

1-ブロモ-3-クロロプロバンのラットを用いた
吸入による 13 週間毒性試験報告書

試験番号：0397

APPENDIXES

APPENDIXES

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(13-WEEK STUDY)

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(13-WEEK STUDY)

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(13-WEEK STUDY)

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ALL ANIMALS (13-WEEK STUDY)

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ALL ANIMALS (13-WEEK STUDY)

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APPENDIX A 1

CLINCAL OBSERVATION : SUMMARY, RAT : FEMALE

(13-WEEK STUDY)

STUDY NO. : 0397
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

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
CATARACT	Control	0	0	0	0	0	0	0	0	0	0	0	0	0
	25ppm	0	0	0	0	0	0	0	0	0	0	0	1	1
	50ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	100ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	200ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	400ppm	0	0	0	0	0	0	0	0	0	0	0	0	0

(HAN190)

BAIS 8

APPENDIX B 1

BODY WEIGHT CHANGES : SUMMARY, RAT : MALE

(13-WEEK STUDY)

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 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	
Control	117±	5	145±	6	172±	9	197±	11	216±	10	232±	11
25ppm	117±	5	148±	6	176±	7	200±	8	220±	9	237±	10
50ppm	117±	5	147±	6	176±	8	201±	9	222±	9	239±	9
100ppm	117±	5	148±	7	179±	9	204±	10	226±	13	243±	13
200ppm	117±	5	139±	5	168±	7	193±	8	214±	8	231±	9
400ppm	117±	5	131±	6**	149±	7**	168±	9**	180±	10**	195±	10**

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 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			
Control	256±	12	268±	15	277±	15	283±	16	288±	18	295±	18	297±	18		
25ppm	264±	11	275±	12	283±	12	291±	11	300±	10	303±	12	306±	12		
50ppm	265±	9	278±	9	286±	9	294±	9	302±	10	308±	9	311±	9		
100ppm	269±	15	282±	18	290±	18	297±	18	303±	19	309±	20	311±	19		
200ppm	259±	10	270±	11	281±	12	288±	11	296±	12	300±	11	307±	11		
400ppm	213±	11**	222±	11**	228±	11**	234±	11**	240±	12**	242±	13**	245±	13**		

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

Test of Dunnett

(HAN260)

BAIS 3

APPENDIX B 2

BODY WEIGHT CHANGES : SUMMARY, RAT : FEMALE

(13-WEEK STUDY)

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 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	
Control	93±	3	108±	4	121±	5	132±	6	139±	6	146±	6
25ppm	93±	3	107±	2	121±	4	132±	5	139±	5	146±	5
50ppm	93±	3	106±	4	118±	4	128±	5	135±	6	141±	7
100ppm	93±	3	108±	4	121±	4	131±	4	138±	5	145±	5
200ppm	93±	3	105±	4	118±	4	129±	4	138±	5	143±	5
400ppm	93±	3	101±	4**	109±	4**	117±	3**	125±	4**	131±	4**

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

Test of Dunnett

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 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			
Control	155±	7	158±	8	161±	7	165±	8	168±	9	170±	8	170±	11		
25ppm	156±	5	159±	5	164±	5	168±	5	171±	7	175±	9	172±	6		
50ppm	151±	11	153±	11	157±	13	162±	14	164±	14	164±	13	166±	13		
100ppm	155±	4	159±	7	162±	6	167±	6	169±	6	171±	6	173±	6		
200ppm	154±	5	158±	6	163±	9	167±	9	170±	9	170±	8	173±	9		
400ppm	140±	5**	143±	3**	147±	6**	149±	6**	153±	5**	154±	5**	155±	5**		

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

Test of Dunnett

(HAN260)

BAIS 3

APPENDIX C 1

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : MALE

(13-WEEK STUDY)

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 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)
Control	13.5± 0.5	14.6± 0.8	15.7± 0.9	15.7± 0.6	15.8± 0.8	15.4± 0.8	15.1± 0.7
25ppm	14.2± 0.8	15.1± 1.0	16.0± 1.3	16.6± 1.5	16.6± 0.9	16.3± 1.5	16.3± 1.2*
50ppm	14.1± 0.6	15.2± 0.9	16.6± 1.1	16.5± 0.9	16.6± 0.7	15.9± 0.8	16.1± 0.5
100ppm	14.2± 1.1	15.8± 1.4	17.1± 1.3*	17.5± 1.6*	17.4± 1.6	16.9± 1.6	17.2± 1.3**
200ppm	12.0± 0.6**	14.3± 0.6	16.5± 0.9	16.8± 0.8	16.8± 0.8	16.7± 0.5	17.2± 0.7**
400ppm	11.2± 0.7**	13.7± 1.1	14.6± 1.1	15.2± 0.8	15.7± 0.7	16.1± 1.1	16.1± 0.9

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

Test of Dunnett

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 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)
Control	14.9± 1.2	15.6± 1.0	15.3± 0.7	15.2± 1.3	15.3± 1.2	15.5± 1.2
25ppm	16.1± 1.1	16.2± 1.1	15.9± 0.8	16.2± 0.6	15.6± 1.0	15.8± 0.9
50ppm	16.1± 0.6	16.3± 0.7	15.8± 0.7	16.1± 0.7	15.8± 0.4	15.9± 0.6
100ppm	16.8± 1.6*	16.7± 1.5	16.5± 1.2*	16.7± 1.2**	15.9± 1.2	16.0± 1.2
200ppm	17.1± 0.7**	17.4± 0.8**	16.9± 0.8**	16.8± 0.6**	16.8± 0.8**	16.7± 0.7
400ppm	16.3± 1.0	16.5± 1.2	16.5± 1.2*	16.5± 1.0*	16.3± 1.0	16.5± 1.2
Significant difference ; * : $P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett						
(HAN260)						

BAIS 3

APPENDIX C 2

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : FEMALE
(13-WEEK STUDY)

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 UNIT : g
 REPORT TYPE : A1 13
 SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
 ALL ANIMALS

PAGE : 3

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)
Control	10.1± 0.6	10.5± 0.9	11.0± 1.0	11.0± 0.9	11.0± 0.9	10.8± 0.6	10.7± 0.6
25ppm	10.3± 0.6	10.7± 0.5	11.2± 0.8	11.0± 0.7	10.9± 0.6	10.6± 0.5	10.9± 0.6
50ppm	10.2± 0.5	10.5± 0.6	10.9± 0.3	10.9± 0.5	10.8± 0.5	10.6± 0.7	10.7± 1.0
100ppm	10.1± 0.5	10.8± 0.7	11.2± 0.5	11.2± 0.8	11.1± 0.5	10.6± 0.8	11.1± 0.6
200ppm	9.0± 0.5**	10.4± 0.6	11.6± 0.8	11.8± 1.0	11.6± 0.6	11.4± 0.8	11.5± 0.6
400ppm	9.2± 0.8**	10.5± 0.7	11.0± 0.6	11.2± 0.9	11.8± 1.1	11.5± 1.2	11.5± 1.2

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

Test of Dunnett

(HAN260)

BAIS 3

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 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)
Control	10.2± 0.8	10.6± 0.5	10.4± 0.8	10.7± 1.0	10.4± 0.9	10.1± 0.9
25ppm	10.4± 0.7	10.8± 0.6	10.6± 0.7	11.1± 1.0	11.1± 1.4	10.2± 0.7
50ppm	10.2± 1.1	10.5± 1.1	10.6± 1.1	10.6± 1.2	10.2± 0.6	10.1± 0.7
100ppm	10.7± 0.8	10.9± 0.5	11.0± 0.7	11.0± 0.6	10.8± 0.7	10.8± 0.6
200ppm	11.2± 0.9	11.5± 1.4	11.1± 0.7	11.5± 0.8	10.7± 0.6	11.1± 0.9
400ppm	11.8± 1.1**	11.9± 1.4	12.0± 1.2**	12.0± 1.1**	11.9± 0.9**	12.3± 1.4**

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

Test of Dunnett

(HAN260)

BAIS 3

APPENDIX D 1

URINALYSIS : RAT : MALE

(13-WEEK STUDY)

