ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ- 92 -10083	89110000200	3/22/11

COMMENTS: COMMUN S (DECLASS)

DOES NOT CONTAIN CBI

334113

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

8EHQ-0311-10083B
DCN: 89110000200

RECEIVED
11 MAR 22 AM 6:03

Re: Declassification Activity-Health and Safety Filing 8EHQ-0892-10083 (EPA DCN 88920008384)

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Any CBI substantiation which appears in the original submission is no longer applicable as the information which was originally claimed CBI is disclosed in this revised submission.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

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

8 9 1 1 0 0 0 0 2 0 0

Attachment 1

Public Display Version

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
Magnesium sulfate	
Sodium sulfate	
Water	

COMPANY SANITIZED

Procter&Gamble

8EHQ-0892-10083s

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

92 AUG 31 PM 1:19

Public Display Copy

August 20, 1992

8EHQ-92-10083s INIT

88920008384

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

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 material identified in the attached report as P1947 is a confidential mixture. The composition of the mixture is appended as Attachment 1. The report is titled "Acute Oral Corrosivity Study Final Report". Any correspondence relating to this submission should reference study # 1294-30879.

The attached study report indicates intragastric administration of 5.0 ml/kg of the test material resulted in pharmacotoxic signs including restless behavior and a temporary balance deficit, and an extremely slow to delayed onset of emesis. The acute LD_{50} was not determined in this study.

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.

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

Procter&Gamble

Attachment I

Public Display Copy

Derivitized organic acid

Magnesium sulfate

Sodium sulfate

Alkyl benzene sulfonic acid

Organic acid

Water

1294-30879

DR. K. S. GRADY, Pres.

GRADY INVESTMENT CORPORATION

9211 WINTON ROAD CINCINNATI, OHIO 45231 PHONE (513) 921-8678

ORIGINAL COPY

ACUTE ORAL CORROSIVITY STUDY FINAL REPORT

Date 4-5-85

Sponsor: The Procter & Gamble Company, Cincinnati, Ohio

Test Request: STUDY # H85006C
TSIN # P1947
DRD # BTS-3231
DATE 3-4-85

Test Substance: # P1947 Physical Form Liquid with suspended solids
Color White, Opaque Expiration Date 5-1-85

Refer to Sponsor for further stability and characterization data.

Control Substance: (Distilled water when called for in Protocol)

Study Dates: Initiation 3-21-85 Completion 4-4-85

Quality Assurance: Last Inspection 2-14-85 Reported On 3-5-85

Objective and procedures as stated in Grady Investments, Inc.

Protocol Number 3, Acute Oral Corrosivity Study dated March 1, 1985

Protocol Changes None

Methods and descriptions are contained in protocol above and Grady Investments, Inc. Standard Operating Procedures.

Special Comments None

Reviewed and Accepted by PS&DD/P&RS

K. W. Miller Date 4/15/85
Principal Investigator

Storage Locations:

Test Substances are returned to the Procter & Gamble Company unless otherwise indicated.

The Final Report and all raw data are sent to the Procter & Gamble Company.

A copy of the Final Report is retained at Grady Investments, Inc.

Personnel Involved (GII): D. R. Nelson, D.V.M. Study Director
Technician
J. Behr Secretary

The Study Director performs the actual dosing and supervises the observations and recording performed by the technician and the Study Director.

1/16/85

Test System:

4 Purebred Beagle Dogs (2 M 2 F), approximately 23-30 months old, weighing between 7.5 and 9.5 kilograms obtained from HRA LR N.E.Ph and identified by: tattoo, collar tag, and cage number.

All dogs were fasted approximately 16 hours and deprived of water approximately 3 hours prior to dosing.

Dosing was performed by gavage using the test material P1947 (5.0 ml/kg) one dose per dog according to protocol over a period of 3 minutes 15 seconds.

All observations and other data are recorded on A.O.C. Appendix II.

SUMMARY

Test Substance Dose	Dog #	Wt.(kg)	Sex	Onset of Emesis	Total Number of Emeses	Remarks
P1947	8467	7.50	M	00:10-21	3	Shaking head, inspiratory stridor, restless behavior, slinging of test substance.
P1947 (5 ml/kg)	8494	9.50	F	00:41-42	5	Temporary balance deficit, restless behavior, urination.
Spare	8437	9.25	M	-	-	
Spare	8338	-	F	-	-	Had a seizure and was declared unfit for use in this study.

Discussion and Analysis:

Beagle dogs, 1 male and 1 female, were dosed by gavage with test substance P1947 at a dose rate of 5.0 ml/kg. Dog #8467 had an extremely slow onset of emesis (10 minutes, 21 seconds) and a small number of emetic responses (3 emeses). Dog #8494 had a delayed onset of emesis (41 minutes, 42 seconds) and a small number of emetic responses (5 emeses). The fecal material and the dogs were within the limits of normal for the remainder of the study.

On Day 1, gastroscopic findings of both dogs were marginally abnormal. Dog #8467 had a few scattered petechial hemorrhages in the greater curvature of the fundus. Dog #8494 had a generalized increase in hyperemia in the following areas: the greater curvature of the fundus, the lesser curvature of the fundus, the pyloric antrum, and the pyloric canal. The dog also had a large volume of white foam and mucus obstructing the view of a large portion of the fundic mucosa.

Discussion and Analysis: (Continued)

On Day 7 and 8, one dog had normal gastroscopic findings and one dog had marginally abnormal gastroscopic findings. Dog #8467 was not properly fasted for gastroscopic examination on Day 7, and endoscopy was repeated on Day 8 to find that the dog was normal. Dog #8494 had a few scattered petechial hemorrhages in the proximal portion of the greater curvature of the fundus.

On Day 14, Dog #8494 had normal gastroscopic findings.

Conclusions:

Test substance P1947 as dosed was a mild emetic substance. Mild gastric lesions resolved in 7-14 days.

Attachments:

Test Request (1)
Protocol (1)
Protocol Deviation (1)
Animal Selection Sheet (1)
AOC App. II Page 1 (1)
AOC App. II Page 2 (1)
Gastroscopic Examination Report (10)
Raw Data Sheets (13)

D. R. Nelson, D.V.M. 4-5-85

D. R. NELSON, D.V.M. DATE

Retention Limit: Non-discretionary

REQUEST FOR ACUTE ORAL CORROSIVITY STUDY

Sponsor: The Procter & Gamble Company
Cincinnati, OH

Study # H85006C

TSIN # P1947

Testing Facility: Grady Investments, Inc.
9211 Winton Road
Cincinnati, OH 45231

DRD # BTS-3231

Date 3/4/85

This is to authorize you to carry out an Acute Oral Corrosivity Study according to Grady Investments, Inc. Protocol #3, Issue Date March 1, 1985. This letter should be considered a part of the protocol for this study and included in the final report.

