

エチレングリコールモノエチルエーテルアセテート  
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：0743

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**TABLE A**

**CONCENTRATIONS OF ETHYLENE GLYCOL  
MONOETHYL ETHER ACETATE  
IN THE INHALATION CHAMBER  
OF THE 13-WEEK INHALATION STUDY**

CONCENTRATIONS OF ETHYLENE GLYCOL MONOETHYL ETHER ACETATE  
IN THE INHALATION CHAMBER OF THE 13-WEEK INHALATION STUDY

Group Name	Concentration(ppm)
	Mean $\pm$ S.D.
Control	0.0 $\pm$ 0.0
25 ppm	25.0 $\pm$ 0.5
50 ppm	50.0 $\pm$ 0.9
100 ppm	100.3 $\pm$ 1.1
200 ppm	200.7 $\pm$ 2.3
400 ppm	400.1 $\pm$ 2.9

**TABLE B1**

**SURVIVAL ANIMAL NUMBERS : MALE**

STUDY NO. : 0743

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

REPORT TYPE : A1 13

SEX : MALE

SURVIVAL ANIMAL NUMBERS

PAGE : 1

Group Name	Animals At start	Administration (Weeks)												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Control	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
25ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
50ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
100ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
200ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
400ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Number of survival/ Number of effective animals														
Survival rate(%)														

(HAN360)

BAIS4

**TABLE B2**

**SURVIVAL ANIMAL NUMBERS : FEMALE**



STUDY NO. : 0743

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

REPORT TYPE : A1 13

SEX : FEMALE

## SURVIVAL ANIMAL NUMBERS

PAGE : 2

Group Name	Animals At start	Administration (Weeks)												
		1	2	3	4	5	6	7	8	9	10	11	12	13
Control	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
25ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
50ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
100ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
200ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
400ppm	10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10	10/10
		100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
Number of survival/ Number of effective animals														
Survival rate(%)														

(HAN360)

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**TABLE C1**

**CLINICAL OBSERVATION : MALE**

STUDY NO. : 0743  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)  
ALL ANIMALS

SEX : MALE

PAGE : 1

Clinical sign	Group Name	Administration Week-day												
		1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1
NON REMARKABLE	Control	10	10	10	10	10	10	10	10	10	10	10	10	10
	25ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	50ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	100ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	200ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	400ppm	10	10	10	10	10	10	10	10	10	10	10	10	10

(HAN190)

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**TABLE C2**

**CLINICAL OBSERVATION : FEMALE**

STUDY NO. : 0743  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
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
		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	0	0
	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	1	1	1	1
NON REMARKABLE	Control	10	10	10	10	10	10	10	10	10	10	10	10	10
	25ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	50ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	100ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	200ppm	10	10	10	10	10	10	10	10	10	10	10	10	10
	400ppm	10	10	10	10	10	10	10	10	10	9	9	9	9

(HAN190)

BAIS 4

**TABLE D1**

**BODY WEIGHT CHANGES AND SURVIVAL ANIMAL  
NUMBERS : MALE**

STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 13  
 SEX : MALE

MEAN BODY WEIGHTS AND SURVIVAL

PAGE : 1

Week-Day on Study	Control		25ppm			50ppm			100ppm			200ppm			400ppm		
	Av. Wt.	No. of Surviv. <10>	Av. Wt.	% of cont. <10>	No. of Surviv.	Av. Wt.	% of cont. <10>	No. of Surviv.	Av. Wt.	% of cont. <10>	No. of Surviv.	Av. Wt.	% of cont. <10>	No. of Surviv.	Av. Wt.	% of cont. <10>	No. of Surviv.
1-7	155 (10)	10/10	155 (10)	100	10/10	156 (10)	101	10/10	154 (10)	99	10/10	152 (10)	98	10/10	148 (10)	95	10/10
2-7	189 (10)	10/10	185 (10)	98	10/10	188 (10)	99	10/10	185 (10)	98	10/10	182 (10)	96	10/10	179 (10)	95	10/10
3-7	213 (10)	10/10	209 (10)	98	10/10	214 (10)	100	10/10	207 (10)	97	10/10	204 (10)	96	10/10	201 (10)	94	10/10
4-7	231 (10)	10/10	227 (10)	98	10/10	235 (10)	102	10/10	225 (10)	97	10/10	222 (10)	96	10/10	217 (10)	94	10/10
5-7	250 (10)	10/10	243 (10)	97	10/10	254 (10)	102	10/10	243 (10)	97	10/10	238 (10)	95	10/10	231 (10)	92	10/10
6-7	266 (10)	10/10	257 (10)	97	10/10	268 (10)	101	10/10	255 (10)	96	10/10	250 (10)	94	10/10	240 (10)	90	10/10
7-7	279 (10)	10/10	269 (10)	96	10/10	283 (10)	101	10/10	269 (10)	96	10/10	263 (10)	94	10/10	250 (10)	90	10/10
8-7	292 (10)	10/10	280 (10)	96	10/10	294 (10)	101	10/10	281 (10)	96	10/10	271 (10)	93	10/10	256 (10)	88	10/10
9-7	302 (10)	10/10	288 (10)	95	10/10	302 (10)	100	10/10	290 (10)	96	10/10	280 (10)	93	10/10	261 (10)	86	10/10
10-7	310 (10)	10/10	296 (10)	95	10/10	311 (10)	100	10/10	297 (10)	96	10/10	286 (10)	92	10/10	265 (10)	85	10/10
11-7	317 (10)	10/10	302 (10)	95	10/10	317 (10)	100	10/10	305 (10)	96	10/10	293 (10)	92	10/10	274 (10)	86	10/10
12-7	322 (10)	10/10	309 (10)	96	10/10	323 (10)	100	10/10	311 (10)	97	10/10	297 (10)	92	10/10	280 (10)	87	10/10
13-7	329 (10)	10/10	315 (10)	96	10/10	330 (10)	100	10/10	317 (10)	96	10/10	302 (10)	92	10/10	287 (10)	87	10/10

< >:No. of effective animals, ( ):No. of measured animals Av. Wt. : g

(BI0040)

