Dipropyl isocinchomerate)*, dated April 7, 2003.

All MGK® Repellent 326 products intended for human use contain DEET (N, N-diethyl-m-toluamide) as the primary active ingredient. Therefore, the Agency used frequency and quantity information from a 1990 survey on consumer use of products containing DEET to assess exposure to MGK® Repellent 326, because there are no available data measuring exposures to MGK® Repellent 326 for humans. The DEET survey study was conducted during the months of June and July and was submitted by the DEET Joint Venture/Chemical Specialties Manufacture Association (MRID 41968001). After analyzing the data, the Agency determined that the DEET survey provides the most definitive data for estimating human insect repellent exposures for assessing non-cancer and cancer residential risks of MGK® Repellent 326.

### III. A. 3. b. i. Non-Cancer Residential Risk Summary

*Exposure Scenarios*

As personal insect repellents, MGK® Repellent 326 products may be applied as sprays, lotions, and liquids. There is no standard application rate as the products are applied on an as needed basis. Accordingly, the Agency identified the following as the three major non-cancer residential exposure scenarios: 1) incidental oral exposure of children from topical application (i.e., incidental hand to mouth contact after repellent is applied to a child's skin; 2) dermal exposure from direct application of MGK® Repellent 326 to human skin and clothing; and 3) inhalation exposure from use of repellent sprays.

*Margins of Exposure (MOEs) and Characterization*

Non-cancer residential risk is measured by a Margin of Exposure (MOE) which reflects how close the residential exposure comes to a NOAEL selected from animal studies. The margin of exposure (MOE=NOAEL/exposure) is compared to a level of concern, or target MOE. The target MOE is the same value as the uncertainty factor applied to the NOAEL from the relevant toxicity study. A MOE less than the target MOE is typically of concern to the Agency. For MGK® Repellent 326, the target MOE is 100 for the incidental oral, dermal, and inhalation routes of exposure for the non-cancer residential risk assessment.

Although an endpoint for inhalation toxicity was selected, inhalation exposure is expected to be negligible as explained below; therefore, risks were not quantitatively assessed. The vapor pressure of MGK® Repellent 326 is very low ($4.92 \times 10^{-7}$) so there would be virtually no vapor generated by non-aerosol products. All MGK® Repellent 326 labels prohibit spraying of the face. Additionally, inhalation exposure duration from aerosol application is expected to be extremely short (i.e., typically a few seconds). Based on these considerations, inhalation exposure to MGK® Repellent 326 would not significantly affect the overall risks.

The Agency assumes that the primary route of exposure will be dermal. Therefore, assuming average body weights, a mean amount of product applied to skin and clothing per application, a 5% DAF and 2.5% as the maximum concentration of MGK® Repellent 326 in a product formulation for human application, the following non-cancer residential MOEs were derived for dermal exposure. The MOEs estimated for the residential (personal insect repellent use) dermal exposure scenario for all population subgroups assessed indicate risks are not of concern (i.e., all MOEs are > 100) as indicated in Table 3.

| TABLE 3. MGK® REPELLENT 326 NON-CANCER RESIDENTIAL MOES – DERMAL EXPOSURE | | | | |
|---|---|---|---|---|
| **Population Subgroup** | **Applied Dose (mg/kg/day)** | **Body Weight (kg)** | **Daily Dose (mg/kg/day)** | **MOE[1] (Target MOE = 100)** |
| Child ≤ 12 years | 120 | 25 | 0.24 | 270 |
| Child 13-17 years | 130 | 56 | 0.12 | 565 |
| Adult Female | 107 | 62 | 0.09 | 750 |
| Adult Male | 130 | 77 | 0.08 | 770 |

[1] MOE= Oral NOAEL (65 mg/kg/day) / Daily Dose
where:
Daily Dose = (Applied Dose) x 5% DAF / Body Weight
Applied Dose = Applied Dose of Repellent from DEET Survey x 2.5% MGK® Repellent 326

The above MOEs for dermal exposure assumes MGK® Repellent 326 is applied once a day. However, because insect repellents containing MGK® Repellent 326 may be applied more than once a day, the Agency assessed the number of applications that could be applied in a day and not result in risks of concern. To assess the number of applications allowable per day, the Agency set the MOE to 100 and conducted the calculation in reverse using a set daily dose of 0.65 mg/kg/day, which is the dermal dose adjusted by uncertainty factors.

Table 4 details the number of dermal applications each population subgroup may make and not result in risks of concern: children ages twelve and under may use 3 applications; children ages 13-17 may use 6 applications; and adults may use 8 applications. These estimates are considered to be relatively protective based on the average number of MGK® Repellent 326 applications per year identified in the DEET survey and its limited use pattern.

| TABLE 4. NUMBER OF MGK® REPELLENT 326 APPLICATIONS / DAY WITHOUT EXCEEDING THE AGENCY'S NON-CANCER RESIDENTIAL LEVEL OF CONCERN [1] | | | | |
|---|---|---|---|---|
| **Population Subgroup** | **Applied Dose (mg/kg/day)** | **Body Weight (kg)** | **Daily Dose (mg/kg/day)** | **Number of Applications / Day** |
| Child ≤ 12 years | 325 | 25 | 0.65 | 3 |
| Child 13-17 years | 735 | 56 | | 6 |
| Adult Female | 806 | 62 | | 8 |
| Adult Male | 1001 | 77 | | 8 |

[1]Target MOE = 100

The MOE calculated for incidental oral exposure of children (ages twelve and under) from topical application is 4100. This MOE is well above the Agency's target of 100; therefore, incidental oral exposure is not of risk concern. Although incidental oral exposure is expected to be negligible

when compared to dermal exposure, the Agency assessed combined sources of exposure from direct application of MGK® Repellent 326 to human skin and incidental oral exposure of children from hand-to-mouth activity after topical application. Combined risks from different residential exposure pathways is estimated for the child exposure scenario only, since children are assumed to be exposed via both the incidental oral and dermal pathways. Whereas adults are assumed to be exposed by the dermal route only. The combined MOE for the child is calculated by adding exposure estimates from the oral and dermal pathways. The combined MOE is 250 for children ages twelve and under, which is greater than the target MOE of 100 and, therefore, not a risk concern.

### III. A. 3. b. ii. Cancer Residential Risk Summary

*Exposure Assumptions*

To assess the amount of residential cancer exposure an individual will receive over a lifetime from using MGK® Repellent 326, the following assumptions were applied:

- The Agency used its standard assumption that the average adult weighs 70 kg (as agreed upon by North American Freedom of Trade Agreement (NAFTA) members) over a lifetime. Although the body weights of exposed individuals vary from children to adults, for a lifetime of exposures adult body weights are more appropriate for risk assessment purposes.

- Standard policy for assessing residential/non-occupational lifetime exposure is 70 years. Therefore, the Agency assumes that an individual is exposed every year for 70 years. Also, in calculating lifetime exposure, standard policy is to use an average number of applications applied per year.

- The Agency used the data from a 1990 DEET survey to determine the average number of applications that are likely to occur over a year. The data gathered revealed repellent products containing DEET were used an average of 7.5 times during the months of June and July. Similarly, syndicated market data from 1989-1990 indicated approximately 55-60% of yearly insect repellent sales occur during the months of June and July.

- Using the average of 7.5 applications during the heavy use season and dividing by 60%, which is the volume of insect repellents reportedly sold during the same period from the DEET survey data, the Agency estimates that an individual will make 12.5 MGK® Repellent 326 applications per year on average. The Agency conservatively assumed for the risk assessment that each DEET product reported in the survey also contained MGK® Repellent 326.

- Further, the risk assessment conservatively assumes residues applied to both clothing and skin are absorbed into the skin. Meaning if an individual sprays an insect repellent containing MGK® Repellent 326 over their clothes and exposed skin, not only is the amount contacting

the skin being absorbed, but the residues from the clothing are also being absorbed. Also, it is assumed that 100% of what is applied is contacting the skin and of the amount applied, 5% is absorbed through the skin. Moreover, it is assumed that the concentration of MGK® Repellent 326 in all products is limited to 2.5% a.i. regardless of formulation.

*Risk Estimates*

Cancer risk estimates are calculated by multiplying the Lifetime Average Daily Dose (LADD), which represents oral, dermal, inhalation exposure over a lifetime, by the $Q_1$* or unit risk. Because dermal exposure is the primary route of exposure for MGK® Repellent 326, oral and inhalation routes exposures were not considered in determining the LADD. Therefore, all the exposure assumptions discussed above were considered in calculating the LADD for MGK® Repellent 326, which represents average annual dermal exposure to an individual over a lifetime.

