

ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ- 92 -13387	89110000209	3/22/11

COMMENTS: COMMUN S (DECLASS)

DOES NOT CONTAIN CBI

334122



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

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

8EHQ-0311-13387B
DCN: 89110000209

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11 MAR 22 AM 9:03

**Re: Declassification Activity-Health and Safety Filing
8EHQ-0892-13387 (EPA DCN 88920011007)**

Dear Sir/Madam:

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

This amended submission is composed of the following:

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

Any CBI substantiation which appears in the original submission is no longer applicable as the information which was originally claimed CBI is disclosed in this revised submission.

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

Sincerely,

THE PROCTER & GAMBLE COMPANY

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



Attachment 1
Public Display Version

<u>Chemical Identity</u>	<u>CAS RN</u>
Benzenesulfonic acid, (1-methylethyl)-, sodium salt	28348-53-0
Ethanol, 2-(2-butoxyethoxy)-	112-34-5
Benzenesulfonic acid, dodecyl-, sodium salt	25155-30-0
Amides, C8-18 and C18-unsatd., bis (hydroxyethyl)	68155-07-7
Sulfurous acid, disodium salt	7757-83-7
Benzenesulfonic acid, 2,2'-[(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)diimino]bis[5-methyl-, disodium salt	4403-90-1
1,3,6-Pyrenetrisulfonic acid, 8-hydroxy-, trisodium salt	6358-69-6
Phenol, 4-chloro-2-(phenylmethyl)-	120-32-1

Potassium pyrophosphate

Fragrance

Water

Procter & Gamble COMPANY SANITIZED

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

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8EHQ-92-13387
889200110075 CAP

Public Display Copy

August 20, 1992

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

8E16-0892-133875

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

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

The material identified in the attached report as K0316.01 is a confidential mixture. The composition of the mixture is appended as Attachment 1. The report is titled "Acute Oral Toxicity Study in Albino Rats with K0316.01". Any correspondence relating to this submission should reference study # 1201-27807.

The attached study report indicates oral administration of the test material resulted in pharmacotoxic signs including ataxia, lethargy, and inactivity following oral administration of 6.0 and 7.4 g/kg of the test material. No significant clinical signs were observed in groups dosed 3.2 and 4.6 g/kg. The acute oral LD50 was determined to be >7.4 g/kg.

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

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

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

1. Confidentiality of the chemical constituents and their percentages should be maintained indefinitely. There are no plans for this information to be otherwise disclosed, and this technology has significant commercial value.
2. To our knowledge, there have been no government confidentiality determinations made for this mixture.
3. The specific chemical identity and exact proportions of the constituents of this mixture have not been disclosed outside the Company. There are no plans to disclose publicly the exact composition of this mixture at any time in the future.

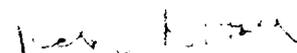
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Procter & Gamble

4. Measures for protection of the compositional information include "need to know" internal restriction within the Company. An internal code is used to protect the identity of the material. Information is maintained in locked files. Employees leaving the Company are contractually bound not to disclose Company secrets.
 5. The exact composition of this mixture has not appeared in advertising or promotional literature, MSD sheets, any publications or any other media available to the general public or competitors.
 6. Disclosure of the information claimed as CBI would result in substantial harm to the Company's competitive position. This formula provides an important commercial opportunity for a competitor. Knowledge of the exact composition of this mixture could enable a competitor to duplicate the formula without R&D cost, thus providing an unfair competitive disadvantage to the Procter & Gamble Company. Development of this formula required many technically trained personnel, hundreds of hours of research and development, and significant capital investment valued in aggregate at Any competitor would normally be required to make a similar investment to duplicate the formula. Disclosure of this information would allow a competitor to duplicate the formula without incurring significant R&D costs, thus doing substantial harm to our competitive position.
 7. The information we have identified as confidential is not health or safety data.
- Any questions concerning this submission, may be directed to me at (513) 627-5551.

Sincerely,

THE PROCTER AND GAMBLE COMPANY



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

1. Sodium alkyl benzene sulfonate
2. Potassium pyrophosphate
3. Substituted ethanol
4. Sodium alkyl benzene sulfonate
5. Substituted alkyl amide
- 6+7 Sodium salt
8. Colorant
9. Fragrance
10. Substituted phenol
11. Water

1201-27807



WIL RESEARCH LABORATORIES, INC.