Notice: This study probably - ☐ will be submitted to the following regulatory agency(ies) _____;
☒ will not be submitted to any agency.

Test substance(s):	Number	Description: Physical Form	Description: Color
	P1947	liquid w/suspended solids	white, opaque

Sample expiration date: 5/1/85 (stability testing will be done by the Sponsor)

Storage Conditions: ☒ Room Temperature (60-80°F.) ☐ Other:

Hazards: ☒ None Known: Take ordinary precautions in handling.
☐ As Follows:

Special Instructions: ☒ None ☐ As Follows:

Dose Preparation: (check appropriate box)

☒ Dose Undiluted

☐ Dose as a _____% (☐ w/v; ☐ w/w) solution/suspension prepared fresh daily. Vehicle _____.
☐ Solution/suspension is stable for day's dosing.
☐ If dosing of solution/suspension is not completed within ___ hours of preparation, prepare a new solution/suspension.

☐ Dose per special instructions (above).

Dose Administration:

☐ By mouth: _____ ml. or gm.

☒ Intragastric: (Complete only one space.)

Liquid substance: 5.0 ml of test solution/kg of body weight.

Solid or Granular substance: (Prepare solution/suspension as described in Dose Prep.)
_____ cc test substance/kg of body weight. [Density of test substance is: _____ gm/cc.] (if known)
_____ gm test substance/kg of body weight.

Study Requested by: K. W. Miller K.W. Miller
(Sponsor's Divisional Toxicologist)

Sponsor's Liaison: G. H. Kay Date: 3/4/85

Proposed Starting Date: 3-21-85
Proposed Completion Date: 4-18-85
Date Final Report Available: 4-26-85
(to be completed by the Test Facility Management)

Study Director: D. T. Nelson Date: 3-15-85 Received on 3-18-85

Revised 03/01/85

GRADY INVESTMENTS, INC. PROTOCOL NO. 3

ACUTE ORAL CORROSIVITY STUDY

Issue Date: March 1, 1985
Supercedes Issue Dated: July 26, 1984

Sponsor:	The Procter & Gamble Company Cincinnati, OH
Testing Facility:	Grady Investments, Inc. 9211 Winton Road Cincinnati, OH 45231
Purpose:	To determine the oral toxicity and the corrosive properties of a test substance on the oral cavity, esophagus and stomach in dogs.
Notice:	The stipulations of this protocol are to be implemented in conformance with Good Laboratory Practice Regulations (21 CFR, Part 58) for non-clinical laboratory studies.
Justification for Selection of Test System:	Dogs are chosen because they are an emetic species and their emetic response is similar to humans; dogs are the ideal size for endoscopy; any gross lesions at necropsy can be demonstrated and photographed; and the range of the weights of the dogs compare to weights of small children.
Route of Administration of Test Substance:	The test substance is given by gavage or *per os*.
Reason for Choice:	The test substance is administered orally to simulate accidental human exposure.
Diet Analysis Required:	None (no known contaminants expected which would interfere with this study).
Water Analysis 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.

GRADY INVESTMENTS, INC. PROTOCOL NO. 3 (cont.)

ACUTE ORAL CORROSIVITY STUDY

Issue Date: March 1, 1985

Animals: Beagle dogs, two (2) per test group.

Animal Selection: One male and one female pure-bred beagle dog, approximately eight months to five years of age, will be selected from the acute colony as test animals for each material tested. In addition, one male and one female dog will be selected to serve as replacements for the test animals in cases of illness of the test dogs on the day of dosing and in cases of misdosing or inappropriate dosing. Each animal will be selected for this study according to the following criteria:

a. The animal has not been dosed on any study or has been scoped and observed normal for at least two weeks previously.
b. The animal appears and behaves normally.
c. The animal is not a chronic vomiter either spontaneously or during routine water dosing (performed approximately every two months using 20 ml distilled H_2O per dog). [Note: Purpose of this procedure is to determine whether mechanical stimulus induces emesis.]
d. The pretest (1) blood urea nitrogen (BUN) and (2) serum glutamic-pyruvic transferase (SGPT) or alanine amino-transferase (ALT) analyses for that dog are within the normal limits.
e. The animal has not been previously used for more than 12 dosings.
f. Animals are judged to be normal in pre-test endoscopic examination conducted 2 to 3 days prior to dosing.

Animal Care and Diet: Follow the approved Standard Operating Procedures of the Test Facility.

Environmental Conditions: Follow the approved Standard Operating Procedures of the Test Facility.

Animal Identification: Follow the approved Standard Operating Procedures of the Test Facility.

GRADY INVESTMENTS, INC. PROTOCOL NO. 3 (cont.)

ACUTE ORAL CORROSIVITY STUDY

Issue Date: March 1, 1985

Dose Preparation: The calculations involved in the preparation of any solution and to determine dose will be recorded permanently on the dose calculation sheet. This is included in the final report as Appendix I. For all calculations, the weight of dog is the fasted body weight.

A. Dry Granular Material

1. Preparation of Dose Per Os.

A 5.0 cc volume of test material will be packed tightly into a cut-off syringe. The test material will then be dosed to the dog.

2. Determination of Dose Per Gavage (Administered as a Slurry)

To prepare a slurry of test material, the test material is analytically weighed and transferred to a graduated cylinder. Then, sufficient water is added to obtain the dosing solution/suspension concentration that is specified on the test request form. The slurry will then be carefully mixed prior to its use.

(a) Dose expressed in "cc/kg"

If the dose of the dry granular material is given in "cc/kg", the density of the granular material needs to be determined if not stated on the test request form. The density, also known as a "g/cc" measurement, is obtained by analytically weighing a known amount of the test material (at least 4 g) and transferring this material into a graduated cylinder. Record the weight (g) of test material. The test material then will be packed tightly and the volume (cc) of the test material will be recorded. The density has now been determined.

Equation: $$\text{"ml"} = \frac{[\text{dose}] \times [\text{density of material}]}{[\text{conc. of slurry}]} \times [\text{weight of dog}]$$

Units: $$\text{"ml"} = \frac{[\text{cc/kg}] \times [\text{g/cc}]}{[\text{g/ml}]} \times [\text{kg}]$$

Example: dose = 2.5 cc/kg
conc. of slurry = 40% w/v = 40 g/100 ml = 4 g/10 ml
density = 4 g/9 cc = 0.44 g/cc
weight of dog = 10 kg

Thus, $$\frac{[2.5\ \text{cc/kg}] \times [0.44\ \text{g/cc}]}{[4\ \text{g/10 ml}]} \times [10\ \text{kg}] = 27.5\ \text{ml}$$

A 10 kg dog will receive 27.5 ml of a 40% w/v slurry of test material.