STUDY NO. : 0397
ANIMAL : RAT F344/DuCrj
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	Bilirubin				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+
Control	10	0	0	0	1	2	2	5		0	5	5	0	0	0		10	0	0	0	0	0		8	2	0	0	0	0		10	0	0	0
25ppm	10	0	0	0	1	1	6	2		0	10	0	0	0	0	**	10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0
50ppm	10	0	0	0	1	3	3	3		0	8	1	1	0	0		10	0	0	0	0	0		8	1	1	0	0	0		10	0	0	0
100ppm	10	0	0	0	0	1	5	4		0	6	3	1	0	0		10	0	0	0	0	0		8	2	0	0	0	0		10	0	0	0
200ppm	10	0	0	0	1	2	5	2		0	4	5	1	0	0		10	0	0	0	0	0		9	1	0	0	0	0		10	0	0	0
400ppm	10	0	0	0	0	1	4	5		0	5	4	1	0	0		10	0	0	0	0	0		7	3	0	0	0	0		10	0	0	0

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

Test of CHI SQUARE

(HCL101)

BAIS 3

STUDY NO. : 0397

URINALYSIS

ANIMAL : RAT F344/DuCrj

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

PAGE : 2

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		-	±	+	2+	3+		±	+	2+	3+	4+	
Control	10	10	0	0	0	0	0	10	0	0	0	0	0
25ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
50ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
100ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
200ppm	10	10	0	0	0	0	0	10	0	0	0	0	0
400ppm	10	10	0	0	0	0	0	10	0	0	0	0	0

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

Test of CHI SQUARE

(HCL101)

BAIS 3

APPENDIX D 2

URINALYSIS : RAT : FEMALE

(13-WEEK STUDY)

STUDY NO. : 0397

ANIMAL : RAT F344/DuCrj

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

URINALYSIS

PAGE : 3

Group Name	NO. of Animals	pH							CHI	Protein					CHI	Glucose					CHI	Ketone body					CHI	Bilirubin				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+
Control	10	0	0	0	0	0	9	1		4	5	1	0	0	0		10	0	0	0	0	0		9	1	0	0	0	0		10	0	0	0	
25ppm	10	0	0	0	0	3	5	2		5	4	1	0	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	
50ppm	10	0	0	0	0	1	7	2		6	3	1	0	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	
100ppm	10	0	0	0	1	3	5	1		6	3	1	0	0	0		10	0	0	0	0	0		9	1	0	0	0	0		10	0	0	0	
200ppm	10	0	0	0	0	2	7	1		5	5	0	0	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	
400ppm	10	0	0	0	0	2	5	3		4	6	0	0	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	

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

Test of CHI SQUARE

(HCL101)

BAIS 3

STUDY NO. : 0397

URINALYSIS

ANIMAL : RAT F344/DuCrJ

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	Occult blood					CHI	Urobilinogen					CHI
		-	±	+	2+	3+		±	+	2+	3+	4+	
Control	10	10	0	0	0	0		10	0	0	0	0	
25ppm	10	10	0	0	0	0		10	0	0	0	0	
50ppm	10	10	0	0	0	0		10	0	0	0	0	
100ppm	10	10	0	0	0	0		10	0	0	0	0	
200ppm	10	10	0	0	0	0		10	0	0	0	0	
400ppm	10	10	0	0	0	0		10	0	0	0	0	

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

Test of CHI SQUARE

(HCL101)

BAIS 8

APPENDIX E 1

HEMATOLOGY : SUMMARY, RAT : MALE

(13-WEEK STUDY)

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 MEASURE. TIME : 1
 SEX : MALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 1

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 ³ /μl	
Control	9	9.50±	0.18	16.3±	0.3	46.7±	1.0	49.2±	0.4	17.2±	0.3	34.9±	0.5	756±	64
25ppm	10	9.71±	0.11*	16.3±	0.2	47.0±	0.6	48.4±	0.5**	16.7±	0.2**	34.6±	0.3	759±	45
50ppm	10	9.64±	0.13	16.3±	0.3	46.6±	0.8	48.3±	0.5**	16.8±	0.2*	34.8±	0.4	744±	57
100ppm	10	9.67±	0.16	16.1±	0.3	46.2±	0.6	47.8±	0.4**	16.6±	0.3**	34.8±	0.5	754±	37
200ppm	10	9.72±	0.16*	16.0±	0.3	46.4±	0.7	47.8±	0.3**	16.5±	0.2**	34.5±	0.4	794±	25
400ppm	10	9.40±	0.23	15.7±	0.3**	46.4±	1.2	49.4±	0.4	16.7±	0.2**	33.9±	0.5**	888±	63**

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

Test of Dunnett

(HCL070)

BAIS 3

STUDY NO. : 0397

ANIMAL : RAT F344/DuCrj

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)

ALL ANIMALS (14W)

PAGE : 2

Group Name	NO. of Animals	RETICULOCYTE ‰		PROTHROMBIN TIME s e c		APTT s e c	
Control	9	17±	3	14.6±	1.7	24.2±	2.0
25ppm	10	14±	3	15.2±	1.4	26.4±	1.5
50ppm	10	15±	3	16.2±	2.4	25.8±	1.6
100ppm	10	16±	4	16.6±	4.2	26.1±	2.2
200ppm	10	17±	3	14.8±	2.0	24.6±	3.1
400ppm	10	21±	4	13.9±	1.1	24.2±	1.9

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 3

STUDY NO. : 0397

ANIMAL : RAT F344/DuCrj

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)

ALL ANIMALS (14W)

PAGE : 3

Group Name	NO. of Animals	WBC 10 ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	9	6.10±	1.67	0±	1	26±	7	1±	1	0±	0	3±	1	70±	6	0±	0
25ppm	10	6.46±	1.55	0±	0	24±	2	1±	1	0±	0	2±	1	72±	3	0±	0
50ppm	10	6.57±	2.03	0±	0	24±	6	0±	1	0±	0	3±	1	72±	7	0±	0
100ppm	10	7.00±	2.09	1±	1	22±	5	1±	1	0±	0	3±	1	74±	5	0±	0
200ppm	10	7.14±	1.88	1±	1	21±	4	1±	1	0±	0	2±	1	76±	3	0±	1
400ppm	10	5.81±	1.59	0±	1	25±	7	1±	0	0±	0	2±	1	72±	7	1±	1

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

Test of Dunnett

(HCL070)

BAIS 3

APPENDIX E 2

HEMATOLOGY : SUMMARY, RAT : FEMALE

(13-WEEK STUDY)

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 MEASURE. TIME : 1
 SEX : FEMALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 4

Group Name	NO. of Animals	RED BLOOD CELL 10 ⁶ /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 ³ /μl	
Control	10	8.62±	0.16	15.9±	0.3	44.5±	1.1	51.6±	0.4	18.5±	0.3	35.8±	0.7	816±	44
25ppm	10	8.78±	0.18	16.2±	0.4	45.2±	1.1	51.5±	0.5	18.5±	0.3	35.9±	0.5	799±	43
50ppm	10	8.84±	0.30	16.4±	0.4	45.6±	1.0	51.6±	0.9	18.5±	0.3	35.9±	0.5	819±	54
100ppm	10	8.99±	0.22**	16.5±	0.4*	46.2±	1.1**	51.4±	0.3	18.4±	0.2	35.7±	0.5	837±	29
200ppm	10	8.86±	0.28	16.1±	0.5	45.8±	1.5	51.7±	0.4	18.2±	0.2*	35.2±	0.5*	860±	35
400ppm	10	8.78±	0.18	16.1±	0.4	46.0±	1.0*	52.4±	0.3**	18.3±	0.3	34.9±	0.6**	856±	106

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

Test of Dunnett

(HCL070)

BAIS 3

STUDY NO. : 0397

ANIMAL : RAT F344/DuCrj

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)

ALL ANIMALS (14W)

