

FINAL REPORT

Volume 1 of 3
(Text and Summary Tables 1-17)

STUDY TITLE

A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE

STUDY NUMBER

WIL-304003

STUDY DIRECTOR

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STUDY INITIATION DATE

October 19, 2001

STUDY COMPLETION DATE

July 2, 2002

PERFORMING LABORATORY

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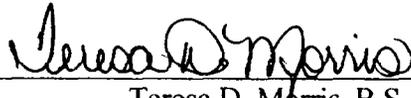
SPONSOR

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COMPLIANCE STATEMENT

This study, designated WIL-304003, was conducted in compliance with the United States Food and Drug Administration (FDA) Good Laboratory Practice Standards (21 CFR Part 58), the standard operating procedures of WIL Research Laboratories, Inc., and the protocol as approved by the sponsor. A Certificate of Analysis was provided by the sponsor (presented in Appendix A); it is unknown whether the characterization analyses were conducted according to Good Laboratory Practices (GLP).

The protocol was designed to be in general accordance with the United States Food and Drug Administration (FDA), the Japanese Ministry of Health, Labour and Welfare (MHLW) and the International Conference on Harmonization (ICH).



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Date

TABLE OF CONTENTS

VOLUME 1	<u>Page</u>
Compliance Statement	2
Table Of Contents	3
Index Of Tables	6
Index Of Appendices	8
1. Summary	9
1.1. Objective	9
1.2. Study Design	9
1.3. Results	9
1.4. Conclusions	10
2. Introduction	11
2.1. General Study Information	11
2.2. Key Study Dates	11
3. Study Design	12
4. Experimental Procedures - Materials And Methods	13
4.1. Test Article And Vehicle	13
4.1.1. Test Article Identification	13
4.1.2. Vehicle Identification	13
4.1.3. Preparation	13
4.1.4. Administration	14
4.1.5. Sampling And Analyses	15
4.2. Animal Receipt And Acclimation/Pretest Period	15
4.3. Animal Housing	16
4.4. Diet, Drinking Water And Maintenance	16
4.5. Environmental Conditions	17
4.6. Assignment Of Animals To Treatment Groups	17
4.7. Data Retention	17
5. Parameters Evaluated	19

VOLUME 1 (continued)	<u>Page</u>
5.1. Clinical Observations And Survival.....	19
5.2. Dermal Observations.....	19
5.3. Body Weights.....	19
5.4. Food Consumption.....	19
5.5. Clinical Pathology.....	20
5.5.1. Hematology.....	20
5.5.2. Serum Chemistry.....	21
5.6. Ophthalmic Examinations.....	21
5.7. Anatomic Pathology.....	21
5.7.1. Macroscopic Examination.....	21
5.7.2. Organ Weights.....	23
5.7.3. Slide Preparation And Microscopic Examination.....	23
5.8. Statistical Methods.....	23
6. Results And Discussion.....	25
6.1. Clinical Observations And Survival.....	25
6.2. Dermal Observations.....	25
6.3. Body Weights.....	26
6.4. Food Consumption.....	27
6.5. Clinical Pathology.....	27
6.5.1. Hematology.....	27
6.5.2. Serum Chemistry.....	27
6.6. Ophthalmic Examinations.....	28
6.7. Anatomic Pathology.....	28
6.7.1. Macroscopic Examination.....	28
6.7.2. Organ Weights.....	28
6.7.3. Microscopic Examination.....	29
7. Conclusions.....	30
8. Key Study Personnel And Report Submission.....	32
9. Quality Assurance Unit Statement.....	34

	<u>Page</u>
VOLUME 1 (continued)	
17. Summary Of Organ Weights Relative To Brain Weights [G/100 G] (Week 13 Necropsy)	105
VOLUME 2	
18. Individual Survival And Disposition.....	111
19. Individual Dermal Observations.....	115
20. Individual Body Weights [G]	125
21. Individual Body Weight Changes [G].....	145
22. Individual Food Consumption [G/Animal/Day]	165
23. Individual Hematology Values (Week 13 Evaluation)	185
24. Individual Leukocyte Differential Counts [%] (Week 13 Evaluation).....	195
25. Individual Leukocyte Counts (Week 13 Evaluation).....	205
26. Individual Serum Chemistry Values (Week 13 Evaluation).....	215
27. Individual Ophthalmic Examination Findings (Week -1 Pretest Examination).....	235
28. Individual Ophthalmic Examination Findings (Week 12 Examination)	240
29. Individual Macroscopic Findings (Week 13 Necropsy)	245
30. Individual Organ Weights And Final Body Weights [G] (Week 13 Necropsy)	345
31. Individual Organ Weights Relative To Final Body Weights [G/100 G] (Week 13 Necropsy)	355
32. Individual Organ Weights Relative To Brain Weights [G/100 G] (Week 13 Necropsy)	365

INDEX OF APPENDICES

VOLUME 3	<u>Page</u>
A. Certificate of Analysis (Sponsor-Provided Data).....	376
B. Analytical Chemistry Report (WIL Research Laboratories, Inc.)	378
C. Pretest Clinical Observations.....	425
D. Scoring Criteria for Dermal Reactions	438
E. Clinical Pathology Methods, Procedures and References.....	440
F. Ophthalmic Examinations (David A. Wilkie, D.V.M., M.S., D.A.C.V.O. and Brian C. Gilger, D.V.M., M.S., D.A.C.V.O.).....	445
G. Pathology Report (Richard H. Bruner, D.V.M., D.A.C.V.P., Pathology Associates - A Charles River Company)	447
H. Individual Clinical Observations	532
I. Study Protocol.....	704

1. SUMMARY

1.1. OBJECTIVE

The objective of the study was to evaluate the possible toxic effects of PCMIX when dermally administered daily in mice for 13 weeks.

1.2. STUDY DESIGN

PCMIX in the vehicle, acetone, was administered dermally once daily for at least 91 consecutive days to three groups (Groups 3-5) of Crl:CD[®]-1 (ICR)BR mice. Dosage concentrations were 15%, 30% and 60%, and the dose volume was 50 µL for all groups. Approximate dosage levels were 250, 500 and 1000 mg/kg/day, respectively. A concurrent control group (Group 2) received the vehicle on a comparable regimen. A naive control group (Group 1) was maintained and observed in the same manner as the test group animals but did not receive the test article or vehicle. Each group consisted of 10 animals/sex.

All animals were observed twice daily for mortality and moribundity. Clinical examinations were performed daily and detailed physical examinations and dermal observations were performed weekly. Individual body weights and food consumption were recorded weekly. Clinical pathology evaluations (hematology and serum chemistry) were performed on all animals at the end of the dosing period (study week 13). Ophthalmic examinations were performed during study weeks -1 and 12. Complete necropsies were conducted on all animals, and selected organs were weighed at the scheduled necropsy. Selected tissues were examined microscopically from all animals.

1.3. RESULTS

All animals survived to the scheduled necropsy. Body weights and food consumption were unaffected by test article administration. No test article-related ophthalmic findings were noted.

Test article-related effects noted in the 60% group consisted of:

- Clinical signs of yellow material on the urogenital area in males.
- Very slight to moderate erythema and edema during the dosing period.
- Macroscopic findings including thickening and scabbing of the treated skin.
- Microscopic changes including epidermal hyperplasia and hyperkeratosis, inflammation in the superficial dermis, serocellular crust formation along the skin surface and necrosis of epidermal cells; increased incidence of granulocytic hyperplasia of the bone marrow associated with the increased demand for circulating leukocytes in conjunction with dermal inflammatory events.

Test article-related effects noted in the 30% group consisted of:

- Clinical signs of yellow material on the urogenital area in males.
- Very slight to moderate erythema and very slight to slight edema during the dosing period.
- Microscopic changes including epidermal hyperplasia and hyperkeratosis, inflammation in the superficial dermis, serocellular crust formation along the skin surface and necrosis of epidermal cells.

Test article-related effects noted in the 15% group consisted of:

- Clinical signs of yellow material on the urogenital area in males.
- Very slight to slight erythema and none to very slight edema during the dosing period.
- Microscopic changes including epidermal hyperplasia and hyperkeratosis, inflammation in the superficial dermis, serocellular crust formation along the skin surface and necrosis of epidermal cells.

The increased incidence of yellow material on the urogenital area observed in the PCMX-treated males was not indicative of systemic toxicity.

1.4. CONCLUSIONS

Based on the results of this study, the no-observed-effect level (NOEL) for dermal administration of PCMX to mice for 13 weeks was less than 15% for local irritation. The no-observed-adverse-effect level (NOAEL) for systemic toxicity was approximately 30% and was considered the maximum tolerated dose (MTD).

2. INTRODUCTION

2.1. GENERAL STUDY INFORMATION

This report presents the data from “A 13-Week Dermal Toxicity Study of PCMX in Mice”.

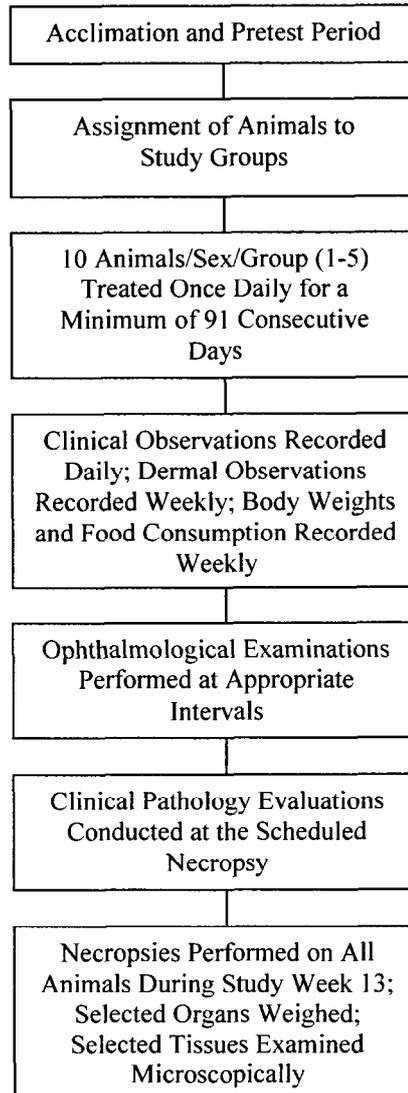
The following computer protocols were used for data collection during the study:

<u>Computer Protocol</u>	<u>Type of Data Collected</u>
WIL-304003.....	Main study data
WIL-304003Q.....	Pretest data

2.2. KEY STUDY DATES

<u>Date(s)</u>	<u>Event(s)</u>
October 30, 2001.....	Experimental starting date (animal receipt)
November 9, 2001.....	Assignment to study groups
November 12, 2001	Initiation of dosing (study week 0)
February 11-12, 2002.....	Primary necropsy (study week 13)
April 23, 2002	Experimental termination date (last histopathological examination)

3. STUDY DESIGN



4. EXPERIMENTAL PROCEDURES - MATERIALS AND METHODS

4.1. TEST ARTICLE AND VEHICLE

4.1.1. TEST ARTICLE IDENTIFICATION

The test article, PCMX, was received from the sponsor via NIPA Laboratories, Oswaldtwistle Accrin, GREAT BRITAIN, on October 11, 2001 as follows:

<u>Identification</u>	<u>Quantity Received</u>	<u>Physical Description</u>
Nipacide PX-R Parachlorometaxylenol UN: 3077 BX: K95-3 [WIL Log No. 5308A]	1 Jar Gross weight: 609.1 g	Off-white crystalline powder

Purity and stability data for the test article were the responsibility of the sponsor. A Certificate of Analysis for the test article was provided by the sponsor and is presented in Appendix A. The purity of the test article was 99.5%. The test article was stored at room temperature, protected from light. A reserve sample of the test article (approximately one gram) was collected on October 16, 2001, and stored in the Archives of WIL Research Laboratories, Inc.

4.1.2. VEHICLE IDENTIFICATION

The vehicle utilized in preparation of the test article formulations and for administration to the vehicle control group animals was acetone (lot no. QN0014, exp. dates: September 27, 2006 and December 19, 2006, received from Spectrum Laboratory Products, New Brunswick, New Jersey).

4.1.3. PREPARATION

For the vehicle control group (Group 2), a sufficient amount of acetone was dispensed into a labeled storage container. The vehicle was dispensed approximately weekly and was divided into daily aliquots for dosing.

The test article formulations were prepared as weight/volume (test article/vehicle) mixtures. For the test article-treated groups, the appropriate amount of the test article for each group was weighed into calibrated storage containers. A sufficient amount of the vehicle was added to each container to bring the formulations to the calibration mark. The formulations were then mixed until uniform using a magnetic stirrer. The test article formulations were prepared weekly as single formulations for each dose level, then divided into aliquots for daily dispensation. The aliquots were stored at room temperature, protected from light and were inverted several times prior to dosing.

4.1.4. ADMINISTRATION

On the day before the initiation of dosing (November 11, 2001), the hair from the back of each animal was clipped, from the scapula to the wing of the ileum and halfway down each flank on each side of the animal. This procedure was repeated as often as needed during the dosing period (at least once per week). The vehicle and test article solutions were administered dermally once daily via a calibrated pipette. Dosing was performed at approximately the same time each day for at least 91 consecutive days, through the first day of the scheduled necropsy. The test article was slowly and evenly discharged from the pipette on the target dose area. The dosage volume for all groups was 50 μ L. The application sites were not dressed or wrapped. The test sites were washed with acetone and gauze swabs once per week. The corners of the application site were marked with indelible ink to allow proper identification of the treated and untreated skin. The area covered by test article was measured and recorded once per week for a representative animal of each sex in each group. The formula used to calculate the total body surface area is as follows: [Total body surface area (cm^2) = K * body weight (grams)^{2/3}]; K = 8.2. The mean area of coverage during the study was 7.7%, 7.8%, 7.1% and 7.8% for males in the vehicle control and 15%, 30% and 60% PCMX groups (Groups 2-5), respectively. The mean area of coverage during the study was 7.4%, 5.8%, 6.4% and 5.2% for females in these same groups, respectively.

The following table presents the study group assignment:

<u>Group Number</u>	<u>Treatment</u>	<u>Approximate Dosage^a (mg/kg/day)</u>	<u>Dose Concentration (%)</u>	<u>Dose Volume (µL)</u>	<u>Number of Animals</u>	
					<u>Males</u>	<u>Females</u>
1	Naive Control	0	0	0	10	10
2	Acetone (vehicle control)	0	0	50	10	10
3	PCMIX	250	15	50	10	10
4	PCMIX	500	30	50	10	10
5	PCMIX	1000	60	50	10	10

^a = Based on 30 gram mouse.

Doses were selected based on results from preliminary studies (WIL-304001¹ and WIL-304002²) which together demonstrated appropriate bioavailability and irritation characteristics for a 60% PCMIX solution in acetone.

The selected route of administration was dermal since the intended use of the test article indicated that dermal contact is the route of exposure for humans. The animal model, the Crl:CD[®]-1 (ICR)BR mouse, is recognized as appropriate for subchronic dermal toxicity studies and is a widely used strain for which significant historical control data are available. It also was the species and strain used for the preliminary studies with PCMIX conducted at WIL Research Laboratories, Inc.

4.1.5. SAMPLING AND ANALYSES

Duplicate samples (5 mL each) for concentration analysis were collected at study weeks 0, 4, 8 and 12 from each dosing formulation.