Project Number: WIL-28005
Client: The Procter & Gamble Company
Doc. Req. No.: CA-STR 141 134
144

Acute Oral Toxicity Study in Albino Rats with K0316.01

RECEIVED BY
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OPERATIONS SECTION

3154 EXON AVENUE

CINCINNATI, OH-O 45241

(513) 563-8060

WIL-28005
Procter & Gamble Company
Doc. Req. No.: CA-STR 141

Acute Oral Toxicity Study in Albino Rats with K0316.01

Introduction:

A sample identified as Spic & Span L.C., 341C27R, K0316.01, was received from The Procter & Gamble Company, Miami Valley Laboratories, Cincinnati, Ohio, Inc., for the purpose of conducting acute toxicity studies. A glass jar containing the green liquid was received on September 19, 1982. The test material and container weighed 1417.3 grams and was stored at room temperature in a locked test compound cabinet.

Objective:

The objective of this study was to determine the toxicity and/or LD₅₀ value of the test material following a single oral dose to albino rats. Verbal study authorization was received from The Procter & Gamble Company, Cincinnati, Ohio followed by a letter dated September 28, 1982. This study was conducted at the Cincinnati facilities of WIL Research Laboratories, Inc. This report presents the results of that investigation from the initiation date, September 20, 1982, to the termination date, September 27, 1982.

Procedure:

Experimental Animals:

Young adult albino rats of the Sprague Dawley CD® strain were employed as test animals. On September 9, 1982, the rats were received from Charles River Breeding Laboratories, Inc., Portage, Michigan and immediately placed in quarantine. They were inspected for general health and suitability as test animals. The animals were randomly placed in numbered cages (males first) using a computer generated list of random numbers. Each rat was sexed, weighed and permanently identified with an ear tag. A card affixed to each cage also served for identification.

The rats were individually housed in wire-bottomed cages suspended above the cage board that was changed three times a week. The animal room was lighted 12 hours each day and room temperature and relative humidity were checked daily. Purina Certified Rodent Chow 5002 and water were offered ad libitum, except during the 24 hour period immediately prior to oral intubation when food was withheld. Immediately after dosing, food was offered.

The rats were quarantined and acclimated to laboratory conditions for 11 days prior to initiation of the study. Animals were observed twice daily during the quarantine period. On the last day of the quarantine period (i.e. the day prior to initiation of exposure to the test material) those animals judged to be suitable test subjects were selected from the animal shipment and used for the study. Body weights were measured

WIL-28005
Procter & Gamble Company
Doc. Req. No.: CA-STR 141

and they ranged from 175.3 to 231.9 grams. (All males were within protocol specified weight range of 190-300 grams. Eight females were between 175.3 and 189.4 grams.)

Experimental Design:

This study used four dose levels of 3.2, 4.6, 6.0 and 7.4 g/kg with ten rats (5 males and 5 females) each. The dose levels were based on a pivotal dose of 6.0 g/kg, the estimated LD₅₀ value. Mortality occurred in only one of the animals and the sponsor was contacted with these results. At the request of the client the study was terminated on day 7.

<u>Group</u>	<u>Concentration</u>	<u>Actual Amount Dosed ml/kg</u>	<u>Dose Level g/kg</u>
1	Undiluted	2.88	3.2
2	Undiluted	4.14	4.6
3	Undiluted	5.40	6.0
4	Undiluted	6.66	7.4

1 ml of test material weighed approximately 0.90 g.

Test Material Administration:

Individual dose amounts were calculated by using day 0 fasted body weights taken prior to dosing. Mean body weights ranged for males: 186.26 - 199.82 grams and for females: 171.02 - 182.68 grams. The undiluted test material was measured in a plastic disposable syringe and administered directly into the rat's stomach using a rubber catheter and tubing adapter.

Body Weights:

All animals selected for the study were weighed on days -1 (pre-fast), 0 (exposure), 6 and 7 (termination). A final body weight was taken on the one animal found dead.