PAGE : 5

Group Name	NO. of Animals	RETICULOCYTE ‰		PROTHROMBIN TIME s e c		APTT s e c	
Control	10	16±	4	13.5±	0.4	19.9±	1.3
25ppm	10	15±	4	13.3±	0.4	19.4±	2.2
50ppm	10	16±	4	13.5±	0.7	20.1±	1.0
100ppm	10	16±	5	13.6±	0.5	19.5±	1.0
200ppm	10	16±	3	13.7±	0.5	19.4±	1.0
400ppm	10	22±	4**	14.0±	0.7	19.9±	1.6

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 3

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 MEASURE. TIME : 1
 SEX : FEMALE

HEMATOLOGY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 6

Group Name	NO. of Animals	WBC 1 O ³ /μl		Differential N-BAND		WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHER	
Control	10	3.05±	0.69	1±	1	24±	5	1±	1	0±	0	2±	1	72±	5	0±	0
25ppm	10	2.38±	0.59	1±	1	27±	4	2±	1	0±	0	2±	1	69±	5	0±	0
50ppm	10	3.15±	1.05	0±	1	28±	5	1±	1	0±	0	3±	2	68±	6	0±	0
100ppm	10	3.92±	1.38	0±	1	24±	4	1±	0	0±	0	2±	1	73±	4	0±	0
200ppm	10	3.35±	0.60	0±	1	23±	4	1±	1	0±	0	2±	1	73±	5	0±	0
400ppm	10	3.67±	0.67	1±	1	24±	6	2±	1	0±	0	2±	1	71±	7	1±	1

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 3

APPENDIX F 1

BIOCHEMISTRY : SUMMARY, RAT : MALE

(13-WEEK STUDY)

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 MEASURE. TIME : 1
 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	
Control	9	6.5±	0.1	4.0±	0.1	1.5±	0.1	0.11±	0.01	171±	15	61±	6	51±	15
25ppm	10	6.6±	0.1	4.0±	0.1	1.5±	0.1	0.11±	0.01	181±	9	58±	4	43±	12
50ppm	10	6.7±	0.1	4.1±	0.1*	1.5±	0.1	0.11±	0.01	188±	14*	63±	5	60±	13
100ppm	10	6.8±	0.2**	4.2±	0.1**	1.6±	0.1	0.11±	0.01	191±	13**	63±	6	63±	26
200ppm	10	6.9±	0.2**	4.2±	0.1**	1.6±	0.0	0.11±	0.01	184±	14	63±	7	56±	12
400ppm	9	7.0±	0.1**	4.3±	0.1**	1.5±	0.1	0.11±	0.01	167±	7	55±	13	33±	9

Significant difference ; * : $P \leq 0.05$

** : $P \leq 0.01$

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0397

ANIMAL : RAT F344/DuCrj

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	
Control	9	108±	10	71±	23	47±	10	188±	43	254±	18	2±	1	104±	13
25ppm	10	105±	6	83±	18	51±	11	195±	47	227±	16**	2±	1	99±	11
50ppm	10	118±	8	84±	30	52±	14	189±	41	225±	21**	2±	1	96±	9
100ppm	10	116±	10	68±	15	43±	8	184±	21	195±	15**	2±	1	94±	12
200ppm	10	118±	11	52±	9	36±	5	160±	28	182±	17**	2±	1	89±	8*
400ppm	9	103±	20	52±	8	38±	12	160±	30	160±	8**	2±	1	82±	15**

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

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0397

ANIMAL : RAT F344/DuCrj

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)

ALL ANIMALS (14W)

PAGE : 3

Group Name	NO. of Animals	UREA NITROGEN mg/dl		CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	9	18.8±	1.6	0.5±	0.1	143±	1	3.5±	0.3	106±	1	10.1±	0.2	5.7±	0.7
25ppm	10	19.5±	1.3	0.5±	0.0	142±	1	3.4±	0.3	107±	1	10.1±	0.2	5.5±	0.7
50ppm	10	20.8±	1.3*	0.5±	0.1	142±	1	3.5±	0.2	108±	2	10.2±	0.2	5.7±	0.8
100ppm	10	20.6±	1.6*	0.5±	0.0	142±	1	3.4±	0.2	111±	2**	10.3±	0.2	5.4±	0.7
200ppm	10	19.4±	1.5	0.5±	0.1	142±	2	3.6±	0.2	116±	2**	10.4±	0.2*	5.6±	0.7
400ppm	9	17.8±	0.8	0.4±	0.1	141±	1**	4.0±	0.2**	124±	3**	10.4±	0.1**	6.0±	0.6

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

Test of Dunnett

(HCL074)

BAIS 3

APPENDIX F 2

BIOCHEMISTRY : SUMMARY, RAT : FEMALE

(13-WEEK STUDY)

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 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	
Control	10	6.2±	0.2	3.7±	0.1	1.5±	0.1	0.12±	0.01	134±	11	70±	10	14±	2
25ppm	10	6.4±	0.1*	3.8±	0.1	1.5±	0.0	0.12±	0.01	141±	8	70±	4	12±	2
50ppm	10	6.3±	0.1	3.8±	0.1	1.5±	0.1	0.13±	0.01	142±	13	73±	6	13±	2
100ppm	10	6.5±	0.1**	3.9±	0.1**	1.5±	0.1	0.12±	0.01	154±	10**	78±	6	13±	3
200ppm	10	6.7±	0.1**	4.1±	0.1**	1.6±	0.1	0.13±	0.01	152±	13**	87±	6**	15±	4
400ppm	10	7.0±	0.2**	4.3±	0.1**	1.6±	0.1	0.13±	0.01	141±	11	88±	11**	17±	4

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

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 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	
Control	10	131±	15	67±	3	34±	4	249±	80	188±	20	2±	1	118±	25
25ppm	10	131±	9	81±	21	50±	23	293±	130	162±	11	3±	1	127±	44
50ppm	10	133±	8	74±	16	43±	23	281±	108	167±	19	2±	1	121±	29
100ppm	10	141±	13	79±	26	48±	23	246±	50	160±	25	2±	1	110±	22
200ppm	10	152±	11**	60±	12	34±	11	249±	87	143±	16**	2±	1	111±	23
400ppm	10	151±	13**	53±	8*	27±	4	254±	92	121±	8**	3±	1	101±	29

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

Test of Dunnett

(HCL074)

BAIS 3

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 MEASURE. TIME : 1
 SEX : FEMALE

BIOCHEMISTRY (SUMMARY)
 ALL ANIMALS (14W)

REPORT TYPE : A1

PAGE : 6

Group Name	NO. of Animals	UREA NITROGEN mg/dl		CREATININE mg/dl		SODIUM mEq/l		POTASSIUM mEq/l		CHLORIDE mEq/l		CALCIUM mg/dl		INORGANIC PHOSPHORUS mg/dl	
Control	10	19.1±	1.6	0.5±	0.1	141±	1	3.5±	0.3	107±	2	9.7±	0.2	5.1±	1.2
25ppm	10	18.1±	2.2	0.5±	0.1	141±	1	3.4±	0.2	110±	2*	9.8±	0.1	4.9±	1.3
50ppm	10	19.1±	2.1	0.5±	0.1	141±	1	3.5±	0.2	110±	2**	9.8±	0.2	4.8±	1.2
100ppm	10	20.5±	1.9	0.5±	0.1	140±	1	3.3±	0.2	112±	2**	9.9±	0.2	4.8±	1.0
200ppm	10	17.7±	2.4	0.5±	0.1	140±	2	3.4±	0.3	118±	2**	10.2±	0.1**	5.1±	0.9
400ppm	10	15.5±	1.3**	0.5±	0.1	139±	2	3.7±	0.3	126±	3**	10.4±	0.2**	5.4±	0.7

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

Test of Dunnett

(HCL074)

BAIS 3

APPENDIX G 1

GROSS FINDINGS : SUMMARY, RAT : MALE

ALL ANIMALS (13-WEEK STUDY)

STUDY NO. : 0397
ANIMAL : RAT F344/DuCrJ
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 1

Organ	Findings	Group Name NO. of Animals	Control		25ppm		50ppm		100ppm	
			10	(%)	10	(%)	10	(%)	10	(%)
thymus	atrophic		0	(0)	0	(0)	0	(0)	0	(0)
gl stomach	red zone		0	(0)	0	(0)	0	(0)	0	(0)
	black zone		0	(0)	0	(0)	0	(0)	0	(0)
liver	herniation		1	(10)	0	(0)	1	(10)	1	(10)

