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

Chapter XXXIV

USE OF ALPHA-CHLORALOSE IN WILDLIFE DAMAGE MANAGEMENT

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EXECUTIVE SUMMARY

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Wildlife Services (WS) uses alpha-chloralose to immobilize (sedate) and live capture birds. Alpha-chloralose is added to bread and whole corn kernel baits and used to hand bait and immobilize certain free-ranging birds when other capture methods are not practical, are dangerous for personnel and target birds, or for publicly sensitive projects.

Risks to the public from WS' use of alpha-chloralose are negligible. WS employees must be on site when alpha-chloralose is being applied and will reduce or control access to application areas by the public and domestic animals as much as possible. There is negligible dietary exposure risk to people from drinking water or consuming birds exposed to alpha-chloralose that are then slaughtered or hunted for food. Alpha-chloralose is rapidly metabolized and excreted by birds. Most birds are not released in WS bird damage projects involving alpha-chloralose. For birds released into huntable bird populations or birds slaughtered for food, WS follows the withdrawal period established by the prescribing veterinarian for that project. Cumulative impacts to human health are not expected because of the lack of significant exposure from WS applications.

The exposure and cumulative risks from WS' use of alpha-chloralose to most ecological resources are negligible. There are some potential direct risks to non-target species that could intercept baits meant for target birds or consume bait accidentally left behind from an application, but WS' methods minimize these potential direct exposures to non-target animals. Accidentally exposed non-target animals can often be captured and released after they recover from the effects of the alpha-chloralose. WS personnel remain at the treatment site and remove immobilized birds and unconsumed bait, minimizing exposure and risks to domestic animals and non-target wildlife species. Past studies and use records indicate the number of directly impacted non-target wildlife is small. There are minimal potential secondary risks to non-target predators or scavengers consuming birds shortly after they have been exposed to alpha-chloralose. WS live captures treated birds once they are immobilized, and most cannot be relocated and released. When treated birds can be relocated and released, WS holds them through a minimum recovery period. Therefore, WS expects minimal to no adverse effects to non-target animals or species from WS' use of alpha-chloralose.

Risks to aquatic species are also anticipated to be negligible. WS almost exclusively baits target birds on dry land rather than baiting birds swimming or wading in water bodies, unless there is no other option. Treated birds and unconsumed alpha-chloralose baits are removed from the area of application, reducing the potential for alpha-chloralose to enter waterbodies in surface runoff or within a dosed bird. Baiting birds that are swimming or wading in water could increase risks to aquatic species and resources, but risks to aquatic species are minimal based on the available aquatic toxicity data for non-target organisms and conservative estimates of alphachloralose concentrations in water from a typical bait application.

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1 INTRODUCTION

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Wildlife Services (WS) uses alpha-chloralose as a component of wildlife management activities. WS uses alpha-chloralose to immobilize and live capture free-ranging and wild birds in nuisance situations, in public health and safety situations (e.g., airports), and in emergency response situations such as removing birds from oil spills and transporting them to a rehabilitation facility. When used as an immobilizing agent or sedative, alpha-chloralose is regulated as an animal drug by the U.S. Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FFDCA).

Between 1992 and 2019, WS used alpha-chloralose combined with bread or whole corn to hand bait, immobilize, and live-capture free-ranging Canada geese (*Branta canadensis*), American coots (*Fulica americana*), and mallards (*Anas platyrhynchos*), including feral and hybrid ducks, and additional wild bird species, such as sandhill cranes (*Grus canadensis*), pigeons (*Columba livia*), common ravens (*Corvus corax*), and wild turkeys (*Meleagris gallopavo*) as allowed by FDA under an FDA Investigational New Animal Drug (INAD) file (INAD number I-006602). WS discontinued use of alpha-chloralose in November 2018 and APHIS officially closed INAD I-006602 with the FDA in February 2019, due to the inability of APHIS to pursue a new animal drug approval or indexing for the use of alpha-chloralose as an immobilizing agent for wild bird species. This left no approved, indexed, or investigational sedative drug available to immobilize free-ranging wild birds for live capture.

In 2022, the FDA announced a new enforcement discretion policy for certain compounded bulk drug substances used as sedatives and anesthetics for free-ranging wildlife species and prescribed by state-licensed veterinarians in accordance with FDA Guidance #256 "Compounding Animal Drugs from Bulk Drug Substances" (FDA 2022). In 2024, FDA extended this enforcement discretion for bulk drug substances under FDA Guidance #256 to alpha-chloralose when it is compounded and used as a sedative for certain free-ranging bird species. Additional free-ranging bird species may be nominated to FDA for alpha-chloralose in the future. Under this enforcement discretion by FDA, alpha-chloralose may not be used to fatally overdose birds intentionally. That would be an unregistered (illegal) pesticide use of alpha-chloralose and would be regulated by the U.S. Environmental Protection Agency (USEPA) under the Federal Fungicide, Insecticide, and Rodenticide Act (FIFRA).

To ensure appropriate use, storage, and control of alpha-chloralose, WS has a committee that 1) reviews and approves immobilization drugs such as alpha-chloralose and accessory immobilization and euthanasia drugs, and 2) establishes training and certification requirements for their use. WS acquisition, storage and use of alpha-chloralose and other chemical immobilization and euthanasia drugs are managed under guidelines established by WS Directive 2.430 (USDA APHIS 2019). Additionally, WS personnel are required to complete an alpha-chloralose training and certification program (USDA APHIS 2024). Policies of WS immobilization and euthanasia program comply with Drug Enforcement Agency (DEA) and FDA

regulations, in addition to compliance with requirements of the states in which WS uses alphachloralose.

This human health and ecological risk assessment (HHERA) is an evaluation of the risks and hazards to human health, and non-target fish and wildlife from WS use of alpha-chloralose. The methods used to assess human health effects follow regulatory guidance and methods (National Research Council 1983, USEPA 2024), and conform to other federal agencies, such as USEPA.

This assessment starts with identifying the hazard (problem formulation) and then evaluates toxicity (the dose-response assessment). The last section combines the discussion about exposure (identifying exposed populations and exposure pathways for these populations) with the effects data to characterize risk for human health and non-target fish and wildlife.

1.1 Alpha-chloralose Use Pattern

WS hand baits and immobilizes certain free-ranging (wild, feral, non-native, and hybrid) birds with alpha-chloralose, which allows their subsequent live capture during bird removal projects. Starting in 2024, technical alpha-chloralose may be "compounded" under the direct supervision of a prescribing veterinarian into an oil suspension, which is then mixed with either bread or whole kernel corn food baits. Bread baits are used for birds that can be fed individually and accept untreated bread bait during pre-baiting. Whole corn baits are used for groups of birds that cannot be baited individually and accept untreated whole corn bait during pre-baiting (USDA APHIS 2024).

In this risk assessment, "target" birds or species refers to the individual animals targeted in a particular bird removal project rather than whether FDA allows the use of compounded alphachloralose to sedate that bird species under FDA Guidance #256. The amount of alphachloralose added per bait depends on the group of target birds and their estimated average bodyweight. Table 1 lists the bird species and the maximum dose (milligrams or mg) of alphachloralose per kilogram (kg) of bodyweight (bw) allowed under FDA Guidance #256 (USDA APHIS 2024). The doses were established from previous dosing studies that estimated the most effect dose (MED) for each species. The MED is the dose that results in the immobilization and live capture of ≥90% of a bird species with no mortality (O'Hare et al. 2007).

Table 1. Bird species and doses of alpha-chloralose allowed under FDA Guidance #256 as of
February 2025.

