United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508P)

EPA 738-R-07-010
September 12, 2008

Reregistration Eligibility Decision for Naphthalene

Reregistration Eligibility Decision (RED) for Naphthalene

List C

Case No. 3058

Approved by:

Steven Bradbury, Ph.D., Director
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Date: 9/12/08

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Glossary of Terms and Abbreviations

ai	Active Ingredient
CFR	Code of Federal Regulations
DCI	Data Call-In
EC	Emulsifiable Concentrate Formulation
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FIRST	FQPA Index Reservoir Screening Tool
FFDCA	Federal Food, Drug, and Cosmetic Act
GLN	Guideline Number
HED	Health Effects Division
HDT	Highest Dose Tested
IRIS	Integrated Risk Information System
LADD	Lifetime Average Daily Dose
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
µmol	Millimoles Per Liter
MOA	Mode of Action
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
N/A	Not Applicable
NAWQA	National Water-Quality Assessment Program
NCEA	National Center for Environmental Assessment
NDETF	Non-Dietary Exposure Task Force
NLAA	Not Likely to Adversely Affect
NR	Not Required
NOAEL	No Observed Adverse Effect Level
NTP	National Toxicology Program
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PCC	Poison Control Center
PII	Primary Irritation Index
PK	Pharmacokinetic
ppb	Parts Per Billion
POD	Point of Departure
ppm	Parts per Million
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfC	Reference Concentration
RfD	Reference Dose
SCI-GROW	Screening Concentration In Ground Water
SF	Safety Factor

TREX	Terrestrial Residue Exposure (T-REX)
USDA	United States Department of Agriculture
USGA	US Geological Survey
UF	Uncertainty Factor
UF_{db}	Database Uncertainty Factor

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Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and ecological risk assessments for naphthalene and is issuing its risk management decision. The human health and ecological risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products. As a result of this review, EPA has determined that naphthalene-containing products are eligible for reregistration, provided that risk mitigation measures described in this document are adopted and labels are amended accordingly. That decision is discussed fully in this document.

Naphthalene is an insecticide; the majority of its pesticidal use is as a moth repellant to protect garments from insect damage (indoor) and as an animal repellant against nuisance vertebrate pests (indoor and outdoor). There are no food uses, and all registered products of naphthalene are intended for residential uses only. The indoor products are formulated as mothballs or flakes, while outdoor products are formulated as flakes or granules. Of the risk scenarios assessed, only the risk from episodic ingestion of mothballs by toddlers was of concern. Mitigation measures, including special packaging and precautionary label language, will be required to address this potential risk of concern.

I. Introduction

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

This document summarizes EPA's human health and ecological risk assessments and reregistration eligibility decision (RED) for naphthalene. The document consists of six sections. Section I contains the regulatory framework for reregistration; Section II provides an overview of the chemical and a profile of its use and usage; Section III gives an overview of the human health and ecological risk assessments; Section IV presents the Agency's decision on reregistration eligibility and risk management; and Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices list related information, supporting documents, and studies evaluated for the reregistration decision. The risk assessments for naphthalene and all other supporting documents are available in the Office of Pesticide Programs (OPP) public docket (http://www.regulations.gov) under docket number EPA-HQ-OPP-2008-0343.

II. Chemical Overview

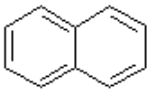
A. Regulatory History

The Agency's predecessor for pesticide registrations, the U.S. Department of Agriculture (USDA), first registered a product containing naphthalene in 1948. The Agency issued a Registration Standard for this active ingredient in 1981 and required submission or citation of the following data: chemistry; environmental fate and effects; acute, subchronic, chronic human health effects; and efficacy data. In the latter half of the 1990s, the Agency initiated a Label Improvement Program (LIP) to update the precautionary text, use directions, storage, and disposal instructions to reduce exposure to naphthalene, especially when used in homes.

Currently, there are 9 registered naphthalene products. One is a manufacturing-use product and 8 are end-use products. All are registered under Section 3 of FIFRA. There are no Special Local Need (SLN) registrations under Section 24(c) of FIFRA. The Agency has registered products for domestic, indoor use to kill moths inside of airtight spaces (closets, chests, and garment bags) and to repel bats, tree squirrels, and birds from attics and wall voids. There are naphthalene products for domestic, outdoor use to repel rabbits, snakes, Norway rats, roof rats, and house mice.

B. Chemical Identification

NAPHTHALENE:



Naphthalene is a white, crystalline solid with a characteristic odor.

Common Name:	Naphthalene
Chemical Class:	Insecticide
PC Code:	055801
Case Number:	0022
CAS Registry Number:	91-20-3
Molecular Weight:	128.18 g/mole
Empirical Formula:	$C_{10}H_8$
Technical Registrants:	Reochem, Inc.

C. Use Profile

The following information on the currently registered uses includes an overview of use sites and application methods. A detailed table of the uses of naphthalene eligible for reregistration is contained in Appendix A.

Type of Pesticide: Insecticide and repellant.

Target Organism: The primary target pests are moths and nuisance vertebrate pests (squirrels, rats, rabbits, bats, etc).

Use Sites: Naphthalene is registered for use on indoor and outdoor residential use sites. It is used indoors as a moth repellant, and placed in closed drawers, closets, and other storage areas. It is also used in attics as a squirrel and bat repellant. Outdoors, it is used around garden and building peripheries to repel animals such as snakes and rabbits.

Use Classification: Naphthalene products are designated as general use.

Formulation Types: Balls**,** granules, and flakes.

Application Methods: By hand.

Application Rates: Actual application rates for naphthalene products are imprecise, based on formulation type and application method. It is registered for use on indoor sites as a moth repellant in mothballs and flakes at rates ranging from 0.25 pounds of active ingredient per 12 cubic feet (0.25 lb ai/12 ft^3) to 0.37 lb ai/12 ft^3. When used indoors as an animal repellant, it is formulated as a flake and applied at a rate of 1 lb ai/400 ft^3 (or 1 oz/3 ft^3 for smaller spaces). When used outdoors and formulated as granules or flakes, it is applied at rates ranging from 0.56 lb ai/treated area to 10.8 lb ai/treated area.

Application Timing: Registered labels for indoor moth treatment use recommend keeping the product in an airtight space for a minimum of seven days. Re-treatment is recommended when the mothballs have dissipated. Since moths are active all year, there is the potential for continual treatment indoors. One moth control label recommends re-treatment twice per year. Re-treatment for indoor/outdoor repellant uses is recommended as needed to maintain odor intensity. Hot weather, wind, and rain may diminish the effectiveness of the product and necessitate re-treatment.

D. Estimated Usage of Pesticide

Approximately 7.5 million lbs of naphthalene are marketed on average per year as a pesticide. The vast majority of the usage is in indoor moth repellant products.

Pesticide usage accounts for a small portion of total US naphthalene exposure. More than 90% of total naphthalene usage comes from other sources. Naphthalene is produced as a naturally occurring constituent of fossil fuels (*i.e.*, petroleum and coal) as well as a byproduct of combustion of organic matter (*e.g.*, it is generated by burning wood). Approximately 369 million lbs. of naphthalene is consumed by the Department of Defense annually, and 1.84 billion lbs. of naphthalene is consumed in the US jet fuel market.

III. Summary of Naphthalene Risk Assessments

The following is a summary of EPA's revised human health and ecological risk assessments for naphthalene, as presented fully in the documents, *Phase 4 Amendment: Response to Comments in Reference to "Naphthalene: HED Chapter for the Reregistration Eligibility Decision Document (RED)*" dated August 22, 2008 and *Revised Ecological Risk Assessment for Reregistration Eligibility Decision (RED) for Naphthalene,* dated April 21, 2008. These documents are available in the OPP Public Docket, docket number EPA-HQ-OPP-2008-0343, and may also be accessed through the Agency's website at https://www.regulations.gov. The purpose of the following summary is to assist the reader by identifying the key features and findings of the naphthalene human health and ecological risk assessments, and to help the reader better understand the conclusions reached in the assessments.

EPA's use of human studies in the naphthalene risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

A. Human Health Risk Assessment

The human health risk assessment incorporates potential exposure, hazard, and risks from all sources, which for naphthalene are indoor and outdoor residential use. Naphthalene has no registered food or occupational uses. The Agency's human health assessment considers all U.S. populations, including infants and young children. For more information on the naphthalene human health risk assessments, see *Phase 4 Amendment: Response to Comments in Reference to "Naphthalene: HED Chapter for the Reregistration Eligibility Decision Document (RED)*" dated

August 22, 2008, and *Naphthalene: Phase 4 Amendment: Response to Comments In Reference to "Naphthalene: Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document*", dated August 8, 2008.

1. Toxicity of Naphthalene

Toxicity assessments are designed to predict whether a pesticide could cause adverse health effects in humans (including short-term or acute effects, such as skin or eye damage, and lifetime or chronic effects, such as cancer, developmental effects, or reproductive effects), and the level or dose at which such effects might occur. The Agency has reviewed all toxicity studies submitted for naphthalene.

a. Acute Toxicity Profile

Naphthalene is considered slightly toxic on an acute basis by the oral and dermal routes (Toxicity Category III). It is considered to be moderately toxic by the inhalation route (Toxicity Category II). It is categorized also as slightly toxic for primary eye and skin irritation (Toxicity Category III). Naphthalene did not induce delayed contact sensitivity (dermal sensitization) when tested in guinea pigs. The acute toxicity profile for naphthalene is summarized in Table 1 below.

Table 1. Acute Toxicity Profile for Naphthalene

Guideline	Study Type	Master Record Identification (MRID)	Results	Toxicity Category[a]
870.1100	Acute Oral - rat	257224	LD_{50}: 2649 mg/kg (♂+♀)	III
870.1200	Acute Dermal	257229	LD_{50} >2000 mg/kg (♂+♀)	III
870.1300	Acute Inhalation	257902	LC_{50} > 0.4 mg/L (77.7 ppm) (♂+♀)	II
870.2400	Primary Eye Irritation	257228	Slight-moderate irritation	III
870.2500	Primary Skin Irritation	257227	Moderate irritation	III
870.2600	Dermal Sensitization	00148173	Nonsensitizer – guinea pig	N/A

a. These 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.

b. Toxicological Endpoints

Based on the use pattern, the standard toxicology database for naphthalene is complete for assessing dermal and oral exposure risks to humans. There is no reproductive study on naphthalene, nor is one required since this is a nonfood use pesticide.

Naphthalene inhalation studies include nose-only, *i.e.* compound introduced directly to the nose (4-week, 13-week, and subchronic 90-day neurotoxicity) and chamber studies (2 year) in rodents, which involves whole body exposures. These studies indicate that naphthalene is a nasal toxicant in rodents at low experimental concentrations. Although standard inhalation rodent toxicity studies are available, some mechanism studies have raised the issue of notable species differences (in regard to respiratory toxicity and metabolism) and the applicability of the

rodent model as a default approach to estimate human risk following inhalation exposures. There is support from published studies and ongoing research on naphthalene that indicate that risk estimates would be considerably less than those using default procedures when known species differences between rodents and primates (including humans) in metabolism and respiratory toxicity are factored into the estimates. The mechanism data are not yet complete and ongoing research, when completed, is expected to significantly refine the potential toxicity hazard associated with human exposure to naphthalene via inhalation. At this time, dose range and endpoints have been qualitatively characterized for the purposes of estimating human inhalation (cancer and non-cancer) risk. See *Phase 4 Amendment: Response to Comments in Reference to "Naphthalene: HED Chapter for the Reregistration Eligibility Decision Document (RED)*" dated August 22, 2008 for additional information.

