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, 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 nontarget aquatic and terrestrial species based on the repellents' toxicity profiles, label requirements, and WS use patterns.

Table of Contents

List of Tables

GLOSSARY OF TERMS AND ABBREVIATIONS

µg	Microgram
a.i.	Active ingredient
bw	Body weight
CAS	Chemical Abstract Service
CDC	Centers 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 nontarget 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 2022e). The methods used to assess potential ecological risk to nontarget fish and wildlife generally follow USEPA (2022e) 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, Westerfield et al. 2019). 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,

[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.

cost per area, 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 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 RUPs.

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).

[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, …).

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.

Chemical Repellent	Species	FY11-15 Repelled	FY11-15 States Used	FY16-20 Repelled	FY16-20 States Used
Anthraquinone	Canada Goose	9,898	IL PA	4,830	IL WI
Total Anthraquinone	**Total (1 spp.)**	**9,898**	**2 States**	**4,830**	**2 States**
Methyl Anthranilate	European Starling*	13,183	NC OR	65	NC VA
Methyl Anthranilate	Red-winged Blackbird	220	NH	2	VA
Methyl Anthranilate	Common Grackle	1,435	NH PA	-	-
Methyl Anthranilate	Boat-tailed Grackle	600	FL	-	-
Methyl Anthranilate	Brown-headed Cowbird	220	NH	-	-
Methyl Anthranilate	Mixed Blackbird sp.**	22,240	FL NH	15	VA
Methyl Anthranilate	Mourning Dove	340	AL	-	-
Methyl Anthranilate	Purple Martin	1	VA	-	-
Methyl Anthranilate	Barn Swallow	30	WV	-	-
Methyl Anthranilate	House Sparrow*	101	NC NH	-	-
Methyl Anthranilate	Canada Goose	600	NE	128	MO OR
Methyl Anthranilate	Laughing Gull	100	VA	64	VA
Methyl Anthranilate	Ring-billed Gull	66	WI	5	VA
Methyl Anthranilate	Herring Gull	66	WI	24	VA
Methyl Anthranilate	Black-crowned Night-	10	PA	-	-
Methyl Anthranilate	Northern Flicker	2	OR	-	-
Total Methyl Anthranilate	**Total (15 spp.)**	**39,214**	**10**	**299**	**5 States**
Napthalene/Sulfur	W. Diamondback	-	-	0.2	TX
Total Napthalene/Sulfur	**Total (1 sp.)**	**-**	**-**	**0.2**	**1 State**
Ammonium Soaps of Fatty Acids	Mule Deer	-	-	8	CA
Total Ammonium Soaps of Fatty Acids	**Total (1 sp.)**	**-**	**-**	**8**	**1 State**
Capsaicin/Oil of Black Pepper/Piperine	Feral House Cat*	-	-	3	PA
Capsaicin/Oil of Black Pepper/Piperine	Louisiana Black Bear	0.2	LA	-	-
Total Capsaicin/Black	**Total (2 spp.)**	**0.2**	**1 State**	**3**	**1 State**
	GRAND TOTAL (19 spp.)	**49,112**	**12**	**5,140**	**9 States**

* Introduced species
** All species were already counted in the total species

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 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 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.

Active Ingredient(s) (% w/w, CAS Number)	Product Name	USEPA Registration Number	FY11-15 Applied (gal or lb)	FY11-15 WTs	FY16-20 Applied (gal or lb)	FY16-20 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
Methyl Anthranilate (20%, 134-20-3)	Avian Fog Force® TR	91897-4	0.1 gal	1	0.1 gal	0.6
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.

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 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.

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 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 nontarget 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 nontarget 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 nontarget 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 2010b;2015c). Most products containing ammonium soaps of fatty acids are comprised primarily of shorter-chain saturated fatty acids (ammonium nonanoate and ammonium octanoate) (USEPA 2015c). 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 2010b;2015c). 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 2015c, 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).

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), 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 2015c).

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	Fatty Acid Type
C8	5972-76-9	Ammonium octanoate or ammonium caprylate	Saturated
C9	63718-65-0	Ammonium nonanoate	Saturated
C10	16530-70-4	Ammonium decanoate	Saturated
C11	32582-95-9	Undecanoic acid, ammonium salt	Saturated
C12	2437-23-2	Ammonium laurate or Dodecanoic acid, ammonium salt	Saturated
C13	191799-95-8	Tridecanoic acid, ammonium salt	Saturated
C14	16530-71-5	Ammonium myristate	Saturated
C15	93917-76-1	Ammonium pentadecanoate	Saturated
C16	5297-93-8	Ammonium palmitate	Saturated
C17	94266-36-1	Ammonium heptadecanoate	Saturated
C18	1002-89-7	Ammonium stearate	Saturated
C18	544-60-5	Ammonium oleate	Unsaturated

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 to 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 a residential area where they were considered 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 2022b, USEPA 2010f;2015c). Given that the longer chain fatty acids of ammonium soaps 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 2010b;2015c). 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 2023b). 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 2010f) with a vapor pressure near that of water. They do not readily vaporize or form aerosol particulates (USEPA 2010f). 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 2015c). Ammonium soaps of fatty acids readily bind to soil particles (USEPA 2010f) and have the potential to bioaccumulate but are not likely to persist (USEPA 2015c).

2.1.4 Hazard Identification

Ammonium soaps of fatty acids are irritating and corrosive to the eye (USEPA 2012b). 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 2010f). 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 2010f).

USEPA reviewed its Office of Pesticide Programs (OPP) Incident Data System (IDS) from 2007-2012 (USEPA 2013b), and no incidents involving ammonium soaps of fatty acids were reported. The USEPA (2024) IDS has 21 incidents and aggregated results that involved a weed killer product (Natria® Grass & Weed Killer Ready-To-Use and other herbicidal soaps) containing ammonium soaps of higher fatty acids, but none for Hinder or mammal repellents for Calendar Years (CY) 2014-2023.

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 2012b). 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 2010f). 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 (*Cavia porcellus*) (USEPA 2010f). 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 2012b). 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 2010f).

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 2004c).

Developmental and Reproductive Effects

No adverse effects occurred in a developmental and maternal toxicity study in rats dosed with nonanoic acid (USEPA 2012b). 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 2015c). However, they are practically nontoxic to estuarine/marine fish (USEPA 2015c). 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 (2015c) 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 2015c).

Terrestrial Effects Analysis

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

Table 5 Acute and chronic toxicity to aquatic vertebrates and invertebrates for ammonium soaps of fatty acids[1].

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

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

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

Chronic toxicity data is unavailable because soap salts undergo rapid degradation in less than one day (USEPA 2015c). 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 2015c).

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)
Northern Bobwhite	LD_{50}	2,150 mg/kg-bw	(USEPA 1992b)
Japanese Quail (*Coturnix japonica*)	8-day dietary LC_{50}	>5,000 mg/kg-diet (practically nontoxic) or 1,100 mg a.i./kg-diet	(USEPA 2015c)
Mallard	8-day dietary LC_{50}	>5,000 mg/kg-diet (practically nontoxic)	(USEPA 1992b)
Northern Bobwhite	8-day dietary LC_{50}	>5,000 mg/kg-diet (practically nontoxic)	(USEPA 1992b)

Ammonium soaps of fatty acids are phytotoxic (USEPA 2015c), 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 2015c). Dicots are more sensitive than monocots (USEPA 2015c). 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 2010f). Ammonium soaps of fatty acids are unlikely to form aerosols due to their vapor pressure, making inhalation an unlikely route of exposure (USEPA 2010f). 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 (2012b) 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 2012b). 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 2012b).

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 2015c).

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 (2015c) reviewed the Ecological Incident Information System (1989–2012) and did not find reported incidents involving ammonium soaps of fatty acids. In 2012, the USEPA (2015c) reviewed the Avian Incident Monitoring System maintained by the American Bird Conservancy and did not find incidents involving these products. A review of USEPA (2024) IDS for CY2014-2023 found no incidents with the labels used for mammalian repellents; it should be noted that ammonium soaps of higher fatty acids used in herbicidal pesticide formulations had 17

incidents and 1 summary of incidents from a product manufacturer that involved 38 minor exposures to people and pets, and toxicity to 13 off-target plants.

Ammonium soaps of fatty acids' environmental fate properties, label requirements, the proposed WS use pattern, and the favorable toxicity data indicate negligible risk to nontarget 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 (2015c) 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 Alexandrian 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 2022b). WS uses anthraquinone under the Flight Control® Max label. Anthraquinone has no approved food uses, and no tolerances or tolerance exemptions have been established for it (USEPA 2022a).