BAIS 4

**TABLE D2**

**BODY WEIGHT CHANGES AND SURVIVAL ANIMAL  
NUMBERS : FEMALE**



STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 13  
 SEX : FEMALE

MEAN BODY WEIGHTS AND SURVIVAL

PAGE : 2

Week-Day on Study	Control		25ppm		No. of Surviv.	50ppm		No. of Surviv.	100ppm		No. of Surviv.	200ppm		No. of Surviv.	400ppm		No. of Surviv.
	Av. Wt.	No. of Surviv. <10>	Av. Wt.	% of cont. <10>		Av. Wt.	% of cont. <10>		Av. Wt.	% of cont. <10>		Av. Wt.	% of cont. <10>		Av. Wt.	% of cont. <10>	
1-7	112 (10)	10/10	111 (10)	99	10/10	112 (10)	100	10/10	111 (10)	99	10/10	108 (10)	96	10/10	106 (10)	95	10/10
2-7	128 (10)	10/10	125 (10)	98	10/10	127 (10)	99	10/10	125 (10)	98	10/10	122 (10)	95	10/10	118 (10)	92	10/10
3-7	139 (10)	10/10	136 (10)	98	10/10	137 (10)	99	10/10	133 (10)	96	10/10	131 (10)	94	10/10	125 (10)	90	10/10
4-7	147 (10)	10/10	143 (10)	97	10/10	144 (10)	98	10/10	141 (10)	96	10/10	139 (10)	95	10/10	130 (10)	88	10/10
5-7	156 (10)	10/10	150 (10)	96	10/10	151 (10)	97	10/10	148 (10)	95	10/10	146 (10)	94	10/10	135 (10)	87	10/10
6-7	161 (10)	10/10	158 (10)	98	10/10	157 (10)	98	10/10	153 (10)	95	10/10	150 (10)	93	10/10	139 (10)	86	10/10
7-7	166 (10)	10/10	163 (10)	98	10/10	162 (10)	98	10/10	159 (10)	96	10/10	156 (10)	94	10/10	145 (10)	87	10/10
8-7	171 (10)	10/10	167 (10)	98	10/10	165 (10)	96	10/10	161 (10)	94	10/10	157 (10)	92	10/10	144 (10)	84	10/10
9-7	174 (10)	10/10	169 (10)	97	10/10	168 (10)	97	10/10	163 (10)	94	10/10	160 (10)	92	10/10	146 (10)	84	10/10
10-7	178 (10)	10/10	171 (10)	96	10/10	171 (10)	96	10/10	166 (10)	93	10/10	161 (10)	90	10/10	148 (10)	83	10/10
11-7	181 (10)	10/10	176 (10)	97	10/10	177 (10)	98	10/10	169 (10)	93	10/10	164 (10)	91	10/10	150 (10)	83	10/10
12-7	184 (10)	10/10	177 (10)	96	10/10	177 (10)	96	10/10	171 (10)	93	10/10	167 (10)	91	10/10	152 (10)	83	10/10
13-7	188 (10)	10/10	181 (10)	96	10/10	181 (10)	96	10/10	173 (10)	92	10/10	170 (10)	90	10/10	156 (10)	83	10/10
< >:No. of effective animals, ( ):No. of measured animals <span style="float: right;">Av. Wt. : g</span>																	

(BI0040)

BAIS 4

**TABLE D3**

**BODY WEIGHT CHANGES : MALE**

STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 13  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 1

Group Name	Administration		week-day													
	1-7		2-7		3-7		4-7		5-7		6-7		7-7			
Control	155±	4	189±	5	213±	6	231±	6	250±	6	266±	5	279±	5		
25ppm	155±	4	185±	4	209±	8	227±	9	243±	9	257±	7	269±	8		
50ppm	156±	7	188±	8	214±	9	235±	9	254±	9	268±	11	283±	13		
100ppm	154±	6	185±	7	207±	7	225±	6	243±	8	255±	10*	269±	10		
200ppm	152±	6	182±	7	204±	6*	222±	9*	238±	10**	250±	11**	263±	12**		
400ppm	148±	7*	179±	7**	201±	7**	217±	8**	231±	6**	240±	8**	250±	10**		

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

Test of Dunnett

STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 13  
 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 2

Group Name	Administration		week-day									
	8-7		9-7		10-7		11-7		12-7		13-7	
Control	292±	5	302±	6	310±	8	317±	9	322±	9	329±	11
25ppm	280±	7*	288±	8*	296±	9*	302±	9*	309±	10	315±	11*
50ppm	294±	14	302±	14	311±	14	317±	15	323±	16	330±	17
100ppm	281±	11	290±	11	297±	10*	305±	9	311±	10	317±	10
200ppm	271±	11**	280±	12**	286±	11**	293±	10**	297±	11**	302±	9**
400ppm	256±	10**	261±	10**	265±	11**	274±	11**	280±	13**	287±	12**

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

Test of Dunnett

**TABLE D4**

**BODY WEIGHT CHANGES : FEMALE**

STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1, 13  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 3

Group Name	Administration		week-day													
	1-7		2-7		3-7		4-7		5-7		6-7		7-7			
Control	112±	4	128±	4	139±	5	147±	5	156±	8	161±	8	166±	9		
25ppm	111±	3	125±	5	136±	6	143±	8	150±	8	158±	8	163±	9		
50ppm	112±	4	127±	4	137±	5	144±	5	151±	6	157±	7	162±	6		
100ppm	111±	5	125±	5	133±	6	141±	7	148±	6*	153±	6*	159±	7		
200ppm	108±	5	122±	5*	131±	3**	139±	4*	146±	5**	150±	5**	156±	6*		
400ppm	106±	4**	118±	5**	125±	4**	130±	5**	135±	5**	139±	5**	145±	6**		

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

Test of Dunnett

STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 13  
 SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)  
 ALL ANIMALS

PAGE : 4

Group Name	Administration		week-day									
	8-7		9-7		10-7		11-7		12-7		13-7	
Control	171±	9	174±	9	178±	9	181±	10	184±	10	188±	9
25ppm	167±	10	169±	10	171±	10	176±	11	177±	11	181±	9
50ppm	165±	7	168±	8	171±	7	177±	7	177±	7	181±	8
100ppm	161±	7*	163±	7**	166±	6**	169±	8**	171±	7**	173±	7**
200ppm	157±	7**	160±	6**	161±	6**	164±	8**	167±	7**	170±	7**
400ppm	144±	6**	146±	5**	148±	5**	150±	5**	152±	5**	156±	6**

