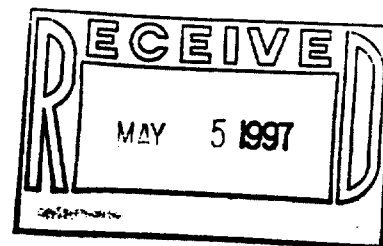


AR 226-0451

CORNING Hazleton

Sponsor:

3M
St. Paul, Minnesota



FINAL REPORT

Study Title:

5 Daily Dose Oral Toxicity Study with T-6669 in Rats

Author:

Susan M. Henwood, MS, DABT

Study Completion Date:

April 30, 1997

Performing Laboratory:

Corning Hazleton Inc.
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Laboratory Project Identification:

CHW 6329-197

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QUALITY ASSURANCE STATEMENT

This report has been reviewed by the Quality Assurance Unit of Corning Hazleton Inc., in accordance with the Food and Drug Administration (FDA) Good Laboratory Practice Regulations, 21 CFR 58 and the Organisation for Economic Cooperation and Development (OECD) Principles of Good Laboratory Practice, C(81)30(Final). The following inspections were conducted and findings reported to the Study Director and management. Written status reports of inspections and findings are issued to Corning Hazleton management according to standard operating procedures.

Inspection Dates		Phase	Date Reported to Study Director	Date to Management
From	To			
12/17/96	12/17/96	Protocol Review	12/17/96	12/17/96
01/21/97	01/21/97	Necropsy	01/21/97	01/21/97
02/28/97	03/04/97	Data Review	03/04/97	03/04/97
03/26/97	03/31/97	Report Review	03/31/97	03/31/97
04/22/97	04/23/97	Report Rereview	04/23/97	04/23/97

Sharon Paulsen
Representative
Quality Assurance Unit

4/30/97
Date

STUDY IDENTIFICATION**5 Daily Dose Oral Toxicity Study with T-6669 in Rats**

Test Material	T-6669
Sponsor	3M Toxicology Services Building 220-2E-02, 3M Center St. Paul, Minnesota, 55144-1000
Study Monitor	Roger G. Perkins, PhD, DABT 3M Toxicology Services Building 220-2E-02, 3M Center St. Paul, Minnesota, 55144-1000 (612) 733-3222
Study Director	Susan M. Henwood, MS, DABT Corning Hazleton Inc. P.O. Box 7545 Madison, Wisconsin 53707-7545 (608) 241-7221
Study Location	Corning Hazleton Inc. 3301 Kinsman Boulevard Madison, Wisconsin 53704
Study Timetable	
Study Initiation Date	December 20, 1996
In-Life Start Date	January 2, 1997
In-Life End Date	January 21, 1997
Study Completion Date	April 30, 1997

KEY PERSONNEL**Toxicology**

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ABSTRACT

The purpose of this study was to assess the oral toxicity produced when the test material, T-6669, was administered by the oral route (gavage) to male rats for 5 consecutive days.

Male Crl:CD®(SD)BR VAF/Plus® rats were assigned to four groups (10/group). Each group received dose preparations containing the carrier (reverse osmosis water) or 5.0, 14.0, or 42.0 mg of test material/kg of body weight/day (mg/kg) for 5 consecutive days at a dose volume of 5 mL/kg. Five animals/group were terminated on Day 6 (the day following the final dose) for hepatic palmitoyl CoA oxidase activity determinations; remaining animals were sacrificed and necropsied on Day 20.

Food and water were provided *ad libitum*. The animals were observed twice daily (a.m. and p.m.) for mortality and moribundity. Additionally, each animal was removed from its cage and observed for clinical signs predose and at approximately 1, 2.5, and 4 hours after each dose administration and daily thereafter. Any abnormal or unusual findings were recorded. Body weight data were collected daily on Days 1 through 20. Blood samples were collected on Days -2 (pretest), 6, 9, 15, and 20; serum and cellular fractions were separated and shipped to the Sponsor. On Day 6, five animals/group were sacrificed, and the liver was removed from each animal and weighed. The right lateral lobe of the liver was collected from each animal and weighed, then analyzed for palmitoyl CoA oxidase activity; the remaining liver tissue was also collected and weighed. On Day 20, the remaining five animals/group were sacrificed and subjected to an abbreviated necropsy; the liver was collected from each animal and weighed. Remaining liver tissues collected at the Day 6 sacrifice and the whole livers collected at the Day 20 necropsy were shipped to the Sponsor.

All animals survived to the respective scheduled sacrifice. There were no test material-related antemortem observations. Mean body weight gains for mid- and high-dose animals (14.0 and 42.0 mg/kg, respectively) were significantly reduced during the dosing period; Day 1 to 6 body weight gains were 23, 23, 0, and -4 g for the control, 5.0-, 14.0-, and 42.0-mg/kg groups respectively. In general, mid- and high-dose animals showed a recovery in body weight gain over the first 3 days after completion of the dosing period. The overall mean body weight gains (Day 1 to 20) were free of significant intergroup differences and were similar for all groups.

Administration of the test material at all dose levels was associated with higher hepatic palmitoyl CoA oxidase activity. Mean palmitoyl CoA oxidase activities on Day 6 for control animals and animals given 5.0, 14.0, and 42.0 mg/kg were 5, 24, 39, and 39 IU/G, respectively.

There were no test material-related macroscopic findings.

Based on significant increases in the levels of hepatic palmitoyl CoA oxidase activity, an indication of peroxisome proliferation, at all dose levels tested, the no-effect level of T-6669 is less than 5.0 mg/kg when administered to male Crl:CD[®](SD)BR VAF/Plus[®] rats for 5 consecutive days.

OBJECTIVE

The purpose of this study was to assess the oral toxicity produced when the test material, T-6669, was administered by the oral route (gavage) to male rats for 5 consecutive days.

REGULATORY COMPLIANCE

All aspects of this study were in accordance with the United States Food and Drug Administration Good Laboratory Practice Regulations for Nonclinical Laboratory Studies, 21 CFR 58, and the Organisation for Economic Co-operation and Development Principles of Good Laboratory Practice, C(81)30, with the exception that analysis of the test material mixtures for concentration, solubility, homogeneity, and stability were not conducted.

MAINTENANCE OF RAW DATA AND RECORDS

Original paper data and a copy of the final report will be retained in the archives of the Wisconsin facility of Corning Hazleton Inc. (CHW), for 1 year following the signing of the final report. One year after the signing of the final report, the Sponsor will determine the final disposition of the materials. Magnetically encoded data will be retained at CHW.

TEST MATERIAL AND CARRIER

Identification and Characterization

Test Material. The test material, T-6669 (FC-143), Lot No. 235, is a white powder and is 93% to 97% ammonium perfluorooctanoate. It was received at CHW on September 25, 1996.

Information on synthesis methods, stability, composition, or other characteristics that define the test material is on file with the Sponsor.

Carrier. The carrier was reverse osmosis water and was provided by CHW.

Information on source and treatment of the reverse osmosis water is on file with CHW.

Storage Conditions

The test material was stored at room temperature. The carrier was obtained directly from the in-house water system under ambient conditions.

Reserve Samples

Reserve samples were not required to be taken.

Disposition

Remaining test material was returned to the Sponsor on March 10, 1997.

Safety Precautions

Personnel involved with the study wore the apparel recommended by the CHW Test Material Safety Committee (TMSC) based on the Material Safety Data Sheet (MSDS; Appendix A). CHW Standard Operating Procedures (SOPs) applied for any apparel not covered by the TMSC recommendations.

TEST SYSTEM

Test Animal

Male Crl:CD[®](SD)BR VAF/Plus[®] rats were obtained from the Portage, Michigan, facility of Charles River Laboratories, Inc., on December 5, 1996. The animals were approximately 8 weeks old and weighed from 303 to 395 g at initiation of treatment (see Protocol Deviations; Appendix A).

Justification

The rat is frequently used in safety evaluation studies as a representative of a rodent species.

Identification

Each animal was assigned a temporary number upon arrival. Before initiation of treatment, an individually coded passive integrated transponder was implanted into each animal. After randomization for placement on test, each animal was assigned a permanent number, and the transponder was coded with the permanent number. All data for an animal are recorded under these numbers.

STUDY DESIGN

Animals were assigned to the study according to the following design:

Group	T-6669	Number of Animals
	Dose Level ^a (mg/kg)	
1 (Control)	0.0	10
2 (Low)	5.0	10
3 (Mid)	14.0	10
4 (High)	42.0	10

- a The control group was given the carrier (reverse osmosis water) only. The dose volume was 5 mL/kg for all groups.
- b Five animals in each group were sacrificed for hepatic palmitoyl CoA oxidase analysis on Day 6. The remaining animals in each group were observed for reversibility, persistence, or delayed occurrence of toxic effects until sacrifice on Day 20.

Dose Level Selection Criteria

Doses were selected based on the results of an acute toxicity study. In the acute toxicity study (CHW 61001760), animals were dosed with T-6669 at concentrations up to 500 mg/kg. Mortality was noted for animals given 500 mg/kg. At 250 mg/kg, clinical signs were limited to red-stained face and wet urogenital area for two of five females; all

animals survived to the scheduled sacrifice. The high dose of 42.0 mg/kg selected for this study is one sixth of the acute toxicity no-adverse-effect level of 250 mg/kg. The low- and mid-dose levels were selected to provide an adequate dose response.

PROCEDURES

This study was conducted in accordance with CHW Protocol TP6785 dated December 20, 1996. The protocol and protocol deviations are in Appendix A.

Acclimation

Fifty males were received on December 5, 1996, and acclimated in Animal Room 512A for 28 days before initiation of treatment. In general, animals in this shipment appeared healthy. During acclimation, the animals were examined for abnormalities indicative of health problems, and body weights were recorded for all animals at randomization.

Housing and Maintenance

Animal Room 512A was used for this study. Environmental controls for the animal room were set to maintain 19° to 25°C (66° to 77°F), a relative humidity of 50% ±20%, and a 12-hour light/12-hour dark cycle.

The animals were housed individually (except for the first six days following arrival when the animals were group-housed) in stainless steel, screen-bottom cages.

Certified Rodent Diet #5002 meal (PMI® Feeds, Inc.) was provided *ad libitum*. The lot numbers are recorded in the data. The diet is routinely analyzed by the manufacturer for nutritional components and environmental contaminants.

Water was provided *ad libitum*. Samples of the water are analyzed for total dissolved solids and specified microbiological content and for selected elements, heavy metals, organophosphates, and chlorinated hydrocarbons. The results are on file with CHW.

There were no known contaminants in the food or water that would have interfered with this study.

Placement of Animals into Groups

The animals were examined by a laboratory animal veterinarian on December 31, 1996, and found to be suitable for study consideration. On Day -2, animals were ranked by body weight. Animals with body weights exceeding ± 2 standard deviations of the mean body weight and those with significant physical abnormalities were excluded from selection. The number of animals available for selection was reduced to the required number by excluding animals at the ends of the body weight range. The animals selected for the study (40 males) were assigned a computer-generated random number and allocated to groups (10/group) according to the relative rank of the random numbers. Group mean body weights were analyzed using Bartlett's test for homogeneity of variance at the 5.0% probability level (Winer, 1971) and found to be homogeneous.