All analyses were conducted by the Analytical Chemistry Department, WIL Research Laboratories, Inc. The methodology and results of these analyses are presented in Appendix B. The test article formulations were found to be homogeneous and contain the amounts of test article specified in the protocol.

4.2. ANIMAL RECEIPT AND ACCLIMATION/PRETEST PERIOD

Seventy-one male and seventy-one female Crl:CD[®]-1 (ICR)BR mice in good health were received on October 30, 2001, from Charles River Laboratories, Inc., Raleigh, North

Carolina. The animals were 28 days old at receipt. Each animal was examined by a qualified technician on the day of receipt and weighed three days later. Animals were uniquely identified by tail tattoos displaying the permanent identification number. All animals were housed for a 13-day acclimation period. During this period, each animal was observed twice daily for mortality/moribundity and general changes in appearance or behavior.

Pretest data collection began on November 2, 2001. Individual body weights were recorded and detailed physical examinations were performed on November 2, 2001 and November 9, 2001. Food consumption and ophthalmic examinations were also recorded for pretest animals prior to the initiation of dosing. Pretest clinical observations are presented in Appendix C.

4.3. ANIMAL HOUSING

Upon arrival, all animals were housed three per cage by sex for approximately three days. Thereafter, all animals were housed individually in clean, wire-mesh cages suspended above cage-board. Animals were maintained in accordance with the "Guide for the Care and Use of Laboratory Animals"³. The animal facilities at WIL Research Laboratories, Inc., are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

4.4. DIET, DRINKING WATER AND MAINTENANCE

The basal diet used in this study, PMI Nutrition International, Inc. Certified Rodent LabDiet[®] 5002, is a certified feed with appropriate analyses performed by the manufacturer and provided to WIL Research Laboratories, Inc. Municipal water supplying the facility is sampled for contaminants according to the standard operating procedures. The results of the diet and water analyses are maintained at WIL Research Laboratories, Inc. No contaminants were present in animal feed or water at concentrations sufficient to interfere with the objectives of this study. Reverse

osmosis-treated (on-site) drinking water, delivered by an automatic watering system, and the basal diet were provided *ad libitum* throughout the study.

4.5. ENVIRONMENTAL CONDITIONS

All animals were housed throughout the acclimation period and during the study in an environmentally controlled room. Controls were set to maintain a temperature of $71 \pm 5^{\circ}\text{F}$ ($22 \pm 3^{\circ}\text{C}$) and a relative humidity of approximately 30-70%. Room temperature and relative humidity were recorded daily. The actual temperature ranged from 69.8 to 74.9°F (21.0 to 23.8°C) and humidity ranged from 30.0% to 51.4% during the study. Light timers were set to provide a 12-hour light/12-hour dark photoperiod. The 12-hour light/12-hour dark photoperiod was interrupted as necessary to allow for the performance of protocol-specified activities.

4.6. ASSIGNMENT OF ANIMALS TO TREATMENT GROUPS

On November 9, 2001 (three days prior to the initiation of dosing), all available mice were weighed using the WIL Toxicology Data Management System (WTDMS™) and examined in detail for physical abnormalities. These data were reviewed by the study director and animals judged suitable for assignment to the study were selected for use in the computerized randomization procedure. A printout containing the animal numbers, corresponding body weights and individual group assignments was generated based on body weight stratification in a block design. The animals then were arranged according to the printout. Each group consisted of 10 males and 10 females. The selected animals were approximately six weeks old at the initiation of dosing; body weight values ranged from 22.7 g to 29.6 g for males and from 19.8 g to 24.0 g for females. Individual body weights at randomization were within $\pm 20\%$ of the mean for each sex.

4.7. DATA RETENTION

The sponsor has title to all documentation records, raw data, specimens or other work product generated during the performance of the study. All work product generated by

WIL-304003
Clariant Corporation

PCMX

WIL Research Laboratories, Inc., including raw paper data and specimens, are retained in the Archives at WIL Research Laboratories, Inc., as specified in the study protocol.

Reserve samples of the test and control articles, pertinent electronic storage media and the original final report are retained in the Archives at WIL Research Laboratories, Inc., in compliance with regulatory requirements.

5. PARAMETERS EVALUATED

5.1. CLINICAL OBSERVATIONS AND SURVIVAL

All animals were observed twice daily, once in the morning and once in the afternoon, for mortality and moribundity.

Clinical examinations were performed once daily at approximately three hours following dosing. All significant findings were recorded. Detailed physical examinations were conducted on all animals weekly, beginning one week prior to test article administration and ending just prior to the scheduled necropsy.

5.2. DERMAL OBSERVATIONS

Application sites were examined for erythema, edema and other dermal findings once per week at the time of the detailed physical examination. Erythema and edema were evaluated in accordance with the method of Draize based on a four-step grading system of very slight, slight, moderate and severe (Appendix D). Other dermal findings, if present, were noted.

5.3. BODY WEIGHTS

Individual body weights were recorded at least weekly, beginning approximately two weeks prior to test article administration (study week -2). Mean body weights and mean body weight changes were calculated for the corresponding intervals.

5.4. FOOD CONSUMPTION

Individual food consumption was recorded weekly, beginning approximately two weeks prior to test article administration (study week -2). Food intake was calculated as g/animal/day for the corresponding body weight intervals. When food consumption could not be measured for a given interval (due to spillage, weighing error, obvious erroneous value, *etc.*), the appropriate interval was footnoted as "NA" (Not Applicable) on the individual tables.

5.5. CLINICAL PATHOLOGY

Blood samples for clinical pathology evaluations (hematology and serum chemistry) were collected from all animals at the end of the dosing period (study week 13). Samples for hematology assessment were collected from half of the animals and samples for serum chemistry assessment were collected from the remaining five animals/sex/group. Blood was collected from the vena cava at the time of necropsy. Clinical pathology methods, procedures and references are presented in Appendix E.

The following parameters were evaluated.

5.5.1. HEMATOLOGY

Total Leukocyte Count (White Cell)	Differential Leukocyte Count -
Erythrocyte Count (Red Cells)	Percent and Absolute
Hemoglobin	-Neutrophil
Hematocrit	-Lymphocyte
Mean Corpuscular Volume (MCV)	-Monocyte
Mean Corpuscular Hemoglobin	-Eosinophil
(MCH)	-Basophil
Mean Corpuscular Hemoglobin	Platelet Estimate ^a
Concentration (MCHC)	Red Cell Morphology
Platelet Count (Platelet)	(RBC Morphology) ^a

() - Designates tabular abbreviation

^a - Presented on individual tables if the automated differential data (CELL-DYN[®] 3500, Abbott Laboratories, Santa Clara, CA) were verified by manual review of slides.

5.5.2. SERUM CHEMISTRY

Albumin	Aspartate Aminotransferase (Aspartat Transfer)
Total Protein	Gamma Glutamyltransferase (Glutamyl Transfer)
Globulin [by calculation]	Glucose
Albumin/Globulin Ratio (A/G Ratio) [by calculation]	Total Cholesterol (Cholesterol)
Total Bilirubin (Total Bili)	Calcium
Urea Nitrogen	Chloride
Creatinine	Phosphorus
Alkaline Phosphatase (Alkaline Phos'tse)	Potassium
Alanine Aminotransferase (Alanine Transfer)	Sodium
Creatine Kinase	Triglycerides (Triglyceride)

() - Designates tabular abbreviation

5.6. OPHTHALMIC EXAMINATIONS

Ocular examinations were conducted on all animals prior to the initiation of dosing (November 8, 2001; study week -1) and near the end of the dosing period (February 6, 2002; study week 12). All ocular examinations were conducted using an indirect ophthalmoscope (or other suitable equivalent equipment), preceded by pupillary dilation with an appropriate mydriatic agent. Examinations were performed during study week -1 by David A. Wilkie, D.V.M., M.S., D.A.C.V.O. and during study week 12 by Brian C. Gilger, D.V.M., M.S., D.A.C.V.O. (Appendix F).

5.7. ANATOMIC PATHOLOGY

5.7.1. MACROSCOPIC EXAMINATION

A complete necropsy was conducted on all animals. Animals were euthanized by isoflurane anesthesia followed by exsanguination. The necropsies included examination of the external surface, all orifices and the cranial, thoracic, abdominal and pelvic cavities including viscera. The following tissues and organs were collected and placed in 10% neutral buffered formalin (except as noted):

Adrenal glands (2)	Mammary gland (females only)
Aorta	Ovaries with oviducts (2)
Bone with marrow	Pancreas
Femur	Peripheral nerve (sciatic)
Sternum	Pituitary
Bone marrow smear ^a	Prostate
Brain (forebrain, midbrain, hindbrain)	Salivary glands [mandibular (2)]
Epididymides (2) ^b	Seminal vesicles (2)
Eyes with optic nerves (2) ^c	Skeletal muscle (rectus femoris)
Gallbladder	Skin
Gastrointestinal tract	Treated ^d
Esophagus	Untreated
Stomach	Spinal cord (cervical, midthoracic, lumbar)
Duodenum	Spleen
Jejunum	Testes (2) ^b
Ileum	Thymus
Cecum	Thyroid [with parathyroids if present (2)] ^e
Colon	Tongue
Rectum	Trachea
Harderian glands (2)	Urinary bladder
Heart	Uterus with cervix
Kidneys (2)	Vagina
Liver (sections of two lobes)	Gross lesions (when possible)
Lungs (including bronchi, fixed by inflation with fixative)	
Lymph nodes (mesenteric)	

^a = Bone marrow smears were obtained at necropsy but not placed in formalin.

^b = Fixed in Bouin's solution.

^c = Fixed in Davidson's solution.

^d = The entire treated area was collected. Three sections were prepared for microscopic examination.

^e = Parathyroids were examined microscopically if in the plane of section and in all cases where a gross lesion was present.

5.7.2. ORGAN WEIGHTS

The following organs were weighed from all animals at the scheduled necropsy:

Adrenals	Ovaries with oviducts
Brain	Spleen
Epididymides	Testes
Heart	Thymus
Kidneys	Thyroid with parathyroids
Liver	Uterus

Paired organs were weighed together. The thyroid/parathyroids were weighed after fixation. Organ to final body weight and organ to brain weight ratios were calculated.

5.7.3. SLIDE PREPARATION AND MICROSCOPIC EXAMINATION

After fixation, protocol-specified tissues were trimmed according to standard operating procedures and the protocol. Trimmed tissues were processed into paraffin blocks, sectioned at four to eight microns, mounted on glass microscope slides and stained with hematoxylin and eosin.

Microscopic examination was performed on all tissues listed in Section 5.7.1. from all animals in the vehicle control and 60% groups and the skin (treated and untreated) and gross lesions were examined from all animals at the scheduled necropsy. Microscopic examinations were performed by Richard H. Bruner, D.V.M., D.A.C.V.P., Pathology Associates (PAI), A Charles River Company, West Chester, Ohio (Appendix G).

5.8. STATISTICAL METHODS

All statistical tests were performed using appropriate computing devices or programs. Analyses were conducted using two-tailed tests (except as noted otherwise) for minimum significance levels of 1% and 5%, comparing each test article-treated group to the control group by sex. Each mean was presented with the standard deviation (S.D.) and the number of animals (N) used to calculate the mean. Statistical analyses were not conducted if the number of animals was two or less. Due to the different rounding

conventions inherent in the types of software used, the means and standard deviations on the summary and individual tables may differ by ± 1 in the last significant figure.

Body weight, body weight change, food consumption, clinical pathology and organ weight data were subjected to a parametric one-way analysis of variance (ANOVA)⁴ to determine intergroup differences. If the ANOVA revealed statistical significance ($p < 0.05$), Dunnett's test⁵ was used to compare the test article-treated groups to the control group. Clinical pathology values for white blood cell types that occur at a low incidence (*i.e.*, monocytes, eosinophils and basophils) were not subjected to statistical analysis.

6. RESULTS AND DISCUSSION

6.1. CLINICAL OBSERVATIONS AND SURVIVAL

Summary Data: Tables 1, 2, 3

Individual Data: Table 18, Appendix H

All animals survived to the scheduled necropsy. Test article-related clinical signs consisted of increased incidence of yellow material on the urogenital area in the 15%, 30% and 60% group males. However, these findings were not indicative of systemic toxicity. All other clinical signs were observed with similar incidence in the control groups, were not observed in a dose-related manner and/or were findings commonly seen in laboratory mice.

6.2. DERMAL OBSERVATIONS

Summary Data: Table 4

Individual Data: Table 19

No irritation was observed in the naive or vehicle control groups. Test article-related dermal irritation consisting of erythema and/or edema was observed in all test article-treated groups. Overall, irritation was often sporadic and transient in nature and did not increase proportionately with repeated applications beyond study day 14.

Very slight to slight erythema was observed for all males in the 15%, 30% and 60% groups and for 9/10, 10/10 and 10/10 females in the 15%, 30% and 60% groups, respectively, during the study. Moderate erythema was noted for one male in the 30% group and for one male and one female in the 60% group. On study day 7, erythema was observed for 7/20 and 10/20 animals in the 30% and 60% groups, respectively, when males and females were combined. By study day 14, erythema was noted for all animals in the 30% and 60% groups, with the exception of one 30% group female. In the 15% group, erythema was observed for one female on study day 7, but was present for all males and 6/10 females by study day 14. Sporadic erythema persisted throughout the dosing period in all PCMX groups.

Very slight to slight edema was observed in 5/10 males and 2/10 females in the 15% group and for all animals in the 30% and 60% groups. Moderate edema was noted for two 60% group males. On study day 7, edema was observed for 5/20 and 9/20 animals in the 30% and 60% groups, respectively, when males and females were combined. By study day 14, edema was noted for 17/20 and 19/20 animals in the 30% and 60% groups. In the 15% group, edema was not observed at study day 7, but was noted in 3/10 males and 1/10 females by study day 14. With the exception of one female and one male in the 30% group, edema was not observed after study day 42 in any of the PCMX-treated groups.

Scabbing was noted in 1/10 males and 1/10 females in the 30% group and in 4/10 males and 3/10 females in the 60% group. Scabbing was first observed on study day 14 in these animals and was not observed after study day 70.

There were no other adverse test article-related dermal observations. Desquamation was noted on all animals in the PCMX groups and encrustation was noted for two males in the 30% group. These findings were not indicative of test article irritation or considered adverse.

6.3. BODY WEIGHTS

Summary Data: Tables 5, 6, 6A

Individual Data: Tables 20, 21

There were no test article-related effects on body weight data. The only statistically significant ($p < 0.05$ or $p < 0.01$) decreases in mean body weight data when compared to the naive control group were lower body weights in the 30% and 60% group females during study week 7 and lower body weight gains and/or body weight losses for the vehicle control, 15%, 30% and 60% group females during study week 6 to 7. These changes were not attributed to treatment since they were slight and not consistently observed during the dosing period. In addition, increases (significant at $p < 0.05$ or $p < 0.01$) in body weight gain were occasionally noted in the test article-treated males and females during

the study. However, increases in body weight data are generally not considered toxicologically relevant.

6.4. FOOD CONSUMPTION

Summary Data: Table 7

Individual Data: Table 22

There were no test article-related changes in food consumption. Mean food consumption in the 60% group males was significantly ($p < 0.05$ or $p < 0.01$) higher than the naive control group during study weeks 4 to 5, 5 to 6 and 9 to 10. However, these changes were slight and not considered toxicologically significant.