As mentioned in the carcinogenicity section, MGK® Repellent 326 was quantitatively assessed using a non-threshold ($Q_1$*) approach. The $Q_1$* value for MGK® Repellent 326 is based on combined tumors in the rat cancer study. Also, the $Q_1$* is based on extrapolating from animal studies, therefore the Agency used a 3/4 body weight scaling factor to derive a human equivalent. The $Q_1$* value derived for MGK® Repellent 326 is $1.6 \times 10^{-3}$ $(mg/kg/day)^{-1}$.

Cancer risk estimates assessed by a $Q_1$* approach are expressed as a probability. For example, a cancer risk of $1 \times 10^{-6}$ means that a person receiving a lifetime exposure to the pesticide increases his/her risk of developing cancer by one chance in a million. Based on the data and assumptions discussed above and the $Q_1$* value, EPA estimates that individuals exposed to MGK 326 over a lifetime have a potential cancer risk of $4.7 \times 10^{-6}$. The Agency believes the conservative assumptions and factors used in the risk assessment provide adequate assurance that actual risks are lower and do not exceed the Agency's level of concern.

## III. A. 4. Aggregate Risk

Although tolerances are proposed for revocation and an aggregate risk assessment is not required for MGK® Repellent 326, EPA has considered the potential for risk resulting from exposure via multiple sources. EPA has determined that since there is no potential for exposure through food, and potential exposure through drinking water would be negligible, risks resulting from combined sources of exposure (residential, food, and drinking water) would be below EPA's level of concern.

## III. A. 5. Human Incident Reports

In evaluating incidents to humans, the Agency reviews any incident data that may be available and applicable. Although, there have been incidents reported from other active ingredients formulated with MGK® Repellent 326, they were not attributed to MGK® Repellent 326. For more details see

*Review of MGK-326 Incident Reports*, dated September 3, 2003, which is available on the internet and in the public docket.

### III. B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see *MGK 326/Disopropyl isochinomerate [sic] RED*, dated December 24, 2002, which is available on the internet and in the public docket.

### III. B. 1. Ecological Toxicity Data

A limited set of toxicity data for indoor-use pesticides is required to determine precautionary label statements and to assess environmental hazards in case of spills. MGK® Repellent 326 qualifies for a reduced data set, because use patterns are limited to indoor non-food and residential uses. The available data characterize MGK® Repellent 326 as practically nontoxic to birds, slightly toxic to aquatic invertebrates and highly toxic to fish, and are summarized in the Table 5.

**TABLE 5. SUMMARY OF MGK® REPELLENT 326 ECOLOGICAL TOXICITY ENDPOINTS**

| Toxicity Study | Test Species | % a.i. | Endpoint (ppm) | Toxicity Category | MRID |
|---|---|---|---|---|---|
| ***Birds (Subacute: Five days of treated feed)*** | | | | | |
| Avian Dietary | Bobwhite Quail | 98.8 | $LC_{50}$* = 5,000 | Practically nontoxic | 41685502 |
| Avian Dietary | Mallard Duck | 98.8 | $LC_{50}$ = >5,620 | Practically nontoxic | 41685501 |
| ***Aquatic Species (Acute: Single dose)*** | | | | | |
| Freshwater Invertebrate | Daphnid | 99.7 | $EC_{50}$** = 18 | Slightly toxic | 41525302 |
| Freshwater Fish | Bluegill Sunfish | 99.5 | $LC_{50}$ = 0.44 | Highly toxic | 42174501 |
| Freshwater Fish | Rainbow Trout | 100 | $LC_{50}$ = 1.0 | Highly toxic | 41911401 |

*$LC_{50}$ = Median Lethal Concentration. A statistically derived single concentration that can be expected to cause death in 50% of the test animals when administered by the oral route.

**$EC_{50}$ = Effective Concentration for aquatic plants and invertebrates. The concentration of a chemical in water at which an effect is observed that is 50% of the maximum effect.

### III. B. 2. Environmental Fate

The Agency develops a profile of the likely fate (persistence and mobility) of an individual pesticide in the environment based on a combination of standard studies. Because of its limited use pattern, the only environmental fate study required to be conducted for MGK® Repellent 326 was hydrolysis. MGK® Repellent 326 remains stable under acidic conditions (pH 5), no degradation was

observed during the 30 days of the study. However, MGK® Repellent 326 hydrolyzes in neutral (pH 7 half-life=17 days) and alkaline environments (pH 9 half-life=14 hours) (MRID 43073601).

### III. B. 3. Ecological Risk Summary

To assess the potential for significant risk to non-target organisms from use of a pesticide, the Agency compares the estimated environmental exposure concentration to the toxicity effect level. The Agency uses surrogate species (i.e., bobwhite quail, rats, rainbow trout, etc.) to represent all terrestrial and aquatic organism potentially exposed in pesticide use areas.

Ecological risk assessments are not conducted for pesticides with exclusively indoor use patterns. MGK® Repellent 326 is considered to be an "indoor residential" use rather than an outdoor use because it is only applied directly to the human body and/or clothing, cats, dogs, horses, pet quarters, and household/domestic dwellings. Application of MGK® Repellent 326 to these sites is not likely to adversely affect terrestrial wildlife or aquatic organisms; therefore, an environmental risk assessment was not conducted for MGK® Repellent 326.

### III. B. 4. Incident Reports

The Ecological Incident Information System (EIIS) database recorded no incidents to non-target species associated with MGK® Repellent 326.

### III. B. 5. Endangered Species

Based upon the exclusive "indoor residential" use pattern and unlikelihood of MGK® Repellent 326 to adversely affect terrestrial wildlife or aquatic organisms, MGK® Repellent 326 will have no effect on federally listed endangered and threatened species from the uses discussed in this RED.

## IV. RISK MANAGEMENT AND REREGISTRATION DECISION

### IV. A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submissions of relevant data concerning an active ingredient, whether pesticides containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic data required to support reregistration of products containing MGK® Repellent 326 as the active ingredient.

The Agency has completed its assessment of the residential risks associated with the use of MGK® Repellent 326 repellency products. Based on a review of these data and public comments on the Agency's risk assessments for the active ingredient MGK® Repellent 326, EPA has sufficient information on the human health and ecological effects of MGK® Repellent 326 to make a

reregistration decision under FIFRA, as amended by FQPA. The Agency has determined that MGK® Repellent 326 is eligible for reregistration provided that: (i) current data gaps and additional data needs are addressed; and (ii) the risk mitigation measures outlined in this document are adopted, including the label amendments described in Section IV and limiting production and distribution to 20,000 pounds of active ingredient annually by all registrants for use as an insect repellent on humans. The technical registrant(s) must also submit an annual report certifying that production and distribution of MGK® Repellent 326 for use in personal insect repellents did not exceed 20,000 lbs a.i.; and (iii) limits the maximum concentration active ingredient in end-use products for personal insect repellents to 2.5%. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of MGK® Repellent 326, and lists the submitted studies that the Agency found acceptable.

Based on its current evaluation of MGK® Repellent 326 alone, the Agency has determined that MGK® Repellent 326 products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from use of MGK® Repellent 326. Also, this decision does not preclude the Agency from making further FQPA determinations and tolerance-related rulemakings that may be required on this pesticide, or any other, in the future.

## IV. B. Summary of Public Participation Process

When making its reregistration decision for MGK® Repellent 326, the Agency took into account all comments received during the public participation process. The only comments received were from the technical registrant, McLaughlin Gormley King Company (MGK). In their comments, MGK indicated that they intend to take certain steps to address the Agency's estimated cancer risk, including convening a pathology working group to review findings in the kidney and other tissues; investigate advances presented in the scientific literature; reexamine study tissues (in particular liver tissue to look for evidence of cell proliferation); and other actions. The registrant also commented on the cancer risk assessment guidelines and other methods used to derive the cancer risks estimates for MGK® Repellent 326.

The registrant has not provided the appropriate data to allow the Agency to reconsider the cancer classification at this time; however, MGK has engaged the Agency to determine the necessary work to address the identified hazard identification issues, which MGK believes will be responsive to MGK® Repellent 326 cancer classification and risk concerns. The registrant's comments and the Agency's response to these comments are available in their entirety on the internet and the public docket.

