Human Health and Ecological Risk Assessment
for the Use of Wildlife Damage Management Methods
by APHIS Wildlife Services

Chapter XXIV

USE OF REGISTERED CHEMICAL REPELLENTS IN WILDLIFE DAMAGE MANAGEMENT

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EXECUTIVE SUMMARY

Chemical repellents are a tool used to alter animal behavior under various agricultural and nonagricultural uses. The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Wildlife Services (WS) Program uses chemical repellents to reduce bird conflicts at airports, reduce bird damage to crops and property, and reduce mammal damage to gardens, crops, and property. The primary target bird species WS repels include flocking passerine bird species, for example, European starlings and blackbirds, waterfowl, and gulls. The primary target mammal species include white-tailed deer and rabbits.

Chemical substances that are marketed or distributed for use as repellents (hereafter called chemical repellents) are divided into those that require federal registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and those classified as minimum risk pesticides (MRPs) under FIFRA Section 25(b). This risk assessment will cover registered repellents. MRPs are covered in another Risk Assessment.

APHIS evaluated the potential human health and ecological risks from the proposed WS use of the registered active ingredients ammonium soaps of fatty acids, anthraquinone, capsaicin, egg solids, garlic oil, methyl anthranilate, naphthalene, oil of black pepper, piperine, polybutene, sulfur, thiram, and coyote and fox urines as registered active ingredients in chemical repellents used or potentially used in its animal damage management program. WS does not anticipate adverse human health effects from their use of chemical repellents based on the label requirements, WS use pattern, and environmental fate of the repellents. Adherence to the labels' personal protective equipment requirements minimizes potential exposure to workers. Similarly, WS does not expect its use of chemical repellents to impact non-target aquatic and terrestrial species based on the repellents' toxicity profiles, label requirements, and WS use patterns.

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GLOSSARY OF TERMS AND ABBREVIATIONS

µg	Microgram
a.i.	Active ingredient
bw	Body weight
CAS	Chemical Abstract Service
CDC	Center for Disease Control and Prevention
EC_{50}	Median effect concentration. A statistically derived concentration of a substance that can be expected to cause an effect in 50% of test organisms. It is usually expressed as a weight of a substance per weight or volume of water or air, e.g., mg/L.
FDA	Food and Drug Administration
FY	The federal Fiscal Year, which is October 1–September 30.
g	Gram
GRAS	Generally Recognized as Safe
IC_{50}	Median inhibitory concentration. A statistically derived concentration of a substance that can be expected to inhibit a biological process or response by 50% in an enzyme, cell, or microorganism. It is usually expressed as a weight of a substance per weight or volume of water or air, e.g., mg/L.
IDS	Incident Data System
kg	Kilogram
kg-bw	Kilogram of body weight
kg-diet	Kilogram of diet
lb	Pound
L	Liter
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 a weight of a substance per weight or volume of water, air or feed, e.g., mg/L, mg/kg-bw.
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.
LOAEC	Lowest observed adverse effect concentration. The lowest dose concentration of a substance that under defined conditions of exposure causes an observable/detectable adverse effect.
mg	Milligram
mm Hg	Millimeter of mercury
NIOSH	National Institute for Occupational Safety and Health
NOAEC	No observed adverse effect concentration. The highest dose concentration of a substance that under defined conditions of exposure causes no observable/detectable adverse effect.
NOAEL	No observed adverse effect level. The highest dose level of a substance that under defined conditions of exposure causes no observable/detectable adverse effect.
OPP	Office of Pesticide Programs, USEPA
PPE	Personal protective equipment
RfD	Reference dose. An estimate, with uncertainty spanning perhaps an order of magnitude, of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.
SENSOR	Sentinel Event Notification System for Occupational Risk-Pesticides
Tolerance	Maximum amount of pesticide residues allowed on or in food or feed.
USEPA	U.S. Environmental Protection Agency
WDM	Wildlife damage management
WT	Work tasks
w/w	Weight by weight

1 INTRODUCTION

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Wildlife Services (WS) employees conduct wildlife damage management (WDM) activities, which include the use of chemical repellents as a WDM tool. WS uses chemical repellents to reduce bird conflicts at airports, reduce bird damage to crops and property, and reduce mammal damage to gardens, crops, and property. The primary target bird species WS repels include flocking passerine bird species (e.g., European starlings[1] and blackbirds[2]), waterfowl, and gulls. The primary target mammal species include white-tailed deer and rabbits. Successful application of repellents to target specific animals requires 1) knowledge of the animal's learning and sensory abilities; 2) an understanding that repellents are regulated as pesticides; 3) are used to deter animal activity while not causing permanent harm or injury and may require continual training with populations that turn over frequently; and 4) understanding that repellents work best when the animal can find alternative resources (e.g., food, shelter), otherwise the animal may undergo survival hardship (Clark and Avery 2013).

This human health and ecological risk assessment provides a qualitative evaluation of risks and hazards to human health and the environment, including non-target fish and wildlife, because of exposure to chemical repellents from proposed WS uses, which are limited and targeted in scope to repelling wildlife from damage situations. The methods used to assess potential human health effects follow standard regulatory guidance and methodologies (National Research Council 1983) and generally conform to other Federal agencies such as the U.S. Environmental Protection Agency (USEPA 2022f). The methods used to assess potential ecological risk to non-target fish and wildlife generally follow USEPA (2022f) methodologies.

This risk assessment is divided into four sections: problem formulation (identifying hazard), toxicity assessment (dose-response assessment), and exposure assessment (identifying potentially exposed populations and determining potential exposure pathways for these populations). Lastly, the toxicity and exposure assessment information is combined to characterize risk (determining whether there is adverse human health or ecological risk). This risk assessment also includes a discussion of the uncertainties associated with the risk assessment and cumulative effects.

Registered Repellent Products

Repellents are a favored method in WDM because they are a nonlethal way to reduce damage from mammals, birds, and reptiles (Fagerstone 2002). Published investigations regarding the research and development of chemical substances as repellents date back to the 1830s. Identification of the mode of action (e.g., olfactory, taste, pain, conditioned avoidance, or fear), the target species or groups (e.g., blackbirds, waterfowl, or deer), efficacy, cost per area,

[1] Scientific names are given in the Risk Assessment Introduction Chapter I, unless first time used.
[2] Generic use of blackbirds for this risk assessment includes specific species of blackbirds, cowbirds, and grackles as found on product labels.

availability, and potential hazards are considerations in these studies mirroring the public concerns.

Chemical repellents can be grouped by mode of action: chemicals that animals reflexively avoid because they irritate the peripheral chemical senses (e.g., taste or smell) and chemicals that cause gastrointestinal illness and learned avoidance (Sayre and Clark 2001). Many repellents are naturally occurring substances and work by emitting an odor that evokes fear or an undesired taste. Repellents are often sprinkled on or hung within the area to be protected or sprayed on plants or other surfaces to prevent damage or loss. Liquid products can also be soaked into ropes or rags and hung up or dispersed around the area to be protected. Some products cannot be applied to growing or edible portions of agricultural crops because the product may damage the crop, make the plant unpalatable for human consumption, or the product is not approved for food or feed uses. Many factors can affect repellent efficacy. These factors can include the availability of alternative foods, the palatability of treated plants, and the number and density of animals inflicting problems (Nolte et al. 1994, Trent et al. 2001).

Chemical substances that are marketed or distributed for use as repellents (hereafter called chemical repellents) are divided into those that require federal registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and those classified as minimum risk pesticides (MRPs) under FIFRA Section 25(b). This risk assessment will cover registered repellents. MRPs are covered in another Risk Assessment.

Of the repellent products that require federal registration, WS has used products containing the registered active ingredients ammonium soaps of fatty acids, anthraquinone, egg solids, capsaicin, garlic oil, methyl anthranilate, naphthalene, oil of black pepper, and piperidine, 1-[(2E,4E)-5-(1,3-benzodioxol-5-yl)-1-oxo-2,4-pentadienyl]- (hereafter, called piperine), and sulfur. WS has distributed registered repellent products containing additional repellent active ingredients, and those are briefly summarized. WS may potentially use registered repellent products containing thiram, polybutene, or coyote and/or fox urines in the future, which are also included in this risk assessment.

Chemical repellents come in various commercial “ready-to-use” and concentrate products. Registered products must have USEPA-approved labels and instructions to guide their applications. USEPA classifies most vertebrate repellents as general-use or unclassified pesticides rather than restricted use pesticides (RUPs). General-use pesticides can be applied without a certified applicator license in most states and U.S. territories. However, some states and territories require that commercial and public pesticide applicators are also licensed by the state before applying general-use products. None of the registered active ingredients discussed in this risk assessment are restricted use pesticides.

Chemical repellents can be used for a wide variety of target pest animals. Repellents can be used in various sites, including agricultural fields and gardens, residences and other structures, and airports. Many repellents can also be applied at food use sites (e.g., agricultural crops grown for

consumption by an organism) when USEPA has approved pesticide tolerances[3] or tolerance exemptions for those food uses for all active and inert ingredient(s) contained in the products. Most registered vertebrate repellents target mammalian herbivores (e.g., deer, rabbits) and avian herbivores (e.g., Canada geese and other waterfowl), and omnivores (e.g., flocking birds such as gulls, European starlings, and blackbirds). Section 2(ee) of FIFRA is a provision that presents special circumstances where it is permissible to use a pesticide in a manner for which it is not specifically labeled (e.g., use on an alternative target pest species when the label does not prohibit use on target species not listed on the label). A few repellents are used annually to protect human health and safety.

1.1 WS Use Pattern

The registered chemical repellents WS has used, sold, or distributed are given in Tables 1, 2, and 3. Table 1 provides the estimated animals repelled and states where WS used the products. It should be noted that it is not always possible to estimate the number of birds dispersed for all uses of these products by WS personnel in the MIS[4]. It can be challenging to assess the number of birds repelled, especially when used in areas where historic damage has occurred (e.g., a runoff pond near a runway where migratory waterfowl may land), but wildlife is not currently present. WS personnel do not have to enter the number of animals repelled in the MIS for applied repellents. If the numbers of animals repelled were not entered in MIS, they were estimated as follows, 1,000 for small flocking birds, 100 for large flocking birds, and 10 for mammals, large non-flocking birds and reptiles for every one gallon or 3 pounds of product used. Table 2 provides the quantity of each repellent applied and the associated work tasks. Table 3 provides the quantity of each product distributed to producers or homeowners to resolve the problems.

WS repelled an annual average of 49,112 target species with chemical repellents between FY11[5] and FY15 from areas where they were causing damage in 12 states. Between FY16 and FY20, WS repelled an annual average of 5,140 animals in 9 states. The use of methyl anthranilate and anthraquinone dropped off between the two periods. Blackbirds (77%) and Canada geese (20%) were the primary targeted species from FY11 to FY15, while Canada geese (95%) were the primary targeted species from FY16 to FY20. Overall, 16 and 10 known species were repelled during each time frame, respectively. WS had minor uses of naphthalene and sulfur to repel snakes, ammonium soaps of fatty acids to repel deer, and capsaicin, oil of black pepper, and piperine to repel feral house cats and black bears (Table 1).

WS used an annual average of 99 gallons of anthraquinone products in 45 work tasks and 8.2 gallons of methyl anthranilate products in 13 work tasks, and 0.2 gallons of capsaicin and oil of black pepper product in 0.2 work tasks to resolve problems at airports, orchards, parks, and turf from FY11 to FY15 (Table 2). This work involved 6 different products for repelling animals. From

[3]Maximum amount of pesticide residues allowed on or in food or feed.

[4]MIS - Computer-based Management Information System used for tracking APHIS-WS-WDM activities nationwide. Throughout the text, data for a year (i.e. FY11 (*next footnote*)) will be given and is from the MIS. MIS reports will not be referenced in the text or Literature Cited Section because MIS reports are not kept on file. A database is kept that allows queries to be made to retrieve the information needed.

[5]FY11 equals the federal Fiscal Year 2011, which is October 1 2010–September 30 2011 (the year is denoted by FY12, FY13, …).

FY16 to FY20, WS personnel annually averaged the application of 48.3 gallons of anthraquinone products in 21 work tasks, 17.1 gallons of methyl anthranilate products in 7.4 work tasks, 2 gallons of products containing ammonium soaps of fatty acids in 1 work task, 0.3 gallons of a product containing capsaicin and oil of black pepper in 0.6 work tasks, 0.01 gallons of products containing capsaicin, oil of black pepper, and piperine compound in 0.2 work tasks, and 0.2 pounds of naphthalene and sulfur products in 0.2 work tasks to protect airports, gardens, and property (e.g., parks and grass on private land).

Table 1 The annual average number of animals dispersed with chemical repellents and states where applied by WS in WDM during FY11–FY15 and FY16–FY20.

ANNUAL AVERAGE CHEMICAL REPELLENTS USED, SPECIES, AND NUMBER REPELLED				
Species	**FY11–FY15**		**FY16–FY20**	
	Repelled	**States Used**	**Repelled**	**States Used**
Anthraquinone				
Canada Goose	9,898	IL PA	4,830	IL WI
Total (1 spp.)	**9,898**	**2 States**	**4,830**	**2 States**
Methyl Anthranilate				
European Starling*	13,183	NC OR PA VA	61	NC VA
Red-winged Blackbird	220	NH	2	VA
Common Grackle	1,435	NH PA	-	-
Boat-tailed Grackle	600	FL	-	-
Brown-headed Cowbird	220	NH	-	-
Mixed Blackbird spp.**	22,240	FL NH PA	15	VA
Mourning Dove	340	AL	-	-
Purple Martin	1	VA	-	-
Barn Swallow	30	WV	-	-
House Sparrow*	101	NC NH	-	-
Canada Goose	600	NE	128	MO OR VA WI
Laughing Gull	100	VA	64	VA
Ring-billed Gull	66	WI	5	VA
Herring Gull	66	WI	24	VA
Black-crowned Night-Heron	10	PA	-	-
Northern Flicker	2	OR	-	-
Total (15 spp.)	**39,214**	**10 States**	**299**	**5 States**
Naphthalene/Sulfur				
Western Diamondback Rattlesnake	-	-	0.2	TX
Total (1 sp.)	**-**	**-**	**0.2**	**1 State**
Ammonium Soaps of Fatty Acids				
Mule Deer	-	-	8	CA
Total (1 sp.)	**-**	**-**	**8**	**1 State**
Capsaicin/Oil of Black Pepper/Piperine				
Feral House Cat*	-	-	3	PA
Louisiana Black Bear	0.2	LA	-	-
Total (2 spp.)	**0.2**	**1 State**	**3**	**1 State**
GRAND TOTAL (19 spp.)	**49,112**	**12 States**	**5,140**	**9 States**

* Introduced species

** All species were already counted in the total species

WS State Offices and personnel also provide the public with some chemical repellent products, mainly in cooperation with state agencies that manage game animals such as white-tailed deer to lessen problems for farmers and property owners from their damage. From FY11 to FY20, WS distributed an annual average of 0.6 pounds of products containing egg solids; 4.1 gallons

of products containing egg solids, capsaicin, and garlic oil; 8 gallons of products containing denatonium saccharide (which is no longer a registered active ingredient in any product) and

Table 2. The annual average number of gallons of chemical repellents applied by WS in WDM during FY11–FY15 and FY16–FY20 for all products with the number of work tasks associated with the applications.

ANNUAL AVERAGE CHEMICAL REPELLENTS USED BY WS DURING FY11–FY15 AND FY16–FY20						
Active Ingredient(s) (% w/w, CAS Number)	**Product Name**	**USEPA Registration Number**	**FY11–FY15**		**FY16–FY20**	
			Applied (gal or lb)	**WTs**	**Applied (gal or lb)**	**WTs**
Anthraquinone (50%, 84-65-1)	Flight Control® Plus	69969-1[a]	99 gal	45	48.3 gal	21
Methyl Anthranilate (20%, 134-20-3)	Avian Control®	33162-1, then 88889-1[b]	2.8 gal	6	0.03 gal	0.2
	Avian Fog Force® TR	91897-4	0.1 gal	1	-	-
Methyl Anthranilate (14.5%, 134-20-3)	RejeX-it® AG 39 or Avian Migrate®	58035-9, then 91897-3[c]	1.3 gal	1	0.03 gal	0.2
Methyl Anthranilate (40%, 134-20-3)	RejeX-it® TP-40 or RejeX-it Fog Force®	58035-7, then 91897-1[c]	4.0 gal	5	1.6 gal	7
Ammonium Soaps of Fatty Acids (13.8%, 84776-33-0)	Hinder®	5481-508	-	-	2 gal	1
Capsaicin (0.032%, 404-86-4) Oil of Black Pepper (0.48%, 8006-82-4) Piperine(0.185%)	Havahart® Critter Ridder®	50932-10	-	-	0.01 gal	0.2
Capsaicin (unknown % w/w, 404-86-4) Oil of Black Pepper (unknown % w/w, 8006-82-4) Possibly other active ingredients	Not recorded	Not recorded	0.2 gal	0.2	0.3 gal	0.6
Naphthalene (7%, 91-20-3) Sulfur (28%, 7704-34-9)	Snake-A-Way® Snake Repelling Granules	58630-1	-	-	0.2 lb	0.2
TOTAL	**9 Products**	**-**	**107.4 gal**	**58.2**	**52.27 gal 0.2 lb**	**30.4**

[a] This product and all other registered 50% w/w anthraquinone products were canceled as of September 2021. The remaining anthraquinone products are 18.6% w/w anthraquinone or lower.
[b] This registration was transferred to Avian Enterprises, LLC in March 2012.
[c] This registration was transferred to Avian Enterprises Limited, LLC, in December 2015.

thymol; 3.6 gallons of products containing ammonium soaps of fatty acids; 2.6 gallons of anthraquinone products, and 0.9 gallons of methyl anthranilate products (Table 3). Of the 21 average annual work tasks associated with distributing repellents from FY11 to FY20, WS responded to public requests involving white-tailed deer (94% of requests), Canada geese (3%), eastern cottontail rabbits (1%), house sparrows (1%), woodchucks (0.5%), and wild turkeys (0.5%).

Table 3. The annual average number of pounds/gallons of chemical repellents distributed by WS in WDM for FY11–FY15 and FY16–FY20 under all product labels.

ANNUAL AVERAGE CHEMICAL REPELLENTS DISTRIBUTED BY WS DURING FY11–FY15 AND FY16–FY20				
Active Ingredient(s) (% w/w, CAS Number)	**Product Name**	**USEPA Reg. No.**	**FY11–FY15 Distributed**	**FY16–FY20 Distributed**
Eggs Solids (4.63%, 51609-52-0)	Deer Away® Deer and Rabbit Repellent Ready-to-Use	50932-8	0.6 lb	-
Eggs Solids (6.25%, 51609-52-0) Capsaicin (0.0045%, 404-86-4) Garlic Oil (0.005%, 8000-78-0)	Deer-Off® Deer, Rabbit, and Squirrel Repellent	67356-1	3.7 gal	0.4 gal
Denatonium Saccharide[a] (0.65%, 90823-38-4) Thymol (0.35%, 89-83-8)	Ro-pel® Tree Squirrel, Vole, Dog, and Cat Repellent	81117-1[a]	8.0 gal	-
Ammonium Soaps of Fatty Acids (13.8%, 84776-33-0)	Hinder®-H Deer & Rabbit Repellent	8119-7	0.8 gal	0.4 gal
Ammonium Soaps of Fatty Acids (0.66%, 84776-33-0)	Hinder® Deer & Rabbit Repellent	8119-8	2.2 gal	0.2 gal
Methyl Anthranilate (20%, 134-20-3)	Avian Control®	33162-1, then 88889-1[b]	0.6 gal	-
Methyl Anthranilate (20.72%, 134-20-3)	Liquid Fence® Goose Repellent	72041-2	0.2 gal	0.1 gal
Anthraquinone (50%, 84-65-1)	Flight Control® Plus	69969-1[c]	2.4 gal	0.2 gal
TOTAL	**8 Products**		**17.9 gal. 0.6 lb**	**1.3 gal**

[a] Denatonium saccharide is no longer registered for use in any pesticide products. This product and all remaining products containing denatonium saccharide were canceled in 2015.
[b] This registration was transferred to Avian Enterprises, LLC in March 2012.
[c] This product and all other registered 50% w/w anthraquinone products were canceled as of September 2021. The remaining anthraquinone products are 18.6% w/w anthraquinone or lower.

1.2 Individual Chemical Risk Assessment Organization

WS uses the following registered chemical active ingredients covered in this risk assessment: ammonium soaps of fatty acids, anthraquinone, capsaicin, egg solids, garlic oil, methyl anthranilate, naphthalene, oil of black pepper, piperine, and sulfur. WS may also use thiram, polybutene, and coyote and/or fox urines in the future. A problem formulation, dose-response assessment, exposure assessment, and risk characterization are provided below for each registered active ingredient used or potentially used by WS in the future. The problem formulation section covers each registered active ingredient's chemical description, product use, physical and chemical properties, environmental fate, and hazard identification. Environmental fate describes how chemicals move and degrade in the environment. The environmental fate processes include 1) persistence, degradation, and mobility in soil; 2) movement to air; 3) migration potential to groundwater and surface water; 4) degradation in water; and 5) plant uptake.

The dose-response assessment section discusses the dose levels (toxicity criteria) for potential human health effects, including acute and chronic toxicity. It also discusses available ecological effects data for terrestrial and aquatic species. Available acute and chronic toxicity data are summarized for all major taxa. They will be integrated with the exposure analysis section to characterize the risk of chemical repellents to non-target species. Information in this section was

gathered from online databases and searches for relevant peer-reviewed and other published literature.

Unless otherwise specified, the toxicity of the technical a.i. for non-target mammals and birds was assumed to be similar to the toxicity of the end-use formulations, which is a conservative approach. The toxicity of degradants and metabolites of the chemical repellents to non-target species are unknown but are assumed to be similar to the parent chemicals for this risk assessment.

The exposure assessment section evaluates the potential for exposure of humans to the chemical repellents WS applies. The exposure assessment begins with the WS use pattern for chemical repellents (e.g. problem formulation). An exposure pathway for chemical repellents includes (1) a release from a chemical repellent source, (2) an exposure point where human contact can occur, and (3) an exposure route such as ingestion, inhalation, or dermal contact by which contact can occur. Exposures for the identified human populations are evaluated qualitatively for each identified exposure pathway. Risks associated with adverse human health are characterized qualitatively in this section. The ecological exposure potential and risk characterization for each repellent are also discussed. In cases where data is lacking, USEPA assumes that avian toxicity data is representative of reptiles and terrestrial-phase amphibians, and fish toxicity data is representative of aquatic-phase amphibians.

2 AMMONIUM SOAPS OF FATTY ACIDS

2.1 Problem Formulation

2.1.1 Chemical Description and Product Use

Ammonium soaps of fatty acids (CAS number 84776-33-0; synonym: Fatty acids, C8-18 and C18-unsaturated, ammonium salts and sometimes referred to as ammonium soap salts, ammonium soap salts of higher fatty acids or ammonium salts of fatty acids) are a single pesticide active ingredient but include multiple C8-18 and C18-unsaturated fatty acids ammonium salts (Table 4) (USEPA 2010a;2015a). Most products containing ammonium soaps of fatty acids are comprised primarily of shorter-chain saturated fatty acids (ammonium nonanoate and ammonium octanoate) (USEPA 2015a). Ammonium soaps of fatty acids is an odor-aversive active ingredient in repellent products that can be applied directly to plants, such as nursery stock, ornamentals, flowers, vines, shrubs, and trees, to repel deer, rabbits, and other mammals (USEPA 2010a;2015a). Ammonium soaps of fatty acids are mildly noticeable to humans but offensive to the olfactory nerve of deer and are also approved for use on food and feed crops (Andelt et al. 1991, USEPA 2015a, Wagner and Nolte 2001). WS uses and distributes products to cooperators containing ammonium soaps of fatty acids for deer and rabbit damage protection (Tables 2 and 3).