6.5. CLINICAL PATHOLOGY

6.5.1. HEMATOLOGY

Summary Data: Tables 8, 9, 10

Individual Data: Tables 23, 24, 25

Hematology parameters were unaffected by test article administration. Values in the treated groups were comparable to those in the control groups.

6.5.2. SERUM CHEMISTRY

Summary Data: Table 11

Individual Data: Table 26

There were no test article-related changes in serum chemistry parameters. Mean chloride in the vehicle control group males was significantly ($p < 0.05$) lower than the naive control group at study week 13. Mean glucose in the 15% group females and mean sodium in the 30% group females were significantly ($p < 0.05$ or $p < 0.01$) higher than the naive control group. Due to a lack of dose-related trends, these differences were not attributed to test article-administration. Mean aspartate aminotransferase and creatine kinase were higher than the naive control group in the 60% group females. However, these differences were

not considered test article-related and instead attributed to elevated values in a single animal (no. 9531).

6.6. OPHTHALMIC EXAMINATIONS

Summary Data: Tables 12, 13, Appendix F

Individual Data: Tables 27, 28

No test article-related ocular effects were noted during the study.

6.7. ANATOMIC PATHOLOGY

6.7.1. MACROSCOPIC EXAMINATION

Summary Data: Table 14

Individual Data: Table 29

Macroscopic changes attributed to test article administration were observed in the treated skin of the high dose group. One male and one female in the 60% group exhibited thickening of the treated skin and one male in this group displayed scabbing of the treated skin. All other gross findings were observed with similar incidence in the control groups, were noted only for single animals and/or were findings commonly observed in laboratory mice.

6.7.2. ORGAN WEIGHTS

Summary Data: Tables 15, 16, 17

Individual Data: Tables 30, 31, 32

There were no test article-related effects on organ weights. Absolute and relative (to final body and brain weights) mean thymus weights were significantly ($p < 0.05$ or $p < 0.01$) higher in the vehicle control group males and in the 30% group females when compared to the control group. Due to a lack of dose-related trends, these changes were not attributed to treatment. No other remarkable differences in organ weights were noted.

6.7.3. MICROSCOPIC EXAMINATION

Summary and Individual Data: Appendix G

Test article-related microscopic changes in all PCMX-treated groups were consistent with the dermal applicant of a mild irritant and included epidermal hyperplasia and hyperkeratosis, inflammation in the superficial dermis, serocellular crust formation along the skin surface and necrosis of epidermal cells. In general, all changes were of minimal to mild severity with incidence and severity scores slightly increasing in a dose-related manner. In addition, the incidence of granulocytic hyperplasia of the bone marrow was slightly increased in the 60% group. This change was attributed to the slightly increased demand for circulating leukocytes in conjunction with dermal inflammatory events. In addition, skin changes in the 30% group females were similar to those noted in the 60% group females. All other microscopic findings were consistent with common, spontaneous alterations in laboratory mice.

7. CONCLUSIONS

All animals survived to the scheduled necropsy. Body weights and food consumption were unaffected by test article administration. No test article-related ophthalmic findings were noted.

Test article-related effects noted in the 60% group consisted of:

- Clinical signs of yellow material on the urogenital area in males.
- Very slight to moderate erythema and edema during the dosing period.
- Macroscopic findings including thickening and scabbing of the treated skin.
- Microscopic changes including epidermal hyperplasia and hyperkeratosis, inflammation in the superficial dermis, serocellular crust formation along the skin surface and necrosis of epidermal cells; increased incidence of granulocytic hyperplasia of the bone marrow associated with the increased demand for circulating leukocytes in conjunction with dermal inflammatory events.

Test article-related effects noted in the 30% group consisted of:

- Clinical signs of yellow material on the urogenital area in males.
- Very slight to moderate erythema and very slight to slight edema during the dosing period.
- Microscopic changes including epidermal hyperplasia and hyperkeratosis, inflammation in the superficial dermis, serocellular crust formation along the skin surface and necrosis of epidermal cells.

Test article-related effects noted in the 15% group consisted of:

- Clinical signs of yellow material on the urogenital area in males.
- Very slight to slight erythema and none to very slight edema during the dosing period.
- Microscopic changes including epidermal hyperplasia and hyperkeratosis, inflammation in the superficial dermis, serocellular crust formation along the skin surface and necrosis of epidermal cells.

The increased incidence of yellow material on the urogenital area observed in the PCMX-treated males was not indicative of systemic toxicity.

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Based on the results of this study, the no-observed-effect level (NOEL) for dermal administration of PCMX to mice for 13 weeks was less than 15% for local irritation. The no-observed-adverse-effect level (NOAEL) for systemic toxicity was approximately 30% and was considered the maximum tolerated dose (MTD).

8. KEY STUDY PERSONNEL AND REPORT SUBMISSION

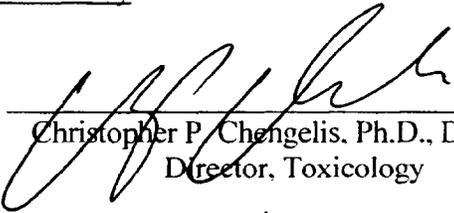
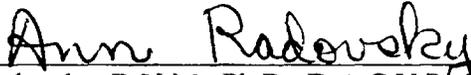
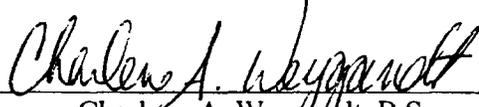
Study Supervisors:

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Report Prepared By:

 _____	<u>7/2/02</u>
Kristen A. Conner, B.A. Associate Study Analyst	Date

Report Reviewed By:

 _____	<u>2 July 02</u>
Christopher P. Chengelis, Ph.D., D.A.B.T. Director, Toxicology	Date
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Jay G. Henson, B.S. Senior Study Analyst	Date
 _____	<u>7/2/02</u>
Ann Radovsky, D.V.M., Ph.D., D.A.C.V.P., D.A.B.T. Staff Pathologist	Date
 _____	<u>7/2/02</u>
Charlene A. Weygandt, B.S. Group Manager, Study Analysis and Reports	Date

WIL-304003
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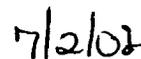
PCMX

KEY STUDY PERSONNEL AND REPORT SUBMISSION (CONTINUED)

Report Approved and Submitted By:



Teresa D. Morris, B.S.
Operations Manager, Toxicology
Study Director



Date

9. QUALITY ASSURANCE UNIT STATEMENT

9.1. PHASES INSPECTED

<u>Date(s) of Inspection(s)</u>	<u>Phase Inspected</u>	<u>Date(s) Findings Reported to Study Director</u>	<u>Date(s) Findings Reported to Management</u>
11/9/01	Test article preparation	11/9/01	12/26/01
11/13/01	Test article administration	11/13/01	12/26/01
12/18/01	Animal care/equipment	12/18/01	1/31/02
2/6/02	Ophthalmological examinations	2/6/02	3/28/02
2/11/02	Necropsy	2/11/02	3/28/02
2/11/02	Blood collection/analysis	2/11/02	3/28/02
3/15/02	Trimming of tissues	3/15/02	4/30/02
5/7-9,15/02	Study records (I-1)	5/15/02	6/28/02
5/9,15/02	Study records (I-2)	5/15/02	6/28/02
5/9,15/02	Study records (Rx-1)	5/15/02	6/28/02
5/9-10,15/02	Study records (C-1,C-2,C-3)	5/15/02	6/28/02
5/10,15/02	Study records (N-1)	5/15/02	6/28/02
5/10,13-16/02	Study records (A-1,A-4,A-5,A-6)	5/16/02	6/28/02
5/14-16/02	Draft analytical report	5/16/02	6/28/02
5/14-16,20,31/02	Draft report without analytical	5/31/02	6/28/02
5/28-29/02	Study records (H-1)	5/29/02	6/28/02

This study was inspected in accordance with the U.S. FDA Good Laboratory Practice Regulations (21 CFR Part 58), the standard operating procedures of WIL Research Laboratories, Inc., and the sponsor's protocol and protocol amendments with the following exceptions. The data located in Appendix A (Certificate of Analysis) were the responsibility of the sponsor. The data located in Appendix G (Pathology Report) were the responsibility of Pathology Associates - A Charles River Company. Quality Assurance findings, derived from the inspections during the conduct of the study and from the inspections of the raw data and draft report, are documented and have been reported to the study director. A status report is submitted to management monthly.

This report accurately reflects the data generated during the study. The methods and procedures used in the study were those specified in the protocol, its amendments and the standard operating procedures of WIL Research Laboratories, Inc.

WIL-304003
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PCMX

The raw data, the retention sample(s), if applicable, and the final report will be stored in the Archives at WIL Research Laboratories, Inc., or another location specified by the sponsor.

9.2. APPROVAL

This study was inspected according to the criteria discussed in Section 9.1.

Report Audited By:

Malinda Tomblin
Malinda Tomblin, A.S.
Auditor I, Quality Assurance

7/2/02
Date

Robyn N. Durr
Robyn N. Durr, B.S.
Auditor I, Quality Assurance

7/2/02
Date

Report Released By:

Heather L. Skelton
Heather L. Skelton, B.S.
Group Supervisor, Quality Assurance

7/2/02
Date

10. REFERENCES

1. WIL-304001. A Rising Dosing Dermal Range-Finding Study of PCMX in Mice. WIL Research Laboratories, Inc., Ashland, OH., **1997**.
2. WIL-304002. A Dermal Absorption Study with [¹⁴C]-labeled PCMX in Mice. WIL Research Laboratories, Inc., Ashland, OH., **2001**.
3. National Research Council Guide for the Care and Use of Laboratory Animals, Institute of Laboratory Animal Resources, Commission on Life Sciences; National Academy Press: Washington, DC, **1996**.
4. Snedecor, G.W.; Cochran, W.G. One Way Classifications; Analysis of Variance. In *Statistical Methods*, 7th ed.; The Iowa State University Press: Ames, IA, **1980**; pp 215-237.
5. Dunnett, C.W. New tables for multiple comparisons with a control. *Biometrics* **1964**, *20*, 482-491.

11. DEVIATIONS FROM THE PROTOCOL

This study was conducted in accordance with the protocol and protocol amendments, except for the following.

- **Section 4.1.4.** On the day before the initiation of dosing (November 11, 2001), 30% PCMX group female no. 9535 was inadvertently not shaved. Instead, the animal was shaved prior to dosing on November 12, 2001 and a dermal observation was subsequently noted.
- **Section 4.1.4.** On November 12, 2001 (study day 0), vehicle control group male no. 9498 was dosed with 100 µL instead of the protocol-specified 50 µL.
- **Section 4.1.4.** On February 10, 2002 (study day 90), there is no documentation for dose administration for 60% group females nos. 9553, 9556, 9558, 9561 and 9576. A dose site measurement for no. 9576 was footnoted on the dose sheet for that day.
- **Section 4.1.4.** There is no documentation for dose site measurements on February 11, 2002 (study day 91).
- **Section 4.2.** On November 2, 2001 (study day -10), pretest animal no. 9511 was inadvertently not weighed.
- **Section 4.4.** There was no documentation for the sanitization of feeders for the weeks of November 5-11, 2001 (study week -1) and February 4-10, 2002 (study week 12).
- **Section 5.1.** Throughout the study, daily clinical observations were performed on days of detailed physical examinations.
- **Section 5.1.** On February 8, 2002 (study day 88), no general comment was entered at the end of the three hour post-dosing observation.
- **Section 5.1.** On February 11, 2002, the three-hour post-dosing observation occurred nearly five hours post-dosing for all animals.
- **Section 5.4.** On December 17, 2001 (study day 35), the amount of food remaining was not recorded for control group male no. 9468. Therefore, food consumption for study week 4 to 5 could not be calculated for this animal.

DEVIATIONS FROM THE PROTOCOL (CONTINUED)

- **Section 5.7.3.** The testes for vehicle control group male no. 9493 were trimmed and placed in a cassette. The cassette was placed into bone decalcification solution instead of 70% alcohol. Upon discovery at bone trimming, the cassette containing the testes was removed from the decal solution and placed in 10% neutral buffered formalin until further processing.
- **Section 5.7.3.** Bone (sternum/femur) for vehicle control group male no. 9493 were trimmed and placed in cassettes. The cassettes were placed into 70% alcohol instead of bone decalcification solution. Upon discovery, the bone cassettes were removed from alcohol, rinsed in formalin, decalcified and then placed in 10% neutral buffered formalin until the time of processing.

These deviations did not negatively impact the quality or integrity of the data nor the outcome of the study.

TABLES 1 - 17

PROJECT NO.:WIL-304003
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TABLE 1
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF SURVIVAL AND DISPOSITION

MALES																								
GROUP : 1					2					3					4					5				
WEEK	LIVE	FD	EE	SE																				
0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0				
1	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0				
2	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0				
3	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0				
4	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0				
5	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0				
6	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0				
7	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0				
8	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0				
9	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0				
10	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0				
11	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0				
12	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0				
13	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0	10	0	0	0	10				

WEEK = WEEK OF STUDY FD = FOUND DEAD EE = EUTHANIZED IN EXTREMIS SE = SCHEDULED EUTHANASIA

1- NAIVE CONTROL 2-VEHICLE CONTROL 3- 15% PCMX 4- 30% PCMX 5- 60% PCMX

41 of 722

PROJECT NO.:WIL-304003
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TABLE 1
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF SURVIVAL AND DISPOSITION

GROUP :		1		2		3		4		5			
WEEK		LIVE	FD	EE	SE	LIVE	FD	EE	SE	LIVE	FD	EE	SE
0		10	0	0	0	10	0	0	0	10	0	0	0
1		10	0	0	0	10	0	0	0	10	0	0	0
2		10	0	0	0	10	0	0	0	10	0	0	0
3		10	0	0	0	10	0	0	0	10	0	0	0
4		10	0	0	0	10	0	0	0	10	0	0	0
5		10	0	0	0	10	0	0	0	10	0	0	0
6		10	0	0	0	10	0	0	0	10	0	0	0
7		10	0	0	0	10	0	0	0	10	0	0	0
8		10	0	0	0	10	0	0	0	10	0	0	0
9		10	0	0	0	10	0	0	0	10	0	0	0
10		10	0	0	0	10	0	0	0	10	0	0	0
11		10	0	0	0	10	0	0	0	10	0	0	0
12		10	0	0	0	10	0	0	0	10	0	0	0
13		0	0	0	10	0	0	0	10	0	0	0	10

WEEK = WEEK OF STUDY FD = FOUND DEAD EE = EUTHANIZED IN EXTREMIS SE = SCHEDULED EUTHANASIA

1- NAIVE CONTROL 2-VEHICLE CONTROL 3- 15% PCMX 4- 30% PCMX 5- 60% PCMX

42 of 722

PROJECT NO.:WIL-304003
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TABLE 2 (DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURENCE/NO. OF ANIMALS

