

ORIGINAL

**TSCA NON-CONFIDENTIAL BUSINESS INFORMATION**

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ-92-10104	<b>89110000202</b>	3 22 11

COMMENTS: COMMUN S (DECLASS)

**DOES NOT CONTAIN CBI**

334115



**The Procter & Gamble Company**  
NA Regulatory & Technical Relations  
One Procter & Gamble Plaza (C-6)  
Cincinnati, OH 45202  
www.pg.com

U.S. EPA  
Office of Pollution Prevention and Toxics  
Document Control Office (7407M)  
1200 Pennsylvania Ave., NW  
Washington, DC 20460  
Attn: TSCA Declassification Coordinator

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POST OFFICE

**Re: Declassification Activity-Health and Safety Filing  
8EHQ-0892-10104 (EPA DCN 88920008405)**

Dear Sir/Madam:

The Procter & Gamble Company (P&G) provides this submission to amend the Public Display Version of our submission pursuant to the TSCA Section 8(e) Compliance Audit Program (CAP) under terms of CAP Agreement # 8ECAP-0003.

This amended submission is composed of the following:

- (a) new information provided in this cover letter and its attachment(s); and
- (b) the unaltered original submission which directly follows.

Any CBI substantiation which appears in the original submission is no longer applicable as the information which was originally claimed CBI is disclosed in this revised submission.

Should you have any questions concerning this amended submission, please contact me at (513) 983-2531 or [froelicher.jm@pg.com](mailto:froelicher.jm@pg.com).

Sincerely,

THE PROCTER & GAMBLE COMPANY

Julie Froelicher  
NA Regulatory & Technical Relations Manager  
The Procter & Gamble Company  
One Procter & Gamble Plaza  
Cincinnati, OH 45202  
(513) 983-2531  
[froelicher.jm@pg.com](mailto:froelicher.jm@pg.com)



# Attachment 1

## Public Display Version

The Public Display version contains no page for formula mixture P1928. None is provided here.

The mixture identified as P1906 is:

<u>Chemical Identity</u>	<u>CAS RN</u>
Benzenesulfonic acid, C10-16-alkyl derivatives	68584-22-5
Poly(oxy-1,2-ethanediyl), .alpha.-sulfo-.omega.hydroxy-, C10-16-alkyl ethers, sodium salts	68585-34-2
Alcohols, C12-13, ethoxylated	66455-14-9
Fatty acids, C8-18 and C18-unsatd.	67701-05-7
1,2,3-Propanetricarboxylicacid, 2-hydroxy-	77-92-9
Glycine, N,N-bis[2-[bis(carboxymethyl)amino]ethyl]-, pentasodium salt	140-01-2
Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5[[4-[(2-hydroxyethyl)methylamino]-6-(phenylamino)-1,3,5-triazin-2-yl]amino]-, disodium salt	13863-31-5
Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5[[1,4-dihydro-4-oxo-6-(phenylamino)-1,3,5-triazin-2-yl]-amino]-, disodium salt	1264-32-0
Formic acid, calcium salt	544-17-2
1,2-Ethanediamine, N-(2-aminoethyl)-N'-[2-[(2-aminoethyl)amino]ethyl]-, polymer with methyloxirane and oxirane	68815-65-6
Subtilisin	9014-01-1
Amylase	900-92-4

Ethanol,. 2-amino-

1,2-Propanediol

Ethanol

Fragrance Mixture

Boric acid

**Attachment 1 (continued)**

**Public Display Version**

*The mixture identified as P1907 is:*

**Chemical Identity**

**CAS RN**

Dodecanediperoxoic acid

66280-55-5

Benzenesulfonic acid, C10-16-alkyl derivatives

68584-22-5

2,6-Pyridinedicarboxylic acid

499-83-2

Sulfuric acid magnesium salt (1:1)

Sulfuric acid disodium salt

Water

Attachment 1 (continued)

Public Display Version

The mixture identified as P1472 is:

<u>Chemical Identity</u>	<u>CAS RN</u>
Benzenesulfonic acid, C10-16-alkyl derivatives	68584-22-5
Poly(oxy-1,2-ethanediyl), .alpha.-sulfo-.omega.hydroxy-, C10-16-alkyl ethers, sodium salts	68585-34-2
Alcohols, C12-13, ethoxylated	66455-14-9
Fatty acids, C12-18	67701-01-3
Glycine, N,N-bis[2-[bis(carboxymethyl)amino]ethyl]-, pentasodium salt	140-01-2
1-Dodecanaminium, N,N,N-trimethyl-, chloride	112-00-5
1,2-Ethanediamine, N-(2-aminoethyl)-N'-[2-[(2-aminoethyl)amino]ethyl]-, polymer with methyloxirane and oxirane	68815-65-6
Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[S[4- [(2-hydroxyethyl) methylamino] -6- (phenylamino)l, 3,5-triazin-2-yl]amino]-, disodium salt	13863-31-5
Benzenesulfonic acid~ 2,2'-(1,2-ethenediyl)bis[S-[[1,4-dihydro-4-oxo-6-(phenylamino)-1,3,5-triazin-2-yl]amino]-, disodium salt	1264-32-0
Formic acid, sodium salt	141-53-7
Calcium chloride	10043-52-4
2-Anthracenesulfonic acid, 4,4'-[(1-methylethylidene)bis(4,1-phenyleneimino)]bis[1-amino-9,10-dihydro-9,10-dioxo-, disodium salt	6471-01-8

Attachment 1 (continued)

Public Display Version

P1472 (cont.):

**Chemical Identity**

**CAS RN**

1,2,3-Propanetricarboxylic acid, 2-hydroxy-

Ethanol

Water

1,2-Propanediol

Ethanol, 2-amino-

Ethanol, 2,2',2"-nitrilotris-

Sodium hydroxide

Potassium hydroxide

Fragrance Mixture

8EHQ-0892-10104

# Procter & Gamble COMPANY SANITIZED

The Procter & Gamble Company  
Ivorydale Technical Center  
5299 Spring Grove Avenue, Cincinnati, Ohio 45217-1087

92 11 15 11 15

## Public Display Copy

August 24, 1992

Document Processing Center (TS-790)  
Office of Toxic Substances  
Environmental Protection Agency  
401 M St. S.W.  
Washington, D.C. 20460

8EHQ-92-10104 INIT  
88920008405

Attn: Section 8(e) Coordinator (CAP Agreement)

This submission is being made pursuant to the TSCA Section 8(e) Compliance Audit Program and the terms of CAP Agreement # 8ECAP-0003. This report discharges our Company obligation to report the attached data under TSCA Section 8(e). The filing of these studies does not indicate that we agree that "substantial risk" exists. We are following the agency's guidance and the terms of the CAP agreement, but we expressly disclaim that the filings reflect a decision that these materials pose any significant human or environmental safety risks.

The materials identified in the attached report as P1906, P1907, P1928 and P1472 are confidential mixtures. Their compositions are appended as Attachment 1. The report is titled "Acute Percutaneous Toxicity". Any correspondence relating to this submission should reference study # 1314-31925.

This submission provides data on the effects of 2 ml/kg of the test materials to rabbits when administered percutaneously for 24 hours under occlusion. Each of the test materials caused marked dermal responses including erythema and edema. Administration of P1906 resulted in the death of 5/12 animals, and 8/12 animals (including all animals which died on test) showed signs of fatty livers at necropsy. Administration of P1928, P1472, or a mixture of P1928 + P1907, (mixtures similar to P1906) resulted in no deaths and fatty livers in 2/18 animals. Subsequent testing of similar mixtures has failed to confirm the finding of fatty livers.

We do not believe findings in this report reasonably support a conclusion of substantial risk to human health or the environment. Nevertheless, we are submitting this report to discharge any potential liability under TSCA Section 8(e).

To our knowledge, this report has not been the subject of a prior submission to EPA under the provisions of TSCA.

The specific chemical constituents and percentage composition of this mixture is claimed as confidential business information. A sanitized version of this submission containing generic chemical names has been included as part of this submission. Answers to the seven questions required to substantiate this claim of confidentiality are provided below:

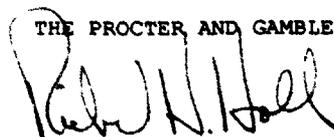
1. Confidentiality of the chemical constituents and their percentages should be maintained indefinitely. There are no plans for this information to be otherwise disclosed, and this technology has significant commercial value.
2. To our knowledge, there have been no government confidentiality determinations made for this mixture.

**Procter & Gamble**

3. The specific chemical identity and exact proportions of the constituents of this mixture have not been disclosed outside the Company. There are no plans to disclose publicly the exact composition of this mixture at any time in the future.
  4. Measures for protection of the compositional information include "need to know" internal restriction within the Company. An internal code is used to protect the identity of the material. Information is maintained in locked files. Employees leaving the Company are contractually bound not to disclose Company secrets.
  5. The exact composition of this mixture has not appeared in advertising or promotional literature, MSD sheets, any publications or any other media available to the general public or competitors.
  6. Disclosure of the information claimed as CBI would result in substantial harm to the Company's competitive position. This formula provides an important commercial opportunity for a competitor. Knowledge of the exact composition of this mixture could enable a competitor to duplicate the formula without R&D cost, thus providing an unfair competitive disadvantage to the Procter & Gamble Company. Development of this formula required many technically trained personnel, hundreds of hours of research and development, and significant capital investment valued in aggregate at . . . Any competitor would normally be required to make a similar investment to duplicate the formula. Disclosure of this information would allow a competitor to duplicate the formula without incurring significant R&D costs, thus doing substantial harm to our competitive position.
  7. The information we have identified as confidential is not health or safety data.
- Any questions concerning this submission, may be directed to me at (513) 627-5551.

Sincerely,

THE PROCTER AND GAMBLE COMPANY



Richard H. Hall, Ph.D.  
Manager  
Regulatory & Government Affairs  
The Procter & Gamble Company

The mixture identified as P1906 is:

Alkyl benzene sulfonic acid

Sodium alkyl ethoxy sulfate

Alkyl ethoxylate

Fatty acid

Citric acid

Substituted amine

Mono ethanol amine

Propylene glycol

Ethanol

Substituted stilbene

Fragrance

Boric Acid

Calcium salt

Substituted amine

Enzyme

*Procter & Gamble*

Attachment I (cont.)

**Public Display Copy**

The mixture identified as P1472 is:

Alkyl benzene sulfonic acid

Sodium alkyl ethoxy sulfate

Alkyl ethoxylate

Fatty acid

Citric acid

Substituted amine

Alkyl trimethyl ammonium chloride

Ethanol

Water

Substituted amine

Propylene glycol

Mono ethanol amine

Tri ethanol amine

Sodium hydroxide

Potassium hydroxide

Fragrance

Substituted stilbene

Sodium salt

Calcium salt

Colorant

1314-31925

THE PROCTER & GAMBLE COMPANY  
Miami Valley Laboratories  
P.O. Box 39175  
Cincinnati, Ohio 45247

ACUTE PERCUTANEOUS TOXICITY

B85-0005

BTS 3200

P1906

P1907

P1472

P1928

May 17, 1985

B85-0005

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Protocol.....	Attached



# THE PROCTER & GAMBLE COMPANY

MIAMI VALLEY LABORATORIES

P. O. BOX 39175  
CINCINNATI, OHIO 45247

The following study was reviewed by the Quality Assurance Unit:

LABORATORY: The Procter & Gamble Company  
BTF - Miami Valley Laboratories  
P.O. Box 39175  
Cincinnati, Ohio 45247

STUDY NUMBER: B85-0005

DIVISIONAL REQUEST DOCUMENT: BTS 3200

TSIN: P1906, P1907, P1472, P1928

TYPE OF STUDY: Acute Percutaneous Toxicity

PORTION(S) OF STUDY REVIEWED:	REVIEWED BY:	DATE(S) OF REVIEW:	DATE(S) FINDINGS REPORTED TO STUDY DIRECTOR:
Gross Necropsy	N.E. Gilman	1/31/85	1/31/85

The protocol was reviewed for compliance to the GLP regulations.

Significant audit findings (if any) were reported to the Study Director and Facility Management immediately. All audit findings are reported to Management on a periodic basis.

The final study report was reviewed for inaccuracies and procedural compliance. The results reflect the raw data of the study.

N E Gilman *NEG* 5/17/85  
Quality Assurance Unit Coordinator

#### SUMMARY AND CONCLUSIONS

Test substance P1906 produced death in 5 of 6 animals within 2-4 days of treatment. The test site skin reactions on these animals were relatively severe, however, they were not judged to be of a severity which would result in the animals' death. Repeat dosing with this test substance did not produce death among any of the animals treated; although, clinical signs indicated that the animals were adversely affected by the treatment. The skin reactions were relatively severe on these animals.

Test substance P1907 alone, test substance P1928 alone, and a combination of these test substances produced relatively severe dermal responses on all animals. Transient signs of anorexia were observed for 4 of 6 animals treated with P1928 alone. There were no other gross signs of systemic toxicity or deaths observed for animals receiving these treatments.

Test substance P1972 produced severe test site irritation on all animals plus, in 2 of 6 animals, transient signs of anorexia. There were no other gross signs observed following treatment with this test substance.