GRADY INVESTMENTS, INC. PROTOCOL NO. 3 (cont.)

ACUTE ORAL CORROSIVITY STUDY

Issue Date: March 1, 1985

(b) Dose expressed in "g/kg"

If the dose of the dry granular material is given in "g/kg", the following calculation is used to determine how much test material to administer.

Equation: $\text{"ml"} = \frac{[\text{dose}]}{[\text{conc. of slurry}]} \times [\text{weight of dog}]$

Units: $\text{"ml"} = \frac{[\text{g/kg}]}{[\text{g/ml}]} \times [\text{kg}]$

Example: dose = 1.0 g/kg
conc. of slurry = 40% w/v = 40 g/100 ml
= 4 g/10 ml
weight of dog = 10 kg

Thus, $\frac{[1.0\ \text{g/kg}]}{[4\ \text{g/10 ml}]} \times [10\ \text{kg}] = 25.0\ \text{ml}$

A 10 kg dog will receive 25.0 ml of a 40% w/v slurry of test material.

B. Liquid Test Material

1. Preparation of Dose Per Os.

A 5.0 ml volume of undiluted liquid test material will be measured into a syringe. The test material will then be dosed to the dog.

2. Determination of Dose Per Gavage

The volume of liquid test material to be used for dosing each dog will be calculated from the following equation:

Equation: "ml" = [dose] x [weight of dog]

Units: "ml" = [ml/kg] x [kg]

Example: dose = 1.0 ml/kg
weight of dog = 10 kg

Thus, [1.0 ml/kg] x [10 kg] = 10.0 ml

A 10 kg dog will receive 10.0 ml of the liquid test material.

GRADY INVESTMENTS, INC. PROTOCOL NO. 3 (cont.)

ACUTE ORAL CORROSIVITY STUDY

Issue Date: March 1, 1985

Procedures:

Administration of Test Material

A. Per Os.

The test material (5.0 cc granular material or 5.0 ml of liquid material) will be injected by a syringe over the base of the tongue into the posterior portion of the mouth. Then, the mouth will be held closed until the material is swallowed.

B. Gavage

The test material will be administered to the dogs by a syringe attached to a stomach tube previously passed into the stomach. The stomach tube will be flushed immediately with water from a second syringe at a volume equivalent to the volume of the stomach tube to ensure that the entire dose of test material is delivered. The stomach tube will then be removed and the dog will be returned to the cage for observation.

Observations:

After dosing, all dogs will be continuously observed for a period of at least one hour if emesis does not occur, or until 30 minutes have elapsed after the last emesis. The times of retching, diarrhea and emesis will be recorded. The animals will also be observed and recorded for gross behavioral changes and abnormal response. Any unusual or unexpected responses will be reported immediately by telephone to the Sponsor Liaison or the Principal Investigator if the Sponsor Liaison is not available. After the initial continuous observation period, the cages housing the dogs will be rinsed completely and additional observations will be made every 20-30 minutes over a period of 4 hours. The dogs will be allowed access to water 4 hours after dosing. In addition to observations on the first day (defined as Day 0 of the study), the animals will be observed at least once daily for evidence of emesis, diarrhea, gross behavioral changes and signs of systemic toxicity. These daily observations will be conducted and recorded until the animal is judged to be normal by gross observation and endoscopic examination.

GRADY INVESTMENTS, INC. PROTOCOL NO. 3 (cont.)

ACUTE ORAL CORROSIVITY STUDY

Issue Date: March 1, 1985

Endoscopic Examination - Gastroscopic examinations will be performed on all animals 2 to 3 days prior to dosing, on the day following dosing, and on days 7, 14, 21, and 28 after dosing until the animal is judged to be normal. All animals will be fasted from food after dosing until the first gastroscopic examination is completed. In addition, water will be removed 2-4 hours prior to the gastroscopic examination. In all the other examinations, the animals will be deprived of food overnight and water for 2-4 hours.

Prior to endoscoping, the animals will be anesthetized with an intravenous injection of sodium thiamylal (Biotal®). After the animal is anesthetized, it will be placed in the left lateral recumbent position and a visual examination of the oral cavity will be performed. Then the esophagus and stomach of the animal will be endoscoped (Olympus Model G.I.F. Gastroscope). All observations will be recorded.

In the event that an animal dies during the study, the Sponsor's Liaison should be contacted immediately by the Study Director. If the Sponsor's Liaison cannot be reached, the Divisional Toxicologist should be contacted. The Sponsor's Liaison, or the Divisional Toxicologist, will inform the Study Director what further action is to be taken.

Protocol Changes: If, after a study is underway, it becomes necessary to change the approved protocol, verbal agreement to make this change should be made between the Study Director and the Sponsor Liaison or Sponsor's Divisional Toxicologist. 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 or Liaison. This document is then attached to the request document as an addendum.

GRADY INVESTMENTS, INC. PROTOCOL NO. 3 (cont.)

ACUTE ORAL CORROSIVITY STUDY

Issue Date: March 1, 1985

Report: Report dates of study initiation and termination. Report all data regarding dose solution and preparation and individual dose level. The report should also include a summary of gross observations and a transcription of the raw data. Report results of the visual and endoscopic observations including any unusual or unexpected responses. This report shall conform to all requirements outlined in Section 58.185, Subpart J, Good Laboratory Practices regulations.

Study Director: D. L. Nelson, DVM. Date: 3-1-85
Grady Investments, Inc.

