This report is required by law (7 USC 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.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0082 22R0082

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

190

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

Product Safety Labs., Inc.
725 Cranbury Road
~~College Drive~~
East Brunswick, NJ 08816
Status: Active

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~~

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	0				
5. Cats	0				
6. Guinea Pigs	0	3737		24	3761
7. Hamsters	0	145			145
8. Rabbits	0	1652	106	156	1914
9. Non-human Primates	0				
10. Sheep	0				
11. Pigs	0				
12. Other Farm Animals	0				
13. Other Animals					
GERBILS	0	19	93		112
			DEC 0 8 1999		

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 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 *(Type or Print)*	DATE SIGNED
[redacted] (b)(6) (b)(7)(C)	[redacted] (b)(6) (b)(7)(C)	11/30/99

APHIS FORM 7023
(AUG 91)

(Replaces VS FORM 18-23 (OCT 88), which is obsolete)

[redacted]

Registration Number: 22-R-0082

22R0082

ATTACHMENT TO USDA/APHIS ANNUAL REPORT OF RESEARCH FACILITY
EXPLANATION OF COLUMN "E" ENTRIES

130 Rabbits - Eye Irritation Test (OPPTS 870.2400): A total of six of these animals vocalized following instillation of the test compound but immediately became calm after they were returned to their cage. Therefore, anaesthetic was not considered. Although, the remaining animals did not exhibit overt signs of pain or distress, they exhibited ocular irritation scores above an arbitrary threshold and were considered to be in pain as a result of their exposure to the test compound. Although in the eye irritation test, ocular anaesthetic may be used prior to instillation, repeated or prolonged use would retard healing and possibly lead to collateral irritation and/or subsequent corneal infection. Therefore, ocular anesthetic was not used.

26 Rabbits – Skin 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 ≤ 1 in^2. Continuous or prolonged use of topical or systemic anesthetic during skin irritation studies was not considered appropriate since it could lead to increased irritation and delayed healing. The use of analgesics would be inappropriate for these studies due to their anti-inflammatory effects. If used they could significantly alter the effects of the test compound.

11 Guinea Pigs – Buehler Sensitization Test (OPPTS 870.2600): Similar to the skin 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 ≤ 1 in^2. Continuous or prolonged use of topical or systemic anesthetic during Sensitization tests was not considered appropriate as it could lead to study complications including increased irritation and delayed healing. The use of analgesics would be inappropriate for these studies due to their anti-inflammatory effects. If used they could significantly alter the effects of the test compound.

13 Guinea Pigs – Antigenicity Test (USP 23): All animals demonstrated severe sensitization and/or anaphylaxis upon intravenous exposure to the positive control or test substance(s), and died as a result of the study treatment. As sensitization and anaphylaxis are the necessary biological responses (endpoints) of sensitization in these studies, prophylactic treatment with compounds intended to alleviate the sensitization and anaphylactic responses would be counter indicative.

DEC 03 1999