Subchronic oral toxicity of naphthalene is manifested by body weight changes, organ weight changes and/or clinical signs of toxicity following gavage treatment to rats. In a 90-day dermal toxicity study in the rat, effects were noted only at the high dose of 1000 mg/kg/day. Because effects were seen only at the limit dose, dermal toxicity is not likely a concern. There was no evidence of developmental toxicity in the rat or rabbit. The toxicological endpoints used in the human health risk assessment for naphthalene are listed in Table 2 below.

To estimate residential (dermal and incidental oral) risk, the Agency calculates a margin of exposure (MOE), which is the ratio of the point of departure (POD) selected for risk assessment to the exposure. The POD is typically a No Observed Adverse Effects Level (NOAEL) or a Lowest Observed Adverse Effects Level (LOAEL). This MOE is compared to a level of concern (LOC), which is the same value as the uncertainty factor (UF) applied to a particular toxicity study. In the case of the naphthalene risk assessment for acute dietary exposure, the endpoint selected occurred following a single exposure and is relevant for all populations, including infants and children. A UF of 1000 was applied to account for the use of a LOAEL because there is no NOAEL (10X), in addition to the standard uncertainty factors (UF) of 10X for intraspecies extrapolation and 10X for interspecies variation.

For chronic oral exposure, an UF of 10X has been applied to the chronic RfD to account for extrapolation from subchronic to chronic oral exposure, in addition to the 100-fold uncertainty factor applied to account for inter and intraspecies differences. The composite uncertainty factor of 1000-fold would address the lack of reproductive toxicity data. The target MOE (*i.e.*, level of concern) for incidental oral and dermal exposures is 100 (10X for intraspecies extrapolation and 10X for interspecies variation).

Table 2. Toxicological Doses and Endpoints for Naphthalene for Use in Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure (POD)**	**Uncertainty Factors (UF)**	**Level of Concern for Risk Assessment (LOC)**	**Study, MRID, and Toxicological Effects**
Acute Dietary All populations including infants and children	LOAEL = 400 mg/kg/day	UF_A= 10X UF_H = 10X UF_L= 10X	aRfD=0.4 mg/kg/day	**Acute Oral Neurotoxicity Study – Rat** (44282801) NOAEL = not identified. LOAEL = 400 mg/kg/day based on hunched posture in females, head shaking in males and females, and reduced motor activity in males and females.
Chronic Dietary All populations including infants and children	NOAEL= 100 mg/kg/day	UF_A= 10X UF_H = 10X UF_S = 10X	cRfD = 0.1 mg/kg/day	**National Toxicology Program (NTP) Subchronic Rat Study** (NTP 1980a) NOAEL = 100 mg/kg/day LOAEL = 200 mg/kg/day based on significant decreases in body weights/body weight gains.
Episodic Ingestion (Short-term; 1-30 days)	NOAEL= 50 mg/kg/day	UF_A= 10X UF_H= 10X	MOE= 100 (residential)	**NTP Developmental Rat Study** (NTP 1991) NOAEL = 50 mg/kg/day LOAEL= 150 mg/kg/day based on maternal effects –transient clinical signs of lethargy and slow breathing, and significant decreases in body weights/body weight gains and decreased food and water consumption.

Table 2. Toxicological Doses and Endpoints for Naphthalene for Use in Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure (POD)**	**Uncertainty Factors (UF)**	**Level of Concern for Risk Assessment (LOC)**	**Study, MRID, and Toxicological Effects**
Dermal (Short-Term; 1-30 days)	Dermal NOAEL= 300 mg/kg/day	UF_A= 10X UF_H= 10X	MOE= 100 (residential)	**90-Day Dermal Toxicity Study – Rat** (40021801) NOAEL = 300 mg/kg/day LOAEL = 1000 mg/kg/day based on atrophy of seminiferous tubules in males, and nonneoplastic lesions in the cervical lymph node (hyperplasia), liver (hemosiderosis), thyroid thyroglossal duct cysts, kidneys (pyelonephritis), urinary bladder (hyperplasia) and skin (acanthosis, hyperkeratosis) in females.
Inhalation (Short-term; 1-30 days)	Inhalation LOAEL = 10 ppm or 52 mg/m^3 NOAEL = 3 ppm or 16 mg/m^3	N/A	N/A	**4-Week (Nose-Only) Inhalation – Rat** (42934901) NOAEL = 3 ppm LOAEL = 10 ppm based increased incidence and severity of nasal lesions (slight disorganization, rosette formation, basal cell hyperplasia, erosion, atrophy, and degenerate cells in the olfactory epithelium; loss of bowman's glands; respiratory epithelium hypertrophy; rosette formation in the septal organ of Masera and fusion of the turbinates).

Table 2. Toxicological Doses and Endpoints for Naphthalene for Use in Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure (POD)**	**Uncertainty Factors (UF)**	**Level of Concern for Risk Assessment (LOC)**	**Study, MRID, and Toxicological Effects**
Inhalation (Intermediate-term; 1-6 months)	Inhalation LOAEL = 2 ppm or 10 mg/m^3 NOAEL = 1 ppm or 5.2 mg/m^3	N/A	N/A	**13-Week (nose-only) Inhalation Rat Study** (44956401)**; Subchronic (nose-only) Neurotoxicity Rat Study** (44856401) NOAEL = 1 ppm (Subchronic neurotoxicity study) NOAEL (13 week inhalation study) – not identified. LOAEL = 2 ppm (13 week inhalation study) based on increased incidence and severity of nasal lesions (degeneration, atrophy and hyperplasia of basal cells of the olfactory epithelium; rosette formation of olfactory epithelium; loss of Bowman's glands; hypertrophy of respiratory epithelium). LOAEL = 10 ppm (subchronic neurotoxicity study) based on atrophy/disorganization of the olfactory epithelium and hyperplasia of the respiratory and transitional epithelium.

Table 2. Toxicological Doses and Endpoints for Naphthalene for Use in Human Health Risk Assessments				
Exposure/ Scenario	**Point of Departure (POD)**	**Uncertainty Factors (UF)**	**Level of Concern for Risk Assessment (LOC)**	**Study, MRID, and Toxicological Effects**
Inhalation (Long-term; > 6 months)	Inhalation LOAEL = 10 ppm or 52 mg/m^3	N/A	N/A	**NTP ChronicToxicity and Carcinogenicity Studies in the Rat and Mouse** (NTP 1992) NOAEL = not identified LOAEL (rat study) = 10 ppm based on increased incidence and severity of atypical (basal cell) hyperplasia, atrophy, chronic inflammation, and hyaline degeneration of the olfactory epithelium; hyperplasia, squamous metaplasia, hyaline degeneration, and goblet cell hyperplasia of the respiratory epithelium; and glandular hyperplasia and squamous metaplasia.
Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of key date (*i.e.*, lack of a critical study). RfD = reference dose. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.				

2. Carcinogenicity of Naphthalene

In the National Toxicology Program (NTP) chronic studies, carcinogenic effects have been observed in both rats and mice following inhalation exposure to naphthalene. In the rat, nasal tumors included neuroblastomas of the olfactory epithelium and adenomas of the respiratory epithelium. There was also an increase in the incidences of adenoma of the respiratory epithelium. The NTP concluded that "under the conditions of this 2-year inhalation study, there was clear evidence of carcinogenic activity of naphthalene in male and female F344/N rats based on increased incidences of respiratory epithelial adenoma and olfactory epithelial neuroblastoma of the nose."

In the mouse study, male mice had statistically significant increased incidences of liver adenomas, and adenomas and carcinomas combined. Female mice exhibited increased incidences of alveolar/bronchiolar adenomas, and adenomas and carcinomas combined. The NTP concluded that "under the conditions of this 2-year inhalation study, there was no evidence of carcinogenic activity' of naphthalene in male B6C3F1 mice exposed to 10 or 30 ppm. There was "some evidence of carcinogenic activity" of naphthalene in female B6C3F1 mice, based on

increased incidences of pulmonary alveolar/bronchiolar adenomas.

The carcinogenic and noncarcinogenic potential of naphthalene is currently undergoing review by the EPA Integrated Risk Information System (IRIS). The EPA process of regulating pesticides allows for re-evaluation at any time if relevant new information becomes available. Thus, when the IRIS assessment is finalized, OPP would determine whether the human health hazard potential of naphthalene warrants revisiting.

3. Metabolites and Degradates

A number of degradates were identified in the open literature. A degradation pathway for naphthalene was proposed, which ultimately resulted in catechol. Transitional degradates included cis-1,2-dihydroxy-1,2-dihydronaphthalene, 1,2-dihydroxy-naphthalene, 2-hydroxchromene-2-carboxylate (HCCA), trans-o-hydroxy-benzylidenpyruvate (tHBPA), salicyladehyde, and salicylate. However, there are no environmental fate data for these degradates, and therefore, exposure estimates are for parent only. For additional details, refer to the *Revised Ecological Risk Assessment for Reregistration Eligibility Decision (RED) for Naphthalene,* dated April 21, 2008.

4. Endocrine Disruption

EPA is required under the Federal Food, Drug, and Cosmetic Act (FFDCA), to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that 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 additional appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, naphthalene may be subjected to further screening and/or testing to better characterize effects related to endocrine disruption.

5. Dietary Risk (Water Only)

There are no agricultural or food-related pesticide uses of naphthalene; therefore, no dietary exposure from food is expected. There is potential for drinking water exposure, since naphthalene is registered for residential outdoor use an animal repellant.

a. Estimated Drinking Water Exposure

A Tier I aquatic exposure assessment was conducted using FIRST (FQPA Index

Reservoir Screening Tool), which is a program that calculates acute, as well as longer-term, estimated environmental concentration (EEC) values in surface water. FIRST considers reduction in dissolved pesticide concentration due to adsorption of a pesticide to soil or sediment, incorporation, degradation in soil before washoff to a water body, direct deposition of spray drift into the water body, and degradation of the pesticide within the water body.

Given the limited use of this compound in an outdoor setting and the fact that it is applied in a band around ornamentals, planting beds, and building perimeters as a repellent, an adjustment to the modeled EEC was made assuming 4.1% of a typical residential lot would be treated. The resultant FIRST EEC has been adjusted by this factor.

Two scenarios were modeled to represent both high and low use scenarios. The high use scenario was modeled at 10.8 lbs active ingredient/acre (ai/A) with six applications per year, while the low use scenario was modeled at 0.56 lbs ai/A with six applications per year. The modeling results are summarized in Table 3.

