

グリシドールのマウスを用いた  
吸入による 13 週間毒性試験報告書

試験番号：0317

## APPENDIX

## APPENDIXES

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## APPENDIX A

CLINICAL OBSERVATION : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0317  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : MALE

PAGE : 1

Clinical sign	Group Name	Administration		Week-day										
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	0ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	5ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	1	1	1	1	1	1	1	1	1	1	1
	40ppm	0	0	1	1	1	1	1	1	1	1	1	1	1
	80ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	0ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	5ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	40ppm	0	1	0	0	0	0	0	0	0	0	0	0	0
	80ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	0ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	5ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	40ppm	0	1	0	0	0	0	0	0	0	0	0	0	0
	80ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
BRADYPNEA	0ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	5ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	40ppm	0	1	0	0	0	0	0	0	0	0	0	0	0
	80ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	0ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	5ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	40ppm	0	1	0	0	0	0	0	0	0	0	0	0	0
	80ppm	0	0	0	0	0	0	0	0	0	0	0	0	0

## APPENDIX B 1

BODY WEIGHT CHANGES :SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 UNIT : g  
 REPORT TYPE : A1 13  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 1

Group Name	Administration week-day						
	0-0	1-7	2-7	3-7	4-7	5-7	6-7
0ppm	22.5± 0.7	23.9± 0.9	24.9± 1.3	26.1± 1.5	26.9± 1.6	27.8± 1.8	28.8± 2.1
5ppm	22.5± 0.7	23.7± 0.9	24.7± 1.0	25.6± 1.0	26.2± 1.4	26.7± 1.3	27.6± 1.5
10ppm	22.5± 0.7	23.5± 0.8	24.9± 1.0	25.7± 1.1	26.7± 1.1	26.9± 1.3	27.5± 1.5
20ppm	22.5± 0.7	23.7± 1.6	24.7± 2.1	25.8± 1.1	26.7± 1.0	27.2± 1.0	27.9± 1.1
40ppm	22.5± 0.7	23.1± 1.4	23.7± 2.9	24.9± 1.3	26.1± 1.3	26.3± 1.6	26.9± 1.7
80ppm	22.5± 0.7	22.4± 0.9*	23.6± 0.7	23.5± 0.8**	24.3± 0.7**	25.2± 0.8**	24.9± 0.6**

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

Test of Dunnett

(HAN260)

BAIS3

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 UNIT : g  
 REPORT TYPE : A1 13  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 2

Group Name	Administration week-day						
	7-7	8-7	9-7	10-7	11-7	12-7	13-7
0ppm	29.3± 2.3	29.6± 2.5	30.4± 2.8	31.7± 3.1	32.5± 3.0	32.9± 3.4	33.8± 3.0
5ppm	28.4± 1.4	28.6± 1.8	28.9± 1.9	30.5± 2.0	31.4± 1.9	31.7± 2.6	33.0± 1.9
10ppm	28.3± 1.6	29.0± 1.6	29.9± 1.7	30.5± 1.8	31.3± 1.9	31.8± 1.9	32.0± 2.2
20ppm	29.0± 1.6	28.9± 1.6	29.5± 1.6	30.3± 1.8	30.9± 2.4	31.7± 2.1	32.1± 2.2
40ppm	27.7± 1.7	27.9± 1.6	27.8± 1.9*	28.8± 2.3	29.1± 1.9	29.6± 2.2	30.0± 1.8**
80ppm	25.6± 0.8**	26.3± 0.7**	25.6± 0.9**	26.9± 0.6**	27.1± 0.7**	27.3± 0.8**	27.3± 1.2**

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

Test of Dunnett

(HAN260)

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## APPENDIX B 2

BODY WEIGHT CHANGES : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)

STUDY NO. : 0317  
 ANIMAL : MOUSE Grj:BDF1  
 UNIT : g  
 REPORT TYPE : A1 13  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 3

Group Name	Administration week-day						
	0-0	1-7	2-7	3-7	4-7	5-7	6-7
0ppm	18.7± 0.7	19.5± 0.6	20.6± 0.6	21.3± 0.4	22.4± 1.1	22.5± 0.9	23.2± 1.2
5ppm	18.7± 0.7	19.2± 0.8	20.5± 0.8	21.4± 0.8	22.2± 0.9	23.2± 1.2	24.1± 1.4
10ppm	18.7± 0.7	19.5± 1.0	21.2± 1.0	21.3± 1.2	22.3± 1.2	22.3± 1.1	23.3± 1.3
20ppm	18.7± 0.7	19.3± 0.3	20.9± 0.7	21.3± 0.6	22.1± 0.8	22.8± 0.8	23.6± 1.1
40ppm	18.7± 0.7	18.7± 2.7	20.8± 1.4	21.2± 1.4	22.2± 1.1	22.5± 1.3	23.2± 1.1
80ppm	18.7± 0.7	19.3± 0.6	20.6± 0.4	20.7± 0.5	21.7± 0.5	21.7± 1.0	22.2± 0.7

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

Test of Dunnett

(HAN260)

BAIS3

STUDY NO. : 0317  
 ANIMAL : MOUSE G-j:BDF1  
 UNIT : g  
 REPORT TYPE : A1 13  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 4

Group Name	Administration week-day						
	7-7	8-7	9-7	10-7	11-7	12-7	13-7
0ppm	23.5± 0.6	24.2± 1.7	24.2± 1.2	24.7± 0.8	24.9± 1.0	25.0± 1.2	25.5± 1.0
5ppm	24.1± 1.2	24.2± 1.2	24.5± 1.2	25.9± 1.5	25.8± 1.9	26.1± 1.8	26.8± 2.4
10ppm	23.4± 1.5	23.5± 1.6	24.2± 1.5	24.9± 2.0	24.5± 0.8	24.9± 1.3	25.1± 2.2
20ppm	23.4± 1.2	24.0± 0.8	24.3± 1.2	24.8± 1.5	24.9± 1.6	25.5± 1.3	25.3± 1.7
40ppm	24.4± 1.7	24.3± 1.1	24.3± 1.3	24.9± 1.2	24.4± 1.4	25.4± 1.3	26.0± 2.0
80ppm	22.6± 0.8	23.3± 0.6	22.7± 0.9*	24.1± 1.0	23.7± 0.8	24.2± 1.1	24.0± 0.8*

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

Test of Dunnett

(HAN260)

BAIS3

## APPENDIX C 1

FOOD CONSUMPTION CHANGES : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0317  
 ANIMAL : MOUSE C<sub>7</sub>:BDF1  
 UNIT : g  
 REPORT TYPE : A1 13  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 1

Group Name	Administration week-day(effective)						
	1-7(6)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
0ppm	4.0± 0.4	4.0± 0.2	4.0± 0.3	4.2± 0.3	4.3± 0.3	4.4± 0.4	4.2± 0.3
5ppm	4.1± 0.2	4.0± 0.2	4.1± 0.3	4.2± 0.3	4.2± 0.3	4.4± 0.3	4.3± 0.3
10ppm	4.0± 0.2	4.2± 0.2	4.2± 0.3	4.3± 0.3	4.4± 0.3	4.4± 0.4	4.4± 0.3
20ppm	3.9± 0.7	4.1± 0.5	4.3± 0.4	4.5± 0.4	4.6± 0.4	4.6± 0.5	4.6± 0.5
40ppm	3.8± 0.5	4.0± 0.6	4.1± 0.3	4.3± 0.3	4.3± 0.4	4.3± 0.3	4.4± 0.3
80ppm	3.4± 0.4**	3.8± 0.2	3.7± 0.3*	4.0± 0.2	4.1± 0.2	3.8± 0.2**	4.1± 0.2

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

Test of Dunnett

(HAN260)

BAIS3

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 UNIT : g  
 REPORT TYPE : A1 13  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 2

Group Name	Administration week-day(effective)					
	8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)
0ppm	4.3± 0.4	4.4± 0.3	4.7± 0.3	4.5± 0.2	4.6± 0.2	4.5± 0.2
5ppm	4.4± 0.3	4.2± 0.4	4.9± 0.3	4.7± 0.4	4.6± 0.5	4.8± 0.3
10ppm	4.6± 0.3	4.5± 0.3	4.6± 0.4	4.6± 0.3	4.6± 0.3	4.5± 0.3
20ppm	4.6± 0.4	4.6± 0.4	4.8± 0.4	4.7± 0.4	4.8± 0.4	4.7± 0.4
40ppm	4.4± 0.3	4.3± 0.4	4.6± 0.4	4.3± 0.3	4.4± 0.4	4.4± 0.3
80ppm	4.0± 0.2	3.9± 0.2**	4.1± 0.2**	3.9± 0.2**	4.0± 0.1**	3.9± 0.2**

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

Test of Dunnett

(HAN260)

BAIS3

## APPENDIX C 2

FOOD CONSUMPTION CHANGES : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 UNIT : g  
 REPORT TYPE : A1 13  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 3