Animals not used for the study (10 males) were sacrificed and discarded.

Dose Preparation

Carrier. The carrier was reverse osmosis water.

Test Material. Dose concentrations were based on the test material as supplied. Dose preparations were mixed daily for dose administration.

Each dose level was prepared independently. The specified amount of test material was weighed. A portion of the carrier was placed into a labeled container and the test material was added and then mixed with a polytron homogenizer until the test material was suspended. The mixture was then placed into a calibrated container and the appropriate volume of carrier was added to achieve the desired concentration. Dose preparations were mixed for at least 10 minutes using a magnetic stir plate and stir bar. All completed dose preparations appeared to be solutions.

The dose preparations were kept at room temperature until dosing.

Dose Analyses

Dose analyses were not done.

Dose Administration

Gavage was used because historically the oral route has been the route of choice for administering a known amount of test material.

The dose preparations were administered once daily for 5 consecutive days. The dose preparations were given at a dose volume of 5 mL/kg of body weight. Individual doses were calculated based on the most recently recorded body weights. Animals were dosed at approximately the same time each day. During dose administration, homogeneous test material solutions were maintained using a magnetic stir plate and stir bar.

Antemortem Observations

The animals were observed at least twice daily (a.m. and p.m.) for mortality and moribundity. Signs of poor health or abnormal behavior were recorded as they were observed.

Predose and Postdose Observations. Each animal was removed from its cage and observed for clinical signs predose and approximately 1, 2.5, and 4 hours after each dose administration and daily thereafter. Any abnormal or unusual findings were recorded.

Body Weights

Individual body weight data were recorded on the first day of treatment and daily thereafter.

Blood Sample Collections

Blood samples were collected from each animal on Days -2 (pretest; see Protocol Deviations), 9, and 15 and at the scheduled sacrifices (Days 6 and 20). Animals were not fasted before blood sampling. Blood samples (approximately 1.5 mL) were collected from a jugular vein of all animals pretest and on Days 9 and 15. At the scheduled sacrifices (Days 6 and 20), as much blood as possible was collected from the posterior vena cava from each animal. At sacrifice, the animals were anesthetized with sodium pentobarbital before blood sample collection.

Following collection, the blood samples were held at room temperature until centrifuged. The serum and cellular fractions were separated and stored in a freezer set to maintain $-20^{\circ}\text{C} \pm 10^{\circ}$ until packed on dry ice and shipped to the Sponsor on January 22, 1997. The Sponsor is responsible for the retention or disposition of these samples.

Palmitoyl CoA Oxidase Activity Analysis (Day 6)

At the Day 6 scheduled sacrifice, five nonfasted animals/group were anesthetized with sodium pentobarbital, weighed, and exsanguinated in random order following the blood sample collections. The abdominal cavity of each animal was opened, and the liver was removed and weighed. The right lateral lobe of the liver was collected from each animal, weighed, and was flash-frozen in liquid nitrogen, then stored in a freezer set to maintain $-70^{\circ}\text{C} \pm 10^{\circ}$ until analyzed by CHW for palmitoyl CoA oxidase activity.

The remaining liver tissue was collected, weighed, and stored in a freezer set to maintain $-20^{\circ}\text{C} \pm 10^{\circ}$ until packed on dry ice and shipped to the Sponsor on January 13, 1997. The Sponsor is responsible for the retention or disposition of these samples.

Animal carcasses were discarded without further examination after liver tissue collection.

Scheduled Sacrifice (Day 20)

On Day 20, the remaining five animals/group were anesthetized with sodium pentobarbital, weighed, exsanguinated, and subjected to an abbreviated gross necropsy in random order following the blood sample collections. The necropsy included a macroscopic examination of the external surface of the body; all orifices; and the cervical, thoracic, and abdominal cavities and viscera. All abnormalities observed were recorded.

The whole liver was collected, weighed, and stored in a freezer set to maintain $-20^{\circ}\text{C} \pm 10^{\circ}$ until packed on dry ice and shipped to the Sponsor on January 27, 1997. The Sponsor is responsible for the retention or disposition of these livers.

No additional tissues were collected, and the animal carcasses were discarded after necropsy.

Statistical Analyses

Only data collected on or after the first day of treatment were analyzed statistically.

One-way analysis of variance [ANOVA (Winer, 1971)] was used to analyze Day 1 body weights; cumulative body weight gains (Day 1 to 6 and Day 1 to 20), and palmitoyl CoA oxidase levels.

Levene's test (Levene, 1960) was done to test for variance homogeneity. In the case of heterogeneity of variance at $p \leq 0.05$, transformations were used to stabilize the variance.

ANOVA was done on the homogeneous or transformed data. If the ANOVA was significant, Dunnett's multiple comparison t-test (Dunnett, 1964) was used for pairwise comparisons between treated and control groups.

Group comparisons were evaluated at the 5.0% two-tailed probability level. Groups 2 through 4 were compared with Group 1 (control).

RESULTS

Antemortem Observations and Survival

Antemortem observations are summarized in Table 1; individual data are in Appendix B.

All animals survived to the respective scheduled sacrifice. There were no test material-related antemortem observations.

Body Weights and Cumulative Body Weight Gains

Body weight data are summarized in Table 2; individual data are in Appendix B.

Cumulative body weight gains over the dosing period (Days 1 to 6) and over the study duration (Days 1 to 20) are included in Table 2. Individual day-to-day body weight gains and individual cumulative body weight gains for Days 1 to 6 and Days 1 to 20 are also in Appendix B.

Mean body weight gains for mid- and high-dose animals (14.0 and 42.0 mg/kg, respectively) were significantly reduced during the dosing period; Day 1 to 6 body weight gains were 23, 23, 0, and -4 g for the control, 5.0-, 14.0-, and 42.0-mg/kg groups

respectively. In general, the mid- and high-dose animals showed a recovery in body weight gain over the first 3 days after completion of the dosing period. The overall body weight gains (Day 1 to 20) were free of significant intergroup differences and were similar for all groups.

Palmitoyl CoA Oxidase Activity Analysis

Day 6 palmitoyl CoA oxidase activity data are summarized in Table 3; individual data are in Appendix C. The Pathology Report contains a discussion of the data.

On Day 6, palmitoyl CoA oxidase activity was significantly increased for treated animals at all dose levels. Mean hepatic palmitoyl CoA oxidase activities for the groups given 0.0, 5.0, 14.0, and 42.0 mg/kg were 5, 24, 39, and 39 IU/G, respectively.

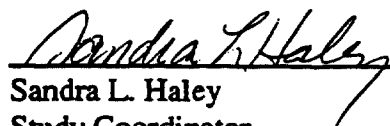
Anatomical Pathology

Results of the Day 20 necropsies and the Day 6 and Day 20 liver weight data are in Appendix D. The Pathology Report contains a discussion of the necropsy findings.

At necropsy on Day 20, one animal from the group given 5.0 mg/kg had multiple, dark red foci of variable size in the right lobe of the thymus, and the pelvis of the left kidney in one animal from the group given 42.0 mg/kg was enlarged. These were considered incidental findings and unrelated to the test material. There were no macroscopic findings in the remaining animals examined.

CONCLUSIONS

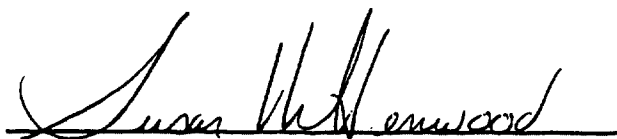
Based on significant increases in the levels of hepatic palmitoyl CoA oxidase activity, an indication of peroxisome proliferation, at all dose levels tested, the no-effect level of T-6669 is less than 5.0 mg/kg when administered to male Crl:CD®(SD)BR VAF/Plus® rats for 5 consecutive days.

SIGNATURES

Sandra L. Haley
Study Coordinator
Toxicology
Corning Hazleton Inc.

4-30-97

Date



Susan M. Henwood, MS
Diplomate, ABT
Study Director
Toxicology
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4/30/97

Date

REFERENCES

Dunnett, C. W., "New Tables for Multiple Comparisons with a Control," Biometrics, 20:482-491 (1964).

Levene, H., "Robust Tests for Equality of Variances," Contributions to Probability and Statistics, (eds.) I. Olkin et al., Ch. 25, pp. 278-292, Stanford University Press: Stanford, California (1960).

Winer, B. J., "Design and Analysis of Single-Factor Experiments," Statistical Principles in Experimental Design, Second Ed., Ch. 3, pp. 149-260, McGraw-Hill: New York, New York (1971).

PATHOLOGY REPORT

SUMMARY

The purpose of this study was to assess the oral toxicity produced when the test material, T-6669, was administered by the oral route (gavage) to rats for 5 consecutive days. The test material was administered at dose levels of 0.0, 5.0, 14.0, and 42.0 mg/kg of body weight/day (mg/kg).

Administration of the test material at all dose levels was associated with higher hepatic palmitoyl CoA oxidase activity. Mean palmitoyl CoA oxidase activities on Day 6 for control animals and animals given 5.0, 14.0, and 42.0 mg/kg were 5, 24, 39, and 39 IU/G, respectively.

There were no test material-related macroscopic findings.

METHODS

Four groups of male Crl:CD®(SD)BR VAF/Plus® rats (10/group) were administered the test material by oral gavage for 5 consecutive days at a dose level of 0.0 (control group; received reverse osmosis water), 5.0, 14.0, or 42.0 mg/kg. Five animals from each group were sacrificed on Day 6 for hepatic palmitoyl CoA oxidase analyses. The whole liver was removed and weighed, and the right lateral lobe of the liver and the remaining liver were weighed. The analyses were performed on the right lateral lobe of liver, and the remaining liver was frozen for shipment to the Sponsor. All remaining animals were sacrificed and subjected to an abbreviated gross necropsy examination on Day 20. At necropsy, macroscopic observations were recorded, and the entire liver from each animal was weighed and frozen for shipment to the Sponsor.

Statistically significant differences cited in the Results and Discussion section are based on comparisons between the control and treated groups.

RESULTS AND DISCUSSION

Mortality

All animals survived to the respective scheduled sacrifice.

Clinical Pathology

Individual values for hepatic palmitoyl CoA oxidase activity are in Appendix C. Mean values and the results of statistical comparisons are in Table 3.

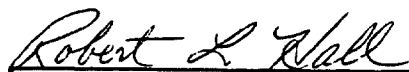
On Day 6, palmitoyl CoA oxidase activity was significantly increased for treated animals at all dose levels. Mean palmitoyl CoA oxidase activities for the groups given 0.0, 5.0, 14.0, and 42.0 mg/kg were 5, 24, 39, and 39 IU/G, respectively.

