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
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- 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 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 7 GROSS FINDINGS (TWO-YEAR STUDY:SUMMARY) MOUSE:MALE:SACRIFICED ANIMALS
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## APPENDIXES (CONTINUED)

- APPENDIX H 1 ORGAN WEIGHT (TWO-YEAR STUDY:SUMMARY),ABSOLUTE RAT:MALE
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- APPENDIX H 3 ORGAN WEIGHT (TWO-YEAR STUDY:SUMMARY),ABSOLUTE MOUSE: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 <sup>6</sup> /µl	HEMOGLOBIN g∕dl	HEMATOCRIT %	MCV f l	MCH Pg	MCHC g∕dl	PLATELET 1 0 <sup>3</sup> /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	$7.39 \pm 1.98$	$12.3\pm$ 3.8	37.4± 9.8	50.8± 3.6	16.5± 1.5	32.5± 2.3	993± 274

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(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)

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oup Name	NO. of Animals	RED BLOOD CELL 1 O <sup>6</sup> /µl	HEMOGLOBIN g∕d£	HEMATOCRIT %	MCV f l	MCII РЕ	MCHC g / dl	PLATELET 1 0 <sup>3</sup> /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	$15.0\pm 2.0$	43.3± 4.8	53.7± 8.1**	18.5± 1.7	34,6± 1,6	$660 \pm 147$

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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						<del>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</del>	
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 0<sup>3</sup>/μl рg Control 39 $9.45 \pm 1.51$ 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

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(IICL070)

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

### PAGE: 1 WBC Group Name NO. of Differential WBC (%) 1 0<sup>3</sup>/με Animals N-BAND N-SEG EOSINO BASO MONO LYMPHO OTHERS Control 39 $2.45 \pm 1.42$ $1\pm$ 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 <sup>6</sup> /µl	HEMOGLOBIN g∕d¢	HEMATOCRIT %	MCV f l	MCH Pg	MCIIC g∕dl	PLATELET 1 0 <sup>3</sup> /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 ;  $*: P \leq 0.05$ 

BAIS 2

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  $1.2\pm 0.2$ 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  $0.30 \pm 0.05$  $142\pm$ 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 $7.0 \pm 1.3$ . \*\* : 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. : 0) ANIMAL : R/ SAMPLING DATE SEX : FEMALE	NT F344 : 104-5	ТУРЕ : А1	URINALYSIS		PAGE : 4
Group Name	NO. of Animals	Occult blaad — ± + 2+ 3+ CNI	Urabilinagen ± + 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		
mqq008	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	pli			Protein				Glucose			Ketane bady (		0cci	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	DUSE BDF1 : 104-4	URIN	NALYSIS	PAGE: 4
Group Name	NO. of Animals	Urobilinogen 土 + 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	nadule		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 nade	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)

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### 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)

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PAGE : 2

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

## GROSS FINDINGS (SUMMARY)

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DEAD AND MORIBUND ANIMALS (0-105W)

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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

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

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

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

SEX : FEMALE

0rgan\_

subcutis lung

lymph nade spleen

heart

forestomach

Findings	Group Name Control NO. of Animals 12 (%)	200ppm 12 (%)	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)
adhes i on	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)
nodule	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)
noclule	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)

1 (8)

2 (17)

1 (8)

1 (8)

2 (17)

1 (8)

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)

erosion thick

gl stomach ulcer

duadenum nadule liver yellaw white zone

red zone

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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						PAGE : 5
Organ	Findings		Control 2 (%)	200pm 12 (%)	800ppm 8 (%)	3200ppm 12 (%)
liver	nodule	(	) ( 0)	0 ( 0)	0 ( 0)	2 (17)
	roush	(	) ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
	nodular	(	) ( 0)	0 ( 0)	1 (13)	0 ( 0)
	herniation	2	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)	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)	1 ( 8)	0 ( 0)	0 ( 0)
	urine:marked retention	:	L ( 8)	1 ( 8)	0 ( 0)	1 ( 8)
	urine:red	(	) ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
pituitary	enlarged	;	3 (25)	4 (33)	1 (13)	3 (25)
	red zone	(	) ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
	nodule	:	L ( 8)	0 ( 0)	1 (13)	2 (17)
adrenal	enlarged	(	) ( 0)	1 ( 8)	0 ( 0)	0 ( 0)
uterus	nodule	1	L ( 8)	3 (25)	2 (25)	3 (25)
	dilated lumen	. (	) ( 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)

PAGE: 5

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 SEX : FEMALE

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

SEX :	FENALE					PAGE : 6
0rgan	Findings	Group Name NO. of Animals	Control 12 (%)	200ppm 12 (%)	مرم(800 (%) 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	nadule		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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(IIPT080)