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

Test of Dunnett

**TABLE E1**

**FOOD CONSUMPTION CHANGES AND SURVIVAL ANIMAL  
NUMBERS : MALE**



STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 13  
 SEX : MALE

MEAN FOOD CONSUMPTION(FC) AND SURVIVAL

PAGE : 1

Week-Day on Study	Control		25ppm		50ppm		100ppm		200ppm		400ppm						
	Av. FC.	No. of Surviv. <10>	Av. FC.	% of cont. <10>	No. of Surviv.	Av. FC.	% of cont. <10>	No. of Surviv.	Av. FC.	% of cont. <10>	No. of Surviv.	Av. FC.	% of cont. <10>	No. of Surviv.	Av. FC.	% of cont. <10>	No. of Surviv.
1-7	15.2 (10)	10/10	15.1 (10)	99	10/10	15.7 (10)	103	10/10	14.7 (10)	97	10/10	14.6 (10)	96	10/10	14.1 (10)	93	10/10
2-7	17.3 (10)	10/10	16.5 (10)	95	10/10	17.1 (10)	99	10/10	16.9 (10)	98	10/10	16.5 (10)	95	10/10	15.5 (10)	90	10/10
3-7	17.9 (10)	10/10	17.2 (10)	96	10/10	18.1 (10)	101	10/10	17.6 (10)	98	10/10	17.3 (10)	97	10/10	16.7 (10)	93	10/10
4-7	17.4 (10)	10/10	17.0 (10)	98	10/10	17.9 (10)	103	10/10	17.0 (10)	98	10/10	17.0 (10)	98	10/10	17.0 (10)	98	10/10
5-7	17.5 (10)	10/10	17.1 (10)	98	10/10	18.2 (10)	104	10/10	17.1 (10)	98	10/10	16.9 (10)	97	10/10	16.7 (10)	95	10/10
6-7	17.5 (10)	10/10	17.3 (10)	99	10/10	18.2 (10)	104	10/10	16.8 (10)	96	10/10	16.6 (10)	95	10/10	15.8 (10)	90	10/10
7-7	17.2 (10)	10/10	16.7 (10)	97	10/10	17.6 (10)	102	10/10	16.9 (10)	98	10/10	16.6 (10)	97	10/10	15.8 (10)	92	10/10
8-7	17.5 (10)	10/10	16.4 (10)	94	10/10	17.3 (10)	99	10/10	16.6 (10)	95	10/10	15.9 (10)	91	10/10	15.0 (10)	86	10/10
9-7	17.3 (10)	10/10	16.2 (10)	94	10/10	17.1 (10)	99	10/10	16.2 (10)	94	10/10	16.2 (10)	94	10/10	15.0 (10)	87	10/10
10-7	17.5 (10)	10/10	16.4 (10)	94	10/10	16.8 (10)	96	10/10	16.4 (10)	94	10/10	16.0 (10)	91	10/10	14.8 (10)	85	10/10
11-7	17.2 (10)	10/10	16.1 (10)	94	10/10	16.8 (10)	98	10/10	16.4 (10)	95	10/10	15.9 (10)	92	10/10	15.0 (10)	87	10/10
12-7	16.8 (10)	10/10	15.8 (10)	94	10/10	16.4 (10)	98	10/10	16.0 (10)	95	10/10	15.2 (10)	90	10/10	14.8 (10)	88	10/10
13-7	16.7 (10)	10/10	15.8 (10)	95	10/10	16.6 (10)	99	10/10	15.9 (10)	95	10/10	15.6 (10)	93	10/10	15.2 (10)	91	10/10
< >:No. of effective animals, ( ):No. of measured animals																	
Av. FC. : g																	

< >:No.of effective animals, ( ):No.of measured animals      Av.FC.: g

(BI0040)

BAIS 4

**TABLE E2**

**FOOD CONSUMPTION CHANGES AND SURVIVAL ANIMAL  
NUMBERS : FEMALE**

STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 UNIT : g  
 REPORT TYPE : A1 13  
 SEX : FEMALE

MEAN FOOD CONSUMPTION(FC) AND SURVIVAL

PAGE : 2

Week-Day on Study	Control		25ppm		50ppm		100ppm		200ppm		400ppm						
	Av. FC.	No. of Surviv. <10>	Av. FC.	% of cont. <10>	No. of Surviv.	Av. FC.	% of cont. <10>	No. of Surviv.	Av. FC.	% of cont. <10>	No. of Surviv.	Av. FC.	% of cont. <10>	No. of Surviv.			
1-7	11.3 (10)	10/10	11.1 (10)	98	10/10	11.6 (10)	103	10/10	10.9 (10)	96	10/10	10.7 (10)	95	10/10	10.4 (10)	92	10/10
2-7	12.1 (10)	10/10	11.6 (10)	96	10/10	12.0 (10)	99	10/10	11.2 (10)	93	10/10	11.3 (10)	93	10/10	11.0 (10)	91	10/10
3-7	12.1 (10)	10/10	11.5 (10)	95	10/10	11.8 (10)	98	10/10	11.6 (10)	96	10/10	11.7 (10)	97	10/10	11.0 (10)	91	10/10
4-7	12.1 (10)	10/10	11.3 (10)	93	10/10	11.6 (10)	96	10/10	11.3 (10)	93	10/10	11.6 (10)	96	10/10	11.1 (10)	92	10/10
5-7	12.2 (10)	10/10	11.5 (10)	94	10/10	11.7 (10)	96	10/10	11.2 (10)	92	10/10	11.5 (10)	94	10/10	10.8 (10)	89	10/10
6-7	11.5 (10)	10/10	11.5 (10)	100	10/10	11.2 (10)	97	10/10	11.0 (10)	96	10/10	11.2 (10)	97	10/10	10.3 (10)	90	10/10
7-7	11.9 (10)	10/10	11.4 (10)	96	10/10	11.2 (10)	94	10/10	10.9 (10)	92	10/10	11.3 (10)	95	10/10	10.4 (10)	87	10/10
8-7	11.5 (10)	10/10	11.4 (10)	99	10/10	11.0 (10)	96	10/10	10.7 (10)	93	10/10	10.6 (10)	92	10/10	9.8 (10)	85	10/10
9-7	11.3 (10)	10/10	10.6 (10)	94	10/10	10.8 (10)	96	10/10	10.4 (10)	92	10/10	10.2 (10)	90	10/10	9.8 (10)	87	10/10
10-7	11.6 (10)	10/10	10.8 (10)	93	10/10	10.9 (10)	94	10/10	10.3 (10)	89	10/10	10.2 (10)	88	10/10	9.5 (10)	82	10/10
11-7	11.5 (10)	10/10	10.7 (10)	93	10/10	11.1 (10)	97	10/10	10.6 (10)	92	10/10	10.5 (10)	91	10/10	10.0 (10)	87	10/10
12-7	11.6 (10)	10/10	10.8 (10)	93	10/10	10.7 (10)	92	10/10	10.5 (10)	91	10/10	10.2 (10)	88	10/10	9.4 (10)	81	10/10
13-7	11.4 (10)	10/10	10.8 (10)	95	10/10	10.6 (10)	93	10/10	10.2 (10)	89	10/10	10.4 (10)	91	10/10	9.8 (10)	86	10/10
< >:No. of effective animals, ( ):No. of measured animals																	
Av. FC.: g																	