Group Name	Administration 1-7(6)	week-day(effective) 2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
0ppm	3.5± 0.3	3.6± 0.2	3.7± 0.2	4.0± 0.2	4.0± 0.2	4.1± 0.3	4.1± 0.2
5ppm	3.4± 0.2	3.7± 0.2	4.0± 0.1**	4.3± 0.2**	4.5± 0.2**	4.6± 0.3**	4.5± 0.3**
10ppm	3.6± 0.3	3.8± 0.2	3.7± 0.2	4.0± 0.2	4.0± 0.2	4.2± 0.3	4.2± 0.2
20ppm	3.5± 0.2	3.8± 0.1	3.9± 0.1	4.1± 0.2	4.3± 0.2*	4.4± 0.2	4.5± 0.2**
40ppm	3.3± 0.6	3.8± 0.6	3.8± 0.3	4.1± 0.2	4.1± 0.3	4.2± 0.2	4.3± 0.4
80ppm	3.1± 0.3	3.7± 0.2	3.5± 0.2	3.7± 0.2*	3.8± 0.3	3.8± 0.2*	4.0± 0.2

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

Test of Dunnett



STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 UNIT : g  
 REPORT TYPE : A1 13  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 4

Group Name	Administration week-day(effective)					
	8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)
0ppm	4.1± 0.3	4.1± 0.3	4.3± 0.2	4.1± 0.4	4.1± 0.2	4.1± 0.3
5ppm	4.4± 0.2	4.3± 0.2	4.7± 0.2**	4.2± 0.2	4.4± 0.2*	4.3± 0.3
10ppm	4.3± 0.2	4.3± 0.1	4.3± 0.2	4.0± 0.2	4.3± 0.4	4.4± 0.4
20ppm	4.4± 0.2*	4.4± 0.2*	4.4± 0.3	4.1± 0.2	4.4± 0.3	4.2± 0.3
40ppm	4.3± 0.2	4.1± 0.3	4.2± 0.2	3.9± 0.1	4.2± 0.2	4.2± 0.3
80ppm	4.0± 0.3	3.9± 0.3	4.1± 0.3	3.7± 0.3	3.9± 0.2	3.6± 0.2**

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

Test of Dunnett

## APPENDIX D 1

HEMATOLOGY : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : MALE

HEMATOLOGY (SUMMARY)  
 ALL ANIMALS ( 14W)

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 <sup>6</sup> /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 <sup>3</sup> /μl	
0ppm	10	10.75±	0.35	16.0±	0.5	50.1±	2.1	46.6±	0.9	14.9±	0.2	32.0±	0.8	1435±	100
5ppm	10	10.52±	0.31	15.9±	0.4	48.9±	1.2	46.5±	0.7	15.1±	0.5	32.5±	0.9	1456±	83
10ppm	10	10.79±	0.30	16.0±	0.6	50.1±	2.0	46.5±	0.8	14.8±	0.3	31.9±	0.5	1449±	93
20ppm	9	10.32±	0.25*	15.6±	0.3	47.9±	1.3*	46.3±	0.6	15.1±	0.5	32.7±	1.1	1441±	99
40ppm	9	10.54±	0.25	15.6±	0.2	48.7±	1.5	46.3±	0.7	14.8±	0.3	32.0±	0.8	1528±	75
80ppm	10	10.33±	0.38*	15.2±	0.5**	48.0±	1.9*	46.4±	1.1	14.7±	0.3	31.6±	0.7	1606±	95**

Significant difference ; \* : P ≤ 0.05

\*\* : P ≤ 0.01

Test of Dunnett

(HCL070)

BAIS3

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : MALE

HEMATOLOGY (SUMMARY)  
 ALL ANIMALS ( 14W)

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
0ppm	10	2.08±	1.27	0±	0	13±	3	2±	1	0±	0	3±	1	83±	3	0±	0
5ppm	10	1.88±	1.22	1±	1	14±	4	2±	1	0±	0	3±	1	80±	4	0±	0
10ppm	10	1.68±	1.08	0±	0	13±	3	1±	1	0±	0	2±	1	83±	4	0±	0
20ppm	9	1.35±	0.90	0±	0	14±	5	2±	1	0±	0	3±	1	81±	5	0±	0
40ppm	9	1.33±	1.08	0±	1	12±	2	2±	2	0±	0	2±	1	83±	4	0±	0
80ppm	10	1.12±	0.74	0±	0	14±	3	2±	1	0±	0	3±	1	82±	4	0±	0

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 3

## APPENDIX D 2

HEMATOLOGY : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)

STUDY NO. : 0317  
 ANIMAL : MOUSE C<sub>7</sub>:BDF<sub>1</sub>  
 MEASURE. TIME : 1  
 SEX : FEMALE

HENATOLOGY (SUMMARY)  
 ALL ANIMALS ( 14W)

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	RED BLOOD CELL 10 <sup>6</sup> /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 <sup>9</sup> /μl	
0ppm	10	10.39±	0.52	16.0±	0.5	48.1±	2.3	46.3±	0.6	15.4±	0.6	33.2±	1.1	1299±	84
5ppm	10	10.66±	0.28	16.1±	0.4	49.5±	1.4	46.5±	0.8	15.1±	0.2	32.5±	0.4	1265±	39
10ppm	10	10.62±	0.42	16.2±	0.5	49.7±	2.4	46.8±	0.6	15.3±	0.3	32.7±	0.7	1364±	97
20ppm	10	10.86±	0.19	16.2±	0.7	50.2±	1.1	46.2±	0.5	14.9±	0.5	32.3±	1.0	1382±	78
40ppm	10	10.55±	0.39	15.8±	0.5	48.8±	1.9	46.2±	0.6	15.0±	0.3	32.5±	0.6	1340±	118
80ppm	10	10.42±	0.27	15.7±	0.3	48.6±	1.5	46.6±	0.7	15.1±	0.4	32.4±	0.6	1370±	84

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

Test of Dunnett

(HCL070)

BAIS3

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : FEMALE

HEMATOLOGY (SUMMARY)  
 ALL ANIMALS ( 14W)

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
0ppm	10	1.85±	1.54	0±	0	14±	4	2±	1	0±	0	2±	1	82±	4	0±	0
5ppm	10	1.48±	1.25	0±	0	19±	7	2±	1	0±	0	2±	2	77±	7	0±	0
10ppm	10	1.57±	1.10	0±	0	15±	6	2±	1	0±	0	2±	1	81±	7	0±	0
20ppm	10	1.74±	0.99	0±	0	14±	5	2±	1	0±	0	3±	1	82±	5	0±	0
40ppm	10	1.58±	0.67	0±	0	14±	4	2±	2	0±	0	3±	1	81±	5	0±	0
80ppm	10	1.37±	0.43	0±	0	15±	4	3±	1	0±	0	2±	1	80±	4	0±	0

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS3

## APPENDIX E 1

BIOCHEMISTRY : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)



STUDY NO. : 0317  
ANIMAL : MOUSE Crj:BDF1  
MEASURE. TIME : 1  
SEX : FEMALE

BIOCHEMISTRY (SUMMARY)  
ALL ANIMALS ( 14W)

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
0ppm	10	5.2±	0.1	3.1±	0.1	1.5±	0.1	0.18±	0.02	162±	25	75±	13	23±	11
5ppm	10	5.2±	0.2	3.2±	0.1	1.6±	0.1	0.16±	0.01	169±	26	78±	11	20±	9
10ppm	10	5.3±	0.3	3.3±	0.2	1.6±	0.1	0.17±	0.02	169±	20	78±	8	19±	8
20ppm	10	5.2±	0.1	3.2±	0.1	1.6±	0.1	0.17±	0.01	189±	22	81±	4	17±	3
40ppm	10	5.2±	0.1	3.2±	0.2	1.6±	0.1	0.17±	0.03	187±	23	86±	11	18±	3
80ppm	10	5.2±	0.2	3.2±	0.1	1.6±	0.1	0.16±	0.01	173±	19	83±	6	14±	4**

Significant defference ; \* :  $P \leq 0.05$

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS3

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS ( 14W)

REPORT TYPE : A1

PAGE : 5

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT IU/l		GPT IU/l		LDH IU/l		ALP IU/l		G-GTP IU/l		CPK IU/l	
0ppm	10	148±	30	62±	10	29±	5	227±	29	249±	34	2±	1	63±	38
5ppm	10	148±	26	67±	15	28±	5	261±	91	243±	49	2±	1	77±	64
10ppm	10	150±	18	55±	7	25±	4	231±	42	245±	28	2±	1	50±	12
20ppm	10	155±	8	51±	6	23±	3**	226±	27	252±	23	2±	1	44±	8
40ppm	10	162±	19	48±	9*	22±	5**	210±	55	219±	24	1±	1	40±	10
80ppm	10	152±	9	46±	6**	21±	4**	212±	46	240±	22	2±	1	39±	14

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS3

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : FEMALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS ( 14W)

PAGE : 6

Group Name	NO. of Animals	UREA NITROGEN mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
0ppm	10	20.9±	2.6	149±	2	4.6±	0.4	118±	1	8.4±	0.7	6.8±	1.2
5ppm	10	21.4±	2.3	149±	2	4.7±	0.5	118±	1	8.8±	0.3	6.7±	1.6
10ppm	10	22.2±	1.6	149±	1	4.7±	0.4	118±	1	8.8±	0.3	6.7±	0.9
20ppm	10	21.2±	3.5	148±	2	4.8±	0.5	117±	2	8.9±	0.2	6.8±	1.3
40ppm	10	20.2±	3.4	148±	1	4.9±	0.4	116±	2**	8.7±	0.8	7.2±	0.5
80ppm	10	20.3±	3.6	148±	1	5.0±	0.3	115±	2**	8.7±	0.4	7.1±	1.3