BAIS 2

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

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

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

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| Organ       | Findings   | Group Name<br>NO. of Animals | Control<br>34 (%) | 200ppm<br>36 (%) | 800ppm<br>36 (%) | 3200ppm<br>28 (%) |
|-------------|------------|------------------------------|-------------------|------------------|------------------|-------------------|
| pituitary   | red zone   |                              | 0 ( 0)            | 0 ( 0)           | 1 ( 3)           | 0 ( 0)            |
|             | nadule     |                              | 4 (12)            | 3 (8)            | 2 ( 6)           | 5 (18)            |
| thyroid     | enlarged   |                              | 2 ( 6)            | 4 (11)           | 4 (11)           | 2 (7)             |
|             | nodule     |                              | 0 ( 0)            | 1 (3)            | 0 ( 0)           | 0 ( 0)            |
| adrenal     | enlarged   |                              | 2 ( 6)            | 3 (8)            | 0 ( 0)           | 2 (7)             |
| testis      | 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)            |
| epididymis  | absence    |                              | 1 (3)             | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| prep/cligl  | enlarged   |                              | 0 ( 0)            | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |
|             | nodute     |                              | 1 (3)             | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| spinal cord | hemorrhage |                              | 1 ( 3)            | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| өхө         | turbid     |                              | 2 ( 6)            | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |
|             | white zone |                              | 1 ( 3)            | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| Zymbal gl   | nodule     |                              | 0 ( 0)            | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |
|             | mass       |                              | 0 ( 0)            | 0 ( 0)           | 1 ( 3)           | 0 ( 0)            |
| muscle      | nodule     |                              | 0 ( 0)            | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |
| peritoneum  | nodule     |                              | 0 ( 0)            | 0 ( 0)           | 1 ( 3)           | 5 (18)            |
|             | mass       |                              | 0 ( 0)            | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |
| retroperit  | mass       |                              | 2 ( 6)            | 0 ( 0)           | 0 ( 0)           | 1 ( 4)            |
|             | cyst       |                              | 1 (3)             | 2 ( 6)           | 0 ( 0)           | 0 ( 0)            |
| abdominal c | ascites    |                              | 0 ( 0)            | 0 ( 0)           | 0 ( 0)           | 3 (11)            |

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

| 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 (%) |
|------------|---------------|------------------------------|-------------------|------------------|------------------|-------------------|
| əsenterium | 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)             |
| nole 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

## PAGE: 4

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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        | nadule         | 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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(IIPT080)

BAIS 2

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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 Control 200ppm 800ppm 3200ppm

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| Organ       | Findings   | Group Name Control<br>NO, of Animals 10 (%) | 200ppm<br>16 (%) | 800ppm<br>16 (%) | 3200ppm<br>19 (%) |
|-------------|------------|---------------------------------------------|------------------|------------------|-------------------|
| skin/app    | ulcer      | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 1 (5)             |
|             | erasion    | 1 (10)                                      | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
|             | scab       | 1 (10)                                      | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| subcutis    | edema      | 1 (10)                                      | 1 (6)            | 0 ( 0)           | 0 ( 0)            |
|             | mass       | 0 ( 0)                                      | 2 (13)           | 0 ( 0)           | 0 ( 0)            |
| lung        | rəd        | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 2 (11)            |
|             | white zone | 0 ( 0)                                      | 0 ( 0)           | 1 (6)            | 0 ( 0)            |
|             | red zone   | 1 (10)                                      | 1 (6)            | 0 ( 0)           | 0 ( 0)            |
|             | nodule     | 0 ( 0)                                      | 2 (13)           | 1 (6)            | 5 (26)            |
| lymph node  | enlarged   | 0 ( 0)                                      | 3 (19)           | 6 (38)           | 4 (21)            |
| spleen      | enlarged   | 2 (20)                                      | 2 (13)           | 4 (25)           | 4 (21)            |
|             | atrophic   | 0 ( 0)                                      | 0 ( 0)           | 1 ( 6)           | 0 ( 0)            |
|             | white zone | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 1 (5)             |
|             | nodule     | 1 (10)                                      | 2 (13)           | 2 (13)           | 1 (5)             |
|             | nodular    | 0 ( 0)                                      | 1 ( 6)           | 0 ( 0)           | 0 ( 0)            |
| salivary gl | enlarged   | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 1 ( 5)            |
|             | nodule     | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 1 (5)             |
| small intes | nodule     | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 1 (5)             |
| large intes | dilated    | 0 ( 0)                                      | 0 ( 0)           | 1 ( 6)           | 0 ( 0)            |
| liver       | enlarged   | 1 (10)                                      | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
|             | pale       | 0 ( 0)                                      | 1 ( 6)           | 0 ( 0)           | 0 ( 0)            |
|             | white zone | 1 (10)                                      | 2 (13)           | 1 ( 6)           | 2 (11)            |
|             |            |                                             |                  |                  |                   |