Observations and Mortality:

Each group was observed closely for gross signs of systemic toxicity and mortality at frequent intervals during the day of dosing and at least twice daily thereafter for a total of 8 days. Room conditions, as well as availability of adequate food and water, were checked and any noteworthy conditions recorded.

Calculation LD₅₀

The WIL computer program based on the techniques of Litchfield and Wilcoxon^a would be used to calculate the LD₅₀ if adequate mortality was obtained.

^aLitchfield, J. J. and F. Wilcoxon, "A Simplified Method of Evaluation of Dose-Effect Experiments," J. Pharm. and Exp. Ter., 99-113 (1949).

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Doc. Req. No.: CA-STR 141

Necropsy:

A gross necropsy was performed on the visceral and thoracic cavities of the one animal found dead. All surviving animals were sacrificed by carbon dioxide inhalation. By request of the client, no necropsy was performed on them.

Results:

Body Weight Change Data

Individual body weights, means and gains are presented in Tables 1 and 2. Mean body weights for survivors increased at 6 days and were considered within normal limits.

Observations and Mortality:

On the day of dosing, all animals were observed at 0.50, 2.0 and 4.0 hours. Signs of systemic toxicity were observed at only the 6.0 and 7.4 g/kg dose levels and first occurred from .50 to 2 hours after dosing. A summary of clinical observations by dose level is presented below. Mortality indices are presented in Table 3.

On the day of dosing clinical signs consisted of the following:

Dose Level

- 3.2 g/kg No significant clinical observations (all animals).
- 4.6 g/kg No significant clinical observations (all animals).
- 6.0 g/kg Slight to mild urine stains (1M and 1F).
- 7.4 g/kg Red material around the mouth (2M and 1F), slight lethargy (5M), slight ataxia (5M and 1F), slight to mild salivation (2M), slight urine stains (1F).

On the days following dosing clinical signs consisted of the following:

Dose Level

- 3.2 g/kg No significant clinical observations (all animals).
- 4.6 g/kg No significant clinical observations (all animals).
- 6.0 g/kg Slight to moderate lethargy and inactivity (5M and 5F), slight to moderate ataxia (5M and 5F), slight to mild ataxia (5M), red material on forepaws, nose and chin (1M), mild to moderate urine stains (1M) and decreased defecation (1F). All males appeared normal by day 4 and all females by day 3.
- 7.4 g/kg Slight to moderate lethargy and inactivity (5M and 5F), slight to moderate ataxia (5M and 1F), dried red material around the nose, chin and on forepaws (1M), decreased defecation (3M and 4F), no defecation (2M and 1F) and slight to moderate urine stains (3M and 3F). All males appeared normal by day 5 and all females by day 3. One female (3081) was found dead on day 2.

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Procter & Gamble Company
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Calculation of LD₅₀:

As mortality occurred only in one of the animals at the 7.4 g/kg dose level the LD₅₀ could not be calculated. Instead a general statement was provided that the LD₅₀ was greater than the highest level dosed.

Summary:

When K0316.01 was administered orally at four dose levels of 3.2, 4.6, 6.0, and 7.4, g/kg undiluted to four groups of ten albino rats (5 male and 5 female) each, signs of systemic toxicity were observed at only the 6.0 and 7.4 g/kg dose levels. These signs consisted of the following clinical observations: lethargy, inactivity, ataxia, urine stains, decreased feces and red material around the nose, chin, mouth and/or forepaws (6.0 and 7.4 g/kg), salivation, no defecation (7.4 g/kg), and death in one female (7.4 g/kg).

The incidence severity and duration of reactions was directly related to dose levels. Males and females appeared similarly affected. Survivors appeared normal on days 0 to 5: on day 0 (males and females at 3.2 and 4.6 g/kg dose levels); on day 3 (females at 6.0 and 7.4 g/kg); on day 4 (males at 6.0 g/kg) and on day 5 (males at 7.4 g/kg). Body weights increased at 6 days and were considered within normal limits.

One death occurred at the 7.4 g/kg dose level (1F on day 2). A gross necropsy conducted on this female revealed: stomach contained clear fluid and postmortem autolysis was present. A gross necropsy was not performed on the surviving animals per client request.