Post mortem examination of the 5 animals that died prematurely following administration of test substance P1906 revealed severe dorsal treatment area skin erythema, and a possible systemic effect (fatty livers). A probable cause for the premature deaths could, however, not be determined. The remaining 1906-treated animal and all P1907-treated animals were necropsied according to schedule, and although dorsal treatment area skin alterations consistent with those reported in the final in-life observations were present in each animal, there was no evidence of any other alterations. The significance of fatty alterations in livers of animals that died prematurely could not be determined within the confines of this study.

Twenty-four animals that received undilute test substance P1906, P1472, or P1928, or a mixture of 1 volume P1907 in 5.5 volumes P1928 were sacrificed according to schedule, and dorsal treatment area skin alterations consistent with those reported in the final in-life observations were present in each animal. Gross examination also revealed comparable liver alterations in P1906, P1472, and P1928-treated animals as well as a lung lesion in one P1906-treated animal. Each of these alterations was uncommon to acute percutaneous toxicity studies, and was therefore considered treatment-related. However, factors responsible for these tissue alterations could not be determined within confines of the present study.

#### OBJECTIVES AND BACKGROUND

The purpose of this study was to determine skin irritancy, potential gross systemic and lethal effects produced by P1906, P1907, P1472, P1928 and a mixture of 1907 and P1928 when each was applied to the backs of rabbits at a dose level of 2 ml/kg.

STUDY IDENTIFICATION

STUDY DIRECTOR: G. A. Nixon  
DIVISIONAL TOXICOLOGIST: K. W. Miller  
SPONSORING DIVISION: Packaged Soap & Detergent  
TESTING FACILITY: The Procter & Gamble Company  
Miami Valley Laboratories  
Biological Testing Facility

DIVISIONAL REQUEST DOCUMENT

NUMBERS: BTS 2200  
STUDY NUMBER: B85-0005  
NOTEBOOK NUMBER: YE-737J  
IN-LIFE STARTING -  
COMPLETION DATES: 1/10/85 - 2/19/85

MATERIALS AND METHODS (PROTOCOL AND AMENDMENT ATTACHED)

TEST SUBSTANCE

TEST SUBSTANCE  
IDENTIFICATION: P1906, P1907, P1472, P1928  
CONCENTRATION OF TEST  
SUBSTANCE TESTED: P1906, P1907, P1472, P1928-Undilute; 1 part test  
substance P1907 to 5.5 parts test substance P1928  
TEST SUBSTANCE STORAGE  
CONDITION: Room temperature and humidity  
CONTROL SUBSTANCE: N/A  
ANALYSIS OF TEST  
SUBSTANCE/CARRIER  
MIXTURE: N/A, See Protocol Page 3

TEST SYSTEM

SPECIES, STRAIN AND SOURCE  
OF ANIMALS: Rabbit, New Zealand Albino,  
Hazleton Research Animals  
INITIAL ANIMAL WEIGHT RANGE: 2281-3369  
ANIMAL RESTRAINT: Harness or collar

GROUP AND TREATMENT:

GROUP	NUMBER OF ANIMALS		TREATMENT
	MALE	FEMALE	
1	4621,4639,4640	4599,4606,4619	P1906, undilute, 2 ml/kg, (Intact skin)
2	4637,4642,4624	4591,4603,4611	P1907, undilute, 2 ml/kg (Intact skin)
3	4787,4788,4806	4815,4818,4829	P1906, undilute, 2 ml/kg (Intact skin)
4	4793,4799,4804	4811,4813,4816	P1472 undilute, 2 ml/kg (Intact skin)
5	4797,4800,4810	4812,4819,4826	P1928, undilute, 2 ml/kg (Intact skin)
6	4801,4802,4805	4825,4827,4828	P1907 & P1928, 1 part/5.5 parts, 2 ml/kg (Intact Skin)

IN-LIFE

The study was conducted according to the attached protocol and amendment. There were no known deviations.

Five animals were found dead on January 13 and 14, 1985 and postmortem examinations were performed on these animals on January 14, 1985 by P. H. Long, D.V.M., of the Pathology Section.

Scheduled postmortem examinations were performed on seven animals on January 24, 1985.

Postmortem examinations were performed on 24 additional animals on February 19, 1985, as per protocol amendments #1-3. The following pathology personnel were in attendance at the 1/24/85 and 2/19/85 sacrifices.

R. L. Kenerva	Pathologist Designate
W. E. Wyder	Necropsy Coordinator
D. M. Barnett	Prosecutor
F. P. Lefever	Prosecutor (2/19/85 only)

No tissues were taken at any sacrifice for histologic processing.

RESULTS AND DISCUSSION

IN-LYFF:

Group 1 (P1906) - The abdominal hair of all animals was moist when the wrappings were removed following the 24 hour exposure period. The test substance produced severe erythema (6 of 6) and slight (2 of 6) to moderate (3 of 6) edema, slight (3 of 6), moderate (1 of 6) and severe (1 of 6) atonia. Hemorrhagic areas involving 25-50% of treatment area were observed in 2 of 6 test sites. Beginning on day 1, signs of anorexia (all animals) and general morbidity (2 animals) were observed. By days 3-4, 5 of 6 animals had died. At the conclusion of the study, eschar and exfoliation were evident on the test site skin of the surviving animal. Body weight loss was also noted for this animal.

Group 2 (P1907) - This test substance produced severe erythema and moderate edema on all sites following the 24 hour exposure. Severe atonia was noted on each test site during the observation period. Eschar (Day 7) leading to exfoliation (Day 9) developed on the sites which persisted for the duration of the study on all animals. The test site skin of 4 of 6 animals revealed a high sheen and denuded appearance on the final 1-2 days of observation.

Group 3 (P1906) - The test sites of animals treated with P1906 displayed moderate (1 of 6) to severe (5 of 6) erythema, moderate (4 of 6) to severe (2 of 6) edema, slight (4 of 6) to moderate (2 of 6) atonia, marked (5 of 6) desquamation and slight (3 of 6) to moderate (2 of 6) to marked (1 of 6) fissuring. Eschar and exfoliation were observed on all sites beginning on day 7. Skin responses persisted at the conclusion of the study, however, overall irritation had decreased.

Upon removal of the wrapping after the 24 hour exposure, the abdominal area of all six animals appeared wet. By the seventh day, the abdominal area and hind legs of all 6 animals displayed one or more of the following: stripping of hair, skin appeared raw with scratch marks and/or bite marks, scabs, thickened skin and several hemorrhagic areas.

On day 3-4, all animals showed signs of anorexia, 4 animals appeared lethargic and 2 animals displayed labored breathing. Two animals continued to show signs of anorexia for 6-7 days. One female showed a terminal body weight loss (78 grams) while all other animals gained weight.

Group 4 (P1472) - Test sites of animals treated with P1472 exhibited severe (6 of 6) erythema, moderate (6 of 6) edema, slight (6 of 6) atonia, moderate (1 of 6) to marked (4 of 6) desquamation and slight (4 of 6) to moderate (2 of 6) fissuring. Eschar (6 of 6) and exfoliation (4 of 6) were also observed. Skin effects persisted throughout the 14 day period. Two rabbits displayed areas of thickened skin in the abdominal area on day 6 which persisted for 4-6 days. Beginning on day 3, 3 animals showed signs of anorexia which persisted for 1-2 days. All animals showed a weight gain.

Group 5 (P1928) - The test sites of animals treated with P1928 displayed moderate (4 of 6) to severe (2 of 6) erythema, moderate (6 of 6) edema, slight (5 of 6) to moderate (1 of 6) atonia, moderate (6 of 6) desquamation and slight (6 of 6) fissuring. Eschar (5 of 6) and exfoliation (1 of 6) were also observed. Skin effects, while appearing less severe on day 14, persisted throughout the observation period. Prior to eschar formation, two rabbits exhibited numerous superficial hemorrhagic areas 0.5 cm or smaller in diameter. Beginning on day 3, 4 animals showed signs of anorexia. This condition persisted for 1-2 days. All animals gained weight; however, one animal gained only 19 grams during the observation period.

Group 6 (P1907, P1928) - The test sites of animals treated with a mixture of test substance P1907 (1 part) and P1928 (5.5 parts) displayed severe (6 of 6) erythema, moderate (4 of 6) to severe (2 of 6) edema, slight (6 of 6) atonia, moderate (5 of 6) desquamation and slight (5 of 6) to moderate (1 of 6) fissuring. Eschar (3 of 6) and exfoliation (2 of 6) were also observed. Skin effects persisted throughout the observation period; however, overall responses were less severe at the conclusion of the study. Beginning on day 3, 4 animals showed signs of anorexia. This condition persisted for a 1-2 day period. All animals showed a weight gain.

Individual animal body weights for all animals are summarized in In-Life Table 1. Individual animal skin and health observation sheets are attached. (In-Life Appendix 1,2).

#### ANATOMIC PATHOLOGY

Five of 6 animals from Group 1 died prematurely. Postmortem examination of each of these animals revealed severe dorsal treatment area skin erythema, little or no food in the stomach, and evidence of a fatty change in the liver. Evidence of pulmonary congestion was also observed in two animals, and was considered the probable cause of death of one of these animals. A probable cause of death could not be determined for the other four animals that died prematurely. (Pathology Appendix 1).

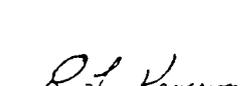
The remaining animal from Group 1 and all animals from Group 2 were necropsied according to schedule. Gross examination of each of these animals revealed dorsal treatment area skin alterations consistent in degree and nature with the final in-life observations. No evidence of any other treatment-related alterations were observed. The significance of the fatty alteration observed in livers of all Group 1 treated animals that died prematurely could not be determined within the confines of this study.

All 24 of the animals in Groups 3-6 were sacrificed according to schedule, and had dorsal treatment area skin lesions consistent in degree and nature with the final in-life observations. In addition, 3 of 6 animals from Group 3 had liver lesions characterized by multiple, scattered, yellowish-white foci observed on both external and cut surfaces. On incision these lesions appeared to represent foci of caseous material walled off by connective tissue. Lesions were also grossly visible in the left lung of one Group 3 animal. The lung lesion was characterized by the presence of multiple whitish, hard nodules visible on external and cut surfaces. Liver alterations consistent with those in Group 3 animals were also observed in 1 of 6 from Groups 4 and 6. One of the remaining 5 animals in Group 4 and 1 of the 6 animals in Group 5 had consolidation in the apical lobes of their lungs.

The liver lesions and lung lesions observed in some animals are not commonly observed at the conclusion of acute percutaneous toxicity studies, suggesting these lesions are, in the present study, treatment related. However, their biological significance cannot be determined within the confines of the present study.

  
Study Director

  
Pathologist

  
Pathologist Designate

In-Life Table 1  
B85-0005

INDIVIDUAL ANIMAL BODY WEIGHTS

<u>GP</u>	<u>TSTN</u>	<u>ANIMAL #/</u>	<u>SEX</u>	<u>INITIAL (g)</u>	<u>FINAL (g)</u>	<u>CHANGE (g)</u>
1	P1906	4619	F	3092	3072	-20
		4590	F	2787	•	
		4606	F	2801	•	
		4621	M	2941	•	
		4639	M	2828	•	
		4640	M	3091	•	
2	P1907	4591	F	3269	3731	362
		4603	F	2956	3267	311
		4611	F	2997	3249	252
		4637	M	2995	3163	168
		4642	M	3092	3265	173
		4624	M	2924	3177	253
3	P1906	4815	F	2525	2676	151
		4818	F	2365	2613	248
		4829	F	2805	2727	-78
		4787	M	2705	2852	147
		4788	M	2842	3091	249
		4806	M	2566	2821	255
4	P1472	4811	F	2442	2706	264
		4813	F	2664	2952	288
		4816	F	2847	3200	353
		4793	M	2477	2596	119
		4799	M	2810	3066	256
		4804	M	2767	3169	402
5	P1928	4812	F	2801	3139	338
		4819	F	2545	2564	19
		4826	F	2281	2676	395
		4797	M	2590	2998	408
		4800	M	2618	2739	121
		4810	M	2395	2690	295
6	P1907 & P1928	4825	F	2577	2913	336
		4827	F	2964	3152	188
		4828	F	2674	2913	239
		4801	M	2719	3093	374
		4802	M	2355	2577	222
		4805	M	2464	2750	286

\*Died days 4-5



ACUTE PERCUTANEOUS TOXICITY

Study #: 585-0005 DOD #: 678 3200 TSPN #: 01906 Initial Body Wt. (g.): 2801 Balance # N.Y.: 23152  
 Animal #: 4606 Sex: (M) (F) Total Dosed (Test Substance and Vehicle): 5.6 gm  
 Dosage Level: 2 ml/kg As Received: ( ) Diluent: ( ) Time Treated: 1:49 PM Abraded (A): ( ) Intact (I): ( )  
 Concentration: 2 substrate Signature: Roman Frank Date: 1-10-85  
 Animal Source/Species: Hydromysys / New Zealand Time/Date Wrapping Removed: 1:49 PM 1-11-85  
 Date(s) Clipped: 1-10-85 Final Body Wt. (g.): ( ) Date: ( )  
Albino Rabbit Balance # N.Y.: ( ) Study Room #: R-17  
Restraint: Manual

