1, 1, 1 - トリクロロエタンのラット及びマウスを用いた 吸入によるがん原性試験報告書

試験番号:ラット/0189;マウス/0190

APPENDIX

(D1~I4)

APPENDIXES (CONTINUED)

- APPENDIX D 1 HEMATOLOGY (TWO-YEAR STUDY:SUMMARY) RAT:MALE
- APPENDIX D 2 HEMATOLOGY (TWO-YEAR STUDY:SUMMARY) RAT:FEMALE
- APPENDIX D 3 HEMATOLOGY (TWO-YEAR STUDY:SUMMARY) MOUSE:MALE
- APPENDIX D 4 HEMATOLOGY (TWO-YEAR STUDY:SUMMARY) MOUSE:FEMALE
- APPENDIX E 1 BIOCHEMISTRY (TWO-YEAR STUDY:SUMMARY) RAT:MALE
- APPENDIX E 2 BIOCHEMISTRY (TWO-YEAR STUDY:SUMMARY) RAT:FEMALE
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- APPENDIX F 1 URINALYSIS (TWO-YEAR STUDY:SUMMARY) RAT:MALE
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- APPENDIX F 4 URINALYSIS (TWO-YEAR STUDY:SUMMARY) MOUSE:FEMALE

APPENDIXES (CONTINUED)

- APPENDIX G 1 GROSS FINDINGS (TWO-YEAR STUDY:SUMMARY) RAT:MALE:DEAD AND MORIBUND ANIMALS
- APPENDIX G 2 GROSS FINDINGS (TWO-YEAR STUDY:SUMMARY) RAT:FEMALE:DEAD AND MORIBUND ANIMALS
- APPENDIX G 3 GROSS FINDINGS (TWO-YEAR STUDY:SUMMARY) RAT:MALE:SACRIFICED ANIMALS
- APPENDIX G 4 GROSS FINDINGS (TWO-YEAR STUDY:SUMMARY) RAT:FEMALE:SACRIFICED ANIMALS
- APPENDIX G 5 GROSS FINDINGS (TWO-YEAR STUDY:SUMMARY) MOUSE:MALE:DEAD AND MORIBUND ANIMALS
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- APPENDIX G 8 GROSS FINDINGS (TWO-YEAR STUDY: SUMMARY) MOUSE: FEMALE: SACRIFICED ANIMALS

APPENDIXES (CONTINUED)

- APPENDIX H 1 ORGAN WEIGHT (TWO-YEAR STUDY:SUMMARY),ABSOLUTE RAT:MALE
- APPENDIX H 2 ORGAN WEIGHT (TWO-YEAR STUDY:SUMMARY), ABSOLUTE RAT:FEMALE
- APPENDIX H 3 ORGAN WEIGHT (TWO-YEAR STUDY:SUMMARY),ABSOLUTE MOUSE:MALE
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- APPENDIX I 1 ORGAN WEIGHT (TWO-YEAR STUDY:SUMMARY), RELATIVE RAT:MALE
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APPENDIX D 1

HEMATOLOGY : SUMMARY, RAT : MALE

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1

HEMATOLOGY(1) (SUMMARY) SURVIVAL ANIMALS (105)

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up Name	NO. of Animals	RED BLOOD CELL 1 0 ⁶ /µl	HEMOGLOBIN g∕dl	HEMATOCRIT %	MCV f l	MCH Pg	MCHC g∕dl	PLATELET 1 0 ³ /µl
Control	33	7.90± 1.84	13.8± 3.3	40.5± 9.1	51.7± 4.4	17.5± 1.5	33.9± 1.3	950± 327
200ppm	36	7.85± 1.57	13.3± 3.1	39.5± 8.1	50.3± 3.4	16.9± 1.5	33.6± 1.6	1005± 295
800ppm	36	8.45± 1.42	14.3± 2.5	42.2± 7.0	50.1± 4.0	16.9± 1.4	33.8± 1.1	919± 192
3200ppm	27	7.39 ± 1.98	$12.3\pm$ 3.8	37.4± 9.8	50.8± 3.6	16.5± 1.5	32.5± 2.3	993± 274

(IICL070)

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : MALE

HEMATOLOGY(2) (SUMMARY) SURVIVAL ANIMALS (105)

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roup Name	NO. of Animals	₩BC 1 O³,			fferentia BAND		6) SEG	EOS	INO	BAS	:0	MON	10	LY	MPHO	OT	HERS
Control	33	10.44±	22.74	1±	1	53±	15	1±	1	0±	0	5±	3	$35\pm$	12	5±	15
200pm	36	6.15±	1.60	1±	1	51±	9	1±	1	0±	0	5±	2	36±	9	5±	4
mqq008	36	6.07±	1.99	1土	1	53±	12	1±	1	0±	0	5±	2	36±	11	4±	4
3200ppm	27	6.00±	4.00	1±	2	51±	14	2±	3	0±	0	5±	2	35±	12	7±	12
Significan	t difference	: *;₽≦	≨ 0.05	** : P ≦	0.01			Test	of Dunne	tt							

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APPENDIX D 2

HEMATOLOGY : SUMMARY, RAT : FEMALE

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : FEMALE

HEMATOLOGY(1) (SUMMARY) SURVIVAL ANIMALS (105)

oup Name	NO. of Animals	RED BLOOD CELL 1 O ⁶ /µl	HEMOGLOBIN g∕d£	HEMATOCRIT %	MCV f l	MCII РЕ	MCHC g / dl	PLATELET 1 0 ³ /µl
Control	38	7.95± 1.56	15.0± 2.4	43.1± 6.6	55.1± 5.8	19.1± 3.2	34.7± 2.9	618± 138
200ppm	38	8.15± 0.94	15.1± 1.7	43.8± 4.2	54.0± 2.2	18.6± 0.7	34.4± 1.3	678± 183
800pm	41	7.99± 1.43	14.6± 2.7	42.4± 6.6	53.6± 6.4	18.2± 1.8	34.1± 2.4	645± 175
3200ppm	38	8,22± 1,30	15.0 ± 2.0	43.3± 4.8	53.7± 8.1**	18.5± 1.7	34,6± 1,6	660 ± 147

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(IICL070)

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : FEMALE

HEMATOLOGY(2) (SUMMARY) SURVIVAL ANIMALS (105)

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PAGE: 2

38 38	22.94± 90 5.45± 9	0.33 9.82	1± 1±	1 2	47土 45土	14 13	1± 1±	1	0± 0±	0	5± 5±	2	39±	13	7±	21
38	5.45± §	9.82	1±	2	45±	13	1±	1	0+	0	E L		40.1			
									04	v	δ±	2	42±	13	5±	15
41	5.19± 6	6.75	1±	1	41±	13	1±	1	0±	0	5±	2	46±	14	6±	15
38	3.11± 1	1.59	2土	2	46±	9	$2\pm$	1	0±	0	5±	2	42±	10	3±	7
erence i	: *:P≦(0.05	**:Р≦	0.01			Test	of Dunne	tt						ag 2012-01-2012-01-2012-01-2012-01-2012-01-2012-01-2012-01-2012-01-2012-01-2012-01-2012-01-2012-01-2012-01-20	
er	ence i	rence; *:P≦	rence; *:P≦0.05	rence; *:P≦0.05 **:P≦	rence; *:P≦0.05 **:P≦0.01											

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(IICL071)

APPENDIX D 3

HEMATOLOGY : SUMMARY, MOSUE : MALE

HEMATOLOGY(1) (SUMMARY) SURVIVAL ANIMALS (105)

PAGE : 1 Group Name NO. of RED BLOOD CELL HEMOGLOBIN HEMATOCRIT MCV MCH MCHC PLATELET Animals 1 06/µl % g / dl fℓ g / dl 1 0³/μl рg Control 39 9.45 ± 1.51 13.4± 1.9 41.6± 5.2 $44.3 \pm$ 2.7 $14.2 \pm$ 32,0± $1833 \pm$ 396 0.8 1.0 200ppm 31 9.87± 1.26 42.8± 4.2 13.8± 1.3 $43.5\pm$ 2.5 14.0± 0.8 $32.2 \pm$ 0.9 $1902\pm$ 420 800ppm 33 9.40± 1.33 $13.2 \pm$ 1.8 $41.4 \pm$ 4,6 $44.6 \pm$ 4.5 $14.1 \pm$ 0.6 $31.8 \pm$ 1.8 $1841\pm$ 582 3200ppm 29 9.79± 1.77 13.7± 2.1 42.7± 5.8 44.4± 1846± 473 5.3 $14.2 \pm$ 1.0 32.1± 1.4 Significant difference ; $*: P \leq 0.05$ ** : P ≦ 0.01 Test of Dunnett

(IICL070)

HEMATOLOGY(2) (SUMMARY) SURVIVAL ANIMALS (105)

PAGE: 1 WBC Group Name NO. of Differential WBC (%) 1 0³/με Animals N-BAND N-SEG EOSINO BASO MONO LYMPHO OTHERS Control 39 2.45 ± 1.42 $1\pm$ 1 $33\pm$ 15 $1\pm$ 15 $2\pm$ 4 0± 0 $3\pm$ 2 $59\pm$ 3 200ppm 31 2.85± 1.56 0± 1 $30\pm$ 15 $1\pm$ 1 0± 0 $4\pm$ 2 $62\pm$ 14 $2\pm$ 3 800ppm 33 2.51± 1.71 0± $1\pm$ 1 $38\pm$ 19 $1\pm$ 2 0 4土 2 $54\pm$ 21 $3\pm$ 4 3200ppm 29 2.30± 1.30 $1\pm$ 2 $32\pm$ 14 $1\pm$ 2 0± 0 4± 2 $60\pm$ 16 $2\pm$ 4 Significant difference ; $*: P \leq 0.05$ ** : P ≦ 0.01 Test of Dunnett

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(IICL071)

APPENDIX D 4

HEMATOLOGY : SUMMARY, MOSUE : FEMALE

HEMATOLOGY(1) (SUMMARY) SURVIVAL ANIMALS (105)

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Group Name	NO. of Animals	RED BLOOD CELL 1 0 ⁶ /µl	HEMOGLOBIN g∕d¢	HEMATOCRIT %	MCV f l	MCH Pg	MCIIC g∕dl	PLATELET 1 0 ³ /µl
Control	27	9.03± 1.87	13.1± 2.5	40.6± 6.4	46.3± 9.1	14.7± 1.8	32.0± 1.9	984± 380
200ppm	25	9.14± 1.42	13.3± 1.7	41.0± 4.4	45.6± 6.5	14.7± 1.4	32.4± 1.5	924± 410
mqq008	27	9.64± 0.77	13.9± 1.1	42.7± 3.1	44.4± 1.3	14.5± 0.5	32.6± 1.0	1052± 292
3200pm	25	9.04± 1.67	$13.0\pm$ 2.5	40.4± 7.1	44.9± 2.3	14.3± 0.8	32.0± 1.1	780± 288

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(IICL070)

## HEMATOLOGY(2) (SUMMARY) SURVIVAL ANIMALS (105)

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PAGE : 2

| roup Name | NO. of<br>Animals | ₩ВС<br>1 0 <sup>3</sup> /µя |    | fferential<br>BAND | WBC (%<br>N-S |    | EOS | INO | BAS | 0 | MON | 0  | LY      | npho | OTI | HERS |
|-----------|-------------------|-----------------------------|----|--------------------|---------------|----|-----|-----|-----|---|-----|----|---------|------|-----|------|
| Control   | 27                | 5.14± 16.46                 | 1± | 2                  | 39±           | 18 | 1±  | 1   | 0±  | 0 | 3±  | 2  | $50\pm$ | 17   | 5±  | 9    |
| 200ppm    | 25                | 2.26± 1.47                  | 1± | 4                  | 37±           | 21 | 1±  | 2   | 0±  | 0 | 4±  | 2  | 50±     | 22   | 6±  | 8    |
| 800ppm    | 27                | 2.52± 2.61                  | 0± | 1                  | 34±           | 14 | 2±  | 5   | 0±  | 0 | 5±  | 2* | $55\pm$ | 13   | 4±  | 6    |
| 3200ppm   | 25                | 2.02± 2.22                  | 1± | 2                  | 37±           | 18 | 1±  | 4   | 0±  | 0 | 4±  | 3  | $53\pm$ | 19   | 4±  | 4    |

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(HCL071)