Anatomical Pathology

Individual anatomical pathology data for the animals necropsied on Day 20 are in Appendix D. Individual liver weight values for the animals sacrificed on Day 6 are also in Appendix D.

Day 20. At necropsy, one animal from the group given 5.0 mg/kg had multiple, dark red foci of variable size in the right lobe of the thymus, and the pelvis of the left kidney in one animal from the group given 42.0 mg/kg was enlarged. These were considered incidental findings and unrelated to the test material. There were no macroscopic findings in the remaining animals examined.

Pathologists:



Robert L. Hall, DVM, PhD
Diplomate, ACVP
(Clinical Pathology)



Date



Thomas E. Palmer, PhD
Pathologist



Date

COMMENTS ON THE DATA

Various models of calculators, computers, and computer programs were used to analyze data in this study. Because different models round off or truncate numbers differently, values in some tables (e.g., means, standard deviations, or individual values) may differ slightly from those in other tables, from individually calculated data, or from statistical analysis data. Neither the integrity nor the interpretation of the data was affected by these differences.

The units for dose levels on the Hazleton Path/Tox System (HPTS) summary tables are "mg/kg/day."

The number of animals listed in the heading of the summary tables for antemortem observations reflects the number of animals assigned to each group at the start of the study.

The summary tables for antemortem observations indicate the number of animals for which a condition was observed without regard to the specific nature, severity, reversibility, number of incidences per animal, or the length of time the condition persisted.

Only observations for each animal other than normal are indicated on the summary and individual antemortem observations tables.

HPTS considers the day of initiation of treatment as "Day 1, Week 1. Body weight data are entered at the start of a study week (e.g., a body weight recorded on Day 1 is considered a Week 1 body weight, a body weight recorded on Day 8 is considered a Week 2 body weight). Daily body weight gain data are calculated from day to day and are indicated in the appendix by the end point day (e.g., body weight gain from Day 1 to 2 is shown as Day 2 gain, Day 2 to 3 as Day 3 gain, etc.). Cumulative body weight gain data are calculated from the first day of the study to the appropriate day (e.g., Days 1 to 6 and Days 1 to 20) and are indicated in the tables as 1 - 6 CHNG and 1 - 20 CHNG.

CODES, ABBREVIATIONS, AND UNITS

General Codes and Abbreviations

Codes for Clinical Pathology

Abbreviations and Units for Clinical Chemistry

Codes for Anatomical Pathology

Note: The following lists of codes, abbreviations, and units are used by CHW. Some, but not necessarily all, of this information may be needed for this report.

General Codes and Abbreviations

WK	Week.
N	Number of measurements in a group.
Mean; MEAN	Arithmetic mean.
SD; S.D.; STAND DEV; STANDARD DEV; sd	Standard deviation.
CHNG	Change.
PRE/DLY	Predose observation; daily observation once dosing is completed.
*	Group mean is significantly different from the mean of the control group (Group 1) at $p \leq 0.05$.
†	Indicates body weight data that was analyzed statistically.
-; NA	No value; not applicable; not present.
P	Present.

General Codes and Abbreviations (Continued)

DISPATCH	Observations dispatched from the in-life module of the Hazleton Path/Tox System (HPTS) to the necropsy module for data collection purposes. Observations are duplicates of the last in-life observations.
TBW	Terminal body weight.
#, No.	Number.
Animal Death Codes:	
1	Terminal sacrifice at Day 6.
T	Terminal sacrifice at Day 20.

Codes for Clinical Pathology**GENERAL CODES**

NS	No sample
QS/QNS	Quantity not sufficient
NR	No repeat (sample volume not sufficient for repeat analysis)
TJ	Technician judgment to repeat test
TE	Technical error (instrument or technician error that results in unacceptable data, e.g., unacceptable instrument output, sample spilled, entry of invalid data)
RE	Recording error (recorded incorrect data, e.g., wrong number, spelling error, incorrect date)
EE	Entry error (incorrect keyboard entry)
SE	Sampling error

Abbreviations and Units for Clinical Chemistry

Test	Abbreviation (Units)
Palmitoyl CoA oxidase	PCOAO (IU/G)

Codes for Anatomical Pathology

Code	Definition
-------------	-------------------

ANIMAL DEATH CODES

1	Terminal sacrifice at Day 6
T	Terminal sacrifice at Day 20

TISSUE ABBREVIATIONS

LN	Lymph node
GL	Gland
STOMACH, GL	Glandular stomach
STOMACH, NONGL	Nonglandular
SALIV GL, MANDIB	Mandibular salivary gland
LN, ANT MES/PANC	Anterior mesenteric/pancreatic lymph node
AUDITORY SEB GL	Auditory sebaceous gland
LACRIMAL GLAND, EX	Exorbital lacrimal gland
HEMATO NEOPLASIA	Hematopoietic neoplasia
LACRIMAL GL, INT	Internal lacrimal gland
CAVITY, ABDOM	Abdominal cavity
SALIV GL, PAROTID	Parotid salivary gland
LN, TRACHEOBRON	Tracheobronchial lymph node

Table 1
Summary of Antemortem Observations

Corning Hazleton Inc.
Madison, Wisconsin USA

PAGE: 1

DAYS 1-20		NUMBER OF ANIMALS AFFECTED			
CATEGORY KEYWORD QUALIFIER	SEX:	-----MALE-----			
	GROUP:	1	2	3	4
	DOSE:	0	5	14	42
	NUMBER:	10	10	10	10
*** TOP OF LIST ***					
APPEARANCE					
SWOLLEN					
NOSE					
		0	1	0	0
*** END OF LIST ***					

Table 2
Summary of Body Weight Data (g)

Corning Hazleton Inc.
Madison, Wisconsin USA

PAGE: 1

DAY	SEX: ----- MALE -----				
	GROUP:	1	2	3	4
	DOSE:	0	5	14	42
	UNITS:	MG/KG	MG/KG	MG/KG	MG/KG
1†	N	10	10	10	10
	MEAN	349	359	372	349
	S.D.	27.5	22.5	16.5	15.0
2	N	10	10	10	10
	MEAN	357	362	378	352
	S.D.	31.1	23.4	16.7	13.8
3	N	10	10	10	10
	MEAN	360	367	382	349
	S.D.	30.5	23.2	18.8	13.8
4	N	10	10	10	10
	MEAN	365	373	382	343
	S.D.	31.7	23.4	18.8	15.6
5	N	10	10	10	10
	MEAN	366	375	376	339
	S.D.	32.8	24.7	23.1	21.4
6	N	10	10	10	10
	MEAN	372	382	372	345
	S.D.	34.6	25.2	28.1	23.6
1-6†	N	10	10	10	10
CHNG	MEAN	23	23	0*	-4*
	S.D.	8.3	6.3	22.1	20.6
CHNG	AS % OF				
CONTROL		-	99	0	-17

† Indicates data was analyzed statistically.
* Denotes statistical significance at ps 0.05.

Table 2
Summary of Body Weight Data (g)

Corning Hazleton Inc.
Madison, Wisconsin USA

PAGE: 2

DAY	SEX: GROUP: DOSE: UNITS:	MALE			
		1 0 MG/KG	2 5 MG/KG	3 14 MG/KG	4 42 MG/KG
7	N	5	5	5	5
	MEAN	375	375	376	351
	S.D.	33.2	25.8	35.9	27.4
8	N	5	5	5	5
	MEAN	374	373	374	355
	S.D.	36.1	27.0	37.6	19.5
9	N	5	5	5	5
	MEAN	389	389	395	374
	S.D.	35.9	26.2	34.0	16.1
10	N	5	5	5	5
	MEAN	384	385	392	373
	S.D.	36.5	29.1	29.4	14.2
11	N	5	5	5	5
	MEAN	386	388	396	376
	S.D.	36.1	28.8	27.7	13.1
12	N	5	5	5	5
	MEAN	403	402	412	390
	S.D.	37.9	28.8	27.9	12.6
13	N	5	5	5	5
	MEAN	407	407	415	394
	S.D.	40.3	29.9	28.3	12.1
14	N	5	5	5	5
	MEAN	413	412	422	400
	S.D.	40.9	31.4	28.8	12.6

Table 2
Summary of Body Weight Data (g)

Corning Hazleton Inc.
Madison, Wisconsin USA

PAGE: 3

DAY	SEX: -----MALE-----				
	GROUP:	1	2	3	4
	DOSE:	0	5	14	42
	UNITS:	MG/KG	MG/KG	MG/KG	MG/KG
15	N	5	5	5	5
	MEAN	414	414	425	405
	S.D.	39.7	30.8	28.1	13.2
16	N	5	5	5	5
	MEAN	413	411	423	404
	S.D.	43.1	32.4	26.6	11.3
17	N	5	5	5	5
	MEAN	421	421	436	414
	S.D.	42.0	32.6	26.1	10.8
18	N	5	5	5	5
	MEAN	428	426	443	419
	S.D.	44.3	33.5	28.8	9.6
19	N	5	5	5	5
	MEAN	431	431	445	424
	S.D.	44.1	36.0	27.7	11.6
20	N	5	5	5	5
	MEAN	438	434	450	431
	S.D.	43.9	33.9	28.8	14.3
1-20†	N	5	5	5	5
CHNG	MEAN	88	83	81	83
	S.D.	20.2	10.2	13.1	8.0
AS % OF					
CONTROL		-	94	92	94

† Indicates data was analyzed statistically.
* Denotes statistical significance at $p < 0.05$.

Table 3
Summary of Clinical Chemistry Data
Males Day 6

DOSE mg/kg		PCOAO IU/G
0.0	MEAN	5
	S.D.	1.4
	N	5
5.0	MEAN	24 *
	S.D.	1.8
	N	5
14.0	MEAN	39 *
	S.D.	3.3
	N	5
42.0	MEAN	39 *
	S.D.	5.4
	N	5

APPENDIX A

**Protocol Deviations
Protocol TP6785
Material Safety Data Sheet**

Protocol Deviations

Protocol. Animals. Weight at Initiation of Treatment. "210 to 250 g"

Actual Procedure. All animals assigned to study exceeded 250 g at initiation: body weights at study initiation ranged from 303 to 395 g.

Protocol. Blood Sample Collections. Frequency. "Predose (1 day before the initial dose administration to Day 1), on Days 9 and 15, at the scheduled sacrifice intervals (Days 6 and 20), and at unscheduled sacrifice intervals."

Actual Procedure. The predose (pretest) blood samples were collected on Day -2.

These deviations are not expected to have affected the results of the study.

