OMB APPROVED
0579-0036

Interagency Report Control No. 0180-DOA-AN

Fiscal year: 2021

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Annual Report of Research Facility
Column E Explanation

(TYPE OR PRINT)

This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure to report according to the regulations can result in an order to cease and desist.

1. REGISTRATION NUMBER

84-F-0001

2. Research Facility Headquarters address

USDA, APHIS, WS, NWRC
4101 LaPorte Ave
Fort Collins, CO 80521

3. Number of animals used in the study.

20 Domestic Pigs

4. Species (common name) of animals used in the study.

Sus scrofa domesticus

5. Explain the procedure producing pain and distress.

The test diet HOGGONE 2 (5% sodium nitrite active ingredient) will be offered to same-sex pairs of pigs in free-feeding two-choice trials over a 2-day toxic bait exposure period (following a 2-day non-toxic pre-feed exposure period), along with a non-toxic challenge diet. Severe methemaglobinemia from sodium nitrite overdose may cause more than momentary pain or distress in some animals.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

Two-choice laboratory efficacy data is required for registration of toxicants for vertebrate target species that are public health pests. EPA and state pesticide regulatory agencies do NOT consider euthanasia an acceptable end point in laboratory efficacy trials of vertebrate toxicants. Euthanasia of any of the test animals during the two-choice and post-test periods will negate the results of the entire trial.

In addition, the study must be conducted under controlled conditions. Normal metabolic and physiological processes must be occurring in the animals. Hence, sedatives or analgesics are not appropriate because they may affect-and in particular, slow down--those metabolic processes.

Symptoms of severe methemoglobinemia from sodium nitrite overdose can range from mild to severe, but are short in duration (minutes to hours).

Animals will be examined at least four times daily for the two days when the animals are exposed to toxic bait, with notes of animal condition recorded in the animal health logs. However, no euthanasia of animals will occur during the two-choice or post-test periods, because if any animals are euthanized, the study results will be deemed invalid by EPA and state pesticide regulatory agencies and the study must be repeated.

7. What, if any, Federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number, and the specific section number (e.g., APHIS, 9 CFR 113, 102):

Agency US Environmental Protection Agency

CFR 40 CFR 158.400 (Subpart E- Product Performance)
Product Performance OPPTS 810.1000
EPA OPP guideline 1.210

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2. Research Facility Headquarters address

USDA, APHIS, WS, NWRC
4101 LaPorte Ave
Fort Collins, CO 80521

3. Number of animals used in the study.

2 Coyotes

4. Species (common name) of animals used in the study.

Canis latrans

5. Explain the procedure producing pain and distress.

These two (2) captive coyotes will be caught in a Victor #3 soft-catch foothold trap for a maximum of 10 minutes while other coyotes are able to observe the activity before being presented with a modified trap.

To ensure the trapped coyote does not injure itself or become overly distressed, the following components are part of the protocol:
- All this work is done in captivity to help control as many variables as possible
- Coyotes will only be in the foothold traps for a maximum of 10 minutes
- Coyotes will be monitored during their period of entrapment and the observer is prepared to release the animal from the trap earlier if the coyote becomes overly distressed.
- The number of animals tested is very small (5 animals)
- Should an animal become injured or require veterinary care after being released from the trap, the veterinarian can utilize any to reduce pain and or lingering distress.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

The purpose of the protocol is to determine if coyotes learn to avoid traps if they note another coyote caught in the trap. To study this, other coyotes need to observe the trapped coyote. We cannot use sedatives or anxiolytics as those would affect the behavior of the coyotes, providing misleading results.

7. What, if any, Federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number, and the specific section number (e.g., APHIS, 9 CFR 113, 102):

Agency N/A

CFR N/A

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USDA, APHIS, WS, NWRC
4101 LaPorte Ave
Fort Collins, CO 80521

3. Number of animals used in the study.

5 Coyotes

4. Species (common name) of animals used in the study.

Canis latrans

5. Explain the procedure producing pain and distress.

Para-aminopropiopherone (PAPP) will be tested on captive coyotes at 880 mg delivered using M-44 devices. PAPP induces the formation of methemaglobin which reduces the oxygen carrying capacity of hemoglobin and induces hopoxia in exposed animals.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

It is expected that this dosage of PAPP will be rapidly lethal and induce no pain or distress, until the product has been tested at this does using this delivery device. Since this is a test for a lethal substance, the animals must be observed until death occurs. In the protocol, if the animal has not died within 3 hours of delivery of the PAPP, it will be euthanized.