(HPT080)

BAIS 3

STUDY NO. : 0397
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 2

Organ	Findings	Group Name NO. of Animals	200ppm		400ppm	
			10	(%)	10	(%)
thymus	atrophic		0	(0)	1	(10)
gl stomach	red zone		0	(0)	2	(20)
	black zone		0	(0)	1	(10)
liver	herniation		1	(10)	1	(10)

(HPT080)

BAIS 3

APPENDIX G 2

GROSS FINDINGS : SUMMARY, RAT : FEMALE

ALL ANIMALS (13-WEEK STUDY)

STUDY NO. : 0397
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 3

Organ	Findings	Group Name NO. of Animals	Control		25ppm		50ppm		100ppm	
			10	(%)	10	(%)	10	(%)	10	(%)
liver	herniation		2	(20)	1	(10)	4	(40)	2	(20)
pituitary	nodule		0	(0)	0	(0)	0	(0)	1	(10)
ovary	cyst		0	(0)	1	(10)	0	(0)	1	(10)
eye	white		0	(0)	1	(10)	0	(0)	0	(0)

(HPT080)

BAIS 3

STUDY NO. : 0397
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 4

Organ	Findings	Group Name NO. of Animals	200ppm		400ppm	
			10	(%)	10	(%)
liver	herniation		2	(20)	1	(10)
pituitary	nodule		0	(0)	0	(0)
ovary	cyst		0	(0)	0	(0)
eye	white		0	(0)	0	(0)

(HPT080)

BAIS 3

APPENDIX H 1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : MALE

(13-WEEK STUDY)

STUDY NO. : 0397
ANIMAL : RAT F344/DuCrJ
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
Control	10	279± 19	0.220± 0.028	0.048± 0.003	3.012± 0.098	0.873± 0.047	0.992± 0.062
25ppm	10	283± 11	0.231± 0.015	0.048± 0.004	2.974± 0.106	0.889± 0.056	0.983± 0.063
50ppm	10	287± 9	0.239± 0.027	0.047± 0.005	2.975± 0.146	0.878± 0.030	0.971± 0.030
100ppm	10	288± 19	0.239± 0.026	0.051± 0.003	2.980± 0.149	0.917± 0.069	1.002± 0.043
200ppm	10	284± 11	0.240± 0.025	0.045± 0.002	3.110± 0.129	0.931± 0.058	1.021± 0.056
400ppm	10	223± 12**	0.178± 0.024**	0.045± 0.003	2.712± 0.325	0.837± 0.032	0.933± 0.042*

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

Test of Dunnett

(HCL040)

BAIS 8

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 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	
Control	10	1.705±	0.118	0.529±	0.037	6.896±	0.594	1.843±	0.044
25ppm	10	1.719±	0.070	0.541±	0.037	7.307±	0.346	1.855±	0.043
50ppm	10	1.738±	0.092	0.537±	0.015	7.840±	0.310**	1.828±	0.070
100ppm	10	1.790±	0.093	0.562±	0.027	8.547±	0.747**	1.835±	0.046
200ppm	10	1.884±	0.082**	0.576±	0.030**	9.176±	0.430**	1.841±	0.047
400ppm	10	1.838±	0.108*	0.491±	0.037*	8.514±	0.505**	1.705±	0.096**

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

Test of Dunnett

(HCL040)

BAIS 3

APPENDIX H 2

ORGAN WEIGHT, ABSOLUTE : SUMMARY, RAT : FEMALE

(13-WEEK STUDY)

STUDY NO. : 0397
ANIMAL : RAT F344/DuCrj
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	
Control	10	156±	9	0.179±	0.023	0.052±	0.005	0.110±	0.018	0.558±	0.030	0.748±	0.044
25ppm	10	158±	6	0.191±	0.019	0.056±	0.006	0.109±	0.016	0.585±	0.020	0.714±	0.022
50ppm	10	152±	12	0.178±	0.021	0.050±	0.005	0.106±	0.020	0.573±	0.032	0.715±	0.042
100ppm	10	158±	6	0.183±	0.022	0.052±	0.004	0.113±	0.018	0.573±	0.018	0.720±	0.024
200ppm	10	158±	8	0.200±	0.050	0.053±	0.004	0.103±	0.014	0.610±	0.026**	0.741±	0.032
400ppm	10	142±	5**	0.154±	0.012*	0.057±	0.004	0.101±	0.016	0.615±	0.025**	0.733±	0.051

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

Test of Dunnett

(HCL040)

BAIS 3

STUDY NO. : 0397
ANIMAL : RAT F344/DuCrj
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	
Control	10	1.038±	0.053	0.368±	0.033	3.755±	0.190	1.698±	0.038
25ppm	10	1.037±	0.054	0.360±	0.027	4.007±	0.226	1.701±	0.065
50ppm	10	1.017±	0.041	0.351±	0.018	3.931±	0.258	1.662±	0.087
100ppm	10	1.043±	0.037	0.355±	0.019	4.304±	0.180**	1.659±	0.050
200ppm	10	1.135±	0.066**	0.382±	0.022	4.941±	0.405**	1.672±	0.031
400ppm	10	1.208±	0.064**	0.391±	0.025	5.698±	0.321**	1.602±	0.047**

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

Test of Dunnett

(HCL040)

BAIS 3

APPENDIX I 1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

(13-WEEK STUDY)

STUDY NO. : 0397
ANIMAL : RAT F344/DuCrj
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
Control	10	279± 19	0.079± 0.007	0.017± 0.002	1.085± 0.056	0.314± 0.010	0.357± 0.025
25ppm	10	283± 11	0.082± 0.006	0.017± 0.001	1.052± 0.030	0.315± 0.021	0.348± 0.015
50ppm	10	287± 9	0.083± 0.009	0.016± 0.002	1.037± 0.046	0.306± 0.009	0.339± 0.011
100ppm	10	288± 19	0.083± 0.007	0.018± 0.001	1.039± 0.080	0.319± 0.021	0.349± 0.019
200ppm	10	284± 11	0.085± 0.009	0.016± 0.001	1.098± 0.052	0.329± 0.024	0.360± 0.015
400ppm	10	223± 12**	0.079± 0.009	0.020± 0.002**	1.216± 0.132	0.375± 0.016**	0.418± 0.017**

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

Test of Dunnett

(HCL042)

BAIS 3

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE
 UNIT: %

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

PAGE : 2

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.613± 0.021	0.190± 0.004	2.475± 0.104	0.664± 0.035
25ppm	10	0.608± 0.015	0.191± 0.012	2.585± 0.077	0.657± 0.025
50ppm	10	0.606± 0.025	0.187± 0.005	2.733± 0.080**	0.638± 0.031
100ppm	10	0.623± 0.027	0.195± 0.007	2.966± 0.122**	0.640± 0.042
200ppm	10	0.665± 0.018**	0.204± 0.012*	3.237± 0.104**	0.650± 0.021
400ppm	10	0.824± 0.040**	0.220± 0.011**	3.815± 0.114**	0.765± 0.028**

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

Test of Dunnett

(HCL042)

BAIS 3

APPENDIX I 2

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : FEMALE

(13-WEEK STUDY)

STUDY NO. : 0397
ANIMAL : RAT F344/DuCrj
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
Control	10	156±	9	0.114± 0.011	0.033± 0.003	0.070± 0.011	0.357± 0.009	0.479± 0.017
25ppm	10	158±	6	0.121± 0.012	0.035± 0.003	0.069± 0.012	0.371± 0.018	0.452± 0.018
50ppm	10	152±	12	0.118± 0.013	0.033± 0.003	0.070± 0.012	0.378± 0.025	0.472± 0.035
100ppm	10	158±	6	0.116± 0.012	0.033± 0.002	0.072± 0.011	0.363± 0.011	0.457± 0.016
200ppm	10	158±	8	0.127± 0.033	0.034± 0.002	0.065± 0.008	0.386± 0.010**	0.469± 0.023
400ppm	10	142±	5**	0.109± 0.009	0.040± 0.002**	0.071± 0.012	0.435± 0.013**	0.518± 0.031**