APPENDIX E 1

BIOCHEMISTRY : SUMMARY, RAT : MALE

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : MALE

### BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (105)

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| roup Name | NO. of<br>Animals | TOTAL PRO<br>g /dl | DTEIN | ALBUMIN<br>g⁄dશ |     | A/G RAT | 10  | T-BILII<br>mg∕dl |      | GLUCOSE<br>mg⁄dl |    | T−CHOLE<br>mg∕dl | STEROL | TRIGLYC<br>mg∕dશ | ERIDE |
|-----------|-------------------|--------------------|-------|-----------------|-----|---------|-----|------------------|------|------------------|----|------------------|--------|------------------|-------|
| Control   | 34                | 6.6±               | 0.6   | 3.0±            | 0.3 | 0.8±    | 0.1 | 0.33±            | 0.47 | 161±             | 22 | 192±             | 53     | 252±             | 139   |
| 200ppm    | 36                | 6.7±               | 0.4   | $3.1\pm$        | 0.2 | 0.9±    | 0.1 | 0.25±            | 0.07 | 164土             | 22 | 186±             | 54     | $237\pm$         | 131   |
| mqq008    | 36                | 6 <b>.</b> 7±      | 0.5   | 3.1±            | 0.3 | 0.9±    | 0.1 | 0.25±            | 0.06 | 160±             | 28 | 173±             | 47     | 197±             | 124   |
| 3200ppm   | 27                | 6.6±               | 0.5   | 2.9±            | 0.3 | 0.8±    | 0.1 | 0.23±            | 0.06 | $161\pm$         | 21 | 179±             | 54     | 224±             | 152   |

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(IICL074)

PAGE : 1

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1

# BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (105)

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| oup Name | NO. of<br>Animals | PHOSPHO<br>mg∕dl | LIPID | GOT<br>IU/4 | ?   | GPT<br>IU/Ø |    | LDH<br>IU/e |     | ALP<br>IU/6 | ,   | G-GTP<br>IU∕ℓ |   | CPK<br>IU/Ø |    |
|----------|-------------------|------------------|-------|-------------|-----|-------------|----|-------------|-----|-------------|-----|---------------|---|-------------|----|
| Control  | 34                | $331\pm$         | 108   | 109±        | 264 | 26±         | 36 | 194±        | 149 | 186±        | 133 | 5±            | 2 | 86±         | 61 |
| 200ppm   | 36                | 309±             | 91    | 66±         | 24  | 20±         | 5  | 156±        | 33  | $181\pm$    | 68  | 6±            | 5 | 72±         | 10 |
| mqq008   | 36                | $291\pm$         | 92    | 74±         | 36  | 23±         | 9  | $158\pm$    | 37  | 169±        | 72  | 6土            | 3 | 72±         | 15 |
| 3200ppm  | 27                | 307±             | 112   | 74±         | 33  | $22\pm$     | 8  | $157\pm$    | 42  | 170±        | 67  | 5±            | 3 | 75±         | 14 |

(HCL074)

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : MALE

### BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (105)

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PAGE : 3 Group Name NO. of UREA NITROGEN CREATININE SODIUM POTASSIUM CHLORIDE CALCIUM INORGANIC PHOSPHORUS Animals mg∕dl mg∕dl mEq/l mEq∕ℓ mEq∕ℓ mg/dl ∏g∕dl Control 34 39.7± 44.4 1.1± 1.4 2  $144\pm$  $3.9\pm$ 0.5  $106 \pm$ 4 10.9± 1.2 5.5± 4.0 200ppm 36 28.6± 17.3 0.8± 0.6  $144 \pm$ 1 3.8±  $106\pm$ 2 4.7± 1.5 0.4 10.8± 1.0 800ppm 36 27.6± 16.6 0.7± 0.5  $144 \pm$ 2  $3.6\pm$ 0.3\*  $107\pm$ 2 10.6± 0.7 4.5± 1.6 3200ppm 27  $32.5 \pm 13.3$ 0.8± 0.3  $144\pm$ 2 3.9± 0.4  $107 \pm$ 2 11.0± 0.7 5.2± 1.4 Significant difference ;  $*: P \leq 0.05$ \*\* : P ≦ 0.01 Test of Dunnett

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(IICL074)

APPENDIX E 2

BIOCHEMISTRY : SUMMARY, RAT : FEMALE

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : FEMALE

## BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (105)

 $\overline{\phantom{a}}$ 

| oup Name | NO, of<br>Animals | TOTAL PI<br>g /dl | ROTEIN | ALBUMIN<br>g⁄dl | A/G RAT | 10  | T-BILIRUBIN<br>mg∕dl | GLUCOSE<br>mg∕dℓ |    | T−CHOLE:<br>mg∕dl | STEROL | TRIGLYC<br>mg∕dl | ERIDE |
|----------|-------------------|-------------------|--------|-----------------|---------|-----|----------------------|------------------|----|-------------------|--------|------------------|-------|
| Control  | 38                | 6.9±              | 0.7    | 3.6± 0.         | 4 1.1±  | 0.1 | 0.44± 1.27           | 156±             | 23 | $150\pm$          | 43     | $147\pm$         | 66    |
| 200ppm   | 38                | 7.0±              | 0.4    | 3.6± 0.         | 3 1.1±  | 0.2 | 0.25± 0.05           | 160±             | 22 | 161±              | 60     | 199±             | 156   |
| mqq008   | 42                | 7.1±              | 0.5    | 3.6± 0.         | 3 1.1±  | 0.1 | 0.31± 0.43           | 162±             | 18 | 159±              | 45     | 196±             | 118   |
| 3200ppm  | 38                | 6.9±              | 0.6    | 3.6± 0.         | 3 1.1±  | 0.1 | 0,24± 0,10           | 157±             | 23 | 160±              | 37     | 149±             | 76    |

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(IICL074)

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SE

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (105)

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| <b>a</b> |    |          |     |          |       |     |     |          |        | IU/4     |     | IU/¢ | • | IU/ |     |
|----------|----|----------|-----|----------|-------|-----|-----|----------|--------|----------|-----|------|---|-----|-----|
| Control  | 38 | $295\pm$ | 102 | $195\pm$ | 494   | 42± | 43  | 497±     | 1217   | 236±     | 432 | 4±   | 2 | 94± | 82  |
| 200ppm   | 38 | $314\pm$ | 125 | 105±     | 46    | 36± | 18  | 211±     | 97     | 228±     | 606 | 5±   | 2 | 73± | 13  |
| mqq008   | 42 | $312\pm$ | 90  | $130\pm$ | 161   | 38± | 23  | $194\pm$ | 77     | 149±     | 84  | 5±   | 3 | 75± | 36  |
| 3200ppm  | 38 | 309±     | 76  | 187±     | 684** | 46± | 103 | $381\pm$ | 1426** | $145\pm$ | 85  | 4±   | 1 | 90± | 119 |

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STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : FEMALE

### BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (105)

\*\* : P ≦ 0.01

### NO. of Group Name UREA NITROGEN CREATININE SODIUM POTASSIUM CHLORIDE CALCIUM INORGANIC PHOSPHORUS Animals ng∕dl mg∕d£ mEq∕ℓ mEq∕ℓ mEq∕ℓ mg∕dℓ πg∕dℓ Contral 38 18.3± 6.0 0.5± 0.1 $143\pm$ 2 $3.5\pm$ 0.3 $106 \pm$ 3 10.4± 0.3 3.7± 0.8 200ppm 38 $18.5 \pm$ 4.2 $0.5\pm$ 0.1 $143\pm$ 2 $3.5\pm$ 0.3 $105\pm$ 2 $10.5\pm$ 0.4 $3.6\pm$ 0.9 800ppm 42 $17.1 \pm$ 1.6 0.5± 0.1 $143\pm$ 2 3.6± 0.5 $105\pm$ Z 10.5± 0.5 3.9± 0.8 3200ppm 38 18.6± 5.8 0.4± 0.1 $143\pm$ 2 $3.5\pm$ 0.4 $105\pm$ 2, 10.4± 0.4 3.9± 1.0

Test of Dunnett

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(HCL074)

Significant difference ;  $*: P \leq 0.05$ 

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PAGE: 6

APPENDIX E 3

BIOCHEMISTRY : SUMMARY, MOSUE : MALE

NO. of

Animals

40

32

33

30

,

Group Name

Control

200ppm

800ppm

3200ppm

## BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (105)

1.1± 0.2

 $1.0\pm 0.2$ 

1.1± 0.1

0.2

 $1.0\pm$ 

**~\_\_**\_\_

 $2.8\pm$ 

2.8±

 $2.8\pm$ 

 $2.9\pm$ 

0.3

0.4

0.4

0.5

## ALBUMIN A/G RATIO T-BILIRUBIN GLUCOSE g/dl mg/dl mg/dl

Significant difference ;  $*: P \leq 0.05$   $**: P \leq 0.01$ 

TOTAL PROTEIN

5.5± 0.6

0.7

0,6

1.2

g/dl

 $5.6\pm$ 

5.5土

 $5.7 \pm$ 

Test of Dunnett

0.30± 0.13

0.29± 0.14

0.39± 0.43

0.32± 0.11

 $197\pm$ 

 $200\pm$ 

 $180\pm$ 

 $197 \pm$ 

42

40

55

42

(HCL074)

PAGE : 1 TRIGLYCERIDE

mg∕d&

 $54\pm$ 

 $57\pm$ 

 $60\pm$ 

 $52\pm$ 

18

15

16

16

T-CHOLESTEROL

25

39

26

71

mg / dl

 $103\pm$ 

 $101\pm$ 

 $103\pm$ 

 $124\pm$ 

### BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (105)

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### PAGE : 2 Group Name NO. of GOT GPT LDH ALP CPK UREA NITROGEN SODIUM Animals IU∕ℓ IU∕ℓ IU∕ℓ IU/l IU∕ℓ mg/dl mEq/l Control 40 $320\pm$ 796 $175\pm$ 655 $1575 \pm 6148$ 99 2 $202\pm$ $92\pm$ 217 28.3± 25.9 $155\pm$ 200ppm 32 $223\pm$ 514 64± 113 $537\pm$ 621 $203\pm$ 124 $62\pm$ 40 25.5± 9.2 $155\pm$ 2 800ppm 33 651± 2878 $203\pm$ 776 2409± 10854 $205\pm$ 110 $85\pm$ 76 $27.0 \pm 15.6$ $154\pm$ 2 3200ppm 30 $157\pm$ 298 118 570± 619 $68\pm$ $320\pm$ 396 $60\pm$ 34 25.5± 5.9 $155\pm$ 2 Significant difference ; $*: P \leq 0.05$ \*\* : P ≦ 0.01 Test of Dunnett

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(HCL074)

### BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (105)

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### PAGE : 3 Group Name NO. of POTASSIUM CHLORIDE CALCIUM INORGANIC PHOSPHORUS Animals mEq∕ℓ mEq/l mg/dl πg∕dl Control 40 4.3± 0.7 $123\pm$ 3 8.8± 0.6 7.2± 3.4 200ppm $4.3\pm$ 32 0.4 $123\pm$ 3 8.9± 0.4 6.7± 1.1 800ppm 33 $4.4 \pm$ $123\pm$ 0.6 3 8.8± 0.4 7.0± 1.5 3200ppm 30 4.4± 0.7 3 $124\pm$ 9.0± 0.9 7.0± 1.2 Significant difference ; $*: P \leq 0.05$ \*\* : P ≦ 0.01 Test of Dunnett

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(IICL074)

APPENDIX E 4

## BIOCHEMISTRY : SUMMARY, MOSUE : FEMALE

| Group Name | NO. of<br>Animals | pII_<br>5.0 | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 CH | II | Protei<br>— ± |   |      | 4+ | CIII |    | cose_<br>± + | 2+ | 3+ 4+ | СНІ |    | ne bo<br>E + |     | 4+ CHI |    | lirubin<br>+ 2+ |   |  |
|------------|-------------------|-------------|-----|-----|-----|-----|-----|--------|----|---------------|---|------|----|------|----|--------------|----|-------|-----|----|--------------|-----|--------|----|-----------------|---|--|
| Control    | 34                | 0           | 1   | 6   | 8   | 11  | 7   | 1      |    | 0 0           | 0 | 1 30 | 3  |      | 34 | 0 0          | 0  | 0 0   |     | 33 | 1 0          | 0 0 | 0      | 32 | 1 0             | 1 |  |
| 200ppm     | 37                | 1           | 0   | 7   | 9   | 9   | 11  | 0      |    | 0 0           | 0 | 4 30 | 3  |      | 36 | 1 0          | 0  | 0 0   |     | 37 | 0 0          | 0 0 | 0      | 37 | 0 0             | 0 |  |
| 800ppm     | 36                | 0           | 1   | 5   | 6   | 9   | 15  | 0      |    | 0 0           | 0 | 3 31 | 2  |      | 36 | 0 0          | 0  | 0 0   |     | 36 | 0 0          | 0 0 | 0      | 36 | 0 0             | 0 |  |
| 3200ppm    | 28                | 0           | 0   | 3   | 9   | 12  | 4   | 0      |    | 0 0           | 0 | 2 25 | 1  |      | 28 | 0 0          | 0  | 0 0   |     | 28 | 0 0          | 0 0 | 0      | 28 | 0 0             | 0 |  |