Table 3. Results of FIRST Modeling for Naphthalene

Use Site	Application Rate (lbs/acre)	Number of Applications (interval)	Peak EEC (ppb)	Annual Average EEC (ppb)
Ornamentals for rabbit & dog repellent	10.8	6 (2 months)	43.4	6.5
Ornamentals for snake repellent	0.56	6 (2 months)	2.2	0.3

Unaccounted for in this exposure assessment is the fact that naphthalene is volatile. Given the potential volatility of this compound and the fact that the Tier I model used to estimate exposure does not account for volatility as a route of dissipation, it is likely that the exposure estimates derived above are over-predictions of potential exposure to naphthalene in drinking water derived from surface water sources.

The Tier I Screening Concentration in Ground Water (SCI-GROW) model was used to estimate naphthalene residues in groundwater. Because the EECs for groundwater residues (ranging from 4.5 to 0.2 ppb) are lower than those for surface water, the FIRST surface water exposure estimates are used for the drinking water risk assessment and are considered to be protective.

b. Reference Dose

Dietary risk assessment incorporates both exposure to and toxicity of a given pesticide. For chemicals with no food uses, such as naphthalene, acute and chronic dietary risk is expressed as a percentage of the acute or chronic Reference Dose (RfD). The RfD is the POD (NOAEL or LOAEL) divided by uncertainty factors (UFs). A total UF of 1000 was applied to both the acute and chronic LOAELs to calculate the acute and chronic RfDs, respectively. To estimate risks

from potential dietary exposure to naphthalene, exposure estimates are compared to the acute or chronic RfDs. An acute or chronic exposure that is less than100% of the acute or chronic RfD is not of concern.

c. Dietary (Drinking Water Only) Risk Estimates

The dietary exposure and risk estimates resulting from intake of water with residues of naphthalene were determined for the general U.S. population and all population sub-groups using the Dietary Exposure Evaluation Model (DEEM-FCID), which uses food consumption data from the U.S. Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. The screening-level acute drinking water assessment using the DEEM-FCID Model was reported at the 95th percentile of exposure for the general U.S. population and all of its sub-groups. It is based exclusively on the peak EEC of 43.4 ppb for all direct and indirect drinking water sources. Risk estimates were all found to be well below the 100% acute Reference Dose (aRfD) threshold level of concern. The acute drinking water exposure for naphthalene was estimated to be 0.0023 mg/kg/day at 0.6% of the aRfD for the general U.S. population. The acute drinking water exposure for the most highly exposed population subgroup, all infants, was estimated to be 0.0085 mg/kg/day at 2.1% of the aRfD.

The chronic screening-level drinking water assessment is another conservative evaluation based exclusively on the annual average EEC of 6.5 ppb for all direct and indirect drinking water sources. Risk estimates were all found to be well below the 100% chronic Reference Dose (cRfD) threshold level of concern. The chronic drinking water exposure for naphthalene was estimated to be 0.0001 mg/kg/day at 0.1% of the cRfD for the general U.S. population. The chronic drinking water risk for the most highly exposed population sub-group, all infants, was estimated to be 0.0004 mg/kg/day at 0.4% of the cRfD.

As previously noted, a drinking water assessment for naphthalene was carried out by the Agency for its use as a pest repellant outdoors around the home. This screening-level assessment relied on modeling analyses to calculate EECs for drinking water. Given the potential volatility of this compound and the fact that the Tier I model used to estimate exposure does not account for volatility as a route of dissipation it is likely that the EECs are overestimated. Additionally, the dietary (drinking water only) assessment used only the high end EECs from a maximum use rate and the resulting risk estimates, while not of concern, can be considered upper bound. Although a number of potential water degradates have been identified, the drinking water assessment is only for the parent compound naphthalene. There were no data on the environmental fate of the degradates, or on the toxicity of the degradates in relation to the parent. However, given the overall conservative nature of the water assessment it is unlikely that risks from exposure to naphthalene in drinking water were underestimated.

Available water monitoring data, while non-targeted, indicate that naphthalene was infrequently detected in water supplies, and those detects were usually well below the Health Reference Level (HRL) of 140 ppb. EPA's Office of Water has concluded that the regulation of naphthalene in drinking water is unlikely to represent a meaningful opportunity for health risk reduction. While it is not known if detects in ambient water are from pesticide or industrial uses, it should be noted that about 190,000 lbs of naphthalene a year is used for outdoor pest control

compared to the approximately 1.8 billion lbs of naphthalene used for the US jet fuel market.

6. Residential (Non-Occupational) Exposure Risk

The Agency has determined that there is a potential for exposure (dermal and inhalation) in residential settings during the application process for homeowners who purchase and use pesticide products containing naphthalene. There is also a potential for postapplication inhalation exposure from inhabiting indoor areas previously treated with naphthalene, as well as potential (postapplication) episodic ingestion exposure to toddlers.

To quantitatively estimate residential risks, the Agency calculates a margin of exposure (MOE), which is the ratio of the endpoint derived from a toxicity study (NOAEL) to the exposure. This MOE is compared to a level of concern (LOC), which is the same value as the uncertainty factor (UF) applied to the endpoint. For naphthalene, the uncertainty factors are 100 for both dermal and episodic ingestion exposures. A summary of naphthalene residential risk follows. For further information on residential risk, refer to the *Naphthalene: Phase 4 Amendment: Response to Comments In Reference to "Naphthalene: Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document,*" dated September 10, 2008.

A quantitative exposure assessment was performed for homeowners applying naphthalene in the residential environment (dermal) and for toddler episodic (oral) ingestion of naphthalene used for indoor/outdoor treatments. Human health risk estimates were not calculated for postapplication inhalation scenarios because of the uncertainties associated with extrapolating animal (rodent) data to humans as discussed previously in this document. Rather than quantifying inhalation (cancer and noncancer) risks to humans, the levels of ambient naphthalene measured in the human exposure study were compared directly to the levels resulting in 1) no adverse effects in the rodent studies (NOAELs) and 2) a toxic effect in rodents (LOAELs). This comparison provides a sense of the difference between actual naphthalene concentrations that a human may encounter and the doses which elicit either no adverse response or a toxic response in rodents.

a. Residential Handler Risk

The Agency determined that there is potential for exposure in residential settings during the application process for homeowners who purchase and use naphthalene-containing products. According to label instructions, homeowners must physically place naphthalene formulations into indoor storage areas and around the perimeter of outdoor areas to be protected. The Agency anticipates handler dermal and inhalation exposure during the application process. However, as previously described, the Agency did not select an inhalation endpoint, nor is there inhalation exposure data available to assess this handler scenario. Furthermore, data for acute (15 minute) inhalation exposure were used in conjunction with animal studies to derive a direct comparison for postapplication inhalation exposure to areas treated with naphthalene. The Agency assumes that the acute postapplication inhalation assessment is protective for handler inhalation exposure. Measured concentrations of naphthalene would likely be greater in the acute post-application exposure scenario due to the time allotted in the exposure study (4-6 days) for the vapors of the

product to accumulate in the enclosed areas that would be accessed than a handler would experience during an application event. Therefore, only dermal handler exposure was quantitatively assessed.

Applications of naphthalene are expected to be short-term in nature because the products are typically applied only intermittently and usually on a seasonal basis, *i.e.* when storing winter clothes or when outdoor pests are active. As a result, no intermediate-term or long-term exposure scenarios were assessed for handlers.

Exposure data for the residential handler dermal assessment were taken from the exposure study, "Estimation of Homeowner Exposure to LX1298-01 (Naphthalene) Resulting from Simulated Residential Use as an Insect Repellent" (MRID 43716501). EPA determined that this study utilized adult human subjects that were intentionally exposed, and therefore, required review of its ethical conduct; the study has received that review, and it was concluded that there are no regulatory barriers to EPA's reliance on this study in its actions under FIFRA. In the study, dermal handler exposure data was derived from the result of monitoring a person weighing out and placing mothballs in a closet and dresser at three different locations. In addition, standard assumptions for residential applicators were used.

The residential handler dermal MOEs for both scenarios assessed (applying mothballs and animal repellant treatments) were greater than 100 (MOE = 28,000 and 17,000, respectively) and, therefore, are below the Agency's LOC.

b. Residential Postapplication Risk

i. Episodic Ingestion Risk

Naphthalene applications are made indoors for moth treatments and indoors/outdoors for animal repellency. The Agency anticipates that toddlers could come in contact with naphthalene formulations inside a treated home or in treated outdoor areas. While labels specify that indoor moth treatments be made in airtight containers, it is assumed that a toddler could potentially access these areas and ingest naphthalene products. Outdoor applications of naphthalene are labeled for use around the perimeter of areas to be protected. While a toddler could potentially access outdoor treated areas, naphthalene incident reports indicate that a large majority of incidents for children under six years old are from ingestion of indoor products.

Inhalation and episodic ingestion routes of exposure were not combined for toddlers in order to differentiate the occurrence of a discrete accidental event (assessed to give a worst-case estimate of risk) from the expected daily exposure via the inhalation route. It would not be appropriate to combine episodic exposure for comparison to a short-(or longer) term endpoint.

The Agency's standard assumptions and risk assessment procedures were used to derive the potential dose rate of a toddler ingesting one mothball, which was then compared to the incidental oral endpoint to calculate an MOE. In addition, the Agency estimated the amount of a single mothball that a toddler could ingest to result in an MOE of 100.

Toddler episodic ingestion of one naphthalene mothball results in an MOE < 1 and, therefore, is of concern (LOC = 100). An oral dose of 0.5 mg/kg/day would be required to result in an MOE of 100. This dose is equivalent to a toddler ingesting less than 1% of one mothball.

It is important to note that the episodic ingestion MOE is calculated from an endpoint derived from a developmental oral rat study in which dams were repeatedly treated with a high oral bolus dose and the resulting clinical signs (lethargy and slow breathing) and body weight decrement were transient. The effects were attributed to the administration of a high bolus and were not permanent; the animals displayed quick recovery. There were no persistent effects or treatment-related deaths. While the episodic ingestion of naphthalene by a toddler results in an MOE below the LOC, and does represent an exposure concern, the effects of this type of exposure, if any, are not expected to be severe. The study results are consistent with what might be inferred from the incident reports, which are described in more detail below.

ii. Inhalation (Cancer and Noncancer) Risk

The Agency has determined that there is potential for inhalation exposure to adults and children from naphthalene applications made indoors for moth treatments and animal repellency, and to a lesser extent, outdoors for animal repellency. While labels specify that treated indoor areas should be airtight to be effective, the Agency anticipates that naphthalene will volatilize and be inhaled by adults accessing treated areas (*i.e.*, containers, dresser drawers, closets, etc.) and by adults and children that inhabit treated areas exposed to ambient concentrations of naphthalene. Exposures from accessing treated areas are expected to be acute (approximately 15 minutes) in duration, and exposures from inhabiting treated areas are short-(<1 month), intermediate- (1-6 months), and long-term (>6 months) in duration.

As previously described, there is support from published studies and ongoing research on naphthalene that indicate that risk estimates, factoring in known species differences between rodents and primates (including humans) in metabolism and respiratory toxicity, would be considerably less than those using default procedures. Therefore, rather than quantifying inhalation risks to humans, the levels of ambient naphthalene measured in the human exposure study were compared directly to the levels resulting in a 1) no adverse effects in the rodent studies (NOAELs) and 2) a toxic effect in rodents (LOAELs). This comparison provides a sense of the difference between actual naphthalene concentrations that a human may encounter and the doses which elicit either no adverse response or a toxic response in rodents.