PAGE 1

----- M A L E -----

TABLE RANGE: GROUP:	1	11-12-01 TO 2	02-12-02 3	4	5
NORMAL					
-NO SIGNIFICANT CLINICAL OBSERVATIONS	125/10	116/10	116/10	113/10	113/10
DISPOSITION					
-TERMINAL NECROPSY	10/10	10/10	10/10	10/10	10/10
BODY/INTEGUMENT					
-SCABBING AT TATTOO SITE	6/ 2	1/ 1	0/ 0	1/ 1	0/ 0
-TAIL BROKEN	0/ 0	1/ 1	7/ 1	0/ 0	0/ 0
-DERMAL ABRASIONS NOT WITHIN DOSE SITE	0/ 0	0/ 0	0/ 0	2/ 2	2/ 2
-SCABBING DORSAL TRUNK	1/ 1	0/ 0	0/ 0	0/ 0	0/ 0
-SCABBING DORSAL TRUNK NOT WITHIN DOSE SITE	0/ 0	3/ 3	0/ 0	4/ 4	4/ 3
-ERYTHEMA DORSAL TRUNK NOT WITHIN DOSE SITE	0/ 0	1/ 1	0/ 0	0/ 0	1/ 1
-EXFOLIATION DORSAL TRUNK NOT WITHIN DOSE SITE	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
-SOFT PROTRUSION UMBILICAL AREA	0/ 0	0/ 0	3/ 1	0/ 0	0/ 0
-SOFT PROTRUSION UROGENITAL AREA	0/ 0	5/ 1	0/ 0	0/ 0	3/ 1
EYES/EARS/NOSE					
-DRIED RED MATERIAL ON RIGHT EAR	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
1- NAIVE CONTROL	2-VEHICLE CONTROL	3- 15% PCMX	4- 30% PCMX	5- 60% PCMX	

43 of 722

PROJECT NO.:WIL-304003
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TABLE 2 (DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

PAGE 2

----- M A L E -----

TABLE RANGE: GROUP:	1	11-12-01 TO 2	3	4	5
EYES/EARS/NOSE					
-DRIED RED MATERIAL ON LEFT EAR	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0
-DISTAL END OF RIGHT EAR MISSING	2/ 1	0/ 0	0/ 0	0/ 0	2/ 1
-REDDENED AREA LEFT EAR	8/ 2	13/ 3	0/ 0	3/ 1	2/ 1
-RIGHT EAR REDDENED	1/ 1	0/ 0	0/ 0	0/ 0	0/ 0
-REDDENED AREA RIGHT EAR	4/ 2	3/ 1	0/ 0	0/ 0	5/ 1
-DISTAL END OF LEFT EAR MISSING	2/ 1	6/ 3	0/ 0	2/ 1	0/ 0
EXCRETA					
-WET YELLOW MATERIAL UROGENITAL AREA	0/ 0	0/ 0	3/ 3	6/ 3	4/ 3
-DRIED YELLOW MATERIAL UROGENITAL AREA	0/ 0	0/ 0	14/ 5	11/ 3	9/ 3
1- NAIVE CONTROL	2-VEHICLE CONTROL	3- 15% PCMX	4- 30% PCMX	5- 60% PCMX	

PROJECT NO.:WIL-304003
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TABLE 2 (DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

PAGE 3

----- F E M A L E -----

TABLE RANGE: GROUP:	1	11-12-01 TO 02-12-02 2	3	4	5
NORMAL					
-NO SIGNIFICANT CLINICAL OBSERVATIONS	126/10	125/10	114/ 9	104/10	116/10
DISPOSITION					
-TERMINAL NECROPSY	10/10	10/10	10/10	10/10	10/10
BODY/INTEGUMENT					
-TAIL BROKEN	0/ 0	0/ 0	14/ 1	13/ 1	0/ 0
-DERMAL ABRASIONS NOT WITHIN DOSE SITE	2/ 2	3/ 3	4/ 4	2/ 2	5/ 5
-SCABBING DORSAL TRUNK NOT WITHIN DOSE SITE	0/ 0	3/ 2	0/ 0	1/ 1	1/ 1
-ERYTHEMA DORSAL TRUNK NOT WITHIN DOSE SITE	0/ 0	0/ 0	1/ 1	0/ 0	2/ 2
-EXFOLIATION DORSAL TRUNK NOT WITHIN DOSE SITE	0/ 0	1/ 1	1/ 1	0/ 0	2/ 2
-DISTAL END OF TAIL BLACKENED	3/ 1	4/ 2	0/ 0	11/ 3	8/ 2
-DISTAL END OF TAIL REDDENED	6/ 1	2/ 1	7/ 1	4/ 3	6/ 2
-DISTAL END OF TAIL MISSING	0/ 0	0/ 0	0/ 0	5/ 1	0/ 0
-WHITE AREA TIP OF TAIL	0/ 0	0/ 0	1/ 1	0/ 0	0/ 0
-HAIR LOSS RIGHT LATERAL NECK	1/ 1	0/ 0	0/ 0	0/ 0	0/ 0
-HAIR LOSS LEFT FORELIMB	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0
EYES/EARS/NOSE					
-DISTAL END OF RIGHT EAR MISSING	0/ 0	0/ 0	7/ 1	0/ 0	0/ 0
1- NAIVE CONTROL	2-VEHICLE CONTROL	3- 15% PCMX	4- 30% PCMX	5- 60% PCMX	

45 of 722

PROJECT NO.:WIL-304003
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TABLE 2 (DETAILED PHYSICAL EXAMINATIONS/DISPOSITIONS)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

PAGE 4

----- F E M A L E -----

TABLE RANGE:	11-12-01 TO 02-12-02				
GROUP:	1	2	3	4	5
EYES/EARS/NOSE					
-REDDENED AREA LEFT EAR	0/ 0	0/ 0	0/ 0	0/ 0	1/ 1
-RIGHT EAR REDDENED	0/ 0	0/ 0	4/ 1	0/ 0	0/ 0
-REDDENED AREA RIGHT EAR	3/ 1	1/ 1	1/ 1	0/ 0	1/ 1
-LATERAL PORTION OF RIGHT EAR MISSING	1/ 1	0/ 0	0/ 0	0/ 0	0/ 0
EXCRETA					
-DRIED RED MATERIAL ON CAGE FLOOR	0/ 0	1/ 1	0/ 0	0/ 0	1/ 1

1- NAIVE CONTROL 2-VEHICLE CONTROL 3- 15% PCMX 4- 30% PCMX 5- 60% PCMX

PCSUv4.04
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TABLE 3 (3-HOURS POST-DOSING)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

PAGE 1

----- M A L E -----

TABLE RANGE: GROUP:	1	11-12-01 TO 2	02-11-02 3	4	5
BODY/INTEGUMENT					
-WET YELLOW MATERIAL VENTRAL TRUNK	0/ 0	0/ 0	2/ 2	3/ 3	4/ 1
-DRIED YELLOW MATERIAL VENTRAL TRUNK	0/ 0	0/ 0	3/ 2	3/ 2	15/ 2
EYES/EARS/NOSE					
-DRIED RED MATERIAL ON RIGHT EAR	1/ 1	2/ 1	0/ 0	0/ 0	0/ 0
-DRIED RED MATERIAL ON LEFT EAR	1/ 1	2/ 1	0/ 0	0/ 0	0/ 0
-WET RED MATERIAL ON LEFT EAR	0/ 0	1/ 1	0/ 0	0/ 0	0/ 0
EXCRETA					
-WET YELLOW MATERIAL UROGENITAL AREA	2/ 1	3/ 1	64/ 6	49/10	67/10
-DRIED YELLOW MATERIAL UROGENITAL AREA	8/ 2	2/ 2	165/ 6	139/ 9	138/ 9
1- NAIVE CONTROL	2-VEHICLE CONTROL	3- 15% PCMX	4- 30% PCMX	5- 60% PCMX	

PROJECT NO.:WIL-304003
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TABLE 3 (3-HOURS POST-DOSING)
A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
SUMMARY OF CLINICAL FINDINGS: TOTAL OCCURRENCE/NO. OF ANIMALS

PAGE 2

----- F E M A L E -----

TABLE RANGE: GROUP:	1	11-12-01 TO 2	02-11-02	3	4	5
BODY/INTEGUMENT						
-WET YELLOW MATERIAL VENTRAL TRUNK	0/ 0	0/ 0	0/ 0	1/ 1	0/ 0	0/ 0
EYES/EARS/NOSE						
-DRIED RED MATERIAL ON RIGHT EAR	0/ 0	0/ 0	5/ 1	0/ 0	0/ 0	0/ 0
EXCRETA						
-WET YELLOW MATERIAL UROGENITAL AREA	0/ 0	0/ 0	1/ 1	1/ 1	0/ 0	0/ 0

1- NAIVE CONTROL 2-VEHICLE CONTROL 3- 15% PCMX 4- 30% PCMX 5- 60% PCMX

PCSUv4.04
06/06/2002
R:06/06/2002

PROJECT NO.: WIL-304003
 SPONSOR: CLARIANT CORP.

TABLE 4
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 DERMAL OBSERVATIONS: TOTAL INCIDENCE / NO. OF ANIMALS

PAGE 1

----- M A L E -----

TABLE RANGE:	11-12-01 TO 02-12-02				
GROUP:	1	2	3	4	5
DERMAL OBS					
-SCORED, NOT REMARKABLE	140/10	141/10	57/10	17/10	13/10
-NO ERYTHEMA	0/0	0/0	29/9	33/9	21/6
-ERYTHEMA - VERY SLIGHT	0/0	0/0	46/10	70/10	72/10
-ERYTHEMA - SLIGHT	0/0	0/0	8/5	19/9	33/10
-ERYTHEMA - MODERATE	0/0	0/0	0/0	1/1	1/1
-NO EDEMA	0/0	0/0	76/10	100/10	92/10
-EDEMA - VERY SLIGHT	0/0	0/0	7/5	16/9	26/10
-EDEMA - SLIGHT	0/0	0/0	0/0	7/6	7/6
-EDEMA - MODERATE	0/0	0/0	0/0	0/0	2/2
-DESQUAMATION	0/0	0/0	78/10	117/10	124/10
-ENCRUSTATION	0/0	0/0	0/0	3/3	0/0
-SCABBING	0/0	0/0	0/0	1/1	6/4
1- NAIVE CONTROL	2-VEHICLE CONTROL	3- 15% PCMX	4- 30% PCMX	5- 60% PCMX	

49 OF 722

PROJECT NO.: WIL-304003
 SPONSOR: CLARIANT CORP.

TABLE 4
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 DERMAL OBSERVATIONS: TOTAL INCIDENCE / NO. OF ANIMALS

----- F E M A L E -----

DERMAL OBS	1	2	3	4	5
-SCORED, NOT REMARKABLE	140/10	140/10	54/10	27/10	14/10
-NO ERYTHEMA	0/0	0/0	46/10	46/10	32/8
-ERYTHEMA - VERY SLIGHT	0/0	0/0	40/9	59/10	61/10
-ERYTHEMA - SLIGHT	0/0	0/0	0/0	8/3	32/9
-ERYTHEMA - MODERATE	0/0	0/0	0/0	0/0	1/1
-NO EDEMA	0/0	0/0	84/10	99/10	93/10
-EDEMA - VERY SLIGHT	0/0	0/0	2/2	12/9	28/10
-EDEMA - SLIGHT	0/0	0/0	0/0	2/2	5/4
-DESQUAMATION	0/0	0/0	72/10	105/10	120/10
-SCABBING	0/0	0/0	0/0	1/1	8/3

1- NAIVE CONTROL 2-VEHICLE CONTROL 3- 15% PCMX 4- 30% PCMX 5- 60% PCMX

PCSUv4.04
 06/06/2002

TABLE 5
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF BODY WEIGHTS [G]

GROUP:		----- M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK -1	MEAN	26.6	26.5	26.6	26.5	26.6
	S.D.	1.45	1.42	1.45	1.46	1.29
	N	10	10	10	10	10
0	MEAN	27.3	26.6	26.8	27.2	27.0
	S.D.	1.40	2.09	1.64	1.52	1.59
	N	10	10	10	10	10
1	MEAN	28.8	27.8	27.4	28.1	28.1
	S.D.	1.25	1.77	1.92	1.68	1.85
	N	10	10	10	10	10
2	MEAN	30.0	29.4	29.2	29.6	29.4
	S.D.	1.37	1.80	2.31	2.03	2.15
	N	10	10	10	10	10
3	MEAN	31.4	30.9	30.2	30.8	30.7
	S.D.	1.31	1.40	2.35	2.01	2.23
	N	10	10	10	10	10

None significantly different from control group

51 of 722

TABLE 5
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF BODY WEIGHTS [G]

GROUP:		----- M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK 4	MEAN	32.3	31.8	31.2	32.2	32.2
	S.D.	1.53	1.91	2.77	1.79	2.37
	N	10	10	10	10	10
5	MEAN	32.5	32.7	32.2	32.4	32.8
	S.D.	1.41	2.19	2.62	1.83	2.08
	N	10	10	10	10	10
6	MEAN	32.9	33.4	33.1	33.3	33.9
	S.D.	1.69	2.44	2.68	1.97	2.16
	N	10	10	10	10	10
7	MEAN	33.9	34.2	33.8	33.9	34.1
	S.D.	1.98	2.34	2.77	2.34	2.64
	N	10	10	10	10	10
8	MEAN	34.2	34.4	33.8	33.8	34.5
	S.D.	2.08	2.50	2.72	1.96	2.54
	N	10	10	10	10	10

 None significantly different from control group

TABLE 5
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF BODY WEIGHTS [G]

GROUP:		M A L E				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK 9	MEAN	34.6	34.9	34.2	34.6	34.7
	S.D.	2.03	2.57	2.98	2.19	2.74
	N	10	10	10	10	10
10	MEAN	35.4	35.2	34.7	34.8	35.2
	S.D.	2.01	2.65	2.49	1.99	2.57
	N	10	10	10	10	10
11	MEAN	35.3	35.4	34.6	35.4	36.2
	S.D.	1.91	2.89	2.41	2.05	2.89
	N	10	10	10	10	10
12	MEAN	35.5	35.7	35.4	35.6	36.0
	S.D.	2.24	2.95	2.59	1.73	2.91
	N	10	10	10	10	10
13	MEAN	35.4	35.8	35.5	35.6	36.4
	S.D.	2.56	3.09	2.57	1.94	3.54
	N	10	10	10	10	10

None significantly different from control group

53 of 722

TABLE 5
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF BODY WEIGHTS [G]

GROUP:		NAIVE CONTROL	----- F E M A L E -----			
		VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX	
WEEK -1	MEAN	21.9	21.8	21.9	21.8	22.0
	S.D.	0.96	1.02	1.06	1.04	1.12
	N	10	10	10	10	10
0	MEAN	22.3	21.7	22.1	21.6	21.8
	S.D.	1.12	0.98	1.22	1.31	1.12
	N	10	10	10	10	10
1	MEAN	23.8	23.1	23.4	22.9	22.9
	S.D.	0.98	1.32	1.58	1.36	0.61
	N	10	10	10	10	10
2	MEAN	25.6	25.1	24.7	24.6	24.6
	S.D.	1.49	1.70	1.79	1.39	0.90
	N	10	10	10	10	10
3	MEAN	27.2	26.1	26.4	25.7	25.7
	S.D.	1.51	2.15	1.78	1.38	1.25
	N	10	10	10	10	10

 None significantly different from control group

54 OF 722

TABLE 5
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF BODY WEIGHTS [G]