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Group Name	NO. of Animals	0ccult blood — ± + 2+ 3+ CIII	Vrobilinogen ± + 2+ 3+ 4+ CHI		
Control	34	33 1 0 0 0	33 1 0 0 0		
200ppm	37	36 0 0 0 1	37 0 0 0 0		
800ppm	36	35 0 1 0 0	36 0 0 0 0		
3200ppm	28	27 1 0 0 0	28 0 0 0 0		

APPENDIX F 1

URINALYSIS : SUMMARY, RAT : MALE

Group Name

Control

200ppm

800ppm

3200ppm

BIOCHEMISTRY (SUMMARY)

SURVIVAL ANIMALS (105)

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** : P ≦ 0.01

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NO. of TOTAL PROTEIN ALBUMIN A/G RATIO T-BILIRUBIN GLUCOSE T-CHOLESTEROL TRIGLYCERIDE Animals g∕dl g / dl πg∕dl mg/dl mg∕dl πg∕dℓ 29 5.0± 0.7 2.7± 0.4 1.2 ± 0.2 0.33± 0.09 $139\pm$ 49 $65\pm$ 14 $51\pm$ 22 26 $5.3\pm$ 1.0 $2.7\pm$ 0.4 $1.1 \pm$ 0.2 0.36± 0.25 $135\pm$ 33 $70\pm$ 25 80± 100 27 $5.6\pm$ 0.9** $2.9\pm$ 0.3* 1.1± 0.2 0.30 ± 0.05 $142\pm$ 34 $86\pm$ 44 $56\pm$ 19 25 5.2± 0.5 2.7± 0.3 1.1± 0.3 0.32± 0.10 $146 \pm$ 34 $69\pm$ 18 $63\pm$ 51

Significant difference ; $*: P \leq 0.05$

Test of Dunnett

(HCL074)

BAIS 2

PAGE: 4

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (105)

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Group Name Control	NO. of Animals	GOT IU∕ℓ		GPT IU/l		LDH IU⁄¢		NLP IU∕ℓ		CPK IU/l		UREA NITROGEN mg/dl		SODIUM mEq∕ℓ	
	29	166±	164	38±	34	1136±	2400	304±	163	162±	214	22.0±	12.6	153±	3
200ppm	26	172±	194	42±	42	704±	743	215±	83	82±	70	18.5±	13.0	$152\pm$	2
mqq008	27	146±	116	34±	19	428±	154	244土	112	108±	151	19.0±	6.4	$152\pm$	2
3200ppm	25	$222\pm$	231	$44\pm$	40	$851\pm$	1170	$344\pm$	304	$73\pm$	52	21.3±	15.1	$154\pm$	2

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(IICL074)

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (105)

NO, of Group Name POTASSIUM CHLORIDE CALCIUM INORGANIC PHOSPHORUS Animals mEq∕ℓ mEq∕ℓ πg∕dl ∏g∕dl Control 29 4.1± 0.7 $123\pm$ 3 8.8± 0.6 7.0± 1.4 200ppm 26 4.2± 0.9 $123\pm$ 4 9.0± 0.6 $6.5\pm$ 0.9 800ppm 27 4.0± 0.5 $122\pm$ 3 9.1± 0.6 6.6± 1.1 3200ppm 25 4.0± 0.5 $123\pm$ 3 8.9± 0.5 7.0 ± 1.3 . ** : P ≦ 0.01 Test of Dunnett

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Significant difference ; $*: P \leq 0.05$

(IICL074)

BAIS 2

PAGE: 6

APPENDIX F 2

URINALYSIS : SUMMARY, RAT : FEMALE

Group Name	NO. of Animals	pll_ 5.0	6.0	6.5	7.0	7.5	8.0	8.5	CIII	Protein - ± + 2+ 3+ 4+ CHI	Glucose - ± + 2+ 3+ 4+ CHI	Ketane bady - ± + 2+ 3+ 4+ CIII	Bilirubin — + 2+ 3+ CHII
Control	38	1	2	3	5	12	15	0		0 0 1 8 17 12	38 0 0 0 0 0	34 3 1 0 0 0	38 0 0 0
200ppm	38	0	1	2	9	12	13	1		0 0 1 3 16 18	38 0 0 0 0 0	35 3 0 0 0 0	38 0 0 0
800ppm	42	0	1	3	9	16	12	1		0 0 4 3 18 17	42 0 0 0 0 0	41 1 0 0 0 0	41 0 0 1
3200ppm	39	0	2	5	6	9	14	3		0 0 3 5 21 10	39 0 0 0 0 0	35 3 1 0 0 0	39 0 0 0

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STUDY NO. : 0189 ANIMAL : RAT F344 SAMPLING DATE : 104-5 SEX : FEMALE REPORT TYPE : A1			URINALYSIS		PAGE: 4
Group Name	NO. of Animals	Occult blaad ー 土 + 2+ 3+ CNI	Urobilinogen ± + 2+ 3+ 4+ CIII		
Control	38	36 2 0 0 0	38 0 0 0 0		
200ppm	38	38 0 0 0 0	38 0 0 0 0		
800ppm	42	39 2 1 0 0	41 1 0 0 0		
3200ppm	39	37 1 0 1 0	39 0 0 0 0		
Significer	nt difference	; *:P≦0.05 **	• : P ≤ 0.01	Test of CHI SQUARE	
(JCL101)					BAIS 2

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APPENDIX F 3

URINALYSIS : SUMMARY, MOSUE : MALE

roup Name	NO. of	_llq								Proteir	. <u> </u>			Glu	Glucose		Ketone body		Occult blood							
	Animals	5.0	6.0	6,5	7.0	7.5	8.0	8.5	CHI	- ± ·	+ 2	+ 3+	4+ Cl	II —	± -	+ 2+	3+ 4	+ CHI	- ±	+ 2+	3+ 4+	CHI	- :	± + 2·	+ 3+	CHI
																							·			
Control	40	0	10	14	8	4	3	1		063	28	51	0	40	0	0 0	0	0	13 24	30	0 0		36	2 1	01	
200ppm	34	0	3	14	10	6	1	0		071	24	30	0	34	0	0 0	0	0	11 19	4 0	0 0		32	0 0	1 1	
800ppm	34	0	7	10	12	4	1	0		0 14	8	20	0	34	0	0 0	0	0	15 16	30	0 0		32	1 0	10	
3200ppm	31	0	13	10	5	2	1	0		0 5	19	70	0	31	0	0 0	0	0	6 12	10 3	0 0	**	28	2 0	1 0	

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STUDY NO. : 01 ANIMAL : MC SAMPLING DATE SEX : MALE)USE BDF1 : 104-4	TYPE : A1	URINALYSIS		PAGE : 2
Group Name	NO. of Animals	Vrabilinagen ± + 2+ 3+ 4+ CHI			
Control	40	40 0 0 0 0			
200ppm	34	34 0 0 0 0			
800ppm	34	34 0 0 0 0			
3200ppm	31	31 0 0 0 0			
Significer	nt difference	*:P≤0.05 **:P≤0.01		Test of CHI SQUARE	
(JCL101)					 BAIS 2

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APPENDIX F 4

URINALYSIS : SUMMARY, MOSUE : FEMALE

iroup Name	NO. of Animals	pll_ 5,0	6.0	6,5	7.0	7.5	8.0	8.5	CHI	Protein - ± + 2+ 3+ 4+ CHI	Glucase - ± + 2+ 3+ 4+ CIII	Ketone body - ± + 2+ 3+ 4+ CIII	0ccult blood — ± + 2+ 3+ CIII
Control	29	0	3	4	6	9	7	0		1 10 10 8 0 0	29 0 0 0 0 0	9 18 1 1 0 0	20 1 1 2 5
200ppm	28	0	1	7	10	5	5	0		0 7 18 3 0 0	28 0 0 0 0 0	10 15 2 1 0 0	24 1 2 0 1
800ppm	29	0	2	9	10	7	1	0		0 9 13 6 1 0	29 0 0 0 0 0	11 14 4 0 0 0	21 3 0 0 5
3200ppm	29	0	6	9	9	3	2	0		0 4 18 7 0 0	29 0 0 0 0 0	5 18 6 0 0 0	24 3 1 0 1

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STUDY NO. : 01 ANIMAL : NC SAMPLING DATE SEX : FEMALE	USE BDF1 : 104-4	URINA	ILYSTS	PAGE : 4
Group Name	NO. of Animals	Urobilinogen ± + 2+ 3+ 4+ CNI		
Control	29	29 0 0 0 0		
200ppm	28	28 0 0 0 0		
800ppm	29	29 0 0 0 0		
3200ppm	29	29 0 0 0 0		
Significer	nt difference	; *:P≦0.05 **:P≦0.01	Test of CHI SQUARE	· · · ·
(JCL101)				BAIS 2

GROSS FINDINGS : SUMMARY, RAT : MALE : DEAD AND MORIBUND ANIMALS

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : MALE

GROSS FINDINGS (SUMMARY) DEAD AND MORIBUND ANIMALS (0-105W)

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Organ	Findings	Group Name NO. of Animals	Cantrol 16 (%)	200ppm 14 (%)	800ppm 14 (%)	3200ppm 22 (%)
skin/app	nodule		2 (13)	1 (7)	0 (0)	0 (0)
subcutis	jaundice		0 (0)	0 (0)	1 (7)	0 (0)
	mass		4 (25)	3 (21)	2 (14)	4 (18)
lung	red		1 (6)	2 (14)	0 (0)	0 (0)
	White zone		0 (0)	0 (0)	1 (7)	0 (0)
	red zone		0 (0)	0 (0)	2 (14)	1 (5)
	red patch		0 (0)	1 (7)	0 (0)	0 (0)
	nodule		1 (6)	0 (0)	0 (0)	0 (0)
	voluminus		0 (0)	3 (21)	3 (21)	2 (9)
lymph node	enlarged		1 (6)	0 (0)	1 (7)	3 (14)
thymus	enlarged		0 (0)	0 (0)	1 (7)	0 (0)
spleen	enlarged		4 (25)	6 (43)	5 (36)	5 (23)
	black zone		0 (0)	0 (0)	0 (0)	1 (5)
heart	white		0 (0)	0 (0)	0 (0)	1 (5)
	white zone		0 (0)	0 (0)	0 (0)	1 (5)
esophagus	dilated		0 (0)	1 (7)	0 (0)	0 (0)
forestomach	nodule		0 (0)	1 (7)	0 (0)	0 (0)
	ulcer		6 (38)	3 (21)	1 (7)	0 (0)
	thick		1 (6)	0 (0)	0 (0)	0 (0)
gl stomach	white zone		0 (0)	0 (0)	0 (0)	1 (5)
	ulcer		0 (0)	1 (7)	0 (0)	2 (9)
	thick		0 (0)	0 (0)	0 (0)	1 (5)

PAGE: 1

GROSS FINDINGS (SUMMARY) DEAD AND MORIBUND ANIMALS (0-105W)

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1

: MALE

SEX

Group Name Control 200ppm 800ppm 3200ppm 0rgan_ Findings 22 (%) NO. of Animals 16 (%) 14 (%) 14 (%) liver enlarged 0 (0) 0 (0) 2 (9) 1 (7) white zone 0 (0) 0 (0) 0 (0) 2 (9) red zone 1 (6) 0 (0) 0 (0) 0 (0) nodule 0 (0) 2 (14) 0 (0) 1 (5) rough 0 (0) 1 (7) 0 (0) 1 (5) kidney white zone 0 (0) 1 (7) 0 (0) 0 (0) nodule 0 (0) 1 (7) 0 (0) 1 (5) granular 6 (38) 7 (50) 3 (21) 6 (27) hydronephrosis 0 (0) 1 (7) 0 (0) 0 (0) urin bladd nodule 0 (0) 1 (7) 0 (0) 0 (0) urine:marked retention 0 (0) 0 (0) 0 (0) 1 (5) fluid:red 0 (0) 0 (0) 1 (7) 0 (0) pituitary enlarged 6 (38) 1 (7) 5 (36) 0 (0) red zone 1 (6) 0 (0) 0 (0) 0 (0) thyroid enlarged 0 (0) 1 (7) 0 (0) 0 (0) nadule 0 (0) 0 (0) 0 (0) 1 (7) adrenal enlarged 1 (6) 0 (0) 1 (7) 0 (0) testis enlarged 0 (0) 0 (0) 1 (7) 0 (0) atrophic 0 (0) 1 (7) 0 (0) 1 (5) nodule 9 (56) 13 (93) 12 (86) 14 (64) semin ves enlarged 0 (0) 0 (0) 0 (0) 1 (7) brain red zone 0 (0) 2 (14) 0 (0) 2 (9)