Anticipated acute and short-term exposures were calculated using standard assumptions and the results of the aforementioned naphthalene exposure study (MRID 43716501). The 15 minute (acute) and 24 hour (short-term) samples resulted in average concentrations of 0.85 and 0.66 mg/m^3 of naphthalene, respectively. These values were compared directly to the animal LOAEL (10 ppm or 52 mg/m^3) and NOAEL (3 ppm or 16 mg/m^3) selected for acute and short-term exposure durations.

Estimated acute and short-term exposures to naphthalene in residences are 20X and 30X, respectively, below the rodent dose resulting in no adverse effects (NOAEL). Anticipated acute and short-term exposures to naphthalene in residences are 60X and 80X, respectively, below the rodent dose resulting in respiratory toxicity, specifically olfactory epithelium lesions (LOAEL).

Anticipated intermediate- and long-term exposures were also calculated using standard assumptions; however, because of the lack of a naphthalene-specific study of an appropriate duration, a different exposure study was used to assess these durations of exposure ("Polycyclic Aromatic Hydrocarbon Exposure of Children in Low-Income Families, Chuang et al., 1999"). This study was reviewed for its ethical conduct, and it was concluded that it does not meet the regulatory definition of research involving intentional human exposure. Therefore, it is not required to undergo ethical review and that there are no regulatory, ethical, or policy barriers to using this study for risk assessment. The study was conducted to observe exposures to polycyclic aromatic hydrocarbons (PAHs), including naphthalene, inside of 24 homes from air, dust, soil, and food. This study is not specific to intermediate- or long-term exposure durations, nor does naphthalene necessarily originate from a mothball source; however, it has been identified as the best available data source to account for naphthalene volatilization and dissipation over time. Due to the uncertainty associated with the use of an exposure study which is not specific to the duration assessed, the Agency selected the most conservative exposure value (*i.e.*, maximum concentration observed) to represent intermediate- and long- term exposure levels. During reregistration for naphthalene, a Data Call-In will be issued requiring a confirmatory chamber study to determine levels of naphthalene in the air resulting from use of mothballs at the maximum label rate.

The indoor ambient samples which pertain to the air concentrations of naphthalene resulted in a maximum level of 0.0097 mg/m^3. This exposure value was directly compared to the animal LOAEL for olfactory epithelium lesions selected for intermediate- (2 ppm or 10 mg/m^3 identified in a nose-only study) and long-term (10 ppm or 52 mg/m^3 identified in an exposure chamber study) durations, as well as to the NOAEL selected for the intermediate-term duration (1 ppm or 5.2 mg/m^3). A NOAEL was not identified for long-term inhalation exposure.

Intermediate- and long-term exposures to naphthalene in residences are 1000X and 5400X, respectively, below the animal dose (LOAEL) resulting in respiratory toxicity (olfactory epithelium lesions) and intermediate-term exposure is 540X below the animal dose NOAEL. The long-term duration was not assessed since a NOAEL was not identified.

Generally, in the absence of information on kinetics/dynamics, it is assumed that humans may be 10 times more sensitive than animals (10X interspecies factor). The current research indicates that primates, thus humans, are less sensitive than rodents because of differences in the rate of bioactivation of naphthalene as well as anatomical and physiological differences in the nose and respiratory tract. These critical differences between primates and rodents have not been accounted for in this assessment. Thus, with consideration of differences in dosimetry and species metabolism of naphthalene, the margins of exposure for human inhalation risk assessment are likely larger than the differences calculated here between the rodent NOAELs and LOAELs and the measured ambient naphthalene levels from the best available exposure study.

Studies determining the differences in nasal metabolism of naphthalene between rodents and primates are part of ongoing research. There are no data to indicate that humans have a slower rate of clearance, but if they did, then there would be a longer time for humans to produce

the active metabolite. These issues are being addressed in current pharmacokinetic research.

7. Aggregate Risk

An aggregate risk assessment for all expected routes of exposure was not performed as there is no common toxicity among all the routes of exposure. A short-term aggregate risk assessment could be performed by combining short-term incidental oral exposure and average/background dietary (in this case drinking water) exposures. However, a short-term aggregate risk assessment was not performed for naphthalene since the short-term incidental oral exposure risk estimate alone exceeds the LOC, and combining with other routes of exposure would only further exceed the LOC.

8. Occupational Risk

Naphthalene pesticide products are not registered for occupational use and, therefore occupational exposure to the pesticidal uses of naphthalene is not anticipated and has not been assessed

9. Human Incident Data

Four databases were consulted for poisoning incident data on naphthalene for the period of 1993 to 2005. These include: OPP Incident Data System (IDS), Poison Control Centers (PCC), California Department of Pesticide Regulation, and National Institute of Occupational Safety and Health's Sentinel Event Notification System for Occupational Risks (NIOSH SENSOR). A summary of the findings from the *"Review of Naphthalene Incident Reports,"* dated June 25, 2007 is as follows:

- Naphthalene produces a disproportionately high number of exposure incidents when compared to the composite average of exposure incidents reported for all other pesticides. This pattern observed in the combined population (occupational, non-occupational, children) is largely due to the frequency of reported incidents among children less than 6 years;
- Exposure to children is much higher than a typical pesticide;
- Naphthalene PCC data show average results of about 1647 exposures/year, 133 symptomatic cases/year, and 310 cases/year seen in a heath care facility;
- No apparent annual trend is evident in the 13 year-span of data collected, as the number of reported incidents/year has remained relatively stable;
- NIOSH/SENSOR data indicate that indoor uses of naphthalene are responsible for a large number of cases; and
- The large majority of incidents for children under 6 years of age were from ingestion of mothball products used indoors.

Reported incidents of naphthalene ingestion among children account for the majority of reported exposures, and occur with much greater frequency than for most other pesticides. This may be attributed to the widespread use of naphthalene products in homes and the ease of accessing the product as it is applied as loose mothballs. The severity of the reported incidents

are much lower than for other pesticides as a whole. From a 13-year period of PCC data, approximately 7% of naphthalene incidents in children resulted in any symptoms at all, and less than 1% had moderate or major symptoms. Symptoms that did occur (both adults and children; all routes of exposure) were not life-threatening and include nausea, vomiting, headache, dizziness, drowsiness/lethargy, eye irritation, respiratory irritation, and dermal edema and erythema.

B. Environmental Risk Assessment

Indoors, naphthalene is used principally as mothballs, and this use is not considered likely to result in exposure to non-target organisms (other than humans), and therefore, is not considered in the ecological risk assessment. It is also used indoors in attics as an animal repellant (*e.g.*, Chaperone Squirrel and Bat Repellent), and while there is potential for exposure to animals from this use, it only affects pest species trying to enter homes. Currently, four registered naphthalene products include outdoor uses. These products are formulated as flakes or granules, and are applied in a band around ornamentals, planting beds and gardens as an animal repellent. The following is a summary of EPA's revised ecological risk assessment for naphthalene, as presented fully in the *Revised Ecological Risk Assessment for Reregistration Eligibility Decision (RED) for Naphthalene,* dated April 21, 2008. This document is available in the OPP Public Docket, docket number EPA-HQ-OPP-2008-0343, and may also be accessed through the Agency's website at https://www.regulations.gov.

For naphthalene, ecological risk was assessed to determine the potential for acute effects (*i.e.,* lethality) to mammals, birds, fish and invertebrates using screening-level risk assessment models. Risk was assessed for the treated site for birds and mammals, and in an adjacent pond for freshwater fish and invertebrates. Ecotoxicity data on sublethal (*e.g.,* reproductive, growth) effects were not available, so chronic risk was not addressed.

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity studies using the risk quotient method. A risk index (RQ or LD_{50}/ft^2) is calculated by dividing acute estimated environmental concentrations (EECs) by ecotoxicity values for various wildlife species. The LD_{50}/ft^2 (for terrestrial animals) or RQ (for aquatic animals) is then compared to the Agency's Levels of Concern (LOCs), which serve as criteria for categorizing potential risk to non-target species. At the screening level, the Agency presumes that there is not an unreasonable risk for a particular category if the risk quotient is below the LOC. If calculated RQs exceed the LOC, the Agency presumes that there is a potential for risk in that category. See Table 4 below for the Agency's ecological LOCs. Risk characterization provides further information on potential adverse effects and the possible impact of those effects by considering the fate of the chemical and its degradates in the environment, organisms potentially at risk, and the nature of the effects observed.

Table 4. EPA's Ecological Levels of Concern (LOCs) and Risk Presumptions			
If a calculated RQ is greater than the LOC presented, then the Agency presumes that…	**LOC terrestrial animals**	**LOC aquatic animals**	**LOC plants**
Acute Risk …there is potential for acute risk; regulatory action may be warranted in addition to restricted use classification	0.5	0.5	1.0
Acute Endangered Species …endangered species may be adversely affected	0.1	0.05	1.0
Chronic Risk …there is potential for chronic risk	1	1	NA

1. Environmental Fate and Transport

There are no acceptable fate studies for naphthalene. A single supplemental study has been provided which summarizes open literature data on adsorption/desorption and aerobic soil metabolism data (MRID 45346801). Other fate parameters needed to conduct the ecological assessment have either been extrapolated from the open literature data (*e.g.,* aerobic aquatic metabolism half life) or conservatively assumed to be stable (photolysis and hydrolysis). The lack of these data provides uncertainty to this assessment. Elimination of this uncertainty would require submission of additional data for these fate processes. However, the data used in the assessment are sufficient to allow evaluation of potential risk, and no additional environmental fate data are needed for current outdoor uses of naphthalene.

Open literature data indicated that the solubility of naphthalene ranged from 30 to 31.7 mg/L and that the Koc ranged from 200 to 1470 for a variety of soils from North America, Europe and China. The study citation concluded that naphthalene was bound relatively rapidly to soils with a sustained desorption over days to weeks. For biodegradation, naphthalene degraded with aerobic soil metabolism half-lives between 3.5 and 40 days with no appreciable degradation under anaerobic conditions. Possible dissipation processes affecting naphthalene include volatilization, bioaccumulation, adsorption, and leaching. Volatilization is the method by which naphthalene is effective as an animal repellant. Data suggest that once in air, naphthalene should degrade or dissipate rapidly. Naphthalene principally dissipates via direct sublimation from granules, but data suggests that if naphthalene does enter soil, up to 30% of loss from soil can occur due to volatilization.

Additional open literature data describe both aerobic soil degradation and adsorption values that are consistent with values described above, although under certain conditions degradation from soil may be somewhat longer. In addition, these data suggest that naphthalene degrades rapidly by aqueous photolysis. The data also suggest that under certain conditions naphthalene dissipates rapidly from open water systems, although it is unclear whether the dissipation observed was due to degradation or lumped dissipation processes including transport out of the systems by flowing water. Finally, these data confirm that naphthalene is relatively stable under anaerobic conditions.