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 2022b). 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 2021). 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; however, it is stable for 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 2022a). When ingested, anthraquinone is slowly distributed to tissues and slowly metabolized and excreted via a saturable kinetic process (USEPA 2022a). Females may have slower clearance and metabolism than males and, therefore, can have higher tissue concentrations (USEPA 2022a).

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 2022a).

No adverse incidents from anthraquinone use have been reported in the USEPA IDS and the Centers for Disease Control 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 2022a). A search of the USEPA (2024) IDS identified no incidents or aggregated results that involved anthraquinone for Calendar Years (CY) 2014-2023. USEPA has not established any tolerances for anthraquinone use. USEPA (2022a) estimated a chronic population-adjusted dose (cPAD) of 0.03 mg/kg-bw/day that was derived from the LOAEL (25 mg/kg-bw/day). 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
House Mouse	Skin Sensitizer	No	-	NA
Guinea Pig	Skin Sensitizer	-	Not a sensitizer	NA

NA = Not applicable
References: (Arkion 2021, USEPA 2022a)

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 2022a). 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 M/F 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 on mortality, clinical signs, or food consumption at any dose. Plasma concentrations were approximately two- to three-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 M/F rats (USEPA 2022a).

Developmental and Reproductive Effects

Two studies are available that evaluated 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 2022a). 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 a 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 2022a). However, in the subchronic oral toxicity study in rats, adverse changes to the reproductive tract of females were noted at the highest 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 (2022a) 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, Cancer Assessment Review Committee determined that kidney tumors observed in female rats at 50, 100, and 200 mg/kg-bw/day were determined to be treatment-related (USEPA 2022a). However, urinary and bladder kidney tumors observed at the highest test concentration in male rats were not treatment-related. The Cancer Assessment Review Committee determined that thyroid tumors observed at the various doses in female rats were also not treatment-related.

In a second carcinogenicity study, M/F 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 Cancer Assessment Review Committee 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 2022a).

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 2022a).

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 plaque-forming assays were measured using splenocyte suspensions from each mouse. The NOAEL for anti- sheep red blood cell plaque-forming assays 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 2022a).

Endocrine Effects

In the subchronic dietary toxicity study (30 days and 13 weeks), 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 2022a). 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, the freshwater scud (*Hyallela azteca*) and midge larvae (*Chironomus tentans*) (Table 8).

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).

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

Taxon Group	Test Species	Test	Result (mg/L)	Reference
Freshwater Fish	Bluegill	LC_{50}	>5	(Verschueren 2001)
Freshwater Fish	Bluegill	96-hr LC_{50}	>0.190	(USEPA 2022g)
Freshwater Fish	Fathead Minnow	LC_{50}	2,650	(Verschueren 2001)
Freshwater Fish	Rainbow	96-hr LC_{50}	>0.150	(USEPA 2022g)
Freshwater Invertebrates	Water Flea	48-hr EC_{50}	>0.240	(USEPA 2022g)
Freshwater Invertebrates	Scud	96-hr EC_{50}	0.338	(USEPA 2022g)
Freshwater Invertebrates	Midge	14-day NOAEC	0.058	(USEPA 2022g)
Estuarine/Marine Invertebrates	Mysid Shrimp	48-hr LC_{50}	0.0942	(USEPA 2022g)
Estuarine/Marine Invertebrates	Eastern Oyster (*Crassostrea virginica*)	96-hr EC_{50}	>0.017	(USEPA 2022g)

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 2022g). There are no data available on the phytotoxicity of anthraquinone to terrestrial plants. Anthraquinone is considered practically nontoxic to birds and mammals in acute exposures (Table 9). Sublethal effects from subchronic dietary exposures to rats at the LOAEC included weight loss (USEPA 2022g). USEPA (2022g) 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 nontoxic 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 2022g).

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 2022a)
Brown Rat (lab)	90-day NOAEC and LOAEC	11 mg/kg-bw and 40 mg/kg-bw	(USEPA 2022a)
House Mouse	LD_{50}	>5,000 mg/kg-bw	(USEPA 1998a)
Northern Bobwhite	LD_{50}	>2,000 mg/kg-bw	(USEPA 2022g)

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 (2022a;g) 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 2022a). 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 2022b). 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 2022a). 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 2022g). The maximum estimated surface water concentrations were compared to the available effects data to determine the potential risk to nontarget 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 nontarget aquatic organisms.

Exposure of terrestrial nontarget 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, landfills, and managed waste dumpsites. Applications are only allowed to turf on these sites to repel geese, reducing exposure to terrestrial nontarget 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 nontarget 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 nontarget birds, amphibians, and mammals under various use scenarios (USEPA 2022g). 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 nontarget 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 nontarget terrestrial vertebrates. The risk assessment concluded that the risk to nontarget birds, amphibians, and mammals did not exceed USEPA levels of concern, suggesting a negligible risk to nontarget 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 nontarget terrestrial plants due to a lack of toxicity data. No reports of adverse effects on target or nontarget 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 2022c). 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 2022c).

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 2009d;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 2009c). 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 2009c;2010e).

USEPA reviewed the Incident Data System (IDS), 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 case lacked information 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 2009c). Five incidents caused minor irritation to the skin, eye or respiratory system, and one had unspecified symptoms. A search of the USEPA (2024) IDS identified 23 incidents or aggregated results that involved capsaicin alone or with other products for Calendar Years (CY) 2014-2023. Of these, three were aggregated incidents from the National Pesticide Information Center (NPIC) related to bear spray causing adverse reactions to humans (six with an alleged fatality) and one from a product manufacturer with a dog spray to repel attacking dogs that caused injuries to five people (e.g., vomiting and swollen eyes). Twelve aggregated results occurred with two Havahart Critter Ridder products (concentrate or ready-to-use), which contain capsaicin and other active ingredients, with eight people and five domestic pets injured with minor to moderate or unknown symptoms; one pet got a lethal dose, but information on the poisoning was lacking. Additionally, seven aggregated results occurred with three Deer Off II formulations (concentrate or ready to use) causing minor or unknown injuries to five people and five domestic animals, but it was fatal to one domestic animal (no information on fatality). Finally, one incident involved capsaicin mixed with garlic and canola oils where 55 field workers were taken for precautionary medical care as a result of a strong pesticide-like odor in a field they were working; it is unknown if any were treated for any s,ymptoms but the impact of the incident was determined to be moderate to human health.

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 2009c). 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 2009b). 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 2009b).

4.2 Dose-Response Assessment

4.2.1 Human Health Dose-Response

Acute Toxicity

Capsaicin is nontoxic 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 nontoxic 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 2009f). 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, but following further review, USEPA found it unlikely capsaicin will cause mutagenic effects when repellent products are used according to label instructions (USEPA 2009b;c).

4.2.2 Ecological Effects Dose-Response

Aquatic Effects Analysis

Capsaicin is nontoxic and does not persist in the environment, indicating minimal risks to all nontarget organisms. As such, the USEPA (2009f) 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 2009f). 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 to prevent dermal exposure along with protective language to reduce potential exposure to workers (USEPA 2022c). Capsaicin's environmental fate properties indicate human exposure to residues is expected to be minimal (USEPA 2009c). USEPA (2009c) 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 nontarget terrestrial and aquatic species due to its favorable toxicity profile, environmental fate, label requirements, and WS use patterns. The USEPA (2009f) concluded the same findings. Capsaicin is nontoxic and does not persist in the environment, indicating minimal risks to all nontarget organisms (USEPA 2009f).

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;2022d).

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 2011f). They are practically insoluble in water (USEPA 2011e).

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 nontoxic 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 2011c).

The odor and taste of egg solids act as a foraging repellent that when applied to plants repels white-tailed deer and other target mammals (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 nontoxic on an acute oral, dermal, and inhalation basis (Toxicity Category IV for all exposures) (USEPA 2011f). The LD_{50} values for acute oral and dermal toxicity are >5,000 mg/kg-bw (Toxicity Category IV) (USEPA 2011c). The acute inhalation LC_{50} is >2.10 mg/L (USEPA 2011c). In acute eye irritation studies, egg solids caused corneal irritation, which cleared within 48 hours (Toxicity Category III) (USEPA 2011f). Egg solids are a slight dermal irritant (Toxicity Category IV) (USEPA 2011f) and may be a skin sensitizer (USEPA 2011f).

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;2011c).

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 2011b).

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 2011b). USEPA (2011b) concluded egg solids would not result in a hazard or toxic risk to nontarget organisms.