< >:No.of effective animals, ( ):No.of measured animals Av.FC.: g

(BI0040)

BAIS 4

**TABLE E3**

**FOOD CONSUMPTION CHANGES : MALE**

STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[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(7)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	15.2± 0.6	17.3± 0.8	17.9± 0.9	17.4± 0.6	17.5± 0.7	17.5± 1.0	17.2± 0.7
25ppm	15.1± 0.8	16.5± 0.9	17.2± 1.1	17.0± 1.0	17.1± 0.7	17.3± 0.8	16.7± 0.9
50ppm	15.7± 0.9	17.1± 1.0	18.1± 1.1	17.9± 0.8	18.2± 0.7	18.2± 1.2	17.6± 1.0
100ppm	14.7± 0.7	16.9± 1.5	17.6± 1.8	17.0± 0.8	17.1± 0.9	16.8± 0.9	16.9± 0.8
200ppm	14.6± 0.6	16.5± 1.0	17.3± 0.9	17.0± 0.9	16.9± 0.9	16.6± 0.7	16.6± 1.0
400ppm	14.1± 1.2*	15.5± 1.4**	16.7± 1.3	17.0± 1.4	16.7± 0.5	15.8± 0.7**	15.8± 1.1**

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

Test of Dunnett

STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[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	17.5± 0.8	17.3± 1.1	17.5± 1.0	17.2± 1.0	16.8± 1.0	16.7± 0.9
25ppm	16.4± 0.7*	16.2± 0.5*	16.4± 0.7*	16.1± 0.6	15.8± 0.6	15.8± 1.0
50ppm	17.3± 0.9	17.1± 0.9	16.8± 0.9	16.8± 1.1	16.4± 1.3	16.6± 1.2
100ppm	16.6± 0.8	16.2± 0.7*	16.4± 0.8*	16.4± 0.7	16.0± 0.5	15.9± 0.5
200ppm	15.9± 1.0**	16.2± 0.7*	16.0± 0.7**	15.9± 0.8**	15.2± 0.7**	15.6± 0.7*
400ppm	15.0± 0.8**	15.0± 0.8**	14.8± 0.7**	15.0± 1.2**	14.8± 1.1**	15.2± 1.0**

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

Test of Dunnett

**TABLE E4**

**FOOD CONSUMPTION CHANGES : FEMALE**

STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[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(7)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
Control	11.3± 0.6	12.1± 0.8	12.1± 0.6	12.1± 0.6	12.2± 1.1	11.5± 0.7	11.9± 1.1
25ppm	11.1± 0.6	11.6± 0.8	11.5± 1.0	11.3± 1.0	11.5± 1.0	11.5± 1.1	11.4± 1.0
50ppm	11.6± 0.4	12.0± 0.6	11.8± 0.8	11.6± 0.6	11.7± 0.6	11.2± 0.7	11.2± 0.6
100ppm	10.9± 0.7	11.2± 0.8*	11.6± 0.9	11.3± 0.8	11.2± 0.8*	11.0± 0.4	10.9± 0.7
200ppm	10.7± 0.6	11.3± 0.6*	11.7± 0.7	11.6± 0.7	11.5± 0.8	11.2± 0.4	11.3± 1.0
400ppm	10.4± 0.6**	11.0± 0.8**	11.0± 0.7	11.1± 0.8	10.8± 0.8**	10.3± 0.7**	10.4± 0.8**

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

Test of Dunnett



STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[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	11.5± 0.9	11.3± 0.9	11.6± 0.8	11.5± 0.5	11.6± 1.1	11.4± 0.6
25ppm	11.4± 1.4	10.6± 1.1	10.8± 0.8*	10.7± 0.7*	10.8± 1.2	10.8± 0.8
50ppm	11.0± 0.7	10.8± 0.6	10.9± 0.7	11.1± 0.5	10.7± 0.8	10.6± 0.9*
100ppm	10.7± 0.4	10.4± 0.5	10.3± 0.6**	10.6± 0.5*	10.5± 0.7	10.2± 0.5**
200ppm	10.6± 0.9	10.2± 0.5*	10.2± 0.7**	10.5± 0.6**	10.2± 0.6**	10.4± 0.5**
400ppm	9.8± 0.8**	9.8± 0.5**	9.5± 0.5**	10.0± 0.7**	9.4± 0.4**	9.8± 0.6**

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

Test of Dunnett

**TABLE F1**

**HEMATOLOGY : MALE**

STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[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 <sup>6</sup> /μl		HEMOGLOBIN g/dl		HEMATOCRIT %		MCV fl		MCH pg		MCHC g/dl		PLATELET 10 <sup>3</sup> /μl	
Control	10	9.46±	0.15	15.4±	0.3	44.7±	0.7	47.2±	0.3	16.3±	0.1	34.5±	0.3	784±	63
25ppm	10	9.49±	0.23	15.6±	0.4	45.0±	1.0	47.4±	0.3	16.4±	0.1	34.6±	0.3	773±	54
50ppm	10	9.54±	0.10	15.5±	0.2	44.9±	0.6	47.0±	0.5	16.2±	0.2	34.5±	0.4	766±	56
100ppm	10	9.51±	0.21	15.6±	0.3	45.2±	1.0	47.5±	0.5	16.4±	0.2	34.4±	0.3	784±	61
200ppm	10	9.54±	0.26	15.5±	0.4	45.2±	1.0	47.4±	0.6	16.2±	0.1	34.2±	0.5	811±	81
400ppm	10	9.42±	0.26	15.3±	0.4	45.1±	0.6	47.9±	0.8	16.2±	0.1	33.9±	0.5**	860±	57*