Signature: P. H. Bey, PhD Date: 3-1-85
PS&DD Liaison

Signature: P. J. Hall, PhD Date: 3-5-85
BS&HCPD Liaison

/jss

ACUTE ORAL CORROSIVITY TESTING
CALCULATIONS FOR GRANULAR TEST MATERIAL SLURRY

PROJECT # _____ TEST MATERIAL _____

I. Test Material slurry for calculations _____ % w/v

A. *Weight of test material _____ g (W_1) = _____ cc(V_1) - Volume of test material in graduated cylinder

*Weights for different concentrations of slurry (w/v):

	10%	25%	40%
W_1	1 g	2.5 g	4 g

B Sufficient amount of distilled water _____ ml added to make 10 ml (V_2) Total volume of slurry in graduated cylinder

---

II. Test Material Slurry for Dosing _____ % w/v

A Total volume needed (_____ multiples of 10) = _____ ml

B Amount of test material _____ (same multiple) = _____ (W_1) = _____ g

C. Put test material weighed out in graduated beaker and add distilled water slowly with stirring to total volume

---

III. **Dose Rate**

A. If stated in cc of test material per kg:

Dose Rate of Test Material		Slurry Concentration		Slurry Dose Rate
_____ cc / kg	×	10 ml / cc(V_1)	=	_____ ml/kg

B If stated in g of test material per kg:

Dose Rate of Test Material		Slurry Concentration		Slurry Dose Rate
_____ g / kg	×	10 ml / g(W_1)	=	_____ ml/kg

Calculated by _____ Date _____

Examined by _____ Date _____

Typed copy examined by _____ Date _____

Rev. 2/85

ACUTE ORAL CORROSIVITY DOSING AND MONITORING

STUDY # _____ TEST SUBSTANCE _____ WARD _____ DOSE DATE _____

WATER REMOVED _____ (time) AND DOGS FASTED _____ (minutes) SYRINGE SIZE _____

Dose Rate

I. Liquid — Use ml/kg or as otherwise stated on Test Request

II. Granular or Solid Material (1) as a W/V Slurry — Use ml/kg from calculation III. A or B
(2) as otherwise stated on Test Request

ADMINISTRATION: BY GAVAGE _____ BY MOUTH _____ OTHER _____

Dog # _____ Cage # _____ Sex _____			Dog # _____ Cage # _____ Sex _____		
_____ ×	_____ =	_____	_____ ×	_____ =	_____
Wt (kg)	Dose Rate*	DOSE	Wt (kg)	Dose Rate*	DOSE
Dose Time _____			Dose Time _____		
DEFECATION/OTHER	RETCH	VOMIT	DEFECATION/OTHER	RETCH	VOMIT

Descriptive Abbreviations will be added behind the time as indicated:

Feces and or vomitus	BS	=	Blood streaked, small amounts or flecks of blood					
	BI	=	Blood Intermediate increased areas of bloody discoloration (up to one-half)					
	BL	=	Blood Large almost all blood or bloody discoloration					
Defection: (D)	N	=	Normal	F	=	Fluid	T	= Test material in feces
	S	=	Soft	M	=	Mucus		

Dosed by _____ Date _____

Observed by _____ Date _____

Examined by _____ Date _____

Typed copy examined by _____ Date _____

Rev. 10/4

DEFECATION	OTHER	RETCH	VOMIT	DEFECATION	OTHER	RETCH	VOMIT

ACUTE ORAL CORROSIVITY FORM
CONTINUATION SHEET

Project # _____ Test Material _____

Date of Dosing _____

DOG # _____ Ward _____ DOG # _____ Ward _____

N.A.N. = No Abnormalities Noted

ANIMAL SELECTION

STUDY # _____ TEST SUBSTANCE _____ DOSE DATE _____

The following animals appear normal and are selected as test animals for this study:

Dog #	Sex	Fasted Weight Day of Study	Ward	Last Usage	Times Used	Source	Age (mo.)	Pretest Blood

The following animals appear normal and are selected as spares (in event an animal cannot be used from the above selection or if extra animals are needed on the study):

Dog #	Sex	Fasted Weight Day of Study	Ward	Last Usage	Times Used	Source	Age (mo.)	Pretest Blood

Selection by _____ Date _____

Examined by _____ Date _____

If unable to use selected animals for dosing, reason for using spare(s) is as follows:

_____

_____

Signed _____ Date _____

Typed Copy Examined By _____ Date _____

GI 1/84

GRADY INVESTMENTS INC.

GASTROSCOPIC EXAMINATION REPORT

Project # _____
Test Substance _____
Date Dosed _____
Date Scoped _____

Dog # _____ Study day _____
Sex _____ Ward # _____

Number of Pictures		Observations
_____	Oral Cavity:	
_____	Esophagus:	
_____	Stomach:	

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by _____ Date _____

Examined by _____ Date _____

Typed Copy Examined by _____ Date _____

GII 12/81 (rev.)

PROTOCOL DEVIATION IN
STUDY H85006C

Date: 3-28-85

Gastroscopic examination for dog #8467 was performed on Day 8, because the dog was not fasted on Day 7.

D R Nelson, D.V.M. 4-5-85

D. R. NELSON, D.V.M. DATE

ANIMAL SELECTION

STUDY # H85006C TEST SUBSTANCE P1947 DOSE DATE 3-21-85

The following animals appear normal and are selected as test animals for this study:

Dog #	Sex	Fasted Weight Day of Study	Ward	Last Usage	Times Used	Source	Age (mo.)	Pretest Blood
8467	M	7.5 kg	7	-	0	N.E.Ph.	23	Normal
8494	F	9.5 kg	2	-	0	N.E.Ph.	24	Normal

The following animals appear normal and are selected as spares (in event an animal cannot be used from the above selection or if extra animals are needed on the study):

Dog #	Sex	Fasted Weight Day of Study	Ward	Last Usage	Times Used	Source	Age (mo.)	Pretest Blood
8437	M	9.25 kg	2	-	0	N.E.Ph.	29	Normal
*8338	F	--	2	12-6-83	2	HRA	30	Normal

Selection by D. R. Nelson, D.V.M. Date 3-19-85

Examined by D. R. Nelson, D.V.M. Date 3-19-85

If unable to use selected animals for dosing, reason for using spare(s) is as follows:

*Dog #8338 had a seizure and was declared unfit for use.

Signed _____ Date _____

Typed Copy Examined By D. R. Nelson, D.V.M. Date 4-5-85

GII 1/84

ACUTE ORAL CORROSIVITY DOSING AND MONITORING

STUDY # H85006C TEST SUBSTANCE P1947 WARD 9 DOSE DATE 3-21-85

WATER REMOVED 0600 (time) AND DOGS FASTED DRN (initials) SYRINGE SIZE 35 cc and 6.0 cc

Dose Rate

** I. Liquid — Use ml/kg or as otherwise stated on Test Request

~~II. Granular or Solid Material (1) as a W/V Slurry — Use ml/kg from calculation III. A or B~~

~~(2) as otherwise stated on Test Request~~

ADMINISTRATION: BY GAVAGE X BY MOUTH ____ OTHER ____

Dog # 8467	Cage # 8	Sex M	Dog # 8494	Cage # 7	Sex F
7.5 Wt (kg)	× 5.0 cc/kg Dose Rate*	= 37.5 cc DOSE	9.5 Wt (kg)	× 5.0 cc/kg Dose Rate*	= 47.5 cc DOSE
Dose Time 1019-09			Dose Time 1015-54		