(USEPA 2018c) reviewed the Incident Data System (IDS) 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). A search of USEPA (2024) IDS for CY 2014-2023 identified six incidents involving egg solids alone with minor or unknown injuries to two people, two domestic animals, and 3 plants; one aggregated result involving 67 incidents from a product manufacturer had 19 human injuries (one major) and 119 plant injuries, but no other information was available on the incidents. A search of USEPA (2024) for CY 2014-2023 also identified seven incidents involving egg solids mixed with capsaicin and garlic oils with minor or unknown injuries to five people and five domestic animals, and one domestic animal fatality (no additional information provided); 67 aggregated incidents from a product manufacturer had 19 human injuries with one major and 119 plant injuries, but no other information was available. Finally a product manufacturer reported in two aggregated incidents that two cities had an estimated 78 human incidents and 460 major plant damage incidents from the use of egg solids with garlic and clove oils.

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 (2011c;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 2009c).

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 (2011b) concluded egg solids would not result in a hazard or toxic risk to nontarget 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 nontarget 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 2022f). 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 2022f). 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 2010c). 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 2009a;2022f). It has a pungent odor and is partial to fully soluble in water (USEPA 2009a;2022f).

6.1.3 Environmental Fate

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

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 2010c;2022f).

USEPA (2022f) 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 2022f).

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

6.2.2 Ecological Effects Dose Response

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

USEPA (2022f) reviewed the Incident Data System (IDS) 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. A search of USEPA (2024) IDS for CY 2014-2023 identified seven incidents involving egg solids mixed with capsaicin and garlic oils with minor or unknown injuries to five people and five domestic animals, and one domestic animal fatality (no additional information provided) 67 aggregated incidents from a product manufacturer had 19 human injuries with one major and 119 plant injuries, but no other information was available. One product that NPIC reported from a veterinary portal found that egg solids with blood, denatured glyoxal, and garlic oil caused 33 domestic animal injuries, with 4 of them being fatal. Another formulation of garlic oil mixed with peppermint (*Mentha* x *piperita*) had 12 minor to moderate human cases (allergic reactions, malaise, hives, dyspnea, and erythema). Finally, one incident involved capsaicin mixed with garlic and canola oils where 55 field workers were taken for precautionary medical care as a result of a strong pesticide-like odor in a field where they were working; it is unknown if any were treated for any symptoms, but the impact of the incident was determined to be moderate to human health. Garlic may or may not have contributed to these cases as they involved other chemicals that are more likely the major culprit.

6.3 Exposure Assessment and Risk Characterization

6.3.1 Human Health Exposure and Risk Characterization

USEPA (2022f) 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 (2022f) concluded garlic oil would not result in a hazard or toxic risk to nontarget 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 nontarget 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 2011a;2020). Methyl anthranilate is categorized as GRAS by FDA when used as a food additive (flavoring agent) (USEPA 2020).

Methyl anthranilate is a food and non-food use biopesticide or biochemical pesticide active ingredient when used as a nontoxic, non-lethal bird repellent (USEPA 2020). 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 to be 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 2020). Birds exposed to methyl anthranilate associate the discomfort with the treatment area (USEPA 2018d).

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 2022c). It is slightly soluble in water with a water solubility of 2,850 mg/L at 25ºC (NIH 2022c). It has a soil adsorption coefficient (K_{oc}) of 75 (NIH 2022c).

7.1.3 Environmental Fate

Methyl anthranilate is nontoxic 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 nontoxic components such as anthranilic acid (USEPA 2020). Methyl anthranilate is extremely volatile and will rapidly dissipate from foliar and soil surfaces, with an atmospheric half-life of 11 hours (NIH 2022c, USEPA 2011d). Methyl anthranilate undergoes rapid photodegradation (USEPA 2020). Methyl anthranilate is expected to have high mobility in soil based on an estimated K_{oc} (NIH 2022c). However, mobility may be much slower in some soils as aromatic amines are expected to bind strongly to humus or organic matter (NIH 2022c). 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 2022c). 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 2022c). 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 2022c). 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 2022c).

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 2020). It is often used as a flavoring in food and is considered GRAS by the FDA when used as a food additive (USEPA 2018d;2020). 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 2020).

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 2022c). USEPA (2011a) 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 2011a). A search of the (USEPA 2024) IDS for CY 2014-2023 identified one incident in 2022 related to methyl anthranilate that caused a minor adverse reaction due to a fogging device causing drift onto private property.

7.2 Dose-Response Assessment

7.2.1 Human Health Dose-Response

Acute Toxicity

Methyl anthranilate is virtually nontoxic 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	USEPA Toxicity
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 2011a)

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 2011a).

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 2011a). 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 2011d). Methyl anthranilate is practically nontoxic to freshwater fish on a dietary basis (USEPA 2011d).

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

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

Terrestrial Effects Analysisr

The single dose oral LD_{50} for bobwhite quail was >2,036 mg/kg-bw, classifying methyl anthranilate as nontoxic to upland game birds (Table 12). The NOEL was 2,036 mg/kg-bw. In the mallard , the dietary toxicity LC_{50} was >5,620 mg/kg-diet. This classifies methyl anthranilate as practically nontoxic to waterfowl. Methyl anthranilate is practically nontoxic to mammals (Table 12) (USEPA 2011d). Methyl anthranilate is practically nontoxic to the honey bee with a 48-hr contact toxicity LC_{50} >25 µg/bee (USEPA 2011d).

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

Test Species	Test	Result	Reference
Laboratory Brown Rat	LD_{50}	2,910 mg/kg-bw	(Lewis 2004)
Laboratory Brown Rat	LD_{50}	>5,000 mg/kg-bw	(USEPA 2011d)
Laboratory Brown Rat	90-day dietary LC_{50}	>500 mg/kg-bw/day (no effects on growth or survival)	(USEPA 2011d)
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	LD_{50}	>292 mg/kg-bw	(USEPA 2011d)
Mallard	LC_{50}	>5,620 mg/kg-diet (practically nontoxic)	(USEPA 2011d)
Northern Bobwhite	LD_{50}	>2,036 mg/kg-bw, >2,250 mg/kg-bw (practically nontoxic)	(USEPA 2011d)
Ring-necked Pheasant	Subacute LC_{50}	>5,620 mg/kg-diet	(USEPA 2011d)
White-crowned Sparrow	LC_{50}	>2,200 mg/kg-diet (practically nontoxic)	(USEPA 2011d)

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 2011d).

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 (2020) 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 2018d). 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 reduces 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 2020). USEPA (2011a) 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 nontoxic to practically nontoxic to mammals and birds (USEPA 2011d). WS expects target birds and any nontarget 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 nontoxic to terrestrial invertebrates, including pollinators. Methyl anthranilate is a naturally occurring substance found in many plant species, which invertebrates are exposed to on a regular basis (USEPA 2011d).

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

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 2008c).

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 crop fields 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 (2018a) 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. 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 2018b). 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 x 10^{-4} (NIH 2022a). Its log octanol/water partition coefficients (K_{ow}) range from 3.29 to 3.37 (NIH 2022a, USEPA 2018b), 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 has poor solubility in water (NIH 2022a) and is likely to volatilize from surface water based on its chemical properties. 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 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 2018b). 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 2018b). 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 2018b). 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 (2008a) 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 (2018b) updated their incident review from USEPA (2008a) and found incidents involving naphthalene had declined, but not ceased. 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. A search of the USEPA (2024) IDS identified 19 incidents or aggregated results that involved naphthalene with sulfur for Calendar Years (CY) 2014-2023. Of these, there were 49 human cases (two were allegedly major) with minor symptoms including nausea, headaches, and sorethroats, and 12 domestic animal cases (one major and one alleged incident was said to have caused three dog deaths.

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 2008c). 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 2008c). 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 2008c).

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 2018b). 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 2018b).

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 2018b). 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 2018b).

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 2018b). The NOAEL was 300 mg/kg-bw/day. This study indicated that dermal toxicity is not likely a concern (USEPA 2008c).

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 2008c;2018b). 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 2008c).

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 2018b). 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 2018b). 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 2018b).

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;c). 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 2012a). 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 2018b). 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 rainbow trout and bluegill, 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, 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.

Taxon Group	Test Species	Test	Result (mg/L)	Reference
Freshwater Fish	Rainbow Trout	96-hr LC_{50} NOAEC	2.0 0.86	(USEPA 2008b) (USEPA 2016a)
Freshwater Fish	Bluegill	96-hr LC_{50} NOAEC	3.2 1.4	(USEPA 2008b) (USEPA 2016a)
Freshwater Fish	Fathead Minnow	96-hr LC_{50}	6.6	(USEPA 2008b) (USEPA 2016a)
Aquatic Invertebrates	Water Flea	48-hr EC_{50} NOAEC	1.6 0.48	(USEPA 2008b) (USEPA 2016a)
Aquatic Invertebrates	Pacific Oyster (*Crassostrea gigas*)	96-hr EC_{50}	199	(USEPA 2008b) (USEPA 2016a)
Aquatic Invertebrates	Grass Shrimp (*Palaemonetes pugio*)	96-hr LC_{50}	2.35	(USEPA 2008b) (USEPA 2016a)

Terrestrial Effects Analysis

Naphthalene is classified as practically nontoxic 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 nontoxic 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)
Northern Bobwhite	Acute oral LD_{50}	2,690 mg/kg-bw	(USEPA 2008b)
Northern Bobwhite	NOAEC	810 mg/kg-bw	(USEPA 2008b)
Northern Bobwhite	Subacute dietary LC_{50}	>5,620 mg/kg-bw/day	(USEPA 2008b)

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, therefore, dietary exposure from food is not expected. USEPA determined outdoor post-application inhalation and dermal exposure to be negligible or minimal (USEPA 2018b).