Table 4 The chemical name and CAS number for the individual C8- to C18-saturated and C18-unsaturated fatty acids ammonium salts within the pesticide active ingredient ammonium soaps of fatty acids (CAS Number 84776-33-0).

Chain length	CAS Number	Chemical name
Saturated		
C8	5972-76-9	Ammonium octanoate or ammonium caprylate
C9	63718-65-0	Ammonium nonanoate

C10	16530-70-4	Ammonium decanoate
C11	32582-95-9	Undecanoic acid, ammonium salt
C12	2437-23-2	Ammonium laurate or Dodecanoic acid, ammonium salt
C13	191799-95-8	Tridecanoic acid, ammonium salt
C14	16530-71-5	Ammonium myristate
C15	93917-76-1	Ammonium pentadecanoate
C16	5297-93-8	Ammonium palmitate
C17	94266-36-1	Ammonium heptadecanoate
C18	1002-89-7	Ammonium stearate
Unsaturated		
C18	544-60-5	Ammonium oleate

Ammonium soaps of fatty acids is the sole active ingredient in Hinder® (USEPA Registration Number 5481-508, label version May 6, 2015, AMVAC®) and Hinder®-H Deer & Rabbit Repellent (USEPA Registration Number 8119-7, label version July 11, 2008, Matson, LLC), which are 13.8% w/w concentrate products that require dilution before application. It is also the active ingredient in Hinder® Deer & Rabbit Repellent (0.66% w/w; USEPA Registration Number 8119-8, label version February 4, 2010, Matson, LLC), which is a ready-to-use product. These products are labeled to limit browsing by white-tailed deer and black-tailed or mule deer on apple and pear trees, soybeans, peanuts, carrots, nursery stock, ornamental trees and shrubs, and flowers. These products are also labeled to discourage browsing by cottontail rabbits (and other *Sylvilagus* spp.) and black-tailed jackrabbits on home gardens and the trunks of nursery stock and ornamental trees (USEPA 2015b). They are labeled for terrestrial food and feed crops, such as grapes, cereal grains, vegetables, orchards, forage, fodder, and hay (USEPA 2015a).

Products containing ammonium soaps of fatty acids can be applied by ground equipment or by hand with a brush. The application rate for repelling deer on nursery stock and ornamental trees and shrubs for the concentrate products is 2–4 gallons of concentrate per 100 gallons of water for large applications and 3.2–6.4 fluid ounces per gallon of water for smaller applications (USEPA 2015b). For repelling rabbits on nursery stock and ornamental trees, the concentrate products are mixed with equal parts water and applied by brush to trunks of plants, just above the height that rabbits might reach. Products containing ammonium soaps of fatty acids should be applied every 10–14 days for as long as plant protection is needed. Between FY2016 and FY2020, WS used Hinder® on an airbase in California to repel an annual average of 8 mule deer browsing ornamental plants in the residential area and presenting a human health hazard (Table 1).

2.1.2 Physical and Chemical Properties

Nonanoic acid, a shorter fatty chain parent and component compound of ammonium nonanoate is soluble in water and can be a major constituent of some products containing ammonium soaps of fatty acids (NIH 2022c, USEPA 2010b;2015a). Given that the longer chain fatty acids of ammonium soaps of fatty acids are less soluble in water, data on nonanoic acid was often used by USEPA as a surrogate for ammonium soaps of fatty acids in their risk assessments (USEPA 2010a;2015a). Nonanoic acid is an oily liquid with an unpleasant, rancid odor. Nonanoic acid has a melting point of 12.3ºC and a boiling point of 254.5ºC at 760 mm Hg (O'Neil 2001). Nonanoic acid has a reported vapor pressure of 1.65×10^{-3} mm Hg at 25ºC and a calculated air-water partition coefficient (Henry's Law Constant) of 1.625×10^{-6} atm/m^3/mol at 25ºC. Nonanoic acid

has a density of 0.9052 grams (g)/milliliter (mL). The water solubility for nonanoic acid is 284 milligrams/Liter (mg/L) at 30ºC (NIH 2023a). The estimated K_{oc} for nonanoic acid is from 53 mL/g to 111 mL/g. USEPA assumed a value of 100 mL/g is representative of ammonium soaps of fatty acids of lengths up to C11-saturated.

2.1.3 Environmental Fate

Ammonium soaps of fatty acids are slightly soluble in water (USEPA 2010b) with a vapor pressure near that of water. They do not readily vaporize or form aerosol particulates (USEPA 2010b). Ammonium soaps of fatty acids are expected to degrade rapidly in aerobic soil, primarily via microbial action, with a half-life of less than one day (USEPA 2015a). Ammonium soaps of fatty acids have the potential to bioaccumulate but are not likely to persist (USEPA 2015a). Ammonium soaps of fatty acids readily bind to soil particles (USEPA 2010b).

2.1.4 Hazard Identification

Ammonium soaps of fatty acids are irritating and corrosive to the eye (USEPA 2012a). When applied to human skin for longer periods of time (24 hours), 2.5 milligrams (mg) of ammonium soaps of fatty acids can produce mild to moderate irritation (USEPA 2010b). Ammonium soaps of fatty acids may also cause allergic skin reactions in some individuals, but the USEPA believes allergic reactions are uncommon and transient (USEPA 2010b).

USEPA reviewed the OPP IDS from 2007-2012 (USEPA 2013a), and no incidents involving ammonium soaps of fatty acids were reported.

2.2 Dose-Response Assessment

2.2.1 Human Health Dose-Response

Acute Toxicity

USEPA waived all generic human health toxicity data requirements for soap salts due to the lack of effects at high doses (USEPA 2012a). Ammonium soaps of fatty acids are of low acute oral and dermal toxicity and have been placed in Toxicity Category IV and III, respectively, for these routes of exposure (USEPA 2010b). The acute oral median lethality values (LD_{50}) in the rat is >5g/kg-bw, and the acute dermal LD_{50} is >3 g/kg-bw in the guinea pig (USEPA 2010b). Ammonium soaps of fatty acids are not classified as skin sensitizers but may cause allergic skin reactions in some individuals. Ammonium soaps of fatty acids are irritating and corrosive to the eyes (USEPA 2012a). Information on its acute inhalation toxicity is lacking; however, USEPA assumes it will be strongly irritating through the inhalation route because it is an eye and skin irritant (USEPA 2010b).

Subchronic and Chronic Toxicity

Oral dietary exposure of 8 male rats to nonanoic acid at 4.17% in the diet (approximately 2,100 g/kg-bw/day) for 4 weeks had no effect on survival. A slight 4% decrease in mean growth rate was observed but was not statistically significant (USEPA 2004d).

Developmental and Reproductive Effects

No adverse effects occurred in a developmental and maternal toxicity study in rats dosed with nonanoic acid (USEPA 2012a). In the study, the no observable adverse effect level (NOAEL) was 1,500 mg/kg-bw/day, the highest test concentration tested, and the lowest observed adverse effect level (LOAEL) was >1,500 mg/kg-bw/day.

Neurotoxicity Effects

A literature review did not identify any reported studies on neurotoxicity effects due to ammonium soaps of fatty acids exposure.

Carcinogenicity and Mutagenicity

A study on chronic toxicity/carcinogenicity in mice was conducted for 80 weeks. A dose of 50 mg of nonanoic acid (the parent compound of ammonium soaps of fatty acids) was dermally applied to each shaved mouse twice a day for 80 weeks. Histopathology showed no non-neoplastic or neoplastic lesions on the skins and internal organs of mice (USEPA 2003b).

Immunotoxicity Effects

A literature review did not identify any reported studies on immunotoxicity effects due to exposure of ammonium soaps of fatty acids.

Endocrine Effects

There is no known evidence that ammonium soaps of fatty acids act as an endocrine disrupter. No adverse effects on the endocrine system are known or expected (USEPA 2008d).

2.2.2 Ecological Effects Dose-Response

Aquatic Effects Analysis

Ammonium soaps of fatty acids are slightly toxic to freshwater fish and freshwater and estuarine/marine invertebrates (Table 5) (USEPA 2015a). However, they are practically non-toxic to estuarine/marine fish (USEPA 2015a). Freshwater fish are used as a surrogate for aquatic-phase amphibians; therefore, ammonium soaps of fatty acids are slightly toxic to aquatic-phase amphibians.

USEPA (2015a) evaluated risks to terrestrial, semi-aquatic, and aquatic plants adjacent to a treated field from surface water runoff and spray drift after broadcast application of ammonium soaps of fatty acids at 20 pounds a.i./acre and did not find a potential for adverse effects (USEPA 2015a).

Table 5 Acute and chronic toxicity to aquatic vertebrates and invertebrates for ammonium soaps of fatty acids.

Repellent	Test species	Test	Result (mg/L)	Reference
Ammonium Soaps of Fatty Acids[1]				

Freshwater Fish	Fathead Minnow (*Pimephales promelas*)	LC_{50}	104	(USEPA 1992b)
	Rainbow Trout (*Oncorhynchus mykiss*)	LC_{50}	18.06	(USEPA 1992b)
	Rainbow Trout	96-hr LC_{50}	12	(USEPA 2015a)
	Rainbow Trout	NOAEC (estimated)	10.3	(USEPA 2015a)
	Bluegill Sunfish (*Lepomis macrochirus*)	LC_{50}	35.35	(USEPA 1992b)
Freshwater Invertebrates	Water Flea (*Daphnia magna*)	48-hr EC_{50} (immobility)	27	(USEPA 2015a)
	Water Flea	NOAEC (time to 1st brood release)	23	(USEPA 2015a)
Estuarine/Marine Fish	Sheepshead Minnow (*Cyprinodon variegatus*)	96-hr LC_{50}	>105	(USEPA 2015a)
	Sheepshead Minnow	NOAEC (estimated)	>90	(USEPA 2015a)
Estuarine/Marine Invertebrates	Mysid Shrimp (*Americamysis bahia*)	96-hr LC_{50}	67	(USEPA 2015a)
	Mysid Shrimp	NOAEC (estimated)	57	(USEPA 2015a)
Aquatic Plants	Duckweed (*Lemna gibba*)	7-day EC_{50} (frond count)	200	(USEPA 2015a)
	Duckweed	NOAEC	15	(USEPA 2015a)
	Green Algae (*Pseudokirchneriella subcapitata*)	96-hr EC_{50} (cell density)	6.6	(USEPA 2015a)
	Green Algae	NOAEC	2.9	(USEPA 2015a)

[1] Data are for soluble, short-chain (93% C9-saturated) fatty acids.

Terrestrial Effects Analysis

Ammonium soaps of fatty acids are practically non-toxic to mammals and birds from acute exposures (USEPA 2015a) (Table 6). Birds are surrogates for reptiles and terrestrial-phase amphibians; therefore, ammonium soap salts are likely practically non-toxic to reptiles and terrestrial-phase amphibians.

Ammonium soaps of fatty acids are practically non-toxic to honeybees, based on acute contact tests (48-hr LD_{50} >100 μg/bee) (USEPA 2015a).

Chronic toxicity data is unavailable because soap salts undergo rapid degradation in less than one day (USEPA 2015a). Mammals (including humans), birds, and invertebrates ingest fatty acids as part of their normal daily diet since they are found in lipids in all living tissues, including seeds (USEPA 2015a).

Table 6. Acute oral median lethality and subacute dietary toxicity studies for mammals and birds for ammonium soaps of fatty acids.

Test species	Test	Result	Reference
Brown Rat (lab)	LD_{50}	>74,000 mg/kg-bw	(PMRA 2017)
Bobwhite Quail	LD_{50}	2,150 mg/kg-bw	(USEPA 1992b)

Japanese Quail	8-day dietary LC_{50}	>5,000 mg/kg-diet (practically non-toxic) or 1,100 mg a.i./kg-diet	(USEPA 2015a)
Mallard Duck	8-day dietary LC_{50}	>5,000 mg/kg-diet (practically non-toxic)	(USEPA 1992b)
Bobwhite Quail	8-day dietary LC_{50}	>5,000 mg/kg-diet (practically non-toxic)	(USEPA 1992b)

Ammonium soaps of fatty acids are phytotoxic (USEPA 2015a), and some registered products are intended for use as terrestrial herbicides. Ammonium soaps of fatty acids are more toxic to plants when the foliage is exposed to spray drift than by exposure through the roots due to surface water runoff (USEPA 2015a). Dicots are more sensitive than monocots (USEPA 2015a). The general herbicidal mode of action for ammonium soaps of fatty acids involves the disruption of photosynthesis through the destruction of cell membranes resulting in plant death (PMRA 2017).

2.3 Exposure Assessment and Risk Characterization

2.3.1 Human Health Exposure and Risk Characterization

Exposure to ammonium soaps of fatty acids through dietary exposure is possible; however, the unpleasant taste and the ammonia odor would limit oral exposure. Contamination of drinking water is unlikely due to ammonium soaps of fatty acids' environmental fate properties and label restrictions that make it unlikely for the repellent to reach surface water via runoff or leach into groundwater (USEPA 2010b). Ammonium soaps of fatty acids are unlikely to form aerosols due to their vapor pressure, making inhalation an unlikely route of exposure (USEPA 2010b). The limited uses of ammonium soaps of fatty acids minimize potential exposure. WS does not anticipate exposure to the general public. The Hinder® label requires occupational workers to wear long-sleeved shirts and pants, chemical-resistant gloves, chemical-resistant footwear, socks, and protective eyewear. As such, WS expects minimal dermal, inhalation and eye exposure of workers to ammonium soaps of fatty acids.

USEPA (2012a) concluded that no risks to human health are expected from the use of ammonium soaps of fatty acids based on their low toxicity, environmental fate properties, and low exposure potential. They also concluded that residues from pesticide uses are not likely to exceed the levels of naturally occurring or intentionally added fatty acids in commonly eaten foods (USEPA 2012a). WS historical use patterns for ammonium soaps of fatty acids are limited (repelling mule deer); however, this does not indicate future use patterns. Should WS increase its use of ammonium soaps of fatty acids, this assessment's exposure and risk conclusions would remain the same.

Ammonium soaps of fatty acids are exempt from the requirement of a tolerance for all labeled food and feed uses (40 CFR § 180.1284) (USEPA 2012a).

2.3.2 Ecological Exposure and Risk Characterization

The Hinder® label does not allow applications of the product directly to water, reducing exposure to aquatic resources. Aquatic species living in waterways adjacent to or downstream from treatment areas may be exposed through surface runoff and spray drift from broadcast applications. However, ammonium soaps of fatty acids undergo rapid microbial degradation and readily bind to soil which indicates runoff or leaching of significant concentrations of ammonium soaps of fatty acids into water bodies is not expected (USEPA 2015a).

Applications of products containing ammonium soaps of fatty acids may expose nontarget birds, mammals, reptiles, and the terrestrial stages of amphibians in the treatment area or adjacent to the treatment area. USEPA (2015a) reviewed the Ecological Incident Information System (1989–2012) and did not find reported incidents involving ammonium soaps of fatty acids. In 2012, the USEPA (2015a) reviewed the Avian Incident Monitoring System maintained by the American Bird Conservancy and did not find incidents involving these products. Ammonium soaps of fatty acids' environmental fate properties, label requirements, the proposed WS use pattern, and the favorable toxicity data indicate negligible risk to non-target terrestrial and aquatic species. Ammonium soaps of fatty acids can be phytotoxic (some formulations are labeled herbicides). The Hinder® label indicates that applications when plants are in bloom, may result in phytotoxicity. USEPA (2015a) found it unlikely that the use of products containing ammonium soaps of fatty acids would cause direct effects on threatened and endangered Federally listed species.

3 ANTHRAQUINONE

3.1 Problem Formulation

3.1.1 Chemical Description and Product Use

Anthraquinone (CAS number 84-65-1; synonyms: 9,10-Anthraquinone and anthracene-9,10-dione) is an aromatic organic compound that occurs naturally in certain insects, fungi, and plants such as Senna pods. It is a coloring pigment in organisms and is used commercially to manufacture dyes. It has been used medicinally as a natural laxative. For example, the Egyptian senna (*Senna alexandrina*) brewed as tea has been used for its laxative properties. Anthraquinone has been used as a bird repellent since the 1940s when German scientists first patented it. Many research studies on the repellent efficacy of anthraquinone with various species have been published and summarized in a review by Deliberto and Werner (2016). Anthraquinone has a long history of use as a bird repellent for geese and may be effective due to post-ingestional distress caused by irritation of the gut. It has been shown to be effective for Canada geese on turf during 7-day tests (Dolbeer et al. 1998).

Anthraquinone is the active ingredient in Flight Control® Plus (50% w/w; USEPA Registration Number 69969-1) and Flight Control® Max (18.6% w/w; USEPA Registration Number 69969-7; alternate brand names are AV-5055 and AV-1011® Liquid Rice Seed Treatment). The registration for Flight Control® Plus was canceled on September 7, 2021. Flight Control® Max contains 18.6% w/w anthraquinone and 81.4% w/w other ingredients. Other ingredients include limestone (15–40% w/w) and water (30–60% w/w) (Arkion 2021, USEPA 2022c). WS uses anthraquinone under the Flight Control® Max label. There are no approved food uses, and no tolerances or tolerance exemptions have been established for anthraquinone (USEPA 2022i).

Although WS only used Flight Control® Plus between FY11 and FY20, WS may use the Flight Control® Max product in the future. Flight Control® Max is registered to repel Canada geese from turf. Recent label changes to Flight Control® Max restricted the allowed-use sites to areas adjacent to or on airport property, commercial sites, industrial sites, cemeteries, landfills, and managed waste dumpsites (USEPA 2022c). The maximum single application rate is 1.03 pounds a.i./acre with a maximum of 7 applications per year and a 14-day minimum retreatment interval. Under previous labels, WS used Flight Control Plus to protect property composed of parks and

privately managed grass areas. Due to label restrictions, future WS use of anthraquinone will mainly be at airports to reduce bird air strike hazards.

An anthraquinone seed-treatment product, Avipel® Liquid Corn Seed Treatment (USEPA Registration Number 69969-6), is labeled as a bird repellent for seeds, which is a non-food use. Avipel® Liquid Corn Seed Treatment contains 13.6% w/w anthraquinone and 86.4% w/w other ingredients and is labeled for the treatment of field and sweet corn seed to protect against consumption by pheasants, blackbirds, crows, grackles, cowbirds, starlings, and cranes (USEPA 2021a). WS has not used this product; however, they may recommend it to cooperators.

From FY11 to FY15, WS applied an annual average of 99 gallons of Flight Control® Plus in 45 work tasks to repel Canada geese (Tables 1 and 2). From FY16 to FY20, WS applied an annual average of 48.3 gallons of Flight Control® Plus in 21 work tasks to repel Canada geese (Tables 1 and 2).

3.1.2 Physical and Chemical Properties

Anthraquinone ($C_{14}H_8O_2$) is a light-yellow crystal with an aromatic odor. Anthraquinone has a melting point of 286ºC and a boiling point of 377ºC at 760 mm Hg (European Chemicals Agency 2019, O'Neil 2001). Anthraquinone has a reported vapor pressure of 1.16×10^{-7} mm Hg at 25ºC and calculated air–water partition coefficient of 2.35×10^{-8} atm/m^3/mol at 25ºC suggesting it does not volatilize into the air from soil or water. Anthraquinone is moderately soluble in water (1.75 mg/L). The log octanol-water partition coefficient (K_{ow}) is 3.39 at 25ºC, suggesting it may bioconcentrate in aquatic organisms (USEPA 2022b). Fish bioaccumulation data is lacking. However, USEPA estimated the log octanol-air partition coefficient (K_{OA}) as -6.017, which suggests anthraquinone may not bioaccumulate in terrestrial organisms (USEPA 2022b).

3.1.3 Environmental Fate

Anthraquinone breaks down quickly in water in the presence of light with a reported half-life of 0.0456 days at a neutral pH; but is stable to hydrolysis as it has no hydrolyzable groups. Anthraquinone is moderately susceptible to microbial degradation in the presence of soil and water. It is moderately persistent in soils with aerobic soil metabolism half-life values ranging from 59.4 to 86.7 days. The aerobic aquatic metabolism half-life ranges from 28.4 to 34.9 days in water and sediment. Anthraquinone is considered slightly mobile in soil based on estimated organic-carbon partition coefficients (K_{oc}) (USEPA 2022b).

3.1.4 Hazard Identification

The mode of action for anthraquinone is not well understood, but its post-ingestive effects are likely responsible for subsequent feeding repellency. The emetic response is produced through irritation of the gut, but the actual mechanism is unclear. The post-ingestive distress that occurs after eating anthraquinone-treated food results in a conditioned avoidance of that food type (DeLiberto and Werner 2016).

Humans can be exposed to anthraquinone in food, drinking water, and applicators through occupational exposure (USEPA 2022i). When ingested, anthraquinone is slowly distributed to tissues and slowly metabolized and excreted via a saturable kinetic process (USEPA 2022i).

Females may have slower clearance and metabolism than males and, therefore, can have higher tissue concentrations (USEPA 2022i).

No serious side effects or adverse effects have been reported with the use of anthraquinone when used for medicinal use. Patients may experience irritability, difficulty sleeping, confusion, nightmares, mood swings, depression, and suffer from delusions and suicidal thoughts in cases where an excess dose is taken. The liver, kidneys, and thyroid are the primary organs affected by repeated exposure to anthraquinone (USEPA 2022i).

No adverse incidents from anthraquinone use have been reported in the OPP IDS and the CDC and Prevention/National Institute for Occupational Safety and Health (CDC/NIOSH) Sentinel Event Notification System for Occupational Risk-Pesticides (SENSOR) database. The reporting period for the IDS database was from January 1, 2016, through July 14, 2021. The reporting period for the SENSOR database was 1998-2017 (USEPA 2022i). USEPA has not established any tolerances for anthraquinone use. USEPA did estimate a chronic population-adjusted dose (cPAD) of 0.03 mg/kg-bw/day that was derived from the LOAEL (25 mg/kg-bw/day) (USEPA 2022i). The cPAD is equivalent to a chronic reference dose. An acute reference dose was not estimated.

3.2 Dose-Response Assessment

3.2.1 Human Health Dose-Response

Acute Toxicity

Acute median lethality (LD_{50}) values suggest that anthraquinone has low mammalian acute toxicity via oral, dermal, and inhalation exposure routes (Table 7). The eye and dermal irritation studies show that anthraquinone is a slight irritant to the skin and eyes when using rabbits as a test species (Toxicity Category III). The dermal sensitization study shows that anthraquinone is not a skin sensitizer in guinea pigs. The Safety Data Sheet for Flight Control® Max (18.6% w/w anthraquinone) reports that the formulation is a moderate eye irritant and a slight skin irritant (Arkion 2021). Acute toxicity is similar between technical anthraquinone (99% w/w) and the 18.6% w/w end-use formulation that WS may use in the future.

Table 7 Acute oral median lethality studies for mammals for technical anthraquinone and an end-use product.