PAGE : 2

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STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : MALE

GROSS FINDINGS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0-105W)

SEX :	MALE				PAGE :
0rgan	Findings	Group Name Contro NO. of Animals 16 (%)		800ppm 14 (%)	3200ppm 22 (%)
spinal cord	red zone	0 (0) 1 (7)	0 (0)	0 (0)
өуө	turbid	0 (0) 1 (7)	0 (0)	0 (0)
	red	0 (0) 1 (7)	0 (0)	0 (0)
muscle	mass	0 (0) 0 (0)	0 (0)	1 (5)
peritoneum	enlarged	0 (0) 0 (0)	0 (0)	1 (5)
	nodule	1 (6) 1 (7)	0 (0)	10 (45)
	mass	1 (6) 0 (0)	0 (0)	0 (0)
retroperit	mass	1 (6) 0 (0)	0 (0)	0 (0)
abdominal c	hemorrhage	0 (0) 0 (0)	0 (0)	1 (5)
	ascites	2 (1	3) 2 (14)	0 (0)	11 (50)
thoracic ca	pleural fluid	1 (6) 3 (21)	1 (7)	3 (14)
other	nodule	0 (0) 0 (0)	1 (7)	0 (0)
	ear:nodule	0 (0) 1 (7)	0 (0)	0 (0)
whale body	anemic	0 (0) 0 (0)	0 (0)	1 (5)

(IIPT080)

BAIS 2

GROSS FINDINGS : SUMMARY, RAT : FEMALE : DEAD AND MORIBUND ANIMALS

GROSS FINDINGS (SUMMARY) DEAD AND MORIBUND ANIMALS (0-105W)

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1

SEX : FEMALE

0rgan_

subcutis lung

lymph nade spleen

Findings		ontrol (%) 1:	200ppm 2 (%)	800ppm 8 (%)	3200ppm 12 (%)
mass	5	(42)	1 (8)	3 (38)	5 (42)
red	0	(0)	1 (8)	0 (0)	0 (0)
red zone	1	(8)	2 (17)	0 (0)	0 (0)
red patch	0	(0)	0 (0)	1 (13)	0 (0)
nodule	2	(17)	1 (8)	0 (0)	1 (8)
adhesion	1	(8)	0 (0)	0 (0)	0 (0)
enlarged	1	(8)	0 (0)	0 (0)	1 (8)
enlarged	1	(8)	5 (42)	4 (50)	6 (50)
nadule	2	(17)	1 (8)	0 (0)	0 (0)
adhesion	0	(0)	0 (0)	1 (13)	0 (0)
white zone	0	(0)	0 (0)	0 (0)	1 (8)
nadule	0	(0)	0 (0)	0 (0)	1 (8)
nodule	0	(0)	1 (8)	0 (0)	0 (0)
rupture	0	(0)	0 (0)	1 (13)	0 (0)
ulcer	2	(17)	1 (8)	1 (13)	0 (0)

0 (0)

0 (0)

4 (33)

0 (0)

0 (0)

0 (0)

0 (0)

1 (13)

0 (0)

1 (13)

0 (0)

0 (0)

0 (0)

0 (0)

	nadule	2 (17)
	adhesion	0 (0)
heart	white zone	0 (0)
	nadule	0 (0)
forestomach	nodule	0 (0)
	rupture	0 (0)
	ulcer	2 (17)
	erosion	0 (0)
	thick	1 (8)
gl stomach	ulcer	2 (17)
duadenum	nodule	1 (8)
liver	yellaw	1 (8)
	white zane	2 (17)
	red zone	1 (8)
(UDTORO)		

0 (0)

0 (0)

0 (0)

0 (0)

0 (0)

0 (0)

0 (0)

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PAGE: 4

STUDY NO. : 0189 ANIMAL. : RAT F344 REPORT TYPE : A1

SEX : FENALE

GROSS FINDINGS (SUMMARY) DEAD AND MORIBUND ANIMALS (0-105W)

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SEX :	FENALE					PAGE: 5
0rgan	Findings		ntrol (%)	200pm 12 (%)	800ppm 8 (%)	3200ppm 12 (%)
liver	nadule	0	(0)	0 (0)	0 (0)	2 (17)
	rough	0	(0)	1 (8)	0 (0)	0 (0)
	nodular	0	(0)	0 (0)	1 (13)	0 (0)
	herniation	2	(17)	0 (0)	0 (0)	0 (0)
pancreas	red zone	1	(8)	0 (0)	0 (0)	0 (0)
kidney	pale	1	(8)	0 (0)	0 (0)	0 (0)
	white zone	0	(0)	0 (0)	1 (13)	0 (0)
	granular	1	(8)	1 (8)	1 (13)	1 (8)
	hydronephrosis	1	(8)	0 (0)	0 (0)	0 (0)
urin bladd	red zone	0	(0)	1 (8)	0 (0)	0 (0)
	urine:marked retention	1	(8)	1 (8)	0 (0)	1 (8)
	urine:red	0	(0)	1 (8)	0 (0)	0 (0)
pituitary	enlarged	3	(25)	4 (33)	1 (13)	3 (25)
	red zone	0	(0)	1 (8)	0 (0)	0 (0)
	nodule	1	(8)	0 (0)	1 (13)	2 (17)
adrenal	enlarged	0	(0)	1 (8)	0 (0)	0 (0)
uterus	nodule	1	(8)	3 (25)	2 (25)	3 (25)
	dilated lumen	. 0	(0)	1 (8)	0 (0)	0 (0)

1 (8)

0 (0)

0 (0)

0 (0)

1 (8)

0 (0)

1 (8)

1 (8)

0 (0)

0 (0)

1 (13)

0 (0)

spinal cord

brain

red zone

red zone

hemorrhage

yellow zone

0 (0)

1 (8)

0 (0)

0 (0)

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STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1

GROSS FINDINGS (SUMMARY) DEAD AND MORIBUND ANIMALS (0-105W)

SEX :	FEMALE					PAGE : 6
0rgan	Findings	Group Name NO. of Animals	Control 12 (%)	200ppm 12 (%)	mحرح008 (%) 8	3200ppm 12 (%)
өуө	turbid		2 (17)	0 (0)	0 (0)	0 (0)
	white		1 (8)	1 (8)	0 (0)	1 (8)
Zymbal gl	nodule		1 (8)	0 (0)	0 (0)	0 (0)
mediastinum	mass		1 (8)	0 (0)	0 (0)	0 (0)
peritoneum	nodule		1 (8)	0 (0)	1 (13)	0 (0)
retroperit	nodule		1 (8)	0 (0)	0 (0)	0 (0)
abdominal c	hemorrhage		2 (17)	0 (0)	0 (0)	0 (0)
	ascites		2 (17)	1 (8)	0 (0)	0 (0)
thoracic ca	pleural fluid		2 (17)	2 (17)	0 (0)	2 (17)
whole body	anemic		2 (17)	0 (0)	1 (13)	1 (8)

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0 ( 0) 1 ( 13)

(IIPT080)

BAIS 2

1 ( 8)

GROSS FINDINGS : SUMMARY, RAT : MALE : SACRIFICED ANIMALS

#### GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (105W)

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : MALE

#### Group Name 200ppm 800ppm 3200ppm Control 0rgan\_ Findings\_ NO. of Animals 34 (%) 36 (%) 36 (%) 28 (%) skin/app nadule 3 (9) 2 (6) 3 (8) 2 (7) subcutis 8 (22) mass 2 (6) 3 (8) 4 (14) lung white zone 0 ( 0) 0 ( 0) 3 (8) 1 (4) black zone 0 ( 0) 0 ( 0) 0 ( 0) 1 (4) nodule 0 ( 0) 0 ( 0) 2 (6) 3 (11) voluminus 0 ( 0) 0 ( 0) 0 ( 0) 1. (4) spleen enlarged 3 (9) 1 (3) 3 (11) 3 (8) nodule 1 (3) 1 (3) 0 ( 0) 0 ( 0) deformed 1 (3) 1 (3) 0 ( 0) 1 (4) heart enlarged 1 (3) 0 ( 0) 0 ( 0) 0 ( 0) white zone 0 ( 0) 0 ( 0) 1 (3) 1 (4) forestomach ulcer 0 ( 0) 0 ( 0) 1 (3) 0 ( 0) small intes nodule 0 ( 0) 2 (6) 0 ( 0) 0 ( 0) liver enlarged 1 (3) 0 ( 0) 0 ( 0) 1 (4) nodule 2 (6) 1 (3) 2 ( 6) 0 ( 0) cyst 0 ( 0) 0 ( 0) 0 ( 0) 1 (4) rough 1 (3) 1 (3) 0 ( 0) 3 (11) herniation 0 ( 0) 2 ( 6) 0 ( 0) 0 ( 0) pancreas nodule 1 (3) 0 ( 0) 0 ( 0) 0 ( 0) kidney cyst 0 ( 0) 0 ( 0) 1 (3) 0 ( 0) granular 22 (65) 18 (50) 18 (50) 19 (68) pituitary enlarged 2 ( 6) 3 (8) 2 (6) 1 (4)

PAGE: 1

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : MALE

# GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (105W)

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SEX

| fgan       | Findings   | Group Name Control<br>NO. of Animals 34 (%) | 200ppm<br>36 (%) | 800ppm<br>36 (%) | 3200ppm<br>28 (%) |
|------------|------------|---------------------------------------------|------------------|------------------|-------------------|
| vituitary  | red zone   | 0 ( 0)                                      | 0 ( 0)           | 1 (3)            | 0 ( 0)            |
|            | nodule     | 4 (12)                                      | 3 ( 8)           | 2 (6)            | 5 (18)            |
| hyroid     | enlarged   | 2 ( 6)                                      | 4 (11)           | 4 (11)           | 2 (7)             |
|            | nodule     | 0 ( 0)                                      | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |
| idrena l   | enlarged   | 2 ( 6)                                      | 3 ( 8)           | 0 ( 0)           | 2 (7)             |
| estis      | enlarged   | 0 ( 0)                                      | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |
|            | nadule     | 34 (100)                                    | 35 (97)          | 35 (97)          | 27 (96)           |
|            | absence    | 1 ( 3)                                      | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| pididymis  | absence    | 1 ( 3)                                      | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| rep/cli gl | enlarged   | 0 ( 0)                                      | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |
|            | nodule     | 1 ( 3)                                      | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| pinal cord | hemorrhage | 1 ( 3)                                      | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| ууө        | turbid     | 2 ( 6)                                      | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |
|            | white zone | 1 ( 3)                                      | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| ymbal gl   | nodule     | 0 ( 0)                                      | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |
|            | mass       | 0 ( 0)                                      | 0 ( 0)           | 1 (3)            | 0 ( 0)            |
| uscle      | nodule     | 0 ( 0)                                      | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |
| eritoneum  | nodule     | 0 ( 0)                                      | 0 ( 0)           | 1 (3)            | 5 (18)            |
|            | mass       | 0 ( 0)                                      | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |
| etroperit  | mass       | 2 ( 6)                                      | 0 ( 0)           | 0 ( 0)           | 1 ( 4)            |
|            | cyst       | 1 (3)                                       | 2 ( 6)           | 0 ( 0)           | 0 ( 0)            |
| bdominal c | ascites    | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 3 (11)            |

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| STUDY NO.   | : 0189     | GROSS FINDINGS  |
|-------------|------------|-----------------|
| ANIMAL      | : RAT F344 | SACRIFICED ANIA |
| REPORT TYPE | E : A1     |                 |
| SEX         | : MALE     |                 |

| 1 | GROSS | FINDINGS | (SUMMA |
|---|-------|----------|--------|
|   |       |          |        |

# S (SUMMARY) IIMALS (105W)

| rgan       | Findings      | Group Name<br>NO, of Animals | Control<br>34 (%) | 200ppm<br>36 (%) | 800ppm<br>36 (%) | 3200ppm<br>28 (%) |
|------------|---------------|------------------------------|-------------------|------------------|------------------|-------------------|
| esenterium | mass          |                              | 0 ( 0)            | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |
| noracic ca | pleural fluid |                              | 0 ( 0)            | 0 ( 0)           | 0 ( 0)           | 1 ( 4)            |
| her        | tail:nodule   |                              | 0 ( 0)            | 0 ( 0)           | 0 ( 0)           | 1 (4)             |
| ole body   | anemic        |                              | 1 ( 3)            | 2 (6)            | 0 ( 0)           | 2 (7)             |