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 2008c;2018b). 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 2018b). 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 2018b).

When used outdoors as an animal repellent, migration to water resources (drinking water) is potentially possible. USEPA (2008c;2018b) 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 from WS 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.

Care in the selection of use sites by WS 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 nontarget 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 (2018a) 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 (2018a) 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 USEPA (2008b) estimates above indicate adverse effects to some birds and mammals, USEPA indicates exposure would be much less because the estimate assumes that nontarget 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 nontarget species. However, should WS usage of naphthalene increase significantly, WS applications could possibly have some adverse impacts on nontarget 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;2019a).

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 2015a). Although piperine can be extracted from dried black peppercorns, it is manufactured synthetically for commercial uses (USEPA 2004d).

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 2019a).

WS may use and distribute products containing oil of black pepper and piperine to cooperators to repel animals such as dogs, cats, raccoons, skunks, squirrels, marmots, 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 2004b). 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 2004d). 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 2023a).

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 nontoxic results (USEPA 2005b). Risks to nontarget 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 2019a).

USEPA (2019a) 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). A search of the USEPA (2024) IDS identified 12 incidents or aggregated results that involved capsaicin with black pepper oil and piperine for Calendar Years (CY) 2014-2023 that caused eight minor human exposures, six domestic animal injuries (one fatal), and one plant incident; as discussed, these were more likely attributed to the capsaicin in the formulation.

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 (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 or birds, given their widespread use as food additives. Mallards 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 nontarget 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 nontarget 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 2010a). 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 2010a).

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 did not use products containing polybutene between FY11 and 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 x 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 x 10^9 L/kg (USEPA 2010a).

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;2010a).

10.1.4 Hazard Identification

The pesticidal mode of action for polybutene is mechanical in nature rather than chemical, relying on an adhesive/sticky surface which, upon contact, discourages animals from roosting, perching, walking, or gnawing on treated surfaces (USEPA 1995;2010a;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 2022h). 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;2010a). 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
Laboratory Brown 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 2010a)

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 (2022h) 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 (Cosmetic Ingredient Review Panel 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 2022h).

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 2022h). 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 2022h).

No evidence of immunotoxicity, carcinogenicity, or mutagenicity for polybutene has been found (USEPA 2022h).

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 an effect similar to that produced by a naturally occurring estrogen, androgen, or thyroid hormone in humans or any other organism (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 2010a).

Terrestrial Effects Analysis

Polybutene is practically nontoxic to mammals and birds from acute exposures (Table 16) (USEPA 2010a). Birds are surrogates for reptiles and terrestrial-phase amphibians; therefore, polybutene is likely practically nontoxic 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 2010a).

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

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

Reference: (USEPA 2010a)

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 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 2022h). 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 2010a). Inhalation exposure from the gel formulation is not of concern due to the use pattern and application method (paintbrush and caulking gun) (USEPA 2022h). 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 (2022h) 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, undue risks to aquatic animals are not 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 (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 not as likely to be prevalent as invasive bird species, the risk to most nontarget birds is alleviated (USEPA 1994).

USEPA (2022h) reviewed the IDS (2017-2022) and found 11 incidents involving polybutene resins classified as minor severity. USEPA (2022h) 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 (2010a) 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. A search of the USEPA (2024) IDS identified 11 incidents with minor exposures to people that involved polybutene for Calendar Years (CY) 2014-2023. Polybutene’s environmental fate properties, label requirements, the proposed WS use pattern, and the favorable toxicity data indicate negligible risk to nontarget terrestrial and aquatic species with the exception of nontarget migratory birds. WS adherence to the application of polybutene products according to label directions will minimize risk to nontarget 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;2013a). 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 (2018a) 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 2018a). 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 2013c). Sulfur is an odorless, tasteless, yellow crystalline solid (USEPA 2013c). 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 2013c). Sulfur is largely insoluble in water at 1.9×10^{-8} mol S_8/L or 4.87 parts per billion (USEPA 2013c).

11.1.3 Environmental Fate

USEPA (2013a) 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 2013c). 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 2013c). The subsequent fate of sulfide depends on metal sulfide precipitation or volatilization to hydrogen sulfide (H_2S; gas) (USEPA 2013c). The dissipation of sulfate is dependent on leaching and soil organic matter immobilization (USEPA 2013c).

11.1.4 Hazard Identification

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

of the (USEPA 2024) Incident Data System identified 19 incidents or aggregated results that involved sulfur for Calendar Years (CY) 2014-2023. Of these, there were 49 human cases (two were allegedly major) with minor symptoms including nausea, headaches, and sorethroats and 12 domestic animal cases (one major and one alleged incident was said to have caused three dog deaths).The symptoms may be due to naphthalene which is also an active ingredient in the products.

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

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 2013a).

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 2013a).

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;2013a).

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

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 2013c). 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 2013c). 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 2013c).

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

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

[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 2013c).

Terrestrial Effects Analysis

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

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

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.

Sulfur in repellent products 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 2013c). Sulfur is practically insoluble in water. Therefore, minimal exposure is expected to aquatic species from any runoff (USEPA 2013c). Even if exposure occurs, sulfur is practically nontoxic to aquatic species (USEPA 2013c).

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 2013c). However, all 5 occurred between 1999 and 2001, and USEPA rated only one as “probable” (USEPA 2013c).

Ingestion by nontarget 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 nontarget species (USEPA 2013c). No ecological incidents are reported for any other terrestrial species despite sulfur’s extensive use in various pesticide products (USEPA 2013c). However, USEPA (2018a) 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 2018a).

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

12 URINES, COYOTE, AND FOX

12.1 Problem Formulation

12.1.1 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 2019b). 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 2009e). 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;2019b). 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 2019b).

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.

12.1.2 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).

12.1.3 Environmental Fate

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

12.1.4 Hazard Identification

As of May 2024, there were no adverse human incidents reported for coyote or fox urines in USEPA’s Incident Data System (USEPA 2024).

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

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

12.2 Dose-Response Assessment

12.2.1 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 2019b). 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 nontoxic 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).

12.2.2 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 nontoxic to freshwater invertebrates and fish (Table 18; (USEPA 2016b).

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

Taxon Group	Test Species	Test	Result (mg/L)	Reference
Freshwater Fish	Barna Baril (*Barilius barna*)	96-hr LC_{50}	>9,100	(USEPA 2016b)
Freshwater Fish	Ide (*Leuciscus idus melanotous*)	48-hr LC_{50}	>10,000	(USEPA 2016b)
Aquatic Invertebrates	Water Flea	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 nontoxic to practically nontoxic to birds, mammals, and insects (Table 19; (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 19 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)
Rock Dove (domestic)	Acute oral lowest lethal dose	16,000 mg/kg-bw	(USEPA 2016b)
Rock Dove (domestic)	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)

12.3 Exposure Assessment and Risk Characterization

12.3.1 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 2019b).

Coyote and fox urine repellent products are not registered for food uses (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 2019b).

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).

13 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 nontarget 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.

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 nontarget 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 these chemical repellents' have mostly favorable toxicity profiles and label requirements minimize exposure risks to workers and the public (Table 20). 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 nontarget wildlife are low due to relatively low toxicity and mitigated exposure pathways (Tables 21-22).

Table 20 Summary of chemical repellent toxicity to humans.

Active Ingredient	Dermal Exposure Route[1]	Ocular Exposure Route[1]	Inhalation Exposure Route[1]	Oral Exposure Route[1]	FDA Classification for Food Additives
Ammonium soaps of fatty acids	Nontoxic	Moderate toxicity	Nontoxic	Nontoxic	N/A
Anthraquinone	Low toxicity	Low toxicity	Nontoxic	Nontoxic	N/A
Capsaicin	Nontoxic	Nontoxic	Low toxicity	Nontoxic	GRAS
Egg solids	Nontoxic	Low toxicity	Nontoxic	Nontoxic	GRAS
Garlic oil	Nontoxic	Nontoxic	Nontoxic	Nontoxic	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	Nontoxic	Nontoxic	Nontoxic	Nontoxic	GRAS
Polybutene	Low toxicity	Moderate toxicity	Waived	Nontoxic	N/A
Sulfur	Low toxicity	Low toxicity	Low toxicity	Nontoxic	N/A
Urines, Coyote and Fox	Nontoxic	Nontoxic	Nontoxic	Nontoxic	N/A

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

Table 21 Summary of chemical repellent acute toxicity to aquatic species.