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

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0743

ANIMAL : RAT F344/DuCr1Cr1j[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	10	1.7±	0.1	14.8±	0.9	22.1±	1.1
25ppm	10	1.8±	0.2	15.2±	1.6	22.1±	0.9
50ppm	10	1.9±	0.1*	15.3±	1.8	22.0±	1.9
100ppm	10	1.8±	0.1	14.6±	0.9	22.0±	0.7
200ppm	10	1.9±	0.1	15.0±	1.7	21.5±	1.7
400ppm	10	2.1±	0.2**	14.8±	1.3	20.3±	1.4*

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

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 MEASURE. TIME : 1  
 SEX : MALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY)  
 ALL ANIMALS ( 14W)

PAGE : 3

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μl		Differential		WBC (%)		MONO		EOSINO		BASO		OTHER	
				NEUTRO		LYMPHO									
Control	10	6.19±	1.81	25±	3	71±	4	2±	1	2±	1	0±	0	1±	0
25ppm	10	5.90±	1.56	26±	7	69±	7	3±	1	1±	0	0±	0	1±	0
50ppm	10	6.40±	1.32	25±	7	70±	7	3±	1	1±	0	0±	0	1±	0
100ppm	10	6.45±	1.72	27±	6	69±	6	2±	1	1±	0	0±	0	1±	0
200ppm	10	5.60±	1.65	24±	3	72±	3	2±	0	1±	1	0±	0	1±	0
400ppm	10	5.72±	1.44	25±	5	71±	5	2±	0	2±	1	0±	0	0±	1

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

\*\* :  $P \leq 0.01$

Test of Dunnett

(HCL070)

BAIS 4

**TABLE F2**

**HEMATOLOGY : FEMALE**

STUDY NO. : 0743

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

## HEMATOLOGY (SUMMARY)

ALL ANIMALS ( 14W)

PAGE : 4

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	
Control	10	8.91±	0.19	15.9±	0.3	44.4±	0.9	49.9±	0.4	17.8±	0.2	35.7±	0.3	887±	52
25ppm	10	8.92±	0.19	15.9±	0.3	44.4±	1.0	49.8±	0.4	17.8±	0.2	35.9±	0.5	848±	46
50ppm	10	8.90±	0.16	15.8±	0.2	44.2±	0.6	49.7±	0.4	17.8±	0.2	35.8±	0.4	876±	63
100ppm	10	8.93±	0.16	15.8±	0.3	44.4±	0.8	49.7±	0.6	17.7±	0.2	35.6±	0.4	881±	20
200ppm	10	8.95±	0.27	15.5±	0.5	44.5±	1.3	49.8±	0.7	17.3±	0.2**	34.9±	0.8**	912±	84
400ppm	10	8.90±	0.23	15.4±	0.3*	44.3±	0.7	49.8±	0.8	17.4±	0.1**	34.8±	0.5**	924±	108

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

Test of Dunnett

(HCL070)

BAIS 4

STUDY NO. : 0743

ANIMAL : RAT F344/DuCr1Cr1j[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	1.8±	0.3	13.5±	0.6	16.0±	0.8
25ppm	10	1.8±	0.2	13.4±	0.5	16.3±	0.7
50ppm	10	1.8±	0.2	13.5±	0.3	16.3±	0.9
100ppm	10	1.8±	0.2	13.4±	0.5	16.1±	0.5
200ppm	10	1.9±	0.2	13.7±	0.4	16.1±	0.5
400ppm	10	2.1±	0.4	13.7±	0.6	15.6±	1.2

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

Test of Dunnett

(HCL070)

BAIS 4



STUDY NO. : 0743  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
MEASURE. TIME : 1  
SEX : FEMALE

HEMATOLOGY (SUMMARY)  
ALL ANIMALS ( 14W)

REPORT TYPE : A1

PAGE : 6

Group Name	NO. of Animals	WBC 10 <sup>3</sup> /μl		Differential		WBC (%)		MONO		EOSINO		BASO		OTHER	
				NEUTRO		LYMPHO									
Control	10	4.69±	1.58	24±	5	72±	5	3±	1	2±	1	0±	0	1±	0
25ppm	10	4.64±	1.58	27±	4	68±	4	2±	0	1±	1	0±	0	1±	0
50ppm	10	4.25±	1.03	27±	6	68±	7	2±	1	2±	1	0±	0	1±	0
100ppm	10	4.30±	1.31	26±	5	69±	5	3±	0	2±	0	0±	0	1±	0
200ppm	10	4.24±	1.05	23±	3	72±	3	3±	1	2±	1	0±	0	1±	0
400ppm	10	4.22±	1.48	20±	6	75±	6	2±	1	2±	1	0±	0	1±	1

Significant difference ; \* : P ≤ 0.05      \*\* : P ≤ 0.01

Test of Dunnett

(HCL070)

BAIS 4

**TABLE G1**

**BIOCHEMISTRY : MALE**

STUDY NO. : 0743

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

## BIOCHEMISTRY (SUMMARY)

ALL ANIMALS ( 14W)

PAGE : 1

Group Name	NO. of Animals	TOTAL PROTEIN g /dl		ALBUMIN g /dl		A/G RATIO		T-BILIRUBIN mg/dl		GLUCOSE mg/dl		T-CHOLESTEROL mg/dl		TRIGLYCERIDE mg/dl	
Control	10	6.5±	0.2	3.4±	0.1	1.1±	0.0	0.09±	0.01	182±	12	66±	4	61±	18
25ppm	10	6.6±	0.1	3.5±	0.1	1.1±	0.1	0.09±	0.01	184±	10	61±	5	43±	10*
50ppm	10	6.6±	0.2	3.5±	0.1	1.1±	0.0	0.09±	0.01	187±	12	64±	6	55±	9
100ppm	10	6.5±	0.2	3.5±	0.1	1.2±	0.1	0.09±	0.01	185±	5	62±	5	56±	17
200ppm	10	6.5±	0.1	3.5±	0.1	1.2±	0.1	0.09±	0.01	184±	8	60±	3*	51±	16
400ppm	10	6.4±	0.2	3.5±	0.1	1.2±	0.1**	0.09±	0.01	185±	7	55±	6**	45±	7*

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

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0743

ANIMAL : RAT F344/DuCr1Cr1j[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		AST I U / l		ALT I U / l		LDH I U / l		ALP I U / l		G-GTP I U / l		CK I U / l	
Control	10	114±	7	106±	35	58±	15	134±	26	367±	32	1±	1	111±	16
25ppm	10	109±	9	99±	22	51±	8	123±	33	374±	30	1±	0	106±	18
50ppm	10	114±	7	109±	32	57±	11	134±	38	359±	42	1±	0	105±	12
100ppm	10	112±	7	109±	28	55±	10	124±	28	358±	24	1±	0	104±	9
200ppm	10	110±	7	106±	48	53±	18	134±	71	351±	32	1±	0	108±	18
400ppm	10	107±	8	79±	18	41±	7**	103±	40	348±	21	1±	0	105±	15