DEFECATION/OTHER	RETCH	VOMIT	DEFECATION/OTHER	RETCH	VOMIT
	1029-28		1046-00 Barking and restless behavior pattern		
		1029-30			
		1031-50	1047-00 (D) N		
		1032-50	1047-09 (D) N		
	1033-29		1048-42 Urination		
	1034-30			1057-30	
	1034-48				1057-36
1035-30 Shaking head					1058-03
1037-30 Shaking head, inspiratory stridor					1058-28
1038-33 Restless behavior pattern					1058-49
1039-22 Shaking head; slinging test substance					1059-05
1041-26 Inspiratory stridor			1101-15 Temporary balance deficit(loss)		
	1042-15		1130 Stopped continuous observation		
	1042-43		1200 N.A.N.		
1048-29 Shaking head			1215 N.A.N.		
1053 Stopped continuous observation			1230 N.A.N.		
1100 N.A.N.			1300 N.A.N.		
1130 N.A.N.			1330 N.A.N.		
1200 N.A.N.			1400 N.A.N.		
1215 N.A.N.			1430 N.A.N.		

Descriptive Abbreviations will be added behind the time as indicated:

Feces and or vomitus: BS = Blood streaked: small amounts or flecks of blood; BI = Blood Intermediate: increased areas of bloody discoloration (up to one-half); BL = Blood Large, almost all blood or bloody discoloration

Defection: (D) N = Normal; S = Soft; F = Fluid; M = Mucus; T = Test material in feces; N.A.N. = No Abnormalities Noted

Dosed by D. R. Nelson, D.V.M. Date 3-21-85

Observed by D. R. Nelson, D.V.M. Date 3-21-85

Examined by D. R. Nelson, D.V.M. Date 3-21-85

Typed copy examined by D. R. Nelson, D.V.M. Date 4-3-85

Rev. 10/4

8467

DEFECATION OTHER	RETCH	VOMIT
1230 N.A.N.		
1300 N.A.N.		
1400 N.A.N.		
1430 N.A.N.		
1500 N.A.N.		

8494

DEFECATION OTHER	RETCH	VOMIT
1500 N.A.N.		
1530 N.A.N.		

ACUTE ORAL CORROSIVITY FORM
CONTINUATION SHEET

Project # H85006C

Test Material P1947

Date of Dosing 3-21-85

DOG # 8467 Ward 7		DOG # 8494 Ward 2	
3-22-85	Anesthesia: Biotal	3-22-85	Anesthesia: Biotal
	Endoscopy: Margianlly abnormal		Endoscopy: Martinally abnormal
	No feces		No feces - N.A.N.
3-23-85	N.A.N.	3-23-85	N.A.N.
3-24-85	N.A.N.	3-24-85	N.A.N.
3-25-85	N.A.N.	3-25-85	N.A.N.
3-26-85	N.A.N.	3-26-85	N.A.N.
3-27-85	N.A.N.	3-27-85	N.A.N.
3-28-85	No feces seen - N.A.N.	3-28-85	No feces - N.A.N.
	Endoscopy: Not properly fasted		Endoscopy: Marginally abnormal
	Anesthesia: Biotal		Anesthesia: Biotal
3-29-85	Endoscopy: Normal	3-29-85	No observation made
	No feces seen - N.A.N.	3-30-85	N.A.N.
4-1-85	Formed stool - normal	3-31-85	No feces seen
4-2-85	N.A.N.	4-1-85	Normal stool - N.A.N.
4-3-85	N.A.N.	4-2-85	N.A.N.
4-4-85	N.A.N.	4-3-85	N.A.N.
		4-4-85	Anesthesia: Biotal
Observations were made after the			Scoped: Normal
study ended for Dog #8467.			

N.A.N. = No Abnormalities Noted

D. R. Nelson, D.V.M. 4-5-85

Rev. 10 84 D. R. Nelson, D.V.M. 4-5-85

GASTROSCOPIC EXAMINATION REPORT

Project # H85006C
Test Substance P1947
Date Dosed Prestudy
Date Scoped 3-19-85

Dog # 8467 Study day -2
Sex M Ward # 7

Number of Pictures		Observations
0	Oral Cavity:	NR - Not Remarkable
0	Esophagus:	NR
0	Stomach:	Normal
		Cardia: Moderate diffuse hyperemia
		Fundus: Greater curvature - a large quantity of fecal material and severe diffuse hyperemia Lesser curvature - moderate diffuse hyperemia
		Pylorus: Pyloric antrum - moderate diffuse hyperemia Pyloric canal - moderate diffuse hyperemia

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D. R. Nelson, D.V.M. Date 3-19-85

Examined by D. R. Nelson, D.V.M. Date 3-19-85

Typed Copy Examined by D. R. Nelson, D.V.M. Date 4-5-85

GII 12/81 (rev.)

GASTROSCOPIC EXAMINATION REPORT

Project # H85006C
Test Substance P1947
Date Dosed 3-21-85
Date Scoped 3-22-85

Dog # 8467 Study day 1
Sex M Ward # 7

Number of Pictures		Observations
0	Oral Cavity:	NR - Not Remarkable
0	Esophagus:	NR
0	Stomach:	Marginally abnormal Cardia: NR Fundus: Greater curvature - a few scattered petechial hemorrhages Lesser curvature - NR Pylorus: Pyloric antrum - NR Pyloric canal - NR

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D. R. Nelson, D.V.M. Date 3-22-85

Examined by D. R. Nelson, D.V.M. Date 3-22-85

Typed Copy Examined by D. R. Nelson D.V.M. Date 4-5-85

GII 12/81 (rev.)

GRADY INVESTMENTS INC.

GASTROSCOPIC EXAMINATION REPORT

Project # H85006C
Test Substance P1947
Date Dosed 3-21-85
Date Scoped 3-28-85

Dog # 8467 Study day 7
Sex M Ward # 7

Number of Pictures		Observations
0	Oral Cavity:	NR - Nor Remarkable
0	Esophagus:	NR
0	Stomach:	Not properly fasted. Repeat on Day 8.

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D. R. Nelson, D.V.M. Date 3-28-85

Examined by D. R. Nelson, D.V.M. Date 3-28-85

Typed Copy Examined by D. R. Nelson, D.V.M. Date 4-5-85

GII 12/81 (rev.)

