

アリルクロリドのマウスを用いた  
吸入による 13 週間毒性試験報告書

試験番号 : 0341

## APPENDIX

## APPENDIXES

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## APPENDIX A 1

CLINICAL OBSERVATION : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0341  
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
DEATH	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	12.5 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	25 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	50 ppm	0	0	0	1	1	1	1	1	1	1	1	1	1
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
INTERNAL MASS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	12.5 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	25 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1
	50 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

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## APPENDIX A 2

CLINICAL OBSERVATION : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)

STUDY NO. : 0341  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : FEMALE

PAGE : 2

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
INTERNAL MASS	0 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	12.5 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	25 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	50 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	100 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	200 ppm	0	0	0	0	0	0	0	0	0	0	0	0	1

(HAN190)

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## APPENDIX B 1

BODY WEIGHT CHANGES :SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0341  
 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
0 ppm	22.0± 0.8	22.4± 3.1	24.4± 1.1	25.0± 1.1	26.0± 1.1	26.5± 1.2	26.8± 1.3
12.5 ppm	22.0± 0.8	23.4± 1.0	24.3± 1.2	24.8± 1.2	25.7± 1.2	26.4± 1.4	26.6± 1.6
25 ppm	22.0± 0.7	22.8± 0.7	23.7± 0.7	24.4± 0.7	24.9± 0.6	25.7± 0.9	25.6± 0.9
50 ppm	22.0± 0.7	23.1± 0.9	23.7± 0.6	24.2± 1.1	24.7± 0.6	25.4± 0.6	25.3± 0.6*
100 ppm	22.0± 0.9	23.4± 1.0	24.1± 0.9	24.8± 1.3	25.6± 1.2	26.4± 1.3	26.9± 1.3
200 ppm	22.0± 0.8	23.2± 0.9	24.2± 0.9	25.0± 1.0	25.5± 1.0	26.1± 0.8	26.4± 0.9

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

Test of Dunnett

BODY WEIGHT CHANGES (SUMMARY)  
ALL ANIMALS

[illegible]

BAIS 3

## APPENDIX B 2

BODY WEIGHT CHANGES : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)

BODY WEIGHT CHANGES (SUMMARY)  
ALL ANIMALS

Group Name	Administration week-day						
	0-0	1-7	2-7	3-7	4-7	5-7	6-7
0 ppm	18.5± 0.7	19.4± 0.7	20.4± 0.9	20.9± 0.9	22.2± 0.9	22.4± 1.1	23.1± 1.0
12.5 ppm	18.6± 0.7	19.5± 0.7	20.1± 1.0	21.1± 1.0	21.7± 0.9	22.6± 0.9	23.1± 0.7
25 ppm	18.5± 0.7	19.4± 0.7	20.4± 1.1	21.1± 1.0	21.5± 0.6	22.2± 0.9	22.9± 1.3
50 ppm	18.6± 0.6	19.1± 0.6	19.8± 0.7	21.1± 0.6	21.5± 0.6	22.3± 1.0	22.7± 0.7
100 ppm	18.5± 0.7	19.4± 0.7	20.3± 1.0	20.7± 0.7	21.7± 0.8	22.2± 0.8	22.7± 0.7
200 ppm	18.6± 0.6	19.0± 0.6	20.2± 0.6	21.2± 0.8	21.2± 0.8	21.7± 0.7	22.3± 0.8

Test of Dunnett

BAIS 3

STUDY NO. : 0341  
 ANIMAL : MOUSE Crj:BDF1  
 UNIT : g  
 REPORT TYPE : A1 13  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 4

Group Name	Administration 7-7	week-day 8-7	9-7	10-7	11-7	12-7	13-7
0 ppm	23.2± 0.8	23.1± 0.9	23.3± 1.1	23.6± 0.9	24.3± 1.3	24.5± 1.3	24.3± 1.2
12.5 ppm	23.3± 1.6	23.8± 0.8	24.0± 0.7	24.2± 1.2	24.6± 1.7	24.6± 0.9	25.2± 1.3
25 ppm	23.4± 1.0	23.3± 1.1	23.8± 1.1	23.8± 1.4	23.9± 1.3	24.9± 2.1	24.3± 1.4
50 ppm	23.4± 1.2	23.0± 1.0	23.2± 1.0	23.8± 1.1	23.8± 1.2	23.8± 1.0	24.3± 1.2
100 ppm	23.3± 0.9	23.4± 1.2	23.4± 1.2	23.5± 1.2	23.7± 1.2	24.0± 1.2	24.1± 1.1
200 ppm	23.1± 0.7	23.0± 0.9	22.9± 0.9	23.1± 1.0	23.0± 0.5	23.9± 0.3	24.1± 0.9

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. : 0341  
 ANIMAL : MOUSE Crj: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)
0 ppm	4.0± 0.7	4.2± 0.5	4.2± 0.2	4.3± 0.2	4.2± 0.2	4.3± 0.2	4.3± 0.2
12.5 ppm	4.3± 0.2	4.2± 0.3	4.2± 0.2	4.4± 0.2	4.5± 0.3	4.4± 0.2	4.5± 0.3
25 ppm	4.0± 0.2	4.1± 0.3	4.2± 0.2	4.2± 0.3	4.4± 0.3	4.3± 0.2	4.5± 0.3
50 ppm	4.2± 0.2	4.1± 0.4	4.2± 0.3	4.2± 0.2	4.3± 0.2	4.2± 0.2	4.3± 0.1
100 ppm	4.2± 0.2	3.9± 0.4	4.3± 0.4	4.2± 0.3	4.3± 0.3	4.2± 0.3	4.3± 0.2
200 ppm	4.1± 0.3	4.2± 0.4	4.4± 0.3	4.2± 0.3	4.4± 0.3	4.5± 0.2	4.6± 0.2*

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

Test of Dunnett



STUDY NO. : 0341  
 ANIMAL : MOUSE Crj:BDF1  
 UNIT : g  
 REPORT TYPE : A1 13  
 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 2

Group Name	Administration 8-7(7)	week-day(effective) 9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)
0 ppm	4.4± 0.2	4.3± 0.2	4.4± 0.2	4.3± 0.2	4.4± 0.2	4.5± 0.2
12.5 ppm	4.5± 0.3	4.6± 0.2	4.7± 0.2*	4.6± 0.2	4.7± 0.2*	4.6± 0.3
25 ppm	4.3± 0.3	4.4± 0.2	4.4± 0.2	4.6± 0.2	4.5± 0.2	4.6± 0.2
50 ppm	4.2± 0.1	4.4± 0.2	4.4± 0.1	4.4± 0.2	4.5± 0.2	4.5± 0.2
100 ppm	4.1± 0.2*	4.3± 0.3	4.4± 0.2	4.4± 0.2	4.4± 0.2	4.3± 0.3
200 ppm	4.4± 0.2	4.5± 0.3	4.6± 0.2	4.4± 0.3	4.5± 0.3	4.6± 0.3
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)