Active Ingredient	Freshwater Fish	Freshwater Invertebrate	Esturaine/Marine Fish	Estuarine/Marine Invertebrate	Amphibian	Plant
Ammonium soaps of fatty acids	Slightly toxic	Slightly toxic	Nontoxic	Slightly toxic	Slightly toxic	--
Anthraquinone	Low toxicity	Slight to high toxicity	Low toxicity	High toxicity	Low toxicity[1]	Low toxicity
Capsaicin	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]
Egg solids	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]
Garlic Oil	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]
Methyl anthranilate	Slight to moderate acute toxicity; practically nontoxic on a dietary basis	Slight toxicity	--	--	Slight to moderate acute toxicity[1]	--
Naphthalene	Moderately toxic	Moderately toxic	--	--	Moderately toxic [1]	Slightly toxic
Oil of black pepper Piperine	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]
Polybutene	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]	-- [3]
Sulfur	Practically nontoxic	Practically nontoxic	--	--	Practically nontoxic	-- [3]
Urines, coyote and fox	-- [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 nontoxic. USEPA waived toxicity data requirements.

Table 22 Summary of chemical repellent acute toxicity to terrestrial species.

Active Ingredient	Invertebrate	Bird	Mammal (wildlife)	Reptile/ Amphibian	Plant
Ammonium soaps of fatty acids	Practically nontoxic	Practically nontoxic	Practically nontoxic	Practically nontoxic [1]	Phytotoxicity can occur
Anthraquinone	Low toxicity	Low toxicity	Practically nontoxic	Low toxicity [1]	--
Capsaicin	-- [2]	-- [2]	-- [2]	-- [2]	-- [2]
Egg solids	-- [2]	-- [2]	-- [2]	-- [2]	-- [2]
Garlic Oil	-- [2]	-- [2]	-- [2]	-- [2]	-- [2]
Methyl anthranilate	Practically nontoxic	Practically nontoxic	Practically nontoxic	Practically nontoxic [2]	May cause foliar burn
Naphthalene	--	Practically nontoxic	Practically nontoxic	Practically nontoxic [2]	--
Oil of black pepper Piperine	-- [2]	Practically nontoxic	-- [2]	-- [2]	-- [2]
Polybutene	-- [2]	Practically nontoxic	Practically nontoxic	Practically nontoxic [1]	--
Sulfur	Practically nontoxic	Practically nontoxic	Practically nontoxic	Practically nontoxic [1]	-- [2]
Urines, coyote and fox	-- [2]	-- [2]	-- [2]	-- [2]	-- [2]

[1] Data was unavailable for terrestrial-phase amphibians and reptiles. Birds are surrogate species.
[2] This chemical is nontoxic. USEPA waived toxicity data requirements.

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14 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., aircraft strike hazard). Chemical repellents pose a negligible risk of primary or secondary poisoning to nontarget animals, including scavengers. Label use restrictions, lack of toxicity, and/or environmental fate properties indicate that WS use of chemical repellents poses little or no risk to aquatic nontarget 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 nontoxic to people, do not threaten drinking water, and many are not used on edible plant parts. The occupational risk to WS applicators is also low because they receive training in the product's use and follow label instructions, including appropriate PPE, or product uses are limited in scope. The release of chemical repellents into the environment is expected to have no or negligible impacts on nontarget 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 nontoxic to reptiles and terrestrial-phase amphibians when considering the absence of sensitivities to surrogate avian species (Tables 21-22). 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.

Although several chemical repellents range in their toxicity to aquatic species (Table 22), 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 nontoxic to terrestrial species, including mammals and birds (Table 22). Anthraquinone demonstrates some toxicity to terrestrial invertebrates, birds, and mammals. However, the label restrictions, use patterns, and environmental fate properties for these products minimize exposure to nontarget terrestrial species.

WS believes that the overall risks associated with using the repellents discussed are minor. Additionally, WS has had no recorded exposures to repellent products.

15 LITERATURE CITED

Andelt, W.F., K.P. Burnham, and J.A. Manning. 1991. Relative effectiveness of repellents for reducing mule deer damage. Journal of Wildlife Management 55:341-347.

Arkion. 2021. Flight Control Max, Safety Data Sheet. *in* Arkion Life Sciences.

Askham, L.R. 1992. Efficacy of methyl anthranilate as a bird repellent on cherries, blueberries and grapes. Proceedings of the Vertebrate Pest Conference 15:137-141.

ATSDR. 2005. Toxicological Profile for Naphthalene, 1-Methylnaphthalene, and 2-Methylnaphthalene. U.S. Department of Health and Human Services, Public Health, Service, Agency for Toxic Substances and Disease Registry.

Avery, M.L. 1992. Evaluation of methyl anthranilate as a bird repellent in fruit crops. Proceedings of the Vertebrate Pest Conference 15:130-133.

Baker, B.P., and J.A. Grant. 2018. Putrescent Whole Egg Solids Profile. Cornell Cooperative Extension, New York State Integrated Pest Management Program.

Burdock, G.A., editor. 2010. Fenaroli's Handbook of Flavor Ingredients. 6th ed. (page 1213). CRC Press, Boca Raton, FL.

Clark, L., J. Cummings, S. Bird, and E. Aronov. 1993. Acute toxicity of the bird repellent, methyl anthranilate, to fry of *Salmo salar*, *Oncorhynchus mykiss*, *Ictalurus punctatus,* and *Lepomis macrochirus*. Pesticide Science 39:313-317.

Clark, L., C. Goulden, and J.N. McNair. 1994. Daphnid Acute Toxicity Test. EPA MRID No. 427182-03.

Clark, L., and M.L. Avery. 2013. Effectiveness of chemical repellents in managing birds at airports. Pages 25-35 *in* T. L. DeVault, B. F. Blackwell, andJ. L. Belant, eds. Wildlife in Airport Environments: Preventing Animal-aircraft Collisions through Science-based Management. The Johns Hopkins University Press in association with The Wildlife Society, Baltimore, Maryland.

Cosmetic Ingredient Review Panel. 1982. Final Report on the Safety Assessment of Polybutene. Journal of American College of Toxicology 1:103-118.

DeLiberto, S.T., and S.J. Werner. 2016. Review of anthraquinone applications for pest management and agricultural crop protection. Pest Management Science 72:1813-1825.

Dolbeer, R.A., M.A. Link, and P.P. Woronecki. 1988. Naphthalene shows no repellency for starlings. Wildlife Society Bulletin 16:62-64.

Dolbeer, R.A., L. Clark, P.P. Woronecki, and T.W. Seamans. 1992. Pen tests of methyl anthanilate as a bird repellent in water. Proceedings of the Eastern Wildlife Damage Management Conference 5:112-116.

Dolbeer, R.A., J.L. Belant, and L. Clark. 1993. Methyl anthranilate formulations to repel birds from water at airports and food at landfills. Proceedings of the Great Plains Wildlife Damage Control Workshop 11:42-53.

Dolbeer, R.A., T.W. Seamans, B.F. Blackwell, and J.L. Belant. 1998. Anthraquinone formulation (Flight Control) shows promis as avian feeding repellent. Journal of Wildlife Management 64:1558-1564.

European Chemicals Agency. 2019. Anthraquinone. ECHA Substance Information. Updated September 19.

Fagerstone, K. 2002. Professional use of pesticides in wildlife management - An overview of professional wildilfe damage management. Proceedings of the Vertebrate Pest Conference 20:253-260.

Husson, R. 1986. Letter sent to J. Rockwell dated Sept 17, 1986: [Data requested to complete review of 48 hour LC50 study on Daphnia magna: thiram]. UCB Societe Anonyme. 3p.

Kare, M.R., and H.L. Pick. 1960. The influence of the sense of taste on feed and fluid consumption. Poultry Science 39:697-706.

Komarnisky, L.A., R.J. Christopherson, and T.K. Basu. 2003. Sulfur: Its clinical and toxicologic aspects. Nutrition 19:54-61.

Lewis, R.J.S., editor. 2004. Sax's Dangerous Properties of Industrial Materials. 11th Edition (page 272). Wiley-Interscience, Wiley & Sons, Inc., Hoboken, NJ.