## IV. C. Regulatory Position

### IV. C. 1. Determination of Safety for U.S. Population under FQPA

As detailed above, all registrations for uses of MGK® Repellent 326 on or in food have been voluntarily cancelled by the technical registrant. Therefore, the Agency has concluded that a FQPA safety factor is not applicable for this pesticide. Additionally, EPA is recommending revocation of tolerances for residues resulting from dermal application in/on livestock commodities that have been removed from the MGK® Repellent 326 technical label.

Although a FQPA safety factor is not applicable for MGK® Repellent 326, the Agency considered the available information to determine if there is an increased susceptibility to infants and children from exposures to MGK® Repellent 326. Based on that evaluation, the Agency concluded that the MGK® Repellent 326 human health assessment is adequately protective of all population subgroups, including infants and children.

### IV. C. 1. a. Tolerance Summary

*Tolerance Reassessment*

The tolerances listed under 40 CFR §180.143 are "for negligible residues of the insect repellent dipropyl isocinchomronate" (MGK® Repellent 326). The Agency is now proposing to revoke tolerances for residues resulting from dermal application in/on livestock commodities that have been removed from the MGK® Repellent 326 technical label.

The established tolerances for milk, fat, meat, and meat byproducts of cattle, goat, hog, horse, and sheep are no longer applicable for MGK® Repellent 326. The Agency's tolerance reassessment summary is provided in Table 6.

| TABLE 6. TOLERANCE REASSESSMENT SUMMARY FOR MGK® REPELLENT 326 | | | |
|---|---|---|---|
| **Commodity** | **Current Tolerance (ppm)** | **Reassessed Tolerance (ppm)** | **Comment** |
| **Tolerances Listed Under 40 CFR §180.143** | | | |
| Cattle, fat | 0.1 (N) | Revoke | Livestock (food) uses have been deleted, therefore tolerances to be revoked.<br><br>Delete Section 40 CFR §180.143. |
| Cattle, meat | 0.1 (N) | | |
| Cattle, meat byproducts | 0.1 (N) | | |
| Goats, fat | 0.1 (N) | | |
| Goats, meat | 0.1 (N) | | |
| Goats, meat byproducts | 0.1 (N) | | |
| Hogs, fat | 0.1 (N) | | |
| Hogs, meat | 0.1 (N) | | |
| Hogs, meat byproducts | 0.1 (N) | | |
| Horses, fat | 0.1 (N) | | |
| Horses, meat | 0.1 (N) | | |
| Horses, meat byproducts | 0.1 (N) | | |
| Milk | 0.004 (N) | | |
| Sheep, fat | 0.1 (N) | | |
| Sheep, meat | 0.1 (N) | | |
| Sheep, meat byproducts | 0.1 (N) | | |

(N) = negligible residues

*Codex Harmonization*

No Codex Maximum Residue Levels (MRLs) are necessary for MGK® Repellent 326; therefore, issues of compatibility between Codex MRLs and U.S. tolerances do not exist.

*Residue Analytical Methods*

The *Pesticide Analytical Manual*, Volume II lists the available methods for tolerance enforcement. However, enforcement methods are not required for determining residues of MGK® Repellent 326 because there are no food uses registered for MGK® Repellent 326 and the tolerances are to be revoked.

### IV. C. 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 such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, 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). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, MGK® Repellent 326 may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

### IV. C. 3. Cumulative Risk

FQPA of 1996 stipulates that when considering whether to establish, modify, or revoke a tolerance, the Agency must consider "available information" concerning cumulative effects of a particular pesticide's residues and "other substances that may have a common mechanism of toxicity." The Agency did not perform a cumulative risk assessment as part of this assessment for MGK® Repellent 326 because the Agency has not yet initiated a review to determine if there are any other chemical substances that have a mechanism of toxicity common with that of MGK® Repellent 326. Therefore, for purposes of the RED, the Agency assumes that MGK® Repellent 326 does not share a common mechanism of toxicity with any other substance(s). Should a common mechanism of toxicity be determined in the future, EPA may need to reconsider the cumulative risks of MGK® Repellent 326.

### IV. C. 4. Public Health Benefits

Under section 4(n) of FIFRA, the Agency requested a consultation with the Centers for Disease Control and Prevention (CDC) for potential public health benefits for the insect repellent MGK® Repellent 326. CDC responded that because there is little information in the published literature concerning the effectiveness of the pesticide, CDC found it difficult to evaluate the public health benefits derived from MGK® Repellent 326. Despite the lack of data, CDC has indicated that they support the reregistration of MGK® Repellent 326 from a public health perspective. For more details, see the letter from CDC dated August 25, 2003, which is available on the internet and in the public docket.

## IV. D. Regulatory Rationale

The following is a summary of the rationale for managing risks associated with the use of MGK® Repellent 326. Where labeling revisions are warranted, specific language is set forth in the summary Table of Section V (Table 8) of this document.

### IV. D. 1. Human Health Risk Mitigation

#### IV. D. 1. a. Dietary Risk Mitigation

Dietary risk from food and drinking water are not of concern, based on the current use pattern and the absence of dietary exposure for the chemical. Therefore, mitigation measures to address dietary (food and drinking water) risks are not necessary for MGK® Repellent 326.

#### IV. D. 1. b. Residential Risk Mitigation

##### IV. D. 1. b. i. Non-Cancer

Non-cancer residential exposures do not pose a risk of concern. The MOEs for individual and combined routes of exposure from single applications of MGK® Repellent 326 are all greater than 100, the Agency's level of concern. Therefore, mitigation measures to address non-cancer residential risk are not necessary for MGK® Repellent 326. However, because MGK® Repellent 326 is an insect repellent which may be applied multiple times directly to skin of individuals of all age groups including young children, the Agency assessed the number of dermal applications a population subgroup may make without resulting in risks of concern (see Table 4). The results of this analysis indicates that children, ages 12 and under, may make up to 3 applications in a single day without exceeding levels of concern. Therefore, to limit the potential exposure of MGK® Repellent 326 to children, a statement shall be added to MGK® Repellent 326 products for human use specifying the number of applications to children ages twelve and under. The statement will read as follows: "Do not apply more than 3 times per day to children ages twelve and under."

##### IV. D. 1. b. ii. Cancer

The Agency conducted a conservative (high-end) cancer risk assessment, which resulted in a potential lifetime cancer risk estimate of $4.7 \times 10^{-6}$. Although the cancer assessment suggests a risk of concern (greater than $1 \times 10^{-6}$), the Agency believes that the actual risk is lower, in light of the conservative assumptions used in the Agency's assessment. For instance, although the carcinogenic effects for MGK® Repellent 326 were identified only at the highest dose tested, using a non-threshold ($Q_1^*$) approach, it is assumed that any dose, however small, can lead to cancer.

Also, in using the DEET survey data to estimate cancer risk, the Agency assumed that every DEET product sold and applied also contains MGK® Repellent 326. This assumption seems to be highly conservative, because of the significant difference in annual poundage produced and used yearly (DEET averages about 7-8 million pounds of a.i annually compared to 31,000 to 36,000 lbs for MGK® Repellent 326, of which only approximately 15,000 to 20,000 lbs of MGK® Repellent 326 are used for personal insect repellent products). Furthermore, insect repellents such as MGK® Repellent 326 are generally used on a seasonal and intermittent basis, as indicated by DEET survey sales data which denotes 60% of the products are sold in June and July. Based on this information, it is unlikely an individual would spend 70 years in a seasonally insect populated environment and use the same DEET repellent products that also contains MGK® Repellent 326 each year.

Spray-type products, aerosol and pump-types, are the most common forms available for application of MGK® Repellent 326, and are generally used to treat both skin and clothing to repel biting flies. The cancer risk estimates were based on the total amount of MGK® Repellent 326 product measured from typical spray-type applications, which were made to both clothing and skin and assumed available for absorption into the skin. Yet it is unlikely that the total amount applied to clothing would be available for absorption into the skin because of the lack of contact between the treated clothing surface and the individual's skin. Furthermore, because of the nature of spray applications, particularly aerosol, the amount of product sprayed from a container is not likely to all be deposited on the target area. In other words, a certain amount of the released spray does not even contact the individual's skin or clothing. Therefore, the actual dose is expected to be less than the dose used in the cancer risk calculations.

To present a more realistic estimate of exposure and risk, EPA modified some of the screening-level assumptions used in the risk assessment, such as the number of years an individual may be exposed over a lifetime, and the level of MGK® Repellent 326 residues applied to skin only rather than to both skin and clothing. The range of risks calculated using these different assumptions is presented in Table 7.