Bird species	Scientific name	Maximum alpha-chloralose concentration (mg/kg-bw per dose) ⁺
Non-native and feral swans**	<i>Cygnus</i> spp.	15
Canada geese*	Branta canadensis	30
Non-native and feral geese**	Multiple genera and spp.	30
American coots*	Fulica americana	30

Mallards*	Anas platyrynchus	30
Non-native and feral ducks**	Multiple genera and spp.	30
Non-native and feral chickens**	Gallus spp.	45
Common ravens**	Corvus corax	47
Sandhill cranes*	Grus canadensis	50
Wild and feral turkeys**	Meleagris spp.	180
Pigeons (rock pigeon)**	Columba livia	180

* Bird species already reviewed by FDA for alpha-chloralose and added by FDA to the "List"¹ of bulk drug substances that may be compounded as sedative for free-ranging wildlife in 2024.

** Bird species or groups still "Under Review"² by FDA for alpha-chloralose at the time of this risk assessment. Alphachloralose can also be prescribed and compounded as a sedative for free-ranging bird species or groups of birds still "Under Review."

⁺ Represents the FDA's maximum allowable dose of alpha-chloralose per bodyweight for each bird species or group, which is based on their most effective dose (MED).

Starting in 2024, WS can use alpha-chloralose under FDA Guidance #256 to immobilize and live capture the bird species and groups listed in Table 1. These species are either on the <u>List of Bulk Drug Substances for Compounding Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species | FDA¹ or <u>Bulk Drug Substances Currently Under Review | FDA²</u>. Alpha-chloralose can also be prescribed and compounded as a sedative for free-ranging bird species or groups of birds that are still "Under Review." If FDA decides, at a future date, that a bird species cannot be listed or can no longer be listed for alpha-chloralose use, FDA will move that species to their <u>Bulk Drug Substances Reviewed and Not Listed | FDA³</u> and alpha-chloralose can no longer be compounded as a sedative for that species under FDA Guidance #256 ((FDA 2022); (USDA APHIS 2024)).</u>

The primary requirements in FDA Guidance #256 (FDA 2022) for use of alpha-chloralose as a sedative for free-ranging birds are summarized below. More detailed information is found in the APHIS-WS alpha-chloralose training manual (USDA APHIS 2024).

- The use of alpha-chloralose for the target bird species must be listed on FDA's "List"¹ or "Under Review"² by FDA. If the use of alpha-chloralose for the target bird species was reviewed by FDA and not listed³, alpha-chloralose can no longer be used for that species.
- Alpha-chloralose must be prescribed by a state-licensed veterinarian under a valid veterinarian-client-patient relationship (VCPR).
- FDA classifies most game species as food animals. As per FDA Guidance #256, any withdrawal, withholding, or discard time(s) for meat or eggs from any birds used for food for humans or domestic animals must be set by the prescribing veterinarian. The veterinarian may make the decision based on a case-by-case basis with consideration for the specific situation and birds that will to be treated. WS may further choose to avoid

- ² URL: <u>https://www.fda.gov/animal-veterinary/animal-drug-compounding/bulk-drug-substances-currently-under-review</u>
- ³ URL: <u>https://www.fda.gov/animal-veterinary/animal-drug-compounding/bulk-drug-substances-reviewed-and-not-listed</u>

¹ URL: <u>https://www.fda.gov/animal-veterinary/animal-drug-compounding/list-bulk-drug-substances-compounding-drugs-use-food-producing-animals-or-free-ranging-wildlife</u>

using alpha-chloralose on certain gamebird populations during certain periods of time, but this is not an FDA requirement for use of alpha-chloralose under FDA Guidance #256.

- Alpha-chloralose can be compounded (formulated) into the corn oil suspension or into the final bread or corn baits by the prescribing veterinarian or by WS personnel at any federal facility under the direct supervision of the prescribing veterinarian. The prescribing veterinarian is not required to be physically present at the federal facility during compounding. Alternatively, alpha-chloralose can be compounded into an oil suspension at these locations and then added to the bread or corn food baits prior to application in the field.
- Alpha-chloralose baits or oil suspensions must be labeled for storage, transport, and disposal.
- Alpha-chloralose baits may be applied by WS personnel in bird removal projects conducted in coordination with the prescribing veterinarian. The prescribing veterinarian does not need to be physically present during the application but must be readily available for follow-up in case of adverse reactions.
- The prescribing veterinarian must report any adverse events or product failure to the FDA-Center for Veterinary Medicine (CVM) using Form FDA 1932a within 15 business days of the event or product failure.
- Veterinarians can use the FDA checklist as a resource: <u>For Veterinarians: Prescribing</u> <u>Animal Drugs Compounded from Bulk Drug Substances (fda.gov)</u>⁴.

1.1.1 Historical Use Pattern

The following information describes how WS used alpha-chloralose to immobilize birds for the set of species and uses allowed under INAD number I-006602, which differed in some ways from the uses allowed under FDA Guidance #256. Between FY11 and FY19, WS immobilized an average of 2,096 target birds per year with alpha-chloralose by making baits with alpha-chloralose technical powder (Tables 2 and A1) or tablets (Tables A2 and A3).

Most target birds were Canada geese and American coots (Tables 2, A1–A3). The majority of target birds (94.4% per year on average) captured after immobilization with alpha-chloralose baits were later euthanized using an approved WS method. On average, 35.8 target birds per year (0.02%) baited with alpha-chloralose died from the alpha-chloralose. Nontarget birds accidentally baited with alpha-chloralose averaged 19.3 birds per year. Of these non-target birds accidentally baited with alpha-chloralose 4.7 birds per year later died from the alpha-chloralose and the rest recovered and were released or were euthanized. Furthermore, most of the non-target birds accidentally baited with alpha-chloralose but were not the target of that particular bird removal project.

⁴ URL: <u>https://www.fda.gov/media/157333/download?attachment</u>

Table 2. The annual average numbers and percentages of target and non-target birds immobilized with alpha-chloralose, live captured, and their final disposition, and annual average amounts of alpha-chloralose (technical powder) used in the United States by WS in WDM activities between FY16 and FY20 for the uses allowed under the old investigational new animal drug file (INAD). (WS discontinued use of alpha-chloralose under the INAD in November 2018. The annual averages were calculated using 3 years and 1 month of usage data instead of 5 years).

	Target birds	Target birds	Target birds that	Nontarget birds	Nontarget birds	Nontarget birds	Alpha-
Species	•	U U		immobilized then	-	-	•
Species	immobilized	immobilized	died during		immobilized	that died during	chloralose
	then euthanized	then released	immobilization	euthanized	then released	immobilization	used (g)
Domestic goose (feral) ¹	0	0.6	0	0	0	0	0.1
Canada goose ²	177.4	28.1	9.4	0	0	0	73.8
Domestic Muscovy	00.0	0.0	0	0	0	0	4.0
duck (feral) ¹	26.8	0.3	0	0	0	0	4.0
Mallard	45.2	0.3	0.3	0	0.6	0	11.2
Domestic mallard	56.5	1.6	1.3	0	0	0	6.9
(feral) ¹	50.5	1.0	1.3	0	0	0	0.9
American coot	318.1	0	0	0	0	0	16.3
Other bird species	3.9	0.6	0	0.3	0	0	0.9
(5 spp.) ³	5.9	0.0	U	0.5	0	0	0.9
Subtotal	627.7	31.6	11.0	0.3	0.6	0	113.2
(12 spp.)	021.1	51.0	11.0	0.5	0.0	0	113.2
% of all birds							
treated with alpha-	00 50/	4 70/	4.00/	0.05%	0.40/	00/	
chloralose	93.5%	4.7%	1.6%	0.05%	0.1%	0%	-
(n = 671.3)							

¹ Introduced species

² Introduced populations

³ Other birds – American crow, American wigeon, ring-necked duck, laughing gull, sandhill crane. Individual accounts of species are given only for those species that had an annual average of more than 10 taken, target and nontarget numbers combined.