Lewison, R., N.J. Bean, E.V. Aronov, J.E.J. McConnell, and J.R. Mason. 1993. Similarities between big game repellent and predator urine repellency to white-tailed deer: the importance of sulfur and fatty acids. Proceedings of the Vertebrate Pest Conference 6:145-148.

Mallakin, A., B.J. McConkey, G. Miao, B. McKibben, V. Snieckus, D.G. Dixon, and B.M. Greenberg. 1999. Impacts of structural photomodification on the toxicity of environmental contaminants: Anthracene photooxidation products. Ecotoxicology and Environmental Safety, Environmental Research, Section B 43:204-212.

Mason, J.R., J.F. Glahn, R.A. Dolbeer, and R.F. Reidinger. 1985. Field evaluation of dimethyl anthranilate as a bird repellent livestock feed additive. Journal of Wildlife Management 49:636-642.

NCBI. 2022a. PubChem Compound Summary for CID 227, Anthranilic acid. National Center for Biotechnology Information.

_____. 2022b. PubChem: Capsaicin National Institutes of Health, National Library of Medicine, National Center for Biotechnology Information.

NIH. 2022a. PubChem: Naphthalene, CID 931. National Institutes of Health, National Library of Medicine, National Center for Biotechnology Information.

_____. 2022b. Ammonium nonanoate, PubChem CID 21902950.

_____. 2022c. Methyl anthranilate, PubChem CID 8635. National Institutes of Health, National Library of Medicine, National Center for Biotechnology Information.

_____. 2023a. Piperine Compound Summary. https://pubchem.ncbi.nlm.nih.gov/compound/Piperine#:~:text=Piperine%20is%20a%20N%2Dacylpiperidine,from%20the%20plant%20Piper%20nigrum. accessed 03/10/2023.

_____. 2023b. Nonanoic Acid. PubChem CID 8158. National Institutes of Health, National Library of Medicine, National Center for Biotechnology Information.

Nolte, D.L., D.L. Campbell, and J.R. Mason. 1994. Potential repellents to reduce damage by herbivores. Proceedings of the Vertebrate Pest Conference 16:226-231.

O'Neil, M.J., editor. 2001. The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. 13th Edition (page 117). Merck and Co., Inc., Whitehouse Station, NJ.

Opdyke, D.L.J. 1974. Fragrance raw materials monographs. Food and Cosmetics Toxicology 12:935-936.

PMRA. 2017. Ammonium salt of fatty acid, proposed registration decision. Health Canada, Pest Management Regulatory Agency.

Sayre, R.W., and L. Clark. 2001. Effect of primary and secondary repellents on European starlings: an initial assessment. Journal of Wildlife Management 65:461-469.

Schrader, K.K., M.Q. de Regt, P.R. Tidwell, C.S. Tucker, and S.O. Duke. 1998. Selective growth inhibition of the musty-odor producing *Cyanobacterium oscillatoria* c.f. *chalybea* by natural compounds. Bulletin of Environmental Contamination and Toxicology 60:651-658.

Stevens, G.R., and L. Clark. 1998. Bird repellents: development of avian-specific tear gases for resolution of human-wildlife conflicts. International Biodeterioration & Biodegratation 42:153-160.

Sullivan, T.P., L.O. Nordstrom, and D.S. Sullivan. 1985. Use of predator odors as repellents to reduce feeding damage by herbivores. Journal of Chemical Ecology 11:921-935.

Trent, A., D.L. Nolte, and K. Wagner. 2001. Timber Tech Tips: Comparison of Commerial deer repellents. U.S. Department of Agriculture, Forest Service, Technology & Development Program.

USEPA. 1991. R.E.D. Facts Sulfur (738-F-91-110). United States Environmental Protection Agency.

_____. 1992a. Reregistration Eligibility Document: Putrescent Whole Egg Solids. https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-105101_1-Jun-92.pdf accessed March 23, 2023.

_____. 1992b. Reregistration Eligibility Document for Soap Salts Case 4083 Chemical 031801, 079021 (EPA-HQ-OPP-2008-0519-0007). U.S. Environmental Protection Agency.
_____. 1994. Reregistration Eligibility Decision (RED) Polybutene List D Case 4076 (EPA-738-R-95-007). U.S. Environmental Protection Agency, Prevention, Pesticides and Toxic Substances.
_____. 1995. R.E.D. Facts Polybutene (EPA-738-F-95-008). https://archive.epa.gov/pesticides/reregistration/web/pdf/4076fact.pdf accessed 03/23/2023.
_____. 1998a. Biopesticide Fact Sheet. Anthraquinone (122701). https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/fs_PC-122701_01-Dec-98.pdf accessed March 23, 2023.
_____. 1998b. Naphthalene, Integrated Risk Information System (IRIS) Assessment. https://iris.epa.gov/ChemicalLanding/&substance_nmbr=436 accessed March 23, 2023.
_____. 2003a. Pesticide Product Registration Applications. https://www.regulations.gov/document/EPA-HQ-OPP-2003-0388-0001 accessed 03/10/2023.
_____. 2003b. Pelargonic acid (nonanoic acid); exemption from the requirement of a pesticide tolerance. Federal Register 68 FR 7931. Pages 7931-7935. U.S. Environmental Protection Agency.
_____. 2004a. Biopesticides Registration Action Document Predator Urines: Coyote Urine (PC code 029007) Fox Urine (PC code 029008). https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/decision_G-4640_1-Dec-04.pdf accessed 03/16/2023.
_____. 2004b. Biopesticide Fact Sheet Black Pepper Oil. https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/fs_PC-000669_01-Oct-04.pdf accessed 03/10/2023.
_____. 2004c. Ammonium nonanoate; Notice of filing a pesticide petition to establish a tolerance for a certain pesticide chemical in or on food (FRL-7343-5). https://www.govinfo.gov/content/pkg/FR-2004-03-17/pdf/E4-553.pdf accessed 03/23/2023.
_____. 2004d. Biopesticide Fact Sheet Piperine. https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/fs_PC-043501_01-Oct-04.pdf accessed 03/10/2023.
_____. 2005a. Biochemial Pesticide Cases; Draft Registration Review Cases. https://www.regulations.gov/document/EPA-HQ-OPP-2004-0404-0012 accessed 03/10/2023.
_____. 2005b. Biopesticides Registration Action Document Oil of Black Pepper (PC Code 000669). https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/decision_PC-000669_18-May-05.pdf accessed 03/10/2023.
_____. 2008a. Naphthalene: Phase 2 Amendment: Response to Registrant Submitted Error Only Comments In Reference to “Naphthalene: HED Chapter for the Reregistration Eligibility Decision Document (RED)” (EPA-HQ-OPP-2008-0343-0005). U.S. Environmental Protection Agency.
_____. 2008b. Revised Ecological Risk Assessment for Reregistration Eligibility Decision (RED) for Naphthalene (EPA-HQ-OPP-2008-0343-0004). U.S. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances.
_____. 2008c. Reregistration Eligibility Decision for Naphthalene, List C, Case Number 3058 (EPA 738-R-07-010). U.S. Environmental Protection Agency.
_____. 2008d. Biopesticide Registration Action Document Ammonium nonanoate, PC Code 031802. https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/decision_PC-031802_23-Jun-08.pdf accessed March 23, 2023.
_____. 2009a. Registration Review: Product Chemistry Data Review for the Repellent Garlic Oil. https://www.regulations.gov/document/EPA-HQ-OPP-2009-0113-0004 accessed 03/09/2023.

_____. 2009b. Analysis of Mutagenicity Concern to Support the Preliminary Work Plan for the Registration Review of Capsaicin (EPA-HQ-OPP-2009-0121-0006). U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances.

_____. 2009c. Preliminary Human Health Assessment for the Registration Review of Capsaicin, Registration Review Case #: 4018 (EPA-HQ-OPP-2009-0121-0003). U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances.

_____. 2009d. Registration Review: Product Chemistry Data Review for Capsaicin and Related Capsaicinoids (EPA-HQ-OPP-2009-0121-0005). U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances.

_____. 2009e. Predator Urine: Coyote Urine (PC Code 029007) and Fox Urine (PC Code 029008). Biopesticides Registration Action Document. https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/decision_PC-029008_05-Feb-09.pdf accessed March 23, 2023.

_____. 2009f. Summary of Ecotoxicity Data for Capsaicin Registration Review EPA-HQ-OPP-2009-0121-0004). U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances.

_____. 2010a. Ecological Effects Problem Formulation for the Registration Review of Polybutene (EPA-HQ-OPP-2009-0649-0006). U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention.

_____. 2010b. Ammonium Soap Salts of Fatty Acids (C_8-C_{18} Saturated); Exemption from the Requirement of Tolerance (EPA-HQ-OPP-2008-0652-0003). Federal Register.