Test Species	Test	Result (Anthraquinone 97–99% w/w)	Result (Flight Control® Max, 18.6% w/w)	USEPA Toxicity Category
Laboratory Brown Rat	Acute Oral LD_{50}	>5,143 mg/kg/bw	>5,000 mg/kg-bw	IV
Domestic Rabbit	Acute Dermal LD_{50}	>5,000 mg/kg-bw	>5,000 mg/kg-bw	IV
Laboratory Brown Rat	Acute Inhalation LC_{50}	>2.14 mg/L	>2.04 mg/L	IV
Domestic Rabbit	Primary Dermal Irritation	Slight	Slight	IV
Domestic Rabbit	Primary Eye Irritation	Mild	Moderate	IV and III
Mouse	Skin Sensitizer	No	-	NA
Guinea Pig (*Cavia porcellus*)	Skin Sensitizer	-	Not a sensitizer	NA

NA = Not applicable

References: (Arkion 2021, USEPA 2022i)

Subchronic and Chronic Toxicity

Subchronic short-term (30 days) and intermediate-term (13 weeks) dietary exposure and chronic (105 weeks) dietary studies are available (USEPA 2022i). In the subchronic oral toxicity study, male/female (M/F) rats were exposed to 0/0, 40/44, 125/150, or 495/661 mg/kg-bw/day for 30 days and then the 40/44 mg/kg-bw/day dose level was lowered to 11/16 mg/kg-bw/day (M/F) for weeks 5–13 weeks. Various physiological endpoints were assessed, including neurological, liver, kidney, hematological, and thyroid impacts at the different dose levels in male and female rats. Some impacts were noted in liver, hematological, thyroid, adrenal, and kidney endpoints but were not observed in a dose-dependent manner or were not considered adverse. The LOAEL for these studies was 44 mg/kg-bw/day, the lowest dose tested, based on a decrease in body weight in female rats.

A combined chronic dietary and carcinogenicity study is available for anthraquinone, where rats were exposed for 105 weeks to either 0/0, 20/25, 45/50, 90/100, or 180/200 mg/kg-bw/day (M/F) by dietary exposure. There were no effects of any dose on mortality, clinical signs, or food consumption. Plasma concentrations were approximately 2 to 3-fold in female rats compared to males, which is reflected in the difference in effects that were noted in female rats compared to male rats during the study. A NOAEL was not established for either sex since the LOAEL was the lowest test concentration tested (20/25 mg/kg-bw/day, M/F). The LOAEL was based on a decrease in body weights and kidney and liver histopathological effects in male and female rats (USEPA 2022i).

Developmental and Reproductive Effects

Two studies are available that evaluate developmental effects. In a rat study, pregnant female rats were administered technical anthraquinone by oral gavage at doses of 0, 10, 50, or 150 mg/kg-bw/day on gestation days 6 through 19 (USEPA 2022i). The maternal NOAEL was 50 mg/kg-bw/day, and the LOAEL was 150 mg/kg-bw/day based on decreased body weight and food consumption. The developmental NOAEL and the LOAEL were the same as the maternal values and were based on decreased fetal, litter, and placental weight. In the rabbit study, pregnant rabbits were dosed at 0, 25, 50, or 100 mg/kg-bw/day from gestation days 6 through 28. The maternal NOAEL was 25 mg/kg-bw/day, and the LOAEL was 50 mg/kg-bw/day based on increased mortality, late abortions, and clinical signs such as decreased feces output and red urine. The developmental NOAEL and LOAEL were the same based on late abortions.

USEPA waived the reproductive study that is associated with pesticide registration (USEPA 2022i). However, in the subchronic oral toxicity study in rats, adverse changes to the reproductive tract of females were noted at the highest test concentration tested, 495 mg/kg-bw/day. This included effects on the ovaries, vagina, and uterus in dosed rats. In another subchronic study using rats, there was a dose-dependent increase in estrous cycle length at doses equal to or greater than 1,130 mg/kg-bw/day.

Neurotoxicity Effects

A literature review did not identify any reported studies on neurotoxicity effects due to anthraquinone exposure. USEPA (2022i) waived acute and subchronic neurotoxicity studies for anthraquinone. Neurotoxicity is not expected to be a sensitive endpoint compared to other endpoints. Available subchronic toxicity data in the rat study shows a lack of effects on neurohistopathology and neurological parameters.

Carcinogenicity and Mutagenicity

A review of a combined chronic and carcinogenicity study in rats at 0/0, 20/25, 45/50, 95/100, and 180/200 mg/kg-bw/day (M/F) by dietary exposure conducted by the USEPA OPP Health Effects Division (HED), Cancer Assessment Review Committee (CARC) determined that kidney tumors observed in female rats at 50, 100, and 200 mg/kg-bw/day were determined to be treatment-related (USEPA 2022i). However, urinary and bladder kidney tumors observed at the highest test concentration in male rats were not treatment-related. The CARC determined that thyroid tumors observed at the various doses in female rats were also not treatment-related.

In a second carcinogenicity study, male/female mice were exposed to dietary concentrations of (0/0, 90/80, 265/235, or 825/745 mg/kg-bw/day) for 105 weeks. No effects on clinical symptoms and food consumption were noted in either sex. The LOAEL was 90/80 mg/kg-bw/day (M/F), the lowest dose tested, based on histopathology impacts related to centrilobular hypertrophy in the liver. A NOAEL was not established. A review by the CARC determined that liver and thyroid tumors observed during the study were treatment-related. The incidence of liver carcinomas was significant at dose levels of 265/235 and 825/745 mg/kg-bw/day (M/F); the incidence of thyroid carcinomas was significant at the highest dose level tested (USEPA 2022i).

Based on these study results and mutagenicity data showing that the major metabolite of anthraquinone, 2-hydroxyanthraquinone, is mutagenic, USEPA currently classifies anthraquinone as “Likely to be Carcinogenic to Humans” (USEPA 2022i).

Immunotoxicity Effects

Female mice were administered technical anthraquinone at either 0, 98, 373, or 1245 mg/kg-bw/day by dietary exposure for 4 weeks in an immunotoxicity study. No significant effects were seen at any concentration on clinical signs, body weights, mortality, body weight gains, food consumption, or organ (thymus, spleen, and brain) weights. Anti-sheep red blood cell (SRBC) plaque-forming assays (PFC) were measured using splenocyte suspensions from each mouse. The NOAEL for anti-SRBC PFC response was 1,245 mg/kg-bw/day, and the LOAEL was greater than 1,245 mg/kg-bw/day, suggesting that anthraquinone is not an immunotoxic chemical (USEPA 2022i).

Endocrine Effects

In the subchronic dietary toxicity study (30 days and 13 weeks), male/female (M/F) rats were exposed to technical anthraquinone at 0/0, 40/44, 125/150, or 495/661 mg/kg-bw/day for 30 days and then the 40/44 mg/kg-bw/day dose level was lowered to 11/16 mg/kg-bw/day (M/F) for weeks 5–13. Thyroid follicular cell hypertrophy was observed in male rats at ≥125 mg/kg-bw/day, with

the incidence and severity increasing in a dose-dependent manner. There was an increase in thyroid weight in males fed 495 mg/kg-bw/day. Thyroid follicular cell hypertrophy was not observed in female rats; however, increased thyroid weights were noted but were not dose-dependent. There were impacts on adrenal gland weights and histology in female rats at concentrations ≥150 mg/kg-bw/day (USEPA 2022i). The resulting LOAEL in the study (44 mg/kg-bw/day) was based on decreased body weights in female rats.

In another study, Sprague-Dawley rats were dermally exposed daily for 28 days to technical anthraquinone at dose levels of 0, 100, 300, or 1000 mg/kg-bw/day. The LOAEL was 1,000 mg/kg-bw/day based on thyroid follicular cell hypertrophy. The NOAEL was 300 mg/kg-bw/day.

3.2.2 Ecological Effects Dose-Response

Aquatic Effects Analysis

Anthraquinone has low toxicity to fish based on available data. The acute toxicity of anthraquinone to aquatic invertebrates is variable. The freshwater cladoceran, *Daphnia magna*, appears to be the least sensitive aquatic invertebrate to anthraquinone; however, it is highly toxic to the marine mysid shrimp, *Mysidopsis bahia*, the freshwater scud (*Hyallela azteca*) and midge larvae (*Chironomus tentans*) (Table 8).

Table 8. Acute and chronic toxicity to aquatic vertebrates and invertebrates for anthraquinone.

Taxonomic group	Test species	Test	Result (mg/L)	Reference
Freshwater Fish	Bluegill Sunfish (*Lepomis macrochirus*)	LC_{50}	>5	(Verschueren 2001)
	Bluegill Sunfish	96-hr LC_{50}	>0.190	(USEPA 2022b)
	Fathead Minnow (*Pimephales promelas*)	LC_{50}	2,650	(Verschueren 2001)
	Rainbow Trout (*Oncorhynchus mykiss*)	96-hr LC_{50}	>0.150	(USEPA 2022b)
Freshwater Invertebrates	Water Flea (*Daphnia magna*)	48-hr EC_{50}	>0.240	(USEPA 2022b)
	Scud (*Hyallela azteca*)	96-hr EC_{50}	0.338	(USEPA 2022b)
	Midge (*Chironomus tentans*)	14-day NOAEC	0.058	(USEPA 2022b)
Estuarine/Marine Invertebrates	Mysid Shrimp (*Mysidopsis bahia)*	48-hr LC_{50}	0.0942	(USEPA 2022b)
	Eastern Oyster (*Crassostrea virginica*)	96-hr EC_{50}	>0.017	(USEPA 2022b)

Anthraquinone toxicity to aquatic vascular plants and algae is low based on available data. The 8-day EC_{50} for *Lemna minor* is 0.500 mg/L, while the 5-day EC_{50} for the green algae, *Raphidocelis subcapitata,* was reported as greater than 20.8 mg/L (Mallakin et al. 1999, Schrader et al. 1998). Anthraquinone is toxic to the cyanobacterium, *Oscillatoria chalybea*, with a reported 5-day median inhibition concentration (IC_{50}) of 0.0208 mg/L (Schrader et al. 1998).

Terrestrial Effects Analysis

Anthraquinone contact toxicity to honeybees (*Apis mellifera*) is low, with a reported LD_{50} greater than 0.025 mg a.i./bee (USEPA 2022b). There are no data available on the phytotoxicity of anthraquinone to terrestrial plants. Anthraquinone is considered practically non-toxic to birds and mammals in acute exposures (Table 9). Sublethal effects from subchronic dietary exposures to rats at the LOAEC included weight loss (USEPA 2022b). USEPA (2022b) reported that in the bobwhite quail acute oral toxicity study, the LD_{50} was greater than 2,000 mg/kg-bw in a limit test, suggesting it is practically non-toxic to birds on an acute basis. Mortalities were observed at 2,000 and 3,000 mg/kg-bw, with sublethal effects noted in all three treatment groups of 1,000, 2,000, and 3,000 mg/kg-bw. Sublethal effects noted in acute exposures include hypoactivity, emaciation, moribundity, and reduced body weight (USEPA 2022b).

Table 9. Acute oral median lethality and subacute dietary toxicity studies for mammals and birds for anthraquinone.

Test species	Test	Result	Reference
Brown Rat (lab)	LD_{50}	>5,143 mg/kg-bw	(USEPA 2022i)
	90-day NOAEC and LOAEC	11 mg/kg-bw and 40 mg/kg-bw	(USEPA 2022i)
Mouse	LD_{50}	>5,000 mg/kg-bw	(USEPA 1998a)
Bobwhite Quail	LD_{50}	>2,000 mg/kg-bw	(USEPA 2022b)

3.3 Exposure Assessment and Risk Characterization

3.3.1 Human Health Exposure and Risk Characterization

WS's use of anthraquinone products in the future will be limited to repelling geese at label-approved locations, including on and around airport properties. The recent label changes to Flight Control® Max that restrict use at other turf use sites suggest exposure to the public, including children, will be low for all anthraquinone uses by WS. Anthraquinone use by WS will not result in residues on food items. Estimates of residues that could occur in drinking water for current and past uses suggest that drinking water is not a significant exposure pathway. USEPA (2022i) estimated drinking water residues of anthraquinone for a range of uses and, in an aggregate risk analysis, determined that current uses of anthraquinone will not result in risks to the public. USEPA evaluated the risk to the public from residential turf applications which were recently canceled (USEPA 2022i). Exposure assumptions for residential turf use are highly conservative when compared to the exposure assumptions that would occur from anthraquinone use on turf at airports. The frequency of access by the public to residential turf would be much greater than what would occur at airports, where access to treatment areas would be restricted due to safety concerns. Regardless the residential turf uses did not result in a risk to the public, including children in acute and chronic exposures. These risks would be negligible in airport settings where WS uses anthraquinone products.

Exposure and risks to human health are greatest for workers who apply anthraquinone. Recent changes to the label regarding Personal Protective Equipment (PPE) reduce the potential risk to workers who apply anthraquinone. Current PPE requirements for all anthraquinone uses include long-sleeved shirts and pants, shoes and socks, chemical-resistant gloves, protective goggles,

and NIOSH-approved particulate filter facepiece respirator with an N, R, or P filter (USEPA 2022c). Recent risk assessments that evaluated cancer and non-cancer risk to workers during and after the application of anthraquinone did not identify significant risks to workers following these PPE requirements (USEPA 2022i). Occupational risks were estimated for both inhalation and dermal exposure pathways.

3.3.2 Ecological Exposure and Risk Characterization

Label restrictions for anthraquinone will reduce the potential for runoff and drift during application. The label states that applications should not be made when the surface to be treated is wet, or rain is expected. The formulation also contains a sticking adjuvant that allows the product to adhere more effectively to turf, reducing the chances of washing off during a rain event after application. The label also states to avoid applications during windy conditions reducing the potential for offsite drift.

Recent environmental fate modeling conducted by USEPA estimated peak and 21-day surface water concentrations of 12.2 and 3.4 µg/L, respectively. The estimates were based on maximum turf use rates applied seven times every 14 days. Rainfall patterns and soil types in Florida and Pennsylvania were used as representative use sites in the modeling scenario (USEPA 2022b). The maximum estimated surface water concentrations were compared to the available effects data to determine the potential risk to non-target aquatic vertebrates, aquatic invertebrates, and aquatic plants. No levels of concern were exceeded for non-listed (species not listed as threatened or endangered) freshwater vertebrates, invertebrates, or aquatic plants. The screening level risk assessment suggests negligible risks to aquatic biota under maximum labeled use rates. Low rates or less frequent applications would lower the risk to non-target aquatic organisms.

Exposure of terrestrial non-target organisms to anthraquinone is anticipated to occur primarily for those species that occur at use sites which consist of developed areas such as areas adjacent to or on airport property, commercial and industrial sites, cemeteries, and landfills, and managed waste dumpsites. Applications are only allowed to turf on these sites to repel geese, reducing exposure to terrestrial non-target organisms. Exposure would be greatest for those animals that consume turf after anthraquinone application. Mammals and birds that forage on treated turf would have the greatest potential for dietary exposure. Although previous use of anthraquinone by WS included turf applications, current WS use of anthraquinone is on turf at airports that are highly managed and disturbed areas where non-target terrestrial vertebrates and invertebrates would not be expected to use for foraging or nesting habitat.

USEPA recently prepared a terrestrial risk assessment characterizing the risks of anthraquinone to non-target birds, amphibians, and mammals under various use scenarios (USEPA 2022b). For turf, the WS use pattern, the highest maximum application rate, and application frequency were used to estimate residues that could occur on forage items for non-target terrestrial vertebrates. Anthraquinone residues were estimated using the USEPA Terrestrial Exposure Model (T-REX). Maximum residues ranged from highest on short and long grass, ranging from 54.6 mg/kg for seed pods and fruit to 874 mg/kg for short grass. These values represent residues that would occur if directly treated with anthraquinone.

The estimated residues were compared to the available effects data for anthraquinone to determine if there is a risk to non-target terrestrial vertebrates. The risk assessment concluded that the risk to non-target birds, amphibians, and mammals did not exceed USEPA levels of concern, suggesting a negligible risk to non-target vertebrate species from anthraquinone use by WS. Risks are also not anticipated for terrestrial invertebrates based on the available toxicity data for honeybees. There is uncertainty regarding risks to non-target terrestrial plants due to a lack of toxicity data. No reports of adverse effects on target or non-target plants have been reported suggesting that risks are low. In addition, the use sites for anthraquinone are highly managed areas where diverse terrestrial plant life is not expected to be present.

4 CAPSAICIN

4.1 Problem Formulation

4.1.1 Chemical Description and Product Use

Capsaicin and related capsaicinoids (CAS number 404-86-4) are naturally occurring chemical compounds found in edible fruits of the genus *Capsicum*. Capsaicin is regulated as a biopesticide or biochemical active ingredient (USEPA 2010e). The products used to repel animals have a low concentration of capsaicin, ranging from 0.001% to 2.5% w/w, and are unlikely to result in harm to the general population (USEPA 2022e). Capsaicin is registered for use in liquid sprays to apply directly to plants to repel mammalian herbivores such as voles, deer, rabbits, and squirrels. Capsaicin is also used in a gel on roosting structures (0.04% w/w capsaicin) for pigeons to keep them from landing and as an aerosol spray for predators that may attack humans (1–2.5% w/w capsaicin) (USEPA 2022e).

As a plant repellent, it makes the vegetation distasteful to mammalian herbivores. Animals attempting to eat treated plant material are not harmed, but the hot sensation in their mouth or throat will discourage further feeding. For predators, it is formulated into a spray, "*pepper spray,*" which sprays bursts of atomized capsaicin that spread up to 25 feet. Inhalation results in the swelling of nasal and lung membranes and eye exposure causing temporary blindness and general discomfort. Capsaicin is also an active ingredient in some products containing egg solids, which are used to repel white-tailed deer and other mammal target species; the active ingredient of egg solids is covered elsewhere in this risk assessment.

WS makes ground applications of repellent products containing capsaicin to plant foliage to deter herbivores from browsing. WS employees in areas with active bears may carry bear repellents containing capsaicin to protect themselves from a potential bear attack.

4.1.2 Physical and Chemical Properties

Capsaicin ($C_{18}H_{27}NO_3$) is a white crystalline powder or dark red to orange solid or liquid (NCBI 2022b, USEPA 2009b;2010e). It is practically insoluble in water. It has a pungent odor (USEPA 2010e).

4.1.3 Environmental Fate

Capsaicin rapidly breaks down and is not persistent in the environment (USEPA 2009a). Capsaicin degrades rapidly in soils, with a half-life ranging from 2 to 8 days, and is metabolized by bacteria in soil (USEPA 2010e).

4.1.4 Hazard Identification

Capsaicin is classified as "generally recognized as safe" (GRAS) when used as a food additive. Capsaicin is also exempt from the requirement of a tolerance in or on all food commodities when used as a pesticide active ingredient in accordance with approved label rates and good agricultural practices (USEPA 2009a;2010e).

USEPA reviewed the Incident Data System, and 5 of the 9 incidents reported were attributed to bear and dog repellents, mostly due to a lack of efficacy. One incident occurred with a red pepper spray, but the information was lacking on the cause. Two incidents were from misuse or not following label instructions. One incident was considered minor and caused minor irritation to the throat and eyes; however, USEPA did not specify the product or formulation associated with the report (USEPA 2009a).

USEPA waived data requirements for the 90-day oral toxicity, prenatal development, and mutagenicity studies due to capsaicin's use as a food additive without adverse impacts on human health (USEPA 2009a). USEPA evaluated one study that found capsaicin weakly mutagenic at the highest dose tested and concluded no harm to human health would occur when repellent products containing capsaicin are used according to label instructions (USEPA 2009e). USEPA considered the history of capsaicin used in food with no observed effect, the low concentration of capsaicin in repellent products, and its rapid degradation in the environment (USEPA 2009e).

4.2 Dose-Response Assessment

4.2.1 Human Health Dose-Response

Acute Toxicity

Capsaicin is non-toxic to mammals based on acute oral and dermal toxicity studies. A 2.5% w/w capsaicin product's LD_{50} was >5,000 mg/kg-bw, Toxicity Category IV, for both oral and dermal exposures. Acute inhalation toxicity for a product containing 2.5% w/w capsaicin is Toxicity Category III. It is virtually non-toxic through the inhalation route of exposure, but direct inhalation of defensive sprays can cause temporary coughing and breathing discomfort, which dissipates rapidly within 3 to 15 minutes with no long-term effects (USEPA 2010e). The 2.5% w/w capsaicin substance was not considered an eye or dermal irritant (Toxicity Category IV for both) and was not a dermal sensitizer (USEPA 2009c). However, direct eye and skin contact with defensive sprays will cause eye discomfort and even temporary blindness and a temporary burning sensation of the skin (USEPA 2010e).

Subchronic and Chronic Toxicity, Developmental Toxicity, Mutagenicity, Immunotoxicity

USEPA waived the requirements for subchronic and developmental toxicity, mutagenicity, immunotoxicity, and chronic testing for capsaicin due to its lack of acute toxicity and use as a food additive. USEPA reviewed one study where capsaicin was weakly mutagenic at the highest dose

tested; upon further review, USEPA found it unlikely capsaicin will cause mutagenic effects when repellent products are used according to label instructions (USEPA 2009a;e).

4.2.2 Ecological Effects Dose-Response

Aquatic Effects Analysis

Capsaicin is non-toxic and does not persist in the environment, indicating minimal risks to all non-target organisms. As such, the USEPA (2009c) waived the tier I ecotoxicity data requirements for capsaicin.

Terrestrial Effects Analysis

USEPA waived capsaicin's ecotoxicity data requirements for terrestrial species because of its low hazard and risk to the environment (USEPA 2009c). USEPA assumes that terrestrial species would avoid exposure to capsaicin because it is a fast-acting irritant when consumed or exposed to the skin, resulting in minimal risk to these species.

4.3 Exposure Assessment and Risk Characterization

4.3.1 Human Health Exposure and Risk Characterization

WS does not expect an exposure risk to the general public through its use of capsaicin repellents. WS uses repellents containing capsaicin to prevent mammals from browsing vegetation. It may carry capsaicin-containing repellent to protect them from potentially human-threatening animals as they work in the field (e.g., bear spray in grizzly bear habitat). Dietary exposure through capsaicin residues on food and drinking water is not expected. Consumption of capsaicin is a regular part of the human diet and is not associated with deleterious effects (USEPA 2010e). The product labels do not allow applications to water resources, and capsaicin's environmental fate properties indicate runoff and leaching into water resources is unlikely. WS makes ground applications and does not expect exposure to the general public due to spray drift.

Capsaicin can cause slight eye and skin irritation. Several product labels with capsaicin listed as an active ingredient require PPE to protect the hands and face and to prevent dermal exposure and protective language to reduce potential exposure to workers (USEPA 2022e). Capsaicin's environmental fate properties indicate human exposure to residues is expected to be minimal (USEPA 2009a). USEPA (2009a) reviewed the Incident Data System (date range not provided). Of the nine reports involving capsaicin, one caused minor irritation to the throat and eyes; however, information was lacking to determine if this was from product misuse. The other incidents involved misuse, not following label directions, or the repellent not working as expected against bears and dogs. None were occupational exposures (USEPA 2010e) and none involved WS.

WS use pattern for repellent products containing capsaicin and capsaicin's environmental fate properties, label language, and favorable toxicity profile indicates a negligible risk to the general public and WS applicators.

4.3.2 Ecological Exposure and Risk Characterization

The labels for repellent products containing capsaicin do not allow applications to water resources, which reduces aquatic exposure risk. The rapid breakdown of capsaicin in the environment indicates runoff or leaching into water resources would be minimal.

Capsaicin's low-use volumes, biodegradability, and lack of persistence in the environment (minimal residue exposure) indicate minimal exposure risk to terrestrial species. Capsaicin acts as a repellent, and mammals sensitive to it would stop browsing on foliage treated with repellents containing capsaicin.

WS finds capsaicin is not expected to have adverse effects on non-target terrestrial and aquatic species due to its favorable toxicity profile, environmental fate, label requirements, and WS use patterns. The USEPA (2009c) concluded the same findings. Capsaicin is non-toxic and does not persist in the environment, indicating minimal risks to all non-target organisms (USEPA 2009c).