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## PAGE : 3

GROSS FINDINGS : SUMMARY, RAT : FEMALE : SACRIFICED ANIMALS (TOW-YERA STUDY)

### GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (105W)

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : FEMALE

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| )rgan       | Findings       | Group Name Control<br>NO. of Animals 38 (%) | 200ppm<br>38 (%) | 800ppm<br>42 (%) | 3200ppm<br>38 (%) |
|-------------|----------------|---------------------------------------------|------------------|------------------|-------------------|
| skin/app    | nadule         | 0 ( 0                                       | ) 0 ( 0)         | 1 (2)            | 1 (3)             |
| subcutis    | jaundice       | 1 ( 3                                       | s) 0 ( 0)        | 0 ( 0)           | 0 ( 0)            |
|             | mass           | 5 (13                                       | 8 (21)           | 5 (12)           | 6 (16)            |
| lung        | nodule         | 1 ( 3                                       | ) 2 ( 5)         | 1 (2)            | 1 ( 3)            |
| thymus      | nadule         | 1 ( 3                                       | 3) 0 ( 0)        | 0 ( 0)           | 0 ( 0)            |
| spleen      | enlarged       | 3 ( 8                                       | 3) 0 ( 0)        | 3 (7)            | 2 (5)             |
|             | deformed       | 0 ( 0                                       | ) 0 ( 0)         | 1 (2)            | 0 ( 0)            |
| oral cavity | nodule         | 0 ( 0                                       | ) 0 ( 0)         | 0 ( 0)           | 1 ( 3)            |
| tongue      | nodule         | . 0 ( 0                                     | ) 1 (3)          | 0 ( 0)           | 0 ( 0)            |
| liver       | white zone     | 0 ( 0                                       | ) 0 ( 0)         | 0 ( 0)           | 1 ( 3)            |
|             | red zone       | 0 ( 0                                       | )) 2 (5)         | 0 ( 0)           | 0 ( 0)            |
|             | black zone     | 0 ( 0                                       | )) 1 (3)         | 1 (2)            | 0 ( 0)            |
|             | nadule         | 1 ( 5                                       | 3) 0 ( 0)        | 0 ( 0)           | 1 (3)             |
|             | rough          | 1 ( 3                                       | 3) 0 ( 0)        | 1 (2)            | 1 (3)             |
|             | nodular        | 0 ( 0                                       | )) 0 ( 0)        | 1 (2)            | 1 ( 3)            |
|             | herniation     | 2 ( 5                                       | 5) 1 (3)         | 1 ( 2)           | 2 (5)             |
| kidney      | hydranephrosis | 0 ( (                                       | )) 0 ( 0)        | 0 ( 0)           | 1 ( 3)            |
| urin bladd  | nadule         | 1 ( 3                                       | 3) 0 ( 0)        | 0 ( 0)           | 0 ( 0)            |
| pituitary   | enlarged       | 4 (1)                                       | 1) 4 (11)        | 4 (10)           | 5 (13)            |
|             | red zane       | 7 (18                                       | 3) 3 ( 8)        | 2 (5)            | 2 (5)             |
|             | nadule         | 3 ( 8                                       | 3) 3 ( 8)        | 5 (12)           | 2 (5)             |
|             | cyst           | 0 ( (                                       | )) 1 (3)         | 0 ( 0)           | 0 ( 0)            |

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX

: FEMALE

#### GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (105W)

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#### Group Name Control 200ppm 800ppm 3200ppm 0rgan Findings\_ 42 (%) NO. of Animals 38 (%) 38 (%) 38 (%) thyroid enlarged 1 (3) 2 (5) 0 ( 0) 0 ( 0) nodule 0 ( 0) 0 ( 0) 0 ( 0) 1 (3) enlarged ovary 1 (3) 0 ( 0) 0 ( 0) 0 ( 0) cyst 3 (8) 2 (5) 0 ( 0) 1 (3) uterus nadule 3 (8) 5 (13) 4 (10) 1 (3) cyst 1 (3) 0 ( 0) 0 ( 0) 1 (3) uagina nodule 0 ( 0) 2 (5) 0 ( 0) 0 ( 0) prep/cli gl nodule 0 ( 0) 1 (3) 0 ( 0) 0 ( 0) өуө white 0 ( 0) 0 ( 0) 1 (2) 0 ( 0) Zymbal gl nadule 0 ( 0) 2 (5) 0 ( 0) 1 (3) thoracic ca pleural fluid 1 (3) 0 ( 0) 0 ( 0) 0 ( 0) whole body anemic 1 (3) 1 (3) 2 (5) 0 ( 0)

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BAIS 2

#### PAGE : 5

GROSS FINDINGS : SUMMARY, MOSUE : MALE : DEAD AND MORIBUND ANIMALS

#### GROSS FINDINGS (SUMMARY) DEAD AND MORIBUND ANIMALS (0-105W)

STUDY NO. : 0190 ANIMAL : MOUSE BDF1 REPORT TYPE : A1 SEX : MALE

Group Name 200ppm 800ppm 3200ppm Control 16 (%) 19 (%) Findings\_ NO. of Animals 10 (%) 16 (%) skin/app 0 ( 0) ulcer 0 ( 0) 1 (5) 0 ( 0) erosion 1 (10) 0 ( 0) 0 ( 0) 0 ( 0) scab subcutis edema mass

0rgan\_

lung

Lymph node

salivary gl

small intes

large intes

Liver

spleen

red

white zone

red zone

nodule

enlarged

enlarged

atrophic

white zone

nodule

nodular

enlarged

nodule

nodule

dilated

enlarged

white zone

pale

|        | • •    | • •    |        |
|--------|--------|--------|--------|
| 1 (10) | 0 ( 0) | 0 ( 0) | 0 ( 0) |
| 1 (10) | 1 ( 6) | 0 ( 0) | 0 ( 0) |
| 0 ( 0) | 2 (13) | 0 ( 0) | 0 ( 0) |
| 0 ( 0) | 0 ( 0) | 0 ( 0) | 2 (11) |
| 0 ( 0) | 0 ( 0) | 1 ( 6) | 0 ( 0) |
| 1 (10) | 1 ( 6) | 0 ( 0) | 0 ( 0) |
| 0 ( 0) | 2 (13) | 1 ( 6) | 5 (26) |
| 0 ( 0) | 3 (19) | 6 (38) | 4 (21) |
| 2 (20) | 2 (13) | 4 (25) | 4 (21) |
| 0 ( 0) | 0 ( 0) | 1 ( 6) | 0 ( 0) |
| 0 ( 0) | 0 ( 0) | 0 ( 0) | 1 (5)  |
| 1 (10) | 2 (13) | 2 (13) | 1 (5)  |
| 0 ( 0) | 1 ( 6) | 0 ( 0) | 0 ( 0) |
| 0 ( 0) | 0 ( 0) | 0 ( 0) | 1 (5)  |
| 0 ( 0) | 0 ( 0) | 0 ( 0) | 1 (5)  |
| 0 ( 0) | 0 ( 0) | 0 ( 0) | 1 (5)  |
| 0 ( 0) | 0 ( 0) | 1 ( 6) | 0 ( 0) |
| 1 (10) | 0 ( 0) | 0 ( 0) | 0 ( 0) |
| 0 ( 0) | 1 ( 6) | 0 ( 0) | 0 ( 0) |

1 (10)

2 (13)

1 ( 6)

2 (11)

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PAGE : 1

#### STUDY NO. : 0190 ANIMAL : MOUSE BDF1 REPORT TYPE : A1

#### GROSS FINDINGS (SUMMARY) DEAD AND MORIBUND ANIMALS (0-105W)

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: MALE SEX

| 0rgan       | Findings               | Group Name Control<br>NO. of Animals 10 (%) | 200ppm<br>16 (%) | 800ppm<br>16 (%) | 3200ppm<br>19 (%) |
|-------------|------------------------|---------------------------------------------|------------------|------------------|-------------------|
| liver       | red zone               | 0 ( 0)                                      | 2 (13)           | 1 ( 6)           | 0 ( 0)            |
|             | nodule                 | 4 (40)                                      | 6 (38)           | 13 (81)          | 10 (53)           |
|             | nodular                | 1 (10)                                      | 0 ( 0)           | 0 ( 0)           | 1 (5)             |
| pancreas    | nodule                 | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 1 ( 5)            |
| kidney      | enlarged               | 0 ( 0)                                      | 1 (6)            | 1 (6)            | 0 ( 0)            |
|             | pale                   | 0 ( 0)                                      | 2 (13)           | 0 ( 0)           | 0 ( 0)            |
|             | red zone               | 0 ( 0)                                      | 0 ( 0)           | 1 (6)            | 0 ( 0)            |
|             | nodule                 | 0 ( 0)                                      | 2 (13)           | 1 (6)            | 0 ( 0)            |
|             | cyst                   | 1 (10)                                      | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
|             | rupture                | 0 ( 0)                                      | 1 (6)            | 0 ( 0)           | 0 ( 0)            |
|             | hydronephros i s       | 1 (10)                                      | 3 (19)           | 2 (13)           | 0 ( 0)            |
| urin bladd  | urine:marked retention | 2 (20)                                      | 2 (13)           | 2 (13)           | 2 (11)            |
| epididymis  | enlarged               | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 1 (5)             |
|             | nadule                 | 1 (10)                                      | 0 ( 0)           | 1 (6)            | 0 ( 0)            |
| semin ves   | nadule                 | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 1 ( 5)            |
| prep/cli gl | enlarged               | 0 ( 0)                                      | 1 (6)            | 0 ( 0)           | 0 ( 0)            |
|             | nadule                 | 0 ( 0)                                      | 0 ( 0)           | 1 ( 6)           | 1 (5)             |
|             | cyst                   | 0 ( 0)                                      | 1 (6)            | 0 ( 0)           | 0 ( 0)            |
| brain       | hemorrhage             | 0 ( 0)                                      | 1 ( 6)           | 0 ( 0)           | 0 ( 0)            |
| llarder gl  | enlarged               | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 2 (11)            |
| mediastinum | nadule                 | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 1 ( 5)            |
| retroperit  | mass                   | 0 ( 0)                                      | 0 ( 0)           | 2 (13)           | 0 ( 0)            |

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# GROSS FINDINGS (SUMMARY) DEAD AND MORIBUND ANIMALS (0-105W)

STUDY NO. : 0190 ANIMAL : MOUSE BDF1 REPORT TYPE : A1 SEX ; MALE

| Iorrhage    | 1 (10) | 0 ( 0) | 1 (6)  | 2 (11) |
|-------------|--------|--------|--------|--------|
| pites       | 1 (10) | 3 (19) | 1 ( 6) | 1 (5)  |
| lorrhage    | 0 ( 0) | 0 ( 0) | 0 ( 0) | 1 (5)  |
| eural fluid | 4 (40) | 2 (13) | 1 ( 6) | 3 (16) |
| əmic        | 0 ( 0) | 0 ( 0) | 0 ( 0) | 1 (5)  |
|             |        |        |        |        |

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## PAGE: 3

GROSS FINDINGS : SUMMARY, MOSUE : FEMALE : DEAD AND MORIBUND ANIMALS

#### GROSS FINDINGS (SUMMARY) DEAD AND MORIBUND ANIMALS (0-105W)

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ANIMAL : MOUSE BDF1 REPORT TYPE : A1