GASTROSCOPIC EXAMINATION REPORT

Project # H85006C
Test Substance P1947
Date Dosed 3-28-85
Date Scoped 3-29-85

Dog # 8467 Study day 8
Sex M Ward # 7

Number of Pictures		Observations
0	Oral Cavity:	NR - Not Remarkable
0	Esophagus:	NR
0	Stomach:	Normal Cardia: NR Fundus: Greater curvature - mild diffuse hyperemia Lesser curvature - mild diffuse hyperemia Pylorus: Pyloric antrum - mild diffuse hyperemia Pyloric canal - NR

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D. R. Nelson, D.V.M. Date 3-29-85

Examined by D. R. Nelson, D.V.M. Date 3-29-85

Typed Copy Examined by D. R. Nelson, D.V.M. Date 4-5-85

GII 12/81 (rev.)

GRADY INVESTMENTS INC.

GASTROSCOPIC EXAMINATION REPORT

Project # H85006C
Test Substance P1947
Date Dosed Prestudy
Date Scoped 3-19-85

Dog # 8494 Study day -2
Sex F Ward # 2

Number of Pictures		Observations
0	Oral Cavity:	NR - Not Remarkable
0	Esophagus:	NR
0	Stomach:	Normal
	Cardia:	NR
	Fundus:	Greater curvature - mild diffuse hyperemia Lesser curvature - mild diffuse hyperemia
	Pylorus:	Pyloric antrum - mild diffuse hyperemia Pyloric canal - NR

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D. R. Nelson, D.V.M. Date 3-19-85

Examined by D. R. Nelson, D.V.M. Date 3-19-85

Typed Copy Examined by D. R. Nelson, D.V.M. Date 4-5-85

GII 12/81 (rev.)

GASTROSCOPIC EXAMINATION REPORT

Project # H85006C
Test Substance P1947
Date Dosed 3-21-85
Date Scoped 3-22-85

Dog # 8494 Study day 1
Sex F Ward # 2

Number of Pictures		Observations
0	Oral Cavity:	NR - Not Remarkable
0	Esophagus:	NR
0	Stomach:	Marginally abnormal Cardia: NR Fundus: Greater curvature - a large volume of white foam and mucus obstructed view of a large portion of the fundic mucosa. Moderate diffuse hyperemia was present in the caudal portion of the fundus. Lesser curvature - moderate diffuse hyperemia Pylorus: Pyloric antrum - moderate diffuse hyperemia Pyloric canal - moderate diffuse hyperemia

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D. R. Nelson, D.V.M. Date 3-22-85

Examined by D. R. Nelson, D.V.M. Date 3-22-85

Typed Copy Examined by D. R. Nelson, D.V.M. Date 4-5-85

GII 12/81 (rev.)

GASTROSCOPIC EXAMINATION REPORT

Project # H85006C
Test Substance P1947
Date Dosed 3-21-85
Date Scoped 3-28-85

Dog # 8494 Study day 7
Sex F Ward # 2

Number of Pictures		Observations
0	Oral Cavity:	NR - Not Remarkable
0	Esophagus:	NR
0	Stomach:	Marginally Abnormal Cardia: NR Fundus: Greater curvature - a few petechial hemorrhages in the proximal portion Lesser curvature - NR Pylorus: Pyloric antrum - mild diffuse hyperemia Pyloric canal - NR

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D. R. Nelson, D.V.M. Date 3-28-85
Examined by D. R. Nelson, D.V.M. Date 3-28-85
Typed Copy Examined by D. R. Nelson, DVM Date 4-5-85

GII 12/81 (rev.)

GRADY INVESTMENTS INC.

GASTROSCOPIC EXAMINATION REPORT

Project # H85006C
Test Substance P1947
Date Dosed 3-21-85
Date Scoped 4-4-85

Dog # 8494 Study day 14
Sex F Ward # 2

Number of Pictures		Observations
0	Oral Cavity:	NR - Not Remarkable
0	Esophagus:	NR
0	Stomach:	Normal Cardia: Mild diffuse hyperemia Fundus: Greater curvature - mild diffuse hyperemia with a moderate quantity of mucus Lesser curvature - mild diffuse hyperemia Pylorus: Pyloric antrum - mild diffuse hyperemia Pyloric canal - mild diffuse hyperemia

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D. R. Nelson, D.V.M. Date 4-4-85

Examined by D. R. Nelson, D.V.M. Date 4-4-85

Typed Copy Examined by D. R. Nelson, D.V.M. Date 4-5-85

GII 12/81 (rev.)

GRADY INVESTMENTS INC.

GASTROSCOPIC EXAMINATION REPORT

Project # H85005C/H85006C
Test Substance P1946/P1947
Date Dosed Prestudy
Date Scoped 3-19-85

Dog # 8338 Study day -2
Sex F Ward # 2

Number of Pictures		Observations
0	Oral Cavity:	NR - Not Remarkable
0	Esophagus:	NR
0	Stomach:	Normal
	Cardia:	Moderate diffuse hyperemia
	Fundus:	Greater curvature - NR Lesser curvature - moderate diffuse hyperemia
	Pylorus:	Pyloric antrum - moderate diffuse hyperemia Pyloric canal - moderate diffuse hyperemia

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D. R. Nelson, D.V.M. Date 3-19-85

Examined by D. R. Nelson, D.V.M. Date 3-19-85

Typed Copy Examined by D. R. Nelson, D.V.M. Date 4-5-85

GII 12/81 (rev.)

GASTROSCOPIC EXAMINATION REPORT

Project # H85005C/H85006C Spare
Test Substance P1946/P1947
Date Dosed Prestudy
Date Scoped 3-19-85

Dog # 8437 Study day -2
Sex M Ward # 2

Number of Pictures		Observations
0	Oral Cavity:	NR - Not Remarkable
0	Esophagus:	NR
0	Stomach:	Normal Cardia: NR Fundus: Greater curvature - NR Lesser curvature - NR Pylorus: Pyloric antrum - NR Pyloric canal - NR

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D. R. Nelson, D.V.M. Date 3-19-85

Examined by D. R. Nelson, D.V.M. Date 3-19-85

Typed Copy Examined by D. R. Nelson, D.V.M. Date 3-19-85

GII 12/81 (rev.)