5 EGG SOLIDS

5.1 Problem Formulation

5.1.1 Chemical Description and Product Use

Egg solids (CAS number 51609-52-0; synonym: putrescent whole egg solids) are simply dried chicken eggs that have been pasteurized and are free of viable pathogens (USEPA 2018c). Egg solids are found in several registered pesticide formulations to repel mammals, primarily from feeding on vegetation by an aversive odor and taste (USEPA 2018c). The FDA considers egg solids as a GRAS chemical when it is used as a food additive. The USEPA classified egg solids as a biopesticide or biochemical pesticide active ingredient (USEPA 2018c). Putrescent whole egg solids (same CAS number) are also included in the list of allowed MRP active ingredients in 40CFR 152.25(f). MRP products containing putrescent whole egg solids are covered in another Risk Assessment.

Pesticide products containing egg solids as the active ingredient are registered for use in home gardens, nurseries, greenhouses, and forestry plantations, on various fruit and nut trees, and on ornamental woody shrubs (USEPA 2018c). Applications are applied in dust and liquid forms (USEPA 2018c). Products containing egg solids can be used before and after flowering. USEPA has established a tolerance exemption for egg solids for pesticide food uses in accordance with the criteria specified in 40 CFR 180.1071. However, product labels for repellent products do not allow for use on or drift onto plant parts intended for human consumption because the proteins in egg solids may cause allergic reactions in some people (USEPA 2018c;2022h).

Some registered products containing egg solids include other active ingredients in their formulation, including capsaicin and garlic oil. Capsaicin and garlic oil also have repellent properties and are covered separately in this assessment.

5.1.2 Physical and Chemical Properties

Egg solids are a light brown to beige powder with a malty odor (USEPA 2011c). They are practically insoluble in water (USEPA 2011b).

5.1.3 Environmental Fate

Egg solids are organic matter that rapidly degrades (decomposes) in the environment and are expected to be non-persistent (USEPA 1992a).

5.1.4 Hazard Identification

Egg solids are non-toxic to humans and are classified as a biopesticide by EPA and GRAS by FDA when used as a food additive (USEPA 1992a;2018c). USEPA waived most of the data requirements for the reregistration of pesticide products containing egg solids, including data for toxicology, residue chemistry, human exposure, and ecological effects and environmental fate (USEPA 2011f).

Egg solids' odor and taste act as a repellent when applied to plants that repel white-tailed deer and other target animals from foraging (USEPA 2018c). The target mammals are sensitive to the smell and taste of egg solids; however, the odor is barely detectable to humans (USEPA 2018c).

Between April 1, 1996, and March 30, 2016, there were 32 human health-related incidents involving accidental ingestion resulting in nausea, inhalation exposures, and eye exposures resulting in eye irritation in the National Pesticide Information Center (NPIC) (Baker and Grant 2018). USEPA (2018c) reviewed the Incident Data System and found one incident report of a person that experienced discomfort after inhaling a product containing egg solids, which was deemed a misuse of the product.

5.2 Dose-Response Assessment

5.2.1 Human Health Dose Response

Acute Toxicity

Egg solids are practically non-toxic on an acute oral, dermal, and inhalation basis (Toxicity Category IV for all exposures) (USEPA 2011c). The LD_{50} values for acute oral and dermal toxicity are >5,000 mg/kg-bw (Toxicity Category IV) (USEPA 2011f). The acute inhalation LC_{50} is >2.10 mg/L (USEPA 2011f). In acute eye irritation studies, egg solids caused corneal irritation, which cleared within 48 hours (Toxicity Category III) (USEPA 2011c). Egg solids are a slight dermal irritant (Toxicity Category IV) (USEPA 2011c) and may be a skin sensitizer (USEPA 2011c).

Subchronic and Chronic Toxicity

Data is not available on the subchronic and chronic toxicity of egg solids. USEPA waived these studies due to the lack of acute toxicity.

Developmental and Reproductive Toxicity, Neurotoxicity Effects, Carcinogenicity and Mutagenicity, Immunotoxicity Effects, Endocrine Effects

USEPA waived these studies due to the lack of acute toxicity. There are no reports of adverse effects submitted to the USEPA, and it is not expected to have adverse effects on humans (USEPA 1992a;2011f).

5.2.2 Ecological Effects Dose-Response

Aquatic Effects Analysis

USEPA waived the ecotoxicity data requirements for aquatic species for egg solids because of their low hazard and risk to the environment (USEPA 2011e).

Terrestrial Effects Analysis

USEPA waived the ecotoxicity data requirements for terrestrial species because of the low hazard and risk to the environment from egg solids (USEPA 2011e). USEPA (2011e) concluded egg solids would not result in a hazard or toxic risk to non-target organisms.

USEPA (2018c) reviewed the Incident Data System for reported incidents and determined it unlikely that egg solids used according to their labels would not cause adverse effects on the environment. Four incidents involved dogs ingesting small amounts of the product, with some experiencing diarrhea and vomiting. Four incidents reported plant damage. From the incidents reported to NPIC between April 1, 1996, and March 30, 2016, accidental ingestion was the main exposure route, with some of the exposed animals vomiting; however, many reported no symptoms (Baker and Grant 2018).

5.3 Exposure Assessment and Risk Characterization

5.3.1 Human Health Exposure and Risk Characterization

The product labels for repellents containing egg solids do not allow applications or drift to plant parts meant for human consumption. This limits exposure through dietary consumption; egg solids may cause an allergic reaction in some people. The labels for registered products containing egg solids do not require PPE.

USEPA (2011f;2018c) concluded that applications of products containing egg solids as the active ingredient according to label instructions would not result in harm to the general population or applicators. Similarly, products containing egg solids that also contain capsaicin and/or garlic oil will not result in harm to people (USEPA 2009a).

5.3.2 Ecological Exposure and Risk Characterization

The labels for registered products containing egg solids do not allow applications to water resources, which reduces aquatic exposure risk. Egg solids break down rapidly in the environment, indicating runoff and leaching into water resources would be minimal. WS expects aquatic exposure to egg solids from its program applications will be negligible.

USEPA (2011e) concluded egg solids would not result in a hazard or toxic risk to non-target organisms. The lack of toxicity and the environmental fate properties for egg solids, WS use patterns, and the product label requirements indicate WS use of registered products containing egg solids will not harm non-target terrestrial and aquatic species.

6 GARLIC OIL

6.1 Problem Formulation

6.1.1 Chemical Description and Product Use

Garlic oil (CAS number 8000-78-0) is a naturally occurring oil extract from the bulb and other parts of the garlic plant (*Allium sativum*). Garlic oil is a volatile and strongly scented oil that works to deter and prevent the feeding of some species of mammals (including squirrels, rabbits, and deer) (USEPA 2022a). The end-use products used to repel animals have concentrations of garlic oil ranging from 0.001 to 0.12% w/w active ingredient. Garlic oil is currently registered as an active ingredient in 18 products (USEPA 2022a). The labels for these products interchangeably list the active ingredient as Garlic oil, Garlic juice, Garlic water, or Garlic. All products are water-based compounds with an extract of *A. sativum* or powder. USEPA considers all such variations of *A. sativum* to be Garlic oil under the Pesticide Chemical (PC) Code 128827 (USEPA 2010f). Garlic oil is an active ingredient in some products also containing egg solids, which are used to repel white-tailed deer and other mammal target species; the active ingredient of egg solids is covered elsewhere in this risk assessment. Garlic and garlic oil are also included in the list of allowed MRP active ingredients in 40CFR 152.25(f). MRP products containing garlic and garlic oil are covered in another Risk Assessment.

WS may use and distribute products containing garlic oil to cooperators to deter herbivores from browsing.

6.1.2 Physical and Chemical Properties

Garlic oil is a light tan to dark green liquid or powder (USEPA 2009f;2022a). It has a pungent odor and is partial to fully soluble in water (USEPA 2009f;2022a).

6.1.3 Environmental Fate

Garlic oil biodegrades rapidly and has low to no persistence in the environment (USEPA 2022a).

6.1.4 Hazard Identification

Garlic oil is classified as GRAS when used as a food additive. Garlic oil is also exempt from the requirement of a tolerance in or on all food commodities when used as a pesticide active ingredient or inert ingredient under 40 CFR 180.950(a) because it is considered a commonly consumed food commodity (USEPA 2010f;2022a).

USEPA (2022a) reviewed the Incident Data System and identified 15 reported incidents associated with garlic oil, eight incidents pertaining to human health, six involving domestic animals, and one involving human health and a domestic animal. None of the incidents were serious, and all the products contained other active ingredients, such as capsaicin and egg solids.

USEPA waived data requirements for quantitative dietary (food and drinking water) exposure due to garlic oils' composition and physical and chemical properties, broad availability for human consumption, and its benefits to human health (USEPA 2022a).

6.2 Dose-Response Assessment

6.2.1 Human Health Dose-Response

Garlic oil has minimal human health hazards, is a commonly consumed food commodity, and has a significant history of exposure to humans, demonstrating minimal toxicity (USEPA 2022a).

USEPA has not yet assessed garlic oil under their Endocrine Disruptor Screening Program (USEPA 2022a).

6.2.2 Ecological Effects Dose Response

USEPA waived all non-target organism and environmental fate data requirements for garlic oil due to garlic oils' natural occurrence, non-toxic mode of action as a repellent, and biodegradability (USEPA 2022a).

USEPA (2022a) reviewed the Incident Data System and identified four reported incidents associated with garlic oil. These incidents included minor exposure and damage to plants, although it is unclear if the damage resulted from garlic oil as the products also contained capsaicin and egg solids.

6.3 Exposure Assessment and Risk Characterization

6.3.1 Human Health Exposure and Risk Characterization

USEPA (2022a) concluded that applications of products containing garlic oil as the active ingredient according to label instructions would not result in harm to the general population or applicators.

6.3.2 Ecological Exposure and Risk Characterization

USEPA (2022a) concluded garlic oil would not result in a hazard or toxic risk to non-target organisms. The lack of toxicity and the environmental fate properties for garlic oil, WS use patterns, and the product label requirements indicate WS use of registered products containing garlic oil will not harm non-target terrestrial and aquatic species.

7 METHYL ANTHRANILATE

7.1 Problem Formulation

7.1.1 Chemical Description and Product Use

Methyl anthranilate (CAS number 134-20-3; synonyms: methyl-2-aminobenzoate and anthranilic acid, methyl ester) is a naturally occurring ester found in plants such as sunflowers, grapes, corn, cherries, cocoa, and black tea (USEPA 2011d;2020f). Methyl anthranilate is categorized as GRAS by FDA when used as a food additive (flavoring agent) (USEPA 2020f).

Methyl anthranilate is a food and non-food use biopesticide or biochemical pesticide active ingredient when used as a non-toxic, non-lethal bird repellent (USEPA 2020f). Methyl anthranilate has been used as a bird repellent since the 1990s, though its bird repellency was first discovered in the late 1950s (Kare and Pick 1960). Several research studies found methyl anthranilate an effective bird repellent for turf, water, and fruit crops (Askham 1992, Avery 1992, Dolbeer et al. 1992, Dolbeer et al. 1993, Mason et al. 1985). Methyl anthranilate acts by causing pain in birds by triggering the trigeminal nerve (USEPA 2020f). Birds exposed to methyl anthranilate associate the discomfort with the treatment area (USEPA 2018a).

There are several registered end-use products with methyl anthranilate as the active ingredient, ranging from 14.5% to 40% w/w. Methyl anthranilate can be applied as a spray or a fog to repel

pest birds for a range of food and non-food uses. The labels do not list mammals as target species.

7.1.2 Physical and Chemical Properties

Methyl anthranilate ($C_8H_9NO_2$) is a colorless to pale yellow liquid or crystal with bluish fluorescence and a grape-like odor with a slightly bitter or pungent taste (Burdock 2010). It has a melting point of 24–25ºC and a boiling point of 256ºC at 760 mm Hg (USEPA 2011g). It has a reported vapor pressure of 2.71 x 10^{-2} mm Hg at 25ºC and a calculated air-water partition coefficient of 1.89 x 10^{-6} atm-m^3/mole at 25ºC (NIH 2022b). Methyl anthranilate has a density of 1.168 g/mL at 20ºC (NIH 2022b). It is slightly soluble in water with a water solubility of 2,850 mg/L at 25ºC (NIH 2022b). It has a soil adsorption coefficient (K_{oc}) of 75 (NIH 2022b).

7.1.3 Environmental Fate

Methyl anthranilate is non-toxic to humans and is classified as a biopesticide by EPA and GRAS by FDA when used as a food additive. As a result, extensive environmental fate and groundwater data have not been submitted for the registration of methyl anthranilate. However, other publicly available environmental fate information is summarized below.

Methyl anthranilate degrades rapidly in the environment into non-toxic components such as anthranilic acid (USEPA 2020f). Methyl anthranilate is extremely volatile and will rapidly dissipate from foliar and soil surfaces, with an atmospheric half-life of 11 hours (NIH 2022b, USEPA 2011a). Methyl anthranilate undergoes rapid photodegradation (USEPA 2020f). Methyl anthranilate is expected to have high mobility in soil based on an estimated K_{oc} (NIH 2022b). However, mobility may be much slower in some soils as aromatic amines are expected to bind strongly to humus or organic matter (NIH 2022b). Volatilization from moist soil surfaces (based on its air–water partition coefficient) and soil biodegradation (100% biodegradation in 64 days) are expected to be important fate processes (NIH 2022b). In water, methyl anthranilate is not expected to adsorb to suspended solids and sediment based on the estimated K_{oc}. Biodegradation in water may be an important environmental fate process as methyl anthranilate, present at 50 mg/L, exhibited 100% biodegradation in 20 days when incubated in dechlorinated, charcoal-filtered water (NIH 2022b). Volatilization from water surfaces is rapid based on the estimated air-water partition coefficient and estimated volatilization half-lives of 24 and 180 days for a model river and model lake, respectively (NIH 2022b). An estimated bioconcentration factor (BCF) of 8 suggests a low potential for bioconcentration in aquatic organisms. Studies indicate hydrolysis is not expected to be an important environmental fate process (NIH 2022b).

7.1.4 Hazard Identification

Methyl anthranilate is a naturally occurring compound in plants such as sunflowers, corn, grapes, cherries, cocoa, and black tea (USEPA 2020f). It is often used as a flavoring in food and is considered GRAS by the FDA when used as a food additive (USEPA 2018a;2020f). USEPA evaluated exposure scenarios and found methyl anthranilate occurs at higher concentrations in commonly consumed foods, such as corn, grapes, cherries, cocoa, and black tea than in pesticidal exposure scenarios, indicating negligible risk to people (USEPA 2020f).

Methyl anthranilate is hydrolyzed in the small intestine to alcohol and either anthranilic acid or an N-alkyl anthranilic acid. In humans, anthranilic acid is a normal metabolite and is excreted in the urine primarily as o-amino hippuric acid and, to a lesser extent, as anthranilic acid glucuronide (NIH 2022b). USEPA (2011d) found it unlikely that products containing methyl anthranilate will have adverse effects on human health.

USEPA found three reported incidents of methyl anthranilate exposure from January 1, 1992, to October 29, 2010. All incidents were attributable to misuse or to the inert ingredients in the product and not from the active ingredient, methyl anthranilate (USEPA 2011d).

7.2 Dose-Response Assessment

7.2.1 Human Health Dose-Response

Acute Toxicity

Methyl anthranilate is virtually non-toxic to mammals through all routes of exposure. Methyl anthranilate is classified as Toxicity Category III for acute oral and dermal toxicity (Table 10). USEPA waived the inhalation toxicity study. Methyl anthranilate is an eye irritant but not a dermal irritant (Table 10) (USEPA 2011d). It is not a dermal sensitizer (USEPA 2011d). Limited data are available on the acute toxicity of anthranilic acid (a major metabolite of methyl anthranilate); however, an oral LD_{50} as high as 5,410 mg/kg-bw in rats has been reported, which indicates low to no toxicity (NCBI 2022a).

Table 10 Acute oral median lethality studies for mammals for Methyl anthranilate.

Test Species	**Test**	**Result (Methyl Anthranilate 40-98% w/w)**	**USEPA Toxicity Category**
Laboratory Brown Rat (M)	Acute Oral LD_{50}	3,633 mg/kg-bw	III
Laboratory Brown Rat (F)	Acute Oral LD_{50}	3,000 mg/kg-bw	III
Laboratory Brown Rat	Acute Oral LD_{50}	3,288 mg/kg-bw	III
Domestic Rabbit	Acute Dermal LD_{50}	>2,000 mg/kg-bw	III
Laboratory Brown Rat	Acute Inhalation LC_{50}	Waived	N/A
Domestic Rabbit	Primary Eye Irritation	Slight to Moderate Irritant	II
Domestic Rabbit	Primary Dermal Irritation	No Irritation	IV
Guinea Pig	Dermal Sensitization	Not a Sensitizer	N/A

M = male, F = female, N/A = Not applicable
Reference: (USEPA 2011d)

Subchronic and Chronic Toxicity

USEPA did not require information on subchronic and chronic toxicity because methyl anthranilate is a naturally occurring substance found in many foods, and it is unlikely products containing it will have adverse effects on human health (USEPA 2011d).

Developmental and Reproductive Effects, Neurotoxicity Effects, Carcinogenicity and Mutagenicity, Immunotoxicity Effects, and Endocrine Effects

USEPA did not require information on developmental and reproductive effects, neurotoxicity effects, carcinogenicity, mutagenicity, immunotoxicity, or endocrine effects of methyl anthranilate (USEPA 2011d). There is no known evidence that methyl anthranilate causes these types of effects or affects these systems in humans.

7.2.2 Ecological Effects Dose-Response

Aquatic Effects Analysis

Methyl anthranilate has moderate to slight acute toxicity to freshwater fish and is slightly toxic to aquatic invertebrates (i.e., water flea) (Table 11) (USEPA 2011a). Methyl anthranilate is practically non-toxic to freshwater fish on a dietary basis (USEPA 2011a).

Table 11 Acute and chronic toxicity to aquatic vertebrates and invertebrates for methyl anthranilate.

Taxonomic group	Test species	Test	Result (mg/L)	Reference
Freshwater Fish	Atlantic Salmon (*Salmo salar*)	LC_{50}	34.28	(Clark et al. 1993)
	Atlantic Salmon	96-hr LC_{50}	32.25 (slightly toxic)	(USEPA 2011a)
	Rainbow Trout (*Oncorhynchus mykiss*)	LC_{50}	23.47	(Clark et al. 1993)
	Rainbow Trout	96-hr LC_{50}	22.91–25.40 (slightly toxic)	(USEPA 2011a)
	Channel Catfish (*Ictalarus punctatus*)	LC_{50}	20.08	(Clark et al. 1993)
	Channel Catfish	96-hr LC_{50}	16.23 (slightly toxic)	(USEPA 2011a)
	Bluegill Sunfish (*Lepomis macrochirus*)	LC_{50}	19.80	(Clark et al. 1993)
	Bluegill Sunfish	96-hr LC_{50}	9.12–42.56 (moderately to slightly toxic)	(USEPA 2011a)
	Striped Bass (*Morone saxatilis*)	12-hr dietary LC_{50} (non-guideline)	>1,000 mg/kg (no effects on growth or survival)	(USEPA 2011a)
Freshwater Invertebrates	Water Flea (*Daphnia magna*)	EC_{50}	18.2	(Clark et al. 1994)
	Aquatic freshwater invertebrates (not specified)	48-hr EC_{50}	17–29.1 (slightly toxic)	(USEPA 2011a)

Terrestrial Effects Analysis

The single dose oral LD_{50} for bobwhite quail was >2,036 mg/kg-bw, classifying methyl anthranilate as non-toxic to upland game birds (Table 12). The NOEL was 2,036 mg/kg-bw. In the mallard duck (*Anas platyrhynchos*), the dietary toxicity LC_{50} was >5,620 mg/kg-diet. This classifies methyl anthranilate as practically non-toxic to waterfowl. Methyl anthranilate is practically non-toxic to

mammals (Table 12) (USEPA 2011a). Methyl anthranilate is practically non-toxic to the honey bee with a 48-hr contact toxicity LC_{50} >25 µg/bee (USEPA 2011a).

Table 12 Acute oral median lethality and subacute dietary toxicity studies for mammals and birds for methyl anthranilate.

Test species	Test	Result	Reference
Brown Rat (lab)	LD_{50}	2,910 mg/kg-bw	(Lewis 2004)
	LD_{50}	>5,000 mg/kg-bw	(USEPA 2011a)
	90-day dietary LC_{50}	>500 mg/kg-bw/day (no effects on growth or survival)	(USEPA 2011a)
House Mouse (lab)	LD_{50}	3,900 mg/kg-bw	(Lewis 2004)
Guinea Pig	LD_{50}	2,780 mg/kg-bw	(Lewis 2004)
European Rabbit	LD_{50}	5,000 mg/kg-bw	(Opdyke 1974)
Mallard Duck	LD_{50}	>292 mg/kg-bw	(USEPA 2011a)
	LC_{50}	>5,620 mg/kg-diet (practically non-toxic)	(USEPA 2011a)
Bobwhite Quail	LD_{50}	>2,036 mg/kg-bw, >2,250 mg/kg-bw (practically non-toxic)	(USEPA 2011a)
Ring-necked Pheasant	Subacute LC_{50}	>5,620 mg/kg-diet	(USEPA 2011a)
White-crowned Sparrow	LC_{50}	>2,200 mg/kg-diet (practically non-toxic)	(USEPA 2011a)

Methyl anthranilate applied at a rate of 18 kg/ha caused a minor foliar burn on 90% of sprayed blueberry leaves (Avery 1992). Additional studies showed the appearance of minor foliar desiccation or burn at greater than 2.0% methyl anthranilate concentration rates applied to raspberries and 8.0% concentrations applied to cherries, blueberries, and grapes (Askham 1992). However, the foliar desiccation in Askham (1992) was later attributed to the inert ingredients (surfactants) in the product and not to the methyl anthranilate (USEPA 2011a).

7.3 Exposure Assessment and Risk Characterization

7.3.1 Human Health Exposure and Risk Characterization

WS mostly applies methyl anthranilate to repel birds at airports to prevent interference with aircraft. WS made one application on turf for Canada geese at an office park in Missouri and two agricultural applications to protect wheat fields in Oregon between FY11 and FY20. Applications are in areas where the general public is not present during the time of application.

USEPA (2020f) evaluated residue levels at harvest when methyl anthranilate is used on food crops and concluded no significant residues were expected. Methyl anthranilate is not applied to potable water resources, and its environmental fate properties indicate movement into and persistence in water resources is unlikely. Low application rates and rapid biodegradation of methyl anthranilate result in a minimal risk of human exposure (USEPA 2018a). Therefore, the risk of injury to the general public is negligible.

Occupational exposure, particularly through inhalation and dermal contact, is possible for mixers and applicators; however, oral exposure through the ingestion of food and water contaminated

with methyl anthranilate is not an expected exposure pathway. The labels for methyl anthranilate require applicators and handlers to wear long-sleeved shirts and long pants, waterproof gloves, and shoes plus socks (USEPA 2015b). The proper use of PPE will reduce dermal exposure.

Methyl anthranilate does not have mammalian toxicity, and residues in food and water are unlikely based on the use pattern and environmental fate (USEPA 2020f). USEPA (2011d) concluded methyl anthranilate would not cause harm to the general public based on its lack of toxicity. In addition, WS's use pattern for methyl anthranilate does not expose the general public.

7.3.2 Ecological Exposure and Risk Characterization

The label restrictions for methyl anthranilate do not allow applications to potable water resources, reducing the exposure potential to aquatic species. Methyl anthranilate's environmental fate properties, label restrictions, and WS use pattern indicate exposure to aquatic species is negligible. Based on the negligible aquatic exposure potential and its toxicity to aquatic species ranging from negligible to moderate (Table 11), there is negligible risk to aquatic species from the WS use of methyl anthranilate.