GROUP:		NAIVE CONTROL	----- F E M A L E -----				
			VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX	
WEEK	4	MEAN	27.5	27.1	27.0	26.1	26.3
		S.D.	1.70	1.80	1.81	1.50	1.28
		N	10	10	10	10	10
	5	MEAN	27.8	27.1	26.9	26.5	26.2
		S.D.	1.62	2.38	2.10	1.26	1.17
		N	10	10	10	10	10
	6	MEAN	27.9	28.6	27.3	27.1	27.0
		S.D.	1.89	3.12	1.95	1.55	1.36
		N	10	10	10	10	10
	7	MEAN	29.4	28.2	27.4	27.2*	26.9*
		S.D.	1.80	3.16	1.71	1.44	1.05
		N	10	10	10	10	10
	8	MEAN	29.0	28.7	27.8	27.4	27.4
		S.D.	1.35	3.13	1.54	1.63	1.09
		N	10	10	10	10	10

* = Significantly different from the control group at 0.05 using Dunnett's test

55 of 722

TABLE 5
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF BODY WEIGHTS [G]

GROUP:		NAIVE CONTROL	F E M A L E			
		VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX	
WEEK 9	MEAN	28.8	29.1	28.6	28.5	27.6
	S.D.	2.26	2.93	2.17	1.56	1.41
	N	10	10	10	10	10
10	MEAN	29.8	29.7	29.3	28.5	28.1
	S.D.	1.84	3.27	1.92	1.99	1.38
	N	10	10	10	10	10
11	MEAN	29.8	29.7	29.0	29.0	28.4
	S.D.	1.83	2.97	1.98	2.43	1.51
	N	10	10	10	10	10
12	MEAN	30.1	30.9	29.8	28.8	28.3
	S.D.	1.59	3.63	2.02	2.26	1.52
	N	10	10	10	10	10
13	MEAN	29.5	29.8	29.5	28.9	28.3
	S.D.	2.17	2.77	2.47	2.25	1.38
	N	10	10	10	10	10

None significantly different from control group

56 of 722

TABLE 6
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF BODY WEIGHT CHANGES [G]

GROUP:		M A L E				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK	-1 TO 0					
	MEAN	0.7	0.1	0.2	0.7	0.4
	S.D.	0.30	0.89	0.60	0.67	0.45
	N	10	10	10	10	10
	0 TO 1					
	MEAN	1.5	1.2	0.6	0.9	1.1
	S.D.	0.52	0.82	0.70	0.73	0.79
	N	10	10	10	10	10
	1 TO 2					
	MEAN	1.3	1.6	1.9	1.5	1.3
	S.D.	0.80	0.38	1.00	1.05	0.49
	N	10	10	10	10	10
	2 TO 3					
	MEAN	1.4	1.5	1.0	1.2	1.3
	S.D.	0.61	0.99	0.50	0.77	0.67
	N	10	10	10	10	10
	3 TO 4					
	MEAN	0.9	1.0	1.0	1.3	1.5
	S.D.	0.58	0.84	1.20	0.48	0.55
	N	10	10	10	10	10

None significantly different from control group

57 of 722

TABLE 6
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF BODY WEIGHT CHANGES [G]

GROUP:		----- M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK 4 TO 5	MEAN	0.3	0.9	1.1	0.3	0.6
	S.D.	0.58	0.67	0.76	0.30	1.01
	N	10	10	10	10	10
5 TO 6	MEAN	0.4	0.7	0.9	0.9	1.2
	S.D.	0.61	0.85	0.75	0.53	0.40
	N	10	10	10	10	10
6 TO 7	MEAN	0.9	0.9	0.6	0.6	0.1
	S.D.	0.65	0.32	0.93	0.67	0.59
	N	10	10	10	10	10
7 TO 8	MEAN	0.3	0.2	0.0	-0.1	0.5
	S.D.	0.59	0.62	0.50	0.50	0.53
	N	10	10	10	10	10
8 TO 9	MEAN	0.4	0.4	0.4	0.8	0.2
	S.D.	0.60	0.76	0.62	0.62	0.96
	N	10	10	10	10	10

None significantly different from control group

58 of 722

TABLE 6
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF BODY WEIGHT CHANGES [G]

GROUP:		----- M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK	9 TO 10					
	MEAN	0.8	0.3	0.5	0.3	0.5
	S.D.	0.46	0.58	0.70	0.64	0.98
	N	10	10	10	10	10
	10 TO 11					
	MEAN	-0.2	0.2	-0.1	0.6*	1.0**
	S.D.	0.62	0.28	0.55	0.67	1.00
	N	10	10	10	10	10
	11 TO 12					
	MEAN	0.2	0.4	0.8	0.2	-0.2
	S.D.	0.62	0.47	0.38	0.71	0.39
	N	10	10	10	10	10
	12 TO 13					
	MEAN	0.0	0.1	0.1	0.0	0.4
	S.D.	1.07	0.34	0.39	0.79	0.77
	N	10	10	10	10	10

* = Significantly different from the control group at 0.05 using Dunnett's test
 ** = Significantly different from the control group at 0.01 using Dunnett's test

59 of 722

TABLE 6
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF BODY WEIGHT CHANGES [G]

GROUP:		----- F E M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK	-1 TO 0					
	MEAN	0.4	-0.1	0.2	-0.2	-0.2
	S.D.	0.68	0.50	0.55	0.50	0.72
	N	10	10	10	10	10
	0 TO 1					
	MEAN	1.5	1.4	1.3	1.3	1.1
	S.D.	0.58	0.71	1.03	0.55	0.94
	N	10	10	10	10	10
	1 TO 2					
	MEAN	1.9	2.0	1.4	1.6	1.7
	S.D.	1.17	1.02	0.59	0.65	0.70
	N	10	10	10	10	10
	2 TO 3					
	MEAN	1.6	1.0	1.7	1.1	1.1
	S.D.	0.87	1.03	0.52	0.86	0.88
	N	10	10	10	10	10
	3 TO 4					
	MEAN	0.3	1.1	0.6	0.5	0.7
	S.D.	1.07	1.18	0.40	0.62	0.62
	N	10	10	10	10	10

None significantly different from control group

60 of 722

TABLE 6
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF BODY WEIGHT CHANGES [G]

GROUP:		----- F E M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK 4 TO 5	MEAN	0.3	0.0	-0.1	0.3	-0.1
	S.D.	0.57	0.80	0.99	0.80	0.63
	N	10	10	10	10	10
5 TO 6	MEAN	0.1	1.5**	0.4	0.6	0.8
	S.D.	1.10	1.13	0.85	0.70	0.68
	N	10	10	10	10	10
6 TO 7	MEAN	1.6	-0.4**	0.2**	0.2**	-0.1**
	S.D.	1.12	0.52	0.65	0.95	0.61
	N	10	10	10	10	10
7 TO 8	MEAN	-0.4	0.5	0.3	0.2	0.6
	S.D.	1.38	1.23	0.78	0.81	0.46
	N	10	10	10	10	10
8 TO 9	MEAN	-0.3	0.4	0.9	1.0	0.2
	S.D.	1.15	1.32	1.12	0.88	0.66
	N	10	10	10	10	10

** = Significantly different from the control group at 0.01 using Dunnett's test

61 of 722

PROJECT NO.:WIL-304003
 SPONSOR:CLARIANT CORP.

TABLE 6
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF BODY WEIGHT CHANGES [G]

PAGE 6

GROUP:		----- F E M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK	9 TO 10					
	MEAN	1.0	0.7	0.6	0.0	0.5
	S.D.	1.04	1.37	0.74	0.93	0.73
	N	10	10	10	10	10
	10 TO 11					
	MEAN	0.0	0.0	-0.3	0.5	0.2
	S.D.	0.60	1.17	0.66	0.96	0.64
	N	10	10	10	10	10
	11 TO 12					
	MEAN	0.2	1.2	0.8	-0.2	-0.1
	S.D.	1.13	1.36	0.86	0.49	0.39
	N	10	10	10	10	10
	12 TO 13					
	MEAN	-0.5	-1.2	-0.3	0.1	-0.1
	S.D.	1.22	1.16	1.34	1.12	0.73
	N	10	10	10	10	10

62 of 722

None significantly different from control group

PBFSTv5.01
 06/06/2002

TABLE 6A
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF CUMULATIVE BODY WEIGHT CHANGES [G]

GROUP:		----- M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK	0 TO 1					
	MEAN	1.5	1.2	0.6	0.9	1.1
	S.D.	0.52	0.82	0.70	0.73	0.79
	N	10	10	10	10	10
	0 TO 2					
	MEAN	2.8	2.8	2.4	2.4	2.4
	S.D.	1.04	0.98	1.25	1.35	0.94
	N	10	10	10	10	10
	0 TO 3					
	MEAN	4.1	4.3	3.4	3.6	3.7
	S.D.	1.20	1.65	1.52	1.49	1.26
	N	10	10	10	10	10
	0 TO 4					
	MEAN	5.0	5.3	4.4	5.0	5.2
	S.D.	1.31	1.87	1.60	1.55	1.40
	N	10	10	10	10	10
	0 TO 5					
	MEAN	5.3	6.2	5.4	5.2	5.8
	S.D.	1.30	1.92	1.54	1.55	1.28
	N	10	10	10	10	10

 None significantly different from control group

63 of 722

TABLE 6A
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF CUMULATIVE BODY WEIGHT CHANGES [G]

GROUP:		M A L E				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK	0 TO 6					
	MEAN	5.7	6.8	6.3	6.1	7.0
	S.D.	1.58	1.60	1.82	1.75	1.45
	N	10	10	10	10	10
	0 TO 7					
	MEAN	6.6	7.7	7.0	6.7	7.1
	S.D.	1.96	1.54	1.75	2.03	1.94
	N	10	10	10	10	10
	0 TO 8					
	MEAN	6.9	7.9	7.0	6.6	7.5
	S.D.	1.88	1.52	1.70	1.83	1.79
	N	10	10	10	10	10
	0 TO 9					
	MEAN	7.3	8.3	7.4	7.4	7.7
	S.D.	1.85	1.79	1.98	2.09	1.94
	N	10	10	10	10	10
	0 TO 10					
	MEAN	8.2	8.7	7.9	7.6	8.2
	S.D.	1.89	1.73	1.61	2.00	1.90
	N	10	10	10	10	10

None significantly different from control group

PROJECT NO.:WIL-304003
 SPONSOR:CLARIANT CORP.

TABLE 6A
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF CUMULATIVE BODY WEIGHT CHANGES [G]

PAGE 3

GROUP:		----- M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK	0 TO 11					
	MEAN	8.0	8.8	7.8	8.2	9.2
	S.D.	1.77	1.93	1.44	1.95	2.33
	N	10	10	10	10	10
	0 TO 12					
	MEAN	8.2	9.2	8.6	8.4	9.0
	S.D.	2.02	1.95	1.69	1.96	2.37
	N	10	10	10	10	10
	0 TO 13					
	MEAN	8.2	9.3	8.7	8.4	9.4
	S.D.	2.44	2.08	1.80	2.13	2.84
	N	10	10	10	10	10

 None significantly different from control group

65 of 722

TABLE 6A
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF CUMULATIVE BODY WEIGHT CHANGES [G]

GROUP:		----- F E M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK	0 TO 1					
	MEAN	1.5	1.4	1.3	1.3	1.1
	S.D.	0.58	0.71	1.03	0.55	0.94
	N	10	10	10	10	10
	0 TO 2					
	MEAN	3.4	3.4	2.6	3.0	2.8
	S.D.	1.15	1.04	1.29	0.69	0.88
	N	10	10	10	10	10
	0 TO 3					
	MEAN	4.9	4.4	4.3	4.1	3.9
	S.D.	1.26	1.49	1.18	0.91	1.45
	N	10	10	10	10	10
	0 TO 4					
	MEAN	5.2	5.5	4.9	4.5	4.5
	S.D.	1.39	1.02	1.16	0.87	1.24
	N	10	10	10	10	10
	0 TO 5					
	MEAN	5.5	5.5	4.8	4.9	4.4
	S.D.	1.23	1.57	1.29	0.79	1.16
	N	10	10	10	10	10

None significantly different from control group

66 of 722

TABLE 6A
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF CUMULATIVE BODY WEIGHT CHANGES [G]

GROUP:		----- F E M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK	0 TO 6					
	MEAN	5.6	6.9	5.2	5.4	5.2
	S.D.	1.71	2.38	1.09	1.29	0.88
	N	10	10	10	10	10
	0 TO 7					
	MEAN	7.2	6.6	5.3*	5.6	5.1*
	S.D.	1.59	2.40	0.93	1.57	0.80
	N	10	10	10	10	10
	0 TO 8					
	MEAN	6.8	7.0	5.6	5.8	5.6
	S.D.	1.55	2.27	0.69	1.68	0.89
	N	10	10	10	10	10
	0 TO 9					
	MEAN	6.5	7.4	6.5	6.8	5.8
	S.D.	2.05	2.20	1.64	1.30	1.12
	N	10	10	10	10	10
	0 TO 10					
	MEAN	7.5	8.1	7.1	6.9	6.3
	S.D.	1.87	2.53	1.11	1.61	0.97
	N	10	10	10	10	10

* = Significantly different from the control group at 0.05 using Dunnett's test

67 of 722

PROJECT NO.:WIL-304003
 SPONSOR:CLARIANT CORP.