State	FY16–FY20 ¹	Target species		
	Alpha-chloralose (g) used			
AL	10.1	Canada goose		
AZ	25.7	American coot, Canada goose, mallard, non-native		
		and feral goose, non-native and feral duck,		
		American wigeon, ring-necked duck		
CA	4.7	American coot, non-native and feral goose		
CO	2.2	Canada goose		
KS	4.0	Canada goose		
KY	10.0	Canada goose, non-native and feral duck		
МО	9.2	Canada goose, Muscovy duck, non-native and		
		feral goose, non-native and feral duck, mallard		
NC	0.5	Canada goose		
NH	8.6	Canada goose, mallard		
NJ	1.0	Canada goose		
PA	0.6	Canada goose, non-native and feral duck, mallard		
TN	9.5	Canada goose, non-native and feral duck		
ТΧ	8.1	Canada goose, Muscovy duck, non-native and		
		feral duck, mallard		
UT	7.3	Canada goose, non-native and feral duck, mallard		
VA	5.9	Canada goose		
VT	2.1	Canada goose		
WA	2.6	Canada goose		
WV	9.9	Canada goose, non-native and feral duck, mallard		
WI	0.43	Canada goose, Sandhill crane		
Total	121.93			
States	19			

Table 3. WS annual average alpha-chloralose use (technical powder and tablets) by state (FY16–FY20).

¹Use of A-C was discontinued in November 2018, so the annual averages were calculated using 3 years and 1 month of usage data instead of 5 years. Totals include alpha-chloralose technical powder (Table 2) and tablets (Table A2).

2 PROBLEM FORMULATION

Starting in 2024, FDA is exercising enforcement discretion under the FFDCA when alphachloralose technical (powder), a bulk drug substance, is compounded as a sedative for certain free-ranging bird populations in accordance with FDA Guidance #256 (briefly described in Section 1.1). Additionally, WS has established additional procedures that all WS personnel must follow when making, applying, and disposing of alpha-chloralose baits.

During bird damage management and removal projects, WS may hand bait and immobilize certain free-ranging (wild, feral, non-native, and hybrid) birds with alpha-chloralose, which then allows their live capture. Bread baits are used for target birds that can be fed individually and accept untreated bread bait during pre-baiting. Whole corn baits are used for groups of target birds that cannot be baited individually and accept untreated whole corn bait during pre-baiting

(USDA APHIS 2024). In this risk assessment, "target" birds or species refers to the individual animals targeted in a particular bird removal project.

Under FDA Guidance #256, the prescribing state-licensed veterinarian for the compounded alpha-chloralose must have a VCPR with the free-ranging bird population and is responsible for setting a withdrawal period (i.e., a period after a drug is administered that must lapse before an animal may be slaughtered for food) for animals that could be used as food or feed. Animals that might be harvested or slaughtered for food or feed within the withdrawal period should be held for the duration of the withdrawal period or released with tags (neck or leg bands, etc.) that states the withdrawal period end date.

Once immobilized and live captured with alpha-chloralose, WS may hold birds until they have recovered from the effects of the alpha-chloralose or until the end of their withdrawal period and then release them or send them to be processed for food or feed. Alternately, WS may euthanize captured birds using WS-approved methods and dispose of the carcasses using a WS-approved carcass disposal method.

2.1 Chemical Description and Product Use

Alpha-chloralose (chemical formula: $C_8H_{11}Cl_3O_6$; CAS Number: 15879-93-3; synonyms: α chloralose, chloralose) is used as a sedative and anesthetic drug for laboratory mammals and wild birds. At higher lethal concentrations, alpha-chloralose is also used as an active ingredient in rodenticides, including registered products for house mice (*Mus musculus*) in the U.S., and in avicides in other countries.

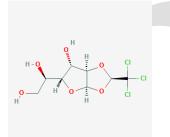


Figure 1. Chemical structure for alpha-chloralose (Source: PubChem)

WS uses alpha-chloralose at therapeutic doses to immobilize (sedate) and live capture certain free-ranging birds in nuisance situations, if there is a public health and safety concern, and in emergency response situations such as removing birds from oil spills and transporting them to a rehabilitation facility under the supervision of a state-licensed prescribing veterinarian. For birds that can be hand baited individually, WS mixes alpha-chloralose technical powder in corn oil and injects individual bread baits (bread pieces), so that each bait contains one dose (the estimated MED for the target birds). For target species that cannot be hand fed, WS mixes alpha-chloralose with dry whole corn kernels then adds corn oil to coat the kernels at a concentration of 1 mg alpha-chloralose per kernel. WS personnel stay at the site of application

during baiting to retrieve immobilized birds. WS personnel also remove unconsumed baits from the site following baiting. For populations of game birds that may be hunted and used for food that have been immobilized using alpha-chloralose, the prescribing veterinarian determines whether there is a minimum holding period or a tagging requirement prior to releasing the birds into a huntable population. Any such requirements are made by the prescribing veterinarian on a case-by-case basis for the particular birds being treated. For example, the veterinarian can require that all birds treated with alpha-chloralose are given a tag that states the withdrawal period end date. For huntable game birds that are released back into the wild following full recovery from sedation, but still within the withdrawal period set by the prescribing veterinarian, FDA does require that each bird is tagged (i.e., banded) with the following language: "DO NOT CONSUME if harvested before MM-DD-YYYY. Call xxx-xxxx [phone number of veterinarian or animal health professional]." WS may further choose to avoid using alpha-chloralose on certain gamebird populations during certain periods of time, but this is not an FDA requirement for use of alpha-chloralose under FDA Guidance #256.

2.2 Physical and Chemical Properties

Alpha-chloralose has a low potential to volatilize into the atmosphere based on its low vapor pressure of $<1.2 \times 10^{-10}$ mm Hg at 25 °C and $<9.75 \times 10^{-11}$ mm Hg at 20 °C (USEPA 2016b). It has a low estimated Henry's Law Constant of 9.62×10^{-17} atm-m³/mol at 25 °C (NIH 2019) suggesting it will not volatilize into the atmosphere if baits are immersed in water. Alpha-chloralose has a low log K_{ow} (octanol-water partition coefficient) of 0.85 at 22–26 °C and is soluble in water with a solubility of 4,440 mg/L at 15 °C (USEPA 2016b, NIH 2019). The log K_{ow} suggests that alpha-chloralose does not bioaccumulate.

2.3 Environmental Fate

Alpha-chloralose is highly soluble in water and has low volatility. It is very mobile in soil (University of Hertfordshire 2018), and is expected to move from soil into water. Alphachloralose is not expected to degrade through hydrolysis or photolysis in water (USEPA 2016a). Alpha-chloralose was shown to be stable to hydrolysis at pH values ranging from 4 to 9 (USEPA 2016a). In air, it is expected to degrade through photo-oxidation (USEPA 2016a). The calculated bioconcentration factor (BCF) for alpha-chloralose in fish is low (BCF = 1.05) suggesting a low potential to bioconcentrate in aquatic organisms (University of Hertfordshire 2018). WS applies small quantities of alpha-chloralose to bait instead of directly to soil and removes unused bait that could leach alpha-chloralose into the surrounding soil. Any oil residues or fragments of bait left behind would have negligible amounts of alpha-chloralose. Alpha-chloralose will not accumulate in soils between applications.

2.4 Hazard Identification

Alpha-chloralose affects the central nervous system (CNS), causing sedation, narcosis, and CNS depression in mammals and birds (USEPA 2016a). Alpha-chloralose can induce hypothermia, which can cause mortality in small animals that receive a large enough dose (USEPA 2016a).