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	1/10	1/11	1/12	1/13	1/14	1/15	1/16	1/17	1/18	1/19	1/20	1/21	1/22	1/23	1/24	1/25
EYEDRO	0	3	3	3												
ECCH	0	1	1	1												
ATONIA	0	0	0	0												
DESQUAMATION	0	0	0	0												
FISSURING	0	0	0	0												
ESCHAR	N	N	N	N												
EXFOLIATION	N	N	N	N												
VORZEL'S INITIALS	RF	RF	RF	RF												

Comments:

TLF/A/JP

ACUTE PERCUTANEOUS TOXICITY

Study #: B85-0005 Sub #: BTD 3200 Yarn #: R1906 Initial Body Wt. (G.): 2941 Balance # N.Y.: 23152  
 Animal #: 1621 Sex: ♂ (M) (F) Total Dosed (Test Substance and Vehicle): 5.9 ml  
 Dose Level: 2 ml/kg as measured ✓ Dilution: \_\_\_\_\_ Time Treated: 1:54 PM Abraded (1): F  
 Concentration: Handwritten Signature: Roman Brand Date: 1-10-85  
 Animal Source/Species: Hagerstrand/White Rabbit Time/Date Wrapping Removed: 1:54 am 1-11-85  
 Date(s) Clipped: 1-10-85 Final Body Wt. (G.): \_\_\_\_\_ Date: \_\_\_\_\_  
 Balance # N.Y.: \_\_\_\_\_ Study Num #: R-12  
 Restrict: None

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	1/10	1/11	1/12	1/13														
EARTHQUAKE	0	3+	3	3														
EDOMA	0	1	1	1														
ATONIA	0	0	0	1														
DESQUAMATION	0	0	0	0														
FISSURING	0	0	0	0														
ESCHAR	N	N	N	N														
EXFOLIATION	N	N	N	N														
WORKER'S INITIALS	RF	RF	RF	RF														

Comments: Minor skin hemolysis area (25%) appears superficial. RF 11/1/85

ACUTE PERCUTANEOUS TOXICITY

Study #: 885-0005 DMD #: BTA 3200 Taisa #: P1906 Initial Body Wt. (g.): 2828 Balance # M.Y.: 23152  
 Animal #: 4659 Sex: K (M) \_\_\_\_\_ (F) \_\_\_\_\_ Total Dosed (Test Substance and Vehicle): 5.7 mg  
 Dose Level: 2 mg/kg As Received: K Dilutions: \_\_\_\_\_ Time Treated: 1:56 PM Abraded (A): \_\_\_\_\_ Intact (I): I  
 Concentration: Handwritten Animal Source/Species: Handwritten Signature: Roman Raul Date: 1-10-85  
 Animal Source/Species: Handwritten Date/Date Wrapping Removed: 1:56 PM 1-10-85 Final Body Wt. (g.): \_\_\_\_\_ Date: \_\_\_\_\_  
 Date(s) Clipped: 1-10-85 Balance # M.Y.: \_\_\_\_\_ Study No: 12-17  
 Treatment: Handwritten

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	1/10	1/11	1/12	1/13																
ERYTHEMA	0	3	3	3																
EDOMA	0	1	1	2																
ATONIA	0	0	0	1																
DESCAMATION	0	0	0	0																
FISSURING	0	0	0	0																
ESCHAR	N	N	N	N																
EXFOLIATION	N	N	N	N																
WORKER'S INITIALS	RF	RF	RS	RS																AF

Comments:

TBLM/JP

ACUTE PERCUTANEOUS TOXICITY

Study #: 285-0005 DSD #: RTA 3200 YSIN #: R1906 Initial Body Wt. (G.): 30.91 Balance # N.Y.: 23152  
 Animal #: 4640 Sex: ✓ (M) (F) Total Dosed (Test Substance and Vehicle): 6-2-85  
 Dose Level: 2 ml/kg As Received: ✓ Dilution: \_\_\_\_\_ Time Treated: 1:58 PM Abraded (A): I  
 Concentration: Maxibrite Signature: Roman Frank Date: 1-10-85  
 Animal Source/Species: Hybrid B6C3F1/Jax Zealand Time/Date Weighing: 1:58 PM 1-11-85  
 Date(s) Clipped: 1-10-85 Final Body Wt. (G.): \_\_\_\_\_ Date: \_\_\_\_\_  
 Balance # N.Y.: \_\_\_\_\_ Study Room #: R-17  
 Restraint: Human

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	10	11	12	13															
ERYTHEMA	0	3	3	-															
EDDMA	0	1	1	-															
ATONIA	0	0	0	-															
DESCAMATION	0	0	0	-															
FISSURING	0	0	0	-															
ESCHAR	N	N	N	-															
EXFOLIATION	N	N	N	-															
WORKER'S INITIALS	RF	RF	RF	RF															

Comments: Found dead 1/13/85 6:30

ACUTE PERCUTANEOUS TOXICITY

Study #: 685-0005 DAD #: BTA 3200 TSIN #: R1906 Initial Body Wt. (G.): 3092 Balance # N.Y.: 23152  
 Animal #: 4614 Sex: (M) 2 (F) Total Dosed (Test Substance and Vehicle): 6.2 ml  
 Dose Level: 2 mg/kg as received Dilution: \_\_\_\_\_ Time Treated: 1:51 PM Abraded (A): Intact (I): I  
 Concentration: 1 mg/ml Signature: [Signature] Date: 1-10-85  
 Initial Source/Species: Harlan Winkelmann / Mus. Zeland Time/Date Wrapping Removed: 1:51 PM 1-11-85  
 Date(s) Clipped: 1-10-85 Final Body Wt. (G.): 2072 Balance # N.Y.: 23152 Date: 1-24-85  
 Restraint: None Study Room #: 12-17

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
EYEDROPS	0	3	3	3	3	*	**	**	**	**	**	**	**	**	**
EDOMA	0	1	1	2	2	2	**	**	**	**	**	**	**	**	**
ATONIA	0	0	1	1	2	2	3	3	3	3	3	**	**	**	**
DESQUAMATION	0	0	0	0	0	0	0	0	0	0	0	**	**	**	**
FISSURING	0	0	0	0	0	0	0	0	0	0	0	**	**	**	**
ESCHAR	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
EXFOLIATION	N	N	N	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y
WORKER'S INITIALS	RF	RF	DS	DS	RF										

Comments: \* Test site skin crusty.  
 \*\* Unable to evaluate due to necrosis.

ACUTE PERCUTANEOUS TOXICITY

Study #: B85-0005 DND #: BTA 3200 TSIN #: R1907 Initial Body Wt. (g.): 3369 Balance # N.Y.: 23152  
 Animal #: 4591 Sex: (M)  (F) Total Dosed (Test Substance and Vehicle): 6.7 ml  
 Dose Level: 200 mg Ag Received: ✓ Dilution: \_\_\_\_\_ Time Treated: 2:00 PM Abraded (A): Intact (I): I  
 Concentration: 100 mg/ml Signature: Kenneth Frank Date: 1-10-85  
 Animal Source/Species: Hesperomorphia / New Zealand Time/Date Wrapping Removed: 2:00 PM 1-11-85  
 Date(s) Clipped: 1-10-85 Final Body Wt. (g.): 3731 Date: 1-24-85  
 Balance # N.Y.: 23152 Study Room #: 8-17  
 Restrictant: Harman

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
DATE															
ERTHRODIA	0	3	3	3	3	3	**	**	**	**	**	**	**	**	**
EDOMA	0	2	2	2	2	2	**	**	**	**	**	**	**	**	**
ATONIA	0	0	1	2	2	2	3	3	3	3	3	**	**	**	**
DESQUAMATIOF	0	0	0	0	0	0	0	0	0	0	0	**	**	**	**
FISSURING	0	0	0	0	0	0	0	0	0	0	0	**	**	**	**
ESCHAR	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
EXFOLIATION	N	N	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y
WORKER'S INITIALS	RF														

Comments: skin site factors appear denuded. RF 1-11-85  
\* \* \* \* \* to evaluate due to unclear

ACUTE PERCUTANEOUS TOXICITY

Study #: B85-0005 DSD #: BTD 320 TS18 #: F1907 Initial Body Wt. (g.): 2995 Balance # M.V.: 23152  
 Animal #: 1631 Sex: K (M) Age Received: ✓ Dilution: \_\_\_\_\_ Total Dosed (Test Substance and Vehicle): 6.0 ml  
 Doseg Level: 2m/kg As Received: \_\_\_\_\_ Abraded (A): Intact (I): \_\_\_\_\_ Time Treated: 2:02 PM Signature: [Signature] Date: 1-10-85  
 Concentration: Undiluted Animal Source/Species: Highway Right of Way, Rabbit Time/Date Wrapping Removed: 2:01 PM 1-11-85 Balance # M.V.: 23153 Date: 1-24-85  
 Date(s) Clipped: 1-10-85; 1-23-85 Balance # M.V.: 23152 Study Room #: 11-17  
 Request: MANUA

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
ERTHRIA	0	3	3	3	3	3	**	**	**	**	**	**	**	**	*
EDCHA	0	2	2	2	2	2	**	**	**	**	**	**	**	**	0
ATONIA	0	0	1	1	2	2	3	3	3	3	3	**	**	**	0
DESQUAMATION	0	0	0	0	0	0	0	0	0	0	0	**	**	**	0
FISSURING	0	0	0	0	0	0	0	0	0	0	0	**	**	**	0
ESCHAR	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	N
EXFOLIATION	N	N	N	N	N	N	N	N	N	N	N	Y	Y	Y	N
WORKER'S INITIALS	RF														

Comments: Test site background appears blurred. RF 1-11-85

\*\* Wash + evaluate skin to solar

\* High shear noticed on portions of test site (~50%). RF 1-23-85

THP/MJP

ACUTE PERCUTANEOUS TOXICITY

Study #: B85-0005 DAD #: ATA 3200 TSIN #: F1901 Initial Body Wt. (g.): 3092 Balance # N.Y.: 23152  
 Animal #: 1642 Sex: ✓ (M) (F) Total Dose (Test Substance and Vehicle): 6.2 ml  
 Dose Level: 2.04 mg/kg by gavage Dilution: \_\_\_\_\_ Time Treated: 2:04 PM Absorbed (A): \_\_\_\_\_ Intact (I): I  
 Concentration: Handwritten Signature: Robert Date: 1-10-85  
 Animal Source/Species: Dayton Rabbit / White Rabbit Time/Date Wrapping Removed: 2:04 PM 1-11-85  
 Date(s) Clipped: 1-10-85 Final Body Wt. (g.): 3265 Date: 1-24-85  
 Balance # N.Y.: 23152 Study Room #: 11-17  
 Restraint: Manual

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
ERTHEMA	0	3	3	3	3	3	**	**	**	**	**	**	**	**	**
EDOMA	0	2	2	2	2	2	**	**	**	**	**	**	**	**	**
ATONIA	0	0	0	0	0	0	3	3	3	3	3	**	**	**	0
DESQUAMATION	0	0	0	0	0	0	0	0	0	0	0	**	**	**	0
FISSURING	0	0	0	0	0	0	0	0	0	0	0	**	**	**	0
ESCHARS	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
EXFOLIATION	N	N	N	N	N	N	N	N	N	N	N	Y	Y	Y	Y
VORWER'S INITIALS	RF														

Comments: skin not evaluated RF 1-11-85  
 \*\* well to evaluate due to ulcer  
 \* Portions of the test site have a high shear and appear denuded. RF 1-24-85

ACUTE PERCUTANEOUS TOXICITY

Study #: B85-0005 DND #: B183740 TSIN #: F1907 Initial Body Wt. (g.): 29.24 Balance # N.Y.: 23152  
 Animal #: 4624 Sex: ✓ (M) (F) Total Doses (Test Substance and Vehicle): 5.8 and  
 Dose Level: 2.06 gm/kg by Received: ✓ Dilution: \_\_\_\_\_ Time Treated: 2:06 PM Abreved (A): Inbreed (I): I  
 Concentration: Handheld Signature: Robert F. Stahl Date: 1-10-85  
 Animal Source/Species: Hypotrachyna rufipes Time/Date Wrapping Removed: 2:06 PM 1-11-85  
 Date(s) Clipped: 1-10-85 Final Body Wt. (g.): 31.77 Balance # N.Y.: 23152 Study Room #: R-17  
 Restraint:  harness

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
ERTHROA	0	3	3	3	3	3	**	**	**	**	**	**	**	**	**
EDOMA	0	2	2	2	2	2	**	**	**	**	**	**	**	**	**
ATROIA	0	0	1	2	2	2	3	3	3	3	3	**	**	**	**
DEQUAMATION	0	0	0	0	0	0	0	0	0	0	0	**	**	**	**
FLUSSING	0	0	0	0	0	0	0	0	0	0	0	**	**	**	**
ESCHAR	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
EXFOLIATION	N	N	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y
WORKER'S INITIALS	RF														

Comments: skin irritation appears double. RF 1-11-85

\*\* Unable to evaluate due to eschar.