SEX : FEMALE

STUDY NO. : 0190

| -gan      | Findings   | Group Name<br>NO. of Animals | Control<br>21 (%) | 200ppm<br>20 (%) | 800ppm<br>21 (%) | 3200ppm<br>20 (%) |
|-----------|------------|------------------------------|-------------------|------------------|------------------|-------------------|
| ubcutis   | edema      |                              | 1 (5)             | 7 (35)           | 4 (19)           | 6 (30)            |
|           | mass       |                              | 0 ( 0)            | 2 (10)           | 0 ( 0)           | 2 (10)            |
| ⊤own fat  | enlarged   |                              | 0 ( 0)            | 0 ( 0)           | 0 ( 0)           | 1 ( 5)            |
| ing       | red        |                              | 1 (5)             | 0 ( 0)           | 2 (10)           | 1 ( 5)            |
|           | red zone   |                              | 0 ( 0)            | 0 ( 0)           | 1 ( 5)           | 1 ( 5)            |
|           | nodule     |                              | 1 (5)             | 2 (10)           | 0 ( 0)           | 1 ( 5)            |
| mph node  | enlarged   |                              | 4 (19)            | 5 (25)           | 5 (24)           | 3 (15)            |
| ymus      | enlarged   |                              | 0 ( 0)            | 0 ( 0)           | 1 ( 5)           | 0 ( 0)            |
| leen      | enlarged   |                              | 7 (33)            | 4 (20)           | 9 (43)           | 5 (25)            |
|           | black zone |                              | 0 ( 0)            | 1 (5)            | 0 ( 0)           | 0 ( 0)            |
|           | nodule     |                              | 1 (5)             | 0 ( 0)           | 1 ( 5)           | 2 (10)            |
|           | nodular    |                              | 0 ( 0)            | 1 (5)            | 0 ( 0)           | 0 ( 0)            |
| livary gl | nodule     |                              | 1 (5)             | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| restomach | nodule     |                              | 0 ( 0)            | 1 (5)            | 0 ( 0)           | 0 ( 0)            |
|           | ulcer      |                              | 0 ( 0)            | 0 ( 0)           | 1 (5)            | 0 ( 0)            |
| all intes | nodule     |                              | 0 ( 0)            | 1 (5)            | 0 ( 0)           | 0 ( 0)            |
| rge intes | nodule     |                              | 0 ( 0)            | 1 (5)            | 0 ( 0)           | 0 ( 0)            |
| ver       | reticular  |                              | 0 ( 0)            | 0 ( 0)           | 0 ( 0)           | 1 (5)             |
|           | enlarged   |                              | 2 (10)            | 3 (15)           | 6 (29)           | 2 (10)            |
|           | white zone |                              | 1 (5)             | 2 (10)           | 3 (14)           | 5 (25)            |
|           | red zone   |                              | 1 (5)             | 1 (5)            | 0 ( 0)           | 0 ( 0)            |
|           | nodule     |                              | 4 (19)            | 6 (30)           | 5 (24)           | 6 (30)            |

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#### STUDY NO. : 0190 ANIMAL : MOUSE BDF1 REPORT TYPE : A1 .....

# GROSS FINDINGS (SUMMARY) DEAD AND MORIBUND ANIMALS (0-105W)

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| SEX :      | FENALE         |                              |                   |                  |                  | PAGE : 5          |
|------------|----------------|------------------------------|-------------------|------------------|------------------|-------------------|
| 0rgan      | Findings       | Group Name<br>NO. of Animals | Control<br>21 (%) | 200ppm<br>20 (%) | 800ppm<br>21 (%) | 3200ppn<br>20 (%) |
| liver      | cyst           |                              | 0 ( 0)            | 0 ( 0)           | 2 (10)           | 1 (5)             |
|            | deformed       |                              | 0 ( 0)            | 1 ( 5)           | 1 (5)            | 0 ( 0)            |
|            | rough          |                              | 0 ( 0)            | 1 (5)            | 2 (10)           | 1 (5)             |
|            | nodular        |                              | 0 ( 0)            | 1 (5)            | 0 ( 0)           | 0 ( 0)            |
| pancreas   | nodule         |                              | 1 (5)             | 0 ( 0)           | 0 ( 0)           | 1 (5)             |
| kidney     | enlarged       |                              | 0 ( 0)            | 0 ( 0)           | 1 (5)            | 1 (5)             |
|            | pale           |                              | 1 (5)             | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
|            | hemorrhage     |                              | 0 ( 0)            | 0 ( 0)           | 1 (5)            | 0 ( 0)            |
|            | elevated       |                              | 1 (5)             | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
|            | nadule         |                              | 0 ( 0)            | 2 (10)           | 0 ( 0)           | 1 (5)             |
|            | hydronephrosis |                              | 1 (5)             | 1 (5)            | 1 (5)            | 0 ( 0)            |
| urin bladd | thick          |                              | 0 ( 0)            | 0 ( 0)           | 1 (5)            | 0 ( 0)            |
| pituitary  | enlarged       |                              | 3 (14)            | 1 (5)            | 2 (10)           | 1 ( 5)            |
|            | nodule         |                              | 1 (5)             | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| ouary      | enlarged       |                              | 2 (10)            | 0 ( 0)           | 4 (19)           | 5 (25)            |
|            | nodule         |                              | 0 ( 0)            | 1 (5)            | 0 ( 0)           | 0 ( 0)            |
|            | cyst           |                              | 3 (14)            | 2 (10)           | 0 ( 0)           | 2 (10)            |
| uterus     | nadule         |                              | 6 (29)            | 8 (40)           | 5 (24)           | 8 (40)            |
|            | nodular        |                              | 0 ( 0)            | 1 (5)            | 0 ( 0)           | 0 ( 0)            |

1 (5)

0 ( 0)

1 (5)

0 ( 0)

0 ( 0)

0 ( 0)

0 ( 0)

1 (5)

0 ( 0)

brain

spinal cord

(IIPT080)

red zone

hemorrhage

nodule

0 ( 0)

0 ( 0)

0 ( 0)

STUDY NO. : 0190 ANIMAL : MOUSE BDF1 REPORT TYPE : A1 SEX : FEMALE

#### GROSS FINDINGS (SUMMARY) DEAD AND MORIBUND ANIMALS (0-105W)

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| SEX :       | FEMALE           |                                             |                  |                  | PAGE : 6          |
|-------------|------------------|---------------------------------------------|------------------|------------------|-------------------|
| 0rgan       | Findings         | Group Name Control<br>NO. of Animals 21 (%) | 200ppm<br>20 (%) | 800ppm<br>21 (%) | 3200ppm<br>20 (%) |
| muscle      | nodule           | 0 ( 0)                                      | 1 (5)            | 0 ( 0)           | 0 ( 0)            |
| bane        | nodule           | 0 ( 0)                                      | 0 ( 0)           | 1 (5)            | 0 ( 0)            |
| mediastinum | nodule           | 1 ( 5)                                      | 0 ( 0)           | 0 ( 0)           | 1 (5)             |
|             | mass             | 1 ( 5)                                      | 1 ( 5)           | 0 ( 0)           | 2 (10)            |
| peritoneum  | nadule           | 0 ( 0)                                      | 1 ( 5)           | 0 ( 0)           | 0 ( 0)            |
|             | mass             | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 1 (5)             |
| retroperit  | mass             | 1 ( 5)                                      | 1 ( 5)           | 1 (5)            | 0 ( 0)            |
| abdominal c | hemorrhage       | 0 ( 0)                                      | 1 (5)            | 4 (19)           | 2 (10)            |
|             | mass             | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 1 (5)             |
|             | ascites          | 6 (29)                                      | 10 ( 50)         | 4 (19)           | 9 (45)            |
| mesenterium | nodule           | 0 ( 0)                                      | 0 ( 0)           | 1 ( 5)           | 1 (5)             |
| thoracic ca | hemorrhage       | 1 ( 5)                                      | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
|             | mass             | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 1 (5)             |
|             | pleural fluid    | 8 (38)                                      | 10 ( 50)         | 5 (24)           | 6 (30)            |
| other       | nodule           | 0 ( 0)                                      | 0 ( 0)           | 1 (5)            | 0 ( 0)            |
|             | lower jaw:nocule | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 1 (5)             |
| whale bady  | anomic           | 0 ( 0)                                      | 1 (5)            | 0 ( 0)           | 0 ( 0)            |
|             |                  |                                             |                  |                  |                   |

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GROSS FINDINGS : SUMMARY, MOSUE : MALE : SACRIFICED ANIMALS

# STUDY NO.: 0190GROSS FINDINGS (SUMMARY)ANIMAL: MOUSE BDF1SACRIFICED ANIMALS (105W)REPORT TYPE : A1SEX: MALE

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| 0rgan       | Findings         | Group Name Control<br>NO. of Animals 40 (%) | 200ppm<br>34 (%) | 800ppm<br>34 (%) | 3200ppm<br>31 (%) |
|-------------|------------------|---------------------------------------------|------------------|------------------|-------------------|
| skin/app    | nadule           | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 1 (3)             |
|             | erosion          | 0 ( 0)                                      | 1 ( 3)           | 1 ( 3)           | 0 ( 0)            |
| subcutis    | mass             | 3 ( 8)                                      | 1 (3)            | 0 ( 0)           | 2 ( 6)            |
| lung        | red zone         | 1 ( 3)                                      | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
|             | nadule           | 8 (20)                                      | 13 (38)          | 8 (24)           | 7 (23)            |
| lymph nade  | enlarged         | 2 ( 5)                                      | 2 (6)            | 7 (21)           | 2 (6)             |
| thymus      | nodule           | 1 ( 3)                                      | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| spleen      | enlarged         | 2 (5)                                       | 2 (6)            | 2 (6)            | 4 (13)            |
|             | black zone       | 2 ( 5)                                      | 1 (3)            | 1 ( 3)           | 1 ( 3)            |
|             | nodule           | 0 ( 0)                                      | 2 ( 6)           | 0 ( 0)           | 1 ( 3)            |
|             | deformed         | 1 ( 3)                                      | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| salivary gl | nadule           | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 1 ( 3)            |
| small intes | nodule           | 2 ( 5)                                      | 0 ( 0)           | 1 (3)            | 0 ( 0)            |
| liver       | white zone       | 1 ( 3)                                      | 1 (3)            | 1 ( 3)           | 0 ( 0)            |
|             | red zone         | 1 ( 3)                                      | 6 (18)           | 6 (18)           | 4 (13)            |
|             | nodule           | 24 (60)                                     | 19 ( 56)         | 13 (38)          | 20 (65)           |
|             | cyst             | 0 ( 0)                                      | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |
| pancreas    | nodule           | 1 ( 3)                                      | 0 ( 0)           | 1 ( 3)           | 0 ( 0)            |
| kidney      | enlarged         | 0 ( 0)                                      | 1 ( 3)           | 0 ( 0)           | 1 (3)             |
|             | nadule           | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 1 ( 3)            |
|             | hydronephros i s | 2 (5)                                       | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| urin bladd  | nadule           | 1 (3)                                       | 0 ( 0)           | 1 ( 3)           | 1 ( 3)            |

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STUDY NO. : 0190 ANIMAL. : MOUSE BDF1 REPORT TYPE : A1 SEX : MALE

# GROSS FINDINGS (SUMMARY)

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## SACRIFICED ANIMALS (105W)

| •                     |                        |                              |                   |                  |                  | INCE ·            |  |
|-----------------------|------------------------|------------------------------|-------------------|------------------|------------------|-------------------|--|
| rgan                  | Findings               | Group Name<br>NO. of Animals | Control<br>40 (%) | 200ppm<br>34 (%) | 800ppm<br>34 (%) | 3200ppm<br>31 (%) |  |
| rin bladd             | urine:marked retention |                              | 0 ( 0)            | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |  |
| pituitary             | enlarged               |                              | 0 ( 0)            | 0 ( 0)           | 1 (3)            | 0 ( 0)            |  |
|                       | cyst                   |                              | 1 (3)             | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |  |
| nyroid                | enlarged               |                              | 1 ( 3)            | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |  |
| oididymis             | nodule                 |                              | 1 ( 3)            | 1 (3)            | 0 ( 0)           | 0 ( 0)            |  |
| emin ves              | cyst                   |                              | 0 ( 0)            | 0 ( 0)           | 1 ( 3)           | 0 ( 0)            |  |
|                       | adhesion               |                              | 1 ( 3)            | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |  |
| ep/cligl              | nodule                 |                              | 0 ( 0)            | 0 ( 0)           | 0 ( 0)           | 1 ( 3)            |  |
| ain                   | deformed               |                              | 1 (3)             | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |  |
| <b>/</b> <del>0</del> | turbid                 |                              | 0 ( 0)            | 0 ( 0)           | 1 ( 3)           | 0 ( 0)            |  |
| arder gl              | nodule                 |                              | 0 ( 0)            | 0 ( 0)           | 0 ( 0)           | 2 ( 6)            |  |
| enc                   | red zone               |                              | 1 ( 3)            | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |  |
| əritoneum             | nodule                 |                              | 0 ( 0)            | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |  |
|                       | mass                   |                              | 1 ( 3)            | 1 (3)            | 0 ( 0)           | 0 ( 0)            |  |
| etroperit             | mass                   |                              | 0 ( 0)            | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |  |
| abdominal c           | hemorrhage             |                              | 0 ( 0)            | 0 ( 0)           | 0 ( 0)           | 1 ( 3)            |  |
|                       | mass                   |                              | 0 ( 0)            | 0 ( 0)           | 1 ( 3)           | 0 ( 0)            |  |
|                       | ascites                |                              | 1 ( 3)            | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |  |
| noracic ca            | pleural fluid          |                              | 2 (5)             | 0 ( 0)           | 1 ( 3)           | 1 ( 3)            |  |
| ther                  | tail:nodule            |                              | 1 (3)             | 0 ( 0)           | 0 ( 0)           | 1 (3)             |  |