Sponsor:

**3M
St. Paul, Minnesota**

PROTOCOL TP6785

Study Title:

**5 Daily Dose Oral Toxicity Study
with T-6669 in Rats**

Date:

December 20, 1996

Performing Laboratory:

**Corning Hazleton Inc.
3301 Kinsman Boulevard
Madison, Wisconsin 53704**

Laboratory Project Identification:

CHW 6329-197

STUDY IDENTIFICATION

**5 Daily Dose Oral Toxicity Study
with T-6669 in Rats**

Test Material	T-6669
Sponsor	3M Toxicology Services Building 220-2E-02, 3M Center St. Paul, Minnesota, 55144-1000
Sponsor Representative	Roger G. Perkins, PhD, DABT 3M Toxicology Services Building 220-2E-02, 3M Center St. Paul, Minnesota, 55144-1000 (612) 733-3222 Facsimile No. (612) 733-1773
Study Director	Susan M. Henwood, MS, DABT Corning Hazleton Inc. P.O. Box 7545 Madison, WI 53707-7545 (608) 241-7221 Facsimile No. (608) 242-2736
Study Location	Corning Hazleton Inc. 3301 Kinsman Boulevard Madison, Wisconsin 53704
Proposed Study Timetable	
In-Life (Experimental) Start Date	January 2, 1997
In-Life Termination Date	January 21, 1997
Experimental Termination Date	To be determined

1. **Study**
5 Daily Dose Oral Toxicity Study with T-6669 in Rats
2. **Purpose**
To assess the oral toxicity produced when the test material is administered by the oral route (gavage) to rats for 5 consecutive days
3. **Regulatory Compliance**
This study will be conducted in accordance with the Food and Drug Administration Good Laboratory Practice Regulations for Nonclinical Laboratory Studies, 21 CFR 58 and the Organisation for Economic Co-operation and Development Principles of Good Laboratory Practice, C(81)30, with the exception that analysis of the test material mixtures for concentration, solubility, homogeneity, and stability will not be conducted.
4. **Quality Assurance**
The protocol, study conduct, and final report will be audited by the Quality Assurance Unit in accordance with the Standard Operating Procedures (SOPs) of the Wisconsin facility of Corning Hazleton Inc. (CHW).
5. **Test Material**
 - A. **Identification**
T-6669
 - B. **Physical Description**
To be documented in the raw data
 - C. **Purity and Stability**
Responsibility of the Sponsor (including under test conditions). Samples of test material and carrier mixtures for concentration, homogeneity, solubility, and stability analyses will not be taken before administration.
 - D. **Storage Conditions**
Room temperature
 - E. **Reserve Samples**
Reserve samples of test material are not required to be taken.

F. Disposition of Test Material

Any unused test material will be returned to the Sponsor after completion of in-life testing.

G. Safety Precautions

As required by CHW SOPs and policies

6. Carrier

A. Identification

Reverse osmosis water (RO water)

B. Physical Description

Clear, colorless liquid

C. Storage Conditions

Ambient

7. Experimental Design

A. Animals

(1) **Species**
Rat

(2) **Strain**
Crl:CD[®](SD)BR VAF/Plus[®]

(3) **Source**
Charles River Laboratories, Inc.

(4) **Age at Initiation of Treatment**
Young adult

(5) **Weight at Initiation of Treatment**
210 to 250 g

(6) **Number and Sex**
40 males

(7) **Identification**
Individually coded passive integrated transponder implants

(8) Husbandry

(a) Housing

Individual (may be group-housed during acclimation)

(b) Food

Certified Rodent Diet #5002 meal (PMI® Feeds, Inc.) *ad libitum*, unless otherwise specified. The food is routinely analyzed by the manufacturer for nutritional components and environmental contaminants.

(c) Water

Ad libitum. Samples of the water are analyzed for total dissolved solids and specified microbiological content and for selected elements, heavy metals, organophosphates, and chlorinated hydrocarbons.

(d) Contaminants

There are no known contaminants in the food or water that would interfere with this study.

(e) Environment

Environmental controls for the animal room will be set to maintain 19° to 25°C (66° to 77°F), a relative humidity of 50% ±20%, and a 12-hour light/12-hour dark cycle.

(f) Acclimation

At least 1 week

(9) Randomization

Via computer-generated random numbers for assignment to groups. The animals will be weighed. The weight variation of the animals selected for the study will not exceed ±2 standard deviations of the mean weights.

(10) Justification

The rat is frequently used in safety evaluation studies as a representative of a rodent species.

B. Group Designations

Group	Dose Level ^a (mg/kg)	Number of Males ^b
1 (Control)	0.0	10
2 (Low)	5.0	10
3 (Mid)	14.0	10
4 (High)	42.0	10

- a The control group will receive RO water only. The dose volume will be 5 mL/kg.
- b Five animals in each group will be sacrificed for palmitoyl-CoA oxidase analysis on Day 6. The remaining animals in each group will be observed for reversibility, persistence, or delayed occurrence of toxic effects until sacrificed on Day 20.

C. Dosing Procedures

- (1) **Dosing Route**
Oral gavage
- (2) **Reason for Dosing Route**
Historically, the oral route has been the route of choice for administering a known amount of test material.
- (3) **Dosing Duration**
Five consecutive days of dose administration. The first day of treatment will be designated as Day 1. The doses will be administered at approximately the same time each day.
- (4) **Dose Preparation**
The control animals will receive RO water only. Test mixtures will be prepared on each day of administration. The test material will be mixed in RO water at a specific concentration for each dose level. The dose for each animal for each day of dosing will be based on the most recently recorded body weight. The prepared test mixtures will be stored at room temperature until administration. During dose administration, homogeneous test material mixtures will be maintained using a magnetic stir plate and stir bar.

D. Observation of Animals

(1) Clinical Observations

Twice daily (a.m. and p.m.) for mortality through Day 20 (a.m. mortality only on Day 20. Animals will be observed predose; at approximately 1, 2.5, and 4 hours after each dose; and daily thereafter for clinical signs. Observations may be extended when directed by the study director.

(2) Body Weights

For randomization, before initiation of treatment (Day 1), daily thereafter, at scheduled sacrifices (Days 6 and 20), and at death (when survival exceeds 1 day).

(3) Blood Sample Collections

(a) Frequency

Predose (1 day before the initial dose administration to Day 1), on Days 9 and 15, at the scheduled sacrifice intervals (Days 6 and 20), and at unscheduled sacrifice intervals

(b) Method of Collection/Number of Animals

Animals will not be fasted overnight for scheduled collections. Blood samples (approximately 1.5 mL) will be collected from a jugular vein of all animals at the predose interval and on Days 9 and 15.

A blood sample (as much as possible) will also be collected from the posterior vena cava of each animal sacrificed in a moribund condition (if possible) and from each animal at scheduled sacrifices (Days 6 and 20).

The blood samples will be stored at room temperature and then centrifuged; the separate serum and cellular fractions will be stored in a freezer set to maintain $-20^{\circ}\text{C} \pm 10^{\circ}$. The serum and cellular fractions will be packed on dry ice and sent to the Sponsor within 1 week after in-life termination. The Sponsor is responsible for the retention and disposition of the samples.

The serum and cellular fraction samples will be shipped to:

James D. Johnson
3M E.T. & S
Bldg. 2-3E-09
935 Bush Avenue
St. Paul, Minnesota 55106

James D. Johnson or his alternate will be notified regarding the shipment of the samples.

E. Palmitoyl-CoA Oxidase Analysis

- (1) **Frequency and Number of Animals**
Five animals/group on Day 6 in random order

- (2) **Method of Collection**
On the day of the scheduled sacrifice, nonfasted animals will be anesthetized with sodium pentobarbital, weighed, and exsanguinated. The abdominal cavity of each animal will be opened, and the liver will be removed and weighed. The right lateral lobe of the liver will be collected from each animal, weighed, and flash-frozen in liquid nitrogen. The liver tissue will be stored in a freezer set to maintain $-70^{\circ}\text{C} \pm 10^{\circ}$ until analyzed by CHW for palmitoyl-CoA oxidase activity.

The remaining liver will be collected, weighed, and placed into a freezer set to maintain $-20^{\circ}\text{C} \pm 10^{\circ}$. The livers will be packed on dry ice and shipped to James D. Johnson within 1 week after in-life termination. The Sponsor is responsible for the retention and disposition of the livers. Animals will be discarded after scheduled liver tissue collection.

Any animal selected for palmitoyl-CoA oxidase analysis that dies or is sacrificed in a moribund condition will be subjected to an abbreviated gross necropsy examination, and all abnormalities will be recorded. Tissues will be discarded after necropsy.

F. Termination (animals not designated for palmitoyl-CoA oxidase analysis)

(1) Unscheduled Sacrifices and Deaths

Any animal that is found dead or is sacrificed in a moribund condition will be subjected to an abbreviated gross necropsy examination and all abnormalities will be recorded. Animals to be sacrificed will be anesthetized with sodium pentobarbital, weighed, bled via the posterior vena cava, and exsanguinated. The whole liver will be collected, weighed, and placed into a freezer set to maintain $-20^{\circ}\text{C} \pm 10^{\circ}$. The livers will be packed on dry ice and shipped to James D. Johnson within 1 week after in-life termination. The Sponsor is responsible for the retention or disposition of the livers. The animals will be discarded after necropsy.

(2) Scheduled Sacrifice

On Day 20, the animals will be anesthetized with sodium pentobarbital, weighed, bled via the posterior vena cava, exsanguinated, and subjected to an abbreviated gross necropsy examination. The animals will be necropsied in random order, and all abnormalities will be recorded. The whole liver will be collected, weighed, and placed into a freezer set to maintain $-20^{\circ}\text{C} \pm 10^{\circ}$. The livers will be packed on dry ice and shipped to James D. Johnson within 1 week after in-life termination. The Sponsor is responsible for the retention or disposition of the livers. The animals will be discarded after necropsy.

G. Statistical Analyses

Statistical analyses will be performed on Day 1 body weights, cumulative body weight gains (Day 2 through termination), and palmitoyl-CoA oxidase levels. A description of statistical analyses is in Attachment 1. Groups 2 through 4 will be compared with Group 1 (control).

8. Report

A final report including those items listed below will be submitted.

Description of the control and test materials

Description of the test system

Procedures

Dates of experimental initiation and termination

Tabulation of mortality data by dose level

Description of any toxic effects

Tabulation of mean body weights by dose level

Macroscopic observations

Pathology report
Palmitoyl-CoA oxidase levels
Statistical findings

9. Location of Raw Data, Records, and Final Report

Original data, or copies thereof, will be available at CHW to facilitate auditing the study during its progress and before acceptance of the final report. When the final report is completed, all original paper data, including those items listed below will be retained in the archives of CHW for a period of 1 year following signing of the final report. One year after signing of the final report, all of the aforementioned materials will be sent to the Sponsor, and a return fee will be charged. The Sponsor may elect to have the materials retained in the CHW archives for an additional time and CHW will charge a storage fee. If the Sponsor chooses to have CHW dispose of the materials, a disposal fee will be charged.

Protocol and protocol amendments
Dose preparation records
In-life records
 Body weights
 Randomization data
 Dose administration
 Antemortem observations
Anatomical pathology records
Palmitoyl-CoA oxidase analysis records
Statistical records
Sample collection records
Shipping records
Study correspondence
Final report (original signed copy)

The following supporting records will be retained at CHW but will not be archived with the study data.