\* High shear noticed on portions of test site (60%) having a double appearance. RF 1-29-85

TRUMP/JP

ACUTE PERCUTANEOUS TOXICITY

Study #: B85-0005 DRD #: BTA 3200 TSM #: F1907 Group # 2  
 Animal #: 4603 Sex: (M) (F) Initial Body Wt. (g.): 2956 Balance # N.Y.: 23/52  
 Dose Level: 200/100 by received: ✓ Dilution: \_\_\_\_\_ Total Dosed (Test Substance and Vehicle): 5.9 ml  
 Concentration: Handwritten \_\_\_\_\_ Time Treated: 2:08 PM Abraded (A): \_\_\_\_\_ Intact (I): I  
 Animal Source/Species: Hayden Research Corp. Zeland Signature: Handwritten Date: 1-10-85  
 \_\_\_\_\_ Alice Baker Final Body Wt. (g.): 3267 Date: 1-24-85  
 Date(s) Clipped: 1-10-85 Balance # N.Y.: 23152 Study Room #: 10-17  
Restrict: Human

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
ERYTHEMA	0	3	3	3	3	3	**	**	**	**	**	**	**	**	**
EDCHA	0	2	2	2	2	2	**	**	**	**	**	**	**	**	**
ATONIA	0	0	1	2	2	2	3	3	3	3	3	**	**	**	**
BESQUAMATION	0	0	0	0	0	0	0	0	0	0	0	**	**	**	**
FISSURING	0	0	0	0	0	0	0	0	0	0	0	**	**	**	**
ESCHAR	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
EXFOLIATION	N	N	N	N	N	N	N	N	N	N	N	Y	Y	Y	Y
WORKER'S INITIALS	RF	RF	DS	DS	RF										

Comments: skin test site has been examined and found RF-14-85

\*\* Unable to evaluate due to eschar

ACUTE PERCUTANEOUS TOXICITY

Group # 2

Study #: B85-0005 DND #: BTD 3200 TSIN #: F1907 Initial Body Wt. (g.): 2997 Balance # M.V.: 23152  
 Animal #: 4611 Sex: (M)  (F) Total Dosed (Test Substance and Vehicle): 6 Dose  
 Dose Level: 20000 mg Received: ✓ Dilution: \_\_\_\_\_ Time Treated: 2:11 PM Abreved (A); Intact (I): F  
 Concentration: Handheld Signature: Roman Frank Date: 1-10-85  
 Animal Source/Species: Hysteria Acute / New Zealand Time/Date Wrapping Removed: 2:11 PM 1-11-85  
 Date(s) Clipped: 1-10-85 Final Body Wt. (g.): 2249 Date: 1-20-85  
 Study Room #: R-17 Restraint: Harness

SKIN OBSERVATIONS - Code for evaluating skin reactions to found in protocol:

	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
DATE															
ERYTHEMA	0	3	3	3	3	3	**	**	**	**	**	**	**	**	**
EDGE	0	2	2	2	2	2	*	*	*	*	*	*	*	*	*
ATONIA	0	0	1	1	2	2	3	3	3	3	3	**	**	**	**
DEQUAMATION	0	0	0	0	0	0	0	0	0	0	0	*	*	*	*
FISSURING	0	0	0	0	0	0	0	0	0	0	0	*	*	*	*
ESCHAR	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	N
EXFOLIATION	N	N	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y	N
WORKER'S INITIALS	RF	RF	TS	TS	RF										

Comments: First site shows skin reaction appears double. RF 1-11-85

\* \* Unable to evaluate due to eschar

\* High adverse noticed on entire site having a denuded appearance. RF 1-23-85

ACUTE PERCUTANEOUS TOXICITY

Study #: BKS-0005 Inventory # 2  
 Animal #: 4787 Initial Body Wt. (g.): 2105 Balance of M.V.: 16303  
 Dose Level: 300/16 Total Dosed (Test Substance and Vehicle): 54 ml  
 Concentration: und. / uc Time Treated: 1:15 P.M. Abraded (A): I Intact (I): I  
 Animal Source/Species: Hazleton Research Signature: [Signature] Date: 2/15/85  
 Date(s) Clipped: 2/15/85 Time/Date Wrapping Removed: 1:15 P.M. 2/18/85 Date: 2/18/85  
Balance of M.V.: 16303 Study Room #: C-17

SKIN OBSERVATIONS - Code for evaluating skin reactions to found in protocol

DATE	2/6	2/7	2/8	2/9	2/10	2/11	2/12	2/13	2/14	2/15	2/16	2/18	2/19
EARTHQUAKE	2	3	3	3	3	X <sup>2</sup>							
EDOMA	1	2	2	2	2	X <sup>2</sup>							
ATONIA	0	0	2	2	2	X <sup>2</sup>							
DESCAMATION	0	0	0	0	0	X <sup>2</sup>							
FISSURING	0	0	1	1	1	2	2	2	2	2	2	2	2
ESCHAR	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y
EXFOLIATION	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y
WORKER'S INITIALS	JA	JA	JA	GR	GR	JA	JA	RE	JA	JA	AB	RE	JA

Comments: \* Abdominal area appeared wet upon removal of wrapping  
 \* Eschar of test site prevented evaluating  
 \* 3 Hind legs and abdominal area stripped of hair  
 \* 4 Hind legs and abdominal area stripped of hair  
 \* 5 Eschar involves ~ 50% of the test site

TLP/JP

Group # 3

ACUTE PERCUTANEOUS TOXICITY

Study # B85-0057 DAD # BTS-3240 TRIN # 1706 Initial Body Wt. (g.) 2842 Balance # N.Y. # 16303  
 Animal # 4788 Sex N (M) (F) Total Doses (Test Substance and Vehicle) 5.7 ml  
 Dose Level 2.0 ml/kg As Received N Dilution \_\_\_\_\_ Time Treated 1:17 PM Abridged (A): Intake (I): \_\_\_\_\_ Doses 2/5/85  
 Concentration und/lc Signature J. Kasper Date 2/5/85  
 Animal Source/Species Hazleton Research Time/Date Wrapping Removed 1:17 PM 2/6/85 Date 2/10/85  
 Date(s) Clipped 2/5/85, 2/6/85 Balance # N.Y. # 16303 Study Room # 5-27  
 Treatment: collar

SKIN OBSERVATIONS - Code for evaluating skin reactions to found in protocol

DATE	*2/6	2/7	2/8	2/9	2/10	2/11	2/12	2/13	2/14	2/15	2/16	2/17	2/18	2/19	2/20
ERYTHEMA	2	3	3	3	3	*	*	*	*	*	*	*	*	*	*
EDDMA	1	2	3	3	2	*	*	*	*	*	*	*	*	*	*
ATONIA	0	0	1	1	1	*	*	*	*	*	*	*	*	*	*
DESQUAMATION	0	0	0	0	0	*	*	*	*	*	*	*	*	*	*
FISSURING	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1
ESCHAR	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
EXFOLIATION	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
WOUNDED INITIALS	JA	JA	JA	GR	GR	JA	JA	RF	JA	JA	RF	RF	RF	RF	RF

Comments: \* Abdominal area appeared wet upon removal of wrapping  
 \* 2 Eschar of test site prevented evaluating  
 \* 3 Abdominal area stripped of hair, some scratch and/or bite marks  
 \* 4 Abdominal area stripped of hair  
 \* 5 Eschar similar to 80% of test site



ACUTE PERCUTANEOUS TOXICITY

Study # B85-005 MD # BIS-320 TRIN # 21006 Initial Body Wt. (g.) 2805 Balance # M.V. # 16303  
 Animal # 4829 Sex (M) X (F) Total Dosed (Test Substance and Vehicle) 5.6ml  
 Dose Level 2.0ml/kg as received Y Dilution 1 Time Treated 1:33 PM Abraded (A) Intact (I) I  
 Concentration undiluted Signature J. H. [unclear] Date 2/15/85  
 Animal Source/Species Hazleton Research Time/Date Wrapping Removed 1:32 PM 2/16/85 Date 2/16/85  
Animal / New Zealand Albino Rabbits Final Body Wt. (g.) 2737 Date 2/16/85  
 Date(s) Clipped 2/5/85 2/16/85 Balance # M.V. # 16303 Study Room # 5-37  
 Recipient: collar

SKIN OBSERVATIONS - Code for evaluating skin reactions to found in protocol

DATE	#	2/6	2/7	2/8	2/15	2/16	2/17	2/18	2/19	2/20
ERYTHEMA	2	3	3	3	3	3	3	3	3	3
EDOMA	0	2	2	2	2	2	2	2	2	2
ATONIA	0	0	0	0	0	0	0	0	0	0
RESQUAMATION	0	0	0	0	0	0	0	0	0	0
FISSURING	0	0	0	0	0	0	0	0	0	0
ESCHAR	N	N	N	N	N	N	N	N	N	N
EXFOLIATION	N	N	N	N	N	N	N	N	N	N
WORKER'S INITIALS	JH	JH	JH	JH	JH	JH	JH	JH	JH	JH

Comments: \* Abdominal area appeared wet upon removal of wrapping

\* 2 Hemorrhagic Area 5x3.5cm, Appears Superficial

\* 3 Eschar of test site prevented evaluating

\* 4 Areas of thickened skin can be felt in abdominal area, also abdominal area stripped of hair

\* 5 Eschar covering ~ 20-40% of test site

ACUTE PERCUTANEOUS TOXICITY

Study #1 BRE-0005 DSD #1 BIS-3200 TRIN #1 01906 Initial Body Wt. (g): 2535 Balance / N.Y. # 16303  
 Animal #1 4815 Sex (M) Y (F) Total Dosed (Test Substance and Vehicle): 5/1/1  
 Dose Level 2.071/g As Received Y Dilution: \_\_\_\_\_ Time Treated: 1:26 PM Absorbed (A): Insect (I): \_\_\_\_\_  
 Concentration: Hand/alc Signature: [Signature] Date: 3/5/85  
 Animal Source/Species: Hazleton Research Time/Date Wrapping Removed: 1:35 PM Date: 3/5/85  
 Date(s) Clipped: 2/5/85 2/5/85 Final Body Wt. (g): 2676 Balance / N.Y. # 16303 Study Room #1 6-27  
 Res. Animal: collar

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10	#11	#12	#13	#14	#15	#16	#17	#18	#19	#20
ERTINDA																				
EDOMA																				
ATONIA																				
DESQUAMATION																				
FISSURING																				
ESCHAR																				
EXFOLIATION																				
WORKER'S INITIALS																				

Comments: \* Abdominal area appeared wet upon removal of wrapping  
 \*<sup>2</sup> Eschar of test site prevented evaluating  
 \*<sup>3</sup> Most of abdominal area stripped of hair, some scabs noted  
 \*<sup>4</sup> Abdominal area stripped of hair  
 \*<sup>5</sup> Eschar number ~ 908 photo site

ACUTE PERCUTANEOUS TOXICITY

Study # BBS-0055 DMD # BTS-2420 TSH # 01906 Initial Body Wt. (g.): 2365 Balance # N.V.: 16303  
 Animal # 4818 Sex (M) (F) Total Dosed (Test Substance and Vehicle): 47  
 Dose Level: 20ml/kg As Received: X Dilution: \_\_\_\_\_ Time Treated: 1:25 PM Absorbed (A): Intact (I): I  
 Concentration: Undilute Signature: S. Koyan Date: 2/5/85  
 Animal Source/Species: Hazleton Research Time/Date Wrapping Removed: 1:28 PM 2/5/85 JH  
Bureau / New Zealand Albino Rats Final Body Wt. (g.): 2613 Date: 2/10/85  
 Date(s) Clipped: 2/5/85, 2/14/85 Balance # N.V.: 16303 Study Room #: 5-27  
 Treatment: collar

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	*3	2/6	2/7	2/8	2/9	2/10	2/11	2/12	2/13	2/14	2/15	2/16	2/17	2/18	2/19	2/20
ERYTHEMA		1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
EDDMA		0	2	2	2	2	2	2	2	2	2	2	2	2	2	2
ATONIA		0	0	1	1	1	2	2	2	2	2	2	2	2	2	2
DESCAMATION		0	0	0	0	0	2	2	2	2	2	2	2	2	2	2
FISSURING		0	0	0	0	0	1	1	1	1	1	1	1	1	1	0
ESCHAR		N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
EXFOLIATION		N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y
WOOLER'S INITIALS		JH	JH	JH	JH	JH	JH	JH	JH	JH	JH	JH	JH	JH	JH	JH

Comments:  
 \* Abdominal area appeared wet upon removal of wrappings  
 \* 2 Eschar of test site prevented evaluating  
 \* 3 Hair stripped from abdominal area raw area N/44 cm. Some scabs

ACUTE PERCUTANEOUS TOXICITY

Study #: BKS-0055 DSD #: BTS-3200 Y318 #: P17A Initial Body Wt. (g.): 2810 Balance # M.V.1: 16303  
 Animal #: 4789 Sex: M (M) (F) Total Doses (Test Substance and Vehicle): 5 G.M.I.  
 Dose Level: 2.0 ml/kg As Received: Y Dilutions: \_\_\_\_\_  
 Concentration: Undiluted Signature: [Signature] Date: 2/18/85  
 Animal Source/Species: Hannover Research Time/Date Wrapping Removed: 1:32 PM 2/18/85  
Bristol/Nov Zealand Albino Rabbits Final Body Wt. (g.): 3066 Date: 2/18/85  
 Date(s) Clipped: 2/5/85, 2/18/85 Balance # M.V.1: 16303 Study Room #: 5-211  
 Assistant: Collin