PAGE: 2

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(IIPT080)

GROSS FINDINGS : SUMMARY, MOSUE : FEMALE : SACRIFICED ANIMALS (TOW-YERA STUDY)

## STUDY NO. : 0190 ANIMAL : MOUSE BDF1 REPORT TYPE : A1

# GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (105W)

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SEX : FEMALE

| rgan       | Findings       |     | ontrol<br>(%) | 200ppm<br>28 (%) | 800ppm<br>29 (%) | 3200ppm<br>29 (%) |
|------------|----------------|-----|---------------|------------------|------------------|-------------------|
| ubcutis    | mass           | 1   | (3)           | 2 (7)            | 1 (3)            | 2 (7)             |
| rown fat   | nadule         | 0   | ( 0)          | 0 ( 0)           | 0 ( 0)           | 1 (3)             |
| ung        | nodule         | 1   | (3)           | 1 ( 4)           | 2 (7)            | 4 (14)            |
| ymph nade  | enlarged       | 5   | (17)          | 5 (18)           | 3 (10)           | 7 (24)            |
| spleen     | enlarged       | 5   | (17)          | 4 (14)           | 2 (7)            | 5 (17)            |
|            | nodule         | 2   | (7)           | 2 (7)            | 1 ( 3)           | 0 ( 0)            |
| alivary gl | nadule         | 1   | (3)           | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| orestomach | nadule         | 0   | ( 0)          | 1 ( 4)           | 0 ( 0)           | 1 ( 3)            |
| mall intes | nodule         | 0   | (0)           | 1 (4)            | 0 ( 0)           | 0 ( 0)            |
| ecum       | nadule         | 0   | ( 0)          | 1 ( 4)           | 0 ( 0)           | 0 ( 0)            |
| liver      | enlarged       | 1   | ( 3)          | 2 (7)            | 0 ( 0)           | 0 ( 0)            |
|            | white zone     | . 0 | ( 0)          | 2 (7)            | 0 ( 0)           | 0 ( 0)            |
|            | red zone       | 4   | (14)          | 3 (11)           | 9 (31)           | 9 (31)            |
|            | nodule         | 5   | (17)          | 10 (36)          | 10 ( 34)         | 20 (69)           |
|            | cyst           | 1   | (3)           | 0 ( 0)           | 0 ( 0)           | 1 (3)             |
| Dancreas   | nodule         | 2   | (7)           | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
|            | cyst           | 0   | ( 0)          | 0 ( 0)           | 0 ( 0)           | 1 ( 3)            |
| cidney     | enlarged       | 1   | (3)           | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
|            | white zone     | 0   | ( 0)          | 0 ( 0)           | 0 ( 0)           | 1 ( 3             |
|            | nadule         | 0   | ( 0)          | 0 ( 0)           | 0 ( 0)           | 1 ( 3)            |
|            | hydronephrosis | 2   | (7)           | 0 ( 0)           | 0 ( 0)           | 1 ( 3)            |
| ituitary   | enlarged       | 1   | (3)           | 1 ( 4)           | 4 (14)           | 1 ( 3)            |

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STUDY NO. : 0190 ANIMAL : MOUSE BDF1

# GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (105W)

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# REPORT TYPE : A1 SEX : FEMA

: FEMALE

| an       | Findings      | Group Name<br>NO. of Animals | Control<br>29 (%) | 200ppm<br>28 (%) | 800ppm<br>29 (%) | 3200ppm<br>29 (%) |
|----------|---------------|------------------------------|-------------------|------------------|------------------|-------------------|
| uitary   | red           |                              | 0 ( 0)            | 0 ( 0)           | 1 (3)            | 0 ( 0)            |
|          | red zone      |                              | 0 ( 0)            | 1 ( 4)           | 3 (10)           | 0 ( 0)            |
|          | nadule        |                              | 2 (7)             | 2 (7)            | 2 (7)            | 1 (3)             |
| гy       | enlarged      |                              | 1 (3)             | 1 ( 4)           | 1 (3)            | 2 (7)             |
|          | cyst          |                              | 11 (38)           | 9 (32)           | 7 (24)           | 5 (17)            |
| ามร      | nodule        |                              | 7 (24)            | 6 (21)           | 2 (7)            | 5 (17)            |
|          | dilated lumen |                              | 1 (3)             | 0 ( 0)           | 0 ( 0)           | 1 (3)             |
| n        | nadule        |                              | 0 ( 0)            | 0 ( 0)           | 1 (3)            | 0 ( 0)            |
| ph nerv  | swollen       |                              | 0 ( 0)            | 0 ( 0)           | 1 (3)            | 0 ( 0)            |
|          | white         |                              | 0 ( 0)            | 1 (4)            | 0 ( 0)           | 0 ( 0)            |
| der gl   | nodule        |                              | 1 ( 3)            | 1 ( 4)           | 0 ( 0)           | 2 (7)             |
| iastinum | mass          |                              | 0 ( 0)            | 0 ( 0)           | 1 ( 3)           | 0 ( 0)            |
| itoneum  | nodule        |                              | 1 ( 3)            | 1 ( 4)           | 0 ( 0)           | 0 ( 0)            |
| ominal c | ascites       |                              | 2 (7)             | 4 (14)           | 2 (7)            | 2 (7)             |
| enterium | nodule        |                              | 0 ( 0)            | 0 ( 0)           | 1 ( 3)           | 0 ( 0)            |
| ⊓acic ca | pleural fluid |                              | 0 ( 0)            | 4 (14)           | 1 (3)            | 1 (3)             |

BAIS 2

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APPENDIX H 1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : MALE

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : MALE UNIT: g

### ORGAN WEIGHT: ABSOLUTE (SUMMARY) SURVIVAL ANIMALS (105)

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| roup Name | NO. of<br>Animals | Body Weight | ADRENALS     | TESTES            | HEART        | LUNGS        | KIDNEYS      |  |
|-----------|-------------------|-------------|--------------|-------------------|--------------|--------------|--------------|--|
| Control   | 34                | 399± 48     | 0.098± 0.047 | 5.489± 2.085      | 1.328± 0.179 | 1.543± 0.222 | 3.165± 0.339 |  |
| 200ppm    | 36                | 406土 23     | 0.169± 0.423 | 6.393± 4.376      | 1.317± 0.096 | 1.524± 0.105 | 3.180± 0.392 |  |
| mqq008    | 36                | 412土 39     | 0.081± 0.013 | 5.786± 2.084      | 1.297± 0.088 | 1.525± 0.173 | 3.190± 0.421 |  |
| 3200ppm   | 28                | 380± 34*    | 0.134± 0.200 | $6.556 \pm 2.233$ | 1.367± 0.291 | 1.638± 0.561 | 3.176± 0.419 |  |

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BAIS 2

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STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : MALE UNIT: g

# ORGAN WEIGHT:ABSOLUTE (SUMMARY) SURVIVAL ANIMALS (105)

PAGE : 2

| Group Name | NO. of<br>Animals | SPLEEN       | LIVER              | BRAIN             |      |
|------------|-------------------|--------------|--------------------|-------------------|------|
| Control    | 34                | 1.500± 1.101 | 13.373± 1.664      | 2.027± 0.055      |      |
| 200ppm     | 36                | 1.560± 1.080 | 13.558± 1.900      | 2.040± 0.057      |      |
| mqq008     | 36                | 1.423± 0.638 | 13.243± 1.796      | $2.030 \pm 0.049$ |      |
| 3200ppm    | 28                | 1.473± 0.750 | $14.330 \pm 3.315$ | 2.028± 0.047      |      |
| Significar | nt difference ;   | *:P≦ 0.05    | ** : P ≦ 0.01      | Test of Dunnett   |      |
| (IICL040)  |                   |              |                    |                   | BAIS |

APPENDIX H 2

## ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : FEMALE

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : FEMALE UNIT: g

# ORGAN WEIGHT:ABSOLUTE (SUMMARY) SURVIVAL ANIMALS (105)

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PAGE: 3

| roup Name  | NO. of<br>Animals | Bady   | Weight | ADRE       | NALS  | OVAR   | IES   | HEAR         | r     | LUNG        | 5     | KIDN       | EYS   |  |
|------------|-------------------|--------|--------|------------|-------|--------|-------|--------------|-------|-------------|-------|------------|-------|--|
| Control    | 38                | 307±   | 30     | 0.081±     | 0.016 | 0.506± | 2.543 | 1.022±       | 0.138 | 1.121±      | 0.220 | 2.076±     | 0.165 |  |
| 200ppm     | 38                | 302±   | 37     | 0.081±     | 0.011 | 0.091± | 0.017 | 0.994±       | 0.091 | 1.093±      | 0.124 | 2.106±     | 0.214 |  |
| 800pm      | 42                | 304±   | 31     | 0,079±     | 0.010 | 0.087± | 0.021 | 0.995±       | 0.100 | $1.125 \pm$ | 0.226 | $2.151\pm$ | 0.191 |  |
| 3200ppm    | 38                | 285±   | 54**   | 0.077±     | 0.012 | 0.091± | 0.034 | 0.984±       | 0.077 | 1.076±      | 0.127 | $2.131\pm$ | 0.204 |  |
| Significar | nt difference ;   | *:P≦0. | 05 **  | : P ≦ 0.01 |       |        | Test  | t of Dunnett |       |             |       |            |       |  |
| IICL040)   |                   |        |        |            |       |        |       |              |       |             |       |            |       |  |

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STUDY NO. : 0189 ORGAN WEIGHT: ABSOLUTE (SUMMARY) ANIMAL : RAT F344 SURVIVAL ANIMALS (105) REPORT TYPE : A1 SEX : FEMALE UNIT: g PAGE: 4 Group Name SPLEEN NO, of LIVER BRAIN Animals Control 38 0.849± 0.933 7.890± 1.181 1.858± 0.047 0.662± 0.337 200ppm 38 8.026± 1.439 1.839± 0.047 800ppm 42  $1.529 \pm 3.257$ 8.303± 1.405 1.854± 0.050 3200ppm 38 0.824± 1.343 7.912± 1.730 1.829± 0.048\* Significant difference ;  $*: P \leq 0.05$ \*\* : P ≦ 0.01 Test of Dunnett (IICL040) BAIS 2

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APPENDIX H 3

## ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : MALE

STUDY NO. : 0190 ANIMAL : MOUSE BDF1 REPORT TYPE : A1 SEX : MALE UNIT: #

### ORGAN WEIGHT:ABSOLUTE (SUMMARY) SURVIVAL ANIMALS (105)

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| oup Name | NO. of<br>Animals | Bady Weight | ADRENALS     | TESTES       | HEART        | LUNGS        | KIDNEYS      |  |
|----------|-------------------|-------------|--------------|--------------|--------------|--------------|--------------|--|
| Control  | 40                | 41.5± 6.6   | 0.013± 0.005 | 0.200± 0.036 | 0.218± 0.022 | 0.224± 0.055 | 0.642± 0.059 |  |
| 200ppm   | 34                | 41.1± 7.7   | 0.014± 0.005 | 0.210± 0.032 | 0.226± 0.056 | 0.230± 0.057 | 0.685± 0.233 |  |
| 800pm    | 34                | 40.4± 6.8   | 0.015± 0.006 | 0.205± 0.033 | 0.219± 0.025 | 0.259± 0.154 | 0.662± 0.059 |  |
| 3200ppm  | 31                | 38.9± 6.1   | 0.014± 0.005 | 0.215± 0.046 | 0.224± 0.051 | 0.257± 0.154 | 0.702± 0.196 |  |

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BAIS 2

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STUDY NO. : 0190 ANIMAL : MOUSE BDF1 REPORT TYPE : A1 SEX : MALE UNIT: g