TABLE 6A
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF CUMULATIVE BODY WEIGHT CHANGES [G]

GROUP:		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
----- F E M A L E -----						
WEEK	0 TO 11					
	MEAN	7.6	8.1	6.9	7.4	6.5
	S.D.	1.89	2.13	1.19	1.97	1.13
	N	10	10	10	10	10
	0 TO 12					
	MEAN	7.8	9.3	7.7	7.2	6.5
	S.D.	1.12	2.74	1.08	1.74	0.99
	N	10	10	10	10	10
	0 TO 13					
	MEAN	7.2	8.1	7.4	7.3	6.4
	S.D.	2.05	1.86	1.66	1.86	0.76
	N	10	10	10	10	10

None significantly different from control group

TABLE 7
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF WEEKLY FOOD CONSUMPTION [G/ANIMAL/DAY]

GROUP:		----- M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK	0 TO 1					
	MEAN	6.5	5.8	6.2	6.7	6.7
	S.D.	0.91	0.74	0.48	1.10	0.46
	N	10	10	10	10	10
	1 TO 2					
	MEAN	6.3	5.8	6.2	6.7	6.9
	S.D.	0.93	0.74	0.53	0.86	1.31
	N	10	10	10	10	10
	2 TO 3					
	MEAN	6.4	6.2	6.4	6.7	7.0
	S.D.	0.80	0.68	0.70	0.77	1.11
	N	9	10	10	10	10
	3 TO 4					
	MEAN	6.6	6.3	6.4	6.8	7.0
	S.D.	1.01	0.85	0.69	0.66	0.91
	N	10	10	10	10	10
	4 TO 5					
	MEAN	6.3	6.0	6.5	6.7	7.4*
	S.D.	0.48	0.59	0.82	0.62	1.00
	N	9	10	10	10	10

69 of 722

* = Significantly different from the control group at 0.05 using Dunnett's test

TABLE 7
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF WEEKLY FOOD CONSUMPTION [G/ANIMAL/DAY]

GROUP:		----- M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK 5 TO 6	MEAN	6.2	6.4	6.4	6.7	7.5*
	S.D.	0.98	1.02	0.39	0.49	1.34
	N	10	10	10	10	10
6 TO 7	MEAN	6.0	6.2	6.5	6.7	7.3
	S.D.	1.87	1.00	0.40	1.16	1.03
	N	10	10	10	10	10
7 TO 8	MEAN	6.5	6.4	6.5	6.5	7.6
	S.D.	0.86	1.05	0.61	0.50	1.86
	N	10	10	10	10	10
8 TO 9	MEAN	6.4	5.9	6.5	6.5	7.3
	S.D.	1.40	0.44	0.44	0.52	2.42
	N	10	10	10	10	10
9 TO 10	MEAN	5.9	5.7	6.3	6.4	7.4**
	S.D.	0.40	0.59	0.43	0.41	2.01
	N	10	10	10	10	10

* = Significantly different from the control group at 0.05 using Dunnett's test
 ** = Significantly different from the control group at 0.01 using Dunnett's test

70 of 722

TABLE 7
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF WEEKLY FOOD CONSUMPTION [G/ANIMAL/DAY]

GROUP:		M A L E				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK 10 TO 11	MEAN	6.1	5.7	6.1	6.5	6.7
	S.D.	0.71	0.63	0.42	0.73	1.01
	N	10	10	10	10	10
11 TO 12	MEAN	6.3	5.7	6.2	6.3	6.4
	S.D.	0.90	0.60	0.43	0.47	0.56
	N	10	10	10	10	10
12 TO 13	MEAN	5.8	5.2	5.9	6.3	6.5
	S.D.	0.87	1.46	0.28	0.51	0.82
	N	10	10	10	10	10

None significantly different from control group

71 of 722

TABLE 7
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF WEEKLY FOOD CONSUMPTION [G/ANIMAL/DAY]

GROUP:		----- F E M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK 0 TO 1	MEAN	5.6	6.0	6.3	6.0	6.0
	S.D.	0.45	0.70	1.85	1.08	0.83
	N	10	10	10	10	10
1 TO 2	MEAN	6.1	6.2	5.9	6.0	6.8
	S.D.	0.49	0.56	0.97	0.73	1.25
	N	10	10	10	10	10
2 TO 3	MEAN	6.7	6.9	5.7	6.8	6.9
	S.D.	0.68	1.05	1.89	1.22	0.83
	N	10	10	10	10	10
3 TO 4	MEAN	6.9	6.6	6.3	6.7	7.0
	S.D.	0.74	0.83	0.72	0.92	0.62
	N	10	10	10	10	10
4 TO 5	MEAN	6.9	6.5	6.6	6.7	7.0
	S.D.	0.74	0.74	1.01	0.62	0.61
	N	9	10	10	10	10

72 of 722

None significantly different from control group

TABLE 7
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF WEEKLY FOOD CONSUMPTION [G/ANIMAL/DAY]

GROUP:		NAIVE CONTROL	----- F E M A L E -----			
			VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK	5 TO 6					
	MEAN	7.0	6.7	6.4	7.3	6.9
	S.D.	0.95	0.81	0.68	1.73	0.88
	N	10	10	10	10	10
	6 TO 7					
	MEAN	7.5	6.0	6.2	7.0	6.5
	S.D.	2.24	1.40	0.54	1.49	0.42
	N	10	10	10	10	10
	7 TO 8					
	MEAN	6.3	6.3	6.2	7.0	6.7
	S.D.	0.59	0.88	0.64	1.53	0.68
	N	8	10	10	10	10
	8 TO 9					
	MEAN	6.6	6.4	6.3	6.9	6.5
	S.D.	1.63	0.96	0.53	1.33	0.39
	N	10	10	10	10	10
	9 TO 10					
	MEAN	6.7	6.1	6.3	6.6	6.5
	S.D.	1.72	0.86	0.63	1.16	0.49
	N	10	10	10	10	10

None significantly different from control group

73 of 722

TABLE 7
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF WEEKLY FOOD CONSUMPTION [G/ANIMAL/DAY]

GROUP:		NAIVE CONTROL	----- F E M A L E -----			
			VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WEEK	10 TO 11					
	MEAN	6.0	6.1	6.2	6.6	6.2
	S.D.	0.69	0.82	0.74	1.12	0.30
	N	10	10	10	10	10
	11 TO 12					
	MEAN	6.5	6.2	5.9	6.3	6.1
	S.D.	1.45	0.76	0.62	1.05	0.31
	N	10	10	10	10	10
	12 TO 13					
	MEAN	6.0	5.8	6.2	6.4	6.5
	S.D.	1.21	0.76	0.94	0.99	0.61
	N	10	10	10	10	10

None significantly different from control group

PROJECT NO.: WIL-304003
 SPONSOR: CLARIANT CORP.

TABLE 8
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF HEMATOLOGY VALUES

PAGE 1
 WEEK 13

ANALYSIS	GROUP:	M A L E				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WHITE CELL (thous/uL)	MEAN	3.4	3.3	3.2	3.5	4.1
	S.D.	1.45	0.88	2.18	1.98	1.61
	N	5	5	5	5	5
RED CELLS (mil/uL)	MEAN	8.79	8.95	8.74	8.88	8.92
	S.D.	0.448	0.739	0.484	0.223	0.299
	N	5	5	5	5	5
HEMOGLOBIN (g/dL)	MEAN	13.4	14.0	13.9	13.9	14.1
	S.D.	1.08	1.20	0.50	0.36	0.29
	N	5	5	5	5	5
HEMATOCRIT (%)	MEAN	40.1	41.7	40.9	41.6	42.0
	S.D.	3.36	3.43	1.50	0.97	1.15
	N	5	5	5	5	5
MCV (fL)	MEAN	45.6	46.6	46.9	46.8	47.0
	S.D.	2.60	2.02	1.72	0.55	1.17
	N	5	5	5	5	5

g/dL = GRAMS/DECILITER, thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, uug = PICOGRAMS,
 fL = FEMTOLITERS

None significantly different from control group

75 of 722

PROJECT NO.: WIL-304003
 SPONSOR: CLARIANT CORP.

TABLE 8
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF HEMATOLOGY VALUES

PAGE 2
 WEEK 13

ANALYSIS	GROUP:	M A L E				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
MCH (uug)	MEAN	15.2	15.6	15.9	15.7	15.8
	S.D.	0.78	0.72	0.54	0.40	0.43
	N	5	5	5	5	5
MCHC (g/dL)	MEAN	33.4	33.5	34.0	33.5	33.6
	S.D.	0.58	0.25	0.22	0.58	0.53
	N	5	5	5	5	5
PLATELET (thous/uL)	MEAN	1154.	1100.	1138.	1240.	1137.
	S.D.	279.8	197.3	152.5	248.6	221.2
	N	5	5	5	5	5

g/dL = GRAMS/DECILITER, thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, uug = PICOGRAMS,
 fL = FEMTOLITERS

None significantly different from control group

76 of 722

PROJECT NO.:WIL-304003
 SPONSOR:CLARIANT CORP.

TABLE 8
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF HEMATOLOGY VALUES

PAGE 3
 WEEK 13

-----F E M A L E -----						
ANALYSIS	GROUP:	NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
WHITE CELL (thous/uL)	MEAN	4.2	2.5	3.8	3.4	5.7
	S.D.	1.03	0.99	1.34	1.74	0.80
	N	5	5	5	5	5
RED CELLS (mil/uL)	MEAN	8.75	8.62	8.72	8.54	8.98
	S.D.	0.463	0.552	0.635	0.839	0.322
	N	5	5	5	5	5
HEMOGLOBIN (g/dL)	MEAN	14.2	13.8	14.2	13.6	14.4
	S.D.	0.87	1.01	0.77	0.66	0.25
	N	5	5	5	5	5
HEMATOCRIT (%)	MEAN	41.3	40.8	41.9	40.3	42.5
	S.D.	1.91	3.25	1.98	2.51	1.16
	N	5	5	5	5	5
MCV (fL)	MEAN	47.2	47.4	48.1	47.4	47.4
	S.D.	2.07	1.06	1.38	3.04	1.25
	N	5	5	5	5	5

g/dL = GRAMS/DECILITER, thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, uug = PICOGRAMS,
 fL = FEMTOLITERS

None significantly different from control group

77 of 722

PROJECT NO.:WIL-304003
 SPONSOR:CLARIANT CORP.

TABLE 8
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF HEMATOLOGY VALUES

PAGE 4
 WEEK 13

ANALYSIS	GROUP:	-----F E M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
MCH (uug)	MEAN	16.2	16.0	16.3	16.0	16.0
	S.D.	0.94	0.32	0.45	1.18	0.48
	N	5	5	5	5	5
MCHC (g/dL)	MEAN	34.3	33.8	34.0	33.8	33.9
	S.D.	0.58	0.37	0.69	0.47	0.43
	N	5	5	5	5	5
PLATELET (thous/uL)	MEAN	1109.	965.	1055.	927.	1031.
	S.D.	128.2	164.0	23.7	435.4	181.3
	N	5	5	5	5	5

g/dL = GRAMS/DECILITER, thous/uL = THOUSANDS/MICROLITER, mil/uL = MILLIONS/MICROLITER, uug = PICOGRAMS,
 fL = FEMTOLITERS

None significantly different from control group

PCPSv5.03
 06/06/2002

78 of 722

PROJECT NO.:WIL-304003
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TABLE 9
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF LEUKOCYTE DIFFERENTIAL COUNTS [%]

PAGE 1
 WEEK 13

ANALYSIS	GROUP:	----- M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
NEUTROPHIL						
	MEAN	29	25	20	25	24
	S.D.	14.1	11.8	6.9	10.0	10.5
	N	5	5	5	5	5
LYMPHOCYTE						
	MEAN	64	67	73	67	63
	S.D.	12.9	12.8	2.5	7.4	12.5
	N	5	5	5	5	5
MONOCYTE						
	MEAN	6	6	6	5	10
	S.D.	3.3	2.7	4.3	3.2	3.3
	N	5	5	5	5	5
EOSINOPHIL						
	MEAN	1	0	1	1	1
	S.D.	1.3	0.4	1.0	0.7	0.7
	N	5	5	5	5	5
BASOPHIL						
	MEAN	1	1	0	1	2
	S.D.	1.3	0.8	0.5	1.6	1.6
	N	5	5	5	5	5

None significantly different from control group

79 of 722

TABLE 9
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF LEUKOCYTE DIFFERENTIAL COUNTS [%]

ANALYSIS	GROUP:	-----F E M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
NEUTROPHIL	MEAN	23	18	16	19	21
	S.D.	10.4	3.7	4.0	7.2	3.4
	N	5	5	5	5	5
LYMPHOCYTE	MEAN	69	73	76	74	70
	S.D.	14.0	5.5	2.6	7.3	5.2
	N	5	5	5	5	5
MONOCYTE	MEAN	7	6	5	5	6
	S.D.	3.9	1.1	2.2	2.2	2.1
	N	5	5	5	5	5
EOSINOPHIL	MEAN	1	2	1	1	2
	S.D.	0.8	1.5	0.5	0.8	2.3
	N	5	5	5	5	5
BASOPHIL	MEAN	1	2	2	1	1
	S.D.	0.0	0.8	1.3	0.8	1.0
	N	5	5	5	5	5

None significantly different from control group

80 of 722

TABLE 10
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF LEUKOCYTE COUNTS

ANALYSIS	GROUP:	----- M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
NEUTROPHIL (thous/uL)	MEAN	0.9	0.9	0.5	0.8	0.9
	S.D.	0.43	0.65	0.39	0.20	0.52
	N	5	5	5	5	5
LYMPHOCYTE (thous/uL)	MEAN	2.3	2.2	2.3	2.5	2.6
	S.D.	1.30	0.56	1.63	1.55	1.25
	N	5	5	5	5	5
MONOCYTE (thous/uL)	MEAN	0.2	0.2	0.2	0.2	0.4
	S.D.	0.09	0.10	0.21	0.19	0.16
	N	5	5	5	5	5
EOSINOPHIL (thous/uL)	MEAN	0.0	0.0	0.0	0.0	0.0
	S.D.	0.04	0.01	0.03	0.04	0.02
	N	5	5	5	5	5
BASOPHIL (thous/uL)	MEAN	0.0	0.0	0.0	0.1	0.1
	S.D.	0.04	0.03	0.02	0.08	0.09
	N	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER

None significantly different from control group

81 of 722

TABLE 10
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF LEUKOCYTE COUNTS

ANALYSIS	GROUP:	-----F E M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
NEUTROPHIL (thous/uL)	MEAN	0.9	0.5	0.6	0.6	1.2
	S.D.	0.21	0.21	0.31	0.29	0.31
	N	5	5	5	5	5
LYMPHOCYTE (thous/uL)	MEAN	3.0	1.8	2.9	2.6	4.0
	S.D.	1.23	0.68	0.96	1.44	0.53
	N	5	5	5	5	5
MONOCYTE (thous/uL)	MEAN	0.3	0.1	0.2	0.2	0.3
	S.D.	0.14	0.08	0.10	0.08	0.11
	N	5	5	5	5	5
EOSINOPHIL (thous/uL)	MEAN	0.0	0.0	0.1	0.0	0.1
	S.D.	0.03	0.04	0.04	0.02	0.15
	N	5	5	5	5	5
BASOPHIL (thous/uL)	MEAN	0.0	0.1	0.1	0.0	0.1
	S.D.	0.01	0.04	0.05	0.05	0.06
	N	5	5	5	5	5

thous/uL = THOUSANDS/MICROLITER

None significantly different from control group

PROJECT NO.: WIL-304003
 SPONSOR: CLARIANT CORP.

TABLE 11
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF SERUM CHEMISTRY VALUES

PAGE 1
 WEEK 13

ANALYSIS	GROUP:	----- M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX

ALBUMIN (g/dL)						
	MEAN	3.0	3.1	3.2	3.0	2.7
	S.D.	0.19	0.23	0.18	0.22	0.31
	N	5	5	5	5	5

TOTAL PROTEIN (g/dL)						
	MEAN	5.1	5.1	5.3	5.0	5.0
	S.D.	0.15	0.31	0.36	0.36	0.18
	N	4	3	5	5	4

GLOBULIN (g/dL)						
	MEAN	2.1	2.2	2.1	1.9	2.4
	S.D.	0.19	0.17	0.24	0.13	0.45
	N	4	3	5	5	4

A/G RATIO						
	MEAN	1.51	1.36	1.49	1.57	1.20
	S.D.	0.214	0.144	0.161	0.094	0.319
	N	4	3	5	5	4

TOTAL BILI (mg/dL)						
	MEAN	0.5	0.6	0.3	0.3	0.5
	S.D.	0.28	0.41	0.04	0.07	0.30
	N	4	5	5	5	5

 U/L = INTERNATIONAL UNIT/LITER, g/dL = GRAMS/DECILITER, mg/dL = MILLIGRAMS/DECILITER,
 mEq/L = milliEquivalents/Liter

None significantly different from control group

83 of 722

PROJECT NO.: WIL-304003
 SPONSOR: CLARIANT CORP.