Group # 4

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	2/6	2/7	2/8	2/9	2/10	2/11	2/12	2/13	2/14	2/15	2/16	2/17	2/18	2/19
EATHCHA	0	2	3	3	2	*	*	*	*	*	2	2	2	2
EDCHA	0	1	2	2	2	*	*	*	*	1	1	1	0	0
ATONIA	0	0	1	1	1	*	*	*	*	0	0	0	0	0
DESCAMATION	0	0	0	0	0	*	*	*	*	2	2	2	2	1
FISSURING	0	0	0	0	0	1	1	1	1	0	0	0	0	0
ESCHAR	N	N	N	N	N	Y	Y	Y	Y	N	N	N	N	N
EXFOLIATION	N	N	N	N	N	N	N	N	N	N	N	N	N	N
WORKER'S INITIALS	JA	JA	JA	GL	GL	JA	JA	RE	JA	JA	JA	RE	RE	JA

Comments: \* Eschar of feet site prevented evaluating

TULP/JP

ACUTE PERCUTANEOUS TOXICITY

Study # BKS-2005 Army # 4  
 Animal # 4804 Initial Body Wt. (g.) 2767 Balance # N.Y. 16303  
 Dose Level 20ml/kg Total Dose (Test Substance and Vehicle) 5.5 ml  
 Concentration 1.35 PA Time Treated 1:35 PM Absorbed (A) Intest (I) I  
 Animal Source/Species Hazleton Research Signature [Signature] Date 2/4/85  
 Date(s) Clipped 2/5/85 Time/Date Wrapping Removed 1:34 PM Date 2/6/85  
Final Body Wt. (g.) 3164 Balance # N.Y. 16303 Study Room # 5-27

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	2/6	2/7	2/8	2/9	2/10	2/11	2/12	2/13	2/14	2/15	2/16	2/17	2/18
ERTINDA	1	2	3	3	*	*	*	*	*	*	*	*	*
EDOMA	0	2	2	2	*	*	*	*	*	*	*	*	*
ATONIA	0	0	1	1	*	*	*	*	*	*	*	*	*
DESCAMATION	0	0	0	0	*	*	*	*	*	*	*	*	*
FISSURING	0	0	1	1	1	1	1	1	1	1	1	1	1
ESCHAR	N	N	N	N	N	X	Y	Y	Y	Y	N	N	N
EXFOLIATION	N	N	N	N	N	Y	Y	Y	Y	Y	N	N	N
WORKER'S INITIALS	JA	JA	JA	GR	JA	JA	JA	RF	JA	JA	RF	RF	JA

Comments \* Eschar of test site prevented evaluating

ACUTE PERCUTANEOUS TOXICITY

Study # B85-0005 DAD # BTS-3200 T818 # P1Y72 Initial Body Wt. (g.): 2887 Balance # M.V.1 16302  
 Animal # 4876 Sex (M) X (F) Total Doses (Test Substance and Vehicle): 5.7 ml  
 Dose Level: 2 ml/kg As Received: X Dilutions: I  
 Concentration: Lead, 1% Signature: J. R. [unclear] Date: 2/5/85  
 Animal Source/Species: Harlem Research Time/Date Wrapping Removed: 1:36 P.M. 2/4/85 Date: 2/18/85  
B2-01 / New Zealand Albino Rabbits Final Body Wt. (g.): 2290 Date: 2/18/85  
 Date(s) Clipped: 2/5/85, 2/15/85 Balance # M.V.1: 16302 Study Bone #1: 6-0-27  
 Assistant: Collin

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	2/6	2/7	2/8	2/9	2/10	2/11	2/12	2/13	2/14	2/15	2/16	2/17	2/18	2/19
EATHONA	1	2	3	3	3	*	*	X	*	*	3	3	2	2
ED04	0	2	2	2	2	*	*	*	*	*	1	1	1	1
ATONIA	0	0	1	1	1	*	*	*	*	*	0	0	0	0
DESQUAMATION	0	0	0	0	0	*	*	*	*	*	3	3	0	2
IRRITATION	0	0	1	1	1	2	2	2	2	2	2	1	0	0
ESCHAR	N	N	N	N	N	X	Y	Y	Y	Y	Y	Y	Y	N
EXFOLIATION	N	N	N	N	N	N	N	N	Y	Y	Y	Y	Y	N
WORKER'S INITIALS	JA	JA	JA	GR	GR	JA	JA	RF	JA	JA	RF	RF	RF	JA

Comments: \* Eschar of Test Site prevented evaluating  
 \* 2 Areas of thickened skin can be felt in abdominal area  
 \* 3 Eschar ~ 50% of test site.

ACUTE PERCUTANEOUS TOXICITY

Study #1 B85-0055      Date #1 ATS-2200      Test #1 P1472      Initial Body Wt. (g): 2664      Balance / N.Y.: 16303  
 Initial #1 4513      Sex (M)  (F)      Dose Level 2.07/100      Anesthetic Y      Dilutions:      Total Dose (Test Substance and Vehicle): 5.3 ml  
 Concentration: Lead Tell.      Animal Source/Species: Hawkeston Research      Signature: J. K. ...      Date: 2/5/85  
 Date(s) Clipped: 2/5/85, 2/18/85      Date(s) Clipped: 2/18/85, 2/19/85, 2/21/85      Final Body Wt. (g): 2953      Time/Date Wrapping Removed: 1:40 PM 2/18/85      Abraded (A):      Intact (I):      Balance / N.Y.: 16303      Final Body Wt. (g): 2953      Date: 2/19/85  
 Assistant: Collin      Study Room #1: 5-27

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	2/6	2/7	2/8	2/9	2/10	2/11	2/12	2/13	2/14	2/15	2/16	2/17	2/18	2/19
ERYTHEMA	1	2	3	3	3	*	*	*	*	*	*	*	*	*
EDDMA	0	1	2	2	2	*	*	*	*	*	*	*	*	*
ATONIA	0	0	1	1	1	*	*	*	*	*	*	*	*	*
DESQUAMATION	0	0	0	0	0	*	*	*	*	*	*	*	*	*
FISSURING	0	0	0	1	1	2	2	2	1	1	1	1	1	1
ESCHAR	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
EXFOLIATION	N	N	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y
WORKER'S INITIALS	JA	JA	JA	GR	GR	JA								
Comments:														

\* Eschar of test site prevented evaluating

TELEP/JP

ACUTE PERCUTANEOUS TOXICITY

Study #1 B85-0005    QIP #1 BIS-3200    TSIR #1 P1473    Initial Body Wt. (g.): 2442    Balance # M.V.: 16303    Group # 4  
 Animal #1 4811    Sex: (M)    Y (F)    Total Dosed (Test Substance and Vehicle): 4.9 ml  
 Dose Level: 2.0 ml/kg    As Received: Y    Dilution: \_\_\_\_\_    Time Treated: 1:44 PM    Abraded (A):    Intact (I): \_\_\_\_\_  
 Concentration: 1 mg/ml    Animal Source/Species: Hawkeiata Research    Signature: \_\_\_\_\_    Date: \_\_\_\_\_  
 Date(s) Clipped: 2/15/85    Animal / New Zealand Albino Rabbits    Time/Date Wrapping Removed: \_\_\_\_\_    Date: \_\_\_\_\_  
 Final Body Wt. (g.): \_\_\_\_\_    Final Body Wt. (g.): 2106    Time/Date: 1:43 P.M. 2/16/85    Date: 2/16/85  
 Balance # M.V.: \_\_\_\_\_    Balance # M.V.: 16303    Study Room #1: \_\_\_\_\_    Date: 2/16/85  
 Restrainer: collar    Study Room #1: \_\_\_\_\_    Date: \_\_\_\_\_

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	2/6	2/7	2/8	2/9	2/10	2/11	2/12	2/13	2/14	2/15	2/16	2/17	2/18	2/19
EMPHASIS	2	2	3	3	2	*	*	*	*	*	*	*	*	*
EDOMA	0	1	2	2	2	*	*	*	*	*	*	*	*	*
ATONIA	0	0	1	1	1	*	*	*	*	*	*	*	*	*
DESCUMATION	0	0	0	0	0	*	*	*	*	*	*	*	*	*
FISSURING	0	0	0	0	0	*	*	*	*	*	*	*	*	*
ESCHAR	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
EPIDERMOLATION	N	N	N	N	N	N	N	N	N	N	N	N	N	N
WORKER'S INITIALS	JH	JH	JH	GTL	GTL	JH	JH	RF	JH	JH	JH	RF	JH	JH

Comments: \* Eschar of test site prevented evaluating

ACUTE PERCUTANEOUS TOXICITY

Study # B85-005 DMD # BIS-3200 TRIN # P1472 Initial Body Wt. (g.) 2477 Balance # N.Y. # 16303  
 Animal # 4793 Sex M (M) (F) Total Doses (Test Substance and Vehicle) 5  
 Dose Level 2.0 ml/kg As Received Y Dilution: \_\_\_\_\_ Time Treated: 1:29 PM Abraded (A): Intact (I) I  
 Concentration \_\_\_\_\_ Signature: J. K. [unclear] Date: 2/5/85  
 Animal Source/Species: Hawke's Research Time/Date Wrapping Removed: 1:30 PM 2/6/85  
Barnes / New Zealand Albino Bebbles Final Body Wt. (g.): 2516 Date: 2/10/85  
 Date(s) Clipped: 2/5/85, 2/5/85 Balance # N.Y. # 16303 Study Room # 5-27  
 Assistant: Collin

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	
ERYTHEMA	0	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
EDOMA	0	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
ATONIA	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
DESCAMATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FISSURING	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ESCHAR	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EXFOLIATION	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
MOLEK'S INITIALS	JA	JA	JA	GR	GR	GR	JA														

Comments: \* Eschar of test site prevented evaluating  
 \* 2 Areas of thickened skin can be felt in abdominal area  
 \* 3 Eschar on 50% feet site.

ACUTE PEROXIDIC TOXICITY

Study # BRE-005 Group # 5  
 Animal # 4526 DAD # BIS-200 TSH # P1928 Initial Body Wt. (g.): 2781 Balance # M.V.: 16303  
 Dose Level: 2.0 ml/kg Sex: (M) (F) Total Dose (Test Substance and Vehicle): 4.5 ml  
 Concentration: undiluted Dilution: \_\_\_\_\_  
 Animal Source/Species: Hazleton Research Time Treated: 2:03 PM Abraded (A): Intact (I): I  
 Date(s) Clipped: 2/18/85 Signature: J. Kuyper Date: 2/18/85  
 Final Body Wt. (g.): 2676 Time/Date Wrapping Removed: 2:03 PM 2/18/85 Date: 2/18/85  
 Balance # M.V.: 16303 Study Room # 6-112  
 Registrar: Collier

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	2/6	2/7	2/8	2/9	2/10	2/11	2/12	2/13	2/14	2/15	2/16	2/17	2/18	2/19
ERYTHEMA	2	3	3	3	3	3	3	3	3	3	3	3	3	3
EDOMA	1	2	2	2	2	2	2	2	2	2	2	2	2	2
ATONIA	0	0	1	1	1	1	1	1	1	1	1	1	1	1
DESCAMATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FISSURING	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ESCHAR	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EXFOLIATION	N	N	N	N	N	N	N	N	N	N	N	N	N	N
WORKER'S INITIALS	SA	SA	SA	SA	SA	SA	SA	SA	SA	SA	SA	SA	SA	SA

Comments: \* Hemorrhagic areas .5 cm dia. or smaller on test site  
 \* Eschar of test site prevented evaluating

TJL/JP

ACUTE PERCUTANEOUS TOXICITY

Study # BES-0003 Spring 05  
 Animal # 5232 Initial Body Wt. (g.) 3590 Balance # N.Y. # 16303  
 Dose Level: 3.0 ml/kg Total Dose (Test Substance and Vehicle) 5.3 ml  
 Concentration: 100 mg/ml Time Treated: 1:45 PM Abraded (A): Intact (I): I  
 Animal Source/Species: Harlequin Research Signature: [Signature] Date: 2/15/85  
 Date(s) Collected: 2/15/85 Time/Data Wrapping Removed: 1:45 PM Date: 2/15/85  
Balance # N.Y. # 16303 Study Room # C-12  
Resident: Coller

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	2/6	2/7	2/8	2/9	2/10	2/11	2/12	2/13	2/14	2/15	2/16	2/17	2/18	2/19
ERYTHEMA	3	3	3	3	2	2	2	2	2	2	2	2	2	2
EDOMA	1	2	2	2	2	2	2	2	2	1	1	1	0	0
ATONIA	0	1	2	2	2	2	2	2	2	0	0	0	0	0
DESCUMATION	0	0	0	0	0	2	2	2	2	2	2	2	1	1
FISSURING	0	0	0	1	1	1	1	1	1	1	1	0	0	0
ESCHAR	N	N	N	N	N	Y	Y	Y	Y	N	N	N	N	N
EXFOLIATION	N	N	N	N	N	Y	Y	Y	Y	N	N	N	N	N
WORKER'S INITIALS	JA	JA	JA	GR	GR	JA	JA	RF	JA	JA	JA	RF	RF	JA