Birds may encounter hazards after ingesting alpha-chloralose and prior to being captured. Birds generally take 30 to 90 minutes to reach the capture stage after feeding on treated bait. As the drug takes effect, dosed birds can still fly in an uncoordinated manner if aroused (0–40 minutes after dosing). If startled prior to sedation, dosed birds may fly into hazards such as bodies of water or move to inaccessible locations where they cannot be captured. Recovery normally occurs within 8 hours but can take up to 24 hours (USDA APHIS 2024).

Death can also occur from an accidental overdose of alpha-chloralose, such as if a bird consumes multiple treated baits (O'Hare et al. 2007).

3 Dose Response Assessment

This section of the risk assessment summarizes the available human health and ecological effects data for alpha-chloralose. Data includes information cited in USEPA documents to support the registration of alpha-chloralose as a pesticide, as well as data from online databases, peer reviewed studies, and other publicly available literature.

3.1 Human Health Dose Response

Alpha-chloralose has a depressive effect on the central nervous system in humans, causing sedation and anesthesia, and a stimulant effect on spinal reflexes (Gerace et al. 2012). Previously, alpha-chloralose had been used in the human medical field as an anesthetic in 75–300 mg oral and rectal dosage forms.

Based on an acute oral toxicity study on Sprague Dawley female rats, alpha-chloralose technical is moderately toxic (USEPA toxicity category II) (Table 4). The acute inhalation and dermal toxicity values are lower (USEPA toxicity category III) for both routes of exposures based on studies on Wistar rats (USEPA 2016b). This dermal toxicity category is likely conservative given that the median lethal dose (LD₅₀) was higher than the highest concentration tested. Alpha-chloralose is not categorized as an eye or dermal irritant (USEPA toxicity category IV). Alpha-chloralose is not a skin sensitizer.

Study type (Test animal)	Results	USEPA Toxicity
		Category
Acute oral (rat)	LD ₅₀ = 212 mg/kg-bw	II
Acute dermal (rat)	LD ₅₀ >2,000 mg/kg-bw	III
Acute inhalation (rat)	LC ₅₀ = 1.05 mg/L	III
Acute eye irritation (rabbit)	Redness noted in one eye at 1 hour	IV
Acute dermal irritation (rabbit)	No irritation observed	IV
Skin sensitization (guinea pig)	Negative	NA

Table 4. Acute toxicity of alpha-chloralose to mammals.

NA = Not applicable. LD_{50} = median lethal dose. LC_{50} = median lethal concentration.

Alpha-chloralose is considered moderately toxic to humans, but only if ingested in sufficient quantities (University of Hertfordshire 2018). The oral toxic dose of alpha-chloralose is

approximately 1 g in adults and 20 mg/kg-bw in infants (Thomas et al. 1988, Gerace et al. 2012). Adverse effects associated with overdoses include tachycardia, ataxia, hypo- or hyperthermia, rhabdomyolysis, miosis, and respiratory depression (Gerace et al. 2012).

Alpha-chloralose toxicity has also been evaluated in longer term studies measuring sublethal effects. In a 90-day oral exposure in rats the lowest observable adverse effect level (LOAEL) (15 mg/kg-bw/day) was based on breathing difficulties, tremors, pallor, loss of hearing and pupillary reflexes, static righting reflex, and reduced motor activity (USEPA 2016b). The no observable adverse effect level (NOAEL) was 5 mg/kg-bw/day.

In prenatal development toxicity study in rats at 0, 5, 15, and 60 mg/kg-bw/day, the maternal NOAEL was 5 mg/kg-bw/day for alpha-chloralose technical and the maternal LOAEL was 15 mg/kg-bw/day based on uncoordinated movement and lethargy (USEPA 2016b). New Zealand white rabbits in another prenatal development toxicity study at 0, 5, and 15 mg/kg-bw/day had the same maternal NOAEL and LOAEL (based on difficulty breathing) as in the rat study. The developmental NOAEL was 60 mg/kg-bw/day for rats and 15 mg/kg-bw/day for rabbits, and the developmental LOAEL was not determined in either study (USEPA 2016b).

Alpha-chloralose is not mutagenic, genotoxic, or carcinogenic based on a summary of studies and evaluation by the European Union (SCBP 2008).

Alpha-chloralose is rapidly metabolized and excreted. In a rat study using a single oral gavage dose of alpha-chloralose at 200 mg/kg-bw, the plasma half-life of the parent compound was 1.6 hours (USEPA 2016b). The primary metabolite is chloral hydrate. Elimination of alpha-chloralose is not dose dependent and occurs within 24 hours primarily through the urine (60–70%) with the remaining amount in feces (20–30%). The rapid metabolism and elimination of alpha-chloralose in mammals suggests that bioaccumulation will not occur in exposed individuals.

3.2 Ecological Dose Response

3.2.1 Terrestrial

Toxicity to wild mammals is considered moderate based on acute oral toxicity testing in the rat and mouse (Table 5). Toxicity data for domestic mammals shows cats are more sensitive to the effects of alpha-chloralose compared to dogs. The minimum lethal dose for cats (*Felis catus*) is 100 mg/kg-bw and for dogs (*Canis lupus familiaris*) ranges from 600 to 1,000 mg/kg-bw (as cited in (Segev et al. 2006, McLeod and Saunders 2013)).

Acute oral dosing studies indicate alpha-chloralose is moderately to highly toxic to birds, depending on the test species. The most sensitive bird species tested were the Japanese quail (*Coturnix japonica*), red-winged blackbird (*Agelaius phoeniceus*), and mallard (*A. platyrhynchos*); the chicken (*Gallus gallus domesticus*) and rock dove (*C. livia*), are the least sensitive (Table 5). No acute reptile or terrestrial phase amphibian toxicity data is available for alpha-chloralose.

Test species	Scientific name	LD ₅₀ values	Reference
Rat	Rattus sp.	200 mg/kg-bw	(Sigma-Aldrich
			Corporation 2024)
Mouse	Mus musculus	300 mg/kg-bw	(McLeod and
			Saunders 2013)
Japanese quail	Coturnix japonica	31.6 mg/kg-bw	(Schafer et al. 1983)
Red-winged blackbird	Agelaius phoeniceus	32 mg/kg-bw	(Schafer 1972)
Mallard	Anas platyrhynchos	34–55.0 mg/kg-bw	(USDA APHIS 2024)
House sparrow	Passer domesticus	42 mg/kg-bw	(Schafer 1972)
American coots	Fulica americana	46.6–58.0 mg/kg-bw	(USDA APHIS 2024)
Canada goose	Branta canadensis	53.9 mg/kg-bw	(USDA APHIS 2024)
European starling	Sturnus vulgaris	75 mg/kg-bw	(Schafer 1972)
Ring-necked	Phasianus colchicus	>100 mg/kg-bw	(Schafer 1972)
pheasant			
Rock dove	Columba livia	215 mg/kg-bw	(USDA APHIS 2024)
Chicken	Gallus gallus domesticus	300 mg/kg-bw	(Loibl et al. 1988)

Table 5. Acute mammal and avian	oral toxicity	/ values for al	pha-chloralose.
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No alpha-chloralose chronic toxicity test data is available for birds, reptiles or terrestrial phase amphibians.

Like mammals, alpha-chloralose is metabolized rapidly in birds. Goldade et al (2014) reported alpha-chloralose half-lives of 9.0, 9.8, and 9.1 hours for tissue (breast muscle), liver, and skin, respectively for a mallard that was dosed orally in a metabolism study. WS use patterns of alpha-chloralose, and its rapid metabolism in birds suggest chronic exposures are not likely.

3.2.2 Aquatic

Alpha-chloralose is moderately toxic to fish (Table 6); bluegill (*Lepomis macrochirus*) had an acute 96-hour LC_{50} of 5 mg/L and the rainbow trout (*Oncorhynchus mykiss*), had an LC_{50} value of 2.4 mg/L (University of Hertfordshire 2018). Aquatic phase amphibian toxicity data for alpha-chloralose was not available. In the absence of toxicity data for amphibians, their sensitivity was assumed to be comparable to the effects reported for fish.