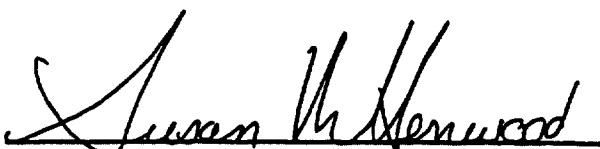
Animal receipt and acclimation records
Water analysis records
Animal room temperature and humidity records
Refrigerator and freezer temperature records
Instrument calibration and maintenance records

PROTOCOL APPROVAL



Roger G. Perkins, PhD
Diplomate, ABT
Sponsor Representative
3M

12/30/96
Date



Susan M. Henwood, MS
Diplomate, ABT
Study Director
Toxicology
Corning Hazleton Inc.

12/20/96
Date



Representative
Quality Assurance Unit
Corning Hazleton Inc.

12-20-96
Date

ATTACHMENT 1

Statistical Methods

The statistical methods that will be used are described below. Levene's test (Levene, 1960) will be done to test for variance homogeneity. In the case of heterogeneity of variance at $p \leq 0.05$, transformations will be used to stabilize the variance.

Analysis of variance [ANOVA (Winer, 1971a)] will be done on the homogeneous or transformed data. If the ANOVA is significant, Dunnett's t-test (Dunnett, 1964) will be used for pairwise comparisons between treated and control groups.

One-way ANOVA will be used (if applicable) to analyze Day 1 body weights, cumulative body weight gains (Days 2 through termination), and palmitoyl-CoA oxidase levels.

If the ANOVA shows significance for body weights at initiation of treatment (Day 1), one-way analysis of covariance [ANCOVA (Winer, 1971b)] will be used to analyze body weights, with the initial body weights as the covariate. Although Levene's test for variance homogeneity will be done (see above), no transformations will be used because covariance adjustment removes extraneous heterogeneity. If the ANCOVA is significant, least squares means t-test (SAS, 1989) will be used for pairwise comparisons between treated and control groups.

Group comparisons will be evaluated at the 5.0% two-tailed probability level.

References

Dunnett, C. W., "New Tables for Multiple Comparisons with a Control," Biometrics, 20:482-491 (1964).

Levene, H., "Robust Tests for Equality of Variances," Contributions to Probability and Statistics, (eds.) I. Olkin et al., Ch. 25, pp. 278-292, Stanford University Press: Stanford, California (1960).

SAS Institute Inc., SAS/STAT® User's Guide, Version 6, Fourth Ed., Vol. 2, p. 909, SAS Institute Inc.: Cary, North Carolina (1989).

Attachment 1 (Continued)

Winer, B. J., "Design and Analysis of Single-Factor Experiments," Statistical Principles in Experimental Design, Second Ed., Ch. 3, pp. 149-260, McGraw-Hill: New York, New York (1971a).

Winer, B. J., "Analysis of Covariance," Statistical Principles in Experimental Design, Second Ed., Ch. 10, pp. 752-812, McGraw-Hill: New York, New York (1971b).

**MATERIAL SAFETY
DATA SHEET**

3M
3M Center
St. Paul, Minnesota
55144-1000
(612) 733-1110

CHW 6329-197

2c: T-6669

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DIVISION: SPECIALTY CHEMICALS DIVISION

TRADE NAME:

FC-143 FLUORAD Brand Fluorochemical Surfactant

ID NUMBER/U.P.C.:

98-0211-0008-0 00-51135-09138-8 98-0211-0891-9 00-51135-09365-8
98-0211-5489-7 00-51135-02941-1 98-0211-6581-0 00-51135-10405-7
98-0211-7394-7 00-51135-10762-1 ZF-0002-0378-4

ISSUED: August 23, 1996

SUPERSEDES: May 20, 1996

DOCUMENT: 10-3808-2

1. INGREDIENT	C.A.S. NO.	PERCENT
AMMONIUM PERFLUOROOCTANOATE.....	3825-26-1	93 - 97
AMMONIUM PERFLUOROHEPTANOATE.....	6130-43-4	1 - 3
AMMONIUM PERFLUOROPENTANOATE.....	68259-11-0	1 - 3
AMMONIUM PERFLUOROHXANOATE.....	21615-47-4	0.1 - 1

2. PHYSICAL DATA

BOILING POINT:..... N/A
VAPOR PRESSURE:..... N/A
VAPOR DENSITY:..... N/A
EVAPORATION RATE:..... N/A
SOLUBILITY IN WATER:..... apprec.
SPECIFIC GRAVITY:..... 0.4 - 0.5 Water=1
(Bulk)
PERCENT VOLATILE:..... N/A
pH:..... ca. 5
(0.5% Aqueous)
VISCOSITY:..... N/D
MELTING POINT:..... N/A

APPEARANCE AND ODOR:

Light colored powder; slight odor.

Abbreviations: N/D - Not Determined N/A - Not Applicable

.....
3. FIRE AND EXPLOSION HAZARD DATA
.....

FLASH POINT:..... Non-flammable
FLAMMABLE LIMITS - LEL:....., N/A
FLAMMABLE LIMITS - UEL:..... N/A
AUTOIGNITION TEMPERATURE:..... N/A

EXTINGUISHING MEDIA:

Water, Carbon dioxide, Dry chemical, Foam

SPECIAL FIRE FIGHTING PROCEDURES:

Wear full protective clothing, including helmet, self-contained, positive pressure or pressure demand breathing apparatus, bunker coat and pants, bands around arms, waist and legs, face mask, and protective covering for exposed areas of the head.

UNUSUAL FIRE AND EXPLOSION HAZARDS:

See Hazardous Decomposition section for products of combustion.

.....
4. REACTIVITY DATA
.....

STABILITY: Stable

INCOMPATIBILITY - MATERIALS/CONDITIONS TO AVOID:

Not Applicable

HAZARDOUS POLYMERIZATION: Hazardous polymerization will not occur.

HAZARDOUS DECOMPOSITION PRODUCTS:

Carbon Monoxide and Carbon Dioxide, Oxides of Nitrogen, Hydrogen Fluoride, Ammonia.

.....
5. ENVIRONMENTAL INFORMATION
.....

SPILL RESPONSE:

Observe precautions from other sections. Collect spilled material. Use wet sweeping compound or water to avoid dusting. Clean up residue. Place in a closed container.

RECOMMENDED DISPOSAL:

Incinerate in an industrial or commercial facility in the presence of a combustible material. Combustion products will include HF. Disposal alternative: Dispose of waste product in a facility permitted to accept chemical waste.

.....
Abbreviations: N/D - Not Determined N/A - Not Applicable

.....
5. ENVIRONMENTAL INFORMATION (continued)
.....

ENVIRONMENTAL DATA:

Chemical Oxygen Demand (COD) = Nil(.00070 g/g); 20-Day Biochemical Oxygen Demand (BOD20) = Nil; Theoretical Oxygen Demand (ThOD) = 0.32 g/g; Fathead Minnow (*Pimephales promelas*) 96-hr LC50 = 740 mg/L; Water flea (*Daphnia magna*) 48-hr EC50 = 460 mg/L; Green Algae (*Selenastrum capricornutum*) 14-day EC50 (cell dry weight) = 73 mg/L; Green Algae (*Selenastrum capricornutum*) 14-day EC50 (cell count) = 43 mg/L

bioconcentration factor (BCF) for ammonium perfluorooctanoate (PFO) = 1.8

REGULATORY INFORMATION:

Volatile Organic Compounds: N/A.
VOC Less H2O & Exempt Solvents: N/A.

Since regulations vary, consult applicable regulations or authorities before disposal. U.S. EPA Hazardous Waste Number = None (Not U.S. EPA Hazardous).

The components of this product are in compliance with the chemical registration requirements of TSCA, EINECS, CDSL, AICS, MITI and KTCCL.

EPCRA HAZARD CLASS:

FIRE HAZARD: No PRESSURE: No REACTIVITY: No ACUTE: Yes CHRONIC: Yes

.....
6. SUGGESTED FIRST AID
.....

EYE CONTACT:

Immediately flush eyes with large amounts of water for at least 15 minutes. Get immediate medical attention.

SKIN CONTACT:

Flush skin with large amounts of water. If irritation persists, get medical attention.

INHALATION:

If signs/symptoms occur, remove person to fresh air. If signs/symptoms continue, call a physician.

IF SWALLOWED:

Do not induce vomiting. Drink two glasses of water. Call a physician.

.....
Abbreviations: N/D - Not Determined N/A - Not Applicable

7. PRECAUTIONARY INFORMATION

EYE PROTECTION:

Avoid eye contact. Wear vented goggles.

SKIN PROTECTION:

Avoid skin contact. Wear appropriate gloves when handling this material. A pair of gloves made from the following material(s) are recommended: butyl rubber. Use one or more of the following personal protection items as necessary to prevent skin contact: head covering, coveralls. Protective garments (other than gloves) should be made of either of the following materials: polyethylene/polyvinylidene chloride (Saranex).

RECOMMENDED VENTILATION:

Use with appropriate local exhaust ventilation. Provide sufficient ventilation to maintain emissions below recommended exposure limits. If exhaust ventilation is not adequate, use appropriate respiratory protection.

RESPIRATORY PROTECTION:

Avoid breathing of airborne material. Select one of the following NIOSH approved respirators based on airborne concentration of contaminants and in accordance with OSHA regulations: full-face high-efficiency filter respirator, full-face supplied air respirator.

PREVENTION OF ACCIDENTAL INGESTION:

Do not eat, drink or smoke when using this product. Wash exposed areas thoroughly with soap and water. Wash hands after handling and before eating.

RECOMMENDED STORAGE:

Do not store containers on their sides. Store at room temperature. Keep container dry. Keep container closed when not in use.

****PREVENT MOISTURE CONTAMINATION TO KEEP POWDER FREE FLOWING.****

FIRE AND EXPLOSION AVOIDANCE:

Keep container tightly closed. No smoking while handling this material.

HMIS HAZARD RATINGS: HEALTH: 3 FLAMMABILITY: 0 REACTIVITY: 0
PERSONAL PROTECTION: X (See precautions, section 7.)

EXPOSURE LIMITS

INGREDIENT	VALUE	UNIT	TYPE	AUTH	SKIN*
AMMONIUM PERFLUOROOCTANOATE.....	0.01	MG/M3	TWA	ACGIH	Y
AMMONIUM PERFLUOROHEPTANOATE.....	0.1	MG/M3	TWA	3M	Y
AMMONIUM PERFLUOROPENTANOATE.....	0.1	MG/M3	TWA	3M	Y
AMMONIUM PERFLUOROHEXANOATE.....	0.1	MG/M3	TWA	3M	Y

Abbreviations: N/D - Not Determined N/A - Not Applicable

EXPOSURE LIMITS (continued)

INGREDIENT	VALUE	UNIT	TYPE	AUTH	SKIN*
------------	-------	------	------	------	-------

* SKIN NOTATION: Listed substances indicated with 'Y' under SKIN refer to the potential contribution to the overall exposure by the cutaneous route including mucous membrane and eye, either by airborne or, more particularly, by direct contact with the substance. Vehicles can alter skin absorption.