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS3

## APPENDIX E 2

BIOCHEMISTRY : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS ( 14W)

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g/dl		ALBUMIN g/dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
0ppm	10	5.1±	0.1	2.9±	0.1	1.4±	0.0	0.18±	0.04	231±	33	82±	5	29±	10
5ppm	10	5.0±	0.1	2.8±	0.1	1.3±	0.0	0.17±	0.01	203±	37	81±	9	28±	9
10ppm	10	5.1±	0.3	2.9±	0.2	1.4±	0.1	0.17±	0.03	195±	35	77±	7	24±	7
20ppm	9	5.0±	0.1	2.9±	0.0	1.4±	0.1	0.17±	0.01	200±	29	77±	9	19±	7*
40ppm	9	5.0±	0.1	2.9±	0.1	1.4±	0.1	0.17±	0.01	219±	17	77±	7	19±	7*
80ppm	10	5.1±	0.2	3.0±	0.1	1.4±	0.1	0.18±	0.01	217±	23	83±	8	15±	4**

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

Test of Dunnett

(HCL074)

BAIS3

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS ( 14W)

PAGE : 2

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT IU/l		GPT IU/l		LDH IU/l		ALP IU/l		G-GTP IU/l		CPK IU/l	
0ppm	10	166±	16	47±	7	22±	6	216±	85	168±	12	2±	1	43±	14
5ppm	10	162±	18	49±	6	21±	3	196±	20	169±	8	2±	1	44±	8
10ppm	10	156±	16	48±	5	20±	3	212±	48	168±	9	1±	1	48±	14
20ppm	9	154±	21	47±	11	22±	3	225±	58	162±	11	1±	1	61±	45
40ppm	9	152±	15	41±	5	21±	5	210±	36	168±	13	2±	1	49±	41
80ppm	10	158±	11	38±	3**	19±	1	198±	25	164±	18	2±	1	37±	8

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS3

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS ( 14W)

PAGE : 3

Group Name	NO. of Animals	UREA NITROGEN mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
0ppm	10	25.7±	3.7	150±	2	4.7±	0.3	119±	2	8.8±	0.3	7.3±	1.1
5ppm	10	23.5±	3.3	150±	1	4.8±	0.4	119±	1	8.8±	0.2	7.2±	0.8
10ppm	10	23.5±	3.5	150±	1	5.0±	0.5	120±	2	8.8±	0.3	7.6±	1.2
20ppm	9	24.2±	2.7	150±	1	4.7±	0.3	118±	2	8.7±	0.2	7.9±	0.6
40ppm	9	24.3±	2.6	149±	2	4.7±	0.3	117±	2	8.7±	0.2	7.2±	0.9
80ppm	10	23.9±	4.5	149±	1	4.8±	0.4	116±	2**	8.9±	0.3	7.6±	1.5

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

Test of Dunnett

(HCL074)

BAIS3

## APPENDIX F 1

URINALYSIS : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)



STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : MALE

URINALYSIS

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	pH							CHI	Protein					CHI	Glucose					CHI	Ketone body					CHI	Occult blood				CHI				
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	±	+		2+	3+	4+	-		±	+	2+	3+
0ppm	10	0	0	0	0	3	5	2		0	1	9	0	0	0		10	0	0	0	0	0		3	6	1	0	0	0		10	0	0	0	0	
5ppm	10	0	0	0	0	5	4	1		0	0	7	3	0	0		10	0	0	0	0	0		0	10	0	0	0	0		10	0	0	0	0	
10ppm	10	0	0	0	0	1	9	0		0	0	8	2	0	0		10	0	0	0	0	0		1	8	1	0	0	0		10	0	0	0	0	
20ppm	9	0	0	0	0	3	6	0		0	0	5	4	0	0	*	9	0	0	0	0	0		0	6	3	0	0	0		9	0	0	0	0	
40ppm	9	0	0	0	2	0	7	0		0	0	5	4	0	0	*	9	0	0	0	0	0		0	7	2	0	0	0		9	0	0	0	0	
80ppm	10	0	0	1	0	5	4	0		0	0	6	4	0	0		10	0	0	0	0	0		0	5	3	2	0	0		10	0	0	0	0	

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

Test of CHI SQUARE

(HCL101)

BAIS 3

STUDY NO. : 0317

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

URINALYSIS

PAGE : 2

Group Name	NO. of Animals	Urobilinogen ± + 2+ 3+ 4+					CHI
0ppm	10	10	0	0	0	0	
5ppm	10	10	0	0	0	0	
10ppm	10	10	0	0	0	0	
20ppm	9	9	0	0	0	0	
40ppm	9	9	0	0	0	0	
80ppm	10	10	0	0	0	0	

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

Test of CHI SQUARE

(HCL101)

BAIS3

## APPENDIX F 2

URINALYSIS : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 MEASURE. TIME : 1  
 SEX : FEMALE

# URINALYSIS

REPORT TYPE : A1

PAGE : 3

Group Name	NO. of Animals	pH							CHI	Protein					CHI	Glucose					CHI	Ketone body					CHI	Occult blood				CHI					
		5.0	6.0	6.5	7.0	7.5	8.0	8.5		-	±	+	2+	3+		4+	-	±	+	2+		3+	4+	-	±	+		2+	3+	4+	-		±	+	2+	3+	
	0ppm	10	0	0	1	1	4	4	0		0	0	10	0	0	0		10	0	0	0	0	0		7	3	0	0	0	0		10	0	0	0	0	
	5ppm	10	0	0	0	3	1	5	1		0	0	8	2	0	0	0	10	0	0	0	0	0		1	6	1	2	0	0	*	10	0	0	0	0	
	10ppm	10	0	0	1	2	0	7	0		0	0	10	0	0	0		10	0	0	0	0	0		0	9	1	0	0	0	**	10	0	0	0	0	
	20ppm	10	0	0	3	0	2	5	0		0	1	7	2	0	0		10	0	0	0	0	0		0	4	3	3	0	0	**	10	0	0	0	0	
	40ppm	10	0	0	0	1	2	6	1		0	1	9	0	0	0		10	0	0	0	0	0		0	4	4	2	0	0	**	10	0	0	0	0	
	80ppm	10	0	1	0	2	2	4	1		0	2	8	0	0	0		10	0	0	0	0	0		0	2	4	4	0	0	**	10	0	0	0	0	

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

Test of CHI SQUARE

(HCL101)

BAIS3

STUDY NO. : 0317

URINALYSIS

ANIMAL : MOUSE Crj:BDF1

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Urobilinogen ± + 2+ 3+ 4+ CHI
0ppm	10	10 0 0 0 0
5ppm	10	10 0 0 0 0
10ppm	10	10 0 0 0 0
20ppm	10	10 0 0 0 0
40ppm	10	10 0 0 0 0
80ppm	10	10 0 0 0 0

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

Test of CHI SQUARE

(HCL101)

BAIS3

## APPENDIX G 1

GROSS FINDINGS : SUMMARY, MOUSE : MALE

DEAD AND MORIBUND ANIMALS

(13 - WEEK STUDY)

STUDY NO. : 0317  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
DEAD AND MORIBUND ANIMALS (0- 14W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	0 ppm 0 (%)	5ppm 0 (%)	10ppm 0 (%)	20ppm 1 (%)
kidney	hydronephrosis		- ( -)	- ( -)	- ( -)	1 (100)

(HPT080)

BAIS3

STUDY NO. : 0317  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
DEAD AND MORIBUND ANIMALS (0- 14W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	40ppm	80ppm
			1 (%)	0 (%)
kidney	hydronephrosis		0 ( 0)	- ( -)

(HPT080)

BAIS 3



## APPENDIX G 2

GROSS FINDINGS : SUMMARY, MOUSE : MALE : SACRIFICED ANIMALS

(13 - WEEK STUDY)

STUDY NO. : 0317  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS ( 14W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	0ppm		5ppm		10ppm		20ppm	
			10	(%)	10	(%)	10	(%)	9	(%)
spleen	black zone		0	( 0)	0	( 0)	0	( 0)	2	( 22)
kidney	hydronephrosis		0	( 0)	0	( 0)	0	( 0)	1	( 11)
urin bladd	urine:marked retention		0	( 0)	0	( 0)	0	( 0)	0	( 0)
testis	atrophic		0	( 0)	0	( 0)	0	( 0)	0	( 0)

(HPT080)

BAIS 3

STUDY NO. : 0317  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS ( 14W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	40ppm		80ppm	
			9	(%)	10	(%)
spleen	black zone		0	( 0)	2	( 20)
kidney	hydronephrosis		1	( 11)	2	( 20)
urin bladd	urine:marked retention		0	( 0)	1	( 10)
testis	atrophic		0	( 0)	1	( 10)

(HPT080)

BAIS3

## APPENDIX G 3

GROSS FINDINGS : SUMMARY, MOUSE : FEMALE : SACRIFICED ANIMALS

(13 - WEEK STUDY)