Alpha-chloralose is very highly toxic to aquatic invertebrates and highly toxic to aquatic plants based on the limited acute toxicity data (Table 6). The 48-hr EC_{50} value for *Daphnia magna* was 0.027 mg/L and the 72-hour EC_{50} was 0.52 mg/L for green algae (*Raphidocelis subcapitata*) (Sigma-Aldrich Corporation 2024).

	1	,	1 5	
Test Species	Scientific name	Endpoint/Length	Toxicity Value/	Reference
			Avg. Acute	
			Toxicity	
Bluegill	Lepomis	24-hour LC50	5 mg/L	(University of
	macrochirus			Hertfordshire 2018)

Table 6. Alpha-chloralose acute a	auatic toxicity value	s in aquatic organisms
		s in aquallo organismo.

Test Species	Scientific name	Endpoint/Length	Toxicity Value/ Avg. Acute Toxicity	Reference
Rainbow trout	Oncorhynchus mykiss	96-hour LC ₅₀	2.4 mg/L	(Sigma-Aldrich Corporation 2024)
Freshwater cladoceran	Daphnia magna	48-hour EC ₅₀	0.027 mg/L	(Sigma-Aldrich Corporation 2024)
Green algae	Raphidocelis subcapitata	72-hour EC ₅₀	0.52 mg/L	(Sigma-Aldrich Corporation 2024)

No chronic aquatic toxicity data is available for alpha-chloralose. The use pattern for alphachloralose and the preference to make applications on land is not anticipated to result in significant chronic exposure to aquatic species.

4 EXPOSURE ASSESSMENT and RISK CHARACTERIZATION

Evaluating exposure to alpha-chloralose involves both the potential for an environmental release of alpha-chloralose into the environment and its environmental fate. The environmental fate describes the processes by which alpha-chloralose moves and is transformed in the environment. The environmental fate processes include: 1) mobility, and migration potential to groundwater and surface water, 2) persistence and degradation, and 3) plant uptake.

Available acute and chronic toxicity data and environmental fate information are summarized earlier in this document and integrated with the exposure analysis to characterize the risk of alpha-chloralose to the public and WS personnel and to non-target wildlife and domestic animals.

4.1 Human Health Exposure Assessment and Risk Characterization

Although alpha-chloralose can pose a hazard to human health (see hazard identification and dose-response assessment sections), the WS use pattern for alpha-chloralose is expected to pose minimal risks to human health. Alpha-chloralose exposure is greatest for workers who prepare the baits and applicators who administer the baits and collect sedated birds and unused baits after treatment. The use pattern for alpha-chloralose and its chemical properties reduces the likelihood of oral and inhalation exposures. The alpha-chloralose oil suspension or final baits are mixed by WS personnel at any federal facility under the direct supervision of the prescribing veterinarian prior to being transported and used in the field. Individuals who handle alpha-chloralose in the mixing process use appropriate personal protective equipment (PPE) to minimize oral, dermal, and inhalation exposure. The current SDS for alpha-chloralose recommends the following PPE that would be used when preparing the baits (Sigma-Aldrich Corporation 2024):

- Eye protection,
- Nitrile gloves,
- Protective clothing, and:

• Respiratory Particulate Filter (P3).

WS personnel who apply the baits in the field are required to wear disposable gloves (USDA APHIS, 2024).

Human risk is negligible during bait preparation based on the toxicity profile for alphachloralose, combined with the low likelihood of oral, dermal, and inhalation exposures. Similarly, workers who transport and place alpha-chloralose baits in the field are properly trained to make these types of applications and will use PPE to reduce oral, inhalation, and dermal exposure and risk.

The potential for human exposure to alpha-chloralose is greatest for WS personnel, cooperators, or veterinarians. WS restricts use to WS personnel who complete training and become WS-certified to apply alpha-chloralose (USDA APHIS 2019;2024). WS also properly stores and secures alpha-chloralose in approved containers and maintains accurate records for its distribution and use (USDA APHIS 2024). WS acquisition, storage, and use of alpha-chloralose and other chemical immobilization and euthanasia drugs are managed under guidelines established by WS Directive 2.430 (USDA APHIS 2019). There is some risk to WS personnel handling animals that may not be fully sedated. WS are trained to recognize and use caution when approaching alpha-chloralose sedated animals (USDA APHIS 2024).

Exposure of alpha-chloralose to the public is anticipated to be very low. Low exposure potential and alpha-chloralose's moderate to low mammalian toxicity suggests acute risk will be negligible. Chronic exposure is also not anticipated for the public based on the use pattern of alpha-chloralose; therefore, there are no chronic risks to the public. Baits are prepared at facilities where the public would not have access. Applications in the field are done in areas where the public may be; however, WS personnel are on site during the baiting operations and ensure the public would not access areas where treatments occur. Treated birds and unused baits are removed during and after treatment; this reduces the possibility of alpha-chloralose exposure to the public who access areas after treatment.

There is the potential for exposure to the public who harvest treated birds; however, the acute and chronic risks to the public are negligible (USDA APHIS 2024) based on the following:

- Alpha-chloralose use by WS is mainly for nuisance waterfowl (e.g., geese, American coots) in urban/suburban areas where hunting is prohibited by state and local regulations. WS historical alpha-chloralose use occurred in urban/suburban areas in 94% of WS operations (O'Hare et al. 2007).
- In the rare event that a treated bird escapes capture, there is minimal to no risk of human exposure to tissue residues in harvested meat or other edible tissues. Alpha-chloralose is metabolized and excreted from edible bird tissues in 37 hours or less (Goldade et al. 2014).

- In addition to the withdrawal period established by the veterinarian, WS may choose to not use alpha-chloralose within certain periods prior to or during the hunting season for any target bird populations in an area where hunting of that game bird is allowed.
- WS would notify applicable federal, state, and local agencies before using alphachloralose on a target population (USDA APHIS 2024).

Dietary exposure from drinking water is also negligible. Treatments are mostly directed on land where water contamination is unlikely to occur. Any treatments over water would result in nondetectable aquatic concentrations of alpha-chloralose due to the low concentrations used in baiting and the removal of alpha-chloralose by the target species. The lack of significant exposure from dietary exposure and the acute oral toxicity data suggests adverse effects are not expected under the proposed use conditions.

WS has no record of accidental exposure or adverse effects to the public or WS applicators from alpha-chloralose use. This historical data demonstrates that the use pattern of alpha-chloralose and program measures to reduce risk to human health are protective.

4.2 Ecological Exposure Assessment and Risk Characterization

4.2.1 Terrestrial Exposure Assessment and Risk Characterization

Alpha-chloralose field studies and normal applications by WS have resulted in exposures and risks to non-target animals. WS reported the immobilization as well as death of non-target birds that ingested alpha-chloralose baits in field trials and during actual applications, although the number of animals was low (Woronecki et al. 1990, Woronecki et al. 1992, Belant et al. 1999). McLeod and Saunders (2013) noted non-target deaths from the use of alpha-chloralose in several bird species but that larger bird species and mammals such as cats typically recover from accidental alpha-chloralose exposures. Non-target adverse effects have not been noted in reptiles and terrestrial phase amphibians in previous alpha-chloralose applications.

WS personnel use several measures to reduce the risk of exposure to domestic animals and non-target terrestrial wildlife including wild mammals, birds, reptiles, and terrestrial phase amphibians:

- Pre-bait with untreated baits to determine if the target species will accept the bread or whole kernel corn baits.
- Determine if non-target animals are present during baiting.
- Hand feed baits one at a time to individual birds whenever possible.
- Remove immobilized target and non-target animals.
- Collect any unused bait after the application to target animals is completed.
- Unused or unusable alpha-chloralose suspensions or baits are disposed of through a hazardous/universal waste disposal service.

