SH

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED 0579-0036

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: 2009

**UNITED STATES DEPARTMENT OF AGRICULTURE**
**ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

# ANNUAL REPORT OF RESEARCH FACILITY

*(TYPE OR PRINT)*

**REGISTRATION NUMBER:** 50-R-0001

**Customer Number:** 41

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

*E I Dupont Denemours & Company Inc*
*Elkton Road*
*P.O. Box 50*
*Newark, DE 19714*

*Telephone: (302) 366 5010*

**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)* *See Attached Listing*

**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 | | | | | |
| 5. Cats | | | | | |
| 6. Guinea Pigs | | | | | |
| 7. Hamsters | | | | | |
| 8. Rabbits | 16 | 373 | 3 | 13 | 389 |
| 9. Non-human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 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 (L.O.))***
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)c

DATE SIGNED 11/19/2009

AUG 2009

EC 12-3-09

NOV 23 2009

DuPont Haskell Global Centers
for Health & Environmental Sciences
Elkton Road, P.O. Box 50
Newark, DE 19714-0050

November 20, 2009

Elizabeth Goldentyer, DVM
USDA, APHIS, REAC
Eastern Regional Office
920 Main Campus Drive
Raleigh, NC 27606

RE: ANNUAL REPORT, CUSTOMER NO: 41, CERTIFICATE NO: 50-R-0001

Dear Dr. Goldentyer:

In accordance with the Animal Welfare Act (AWA) regulations, DuPont Haskell Global Centers for Health and Environmental Sciences is filing its Annual Research Facility Report (APHIS Form 7023) documenting animal usage for the Federal Fiscal Year 2009 (October 1, 2008 through September 30, 2009).

**Acute Dermal Irritation Study**

Two (2) rabbits used in Acute Dermal Irritation studies met the criteria described on APHIS Form 7023 Column "E". All procedures and methodology on these tests followed test guidelines OPPTS 870.2500 (1998) and OECD 404 (1992), with the only exception that fewer animals were used. The guidelines require 3 animals per test substance. We (keeping in mind the three R's) used 2 animals which is predictive of previous test substance responses, safety assessment information, as well as for registration of the product. The IACUC approved this work which is predictive of the results of the guideline-compliant studies.

**Acute Eye Irritation Study**

Three (3) rabbits used in Acute Eye Irritation studies met the criteria described on the APHIS Form 7023 Column "E". These studies comply with test guidelines OPPTS 870.2400 (1998) and OECD 405 (1987).

Acute Eye Irritation Study – the purpose is to provide DuPont with a safety assessment and/or information for registration of the product.

Animals experiencing extreme pain are euthanized immediately. Most tested substances are novel materials. Any exceptions must be approved by the IACUC. Acute irritation studies are not conducted for test substances if it is expected they will produce corrosion or severe irritation, based on measured pH or the results of an *in vitro* assay (i.e, Corrositex). Haskell follows the principles of the three R's in all of our work.

**Developmental Toxicity Study**

Eight (8) rabbits used in Developmental Toxicity Studies met the criteria described on APHIS Form 7023 Column "E".

Developmental Toxicity Main Study – the purpose of this study is to evaluate the potential developmental toxicity of a test substance when administered orally to pregnant rabbits during gestation. These are safety assessment studies that are often required by regulatory agencies in support of product registration.

Regulatory agency guidelines related to this type of testing include:

U.S. EPA, OPPTS 870.3700 Prenatal Developmental Toxicity Study, Health Effects Test Guidelines (1998).

OECD, Section 4 (Part 414): Prenatal Developmental Toxicity Study, Guideline for the Testing of Chemicals (2001).

Official Journal of the European Communities, 87/302/EEC, Part B: Methods for the Determination of Toxicity.

MAFF Japan, Notification 12 Nousan Number 8147, The Guidelines Related to the Study Reports for the Registration Application of Pesticides, 24 November 2000.

The IACUC approved the studies listed above without the use of anesthetics, analgesics or tranquilizing drugs. These studies are designed to evaluate the safety of test substances: co-administration of drugs intended to manage pain and distress in surviving animals could potentially interfere with the objective of the test and invalidate the results of the study.

Haskell's IACUC has not approved any exceptions to the AWA standards during the previous year for any USDA covered species.