FOOD CONSUMPTION CHANGES (SUMMARY)  
ALL ANIMALS

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)
0 ppm	3.7± 0.3	3.6± 0.2	3.9± 0.2	4.0± 0.2	4.1± 0.3	4.1± 0.3	4.4± 0.3
12.5 ppm	3.8± 0.3	3.6± 0.2	3.9± 0.3	4.0± 0.2	4.1± 0.2	4.1± 0.3	4.4± 0.3
25 ppm	3.6± 0.2	3.7± 0.2	3.8± 0.2	3.9± 0.3	4.1± 0.3	4.2± 0.3	4.2± 0.2
50 ppm	3.5± 0.2	3.7± 0.2	3.8± 0.2	3.9± 0.3	4.0± 0.2	4.1± 0.2	4.3± 0.3
100 ppm	3.6± 0.3	3.6± 0.3	3.8± 0.2	3.9± 0.2	4.0± 0.3	4.1± 0.2	4.3± 0.2
200 ppm	3.4± 0.3	3.7± 0.2	3.9± 0.2	3.8± 0.2	4.0± 0.3	4.1± 0.2	4.2± 0.2

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

BAIS 3

STUDY NO. : 0341  
 ANIMAL : MOUSE Crj:BDF1  
 UNIT : g  
 REPORT TYPE : A1 13  
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 4

Group Name	Administration 8-7(7)	week-day(effective) 9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)
0 ppm	4.4± 0.3	4.3± 0.2	4.3± 0.3	4.5± 0.3	4.4± 0.4	4.4± 0.3
12.5 ppm	4.4± 0.3	4.3± 0.3	4.3± 0.3	4.6± 0.7	4.2± 0.4	4.4± 0.3
25 ppm	4.2± 0.3	4.2± 0.3	4.3± 0.2	4.4± 0.2	4.3± 0.5	4.3± 0.2
50 ppm	4.1± 0.2*	4.2± 0.2	4.1± 0.2	4.1± 0.2*	4.1± 0.2	4.3± 0.2
100 ppm	4.1± 0.2*	4.2± 0.3	4.1± 0.3	4.2± 0.3	4.2± 0.2	4.3± 0.3
200 ppm	4.1± 0.2**	4.2± 0.2	4.2± 0.2	4.3± 0.3	4.3± 0.2	4.3± 0.3
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett						
(HAN260)						BAIS3

## APPENDIX D 1

HEMATOLOGY : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0341  
 ANIMAL : MOUSE Crj:BDF1  
 SAMPLING DATE : 014-1  
 SEX : MALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)  
 ALL ANIMALS ( 14W)

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	
0 ppm	10	10.72±	0.21	15.8±	0.3	50.1±	0.9	46.7±	0.4	14.8±	0.3	31.6±	0.5	1382±	25
12.5 ppm	10	10.73±	0.37	15.7±	0.5	49.9±	1.6	46.6±	0.5	14.6±	0.1	31.3±	0.2	1284±	78*
25 ppm	9	10.73±	0.26	15.7±	0.4	49.7±	1.2	46.3±	0.9	14.6±	0.3	31.6±	0.3	1275±	90*
50 ppm	8	10.55±	0.26	15.4±	0.4	49.2±	1.4	46.7±	0.5	14.6±	0.3	31.3±	0.6	1312±	81
100 ppm	10	10.38±	0.37	15.4±	0.5	48.8±	2.0	47.0±	0.9	14.8±	0.5	31.5±	1.2	1304±	77
200 ppm	10	10.20±	0.37**	15.2±	0.6*	49.3±	1.8	48.4±	0.6**	14.9±	0.2	30.7±	0.3**	1392±	94

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

Test of Dunnett

STUDY NO. : 0341  
ANIMAL : MOUSE Crj:BDF1  
SAMPLING DATE : 014-1  
SEX : MALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)  
ALL ANIMALS ( 14W)

PAGE : 2

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
0 ppm	10	1.81±	1.03	0±	0	14±	4	1±	1	0±	0	4±	3	80±	3	0±	0
12.5 ppm	10	1.75±	1.03	0±	0	15±	5	1±	1	0±	0	4±	2	80±	5	0±	0
25 ppm	9	1.09±	0.66	0±	1	17±	7	1±	1	0±	0	2±	1	80±	7	0±	0
50 ppm	8	1.19±	1.03	1±	1	18±	6	1±	1	0±	0	3±	1	78±	7	0±	0
100 ppm	10	1.86±	1.37	0±	0	17±	3	1±	1	0±	0	4±	3	78±	5	0±	0
200 ppm	10	1.90±	1.26	0±	0	13±	2	1±	1	0±	0	3±	1	82±	3	0±	1

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS3

## APPENDIX D 2

HEMATOLOGY : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)



STUDY NO. : 0341  
 ANIMAL : MOUSE Crl:BDF1  
 SAMPLING DATE : 014-1  
 SEX : FEMALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)  
 ALL ANIMALS ( 14W)

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>3</sup> /μl	
0 ppm	8	10.70±	0.37	15.8±	0.4	49.7±	1.6	46.4±	0.6	14.8±	0.3	31.9±	0.5	1152±	87
12.5 ppm	10	10.57±	0.44	15.8±	0.6	49.1±	2.3	46.4±	0.5	14.9±	0.3	32.2±	0.7	1240±	64
25 ppm	10	10.54±	0.23	15.7±	0.4	48.8±	1.3	46.3±	0.5	14.9±	0.7	32.3±	1.5	1227±	72
50 ppm	10	10.61±	0.28	15.7±	0.5	49.2±	1.3	46.4±	0.4	14.8±	0.1	32.0±	0.2	1219±	55
100 ppm	10	10.56±	0.40	15.7±	0.5	49.6±	1.9	47.0±	0.4	14.9±	0.2	31.7±	0.6	1232±	107
200 ppm	10	10.11±	0.21**	15.3±	0.4	48.7±	1.2	48.2±	0.6**	15.2±	0.3	31.4±	0.4	1242±	64

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

Test of Dunnett

(HCL070)