**Table 7. ESTIMATED CANCER RISK FROM RESIDENTIAL USE OF MGK® REPELLENT 326**

| No. of Years Applied | Skin and Clothing[1] | Skin Only[2] |
|---|---|---|
| 70 | $4.7 \times 10^{-6}$ | $3.3 \times 10^{-6}$ |
| 50 | $3.4 \times 10^{-6}$ | $2.4 \times 10^{-6}$ |
| 30 | $2.0 \times 10^{-6}$ | $1.4 \times 10^{-6}$ |
| 20 | $1.3 \times 10^{-6}$ | $9.5 \times 10^{-7}$ |
| 15 | $1.0 \times 10^{-6}$ | $7.1 \times 10^{-7}$ |
| 10 | $6.7 \times 10^{-7}$ | $4.8 \times 10^{-7}$ |
| 5 | $3.4 \times 10^{-7}$ | $2.4 \times 10^{-7}$ |

[1] Average amount of product per application for skin and clothing (high-end) = 4.8 g

[2] Average amount of product per application for skin only (low-end) = 3.4 g

In Table 7, cancer risks were estimated from a range of 5 to 70 years of exposure. Each exposure duration was also divided into two categories, skin and clothing (high-end) and skin only (low-end) exposure. The Agency chose to present a range of estimated cancer risks for MGK® Repellent 326 for application to skin only and skin and clothing to present more appropriate estimates of cancer risk, because of the limited use pattern and availability of MGK® Repellent 326 products, and the conservative exposure assumptions used in the cancer risk assessment. As indicated in Table 7, the estimated cancer risk decreases proportionally with the reduction in years of exposure. Therefore, because it is highly unlikely that an individual would use products containing MGK® Repellent 326 over a period of many years, due to the small proportion of insect repellents available that contain MGK® Repellent 326, the actual cancer risks associated with this use are likely lower.

As previously discussed, use of product sprays (aerosol and pump-type) are likely to result in applications to both skin and clothing, which were included in the cancer risk assessment as high-end exposures. However, the high-end amount of MGK® Repellent 326 applied by sprays to the skin and clothing is not expected to be fully available to be absorbed into the skin. Further, current product labels include the statement "do not use under clothing," and not all registered product formulations containing MGK® Repellent 326 are aerosol sprays. Thus, using more realistic exposure assumptions, calculations indicate that an individual could be continuously exposed for nearly 30 years without exceeding the Agency's level of concern. For more details see *MGK® Repellent 326 (Di-n-propyl isocinchomeronate) cancer Risk Estimates for Residential Use of MGK® Repellent 326*, dated August 29, 2003, which is available on the internet and in the public docket.

Thus, based on the Agency's understanding of the use of MGK® Repellent 326 and the conservative (high-end) assumptions which were used to calculate lifetime exposures, it is the Agency's position that the estimated cancer risks are an overestimate and that actual risks are not of concern, provided the following measures are complied with and fully implemented:

- Because the estimated cancer risks are based on an assumption that an individual is continuously exposed to MGK® Repellent 326 for up to 70 years, which use information indicates is highly unlikely because of the limited availability of MGK® Repellent 326 products, the Agency believes it is necessary for production and distribution of MGK® Repellent 326 to be limited. A limitation on the amount of MGK® Repellent 326 annually produced and distributed, is imposed to provide assurance that human exposure to MGK® Repellent 326 in the United States will not increase from current levels, and to reduce the potential of an individual from encountering long-term exposure to MGK® Repellent 326. Hence, the sole technical registrant, MGK, has agreed to limit production of MGK® Repellent 326 for human use products to a total of 20,000 pounds of active ingredient per year.

  Pending receipt and review of additional information regarding the cancer risks associated with the use of MGK® Repellent 326 for human-use products, the Agency may revisit the specified production limit determination.

- Because the cancer risk assessment was conducted based on MGK® Repellent 326 products containing 2.5% a.i. (for human use, most registered products contain 2.5% a.i. or less, although there are some products which contain more than 2.5% a.i.), the technical registrant has agreed to reduce and limit the maximum concentration of a.i. to 2.5% for all manufacturing-use products containing MGK® Repellent 326 intended for human use only. As a result all end-use registrations containing MGK® Repellent 326 intended for human use only must also include this restriction.

**IV. D. 1. c. Aggregate Risk Mitigation**

Aggregate risk from combined exposure from dietary (food and drinking water) and residential sources where not considered, because there are no dietary exposures. Therefore, no mitigation is needed to address aggregate risk.

**IV. D. 2. Environmental Risk Mitigation**

Environmental risks do not pose a risk of concern, based on the current use pattern and the absence of exposure to terrestrial wildlife or aquatic organisms for the chemical. Therefore, mitigation measures to address environmental risks are not necessary for MGK® Repellent 326.

**IV. E. Label Amendments**

A number of label amendments, in addition to the existing label requirements, are necessary in order for MGK® Repellent 326 products to be reregistered. The listing below identifies the label statements/amendments needed on MGK® Repellent 326 labels in order for products to be reregistered:

*Label Statements for Human Products:*
- "Do not apply more than 3 times per day to children ages twelve (12) and under."

*Label Statements for Companion Animal/Premise Products:*
- "Do not use on horses or foals intended for slaughter"
- "For use in companion animal quarters only, do not broadcast outdoors."
- "Remove animals from quarters before treating premises."

**V. WHAT REGISTRANTS NEED TO DO**

In order for MGK® Repellent 326 to be eligible for reregistration, registrants need to implement the risk mitigation measures outlined in sections IV and V, which include, among other things, submission of the following:

## V. A. Data Call-In (DCI) Responses

For MGK® Repellent 326 technical grade active ingredient products, registrants need to submit the following items:

**Within 90 days from receipt of the generic data call-in (DCI):** (1) completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and (2) submit any time extension and/or waiver requests with a full written justification.

**Within the time limit specified in the generic DCI:** cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Tawanda Spears at (703) 308-8050 with questions regarding generic reregistration and/or the DCI. All materials submitted in response to the generic DCI should be addressed:

By US mail:
Document Processing Desk (DCI/SRRD)
Tawanda Spears
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Tawanda Spears
Office of Pesticide Programs (7508C)
Crystal Mall 2, Room 266A
1801 South Bell St.
Arlington, VA 22202

For end-use products containing the active ingredient MGK® Repellent 326, registrants need to submit the following items for each product:

**Within 90 days from the receipt of the product-specific data call-in (PDCI):** (1) completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and (2) submit any time extension or waiver requests with a full written justification.

**Within eight months from the receipt of the PDCI:** (1) two copies of the confidential statement of formula (EPA Form 8570-4); (2) a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration"; (3) five copies of the draft label incorporating all label amendments outlined in Table 21 of this document; (4) a completed form certifying compliance with data compensation requirements (EPA Form 8570-34); (5) if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and (6) the product-specific data responding to the PDCI.

Please contact Barbara Briscoe at (703) 308-8177 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed:

By US mail:
Document Processing Desk (DCI/PRB)
Barbara Briscoe
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/PRB)
Barbara Briscoe
Office of Pesticide Programs (7508C)
Crystal Mall 2, Room 266A
1801 South Bell St.
Arlington, VA 22202

**V. B. Manufacturing-Use Products**

**V. B. 1. Generic Data Requirements**

The generic database supporting the reregistration of di-n-propyl isocinchomeronate (MGK® Repellent 326) has been reviewed and determined to be complete. However, the following product chemistry data requirements have been identified by the Agency as outstanding (required in a previous DCI, therefore will not be included in the generic DCI for this RED) or confirmatory (included in the generic DCI for this RED):

Outstanding:

| | |
|---|---|
| 830.1700 | Preliminary Analysis |
| 830.1750 | Certified Limits |
| 830.1800 | Enforcement Analytical Method |

Confirmatory:

| | |
|---|---|
| 830.7050 | UV/Visible Absorption |

**V. B. 2. Labeling for Manufacturing-Use Products**

To remain in compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulation, PR Notices and applicable policies. The MUP labeling should bear the labeling contained in Table 8 at the end of this section.

**V. C. End-Use Products**

**V. C. 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. Registrants 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.

### V. C. 2. Labeling for End-Use Products

Labeling changes are necessary to implement the mitigation measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 8 at the end of this section.

### V. D. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this RED document. Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, 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. For more information, refer to "Existing Stocks of Pesticide Products; Statement of Policy"; *Federal Register,* Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell MGK® Repellent 326 products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrants may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than the registrant remain obligated to meet pre-existing label requirements and existing stocks requirements applicable to products they sell or distribute.