Comments \* Numerous, superficial, hemorrhagic areas 5cm dia. or smaller  
 \* Eschar of test site prevented evaluating

ACUTE PERCUTANEOUS TOXICITY

Study #1 BBE-0005 Group A 5  
 Animal #1 4800 16303  
 Dose Levels 2 mg/kg 1:49 PC  
 Concentration (Indicate)  
 Animal Source/Species Harvested Research  
 Date(s) Clipped: 2/15/85  
 Initial Body Wt. (g.): 2618 Balance of N.Y.: 16303  
 Total Dosed (Test Substance and Vehicle): 5-2-85  
 Time Treated: 1:49 PC Absorbed (g): Intest (g): 1  
 Signature: [Signature] Date: 2/15/85  
 Time/Date Weighing Resorbed: 1:48 PC Date: 2/15/85  
 Final Body Wt. (g.): 2737 Balance of N.Y.: 16303 Study Room #: 5-12  
 Re: Retreat. Coller

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	2/6	2/7	2/8	2/9	2/10	2/11	2/12	2/13	2/14	2/15	2/16	2/17	2/18	2/19
ERYTHEMA	2	2	1	2	2	2	2	2	2	2	2	2	2	2
ECCHY	0	1	2	1	1	1	1	0	0	0	0	0	0	0
ATONIA	0	0	1	1	1	1	1	1	0	0	0	0	0	0
DECOLORATION	0	0	0	0	0	2	2	2	2	2	2	2	2	2
FISSURING	0	0	0	1	1	1	1	1	1	1	1	1	1	1
ESCHAR	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EXFOLIATION	N	N	N	N	N	N	N	N	N	N	N	N	N	N
WORKER'S INITIALS	JA	JA	JA	GR	JA	JA	JA	RF	JA	JA	RF	RF	RF	JA

Comments:

TOL/P/JP

ACUTE PERCUTANEOUS TOXICITY

Study # B85-0055 5 QID # BIS-3200 YSIB # 21928 Initial Body Wt. (g.) 2355 Balance # N.Y. 16303  
 Animal # 4810 Sex Y (M) (F) Total Dosed (Test Substance and Vehicle) 48  
 Dose Level 200mg/kg As Received: Y Dilution: \_\_\_\_\_ Time Treated: 1:54 PM Abraded (A) Intact (I) I  
 Concentration (undiluted) Signature: [Signature] Date: 2/5/85  
 Animal Source/Species Hawkeian Rhesus Time/Data Wrapping Removed: 0 1:54 PM 2/6/85 -A  
 Animal # New Zealand Albino Rabbits Final Body Wt. (g.) 2690 Balance # N.Y. 16303 Date: 2/19/85 -H  
 Date(s) Clipped: 2/5/85, 2/15/85 Balance # N.Y. 16303 Study Room # 5-17  
 Reagent: Coller

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	2/6	2/7	2/8	2/9	2/10	2/11	2/12	2/13	2/14	2/15	2/16	2/17	2/18	2/19
ERYTHEM	2	2	2	2	*	*	*	*	*	*	*	*	*	*
EDOMA	0	1	2	2	1	*	*	*	*	*	*	*	*	*
ATONIA	0	0	0	0	1	*	*	*	*	*	*	*	*	*
DESCALMATION	0	0	0	0	0	*	*	*	*	*	*	*	*	*
FISSURING	0	0	0	0	1	1	1	1	1	1	1	1	1	1
ESCHAR	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
EXFOLIATION	N	N	N	N	N	N	N	N	N	N	N	N	N	N
WORKER'S INITIALS	SA JA SA													

Comments: \* Escalation of test site prevented evaluations

TJL/PM/JP



ACUTE PERCUTANEOUS TOXICITY

Study #1 BES-0055 DMD #1 BIS-7200 TSIR #1 P 1928 Initial Body Wt. (g.): 2801 Balance # N.Y.1 16303  
 Animal #1 4872 Sex (M) Y (F) Total Dosed (Test Substance and Vehicle): 5.6 ml  
 Dose Level: 2.0 ml/kg As Received: Y Dilution: \_\_\_\_\_ Time Treated: 1:59 PM Abraded (A): Intraot (I): \_\_\_\_\_  
 Concentration: (undiluted) Signature: [Signature] Date: 2/1/85  
 Animal Source/Species: Hazleton Research Time/Date Wrapping Removed: 1:59 P.M. Date: 2/1/85 FH  
 Date(s) Clipped: 2/5/85, 2/6/85 Final Body Wt. (g.): 3139 Balance # N.Y.1 16303 Study Room #1 5-12  
 Reagent: Control

SKIN OBSERVATIONS - Code for evaluating skin reactions to found in protocol

DATE	2/6	2/7	2/8	2/9	2/10	2/11	2/12	2/13	2/14	2/15	2/16	2/17	2/18	2/19
EARTHQUAKE	1	2	2	2	2	*	*	*	*	*	2	2	1	1
EDOMA	0	1	2	2	2	*	*	*	*	*	0	0	0	0
ATONIA	0	0	0	0	1	*	*	*	*	*	0	0	0	0
DESQUAMATION	0	0	0	0	0	*	*	*	*	*	2	2	1	1
FISSURING	0	0	0	0	1	1	1	1	1	1	1	0	0	0
ESCHAR	N	N	N	N	N	Y	Y	Y	Y	Y	N	N	N	N
EXFOLIATION	N	N	N	N	N	N	N	N	N	N	N	N	N	N
WORKER'S INITIALS	JA	JA	JA	GR	GR	JA								

Comments: \* Eschar of test site prevented evaluating

ACUTE PERCUTANEOUS TOXICITY

Study # 66  
 Study # BBS-2005 DOP # BIS-200 Test # P1907 Initial Body Wt. (g): 2355 Balance # N.Y.: 16203  
 Animal # Y803 Sex Y (M) Y (F) Y Total Dosed (Test Substance and Vehicle): 47 ml  
 Dose Levels 2.0 ml/kg In Vehicle Y Dilution Y Time Treated: 2:15 P.M. Abraded (A): Intact (I): I  
 Concentration 1.0 mg/ml in 5% V/V Vehicle P1907 Signature: J. A. Hopper Date: 2/15/85  
 Animal Source/Species Hazleton Research Time/Date Weighing 2:15 P.M. Balance # N.Y.: 16203 Study Room #1: 5-32  
Animal # Y803 2/15/85 Final Body Wt. (g): 2577 Balance # N.Y.: 16203 Study Room #1: 5-32  
 Date(s) Clipped: 2/15/85 Restraint: Color

SKIN OBSERVATIONS - Code for evaluating skin reactions as found in protocol

DATE	2/6	2/7	2/8	2/9	2/10	2/11	2/12	2/13	2/14	2/15	2/16	2/17	2/18	2/19
ERYTHEMA	2	2	3	2	2	*	*	*	*	*	*	*	*	*
EDDMA	0	2	2	2	2	*	*	*	*	*	*	*	*	*
ATONIA	0	0	0	0	1	*	*	*	*	*	*	*	*	*
DESQUAMATION	0	0	0	0	0	*	*	*	*	*	*	*	*	*
FISSURING	0	0	1	1	1	1	1	1	1	1	1	1	1	1
ESCHAR	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
EVOLUTION	N	N	N	N	N	N	N	N	N	N	N	N	N	N
WORKER'S INITIALS	JA	JA	JA	GR	GR	JA	JA	BE	JA	JA	JA	BE	BE	JA

Comments: \* Eschar of test site prevented evaluating  
 \* Eschar 50% of test site

ACUTE PERCUTANEOUS TOXICITY

Study #1: BBS-0005    MD #1: BIS-3200    Date: 2/19/07    Group # 6  
 Animal #1: 5821    Sex: M    Age: 11W    Dilution: X  
 Dose Level: 20ml/kg    As Received: 20ml/kg  
 Concentration: 1.14mg/ml    In Vehicle: 20ml/kg  
 Animal Source/Species: Harvard Bioscience Research  
 Date(s) Clipped: 2/15/07    2/15/07  
 Initial Body Wt. (g.): 2719    Balance # M.V.: 16303  
 Total Dose (Test Substance and Vehicle): 5.4 ml  
 Time Treated: 2:19 PM    Absorbed (ml) Intake (l): 2  
 Signature: J. K. [unclear]    Date: 2/15/07  
 Time/Date Wrapping Removed: 2:19 PM    Date: 2/15/07  
 Final Body Wt. (g.): 3093    Balance # M.V.: 16303    Date: 2/19/07  
 Respiration: 2.0/0.7    Study Room #1: 6-230

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	2/6	2/7	2/8	2/9	2/10	2/11	2/12	2/13	2/14	2/15	2/16	2/17	2/18	2/19
EARTHQUAKE	2	3	3	2	2	2	2	2	2	2	2	2	2	2
EDOMA	1	2	2	2	1	1	1	1	0	0	0	0	0	0
ATONIA	0	0	0	1	1	1	1	1	1	1	1	1	1	1
DEQUAMATION	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FISSURING	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ESCHAR	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EXFOLIATION	N	N	N	N	N	N	N	N	N	N	N	N	N	N
WORKER'S INITIALS	JH	JH	JH	GC	JH	JH	SE	JH						
Comments														

TALPE/JP

ACUTE PERCUTANEOUS TOXICITY

Study #1 B85-0015 MD #1 BIS-3200 Test #1 P1907  
 Animal #1 4805 Sex Y (M) (F)  
 Dose Level 20ml/5g As Received Dilutions Y  
 Concentration 1.4ml/5g To 5.5Volumex P1907  
 Animal Source/Species Hawke's Research  
 Date(s) Clipped 2/18/85, 2/19/85  
 Initial Body Wt. (g.) 2464 Balance # M.V.1 (6303)  
 Total Dose (Test Substance and Vehicle) 4.9 ml  
 Time Treated 2:22 PM Abraded (A) Y Intact (I) Y  
 Signature J. K. Simpson Date 2/18/85  
 Time/Date Wrapping Removed 2:22 PM Date 2/18/85  
 Final Body Wt. (g.) 3250 Balance # M.V.1 (6303)  
 Residual 4.0/4.0 Study Room #1 S-22

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	2/6	2/7	2/8	2/9	2/10	2/11	2/12	2/13	2/14	2/15	2/16	2/17	2/18	2/19
IRTHDIA	1	2	3	2	2	*	*	*	*	*	*	*	*	*
INDO3	0	2	3	2	2	*	*	*	*	*	*	*	*	*
INDO4	0	0	1	1	1	*	*	*	*	*	*	*	*	*
INDO5	0	0	0	0	0	*	*	*	*	*	*	*	*	*
INDO6	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
INDO7	N	N	N	N	N	N	N	N	N	N	N	N	N	N
INDO8	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

\* Eschar of test site prevented evaluating

ACUTE PERCUTANEOUS TOXICITY

Study # B85-0057 MD # BIS-200 YRS # P 1907 Initial Body Wt. (g.): 2964 Balance # M.V. # 16303  
 Animal # 4827 Sex (M) (F) As Received Dilutions Y Total Dosed (Foot Substance and Vehicle): 5.9 ml  
 Dose Level 3.0 ml/kg Concentration 1.0 mg/ml PLASMA PHASIS P 1948 Time Treated: 2 ACPA Abraded (A): Intact (I) Date: I  
 Animal Source/Species: HARLEIN RESEARCH Signature: J. King Date: 2/15/85  
Barnes / New Zealand Albino Rabbits Time/Date Wrapping Removed: 2:26 P.M. Date: 2/15/85  
 Date(s) Clipped: 2/15/85 Balance # M.V. # 16303 Study Room # 5-32  
 Restraint: collar

SKIN OBSERVATIONS - Code for evaluating skin reactions to found in protocol

DATE	2/6	2/7	2/8	2/9	2/10	2/11	2/12	2/13	2/14	2/15	2/16	2/17	2/18	2/19
ERYTHEMA	2	3	3	3	2	2	2	2	2	2	2	2	2	2
EDOMA	1	2	3	2	2	1	1	1	1	1	1	1	1	0
ATONIA	0	0	1	1	1	1	1	1	1	0	0	0	0	0
DESQUAMATION	0	0	0	0	0	0	1	1	2	2	2	2	2	2
FISSURING	0	0	0	1	1	2	2	2	1	1	1	1	1	1
ESCHAR	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EXFOLIATION	N	N	N	N	N	N	N	N	N	N	N	N	N	N
VEHICLE'S INITIALS	JA	JA	JA	GR	GR	JA	JA	RE	JA	JA	RE	RE	RE	JA

Comments:

TULPA/JP

ACUTE PERCUTANEOUS TOXICITY

Study # BBS-2005 DOD # BIS-2220 Y818 # P1907 Initial Body Wt. (g.) 25.77 Balance # N.Y. # 16303  
 Animal # 4825 Sex (M) (F) No. 2 (N) (F) Total Dosed (Test Substances and Vehicles) 52 21  
 Dose Level 2.0 ml/kg as described Dilution X Time Treated 2.29 PM Absorbed (a) Intact (b) I  
 Concentration 1.0 mg/ml in 5.5 volumes P1907 Signature J. H. [unclear] Date 2/5/85  
 Initial Source/Species Hazleton Research Time/Date Weighing Removed 2.28 PM 2/6/85 Date 2/6/85  
Bureau of New Zealand Rabbit Final Body Wt. (g.) 27.13 Date 2/6/85  
 Date(s) Clipped 2/5/85 2/6/85 Balance # N.Y. # 16303 Study Item # 5-22  
 Restraint: collar