BAIS3

STUDY NO. : 0341  
 ANIMAL : MOUSE Crj:BDF1  
 SAMPLING DATE : 014-1  
 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	
0 ppm	8	1.44±	1.18	0±	0	21±	6	0±	1	0±	0	2±	1	76±	7	0±	0
12.5 ppm	10	1.43±	0.94	0±	0	19±	6	1±	1	0±	0	3±	1	77±	7	0±	0
25 ppm	10	0.86±	0.79	0±	0	23±	13	1±	1	0±	0	3±	2	73±	11	0±	0
50 ppm	10	1.34±	1.19	0±	0	18±	8	1±	1	0±	0	3±	2	78±	7	0±	0
100 ppm	10	1.41±	1.28	0±	0	22±	7	1±	1	0±	0	3±	2	73±	8	0±	0
200 ppm	10	1.42±	0.71	0±	0	19±	6	1±	1	0±	0	2±	1	77±	7	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. : 0341  
ANIMAL : MOUSE Crj:BDF1  
SAMPLING DATE : 014-3  
SEX : MALE

BIOCHEMISTRY (SUMMARY)  
ALL ANIMALS ( 14W)

REPORT TYPE : A1

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	
0 ppm	10	5.0±	0.1	2.9±	0.1	1.3±	0.1	0.14±	0.01	189±	31	75±	4	24±	5
12.5 ppm	10	4.8±	0.1	2.8±	0.1	1.3±	0.1	0.14±	0.01	180±	41	70±	7	23±	11
25 ppm	9	4.9±	0.2	2.8±	0.1	1.4±	0.1	0.14±	0.01	173±	42	74±	7	16±	7*
50 ppm	9	4.9±	0.2	2.8±	0.1	1.4±	0.1	0.14±	0.03	168±	32	68±	9	14±	5**
100 ppm	10	5.0±	0.2	2.9±	0.1	1.3±	0.1	0.14±	0.01	180±	38	78±	10	14±	5**
200 ppm	10	4.9±	0.1	2.8±	0.1	1.3±	0.1	0.15±	0.01	175±	40	78±	11	16±	6

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

Test of Dunnett

STUDY NO. : 0341  
 ANIMAL : MOUSE Crj:BDF1  
 SAMPLING DATE : 014-3  
 SEX : MALE

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS ( 14W)

REPORT TYPE : A1

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	
0 ppm	10	158±	7	45±	5	18±	3	193±	30	155±	5	1±	1	47±	15
12.5 ppm	10	148±	15	49±	10	20±	3	192±	35	159±	12	2±	1	49±	19
25 ppm	9	154±	16	56±	16	29±	24**	205±	32	164±	14	1±	1	42±	12
50 ppm	9	139±	16	50±	5	22±	5	243±	88	161±	5	1±	1	61±	29
100 ppm	10	157±	20	42±	7	18±	4	172±	27	161±	13	1±	1	34±	10
200 ppm	10	150±	18	40±	3	17±	2	187±	28	144±	8	1±	1	30±	6*

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

Test of Dunnett

(HCL074)

BAIS3

STUDY NO. : 0341  
 ANIMAL : MOUSE C<sub>7</sub>:BDF1  
 SAMPLING DATE : 014-3  
 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	
0 ppm	10	25.9±	2.3	150±	1	4.8±	0.2	122±	2	8.8±	0.2	7.2±	0.9
12.5 ppm	10	25.0±	2.6	151±	2	4.5±	0.4	122±	3	8.7±	0.2	7.0±	1.0
25 ppm	9	27.8±	7.2	151±	2	4.5±	0.6	122±	3	8.7±	0.2	6.7±	0.7
50 ppm	9	26.0±	3.4	151±	1	4.8±	0.6	123±	2	8.6±	0.3	7.2±	1.2
100 ppm	10	27.8±	5.8	151±	1	4.3±	0.3	121±	3	8.8±	0.2	6.7±	1.0
200 ppm	10	24.1±	5.4	151±	2	4.6±	0.3	122±	2	8.6±	0.2	6.8±	1.0

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. : 0341

ANIMAL : MOUSE Crj:BDF1

SAMPLING DATE : 014-3

SEX : FEMALE

REPORT TYPE : A1

## BIOCHEMISTRY (SUMMARY)

ALL ANIMALS ( 14W)

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	
0 ppm	9	5.2±	0.1	3.2±	0.1	1.6±	0.1	0.13±	0.02	154±	28	68±	9	13±	7
12.5 ppm	10	5.1±	0.1	3.1±	0.1	1.6±	0.1	0.13±	0.01	157±	23	73±	9	18±	4
25 ppm	10	5.1±	0.1	3.1±	0.1	1.6±	0.1	0.14±	0.01	161±	28	64±	7	13±	7
50 ppm	10	5.3±	0.1	3.2±	0.1	1.5±	0.1	0.13±	0.01	171±	22	72±	11	12±	5
100 ppm	10	5.2±	0.1	3.1±	0.1	1.6±	0.1	0.14±	0.02	156±	30	71±	9	12±	4
200 ppm	10	5.0±	0.1*	3.0±	0.1*	1.6±	0.1	0.14±	0.01	164±	20	76±	5	10±	3

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

Test of Dunnett

(HCL074)

BAIS3



STUDY NO. : 0341  
 ANIMAL : MOUSE Crj:BDF1  
 SAMPLING DATE : 014-3  
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)  
 ALL ANIMALS ( 14W)

REPORT TYPE : A1

PAGE : 5

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		GOT I U / l		GPT I U / l		LDH I U / l		ALP I U / l		G-GTP I U / l		CPK I U / l	
0 ppm	9	133±	27	77±	37	28±	10	311±	182	263±	51	1±	1	141±	155
12.5 ppm	10	148±	23	64±	17	23±	4	252±	105	251±	47	2±	1	104±	108
25 ppm	10	130±	18	70±	19	26±	4	286±	88	251±	23	2±	1	119±	115
50 ppm	10	140±	24	59±	19	23±	7	236±	82	230±	31	2±	1	63±	51
100 ppm	10	135±	25	75±	41	24±	8	326±	200	244±	34	1±	1	85±	83
200 ppm	10	138±	14	53±	10	22±	6	229±	39	216±	18*	1±	1	46±	29**

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS3

STUDY NO. : 0341  
ANIMAL : MOUSE Crj:BDF1  
SAMPLING DATE : 014-3  
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	
0 ppm	9	25.0±	6.3	150±	2	4.6±	0.5	123±	3	8.8±	0.3	7.2±	1.3
12.5 ppm	10	21.1±	4.8	150±	2	4.7±	0.4	122±	3	9.0±	0.2	6.4±	0.8
25 ppm	10	21.1±	2.7	150±	1	4.7±	0.4	122±	2	8.9±	0.2	6.7±	0.7
50 ppm	10	21.7±	5.3	150±	2	4.8±	0.5	121±	3	9.0±	0.2	6.6±	0.4
100 ppm	10	24.6±	5.5	150±	3	4.5±	0.4	123±	4	8.9±	0.2	6.6±	0.9
200 ppm	10	22.3±	3.7	150±	2	4.4±	0.4	121±	3	8.9±	0.2	6.1±	0.7