_____. 2010c. Garlic Oil FInal Registration Review Decision Case 4007. https://www.regulations.gov/document/EPA-HQ-OPP-2009-0113-0011 accessed 03/09/2023.

_____. 2010d. Human Health Scoping Document for the Registration Review of Polybutene (EPA-HQ-OPP-2009-0649-0004). U.S. Environmental Protection Agency.

_____. 2010e. Capsaicin Final Registration Review Decision Case 4018 (EPA-HQ-OPP-2009-0121-0012). U.S. Environmental Protection Agency, Biopesticides and Pollution Prevention Division.

_____. 2010f. Decision Document for Petition Number 8E7402; Ammonia salts of higher fatty acids (C8-C18 saturated) (EPA-HQ-OPP-2008-0652-0004). U.S. Environmental Protection Agency, Office of Prevention, Pesticide, and Toxic Substance.

_____. 2011a. Preliminary Human Health Assessment for Registration Review of Methyl Anthranilate (EPA-HQ-OPP-2011-0678-0004). U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances.

_____. 2011b. Ecotoxicity Assessment for Putrescent Egg Solids Registration Review (EPA-HQ-OPP-2010-0726-0006). U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention.

_____. 2011c. Preliminary Human Health Assessment for the Registration Review of Putrescent Whole Egg Solids (EPA-HQ-OPP-2010-0726-0004). U.S. Environmental Protection Agency, Office of Pesticides and Toxic Substances.

_____. 2011d. Non-target Organism and Endangered Species Screening Risk Assessment for the Methyl Anthranilate (Benzoic Acid, 2-Amino, Methyl Ester) Registration Review Preliminary Work Plan (EPA-HQ-OPP-2011-0678-0002). U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention.

_____. 2011e. Chemistry Scoping Document for Registration Review of Putrescent Whole Egg Solids (EPA-HQ-OPP-2010-0726-0005). U.S. Environmental Protection Agency.

_____. 2011f. Putrescent Whole Egg Solids Final Work Plan, Registration Review Case Number 4079 (EPA-HQ-OPP-2010-0726-0003). U.S. Environmental Protection Agency.

_____. 2011g. Product Chemistry Scoping Document for the Registration Review of Methyl Anthranilate (EPA-HQ-OPP-2011-0678-0003). U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution.
_____. 2012a. Naphthalene, Immunotoxicity study in Mice. https://www.regulations.gov/document/EPA-HQ-OPP-2016-0113-0025 accessed 03/09/2023.
_____. 2012b. Soap Salts. Preliminary Risk Assessment to Support Registration Review (EPA-HQ-OPP-2008-0519-0018). U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention.
_____. 2013a. Sulfur Human Health Preliminary Risk Assessment (EPA-HQ-OPP-2008-0176-0050). https://www.regulations.gov/document/EPA-HQ-OPP-2008-0176-0050 accessed 03/23/2023.
_____. 2013b. Soap Salts: Updated Tier I Review of Human Incidents (EPA-HQ-OPP-2008-0519-0020). U.S. Environmental Protection Agency.
_____. 2013c. Environmental fate and ecological effects preliminary risk assessment for the registration review of sulfur (EPA-HQ-OPP-2008-0176-0051). United States Environmental Protection Agency.
_____. 2014. Exemption of polybutene from the requirements of the endocrine disruptor screening program (EPA-HQ-OPP-2009-0649-0015). https://www.regulations.gov/document/EPA-HQ-OPP-2009-0649-0015 accessed 03/23/2023.
_____. 2015a. Crop Grouping - Part XVD: Apendices for the analysis fo the USDA IR-4 Petition to amend the crop group regulation 40 CFR 180.41 (c) (26) and commodity definitions [40 CFR 180.1 (g)] related to herb crop group 25 and spice crop group 26. https://www.regulations.gov/document/EPA-HQ-OPP-2006-0766-0104 accessed 03/10/2023.
_____. 2015b. Pesticide Retrieval Information System: Hinder, EPA Registration Number 5481-508. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution.
_____. 2015c. Revised Environmental Fate and Ecological Risk Assessment for Registration Review of Soap Salts: Potassium Salts of Fatty Acids, Ammonium Salts of Fatty Acids, and Sodium Salts of Fatty Acids (EPA-HQ-OPP-2015-0519-0030). U.S. Environmental Protection Agency.
_____. 2016a. Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments to be Conducted for the Registration Review of Naphthalene. https://www.regulations.gov/document/EPA-HQ-OPP-2016-0113-0005 accessed 03/09/2023.
_____. 2016b. Predator Urines: Coyote Urines (PC Code: 029007) and Fox Urine (PC Code: 029008) Preliminary Work Plan and Summary Document Registration Review: Initial Docket June 2016 Case number 6202 (EPA-HQ-OPP-2016-0086-0002). United States Environmental Protection Agency.
_____. 2018a. Registration Review Drinking Water Exposure and Ecological Risk Profile for Naphthalene. https://www.regulations.gov/document/EPA-HQ-OPP-2016-0113-0019 accessed 03/09/2023.
_____. 2018b. Naphthalene: Human Health Risk Assessment in Support of Registration Review. https://www.regulations.gov/document/EPA-HQ-OPP-2016-0113-0018 accessed 03/09/2023.
_____. 2018c. Putrescent Whole Egg Solids, Interim Registration Review Decision, Case Number 4079 EPA-HQ-OPP-2010-0726-0009. U.S. Environmental Protection Agency.
_____. 2018d. Methyl anthranilate final workplan registration review case 6056 (EPA-HQ-OPP-2011-0678-0013. U.S. Environmental Protection Agency.
_____. 2018e. Predator Urines: Coyote Urine and Fox Urine Proposed Interim Registration Review Decision Case Number 6202 (EPA-HQ-OPP-2016-0086-0004). United Stated Environmental Protection Agency.
_____. 2019a. Oil of Black Pepper interim Registration Review Decision. https://www.regulations.gov/document/EPA-HQ-OPP-2017-0262-0007 accessed 03/10/2023.
_____. 2019b. Predator Urines: Coyote Urine and Fox Urine Interim Registration Review Decision Case Number 6202 (EPA-HQ-OPP-2016-0086-0009). United States Environmental Protection Agency.

_____. 2020. Methyl anthranilate, Interim Registration Review Decision, Case Number 6065 (EPA-HQ-OPP-2011-0678-0012). U.S. Environmental Protection Agency, Biopesticides and Pollution Prevention Division.
_____. 2021. Avipel® Liquid Corn Seed Treatment, USEPA Reg. No. 69969-6.
_____. 2022a. 9,10-Anthraquinone: Draft Human Health Risk Assessment for Registration Review (EPA-HQ-OPP-2017-0326-0030). U.S. Environmental Protection Agency.
_____. 2022b. AV-5055 Label, EPA Registration Number 699969-7, Flight Control Max and AV-1011 Liquid Rice Seed Treatment.
_____. 2022c. Pesticide Product and Label System (PPLS): Capsaicin labels. https://ordspub.epa.gov/ords/pesticides/f?p=113:6:::::P6_XCHEMICAL_ID:1699 accessed March 23, 2023.
_____. 2022d. Pesticide Product and Label System (PPLS): Lursect labels https://ordspub.epa.gov/ords/pesticides/f?p=113:6:::::P6_XCHEMICAL_ID:2255 accessed March 23, 2023.
_____. 2022e. Overview of Risk Assessment in the Pesticide Program U.S. Environmental Protection Agency https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program Accessed 12/15/2022.
_____. 2022f. Garlic Oil PC Code 128827 Combined Preliminary Work Plan and Proposed Interim Registration Review Decision Case Number 4007. https://www.regulations.gov/document/EPA-HQ-OPP-2021-0838-0002 accessed 03/09/2023.
_____. 2022g. Anthraquinone: Draft Ecological Risk Assessment for Registration Review (EPA-HQ-OPP-2017-0326-0014). U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention.
_____. 2022h. Memorandum: Polybutene. Combined Human Health Scoping Document/Draft Human Health Risk Assessment for Registration Review (EPA-HQ-OPP-2022-0799-0005). United States Environmental Protection Agency.
_____. 2024. Pesticide Registration Incident Data System (IDS) US Environmental Protection Agency Last Updated 05/02/2024 https://ordspub.epa.gov/ords/pesticides/f?p=359:5:::::: Accessed 04/09/2024.
Verschueren, K. 2001. Handbook of Environmental Data on Organic Chemicals. Volumes 1-2. 4th ed. John Wiley & Sons, New York, NY.
Wagner, K.K., and D.L. Nolte. 2001. Comparison of active ingredients and delivery systems in deer repellents. Wildlife Society Bulletin 29:322-330.
Westerfield, G.D., J.M. Shannon, O.V. Duvuvuei, T.A. Decker, and N.P. Snow. 2019. Methods for managing human-deer conflicts in urban, suburban, and exurban areas. Human Wildlife Interactions Monographs 3:1-99.
Woodstream Corporation. 2013. Dr. T's Snake-A-Way Repelling Granules, EPA Registration Number 58630-1, May 1, 2013. https://www3.epa.gov/pesticides/chem_search/ppls/058630-00001-20130501.pdf accessed August 2, 2022.