From the data presented (1F/10 at 7.4 g/kg dose level) the LD₅₀ of K0316.01 was determined to be greater than 7.4 g/kg.

Michael Briggs
Michael Briggs A.S., Technician

12/3/82
Date

Dale A. Mayhew
Dale A. Mayhew, Ph.D., Study Director

12/3/82
Date

WIL-28005
Procter & Gamble Company
Doc. Req. No.: CA-STR 141

Acute Oral Toxicity Study in Albino Rats with K0316.01

Quality Assurance Unit Statement

<u>Dates of Inspection(s)</u>	<u>Date(s) Findings Reported to Management and Study Director</u>
September 20, 1982	September 24, 1982
December 1, 1982	December 3, 1982

This study was inspected in accordance with the Good Laboratory Practice Regulations, the Standard Operating Procedures of WIL Research Laboratories, Inc. The study was conducted in compliance with the Good Laboratory Practice regulations, the Standard Operating Procedures of WIL Research Laboratories and the sponsor's protocol. To the best of the signatory's knowledge there were no significant deviations from the Good Laboratory Practice regulations which affected the quality or integrity of the study. Quality Assurance findings, derived from the inspection(s) during the conduct of the study and from the inspection of the final report, are documented and have been made available to the study director and to the test facility management.

The raw data and a copy of the final report will be kept in the archives at WIL Research Laboratories, Inc.

Jacquelyn McChesney
Jacquelyn McChesney, B.A.
Supervisor - Quality Assurance Unit

12-3-82
Date

PROJECT NO. HWIL-28005
 SPONSOR: PROCTER & GAMBLE
 STUDY NO. PCA-STR 141

ACUTE ORAL TOXICITY (LD50 VALUE IN RATS) WITH KD 316.01
 INDIVIDUAL BODY WEIGHTS (G) RAW DATA SUMMARY

11122 01-NOV-82 PAGE 1
 DAY -1

TABLE 1

DOSE GROUP	MALE			
	1	2	3	4
459*	218.7	468*	477*	477*
392*	190.2	222.9	198.3	3077*
461*	205.8	465*	474*	209.4
460*	220.0	236.5	228.4	3079*
462*	226.1	231.9	475*	478*
		218.5	214.6	216.4
		489*	489*	483*
		255.6	3076*	488*
			208.8	191.2
MEAN	210.160	225.080	214.040	211.760
S.D.	14.329	4.921	11.385	12.575
S.E.	6.408	2.201	5.091	5.624
N	5	5	5	5

PROJECT NO. 141L-28005
 SPONSOR: PROCTER & GAMBLE
 SPONSOR NO. PCA-SIR 141

TABLE 1
 ACUTE ORAL TOXICITY (LD50 VALUE IN RATS) WITH NO 316-01
 INDIVIDUAL BODY WEIGHTS (G) RAW DATA SUMMARY

11122 01-NOV-82 PAGE 2
 DAY -1

DOSE GROUP:	FEMALE			
	1	2	3	4
	877± 183.6 878± 218.0	862± 196.2 863± 175.3	491± 199.9 896± 177.0	494± 209.5 500± 187.3
	865± 204.6 880± 197.0 880± 197.8	493± 191.2 3070± 211.3 493± 202.8	3067± 186.5 3039± 191.5 3071± 189.3	3072± 189.4 3080± 188.5 3081± 211.9
MEAN	197.200	195.360	188.840	187.320
S.D.	13.036	13.508	8.276	12.266
S.E.	5.830	6.041	3.710	5.486
N	5	5	5	5

TABLE 1
ACUTE ORAL TOXICITY (LD50 VALUE IN RATS) WITH AD 316.01
INDIVIDUAL BODY WEIGHTS (G) RAW DATA SUMMARY

PROJECT NO: HWIL-28005
SPONSOR: FROCTER & GARNER
SPONSOR AD: TCA-SIR 111

DOSE GROUP	SEX			
	1	2	3	4
	----- M A L E -----			
	459# 195.2	468# 177.6	477# 180.1	3077# 182.0
	392# 172.9	465# 201.4	474# 201.4	3079# 196.4
	461# 185.8	466# 202.4	475# 192.7	478# 194.0
	460# 195.1	467# 197.2	489# 194.5	483# 190.5
	463# 193.8	473# 200.5	3076# 182.8	488# 188.4