7. What, if any, Federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number, and the specific section number (e.g., APHIS, 9 CFR 113, 102):

Agency	**CFR**
N/A	N/A

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2. Research Facility Headquarters address

USDA, APHIS, WS, NWRC
4101 LaPorte Ave
Fort Collins, CO 80521

3. Number of animals used in the study.

12 Small Indian Mongoose

4. Species (common name) of animals used in the study.

Herpestes auropunctatus

5. Explain the procedure producing pain and distress.

The test substance (Fish-based bait for mongooses, which contains 0.005% (50ppm) diphacinone will be offered to caged mongooses in free-feeding two-choice trials over a 5-day bait exposure period, along with a non-toxic challenge diet. Intoxication by anticoagulant rodenticides may cause more than momentary pain or distress in some animals.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

This study is a prelude to a planned GLP study. The Environmental Protection Agency (EPA) requires two-choice laboratory efficacy data (product performance data) for vertebrate pesticide products in accordance with EPA guidelines to support the issuance of a future Experimental Use Permit (EUP) for a larger field efficacy study and a subsequent full registration application. The study requires relatively normal metabolic and physiological processes to be occurring in the animals. Hence, sedatives or analgesics are not appropriate because they may affect those metabolic processes.

It is not known to what extent anticoagulants cause pain or distress in treated animals. Mongooses feeding on anticoagulant baits must generally do so for multiple days because of the low concentrations and the slow action of anticoagulants in the body after a large enough dose is consumed. The animals continue to be active and feed for several days after consuming a lethal dose. Eventually, they become more lethargic and stop feeding. Death usually results soon thereafter, however, some animals have been documented to recover despite exhibiting symptoms of anticoagulant poisoning.

Animals will be examined at least three times throughout the light cycle duration by the study director or designee, with notes of animal condition recorded in the animal health log. Sick or injured animals may be euthanized during the pre-test period and replaced with the spare animals that will be obtained for this study. Sick animals will not be euthanized during the two-choice test or post-test period without negating the results of the study. Euthanasia can be considered for documented severe injuries that occur during the two-choice or post-test period

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Agency U.S. Environmental Protection Agency

CFR 40 CFR 158.400 (Subpart E – Product Performance)
Product Performance OPPTS 810.1000

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2. Research Facility Headquarters address

USDA, APHIS, WS, NWRC
4101 LaPorte Ave
Fort Collins, CO 80521

3. Number of animals used in the study.

32 Small Indian Mongoose

4. Species (common name) of animals used in the study.

Herpestes auropunctatus

5. Explain the procedure producing pain and distress.

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2. Research Facility Headquarters address

USDA, APHIS, WS, NWRC
4101 LaPorte Ave
Fort Collins, CO 80521

3. Number of animals used in the study.

65 Norway Rats
(Note: Wild Caught Animals)

4. Species (common name) of animals used in the study.

Rattus norvegicus

5. Explain the procedure producing pain and distress.

We will administer known dosages DR8 dissolved in a suitable carrier (e.g. phosphate buffer) to test animals via oral gavage to determine the approximate LD50. We will assess the LD50 using the up-and-down method (OPPTS Harmonized Test Guideline 870.1100 Acute Oral Toxicity). The up-and-down method relies on a single animal being dosed, observing its response for a period of time and then dosing a second animal with either a higher or lower dose depending on the response of the first animal.

DR8 is selectively more toxic to rats compared to other animals. Its action is dose dependent; the active compound, norbormide. Lethal doses cause death within two hours (usually <90). The cause of death is cardiovascular collapse. Barbiturates and anesthetics may be antidotal to its toxic effects. This means that this s tudy may induce more than momentary distress in treated animals, but the rapid action of the chemical will mean that any distress will be experienced for minutes at the maximum.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

This study is designed to determine the toxicity (LD50) of DR8 to rats. Oral administration of the compound is necessary to ensure that the compound is compatible with field applications. Analgesics/ anesthetics have been shown to interfere with the toxicity of chemicals and will confound the planned studies. Therefore, analgesics/ anesthetics will be withheld.

Staff will visually inspect each animal for signs of distress (lateral recumbent, shaking, blood near nostrils, anus, mouth). The observations will be recorded on a monitoring sheet. The Attending Veterinarian (or representative) will be present during the initial dosing of animals for this study. Once the clinical effects can be assessed, criteria for further testing/observations periods will be discussed and agreed upon. Thereafter, animals determined to be in pain or distress for an unreasonable period by the Study Director, designated personnel, or the Attending Veterinarian will be euthanized. Since this study is designed to determine the lethal effects of an acutely toxic chemical; it is not appropriate to administer sedatives or analgesics to test animals because of possible effects that may alter the pharmacology of the test compound, DR8.

7. What, if any, Federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number, and the specific section number (e.g., APHIS, 9 CFR 113, 102):

Agency N/A

CFR N/A

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4101 LaPorte Ave
Fort Collins, CO 80521

3. Number of animals used in the study.

32 Black Rats (Wild Caught)

Note: Entered as ARS Rats on form because Black Rats is not an option)

4. Species (common name) of animals used in the study.

Rattus rattus

5. Explain the procedure producing pain and distress.

We will administer known dosages DR8 dissolved in a suitable carrier (e.g. phosphate buffer) to test animals via oral gavage to determine the approximate LD50. We will assess the LD50 using the up-and-down method (OPPTS Harmonized Test Guideline 870.1100 Acute Oral Toxicity). The up-and-down method relies on a single animal being dosed, observing its response for a period of time and then dosing a second animal with either a higher or lower dose depending on the response of the first animal.

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Agency N/A

CFR N/A