### V. E. Labeling Changes Summary Table

In order to be eligible for reregistration, all product labels shall be amended to incorporate the risk mitigation measures outlined in Section IV. Table 8 describes how language on the labels should be amended. Label language in Table 8 enclosed in quotation marks represents exact language that should appear on the label. Instructions that are not enclosed in quotation marks represent actions that the registrant must take to amend their labels or product registrations in order for products to be reregistered.

| Table 8. SUMMARY OF LABELING CHANGES FOR MGK® REPELLENT 326 | | |
|---|---|---|
| **Description** | **Labeling Language** | |
| Manufacturing-Use Products | | |
| One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group | "Only for formulation into an insect repellent for the following use(s) [fill blank only with those uses that are being supported by MP registrant]." | Directions for Use |
| | "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)."<br><br>"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 |
| Maximum Concentration for Formulations Intended for Human Use | "For formulations of this product intended for human use, the maximum percent of active ingredient in any formulation type is 2.5." | Directions for Use |
| Environmental Hazard Statements | "This pesticide is toxic to fish. 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." | Precautionary Statements under: Environmental Hazards |
| End-Use Products | | |
| Directions for Use on Humans | "Read and Follow all Directions and Precautions on this Product Label." | Directions For Use: Following the Misuse Statement (It is a violation if Federal Law..) |

| Table 8. SUMMARY OF LABELING CHANGES FOR MGK® REPELLENT 326 | | |
|---|---|---|
| **Description** | **Labeling Language** | |
| General Precautions and Restrictions for Use on Humans | "Do not apply over cuts, wounds, or irritated skin."<br><br>"Do not apply near eyes and mouth. Apply sparingly around ears."<br><br>"Do not allow children to handle this product, and do not apply to children's hands"<br><br>"When using on children, apply to your own hands and then put it on the child."<br><br>"Do not apply more than 3 times per day to children ages twelve (12) and under."<br><br>"Use just enough repellent to cover exposed skin and/or clothing. Avoid overexposure"<br><br>"Do not use under clothing."<br><br>"After returning indoors, wash treated skin with soap and water."<br><br>"Wash treated clothing before wearing it again."<br><br>"Do not spray directly onto face. Spray hands first and then use hands to wipe spray onto face." | Directions for Use under the heading "General Precautions and Restrictions." |
| Replacement First Aid Statement for Dermal Route of Exposure | The following text must be added to the label as per PR Notice 2001-1 and replaces the "If On Skin Or On Clothing" statements:<br><br>"If you suspect a reaction to this product:<br>-Discontinue use.<br>-Rinse skin immediately with plenty of water for 15-20 minutes.<br>-Call a poison control center or doctor for treatment advice." | First Aid Statement |

| Table 8. SUMMARY OF LABELING CHANGES FOR MGK® REPELLENT 326 | | |
|---|---|---|
| **Description** | **Labeling Language** | |
| Directions for Use on Companion Animals | "Do not use on horses or foals intended for slaughter."<br><br>"Do not apply over cuts, wounds, or irritated skin."<br><br>"Do not apply near eyes and mouth. Apply sparingly around ears."<br><br>Include all statements consistent with PR Notice 96-6. | Directions for Use |
| General Precautions and Restrictions for Use in Companion Animal Quarters | "For use in companion animal quarters only, do not broadcast outdoors."<br><br>"Remove animals from quarters before treating premises." | Precautionary Statements |
| Environmental Hazard | "This pesticide is toxic to fish. Do not apply directly to water, or 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 washwaters or rinsate." | Precautionary Statements |

# APPENDICES

## Appendix A. MGK® Repellent 326 (Case 2215): Use Patterns Eligible for Reregistration

| Application Type<br>Timing<br>Equipment | Formulation | Max. Single App. Rate | Max. Seasonal App. Rate | Minimum Retreatment Interval (days) | Restrictions/Comments |
|---|---|---|---|---|---|
| **Cats (Adults/Kittens)** | | | | | |
| Animal Treatment (spray)<br>When Needed<br>Aerosol Can | Pressurized Liquid | Not Specified | Not Specified | Not Applicable | |
| Animal Treatment (lotion/ointment)<br>When Needed<br>By Hand | Ready To Use | Not Specified | Not Specified | Not Applicable | |
| Dip Treatment (shampoo)<br>When Needed<br>Dip | Emulsifiable Concentrate | 1 fl.oz / 1 gal of water | Not Specified | Not Applicable | |
| **Dogs (Adults/Puppies)** | | | | | |
| Animal Treatment (spray)<br>When Needed<br>Aerosol Can | Pressurized Liquid | Not Specified | Not Specified | Not Applicable | |
| Animal Treatment (lotion./ointment)<br>When Needed<br>By Hand | Ready To Use | Not Specified | Not Specified | Not Applicable | |
| Dip Treatment (shampoo)<br>When Needed<br>Dip | Emulsifiable Concentrate | 1 fl.oz / 1 gal of water | Not Specified | Not Applicable | |

## Appendix A. MGK® Repellent 326 (Case 2215): Use Patterns Eligible for Reregistration

| Application Type<br>Timing<br>Equipment | Formulation | Max. Single App. Rate | Max. Seasonal App. Rate | Minimum Retreatment Interval (days) | Restrictions/Comments |
|---|---|---|---|---|---|
| **Horses** | | | | | |
| Animal Treatment<br>When Needed<br>Towelette | Impregnated Material | Not Specified | Not Specified | Not Applicable | Do not use on horses or foals intended for slaughter. |
| Animal Treatment (spray)<br>When Needed<br>Pump Sprayer/Bottle | Pressurized Liquid | Not Specified | Not Specified | Not Applicable | Do not use on horses or foals intended for slaughter. |
| **Human Body/Clothing While Being Worn** | | | | | |
| Clothing Treatment<br>When Needed<br>Aerosol Can | Pressurized Liquid | Not Specified | Not Specified | Not Applicable | Do not apply more than 3 times per day to children ages twelve (12) and under. |
| Clothing Treatment<br>When Needed<br>Sprayer | Pressurized Liquid | Not Specified | Not Specified | Not Applicable | Do not apply more than 3 times per day to children ages twelve (12) and under. |
| Skin Contact Treatment<br>When Needed<br>Aerosol Can | Pressurized Liquid | Not Specified | Not Specified | Not Applicable | Do not apply more than 3 times per day to children ages twelve (12) and under. |

## Appendix A. MGK® Repellent 326 (Case 2215): Use Patterns Eligible for Reregistration

| Application Type<br>Timing<br>Equipment | Formulation | Max. Single App. Rate | Max. Seasonal App. Rate | Minimum Retreatment Interval (days) | Restrictions/Comments |
|---|---|---|---|---|---|
| Skin Contact Treatment<br>(lotion/ointment)<br>When Needed<br>By Hand | Ready<br>To Use | Not Specified | Not<br>Specified | Not<br>Applicable | Do not apply more than 3 times per day to children ages twelve (12) and under. |
| **Interior of Pet Living/Sleeping Quarters** | | | | | |
| Animal Bedding/Litter<br>Treatment<br>When Needed<br>Mist Applicator | Pressurized<br>Liquid | 1 fl. oz/<br>1000 sq. ft | Not<br>Specified | Not<br>Applicable | |
| Spot Treatment<br>When Needed<br>Mist Applicator | Pressurized<br>Liquid | 1 fl. oz/<br>1000 sq. ft | Not<br>Specified | Not<br>Applicable | For use in companion animal quarters only, do not broadcast outdoors. Remove animals from quarters before treating premises |

## Appendix B. Data Supporting Guideline Requirements for the Reregistration of MGK® Repellent 326

## GUIDE TO APPENDIX B

Appendix B contains a listing of data requirements which support the reregistration for active ingredients within the chemical case covered by this RED. It contains generic data requirements that apply in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Columns 1, 2 & 3). The data requirements are listed in the order of New Guideline Number and appear in 40 CFR §158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161-0002, (703) 487-4650.