Raw Data Page 1

ANIMAL SELECTION

STUDY # H850060 TEST SUBSTANCE P1947 DOSE DATE 3-21-85

The following animals appear normal and are selected as test animals for this study:

Dog #	Sex	Fasted Weight Day of Study	Ward	Last Usage	Times Used	Source	Age (mo.)	Pretest Blood
8467	M	7.5 kg	7	—	0	NEPh	23	N
8494	F	9.5 kg	2	—	0	NE.Ph.	24	N

The following animals appear normal and are selected as spares (in event an animal cannot be used from the above selection or if extra animals are needed on the study):

Dog #	Sex	Fasted Weight Day of Study	Ward	Last Usage	Times Used	Source	Age (mo.)	Pretest Blood
8437	M	9.25 kg	2	—	0	NEPh.	29	N
*8338	F	— kg	2	12-6-83	2	HRA	30	N

Selection by D.V.Milson, D.V.M. Date 3-19-85 / 3-21-85

Examined by D.V.Milson, DVM Date 3-19-85

If unable to use selected animals for dosing, reason for using spare(s) is as follows:

Dog 8338 had a seizure and was deemed unfit for use

Signed _____ Date _____

Typed Copy Examined By _____ Date _____

GI 1/84

Raw Data Page

ACUTE ORAL CORROSIVITY DOSING AND MONITORING

AOC App. II
Page 1

STUDY # H85006C TEST SUBSTANCE P1947 WARD 9 DOSE DATE 3-21-85

WATER REMOVED 0600 (time) AND DOGS FASTED EKN (initials) SYRINGE SIZE 35 cc and 60 cc

Dose Rate

I. Liquid — Use ml/kg or as otherwise stated on Test Request

~~II. Granular or Solid Material (1) as a W/V Slurry — Use ml/kg from calculation III. A or B~~

~~(2) as otherwise stated on Test Request~~

EKN use #1 3-21-85

ADMINISTRATION: BY GAVAGE X BY MOUTH ____ OTHER ____

Dog # 8467	Cage # 8	Sex M	Dog # 8494	Cage # 7	Sex F
Wt (kg) 7.5	Dose Rate 5.0 cc/kg	DOSE 37.5 cc	Wt (kg) 9.5	Dose Rate 5.0 cc/kg	DOSE 47.5 cc
Dose Time 1019 09			Dose Time 1015-54		

DEFECATION/OTHER	RETCH	VOMIT	DEFECATION/OTHER	RETCH	VOMIT
	1039-28		(B) Intubation wrong leg (*) 1039-28		~~1039~~
		103930	EKN script 3-21-85		(*) 103930
		103-50	1046 on drinking and written behavior pattern		
		1032-50	1047-00 (D) N		
	103529		1047-09 (D) N		
	103430		1048-43 Urination		
	103448			1057-30	
1035-30	Shaking head				105736
1037-30	Shaking head, inspiratory stridor				1058-03
1038-33	Restless behavior pattern				1058-28
1039-22	Shaking head, sloughing tongue & buccal				1058-49
104126	Inspiratory stridor				1059-05
~~1042-15~~	delete EKN 3-21-85	104215	1101-15	temporary balance deficit (low)	
		104243	1130	stopped continuous observation	
104807	Shaking head		1200	NAN DKN	
1053	Stopped continuous observation		1215	NAN DKN	
1100	NAN DKN		1230	NAN DKN	
1130	NAN DKN		1300	NAN DKN	
1200	NAN DKN		1330	NAN DKN	
1215	NAN DKN		~~1330~~ 1400	NAN DKN	
1230	NAN DKN		~~1400~~ 1430	NAN DKN	
			1500	NAN DKN	
			1530	NAN DKN	

Descriptive Abbreviations will be added behind the time as indicated:

Feces and or vomitus: BS = Blood streaked: small amounts or flecks of blood; BI = Blood Intermediate: increased areas of bloody discoloration (up to one-half); BL = Blood Large, almost all blood or bloody discoloration

Defection: (D) N = Normal; S = Soft; F = Fluid; M = Mucus; T = Test material in feces

Dosed by D. K. Nelson D.V.M. Date 3-21-85

Observed by D. K. Nelson, D.V.M. Date 3-21-85

Examined by D. K. Nelson, D.V.M. Date 3-21-85

Typed copy examined by ____ Date ____

Rev. 10/4

Raw Data Page 4

Page 1 of 10

GRADY INVESTMENTS INC.

GASTROSCOPIC EXAMINATION REPORT

Project # H85006C
Test Substance P1947
Date Dosed Prestudy
Date Scoped 3-19-85

Dog # 8467 Study day -3
Sex M Ward # 7

Number of Pictures		Observations
0	Oral Cavity:	NR - Not Remarkable
0	Esophagus:	NR
0	Stomach:	Normal
	Cardia:	moderate diffuse hyperemia
	Fundus:	Greater Curvature - a large quantity of fecal material and severe diffuse hyperemia
		Lesser Curvature - moderate diffuse hyperemia
	Pylorus:	Pyloric antrum - moderate diffuse hyperemia
		Pyloric canal - moderate diffuse hyperemia

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D. K. Nelson D.V.M. Date 3-19-85

Examined by D. K. Nelson, D.V.M. Date 3-19-85

Typed Copy Examined by _____ Date _____

GII 12/81 (rev.)

Raw Data Page 5

Page 2 of 10

GRADY INVESTMENTS INC.

GASTROSCOPIC EXAMINATION REPORT

Project # N8500bC
Test Substance P1947
Date Dosed 3-21-85
Date Scoped ~~3-22-85~~ 3-22-85
Dog # 8467 Study day 1
Sex M Ward # 7

Number of Pictures		Observations
0	Oral Cavity:	NR = Not Remarkable
0	Esophagus:	NR
0	Stomach:	Marginally abnormal
	Cardia:	NR
	Fundus: Greater Curvature:	A few scattered petechial hemorrhages
	Lesser Curvature:	NR
	Pylorus: Pyloric antrum:	NR
	Pyloric canal:	NR

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D. L. Nelson, D.V.M. Date 3-22-85

Examined by D. L. Nelson, D.V.M. Date 3-22-85

Typed Copy Examined by _____ Date _____

GII 12/81 (rev.)

Raw Data Page 6

Pg 3 of 10

GRADY INVESTMENTS INC.

GASTROSCOPIC EXAMINATION REPORT

Project # H85006C
Test Substance P1947
Date Dosed 3 21-85
Date Scoped 3 28-85

Dog # 8467 Study day 7
Sex M Ward # 7

Number of Pictures		Observations
0	Oral Cavity:	NR - Not Remarkable
0	Esophagus:	NR
0	Stomach:	Not properly fasted Repeat on Day 8

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D.R. Nelson, D.V.M. Date 3-28-85

Examined by D.R. Nelson, D.V.M. Date 3-28-85

Typed Copy Examined by _____ Date _____

GII 12/81 (rev.)

GRADY INVESTMENTS INC.