#### ORGAN WEIGHT:ABSOLUTE (SUMMARY) SURVIVAL ANIMALS (105)

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| roup Name | NO. of<br>Animals | SPLEEN       | LIVER        | BRAIN             |                                       |
|-----------|-------------------|--------------|--------------|-------------------|---------------------------------------|
| Control   | 40                | 0.177± 0.418 | 1.815± 0.683 | 0.464± 0.018      |                                       |
| 200ppm    | 34                | 0.202± 0.436 | 1.891± 0.881 | 0.473± 0.015      | · · · · · · · · · · · · · · · · · · · |
| 800ppm    | 34                | 0.131± 0.115 | 1.871± 1.239 | $0.464 \pm 0.014$ |                                       |
| 3200ppm   | 31                | 0.196± 0.331 | 2.124± 1.016 | 0.463± 0.016      |                                       |

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BAIS 2

APPENDIX H 4

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOSUE : FEMALE

STUDY NO. : 0190 ANIMAL : MOUSE BDF1 REPORT TYPE : A1 SEX : FEMALE UNIT: g

#### ORGAN WEIGHT: ABSOLUTE (SUMMARY) SURVIVAL ANIMALS (105)

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| Group Name | NO. of<br>Animals | Body Weight | ADRENALS     | OVARIES      | HEART        | LUNGS        | KIDNEYS           |  |
|------------|-------------------|-------------|--------------|--------------|--------------|--------------|-------------------|--|
| Control    | 29                | 29.2± 4.2   | 0.015± 0.003 | 0.165± 0.583 | 0.180± 0.020 | 0.214± 0.038 | 0.541± 0.344      |  |
| 200ppm     | 28                | 30.8± 3.5   | 0.015± 0.003 | 0.124± 0.295 | 0.181± 0.031 | 0.233± 0.067 | 0.488± 0.092      |  |
| 800ppm     | 29                | 28.7± 4.1   | 0.014± 0.004 | 0.029± 0.028 | 0.177± 0.024 | 0.210± 0.027 | 0.451± 0.053      |  |
| 3200ppm    | 29                | 28.3± 2.8   | 0.015± 0.003 | 0.062± 0.116 | 0.190± 0.029 | 0.233± 0.053 | $0.546 \pm 0.255$ |  |

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BAIS 2

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STUDY NO. : 0190 ANIMAL : MOUSE BDF1 REPORT TYPE : A1 SEX : FEMALE UNIT: g

#### ORGAN WEIGHT: ABSOLUTE (SUMMARY) SURVIVAL ANIMALS (105)

PAGE: 4 Group Name SPLEEN NO, of LIVER BRAIN Animals Control 29  $0.277 \pm 0.366$ 1.590± 0.556 0.487± 0.012 200ppm 28 0.229± 0.213  $2.020 \pm 1.690$ 0.487± 0.020 800ppm 29 0.169± 0.172 1.384± 0.327 0.502± 0.063 3200ppm 29 0.372± 0.771 1,675± 0,772 0.482± 0.014 Significant difference ;  $*: P \leq 0.05$ \*\* : P ≦ 0.01 Test of Dunnett

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(HCL040)

BAIS 2

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APPENDIX I 1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : MALE UNIT: %

### ORGAN WEIGHT:RELATIVE (SUMMARY) SURVIVAL ANIMALS (105)

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PAGE: 1

| ioup Name | NO. of<br>Animals | Bady We<br>( | aight<br>g) | ADRENALS          | TESTES            | HEART        | LUNGS        | KIDNEYS           |  |
|-----------|-------------------|--------------|-------------|-------------------|-------------------|--------------|--------------|-------------------|--|
| Control   | 34                | $399\pm$     | 48          | 0.025± 0.014      | 1.386± 0.506      | 0.341± 0.095 | 0.395± 0.095 | 0.806± 0.143      |  |
| 200ppm    | 36                | 406±         | 23          | 0.042± 0.107      | $1.586 \pm 1.091$ | 0.325± 0.033 | 0.376± 0.032 | 0.785± 0.112      |  |
| 800ppm    | 36                | 412±         | 39          | 0.020± 0.004      | $1.426 \pm 0.550$ | 0.317± 0.034 | 0.373± 0.052 | 0.784± 0.142      |  |
| 3200ppm   | 28                | 380±         | 34*         | $0.035 \pm 0.046$ | 1.749± 0.648      | 0.364± 0.098 | 0.437± 0.177 | $0.843 \pm 0.149$ |  |

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STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : MALE UNIT: %

### ORGAN WEIGHT: RELATIVE (SUMMARY)

SURVIVAL ANIMALS (105)

Group Name NO. of SPLEEN LIVER BRAIN Animals Control 34  $0.385 \pm 0.320$  $3.371 \pm 0.404$  $0.515 \pm 0.065$ 200ppm 36  $0.385 \pm 0.273$  $3.340 \pm 0.463$  $0.503 \pm 0.029$ 800ppm 36  $0.348 \pm 0.157$  $3.241 \pm 0.519$  $0.497 \pm 0.046$ 3200ppm 28  $0.537 \pm 0.051$  $0.386 \pm 0.192$  $3.817 \pm 1.081$ Significant difference ; \*: P ≦ 0.05 \*\* : P ≦ 0.01 Test of Dunnett

(IICL042)

BAIS 2

PAGE: 2

APPENDIX I 2

## ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : FEMALE

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : FEMALE UNIT: %

#### ORGAN WEIGHT:RELATIVE (SUMMARY) SURVIVAL ANIMALS (105)

Group Name NO. of Body Weight ADRENALS OVARIES HEART LUNGS KIDNEYS (g) Animals Control 38 307± 30  $0.027 \pm 0.005$  $0.161 \pm 0.805$  $0.335 \pm 0.054$  $0.372 \pm 0.113$  $0.681 \pm 0.074$ 200ppm 38 302± 37  $0.027 \pm 0.005$  $0.030 \pm 0.006$  $0.333 \pm 0.045$  $0.367 \pm 0.057$ 0.708± 0.117 800ppm 42 304± 31  $0.026 \pm 0.005$  $0.029 \pm 0.007$  $0.331 \pm 0.057$  $0.373 \pm 0.080$  $0.714 \pm 0.091$ 3200ppm 38 285± 54\*\*  $0.028 \pm 0.004$  $0.033 \pm 0.013$  $0.352 \pm 0.050$ 0.385± 0.067\*\* 0.762± 0.101\*\*

Significant difference ;  $*: P \leq 0.05$   $**: P \leq 0.01$ 

Test of Dunnett

(HCL042)

BAIS 2

PAGE: 3

STUDY NO. : 0189 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : FEMALE UNIT: %

#### ORGAN WEIGHT:RELATIVE (SUMMARY) SURVIVAL ANIMALS (105)

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Group Name NO. of LIVER SPLEEN BRAIN Animals Control 38  $0.295 \pm 0.386$  $2.601 \pm 0.540$ 0.611± 0.069 200ppm 38  $0.225 \pm 0.132$  $2.676 \pm 0.454$  $0.618 \pm 0.079$ 800ppm 42 0.511± 1.083\*  $2.749 \pm 0.495$  $0.616 \pm 0.065$ 38 3200ppm  $0.306 \pm 0.611$  $2.790 \pm 0.384$ 0.658± 0.093\* Significant difference ;  $*: P \leq 0.05$ \*\* : P ≦ 0.01 Test of Dunnett

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(IICL042)

BAIS 2

PAGE: 4

APPENDIX I 3

## ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : MALE

STUDY NO. : 0190 ANIMAL : MOUSE BDF1 REPORT TYPE : A1 SEX : MALE UNIT: %

#### ORGAN WEIGHT: RELATIVE (SUMMARY) SURVIVAL ANIMALS (105)

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PAGE: 1

| iroup Name | NO. of<br>Animals | Bady Weight<br>(g) | ADRENALS     | TESTES            | HEART             | LUNGS        | KIDNEYS      |  |
|------------|-------------------|--------------------|--------------|-------------------|-------------------|--------------|--------------|--|
| Control    | 40                | 41.5± 6.6          | 0.031± 0.012 | 0.491± 0.098      | 0.539± 0.099      | 0.560± 0.195 | 1.585± 0.287 |  |
| 200ppm     | 34                | 41.1± 7.7          | 0.036± 0.013 | $0.520 \pm 0.094$ | 0.575± 0.225      | 0.584± 0.212 | 1.735± 0.784 |  |
| 800pm      | 34                | 40.4± 6.8          | 0.036± 0.014 | 0.522± 0.127      | 0.555± 0.099      | 0.671± 0.464 | 1.673± 0.266 |  |
| 3200ppm    | 31                | 38.9± 6.1          | 0.037± 0.014 | 0.558± 0.116      | $0.591 \pm 0.181$ | 0.693± 0.528 | 1.872± 0.812 |  |
| Significan | t difference ;    | *: P ≤ 0.05 **     | : P ≦ 0.01   | Tes               | t of Dunnett      |              |              |  |
| IICL042)   |                   |                    |              |                   |                   |              |              |  |

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| TUDY NO. : 0<br>NIMAL : MC<br>EPORT TYPE :<br>EX : NALE<br>NIT: % | DUSE BDF1         |                   |                   | WEIGHT:RELATIVE (SUMMARY)<br>AL ANIMALS (105) | PAGE : 2 |
|-------------------------------------------------------------------|-------------------|-------------------|-------------------|-----------------------------------------------|----------|
| roup Name                                                         | NO. of<br>Animals | SPLEEN            | LIVER             | BRAIN                                         | <br>     |
| Control                                                           | 40                | 0.430± 0.901      | 4.539± 2.096      | 1.150± 0.204                                  |          |
| 200ppm                                                            | 34                | $0.592 \pm 1.465$ | 4.860± 3.052      | 1.193± 0.235                                  |          |
| 800ppm                                                            | 34                | 0.335± 0.315      | 4.735± 3.236      | 1.181± 0.210                                  |          |
| 3200ppm                                                           | 31                | 0.549± 0.984      | $5.690 \pm 3.279$ | $1.221 \pm 0.201$                             |          |

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APPENDIX I 4

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : FEMALE

STUDY NO. : 0190 ANIMAL : MOUSE BDF1 REPORT TYPE : A1 SEX : FEMALE UNIT: %

#### ORGAN WEIGHT:RELATIVE (SUMMARY) SURVIVAL ANIMALS (105)

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PAGE: 3

| roup Name  | NO, of<br>Animals | Body Weight<br>(g) | ADRENALS     | OVARIES      | HEART         | LUNGS             | KIDNEYS                               |  |
|------------|-------------------|--------------------|--------------|--------------|---------------|-------------------|---------------------------------------|--|
| Control    | 29                | 29.2± 4.2          | 0.051± 0.012 | 0.505± 1.718 | 0.626± 0.092  | 0.757± 0.258      | 1.848± 1.110                          |  |
| 200ppm     | 28                | 30.8± 3.5          | 0.049± 0.011 | 0.392± 0.925 | 0.593± 0.107  | 0.752± 0.157      | 1,588± 0.249                          |  |
| 800pm      | 29                | 28.7± 4.1          | 0.050± 0.014 | 0.105± 0.109 | 0.625± 0.100  | 0.746± 0.138      | 1.591± 0.206                          |  |
| 3200ppm    | 29                | 28.3± 2.8          | 0.052± 0.013 | 0.214± 0.388 | 0.677± 0.117  | $0.831 \pm 0.208$ | 1.959± 1.012                          |  |
| Significar | nt difference ;   | *:P≦0.05 **        | : P ≤ 0.01   | Tes          | st of Dunnett |                   |                                       |  |
| IICL042)   |                   |                    |              |              |               |                   | · · · · · · · · · · · · · · · · · · · |  |

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STUDY NO. : 0190 ANIMAL : MOUSE BDF1 REPORT TYPE : A1 SEX : FEMALE UNIT: %

### ORGAN WEIGHT:RELATIVE (SUMMARY) SURVIVAL ANIMALS (105)

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PAGE: 4

| roup Name  | NO. of<br>Animals | SPLEEN       | LIVER        | BRAIN           | <br>         |
|------------|-------------------|--------------|--------------|-----------------|--------------|
| Control    | 29                | 0.922± 1.102 | 5.385± 1.343 | 1.700± 0.255    |              |
| 200ppm     | 28                | 0.744± 0.702 | 6.280± 4.084 | 1.597± 0.164    |              |
| mqq008     | 29                | 0.579± 0.571 | 4.815± 0.853 | 1.790± 0.388    |              |
| 3200ppm    | 29                | 1.314± 2.601 | 5.873± 2.417 | 1.717± 0.179    |              |
| Significan | t difference ;    | *:P≦0.05 **: | P ≤ 0.01     | Test of Dunnett | <br><u> </u> |
| liclo42)   |                   |              |              | ······          | <br>BAIS 2   |