2. Use Pattern (Column 4). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

    1. Terrestrial food
    2. Terrestrial feed
    3. Terrestrial nonfood
    4. Aquatic food
    5. Aquatic nonfood outdoor
    6. Aquatic nonfood industrial
    7. Aquatic nonfood residential
    8. Greenhouse food
    9. Greenhouse nonfood
    10. Forestry
    11. Residential
    12. Indoor food
    13. Indoor nonfood
    14. Indoor medical
    15. Indoor residential

3. Bibliographical Citation (Column 5). If the Agency has acceptable data in its files, this column lists the identification number of each study. Normally, this is the Master Record Identification (MRID) Number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography (Appendix D) for a complete citation of the study.

| New Guideline Number | Old Guideline Number | Requirement | Use Pattern | Bibliographical Citation(s) |
|---|---|---|---|---|
| **PRODUCT USE CHEMISTRY** | | | | |
| 830.1550 | 61-1 | Product Identity and Composition | All | 41605101, 42321101, Data Gap |
| 830.1600 | 61-2A | Starting Materials and Manufacturing Process | All | 41605101, 42321101 |
| 830.1620 | 61-2B | Description of Production Process | All | |
| 830.1670 | | Discussion of Formation of Impurities | All | |
| 830.1700 | 62-1 | Preliminary Analysis | All | 41605102, 42321101, 43015101, Data Gap |
| 830.1750 | 62-2 | Certification of Limits | All | 41605101-2, 42321101, Data Gap |
| 830.1800 | 62-3 | Enforcement Analytical Method | All | 41605102, 42321101, 42757901, Data Gap |
| 830.6302 | 63-2 | Color | All | 41605103 |
| 830.6303 | 63-3 | Physical State | All | |
| 830.6304 | 63-4 | Odor | All | |
| 830.7050 | None | UV/Visible Absorption | M, O | Data Gap |
| 830.7220 | 63-6 | Boiling Point/Boiling Range | All | 41605103 |
| 830.7300 | 63-7 | Density, Relative Density, Bulk Density | All | |
| 830.7840<br>830.7860 | 63-8 | Solubility | All | |
| 830.7950 | 63-9 | Vapor Pressure | All | 41548301, 41605103 |
| 830.7370 | 63-10 | Dissociation Constant in Water | All | 42230401, 42321101 |
| 830.7550 | 63-11 | Octanol/Water Partition Coefficient | All | 41520602, 41605103 |
| 830.7000 | 63-12 | pH of Water Solutions or Suspensions | All | 41605103 |
| 830.6313 | 63-13 | Stability | All | 41605103, 43452501, 44190201 |
| 830.6315 | 63-15 | Flammability | All | 41605103 |
| 830.6316 | 63-16 | Explodability | All | |
| 830.6317 | 63-17 | Storage Stability | All | |
| 830.7100 | 63-18 | Viscosity | All | |
| 830.6319 | 63-19 | Miscibility | All | |
| 830.6320 | 63-20 | Corrosion Characteristics | All | |
| **ECOLOGICAL EFFECTS** | | | | |
| 850.2100 | 71-1A | Avian Acute Oral Toxicity, Bobwhite Quail | M, O | Reserved |

| New Guideline Number | Old Guideline Number | Requirement | Use Pattern | Bibliographical Citation(s) |
|---|---|---|---|---|
| | 71-1B | Avian Acute Oral Toxicity, Mallard Duck | M, O | Reserved |
| 850.2200 | 71-2A | Avian Subacute Dietary Toxicity, Bobwhite Quail | M, O | 41685502 |
| | 71-2B | Avian Subacute Dietary Toxicity, Mallard Duck | M, O | 41685501 |
| 850.1075 | 72-1A | Fish Toxicity, Bluegill Sunfish | M, O | 42174501 |
| | 72-1C | Fish Toxicity, Rainbow Trout | M, O | 41911401 |
| 850.1010 | 72-2A | Invertebrate Toxicity | M, O | 41525302 |
| **TOXICOLOGY** | | | | |
| 870.1100 | 81-1 | Acute Oral Toxicity, Rat | M, O | 00155068 |
| 870.1200 | 81-2 | Acute Dermal Toxicity, Rabbit/Rat | M, O | 41648601 |
| 870.1300 | 81-3 | Acute Inhalation Toxicity, Rat | M, O | 41571501 |
| 870.2400 | 81-4 | Primary Eye Irritation, Rabbit | M, O | 41800501 |
| 870.2500 | 81-5 | Primary Skin Irritation | M, O | 41826505 |
| 870.2600 | 81-6 | Dermal Sensitization | M, O | 41648602 |
| 870.3100 | 82-1A | 90-Day Subchronic Feeding, Rodent | M, O | 42093901, 42100101 |
| 870.3200 | 82-2 | 21-Day Dermal, Rabbit/Rat | M, O | 42427202 |
| 870.3465 | 82-4 | 90-Day Inhalation, Rat | M, O | 42990201 |
| 870.4100 | 83-1B | Chronic Feeding Toxicity, Nonrodent (Dog) | M, O | 42320602 |
| 870.4200 | 83-2B | Chronic Carcinogenicity (Feeding), Mouse | M, O | 42100102 |
| 870.3700 | 83-3A | Prenatal Developmental Toxicity, Rat | M, O | 41987802 |
| | 83-3B | Prenatal Developmental Toxicity, Rabbit | M, O | 40433301 |
| 870.3800 | 83-4 | 2-Generation Reproduction and Fertility Effects, Rat | M, O | 41547801 |
| 870.4300 | 83-5 | Combined Chronic Toxicity/Carcinogenicity Study, Rat | M, O | 42093902, 42973501 |
| 870.5100 | 84-2 | Bacterial Reverse Gene Mutation Assay Test | M, O | 40382101 |
| 870.5300 | | Detection of Gene Mutations in Somatic Cells in Culture, Mammalian | M, O | 40382102, 40382103-4 |
| 870.7485 | 85-1 | General Metabolism, Rat | M, O | 42305701, 42246501-2 |
| 870.7600 | 85-2 | Dermal Absorption (Penetration), Rat | M, O | 42246503 |

| New Guideline Number | Old Guideline Number | Requirement | Use Pattern | Bibliographical Citation(s) |
|---|---|---|---|---|
| None | None | Dermal Absorption & Mass Balance, Humans | M, O | 42732101, 42974601-2, 43099401 |
| **ENVIRONMENTAL FATE** | | | | |
| 835.2120 | 161-1 | Hydrolysis | M, O | 43073601, Reserved |

## Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The docket initially contained preliminary risk assessments and related documents as of May, 2003. Sixty days later the first public comment period closed. The EPA then considered comments, revised the risk assessment, and added the formal "Response to Comments" document and the revised risk assessment to the docket on April, 2004.

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.epa.gov/oppsrrd1/reregistration/dipropyliso/

These documents include:

1. Review of MGK 326 Incident Reports
2. MGK® Repellent 326 (Di-N-propyl isocinchomeronate) Cancer Risk Estimates for Residential Use of MGK® Repellent 326
3. MGK® Repellent 326 (Di-N-propyl isocinchomeronate) HED Response to Public Comment on HED's Risk Assessment for Reregistration Eligibility Document (RED)

## Appendix D. Citations Considered to Be Part of the Data Base Supporting the Reregistration Eligibility Decision (Bibliography)

### GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Interim Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the

date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (????), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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## Appendix E. GENERIC DATA CALL-IN

See the following table for a list of generic data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.

## Appendix F. PRODUCT SPECIFIC DATA CALL-IN

See attached table for a list of product-specific data requirements. Note that a complete Data Call-In (DCI), with all pertinent instructions, is being sent to registrants under separate cover.

## Appendix G. EPA's Batching of MGK® Repellent 326 Products for Meeting Acute Toxicity Data Requirements for Reregistration

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing MGK® Repellent 326 as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Not withstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

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

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to

Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Ninety one products were found which contain MGK® Repellent 326 as the active ingredient. These products have been placed into twelve batches and a no batch group in accordance with the active and inert ingredients and type of formulation.

Batching Instructions:

Batch 1: EPA Reg. No. 498-148 may cite data from EPA Reg. No. 10807-127.
Batch 4: EPA Reg. No. 270-301 and EPA Reg. No. 68688-26 may not cite data from EPA Reg. No. 37425-21.
Batch 5: EPA Reg. No. 11715-173 may not cite data from EPA Reg. No. 10806-17 or EPA Reg. No. 13799-8.
Batch 6: EPA Reg. No. 11715-23 may not cite data from EPA Reg. No. 67517-24.
No Batch: Each product in this Batch should generate their own data.