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	2/6	2/7	2/8	2/9	2/10	2/11	2/12	2/13	2/14	2/15	2/16	2/17	2/18	2/19
EARTHQUAKE	2	2	3	3	2	2	2	2	2	2	2	2	1	1
EDOMA	0	2	2	2	2	1	1	0	0	0	0	0	0	0
ATONIA	0	0	0	1	1	1	1	0	0	0	0	0	0	0
DESQUAMATION	0	0	0	0	0	0	1	2	2	2	2	2	2	2
FISSURING	0	0	0	0	1	1	1	1	1	1	1	1	1	1
ESCHAR	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EXFOLIATION	N	N	N	N	N	N	N	N	N	N	N	N	N	N
WORKER'S INITIALS	JH	JH	JH	GR	GR	JH	JH	KE	JH	JH	RF	RF	RF	SA

Comments:

TCLP/JP

ACUTE PERCUTANEOUS TOXICITY

Group # 6

Study # BRS-0002 QAD # BIS-700 YTD # P1907 Initial Body Wt. (g.) 2674 Balance # N.Y. # 16303  
 Animal # 5828 Sex (M) X Dilution X Total Dose (Test Substance and Vehicle) 54 ml  
 Dose Level 2.0 ml/kg As Received: X Time Treated 2:32 PM Absorbed (All Intest (3)) X  
 Concentration 1.0 ml/kg 2.0 ml/kg 4.0 ml/kg 8.0 ml/kg 16.0 ml/kg 32.0 ml/kg 64.0 ml/kg 128.0 ml/kg  
 Animal Source/Species Hazleton Research Signature J. K. Cooper Date 2/5/85  
Humel / New Zealand Albino Rabbits Time/Date Weighing Removed 2:32 PM 2/6/85  
 Date(s) Clipped 2/5/85 Final Body Wt. (g.) 2913 Date 2/15/85  
 Balance # N.Y. # 16303 Study Room # 5-22  
 Assistant: Cooper

SKIN OBSERVATIONS - Code for evaluating skin reactions to found in protocol

DATE	7/2	7/3	7/4	7/5	7/6	7/7	7/8	7/9	7/10	7/11	7/12	7/13	7/14	7/15	7/16	7/17	7/18	7/19	7/20
ERYTHEMA	2	3	3	2	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
EDDMA	0	2	2	2	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
ATONIA	0	0	0	1	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
DESCAMATION	0	0	0	0	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
FISSURING	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
ESCHAR	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EXFOLIATION	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
WORKER'S INITIALS	JA	JA	JA	GR	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA

Comments: \* Eschar of test site prevented evaluating

TBL/PA/JP

HEALTH OBSERVATIONS  
(Excluding Skin)

Study # 1885-0005  
TSIN # 18906

Pathology # \_\_\_\_\_  
Pre-Study Health Records: YE 575  
Weekend Health Checks: \_\_\_\_\_  
Group # 1

Date	11/10/85		11/11/85		11/12/85		11/13/85		11/14/85		11/15/85		11/16/85		11/17/85		11/18/85		11/19/85		11/20/85		11/21/85		11/22/85		11/23/85		
	AM	PM																											
Animal	3:45	3:40	7:45	7:40	7:45	7:40	7:45	7:40	7:45	7:40	7:45	7:40	7:45	7:40	7:45	7:40	7:45	7:40	7:45	7:40	7:45	7:40	7:45	7:40	7:45	7:40	7:45	7:40	7:45
4599 E	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4606 F	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4619 F	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4621 M	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4639 M	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4640 M	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Initials	RE	RE	RE																										

N = no abnormalities present  
A = abnormalities noted, see detailed observation below

\* Time recorded is the time the first animal was observed

NX NOT eating but appears normal  
A0X NOT eating & seem somewhat depressed  
A01 seems somewhat disoriented  
2 Mobilund  
4640 found dead 7:40 AM 11/13  
4606, 4621, 4639 found dead 11/14/85

#4599 found dead at 9:05 AM 11/15/85

HEALTH OBSERVATIONS  
(Excluding Skin)

Study # 1885-0005  
TRIM # 1907

Pathology # \_\_\_\_\_  
Pre-Study Health Records: YE 575  
Weekend Health Checks: \_\_\_\_\_  
Group # 2

Date	11/10/85		11/11/85		11/13/85		11/14/85		11/15/85		11/16/85		11/17/85		11/18/85		11/19/85		11/21/85		11/22/85		11/23/85	
	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Time	10:00	3:45	7:47	3:40	8:25	10:30	8:25	10:30	8:15	2:00	8:15	2:00	8:15	2:00	8:05	2:00	8:00	11:00	7:30	11:00	9:00	2:30	8:10	8:00
Animal #																								
4591 F	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4627 M	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4642 M	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4624 M	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4603 F	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4611 F	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Initials	RF	RF	RF	RF	RF	RF	RF	RF	RF	RF	RF	RF	RF	RF	RF	RF	RF	RF	RF	RF	RF	RF	RF	RF

N = no abnormalities present  
A = abnormalities noted, make detailed observation below

\* \* Time recorded is the time the first animal was observed

HEALTH OBSERVATIONS  
(EXCLUDING SKIN)

Study #: B85-0005  
TRIN #: P1826

Pathology #: B85-0005  
Pre-Study Health Records: YE 787  
Weekend Health Checks: -  
Group #: 3

Date	2/5/85		2/6/85		2/7/85		2/8/85		2/9/85		2/10/85		2/11/85		2/12/85		2/13/85		2/14/85		2/15/85		2/16/85		2/17/85		2/18/85	
	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM								
4787	N	N	N	N	A1	A1	A1	A1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4788	N	N	N	N	A1	A1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4806	N	N	N	N	A1	A1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4839	N	N	N	N	A1	A1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4815	N	N	N	N	A1	A1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4818	N	N	N	N	A1	A1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Initials	EA	EA	EA	EA	EA	EA	EA	EA	EA	EA	EA	EA	EA	EA	EA	EA	EA	EA	EA	EA								

N = no abnormalities present  
A = abnormalities noted, make detailed observation below

\* = Time recorded to the time the first animal was observed

A1 Anoxemia  
A2 Lethargic  
A3 Labored Breathing

HEALTH OBSERVATIONS  
(Excluding skin)

Study #: B85-0005  
TSIN #: P1472

Pathology #: B85-12323  
Pre-Study Health Record: YE 287  
Weekend Health Checks: Group 4

Date	2/5/85		2/6/85		2/7/85		2/8/85		2/9/85		2/10/85		2/11/85		2/12/85		2/13/85		2/14/85		2/15/85		2/16/85		2/17/85		2/18/85			
	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM										
Time *	4:00	8:10	8:55	1:55	8:15	3:55	4:40	9:40	1:00	8:10	4:00	8:10	3:00	8:10	3:00	8:10	3:00	8:10	3:00	8:10	3:00	8:10	3:00	8:10	3:00	8:10	3:00	8:10	3:00	8:10
Animal #																														
4773	N	N	A'	A'	A'	A'	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
4779	N	N	A'	A'	A'	A'	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	
4804	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4816	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4813	N	N	A'	A'	A'	A'	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4811	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Installs	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA								

N = no abnormalities present  
A = abnormalities noted, make detailed observation below

\* = Time recorded to the time the first animal was observed

A' Anorexia



HEALTH OBSERVATIONS  
(EXCLUSION SKIN)

Study #: BBS-0005  
 Pathology #: BBS-4433  
 Pre-Study Health Records: YE 287  
 Weekend Health Checks: Group #6

Study #: BBS-0005  
 TRIN #: P1587 & P1928

Date	2/5/85	2/6/85	2/7/85	2/8/85	2/9/85	2/10/85	2/11/85	2/12/85	2/13/85	2/14/85	2/15/85	2/16/85	2/17/85	2/18/85	2/19/85	2/20/85
Time	8:00	8:10	8:55	8:15	8:00	8:10	8:10	8:00	8:30	8:10	8:30	8:30	8:30	8:30	8:30	8:30
Animal #																
4802	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4801	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4805	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4827	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4825	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4828	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Intake	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA	JA

N = no abnormalities present  
 A = abnormalities noted, make detailed observation below  
 \* = Time recorded to the time the first animal was observed

A1 Anorexia

HERO \_\_\_\_\_

ANIMAL HEALTH EVALUATION REPORT  
MORIBUND OR DEAD ANIMALS

RCV-0936

88-0005

Date: 1-14-85 Study Director: G F Timon Animal No. #: 117

Division: ink doc soap

Species: collie Supplier: Hagleton Animal # 4599 Sex: F

Body Weight: - Time: 10:15 AM Moribund: \_\_\_\_\_ Dead:

Disposition of Carcass: Placed in Formalin \_\_\_\_\_; Placed in bag in cooler

Symptoms Observed: muscle tremor, moribund, died  
1-14-85

Study Directors/Technician Signature Roman Frank Date 1-14-85

NECROPSY REPORT

Method of Euthanasia: NA

Exsanguination: Yes \_\_\_\_\_ No  Lung Perfusion: Yes \_\_\_\_\_ No

Gross Necropsy Comments: ① Ear tag 4599 female ② Dorsal area treatment  
skin severe erythema. Mild fatty liver. Little or no fluid in stomach.  
pulmonary congestion.

See Other Side

Histopath Specimens According to Protocol: Yes \_\_\_\_\_ No \_\_\_\_\_ Other \_\_\_\_\_

- |          |          |          |          |
|----------|----------|----------|----------|
| 1. _____ | 3. _____ | 5. _____ | 7. _____ |
| 2. _____ | 4. _____ | 6. _____ | 8. _____ |

Additional Specimens

Diagnostic Tests

- |          |       |
|----------|-------|
| 1. _____ | _____ |
| 2. _____ | _____ |
| 3. _____ | _____ |

Gross Necropsy Diagnosis: Cause of death could not be determined  
based on gross examination

Veterinarian W. Hoj Date: 1-14-85 Recorder: Bill Wyde Date 1-14-85  
Revised 7/23/84

HER# \_\_\_\_\_

ANIMAL HEALTH EVALUATION REPORT  
MORIBUND OR DEAD ANIMALS

PP 84-0936

B# 85-2105

Date: 1-10-85 Study Director: Y. S. T. [unclear] Animal No. #: 4621

Division: Package Soap

Species: Rabbit Supplier: Faylor Animal # 4621 Sex: M

Body Weight: \_\_\_\_\_ Time: 6:15 am Moribund: \_\_\_\_\_ Dead: ✓

Disposition of Carcass: Placed in Formalin \_\_\_\_\_; Placed in bag in cooler ✓

Symptoms Observed: Diarrhea, found dead 1-14-85

Study Directors/Technician Signature Roman & Paul Date 1-14-85

NECROPSY REPORT

Method of Euthanasia: NA

Exsanguination: Yes \_\_\_\_\_ No ✓ Lung Perfusion: Yes \_\_\_\_\_ No ✓

Gross Necropsy Comments: ① Exc tag 4621 male ② Dorsal area treatment skin - severe erythema ③ Mild fatty liver ④ Little or no food in stomach

See Other Side

Histopath Specimens According to Protocol: Yes \_\_\_\_\_ No \_\_\_\_\_ Other \_\_\_\_\_

1. \_\_\_\_\_ 3. \_\_\_\_\_ 5. \_\_\_\_\_ 7. \_\_\_\_\_

2. \_\_\_\_\_ 4. \_\_\_\_\_ 6. \_\_\_\_\_ 8. \_\_\_\_\_

Additional Specimens

Diagnostic Tests

1. \_\_\_\_\_

2. \_\_\_\_\_

3. \_\_\_\_\_

Gross Necropsy Diagnosis: Cause of death could not be determined based on gross examination

Veterinarian [Signature] Date 1-14-85 Recorder: Bill Wyder Date 1-14-85  
Revised 7/23/84

HER# \_\_\_\_\_

ANIMAL HEALTH EVALUATION REPORT  
MORIBUND OR DEAD ANIMALS

RI 84-0936

84-5-2015

Date: 1/14/85 Study Director: JH Wilson Animal No. #: 217

Division: Package Soap

Species: Lab Rat Supplier: Hazleton Animal # 4634 Sex: M

Body Weight: \_\_\_\_\_ Time: 7:15 PM Moribund: \_\_\_\_\_ Dead:

Disposition of Carcass: Placed in Formalin \_\_\_\_\_; Placed in bag in cooler

Symptoms Observed: Animal seen in package 1-14-85

Study Directors/Technician Signature JH Wilson Date 1-14-85

NECROPSY REPORT

Method of Euthanasia: NA

Exsanguination: Yes \_\_\_\_\_ No  Lung Perfusion: Yes \_\_\_\_\_ No

Gross Necropsy Comments: 1. Ear tag 4639 male 2. No oral pre treatment skin - severe erythema 3. Consolidation of rt middle lung lobe 4. Little or no fat in stomach fatty liver 5. Pulmonary congestion