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

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

SEX : MALE

Group Name 200ppm 800ppm 3200ppm Control 16 (%) 16 (%) 19 (%) Organ\_ Findings NO. of Animals 10 (%) 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) nodule pancreas 0 ( 0) 0 ( 0) 0 ( 0) 1 (5) kidney enlarged 0 ( 0) 1 (6) 1 (6) 0 ( 0) pale 0 ( 0) 0 ( 0) 2 (13) 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) hydronephrosis 1 (10) 3 (19) 0 ( 0) 2 (13) urin bladd urine:marked retention 2 (20) 2 (13) 2 (11) 2 (13) epididymis enlarged 0 ( 0) 0 ( 0) 0 ( 0) 1 (5) nodule 1 (10) 1 (6) 0 ( 0) 0 ( 0) semin ves nodule 0 ( 0) 0 ( 0) 0 ( 0) 1 (5) prep/cligl enlarged 0 ( 0) 1 (6) 0 ( 0) 0 ( 0) nodule 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 nodule 0 ( 0) 0 ( 0) 0 ( 0) 1 (5) retroperit 0 ( 0) 0 ( 0) 2 (13) 0 ( 0) mass

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

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

| hemorrhage    |                                        | 1 (10)                                 | 0 ( 0)                                                     | 1 (6)                                                                        | 2 (11)                                                                                         |
|---------------|----------------------------------------|----------------------------------------|------------------------------------------------------------|------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| ascites       |                                        | 1 (10)                                 | 3 (19)                                                     | 1 (6)                                                                        | 1 (5)                                                                                          |
| hemorrhage    |                                        | 0 ( 0)                                 | 0 ( 0)                                                     | 0 ( 0)                                                                       | 1 (5)                                                                                          |
| pleural fluid |                                        | 4 (40)                                 | 2 (13)                                                     | 1 (6)                                                                        | 3 (16)                                                                                         |
| anemic        |                                        | 0 ( 0)                                 | 0 ( 0)                                                     | 0 ( 0)                                                                       | 1 (5)                                                                                          |
| ł             | ascites<br>nemorrhage<br>pleural fluid | ascites<br>nemorrhage<br>pleural fluid | ascites 1 (10)<br>nemorrhage 0 (0)<br>pleural fluid 4 (40) | ascites 1 (10) 3 (19)   nemorrhage 0 (0) 0 (0)   pleural fluid 4 (40) 2 (13) | ascites 1 (10) 3 (19) 1 (6)   nemorrhage 0 (0) 0 (0) 0 (0)   pleural fluid 4 (40) 2 (13) 1 (6) |

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BAIS 2

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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       | Control<br>21 (%) | 200ppm<br>20 (%) | 800ppm<br>21 (%) | 3200ppm<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)            |
|            | nodule         | 0 ( 0)            | 2 (10)           | 0 ( 0)           | 1 (5)             |
|            | hydronephrasis | 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)            |
| OUAFY      | 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)

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spinal cord

brain

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)

| SEX :       | FEMALE           | <br>             |                  |                  | PAGE : 6          |
|-------------|------------------|------------------|------------------|------------------|-------------------|
| 0rgan       | Findings         | Control<br>1 (%) | 200ppm<br>20 (%) | 800ppm<br>21 (%) | 3200ppm<br>20 (%) |
| muscle      | nadule           | 0 ( 0)           | 1 (5)            | 0 ( 0)           | 0 ( 0)            |
| bone        | 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  | nodule           | 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:nodule | 0 ( 0)           | 0 ( 0)           | 0 ( 0)           | 1 ( 5)            |
| whale bady  | anemic           | 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)             |
|             | nodule           | 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)

|            |                        |                              |                   |                  |                  | 1 NGE •           |
|------------|------------------------|------------------------------|-------------------|------------------|------------------|-------------------|
| )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)            |
| ituitary   | enlarged               |                              | 0 ( 0)            | 0 ( 0)           | 1 (3)            | 0 ( 0)            |
|            | cyst                   |                              | 1 ( 3)            | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| hyroid     | enlarged               |                              | 1 ( 3)            | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| pididymis  | nadule                 |                              | 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)            |
| rep/cli gl | nodule                 |                              | 0 ( 0)            | 0 ( 0)           | 0 ( 0)           | 1 ( 3)            |
| ain        | deformed               |                              | 1 (3)             | 1 ( 3)           | 0 ( 0)           | 0 ( 0)            |
| ve         | turbid                 |                              | 0 ( 0)            | 0 ( 0)           | 1 ( 3)           | 0 ( 0)            |
| arder gl   | nodule                 |                              | 0 ( 0)            | 0 ( 0)           | 0 ( 0)           | 2 (6)             |
| Dhe        | red zane               |                              | 1 ( 3)            | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
| peritoneum | nadule                 |                              | 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)            |
| odominal 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)             |

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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)

SEX : FEMALE

| )rgan       | Findings       | Group Name Control<br>NO. of Animals 29 (%) | 200ppm<br>28 (%) | 800ppm<br>29 (%) | 3200ppm<br>29 (%) |
|-------------|----------------|---------------------------------------------|------------------|------------------|-------------------|
| subcutis    | 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 node   | 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)            |
| salivary gl | nodule         | 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)             |
| ancreas     | nodule         | 2 (7)                                       | 0 ( 0)           | 0 ( 0)           | 0 ( 0)            |
|             | cyst           | 0 ( 0)                                      | 0 ( 0)           | 0 ( 0)           | 1 (3)             |
| kidney      | 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)             |
|             | hydronephrasis | 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)             |

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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   |