SOURCE OF EXPOSURE LIMIT DATA:

- ACGIH: American Conference of Governmental Industrial Hygienists
- 3M: 3M Recommended Exposure Guidelines

8. HEALTH HAZARD DATA

EYE CONTACT:

Moderate Eye Irritation: signs/symptoms can include redness, swelling, pain, tearing, and hazy vision.

Airborne product may cause eye injury consisting of corneal opacity.

SKIN CONTACT:

Product is not expected to be irritating to the skin.

Mild Skin Irritation (after prolonged or repeated contact): signs/symptoms can include redness, swelling, and itching.

May be absorbed through the skin and persist in the body for an extended time.

INHALATION:

Illness requiring medical attention may result from a single exposure by inhalation to moderate quantities of this material.

May be absorbed by inhalation and persist in the body for an extended time.

Single overexposure, above recommended guidelines, may cause:

Irritation (upper respiratory): signs/symptoms can include soreness of the nose and throat, coughing and sneezing.

Prolonged or repeated overexposure, above recommended guidelines, may cause:

Liver Effects: signs/symptoms can include yellow skin(jaundice) and tenderness of upper abdomen.

Repeated inhalation of airborne product above the exposure guideline can result in elevated organofluoride levels in the blood.

Abbreviations: N/D - Not Determined N/A - Not Applicable

B. HEALTH HAZARD DATA (continued)

IF SWALLOWED:

Ingestion is not a likely route of exposure to this product.

Illness may result from a single swallowing of a moderate quantity of this material.

CANCER:

A mixture of ammonium perfluorooctanoate, ammonium perfluoroheptanoate, ammonium perfluoropentanoate and ammonium perfluorohexanoate, that was 93 to 97% AMMONIUM PERFLUOROOCTANOATE (3825-26-1) was fed to albino rats for 2 years, no compound induced carcinogenicity was found in the study. There were statistically significant compound related benign testicular tumors. In a second two-year study there were statistically significant compound related benign tumors in the liver, pancreas, and testis when compared to ad libitum and pair-fed controls. Based on the current knowledge, these findings have no human health implications. (1983 and 1993 studies conducted jointly by 3M and DuPont).

MUTAGENICITY:

Not mutagenic in invitro mutagenicity assays. Did not cause cell transformation in a mammalian cell transformation assay.

REPRODUCTIVE/DEVELOPMENTAL TOXINS:

Not teratogenic in rabbits by oral administration. Not teratogenic to rats by gavage or inhalation exposures.

OTHER HEALTH HAZARD INFORMATION:

A 3M Product Toxicity Summary Sheet is available.

SECTION CHANGE DATES

HEADING	SECTION CHANGED SINCE May 20, 1996	ISSUE
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Abbreviations: N/D - Not Determined N/A - Not Applicable

MSDS: FC-143 FLUORAD Brand Fluorochemical Surfactant
August 23, 1996

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APPENDIX B

Individual Antemortem Observations

Individual Body Weight Data (g)

Individual Body Weight Gain Data (g)

Appendix B

Individual Antemortem Observations
(Only Findings Other Than Normal)Corning Hazleton Inc.
Madison, Wisconsin USA

PAGE: 1

ANIMAL NUMBER	DEATH CODE	WK OF DEATH	CATEGORY KEYWORD QUALIFIER	GROUP: M2	DOSE: 5 MG/KG	DAYS 1-20	DAY	'C' - COMMENTS LISTED AT END OF OBSERVATIONS FOR SEX/GROUP							
								AM CHECK	PRE/DLY	2.5 HR	DISPATCH				
								PM CHECK	1.0 HR	4.0 HR	UNSCHE				
C77265	T	3	APPEARANCE SWOLLEN NOSE				2	-	-	P	P	P	P	-	-

Appendix B
Individual Body Weight Data (g)

Corning Hazleton Inc.
Madison, Wisconsin USA

PAGE: 1

ANIMAL NUMBER	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	DAY 8	DAY 9	DAY 10
GROUP: MALE 1 - 0 MG/KG										
C77251	380	392	392	400	399	408				
C77252	376	384	389	396	397	404				
C77253	359	377	379	381	390	390	391	397	407	404
C77254	344	350	355	361	361	367	371	367	384	378
C77255	311	316	315	318	318	320	321	315	330	324
C77256	333	335	345	342	345	352				
C77257	342	352	358	364	365	374				
C77258	356	365	366	374	371	381	383	386	404	398
C77259	303	304	309	314	311	312				
C77260	382	392	395	399	401	408	409	406	422	417
GROUP: MALE 2 - 5 MG/KG										
C77261	390	390	397	405	405	410				
C77262	384	389	393	397	399	410	411	410	426	429
C77263	345	356	361	370	365	379				
C77264	360	366	364	375	378	384				
C77265	341	342	350	357	361	363	368	365	381	374
C77266	351	352	357	362	361	368	375	367	385	377
C77267	386	392	397	404	411	417				
C77268	320	319	325	331	330	335	339	337	354	351
C77269	348	351	355	359	361	371				
C77270	362	365	371	372	375	378	380	385	398	395
GROUP: MALE 3 - 14 MG/KG										
C77271	345	349	350	349	345	341	354	355	371	369
C77272	349	359	360	363	350	347				
C77273	395	404	412	413	411	407	417	421	439	434
C77274	360	369	371	374	371	378	387	382	401	394
C77275	382	389	393	396	389	391				

Appendix B

Individual Body Weight Data (g)

Corning Hazleton Inc.
Madison, Wisconsin USA

PAGE: 2

ANIMAL NUMBER	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	DAY 8	DAY 9	DAY 10
GROUP: MALE 3 - 14 MG/KG										
C77276	370	373	377	377	369	366				
C77277	383	387	391	386	368	346				
C77278	376	375	380	376	360	339	326	322	352	360
C77279	369	378	385	385	384	388	395	392	410	404
C77280	388	396	402	403	412	415				
GROUP: MALE 4 - 42 MG/KG										
C77281	359	366	361	359	362	367	371	369	387	385
C77282	324	326	322	312	295	316				
C77283	345	352	354	331	308	294	303	321	348	351
C77284	353	350	351	352	347	356	366	367	386	383
C77285	332	335	331	328	332	337				
C77286	352	354	341	340	343	352	357	359	380	378
C77287	331	342	345	347	349	356	358	357	371	366
C77288	362	367	357	358	352	371				
C77289	367	365	364	359	356	347				
C77290	361	360	360	347	342	351				

Appendix B

Individual Body Weight Data (g)

Corning Hazleton Inc.
Madison, Wisconsin USA

PAGE: 3

ANIMAL NUMBER	DAY 11	DAY 12	DAY 13	DAY 14	DAY 15	DAY 16	DAY 17	DAY 18	DAY 19	DAY 20
GROUP: MALE 1 - 0 MG/KG										
C77253	408	421	428	436	437	445	443	456	461	466
C77254	381	396	400	404	405	408	417	424	424	431
C77255	326	340	341	346	349	341	350	353	358	365
C77258	402	419	424	432	430	426	443	446	445	454
C77260	415	437	444	448	449	445	453	461	467	474
GROUP: MALE 2 - 5 MG/KG										
C77262	430	444	449	458	458	457	469	476	482	482
C77265	377	393	396	400	403	399	411	414	419	421
C77266	381	397	403	407	412	403	417	421	424	431
C77268	352	365	368	373	373	370	379	384	384	390
C77270	398	411	419	424	422	425	429	433	444	447
GROUP: MALE 3 - 14 MG/KG										
C77271	373	384	386	389	395	390	403	406	408	411
C77273	438	454	456	463	468	461	473	484	483	489
C77274	396	411	414	423	422	419	433	438	444	441
C77278	369	390	392	402	407	410	424	433	433	446
C77279	403	421	427	434	434	434	447	455	456	463
GROUP: MALE 4 - 42 MG/KG										
C77281	383	399	404	410	417	410	424	432	439	448
C77283	360	375	382	386	393	391	402	409	411	418
C77284	394	405	409	416	421	419	426	425	433	443
C77286	373	389	394	398	402	405	415	418	420	427
C77287	369	380	383	391	393	395	405	411	417	417

Appendix B

Individual Body Weight Gain Data (g)
Days 1 - 6Corning Hazleton Inc.
Madison, Wisconsin USA

PAGE: 1

ANIMAL NUMBER	DAY 1-2	DAY 2-3	DAY 3-4	DAY 4-5	DAY 5-6	TOTAL 1-6
------------------	------------	------------	------------	------------	------------	--------------

GROUP: MALE 1 - 0 MG/KG

C77251	12	0	8	-1	9	28
C77252	8	5	7	1	7	28
C77253	18	2	2	9	0	31
C77254	6	5	6	0	6	23
C77255	5	-1	3	0	2	9
C77256	2	10	-3	3	7	19
C77257	10	6	6	1	9	32
C77258	9	1	8	-3	10	25
C77259	1	5	5	-3	1	9
C77260	10	3	4	2	7	26

GROUP: MALE 2 - 5 MG/KG

C77261	0	7	8	0	5	20
C77262	5	4	4	2	11	26
C77263	11	5	9	-5	14	34
C77264	6	-2	11	3	6	24
C77265	1	8	7	4	2	22
C77266	1	5	5	-1	7	17
C77267	6	5	7	7	6	31
C77268	-1	6	6	-1	5	15
C77269	3	4	4	2	10	23
C77270	3	6	1	3	3	16

GROUP: MALE 3 - 14 MG/KG

C77271	4	1	-1	-4	-4	-4
C77272	10	1	3	-13	-3	-2
C77273	9	8	1	-2	-4	12
C77274	9	2	3	-3	7	18
C77275	7	4	3	-7	2	9

Appendix B

Individual Body Weight Gain Data (g)
Days 1 - 6Corning Hazleton Inc.
Madison, Wisconsin USA

PAGE: 2

ANIMAL NUMBER	DAY 1-2	DAY 2-3	DAY 3-4	DAY 4-5	DAY 5-6	TOTAL 1-6
------------------	------------	------------	------------	------------	------------	--------------

GROUP: MALE 3 - 14 MG/KG

C77276	3	4	0	-8	-3	-4
C77277	4	4	-5	-18	-22	-37
C77278	-1	5	-4	-16	-21	-37
C77279	9	7	0	-1	4	19
C77280	8	6	1	9	3	27

GROUP: MALE 4 - 42 MG/KG

C77281	7	-5	-2	3	5	8
C77282	2	-4	-10	-17	21	-8
C77283	7	2	-23	-23	-14	-51
C77284	-3	1	1	-5	9	3
C77285	3	-4	-3	4	5	5
C77286	2	-13	-1	3	9	0
C77287	11	3	2	2	7	25
C77288	5	-10	1	-6	19	9
C77289	-2	-1	-5	-3	-9	-20
C77290	-1	0	-13	-5	9	-10