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

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0743

ANIMAL : RAT F344/DuCr1Cr1j[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	10	20.0±	1.4	0.5±	0.0	142±	1	3.6±	0.3	105±	1	10.3±	0.1	6.1±	0.7
25ppm	10	18.7±	0.9	0.6±	0.1	142±	1	3.5±	0.2	105±	2	10.2±	0.2	5.8±	1.0
50ppm	10	19.5±	1.7	0.5±	0.0	142±	1	3.5±	0.3	104±	2	10.3±	0.2	6.2±	0.7
100ppm	10	19.5±	1.1	0.5±	0.0	142±	1	3.5±	0.2	105±	1	10.1±	0.2	5.9±	1.1
200ppm	10	19.2±	1.5	0.5±	0.1	142±	1	3.6±	0.2	105±	2	10.1±	0.2	5.8±	0.9
400ppm	10	19.3±	1.3	0.5±	0.1	142±	1	3.7±	0.2	105±	2	10.1±	0.1	6.0±	1.0

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

Test of Dunnett

(HCL074)

BAIS 4

**TABLE G2**

**BIOCHEMISTRY : FEMALE**

STUDY NO. : 0743  
ANIMAL : RAT F344/DuCr1Cr1j[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	6.4±	0.1	3.5±	0.1	1.2±	0.1	0.10±	0.01	141±	10	79±	10	16±	6
25ppm	10	6.4±	0.2	3.4±	0.1	1.2±	0.1	0.10±	0.01	145±	6	76±	5	12±	3
50ppm	10	6.3±	0.2	3.4±	0.1	1.2±	0.1	0.10±	0.01	140±	14	73±	7	12±	2
100ppm	10	6.4±	0.1	3.4±	0.1	1.2±	0.1	0.10±	0.01	141±	16	76±	6	13±	4
200ppm	10	6.2±	0.2**	3.4±	0.1	1.2±	0.1	0.10±	0.01	139±	14	71±	5*	14±	3
400ppm	10	6.0±	0.2**	3.4±	0.1	1.3±	0.1**	0.10±	0.01	138±	12	68±	4**	12±	3

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

Test of Dunnett

(HCL074)

BAIS 4

STUDY NO. : 0743

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : FEMALE

REPORT TYPE : A1

## BIOCHEMISTRY (SUMMARY)

ALL ANIMALS ( 14W)

PAGE : 5

Group Name	NO. of Animals	PHOSPHOLIPID mg/dl		AST I U / l		ALT I U / l		LDH I U / l		ALP I U / l		G-GTP I U / l		CK I U / l	
Control	10	145±	15	80±	13	45±	14	99±	29	292±	22	2±	1	108±	14
25ppm	10	142±	9	83±	12	48±	15	99±	25	302±	24	2±	1	105±	9
50ppm	10	135±	13	76±	7	39±	6	129±	23	294±	25	1±	0	119±	16
100ppm	10	139±	8	73±	6	38±	7	132±	33	290±	29	1±	1	127±	21
200ppm	10	133±	9	71±	7	37±	9	118±	35	297±	20	2±	0	125±	22
400ppm	10	131±	6*	71±	2	33±	2**	127±	32	305±	25	2±	1	137±	40

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

Test of Dunnett

(HCL074)

BAIS 4



STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[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	20.1±	1.6	0.6±	0.1	141±	1	3.6±	0.3	105±	2	10.0±	0.2	5.4±	1.2
25ppm	10	21.0±	1.0	0.6±	0.0	141±	1	3.7±	0.4	106±	1	9.9±	0.2	5.3±	1.2
50ppm	10	20.2±	2.2	0.6±	0.1	141±	1	3.7±	0.4	106±	1	9.9±	0.2	5.6±	1.3
100ppm	10	19.8±	1.4	0.6±	0.1	142±	1	3.6±	0.2	106±	2	9.9±	0.2	5.5±	1.3
200ppm	10	19.2±	1.7	0.6±	0.1	141±	1	3.7±	0.3	106±	1	10.0±	0.2	5.8±	1.4
400ppm	10	20.0±	1.6	0.5±	0.1	142±	1	3.7±	0.3	107±	2**	9.8±	0.2	5.5±	1.3

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

Test of Dunnett

(HCL074)

BAIS 4

**TABLE H1**

**URINALYSIS : MALE**

STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[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+	3+	
Control	10	0	0	0	0	1	9	0		0	5	5	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	6	1		0	7	3	0	0	0		10	0	0	0	0	0		8	2	0	0	0	0		10	0	0	0	
50ppm	10	0	0	0	0	7	2	1	**	0	8	2	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	4	2		0	7	3	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	5	5	0		0	9	1	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	0	10	0		0	6	4	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 4

STUDY NO. : 0743

ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]

MEASURE. TIME : 1

SEX : MALE

REPORT TYPE : A1

URINALYSIS

PAGE : 2

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	9	0	0	0	1		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 4

**TABLE H2**

**URINALYSIS : FEMALE**

STUDY NO. : 0743

ANIMAL : RAT F344/DuCr1Cr1j[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	1	2	7		7	3	0	0	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	
25ppm	10	0	0	0	0	3	1	6		6	3	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	0	2	8		5	4	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	2	3	2	3		6	4	0	0	0	0		10	0	0	0	0	0		10	0	0	0	0	0		10	0	0	0	
200ppm	10	0	0	0	1	1	4	4		4	6	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	1	2	7		5	5	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 4

STUDY NO. : 0743

URINALYSIS

ANIMAL : RAT F344/DuCr1Cr1j[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 4

**TABLE I 1**

**GROSS FINDINGS : MALE**



STUDY NO. : 0743  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 1

Organ	Findings	Group Name		Control		25ppm		50ppm		100ppm	
		NO. of Animals		10	(%)	10	(%)	10	(%)	10	(%)
liver	herniation			2	( 20)	1	( 10)	0	( 0)	0	( 0)

(HPT080)

BAIS 4

STUDY NO. : 0743  
ANIMAL : RAT F344/DuCr1Cr1j[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 (%)
liver	herniation		2 ( 20)	0 ( 0)

(HPT080)