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

Test of Dunnett

(HCL042)

BAIS 3

STUDY NO. : 0397
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

PAGE : 4

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.666± 0.031	0.236± 0.014	2.406± 0.074	1.090± 0.062
25ppm	10	0.656± 0.022	0.228± 0.019	2.535± 0.108	1.077± 0.047
50ppm	10	0.672± 0.051	0.232± 0.019	2.590± 0.086	1.096± 0.049
100ppm	10	0.661± 0.025	0.225± 0.014	2.728± 0.059**	1.052± 0.036
200ppm	10	0.718± 0.017*	0.242± 0.008	3.123± 0.123**	1.060± 0.048
400ppm	10	0.854± 0.028**	0.277± 0.020**	4.027± 0.175**	1.133± 0.045

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

Test of Dunnett

(HCL042)

BAIS 3

APPENDIX J 1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : MALE : ALL ANIMALS

(13-WEEK STUDY)

STUDY NO. : 0397
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 1

Organ	Findings	Control				25ppm				50ppm				100ppm			
		No. of Animals on Study				10				10				10			
		Grade				1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																	
nasal cavit		<10>				<10>				<10>				<10>			
	goblet cell hyperplasia	0	0	0	0	0	0	0	0	1	0	0	0	3	0	0	0
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(30)	(0)	(0)	(0)
	inflammation:squamous 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)
	disarrangement:olfactory 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)
	desquamation:olfactory 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)
	inflammation:transitional 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)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia: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)
nasopharynx		<10>				<10>				<10>				<10>			
	goblet cell hyperplasia	3	0	0	0	3	0	0	0	7	0	0	0	10	0	0	0 **
		(30)	(0)	(0)	(0)	(30)	(0)	(0)	(0)	(70)	(0)	(0)	(0)	(100)	(0)	(0)	(0)
lung		<10>				<10>				<10>				<10>			
	perivascular inflammation	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)

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. : 0397
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 2

		Group Name	200ppm				400ppm			
		No. of Animals on Study	10				10			
Organ	Findings	Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}										
nasal cavit			<10>				<10>			
	goblet cell hyperplasia		1	0	0	0	3	0	0	0
			(10)	(0)	(0)	(0)	(30)	(0)	(0)	(0)
	inflammation:squamous epithelium		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
	disarrangement:olfactory epithelium		0	0	0	0	4	6	0	0 **
			(0)	(0)	(0)	(0)	(40)	(60)	(0)	(0)
	desquamation:olfactory epithelium		0	0	0	0	3	0	0	0
			(0)	(0)	(0)	(0)	(30)	(0)	(0)	(0)
	inflammation:transitional epithelium		1	0	0	0	1	0	0	0
			(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
	hyperplasia:respiratory epithelium		1	0	0	0	3	0	0	0
			(10)	(0)	(0)	(0)	(30)	(0)	(0)	(0)
nasopharynx			<10>				<10>			
	goblet cell hyperplasia		10	0	0	0 **	9	0	0	0 *
			(100)	(0)	(0)	(0)	(90)	(0)	(0)	(0)
lung			<10>				<10>			
	perivascular inflammation		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

STUDY NO. : 0997
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 3

		Group Name	Control				25ppm				50ppm				100ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Organ	Findings		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Circulatory system}																		
heart			<10>				<10>				<10>				<10>			
	inflammatory cell nest		3	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
			(30)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Digestive system}																		
stomach			<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)
	hyperplasia:forestomach		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)	(0)	(0)	(0)	(0)
liver			<10>				<10>				<10>				<10>			
	herniation		1	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
	granulation		1	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(30)	(0)	(0)	(0)
	perivascular inflammation		6	0	0	0	3	0	0	0	5	0	0	0	6	0	0	0
			(60)	(0)	(0)	(0)	(30)	(0)	(0)	(0)	(50)	(0)	(0)	(0)	(60)	(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. : 0397
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 4

		Group Name	200ppm				400ppm			
		No. of Animals on Study	10				10			
Organ	Findings	Grade	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>										
{Circulatory system}										
heart			<10>				<10>			
	inflammatory cell nest		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
{Digestive system}										
stomach			<10>				<10>			
	erosion:forestomach		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
	hyperplasia:forestomach		0	0	0	0	0	1	0	0
			(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)
liver			<10>				<10>			
	herniation		1	0	0	0	1	0	0	0
			(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
	granulation		2	0	0	0	1	0	0	0
			(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
	perivascular inflammation		5	0	0	0	6	1	0	0
			(50)	(0)	(0)	(0)	(60)	(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. : 0397
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0~ 14W)

PAGE : 5

Organ_____	Findings_____	Group Name	Control				25ppm				50ppm				100ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>																		
{Urinary system}																		
kidney			<10>				<10>				<10>				<10>			
	basophilic change		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)	(0)	(0)	(0)	(0)
	eosinophilic body		2	8	0	0	4	6	0	0	2	8	0	0	0	10	0	0
			(20)	(80)	(0)	(0)	(40)	(60)	(0)	(0)	(20)	(80)	(0)	(0)	(0)	(100)	(0)	(0)
	hyaline cast		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)	
	mineralization:papilla		3	0	0	0	2	0	0	0	1	0	0	0	0	0	0	
			(30)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	
{Endocrine system}																		
pituitary			<10>				<10>				<10>				<10>			
	Rathke pouch		0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(30)	(0)	(0)	(0)	
thyroid			<10>				<10>				<10>				<10>			
	ultimibranhial body remanet		2	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
			(20)	(0)	(0)	(0)	(0)	(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 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. : 0397
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 6

		Group Name	200ppm				400ppm			
		No. of Animals on Study	10				10			
Organ	Findings	Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Urinary system}										
kidney			<10>				<10>			
	basophilic change		0	0	0	0	2	0	0	0
			(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
	eosinophilic body		1	9	0	0	0	10	0	0
			(10)	(90)	(0)	(0)	(0)	(100)	(0)	(0)
	hyaline cast		0	0	0	0	2	0	0	0
			(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
	mineralization:papilla		1	0	0	0	1	0	0	0
			(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
{Endocrine system}										
pituitary			<10>				<10>			
	Rathke pouch		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
thyroid			<10>				<10>			
	ultimibranhial body remanet		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 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. : 0397
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 7

Organ	Findings	Group Name No. of Animals on Study Grade	Control				25ppm				50ppm				100ppm			
			10				10				10				10			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Reproductive system}																		
testis			<10>				<10>				<10>				<10>			
	germ cell necrosis		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)	(20)	(0)	(0)	(0)
prostate			<10>				<10>				<10>				<10>			
	inflammation		1	0	0	0	0	0	0	0	1	1	0	0	0	1	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(10)	(0)	(0)	(0)	(10)	(0)	(0)
{Special sense organs/appendage}																		
Harder gl			<10>				<10>				<10>				<10>			
	lymphocytic infiltration		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)
	granulation		0	0	0	0	0	0	0	0	2	0	0	0	2	1	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(20)	(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

(HPT150)

BAIS3

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrJ
 REPORT TYPE : A1
 SEX : MALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 8

		Group Name	200ppm				400ppm			
		No. of Animals on Study	10				10			
Organ	Findings	Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Reproductive system}										
testis			<10>				<10>			
	germ cell necrosis		0	0	0	0	2	0	0	0
			(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
prostate			<10>				<10>			
	inflammation		3	0	0	0	0	0	0	0
			(30)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Special sense organs/appendage}										
Harder gl			<10>				<10>			
	lymphocytic infiltration		1	0	0	0	2	0	0	0
			(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
	granulation		2	0	0	0	0	0	0	0
			(20)	(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

APPENDIX J 2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

RAT : FEMALE: ALL ANIMALS

(13-WEEK STUDY)