A number of transformation products were identified in the various open literature studies. The study author proposed a degradation pathway for naphthalene, which ultimately resulted in catechol. Transitional transformation products included cis-1,2-dihydroxy-1,2-dihydronapthalene, 1,2-dihydroxy-napthalene, 2-hydroxchromene-2-carboxylate (HCCA), trans-

o-hydroxy-benzylidenpyruvate (tHBPA), salicyladehyde, and salicylate. There are no registrant submitted environmental fate data on these degradation products that would allow for an approximation of environmental fate inputs, the available open literature data are sparse, and there are no available toxicity data for these compounds. Therefore, these degradates were not quantitatively assessed in the exposure assessment, and risk estimates are based on the parent only.

2. Terrestrial Organisms

a. Exposure

Naphthalene's outdoor products are formulated as flakes or granules, and are applied in bands 1 to 12 inches wide around ornamental plants, gardens, or building perimeters (snake products only). For birds and rabbits, naphthalene products are formulated with 100% naphthalene ai. This is roughly equivalent to an application rate of 10.8 lbs ai/A. Snake repellant products consist of 7% naphthalene (*i.e.* 0.56 lbs ai/A). For modeling purposes, granules are used as a surrogate for flakes. The Tier-1 model, T-REX (Terrestrial Residue Exposure), was used to estimate terrestrial exposure and risk values for naphthalene. Input values on avian and mammalian toxicity, as well as chemical application and foliar dissipation half-life data, are required to run the model. A default dissipation half-life of 35 days was assumed. The LD_{50}/ft^2 is used to estimate risk for granular formulations through row and banded applications. The appropriate T-REX input parameters were selected from the product labels. For the method of application using granules (or flakes), one row length of 209 feet with a 1-foot bandwidth and 0% incorporation was assumed. These parameters are summarized in Table 5 below. Since naphthalene is used only as a granular or flake application, exposures to animals foraging on food items with naphthalene residues (short and tall grass, broadleaves, seeds) are not estimated in this assessment.

Table 5. Input Parameters for T-REX Analysis

Application Type	Formulation	Input	Guidance	Comments
Rows/Band	Granular	Number of Row, Length	Row spacing is the amount of space (inches) between crop rows and is obtained from the product label.	Only one row was assumed. A row length of 209 foot was used assuming application occurs on one side of a one-acre field.
		Band width	Bandwidth is the width of the applied pesticide row (inches) and is obtained from the product label.	A 12 inch bandwidth was obtained from the Dr. T's Snake-A-Way label (registration # 58630-1), which is the greatest labeled bandwidth.

Table 5. Input Parameters for T-REX Analysis				
Application Type	**Formulation**	**Input**	**Guidance**	**Comments**
		% Incorporated	Value depends on the method of application: T-Banded – covered with specified amount of soil: 99% In-furrow, drill, or shanked-in: 99% Side-dress, banded, mix, or lightly incorporate with soil: 85% Broadcast, mix, or lightly incorporated: 85% Side-dress, banded, unincorporated: 0% Broadcast, aerial broadcast, unincorporated: 0%	Not incorporated according to labels.
		Weight of granule	Estimated from data obtained from registrant	38 mg

b. Toxicity

Effects characterization describes the potential effects a pesticide can produce in an organism, and is generally based on registrant-submitted studies or studies found in the open literature which describe acute and chronic toxicity effects for various animals. Table 6 summarizes the toxicity effects and reference values used to assess risks for naphthalene to terrestrial organisms.

Table 6. Toxicity of Naphthalene to Terrestrial Animals and Plants					
Taxon	**Test Organism**	**Test Type**	**Endpoint**	**Value**	**Ecotoxicity Category**
Bird	Bobwhite quail *Colinus virginianus*	Acute Oral	LD_{50}	2690 mg/kg bw[1]	Practically nontoxic
		Subacute Dietary	LC_{50}	>5620 mg/kg diet	Practically nontoxic
	Mallard duck *Anas platyrhynchos*	Subacute Dietary	LC_{50}	No data	Not available
Mammal	Rat *Rattus norvegicus*	Acute Oral	LD_{50}	2649 mg/kg bw	Practically nontoxic
Beneficial insects	Honey bee *Apis mellifera*	Acute Contact	LD_{50}	No data	Not available
Soil Invertebrates	*Folsomia candida*	Chronic Effects on Soil Invertebrates (reproduction and survival)	NOAEC LOAEC	88 µmol/kg soil 409 µmol/kg soil	None
	Enchytaeus crypticus		NOAEC LOAEC	220 µmol/kg soil 2045 µmol/kg soil	None

Table 6. Toxicity of Naphthalene to Terrestrial Animals and Plants					
Taxon	**Test Organism**	**Test Type**	**Endpoint**	**Value**	**Ecotoxicity Category**
Terrestrial plants	Monocots and dicots	Seedling emergence and Vegetative vigor	EC_{25} NOAEC LOAEC	No data	Not available

1. Body weight

c. Risk to Terrestrial Organisms

i. Birds

At a rate of 10.8 lbs ai/A, risk estimates for birds of all the weight classes, exceed the Agency's LOC. However, naphthalene is a repellent and it is manufactured to ensure that birds will avoid the naphthalene products (*e.g.*, Dr.T's Rabbit, Squirrel, Bat, and Bird Repellent, reg. # 58630-2).

Although it may be unlikely that birds will consume naphthalene granules, since it is not formulated as an attractant but as a repellent to terrestrial animals and is comprised of granules with a strong odor of coal tar, it is uncertain if the repellent nature of the compound will be sufficient to keep birds away entirely. Therefore, further steps were taken to characterize the potential for acute risk to avian species by evaluating how many granules a bird would need to ingest in order to trigger the Agency's LOC; these estimates are presented in Table 7.

Table 7. Estimate of the number of granules ingested to reach an EEC exceeding the adjusted LD_{50} LOC for birds at 10.8 lbs ai/A				
		Bird Size (grams)		
		20	**100**	**1000**
No. of Consumed Granules Required	Adjusted LD_{50}	1	7	92
	Acute Risk LOC (0.5)	0.51	4	46
	Endangered Species LOC (0.1)	0.1	0.65	10
EEC = 112.46 mg/square feet (excluding row spacing, bandwidth, and # of rows input parameters).				

While the Agency believes it is unlikely that birds will consume naphthalene, it is possible that a bird might accidentally ingest it, and if that occurs, the screening-level assessment indicates that a small bird (20 g) will exceed the Agency's LOC at 1 granule if eating avian/mammalian repellant product. These risk estimates assume that birds eat granules containing 100% ai immediately following application, before loss of naphthalene to sublimation. One of the outdoor formulations of naphthalene, "Dr. T's Snake-A-Way", consists of granules that contain 7% naphthalene ai; therefore, a bird would have to consume over 14 times more of the snake repellant granules to exceed an LOC.

Because no toxicity data are available on avian reproductive risk, the Agency was unable to assess chronic risk to birds.

ii. Terrestrial-phase Amphibians and Reptiles

The Agency currently uses data on surrogate species, birds, to assess risk to non-target terrestrial-phase amphibians and reptiles. Based on the evaluation of potential risks to birds, potential risks to reptiles and terrestrial-phase amphibians are also higher than the Agency's levels of concern. However, naphthalene is a repellent and it is formulated to repel reptiles (*e.g.*, Dr. T's Snake-A-Way).

iii. Mammals

The acute risk estimates (LD_{50}/ft^2) to terrestrial mammals, as a result of the assessed uses of naphthalene at 10.8 and 0.56 lbs ai/acre exceed the LOCs for acute risk and endangered species. As for birds, the risk estimates are based on a granular formulation.

Table 8. Mammalian LD_{50}/ft^2 (RQs) from Direct Ingestion of Naphthalene Granules

Weight Class	$LD_{50}/ft^{2\,A}$	LOCs Exceeded
10.8 lb ai/A - EEC/Toxicity (adjusted mg/ft² / adjusted LD_{50})		
15 g	268.18	Acute Risk, Endangered Species
35 g	142.05	Acute Risk, Endangered Species
1000 g	11.49	Acute Risk, Endangered Species
0.56 lb ai/A - EEC/Toxicity (adjusted mg/ft² / adjusted LD_{50})		
15 g	13.91	Acute Risk, Endangered Species
35 g	7.37	Acute Risk, Endangered Species
15 g	13.91	Acute Risk, Endangered Species

[A] Mammal LD_{50} = 2649 mg/kg

Curently, T-REX does not have the capacity to estimate the minimum foraging area needed to allow for direct ingestion of sufficient mass of naphthalene to achieve a dose that exceeds the LOC for mammals. However, naphthalene is a repellent and it is manufactured to ensure that mammals will avoid the naphthalene flakes (*e.g.*, Chaperone Squirrel and Bat Repellent, reg. # 2724-685).

Because no toxicity data is available on mammalian reproductive risk, the Agency was unable to assess chronic risk to mammals.

iv. Non-Target Insects

EPA does not estimate RQs for terrestrial non-target insects. Furthermore, the Agency has no insect toxicity data for naphthalene.

v. Terrestrial Plants

The Agency currently uses terrestrial plant data to estimate potential risks to non-target terrestrial plants from surface water runoff. Some naphthalene labels state that the products should not be applied directly to foliage or stems. This statement indicates that there is a possibility of phytotoxicity. In addition, open literature suggests that naphthalene is selectively

phytotoxic to plants. However, terrestrial plant studies have not been submitted for naphthalene, nor has data been located in published literature. Therefore, the potential risks to terrestrial plants are unknown.

3. Aquatic Organisms

a. Exposure

Risk to aquatic animals was assessed using Generic Estimated Environmental Concentration (GENEEC2), a Tier 1 model that estimates concentrations in a 1-hectare, 2-meter-deep water body adjacent to a 10-hectare treated site that drains into the water body. Since there are no liquid outdoor use formulations of naphthalene and granular applications are assumed, this water body is also assumed to receive no drift from the treated site. The model assumes an area is 100% treated. Given the limited size of the outdoor area treated (it is applied in a band around ornamentals, planting beds and gardens) an adjustment of 4.1% to the modeled EEC was made to account for the use pattern.

Two scenarios were modeled to represent high and low naphthalene use scenarios. The high use scenario was modeled at 10.8 lbs ai/A with six applications per year, while the low use scenario was modeled at 0.56 lbs ai/A with six applications per year. The EECs are summarized in Table 9.

Table 9. Results of GENEEC2 Modeling for Naphthalene Use on Ornamentals

Use Site	Application Rate (lbs/acre)	Number of Applications (interval)	Peak EEC (ppb)	4 day EEC (ppb)	21 day EEC (ppb)	60-day EEC (ppb)	90-day EEC (ppb)
Ornamentals for rabbit & dog repellent	10.8	6 (2 months)	26.9	26.6	25.2	22.4	20.5
Ornamentals for snake repellent	0.56	6 (2 months)	1.4	1.4	1.3	1.2	1.1

Unaccounted for in this exposure assessment is the fact that naphthalene is volatile. No product chemistry data are available, but an estimate of the vapor pressure was made using EpiSuite (http://www.epa.gov/opptintr/exposure/pubs/episuite.html). EpiSuite reported an experimentally derived value for vapor pressure of 8.5 $x10^{-2}$ mm Hg (which is consistent with the registrant reported value of 10.5 Pa, or 7.8 x 10^{-2} mm Hg), suggesting that naphthalene is volatile. Given the volatility of this compound and the fact that the Tier I model used to estimate exposure does not account for volatility as a route of dissipation, it is likely that the exposure estimates derived above are over-predictions of potential exposure. However, it is unknown from the open literature data used in this assessment whether the systems were closed or flow-through. If the aerobic metabolism data (and hence the half-life used in this assessment) were flow-through, then the degradation reported would include volatilization as a process.