Methyl anthranilate is non-toxic to practically non-toxic to mammals and birds (USEPA 2011a). WS expects target birds and any non-target birds exposed to experience discomfort from exposure, but the discomfort is of short duration, likely a minute or less after they leave the area with volatilized methyl anthranilate (Stevens and Clark 1998). Methyl anthranilate is not considered phytotoxic at the concentration in registered end-use products. Methyl anthranilate is practically non-toxic to terrestrial invertebrates, including pollinators. Methyl anthranilate is a naturally occurring substance found in many plant species to which invertebrates are exposed on a regular basis (USEPA 2011a).

WS does not anticipate risks to non-target organisms from using methyl anthranilate. WS use patterns and following product label instructions reduce exposure to non-target organisms. The USEPA determined methyl anthranilate will not negatively impact federally listed threatened or endangered species or designated critical habitats (USEPA 2011a).

8 NAPHTHALENE

8.1 Problem Formulation

8.1.1 Chemical Description and Product Use

Naphthalene (CAS number 91-20-3) is an organic compound derived from distilling coal tar and is classified as a benzenoid polycyclic aromatic hydrocarbon. Naphthalene's pungent odor repels some animals, such as rabbits, squirrels, bats, dogs, and snakes. Naphthalene products are registered for non-food indoor and outdoor residential use. Indoor uses include placement in closed drawers, closets, and storage areas to control moths and in attics to repel squirrels and bats (e.g., mothballs). Outdoor uses are used around buildings and gardens to repel animals such as snakes and rabbits (USEPA 2008a).

Snake-A-Way® Snake Repelling Granules is a granular formulation that contains naphthalene (7%) and sulfur (28%; sulfur is covered in Section 11 of this risk assessment (Woodstream

Corporation 2013). WS infrequently uses Snake-A-Way® Snake Repelling Granules (EPA Registration Number 58630-1) to repel certain snake species at outdoor use sites listed on the label (Table 2).

The Snake-A-Way® Snake Repelling Granules label identifies rattlesnakes (*Crotalus* spp.) and garter snakes (*Thamnophis* spp.) as target pest species to repel from residential dwellings, garages, barns, trailers, utility houses, woodpiles, trash cans, and flower beds. The label allows for use around the perimeter of flower gardens. The product may not be used at sites where snakes are believed to be already present. The label does not allow for use in gardens or fields of crops grown for food or feed. The label does not allow applications near streams, ponds, pools, or water supplies or directly to water, including areas where surface water is present or intertidal areas below the mean high-water mark.

Applications are made by hand in bands surrounding the area to be protected. Bands 4 to 5 inches in width are used for garter snakes, and bands 8 to 12 inches in width for rattlesnakes. The product is lightly sprinkled over the area within the treatment band. The label does not indicate an application rate. During the registration review, USEPA (2018b) determined that a high application rate for outdoor use of naphthalene products was 10.8 pounds a.i./acre based on information provided by the registrant (USEPA 2018b). Retreatment is recommended when the odor fades in seasons when the snakes are active.

8.1.2 Physical and Chemical Properties

Naphthalene ($C_{10}H_8$) is a white, crystalline solid with a characteristic coal-tar odor (USEPA 2018d). Naphthalene has a vapor pressure of 0.085 mm Hg at 25ºC, water solubility of 31.7 mg/L at 20ºC, and a calculated air-water partition coefficient of 4.4×10^{-4} (NIH 2022a). Its log octanol/water partition coefficients (K_{ow}) range from 3.29 to 3.37 (NIH 2022a, USEPA 2018d), which suggests a low potential for bioconcentration in aquatic organisms, and the log organic carbon coefficient (K_{oc}) is 3.11 (ATSDR 2005).

8.1.3 Environmental Fate

Naphthalene is likely to volatilize from surface water based on its chemical properties. It has poor solubility in water (NIH 2022a). In water, naphthalene would largely remain in solution with small quantities binding to suspended solids and benthic sediments and degrades rapidly through photolysis and biological processes. In surface water, its photolysis half-life is about 71 hours (ATSDR 2005). Biodegradation is the dominant fate process for naphthalene in aquatic systems, with a half-life of about 7 days (ATSDR 2005). Naphthalene has moderate bioconcentration in aquatic organisms, but bioaccumulation in the food chain is not expected to occur (ATSDR 2005).

Naphthalene volatilizes from aerated soils (ATSDR 2005). Data from the open literature suggest that naphthalene binds relatively rapidly to soils, degrades with aerobic soil metabolism half-lives between 3.5 and 40 days, and has no apparent degradation under anaerobic soil conditions (USEPA 2018d). In aerobic soil, naphthalene biodegrades to carbon dioxide (ATSDR 2005). In sandy-loam soil with 0.5–1.0% organic carbon, naphthalene has a half-life of 203 days (ATSDR 2005).

Naphthalene reacts with photochemically produced hydroxyl radicals and has an atmospheric half-life of less than one day (ATSDR 2005). The major products from this reaction are 1- and 2-naphthol and 1- and 2-nitro naphthalene (ATSDR 2005).

8.1.4 Hazard Identification

In humans and dogs, but not rodents, naphthalene causes red blood cell hemolysis after inhalation. Oral exposure and hemolysis are the most commonly reported toxicosis from naphthalene exposure (USEPA 2018d). Other symptoms of naphthalene-induced anemia include increased reticulocyte counts and serum bilirubin levels, Heinz body formation, fatigue, lack of appetite, restlessness, and pale appearance (ATSDR 2005, USEPA 2018d). In infants, hemolysis from naphthalene exposure can cause jaundice which can lead to permanent neurological damage, convulsions, motor disturbances, damage to mental faculties, and sometimes death (ATSDR 2005). Exposure of adults and children to large numbers of mothballs in their homes caused nausea, headache, malaise, and confusion (ATSDR 2005).

In animal studies, naphthalene exposure has caused lens opacities (cataracts); however, the formation of cataracts in humans from naphthalene exposure is not verified (ATSDR 2005). In animal studies, naphthalene's reactive metabolites produce neoplastic and nonneoplastic lesions in the respiratory tract (lung or nasal epithelial tissue) (ATSDR 2005). It causes glutathione depletion, lipid peroxidation, DNA fragmentation, and the production of active oxygen species (USEPA 2008b).

The liver is expected to be the principal site of metabolism after oral exposure (ATSDR 2005). Metabolism in other tissues can also occur, including in the nasal olfactory epithelium, Clara cells in pulmonary epithelia, and eye tissue (ATSDR 2005). Excretion mostly occurs in urine (ATSDR 2005).

USEPA (2008c) summarized incident data for 1993 to 2005 from IDS, Poison Control Centers, California Department of Pesticide Regulation, and SENSOR and found most cases involved excessive, inappropriate, or misused indoor uses of naphthalene (e.g., mothballs) with accidental exposure to young children representing a high proportion of the cases. USEPA (2018d) updated their incident review and found incidents involving naphthalene had declined, but not ceased, since their previous review in 2008. The majority of incidents still involved inhalation exposures from homeowners' indoor use of mothballs, and the most frequent symptoms reported were headache, diarrhea, nausea, and vomiting.

8.2 Dose-Response Assessment

8.2.1 Human Health Dose-Response

Acute Toxicity

Naphthalene is slightly toxic in acute oral and acute dermal routes of exposure (Toxicity Category III) (USEPA 2008a). The acute oral LD_{50} (rat) is 2,649 mg/kg-bw, and the acute dermal LD_{50} is >2,000 mg/kg-bw (USEPA 2008a). Naphthalene is moderately toxic (LC_{50} >0.4 mg/L) by the acute inhalation route (Toxicity Category II). It causes slight to moderate eye irritation and moderate

skin irritation (Toxicity Category III). Naphthalene is not considered a skin sensitizer (USEPA 2008a).

Subchronic and Chronic Toxicity

In a 90-day oral toxicity study in rats at 0, 25, 50, 100, 200, or 400 mg/kg-bw/day, the NOAEL for naphthalene was 100 mg/kg-bw/day, and the LOAEL was 200 mg/kg-bw/day (decreased body weights and renal effects) (USEPA 2018d). In the 400 mg/kg-bw/day group, both sexes displayed lethargy, hunched posture, and roughened coats. In a second 90-day oral toxicity study in mice at 0, 12.5, 35, 50, 100, or 200 mg/kg-bw/day, the NOAEL was 100 mg/kg-bw/day, and the LOAEL was 200 mg/kg-bw/day (rough hair and lethargy at weeks 3 and 4) (USEPA 2018y).

In a subchronic 30-day inhalation study (nose only) in rats at 0, 0.005, 0.016, 0.052, 0.157, or 0.404 mg/L for 6 hours per day, the NOAEL was 0.016 mg/L, and the LOAEC was 0.052 mg/L (increased incidence and severity of nasal lesions) (USEPA 2018d). In a 90-day subchronic inhalation toxicity study (nose-only) in rats at 0, 0.010, 0.052, or 0.315 mg/L for 6 hours per day, the NOAEC was not identified. LOAEC was 0.010 mg/L based on increased incidence and severity of nasal lesions (USEPA 2018d).

In a subchronic 90-day dermal toxicity study in rats at 0, 100, 300, or 1,000 mg/kg-bw/day, the only noted effects in the rat were at the high dose (limit test) of 1,000 mg/kg-bw/day (increased incidence and severity of excoriated skin and papules in both sexes, atrophy of seminiferous tubules in males, non-neoplastic lesions in the cervical lymph node, liver, thyroid, kidneys, urinary bladder and skin in females) (USEPA 2018d). The NOAEL was 300 mg/kg-bw/day. This study shows dermal toxicity is likely not a concern (USEPA 2008a).

Developmental and Reproductive Toxicity

There was no evidence of developmental toxicity (oral exposure) in rat and rabbit prenatal developmental toxicity studies or maternal effects in the rabbit study (USEPA 2008a;2018d). Doses were at 0, 50, 150, or 450 mg/kg-bw/day in the rat study and 0, 20, 80, or 120 mg/kg-bw/day in the rabbit study. The maternal NOAELs were 50 mg/kg-bw/day in the rat study and 120 mg/kg-bw/day in the rabbit study. The LOAEL was 150 mg/kg-bw/day (lethargy, slow breathing, rooting behavior, and decreases in body weight or increases in body weight and food and water consumption) in the rat study. Reproductive toxicity studies were not required by USEPA for registration as naphthalene as a non-food use pesticide (USEPA 2008a).

Neurotoxicity Effects

Neurotoxic effects were observed in the developmental toxicity (oral exposure) and an acute oral neurotoxicity study in rats but were only observed at higher bolus doses (USEPA 2018d). In the acute oral neurotoxicity study at 0, 400, 800, or 1,200 mg/kg-bw/day (oral exposure), the LOAEL was 400 mg/kg-bw-day (neurotoxicity symptoms were head shaking, reduced motor activity in males and females, and hunched posture in females) (USEPA 2018d). A neurotoxicity NOAEL was not identified.

In a subchronic neurotoxicity study (inhalation nose-only exposure) in rats at 0, 0.005, 0.052, or 0.329 mg/L for 6 hours per day, the NOAEC was 0.005 mg/L, and the LOAEC was 0.052 mg/L based on nasal lesions (USEPA 2018d).

Carcinogenicity and Mutagenicity

In two-year chronic inhalation studies with rats and mice exposed to naphthalene, carcinogenic effects were observed. In the rat study, nasal tumors of the olfactory epithelium and adenomas of the respiratory epithelium were observed. In the mouse study, there was a statistically significant increase in liver adenomas and adenomas and carcinomas combined. In female mice, there was an increase in alveolar/bronchiolar adenomas. The National Toxicology Program concluded from these studies that there is evidence of carcinogenic activity of naphthalene in male and female rats and some evidence of carcinogenic activity in female mice but not male mice (USEPA 2008a). Naphthalene is classified in Group C as a possible human carcinogen based on limited data on carcinogenicity in humans exposed to naphthalene via the oral and inhalation routes and limited evidence of carcinogenicity in animals via the inhalation route (USEPA 1998b).

Immunotoxicity Effects

A 30-day oral exposure immunotoxicity study in female mice was conducted at 0, 25, 100, or 250 mg/kg-bw/day (USEPA 2012b). The NOAEL was 100 mg/kg-bw/day, and the systemic toxicity LOAEL was 350 mg/kg-bw/day (reduced body weights and spleen and thymus weights). An immunotoxicity LOAEL was not established.

Endocrine Effects

Naphthalene is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (USEPA 2018d). Listed substances will be assessed by computation and modeling methods for the potential of endocrine disruptive activity. Further quantification of endocrine activity will be evaluated for candidate substances in subsequent Tier 1 and Tier 2 studies.

8.2.2 Ecological Effects Dose-Response

Aquatic Effects Analysis

Naphthalene is moderately toxic to freshwater fish (96-hr LC_{50} of 2 mg/L and 3.2 mg/L for the rainbow trout (*Oncorhynchus mykiss*) and bluegill sunfish (*Lepomis macrochirus*), respectively) and aquatic invertebrates (48-hr LC_{50} of 1.6 mg/L for water flea) (Table 13) (USEPA 2008b).

Chronic exposure of Coho salmon (*Oncorhynchus kisutch*) to naphthalene resulted in a 40-day LOAEC and NOAEC of 0.67 and 0.37 mg/L, respectively, with an observed reduction in feeding behavior, growth, and survival (USEPA 2008b). In an embryo-larvae toxicity study with the fathead minnow (*Pimephales promelas*), adverse effects were observed at 0.85 mg/L with a NOAEC of 0.62 mg/L (USEPA 2008b). Freshwater fish species act as surrogates for aquatic-phase amphibians, indicating moderate toxicity for aquatic-phase amphibians (USEPA 2008b).

It is slightly toxic to aquatic nonvascular plants, with a 48-hr EC_{50} of 33 mg/L for green algae (*Chlorella vulgaris*) (USEPA 2008b). Data was not available for aquatic vascular plants.

Table 13 Acute and chronic toxicity to aquatic vertebrates and invertebrates for naphthalene.

Taxonomic group	Test species	Test	Result (mg/L)	Reference
Freshwater Fish	Rainbow Trout (*Oncorhynchus mykiss*)	96-hr LC_{50} NOAEC	2.0 0.86	(USEPA 2008b) (USEPA 2016a)
	Bluegill Sunfish (*Lepomis macrochirus*)	96-hr LC_{50} NOAEC	3.2 1.4	(USEPA 2008b) (USEPA 2016a)
	Fathead Minnow (*Pimephales promelas*)	96-hr LC_{50}	6.6	(USEPA 2008b) (USEPA 2016a)
Aquatic Invertebrates	Water Flea (*Daphnia magna*)	48-hr EC_{50} NOAEC	1.6 0.48	(USEPA 2008b) (USEPA 2016a)
	Pacific Oyster (*Crassostrea gigas*)	96-hr EC_{50}	199	(USEPA 2008b) (USEPA 2016a)
	Grass Shrimp (*Palaemonetes pugio*)	96-hr LC_{50}	2.35	(USEPA 2008b) (USEPA 2016a)

Terrestrial Effects Analysis

Naphthalene is classified as practically non-toxic to wild mammals due to a laboratory rat-acute oral LD_{50} of 2,649 mg/kg-bw (USEPA 2016a). Naphthalene is classified as practically non-toxic to upland game birds; the acute oral LD_{50} for bobwhite quail was 2,690 mg/kg-bw, and the NOAEC was 810 mg/kg-bw (USEPA 2016a). The subacute dietary LC_{50} was >5,620 mg/kg-bw/day (Table 14) (USEPA 2008b). Naphthalene toxicity to waterfowl species is unknown (USEPA 2008b).

Toxicity data for honeybees is not available (USEPA 2008b;2016a). In studies on the chronic effects (reproduction and survival) of naphthalene on soil invertebrates, the springtail *Folsomia candida* had a NOAEC and LOAEC of 88 and 409 µmol/kg soil, respectively, and the annelid worm *Enchytraeus crypticus* had a NOAEC and LOAEC of 220 and 2045 µmol/kg soil, respectively (USEPA 2008b).

No effects data is available for terrestrial plants (USEPA 2008b).

Table 14 Acute oral median lethality and subacute dietary toxicity studies for mammals and birds for naphthalene.

Test species	Test	Results	Reference
Brown Rat (lab)	Acute oral LD_{50}	2,649 mg/kg-bw	(USEPA 2008b) (USEPA 2016a)
Bobwhite Quail	Acute oral LD_{50} NOAEC	2,690 mg/kg-bw 810 mg/kg-bw	(USEPA 2008a) (USEPA 2016a)
	Subacute dietary LC_{50}	>5,620 mg/kg-bw/day	(USEPA 2008a)

8.3 Exposure Assessment and Risk Characterization

8.3.1 Human Health Exposure and Risk Characterization

Naphthalene products are not registered for food uses or use on agricultural crops, and dietary exposure from food is not expected. USEPA determined outdoor post-application inhalation and dermal exposure to be negligible or minimal (USEPA 2018d).

The acute dietary reference dose (RfD) for naphthalene is 0.4 mg/kg-bw/day based on an acute oral neurotoxicity study in rats where the LOAEL of 400 mg/kg-bw/day produced hunched posture in female rats, and head shaking and reduced motor activity in male and female rats (USEPA 2008a;2018d). The acute RfD was derived using a 1,000-fold uncertainty factor (10x for inter-species extrapolation, 10x for intra-species variation, and 10x factor for LOAEL to NOAEL extrapolation) (USEPA 2018d). The chronic dietary RfD is 0.1 mg/kg-bw/day based on a study in rats with NOAEL of 100 mg/kg-bw/day and using a 1,000-fold uncertainty factor (10x for inter-species extrapolation, 10x for intra-species variation, and 10x factor for subchronic to chronic extrapolation) (USEPA 2018d).

When used outdoors as an animal repellent, migration to water resources (drinking water) is potentially possible. USEPA (2008a;2018d) modeled dietary exposure and residential handler exposure (non-cancer) and risk estimates for naphthalene in drinking water. The risk estimates were all found to be below the acute and chronic RfD threshold levels of concern. Dietary exposures through drinking water and food are not expected for WS's use of products containing naphthalene because of the label's use restrictions and WS's low usage of the product.

The annual amount of naphthalene that WS uses in its animal damage management program is limited (Table 2). Between FY16 and FY20, WS only used an average of 0.2 pounds of products containing naphthalene and sulfur per year to repel rattlesnakes (Table 2). WS applicators adhere to label requirements, which include not applying the product to water or areas where surface water is present or intertidal areas below the mean high-water mark. Naphthalene is highly volatile, indicating the chemical's concentration in water and on the ground would dissipate quickly.

WS's care in the selection of use sites minimizes any risks to the public, particularly small children, who may be at risk from accidental ingestion. Adherence to label requirements regarding PPE minimizes risk to WS workers who apply chemical repellents. Any exposure and risk would be short-term based on the methods for application and the low frequency of use for naphthalene by WS.

8.3.2 Ecological Exposure and Risk Characterization

Based on the application rates and naphthalene's environmental fate properties, USEPA (2008b) concluded that leaching into groundwater is not likely a significant route of exposure for non-target species to the pesticidal use of naphthalene.

USEPA (2008b) modeled aquatic exposures and found naphthalene applied at a rate of 10.8 lb/acre six times, 60 days apart, posed a minimal acute risk to aquatic species (risks to aquatic vascular plants are unknown due to lack of toxicity data). This rate is greater than the labeled rate for the snake repellent.

Exposure routes for terrestrial species include direct episodic ingestion of naphthalene granules, ingestion of contaminated soil, and dermal contact with treatment surfaces (USEPA 2008b). Inhalation of naphthalene as it volatilizes from treated surfaces and airborne soil or pesticide dust particulates is also a possible exposure route (USEPA 2008b). USEPA (2018b) reviewed the Ecological Incident Information System for incidents through May 2018. Between 2008 and 2017,

there were 3 separate incidents where 4 dogs died, and 1 dog had diarrhea after likely ingesting Snake-A-Way® Snake Repelling Granules applied in outdoor use sites. Based on these reported adverse incidents and the acute oral LD_{50}s, USEPA (2018b) determined that birds and mammals that consume granules containing naphthalene could be at risk.

Furthermore, birds may not be as repelled by naphthalene as other species. In a study on the effects of naphthalene on starlings, nest boxes were treated with up to 1.3 g of naphthalene per liter space, and no repellency was observed (Dolbeer et al. 1988). The authors noted that bird species differ in their olfactory sensitivities. Birds are a surrogate species for reptiles and terrestrial-phase amphibians; as with birds, the exposure will be much less as terrestrial-phase amphibians and reptiles do not reside strictly in the treatment area. In addition, naphthalene is used as a repellent for reptiles, and minimal consumption of granules is expected.

Studies are lacking on naphthalene's toxicity to terrestrial plants, and its potential risk to plants is unknown.

Although the USEPA estimates above indicate adverse effects to some birds and mammals, USEPA indicates exposure would be much less because the estimate assumes that non-target species would only occur in the treatment area and exclusively feed on the naphthalene granules. WS has used naphthalene products minimally, with only one work task conducted in five years, with an average annual use of 0.2 pounds between FY16 and FY20 (Table 2). Label use requirements and the low application frequency indicate WS usage of naphthalene would have minimal impact on non-target species. However, should WS usage of naphthalene increase significantly, WS applications could possibly have some adverse impacts on non-target species.

9 OIL OF BLACK PEPPER/PIPERINE

9.1 Problem Formulation

9.1.1 Chemical Description and Product Use

Oil of black pepper (CAS number 8006-82-4; synonym and USEPA's Chemical Name for the active ingredient: oils, black pepper) is a naturally occurring oil extract from the black pepper plant (*Piper nigrum*) derived via steam distillation of the plant's dried, unopened fruit (USEPA 2005b;2019b).

Piperine (CAS number 94-62-2; synonym and USEPA's Chemical Name for the active ingredient: Piperidine, 1-[(2E,4E)-5-(1,3-benzodioxol-5-yl)-1-oxo-2,4-pentadienyl]-) is responsible for the pungency of the naturally occurring black pepper plants' dark brown to black berries or peppercorns (USEPA 2015c). Although piperine can be extracted from dried black peppercorns, it is manufactured synthetically for commercial uses (USEPA 2004b).

Woodstream Corporation (Lititz, PA) applied to USEPA to register a pesticide product (Animal Repellent Granular, alternative brand name Havahart® Critter Ridder®; EPA Registration number 50932-10) containing both oil of black pepper and piperine in 2003 (USEPA 2003a). USEPA (2005a) draft registration review schedule for biopesticides put oil of black pepper and piperine under the same case number (6004). For this risk assessment, all of the data for oil of black pepper also applies to piperine.

Oil of black pepper is a pungent oil that repels animals through irritation upon touching or tasting the product (USEPA 2005b). The end-use products used to repel animals have concentrations of oil of black pepper ranging from 0.48 to 3.84% w/w active ingredient. Piperine concentrations in end-use products range from 0.185 to 1.48% w/w active ingredient. Oil of black pepper and piperine are currently registered as active ingredients in 3 products (USEPA 2019b).

WS may use and distribute products containing oil of black pepper and piperine to cooperators to repel animals such as dogs, cats, raccoons, squirrels, skunks, and groundhogs.

9.1.2 Physical and Chemical Properties

Oil of black pepper is a pale yellow liquid with an irritating, sharp peppery odor (USEPA 2004c). Oil of black pepper has a vapor pressure of 5.3 mm Hg at 20ºC, is insoluble in water, and has a boiling point of 187.8ºC (USEPA 2005b).