STUDY NO. : 0397
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 9

Organ	Findings	Group Name No. of Animals on Study Grade	Control				25ppm				50ppm				100ppm			
			10				10				10				10			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}																		
nasal cavit	goblet cell hyperplasia		<10>				<10>				<10>				<10>			
			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)	(20)	(0)	(0)	(0)
	inflammation:squamous epithelium		0	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)
	disarrangement:olfactory 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)
	desquamation:olfactory 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)
	inflammation:transitional epithelium		2	1	0	0	0	2	0	0	1	0	0	0	2	0	0	0
			(20)	(10)	(0)	(0)	(0)	(20)	(0)	(0)	(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
	hyperplasia: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)
nasopharynx	goblet cell hyperplasia		<10>				<10>				<10>				<10>			
			2	0	0	0	2	0	0	0	8	0	0	0 *	10	0	0	0 **
			(20)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(80)	(0)	(0)	(0)	(100)	(0)	(0)	(0)
lung	accumulation of foamy cells		<10>				<10>				<10>				<10>			
			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)	(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. : 0397
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 10

Organ_____	Findings_____	Group Name	200ppm				400ppm			
		No. of Animals on Study	10				10			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

{Respiratory system}										
nasal cavit			<10>				<10>			
	goblet cell hyperplasia		2	0	0	0	4	0	0	0
			(20)	(0)	(0)	(0)	(40)	(0)	(0)	(0)
	inflammation:squamous epithelium		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	disarrangement:olfactory epithelium		0	0	0	0	6	4	0	0 **
		(0)	(0)	(0)	(0)	(60)	(40)	(0)	(0)	
nasopharynx	desquamation:olfactory epithelium		0	0	0	0	3	0	0	0
			(0)	(0)	(0)	(0)	(30)	(0)	(0)	(0)
	inflammation:transitional epithelium		1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hyperplasia:respiratory epithelium		1	0	0	0	8	0	0	0 **
			(10)	(0)	(0)	(0)	(80)	(0)	(0)	(0)
lung	goblet cell hyperplasia		<10>				<10>			
			10	0	0	0 **	9	1	0	0 **
			(100)	(0)	(0)	(0)	(90)	(10)	(0)	(0)
lung	accumulation of foamy cells		<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 : Number of animals with lesion
 (c) c : b / a * 100
 Significant difference ; * : P ≤ 0.05 ** : P ≤ 0.01 Test of Chi Square

STUDY NO. : 0397
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 11

		Group Name	Control				25ppm				50ppm				100ppm				
		No. of Animals on Study	10				10				10				10				
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	
Organ	Findings		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	
<hr/>																			
{Hematopoietic system}																			
bone marrow			<10>				<10>				<10>				<10>				
	granulation		2 (20)	3 (30)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)
spleen			<10>				<10>				<10>				<10>				
	deposit of hemosiderin		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)
 {Digestive system}																			
stomach			<10>				<10>				<10>				<10>				
	epidermal cyst		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
liver			<10>				<10>				<10>				<10>				
	herniation		2 (20)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)	4 (40)	0 (0)	0 (0)	0 (0)	2 (20)	0 (0)	0 (0)	0 (0)	0 (0)
	necrosis:focal		0 (0)	0 (0)	0 (0)	0 (0)	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)
	granulation		2 (20)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	0 (0)	0 (0)	0 (0)	1 (10)	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. : 0397
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 12

		Group Name	200ppm				400ppm			
		No. of Animals on Study	10				10			
Organ	Findings	Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>										
{Hematopoietic system}										
bone marrow			<10>				<10>			
	granulation		1	0	0	0	1	0	0	0
			(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
spleen			<10>				<10>			
	deposit of hemosiderin		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
{Digestive system}										
stomach			<10>				<10>			
	epidermal cyst		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
liver			<10>				<10>			
	herniation		2	0	0	0	3	0	0	0
			(20)	(0)	(0)	(0)	(30)	(0)	(0)	(0)
	necrosis:focal		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	granulation		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

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 13

Organ	Findings	Group Name No. of Animals on Study Grade	Control				25ppm				50ppm				100ppm			
			10				10				10				10			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}																		
liver	perivascular inflammation		<10>				<10>				<10>				<10>			
			7	0	0	0	8	0	0	0	8	0	0	0	7	0	0	0
			(70)	(0)	(0)	(0)	(80)	(0)	(0)	(0)	(80)	(0)	(0)	(0)	(70)	(0)	(0)	(0)
{Urinary system}																		
kidney	mineralization:cortico-medullary junction		<10>				<10>				<10>				<10>			
			0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	mineralization:papilla		<10>				<10>				<10>				<10>			
			1	0	0	0	2	0	0	0	0	0	0	0	1	0	0	0
			(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
{Endocrine system}																		
pituitary	Rathke pouch		<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)
thyroid	degeneration		<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)

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. : 0397
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 14

Organ	Findings	Group Name		200ppm				400ppm			
		No. of Animals on Study		10				10			
		Grade		1	2	3	4	1	2	3	4
				(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Digestive system}											
liver	perivascular inflammation			<10>				<10>			
				9	0	0	0	9	0	0	0
				(90)	(0)	(0)	(0)	(90)	(0)	(0)	(0)
{Urinary system}											
kidney	mineralization:cortico-medullary junction			<10>				<10>			
				0	0	0	0	0	0	0	0
				(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	mineralization:papilla			<10>				<10>			
				0	0	0	0	0	0	0	0
				(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
{Endocrine system}											
pituitary	Rathke pouch			<10>				<10>			
				0	0	0	0	0	0	0	0
				(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
thyroid	degeneration			<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 : 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. : 0397
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 15

Organ	Findings	Group Name No. of Animals on Study Grade	Control				25ppm				50ppm				100ppm			
			10				10				10				10			
			1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}																		
thyroid	ultimibranhial body remanet		<10>				<10>				<10>				<10>			
			2	0	0	0	0	0	0	0	1	0	0	0	1	0	0	0
			(20)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
{Reproductive system}																		
ovary	cyst		<10>				<10>				<10>				<10>			
			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)	(10)	(0)	(0)	(0)
{Special sense organs/appendage}																		
eye	cataract		<10>				<10>				<10>				<10>			
			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)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
Harder gl	lymphocytic infiltration		<10>				<10>				<10>				<10>			
			0	0	0	0	3	0	0	0	2	1	0	0	2	0	0	0
			(0)	(0)	(0)	(0)	(30)	(0)	(0)	(0)	(20)	(10)	(0)	(0)	(20)	(0)	(0)	(0)
	granulation		1	0	0	0	3	0	0	0	2	0	0	0	3	0	0	0
			(10)	(0)	(0)	(0)	(30)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(30)	(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. : 0397
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 16

		Group Name				200ppm				400ppm			
		No. of Animals on Study				10				10			
		Grade											
Organ_____	Findings_____	1	2	3	4	1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Endocrine system}													
thyroid		<10>				<10>							
	ultimibranhial body remanet	2	0	0	0	1	0	0	0				
		(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)				
{Reproductive system}													
ovary		<10>				<10>							
	cyst	0	0	0	0	0	0	0	0				
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)				
{Special sense organs/appendage}													
eye		<10>				<10>							
	cataract	0	0	0	0	0	0	0	0				
		(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)				
Harder gl		<10>				<10>							
	lymphocytic infiltration	1	0	0	0	2	0	0	0				
		(10)	(0)	(0)	(0)	(20)	(0)	(0)	(0)				
	granulation	2	0	0	0	0	0	0	0				
		(20)	(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. : 0397
ANIMAL : RAT F344/DuCrj
REPORT TYPE : A1
SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
ALL ANIMALS (0- 14W)

PAGE : 17

Organ_____	Findings_____	Group Name	Control				25ppm				50ppm				100ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

{Body cavities}

adipose		<10>				<10>				<10>				<10>			
	inflammation	0	0	0	0	1	0	0	0	0	0	0	0	2	0	0	0
		(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(20)	(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

STUDY NO. : 0397
 ANIMAL : RAT F344/DuCrj
 REPORT TYPE : A1
 SEX : FEMALE

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)
 ALL ANIMALS (0- 14W)

PAGE : 18

Organ	Findings	Group Name		200ppm				400ppm			
		No. of Animals on Study		10				10			
		Grade		1	2	3	4	1	2	3	4
				(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

{Body cavities}

adipose	inflammation	<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 K 1

IDENTITY AND IMPURITY OF 1-BROMO-3-CHLOROPROPANE IN THE 13-WEEK INHALATION STUDY

IDENTITY AND IMPURITY OF 1-BROMO-3-CHLOROPROPANE IN THE 13-WEEK INHALATION STUDY

Test Substance : 1-Bromo-3-chloropropane (Wako Pure Chemical Industries, Ltd.)