BAIS 4

**TABLE I 2**

**GROSS FINDINGS : FEMALE**

STUDY NO. : 0743  
ANIMAL : RAT F344/DuCr1Cr1j[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		1	( 10)	1	( 10)	0	( 0)	2	( 20)
eye	white		0	( 0)	0	( 0)	0	( 0)	0	( 0)

(HPT080)

BAIS 4

STUDY NO. : 0743  
ANIMAL : RAT F344/DuCr1Cr1j[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		1	( 10)	1	( 10)
eye	white		0	( 0)	1	( 10)

(HPT080)

BAIS 4

**TABLE J1**

**ORGAN WEIGHT, ABSOLUTE : MALE**

STUDY NO. : 0743  
ANIMAL : RAT F344/DuCr1Cr1j[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	302±	8	0.248±	0.037	0.054±	0.008	3.177±	0.163	0.963±	0.038	0.957±	0.035
25ppm	10	294±	10	0.239±	0.031	0.050±	0.004	3.149±	0.072	0.932±	0.021	0.912±	0.033*
50ppm	10	307±	17	0.227±	0.021	0.050±	0.005	3.191±	0.089	0.973±	0.029	0.935±	0.048
100ppm	10	294±	9	0.237±	0.033	0.049±	0.004	3.156±	0.105	0.930±	0.056	0.902±	0.028**
200ppm	10	280±	10**	0.200±	0.020**	0.050±	0.004	3.119±	0.129	0.907±	0.029**	0.889±	0.020**
400ppm	10	264±	11**	0.189±	0.020**	0.049±	0.009	2.996±	0.090**	0.921±	0.053	0.871±	0.040**

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

Test of Dunnett

(HCL040)

BAIS 4

STUDY NO. : 0743  
ANIMAL : RAT F344/DuCr1Cr1j[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	1.826±	0.044	0.565±	0.038	7.369±	0.337	1.927±	0.027
25ppm	10	1.765±	0.069	0.545±	0.030	7.017±	0.309	1.904±	0.039
50ppm	10	1.842±	0.087	0.569±	0.038	7.484±	0.590	1.912±	0.047
100ppm	10	1.797±	0.066	0.545±	0.026	7.072±	0.309	1.895±	0.035
200ppm	10	1.742±	0.040*	0.514±	0.015**	6.685±	0.295**	1.891±	0.027
400ppm	10	1.667±	0.091**	0.494±	0.033**	6.280±	0.324**	1.852±	0.036**

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

Test of Dunnett

(HCL040)

BAIS 4



**TABLE J2**

**ORGAN WEIGHT, ABSOLUTE : FEMALE**

STUDY NO. : 0743  
ANIMAL : RAT F344/DuCr1Cr1j[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	170±	8	0.190±	0.018	0.054±	0.005	0.091±	0.009	0.627±	0.025	0.679±	0.031
25ppm	10	165±	10	0.177±	0.019	0.051±	0.003	0.095±	0.012	0.609±	0.050	0.657±	0.033
50ppm	10	165±	7	0.188±	0.017	0.054±	0.004	0.095±	0.007	0.606±	0.030	0.669±	0.022
100ppm	10	159±	6**	0.171±	0.017	0.054±	0.007	0.091±	0.010	0.624±	0.048	0.655±	0.046
200ppm	10	155±	7**	0.167±	0.018*	0.052±	0.003	0.089±	0.012	0.606±	0.029	0.644±	0.034
400ppm	10	140±	5**	0.147±	0.017**	0.046±	0.005**	0.084±	0.007	0.597±	0.031	0.630±	0.041*

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

Test of Dunnett

(HCL040)

BAIS 4

STUDY NO. : 0743  
ANIMAL : RAT F344/DuCr1Cr1j[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	1.125±	0.042	0.378±	0.020	3.968±	0.242	1.768±	0.044
25ppm	10	1.076±	0.053	0.362±	0.023	3.766±	0.339	1.741±	0.028
50ppm	10	1.090±	0.036	0.369±	0.023	3.780±	0.215	1.741±	0.031
100ppm	10	1.084±	0.056	0.353±	0.015*	3.701±	0.163	1.741±	0.035
200ppm	10	1.067±	0.046*	0.343±	0.017**	3.597±	0.227**	1.703±	0.040**
400ppm	10	1.036±	0.038**	0.298±	0.020**	3.326±	0.106**	1.684±	0.038**

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

Test of Dunnett

(HCL040)

BAIS 4

**TABLE K1**

**ORGAN WEIGHT, RELATIVE : MALE**

STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[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	302± 8	0.082± 0.011	0.018± 0.003	1.052± 0.059	0.319± 0.017	0.317± 0.014
25ppm	10	294± 10	0.081± 0.009	0.017± 0.002	1.073± 0.049	0.318± 0.009	0.311± 0.008
50ppm	10	307± 17	0.074± 0.007	0.016± 0.002	1.043± 0.048	0.318± 0.011	0.305± 0.011
100ppm	10	294± 9	0.081± 0.011	0.017± 0.001	1.075± 0.031	0.317± 0.017	0.307± 0.008
200ppm	10	280± 10**	0.072± 0.006	0.018± 0.002	1.117± 0.063*	0.325± 0.012	0.319± 0.013
400ppm	10	264± 11**	0.072± 0.009	0.019± 0.003	1.135± 0.049**	0.349± 0.013**	0.330± 0.013

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

Test of Dunnett

(HCL042)

BAIS 4

STUDY NO. : 0743  
ANIMAL : RAT F344/DuCr1Cr1j[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	0.605± 0.020	0.187± 0.011	2.439± 0.071	0.638± 0.018
25ppm	10	0.601± 0.019	0.186± 0.007	2.389± 0.054	0.649± 0.026
50ppm	10	0.601± 0.020	0.185± 0.006	2.437± 0.077	0.625± 0.029
100ppm	10	0.612± 0.019	0.186± 0.006	2.408± 0.066	0.646± 0.021
200ppm	10	0.624± 0.019	0.184± 0.007	2.392± 0.050	0.677± 0.029**
400ppm	10	0.631± 0.018*	0.187± 0.008	2.377± 0.062	0.702± 0.025**

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

Test of Dunnett

(HCL042)