It is possible that naphthalene may leach to groundwater. An overview of US Geological Survey (USGS) National Water-Quality Assessment Program (NAWQA) groundwater data indicates that of 6,977 samples only 37 detections of naphthalene were found. While the

maximum concentration detected was 70 ppb, there are a number of possible sources of naphthalene contamination of groundwater, including many with significantly higher usage (*e.g.*, petroleum, jet fuel). Thus it appears that leaching is not likely a significant route of exposure for the pesticidal use of naphthalene. Potential groundwater leaching was assessed using SciGrow, and a concentration of 16.3 ppb at the highest application rate (10.8 lbs ai/A x 6 applications) and 0.84 ppb at the lowest rate (0.56 lbs ai/A x 6 applications) was estimated. These values are below the surface water concentrations predicted by GENEEC2, are lower than the NAWQA values described above, and assume a much broader area of application than anticipated for this use pattern (bands surrounding gardens and planting beds). Given the lines of evidence described, it is expected that as an exposure route for ecological risk assessment, naphthalene in groundwater resulting from pesticidal use is minimal.

Unlike the drinking water assessment described in the human health risk assessment section of this document, the exposure values used in the ecological risk assessment do not include the Index Reservoir (IR). These factors represent a drinking water reservoir, not the variety of aquatic habitats relevant to a risk assessment for aquatic animals, such as ponds adjacent to treated fields. Therefore, the EEC values used to assess exposure and risk to aquatic animals are not the same as those used to assess exposure and risk to humans from pesticides in drinking water.

b. Toxicity

Available freshwater and estuarine/marine fish and invertebrate acute toxicity data suggest that naphthalene is moderately toxic to most aquatic test species (Table 10). Chronic freshwater fish reproduction data indicates that survival and growth are affected. Aquatic plant growth studies with green algae were less sensitive than animals, and naphthalene is categorized as slightly toxic to green alga. No toxicity study with aquatic vascular plants is available for this ecological risk assessment.

Table 10. Toxicity of Naphthalene to Aquatic Organisms and Plants

Taxon	Test Organism	Endpoint	Value[1] (mg a.i./L)	Ecotoxicity Category
Freshwater Fish	Rainbow trout *Onchorhynchus mykiss*	96-hr LC_{50} NOAEC (mortality) NOAEC (sublethal)	**2.0** 0.86 0.86	Moderately Toxic
	Bluegill sunfish *Lepomis macrochirus*	96-hr LC_{50} NOAEC (mortality) NOAEC (sublethal)	3.2 1.4 1.4	Moderately Toxic
	Coho salmon *Oncorhynchus kisutch*	40D NOAEC 40D LOAEC	**0.37** 0.67	None
Freshwater Invertebrate	Water flea *Daphnia magna*	48-hr EC_{50} NOAEC (mortality) NOAEC (sublethal)	**1.6** 0.48 >8.8	Moderately Toxic

Table 10. Toxicity of Naphthalene to Aquatic Organisms and Plants				
Taxon	**Test Organism**	**Endpoint**	**Value[1] (mg a.i./L)**	**Ecotoxicity Category**
Estuarine/ Marine Fish	Fathead minnow *Pimephales promelas*	96-hr LC_{50} NOAEC (mortality) NOAEC (sublethal)	**6.6** NR NR	Moderately Toxic
		Chronic NOAEC Chronic LOAEC	**0.62** NR	None
Estuarine / Marine Invertebrates	Pacific oyster *Crassostrea gigas*	96-hr EC_{50} NOAEC (mortality) NOAEC (sublethal)	**199** NR NR	Practically Nontoxic
	Grass shrimp *Palaemonetes pugio*	96-hr LC_{50} NOAEC (mortality) NOAEC (sublethal)	**2.35** NR NR	Moderately Toxic
Vascular Plant	Duckweed *Lemna gibba*	7-day EC50 NOAEC	No data	No Data
Non-vascular Plant	Green algae *Chlorella vulgaris*	48-hr EC_{50} NOAEC LOAEC	**33** NR NR	Slightly Toxic

[1]Bolded values indicate toxicity thresholds used to calculate risk quotients.

c. Risk to Aquatic Organisms

RQs for naphthalene do not exceed the acute LOC for aquatic animals and aquatic nonvascular plants (*i.e.*, fish, aquatic-phase amphibians, invertebrates, and algaes) when used at six applications, 60 days apart, at the highest application rate (10.8 lbs ai/A). Therefore, minimal acute risk is also expected from the lower application rate (0.56 lbs ai/A). Risks to aquatic vascular plants are also unknown due to lack of ecotoxicity data. Aquatic organism risk estimates based on the maximum application rate are presented in Table 11 below.

Table 11. Risks to Aquatic Animals and Plants for Naphthalene Use on Ornamentals					
Taxon	**Species**	**Toxicity Endpoint**	**EEC (µg/L)**	**RQ[1]**	**LOCs Exceeded[2]**
Freshwater Fish	Rainbow trout *Onchorhynchus mykiss*	96-hr LC_{50} = 2.0 mg/L (or 2000 µg/L)	26.9 (peak)	0.013	None
	Coho salmon *Oncorhynchus kisutch*	40-day NOAEC = 0.37 mg/L (or 370 µg/L)	22.4 (60D)	0.06	None
Freshwater Invertebrate	Water flea *Daphnia magna*	48-hr LC_{50} = 1.6 mg/L (or 1600 µg/L)	26.9 (peak)	0.017	None
Marine/estuarine Fish	Fathead minnow *Pimephales promelas*	LC_{50} = 6.6 mg/L (or 6600 µg/L)	26.9 (peak)	<0.01	None
		NOAEC = 0.62 mg/L (or 620 µg/L)	22.4 (60D)	0.04	None

Table 11. Risks to Aquatic Animals and Plants for Naphthalene Use on Ornamentals					
Taxon	**Species**	**Toxicity Endpoint**	**EEC (µg/L)**	**RQ[1]**	**LOCs Exceeded[2]**
Marine/estuarine Invertebrate	Grass shrimp *Palaemonetes pugio*	LC_{50} = 2.35 mg/L (or 2350 µg/L)	26.9 (peak)	0.01	None
Vascular Plant	Duckweed *Lemna gibba*	No data	26.9 (peak)	Not available	
Freshwater Non-Vascular Plant	Green Algae *Chlorella vulgaris*	EC_{50} = 33 mg/L (or 33000 µg/L)	26.9 (peak)	<0.01	None

[1] Acute risk quotients= EEC/LC_{50}; Chronic Risk Quotients =EEC/NOAEC.
[2] Aquatic animal acute LOC: >0.05 for endangered species and >0.5 for non-listed species; LOC for aquatic plants: >1; Chronic LOC for aquatic animals: >1.

d. Endangered Species

The acute risk to birds, terrestrial-phase amphibians and reptiles, and mammals exceed the endangered species LOC, and therefore there is a potential for direct effect to these taxa. In addition, there is a potential for indirect effects to species that depend on them. The data are currently insufficient to determine if there is a potential for direct or indirect effect to terrestrial or aquatic plants. Naphthalene is not likely to affect aquatic animals (fish or invertebrates) directly; the potential for indirect effects depends on whether naphthalene could affect semi-aquatic or aquatic plants.

e. Ecological Incidents

A search of the EIIS (Environmental Incident Information System) database for ecological incidents (run on May 31, 2007) identified one ecological incident involving naphthalene. The incident reported includes possible impact to fish. See table 12 for further detail.

The number of documented kills in EIIS is believed to be a very small fraction of total mortality caused by pesticides for a variety of reasons. An absence of reports does not necessarily equate to an absence of incidents given the nature of incident reporting.

Table 12. Naphthalene Ecological Incident						
Formulation	**Crop**	**Date and Location**	**Species Affected**	**Number Found**	**Residue Analysis**	**App. Rate, Method, etc.**
Unknown	N/A	May 2003, Craven Co., NC	Unknown fish	2,000	No	Treated directly

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active

ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (*i.e.*, active ingredient-specific) data required to support reregistration of products containing naphthalene as the active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing naphthalene.

The Agency has completed its assessment of the human health and ecological risks associated with the use of pesticide products containing naphthalene. The Agency has determined that naphthalene-containing products are eligible for reregistration provided that label amendments are made as outlined in Chapter V. Appendix A summarizes the uses of naphthalene that are eligible for reregistration. Appendix B identifies the generic data the Agency reviewed as part of its determination of reregistration eligibility of naphthalene, and lists the submitted studies that the Agency found acceptable.

Based on its evaluation of naphthalene, the Agency has determined that products containing naphthalene, 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 will take regulatory action to address the risk concerns from the use of naphthalene. If all changes outlined in this document are incorporated into the product labels, then all current risks for naphthalene will be adequately mitigated for the purposes of this determination under FIFRA.

B. Public Comment Period

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decision for naphthalene. EPA released the naphthalene preliminary risk assessments for public comment on May 14, 2008, for a 60-day public comment period (Phase 3 of the public participation process). During the public comment period on the risk assessments, which closed on July 14, 2008, the Agency received comments from registrants (technical and end use), Honeywell, and the Naphthalene Council. These comments in their entirety, responses to the comments, as well as the preliminary and revised risk assessments, are available in the public docket (EPA-HQ-OPP-2008-0343) at http:www.regulations.gov. In brief, the comments included the following:

- Landis International, the agent for the technical registrant (Reochem, Inc.), agrees to conduct the required exposure study (Guideline 875.2500).

- An end use registrant, Willert Home Products, suggested that 1) packaging is not necessary to reduce potential risk from episodic ingestion of mothballs, since the symptoms described in incident reports are not severe in nature; and 2) the aquatic exposure modeling overestimates the amount of naphthalene product typically applied.

- Honeywell International Inc. stated that the carbon adsorption coefficient used in the ecological risk assessment was unreasonably low and thus led to an unrealistically high estimate of the risks naphthalene poses to drinking water.

C. Regulatory Position

1. Regulatory Rationale

The Agency has determined that products containing naphthalene are eligible for reregistration provided that specified label amendments are made. The following is a summary of the rationale for managing risks associated with the use of naphthalene. Where labelling revisions are warranted, specific language is set forth in the summary table of Section V.

a. Dietary Risk

There are no agricultural or food uses of naphthalene; therefore, no dietary exposure from food is expected. However, there is potential for drinking water exposure from the outdoor uses of naphthalene. The acute and chronic risk estimates were found to be well below the 100% Reference Dose (RfD) level of concern. Overall dietary exposure to naphthalene via drinking water is expected to be insignificant, and thus, no mitigation measures are required.

b. Residential Risk

Handlers

For residential risk, the MOEs for all handler scenarios assessed were 17,000 or greater, which is greater than the Agency's MOE of 100, and therefore, no mitigation measures are required.