TABLE 11
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF SERUM CHEMISTRY VALUES

PAGE 2
 WEEK 13

ANALYSIS	GROUP:	M A L E				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
UREA NITROGEN (mg/dL)	MEAN	31.8	26.9	31.8	24.1	27.1
	S.D.	9.55	3.76	7.06	4.83	3.72
	N	4	3	5	5	4
CREATININE (mg/dL)	MEAN	0.0	0.1	0.1	0.0	0.1
	S.D.	0.06	0.00	0.00	0.00	0.07
	N	3	2	2	3	2
ALKALINEPHOS'TSE (U/L)	MEAN	47.	42.	52.	46.	43.
	S.D.	27.8	20.7	18.3	13.7	12.0
	N	5	5	5	5	5
ALANINE TRANSFER (U/L)	MEAN	38.	33.	40.	36.	32.
	S.D.	9.8	5.5	10.1	6.0	11.7
	N	5	5	5	5	5
ASPARTATTRANSFER (U/L)	MEAN	87.	67.	74.	60.	66.
	S.D.	50.4	8.7	27.5	4.5	34.4
	N	5	5	5	5	5

U/L = INTERNATIONAL UNIT/LITER, g/dL = GRAMS/DECILITER, mg/dL = MILLIGRAMS/DECILITER,
 mEq/L = milliEquivalents/Liter

None significantly different from control group

84 of 722

PROJECT NO.: WIL-304003
 SPONSOR: CLARIANT CORP.

TABLE 11
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF SERUM CHEMISTRY VALUES

PAGE 3
 WEEK 13

ANALYSIS	GROUP:	M A L E				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
GLUTAMYLTRANSFER (U/L)	MEAN	0.2	NA	NA	NA	1.3
	S.D.	0.00				0.00
	N	1				1
GLUCOSE (mg/dL)	MEAN	184.	265.	175.	238.	211.
	S.D.	18.7	46.5	62.9	49.2	42.7
	N	4	3	5	5	4
CHOLESTEROL (mg/dL)	MEAN	127.	142.	115.	112.	117.
	S.D.	36.3	18.7	16.5	14.1	20.7
	N	4	4	5	5	4
CALCIUM (mg/dL)	MEAN	9.8	10.3	10.5	10.2	10.1
	S.D.	0.13	0.64	0.62	0.34	0.32
	N	4	5	5	5	4
CHLORIDE (mEq/L)	MEAN	114.	109.*	114.	114.	114.
	S.D.	2.9	3.3	2.2	1.5	2.0
	N	5	5	5	5	5

U/L = INTERNATIONAL UNIT/LITER, g/dL = GRAMS/DECILITER, mg/dL = MILLIGRAMS/DECILITER,
 mEq/L = milliEquivalents/Liter

* = Significantly different from the control group at 0.05 using Dunnett's test
 NA = NOT APPLICABLE

85 of 722

PROJECT NO.: WIL-304003
 SPONSOR: CLARIANT CORP.

TABLE 11
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF SERUM CHEMISTRY VALUES

PAGE 4
 WEEK 13

ANALYSIS	GROUP:	----- M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
PHOSPHORUS (mg/dL)	MEAN	12.2	12.1	12.3	11.7	10.6
	S.D.	1.20	1.75	1.03	0.47	1.80
	N	5	5	5	5	5
POTASSIUM (mEq/L)	MEAN	10.57	12.34	10.99	11.39	10.26
	S.D.	3.013	2.077	2.861	2.375	2.579
	N	5	5	5	5	5
SODIUM (mEq/L)	MEAN	153.	148.	152.	151.	150.
	S.D.	4.5	3.9	3.0	2.5	1.9
	N	5	5	5	5	5
CREATINEKINASE (U/L)	MEAN	193.	345.	217.	141.	179.
	S.D.	83.4	391.2	174.0	35.2	86.9
	N	5	5	5	5	5
TRIGLYCERIDE (mg/dL)	MEAN	107.	259.	126.	116.	96.
	S.D.	36.2	254.2	29.6	30.7	25.3
	N	5	5	5	5	5

U/L = INTERNATIONAL UNIT/LITER, g/dL = GRAMS/DECILITER, mg/dL = MILLIGRAMS/DECILITER,
 mEq/L = milliEquivalents/Liter

None significantly different from control group

86 of 722

TABLE 11
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF SERUM CHEMISTRY VALUES

		-----F E M A L E -----				
ANALYSIS	GROUP:	NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
ALBUMIN (g/dL)	MEAN	3.1	3.2	3.4	3.4	3.2
	S.D.	0.56	0.23	0.22	0.32	0.19
	N	5	5	5	5	5
TOTAL PROTEIN (g/dL)	MEAN	4.9	5.0	5.2	5.3	5.0
	S.D.	0.29	0.32	0.33	0.43	0.08
	N	5	4	4	5	4
GLOBULIN (g/dL)	MEAN	1.9	1.9	1.8	1.8	1.8
	S.D.	0.43	0.26	0.16	0.11	0.17
	N	5	4	4	5	4
A/G RATIO	MEAN	1.74	1.67	1.87	1.86	1.81
	S.D.	0.608	0.286	0.149	0.071	0.265
	N	5	4	4	5	4
TOTAL BILI (mg/dL)	MEAN	0.4	0.3	0.4	0.4	0.4
	S.D.	0.19	0.14	0.25	0.09	0.13
	N	5	4	5	5	4

U/L = INTERNATIONAL UNIT/LITER, g/dL = GRAMS/DECILITER, mg/dL = MILLIGRAMS/DECILITER,
 mEq/L = milliEquivalents/Liter

None significantly different from control group

PROJECT NO.:WIL-304003
 SPONSOR:CLARIANT CORP.

TABLE 11
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF SERUM CHEMISTRY VALUES

PAGE 6
 WEEK 13

ANALYSIS	GROUP:	-----F E M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
UREA NITROGEN (mg/dL)						
	MEAN	17.5	20.8	18.0	21.8	21.2
	S.D.	2.37	3.43	2.48	3.06	5.16
	N	5	4	4	5	4
CREATININE (mg/dL)						
	MEAN	0.1	0.0	0.0	0.0	0.0
	S.D.	0.07	0.00	0.00	0.05	0.00
	N	2	1	3	4	1
ALKALINEPHOS' TSE (U/L)						
	MEAN	68.	51.	67.	79.	46.
	S.D.	46.8	3.8	20.4	26.0	14.0
	N	5	5	5	5	5
ALANINE TRANSFER (U/L)						
	MEAN	32.	33.	36.	43.	40.
	S.D.	3.4	4.3	4.8	9.7	11.8
	N	5	5	5	5	5
ASPARTATTRANSFER (U/L)						
	MEAN	74.	69.	68.	79.	126.
	S.D.	22.7	17.2	7.8	5.5	120.7
	N	5	5	5	5	5

U/L = INTERNATIONAL UNIT/LITER, g/dL = GRAMS/DECILITER, mg/dL = MILLIGRAMS/DECILITER,
 mEq/L = milliEquivalents/Liter

None significantly different from control group

88 of 722

TABLE 11
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF SERUM CHEMISTRY VALUES

ANALYSIS	GROUP:	-----F E M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
GLUTAMYLTRANSFER (U/L)	MEAN	1.6	0.6	2.2	3.3	NA
	S.D.	0.00	0.00	0.00	0.00	
	N	1	1	1	1	
GLUCOSE (mg/dL)	MEAN	200.	186.	245.*	202.	201.
	S.D.	25.8	19.7	35.0	17.9	14.6
	N	5	4	4	5	4
CHOLESTEROL (mg/dL)	MEAN	77.	92.	89.	99.	90.
	S.D.	22.6	21.4	10.8	21.7	18.4
	N	5	4	4	5	4
CALCIUM (mg/dL)	MEAN	10.4	10.0	10.6	10.5	10.0
	S.D.	0.31	0.61	0.24	0.56	0.31
	N	5	4	5	5	4
CHLORIDE (mEq/L)	MEAN	113.	113.	113.	116.	113.
	S.D.	3.1	3.1	2.9	3.0	1.6
	N	5	5	5	5	5

U/L = INTERNATIONAL UNIT/LITER, g/dL = GRAMS/DECILITER, mg/dL = MILLIGRAMS/DECILITER,
 mEq/L = milliEquivalents/Liter

* = Significantly different from the control group at 0.05 using Dunnett's test
 NA = NOT APPLICABLE

89 of 722

TABLE 11
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF SERUM CHEMISTRY VALUES

ANALYSIS	GROUP:	-----F E M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
PHOSPHORUS (mg/dL)	MEAN	11.8	11.0	11.8	11.4	10.3
	S.D.	1.47	1.34	1.90	1.30	0.80
	N	5	5	5	5	5
POTASSIUM (mEq/L)	MEAN	11.11	9.07	11.81	9.95	8.58
	S.D.	2.963	3.320	2.031	1.101	1.574
	N	5	5	5	5	5
SODIUM (mEq/L)	MEAN	148.	151.	148.	154.**	151.
	S.D.	0.7	2.5	2.2	2.2	1.5
	N	5	5	5	5	5
CREATINEKINASE (U/L)	MEAN	175.	148.	158.	204.	836.
	S.D.	101.6	80.7	70.3	91.0	1479.9
	N	5	5	5	5	5
TRIGLYCERIDE (mg/dL)	MEAN	101.	117.	111.	106.	85.
	S.D.	11.5	49.7	26.3	19.3	18.1
	N	5	5	5	5	5

U/L = INTERNATIONAL UNIT/LITER, g/dL = GRAMS/DECILITER, mg/dL = MILLIGRAMS/DECILITER,
 mEq/L = milliEquivalents/Liter

** = Significantly different from the control group at 0.01 using Dunnett's test

PROJECT NO.: WIL-304003
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TABLE 12 (WEEK -1 PRETEST EXAMINATION)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF OPHTHALMIC EXAMINATION FINDINGS

PAGE 1

GROUP:	M A L E					F E M A L E				
	1	2	3	4	5	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10	10	10	10	10	10	10
NUMBER OF ANIMALS EXAMINED EXAM 1(WEEK -1)	10	10	10	10	10	10	10	10	10	10
-NO OCULAR LESIONS - BILATERAL	10	10	10	10	10	10	10	10	10	10

1- NAIVE CONTROL 2-VEHICLE CONTROL 3- 15% PCMX 4- 30% PCMX 5- 60% PCMX

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TABLE 13 (WEEK 12 EXAMINATION)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF OPHTHALMIC EXAMINATION FINDINGS

PAGE 1

GROUP:	M A L E					F E M A L E				
	1	2	3	4	5	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10	10	10	10	10	10	10
NUMBER OF ANIMALS EXAMINED EXAM 2 (WEEK 12)	10	10	10	10	10	10	10	10	10	10
-NO OCULAR LESIONS - BILATERAL	10	10	10	10	10	9	10	10	10	10
-NO OCULAR LESIONS - UNILATERAL	0	0	0	0	0	1	0	0	0	0
-PHTHISIS BULBI - UNILATERAL	0	0	0	0	0	1	0	0	0	0

1- NAIVE CONTROL 2-VEHICLE CONTROL 3- 15% PCMX 4- 30% PCMX 5- 60% PCMX

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PROJECT NO.:WIL-304003
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TABLE 14 (WEEK 13 NECROPSY)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF MACROSCOPIC FINDINGS

PAGE 1

SCHEDULED NECROPSY

GROUP:	M A L E					F E M A L E				
	1	2	3	4	5	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10	10	10	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	10	10	10	10	10	10	10	10	10	10
EYES/OPTIC N. -EYE(S)-OPACITY	0	0	0	0	0	1	0	0	0	0
HARDERIAN GLANDS -DISCOLORATION, GRAY	1	0	0	0	1	0	1	0	1	0
JEJUNUM -DIVERTICULUM	0	0	0	0	0	1	0	0	0	0
KIDNEYS -DILATED PELVIS	0	0	0	0	1	0	0	0	0	0
LYMPH NODE, MAND -ENLARGED	1	0	0	0	0	1	0	0	0	0
OVIDUCTS -CYST(S)	NA	NA	NA	NA	NA	0	0	2	1	2
OVARIES -AREA(S), WHITE	NA	NA	NA	NA	NA	1	0	0	0	0
STOMACH -DIVERTICULUM	0	0	0	0	1	0	0	0	0	0
SKIN -SCABBING	0	0	0	0	0	1	0	0	0	0
1- NAIVE CONTROL	2-VEHICLE CONTROL	3-	15% PCMX	4-	30% PCMX	5-	60% PCMX			
NA = NOT APPLICABLE										

93 of 722

PROJECT NO.:WIL-304003
 SPONSOR:CLARIANT CORP.

TABLE 14 (WEEK 13 NECROPSY)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF MACROSCOPIC FINDINGS

PAGE 2

SCHEDULED NECROPSY

GROUP:	M A L E					F E M A L E				
	1	2	3	4	5	1	2	3	4	5
NUMBER OF ANIMALS IN DOSE GROUP	10	10	10	10	10	10	10	10	10	10
NUMBER OF ANIMALS EXAMINED WEEK 13	10	10	10	10	10	10	10	10	10	10
SKIN - CONTINUED										
-MASS	0	0	1	0	0	0	0	0	0	0
SPLEEN										
-ENLARGED	0	0	0	0	0	1	0	0	1	0
SEMINAL VESICLES										
-SMALL	1	0	0	0	0	NA	NA	NA	NA	NA
TESTES										
-SMALL	0	0	0	0	1	NA	NA	NA	NA	NA
-SOFT	0	0	0	0	1	NA	NA	NA	NA	NA
TREATED SKIN										
-THICKENED	0	0	0	0	1	0	0	0	0	1
-SCABBING	0	0	0	0	1	0	0	0	0	0
EAR										
-SCABBING	1	3	0	1	2	1	1	0	0	2
URETER(S)										
-DISTENDED	0	0	0	0	1	0	0	0	0	0
PREPUTIAL GL.										
-MASS	0	0	0	0	1	0	0	0	0	0
LYMPH NODE, PARA										
-ENLARGED	0	0	0	0	1	0	0	0	0	0
NO SIGNIFICANT CHANGES OBSERVED - ALL EXAMINED TISSUES	7	7	9	9	3	7	8	8	8	7

1- NAIVE CONTROL 2-VEHICLE CONTROL 3- 15% PCMX 4- 30% PCMX 5- 60% PCMX
 NA = NOT APPLICABLE

94 of 722

PROJECT NO.: WIL-304003
 SPONSOR: CLARIANT CORP.

TABLE 15 (WEEK 13 NECROPSY)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF ORGAN WEIGHTS [G]

PAGE 1
 WEEK 13

GROUP:		----- M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
BRAIN (G)						
	MEAN	0.4885	0.4792	0.4798	0.4931	0.4815
	S.D.	0.02152	0.03242	0.01758	0.01395	0.04669
	N	10	10	10	10	10
LIVER (G)						
	MEAN	1.7895	1.7435	1.6932	1.7912	1.8724
	S.D.	0.27349	0.33374	0.21192	0.16489	0.18433
	N	10	10	10	10	10
KIDNEYS (G)						
	MEAN	0.6262	0.6280	0.6556	0.6651	0.6502
	S.D.	0.09836	0.08220	0.07484	0.04834	0.08008
	N	10	10	10	10	10
HEART (G)						
	MEAN	0.1914	0.1887	0.1889	0.1971	0.1872
	S.D.	0.01312	0.01474	0.01226	0.01834	0.02713
	N	10	10	10	10	10
SPLEEN (G)						
	MEAN	0.0957	0.0905	0.0936	0.0969	0.1180
	S.D.	0.02197	0.01731	0.01973	0.02497	0.03748
	N	10	10	10	10	10

 None significantly different from control group

95 of 722

PROJECT NO.: WIL-304003
 SPONSOR: CLARIANT CORP.