Exposure of non-target terrestrial species to water or aquatic food sources contaminated with alpha-chloralose is unlikely. As discussed under the aquatic exposure and risk section above, the exposure potential of water resources to alpha-chloralose is negligible. Therefore, dietary exposure through drinking water or consuming aquatic species as prey is negligible.

Secondary exposure and risk to non-target wildlife that could scavenge or prey on treated birds is not anticipated. All birds and other non-target wildlife treated with alpha-chloralose are removed by WS personnel after they have been immobilized. There is a possibility that predators or scavengers could attempt to remove treated birds after dosing but before they are immobilized and removed by WS. This would be a small window of opportunity with birds taking 30 to 90 minutes after dosing to be handled by WS personnel. This is an unlikely exposure scenario due to the short window where treated birds are vulnerable to predators and scavengers and the presence of WS at the treatment area. Birds released after immobilization are not expected to have residues that would result in secondary exposure and risk to birds and mammals. Goldade et al. (2014) reported alpha-chloralose half-lives of 9.0, 9.8, and 9.1 hours for breast muscle, liver and skin, respectively, in a metabolism study with mallards dosed orally at 30 mg/kg-bw. The half-life of alpha-chloralose in edible non-target mammal tissues is likely even shorter, given the plasma half-life of 1.6 hours in a rat metabolism study discussed in Section 3.1. Alpha-chloralose is not expected to bioaccumulate based on its rapid metabolism and elimination in vertebrates (USEPA 2016b). USEPA similarly determined that the secondary exposure risks for scavengers and predators that consume prev animals exposed to registered pesticide (rodenticide) baits containing alpha-chloralose are low (USEPA 2016a).

Any live captured animals that die from an accidental overdose with alpha-chloralose or are later euthanized using a WS-approved method are disposed of according to the WS Directive 2.515, Disposal of Carcasses. WS personnel follow applicable federal, state, county, and local regulations regarding the disposal of euthanized animals. The immediate disposal of euthanized animals removes the risk of exposure and risk to predators and scavengers. If guidance is lacking, carcasses must be disposed of via deep burial, incineration, or at a landfill approved for such disposal.

Exposure of invertebrates and plants to alpha-chloralose is unlikely given its use pattern. WS personnel are present at the site during alpha-chloralose baiting to retrieve the immobilized birds and unused bait. There are no toxicity data available for terrestrial invertebrates and terrestrial plants. However, given the low probability of exposure through soil contamination or directly from the baits, the risks to terrestrial invertebrates and plants are considered negligible.

4.2.2 Aquatic Exposure Assessment and Risk Characterization

The use of alpha-chloralose to immobile birds is conducted mostly on land. In these situations, the potential for alpha-chloralose to move into waterbodies from runoff is negligible. Unused baits are removed after treatment, as well as all immobilized birds. However, there may be rare situations that require over water applications for waterfowl. Over water applications result in a greater chance of aquatic exposure and residues. Alpha-chloralose is water soluble and would be expected to partition into water over time. The amount of alpha-chloralose that could occur in

water would be low based on the amount of alpha-chloralose used in these types of operations and the removal of bait from the water by the target species during treatment.

To demonstrate the low expected aquatic concentrations from an over water bait application of alpha-chloralose, we assumed all of the bread baits used to treat 52 mallards (2.039 grams; (USDA APHIS 2024)) would instead disperse into a body of water that is one acre square in area and one foot deep (i.e., assume that none of the baits were consumed by target or non-target animals). After the alpha-chloralose dissolved and dispersed, the concentration of alpha-chloralose in the shallow water body would be approximately 0.0016 mg/L, assuming no degradation, microbial metabolism, adsorption to silt or sediment, etc. had yet occurred. When compared to the most sensitive aquatic toxicity value (*D. magna*; EC₅₀ = 0.024 mg/L), the alpha-chloralose concentration in the water body would be more than an order of magnitude lower than the median lethal dose for *D. magna*, suggesting very low risk. This conservatively estimated aquatic concentration of alpha-chloralose would not occur in an actual application because the target birds would remove at least some of the bread baits before the alpha-chloralose could disperse into the water; however, it demonstrates a low acute and chronic risk to aquatic organisms from over water bait applications.

Exposure and risk to aquatic organisms from land treatments would be negligible. Removal of baits by the target bird species and removal of unused baits after treatment by WS would eliminate the potential for runoff from baits during a rain event. Any treated birds that wander into aquatic areas after treatment would be collected, eliminating the potential for water contamination.

5 UNCERTAINTIES and CUMULATIVE EFFECTS

The uncertainties associated with this risk evaluation arise primarily from limited information about the effects of alpha-chloralose and its metabolites, and potential mixtures to non-target organisms 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.

Cumulative impacts to human health from the use of alpha-chloralose is not anticipated. Human exposure and risk are negligible for the public. The probability of exposure is greatest for workers involved with the administration of alpha-chloralose. However, the risk to this group will be incrementally negligible based on the low risk of exposure to alpha-chloralose when following applicable safety protocols including wearing the appropriate personal protective equipment. There is the potential for exposure to other chemicals used during wildlife management; however, the use of personal protective equipment reduces the potential for cumulative impacts related to exposure to numerous chemicals. WS does not anticipate cumulative risk to the public from exposure to multiple chemicals because of the methods of application and program controls for alpha-chloralose use. There are no significant pathways of exposure for alpha-chloralose that could result in incrementally significant risks to the public.

The cumulative impacts to wildlife species are expected to be incrementally negligible when put in context with other stressors since alpha-chloralose is used infrequently and in limited areas. Cumulative impacts to aquatic organisms will also be negligible because there is an extremely low probability of exposure and risk to aquatic biota from the proposed use of alpha-chloralose.

6 SUMMARY

Alpha-chloralose is a safe, humane, and effective non-lethal method for immobilizing and live capturing birds. It can be used in various situations such as removal of nuisance birds in suburban/urban areas, in public health and safety applications such as airports, and in emergency response situations such as removing birds from oil spills to allow transport to rehabilitation facilities.

WS use patterns, safety protocols, and required training and certification for the use of alphachloralose by WS personnel minimizes the direct and indirect risks to the public and WS applicators. The risk to most non-target fish and wildlife are negligible except for terrestrial vertebrates that may consume bait treated with alpha-chloralose. WS personnel remaining at the site of treatment to remove immobilized birds and unconsumed bait, reduces the associated risks.