STUDY NO. : 0317  
ANIMAL : MOUSE Crl:BDF1  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS ( 14W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	0ppm		5ppm		10ppm		20ppm	
			10	(%)	10	(%)	10	(%)	10	(%)
spleen	black zone		1	( 10)	1	( 10)	0	( 0)	0	( 0)
kidney	hydronephrosis		0	( 0)	0	( 0)	0	( 0)	1	( 10)

(HPT080)

BAIS 3

STUDY NO. : 0317  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS ( 14W)

PAGE : 4

Organ	Findings	Group Name NO. of Animals	40ppm		80ppm	
			10	(%)	10	(%)
spleen	black zone		1	( 10)	0	( 0)
kidney	hydronephrosis		1	( 10)	0	( 0)

(HPT080)

BAIS3

## APPENDIX H 1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0317  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE  
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
SURVIVAL ANIMALS ( 14W)

PAGE : 1

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
0ppm	10	30.1± 3.0	0.036± 0.007	0.012± 0.002	0.237± 0.024	0.154± 0.009	0.166± 0.013
5ppm	10	29.1± 2.0	0.036± 0.006	0.011± 0.002	0.232± 0.036	0.155± 0.011	0.163± 0.012
10ppm	10	28.5± 1.9	0.034± 0.006	0.012± 0.002	0.222± 0.031	0.153± 0.012	0.164± 0.009
20ppm	9	28.6± 2.3	0.033± 0.005	0.011± 0.002	0.221± 0.042	0.167± 0.011*	0.164± 0.007
40ppm	9	26.3± 1.7**	0.032± 0.004	0.011± 0.002	0.219± 0.019	0.151± 0.013	0.163± 0.009
80ppm	10	24.2± 1.0**	0.028± 0.005**	0.010± 0.002	0.189± 0.058	0.143± 0.007	0.157± 0.010

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

Test of Dunnett

(HCL040)

BAIS 3



STUDY NO. : 0317  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE  
UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
SURVIVAL ANIMALS ( 14W)

PAGE : 2

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
0ppm	10	0.431±	0.033	0.046±	0.004	1.155±	0.072	0.439±	0.014
5ppm	10	0.464±	0.035	0.049±	0.005	1.158±	0.086	0.439±	0.007
10ppm	10	0.463±	0.029	0.047±	0.003	1.138±	0.076	0.437±	0.015
20ppm	9	0.512±	0.069**	0.050±	0.005	1.171±	0.071	0.447±	0.016
40ppm	9	0.525±	0.178	0.045±	0.007	1.109±	0.054	0.443±	0.014
80ppm	10	0.538±	0.219*	0.042±	0.006	1.051±	0.058**	0.431±	0.016

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

Test of Dunnett

(HCL040)

BAIS 3

## APPENDIX H 2

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE  
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
 SURVIVAL ANIMALS ( 14W)

PAGE : 3

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
0ppm	10	21.7± 0.9	0.045± 0.005	0.014± 0.002	0.033± 0.004	0.126± 0.005	0.162± 0.008
5ppm	10	22.4± 2.1	0.044± 0.006	0.014± 0.002	0.031± 0.009	0.129± 0.006	0.163± 0.010
10ppm	10	21.4± 1.8	0.039± 0.008	0.014± 0.002	0.036± 0.006	0.125± 0.007	0.164± 0.011
20ppm	10	21.5± 1.5	0.041± 0.010	0.014± 0.002	0.031± 0.006	0.130± 0.005	0.159± 0.014
40ppm	10	22.2± 1.6	0.041± 0.005	0.013± 0.002	0.032± 0.004	0.127± 0.008	0.164± 0.012
80ppm	10	20.5± 0.9	0.040± 0.005	0.013± 0.002	0.030± 0.005	0.120± 0.008	0.153± 0.008

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

Test of Dunnett

(HCL040)

BAIS3

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE  
 UNIT: g

ORGAN WEIGHT:ABSOLUTE (SUMMARY)  
 SURVIVAL ANIMALS ( 14W)

PAGE : 4

Group Name	NO. of Animals	KIDNEYS		SPLEEN		LIVER		BRAIN	
0ppm	10	0.300±	0.012	0.061±	0.006	0.943±	0.066	0.454±	0.014
5ppm	10	0.328±	0.013	0.060±	0.008	1.002±	0.122	0.454±	0.017
10ppm	10	0.319±	0.022	0.055±	0.008	0.956±	0.109	0.460±	0.017
20ppm	10	0.353±	0.056**	0.055±	0.008	0.955±	0.050	0.452±	0.024
40ppm	10	0.387±	0.124**	0.055±	0.009	0.994±	0.066	0.452±	0.020
80ppm	10	0.355±	0.015**	0.048±	0.004**	0.934±	0.055	0.442±	0.018

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

Test of Dunnett

(HCL040)

BAIS3

## APPENDIX I 1

ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0317  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE  
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)  
SURVIVAL ANIMALS ( 14W)

PAGE : 1

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
0ppm	10	30.1± 3.0	0.118± 0.013	0.040± 0.008	0.790± 0.090	0.513± 0.033	0.556± 0.048
5ppm	10	29.1± 2.0	0.123± 0.020	0.039± 0.004	0.802± 0.148	0.534± 0.061	0.561± 0.044
10ppm	10	28.5± 1.9	0.120± 0.018	0.041± 0.007	0.780± 0.110	0.537± 0.052	0.576± 0.035
20ppm	9	28.6± 2.3	0.114± 0.010	0.039± 0.005	0.779± 0.173	0.587± 0.065**	0.575± 0.042
40ppm	9	26.3± 1.7**	0.121± 0.021	0.042± 0.007	0.837± 0.094	0.573± 0.027*	0.620± 0.049**
80ppm	10	24.2± 1.0**	0.114± 0.018	0.042± 0.006	0.825± 0.245	0.593± 0.042**	0.648± 0.037**

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

Test of Dunnett

(HCL042)

BAIS3

STUDY NO. : 0317  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE  
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)  
SURVIVAL ANIMALS ( 14W)

PAGE : 2

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
0ppm	10	1.439± 0.125	0.155± 0.013	3.857± 0.255	1.470± 0.135
5ppm	10	1.596± 0.119	0.169± 0.017	3.985± 0.206	1.515± 0.122
10ppm	10	1.627± 0.109	0.165± 0.013	3.992± 0.185	1.538± 0.119
20ppm	9	1.805± 0.360**	0.177± 0.022	4.097± 0.142*	1.567± 0.123
40ppm	9	2.005± 0.708**	0.170± 0.022	4.220± 0.147**	1.689± 0.090**
80ppm	10	2.231± 0.927**	0.173± 0.025	4.344± 0.128**	1.787± 0.105**

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

Test of Dunnett

(HCL042)

BAIS3

## APPENDIX I 2

ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)



STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE  
 UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)  
 SURVIVAL ANIMALS ( 14W)

PAGE : 3

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
0ppm	10	21.7± 0.9	0.207± 0.024	0.067± 0.011	0.151± 0.019	0.580± 0.033	0.749± 0.048
5ppm	10	22.4± 2.1	0.196± 0.017	0.063± 0.008	0.140± 0.032	0.578± 0.029	0.733± 0.050
10ppm	10	21.4± 1.8	0.180± 0.031	0.066± 0.008	0.167± 0.030	0.587± 0.047	0.771± 0.078
20ppm	10	21.5± 1.5	0.190± 0.034	0.064± 0.006	0.142± 0.021	0.605± 0.038	0.738± 0.030
40ppm	10	22.2± 1.6	0.184± 0.024	0.060± 0.008	0.142± 0.016	0.576± 0.031	0.742± 0.048
80ppm	10	20.5± 0.9	0.196± 0.022	0.061± 0.007	0.147± 0.022	0.583± 0.031	0.746± 0.029

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

Test of Dunnett

(HCL042)

BAIS3

STUDY NO. : 0317  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : FEMALE  
UNIT: %

ORGAN WEIGHT:RELATIVE (SUMMARY)  
SURVIVAL ANIMALS ( 14W)

PAGE : 4

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
0ppm	10	1.383± 0.059	0.281± 0.021	4.345± 0.183	2.095± 0.104
5ppm	10	1.476± 0.109	0.266± 0.022	4.472± 0.218	2.042± 0.178
10ppm	10	1.496± 0.103	0.256± 0.024	4.459± 0.184	2.160± 0.161
20ppm	10	1.650± 0.314**	0.257± 0.022	4.449± 0.149	2.110± 0.148
40ppm	10	1.743± 0.514**	0.248± 0.034*	4.492± 0.143	2.050± 0.173
80ppm	10	1.731± 0.060**	0.231± 0.018**	4.552± 0.156	2.156± 0.084

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

Test of Dunnett

(HCL042)

BAIS3

APPENDIX J 1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : MALE : DEAD AND MORIBUND ANIMALS

(13 - WEEK STUDY)

STUDY NO. : 0317  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
DEAD AND MORIBUND ANIMALS (0- 14W)