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

\*\* :  $P \leq 0.01$

Test of Dunnett

## APPENDIX F 1

URINALYSIS : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0341  
 ANIMAL : MOUSE Crj:BDF1  
 SAMPLING DATE : 013-6  
 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+	4+
0 ppm	10	0	0	0	1	0	8	1		0	0	3	7	0	0		10	0	0	0	0	0		0	6	4	0	0	0		10	0	0	0	0	0	
12.5 ppm	10	0	0	1	1	4	4	0		0	0	2	8	0	0		10	0	0	0	0	0		0	6	4	0	0	0		10	0	0	0	0	0	
25 ppm	10	0	0	0	0	5	4	1		0	0	5	5	0	0		10	0	0	0	0	0		0	8	2	0	0	0		10	0	0	0	0	0	
50 ppm	9	0	1	0	0	4	4	0		0	0	5	4	0	0		9	0	0	0	0	0		0	5	4	0	0	0		9	0	0	0	0	0	
100 ppm	10	0	0	1	1	5	3	0		0	0	3	6	1	0		10	0	0	0	0	0		0	9	1	0	0	0		10	0	0	0	0	0	
200 ppm	10	0	0	0	0	3	6	1		0	0	6	4	0	0		10	0	0	0	0	0		0	9	1	0	0	0		10	0	0	0	0	0	

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

Test of CHI SQUARE

(HCL101)

BAIS3

STUDY NO. : 0341

URINALYSIS

ANIMAL : MOUSE Crj:BDF1

SAMPLING DATE : 013-6

SEX : MALE

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Urobilinogen ± + 2+ 3+ 4+ CHI
------------	-------------------	----------------------------------

0 ppm	10	10 0 0 0 0
12.5 ppm	10	10 0 0 0 0
25 ppm	10	10 0 0 0 0
50 ppm	9	9 0 0 0 0
100 ppm	10	10 0 0 0 0
200 ppm	10	10 0 0 0 0

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

\*\* :  $P \leq 0.01$

Test of CHI SQUARE

(HCL101)

BATS3

## APPENDIX F 2

URINALYSIS : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)

STUDY NO. : 0341

ANIMAL : MOUSE Crj:BDF1

SAMPLING DATE : 013-6

SEX : FEMALE

REPORT TYPE : A1

## URINALYSIS

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+
0 ppm	10	0	1	2	0	1	6	0		0	1	8	1	0	0		10	0	0	0	0	0		3	5	1	1	0	0		10	0	0	0	0	
12.5 ppm	10	0	0	0	1	5	4	0		0	1	6	3	0	0		10	0	0	0	0	0		2	8	0	0	0	0		10	0	0	0	0	
25 ppm	10	0	0	1	0	6	3	0		0	0	6	4	0	0		10	0	0	0	0	0		1	6	3	0	0	0		10	0	0	0	0	
50 ppm	10	0	0	0	1	1	8	0		0	0	8	2	0	0		10	0	0	0	0	0		2	7	1	0	0	0		10	0	0	0	0	
100 ppm	10	0	0	1	3	2	4	0		0	0	8	2	0	0		10	0	0	0	0	0		1	9	0	0	0	0		10	0	0	0	0	
200 ppm	10	0	0	1	0	3	6	0		0	1	7	2	0	0		10	0	0	0	0	0		3	6	1	0	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. : 0341

URINALYSIS

ANIMAL : MOUSE Crj:BDF1

SAMPLING DATE : 013-6

SEX : FEMALE

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Urobilinogen ± + 2+ 3+ 4+ CHI
------------	-------------------	----------------------------------

0 ppm	10	10 0 0 0 0
12.5 ppm	10	10 0 0 0 0
25 ppm	10	10 0 0 0 0
50 ppm	10	10 0 0 0 0
100 ppm	10	10 0 0 0 0
200 ppm	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. : 0341  
ANIMAL : MOUSE CrJ:BDF1  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name	0 ppm	12.5 ppm	25 ppm	50 ppm
		NO. of Animals	0 (%)	0 (%)	0 (%)	1 (%)
spleen	black zone		- ( -)	- ( -)	- ( -)	1 (100)

(HPT080)

BAIS 3

STUDY NO. : 0341  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 2

Organ	Findings	Group Name	100 ppm	200 ppm
		NO. of Animals	0 (%)	0 (%)
spleen	black zone		- ( -)	- ( -)

(HPT080)

BAIS3

## APPENDIX G 2

GROSS FINDINGS : SUMMARY, MOUSE : MALE : SACRIFICED ANIMALS

(13 - WEEK STUDY)

STUDY NO. : 0341  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS ( 14W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	0 ppm		12.5 ppm		25 ppm		50 ppm	
			10	(%)	10	(%)	10	(%)	9	(%)
spleen	black zone		0	( 0)	1	( 10)	0	( 0)	1	( 11)
forestomach	ulcer		0	( 0)	0	( 0)	0	( 0)	0	( 0)
sl stomach	erosion		0	( 0)	0	( 0)	0	( 0)	0	( 0)
kidney	hydronephrosis		0	( 0)	0	( 0)	1	( 10)	0	( 0)

(HPT080)

BAIS3

STUDY NO. : 0341  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS ( 14W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	100 ppm	200 ppm
			10 (%)	10 (%)
spleen	black zone		0 ( 0)	0 ( 0)
forestomach	ulcer		0 ( 0)	1 ( 10)
sl stomach	erosion		0 ( 0)	1 ( 10)
kidney	hydronephrosis		2 ( 20)	0 ( 0)

(HPT080)

BAIS3

## APPENDIX G 3

GROSS FINDINGS : SUMMARY, MOUSE : FEMALE : SACRIFICED ANIMALS

(13 - WEEK STUDY)

STUDY NO. : 0341  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS ( 14W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	0 ppm		12.5 ppm		25 ppm		50 ppm	
			10	(%)	10	(%)	10	(%)	10	(%)
spleen	black zone		0	( 0)	0	( 0)	3	( 30)	0	( 0)
kidney	hydronephrosis		0	( 0)	0	( 0)	0	( 0)	1	( 10)
ovary	cyst		0	( 0)	1	( 10)	0	( 0)	0	( 0)

(HPT080)

BAIS 3



STUDY NO. : 0341  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : FEMALE

GROSS FINDINGS (SUMMARY)  
SACRIFICED ANIMALS ( 14W)