7 LITERATURE CITED

- Belant, J. L., L. A. Tyson, and T. W. Seamans. 1999. Use of alpha-chloralose by the Wildlife Services Program to capture nuisance birds. Wildlife Society Bulletin 27:938-942.
- FDA. 2022. Compounding Animal Drugs from Bulk Drug Substances, Guidance for Industry, #256. U.S. Food and Drug Administration.
- Gerace, E., V. Ciccotelli, P. Rapetti, A. Salomone, and M. Vincenti. 2012. Distribution of chloralose in a fatal intoxication. Journal of Analytical Toxicology 36:452-456.
- Goldade, D. A., R. S. Stahl, and J. J. Johnson. 2014. Determination of residue levels of alpha chloralose in duck tissues. Human–Wildlife Interactions 8:123–129.
- Loibl, M. F., R. E. Clutton, B. D. Marx, and C. J. McGrath. 1988. Alpha-chloralose as a capture and restraint agent of birds: therapeutic index determination in the chicken. Journal of Wildlife Diseases 24:684-687.
- McLeod, L., and G. Saunders. 2013. Pesticides used in the Management of Vertebrate Pests in Australia: A Review. New South Wales Department of Primary Industries.
- National Research Council. 1983. Risk assessment in the Federal government: managing the process. National Academy Press, Washington, DC.
- NIH. 2019. Toxnet, ChemID*plus*: queried alpha-chloralose. National Institutes of Health, Toxicology Data Network.
- O'Hare, J. R., J. D. Eisemann, K. A. Fagerstone, L. L. Koch, and T. W. Seamans. 2007. Use of alpha-chloralose by USDA Wildlife Services to immobilize birds. Proceedings of the Wildlife Damage Mangagement Conference 12:103-113.
- SCBP. 2008. Directive 98/8/EC concerning the placing biocidal products on the market, Inclusion of active substances in Annex I or IA to Directive 98/8/EC, Assessment Report, Alphachloralose Product-type 14 (rodenticide). Standing Committee on Biocidal Products.
- Schafer, E. W. 1972. The acute oral toxicity of 369 pesticidal, pharmaceutical and other chemicals to wild birds. Toxicology and Applied Pharmacology 21:315-330.
- Schafer, E. W. J., W. A. J. Bowles, and J. Hurlbut. 1983. The acute oral toxicity, repellency, and hazard potential of 998 chemicals to one or more species of wild and domestic birds. Archives of Environmental Contamination and Toxicology 12:355-382.
- Segev, G., E. Yas-Natan, A. Shlosberg, and I. Aroch. 2006. Alpha-chloralose poisoning in dogs and cats: A retrospective study of 33 canine and 13 feline confirmed cases. The Veterinary Journal 172 109–113.
- Sigma-Aldrich Corporation. 2024. α-Chloralose. Safety Data Sheet. St. Louis, MO.
- Thomas, H. M., D. Simpson, and L. F. Prescott. 1988. The toxic effects of alpha-chloralose. Human Toxicology 7:285-287.
- University of Hertfordshire. 2018. Chloralose. International Union of Pure and Applied Chemistry (IUPAC). <u>https://sitem.herts.ac.uk/aeru/iupac/Reports/130.htm</u> Accessed 02/25/2025.
- USDA APHIS. 2019. Wildlife Services Directive: Acquisition, storage, and use of controlled chemical immobilization and euthanasia substances, WS 2.430, dated 3/12/2019. United States Department of Agriculture, Animal and Plant Health Inspection Service.
 - ____. 2024. Alpha-chloralose Manual (Draft). U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Wildlife Services.
- USEPA. 2016a. Alpha-Chloralose Section 3 New Chemical Registration Environmental Fate and Ecological Risk Summary. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention.
- . 2016b. Alpha-Chloralose. Human Health Risk Assessment to Support the Section 3 Registration Use as a Rodenticide. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention.

- 2024. Overview of Risk Assessment in the Pesticide Program Human Health Risk Assessment (<u>https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides#:~:text=Our%20human%20health%20risk%20assessments,through%20their %20work%3B%20or), last accessed 06/04/2024). United States Environmental Protection Agency (USEPA).
 </u>
- Woronecki, P. P., R. A. Dolbeer, and T. Seamans. 1990. Use of alpha-chloralose to remove waterfowl from nuisance and damage situations. Proceedings of the Vertebrate Pest Conference 14:343-349.
- Woronecki, P. P., R. A. Dolbeer, T. W. Seamans, and W. R. Lance. 1992. Alpha-chloralose efficacy in capturing nuisance waterfowl and pigeons and current status of FDA registration. Proceedings of the Vertebrate Pest Conference 15:72-78.

8 PREPARERS: WRITERS, EDITORS, AND REVIEWERS

8.1 APHIS WS Methods Risk Assessment Committee

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Editor: Emily Ruell

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- **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:** Eleven years of experience with APHIS preparing and reviewing vertebrate pesticide registration data submissions and other registration materials, and providing pesticide regulatory guidance to APHIS and collaborators. Prior experience before joining

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Contributor: Thomas C. Hall

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- **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-seven 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, 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. Applied and supervised chlorophacinone use.

8.2 Internal Reviewers

USDA APHIS Wildlife Services

Reviewer: Matt Cleland

Position: USDA APHIS Wildlife Services, State Director/ Supervisory Wildlife Biologist, Port Allen, LA

Education: BS in Wildlife Management, Washington State University

Experience: Expertise in wildlife damage management and wildlife biology. Twenty-four years of service in APHIS Wildlife Services operational programs in WA, CA, TN, KY and LA. Experience in mitigating conflicts caused by a wide variety of wild animals including ungulates, migratory birds/waterfowl, predators, rodents, reptiles and invasive species including feral swine and nutria.

Reviewer: Mark A. Craig

Position: Biological Science Technician (Wildlife)

Education: I received a BS with a major in Wildlife Management from Eastern Kentucky University

Experience: I began my career in the wildlife damage management field with USDA Wildlife Services in 2003. Throughout my time with USDA I have worked damage management projects focusing on property damage, disease prevention, and the protection of human health and safety. I was certified in the application of Alpha-chloralose (AC) in 2003 and had used it often through 2018. I have applied AC in many settings including parks, industrial complexes, residential properties, and airports. My use of AC was primarily for the capture of Canada geese in urban environments.

Reviewer: Patrick Darrow

Position: WS Safety and Health Manager

Education: BS & MS Fish and Wildlife Biology – Utah State University, Logan, UT.

Experience: Three years as a Biological Science Technician at the National Wildlife Research Center, Logan Field Station, conducting animal care work and assisting with research studies. 7 years as a predator biologist with the National Wildlife Research Center, Logan Field

Station conducting research to develop and test wildlife damage management tools and techniques. Thirteen years as the manager of the Wildlife Services, Pocatello Supply Depot, managing daily operations of the depot related to production and regulatory compliance of wildlife damage management products such as pesticides, tools and immobilizing drugs. One year as the Wildlife Services Safety and Health Manager, managing the safety program for Wildlife Services.

Reviewer: Jason Huntington

Position: Biological Science Technician

Education: BS Natural Resource Conservation Management with Concentration in Wildlife Management @ Mcneese State University

Experience: Expertise in wildlife damage management and wildlife- human conflicts. I have worked with multiple agencies including Louisiana Dept of Agriculture and Forestry feral swine removal program, feral swine removal from national wildlife refuges in southeast Louisiana through US Fish and Wildlife services and 5 years of feral swine removal with wildlife services in Mississippi and Louisiana. Human -wildlife conflicts include vultures, pigeons, Canada geese and other migratory birds. I also have worked with the removal of beavers and nutria in both Louisiana and Mississippi.

Reviewer: Dax Lane

Position: Biological Science Technician (Wildlife)

Education: BS in Wildlife Management from Eastern Kentucky University.

Experience: I began employment with USDA Wildlife Services in 2001 for the Tennessee/Kentucky program. I began work in Louisville, KY doing various wildlife damage and disease control activities while also helping with the wildlife damage mitigation for the Louisville and Cincinnati Airports. I presently work various wildlife damage management projects in central Kentucky with the focus being Black Vulture and Feral Swine management. I have been involved with wildlife damage management for 24 years and have extensive experience in dealing with numerous species and conflicts. I first used Alpha Chloralose (AC) sometime around 2002 at a city park in Richmond, KY on urban Canada geese. I have used AC many times since 2002 and consider it a valuable wildlife damage management tool for urban waterfowl. Waterfowl species addressed included Canada geese, mallards, feral geese, and feral ducks.

Reviewer: Leif Stephens

Position: AL/PR/USVI State Director

Education: BS & MFR UGA

Experience: Two years as a Biological Science Technician with GA WS Program conducting beaver, deer, geese, & predator damage management activities and NEPA compliance. Nine years as a Wildlife Biologist with GA WS Program as Project leader for large-scale urban deer/predator/ geese projects, conducting airport WHAs, and leading UGA wildlife damage courses. Four years as District Supervisor for AL/PR/USVI WS Program overseeing all large-scale projects in AL, initiating State aerial gunnery and feral swine cost share programs, implementing outreach programs and strengthening stakeholder support. Five years as Assistant State Director for the AL/PR/USVI WS Program managing AL Districts and associated wildlife damage management programs, coordinator for Farm Bill and Aviation State Programs, assisting with large-scale Caribbean projects, Program wide administration and development, etc. One year as State Director for AL/PR/USVI WS Program.