Lot No. : CKK5616

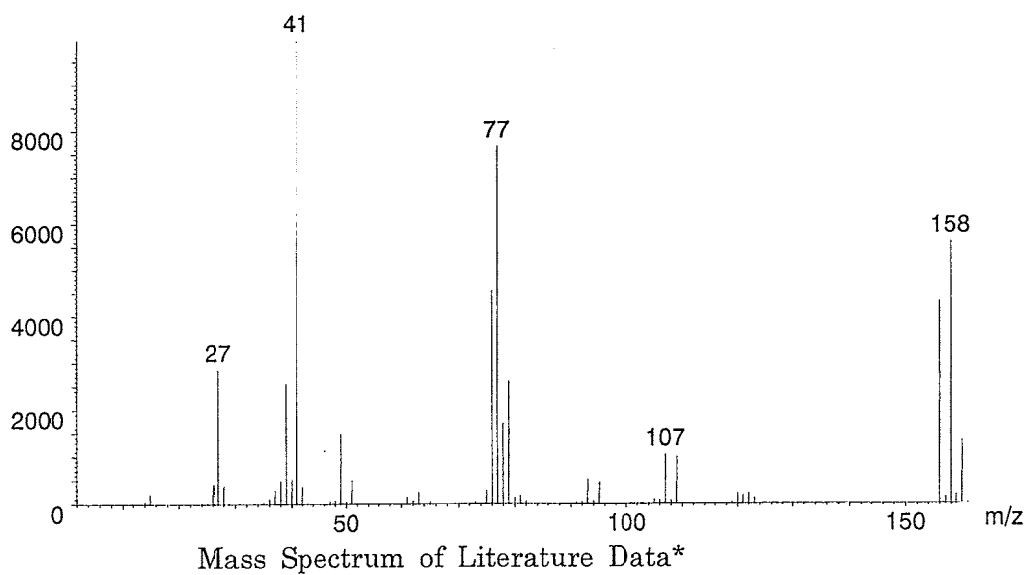
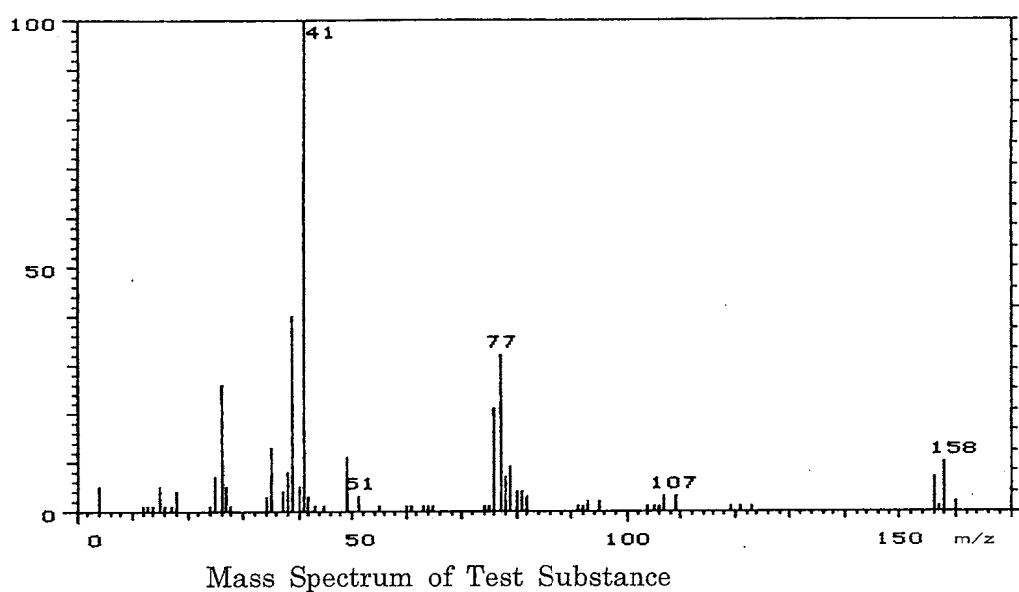
1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Results: The mass spectrum was consistent with literature spectrum.

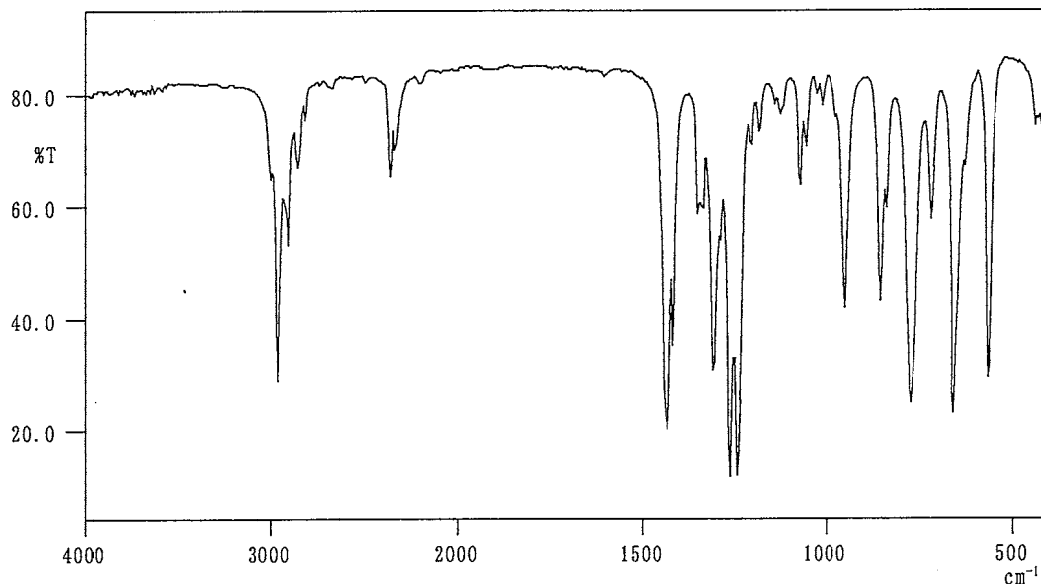
(*Fred W. McLafferty (1994) Wiley Registry of Mass Spectral Data, 6th edition. John Wiley and Sons, Inc. (U.S.), Entry Number 41048)

Infrared Spectrometry

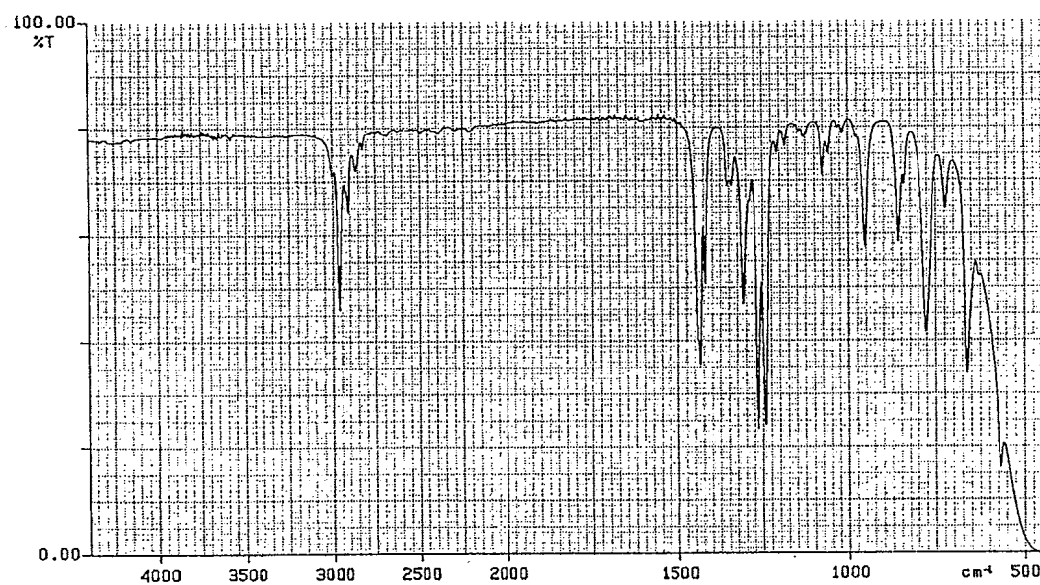
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

Resolution : 4 cm^{-1}



Infrared Spectrum of Test Substance



Infrared Spectrum of Literature Data*

Results: The infrared spectrum was consistent with literature spectrum.