MEAN	180.580	199.820	190.300	186.260
S.D.	9.618	21.313	8.759	11.378
S.E.	4.315	1.035	3.917	5.088
N	5	5	5	5

TABLE I
ACUTE ORAL TOXICITY (LD50 VALUE IN RATS) WITH A.P. 316-01
INDIVIDUAL BODY WEIGHTS (G) RAW DATA SUMMARY

PROJECT NO. 141L-28005
SPONSOR: PROCTER & GAMBLE
SPONSOR NO. 101-SR 141

DOSE GROUP	SEX			
	1	2	3	4
459	271.8	468 ± 287.3	477 ± 237.8	3077 ± 240.6
392	236.4	465 ± 218.7	474 ± 273.4	3079 ± 255.6
461	245.7	466 ± 261.0	475 ± 255.6	478 ± 247.9
480	252.9	487 ± 255.5	489 ± 253.2	483 ± 250.9
452	275.1	473 ± 272.7	3076 ± 253.9	488 ± 232.4
MEAN	256.589	289.040	254.780	245.480
S.D.	16.530	12.195	12.639	9.118
S.E.	7.393	5.454	5.652	4.078
N	5	5	5	5

PROJECT NO. IJUL-28005
 SPONSOR: DOCTER & GARBLE
 STUDY NO. ICA-STR 141

TABLE 1
 ACUTE ORAL TOXICITY (LD50 VALUE IN RATS) WITH KD 316.01
 INDIVIDUAL BODY WEIGHTS (G) RAW DATA SUMMARY

PAGE 2
 DAY 6

DOSE GROUP:	----- FEMALE -----			
	1	2	3	4
	877= 207.2	852= 212.0	491= 220.3	494= 230.9
	876= 235.6	833= 187.9	896= 199.7	500= 201.2
	865= 234.4	496= 208.7	3067= 197.7	3072= 208.6
	880= 198.9	3070= 234.3	3068= 207.6	3080= 191.2
	840= 216.2	493= 224.9	3071= 213.1	
MEAN	210.460	214.360	207.680	207.975
S.D.	16.297	17.632	9.380	16.865
S.E.	7.288	7.885	4.195	8.432
N	5	5	5	4

PROJECT NO.: HWL-20005
 SPONSOR: FORTICER & GAMBLE
 STUDY NO.: CA-STR 141

TABLE 1
 ACUTE ORAL TOXICITY (LD50 VALUE IN RATS) WITH KD 316-01
 INDIVIDUAL BODY WEIGHTS (G) RAW DATA SUMMARY

PAGE 1
 DAY 14

DOSE GROUP	M A L E			
	1	2	3	4
MEAN	0.000	0.000	0.000	0.000
S.D.	0.000	0.000	0.000	0.000
S.E.	0.000	0.000	0.000	0.000
N	0	0	0	0

DOSE GROUP	----- FEMALE -----			
	1	2	3	4
MEAN	0.000	0.000	0.000	177.400
S.D.	0.000	0.000	0.000	0.000
S.E.	0.000	0.000	0.000	0.000
N	0	0	0	1

3081 = 177.4

PROJECT NO. 141L-20005
 SPONSOR: FROCTER & GIBBLE
 SPONSOR NO. 10A-STR 141

TABLE 1
 ACUTE ORAL TOXICITY (LD50 VALUE IN RATS) WITH FD 314-01
 BODY WEIGHT (G) SUMMARY OF MEANS

I	MALE				FEMALE			
	2	3	4		1	2	3	4
312.130	225.080	214.040	211.740		199.200	195.360	188.840	197.320
186.580	199.820	190.300	186.280		182.680	180.400	171.020	177.800
256.580	269.040	254.780	245.480		218.460	214.360	207.480	207.975
1-	1	2	3	4	1	2	3	4