PAGE : 4

Organ	Findings	Group Name NO. of Animals	100 ppm		200 ppm	
			10	(%)	10	(%)
spleen	black zone		2	( 20)	1	( 10)
kidney	hydronephrosis		0	( 0)	1	( 10)
ovary	cyst		0	( 0)	0	( 0)

(HPT080)

BAIS 3

## APPENDIX H 1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0341  
 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
0 ppm	10	26.5± 1.6	0.031± 0.006	0.011± 0.003	0.216± 0.015	0.151± 0.017	0.164± 0.009
12.5 ppm	10	26.8± 2.7	0.035± 0.009	0.009± 0.001	0.227± 0.028	0.151± 0.012	0.158± 0.007
25 ppm	10	25.9± 1.4	0.029± 0.005	0.009± 0.001	0.210± 0.043	0.153± 0.011	0.159± 0.011
50 ppm	9	25.7± 0.9	0.032± 0.006	0.008± 0.001*	0.216± 0.051	0.152± 0.010	0.161± 0.009
100 ppm	10	26.0± 1.3	0.034± 0.006	0.011± 0.001	0.212± 0.023	0.149± 0.009	0.164± 0.009
200 ppm	10	26.0± 1.4	0.034± 0.003	0.010± 0.003	0.186± 0.029	0.143± 0.009	0.164± 0.009

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

Test of Dunnett

(HCL040)

BAIS3

STUDY NO. : 0341  
 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	
0 ppm	10	0.427±	0.021	0.043±	0.003	1.103±	0.042	0.433±	0.020
12.5 ppm	10	0.436±	0.017	0.046±	0.006	1.102±	0.067	0.435±	0.013
25 ppm	10	0.453±	0.134	0.046±	0.004	1.079±	0.041	0.439±	0.016
50 ppm	9	0.430±	0.019	0.044±	0.004	1.093±	0.047	0.429±	0.021
100 ppm	10	0.490±	0.147	0.049±	0.011	1.085±	0.030	0.437±	0.016
200 ppm	10	0.429±	0.016	0.047±	0.005	1.073±	0.041	0.423±	0.018

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

Test of Dunnett

(HCL040)

BAIS3

## APPENDIX H 2

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)

STUDY NO. : 0341  
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
0 ppm	10	20.3± 1.1	0.036± 0.007	0.013± 0.002	0.030± 0.008	0.128± 0.005	0.155± 0.012
12.5 ppm	10	21.1± 1.0	0.040± 0.006	0.013± 0.002	0.035± 0.007	0.126± 0.004	0.159± 0.010
25 ppm	10	20.7± 1.3	0.036± 0.004	0.012± 0.002	0.031± 0.005	0.128± 0.005	0.156± 0.012
50 ppm	10	20.7± 1.2	0.039± 0.007	0.012± 0.002	0.029± 0.004	0.123± 0.011	0.154± 0.013
100 ppm	10	20.2± 0.8	0.038± 0.007	0.012± 0.001	0.028± 0.003	0.121± 0.010	0.152± 0.011
200 ppm	10	20.1± 0.6	0.038± 0.003	0.012± 0.002	0.028± 0.004	0.120± 0.009*	0.156± 0.008

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

Test of Dunnett

(HCL040)

BAIS3

STUDY NO. : 0341  
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	
0 ppm	10	0.298±	0.011	0.052±	0.006	0.898±	0.092	0.447±	0.014
12.5 ppm	10	0.298±	0.015	0.054±	0.006	0.928±	0.091	0.456±	0.011
25 ppm	10	0.305±	0.020	0.052±	0.009	0.903±	0.065	0.451±	0.018
50 ppm	10	0.367±	0.230	0.054±	0.010	0.902±	0.063	0.449±	0.007
100 ppm	10	0.310±	0.014	0.050±	0.007	0.879±	0.079	0.445±	0.018
200 ppm	10	0.391±	0.263	0.056±	0.007	0.886±	0.041	0.429±	0.026

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

Test of Dunnett

(HCL040)

BAIS 3

## APPENDIX I 1

ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)



STUDY NO. : 0341  
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
0 ppm	10	26.5± 1.6	0.116± 0.020	0.041± 0.009	0.819± 0.093	0.570± 0.060	0.619± 0.056
12.5 ppm	10	26.8± 2.7	0.131± 0.029	0.034± 0.005	0.858± 0.153	0.566± 0.037	0.594± 0.060
25 ppm	10	25.9± 1.4	0.113± 0.015	0.036± 0.005	0.810± 0.172	0.592± 0.045	0.614± 0.044
50 ppm	9	25.7± 0.9	0.125± 0.020	0.033± 0.004*	0.844± 0.205	0.591± 0.046	0.628± 0.039
100 ppm	10	26.0± 1.3	0.131± 0.019	0.041± 0.005	0.817± 0.112	0.574± 0.027	0.631± 0.029
200 ppm	10	26.0± 1.4	0.129± 0.013	0.039± 0.011	0.716± 0.113	0.552± 0.032	0.634± 0.050

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

Test of Dunnett

(HCL042)

BAIS3

STUDY NO. : 0341  
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
0 ppm	10	1.611± 0.083	0.162± 0.012	4.162± 0.129	1.638± 0.123
12.5 ppm	10	1.635± 0.137	0.170± 0.013	4.124± 0.228	1.637± 0.184
25 ppm	10	1.762± 0.564	0.178± 0.016	4.176± 0.230	1.697± 0.091
50 ppm	9	1.676± 0.112	0.173± 0.012	4.261± 0.225	1.671± 0.099
100 ppm	10	1.886± 0.590	0.186± 0.037	4.171± 0.122	1.682± 0.122
200 ppm	10	1.652± 0.087	0.179± 0.019	4.129± 0.189	1.631± 0.112

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

Test of Dunnett

## APPENDIX I 2

ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)

STUDY NO. : 0341  
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
0 ppm	10	20.3± 1.1	0.177± 0.025	0.063± 0.010	0.144± 0.033	0.632± 0.026	0.764± 0.036
12.5 ppm	10	21.1± 1.0	0.190± 0.022	0.060± 0.010	0.163± 0.028	0.595± 0.027	0.753± 0.046
25 ppm	10	20.7± 1.3	0.172± 0.019	0.058± 0.010	0.147± 0.015	0.617± 0.029	0.751± 0.045
50 ppm	10	20.7± 1.2	0.189± 0.029	0.056± 0.007	0.141± 0.017	0.598± 0.056	0.747± 0.069
100 ppm	10	20.2± 0.8	0.188± 0.030	0.058± 0.007	0.137± 0.013	0.601± 0.048	0.754± 0.040
200 ppm	10	20.1± 0.6	0.190± 0.015	0.062± 0.011	0.137± 0.023	0.595± 0.038	0.774± 0.041