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

| Batch 1 | EPA Reg. No. | Percent Active Ingredient |
|---|---|---|
| | 498-148 | MGK® Repellent 326: 2.5<br>MGK 264: 5.0<br>Deet: 25.0 |
| | 10807-127 | MGK® Repellent 326: 2.5<br>MGK 264: 5.0<br>Deet: 25.0 |

| Batch 2 | EPA Reg. No. | Percent Active Ingredient |
|---|---|---|
| | 305-40 | MGK® Repellent 326: 2.5<br>MGK 264: 5.0<br>Deet: 17.5 |
| | 769-606 | MGK® Repellent 326: 2.5<br>MGK 264: 5.0<br>Deet: 17.5 |

| Batch 3 | EPA Reg. No. | Percent Active Ingredient |
|---|---|---|
| | 270-300 | MGK® Repellent 326: 1.0<br>MGK 264: 2.0<br>Pyrethrins: 0.2<br>Piperonyl Butoxide: 0.5<br>Permethrin: 0.2<br>Butoxy Polypropylene glycol: 5.0 |
| | 37425-17 | MGK® Repellent 326: 1.0<br>MGK 264: 2.0<br>Pyrethrins: 0.2<br>Piperonyl Butoxide: 0.5<br>Permethrin: 0.2<br>Butoxy Polypropylene glycol: 5.0 |
| | 68688-22 | MGK® Repellent 326: 1.0<br>MGK 264: 2.0<br>Pyrethrins: 0.2<br>Piperonyl Butoxide: 0.5<br>Permethrin: 0.2<br>Butoxy Polypropylene glycol: 5.0 |

| Batch 4 | EPA Reg. No. | Percent Active Ingredient |
|---|---|---|
| | 270-301 | MGK® Repellent 326: 2.50<br>MGK 264: 3.10<br>Pyrethrins: 0.50<br>Piperonyl Butoxide: 1.85<br>Permethrin: 1.00 |
| | 37425-21 | MGK® Repellent 326: 1.25<br>MGK 264: 3.10<br>Pyrethrins: 0.50<br>Piperonyl Butoxide: 1.85<br>Permethrin: 1.00 |
| | 68688-26 | MGK® Repellent 326: 2.50<br>MGK 264: 3.10<br>Pyrethrins: 0.50<br>Piperonyl Butoxide: 1.85<br>Permethrin: 1.00 |

| Batch 5 | EPA Reg. No. | Percent Active Ingredient |
|---|---|---|
| | 10806-17 | MGK® Repellent 326: 1.33<br>MGK 264: 0.67<br>Pyrethrins: 0.20<br>Piperonyl Butoxide: 0.40 |
| | 11715-173 | MGK® Repellent 326: 1.84<br>MGK 264: 0.67<br>Pyrethrins: 0.20<br>Piperonyl Butoxide: 0.40 |
| | 13799-8 | MGK® Repellent 326: 1.33<br>MGK 264: 0.67<br>Pyrethrins: 0.20<br>Piperonyl Butoxide: 0.40 |

| Batch 6 | EPA Reg. No. | Percent Active Ingredient |
|---|---|---|
| | 11715-23 | MGK® Repellent 326: 1.20<br>MGK 264: 0.60<br>Pyrethrins: 0.18<br>Piperonyl Butoxide: 0.36 |
| | 67517-24 | MGK® Repellent 326: 1.20<br>MGK 264: 0.60<br>Pyrethrins: 0.18<br>Piperonyl Butoxide: 0.36 |

| Batch 7 | EPA Reg. No. | Percent Active Ingredient |
|---|---|---|
| | 270-305 | MGK® Repellent 326: 1.00<br>MGK 264: 0.50<br>Pyrethrins: 0.15<br>Piperonyl Butoxide: 1.00 |
| | 769-583 | MGK® Repellent 326: 1.00<br>MGK 264: 0.50<br>Pyrethrins: 0.15<br>Piperonyl Butoxide: 1.00 |

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|---|---|---|
| | 40849-73 | MGK® Repellent 326: 1.00<br>MGK 264: 0.50<br>Pyrethrins: 0.15<br>Piperonyl Butoxide: 1.00 |
| | 67572-20 | MGK® Repellent 326: 1.00<br>MGK 264: 0.50<br>Pyrethrins: 0.15<br>Piperonyl Butoxide: 1.00 |
| | 68688-31 | MGK® Repellent 326: 1.00<br>MGK 264: 0.50<br>Pyrethrins: 0.15<br>Piperonyl Butoxide: 1.00 |

| Batch 8 | EPA Reg. No. | Percent Active Ingredient |
|---|---|---|
| | 9468-31 | MGK® Repellent 326: 0.50<br>MGK 264: 0.50<br>Pyrethrins: 0.15<br>Piperonyl Butoxide: 1.50 |
| | 37425-12 | MGK® Repellent 326: 0.50<br>MGK 264: 0.50<br>Pyrethrins: 0.15<br>Piperonyl Butoxide: 1.50 |
| | 43591-2 | MGK® Repellent 326: 0.50<br>MGK 264: 0.50<br>Pyrethrins: 0.15<br>Piperonyl Butoxide: 1.50 |

| Batch 9 | EPA Reg. No. | Percent Active Ingredient |
|---|---|---|
| | 270-306 | MGK® Repellent 326: 0.50<br>MGK 264: 0.50<br>Pyrethrins: 0.15<br>Piperonyl Butoxide: 1.00 |
| | 769-579 | MGK® Repellent 326: 0.50<br>MGK 264: 0.50<br>Pyrethrins: 0.15<br>Piperonyl Butoxide: 1.00 |

| | | |
|---|---|---|
| | 68688-30 | MGK® Repellent 326: 0.50<br>MGK 264: 0.50<br>Pyrethrins: 0.15<br>Piperonyl Butoxide: 1.00 |
| | 68688-32 | MGK® Repellent 326: 0.50<br>MGK 264: 0.50<br>Pyrethrins: 0.15<br>Piperonyl Butoxide: 1.00 |
| | 69061-4 | MGK® Repellent 326: 0.50<br>MGK 264: 0.50<br>Pyrethrins: 0.15<br>Piperonyl Butoxide: 1.00 |

| Batch 10 | EPA Reg. No. | Percent Active Ingredient |
|---|---|---|
| | 769-615 | MGK® Repellent 326: 0.50<br>MGK 264: 0.50<br>Pyrethrins: 0.15<br>Piperonyl Butoxide: 1.00 |
| | 40849-58 | MGK® Repellent 326: 0.50<br>MGK 264: 0.50<br>Pyrethrins: 0.15<br>Piperonyl Butoxide: 1.00 |

| Batch 11 | EPA Reg. No. | Percent Active Ingredient |
|---|---|---|
| | 40322-2 | MGK® Repellent 326: 1.17<br>Pyrethrins: 0.22 |
| | 51651-1 | MGK® Repellent 326: 1.17<br>Pyrethrins: 0.22 |

| Batch 12 | EPA Reg. No. | Percent Active Ingredient |
|---|---|---|
| | 4691-153 | MGK® Repellent 326: 0.200<br>MGK 264: 1.000<br>Piperonyl Butoxide: 0.500<br>Permethrin: 0.150<br>ESBIOL: 0.100<br>Pyriproxyfen: 0.125 |

| | | |
|---|---|---|
| | 28293-289 | MGK® Repellent 326: 0.200<br>MGK 264: 1.000<br>Piperonyl Butoxide: 0.500<br>Permethrin: 0.150<br>ESBIOL: 0.100<br>Pyriproxyfen: 0.125 |

| No Batch | EPA Reg. No. | Percent Active Ingredient |
|---|---|---|
| | 270-37 | MGK® Repellent 326: 1.0<br>Pyrethrins: 0.2<br>Piperonyl Butoxide: 0.5<br>Butyoxy Propypropylene Glycol: 20.0 |
| | 270-103 | MGK® Repellent 326: 1.0<br>Pyrethrins: 0.2<br>Piperonyl Butoxide: 0.5 |
| | 270-107 | MGK® Repellent 326: 1.0<br>MGK 264: 0.4<br>Pyrethrins: 0.4<br>Piperonyl Butoxide: 1.0 |
| | 270-250 | MGK® Repellent 326: 2.0<br>Pyrethrin: 0.8<br>Piperonyl Butoxide: 6.4<br>Butoxy Polypropylene Glycol: 20.0<br>Cypermethrin: 0.80 |
| | 270-253 | MGK® Repellent 326: 0.50<br>Pyrethrin: 0.20<br>Piperonyl Butoxide: 1.63<br>Butoxy Polypropylene Glycol: 4.85<br>Cypermethrin: 0.15 |
| | 270-326 | MGK® Repellent 326: 2.50<br>MGK 264: 3.10<br>Piperonyl Butoxide: 1.85<br>Permethrin: 1.0<br>Prallethrin: .033 |