Episodic Ingestion

Toddler episodic ingestion of one naphthalene mothball results in an MOE < 1 (LOC = 100). While this represents an exposure concern, the effects of this type of exposure, if any, are not expected to be severe. The episodic ingestion MOE is calculated from an endpoint derived from a developmental oral rat study in which dams were repeatedly treated with a high oral bolus dose, and the resulting clinical signs (lethargy and slow breathing) and body weight decrement were transient. The effects were attributed to the administration of a high bolus and were not permanent; the animals displayed quick recovery. There were no persistent effects or treatment-related deaths.

The study results are consistent with symptoms described in the incident reports. Reported incidents of naphthalene ingestion among children account for the majority of reported naphthalene exposures. This may be attributed to the widespread use of naphthalene products in homes and the ease of accessing the product as it is applied as loose mothballs. The severity of the reported incidents are much lower than for other pesticides as a whole. From a 13-year period of PCC data (1993-2005), approximately 7% of naphthalene incidents in children resulted in any symptoms at all and less than 1% had moderate or major symptoms. Symptoms that did occur (both adults and children; all routes of exposure) were not life-threatening and included nausea, vomiting, headache, dizziness, drowsiness/lethargy, eye irritation, and dermal edema and

erythema. Of greater concern than the potential health effects is the accessibility of the indoor use product to young children, as evidenced by the large number of reported incidents.

Limiting accessibility to naphthalene is expected to significantly reduce the number of incidents, including those that may result in symptoms. To that end, the Agency has conducted risk mitigation discussions with the naphthalene end-use registrants. Since the large majority of naphthalene incidents for children under 6 years of age were from episodic ingestion of indoor use mothball products, the Agency determined that mothballs can no longer be marketed in such a way that individual mothballs are applied to areas accessible to children.

The registrants have agreed to take product stewardship steps to ensure that products are packaged in a way that would discourage children from eating the product. Loose mothballs will no longer be sold, and there are several formulation and packaging options that registrants can employ instead. Mothballs can be sold in sachets, for example, if made with a tear- and moisture-resistant wrapping material. Mothballs can also be packaged in plastic containers that allow for volatilization, but which would prohibit direct contact with the naphthalene product enclosed. Alternatively, naphthalene could be formulated into larger sized cake or block products (minimum of 2.5 inches in diameter), which incident data show are not an exposure source of concern for episodic ingestion. The registrants further agreed that cake and block products will also be enclosed in plastic, metal or cardboard packaging while in use. The implementation of packaging mitigation measures is required within 5 years (September 2013). See Table 13 for details on packaging requirements.

In addition, the Agency will require prominently displayed precautionary label language on packaging which warns consumers of a possible episodic ingestion risk to children and to keep product out of reach of children (see Table 13). These new product labelling requirements will be implemented within 12 months (September 2009). The Agency is confident that based on the rigorous nature of the mitigation measures to be implemented, episodic ingestion exposures will be reduced to such an extent that this scenario no longer poses a risk of concern.

Postapplication Inhalation (Cancer and Noncancer)

A quantification of cancer risk for exposures via inhalation, or derivation of an inhalation reference concentration (RfC) for the nonfood-pesticidal uses of naphthalene was not performed. This is because, as described in Section III of this document, there is support from published studies and ongoing research on naphthalene that indicate that risk estimates, factoring in known species differences between rodents and humans (including humans) in metabolism and respiratory toxicity, would be considerably less than those using default procedures. Pharmacokinetic research may quantify the species difference and is forthcoming (approximately 2-3 years).

Anticipated acute and short-term inhalation exposures to naphthalene in residences are estimated to be 20X and 30X below the rodent dose (NOAEL) resulting in no adverse effects, respectively. Anticipated acute and short-term inhalation exposures to naphthalene in residences are estimated to be 60X and 80X, respectively, below the rodent dose (LOAEL) resulting in respiratory toxicity (olfactory epithelium lesions).

Anticipated intermediate-term inhalation exposures to naphthalene in residences are estimated to be 540X below the rodent dose (NOAEL) resulting in no adverse health effects. Intermediate- and long-term inhalation exposures to naphthalene in residences are estimated to be 1000X and 5400X, respectively, below the rodent dose (LOAEL) resulting in respiratory toxicity (olfactory epithelium lesions).

These inhalation exposure estimates do not represent a risk of concern to the Agency. The carcinogenic and noncarcinogenic potential of naphthalene is currently undergoing review by EPA Integrated Risk Information System (IRIS). The EPA process of regulating pesticides allows for re-evaluation at any time if relevant new information becomes available. Thus, when the IRIS assessment is finalized OPP would determine whether the human health hazard potential of naphthalene warrants revisiting. Similarly, when pharmacokinetic research is complete the Agency will revisit naphthalene inhalation risk.

c. Aggregate Risk

An aggregate risk assessment for all expected routes of exposure was not performed as there is no common toxicity among all the routes of exposure. A short-term aggregate risk assessment could be performed by combining short-term incidental oral exposure and average/background dietary (in this case drinking water) exposures, but this was not done for naphthalene since the short-term incidental oral exposure risk estimate alone exceeds the LOC, and combining with other routes of exposure would only further exceed the LOC. As previously described, while the episodic ingestion of naphthalene by a toddler results in an MOE less then the target MOE, the effects of this type of exposure, if any, are transient and are not expected to be severe.

However, the Agency is requiring extensive mitigation measures, including special packaging of indoor use products and prominent precautionary label language. These mitigation measures are expected to reduce the potential for episodic ingestion to such an extent that this scenario no longer represents a risk of concern. Furthermore, naphthalene's highly conservative dietary risk estimates for potential drinking water exposure are far below the Agency's LOC and are not of concern.

d. Occupational Risk

Naphthalene pesticide products are not registered for occupational use and, therefore, occupational exposure to the pesticidal uses of naphthalene is not anticipated and has not been assessed.

e. Ecological Risk

<u>Birds, Terrestrial-phase amphibians, and Reptiles</u>

Based on a screening-level assessment, naphthalene may pose an acute risk to birds, terrestrial-phase amphibians and reptiles. The ecological assessment was conducted with

conservative use assumptions: six applications per year were assumed, the highest application rate was used (10.8 lbs ai/A, although some products are labeled for use at 0.56 lbs ai/A), and the model did not account for volatilization. Furthermore, animal repellant products are formulated as flakes and granules, but the assessment was conducted for granules only due to modeling limitations. While there is some potential for a bird to accidentally ingest a granule of naphthalene during gritting activities, it is unlikely that a bird would consume naphthalene in flake form. The modeling limitations, the conservative assumptions, and the uncertainty surrounding volatility may have resulted in an over-estimate of risk. Based on the conservative nature of the risk assessment and the fact that naphthalene is a bird repellant, the Agency does not anticipate a risk of concern and is not requiring mitigation measures for the naphthalene animal repellent products.

Mammals

When marketed as a rabbit repellent, the use directions instruct the user to place the product in small bands around ornamentals; this use is limited to small areas during the growing season. While the acute risk estimates to terrestrial mammals exceed the Agency's LOCs, as for birds, the assessment was highly conservative and may have over-estimated risk. In addition, the incident data show very little history of pet exposure. The Agency does not anticipate risk of concern to mammals from the outdoor uses of naphthalene, based on the use pattern (localized treatments around ornamentals as an animal repellant), and is not requiring mitigation.

Aquatic Organisms

Acute risk is not expected for freshwater animals, aquatic-phase amphibians and aquatic nonvascular plants, and therefore, no mitigation is required.

Non-Target Insects and Plants

Due to lack of toxicity data, risks to honey bees and to terrestrial and aquatic vascular plants can not be quantified; however, given its method of application and use as a repellent around gardens, effect on insects and plants are not anticipated.

2. Endocrine Disruptor Effects

Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA, and to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the

EDSP have been developed, individual pesticides may be subject to additional screening and/or testing to better characterize effects related to possible endocrine disruption.

3. Endangered Species

The Endangered Species Act required federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on federally listed endangered and threatened species, and to implement mitigation measures that address these impacts. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, and/or consultations with the Fish and Wildlife Service or National Marine Fisheries Service, as necessary.

For naphthalene, the acute risk to birds, terrestrial-phase amphibians and reptiles, and mammals exceed the endangered species LOC, and therefore there is a potential for direct effect to these taxa. In addition, there is a potential for indirect effects to species that depend on them. The data are currently insufficient to determine if there is a potential for direct or indirect effect to terrestrial or aquatic plants. Naphthalene is not likely to affect aquatic animals (fish or invertebrates) directly; the potential for indirect effects depends on whether naphthalene could affect semi-aquatic or aquatic plants.

D. Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be needed in the labeling of all end-use products containing naphthalene. For the specific labeling statements, refer to Section V of this RED document.

V. What Registrants Need to Do

The Agency has determined that products containing naphthalene are eligible for reregistration provided that the required risk mitigation measures, including product packaging, are adopted and label amendments are made. The Agency intends to issue Data Call-In Notices (DCIs) requiring generic and product-specific data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product-specific data, the registrant will have eight months to submit data. Table 13 describes the packaging requirements and label amendments that the Agency is requiring for naphthalene products to be eligible for reregistration.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of naphthalene for currently registered uses has been reviewed and determined to be substantially complete. However, the Agency

intends to issue a DCI requiring a confirmatory chamber study (Guideline 875.2500) to determine levels of naphthalene in the air resulting from use of mothballs at the maximum label rate. It is recommended that a study protocol be submitted to the Agency for review and approval prior to the inception of the study. The Agency does not currently anticipate requiring additional generic data. Other entities are conducting ongoing naphthalene research to address toxicology issues including:

- More accurate assessment of species differences in metabolism and clearance of naphthalene.
- Cell proliferation data to provide linkage to cytotoxicity.
- DNA adduct and mutagenicity studies in relevant target tissues *in vivo* to confirm lack of direct DNA mutagenicity.
- Physiologically Based Pharmacokinetic (PBPK) model under development (2-3 years rough estimate) to better support the mode of action, and to characterize species differences in metabolism, and address involvement of multiples enzymes and clearance in humans versus rodents. The PBPK model may provide a more accurate determination of a human equivalent dose to be used in inhalation risk assessment.

These data will be included in future assessments of naphthalene.

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 13.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI), outlining specific data requirements. For any questions regarding the PDCI, please contact Veronica Dutch at 703-308-8585.

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 13. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific

existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

C. Labeling Changes Summary Table

For naphthalene to be eligible for reregistration all naphthalene mothball products must be packaged, and labels must be amended to incorporate the risk mitigation measures, as outlined in Section IV. Table 13 describes the packaging requirements and how language on the labels should be amended.