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

Test of Dunnett

(HCL042)

BAIS3

STUDY NO. : 0341  
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
0 ppm	10	1.470± 0.078	0.255± 0.024	4.406± 0.254	2.201± 0.118
12.5 ppm	10	1.413± 0.058	0.256± 0.020	4.385± 0.261	2.165± 0.131
25 ppm	10	1.474± 0.046	0.248± 0.038	4.356± 0.141	2.182± 0.134
50 ppm	10	1.769± 1.079	0.260± 0.039	4.363± 0.231	2.179± 0.133
100 ppm	10	1.538± 0.056	0.247± 0.027	4.348± 0.249	2.209± 0.123
200 ppm	10	1.928± 1.222	0.279± 0.029	4.408± 0.216	2.135± 0.115

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. : 0341  
 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				0 ppm				12.5 ppm				25 ppm				50 ppm			
		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
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Circulatory system]

heart	necrosis	< 0>				< 0>				< 0>				< 1>			
		-	-	-	-	-	-	-	-	-	-	-	-	0	1	0	0
		( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( 0 )	( 100 )	( 0 )	( 0 )

[Urinary system]

kidney	hydronephrosis	< 0>				< 0>				< 0>				< 1>			
		-	-	-	-	-	-	-	-	-	-	-	-	0	0	1	0
		( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( - )	( 0 )	( 0 )	( 100 )	( 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. : 0341  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 2

Organ	Findings	Group Name		100 ppm				200 ppm			
		No. of Animals on Study		0				0			
		Grade		1	2	3	4	1	2	3	4
				(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Circulatory system]

heart																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																				
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[Urinary system]

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

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. : 0341  
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	0 ppm 10				12.5 ppm 10				25 ppm 10				50 ppm 9			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]																		
spleen	deposit of hemosiderin		<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 )
	deposit of melanin		0				1				0				1			
			0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )
[Digestive system]																		
salivary gl	Lymphocytic infiltration		<10>				<10>				<10>				< 9>			
			0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
			( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )
stomach	hyperplasia:forestomach		<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 )
Liver	necrosis:focal		<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 )
	granulation		2				2				0				4			
			2	0	0	0	2	0	0	0	0	0	0	0	4	0	0	0
			( 20 )	( 0 )	( 0 )	( 0 )	( 20 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 44 )	( 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. : 0341  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 2

		Group Name No. of Animals on Study				100 ppm 10				200 ppm 10							
Organ	Findings	1		2		3		4		1		2		3		4	
		(%)		(%)		(%)		(%)		(%)		(%)		(%)		(%)	
[Hematopoietic system]																	
spleen		<10>								<10>							
	deposit of hemosiderin	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	10 ( 100 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
	deposit of melanin	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 )
[Digestive system]																	
salivary gl		<10>								<10>							
	lymphocytic infiltration	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 )
stomach		<10>								<10>							
	hyperplasia:forestomach	1 ( 10 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	6 ( 60 )	1 ( 10 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	0 ( 0 )
liver		<10>								<10>							
	necrosis:focal	1 ( 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 )
	granulation	2 ( 20 )	0 ( 0 )	0 ( 0 )	0 ( 0 )	2 ( 20 )	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 ≤ 0.05 \*\* : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0341  
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 Grade				0 ppm 10				12.5 ppm 10				25 ppm 10				50 ppm 9			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Urinary system]																					
kidney	basophilic change	<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 )
	hydronephrosis																				
		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 )	( 0 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
[Reproductive system]																					
testis	germ cell necrosis	<10>				<10>				<10>				< 9>							
		0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	1	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )
epididymis	decreased:sperma	<10>				<10>				<10>				< 9>							
		0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0	1	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )	( 11 )	( 0 )	( 0 )	( 11 )	( 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

(HPT150)

BAIS3

STUDY NO. : 0341  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 4

Organ	Findings	Group Name No. of Animals on Study Grade	100 ppm				200 ppm			
			10				10			
			1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

[Urinary system]

kidney	basophilic change	<10>				<10>			
		0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )
	hydronephrosis	<10>				<10>			
		0	2	0	0	0	0	0	0
		( 0 )	( 20 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

[Reproductive system]

testis	germ cell necrosis	<10>				<10>			
		0	0	0	0	1	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 10 )	( 0 )	( 0 )	( 0 )
epididymis	decreased:sperma	<10>				<10>			
		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)

BAIS3

## APPENDIX J 3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : FEMALE : SACRIFICED ANIMALS

(13 - WEEK STUDY)

STUDY NO. : 0341  
ANIMAL : MOUSE Crj:BDF1  
REPORT TYPE : A1  
SEX : FEMALE

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

PAGE : 5

Organ	Findings	Group Name No. of Animals on Study Grade				0 ppm 10				12.5 ppm 10				25 ppm 10				50 ppm 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	eosinophilic change:olfactory epithelium	<10>				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 )
	eosinophilic change:respiratory epithelium	0	0	0	0	1	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 )	( 10 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
	inflammation: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 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )
nasopharynx	eosinophilic change	<10>				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 )
[Hematopoietic system]																					
spleen	deposit of hemosiderin	<10>				10	0	0	0	9	0	0	0	10	0	0	0	10	0	0	0
		(100)	( 0 )	( 0 )	( 0 )	(100)	( 0 )	( 0 )	( 0 )	( 90 )	( 0 )	( 0 )	( 0 )	(100)	( 0 )	( 0 )	( 0 )	(100)	( 0 )	( 0 )	( 0 )
	deposit of melanin	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 30 )	( 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 ≤ 0.05 \*\* : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0341  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 6

		Group Name	100 ppm				200 ppm			
		No. of Animals on Study	10				10			
Organ	Findings	Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]										
nasal cavity			<10>				<10>			
	eosinophilic change:olfactory epithelium		0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	eosinophilic change:respiratory epithelium		0	0	0	0	9	0	0	0 **
			( 0)	( 0)	( 0)	( 0)	( 90)	( 0)	( 0)	( 0)
	inflammation:respiratory epithelium		0	0	0	0	1	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)
nasopharynx			<10>				<10>			
	eosinophilic change		0	0	0	0	3	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 30)	( 0)	( 0)	( 0)
[Hematopoietic system]										
spleen			<10>				<10>			
	deposit of hemosiderin		10	0	0	0	4	6	0	0 *
			(100)	( 0)	( 0)	( 0)	( 40)	( 60)	( 0)	( 0)
	deposit of melanin		1	0	0	0	1	0	0	0
			( 10)	( 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 : 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. : 0341  
 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 Grade				0 ppm 10				12.5 ppm 10				25 ppm 10				50 ppm 10			
		1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																					
salivary gl		<10>				<10>				<10>				<10>				<10>			
	lymphocytic infiltration	0	0	0	0	1	0	0	0	1	0	0	0	0	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)
stomach		<10>				<10>				<10>				<10>				<10>			
	erosion:forestomach	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)
	hyperplasia:forestomach	0	0	0	0	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)	( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)
liver		<10>				<10>				<10>				<10>				<10>			
	granulation	2	0	0	0	2	0	0	0	2	0	0	0	1	0	0	0	1	0	0	0
		( 20)	( 0)	( 0)	( 0)	( 20)	( 0)	( 0)	( 0)	( 20)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)
[Urinary system]																					
kidney		<10>				<10>				<10>				<10>				<10>			
	basophilic change	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)
	hydronephrosis	0	0	0	0	0	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)	( 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 : Number of animals with lesion  
 ( c ) c : b / a \* 100  
 Significant difference : \* : P ≤ 0.05 \*\* : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0341  
 ANIMAL : MOUSE Crj:BDF1  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 8

