34R0031

MPI
RESEARCH

Annual Report of Research Facility
November 23, 1999

Registration No: 34-R-0031
MPI Research, Inc.
54943 North Main Street
Mattawan, MI 49071

Detailed Explanation of Animals Presented in Column E:

Consistent with the USDA's Animal Care Resource Guide, Policy #11 regarding Painful Procedures, we have included all animals that were injected with Freund's Complete Adjuvant, or were used in Eye or Skin Irritation Studies in Column E. When consistent with the experimental objectives, procedures are used to minimize potential pain or distress, including treatment.

34 guinea pigs indicated in Column E received Freund's Complete Adjuvant as a component of Skin Sensitization Studies (Maximization Method). These nonclinical laboratory studies are conducted in accordance testing guidelines as set forth by the United States Environmental Protection Agency (EPA), Toxic Substances Control Act (TSCA), Health Effect Test Guidelines, 798.4100; EPA, Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), Series 81-6; The Japanese Ministry of Agriculture, Forestry and Fisheries (JMAFF) "Testing Guidelines for Toxicology Studies (59 NohSan No. 4200); and the Organization for Economic Cooperation and Development (OECD), Guidelines 406, Skin Sensitization. The Freund's Complete Adjuvant is administered, on a single occasion, intradermally. Although these injections typically produce skin ulcers at the injection sites, other clinical signs of pain or distress are not observed. The use of analgesics could potentially interfere with the interpretation of the Skin Sensitization Tests. Alternatively, skin sensitization studies using the Buehler Method, which does not include the use of Freund's Complete Adjuvant, are used whenever possible if scientifically acceptable.

9 of the rabbits indicated in Column E were used in Skin Irritation Studies. These nonclinical laboratory studies are conducted with Good Laboratory Practice Standards as set forth in the Federal Hazardous Substance Act (16 CFR), Consumer Product Safety Commission, Guideline 1500.41, Method of Testing Primary Irritant Substances; EPA, FIFRA, Series 81-2; EPA, TSCA, 798.4470; and OECD, Guideline 404, Acute Dermal Irritation/Corrosion. Typically, the test article is applied to a small gauze patch which is held in place on the skin of the dorsal back for 24 hours. In compliance with EPA, OPPTS, 870-2500; and OECD Guidelines; if the test material is a suspected severe irritant or corrosive a small amount of the material is applied to the back of 1 rabbit to evaluate for a painful response. If the test material is found to be severely irritating or corrosive, further skin irritation testing is not conducted. The use of analgesics could potentially interfere with the interpretation of the Skin Irritation Test.

3 of the rabbits indicated in Column E were used in Eye Irritation Studies. These nonclinical laboratory studies are conducted with Good Laboratory Practice Standards as set forth by EPA, TSCA, Health Effect Test Guidelines, 798.4500; EPA, FIFRA, Series 81-4; JMAFF, Testing Guidelines for Toxicology Studies (59NohSan No. 4200); and OECD, Guideline 405, Acute Eye Irritation/Corrosion. The test article is applied into the conjunctival sac of one eye with the other serving as a nontreated control. A single animal is tested initially and if the results of this test in 1 rabbit indicate the test article to be severely irritating or corrosive to the eye, further testing is not conducted. In addition, if the first animal treated appears to be in obvious pain, the test and control eyes are immediately treated with a topical anesthetic (e.g., proparacaine HCl). Further use of analgesics could potentially interfere with the interpretation of the Eye Irritation Test. In addition, MPI policy maintains that Eye Irritation Studies will not be conducted if the test material is a known or determined to be a dermal irritant.

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. 34-R-0032 34R0032

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

186

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

Dow Corning Corporation
Health & Environmental Sciences
P.O. Box 994
Midland, MI 48686-0994
Status: Active

RECEIVED
NOV 02 1999
BY:

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	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
Hamsters	0	0	0	0	0
8. Rabbits	0	0	18	0	18
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

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)

(b)(6) (b)(7)(C)

cc: [redacted]

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
[redacted]	[redacted]	25OCT99

APHIS FORM 7023 (Replaces VS [redacted] 18-23 (OCT 88), which is obsolete.)

(b)(6) (b)(7)(C)