PAGE : 1

Organ	Findings	Group Name No. of Animals on Study Grade	0ppm				5ppm				10ppm				20ppm			
			0				0				0				1			
			1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)	1 (%)	2 (%)	3 (%)	4 (%)
[Hematopoietic system]																		
thymus	atrophy		< 0>				< 0>				< 0>				< 0>			
		- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	
spleen	atrophy		< 0>				< 0>				< 0>				< 1>			
		- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	
[Circulatory system]																		
heart	necrosis:focal		< 0>				< 0>				< 0>				< 1>			
		- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	0 ( 0 )	1 ( 100 )	0 ( 0 )	0 ( 0 )	
	fibrosis		< 0>				< 0>				< 0>				< 1>			
		- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	0 ( 0 )	1 ( 100 )	0 ( 0 )	0 ( 0 )	
[Urinary system]																		
kidney	vacuolization of proximal tubule		< 0>				< 0>				< 0>				< 1>			
		- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	- ( - )	1 ( 100 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	
Grade	1 : Slight	2 : Moderate	3 : Marked	4 : Severe														
< a >	a : Number of animals examined at the site																	
b	b : Number of animals with lesion																	
( c )	c : b / a * 100																	

STUDY NO. : 0317  
 ANIMAL : MOUSE C-j:BDF1  
 REPORT TYPE : A1  
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0- 14W)

PAGE : 2

		40ppm				80ppm			
		1				0			
Group Name	No. of Animals on Study	1	2	3	4	1	2	3	4
Grade		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
Organ_____	Findings_____								
<hr/>									
[Hematopoietic system]									
thymus		< 1>				< 0>			
	atrophy	0 ( 0)	1 (100)	0 ( 0)	0 ( 0)	- ( -)	- ( -)	- ( -)	- ( -)
spleen		< 1>				< 0>			
	atrophy	0 ( 0)	1 (100)	0 ( 0)	0 ( 0)	- ( -)	- ( -)	- ( -)	- ( -)
[Circulatory system]									
heart		< 1>				< 0>			
	necrosis:focal	0 ( 0)	1 (100)	0 ( 0)	0 ( 0)	- ( -)	- ( -)	- ( -)	- ( -)
	fibrosis	0 ( 0)	1 (100)	0 ( 0)	0 ( 0)	- ( -)	- ( -)	- ( -)	- ( -)
[Urinary system]									
kidney		< 1>				< 0>			
	vacuolization of proximal tubule	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	- ( -)	- ( -)	- ( -)	- ( -)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe  
 < a > a : Number of animals examined at the site  
 b : Number of animals with lesion  
 ( c ) c : b / a \* 100

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 DEAD AND MORIBUND ANIMALS (0- 14W)

PAGE : 3

Organ	Findings	Group Name No. of Animals on Study				0ppm				5ppm				10ppm				20ppm			
		Grade				0				0				0				1			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Urinary system]

kidney	hydronephrosis	< 0>				< 0>				< 0>				< 1>							
		-	-	-	-	-	-	-	-	-	-	-	-	0	1	0	0	0	100	0	0
		( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( 0 )	( 100 )	( 0 )	( 0 )				

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe  
 < a > a : Number of animals examined at the site  
 b b : Number of animals with lesion  
 ( c ) c : b / a \* 100

(HPT150)

BAIS3

STUDY NO. : 0317  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
DEAD AND MORIBUND ANIMALS (0- 14W)

PAGE : 4

Organ	Findings	Group Name		40ppm				80ppm			
		No. of Animals on Study		1				0			
		Grade		1	2	3	4	1	2	3	4
				(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Urinary system]

kidney	hydronephrosis	< 1 >				< 0 >			
		0	1	0	0	-	-	-	-
		( 0 )	( 100 )	( 0 )	( 0 )	( - )	( - )	( - )	( - )

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe  
< a > a : Number of animals examined at the site  
b b : Number of animals with lesion  
( c ) c : b / a \* 100

(HPT150)

BAIS3

APPENDIX J 2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : MALE: SACRIFICED ANIMALS

(13 - WEEK STUDY)



STUDY NO. : 0317  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
SACRIFICED ANIMALS ( 14W)

PAGE : 1

Organ	Findings	Group Name No. of Animals on Study Grade	0ppm				5ppm				10ppm				20ppm			
			10				10				10				9			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
nasal cavity			<10>				<10>				<10>				< 9>			
	eosinophilic change:olfactory epithelium		0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	eosinophilic change:respiratory epithelium		0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	respiratory metaplasia:olfactory epithelium		0	0	0	0	0	0	0	0	2	0	0	0	7	0	0	0 **
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 20 )	( 0 )	( 0 )	( 0 )	( 78 )	( 0 )	( 0 )	( 0 )
	desquamation:olfactory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )
	squamous cell metaplasia:respiratory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	atrophy:olfactory epithelium		0	0	0	0	0	0	0	0	4	0	0	0	9	0	0	0 **
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 40 )	( 0 )	( 0 )	( 0 )	( 100 )	( 0 )	( 0 )	( 0 )

[Hematopoietic system]

spleen			<10>				<10>				<10>				< 9>			
	deposit of hemosiderin		0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 22 )	( 0 )	( 0 )	( 0 )

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe  
< a > a : Number of animals examined at the site  
b : Number of animals with lesion  
( c ) c : b / a \* 100  
Significant difference ; \* : P ≤ 0.05 \*\* : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 SACRIFICED ANIMALS ( 14W)

PAGE : 2

Organ	Findings	40ppm				80ppm			
		9				10			
		1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]									
nasal cavity		< 9 >				<10>			
	eosinophilic change:olfactory epithelium	1 ( 11)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)
	eosinophilic change:respiratory epithelium	2 ( 22)	0 ( 0)	0 ( 0)	0 ( 0)	6 ( 60)	0 ( 0)	0 ( 0)	0 * ( 0)
	respiratory metaplasia:olfactory epithelium	8 ( 89)	0 ( 0)	0 ( 0)	0 ** ( 0)	10 (100)	0 ( 0)	0 ( 0)	0 ** ( 0)
	desquamation:olfactory epithelium	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	7 ( 70)	0 ( 0)	0 ( 0)	0 ** ( 0)
	squamous cell metaplasia:respiratory epithelium	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 20)	0 ( 0)	0 ( 0)	0 ( 0)
	atrophy:olfactory epithelium	6 ( 67)	3 ( 33)	0 ( 0)	0 ** ( 0)	3 ( 30)	7 ( 70)	0 ( 0)	0 ** ( 0)

[Hematopoietic system]

spleen		< 9 >				<10>			
	deposit of hemosiderin	0 ( 0)	0 ( 0)	0 ( 0)	0 ( 0)	2 ( 20)	0 ( 0)	0 ( 0)	0 ( 0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe  
 < a > a : Number of animals examined at the site  
 b : Number of animals with lesion  
 ( c ) c : b / a \* 100  
 Significant difference ; \* : P ≤ 0.05 \*\* : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 SACRIFICED ANIMALS ( 14W)

PAGE : 3

Organ	Findings	Group Name No. of Animals on Study				0ppm				5ppm				10ppm				20ppm			
		Grade				10				10				10				9			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																					
liver	granulation	<10>				<10>				<10>				< 9>							
		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
pancreas	atrophy	<10>				<10>				<10>				< 9>							
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
[Urinary system]																					
kidney	vacuolization of proximal tubule	<10>				<10>				<10>				< 9>							
		9	0	0	0	10	0	0	0	10	0	0	0	9	0	0	0	9	0	0	0
		( 90)	( 0)	( 0)	( 0)	( 100)	( 0)	( 0)	( 0)	( 100)	( 0)	( 0)	( 0)	( 100)	( 0)	( 0)	( 0)	( 100)	( 0)	( 0)	( 0)
	hydronephrosis	<10>				<10>				<10>				< 9>							
		0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	11	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 11)	( 0)	( 0)	( 0)	( 11)	( 0)	( 0)
urin bladd	dilatation	<10>				<10>				<10>				< 9>							
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
[Reproductive system]																					
testis	atrophy	<10>				<10>				<10>				< 9>							
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe

< a > a : Number of animals examined at the site

b b : Number of animals with lesion

( c ) c : b / a \* 100

Significant difference ; \* :  $P \leq 0.05$  \*\* :  $P \leq 0.01$  Test of Chi Square

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 SACRIFICED ANIMALS ( 14W)

PAGE : 4

		40ppm				80ppm			
		No. of Animals on Study				No. of Animals on Study			
		Grade				Grade			
Organ	Findings	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]									
liver		< 9>				<10>			
	granulation	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
pancreas		< 9>				<10>			
	atrophy	1	0	0	0	0	0	0	0
		( 11)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
[Urinary system]									
kidney		< 9>				<10>			
	vacuolization of proximal tubule	4	0	0	0	0	0	0	0 **
		( 44)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
		< 9>				<10>			
	hydronephrosis	0	1	0	0	0	2	0	0
		( 0)	( 11)	( 0)	( 0)	( 0)	( 20)	( 0)	( 0)
urin bladd		< 9>				<10>			
	dilatation	0	0	0	0	1	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)
[Reproductive system]									
testis		< 9>				<10>			
	atrophy	0	0	0	0	0	1	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe

< a > a : Number of animals examined at the site

b b : Number of animals with lesion

( c ) c : b / a \* 100

Significant difference : \* :  $P \leq 0.05$  \*\* :  $P \leq 0.01$  Test of Chi Square

STUDY NO. : 0317  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
SACRIFICED ANIMALS ( 14W)