Piperine ($C_{17}H_{19}NO_3$) is a pale yellow to yellow crystalline solid with a pungent odor and burning aftertaste (USEPA 2004b). Piperidine compound has a vapor pressure of 1.3×10^{-7} mm Hg, a water solubility of 0.04 mg/mL at 18ºC, and a boiling point of 498–499ºC at 760 mm Hg (NIH 2023b).

9.1.3 Environmental Fate

The need for environmental fate and groundwater data were not triggered for oil of black pepper and piperine because of practically non-toxic results (USEPA 2005b). Risks to non-target species is minimal due to the use pattern, application methods, and lack of toxicity (USEPA 2005b).

9.1.4 Hazard Identification

Oil of black pepper and piperine are allowed food additives by FDA. No registered pesticide products containing oil of black pepper and piperine are approved for food use. Therefore, the USEPA did not require a tolerance or an exemption from the requirement of a tolerance for residues of oil of black pepper or piperine found in or on food (USEPA 2019b).

USEPA (2019b) reviewed the Incident Data System and identified one reported incident associated with oil of black pepper and piperine. The incident involved minor human health effects, including burning eyes and sore throat, and may be attributable to other ingredients in the formulated product (i.e., capsaicin).

9.2 Dose-Response Assessment

9.2.1 Human Health Dose-Response

Oil of black pepper and piperine pose minimal human health hazards. Oil of black pepper and piperine are widely used as flavoring agents in foods and have a significant history of exposure to humans, demonstrating minimal toxicity (USEPA 2005b). A qualitative risk assessment for oil of black pepper and piperine was considered adequate by USEPA (USEPA 2005b) due to their uses as flavoring agents and in aromatherapy. Due to the use pattern, demonstrated low toxicity, and low concentration of oil of black pepper and piperine in registered products, USEPA (2005b) determined dietary exposure risk is not of concern for the registered repellent products. There is also no significant risk of toxicity effects from oral, dermal, or eye irritation or inhalation exposure

to oil of black pepper or piperine, and any potential pesticidal residues of oil of black pepper or piperine in food and drinking water are negligible (USEPA 2005b).

Based on the available data, no endocrine system-related effects have been identified for oil of black pepper or piperine, and none are expected (USEPA 2005b).

9.2.2 Ecological Effects Dose Response

Oil of black pepper and piperine are considered to have minimal to no toxicity to mammals, given their widespread use as food additives, or to birds. Mallard ducks (*Anas platyrhynchos*) received a single oral dose of the end-use product Animal Repellent Granular in capsules in an acute oral toxicity study, which resulted in no mortality and no effect on body weight or feed consumption over 14 days. The acute oral LD_{50} was >2,250 mg/kg-bw (USEPA 2005b). Based on the low avian acute oral toxicity, USEPA (2005b) granted a waiver for freshwater fish, invertebrates, and nontarget insect toxicity data requirements.

9.3 Exposure Assessment and Risk Characterization

9.3.1 Human Health Exposure and Risk Characterization

USEPA (2005b) concluded that applications of products containing oil of black pepper and piperine as the active ingredients according to label instructions would not result in harm to the general population or applicators.

9.3.2 Ecological Exposure and Risk Characterization

USEPA (2005b) concluded oil of black pepper and piperine would not result in a hazard or toxic risk to non-target organisms. The lack of toxicity and the environmental fate properties for oil of black pepper and piperine, WS use patterns, and the product label requirements indicate WS use of registered products containing oil of black pepper and piperine will not harm non-target terrestrial and aquatic species.

10 POLYBUTENE

10.1 Problem Formulation

10.1.1 Chemical Description and Product Use

Polybutene (CAS number 9003-29-6; synonym: polybutene oligomer) is a synthetic, nondrying liquid or gel. Polybutene is a homopolymer (same repeating unit) or oligomer of the monomer butene (CAS Number 106-98-9; C_4H_8), both normal and isobutene (USEPA 2010c). Polybutene is not toxic but repels birds and mammals because of its sticky nature. Polybutene is registered for outdoor terrestrial non-food and residential uses on buildings or adjacent structures (e.g., bridges, overpasses, beams, girders, ledges, windowsills, gutters, trees, shrubs, vines) and for indoor non-food use. Polybutene is used to prevent birds, such as pigeons and starlings, from perching or roosting and to prevent damage to trees by beavers (USEPA 2010c).

Polybutene is the sole active ingredient in 4 the Birds® Bird Repellent (93% w/w USEPA Registration Number 8254-5) and Hot Foot® Bird Repellent (93.5% w/w; USEPA Registration Number 55943-1). These products are tactile repellents labeled to repel pigeons and starlings from roosting or perching. It is also the active ingredient in 4 the Birds® Transparent Bird Repellent

Liquid (40% w/w; USEPA Registration Number 8254-3). This product is labeled to repel birds (e.g., blackbirds, starlings) from roosting or perching on the inside supports of buildings and structures or branches of trees, bushes, and vines adjacent to buildings and structures. The product, 4 the Birds® Transparent Bird Repellent Liquid, may also be used to discourage beavers from damaging trees.

Products containing polybutene in a ready-to-use tube or caulking gun can be applied as a bead strip to surfaces. Liquid product may be applied evenly with a paintbrush or sprayed on with a hand or pressure sprayer (USEPA 1994). All labels emphasize the importance of a clean surface before applying the product. For repelling beaver damage to trees, the product is sprayed or brushed on the lower trunk areas (ground level up to two feet high). WS has not used products containing polybutene between FY11 to FY20 but may do so in the future.

10.1.2 Physical and Chemical Properties

Polybutene (C_8H_{16}) is an oily, odorless, colorless liquid. It is a viscous non-drying liquid at room temperature. The boiling point of polybutene is 160ºC, and it decomposes at higher temperatures (USEPA 1994). Polybutene has a reported vapor pressure of 0.13 mm Hg at 25ºC and an estimated– air-water partition coefficient of 4.88×10^5 atm-m^3/mol. Polybutene has a density of 0.89 g/mL at 37.7ºC. The water solubility of polybutene is <0.1%, negligible. It will float on water. The estimated K_{oc} for polybutene is 2.5×10^9 L/kg (USEPA 2010c).

10.1.3 Environmental Fate

Polybutene is considered to be persistent to abiotic hydrolysis, direct photolysis in water (over the short term), and microbial degradation. It is not sensitive to metals, metal ions, or sunlight. Polybutene will change color, and its viscosity will decrease at elevated temperatures and over extended periods in the presence of oxygen. This photooxidation may generate epoxides, aldehydes, and carboxylic acids of low molecular weight. Breakdown of the polymer from oxidation of the double bond may cause a decrease in viscosity. Polybutene can adsorb strongly to soil or other surfaces (USEPA 1994;2010c).

10.1.4 Hazard Identification

The pesticidal mode of action of polybutene is mechanical in nature, not chemical, relying on an adhesive/sticky surface which, upon contact, discourages animals from roosting, perching, walking, or gnawing on treated surfaces (USEPA 1995;2010c;2014).

Polybutene has relatively low acute toxicity but causes eye irritation (USEPA 1995). Dermal toxicity is not anticipated based on the lack of oral effects and the expectation of low absorption due to the relatively large size of polybutene molecules. Inhalation toxicity is of low concern due to the expectation of limited exposure via this route, lack of toxicity in oral studies, and lung effects in rats only following inhalation exposure at very high exposure concentrations (USEPA 2022g). No food-related uses are registered, so dietary exposure is not of concern.

10.2 Dose-Response Assessment

10.2.1 Human Health Dose-Response

Acute Toxicity

The acute oral LD_{50} in the rat is >5,000 mg/kg-bw (Toxicity Category IV), and the acute dermal LD_{50} is >2,000 mg/kg-bw in the rabbit (Toxicity Categories III) (USEPA 1994;2010c). Polybutene is not irritating to the skin (Toxicity Category IV) but is irritating to the eyes (Toxicity Category II) (USEPA 1995). Polybutene is not a sensitizer. A primary eye irritation study with rabbits resulted in transient corneal opacity and iritis at 24 and 48 hours, with conjunctival irritation through day 10, for washed eyes, or day 14, for unwashed eyes (USEPA 1994) (Table 15).

Table 15 Acute oral median lethality studies for mammals for Polybutene.

Test Species	Test	Result	USEPA Toxicity Category
Rat	Acute Oral LD_{50}	>5,000 mg/kg-bw	IV
Domestic Rabbit	Acute Dermal LD_{50}	>2,000 mg/kg-bw	III
Domestic Rabbit	Primary Eye Irritation	Irritating	II
Domestic Rabbit	Primary Dermal Irritation	No Irritation	IV
Guinea Pig	Dermal Sensitization	Not a Sensitizer	N/A

N/A = Not applicable. Reference: (USEPA 2010c)

Subchronic and Chronic Toxicity

In a non-guideline 90-day oral toxicity study (rat) the NOAEL was 2,500 mg/kg-bw/day (the only dose tested), and the LOAEL was not determined (>2,500 mg/kg-bw/day) (USEPA 2010d). There was no toxicity in males or females (body weight changes, hematological and limited clinical chemistry parameters, organ weights, and histopathology) at 2,500 mg/kg-bw/day.

USEPA (USEPA 2022g) assessed the conclusions of the Final Report on the Safety Assessment of Polybutene by the Cosmetic Ingredient Review (CIR) Scientific Panel in their Final Report on the Safety Assessment of Polybutene (1982). In a two-year oral study (rat), no significant toxicity or increased tumor incidence was observed at doses that tested up to 20,000 mg/kg-bw polybutene in the diet. Beagle dogs administered doses up to 1,000 mg/kg-bw/day for two years also showed no adverse effects.

In a two-week inhalation study, male Wistar rats were exposed to polybutene aerosol (7 hrs/day, 5 days/week) at 0, 0.07, or 0.7 mg/L. At 0.7 mg/L, three mortalities occurred, and pulmonary edema and hyperemia were also observed (USEPA 2010d). These effects were attributed to polybutene's oily, viscous, and water-insoluble physical properties, which may coat or clog airways at high ambient concentrations rather than a systemic effect. No effects were observed at the lowest dose (0.07 mg/L). Additional inhalation data were not required since effects were only observed at the highest concentration, and inhalation exposure to polybutene from current uses is expected to be minimal (USEPA 2022g).

Developmental and Reproductive Toxicity, Neurotoxicity Effects, Carcinogenicity and Mutagenicity, Immunotoxicity Effects

No target organs were identified following oral exposure to polybutene. Several oral studies, including subchronic rat, chronic dog, rat reproduction, and developmental toxicity studies, were reviewed by the CIR Scientific Panel (1982) and found no toxic doses at or above the limit dose (USEPA 2022g). Oral dietary exposure to rats (30/sex/dose) of polybutene at 0, 200, 4,000, or 20,000 mg/kg-bw showed no effects except for possible treatment-related mortality in males at the limit dose of 20,000 mg/kg-bw. No other findings were reported, and no toxicity was observed in females. The published study evaluating developmental toxicity of polybutene reported no reproductive or offspring toxicity in rats exposed to 20,000 mg/kg-bw in the diet (USEPA 2022g).

There was no evidence of immunotoxicity, carcinogenicity, or mutagenicity for polybutene (USEPA 2022g).

Endocrine Effects

USEPA exempted polybutene from the requirement for Endocrine Disruptor Screening due to polybutene being an insoluble organic polymer with a molecular weight >1,000 Daltons that is highly stable. Polybutene is not anticipated to produce in humans or any other organism an effect similar to that produced by a naturally occurring estrogen, androgen, or thyroid hormone (USEPA 2014).

10.2.2 Ecological Effects Dose-Response

Aquatic Effects Analysis

Due to the insolubility of polybutene, USEPA waived the requirements for freshwater fish and aquatic invertebrate toxicity studies (USEPA 2010c).

Terrestrial Effects Analysis

Polybutene is practically non-toxic to mammals and birds from acute exposures (Table 16) (USEPA 2010c). Birds are surrogates for reptiles and terrestrial-phase amphibians; therefore, polybutene is likely practically non-toxic to reptiles and terrestrial-phase amphibians. Small birds contacting the sticky material may become entrapped, or their feathers coated with gel, making them unable to fly. An entrapped bird or bird coated with polybutene gel may result in fatality (USEPA 2010c).

Table 16 Acute oral median lethality and subacute dietary toxicity studies for mammals and birds for polybutene.

Test species	Test	Result
Brown Rat (lab)	Acute oral LD_{50}	>5,000 mg/kg-bw/day
Bobwhite Quail	Acute oral LD_{50}	>2,150 mg/kg-bw/day
	Subacute dietary LC_{50}	>5,000 mg/kg-bw/day

Reference: (USEPA 2010c)

10.3 Exposure Assessment and Risk Characterization

10.3.1 Human Health Exposure and Risk Characterization

Exposure to polybutene through dietary exposure is unlikely. Polybutene products have no labeled agricultural uses or other uses that may expose food materials to polybutene residues. Polybutene is a sticky, water-insoluble substance that remains on the treated surface. Based on existing use patterns, contamination of surface or groundwater sources of drinking water from outdoor use is unlikely (USEPA 2022g). Polybutene products are not highly volatile. Dermal exposure may occur from the use of the gel or liquid products; inhalation exposure may also occur from spray application of the liquid product. Inhalation exposure is not of concern because the registered formulations are either gels or water-based liquids (USEPA 2010c). Inhalation exposure from the gel formulation is not of concern due to the use pattern and application method (paintbrush and caulking gun) (USEPA 2022g). WS does not anticipate exposure to the general public. The 4 the Birds® Bird Repellent label requires occupational workers to wear protective eyewear such as goggles or a face shield and to avoid contact with skin. As such, WS expects minimal dermal, inhalation, and eye exposure of workers to polybutene.

USEPA (2022g) concluded that no risks to human health are expected from the use of polybutenes based on their low toxicity, environmental fate properties, and low exposure potential. WS has not used polybutene products recently; however, this does not indicate future use patterns. Should WS increase its use of polybutene, this assessment's exposure and risk conclusions would remain the same.

10.3.2 Ecological Exposure and Risk Characterization

Polybutene contamination of water bodies is not expected to occur due to the use sites and the sticky composition and insolubility of the end-use materials. Therefore, there is no undue risk to aquatic animals anticipated from the registered uses of polybutene (USEPA 1994).

Applications of products containing polybutene may expose nontarget birds, mammals, reptiles, and the terrestrial stages of amphibians in the treatment area. Based on the nature of the test material, toxic exposure is not likely. However, small birds contacting the sticky material may be temporarily trapped, and their feathers coated with gel, rendering them unable to fly. USEPA (USEPA 1994) has some data indicating that such incidents occasionally occur. These incidents can be fatal for some small birds, but such incidents generally only involve one or several individuals (USEPA 1994). Because use sites are principally urban commercial and industrial buildings where small legally protected bird species are unlikely to be prevalent, the risk to most nontarget birds is alleviated (USEPA 1994). USEPA (2022g) reviewed the OPP IDS (2017-2022) and found 11 incidents involving polybutene resins classified as minor severity. USEPA (2022g) also reviewed the CDC and Prevention/National Institute for Occupational Safety and Health Sentinel Event Notification System for Occupational Risk-Pesticides (SENSOR; 2010-2017) databases and did not find reported incidents involving polybutene. In 2009, the USEPA (2010c) reviewed the Environmental Fate and Effects Division’s Environmental Incident Information System and found an incident involving 30–80 cedar waxwings. At least one waxwing was incapacitated, and at least one waxwing was killed from the use of a polybutene product in a building. Polybutene’s environmental fate properties, label requirements, the proposed WS use pattern, and the favorable toxicity data indicate negligible risk to non-target terrestrial and aquatic species with the exception of non-target migratory birds. WS adherence to the application of polybutene products according to label directions will minimize risk to non-target birds.

11 SULFUR

11.1 Problem Formulation

11.1.1 Chemical Description and Product Use

Sulfur (CAS number 7704-34-9; synonym: elemental sulfur) is naturally occurring in the environment (USEPA 1991). Sulfur is a pesticide active ingredient in several miticides, insecticides, fungicides, and fumigant rodenticides and is used as fertilizer (USEPA 1991;2013c). Sulfur is also a pesticide active ingredient in a rodent and snake repellent (granular formulation, 28% w/w sulfur) used by WS with the product name Snake-A-Way® Snake Repelling Granules (USEPA Registration Number 58630-1), which also contains 7% w/w naphthalene (naphthalene is covered in Section 8). The odor of volatile sulfur compounds has been shown to repel herbivorous mammals like rodents (Nolte et al. 1994).

WS infrequently uses Snake-A-Way® Snake Repelling Granules (USEPA Registration Number 58630-1) to repel certain snake species at outdoor use sites listed on the label (Table 3). The Snake-A-Way® Snake Repelling Granules label identifies rattlesnakes (Genus *Crotalus*) and garter snakes (Genus *Thamnophis*) as target pest species to repel from residential dwellings, garages, barns, trailers, utility houses, woodpiles, trash cans, and flower beds. The label allows for use around the perimeter of flower gardens. The product may not be used at sites where snakes are believed to be already present. The label does not allow for use in gardens or fields of crops grown for food or feed; however, sulfur is exempt from the requirement for a tolerance (40 CFR 180.1246). The label does not allow applications near streams, ponds, pools, or water supplies or directly to water, including areas where surface water is present or intertidal areas below the mean high-water mark.

Applications are made by hand in bands surrounding the area to be protected. Bands 4 to 5 inches in width are used for garter snakes, and bands 8 to 12 inches in width for rattlesnakes. The product is lightly sprinkled over the area within the treatment band. The label does not indicate an application rate. During the registration review for naphthalene, USEPA (USEPA 2018b) determined that a high application rate for outdoor use of this repellent product was 10.8 lb a.i./acre based on information provided by the registrant (USEPA 2018b). Retreatment is recommended when the odor fades in seasons when the snakes are active.

11.1.2 Physical and Chemical Properties

There are many allotropes of sulfur, including rhombic or alpha S_8, in the environment (USEPA 2013b). Sulfur is an odorless, tasteless, yellow crystalline solid (USEPA 2013b). Sulfur has a melting point of 112.8–120ºC, a boiling point of 444.6ºC, a vapor pressure of 3.95×10^{-6} mm Hg at 30.4ºC, and an air-water partition coefficient of 3.95×10^{-6} mm Hg at 30.4ºC (USEPA 2013b). Sulfur is largely insoluble in water at 1.9×10^{-8} mol S_8/L or 4.87 parts per billion (USEPA 2013b).

11.1.3 Environmental Fate

USEPA (2013c) waived the environmental fate data requirements for sulfur because sulfur is ubiquitous and naturally occurs in water and soil (USEPA 1991). When applied to the environment, sulfur rapidly enters the natural environmental sulfur cycle (Komarnisky et al. 2003, USEPA 2013b). In this cycle, sulfur oxidizes into sulfate (SO_4^{2-}, under aerobic [oxic or suboxic]

conditions) and reduces into sulfide (S^{2-}, under anaerobic [anoxic] conditions), mainly mediated by microbes (USEPA 2013b). The subsequent fate of sulfide depends on metal sulfide precipitation or volatilization to hydrogen sulfide (H_2S; gas) (USEPA 2013b). The dissipation of sulfate is dependent on leaching and soil organic matter immobilization (USEPA 2013b).

11.1.4 Hazard Identification

Sulfur can cause skin and eye irritation (USEPA 2013c). The number and severity of human health adverse incidents are relatively low and are mainly due to the irritating properties of sulfur (USEPA 2013c). Chronic (lifelong) exposure to sulfur dust, as occurs for mineworkers, showed ocular disturbances, chronic bronchitis, and respiratory and sinus effects (USEPA 1991).

11.2 Dose-Response Assessment

11.2.1 Human Health Dose-Response

Acute Toxicity

Sulfur has very low acute oral toxicity and is Toxicity Category IV with an acute oral LD_{50} >5,000 mg/kg (USEPA 2013c). The acute dermal and inhalation toxicity for sulfur are Toxicity Category III (USEPA 2013c). The dermal LD_{50} is >2,000 mg/kg-bw in rats (USEPA 2013c). The acute inhalation toxicity is >2.56 mg/L for a 4-hour exposure (USEPA 2013c). Sulfur can cause skin (moderate erythema and slight edema) and eye irritation and is Toxicity Category III for both (USEPA 2013c). Sulfur is not a sensitizer (USEPA 2013c).

Subchronic and Chronic Toxicity, Developmental Toxicity, Mutagenicity, Immunotoxicity

Chronic exposure to sulfur is the natural state for all living organisms since sulfur is ubiquitous in the environment, and most aquatic and terrestrial environments are high in sulfur (USEPA 1991). Therefore, USEPA has waived the subchronic and chronic oral exposure data requirements for sulfur during registration and registration review (USEPA 2013c).

In one 28-day dermal toxicity study, the only finding was an increased incidence of hyperkeratosis in both sexes at 1,000 mg/kg-bw/day, the highest dose level tested (USEPA 2013c).

There are no known risks of oncogenic, teratogenic, or reproductive hazards associated with sulfur, and metabolites are well known to be intermediary or end products of mammalian metabolic reactions (USEPA 1991;2013c).

Sulfur is not carcinogenic, genotoxic in bacteria and mammalian cells, or mutagenic to microorganisms (USEPA 1991;2013c).

11.2.2 Ecological Effects Dose-Response

Aquatic Effects Analysis

Available toxicity data submitted to USEPA and from the open literature indicates that sulfur is practically nontoxic to freshwater fish, freshwater aquatic invertebrates, and aquatic-phase amphibians on an acute basis (Table 17) (USEPA 2013b). The 96-hour LC_{50} values for two fish species, bluegill sunfish (*Lepomis macrochirus*) and rainbow trout (*Oncorhynchus mykiss*), were

greater than 180 mg/L (USEPA 2013b). The 48-hour LC_{50} for the water flea (*Daphnia magna*) was greater than 5,000 mg/L, and the 96-hour LC_{50} for mysid shrimp (*Americamysis bahia*) was greater than 736 mg/L (USEPA 2013b).

Table 17 Acute and chronic toxicity to aquatic vertebrates and invertebrates for sulfur.

Taxonomic group	Test species	Test	Result (mg/L)[1]	Reference
Freshwater Fish	Bluegill Sunfish (*Lepomis macrochirus*)	96-hr LC_{50}	>180	(USEPA 2013b)
	Rainbow Trout (*Oncorhynchus mykiss*)	96-hr LC_{50}	>180	(USEPA 2013b)
	Western Mosquitofish (*Gambusia affinis*)	Acute LC_{50}	>10,000	(USEPA 2013b)
Aquatic Invertebrates	Water Flea (*Daphnia magna*)	48-hr LC_{50}	>5,000	(USEPA 2013b)
	Mayfly (*Cloeon dipterum*)	Acute LC_{50}	>40	(USEPA 2013b)
	Mysid Shrimp (*Americamysis bahia*)	96-hr LC_{50}	736	(USEPA 2013b)
	Eastern Oyster (*Crassostrea virginica*)	96-hr EC_{50}	736	(USEPA 2013b)
Amphibians	Bog Frog (*Rana limnocharis*)	LC_{50}	2,560	(USEPA 2013b)

[1] Concentrations greatly exceeded sulfur's solubility in water. The sulfur was primarily in suspension (particulate sulfur; some precipitates were documented) or was lost via volatilization as hydrogen sulfide (H_2S) (USEPA 2013b).

Terrestrial Effects Analysis

Sulfur is practically nontoxic to mammals and birds and, by extension, to reptiles and terrestrial-phase amphibians (USEPA 2013b). Sulfur had an oral LD_{50} of greater than 5,000 mg/kg-bw for rats (USEPA 2013b). In an 8-day dietary study in bobwhite quail (*Colinus virginianus*), the LC_{50} was >5,620 mg/kg-diet (USEPA 2013b).