(*Performed by the Wako Pure Chemical Industries, Ltd.)

2. Conclusions: The test substance was identified as 1-bromo-3-chloropropane by the mass spectrum and the infrared spectrum.

APPENDIX K 2

STABILITY OF 1-BROMO-3-CHLOROPROPANE IN THE 13-WEEK INHALATION STUDY

STABILITY OF 1-BROMO-3-CHLOROPROPANE IN THE 13-WEEK INHALATION STUDY

Test Substance : 1-Bromo-3-chloropropane (Wako Pure Chemical Industries, Ltd.)

Lot No. : CKK5616

1. Sample : This lot was used from 1999.9.9 to 1999.12.8. Test substance was stored in a dark place at room temperature.

2. Gas Chromatography

Instrument : Hewlett Packard 5890A Gas Chromatograph

Column : Methyl Silicone (0.53 mm ϕ \times 60 m)

Column Temperature: 100° C

Flow Rate : 20 mL/min

Detector : FID (Flame Ionization Detector)

Injection Volume : 1 μ L

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
1999.09.08	1	2.012	0.041
	2	7.061	99.959
1999.12.21	1	2.011	0.036
	2	7.041	99.964

Results: Gas chromatography indicated one major peak (peak No.2) and one impurity (peak No.1 < 0.1% of total area) analyzed on 1999.9.8 and one major peak (peak No.2) and one impurity (peak No.1 < 0.1% of total area) analyzed on 1999.12.21. No new trace impurity peak in the test substance analyzed on 1999.12.21 was detected.

3. Conclusions: The test substance was stable for about 15 weeks in a dark place at room temperature.

APPENDIX L 1

CONCENTRATION OF 1-BROMO-3-CHLOROPROPANE IN THE
INHALATION CHAMBER OF THE 13-WEEK INHALATION STUDY

CONCENTRATION OF 1-BROMO-3-CHLOROPROPANE IN THE INHALATION CHAMBER
OF THE 13-WEEK INHALATION STUDY

Group Name	Concentration(ppm) Mean \pm S.D.		
0ppm(Control)	0.0	\pm	0.0
25ppm	25.2	\pm	0.4
50ppm	50.2	\pm	0.9
100ppm	100.7	\pm	0.9
200ppm	201.5	\pm	1.8
400ppm	401.3	\pm	4.4

APPENDIX L 2

ENVORONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 13-WEEK INHALATION STUDY OF 1-BROMO-3-CHLOROPROPANE

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 13 -WEEK INHALATION SYUDY
OF 1-BROMO-3-CHLOROPROPANE

Group Name	Temperature(°C) Mean ± S.D.	Humidity(%) Mean ± S.D.	Ventilation Rate(L/min) Mean ± S.D.	Air Change(time/h) Mean
0ppm(Control)	22.3 ± 0.2	56.1 ± 0.9	211.8 ± 2.7	12.0
25ppm	22.7 ± 0.3	56.4 ± 1.2	212.0 ± 2.7	12.0
50ppm	22.4 ± 0.3	54.8 ± 0.8	211.7 ± 2.6	12.0
100ppm	22.5 ± 0.2	56.6 ± 0.8	211.8 ± 2.6	12.0
200ppm	22.6 ± 0.2	55.6 ± 0.8	211.8 ± 2.7	12.0
400ppm	22.6 ± 0.2	55.4 ± 1.1	211.9 ± 2.5	12.0

APPENDIX M 1

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS IN THE 13-WEEK INHALATION STUDY OF 1-BROMO-3-CHLOROPROPANE

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS IN THE
13-WEEK INHALATION STUDY OF 1-BROMO-3-CHLOROPROPANE

Item	Method
Hematology	
Red blood cell (RBC)	Light scattering method ¹⁾
Hemoglobin (Hgb)	Cyanmethemoglobin method ¹⁾
Hematocrit (Hct)	Calculated as $RBC \times MCV / 10$ ¹⁾
Mean corpuscular volume (MCV)	Light scattering method ¹⁾
Mean corpuscular hemoglobin (MCH)	Calculated as $Hgb / RBC \times 10$ ¹⁾
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as $Hgb / Hct \times 100$ ¹⁾
Platelet	Light scattering method ¹⁾
Reticulocyte	Pattern recognition method ³⁾ (New methyleneblue staining)
Prothrombin time	Quick one stage method ²⁾
Activated partial thromboplastin time (APTT)	Ellagic acid activated method ²⁾
White blood cell (WBC)	Light scattering method ¹⁾
Differential WBC	Pattern recognition method ³⁾ (Wright staining)
Biochemistry	
Total protein (TP)	Biuret method ⁴⁾
Albumin (Alb)	BCG method ⁴⁾
A/G ratio	Calculated as $Alb / (TP - Alb)$ ⁴⁾
T-bilirubin	Alkaline azobilirubin method ⁴⁾
Glucose	GlcK · G-6-PDH method ⁴⁾
T-cholesterol	CE · COD · POD method ⁴⁾
Triglyceride	LPL · GK · GPO · POD method ⁴⁾
Phospholipid	PLD · ChOD · POD method ⁴⁾
Glutamic oxaloacetic transaminase (GOT)	JSCC method ⁴⁾
Glutamic pyruvic transaminase (GPT)	JSCC method ⁴⁾
Lactate dehydrogenase (LDH)	SFBC method ⁴⁾
Alkaline phosphatase (ALP)	GSCC method ⁴⁾
γ -Glutamyl transpeptidase (γ -GTP)	L-γ -Glutamyl-p-nitroanilide method ⁴⁾
Creatine phosphokinase (CPK)	JSCC method ⁴⁾
Urea nitrogen	Urease · GLDH method ⁴⁾
Creatinine	Jaffe method ⁴⁾
Sodium	Ion selective electrode method ⁴⁾
Potassium	Ion selective electrode method ⁴⁾
Chloride	Ion selective electrode method ⁴⁾
Calcium	OCPC method ⁴⁾
Inorganic phosphorus	PNP · XOD · POD method ⁴⁾
Urinalysis	
pH, Protein, Glucose, Ketone body, Bilirubin, Occult Blood, Urobilinogen	Urinalysis reagent paper method ⁵⁾

1) Automatic blood cell analyzer (Technicon H·1 : Bayer Corporation)

2) Automatic coagulometer (Sysmex CA-5000 : Sysmex Corporation)

3) Automatic blood cell differential analyzer (MICROX HEG-120NA : OMRON Corporation)

4) Automatic analyzer (Hitachi 7070 : Hitachi, Ltd.)

5) Ames reagent strips for urinalysis (Multistix : Bayer Corporation)

APPENDIX M 2

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY
IN THE 13-WEEK INHALATION STUDY OF 1-BROMO-3-CHLOROPROPANE

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY
IN THE 13-WEEK INHALATION STUDY OF 1-BROMO-3-CHLOROPROPANE

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
Reticulocyte	%	0
Prothrombin time	sec	1
Activated partial thromboplastin time (APTT)	sec	1
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
γ -Glutamyl transpeptidase (γ -GTP)	IU/L	0
Creatine phosphokinase (CPK)	IU/L	0
Urea nitrogen	mg/dL	1
Creatinine	mg/dL	1
Sodium	mEq/L	0
Potassium	mEq/L	1
Chloride	mEq/L	0
Calcium	mg/dL	1
Inorganic phosphorus	mg/dL	1