PROJECT NO.: HWIL-28005
 SPONSOR: PROCTER & GAMBLE
 SPONSOR NO.: CA-57K 141

TABLE 2
 ACUTE ORAL TOXICITY (LD50 VALUE IN PATS) WITH KD 316.01
 INDIVIDUAL BODY WEIGHT GAINS (G) RAW DATA SUMMARY

PAGE 1
 DAY -1 TO 6

LOOSE GROUP:	MALE			
	1	2	3	4
459=	53.1	468= 64.4	477= 39.5	3077= 31.2
392=	46.2	455= 42.2	474= 45.0	3079= 31.9
461=	40.9	466= 29.1	475= 41.0	478= 31.5
460=	32.9	457= 37.0	489= 31.1	493= 32.8
462=	49.0	473= 47.1	3076= 45.1	488= 41.2
MEAN	44.420	43.930	40.740	33.720
S.D.	7.820	13.229	4.928	4.225
S.E.	3.497	5.916	2.204	1.699
N	5	5	5	5

TABLE 2
 ACUTE ORAL TOXICITY (LD50 VALUE IN RATS) WITH KD 316-01
 INDIVIDUAL BODY WEIGHT GAINS (G) RAW DATA SUMMARY

DOSE GROUP	FEMALE			
	1	2	3	4
877*	23.6	862*	491*	494*
876*	17.6	12.6	896*	500*
885*	29.8	496*	3067*	3072*
880*	6.9	3070*	3068*	3080*
860*	18.4	493*	3071*	23.8
MEAN	19.260	19.000	18.040	14.300
S.D.	8.459	4.167	5.192	8.349
S.E.	3.783	1.864	2.322	4.175
N	5	5	5	4

PROJECT NO.: WTL-28005
 SPONSOR: FUKUOKA & GARBLE
 SPONSOR NO.: CA-STR 141

TABLE 2
 ACUTE ORAL TOXICITY (LD50 VALUE IN RATS) WITH RD 316.01
 INDIVIDUAL BODY WEIGHT GAINS (G) RAW (DATA SUMMARY)

DOSE GROUP	SEX			
	1	2	3	4
			MALE	
	459± 76.6	468± 89.7	477± 57.7	3077± 58.6
	392± 63.5	465± 67.3	474± 72.0	3079± 59.2
	461± 61.1	466± 58.6	475± 62.9	478± 53.9
	460± 57.5	467± 58.3	489± 58.7	493± 60.4
	462± 81.3	473± 72.2	3076± 71.1	488± 64.0
MEAN	68.000	69.220	64.400	59.220
S.D.	10.156	12.684	6.750	3.638
S.E.	4.631	5.762	3.019	1.627
N	5	5	5	5

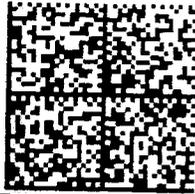
TABLE 2
 ACUTE ORAL TOXICITY (LD50 VALUE IN RATS) WITH KD 316.01
 INDIVIDUAL BODY WEIGHT GAINS (G) RAW DATA SUMMARY

DOSE GROUP	FEMALE			
	1	2	3	4
87*	37.8	82*	491*	491*
876*	36.4	30.5	38.6	41.5
865*	47.4	83*	896*	500*
880*	21.8	26.0	29.1	3072*
860*	35.5	48*	3067*	3080*
		3070*	34.9	21.2
		493*	3071*	42.3
MEAN	35.780	33.960	36.660	33.400
S.D.	9.132	7.000	4.971	6.949
S.E.	4.073	3.130	2.223	4.475
N	5	5	5	4

TABLE 3

Acute Oral Toxicity Study in Albino Rats with K0316.01

Dose Level and Sex g/kg	Mortality Indices			Died/ Tested
	0	1	2	
3.2 M	0	0	0	0/5
3.2 M	0	0	0	0/5
4.6 M	0	0	0	0/5
4.6 F	0	0	0	0/5
6.0 M	0	0	0	0/5
6.0 F	0	0	0	0/5
7.4 M	0	0	0	0/5
7.4 F	0	1	0	1/5



neopost

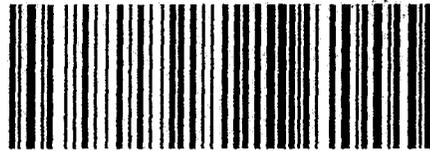
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