Sulfur is practically nontoxic to honey bees on an acute oral and contact basis (USEPA 2013b). Toxicity data are not available for terrestrial plants and were waived during registration and registration review (USEPA 2013b).

11.3 Exposure Assessment and Risk Characterization

11.3.1 Human Health Exposure and Risk Characterization

The annual amount of sulfur that WS uses in its animal damage management program is limited (Table 3). Between FY16 and FY20, WS only used an average of 0.2 pounds of the product containing the active ingredients sulfur and naphthalene per year to repel rattlesnakes (Table 3). WS applicators adhere to label requirements, which include not applying the product to water or areas where surface water is present or intertidal areas below the mean high-water mark.

The currently-registered repellent product containing sulfur and naphthalene is not registered for food uses or use on agricultural crops, and dietary exposure from food is not expected. When used outdoors as an animal repellent, the migration of sulfur to water resources (drinking water) is not expected due to sulfur being practically insoluble and rapidly entering the environmental sulfur cycle, the label's use restrictions, and WS's low usage of the product.

The sulfur in the repellent product could potentially irritate airway passages and eyes if applicators were accidentally exposed. WS's care in the selection of use sites minimizes any risks to the public, particularly small children, who may be at risk from accidental exposure. Adherence to label requirements regarding PPE minimizes risk to WS workers who apply chemical repellents.

Any exposure and risk would be short-term based on the methods for application and the low frequency of use as a chemical repellent by WS.

11.3.2 Ecological Exposure and Risk Characterization

Once released, sulfur is rapidly incorporated into the environmental sulfur cycle (USEPA 2013b). Sulfur is practically insoluble in water. Therefore, minimal exposure is expected to aquatic species from any runoff (USEPA 2013b). Even if exposure occurs, sulfur is practically non-toxic to aquatic species (USEPA 2013b).

Some terrestrial plant species may be adversely affected by registered sulfur applications. As of 2013, there were only 5 ecological incident reports involving terrestrial plants in the Ecological Incident Information System (EIIS) for sulfur (USEPA 2013b). However, all 5 occurred between 1999 and 2001, and USEPA rated only one as "probable" (USEPA 2013b).

Ingestion by non-target terrestrial vertebrate and invertebrate species visiting the outdoor use sites is possible following applications of repellent products containing sulfur, but sulfur likely does not pose a toxicological concern to non-target species (USEPA 2013b). No ecological incidents are reported for any other terrestrial species despite sulfur's extensive use in various pesticide products (USEPA 2013b). However, USEPA (2018b) did review the EIIS for naphthalene incidents through May 2018. Between 2008 and 2017, there were 3 separate incidents where 4 dogs died, and 1 dog had diarrhea after likely ingesting Snake-A-Way® Snake Repelling Granules, which contains both naphthalene and sulfur, applied in outdoor use sites. Based on these reported adverse incidents and the acute oral LD_{50} values for naphthalene and sulfur, these deaths were attributed to naphthalene rather than sulfur exposure (USEPA 2018b).

Label use requirements and the low application frequency indicate WS usage of sulfur as a repellent would have minimal to no impact on non-target species. Even if WS's usage of sulfur increase significantly, WS applications of sulfur are unlikely to have adverse impacts on non-target species.

12 THIRAM

12.1 Problem Formulation

12.1.1 Chemical Description and Product Use

Thiram (CAS number 137-26-8; synonyms: tetramethylthiuram disulfide and tetramethylthioperoxydicarbonic diamide) is a dimethyl dithiocarbonate compound primarily used as a food-use and non-food use fungicide with broad-spectrum antimicrobial properties (USEPA 2020e). Thiram products are commonly used as a foliar spray on strawberries and peaches to control fungal pests and as a seed treatment to protect against fungal damage to seeds of a variety of food crop groups (Liu et al. 2022, USEPA 2021b). Thiram products are also registered as fungicidal foliar treatments for commercial coniferous, evergreen, and softwood trees, dip treatments for ornamental bulbs and roots, and seed treatments for flowering and non-flowering ornamental seeds (USEPA 2021b). In higher concentrations, thiram is also registered as a taste repellent applied directly to vegetation to repel rabbits, rodents, and deer. A tolerance or tolerance exemption is not required for these uses. Taste repellents deter rodents and rabbits from

damaging trunks of trees/saplings and deter deer and elk from inhabiting airport property by rendering forage plants unpalatable.

In 2021, USEPA proposed canceling all non-seed treatment and repellent uses of thiram in their proposed interim registration review decision due to unreasonable human and ecological risks outweighing the benefits (USEPA 2021b). Their final interim decision had not yet been finalized as of March 2023.

In the future, WS may utilize registered thiram concentrate products, such as DeerPro® Winter Animal Repellent (25.8% thiram; USEPA Registration Number 84178-1) or Defiant Turf Fungicide and Animal Repellent (75% thiram; USEPA Registration Number 45728-21), at non-food use sites, including airport runways, trees, vines, and shrubs, to prevent rabbit, deer, and rodent depredation. However, USEPA (USEPA 2021b) proposed the future cancellation of soluble concentrate and liquid formulations, including DeerPro® Winter Animal Repellent, but this product had not yet been canceled as of March 2023. In 2021, USEPA indicated that water-dispersible granular repellent formulations like Defiant Turf Fungicide and Animal Repellent could remain registered, but with some additional label revisions, such as limiting the allowed application methods for repellents containing thiram to spray applications that use a manually pressurized hand wand (USEPA 2021b).

12.1.2 Physical and Chemical Properties

Thiram ($C_6H_{12}N_2S_4$) is a dimethyl dithiocarbamate, solid and crystalline at room temperature, with a melting point of 142–150ºC. Thiram has a density of 0.32–0.35 g/mL, octanol/water partition coefficient of 39.5–54.2, a vapor pressure of 1.6–1.8 x 10^{-5} mm Hg at 25ºC and is slightly soluble in water (0.00165 g/100 mL) (USEPA 2021b).

12.1.3 Environmental Fate

Thiram is of low to moderate persistence in soil and water. It is only slightly soluble in water (30 mg/L) and has a strong tendency to adsorb to soil particles, and thus is not expected to contaminate groundwater. Thiram has a soil half-life of 15 days and degrades more readily in acidic soils and soils high in organic matter. Thiram has been shown to persist for up to 2 months in sandy soil but disappeared within one week from compost soil (USEPA 2020g). The major metabolites of thiram in soil are copper dimethyl dithiocarbamate, dithiocarbamate, dimethylamine, and carbon disulfide. In soil, thiram can be degraded by microbial action or hydrolysis under acidic conditions. Thiram is rapidly broken down in water by hydrolysis and photodegradation, especially under acidic conditions (Lazo and Miller 2014). Thiram's mobility class is slightly mobile to hardly mobile (K_{oc} = 2,245 to 24,526 mL/g_{oc} in 4 soils). Therefore, leaching to groundwater should be minimal. However, thiram has the potential to reach surface water through runoff via erosion or spray drift (USEPA 2020g).

12.1.4 Hazard Identification

Thiram is rapidly absorbed, distributed, extensively metabolized, and excreted primarily via expired air and urine in laboratory rats with no major differences between sexes (USEPA 2020e). In a metabolism and pharmacokinetics study in rats, expired air, urine, and feces account for 47–48%, 33–35%, and 3–5% of the administered dose exposures. Urine analysis 24 hours post-exposure detected no parent compound and five by-products of thiram metabolism. Expired air

contained radio-labeled carbon dioxide, carbamyl sulfide, and carbon disulfide. Bioaccumulation of thiram is low (2–4%) after a single dose, and 2–3% is recovered from tissues at 4 days post-dosing after repeated doses (USEPA 2020e).

Repeated oral exposure to thiram causes toxicity in the liver (bile duct hyperplasia) in dogs and rats, toxicity to blood (anemia) in mice and rats, and toxicity to the eyes and urinary tract in mice (USEPA 2020e). There are no carcinogenicity or mutagenic/genotoxic risks from thiram exposures (USEPA 2020e). Subchronic inhalation exposures to thiram can cause neurotoxic effects, adverse effects on the thymus, olfactory epithelial degeneration in the nasal passage, and hyperplasia of the larynx (USEPA 2020e). Subchronic dermal exposures may also cause toxicity to the liver (USEPA 2020e).

From January 1, 2010, to December 30, 2014, no human adverse effects incidents were reported in the main OPP Incident Data System (IDS) (USEPA 2015d). However, there were 28 minor incidents reported in the aggregate IDS during that period. USEPA (2015d) also reported that the SENSOR-Pesticides injury database documented 14 cases that involved thiram between 1998–2011 and 9 cases involving only thiram, with 8 of the 9 cases being work-related. USEPA also summarized that eight cases were low in severity, and one was moderate in severity, with dermal symptoms reported in five cases and respiratory irritation reported in four cases.

According to the USEPA (2015d), from 2010 to 2014, 1 incident was reported to National Pesticide Information Center (NPIC) involving thiram. The USEPA summarized the incident involved a 45-year-old male that sold vegetable seeds. He was handling seeds treated with a fungicide containing thiram and did not wear PPE. He developed a rash on both his hands and feet. This incident was classified with a certainty index of possible and a severity of moderate (USEPA 2015d).

USEPA (2021b) updated this review, and from January 1, 2015, to February 5, 2020, there was 1 incident in IDS involving just thiram and 14 incidents reported to Aggregate IDS with low severity (USEPA 2020e;2021b). In SENSOR-Pesticides, there were 6 cases of low severity involving thiram between 2012 and 2015 (USEPA 2021b).

12.2 Dose-Response Assessment

12.2.1 Human Health Dose-Response

Acute Toxicity

Thiram falls into Category III for acute oral toxicity, with an LD_{50} of 3,713 mg/kg-bw in male rats, 1,778 mg/kg-bw in female rats, and 2,638 mg/kg-bw combined (USEPA 2020e). Thiram has an acute dermal LD_{50} of >2,000 mg/kg-bw (Category III) and an acute inhalation LC_{50} of >2.06 mg/L (Category IV) (USEPA 2020e). Thiram causes eye irritation (reversible redness, chemosis, and iritis; Category II-III) and is slightly irritating to the skin (Category IV) (USEPA 2020e). Thiram is a moderate skin sensitizer (USEPA 2020e).

Subchronic and Chronic Toxicity

In a 90-day oral toxicity study in rats, the NOAEL could not be verified (no stability data for the test substance), and the LOAEL was 25 mg/kg-bw/day, based on decreases in body weights, hematology, and adverse changes to clinical chemistry (USEPA 2020e). In a 90-day oral toxicity study in dogs, the NOAEL was 1.9 mg/kg-bw/day, and the LOAEL was 6.3 mg/kg-bw/day, based on adverse changes to clinical chemistry, and decreases in body weights and food consumption (USEPA 2020e).

In a combined dietary chronic toxicity/carcinogenicity study, the NOAELs for rats (male/female or M/F) were 1.5/1.8 mg/kg-bw/day and the LOAELs were 7.3/8.9 mg/kg-bw/day, based on changes in hematology, adverse changes to clinical chemistry, and bile duct hyperplasia (USEPA 2020e).

In a 21-day dermal toxicity study in rabbits, the systemic NOAEL was 300 mg/kg-bw/day, and the LOAEL was 1,000 mg/kg-bw/day, based on decreases in body weights and food consumption, and adverse changes in clinical chemistry (USEPA 2020e). The dermal NOAEL was not determined, and the LOAEL was 100 mg/kg-bw/day, based on microscopic dermal lesions.

In a 28-day inhalation study in rats, the systemic NOAEC was 0.012 mg/L/day and the LOAEC was 0.025 mg/L/day, based on decreased locomotor activities in males, decreased thymus weights and histopathologic changes in the thymus in females (USEPA 2020e). The inhalation NOAEC and LOAEC were the same, based upon degeneration of olfactory epithelium and hyperplasia in the larynx in both sexes (USEPA 2020g).

Developmental and Reproductive Toxicity

In a prenatal developmental study in rats, the maternal NOAEL was 15 mg/kg-bw/day, and the LOAEL was 30 mg/kg-bw/day, based on decreased body weights and placental weights (USEPA 2020e). The developmental NOAEL was 15 mg/kg-bw/day, and the LOAEL was 30 mg/kg-bw/day, based on decreased fetal body weights. In a prenatal developmental study in rabbits, the maternal and developmental NOAELs were 10 mg/kg-bw/day, and the LOAELs were not determined (USEPA 2020e).

In a two-generation reproduction and fertility effects study in rats, the parental NOAEL was 5 mg/kg-bw/day, and the LOAEL was 14 mg/kg-bw/day, based on decreased body weights during gestation and lactation in F_0 and F_1 generations and pre-mating in F_1 males and females (USEPA 2020e). The offspring NOAEL was 2 mg/kg-bw/day, and LOAEL was 5 mg/kg-bw/day for rats, based on decreased body weights in the F_1 and F_2 generation offspring. The reproductive NOAEL was >12.2 mg/kg-bw/day, and the LOAEL was not determined.

In a developmental neurotoxicity study in rats, the maternal NOAEL was 3.7 mg/kg-bw/day, and the LOAEL was 7.2 mg/kg-bw, based on decreased body weight, food consumption, palpebral, tremors, cold to touch, and drooping eyes (USEPA 2020e). The offspring NOAEL was 1.4 mg/kg-bw/day, and the LOAEL was 3.7 mg/kg-bw/day based on increased locomotor activity in females on post-natal day 17.

Neurotoxicity Effects

Thiram appears to cause neurotoxic effects at high dose levels. In an oral acute neurotoxicity screening battery study in rats, the NOAEL for neurotoxicity was 5 mg/kg-bw, and the LOAEL was 150 mg/kg-bw, based on reduced motor activity at 3.5 hours and 7 and 14 days post-dosing (USEPA 2020e). USEPA (2020e) conducted a benchmark dose (BMD) analysis, and the benchmark dose level of one standard deviation (BMDL1SD) from 56 mg/kg-bw was 24 mg/kg-bw (USEPA 2020g).

As described in the previous section, a developmental neurotoxicity study in rats found increased locomotor activity in female offspring on post-natal day 17 at the LOAEL of 3.7 mg/kg-bw/day (NOAEL = 1.4 mg/kg-bw/day) (USEPA 2020e).

Carcinogenicity and Mutagenicity

The EPA classifies thiram as “not likely to be carcinogenic to humans” based on studies showing no evidence of carcinogenicity in rat and mouse carcinogenicity studies (dietary exposure) (USEPA 2020e). The NOAELs for mice (M/F) were 2.5/3.1 mg/kg-bw/day, and the LOAELs were 24/57 mg/kg-bw/day, based on changes in mean body weights (gains and losses), anemia, and non-neoplastic lesions in the eyes, non-glandular stomach, and urinary bladder. The NOAELs for rats (M/F) were 1.5/1.8 mg/kg-bw/day, and the LOAELs were 7.3/8.9 mg/kg-bw/day, based on changes in hematology, clinical chemistry, and bile duct hyperplasia.

Additionally, thiram is not considered to be mutagenic/genotoxic as it did not induce DNA repair in rat hepatocytes or cause a significant increase in the frequency of micronucleated polychromatic erythrocytes (USEPA 2015d). The EPA has also not commissioned a Cancer Assessment Review Committee report for thiram. The EPA Hazard Identification Assessment Review Committee, in a 1999 report, identified thiram as a clastogenic agent due to experimental observations of cell growth progression disturbances at 2.4 µg/mL. The EPA states that “thiram was shown to act as a clastogen probably during the S-phase (one of the most tightly regulated cell transition points), strongly suggesting that cells will not progress to the next phase of the cell cycle and will, therefore, not proliferate” (USEPA 2020e).

Immunotoxicity Effects

In an immunotoxicity study in mice, the systemic NOAEL was 74 mg/kg-bw/day, and the LOAEL was not determined (USEPA 2020e). The immunotoxicity NOAEL was 25 mg/kg-bw/day, and the LOAEL was 74 mg/kg-bw/day, based on decreases in anti-sheep red blood cells (SRBC) antibody responses (USEPA 2020e).

Endocrine Effects

Like many mammals, including human females, rodents undergo spontaneous ovulation mediated by norepinephrine hypothalamic control of the pituitary gland. Thiram, like other dithiocarbonates, is known to inhibit dopamine-β-hydroxylase (DBH) activity and decrease hypothalamic norepinephrine synthesis by blocking its conversation from dopamine. An interruption of dopamine conversion reduces gonadotropin-releasing hormone and the subsequent neuronal activation of luteinizing hormone (LH). It has been observed in rodent

models that when a luteinizing hormone surge is blocked by thiram exposure as low as 12 mg/kg-bw administered during the proestrus period of the estrus cycle, then ovulation will be delayed by 24 hours. A reduction in litter size was observed when rats were permitted to mate under these conditions. Rats exposed to thiram during the critical proestrus period exhibited decreased numbers of fertilized oocytes, a 10-fold increase in the number of supernumerary sperm in the perivitelline space (Farmer and Stoker 2018, Stoker et al. 2003), and polyspermic zygotes (Austin and Braden 1953). USEPA has not yet assessed thiram under their Endocrine Disruptor Screening Program (USEPA 2020e).

12.2.2 Ecological Effects Dose-Response

Aquatic Effects Analysis

Thiram is very highly toxic to freshwater and estuarine/marine invertebrates (Table 17) (USEPA 2020g). The freshwater water flea (*Daphnia magna*) was observed to have a significant ($p<0.05$) 19% reduction in dry weight at a chronic thiram exposure level of 0.040 mg/L and signs of toxicity, including lethargy, pale coloration, and diminutive size from thiram a.i. levels of 0.040 and 0.081 mg/L. Mortality was 100% at the highest treatment level (0.081 mg/L) (USEPA 2020g). Thiram was very highly toxic to Pacific oyster (*Crassostrea gigas*) larvae based on increased abnormal development (USEPA 2020h). The 48-hr EC_{50} was approximately 0.0047 mg/L (there were uncertainties in the actual exposure concentrations). Thiram was very highly toxic to mysid shrimp (*Americamysis bahia*), with a 96-hr LC_{50} of approximately 0.00336 mg/L (there were uncertainties in the actual exposure concentrations) (USEPA 2020a).

Thiram is high to very highly toxic to freshwater and marine/estuarine fish on an acute and chronic basis (USEPA 2020g). The most sensitive fish species for thiram is the Harlequin fish (*Rasbora heteromorpha*), with an LC_{50} of 0.007 mg/L for a typical end-use product containing 80% thiram (USEPA 2020g). The most sensitive warm-water fish is the bluegill sunfish (*Lepomis macrochirus*), with an observed LC_{50} of 0.042 mg/L, and the most sensitive cold-water fish is the rainbow trout (*Oncorhynchus mykiss*), with an observed LC_{50} of 0.046 mg/L (USEPA 2020g).

In a chronic thiram exposure life-cycle study, the freshwater fathead minnow (*Pimephales promelas*) had significant ($p<0.05$) reductions in spawning frequency (69.5%), egg production (76.0%), and 4-week survival (24%) at the LOAEC (0.0022 mg/L, NOAEC was 0.0011 mg/L) also, time to hatch was delayed by up to 2 days. USEPA determined this critical effect to be the most sensitive freshwater fish chronic endpoint (USEPA 2020g).

For estuarine/marine fish, thiram is observed to be highly toxic to sheepshead minnow (*Cyprinodon variegatus*) with an observed acute LC_{50} of 0.540 mg/L. The sheepshead minnow exposed to thiram for a 28-day early life-stage study had significant ($p<0.05$) 4.6% and 12% reductions, relative to controls, in length and dry weight from exposure to 0.0020 mg/L (NOAEC was 0.00093 mg/L) (USEPA 2020g).

Thiram is phytotoxic to aquatic plants. For the vascular aquatic plant duckweed (*Lemna gibba*), the IC_{50} was 1.6 mg/L, but the NOAEC was <0.0574 mg/L based on decreased frond numbers (USEPA 2020g). For a typical end-use product (71% thiram, the 96-hr NOAEC was 0.0010 mg/L, and the IC_{50} was 0.0013 mg/L for the most sensitive endpoint (area under the curve) for the marine

algae (diatom) *Skeletonema costatum* (USEPA 2020b). For the non-vascular freshwater algae (diatom) *Navicula pelliculosa* for a typical end-use product containing 71% thiram, the 96-hr NOAEC was 0.00026 mg/L, and the LC_{50} was 0.00058 mg/L for the most sensitive endpoint (yield) (USEPA 2020c).

Table 18 Acute and chronic toxicity to aquatic vertebrates and invertebrates for thiram.

Taxonomic group	Test species	Test	Result (mg/L)	Reference
Freshwater Fish	Bluegill Sunfish (*Lepomis macrochirus*)	96-hr LC_{50}	0.042	(McCann 1968) (USEPA 2020g)
	Rainbow Trout (*Oncorhynchus mykiss*)	96-hr LC_{50}	0.046	(USEPA 2020g)
	Fathead Minnow (*Pimephales promelas*)	210-day NOAEC LOAEC	0.0011 0.0022	(USEPA 2020g)
Marine/Estuarine Fish	Sheepshead Minnow (*Cyprinodon variegatus*)	96-hr LC_{50}	0.540	(Croudace et al. 1992, USEPA 2020g)
	Sheepshead Minnow	34-day NOAEC LOAEC	0.00093 0.0020	(USEPA 2020g)
Aquatic Invertebrates	Water Flea (*Daphnia magna*)	48-hr EC_{50}	0.210	(Husson 1986)
	Water Flea	21-day NOAEC LOAEC	0.020 0.040	(USEPA 2020g)
	Mysid Shrimp (*Americamysis bahia*)	96-hr LC_{50}	~0.00336 (95% C.I. 0.0023–0.0040)	(Thompson et al. 1992b) (USEPA 2020a)
	Pacific Oyster (*Crassostrea gigas*)	48-hr EC_{50}	~0.0047 (95% C.I. 0.0042–0.0053)	(Thompson et al. 1992a) (USEPA 2020h)

95% C.I. = 95% confidence interval

Terrestrial Effects Analysis

Thiram is practically non-toxic to adult honey bees on an acute oral and contact and chronic oral basis. Thiram has an acute oral LD_{50} of >106 µg/bee, and contact LD_{50} of 73.7 µg/bee in honey bees, and a chronic oral 10-day NOAEL and LOAEL of >4.32 µg/bee/day (Atkins and Anderson 1967, USEPA 2020g). However, thiram was observed to be highly toxic to honey bee larvae on an acute dietary basis, with an observed larval acute oral LD_{50} of 0.28 µg/larvae and NOAEL of 0.090 µg/larvae (USEPA 2020g). Thiram is also highly toxic to honey bee larvae on a repeated dose dietary basis (22-day test), with a NOAEL of 0.0254 µg/larvae/day, LOAEL of 0.0757 µg/larvae/day, and an ED_{50} of 0.0872 µg/larva/day (USEPA 2020d;g).

Thiram is slightly to moderately toxic to birds on an acute basis, with the ring-neck pheasant as the most sensitive bird species tested (Table 18) (USEPA 2020g). The most sensitive avian chronic endpoint was in mallard ducks (USEPA 2020g). A NOAEC and LOAEC of 9.6 and 39.7 mg/kg-diet were determined based on significant reductions in egg sets (35%), viable embryos (46%), live 3-week embryos (46%), normal hatchlings (56%), 14-day survivors (56%), eggs

set/eggs laid (11%), normal hatchlings/live 3-week embryos (22%), and normal hatchlings/eggs laid (26%) (Gallagher et al. 2001, USEPA 2020g).

Thiram is categorized as slightly toxic to mammals based on a combined acute oral LD_{50} of 2,638 mg/kg-bw in rats (USEPA 2020e). Studies conducted in wild mammals (mink and ferret) resulted in a dietary LOAEL of 45 and 8 mg/kg, respectively (NOAEL could not be determined), with a critical effect of a decrease in hematocrit (Hornshaw et al. 1983). A large set of acute, chronic, subchronic, and two-generation reproduction and fertility effects dietary studies with laboratory rodents and dogs are available for thiram and are described above in Section 12.2.1.