PAGE : 5

Organ	Findings	Group Name No. of Animals on Study Grade	0ppm				5ppm				10ppm				20ppm			
			10				10				10				9			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Reproductive system]																		
testis	germ cell necrosis		<10>				<10>				<10>				< 9>			
			0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )
epididymis	decreased:sperma		<10>				<10>				<10>				< 9>			
			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	debris of spermatic elements		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe  
< a > a : Number of animals examined at the site  
b b : Number of animals with lesion  
( c ) c : b / a \* 100  
Significant difference ; \* : P ≤ 0.05 \*\* : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 SACRIFICED ANIMALS ( 14W)

PAGE : 6

Organ	Findings	40ppm				80ppm			
		9				10			
		1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Reproductive system]

testis	germ cell necrosis	< 9>				<10>			
		0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

epididymis	decreased: sperma	< 9>				<10>			
		0	0	0	0	0	0	1	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 10)	( 0)

debris of spermatic elements	0	0	0	0	0	0	0	0	0
	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe

< a > a : Number of animals examined at the site

b b : Number of animals with lesion

( c ) c : b / a \* 100

Significant difference ; \* :  $P \leq 0.05$  \*\* :  $P \leq 0.01$  Test of Chi Square

(HPT150)

BA1S3

APPENDIX J 3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : FEMALE : SACRIFICED ANIMALS

(13 - WEEK STUDY)

STUDY NO. : 0317  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
SACRIFICED ANIMALS ( 14W)

PAGE : 7

Organ	Findings	Group Name No. of Animals on Study				0ppm				5ppm				10ppm				20ppm			
		Grade				10				10				10				10			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																					
nasal cavit		<10>				<10>				<10>				<10>				<10>			
	eosinophilic change:olfactory epithelium	0	0	0	0	1	0	0	0	1	0	0	0	3	0	0	0	3	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 30 )	( 0 )	( 0 )	( 0 )	( 30 )	( 0 )	( 0 )	( 0 )
	eosinophilic change:respiratory epithelium	1	0	0	0	3	0	0	0	7	0	0	0 *	10	0	0	0 **	10	0	0	0 **
		( 10 )	( 0 )	( 0 )	( 0 )	( 30 )	( 0 )	( 0 )	( 0 )	( 70 )	( 0 )	( 0 )	( 0 )	( 100 )	( 0 )	( 0 )	( 0 )	( 100 )	( 0 )	( 0 )	( 0 )
	respiratory metaplasia:olfactory epithelium	0	0	0	0	1	0	0	0	8	0	0	0 **	8	2	0	0 **	8	2	0	0 **
		( 0 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 80 )	( 0 )	( 0 )	( 0 )	( 80 )	( 20 )	( 0 )	( 0 )	( 80 )	( 20 )	( 0 )	( 0 )
	desquamation:olfactory epithelium	0	0	0	0	0	0	0	0	2	0	0	0	1	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 20 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )
	squamous cell metaplasia:respiratory epithelium	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	atrophy:olfactory epithelium	0	0	0	0	2	0	0	0	10	0	0	0 **	10	0	0	0 **	10	0	0	0 **
		( 0 )	( 0 )	( 0 )	( 0 )	( 20 )	( 0 )	( 0 )	( 0 )	( 100 )	( 0 )	( 0 )	( 0 )	( 100 )	( 0 )	( 0 )	( 0 )	( 100 )	( 0 )	( 0 )	( 0 )

[Hematopoietic system]

spleen		<10>				<10>				<10>				<10>			
	deposit of hemosiderin	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
		( 10 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe

< a > a : Number of animals examined at the site

b : Number of animals with lesion

( c ) c : b / a \* 100

Significant difference ; \* : P ≤ 0.05 \*\* : P ≤ 0.01 Test of Chi Square



STUDY NO. : 0317  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
SACRIFICED ANIMALS ( 14W)

PAGE : 8

		40ppm				80ppm			
		10				10			
		Grade				Grade			
Organ	Findings	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]									
nasal cavit		<10>				<10>			
	eosinophilic change:olfactory epithelium	9	0	0	0 **	10	0	0	0 **
		( 90)	( 0)	( 0)	( 0)	(100)	( 0)	( 0)	( 0)
	eosinophilic change:respiratory epithelium	4	5	0	0 **	4	6	0	0 **
		( 40)	( 50)	( 0)	( 0)	( 40)	( 60)	( 0)	( 0)
	respiratory metaplasia:olfactory epithelium	10	0	0	0 **	10	0	0	0 **
		(100)	( 0)	( 0)	( 0)	(100)	( 0)	( 0)	( 0)
	desquamation:olfactory epithelium	2	0	0	0	2	0	0	0
		( 20)	( 0)	( 0)	( 0)	( 20)	( 0)	( 0)	( 0)
	squamous cell metaplasia:respiratory epithelium	0	0	0	0	1	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)
	atrophy:olfactory epithelium	6	4	0	0 **	3	7	0	0 **
		( 60)	( 40)	( 0)	( 0)	( 30)	( 70)	( 0)	( 0)

[Hematopoietic system]

spleen	deposit of hemosiderin	<10>				< 9>			
		1	0	0	0	0	0	0	0
		( 10)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe  
< a > a : Number of animals examined at the site  
b : Number of animals with lesion  
( c ) c : b / a \* 100  
Significant difference ; \* : P ≤ 0.05 \*\* : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 SACRIFICED ANIMALS ( 14W)

PAGE : 9

Organ	Findings	Group Name No. of Animals on Study Grade	0ppm				5ppm				10ppm				20ppm			
			10				10				10				10			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																		
Liver	granulation		<10>				<10>				<10>				<10>			
			1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 10)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
[Urinary system]																		
kidney	hydronephrosis		<10>				<10>				<10>				<10>			
			0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)
[Nervous system]																		
brain	epidermal cyst		<10>				<10>				<10>				<10>			
			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe

< a > a : Number of animals examined at the site

b : Number of animals with lesion

( c ) c : b / a \* 100

Significant difference ; \* :  $P \leq 0.05$  \*\* :  $P \leq 0.01$  Test of Chi Square

(HPT150)

BAIS3

STUDY NO. : 0317  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)  
 SACRIFICED ANIMALS ( 14W)

PAGE : 10

Organ	Findings	Group Name		40ppm				80ppm			
		No. of Animals on Study		10				10			
		Grade		1	2	3	4	1	2	3	4
				(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Digestive system]

liver	granulation	<10>				<10>			
		1	0	0	0	0	0	0	0
		( 10)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

[Urinary system]

kidney	hydronephrosis	<10>				<10>			
		1	0	0	0	0	0	0	0
		( 10)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

[Nervous system]

brain	epidermal cyst	<10>				<10>			
		0	0	0	0	1	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe

< a > a : Number of animals examined at the site

b b : Number of animals with lesion

( c ) c : b / a \* 100

Significant difference ; \* :  $P \leq 0.05$  \*\* :  $P \leq 0.01$  Test of Chi Square

## APPENDIX K 1

### IDENTITY OF GLYCIDOL IN THE 13 - WEEK INHALATION STUDY

## IDENTITY OF GLYCIDOL IN THE 13-WEEK INHALATION STUDY

A. Test Substance Lot No.: LER5803

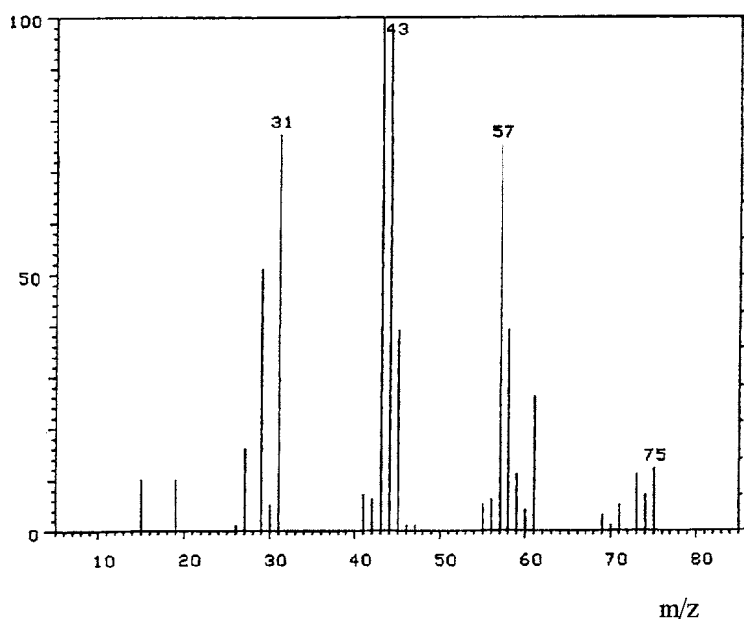
## 1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

<u>Determined</u> Peak(m/z)	<u>Literature Value</u> * Peak(m/z)
31	31
43	43
44	44
57	57
73	73
75	

Results: The mass spectrum was consistent with literature spectrum.