Table 13. Summary of Labeling Changes for Naphthalene		
Description	**Amended Labeling Language**	**Placement on Label**
Manufacturing Use Products		
For All Manufacturing Use Products	"Only for formulation into an ***insecticide/repellent*** for the following use(s) [fill blank only with those uses that are being supported by MP registrant]." *Note to registrant:* Special packaging for moth repellant end use products are required to reduce the risk that children will ingest the product.	Directions for use
For Manufacturing Use Products Formulated as Indoor Use Moth Repellant Products	*Note to registrant:* After September 30, 2013 formulation into loose mothball products is not permitted. See End Use Product requirements for a description of approved indoor moth repellant formulation types and packaging specifications.	Directions for use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements	"ENVIRONMENTAL HAZARDS" "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 Eliminations 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 Environmental Protection Agency."	Precautionary Statements: Environmental Hazards

<table>
<tr><th colspan="3">Table 13. Summary of Labeling Changes for Naphthalene</th></tr>
<tr><th>Description</th><th>Amended Labeling Language</th><th>Placement on Label</th></tr>
<tr><td colspan="3">End-Use Products</td></tr>
<tr><td>Availability Statements</td><td>“IMPORTANT: Keep out of reach of children.”

“Do not place in areas accessible to children.”</td><td>Directions for Use</td></tr>
<tr><td>Indoor Moth Repellant Sachet Products</td><td>“IMPORTANT: It is illegal to sell the sachets individually.”

“Do not open sachets.”</td><td>Directions for Use</td></tr>
<tr><td>For End Use Products Formulated as Indoor Use Moth Repellant Products</td><td>Note to registrant:

After September 30, 2013, naphthalene may no longer be formulated into loose mothball products unless contained in sachets meeting the following minimum manufacturing specifications:
<table>
<tr><th>Physical Property</th><th>Minimum Value</th><th>Test</th></tr>
<tr><td>Tear Initiation Machine Direction</td><td>2.2 lbs</td><td>ASTM D1004 Standard Test Method for Tear Resistance (Graves Tear) of Plastic Film and Sheeting</td></tr>
<tr><td>Tear Initiation Transverse Direction</td><td>2.2 lbs</td><td>ASTM D1004</td></tr>
<tr><td>Tensile Strength Machine Direction</td><td>16,3000 psi</td><td>ASTM D882A Standard Test Method for Tensile Properties of Thin Plastic Sheeting</td></tr>
<tr><td>Tensile Strength Transverse Direction</td><td>20,000 psi</td><td>ASTM D882A</td></tr>
<tr><td>Heat Seal Strength</td><td>500 g/in</td><td>285° F, 40 PSI, 1 sec HS/HS heat seal side to heat seal side</td></tr>
</table>
After September 30, 2013, naphthalene indoor moth repellant products formulated as cakes or blocks must have a minimum diameter size of 2.5</td><td>Directions for use</td></tr>
</table>

Table 13. Summary of Labeling Changes for Naphthalene		
Description	**Amended Labeling Language**	**Placement on Label**
	inches.	
Precautionary Statement for All Indoor Moth Repellant Products	*Note to registrant:* The following statement will be placed within a shaded box within the Precautionary Statements on the label. The coloring of the box and text will be such to provide a contrasting color to other label text. The shaded box must contain the following: "**Keep out of reach of children.** Do not place in areas accessible to children." Include the following statement prominently on the front panel of product packaging (in bold), **"Keep out of reach of children."**	Precautionary Statements

Appendix A. Use Patterns Eligible for Reregistration for Naphthalene					
Use Site	**Formulation Type**	**Product Type**	**Maximum Application Rate/Application[2]**	**Unit**	**Maximum Retreatment Interval**
Attics, Basements, Etc. (indoor animal repellant use)	Crystalline	Flakes	1	lb ai/400 ft^3 or oz ai/3 ft^3	7
Household/Domestic Dwellings Contents	Crystalline	Balls, Flakes, Sachets	0.37	lb ai/12 ft^3	7
Garden or House Perimeter	Crystalline	Granules, Flakes	0.014	gal/ 1000 ft^2	7

Appendix B Data Supporting Guideline Requirements for the Reregistration of Naphthalene				
REQUIREMENT			**Use Pattern**	**CITATION(S)**
PRODUCT CHEMISTRY				
New Guideline Number	**Old Guideline Number**	**Study Description**		
830.1600	158.160	Description of Materials Used to Produce the Product	All	46862001
830.1620	158.162	Description of Production Process	All	43112501
830.1650	158.165	Formulation Process		46862001
830.1670	158.167	Formation of Impurities	All	46862001
830.1700	158.170	Preliminary Analysis	All	43170801
830.1800	158.180	Analytical Method	All	46862001
830.7050	N/A	UV/Visible Absorption	All	Data Gap
830.7550	63-11	Partition Coefficient	All	42335803
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian Acute Oral Toxicity	A, B	148176
850.2200	71-2	Avian Dietary Toxicity - Quail	A, B	00148175
850.1075	72-1	Freshwater Fish Acute Toxicity	A, B	45030801, 44302701
850.1010	72-2	Invertebrate Toxicity	A, B	44302702
850.1400	72-4a	Freshwater Fish Early Life-Stage Toxicity	A, B	46220970
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity	A, B	00148174, 257224
870.1200	81-2	Acute Dermal Toxicity	A, B	00148409, 257229
870.1300	81-3	Acute Inhalation Toxicity	A, B	00144557, 257902
870.2400	81-4	Primary Eye Irritation	A, B	00148408, 257228
870.2500	81-5	Primary Dermal Irritation	A, B	00148177, 257227
870.2600	81-6	Dermal Sensitization	A, B	00148173
Non-guideline		Acute Neurotoxicity – Rat	A, B	44282801
870.3250	82-3	90-Day Dermal – Rodent	A, B	40021801
870.3465	82-4	90-Day Inhalation - Rat	A, B	42835901
Non-guideline		90-Day Neurotoxicity – Mammal	A, B	44856401
Non-guideline		Oncogenicity – Rat	A, B	45630101
Non-guideline		Oncogenicity – Mouse	A, B	42458301
870.3700	83-3	Teratogenicity - Rabbit	A,B	42195401, 00157145
870.3700	83-3	Prenatal Developmental – Rat	A, B	NTP 1991

Appendix B Data Supporting Guideline Requirements for the Reregistration of Naphthalene				
REQUIREMENT			**Use Pattern**	**CITATION(S)**
870.3700	83-3	Prenatal Developmental – Rabbit	A, B	NTP 1992
870.5100	84-2	Gene Mutation – Ames	A, B	42071601
Non-guideline		Genotoxicity	A, B	42071604
870.5300	84-2	Structural Chromosome Aberration	A, B	42071603
870.5550	84-2	UDS Assay	A, B	42071604
870.5375	84-2	CHO Chromosome Aberration	A, B	NTP 2000
870.5375	84-2	CHO Sister Chromatid Exchange	A, B	NTP 2000
870.6200	82-7	Acute Neurotoxicity (Oral) – Rat	A, B	44282801
870.5395	84-2	*In Vivo* Mouse Bone Marrow Micronucleus	A, B	42071603
870.5265	84-2	Gene Mutation in *S.typhimurium*	A, B	42071602
870.6200	82-7	Subchronic Neurotoxicity (Inhalation) – Rat	A, B	44856401
Non-guideline		4-Week Inhalation – Rat	A, B	42934901
Non-guideline		90-Day Oral Toxicity – Rat	A, B	NTP 1980a
Non-guideline		90-Day Oral Toxicity – B6C3F1 Mouse	A, B	NTP 1980b
Non-guideline		90-Day Oral Toxicity – DC1 Mouse	A, B	Shopp et al. 1984
Non-guideline		Chronic Toxicity/ Carcinogenicity (Chamber) Inhalation – Rat	A, B	NTP 2000
Non-guideline		Chronic Toxicity/Carcinogenicity (Chamber) Inhalation – Mouse	A, B	NTP 1992
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
Non-guideline		Indoor Air Monitoring	A, B	43716501
875.2500	133-4	Inhalation Exposure	A, B	Data Gap
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	A, B	45346801
835.1230	163-1	Sediment and Soil Adsorption/Desorption	A, B	45346801

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room S-4400, One Potomac Yard (South Building), 1777 S. Crystal Drive, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

The risk assessments and other supporting documents for naphthalene are available in the Public Docket, under docket number EPA-HQ-OPP-2008-0343, and on the Agency's web page, http://www.regulations.gov. The docket contains risk assessments and related documents as of November, 2008.

Technical support documents for the Naphthalene RED include the following:

Health Effects Documents

1. *Phase 4 Amendment: Response to Comments in Reference to "Naphthalene: HED Chapter for the Reregistration Eligibility Decision Document (RED)*" dated August 22, 2008.
2. *Naphthalene: Phase 4 Amendment: Response to Comments In Reference to "Naphthalene: Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document,*" dated September 10, 2008.
3. R*eview of Naphthalene Incident Reports,* dated June 25, 2007.

Ecological Fate and Effects Documents

1. *Revised Drinking Water Exposure Assessment for the Human Health Risk Assessment for the Reregistration Decision Eligibility (RED) of Naphthalene Incorporating the Registrant's Error Correction Comments,* dated April 9, 2008.
2. *Revised Ecological Risk Assessment for Reregistration Eligibility Decision (RED) for Naphthalene,* dated April 21, 2008.

Appendix D. Citations Considered to be Part of the Database Supporting the Reregistration 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 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 (1999), 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.

MRID	Citation Reference
4898	Means, R.G. (1973) Preliminary evaluation of the effectiveness of Mosquito Beater^(R)I, a granular repellent, against mosquitoes and blackflies. Mosquito News 33(4):542-545. (Also~In~unpub- lished submission received Jul 16, 1975 under 4-123; submitted by Bonide Chemical Co., Inc., Yorkville, N.Y.; CDL:126291-A)
4900	Nowak, L.M. (1975) Interim Material Safety Data Sheet for Naphtha- lene. (Unpublished study received May 6, 1977 under unknown admin. no.; prepared by Ashland Oil, Inc., submitted by Kenova Chemical Co., St. Louis, Mo.; CDL:229765-A)
4901	Samuel J. Milazzo Manufacturing Company (1967) Ten Day Test for Milazzo Company Animal Chaser. (Unpublished study received Sep 12, 1967 under 8218-1; prepared in cooperation with United States Testing Co., Inc. and Hermel Exterminating; CDL:224446-A)
4902	Hunsberger, J.F. (1969) Testing Program. (Unpublished study re- ceived Oct 28, 1969 under 8218-1; prepared by Allentown Testing Laboratories, Inc., submitted by Samuel J. Milazzo Co., Pitts- ton, Pa.; CDL:224446-B)
4903	Niper, R. (1963) Milazzo Brand Animal Chaser Test No. 1. (Unpub- lished study including letter dated Dec 9, 1963 from R. Niper to Samuel J. Milazzo, received Dec 17, 1963 under 8218-1; prepared by Monroe County Society for the Prevention of Cruelty to Ani- mals, submitted by Samuel J. Milazzo Co., Pittston, Pa.; CDL: 224446-C)

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4914 Hamilton, D.W. (1964?) Results of Screening of Naphthalene, ENT No. 278 for Control of Third-Instar Japanese Beetle Grubs. (Un- published study received Sep 23, 1965 under 862-EX-2; prepared by U.S. Agricultural Research Service, Entomology Research Div., Japanese Beetle Investigations, submitted by Sun Oil Co. of Pa., Philadelphia, Pa.; CDL:123929-B)

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