

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0082
CUSTOMER NO. 190

FORM APPROVED
OMB NO. 0579-0036

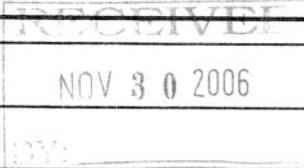
ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)
PRODUCT SAFETY LABS, INC.
2394 ROUTE 130
DAYTON, NJ 08810
(732) 438-5100

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 in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		7449		307	7756
7. Hamsters		26			26
8. Rabbits		1625	758	57	2440
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals Ferrets		101			101

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 the 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 provision 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 or Legally Responsible Institutional official)

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL

DATE SIGNED

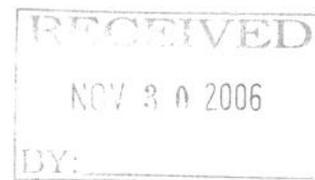
(b)(6), (b)(7)(c)

11/29/06

(AUG 91)

PART 1 - HEADQUARTERS

Flow



ATTACHMENT TO USDA/APHIS ANNUAL REPORT OF RESEARCH FACILITY

EXPLANATION OF COLUMN "E" ENTRIES

10/01/05 through 9/30/06

28 Rabbits – Eye Irritation Test (OPPTS 870.2400): Four (4) of these animals vocalized following instillation of the test compound but immediately became calm after they were returned to their cage. Therefore, anesthetic was not considered. Although the remaining animals (24) did not exhibit overt signs of pain or distress, they exhibited ocular irritation scores above an arbitrary threshold and were considered to be in distress as a result of their exposure to the test compound. Although in the eye irritation test ocular anesthetic may be used prior to instillation, repeated and/or prolonged anesthetic use could retard healing and possibly lead to collateral irritation and/or subsequent corneal infection. Therefore, ocular anesthetic was not used on the animals evidencing ocular irritation scores above this established threshold limit. **Note: Beginning in January, 2006, Product Safety Labs adopted the policy of using anesthetic for all Primary Eye Irritation studies.**

29 Rabbits – Dermal Irritation Test (OPPTS 870.2500): All animals exhibited eschar and/or corrosion at the dose site, which could indicate possible necrosis of the skin. In all cases, the area of exposure and subsequent skin damage was $\leq 1 \text{ in}^2$. Continuous or prolonged use of topical or systemic anesthetic agents during dermal irritation tests was not considered appropriate since it could lead to study complications including increased irritation and delayed healing. The use of analgesic agents would be inappropriate in these studies due to resultant anti-inflammatory effects that could mask the indicators of irritation. If used, they might significantly alter the effects of the test compound and compromise study results.

307 Guinea Pigs – Dermal Sensitization Test (OPPTS 870.2600): Similar to the dermal irritation test noted above, these animals exhibited eschar and/or corrosion at the dose site, which could indicate possible necrosis of the skin. In all cases, the area of exposure and subsequent skin damage was $\leq 1 \text{ in}^2$. Continuous or prolonged use of topical or systemic anesthetic agents during dermal sensitization tests was not considered appropriate since it could lead to study complications including increased irritation and delayed healing. The use of analgesic agents would be inappropriate in these studies due to resultant anti-inflammatory effects that could mask the indicators of sensitization. If used, they might significantly alter the effects of the test compound and compromise study results.