Appendix B

Individual Body Weight Gain Data (g)
Days 1 - 20Corning Hazleton Inc.
Madison, Wisconsin USA

PAGE: 1

ANIMAL NUMBER	DAY 1-2	DAY 2-3	DAY 3-4	DAY 4-5	DAY 5-6	DAY 6-7	DAY 7-8	DAY 8-9	DAY 9-10	DAY 10-11
GROUP: MALE 1 - 0 MG/KG										
C77253	18	2	2	9	0	1	6	10	-3	4
C77254	6	5	6	0	6	4	-4	17	-6	3
C77255	5	-1	3	0	2	1	-6	15	-6	2
C77258	9	1	8	-3	10	2	3	18	-6	4
C77260	10	3	4	2	7	1	-3	16	-5	-2
GROUP: MALE 2 - 5 MG/KG										
C77262	5	4	4	2	11	1	-1	16	3	1
C77265	1	8	7	4	2	5	-3	16	-7	3
C77266	1	5	5	-1	7	7	-8	18	-8	4
C77268	-1	6	6	-1	5	4	-2	17	-3	1
C77270	3	6	1	3	3	2	5	13	-3	3
GROUP: MALE 3 - 14 MG/KG										
C77271	4	1	-1	-4	-4	13	1	16	-2	4
C77273	9	8	1	-2	-4	10	4	18	-5	4
C77274	9	2	3	-3	7	9	-5	19	-7	2
C77278	-1	5	-4	-16	-21	-13	-4	30	8	9
C77279	9	7	0	-1	4	7	-3	18	-6	-1
GROUP: MALE 4 - 42 MG/KG										
C77281	7	-5	-2	3	5	4	-2	18	-2	-2
C77283	7	2	-23	-23	-14	9	18	27	3	9
C77284	-3	1	1	-5	9	10	1	19	-3	11
C77286	2	-13	-1	3	9	5	2	21	-2	-5
C77287	11	3	2	2	7	2	-1	14	-5	3

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Appendix B

Individual Body Weight Gain Data (g)
Days 1 - 20Corning Hazleton Inc.
Madison, Wisconsin USA

PAGE: 2

ANIMAL NUMBER	DAY 11-12	DAY 12-13	DAY 13-14	DAY 14-15	DAY 15-16	DAY 16-17	DAY 17-18	DAY 18-19	DAY 19-20	TOTAL 1-20
GROUP: MALE 1 - 0 MG/KG										
C77253	13	7	8	1	8	-2	13	5	5	107
C77254	15	4	4	1	3	9	7	0	7	87
C77255	14	1	5	3	-8	9	3	5	7	54
C77258	17	5	8	-2	-4	17	3	-1	9	98
C77260	22	7	4	1	-4	8	8	6	7	92
GROUP: MALE 2 - 5 MG/KG										
C77262	14	5	9	0	-1	12	7	6	0	98
C77265	16	3	4	3	-4	12	3	5	2	80
C77266	16	6	4	5	-9	14	4	3	7	80
C77268	13	3	5	0	-3	9	5	0	6	70
C77270	13	8	5	-2	3	4	4	11	3	85
GROUP: MALE 3 - 14 MG/KG										
C77271	11	2	3	6	-5	13	3	2	3	66
C77273	16	2	7	5	-7	12	11	-1	6	94
C77274	15	3	9	-1	-3	14	5	6	-3	81
C77278	21	2	10	5	3	14	9	0	13	70
C77279	18	6	7	0	0	13	8	1	7	94
GROUP: MALE 4 - 42 MG/KG										
C77281	16	5	6	7	-7	14	8	7	9	89
C77283	15	7	4	7	-2	11	7	2	7	73
C77284	11	4	7	5	-2	7	-1	8	10	90
C77286	16	5	4	4	3	10	3	2	7	75
C77287	11	3	8	2	2	10	6	6	0	86

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APPENDIX C

Individual Clinical Chemistry Data
(Day 6 Palmitoyl CoA oxidase activity)

Appendix C
Individual Clinical Chemistry Data

Males Day 6

ANIMAL NUMBER -----	PCOAO IU/G -----	
Group: 1	Dose Level: 0.0	Dosage Unit: mg/kg
C77251	4	
C77252	7	
C77256	6	
C77257	4	
C77259	4	
MEAN	5	
S.D.	1.4	
N	5	
Group: 2	Dose Level: 5.0	Dosage Unit: mg/kg
C77261	24	
C77263	24	
C77264	27	
C77267	24	
C77269	22	
MEAN	24	
S.D.	1.8	
N	5	
Group: 3	Dose Level: 14.0	Dosage Unit: mg/kg
C77272	41	
C77275	38	
C77276	42	
C77277	34	
C77280	41	
MEAN	39	
S.D.	3.3	
N	5	

Appendix C

Individual Clinical Chemistry Data

Males Day 6

ANIMAL NUMBER -----	PCOAO IU/G -----	
Group: 4	Dose Level: 42.0	Dosage Unit: mg/kg
C77282	40	
C77285	42	
C77288	45	
C77289	33	
C77290	33	
MEAN	39	
S.D.	5.4	
N	5	

APPENDIX D

Individual Animal Liver Weight Values (g) - Day 6 Sacrifice

Individual Animal Pathology Data - Day 20 Sacrifice

APPENDIX D

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Individual Animal Liver Weight Values (g)

Day 6 Sacrifice

Corning Hazleton Inc.
Madison, Wisconsin USA

PAGE: 1

TABLE INCLUDES:

SEX=ALL; GROUP=ALL; WEEKS=ALL
DEATH=1; SUBSET=ALL

ORGAN ABBREVIATION: LI0 - WHOLE LIVER, LI1 - LIVER, RIGHT LATERAL LOBE, LI2 - REMAINING LIVER

SEX	DOSE GROUP	ANIMAL NUMBER	TERMINAL BODY WT (g)	LI0	LI1	LI2
<u>0.0 mg/kg</u>						
M	1	C77251	400.4	17.7972	2.8690	14.8583
M	1	C77252	394.5	16.4199	2.5533	13.8876
M	1	C77256	341.5	16.7503	2.4016	14.2603
M	1	C77257	368.5	17.8283	2.5079	15.1980
M	1	C77259	306.8	11.9291	1.7788	10.1344
<u>5.0 mg/kg</u>						
M	2	C77261	403.4	24.1163	3.4006	20.5802
M	2	C77263	370.1	20.6942	2.8659	17.6999
M	2	C77264	378.9	21.0651	2.7795	18.2230
M	2	C77267	408.6	24.2954	3.7472	20.4106
M	2	C77269	363.6	18.5405	2.3964	16.0782
<u>14.0 mg/kg</u>						
M	3	C77272	343.2	23.2873	3.1381	20.0752
M	3	C77275	380.2	24.3657	3.8794	20.4197
M	3	C77276	360.7	20.5304	2.7287	17.7335
M	3	C77277	346.9	16.1233	2.4445	13.6463
M	3	C77280	411.8	28.2782	4.6752	23.4964
<u>42.0 mg/kg</u>						
M	4	C77282	306.8	17.2123	2.3432	14.8110
M	4	C77285	328.8	22.4106	3.6637	18.6428
M	4	C77288	363.5	23.7435	3.3208	20.3694
M	4	C77289	344.7	21.1160	3.2493	17.7983
M	4	C77290	345.7	24.1904	3.5439	20.5800

APPENDIX D
Individual Animal Pathology Data
Day 20 Sacrifice

CHW 6329-197

Corning Hazleton Inc.
Madison, Wisconsin USA

PAGE: 1

ANIMAL NUMBER: C77253 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 461.8 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 10:48 PROSECTOR: DEBBIE PIRKEL RECORDER: DEBBIE PIRKEL
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	18.6810	4.0453 %		WEIGHT TAKEN
RT LAT LOBE LIV (LI1)				NOT TAKEN
REMAINING LIV (LI2)				NOT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
GENERAL COMMENT (GC)	*** GROSS PATHOLOGY OBSERVATIONS *** -NO MACROSCOPIC LESIONS -ABBR NEC PERFORM	

APPENDIX D

CHW 6329-197

Individual Animal Pathology Data

Day 20 Sacrifice

Corning Hazleton Inc.
Madison, Wisconsin USA

PAGE: 2

ANIMAL NUMBER: C77254 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 423.7 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 10:40 PROSECTOR: DEBBIE PIRKEL RECORDER: DEBBIE PIRKEL
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	15.3258	3.6171 %		WEIGHT TAKEN
RT LAT LOBE LIV (LI1)				NOT TAKEN
REMAINING LIV (LI2)				NOT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
GENERAL COMMENT (GC)	-NO MACROSCOPIC LESIONS -ABBR NEC PERFORM	

APPENDIX D

CHW 6329-197

Individual Animal Pathology Data

Day 20 Sacrifice

Corning Hazleton Inc.
Madison, Wisconsin USA

PAGE: 3

ANIMAL NUMBER: C77255 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 355.3 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 10:53 PROSECTOR: DEBBIE PIRKEL RECORDER: DEBBIE PIRKEL
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	13.7530	3.8708 %		WEIGHT TAKEN
RT LAT LOBE LIV (LI1)				NOT TAKEN
REMAINING LIV (LI2)				NOT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES
GENERAL COMMENT (GC)
-NO MACROSCOPIC LESIONS
-ABBR NEC PERFORM

APPENDIX D
Individual Animal Pathology Data
Day 20 Sacrifice

CHW 6329-197

Corning Hazleton Inc.
Madison, Wisconsin USA

PAGE: 4

ANIMAL NUMBER: C77258 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 444.9 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 10:13 PROSECTOR: NANCY DIEDRICH RECORDER: NANCY DIEDRICH
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	17.8225	4.0060 %		WEIGHT TAKEN
RT LAT LOBE LIV (LI1)				NOT TAKEN
REMAINING LIV (LI2)				NOT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
GENERAL COMMENT (GC)	*** GROSS PATHOLOGY OBSERVATIONS *** -NO MACROSCOPIC LESIONS -ABBR NEC PERFORM	

APPENDIX D

CHW 6329-197

Individual Animal Pathology Data

Day 20 Sacrifice

Corning Hazleton Inc.
Madison, Wisconsin USA

PAGE: 5

ANIMAL NUMBER: C77260 SEX: MALE DOSE GROUP: 1 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 462.8 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 10:20 PROSECTOR: DEBBIE PIRKEL RECORDER: DEBBIE PIRKEL
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	17.6747	3.8191 %	-----	WEIGHT TAKEN
RT LAT LOBE LIV (LI1)	-----	-----	-----	NOT TAKEN
REMAINING LIV (LI2)	-----	-----	-----	NOT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