| | | |
|---|---|---|
| | 270-327 | MGK® Repellent 326: 1.0<br>Piperonyl Butoxide: 0.5<br>Butoxy Polypropylene Glycol: 20.0<br>Prallethrin: 0.13 |

| | | |
|---|---|---|
| | 270-328 | MGK® Repellent 326: 1.00<br>MGK 264: 2.00<br>Piperonyl Butoxide: 0.50<br>Butoxy Polypropylene Glycol: 5.00<br>Permethrin: 0.20<br>Prallethrin: 0.13 |
| | 498-175 | MGK® Repellent 326: 2.5<br>MGK 264: 5.0<br>Deet: 25.0 |
| | 769-580 | MGK® Repellent 326: 0.50<br>MGK 264: 0.50<br>Pyrethrin: 0.15<br>Piperonyl butoxide: 1.00 |
| | 769-581 | MGK® Repellent 326: 0.20<br>MGK 264: 0.20<br>Pyrethrin: 0.06<br>Piperonyl butoxide: 0.40 |
| | 769-582 | MGK® Repellent 326: 0.20<br>MGK 264: 0.20<br>Pyrethrin: 0.06<br>Piperonyl butoxide: 0.40 |
| | 1021-461 | MGK® Repellent 326: 97.0 |
| | 1021-501 | MGK® Repellent 326: 50.0<br>MGK 264: 50.0 |
| | 1021-537 | MGK® Repellent 326: 33.33<br>MGK 264: 66.67 |
| | 1021-567 | MGK® Repellent 326: 10.0<br>MGK 264: 20.0<br>Deet: 70.0 |

| | | |
|---|---|---|
| | 1021-579 | MGK® Repellent 326: 39.22<br>MGK 264: 19.60<br>Pyrethrin: 5.88<br>Piperonyl butoxide: 11.77 |
| | 1021-788 | MGK® Repellent 326: 26.67<br>MGK 264: 22.00<br>Pyrethrin: 6.67<br>Piperonyl butoxide: 13.34 |
| | 1021-1208 | MGK® Repellent 326: 40.0<br>MGK 264: 20.0<br>Pyrethrin: 4.0<br>Piperonyl butoxide: 20.0 |
| | 1021-1290 | MGK® Repellent 326: 7.70<br>MGK 264: 15.38<br>Deet: 76.92 |
| | 1021-1600 | MGK® Repellent 326: 2.5<br>MGK 264: 5.0<br>Deet: 25.0 |
| | 1317-83 | MGK® Repellent 326: 0.40<br>MGK 264: 0.20<br>Pyrethrin: 0.06<br>Piperonyl butoxide: 0.12 |
| | 2382-89 | MGK® Repellent 326: 4.0<br>MGK 264: 6.0<br>Pyrethrin: 1.0<br>Piperonyl butoxide: 4.0 |
| | 2382-129 | MGK® Repellent 326: 0.500<br>MGK 264: 0.500<br>Pyrethrin: 1.000<br>Piperonyl butoxide: 0.500<br>Pyriproxfen: 0.005 |
| | 2781-9 | MGK® Repellent 326: 1.0<br>Pyrethrin: 0.2<br>Piperonyl butoxide: 0.5 |

| | | |
|---|---|---|
| | 3546-39 | MGK® Repellent 326: 4.0<br>MGK 264: 8.0<br>Deet: 28.0 |
| | 5481-16 | MGK® Repellent 326: 0.330<br>MGK 264: 0.330<br>Pyrethrin: 0.099<br>Piperonyl butoxide: 0.198 |
| | 5481-52 | MGK® Repellent 326: 0.400<br>MGK 264: 0.501<br>Pyrethrin: 0.150<br>Piperonyl butoxide: 0.300 |
| | 5481-153 | MGK® Repellent 326: 0.20<br>MGK 264: 0.17<br>Pyrethrin: 0.05<br>Piperonyl butoxide: 0.10 |
| | 7754-40 | MGK® Repellent 326: 1.0<br>MGK 264: 2.0<br>Deet: 7.0 |
| | 7754-41 | MGK® Repellent 326: 2.5<br>MGK 264: 5.0<br>Deet: 25.0 |
| | 9444-28 | MGK® Repellent 326: 1.20<br>MGK 264: 0.60<br>Pyrethrin: 0.18<br>Piperonyl butoxide: 0.36 |
| | 10088-97 | MGK® Repellent 326: 1.76<br>MGK 264: 3.52<br>Deet: 12.33 |
| | 10806-34 | MGK® Repellent 326: 1.5<br>MGK 264: 3.0<br>Deet: 10.5 |
| | 10900-72 | MGK® Repellent 326: 2.5<br>MGK 264: 5.0<br>Deet: 25.0 |

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| | 11715-85 | MGK® Repellent 326: 1.92<br>MGK 264: 7.67<br>Deet: 28.76 |
| | 11715-230 | MGK® Repellent 326: 0.998<br>Piperonyl butoxide: 0.796<br>Butoxy Polypropylene Glycol: 20.0<br>S-Bioallethrin: 0.178 |
| | 11715-234 | MGK® Repellent 326: 1.00<br>Butoxy Polypropylene Glycol: 20.00<br>Sumithrin: 0.10<br>Neo-Pynamin: 0.21 |
| | 11715-235 | MGK® Repellent 326: 1.00<br>Pyrethin: 0.25<br>Piperonyl butoxide: 0.50 |
| | 11715-332 | MGK® Repellent 326: 1.55<br>MGK 264: 3.09<br>Deet: 15.46 |
| | 34704-597 | MGK® Repellent 326: 0.20<br>MGK 264: 0.33<br>Pyrethrin: 0.10<br>Piperonyl butoxide: 0.20 |
| | 34704-768 | MGK® Repellent 326: 0.20<br>Pyrethin: 0.03<br>Piperonyl butoxide: 0.25 |
| | 35138-79 | MGK® Repellent 326: 5.0<br>Pyrethin: 2.0<br>Piperonyl butoxide: 20.0 |
| | 37425-14 | MGK® Repellent 326: 1.00<br>MGK 264: 0.50<br>Pyrethrin: 0.15<br>Piperonyl butoxide: 1.50 |
| | 37425-16 | MGK® Repellent 326: 1.00<br>MGK 264: 1.00<br>Pyrethrin: 0.15<br>Piperonyl butoxide: 0.37 |

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| | 37425-19 | MGK® Repellent 326: 1.94<br>MGK 264: 5.70<br>Pyrethrin: 0.97<br>Piperonyl butoxide: 3.74 |
| | 37425-22 | MGK® Repellent 326: 4.00<br>MGK 264: 5.70<br>Pyrethrin: 0.97<br>Piperonyl butoxide: 3.63<br>Permethrin: 3.00 |
| | 37425-32 | MGK® Repellent 326: 0.5<br>MGK 264: 0.5<br>Esbiothrin: 0.30 |
| | 40849-57 | MGK® Repellent 326: 0.50<br>MGK 264: 0.50<br>Pyrethrin: 0.15<br>Piperonyl butoxide: 1.00 |
| | 44446-48 | MGK® Repellent 326: 2.50<br>MGK 264: 5.00<br>Deet: 23.75 |
| | 46813-22 | MGK® Repellent 326: 2.5<br>MGK 264: 5.0<br>Deet: 25.0 |
| | 47000-54 | MGK® Repellent 326: 0.20<br>MGK 264: 0.15<br>Pyrethrin: 0.05<br>Piperonyl butoxide: 0.10<br>Dichlorvos: 0.50 |
| | 50830-3 | MGK® Repellent 326: 3.0<br>MGK 264: 5.0<br>Deet: 25.0 |
| | 54287-8 | MGK® Repellent 326: 2.5<br>MGK 264: 5.0<br>Deet: 17.5 |
| | 54287-13 | MGK® Repellent 326: 2.5<br>MGK 264: 5.0<br>Deet: 17.5 |

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| | 67517-5 | MGK® Repellent 326: 0.70<br>MGK 264: 0.35<br>Pyrethrin: 0.10<br>Piperonyl butoxide: 0.20 |
| | 67517-11 | MGK® Repellent 326: 0.500<br>MGK 264: 1.175<br>Pyrethrin: 0.200<br>Piperonyl butoxide: 0.400 |
| | 68543-27 | MGK® Repellent 326: 2.5<br>MGK 264: 5.0<br>Deet: 25.0 |