TABLE 15 (WEEK 13 NECROPSY)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF ORGAN WEIGHTS [G]

PAGE 2
 WEEK 13

GROUP:	----- M A L E -----				
	NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
EPIDIDYMIDES (G)					
MEAN	0.1081	0.1067	0.1075	0.1120	0.1093
S.D.	0.00871	0.01388	0.01343	0.00751	0.01677
N	10	10	10	10	10
TESTES (G)					
MEAN	0.2403	0.2283	0.2392	0.2445	0.2177
S.D.	0.02947	0.02755	0.03415	0.02666	0.03400
N	10	10	10	10	10
THYMUS (G)					
MEAN	0.0228	0.0312*	0.0280	0.0288	0.0260
S.D.	0.00744	0.00500	0.00634	0.00378	0.00664
N	10	10	10	10	10
ADRENAL GLANDS (G)					
MEAN	0.0054	0.0054	0.0053	0.0063	0.0054
S.D.	0.00155	0.00147	0.00270	0.00168	0.00213
N	10	10	10	10	10
THYROIDS/PARA. (G)					
MEAN	0.0068	0.0070	0.0066	0.0075	0.0062
S.D.	0.00117	0.00137	0.00207	0.00206	0.00136
N	10	10	10	10	10

* = Significantly different from the control group at 0.05 using Dunnett's test

96 of 722

PROJECT NO.:WIL-304003
 SPONSOR:CLARIANT CORP.

TABLE 15 (WEEK 13 NECROPSY)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF ORGAN WEIGHTS [G]

PAGE 3
 WEEK 13

GROUP:		----- F E M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
BRAIN (G)	MEAN	0.4932	0.4882	0.4849	0.4967	0.4843
	S.D.	0.03175	0.02889	0.02012	0.03381	0.03022
	N	10	10	10	10	10
LIVER (G)	MEAN	1.4871	1.4991	1.4603	1.4769	1.3975
	S.D.	0.14986	0.25252	0.20581	0.20165	0.16528
	N	10	10	10	10	10
KIDNEYS (G)	MEAN	0.4297	0.4279	0.4240	0.4063	0.4230
	S.D.	0.06182	0.04518	0.04541	0.05203	0.02947
	N	10	10	10	10	10
HEART (G)	MEAN	0.1596	0.1607	0.1622	0.1650	0.1606
	S.D.	0.01290	0.01528	0.01939	0.03788	0.00781
	N	10	10	10	10	10
SPLEEN (G)	MEAN	0.1308	0.1034	0.1092	0.1235	0.1135
	S.D.	0.06745	0.02867	0.02539	0.07000	0.02959
	N	10	10	10	10	10

 None significantly different from control group

97 of 722

PROJECT NO.: WIL-304003
 SPONSOR: CLARIANT CORP.

TABLE 15 (WEEK 13 NECROPSY)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF ORGAN WEIGHTS [G]

PAGE 4
 WEEK 13

----- F E M A L E -----						
GROUP:	NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX	
UTERUS (G)						
MEAN	0.1690	0.2218	0.2047	0.2298	0.2241	
S.D.	0.04482	0.08226	0.10764	0.09947	0.08149	
N	10	10	10	10	10	
OVARIES/OVIDUCTS (G)						
MEAN	0.0322	0.0346	0.0345	0.0331	0.0356	
S.D.	0.00841	0.01099	0.00995	0.00709	0.00506	
N	10	10	10	10	10	
THYMUS (G)						
MEAN	0.0287	0.0292	0.0351	0.0435*	0.0396	
S.D.	0.00773	0.01356	0.00833	0.01587	0.00844	
N	10	10	10	10	10	
ADRENAL GLANDS (G)						
MEAN	0.0122	0.0117	0.0110	0.0106	0.0112	
S.D.	0.00331	0.00213	0.00243	0.00216	0.00261	
N	10	10	10	10	10	
THYROIDS/PARA. (G)						
MEAN	0.0062	0.0060	0.0071	0.0057	0.0060	
S.D.	0.00191	0.00233	0.00218	0.00116	0.00122	
N	10	10	10	10	10	

* = Significantly different from the control group at 0.05 using Dunnett's test

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98 of 722

PROJECT NO.: WIL-304003
 SPONSOR: CLARIANT CORP.

TABLE 16 (WEEK 13 NECROPSY)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

PAGE 1
 WEEK 13

GROUP:		----- M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
FINAL BODY WT (G)						
	MEAN	35.4	35.8	35.5	35.6	36.4
	S.D.	2.56	3.09	2.57	1.94	3.54
	N	10	10	10	10	10
BRAIN (G)						
	MEAN	1.384	1.343	1.357	1.390	1.327
	S.D.	0.1071	0.1048	0.1005	0.0653	0.0959
	N	10	10	10	10	10
LIVER (G)						
	MEAN	5.033	4.839	4.769	5.044	5.154
	S.D.	0.4942	0.5509	0.5119	0.4509	0.3067
	N	10	10	10	10	10
KIDNEYS (G)						
	MEAN	1.761	1.753	1.850	1.873	1.792
	S.D.	0.1920	0.1837	0.2069	0.1301	0.1778
	N	10	10	10	10	10
HEART (G)						
	MEAN	0.541	0.529	0.534	0.554	0.514
	S.D.	0.0212	0.0420	0.0481	0.0286	0.0437
	N	10	10	10	10	10

 None significantly different from control group

99 of 722

PROJECT NO.:WIL-304003
SPONSOR:CLARIANT CORP.

TABLE 16 (WEEK 13 NECROPSY)
A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

PAGE 2
WEEK 13

----- M A L E -----						
GROUP:	NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX	
SPLEEN (G)						
MEAN	0.270	0.253	0.264	0.272	0.326	
S.D.	0.0583	0.0442	0.0548	0.0670	0.1137	
N	10	10	10	10	10	
EPIDIDYMIDES (G)						
MEAN	0.306	0.299	0.304	0.316	0.302	
S.D.	0.0319	0.0375	0.0448	0.0321	0.0454	
N	10	10	10	10	10	
TESTES (G)						
MEAN	0.681	0.640	0.677	0.689	0.609	
S.D.	0.0932	0.0839	0.1124	0.0736	0.1348	
N	10	10	10	10	10	
THYMUS (G)						
MEAN	0.065	0.088*	0.079	0.081	0.072	
S.D.	0.0220	0.0164	0.0172	0.0109	0.0182	
N	10	10	10	10	10	
ADRENAL GLANDS (G)						
MEAN	0.015	0.015	0.015	0.018	0.015	
S.D.	0.0049	0.0045	0.0081	0.0049	0.0052	
N	10	10	10	10	10	

* = Significantly different from the control group at 0.05 using Dunnett's test

100 of 722

PROJECT NO.: WIL-304003
SPONSOR: CLARIANT CORP.

TABLE 16 (WEEK 13 NECROPSY)
A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

PAGE 3
WEEK 13

GROUP:	----- M A L E -----				
	NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
THYROIDS/PARA. (G)					
MEAN	0.019	0.019	0.018	0.021	0.017
S.D.	0.0037	0.0042	0.0051	0.0057	0.0037
N	10	10	10	10	10

None significantly different from control group

PROJECT NO.:WIL-304003
 SPONSOR:CLARIANT CORP.

TABLE 16 (WEEK 13 NECROPSY)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

PAGE 4
 WEEK 13

GROUP:		----- F E M A L E -----				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
FINAL BODY WT (G)						
	MEAN	29.5	29.8	29.5	28.9	28.3
	S.D.	2.17	2.77	2.47	2.25	1.38
	N	10	10	10	10	10
BRAIN (G)						
	MEAN	1.679	1.648	1.655	1.724	1.718
	S.D.	0.1743	0.1302	0.1759	0.0932	0.1379
	N	10	10	10	10	10
LIVER (G)						
	MEAN	5.042	5.013	4.934	5.109	4.940
	S.D.	0.4253	0.4915	0.3820	0.4981	0.4586
	N	10	10	10	10	10
KIDNEYS (G)						
	MEAN	1.463	1.444	1.440	1.406	1.498
	S.D.	0.2519	0.1676	0.1417	0.1256	0.0883
	N	10	10	10	10	10
HEART (G)						
	MEAN	0.543	0.542	0.549	0.568	0.569
	S.D.	0.0538	0.0443	0.0343	0.0907	0.0294
	N	10	10	10	10	10

 None significantly different from control group

102 of 722

PROJECT NO.: WIL-304003
SPONSOR: CLARIANT CORP.

TABLE 16 (WEEK 13 NECROPSY)
A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

PAGE 5
WEEK 13

GROUP:	----- F E M A L E -----				
	NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX

SPLEEN (G)					
MEAN	0.451	0.345	0.368	0.418	0.400
S.D.	0.2642	0.0741	0.0679	0.1917	0.0898
N	10	10	10	10	10
UTERUS (G)					
MEAN	0.576	0.753	0.700	0.784	0.789
S.D.	0.1607	0.2943	0.3723	0.2811	0.2662
N	10	10	10	10	10
OVARIES/OVIDUCTS (G)					
MEAN	0.109	0.115	0.117	0.114	0.126
S.D.	0.0275	0.0298	0.0312	0.0192	0.0168
N	10	10	10	10	10
THYMUS (G)					
MEAN	0.097	0.098	0.119	0.152*	0.141
S.D.	0.0235	0.0418	0.0277	0.0609	0.0296
N	10	10	10	10	10
ADRENAL GLANDS (G)					
MEAN	0.041	0.040	0.038	0.037	0.040
S.D.	0.0105	0.0086	0.0089	0.0077	0.0088
N	10	10	10	10	10

* = Significantly different from the control group at 0.05 using Dunnett's test

PROJECT NO.:WIL-304003
SPONSOR:CLARIANT CORP.

TABLE 16 (WEEK 13 NECROPSY)
A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
SUMMARY OF ORGAN WTS. RELATIVE TO FINAL BODY WTS. [G/100 G]

PAGE 6
WEEK 13

GROUP:	----- F E M A L E -----				
	NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
THYROIDS/PARA. (G)					
MEAN	0.021	0.020	0.025	0.020	0.021
S.D.	0.0068	0.0075	0.0088	0.0044	0.0043
N	10	10	10	10	10

None significantly different from control group

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TABLE 17 (WEEK 13 NECROPSY)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G]

GROUP:		M A L E				
		NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
BRAIN WT (G)						
	MEAN	0.4885	0.4792	0.4798	0.4931	0.4815
	S.D.	0.02152	0.03242	0.01758	0.01395	0.04669
	N	10	10	10	10	10
LIVER (G)						
	MEAN	365.732	362.955	353.170	363.518	390.077
	S.D.	47.3607	55.1926	44.4580	35.0242	34.0740
	N	10	10	10	10	10
KIDNEYS (G)						
	MEAN	128.445	131.320	136.723	134.979	134.956
	S.D.	20.9605	17.4136	15.6163	10.5980	8.5722
	N	10	10	10	10	10
HEART (G)						
	MEAN	39.212	39.529	39.394	39.953	38.774
	S.D.	2.5556	3.9397	2.4899	3.3618	2.9387
	N	10	10	10	10	10
SPLEEN (G)						
	MEAN	19.526	18.846	19.537	19.619	24.840
	S.D.	3.9675	3.1625	4.2684	4.8960	9.3200
	N	10	10	10	10	10

None significantly different from control group

PROJECT NO.:WIL-304003
 SPONSOR:CLARIANT CORP.

TABLE 17 (WEEK 13 NECROPSY)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G]

PAGE 2
 WEEK 13

GROUP:	M A L E				
	NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX	60% PCMX
EPIDIDYMIDES (G)					
MEAN	22.152	22.305	22.404	22.739	22.687
S.D.	1.9103	2.9481	2.7042	1.9139	2.4978
N	10	10	10	10	10
TESTES (G)					
MEAN	49.207	47.809	49.894	49.569	45.792
S.D.	5.9602	6.5653	7.1704	4.8831	8.9503
N	10	10	10	10	10
THYMUS (G)					
MEAN	4.641	6.563**	5.849	5.841	5.357
S.D.	1.4294	1.3504	1.3918	0.7571	1.0674
N	10	10	10	10	10
ADRENAL GLANDS (G)					
MEAN	1.114	1.129	1.108	1.279	1.107
S.D.	0.3298	0.3381	0.5823	0.3332	0.3846
N	10	10	10	10	10
THYROIDS/PARA. (G)					
MEAN	1.389	1.451	1.367	1.525	1.287
S.D.	0.2598	0.2820	0.4090	0.4116	0.2419
N	10	10	10	10	10

** = Significantly different from the control group at 0.01 using Dunnett's test

106 of 722

PROJECT NO.:WIL-304003
 SPONSOR:CLARIANT CORP.

TABLE 17 (WEEK 13 NECROPSY)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G]

GROUP:	----- F E M A L E -----			
	NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX
BRAIN WT (G)				
MEAN	0.4932	0.4882	0.4849	0.4967
S.D.	0.03175	0.02889	0.02012	0.03381
N	10	10	10	10
LIVER (G)				
MEAN	302.508	306.462	301.782	297.681
S.D.	34.6911	43.7264	45.9801	37.3654
N	10	10	10	10
KIDNEYS (G)				
MEAN	87.622	87.628	87.486	81.789
S.D.	14.7611	7.7640	9.3015	8.6067
N	10	10	10	10
HEART (G)				
MEAN	32.630	32.915	33.513	33.024
S.D.	4.9693	2.3971	4.2937	5.5182
N	10	10	10	10
SPLEEN (G)				
MEAN	26.716	21.193	22.494	24.390
S.D.	13.6659	5.7312	5.0284	11.6448
N	10	10	10	10

 None significantly different from control group

PROJECT NO.:WIL-304003
 SPONSOR:CLARIANT CORP.

TABLE 17 (WEEK 13 NECROPSY)
 A 13-WEEK DERMAL TOXICITY STUDY OF PCMX IN MICE
 SUMMARY OF ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHTS [G/100 G]

GROUP:	----- F E M A L E -----			
	NAIVE CONTROL	VEHICLE CONTROL	15% PCMX	30% PCMX
UTERUS (G)				
MEAN	34.214	45.488	41.941	45.457
S.D.	8.6892	16.5885	20.9334	16.4924
N	10	10	10	10
OVARIES/OVIDUCTS (G)				
MEAN	6.586	7.071	7.130	6.629
S.D.	1.9015	2.1741	2.0715	1.1393
N	10	10	10	10
THYMUS (G)				
MEAN	5.873	5.999	7.233	8.798*
S.D.	1.7767	2.7767	1.7091	3.3053
N	10	10	10	10
ADRENAL GLANDS (G)				
MEAN	2.489	2.398	2.280	2.141
S.D.	0.7597	0.4631	0.5110	0.4765
N	10	10	10	10
THYROIDS/PARA. (G)				
MEAN	1.249	1.227	1.458	1.162
S.D.	0.3597	0.4451	0.4204	0.2695
N	10	10	10	10

* = Significantly different from the control group at 0.05 using Dunnett's test