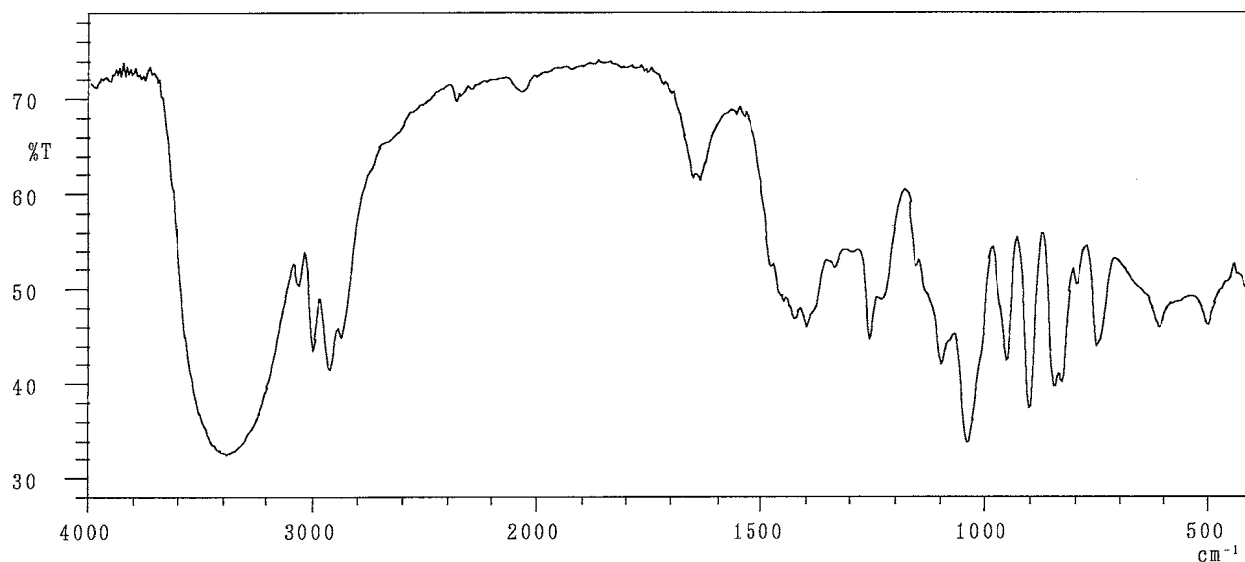
(\*Fred W. McLafferty (1994) Wiley Registry of Mass Spectral Data, 6th edition.  
John Wiley and Sons, Inc. (U.S.), Entry Number 1733)

## Infrared Spectrometry

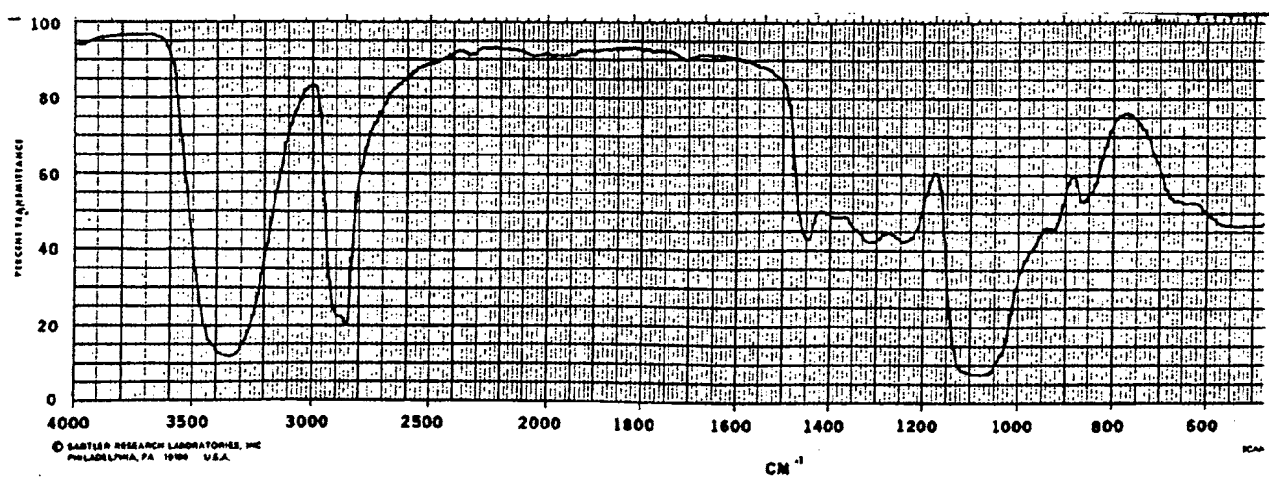
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution :  $4\text{ cm}^{-1}$



Infrared Spectrum of Test Substance



Infrared Spectrum of Glycidol (literature spectrum\*)

Results: The infrared spectrum was consistent with literature spectrum.

(\*William W. Simons (1978) The Sadtler Handbook of Infrared Spectra.  
Sadtler Research Laboratories, Inc. (U.K.), pp.480)

2. Conclusions: The result of the mass spectrum and the infrared spectrum agreed with the literature values. Consequently, the test substance was identified as glycidol.

B. Test Substance Lot No.: LEQ5980

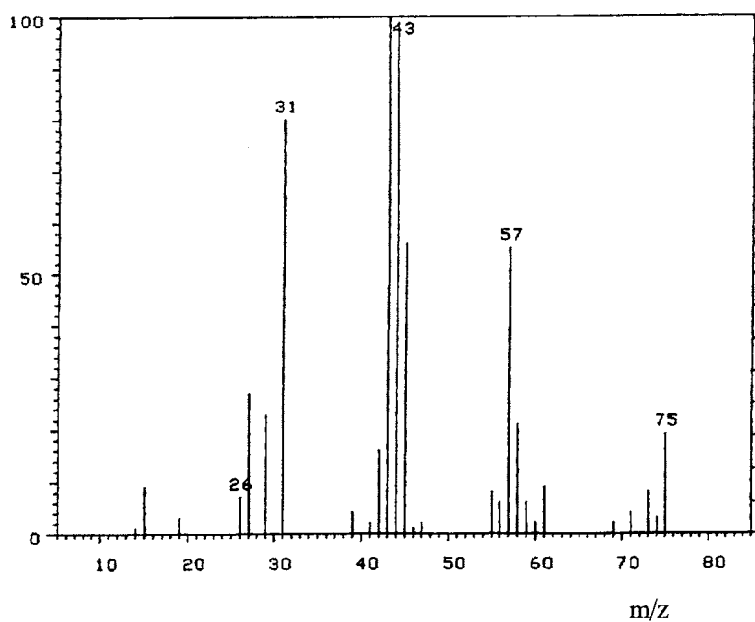
1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

<u>Determined</u> Peak(m/z)	<u>Literature Value</u> * Peak(m/z)
31	31
43	43
44	44
57	57
73	73
75	

Results: The mass spectrum was consistent with literature spectrum.

(\*Fred W. McLafferty (1994) Wiley Registry of Mass Spectral Data, 6th edition.  
John Wiley and Sons, Inc. (U.S.), Entry Number 1733)

### Infrared Spectrometry

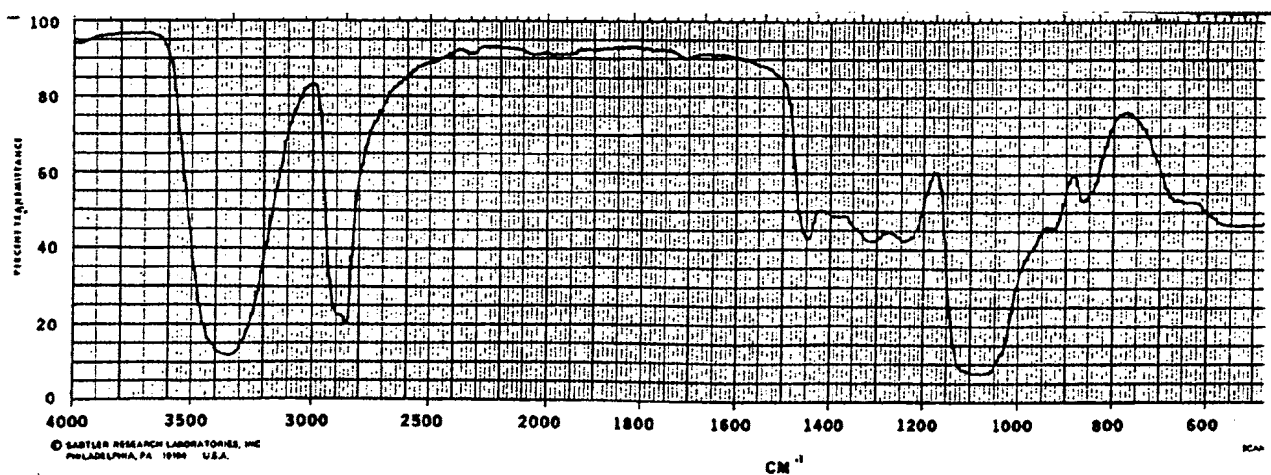
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution :  $4\text{ cm}^{-1}$



Infrared Spectrum of Test Substance



Infrared Spectrum of Glycidol (literature spectrum\*)

Results: The infrared spectrum was consistent with literature spectrum.

(\*William W. Simons (1978) The Sadtler Handbook of Infrared Spectra.  
Sadtler Research Laboratories, Inc. (U.K.), pp.480)

2. Conclusions: The result of the mass spectrum and the infrared spectrum agreed with the literature values. Consequently, the test substance was identified as glycidol.