GASTROSCOPIC EXAMINATION REPORT

Raw Data Page 8

Page 5 of 10

Project # H85066
Test Substance P1947
Date Dosed Prestudy
Date Scoped 3-19-85

Dog # 8494 Study day -2
Sex F Ward # 2

Number of Pictures		Observations
0	Oral Cavity:	NR - Not Remarkable
0	Esophagus:	NR - Not Remarkable
0	Stomach:	Normal

Cardia. NR

Fundus: Greater curvature - mild diffuse hyperemia

Lesser curvature - mild diffuse hyperemia

Pylorus: Pyloric antrum - mild diffuse hyperemia

Pyloric canal - NR

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D.R. Nelson, D.V.M. Date 3-19-85

Examined by D.R. Nelson, D.V.M. Date 3-19-85

Typed Copy Examined by _____ Date _____

GII 12/81 (rev.)

GRADY INVESTMENTS INC.

GASTROSCOPIC EXAMINATION REPORT

Raw Data Page 7

Page 4 of 10

Project # H850006C
Test Substance PA47
Date Dosed 3-25-85
Date Scoped 3-29-85

Dog # 8167 Study day 28
Sex C Ward # 7

Number of Pictures		Observations
0	Oral Cavity:	NR
0	Esophagus:	NR
0	Stomach:	Normal

Cardia: NR
Fundus: Greater curvature - mild diffuse hyperemia
Lesser curvature - mild diffuse hyperemia
Pylorus: Pyloric antrum - mild diffuse hyperemia
Pyloric canal - NR

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D.R. Allen, DVM Date 3-29-85
Examined by D.R. Allen, DVM Date 3-29-85
Typed Copy Examined by _____ Date _____

GII 12/81 (rev.)

GRADY INVESTMENTS INC.

GASTROSCOPIC EXAMINATION REPORT

Raw Data Pg 9
Page 6 of 10

Project # H85006C
Test Substance PA47
Date Dosed 3-21-85
Date Scoped 3-22-85

Dog # 5494 Study day 1
Sex F 5494 Ward # 2
[illegible] 3-5-85

Number of Pictures	Observations
0	Oral Cavity: NR = Not Remarkable
0	Esophagus: NR
0	Stomach: Marginally Abnormal Cardia: NR Fundus: Greater curvature – A large volume of white foam and mucus obstructed view of a large portion of the fundic mucosa. Moderate diffuse hyperemia was present in the caudal portion of the fundus. Lesser curvature – moderate diffuse hyperemia Pylorus: Pyloric antrum – moderate diffuse hyperemia Pyloric canal – moderate diffuse hyperemia

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D.L. Nelson, D.V.M. Date 3-22-85

Examined by D.L. Nelson, D.V.M. Date 3-22-85

Typed Copy Examined by _____ Date _____

GII 12/81 (rev.)

GRADY INVESTMENTS INC.

GASTROSCOPIC EXAMINATION REPORT

Raw Data Page 10
Page 67 of 10
4-5-85

Project # 1850066
Test Substance P1547
Date Dosed 3-21-85
Date Scoped 3-28-85
Dog # 146-5494 Study day 7
Sex F Ward # 2

Number of Pictures		Observations
0	Oral Cavity:	NR - Not Remarkable
0	Esophagus:	NR
0	Stomach:	Marginally Abnormal

Cardia: NR

Fundus: Greater curvature - a few petechial hemorrhages in the proximal portion

Lesser curvature - NR

Pylorus: Pyloric antrum - mild diffuse hyperemia

~~Pyloroscopy~~ Pyloric canal - NR

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D. L. Nelson, DVM Date 3-28-85

Examined by D. L. Nelson, DVM Date 3-28-85

Typed Copy Examined by _____ Date _____

GII 12/81 (rev.)

GRADY INVESTMENTS INC.

GASTROSCOPIC EXAMINATION REPORT

Raw Data Page 11
Page 8 of 10

Project # H850066
Test Substance PIFN
Date Dosed 3-21-85
Date Scoped 4-4-85

Dog # 8494 Study day ~~7~~ 14
Sex F Ward # 2

Number of Pictures		Observations
0	Oral Cavity:	NR - Not Remarkable
0	Esophagus:	NR
0	Stomach:	Normal

Cardia: mild diffuse hyperemia

Fundus: greater curvature - mild diffuse hyperemia with a moderate quantity of mucus.
Lesser curvature - mild diffuse hyperemia

Pylorus: pyloric antrum - mild diffuse hyperemia
pyloric canal - mild diffuse hyperemia

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D. K. Nelson DVM Date 4-4-85

Examined by D. K. Nelson, DVM. Date 4-4-85

Typed Copy Examined by _____ Date _____

GII 12/81 (rev.)

GRADY INVESTMENTS INC.

GASTROSCOPIC EXAMINATION REPORT

Raw Data Page 12
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Project # H55005C / ~~H855006C~~ H85006C
Test Substance PA46/P1947
Date Dosed Pre study
Date Scoped 3-19-85

Dog # 833j Study day -2
Sex F Ward # 0

Number of Pictures		Observations
0	Oral Cavity:	NR - Not Remarkable
0	Esophagus:	NR
0	Stomach:	Normal
	Cardia:	Moderate diffuse hyperemia
	Fundus:	Greater curvature - NR
		Lesser curvature - Moderate diffuse hyperemia
	Pylorus:	Pyloric Antrum - Moderate diffuse hyperemia
		Pyloric Canal - Moderate diffuse hyperemia

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D. R. Nelson, D.V.M. Date 3-19-85

Examined by D. R. Nelson, D.V.M. Date 3-19-85

Typed Copy Examined by _____ Date _____

GII 12/81 (rev.)

GRADY INVESTMENTS INC.

GASTROSCOPIC EXAMINATION REPORT

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Project # H85005C / H85006C spare
Test Substance P1946 / P1947
Date Dosed Prestudy
Date Scoped 3-19-85

Dog # 8437 Study day -2
Sex M Ward # 2

Number of Pictures		Observations
	Oral Cavity:	NR - Not Remarkable
C	Esophagus:	NR
C	Stomach:	Normal
	Cardia:	NR
	Fundus:	Greater curvature - NR
		Lesser curvature - NR
	Pylorus:	Pylloric ~~antrum~~ ~~canal~~ ~~angle stress~~ - NR
		Pylloric canal - NR

If pictures are taken, 2 pictures of the identification block at the top left of this page will be taken after the pictures of the gastrointestinal tract are completed for each dog.

Transcribed by D. R. Nelson D.V.M. Date 3-19-85

Examined by D. R. Nelson D.V.M. Date 3-19-85

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