		Group Name	100 ppm				200 ppm			
		No. of Animals on Study	10				10			
Organ	Findings	Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]										
salivary gl			<10>				<10>			
	lymphocytic infiltration		0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
stomach			<10>				<10>			
	erosion:forestomach		0	0	0	0	1	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)
	hyperplasia:forestomach		4	0	0	0	5	1	0	0 *
			( 40)	( 0)	( 0)	( 0)	( 50)	( 10)	( 0)	( 0)
liver			<10>				<10>			
	granulation		3	0	0	0	0	0	0	0
			( 30)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
[Urinary system]										
kidney			<10>				<10>			
	basophilic change		1	0	0	0	0	0	0	0
			( 10)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	hydronephrosis		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 : 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 ALLYL CHLORIDE IN THE 13 - WEEK INHALATION STUDY

## IDENTITY OF ALLYL CHLORIDE IN THE 13-WEEK INHALATION STUDY

Test Substance : Allyl chloride(Wako Pure Chemical Industries, LTD.)

Lot No. : WTK5293

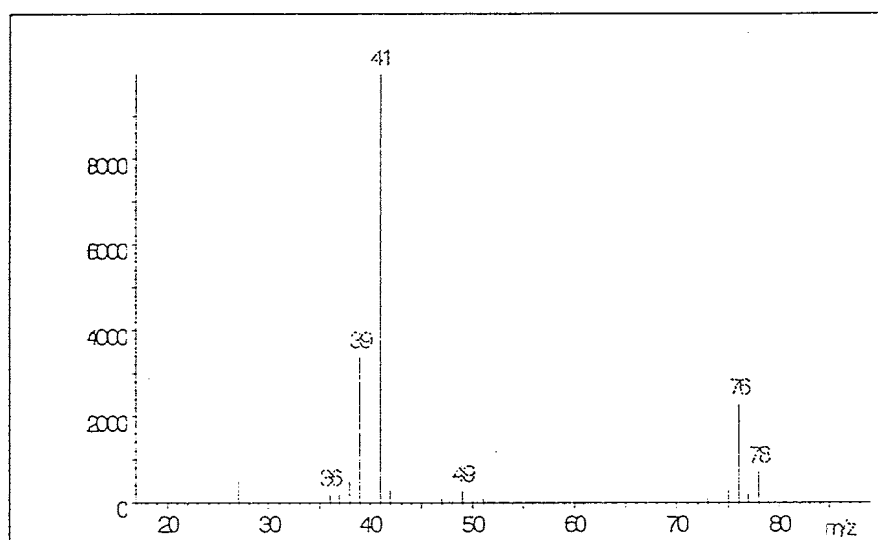
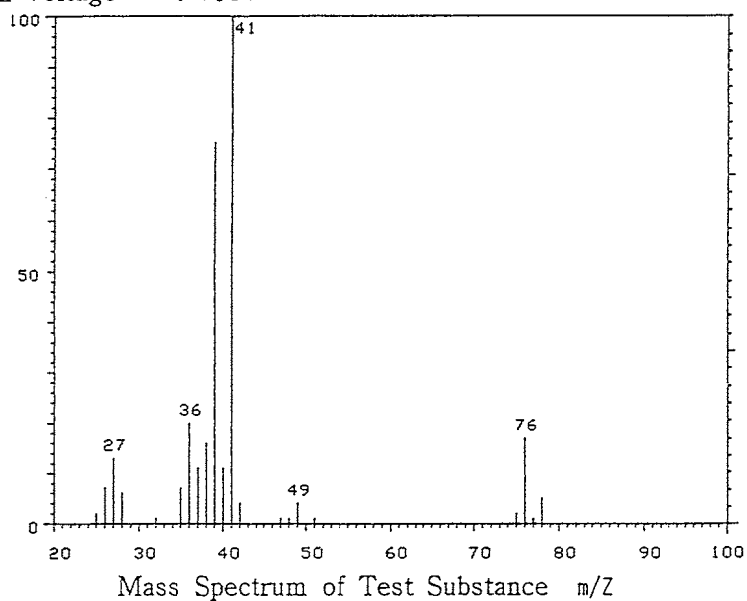
## 1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI(Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Allyl chloride(Literature data\*)

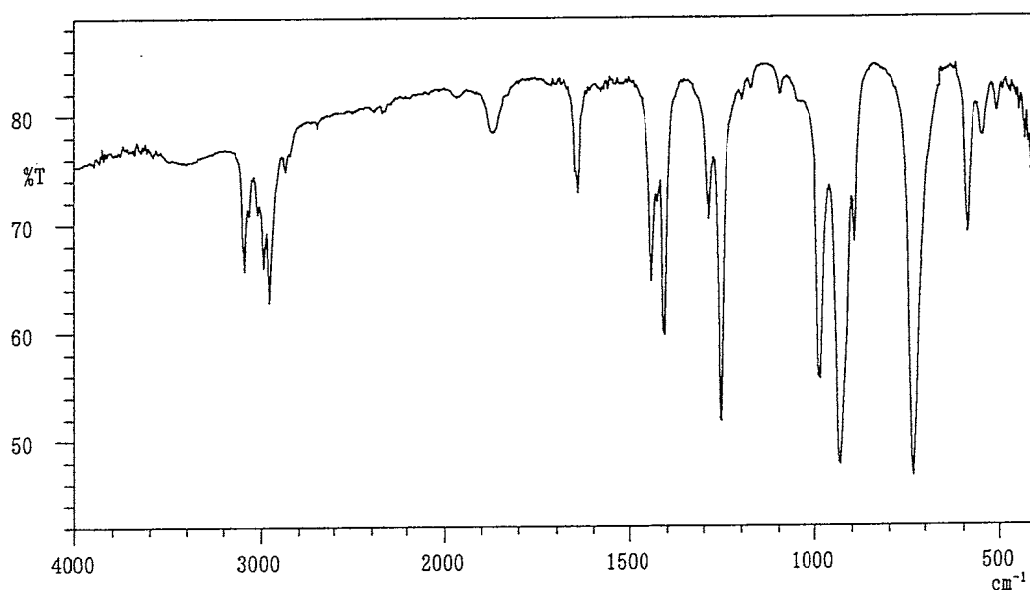
Results: The mass spectrum was consistent with literature spectrum.