16 PREPARERS: WRITERS, EDITORS, AND REVIEWERS

APHIS WS Methods Risk Assessment Committee

16.1 Writers for "Use of Chemical Repellents in Wildlife Damage Management Risk Assessment":

Primary Writer: Shelagh DeLiberto
Position: USDA-APHIS-Wildlife Services (WS), Environmental Coordinator, Fort Collins, CO
Education: BA Biology and Environmental Science – Ithaca College; MS Wildlife Biology – Colorado State University
Experience: Nineteen years of service in APHIS conducting wildlife research. Five years of experience in preparing categorical exclusions and environmental analyses in compliance with the National Environmental Policy Act.

Primary Writer: Andrea Lemay
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Education: BS Plant and Soil Science (Biotechnology) - University of Massachusetts; MS Plant Pathology -North Carolina State University
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Writer/Editor: Thomas C. Hall
Position: USDA-APHIS-WS, Operational Support Staff, Staff Wildlife Biologist, Fort Collins, CO
Education: BS Biology (Natural History) and BA Psychology – Fort Lewis College; MS Wildlife Ecology – Oklahoma State University
Experience: Special expertise in wildlife biology, identification, ecology, and damage management. Thirty-eight years of service in APHIS Wildlife Services including operations and research in CO for research and OR, GU, CA, OK, and NV for operations conducting a wide variety of programs including bird damage research and management, livestock protection (predators and birds), invasive species management, wildlife hazard management at airports, property and natural resource protection including waterfowl, brown tree snake, feral swine, rodent, and beaver damage management. Researched, applied and supervised the use of repellents.

Primary Writer/Editor: Jim Warren
Position: USDA-APHIS-Policy and Program Development (PPD), Environmental and Risk Analysis Services (ERAS), Environmental Toxicologist, Little Rock, AR
Education: B.S. Forest Ecology and M.S. Entomology – University of Missouri; Ph.D. Environmental Toxicology – Clemson University
Experience: Over sixteen years of experience working for APHIS preparing ecological risk assessments and providing assistance on environmental compliance. Prior experience before joining APHIS includes other government and private sector work regarding ecological risk assessments related to various environmental regulations.

Primary Writer: Michael McCaskill

Position: USDA-APHIS-Policy and Program Development (PPD), Environmental and Risk Analysis Services (ERAS), Toxicologist, New Market, MD
Education: B.S. Environmental Science – University of Florida; MPH Industrial Hygiene-University of South Carolina, Ph.D. Toxicology-Florida Agriculture and Mechanical University
Experience: Ten years of experience conducting human toxicological research at Florida Agriculture and Mechanical University, University of Nebraska Medical Center, and Tulane University. Four years of experience conducting human health and environmental toxicological risk assessments and assisting environmental compliance programs at the Florida Department of Health, Commonwealth of Pennsylvania, and USDA.

Primary Writer /Contributor: Emily Ruell
Position: USDA-APHIS-WS, NWRC, Registration Specialist, Fort Collins, CO
Education: B.S. Zoology and Biological Aspects of Conservation – University of Wisconsin - Madison; M.S. Ecology – Colorado State University (CSU); M.A. Political Science – CSU
Experience: Nine years of experience with WS NWRC preparing and reviewing vertebrate pesticide registration data submissions and other registration materials and providing pesticide regulatory guidance to WS, WS NWRC, and collaborators. Prior experience before joining APHIS includes seven years of conducting field and laboratory wildlife research at CSU and environmental policy research for the U.S. Geological Survey.

Editors/Contributors for "Use of Chemical Repellents in Wildlife Damage Management Risk Assessment":

Editor: Ryan Wimberly
Position: USDA-APHIS-WS, Operational Support Staff, Staff Wildlife Biologist, Madison, TN
Education: BS Wildlife Management and Ecology – Northwest Missouri State University
Experience: Special expertise in wildlife biology, ecology, and damage management. Seventeen years of service with APHIS Wildlife Services, including operations and research, conducting a wide variety of programs, including bird damage research and management, livestock protection, invasive species management, wildlife hazard management at airports, property, and natural resource protection. Expert in preparing environmental documents for WS programs to comply with the National Environmental Policy Act and the Endangered Species Act.

Data Contributor: Joey Millison
Position: USDA-APHIS-WS Information and Technology (IT), Junior Applications Developer
Education: Information and Technology coursework from various sources
Experience: Eleven years of experience in APHIS, WS Management Information System (MIS) Group. Retrieves WS field data from the MIS for writers, reviewers, and editors.

16.2 Internal Reviewers

USDA APHIS Wildlife Services

Reviewer: Scott Beckerman
Position: USDA APHIS Wildlife Services, State Director/ Supervisory Wildlife Biologist, Springfield, IL
Education: BS and MS in Fisheries and Wildlife Management, University of Missouri-Columbia
Experience: Expertise in wildlife damage management and wildlife biology. Thirty one years of service in APHIS Wildlife Services operational programs in MO, IA, WI, CA, and IL.

Experience in mitigating conflicts caused by a wide variety of wild animals including, ungulates, migratory birds/waterfowl, predators, rodents, and invasive species including feral swine.

Reviewer: Scott Werner
Position: USDA-APHIS-WS, National Wildlife Research Center, Supervisory Research Wildlife Biologist, Fort Collins, CO.
Education: B.S., M.S., Ph.D. Wildlife and Range Science
Experience: Specialized experience in wildlife science and wildlife biology (35 years; TWS-Certified Wildlife Biologist®). NWRC research experience, including the evaluation and development of wildlife repellents for wildlife damage management (25 years).

16.3 Peer Review

The Office of Management and Budget requires agencies to have peer-review guidelines for scientific documents. The APHIS guidelines were followed to have "Use of Registered Chemical Repellents in Wildlife Damage Management" peer-reviewed. WS worked with the Association of Fish and Wildlife Agencies to have experts review the documents.

16.3.1 Peer Reviewers Selected by the Association of Fish and Wildlife Agencies

Arizona Game and Fish Department
Wisconsin Department of Natural Resources
Montana Fish, Wildlife & Parks

16.3.2 Comments

1. Given the pending decision by USEPA regarding Thiram, WS should expand on when Thiram might be used, under what criteria, and how WS will mitigate environmental and human health risks. Currently the document states ‘strict adherence to current and future product label mandates’. For the remainder of the document, standard operating procedures described in document will minimize or mitigate the risk to human, animal and environmental health.
   Response: We have removed the sections related to Thiram based on the most recent information available from the EPA on proposed changes to Thiram registrations. See Thiram. Amended Proposed Interim Registration Review Decision Case Number 0122 April 2024 (Docket Number EPA-HQ-OPP-2015-0433, which removed all animal uses for thiram.

2. Only one edit or question, in Ammonium soaps of fatty acids 2.1.1 Description and product use: 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. I would think that it needs to be applied from the ground to just above rabbit height.

   Response: We have edited this sentence to indicate the trunks should be treated to just above the height that rabbits might reach, not above the height that rabbits might reach.

3. Might suggest a reference to Westerfield et al. 2019, Methods for Managing Human-deer Conflict in Urban, Suburban, and Exurban Areas, Human-Wildlife Interactions Monograph 31-99, as that publication references the use of many of these. It might be referenced on page 3 in association with Fagerstone 2002.

   Response: We have included this reference as suggested.

Comments received not requiring a response.

1. The document appears to be thorough and detailed, considering the full extent of availalbie information and outlining steps to minimize impacts to nontarget species and humans where risk or uncertainty exists.
2. Standard operating procedures and/or mitigations were well-reasoned and defensible.
3. I have no concerns from a state wildlife agency perspective and have not provided any specific comments within the document.
4. The individual components are complete and the quality of the assessment of the methods is good
5. All assumptions and uncertainties have been clearly stated. References appear appropriate.
6. This review is thorough and complete, and identifies potential risks (which are largely minimal) with the use of these chemical repellants.
7. Of note, relatively little of these chemical repellants are used currently. Should human wildlife conflicts increase, which several authors seem to suggest, the likelihood for the need to increase use of chemical repellants exists. It would appear that most of these chemical repellants are unlikely to create much concern or risk even with substantial increases.