See Other Side

Histopath Specimens According to Protocol: Yes \_\_\_\_\_ No \_\_\_\_\_ Other \_\_\_\_\_

1. \_\_\_\_\_ 3. \_\_\_\_\_ 5. \_\_\_\_\_ 7. \_\_\_\_\_

2. \_\_\_\_\_ 4. \_\_\_\_\_ 6. \_\_\_\_\_ 8. \_\_\_\_\_

Additional Specimens

Diagnostic Tests

1. \_\_\_\_\_

2. \_\_\_\_\_

3. \_\_\_\_\_

Gross Necropsy Diagnosis: Pneumonia / pulmonary congestion

Veterinarian [Signature]  
Revised 7/23/84

Date: 1-14-85

Recorder: [Signature]

Date 1-14-85

HER# \_\_\_\_\_

ANIMAL HEALTH EVALUATION REPORT  
MORIBUND OR DEAD ANIMALS

Re 84-0936

B055-0005

Date: 1-14-85 Study Director: JF Wilson Animal No. 0: 217

Division: Package Soap

Species: Rabbit Supplier: Houghton Animal # 4606 Sex: F

Body Weight: \_\_\_\_\_ Time: 16:15 hr Moribund: \_\_\_\_\_ Dead:

Disposition of Carcass: Placed in Formalin \_\_\_\_\_; Placed in bag in cooler

Symptoms Observed: Anorexia, Tilted head, somewhat depressed  
found dead 1-14-85

Study Directors/Technician Signature Kenneth Paul Date 1-14-85

NECROPSY REPORT

Method of Euthanasia: NA

Exsanguination: Yes \_\_\_\_\_ No  Lung Perfusion: Yes \_\_\_\_\_ No

Gross Necropsy Comments: Cartag #406 female. 2 Decent treatment seen  
skin - severe erythema 3 Moderate post-mortem change  
little rum food in stomach - fatty liver

See Other Side

Histopath Specimens According to Protocol: Yes \_\_\_\_\_ No \_\_\_\_\_ Other \_\_\_\_\_

- |          |          |          |          |
|----------|----------|----------|----------|
| 1. _____ | 3. _____ | 5. _____ | 7. _____ |
| 2. _____ | 4. _____ | 6. _____ | 8. _____ |

Additional Specimens

Diagnostic Tests

- |          |       |
|----------|-------|
| 1. _____ | _____ |
| 2. _____ | _____ |
| 3. _____ | _____ |

Gross Necropsy Diagnosis: Cause of death could not be determined  
based on Gross examination.

Veterinarian W. J. Taylor Date 1-14-85 Recorder: Bell Wyder Date 1-14-85  
Revised 7/23/84

HERP \_\_\_\_\_

ANIMAL HEALTH EVALUATION REPORT  
MORBUND OR DEAD ANIMALS

R# 84-0436

B# 85-0005

Date: 1-14-85 Study Director: S. J. Haxson Animal Rm. #: 117

Division: Package Dept

Species: pig Supplier: Vaylter Animal # 4640 Sex: M

Body Weight: \_\_\_\_\_ Time: 0:50 Moribund: \_\_\_\_\_ Dead:

Disposition of Carcass: Placed in Formalin \_\_\_\_\_; Placed in bag in cooler L

Symptoms Observed: anorexia, round feces 1-13-85

Study Directors/Technician Signature S. J. Haxson Date 1-14-85

NECROPSY REPORT

Method of Euthanasia: NA

Exsanguination: Yes \_\_\_\_\_ No  Lung Perfusion: Yes \_\_\_\_\_ No

Gross Necropsy Comments: ① Ear tag 4640 male. ② No al area treatment skin - severe erythema. ③ No food in stomach. ④ Slightly fatty liver

See Other Side

Histopath Specimens According to Protocol: Yes \_\_\_\_\_ No \_\_\_\_\_ Other \_\_\_\_\_

1. \_\_\_\_\_ 3. \_\_\_\_\_ 5. \_\_\_\_\_ 7. \_\_\_\_\_

2. \_\_\_\_\_ 4. \_\_\_\_\_ 6. \_\_\_\_\_ 8. \_\_\_\_\_

Additional Specimens

Diagnostic Tests

1. \_\_\_\_\_

2. \_\_\_\_\_

3. \_\_\_\_\_

Gross Necropsy Diagnosis: Cause of death could not be determined based only on gross examination.

Veterinarian W. J. Long Date: 1-14-85 Recorder: Bill Wyden Date: 1-14-85  
Revised 7/23/84

THE PROCTER & GAMBLE COMPANY

PROTOCOL NO. C10

Acute Percutaneous Toxicity

Issue Date: May 1, 1984  
Supersedes Issue Dated: June 15, 1983

Test Substance Identification Number (TSIN) # P1906 and P1907

Divisional Request Document Number (DRD) # BTS-3200

Sponsor: The Procter & Gamble Company  
Cincinnati, Ohio

Testing Facility:  
(To be filled in by  
Operations Section) The Procter & Gamble Company  
Miami Valley Laboratories - BTF  
Cincinnati, OH 45247

Study # B85-0005  
(To be filled in by  
Testing Facility)

*Study Notebook # YE737J*

Purpose: To determine the skin irritancy of a test substance  
and its potential gross systemic and lethal effects when  
applied to the skin.

Justification for  
Selection of Test  
System:

Historically, the New Zealand albino rabbit has been  
the animal of choice due to the large amount of back-  
ground information on this species.

Route of Administration  
of Test Substance and  
Reason for Choice:

Place on clipped area of skin under occlusive  
dressing. Historical. Based on Draize  
procedure.

Diet and/or Water  
Analyses Required:

None (no known contaminants expected which would  
interfere with this study)

Records to be  
Maintained:

All records that would be required to reconstruct the  
study and demonstrate adherence to protocol.

Protocol - Page 1 of 6



Acute Percutaneous Toxicity

Issue Date: May 1, 1984

Site Preparation:

Clip an area on the back of each animal from shoulder to rump, approximately 15 cm wide, with a small animal clipper. The skin of all animals is left intact.

Dose Preparation:

Test Group(s) (Check appropriate boxes)

- Dose undiluted as follows:  2 ml/kg, [ ] 2 g/kg
- [ ] Dose as a freshly prepared \_\_\_\_\_ % (w/w) solution/suspension as follows: [ ] 2 ml/kg, [ ] 2 g/kg  
Vehicle: \_\_\_\_\_
- [ ] Dose as a freshly prepared \_\_\_\_\_ % (w/v) solution/suspension as follows: [ ] 2 ml/kg, [ ] 2 g/kg  
Vehicle: \_\_\_\_\_
- [ ] Dose per Special Instructions (See page 2)

Control Group

A control group should be [ ]; should not be  included in this study. If included, the control substance should be tested concurrently with the test substance at a dosage level of \_\_\_\_\_.

Note

A concentration analysis of the test substance - vehicle mixture(s) will [ ]; will not  be required.

If a concentration analysis is required:

- [ ] Prepare a sufficient quantity of the test substance - vehicle mixture(s) so that a portion can be returned to the Sponsor's Divisional Toxicologist. Store solution/mixture at [ ] room temperature; [ ] refrigerator; [ ] freezer; [ ] other \_\_\_\_\_

Shipping Instructions

Send approximately \_\_\_\_\_ ml. Send [ ] frozen; [ ] under ambient conditions; [ ] other \_\_\_\_\_

- [ ] Analyze the test substance - vehicle mixture(s) for test substance concentration using the analytical method in Appendix \_\_\_\_\_.

Acute Percutaneous Toxicity

Issue Date: May 1, 1984

Dosing Instructions:

Spread the test substance over the clipped area. Cover with a layer of 8-ply gauze, rubber dam and several wrappings of 3-inch Elastoplast tape or equivalent wrapping material. Restrain the animal to prevent it from removing the wrappings. Dry or powdered substances are placed directly onto the gauze. The gauze containing the dry test material is placed upon a layer of rubber dam and wrapping tape. Place the animal on his back over the test substance and secure the wrapping tape around the trunk. Repeat this procedure for the remaining animals.

[ ] See Options on page 4

Observations:

After 24 hours, remove the animal from restrainers, uncover the test sites, remove the test substance with wet disposable gauze, paper towel, or equivalent. Observe daily for next 14 days for signs of skin irritation using the attached scale (Appendix 1). Observe twice daily for mortality following the Test Facility's Standard Operating Procedures. There should be at least 4 hours between observations, or the maximum possible elapsed time on weekends of holidays. On the 14th day, count, weigh, and sacrifice the surviving animals.

Necropsy:

Necropsy animals that died or were sacrificed during study and examine grossly for any abnormalities. Perform the necropsy following the Test Facility's Standard Operating Procedures. Record all gross necropsy findings.

[X] See Options on page 5

Protocol Changes:

If it becomes necessary to change the approved protocol, verbal agreement to make this change should be made between the Study Director and the Sponsor. As soon as practical, this change and the reasons for it should be put in writing and signed by both the Study Director and the Sponsor's Divisional Toxicologist. This document is then attached to the protocol as an addendum.

Options:

[ ] Abrade the skin of \_\_\_\_\_ males and \_\_\_\_\_ females to make a total of \_\_\_\_\_ animals/group (including abraded and intact skin). Abrade according to the Test Facility's Standard Operating Procedure so as to penetrate the horny layer of the epidermis without causing bleeding.

Acute Percutaneous Toxicity

Issue Date: May 1, 1984

Options (Cont'd):

(X) Perform a gross necropsy on all animals surviving at the conclusion of the 14-day observation period according to the Test Facility's Standard Operating Procedures. Record all gross necropsy findings.

Report:

Report should include how study was conducted, dates of study initiation and termination, and the individual animal observations including deaths, if any, degree of skin irritation as a function of time, body weights, signs of gross systemic effects and necropsy observations. If no deaths are observed at the 2 ml/kg or 2 gm/kg dose level, the LD50 value is reported as greater than 2 ml (liquids) or 2 gm (solids or semi-solids) per kg of body weight. If deaths were observed at the 2 ml/kg or 2 gm/kg dose level, additional dose levels may be requested to produce a sufficient number of deaths to calculate an LD50 value. If additional dose levels are not requested, the LD50 value will not be reported. This report shall conform to all requirements outlined in Section 58.185, Subpart J, Good Laboratory Practices Regulations.

Sponsor: Kenneth W. Miller  
Divisional Toxicologist

Date Approved by Sponsor's Divisional Toxicologist 12/17/84

Proposed Starting Date 1-10-85

Defined as Treatment Date

Proposed Completion Date: 1-24-85

Defined as Gross Necropsy Date )To be completed )by the Test )Facility

Study Director: D.A. Nejm

Date: 1/7/85

Study Cost: \$1600

5/1/84

THE PROCTER & GAMBLE COMPANY

PROTOCOL - APPENDIX 1

SCALE FOR EVALUATING SKIN REACTIONS

**Erythema**

- 0 - None
- 1 - Slight (barely perceptible)
- 2 - Moderate (well defined)
- 3 - Severe (beet red)

**Edema**

- 0 - None
- 1 - Slight (barely perceptible to well defined by definite raising)
- 2 - Moderate (raised approximately 1 mm)
- 3 - Severe (raised more than 1 mm)

**Atonia (not including eschar area)**

- 0 - Normal
- 1 - Slight (impairment of elasticity)
- 2 - Moderate (slow return to normal)
- 3 - Marked (no elasticity)

**Desquamation (not including eschar area)**

- 0 - None
- 1 - Slight (slight scaling)
- 2 - Moderate (scabs and flakes)
- 3 - Marked (pronounced flaking with denuded areas)

**Fissuring**

- 0 - None
- 1 - Slight (definite cracks in epidermis)
- 2 - Moderate (cracks in dermis)
- 3 - Marked (cracks with bleeding)

**Eschar**

- N - No
- Y - Yes

**Exfoliation (sloughing of the eschar tissue)**

- N - No
- Y - Yes

Amendments to Protocol No. C10  
Study #BR5-0005, DRD #BTS-3200

Amendment #1

Animals: Each test group will consist of six (6) New Zealand albino rabbits (3 males and 3 females) weighing 2.0-3.5 kg. There will be four (4) test groups.

Amendment #2

Test Substances: There will be four (4) test substances. Hazards for P1472 and P192<sup>R</sup> are the same as for P1906.

<u>TSIN #</u>	<u>Color</u>	<u>Physical Form</u>	<u>Expiration Date</u>
P1905	yellow	liquid	indefinite
P1472	blue	liquid	1/1/86
P192 <sup>R</sup>	yellow	liquid	indefinite
P1907	white, opaque	liquid with suspended solids	3/1/85

Amendment #3

Special Instructions: Dose test substances P1906, P1472 and P1928 undiluted at 2 ml/kg.

Add one (1) volume of test substance P1907 to 5.5 volumes of test substance P192<sup>R</sup> and mix for 2 minutes. Dose the fourth test group with this mixture at 2 ml/kg.

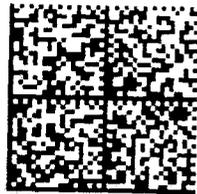
Sponsor: K.W. Miller  
K. W. Miller  
Divisional Toxicologist

Date: 2/1/85

KWM11R:kkk  
1/31/85

B.A. Anjani

2/4/85



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