## APPENDIX K 2

### STABILITY OF GLYCIDOL IN THE 13 - WEEK INHALATION STUDY

## STABILITY OF GLYCIDOL IN THE 13-WEEK INHALATION STUDY

A. Test Substance Lot No.: LER5803

1. Sample: This lot was used from 1996.9.11 to 1996.10.14. Test substance was stored at room temperature.

## 2. Gas Chromatography

Instrument : Hewlett Packard 6890  
Column : Methyl Silicone (0.53 mm  $\phi$   $\times$  60 m)  
Column Temperature : 150°C  
Flow Rate : 10 mL/min  
Detector : FID (Flame Ionization Detector)  
Injection Volume : 1  $\mu$ L

Results: Gas chromatography indicated one major peak (peak No.3) and two impurities (peak No.1,2 < 1% of total area) analyzed at 1996.8.30 and one major peak (peak No.3) and two impurities (peak No.1,2 < 1% of total area) analyzed at 1996.10.15. No new trace impurity peak in the test substance analyzed at 1996.10.15 was detected.

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
1996.08.30	1	1.89	0.15
	2	2.12	0.23
	3	2.52	99.62
1996.10.15	1	1.90	0.14
	2	2.13	0.23
	3	2.52	99.63

4. Conclusions: The results indicated that the test substance did not change when stored at room temperature during this period (for about 2 months).

B. Test Substance Lot No.: LEQ5980

1. Sample: This lot was used from 1996.10.15 to 1996.12.10. Test substance was stored at room temperature.

2. Gas Chromatography

Instrument : Hewlett Packard 6890  
Column : Methyl Silicone (0.53 mm  $\phi$   $\times$  60 m)  
Column Temperature : 150°C  
Flow Rate : 10 ml/min  
Detector : FID (Flame Ionization Detector)  
Injection Volume : 1  $\mu$ L

Results: Gas chromatography indicated one major peak (peak No.3) and two impurities (peak No.1,2 < 1% of total area) analyzed at 1996.10.11 and one major peak (peak No.3) and two impurities (peak No.1,2 < 1% of total area) analyzed at 1996.12.11. No new trace impurity peak in the test substance analyzed at 1996.12.11 was detected.

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
1996.10.11	1	1.82	0.14
	2	2.12	0.23
	3	2.52	99.63
1996.12.11	1	1.89	0.14
	2	2.12	0.23
	3	2.52	99.63

4. Conclusions: The results indicated that the test substance did not change when stored at room temperature during this period (for about 2 months).

## APPENDIX L 1

### CONCENTRATION OF GLYCIDL IN THE INHALATION CHAMBER OF THE 13-WEEK INHALATION STUDY

CONCENTRATION OF GLYCIDOL IN THE INHALATION CHAMBER OF THE 13-WEEK INHALATION STUDY

Group Name	Concentration(ppm)
	Mean $\pm$ S.D.
Control	0.0 $\pm$ 0.0
5.0ppm	5.0 $\pm$ 0.1
10.0ppm	10.2 $\pm$ 0.1
20.0ppm	20.2 $\pm$ 0.2
40.0ppm	40.1 $\pm$ 0.5
80.0ppm	80.0 $\pm$ 0.9

## APPENDIX L 2

### ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 13 - WEEK INHALATION STUDY OF GLYCIDOL

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 13-WEEK INHALATION STUDY OF GLYCIDOL

Group Name	Temperature(°C)	Humidity(%)	Ventilation Rate(L/min)	Air Change(time/h)
	Mean $\pm$ S.D.	Mean $\pm$ S.D.	Mean $\pm$ S.D.	Mean
Control	22.2 $\pm$ 0.2	55.9 $\pm$ 0.7	104.3 $\pm$ 0.5	12.0
25ppm	21.8 $\pm$ 0.2	55.9 $\pm$ 1.9	104.2 $\pm$ 0.8	12.0
50ppm	22.0 $\pm$ 0.1	53.1 $\pm$ 1.3	104.6 $\pm$ 0.8	12.1
100ppm	22.1 $\pm$ 0.2	52.7 $\pm$ 2.4	104.7 $\pm$ 0.5	12.1
200ppm	22.0 $\pm$ 0.3	52.1 $\pm$ 2.6	104.4 $\pm$ 0.9	12.0
400ppm	22.0 $\pm$ 0.1	51.1 $\pm$ 4.0	104.6 $\pm$ 0.5	12.1

## APPENDIX M 1

### METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS IN THE 13 - WEEK INHALATION STUDY OF GLYCIDOL



METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS  
IN THE 13-WEEK INHALATION STUDY OF GLYCIDOL

Item	Method
Hematology	
Red blood cell (RBC)	Light scattering method <sup>1)</sup>
Hemoglobin (Hgb)	Cyanmethemoglobin method <sup>1)</sup>
Hematocrit (Hct)	Calculated as $RBC \times MCV/10$ <sup>1)</sup>
Mean corpuscular volume (MCV)	Light scattering method <sup>1)</sup>
Mean corpuscular hemoglobin (MCH)	Calculated as $Hgb/RBC \times 10$ <sup>1)</sup>
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as $Hgb/Hct \times 100$ <sup>1)</sup>
Platelet	Light scattering method <sup>1)</sup>
White blood cell (WBC)	Light scattering method <sup>1)</sup>
Differential WBC	Pattern recognition method <sup>2)</sup> (May-Grunwald-Giemsa staining)
Biochemistry	
Total protein (TP)	Biuret method <sup>3)</sup>
Albumin (Alb)	BCG method <sup>3)</sup>
A/G ratio	Calculated as $Alb/(TP - Alb)$ <sup>3)</sup>
T-bilirubin	Alkaline azobilirubin method <sup>3)</sup>
Glucose	Enzymatic method (GLK·G-6-PDH) <sup>3)</sup>
T-cholesterol	Enzymatic method (CE·COD·POD) <sup>3)</sup>
Triglyceride	Enzymatic method (LPL·GK·GPO·POD) <sup>3)</sup>
Phospholipid	Enzymatic method (PLD·COD·POD) <sup>3)</sup>
Glutamic oxaloacetic transaminase (GOT)	UV·Rate method <sup>3)</sup>
Glutamic pyruvic transaminase (GPT)	UV·Rate method <sup>3)</sup>
Lactate dehydrogenase (LDH)	UV·Rate method <sup>3)</sup>
Alkaline phosphatase (ALP)	p-Nitrophenylphosphate method <sup>3)</sup>
$\gamma$ -Glutamyl transpeptidase ( $\gamma$ -GTP)	L- $\gamma$ -Glutamyl-p-nitroanilide method <sup>3)</sup>
Creatine phosphokinase (CPK)	UV·Rate method <sup>3)</sup>
Urea nitrogen	Enzymatic method (Urease·GLDH) <sup>3)</sup>
Sodium	Ion selective electrode method <sup>3)</sup>
Potassium	Ion selective electrode method <sup>3)</sup>
Chloride	Ion selective electrode method <sup>3)</sup>
Calcium	OCPC method <sup>3)</sup>
Inorganic phosphorus	Enzymatic method (PNP·XOD·POD) <sup>3)</sup>
Urinalysis	
pH, Protein, Glucose, Ketone body, Occult Blood, Urobilinogen	Urinalysis reagent paper method <sup>4)</sup>

1) Automatic blood cell analyzer (Technicon H·1 : Technicon Instruments Corporation, USA)

2) Automatic blood cell differential analyzer (Hitachi 8200 : Hitachi, Ltd., Japan)

3) Automatic analyzer (Hitachi 7070 : Hitachi, Ltd., Japan)

4) Ames reagent strips for urinalysis (Uro-Labstix : Bayer-Sankyo Co., Ltd., Japan)

## APPENDIX M 2

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE  
13 - WEEK INHALATION STUDY OF GLYCIDOL

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY  
IN THE 13-WEEK INHALATION STUDY OF GLYCIDOL

Item	Unit	Decimal place
Hematology		
Red blood cell (RBC)	$\times 10^6 / \mu\text{L}$	2
Hemoglobin	g/dL	1
Hematocrit	%	1
Mean corpuscular volume (MCV)	fL	1
Mean corpuscular hemoglobin (MCH)	pg	1
Mean corpuscular hemoglobin concentration (MCHC)	g/dL	1
Platelet	$\times 10^3 / \mu\text{L}$	0
White blood cell (WBC)	$\times 10^3 / \mu\text{L}$	2
Differential WBC	%	0
Biochemistry		
Total protein	g/dL	1
Albumin	g/dL	1
A/G ratio	—	1
T-bilirubin	mg/dL	2
Glucose	mg/dL	0
T-cholesterol	mg/dL	0
Triglyceride	mg/dL	0
Phospholipid	mg/dL	0
Glutamic oxaloacetic transaminase (GOT)	IU/L	0
Glutamic pyruvic transaminase (GPT)	IU/L	0
Lactate dehydrogenase (LDH)	IU/L	0
Alkaline phosphatase (ALP)	IU/L	0
$\gamma$ -Glutamyl transpeptidase ( $\gamma$ -GTP)	IU/L	0
Creatine phosphokinase (CPK)	IU/L	0
Urea nitrogen	mg/dL	1
Sodium	mEq/L	0
Potassium	mEq/L	1
Chloride	mEq/L	0
Calcium	mg/dL	1
Inorganic phosphorus	mg/dL	1