BAIS 4

**TABLE K2**

**ORGAN WEIGHT, RELATIVE : FEMALE**

STUDY NO. : 0743  
ANIMAL : RAT F344/DuCr1Cr1j[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	170± 8	0.112± 0.006	0.032± 0.003	0.054± 0.005	0.370± 0.019	0.400± 0.016
25ppm	10	165± 10	0.108± 0.014	0.031± 0.002	0.058± 0.007	0.370± 0.024	0.399± 0.013
50ppm	10	165± 7	0.114± 0.009	0.033± 0.002	0.058± 0.005	0.368± 0.014	0.406± 0.017
100ppm	10	159± 6**	0.108± 0.011	0.034± 0.004	0.057± 0.006	0.392± 0.019*	0.413± 0.025
200ppm	10	155± 7**	0.108± 0.012	0.033± 0.003	0.058± 0.009	0.393± 0.017*	0.416± 0.016
400ppm	10	140± 5**	0.105± 0.011	0.033± 0.003	0.060± 0.004	0.426± 0.018**	0.450± 0.021**

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

Test of Dunnett

(HCL042)

BAIS 4



STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[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	0.663± 0.024	0.223± 0.009	2.337± 0.098	1.043± 0.049
25ppm	10	0.653± 0.020	0.220± 0.005	2.283± 0.092	1.059± 0.051
50ppm	10	0.662± 0.015	0.224± 0.010	2.294± 0.105	1.058± 0.043
100ppm	10	0.683± 0.025	0.223± 0.010	2.333± 0.076	1.099± 0.042*
200ppm	10	0.691± 0.024*	0.222± 0.006	2.326± 0.086	1.103± 0.047*
400ppm	10	0.740± 0.021**	0.213± 0.012	2.374± 0.056	1.203± 0.047**

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

Test of Dunnett

(HCL042)

BAIS 4

**TABLE L1**

**HISTOPATHOLOGICAL FINDINGS :  
NON-NEOPLASTIC LESIONS : MALE**

STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 1

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	squamous cell metaplasia:olfactory epithelium		<10>				<10>				<10>				<10>			
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	
	atrophy: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)	
	necrosis: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)	
{Digestive system}																		
liver	herniation		<10>				<10>				<10>				<10>			
		2	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	
		( 20)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	
{Urinary system}																		
kidney	regeneration:proximal tubule		<10>				<10>				<10>				<10>			
		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	
		( 10)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe  
 < a > a : Number of animals examined at the site  
 b 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. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 2

Organ	Findings	200ppm				400ppm			
		10				10			
		1	2	3	4	1	2	3	4
		(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
{Respiratory system}									
nasal cavit		<10>				<10>			
	squamous cell metaplasia:olfactory epithelium	0	0	0	0	1	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)
		<10>				<10>			
	atrophy:olfactory epithelium	4	0	0	0	6	0	0	0 *
		( 40)	( 0)	( 0)	( 0)	( 60)	( 0)	( 0)	( 0)
		<10>				<10>			
	necrosis:olfactory epithelium	0	0	0	0	2	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 20)	( 0)	( 0)	( 0)
{Digestive system}									
liver		<10>				<10>			
	herniation	2	0	0	0	0	0	0	0
		( 20)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
{Urinary system}									
kidney		<10>				<10>			
	regeneration:proximal tubule	0	0	0	0	0	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)

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

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

b b : Number of animals with lesion

( c ) c : b / a \* 100

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

STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : MALE

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

PAGE : 3

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
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

{Endocrine system}

pituitary		<10>				<10>				<10>				<10>			
	Rathke pouch	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 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)

BAIS4

STUDY NO. : 0743  
ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
REPORT TYPE : A1  
SEX : MALE

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

PAGE : 4

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

{Endocrine system}

pituitary

Rathke pouch

<10>				<10>			
0	0	0	0	2	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)

BAIS4

**TABLE L2**

**HISTOPATHOLOGICAL FINDINGS :  
NON-NEOPLASTIC LESIONS : FEMALE**

STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 5

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	atrophy:olfactory epithelium		<10>				<10>				<10>				<10>			
			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)	( 0)
	necrosis: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)
lung	granulomatous inflammation		<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)
{Hematopoietic system}																		
bone marrow	granulation		<10>				<10>				<10>				<10>			
			3	0	0	0	1	0	0	0	4	1	0	0	2	0	0	0
			( 30)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)	( 40)	( 10)	( 0)	( 0)	( 20)	( 0)	( 0)	( 0)
{Digestive system}																		
liver	herniation		<10>				<10>				<10>				<10>			
			1	0	0	0	1	0	0	0	0	0	0	0	2	0	0	0
			( 10)	( 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



STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

HISTOPATHOLOGICAL 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
						(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
<hr/>													
(Respiratory system)													
nasal cavit		<10>				<10>				0 *			
	atrophy:olfactory epithelium	2	0	0	0	6	0	0	0	( 20)	( 0)	( 0)	( 0)
										( 60)	( 0)	( 0)	( 0)
	necrosis:olfactory epithelium	0	0	0	0	1	0	0	0	( 0)	( 0)	( 0)	( 0)
										( 10)	( 0)	( 0)	( 0)
lung		<10>				<10>							
	granulomatous inflammation	0	0	0	0	0	0	0	0	( 0)	( 0)	( 0)	( 0)
										( 0)	( 0)	( 0)	( 0)
(Hematopoietic system)													
bone marrow		<10>				<10>							
	granulation	4	0	0	0	1	0	0	0	( 40)	( 0)	( 0)	( 0)
										( 10)	( 0)	( 0)	( 0)
(Digestive system)													
liver		<10>				<10>							
	herniation	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 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. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 7

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
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)

{Special sense organs/appendage}

eye	cataract	<10>				<10>				<10>				<10>			
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )	( 0 )

Harder gl	lymphocytic infiltration	<10>				<10>				<10>				<10>			
		1	0	0	0	3	0	0	0	3	1	0	0	2	1	0	0
		( 10 )	( 0 )	( 0 )	( 0 )	( 30 )	( 0 )	( 0 )	( 0 )	( 30 )	( 10 )	( 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 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)

BAIS4

STUDY NO. : 0743  
 ANIMAL : RAT F344/DuCr1Cr1j[F344/DuCrj]  
 REPORT TYPE : A1  
 SEX : FEMALE

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

PAGE : 8

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

{Special sense organs/appendage}

eye	cataract	<10>				<10>			
		0	0	0	0	1	0	0	0
		( 0)	( 0)	( 0)	( 0)	( 10)	( 0)	( 0)	( 0)

Harder gl	lymphocytic infiltration	<10>				<10>			
		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 ; \* :  $P \leq 0.05$  \*\* :  $P \leq 0.01$  Test of Chi Square

(HPT150)

BAIS4