Reviewer: Keith Stucker

Position: District Supervisor

Education: BS Natural Resource Management with concentration in Wildlife Biology @ University of Tennessee at Martin

Experience: I began employment with WS in 1991 at the Atlantic City International Airport. I have worked in an additional four WS programs including New York, Nebraska, North Carolina, and Tennessee/Kentucky. I have extensive experience in wildlife damage management involving numerous species and conflicts. I first used Alpha Chloralose (AC) in 1995 at a city park in Lexington, KY on urban Canada geese and mallards. I used the product, or supervised its use, until 2018. My experience with AC was entirely in urban settings to manage waterfowl damage. Waterfowl species addressed included Canada geese, mallards, feral geese, and feral ducks.

9 APPENDIX

Table A1. The annual average numbers and percentages of target and non-target birds immobilized with alpha-chloralose, live captured, and their final disposition, and annual average amounts of alpha-chloralose (technical powder) used in the United States by WS in WDM activities between FY11 and FY15 for the uses allowed under the old investigational new animal drug file (INAD).

Species	Target birds immobilized then euthanized	Target birds immobilized then released	Target birds that died during immobilization	Nontarget birds immobilized then euthanized	Nontarget birds immobilized then released	Nontarget birds that died during immobilization	Alpha- chloralose used (g)
Domestic goose (feral) ¹	4.8	6.8	0	0	0	0	3.5
Canada goose ²	309.4	20.2	12.6	0	0.2	0	91.9
Domestic Muscovy duck (feral) ¹	35.6	14.2	5.4	0	0	0	14.2
Mallard	112	16.6	2.4	0.4	15.0	5	25.1
Domestic mallard (feral) ¹	94.2	5.0	3.2	0	2.0	0	18.8
American coot	2,147.4	0	15.0	0	0	0	108.6
Sandhill crane	0	12.8	0.2	0	0	0	6.5
Other bird species (7 spp.) ³	5.0	5.0	0.2	6.6	0	1.2	3.5
Subtotal (12 spp.)	2,708.4	80.6	39.0	7.0	17.2	6.2	272.2
% of all birds treated with alpha-chloralose (n = 2,833)	95.5%	2.8%	1.3%	0.2%	0.1%	0.04%	-

¹ Introduced species

² Introduced populations

³ Other birds – American wigeon, redhead, ring-necked duck, rock pigeon, mourning dove, common gallinule, and great-tailed grackle. Individual accounts of species are given only for those species that had an annual average of more than 10 animals treated with alpha-chloralose, target and non-target animal numbers combined.

Table A2. The annual average numbers and percentages of target and non-target birds immobilized with alpha-chloralose, live captured, and their final disposition, and annual average amounts of alpha-chloralose (tablets) used in the United States by WS in WDM activities between FY16 and FY20 for the uses allowed under the old investigational new animal drug file (INAD). (WS discontinued use of alpha-chloralose in November 2018).

Species	Target birds immobilized then euthanized	Target birds immobilized then released	Target birds that died during immobilization	Nontarget birds immobilized then euthanized	Nontarget birds immobilized then released	Nontarget birds that died during immobilization	Alpha- chloralose used (20 mg)	Alpha- chloralose used (40 mg)	Alpha- chloralose used (60 mg)
Domestic goose (feral) ¹	0	9.4	0	0	0	0	7.7	0	19.4
Canada goose ²	20.6	0	0	0	0	0	14.2	6.5	53.5
Domestic Muscovy duck (feral) ¹	2.9	0	0	0	0	0	0	0	11.3
Mallard	1.6	2.3	1.0	0	0	0	0	15.2	0
Domestic mallard (feral) ¹	40.3	0.6	0.6	0	0	0	47.4	39.0	59.0
California gull	0	0	0	0	0	0.3	0	1.9	0
Subtotal (6 spp.)	65.5	12.3	1.6	0	0	0.3	69.4	62.6	143.2
% of all birds treated with alpha-chloralose (n = 671.3)	82.2%	15.4%	2.0%	0%	0%	0.4%	-	-	-

¹ Introduced species

² Introduced populations

Table A3. The annual average numbers and percentages of target and non-target birds immobilized with alpha-chloralose, live captured, and their final disposition, and annual average amounts of alpha-chloralose (tablets) used in the United States by WS in WDM activities between FY11 and FY15 for the uses allowed under the old investigational new animal drug file (INAD).

Species	Target birds immobilized then euthanized	Target birds immobilized then released	Target birds that died during immobilization	Nontarget birds immobilized then euthanized	Nontarget birds immobilized then released	Nontarget birds died during immobilization	Alpha- chloralose used (20 mg)	Alpha- chloralose used (40 mg)	Alpha- chloralo se used (60 mg)
Domestic goose (feral) ¹	0	3.6	1.3	0	0	0	1.3	3.2	18.7
Canada goose ²	51.9	12.9	3.6	0	0	0	47.4	16.5	145.2
Domestic Muscovy duck (feral) ¹	21.0	7.1	7.1	0	0	0	29.7	36.1	53.2
Mallard	2.9	3.2	1.9	0	0	0	8.1	22.6	13.9
Domestic mallard (feral) ¹	34.2	10.3	4.2	0	0	0	29.0	44.5	21.3
American Coot	1.6	0	0	0	0	0	1.6	0	0
Subtotal (6 spp.)	111.6	37.1	18.1	0	0	0	117.1	122.9	252.3
% of all birds treated with alpha-chloralose (n = 671.3)	66.9%	22.2%	10.8%	0%	0%	0%	-	-	-

State	FY11–FY15 Alpha-chloralose (g) used	Target species
AL	26.4	Canada goose, mallard, non-native and feral goose, non-native and feral duck, Muscovy duck
AZ	56.0	American coot, Canada goose, mallard, non-native and feral goose, non-native and feral duck, American wigeon, ring-necked duck, redhead
CA	71.2	American coot, non-native and feral goose, American wigeon, mallard, Canada goose, non-native and feral duck
CO	5.2	Canada goose
FL	5.9	Muscovy, non-native and feral duck
GA	2.0	Canada goose, mallard, non-native and feral goose, non-native and feral duck
IL	0.2	Canada goose
KS	7.5	Canada goose, mallard
KY	23.1	Canada goose, mallard, non-native and feral goose, non-native and feral duck
MD	0.3	Canada goose
MS	4.0	Canada goose, Muscovy duck
MO	9.2	Canada goose, Muscovy duck, domestic goose, domestic duck, mallard
NC	2.3	Canada goose, mallard
NE	0.3	Canada goose, non-native and feral goose
NJ	1.8	Canada goose, Muscovy duck, non-native and feral duck
PA	2.5	Canada goose, mallard, non-native and feral duck, Muscovy duck
SC	3.8	Muscovy duck
TN	11.8	Canada goose, non-native and feral goose, mallard, non-native and feral duck
ТΧ	9.9	Canada goose, non-native and feral goose, mallard, non-native and feral duck, Muscovy duck
UT	26.5	American coot, Canada goose, non-native and feral goose, mallard, non-native and feral duck
VA	19.2	Canada goose, non-native and feral goose, mallard, non-native and feral duck
WA	3.7	Canada goose, non-native and feral duck
WI	6.5	Sandhill crane
Total	286.8	
States	23	

Table A4. WS annual average alpha-chloralose use (technical powder and tablets) by state (FY11–FY15).