GENERAL COMMENT (GC) -NO MACROSCOPIC LESIONS
 -ABBR NEC PERFORM

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002497

APPENDIX D

CHW 6329-197

Individual Animal Pathology Data

Day 20 Sacrifice

Corning Hazleton Inc.
Madison, Wisconsin USA

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ANIMAL NUMBER: C77262 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 476.3 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 10:34 PROSECTOR: DEBBIE PIRKEL RECORDER: NANCY DIEDRICH
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	21.8525	4.5880 %		WEIGHT TAKEN
RT LAT LOBE LIV (LI1)				NOT TAKEN
REMAINING LIV (LI2)				NOT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES
GENERAL COMMENT (GC)
-NO MACROSCOPIC LESIONS
-ABBR NEC PERFORM

APPENDIX D

CHW 6329-197

Individual Animal Pathology Data

Day 20 Sacrifice

Corning Hazleton Inc.
Madison, Wisconsin USA

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ANIMAL NUMBER: C77265 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 415.3 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 10:34 PROSECTOR: NANCY DIEDRICH RECORDER: NANCY DIEDRICH
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	18.8251	4.5329 %		WEIGHT TAKEN
RT LAT LOBE LIV (LI1)				NOT TAKEN
REMAINING LIV (LI2)				NOT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

GENERAL COMMENT (GC)

-NO MACROSCOPIC LESIONS
-ABBR NEC PERFORM

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Individual Animal Pathology Data
Day 20 Sacrifice

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Corning Hazleton Inc.
Madison, Wisconsin USA

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ANIMAL NUMBER: C77266 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 424.6 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 11:07 PROSECTOR: NANCY DIEDRICH RECORDER: DEBBIE PIRKEL
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	20.5301	4.8352 %		WEIGHT TAKEN
RT LAT LOBE LIV (LI1)				NOT TAKEN
REMAINING LIV (LI2)				NOT TAKEN

ORGAN NAME * * * GROSS PATHOLOGY OBSERVATIONS * * *
SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

GENERAL COMMENT (GC)

-NO MACROSCOPIC LESIONS
-ABBR NEC PERFORM

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Individual Animal Pathology Data

Day 20 Sacrifice

Corning Hazleton Inc.
Madison, Wisconsin USA

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ANIMAL NUMBER: C77268 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
 DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 378.9 GRAMS
 DATE AND TIME OF NECROPSY: 01/21/97 10:20 PROSECTOR: NANCY DIEDRICH RECORDER: DEBBIE PIRKEL
 POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	16.0923	4.2471 %		WEIGHT TAKEN
RT LAT LOBE LIV (LI1)				NOT TAKEN
REMAINING LIV (LI2)				NOT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
 SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

ORGAN NAME
GENERAL COMMENT (GC)

-ABBR NEC PERFORM

THYMUS (TH)

-RED FOCUS(I)/AREA(S)

-RIGHT LOBE: MULTIPLE DARK RED FOCI, UP TO 1 MM IN DIAMETER

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Individual Animal Pathology Data

Day 20 Sacrifice

Corning Hazleton Inc.
Madison, Wisconsin USA

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ANIMAL NUMBER: C77270 SEX: MALE DOSE GROUP: 2 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 441.9 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 10:08 PROSECTOR: NANCY DIEDRICH RECORDER: NANCY DIEDRICH
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	20.4477	4.6272 %		WEIGHT TAKEN
RT LAT LOBE LIV (LI1)				NOT TAKEN
REMAINING LIV (LI2)				NOT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
GENERAL COMMENT (GC)	*** GROSS PATHOLOGY OBSERVATIONS ***	
	-NO MACROSCOPIC LESIONS	
	-ABBR NEC PERFORM	

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Individual Animal Pathology Data
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Corning Hazleton Inc.
Madison, Wisconsin USA

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ANIMAL NUMBER: C77271 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 404.5 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 10:26 PROSECTOR: NANCY DIEDRICH RECORDER: DEBBIE PIRKEL
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	20.9805	5.1868 %	-----	WEIGHT TAKEN
RT LAT LOBE LIV (LI1)	-----	-----	-----	NOT TAKEN
REMAINING LIV (LI2)	-----	-----	-----	NOT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
GENERAL COMMENT (GC)	-NO MACROSCOPIC LESIONS -ABBR NEC PERFORM	

APPENDIX D

CHW 6329-197

Individual Animal Pathology Data

Day 20 Sacrifice

Corning Hazleton Inc.
Madison, Wisconsin USA

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ANIMAL NUMBER: C77273 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 480.9 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 10:40 PROSECTOR: NANCY DIEDRICH RECORDER: DEBBIE PIRKEL
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	24.5697	5.1091 %		WEIGHT TAKEN
RT LAT LOBE LIV (LI1)				NOT TAKEN
REMAINING LIV (LI2)				NOT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
GENERAL COMMENT (GC)	*** GROSS PATHOLOGY OBSERVATIONS *** -NO MACROSCOPIC LESIONS -ABBR NEC PERFORM	

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APPENDIX D
Individual Animal Pathology Data
Day 20 Sacrifice

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Corning Hazleton Inc.
Madison, Wisconsin USA

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ANIMAL NUMBER: C77274 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 436.9 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 10:07 PROSECTOR: DEBBIE PIRKEL RECORDER: NANCY DIEDRICH
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	23.1173	5.2912 %		WEIGHT TAKEN
RT LAT LOBE LIV (LI1)				NOT TAKEN
REMAINING LIV (LI2)				NOT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES
GENERAL COMMENT (GC)
-NO MACROSCOPIC LESIONS
-ABBR NEC PERFORM

APPENDIX D

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Individual Animal Pathology Data

Day 20 Sacrifice

Corning Hazleton Inc.
Madison, Wisconsin USA

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ANIMAL NUMBER: C77278 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 440.8 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 10:13 PROSECTOR: DEBBIE PIRKEL RECORDER: DEBBIE PIRKEL
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	22.4307	5.0886 %		WEIGHT TAKEN
RT LAT LOBE LIV (LI1)				NOT TAKEN
REMAINING LIV (LI2)				NOT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES
GENERAL COMMENT (GC)
-NO MACROSCOPIC LESIONS
-ABBR NEC PERFORM

APPENDIX D

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Individual Animal Pathology Data

Day 20 Sacrifice

Corning Hazleton Inc.
Madison, Wisconsin USA

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ANIMAL NUMBER: C77279 SEX: MALE DOSE GROUP: 3 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 450.7 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 11:07 PROSECTOR: DEBBIE PIRKEL RECORDER: DEBBIE PIRKEL
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	20.6890	4.5904 %		WEIGHT TAKEN
RT LAT LOBE LIV (LI1)				NOT TAKEN
REMAINING LIV (LI2)				NOT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES
GENERAL COMMENT (GC)
-NO MACROSCOPIC LESIONS
-ABBR NEC PERFORM

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APPENDIX D
Individual Animal Pathology Data
Day 20 Sacrifice

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Corning Hazleton Inc.
Madison, Wisconsin USA

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ANIMAL NUMBER: C77281 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 441.4 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 11:00 PROSECTOR: NANCY DIEDRICH RECORDER: DEBBIE PIRKEL
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	21.3918	4.8464 %	-----	WEIGHT TAKEN
RT LAT LOBE LIV (LI1)	-----	-----	-----	NOT TAKEN
REMAINING LIV (LI2)	-----	-----	-----	NOT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
GENERAL COMMENT (GC)	*** GROSS PATHOLOGY OBSERVATIONS *** -NO MACROSCOPIC LESIONS -ABBR NEC PERFORM	

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Individual Animal Pathology Data

Day 20 Sacrifice

Corning Hazleton Inc.
Madison, Wisconsin USA

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ANIMAL NUMBER: C77283 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 413.4 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 10:53 PROSECTOR: NANCY DIEDRICH RECORDER: DEBBIE PIRKEL
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	20.9047	5.0568 %		WEIGHT TAKEN
RT LAT LOBE LIV (LI1)				NOT TAKEN
REMAINING LIV (LI2)				NOT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES

GENERAL COMMENT (GC)

-NO MACROSCOPIC LESIONS
-ABBR NEC PERFORM

APPENDIX D

CHW 6329-197

Individual Animal Pathology Data

Day 20 Sacrifice

Corning Hazleton Inc.
Madison, Wisconsin USA

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ANIMAL NUMBER: C77284 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 436.5 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 10:26 PROSECTOR: DEBBIE PIRKEL RECORDER: DEBBIE PIRKEL
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	21.2416	4.8663 %		WEIGHT TAKEN
RT LAT LOBE LIV (LI1)				NOT TAKEN
REMAINING LIV (LI2)				NOT TAKEN

*** GROSS PATHOLOGY OBSERVATIONS ***
ORGAN NAME SEVERITY, KEYWORD(S) OR PHRASE FREE-TEXT COMMENTS AND NOTES
GENERAL COMMENT (GC)
-NO MACROSCOPIC LESIONS
-ABBR NEC PERFORM

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APPENDIX D
Individual Animal Pathology Data
Day 20 Sacrifice

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Corning Hazleton Inc.
Madison, Wisconsin USA

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ANIMAL NUMBER: C77286 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 419.5 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 11:00 PROSECTOR: DEBBIE PIRKEL RECORDER: DEBBIE PIRKEL
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	24.6307	5.8714 %	-----	WEIGHT TAKEN
RT LAT LOBE LIV (LI1)	-----	-----	-----	NOT TAKEN
REMAINING LIV (LI2)	-----	-----	-----	NOT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
GENERAL COMMENT (GC)	*** GROSS PATHOLOGY OBSERVATIONS *** -NO MACROSCOPIC LESIONS -ABBR NEC PERFORM	

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Individual Animal Pathology Data

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Day 20 Sacrifice

Corning Hazleton Inc.
Madison, Wisconsin USA

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ANIMAL NUMBER: C77287 SEX: MALE DOSE GROUP: 4 SACRIFICE STATUS: SCHEDULED, TERMINAL SACRIFICE
DATE OF DEATH: 01/21/97 STUDY DAY OF DEATH: 20 STUDY WEEK OF DEATH: 3 TERMINAL BODY WEIGHT: 411.2 GRAMS
DATE AND TIME OF NECROPSY: 01/21/97 10:47 PROSECTOR: NANCY DIEDRICH RECORDER: NANCY DIEDRICH
POST-FIX WEIGHER: NOT AVAILABLE PATHOLOGIST: DR. TOM PALMER WEIGHER: TROY ELLENBECKER

ORGAN NAME	ABSOLUTE ORGAN WEIGHT (GRAMS)	ORGAN WEIGHT RELATIVE TO BODY WEIGHT (%)	ORGAN TO BRAIN WEIGHT RATIO	ORGAN STATUS
WHOLE LIVER (LI0)	18.9698	4.6133 %		WEIGHT TAKEN
RT LAT LOBE LIV (LI1)				NOT TAKEN
REMAINING LIV (LI2)				NOT TAKEN

ORGAN NAME	SEVERITY, KEYWORD(S) OR PHRASE	FREE-TEXT COMMENTS AND NOTES
GENERAL COMMENT (GC)	-ABBR NEC PERFORM	
KIDNEY (KD)	-LARGE PELVIS(ES)	-LEFT

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002512