\*Wiley 138K Mass Spectral Data Base Entry Number 1989(1990)  
John Wiley and Sons Inc.,U.K.

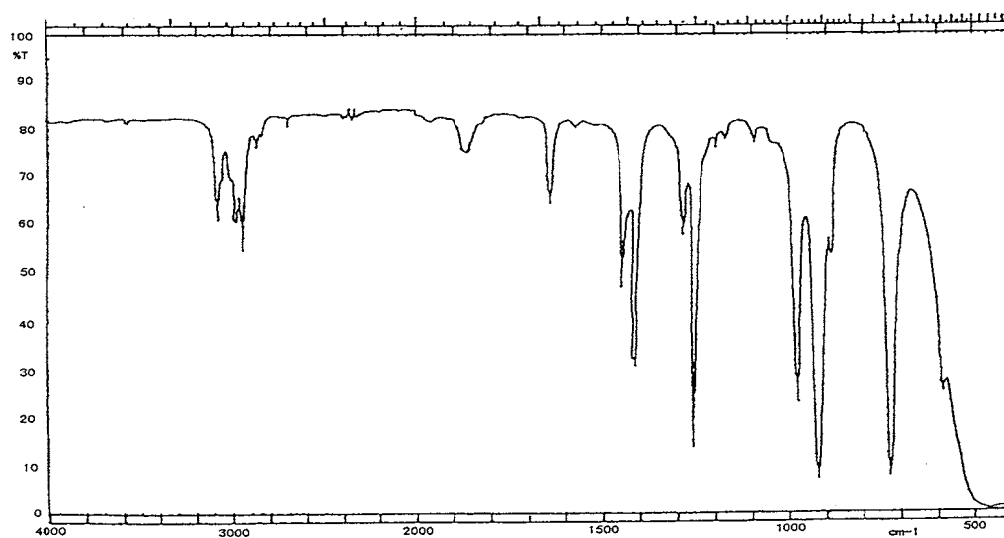
## Infrared Spectrometry

Instrument : Shimadzu FT-IR 8200PC Infrared Spectrometer

Cell : KBr



Infrared Spectrum of Test Substance



Infrared Spectrum of Allyl chloride(Literature data\*)

\*Performed by Wako Pure Chemical Industries, LTD.

Results: The infrared spectrum was consistent with literature spectrum.

2. Conclusions: The test substance was identified as Allyl chloride, by the mass spectrum and the infrared spectrum.

## APPENDIX K 2

STABILITY OF ALLYL CHLORIDE IN THE 13 - WEEK INHALATION STUDY

## STABILITY OF ALLYL CHLORIDE IN THE 13-WEEK INHALATION STUDY

Test Substance : Allyl chloride(Wako Pure Chemical Industries, LTD.)

Lot No. : WTK5293

1.Sample: This lot was used from 1997.9.17 to 1997.12.16. Test substance was stored at room temperature .

## 2. Gas Chromatography

Instrument : Hewlett Packard 6890

Column : Hewlett Packard INNOWAX(0.53mm  $\phi$   $\times$  60m)

Column Temperature : 50°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 three impurities(peak No.1,2,4 < 2% of total area) analyzed at 1997.9.12 and one major peak(peak No.3) and three impurities(peak No.1,2,4 < 2% of total area) analyzed at 1997.12.19. It was identified only by comparing its gas chromatograph with that of the 1-chloropropene(peak No.1) and 1,5-hexadiene(peak No.2) and 2-propanol(peak No.4) in the allyl chloride, the amount in the test substance were 0.12% and 0.25% and 0.004% at 1997.9.12. No new trace impurity peak in the test substance analyzed at 1997.12.19 was detected.

Date (date analyzed)	Peak No.	Retention Time(min)	AREA(%)
1997.09.12	1	2.629	0.519
	2	2.901	0.512
	3	3.249	98.961
	4	5.246	0.008
1997.12.19	1	2.626	0.525
	2	2.898	0.517
	3	3.224	98.952
	4	5.234	0.006

3. Conclusions: The test substance was stable for about 3 months in the dark at room temperature.

## APPENDIX L 1

### CONCENTRATION OF ALLYL CHLORIDE IN THE INHALATION CHAMBER OF THE 13-WEEK INHALATION STUDY



CONCENTRATION OF ALLYL CHLORIDE IN THE INHALATION CHAMBER OF THE 13-WEEK INHALATION STUDY

Group Name	Concentration(ppm)	
	Mean	± S.D.
0ppm(Control)	0.0	± 0.0
12.5ppm	12.4	± 0.1
25ppm	24.9	± 0.1
50ppm	49.9	± 0.2
100ppm	100.1	± 0.3
200ppm	199.3	± 0.8

## APPENDIX L 2

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

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

Group Name	Temperature(°C) Mean $\pm$ S.D.	Humidity(%) Mean $\pm$ S.D.	Ventilation Rate(L/min) Mean $\pm$ S.D.	Air Change(time/h) Mean
0ppm(Control)	22.2 $\pm$ 0.1	56.0 $\pm$ 0.5	131.4 $\pm$ 0.6	15.2
12.5ppm	22.2 $\pm$ 0.1	52.1 $\pm$ 0.6	131.9 $\pm$ 0.3	15.2
25ppm	21.7 $\pm$ 0.1	54.9 $\pm$ 0.8	131.3 $\pm$ 0.5	15.2
50ppm	21.9 $\pm$ 0.1	50.9 $\pm$ 0.5	132.1 $\pm$ 0.4	15.2
100ppm	22.1 $\pm$ 0.1	52.2 $\pm$ 2.3	131.6 $\pm$ 0.2	15.2
200ppm	21.7 $\pm$ 0.2	51.5 $\pm$ 1.0	131.1 $\pm$ 0.3	15.1

## APPENDIX M 1

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

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

Item	Method
<b>Hematology</b>	
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)
<b>Biochemistry</b>	
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>
<b>Urinalysis</b>	
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 ALLYL CHLORIDE

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

Item	Unit	Decimal place
<b>Hematology</b>		
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
<b>Biochemistry</b>		
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