OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2017

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0019

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

US ARMY EDGEWOOD CHEMICAL BIOLOGICAL CTR
BLDG E3150 ATTN: AMSRD-ECB-RT-TV

ABERDEEN PROV GRND, MD 21010

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets, if necessary.)*

FACILITY LOCATIONS *(Sites)*

[redacted]

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets, if necessary, or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	300	300
7. Hamsters	0	0	0	0	0
8. Rabbits	2	209	4	155	368
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	2	0	33	26	59
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

[redacted]

DATE SIGNED
01-FEB-2018

APHIS FORM 7023
JUL 2013

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay person as well as scientists.

1. Registration Number: **51-F-0019 (Edgewood Chemical Biological Center)**

2. Number of animals used in this study: **36**

3. Species (common name) of animals used in the study: **guinea pigs**

4. Explain the procedure producing pain and/or distress.

   Guinea pigs were exposed to a compound intravenously, to determine 24-hour LD_{50}'s (lethal to 50% of the animals tested). The compound caused toxic signs such as gasping and bronchoconstriction in thirty-six (36) guinea pigs.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below.)

   Pre-treating the animals with analgesics was not an option because it would interfere or potentially block clinical signs to be used as endpoints. Additionally, administering analgesics would result in respiratory depression which could alter the respiratory minute volume during the aerosol exposure and exacerbate the expected signs and symptoms following the exposure, thereby confounding the intent of the experiments.

6. 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 _____

13 JAN 2018

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay person as well as scientists.

1. Registration Number: **51-F-0019 (Edgewood Chemical Biological Center)**

2. Number of animals used in this study: **264**

3. Species (common name) of animals used in the study: **guinea pigs**

4. Explain the procedure producing pain and/or distress.

   Guinea pigs were exposed to a military grade chemical agent, via whole-body inhalation for 20 and 60 minutes, to attain LCt_{50}'s (lethal to 50% of the animals tested) and ECt_{50}'s (time to effects data) for each exposure duration. The compound caused toxic signs such as gasping and bronchoconstriction in two hundred sixty-four (264) guinea pigs.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below.)

   Pre-treating the animals with analgesics was not an option because it could potentially affect the lethality results through pre-exposure enhancement of liver metabolism. This potential metabolic enhancement is likely to shift the lethality or no observable adverse effects levels (NOAEL) results and render the study potentially invalid. Toxic signs and their severity had to be documented. The data had to be collected as accurately as possible to analyze the ECt_{50} (time to effects data).

6. 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 _____

13 JAN 2018

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay person as well as scientists.

1. Registration Number: **51-F-0019 (Edgewood Chemical Biological Center)**

2. Number of animals used in this study: **16**

3. Species (common name) of animals used in the study: **rabbits**

4. Explain the procedure producing pain and/or distress.

   Rabbits were exposed to a military grade chemical agent, via whole-body inhalation for 20 and 60 minutes, to attain LCt_{50}'s (lethal to 50% of the animals tested) for each exposure duration. The compound caused toxic signs (gasping and bronchoconstriction) in sixteen (16) rabbits.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below.)

   Pre-treating the animals with analgesics was not an option because it could potentially affect the lethality results through pre-exposure enhancement of liver metabolism. This potential metabolic enhancement is likely to shift the lethality or no observable adverse effects levels (NOAEL) results and render the study potentially invalid. Toxic signs and their severity had to be documented.

6. 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 _____

13 JAN 2018

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay person as well as scientists.

1. Registration Number: **51-F-0019 (Edgewood Chemical Biological Center)**

2. Number of animals used in this study: **39**

3. Species (common name) of animals used in the study: **rabbits**

4. Explain the procedure producing pain and/or distress.

   Rabbits were implanted with telemetric devices and exposed, via nose-only inhalation, to military grade chemical agents. Doses ranged from a no observable adverse effects level (NOAEL) to a 100% blood acetylcholinesterase inhibition level. The compounds caused toxic signs such as gasping and bronchoconstriction in thirty-nine (39) rabbits.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below.)

   Pre-treating the animals with analgesics was not an option because it could potentially affect the sub-lethal results through pre-exposure enhancement of liver metabolism. This potential metabolic enhancement is likely to shift the sub-lethal or NOAEL results and render the study potentially invalid.

6. 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 _____

13 JAN 2018

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay person as well as scientists.

1. Registration Number: **51-F-0019 (Edgewood Chemical Biological Center)**

2. Number of animals used in this study: **37**

3. Species (common name) of animals used in the study: **rabbits**

4. Explain the procedure producing pain and/or distress.

Rabbits were exposed, intravenously, to 4 military grade compounds in an up-and-down procedure to estimate the LD_{50} (lethal to 50% of the animals tested) values. The compounds caused toxic signs such as gasping, bronchoconstriction, and convulsions in thirty-seven (37) rabbits.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below.)

Pre-treating the animals with analgesics was not an option because it could interfere or potentially block observable toxic signs, especially convulsions, to be used as endpoints.

6. 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 _____

13 JAN 2018

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay person as well as scientists.

1. Registration Number: **51-F-0019 (Edgewood Chemical Biological Center)**

2. Number of animals used in this study: **63**

3. Species (common name) of animals used in the study: **rabbits**

4. Explain the procedure producing pain and/or distress.

Fifteen (15) rabbits were exposed, percutaneously, to a compound in an up-and-down procedure to estimate the 24-hour LD_{50} (lethal to 50% of the animals tested) values. Thirty (30) rabbits were exposed, percutaneously, to a compound for 2 minutes, then treated with a decon wipe. Eighteen (18) rabbits were exposed, percutaneously, to determine the volume of a neat compound that can be applied to 8 sites that would result in visual skin damage without causing death in a 24-hour period, then treated with different decon wipes. The compound caused toxic signs such as gasping, bronchoconstriction in sixty-three (63) rabbits.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below.)

Analgesics/anesthetics could not be used so that the onset of toxic signs and survival rate could be accurately documented.

6. 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 _____

13 JAN 2018

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay person as well as scientists.

1. Registration Number: **51-F-0019 (Edgewood Chemical Biological Center)**

2. Number of animals used in this study: **26**

3. Species (common name) of animals used in the study: **minipigs**

4. Explain the procedure producing pain and/or distress.

Minipigs were exposed to military grade chemical agents, via whole-body inhalation, to attain LCt_{50}'s (lethal to 50% of the animals tested) and ECt_{50}'s (time to effects data) for each exposure duration. The compounds caused toxic signs such as gasping and bronchoconstriction in twenty-six (26) minipigs.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below.)

Pre-treating the animals with analgesics was not an option because it would interfere or potentially block clinical signs to be used as endpoints. Additionally, administering analgesics would result in respiratory depression which could alter the respiratory minute volume during the aerosol exposure and exacerbate the expected signs and symptoms following the exposure, thereby confounding the intent of the experiments.

6. 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 _____