Thiram does not appear to be toxic to most terrestrial plants up to at least 4.1 lb/acre (USEPA 2020g).

Table 19 Acute oral median lethality and subacute dietary toxicity studies for mammals and birds for thiram.

Test species	Test	Result	Reference
Brown Rat (lab)	Acute oral LD_{50}	3,713 mg/kg-bw males 1,778 mg/kg-bw females 2,638 mg/kg-bw combined	(USEPA 2020e)
Domestic dog	90-day oral NOAEL LOAEL	1.9 mg/kg-bw/day 6.3 mg/kg-bw/day	(USEPA 2020e)
Mallard Duck	LD_{50}	>2,800 mg/kg-bw	(Hudson et al. 1984)
Red-winged Blackbird	Acute oral LD_{50}	>100 mg/kg-bw	(Schafer 1972, USEPA 2020g)
Ring-necked Pheasant	Acute oral LD_{50}	673 mg/kg-bw	(Hudson et al. 1984, USEPA 2020g)
Bobwhite Quail	Subacute LC_{50}	3,950 mg/kg-diet	(USEPA 2020g)
Canary (*Serinus canaria*)	8-day LC_{50}	>4,240 mg/kg-diet	(USEPA 2020g)
Mallard Duck	23-week NOAEC LOAEC	9.6 mg/kg-diet/day 39.7 mg/kg-diet/day (reductions in egg sets, viable embryos, and survival of embryos, and hatchlings)	(USEPA 2020g)

12.3 Exposure Assessment and Risk Characterization

12.3.1 Human Health Exposure and Risk Characterization

Non-repellent and non-seed treatment uses of thiram include direct application to growing plant material, which may result in contamination of food and drinking water sources. Residential use is restricted, so non-occupation environmental exposures are often associated with adult and child contact with treated commercial areas, such as turf residues resulting from spray drift.

The highest risk of injury due to the use of thiram as an animal repellent is from acute occupational dermal and inhalation exposures. Handlers may be exposed to thiram by mixing and handling the pesticide prior to application, during pesticide application, and during post-application activities such as reentry to treated areas.

The USEPA has established a chronic reference dose (RfD) for thiram of 0.015 mg/kg-bw/day (the NOAEL was 1.5 mg/kg-bw/day), which was derived from the results of two studies: 1) the thiram combined chronic/carcinogenicity study in a rat model with hematological changes, clinical chemistry changes, and increased incidences of bile duct hyperplasia observed at the lowest-observed adverse-effect level (LOAEL) of 7.3 mg/kg-bw/day) (USEPA 2020e). The USEPA has determined that the revised dermal-absorption factor for thiram is 15% (USEPA 2021b). When applied to the developmental neurotoxicity study NOAEL of 1.4 mg/kg-bw/day (USEPA 2020e), a dermal equivalent dose of 9.3 mg/kg-bw/day can be determined.

In their proposed interim registration review decision, USEPA (2021b) determined that non-repellent and non-seed treatment uses did not pose an unreasonable health risk, but there are "unreasonable risks from dermal and inhalation exposures for thiram, even when assuming the use of PPE and engineering controls beyond what is on current product labels" for all other labeled uses. USEPA further states, "Health risks from the use of thiram and its associated end-use products have shown to be unreasonable for non-seed treatment uses, *except animal repellency* [emphasis added], when used according to current label directions and when additional mitigation measures are considered." (USEPA 2021b). However, USEPA (2022d) later revised its occupational risk assessment and determined that dermal occupational exposures were above the level of concern for repellent uses. Inhalation occupational exposures were also above the level of concern for repellent uses unless respirators were included in PPE.

12.3.2 Ecological Exposure and Risk Characterization

Thiram is highly toxic to aquatic species, including fish, aquatic invertebrates, oysters, and shrimp. Label restrictions prohibit the use of thiram directly to water, areas where surface water is present, and intertidal areas below the mean high-water mark. Drift and runoff may be hazardous to aquatic organisms in adjoining areas (USEPA 2020e). To further mitigate these exposures, USEPA proposed adding additional environmental hazard statements for aquatic species and surface water advisory statements to the thiram product labels in the proposed interim decision for the registration review of thiram (USEPA 2021b).

The ring-neck pheasant and mallard duck are the most sensitive bird species for acute and chronic exposures (USEPA 2020g). USEPA (2021b) determined that birds were at risk from thiram products through contact and ingestion exposures and has proposed adding additional environmental hazard label statements to minimize or prevent these exposures.

Only the highest labeled foliar uses exceed the acute level of concern for non-human mammals. However, all chronic exposures exceed the level of concern for all foliar uses for small to medium-sized mammalian species. Acute and chronic levels of concern are exceeded for all thiram uses for birds, reptiles, and amphibians. USEPA (2021b) determined that mammals were at risk from thiram products through contact and ingestion exposures and has proposed adding additional environmental hazard label statements to minimize or prevent these exposures.

Based on available data, USEPA determined that there are potential acute and chronic risks to adult and larval honey bees from thiram use (USEPA 2021b). However, in 2021, USEPA proposed to add the following risk mitigation language to the label for Defiant Turf Fungicide and

Animal Repellent, “Do not apply during bloom” (USEPA 2021b). Once the product label is amended, this or similar label language will minimize honey bee exposure to thiram when this product is used as a repellent for deer, rabbits, and rodents.

WS’s intent to utilize thiram as an animal repellent as per the label will result in higher concentrations applied to target foliage, as opposed to commercial fungicidal uses for thiram. When applying thiram to use sites where non-target animals may be present, care must be taken. There is a possible route of unintended exposure to sensitive aquatic or terrestrial species during the application of thiram post-application due to dislodgeable residues and runoff. Strict adherence to current and future product label mandates concerning application rates and methods will minimize the ecological impact of WS’s thiram use.

13 URINES, COYOTE, AND FOX

13.1 Problem Formulation

13.1.1 Chemical Description and Product Use

Urines from coyotes and foxes (CAS numbers not assigned) are the active ingredients within repellent products registered to repel various pest mammals (deer, elk, domestic cats, groundhogs, armadillo, beavers, javelina, rabbits, woodchucks, opossums, pocket gophers, porcupines, shrews, voles, and moles) at residential indoor and outdoor non-food use sites, including lawns, flower beds, the perimeter of food-producing garden beds, garages, sheds, attics, and basements (USEPA 2019a). Predator urine products applied as repellents can deter other animals from feeding or denning in particular areas because the odor causes the target herbivore pests to avoid the area (USEPA 2016b).

Urines from predators such as coyotes and big cats have been reported effective in preventing deer damage and damage from other vertebrate animals (Sullivan et al. 1985, USEPA 2009d). Urine concentrated from animals that eat meat volatilizes and emits an odor that rodents will avoid, regardless of the predator species (Nolte et al. 1994). Browsing or feeding by deer and rodents was reduced when food items were treated with whole urines (100%) from predators that consumed higher content meat diets versus urines from animals that consumed vegetables (Lewison et al. 1993, Nolte et al. 1994). The specific substance(s) in the urine that triggers behavioral avoidance in target mammals is unknown (USEPA 2016b), but studies suggest that predator urines have higher amounts of sulfur-containing volatiles (Lewison et al. 1993, Nolte et al. 1994). Non-pesticidal uses of predator urines include use as lures and use by game hunters to mask their human scent. However, urine products sold for these non-pesticidal uses cannot be distributed or used as animal repellents (pesticides) without first being registered.

Coyote and fox urines are ubiquitous in nature, readily biodegradable, and thus, are regulated by USEPA as biopesticides or biochemical active ingredients (USEPA 2018e;2019a). Coyote and fox urines are similar in composition and in their registered uses, and therefore, their risk profile is considered to be the same (USEPA 2019a).

Currently-registered products contain either coyote urine at 5% w/w, fox urine at 5% w/w, or are a combination product that contains both urines (3.5% w/w coyote urine, 1.5% w/w fox urine)

formulated into “ready-to-use” granules or in capsules. Granules and capsules are placed or sprinkled by hand on the ground, or hangable packs can be hung 1–4 feet above the ground to create an olfactory barrier or fence around the area to be protected. A granule product containing both urines may also be sprinkled directly into rodent burrows. In the future, WS may use repellent products containing coyote and/or fox urines to deter various mammalian pests from bedding, denning, burrowing, or feeding at labeled use sites. Urine products do not hold up well in inclement weather conditions, so they must be reapplied as necessary.

13.1.2 Physical and Chemical Properties

Coyote and fox urines are naturally-occurring mixtures of water (approximately 95% w/w), urea (approximately 3.6% w/w; CAS number 57-13-6), and the remaining ~1.4% consists of creatinine, sodium, calcium, phosphate, chloride, potassium, and magnesium (USEPA 2016b;2018e). Unprocessed coyote and fox urines are yellow liquids with an ammonia-like scent (USEPA 2004a). They are stable when stored in sealed containers at ambient temperatures and have a vapor pressure of 23.756 mm Hg at 25°C (USEPA 2004a).

13.1.3 Environmental Fate

Coyote and fox urines break down rapidly in the environment and are considered to have no to low persistence (USEPA 2018e).

13.1.4 Hazard Identification

As of May 2019, there were no adverse human incidents reported for coyote or fox urines in USEPA’s Incident Data System (USEPA 2019a).

Manufacturers of repellent products containing coyote and fox urines must process the urines to eliminate any zoonotic pathogens below the threshold of concern (USEPA 2019a).

None of the coyote or fox urine components are known endocrine disruptors or related to any known endocrine disruptors (USEPA 2004a).

13.2 Dose-Response Assessment

13.2.1 Human Health Dose-Response

Acute Toxicity

Coyote and fox urines have low toxicity (USEPA 2016b). USEPA waived the human health effects toxicity data requirements for coyote and fox urines during registration and registration review (USEPA 2019a). There is toxicity data available for urea, the primary non-water constituent in coyote and fox urines, at approximately 3.6% w/w (USEPA 2016b). Urea is non-toxic to mammals based on acute oral toxicity (LD_{50} was >5,000 mg/kg-bw, Toxicity Category IV; (USEPA 2016b). Urea is a slight dermal irritant (Toxicity Category IV) and is not considered to be a skin sensitizer (USEPA 2016b).

Subchronic and Chronic Toxicity, Developmental Toxicity, Mutagenicity, Immunotoxicity

USEPA waived the human health effects data requirements for subchronic, chronic, and developmental toxicity, mutagenicity, and immunotoxicity for coyote and fox urines due to their

significant history of exposure to humans (they are ubiquitous in the environment), and based on the existing toxicity data for urea (USEPA 2016b). Urea and the other constituents within coyote and fox urines are not structurally related to any known mutagen or belong to any chemical class of compounds containing known mutagens (USEPA 2016b).

13.2.2 Ecological Effects Dose-Response

Aquatic Effects Analysis

USEPA waived the ecotoxicity data requirements for fish, aquatic invertebrates, and aquatic plants for coyote and fox urines during registration and registration review (USEPA 2016b). Urea, the primary non-water constituent in coyote and fox urines, is practically non-toxic to freshwater invertebrates and fish (Table 20; (USEPA 2016b).

Table 20 Acute and chronic toxicity to aquatic vertebrates and invertebrates for urea.

Taxonomic group	Test species	Test	Result (mg/L)	Reference
Freshwater Fish	Barna Baril (*Barilius barna*)	96-hr LC_{50}	>9,100	(USEPA 2016b)
	Ide (*Leuciscus idus melanotous*)	48-hr LC_{50}	>10,000	(USEPA 2016b)
Aquatic Invertebrates	Water Flea (*Daphnia magna*)	24-hr EC_{50}	>10,000	(Husson 1986, USEPA 2016b)

Terrestrial Effects Analysis

USEPA waived the ecotoxicity data requirements for avian, mammal, terrestrial invertebrate, and terrestrial plant toxicity for coyote and fox urines during registration and registration review (USEPA 2016b). Urea is considered to be non-toxic to practically nontoxic to birds, mammals, and insects (Table 21; (USEPA 2016b). The acute oral and dietary lowest lethal dose for urea was 16,000 mg/kg-bw in pigeons, which is eight times higher than the maximum dose level typically used in an ecotoxicity pesticide registration study (USEPA 2016b).

Coyote and fox urines are not considered phytotoxic at the low concentrations (≤5% w/w) contained within the registered products (USEPA 2018e).

Table 21 Toxicity studies for mammals, birds, and terrestrial invertebrates for urea.

Test species	Test	Result	Reference
Brown Rat (lab)	Acute oral LD_{50}	>5,000 mg/kg-bw	(USEPA 2016b)
Pigeon	Acute oral lowest lethal dose	16,000 mg/kg-bw	(USEPA 2016b)
	Acute dietary lowest lethal dose	16,000 mg/kg-bw	(USEPA 2016b)
Yellow Fever Mosquito (*Aedes aegypti larva*)	4-hr LC_{50}	60,000 mg/L	(USEPA 2016b)

13.3 Exposure Assessment and Risk Characterization

13.3.1 Human Health Exposure and Risk Characterization

Coyote and fox urines used to produce registered repellent products come from domesticated coyotes and foxes raised on ranches (USEPA 2004a). The manufacturers of coyote and fox

urines are required by USEPA to demonstrate that they have eliminated any zoonotic pathogens below the threshold of concern (USEPA 2019a).

Coyote and fox urine repellent products are not registered for food use (USEPA 2016b). The product labels do not allow applications to aquatic areas, and coyote and fox urines are readily biodegradable in the environment (USEPA 2016b). Therefore, dietary exposures through food and drinking water are negligible (USEPA 2016b).

The urea within coyote and fox urines can cause slight skin irritation, but urea comprises only about 3.6% w/w of coyote and fox urines, which in turn are ≤5% w/w of the registered products (USEPA 2016b). Therefore, registered coyote and fox urine repellent products are not expected to be a dermal irritant (USEPA 2016b).

Any future use by WS of repellent products containing coyote and fox urines would have negligible risk to the general public or WS applicators based on their environmental fate properties, label language, and low toxicity profile.

13.3.2 Ecological Exposure and Risk Characterization

As of May 2019, no adverse ecological incidents were reported in the Ecological Incident Information System for coyote or fox urines (USEPA 2019a).

The labels for repellent products containing coyote and fox urines do not allow applications to aquatic areas, which reduces aquatic exposure risk (USEPA 2016b). The rapid breakdown of coyote and fox urines in the environment indicates runoff or leaching into water resources would be negligible.

The low-use volumes, use sites, biodegradability, and lack of phytotoxicity or persistence in the environment indicate repellents containing coyote and fox urines pose little to no exposure risk to terrestrial species. Furthermore, predator urines are already ubiquitous in the environment (USEPA 2016b). Target pest animals visiting the residential use sites allowed on the labels for these products will be repelled and will avoid further exposure. Dietary exposure to terrestrial species is also not expected (USEPA 2016b).

The USEPA determined that there will be no effects on federally listed threatened and endangered species or designated critical habitats from registered uses of repellent products containing coyote and fox urines (USEPA 2016b).

14 UNCERTAINTIES AND CUMULATIVE IMPACTS

The uncertainties associated with this risk assessment arise primarily from a lack of information about the effects of chemical repellents, their formulations, metabolites, and potential mixtures on non-target organisms that can occur in the environment. These uncertainties are not unique to this assessment but are consistent with uncertainties in human health and ecological risk assessments with any environmental stressor.

Another uncertainty in this risk assessment is the potential for cumulative impacts on human health and the environment from the proposed use of chemical repellents. The potential for

cumulative impacts is expected to be minimal based on the low volume and minor use of chemical repellents in the various WS uses. Areas where cumulative impacts may occur include: 1) repeated worker and environmental exposures to chemical repellents from program activities and other sources, 2) exposure to other chemicals with a similar mode of action, and 3) exposure to other chemicals affecting the toxicity of chemical repellents.

There is higher uncertainty on the potential cumulative impacts for any future use of thiram by WS compared to the other registered chemical repellent active ingredients. USEPA has determined that although thiram has a low oral and dermal acute lethality (Toxicity Category III), thiram has a high acute lethality through the inhalation route and is an ocular irritant. USEPA (2021b) proposed the cancellation of all non-seed treatment thiram uses, except animal repellency, due to "significant risks to occupational handlers" and ecological risks to the environment. Depending on WS use, there is a risk of occupational and non-occupation exposure in humans. To minimize occupational hazards of thiram exposure, the USEPA proposes the termination of non-seed treatment uses, except for animal repellency use, prohibition of product formulation types for specific crops for seed treatment uses, and the doubling of layers of PPE with a respirator for some seed treatment scenarios (USEPA 2020e).

Repeated exposures that could lead to significant risk from chemical repellents are not expected due to label requirements that prevent significant exposure. Accidental exposure may occur from improper use of PPE, but the potential for this is unlikely because WS applicators follow label requirements regarding PPE and are trained in the use of PPE.

Cumulative impacts are not expected from the use of chemical repellents. This is an area of uncertainty since it is unknown what other stressors, including chemicals, humans, and non-target wildlife, may be exposed to during a chemical-repellent application.

From a human health perspective, cumulative impacts on human health are expected to be negligible because of these chemical repellents' mostly favorable toxicity profiles and label requirements minimize exposure risks to workers and the public (Table 22). The lack of exposure and risk to the public suggests that cumulative impacts would also be incrementally negligible when factoring in other stressors.

Cumulative impacts on ecological resources are also expected to be incrementally negligible. When utilized according to label mandates, risks of the reviewed chemical repellents to aquatic resources and most terrestrial non-target wildlife are low due to relatively low toxicity and mitigated exposure pathways (Table 23).

Table 22. Summary of chemical repellent toxicity to humans.

Active ingredient	Exposure Route				FDA Classification for Food Additives
	Dermal[1]	Ocular[1]	Inhalation[1]	Oral[1]	
Ammonium soaps of fatty acids	Non-toxic	Moderate toxicity	Non-toxic	Non-toxic	N/A
Anthraquinone	Low toxicity	Low toxicity	Non-toxic	Non-toxic	N/A
Capsaicin	Non-toxic	Non-toxic	Low toxicity	Non-toxic	GRAS

Egg solids	Non-toxic	Low toxicity	Non-toxic	Non-toxic	GRAS
Garlic oil	Non-toxic	Non-toxic	Non-toxic	Non-toxic	GRAS
Methyl anthranilate	Low toxicity	Moderate toxicity	Waived	Low toxicity	GRAS
Naphthalene	Low toxicity	Low toxicity	Moderate toxicity	Low toxicity	N/A
Oil of black pepper Piperine	Non-toxic	Non-toxic	Non-toxic	Non-toxic	GRAS
Polybutene	Low toxicity	Moderate toxicity	Waived	Non-toxic	N/A
Sulfur	Low toxicity	Low toxicity	Low toxicity	Non-toxic	N/A
Thiram	Low toxicity	Moderate toxicity	High toxicity	Low toxicity	N/A
Urines, Coyote and Fox	Non-toxic	Non-toxic	Non-toxic	Non-toxic	N/A

[1] Non-toxic/Very low toxicity (Toxicity Category IV), low toxicity (Toxicity Category III), moderate toxicity (Toxicity Category II), high toxicity (Toxicity Category I)

Table 23. Summary of chemical repellent acute toxicity to aquatic and terrestrial species.

Active Ingredient	Aquatic species						Terrestrial species				
	Freshwater		Estuarine/Marine								
	Fish	Invertebrate	Fish	Invertebrate	Amphibian	Plant	Invertebrate	Bird	Mammal (wildlife)	Reptile/ Amphibian	Plant
Ammonium soaps of fatty acids	Slightly toxic	Slightly toxic	Non-toxic	Slightly toxic	Slightly toxic	--	Practically non-toxic	Practically non-toxic	Practically non-toxic	Practically non-toxic [2]	Phytotoxicity can occur
Anthraquinone	Low toxicity	Slight to high toxicity	Low toxicity	High toxicity	Low toxicity [1]	Low toxicity	Low toxicity	Low toxicity	Practically non-toxic	Low toxicity [2]	--
Capsaicin	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]
Egg solids	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]
Garlic Oil	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]
Methyl anthranilate	Slight to moderate acute toxicity; practically non-toxic on a dietary basis	Slight toxicity	--	--	Slight to moderate acute toxicity [1]	--	Practically non-toxic	Practically non-toxic	Practically non-toxic	Practically non-toxic [2]	May cause foliar burn
Naphthalene	Moderately toxic	Moderately toxic	--	--	Moderately toxic [1]	Slightly toxic	--	Practically non-toxic	Practically non-toxic	Practically non-toxic [2]	--
Oil of black pepper Piperine	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	Practically non-toxic	-- [3]	-- [3]	-- [3]
Polybutene	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	Practically non-toxic	Practically non-toxic	Practically non-toxic [2]	--
Sulfur	Practically non-toxic	Practically non-toxic	--	--	Practically non-toxic	-- [3]	Practically non-toxic	Practically non-toxic	Practically non-toxic	Practically non-toxic [2]	-- [3]
Thiram	Very highly toxic	Very highly toxic	Highly toxic	Very highly toxic	Slightly toxic [2]	Non-toxic	Practically non-toxic to highly toxic [4]	Slightly toxic	Moderately toxic	Slightly toxic [2]	Non-toxic
Urines, coyote and fox	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]

[1] Data was unavailable for aquatic-phase amphibians. Fish are a surrogate species.
[2] Data was unavailable for terrestrial-phase amphibians and reptiles. Birds are surrogate species.
[3] This chemical is non-toxic. USEPA waived toxicity data requirements.
[4] Thiram is practically non-toxic to adult honey bees but highly toxic to larvae.

15 SUMMARY

WS uses chemical repellents to manage several bird and mammal species that damage a variety of agricultural and non-agricultural resources or pose a risk to human safety (e.g., interfering with aircraft). Chemical repellents pose a negligible risk of primary or secondary poisoning to non-target animals, including scavengers. Label requirements and environmental fate properties indicate chemical repellents pose no risk to aquatic non-target wildlife. The WS use pattern and application rates of repellents mostly on private lands result in a negligible risk for the public. The dietary risk from chemical repellent exposure to the public is low since most of the repellents are considered non-toxic to people, do not threaten drinking water, and many are not used on edible plant parts. The risk to WS applicators is also low because they receive training in the product's use and follow label instructions, including appropriate PPE. The release of chemical repellents into the environment is expected to have no or negligible impacts on non-target species, the public, and the environment, including cumulative impacts.

There are uncertainties in this assumption related to differences between taxa. Still, for this risk assessment, most chemical repellents are considered practically non-toxic to reptiles and terrestrial-phase amphibians when considering the absence of sensitivities to surrogate avian species (Table 23). In contrast, several chemical repellents (ammonium soaps of fatty acids, anthraquinone, methyl anthranilate, and naphthalene) range from slightly to moderately toxic to freshwater fish, indicating similar toxicity to aquatic-phase amphibians. However, thiram is high to very highly toxic to fish and aquatic invertebrates (Table 23).

Although several chemical repellents range in their toxicity to aquatic species (Table 23), aquatic exposure from proposed chemical repellent applications is expected to be negligible based on the application method, proposed use pattern, label mitigation measures to protect aquatic resources, and the chemicals' environmental fate properties. All repellent applications are made by hand or with ground-based equipment.

Most chemical repellents WS proposes to use are practically non-toxic to terrestrial species, including mammals and birds (Table 23). Anthraquinone and thiram demonstrate some toxicity to terrestrial invertebrates, birds, and mammals. However, the label restrictions, use patterns, and environmental fate properties minimize exposure to non-target terrestrial species.

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