1, 1, 1 - トリクロロエタンのラット及びマウスを用いた 吸入によるがん原性予備試験報告書

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 RAT:MALE:DEAD AND MORIBUND ANIMALS
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APPENDIX B 1-1

CLINICAL OBSERVATION: SUMMARY, MOSUE: MALE

STUDY NO.: 0167

ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

PAGE: 1

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Clinical sign	Group Name	Admini:	stration W	ek-day										· · · · · · · · · · · · · · · · · · ·	
		0-0 1	1-7 1	2-7 1	3-7 1	4-7 1	5-7 1	6-7 1	7-7 1	8-7 1	9-7 1	10-7 1	11-7 1	12-7 1	13-7 1
LOSS OF HAIR	Control	0	0	٥	0	0	0	0	0	0	0	0	0	0	0
book or milit	3000 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	Ö
	4400 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	6700 ppm	0	0	0	0	0	0	0	0	0	1	1	1	0	0
	10000 ppm	0	0	-	_	_	-	-	~	-	-		-	-	-
	15000 ppm	0	-	_	-	-	-	_	_	-		-	-	-	-

(HAN190)

APPENDIX B 1-2

CLINICAL OBSERVATION: SUMMARY, MOSUE: FEMALE

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : FEMALE

PAGE: 2

Clinical sign	Group Name	Adminis	stration W	ek-day											
		0-0 1	1-7 1	2-7 1	3-7 1	4-7 1	5-7 1	6-7 1	7-7 1	8-7 1	9-7 1	10-7 1	11-7 1	12-7 1	13-7 1
LOSS OF HAIR	Combral	^				^	Δ	^	9	0	•		0	9	
FOSS OF HAIR	Cantral 3000 ppm	0	0	0	0	0	0	0	2 1	2 1	3 1	3 1	3 1	3 0	0
	4400 ppm	0	0	0	0	0	0	0	0	1	1	1	1	0	0
	6700 ppm	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10000 ppm	0	-	-	-	-	-	-	-	-	-	-	_	-	-
	15000 ppm	0	_		-	_	_	_	_	_	_	_	-	-	_

(HAN190)

APPENDIX B 2-1

BODY WEIGHT CHANGES :SUMMARY, RAT : MALE

STUDY NO.: 0166

ANIMAL : RAT F344

UNIT : g

REPORT TYPE : A1 13

SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)

ALL ANIMALS

Group Name Administration week-day_ 2-7 3-7 4-7 5-7 6-7 0-0 1-7 195± 11 242± 12 257± 15 273± 18 Control 132± 5 163± 8 221± 12 266± 12 132± 5 159± 7 189± 11 216± 11 235 ± 12 252± 13 2000 ppm 238± 17 256 ± 18 270± 18 131 ± 6 158± 10 189± 13 217± 15 3000 ppm 233± 10** 244± 9** 4400 ppm 132± 5 153± 8* 182± 9 202士 10** 219± 11** 211± 20** 225士 21** 233士 21** 6700 ppm 132± 5 $145 \pm$ 8** 171士 13** 193± 16** 10000 ppm 132± 5 131± 144士 7** 159± 8** 173± 11** 184士 14** 191± 16** 5** Significant difference; $*:P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(HAN260)

BAIS 2

PAGE: 1

STUDY NO. : 0166

ANIMAL : RAT F344 UNIT : g

REPORT TYPE : A1 13

SEX : MALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

PAGE: 2

TOUP Name	Admini	stration	week-day											
	7-7		8-7		9-7		10-7		11-7		12-7		13-7	
Control	288士	18	304±	19	315±	18	322±	18	329±	17	337±	20	343±	19
2000 ppm	278±	12	293±	12	303±	13	310±	14	317±	14	323±	16	332±	16
3000 ppm	283±	20	297±	24	305±	27	315±	30	318±	31	328±	30	333±	32
4400 ppm	255士	11**	268±	12**	275±	12**	282±	13**	287±	12**	296±	13**	299±	13**
6700 ppm	245±	23**	253±	23**	262±	23**	270±	23**	276±	23**	282±	23**	287±	24**
10000 ppm	199±	16**	207±	17**	218±	17**	225±	19**	233±	19**	239±	19**	243±	19**
														
Significant difference;	* : P ≦	0.05	**: P ≤ 0.	01			Test of Du	unnett						

(HAN260)

APPENDIX B 2-2

BODY WEIGHT CHANGES: SUMMARY, RAT: FEMALE

STUDY NO.: 0166 ANIMAL: RAT F344

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

UNIT : g
REPORT TYPE : A1 13

SEX : FEMALE

roup Name	Admini	stration	week-day						·					
	0-0	 	1-7		2-7		3-7		4-7		5-7		6-7	
Control	105±	4	121±	5	133±	5	141±	7	147±	6	154±	7	162±	8
2000 ppm	106±	5	120±	6	134±	7	146±	8	154±	11	159±	11	166±	12
3000 ppm	105士	5	119±	6	132±	6	143±	8	151±	8	154±	9	160±	10
4400 ppm	106±	5	117±	8	131±	10	143±	10	149±	10	156±	10	161±	10
6700 ppm	105±	5	113±	4*	127±	-6	139±	6	146土	6	152±	7	157±	8
10000 ppm	105±	5	109±	8**	119士	9**	128±	10**	137±	10	143±	11*	149±	11*
Significant differer	nce; *:P≦0	.05	**: P ≤ 0.0	1			Test of Dur	nett						

(HAN260)

BAIS 2

PAGE: 3

STUDY NO. : 0166 ANIMAL : RAT F344

UNIT : g

REPORT TYPE : A1 13 SEX : FEMALE BODY WEIGHT CHANGES (SUMMARY) ALL ANIMALS

PAGE: 4

roup Name	Admini	stration	week-day									
	7-7		8-7		9–7	10-7		11-7	12-7		13-7	
Cantrol	168±	8	177±	9	181± 9	184±	8	186± 9	191±	a	194±	10
Corta de	100.1	0	1112	9	101 T 9	1041	0	. 100.1. 9	101 1	J	1041	10
2000 ppm	170±	12	175±	12	180± 14	181±	14	186± 16	188±	15	189±	17
3000 ppm	164土	10	168±	12	172± 12	175±	14	178± 14	181±	13	181±	14
4400 ppm	163±	12	168±	11	171± 12	175±	13	177± 12	179±	12	179±	12
6700 ppm	162±	8	165±	8	168± 8*	170±	7*	171± 9*	174±	9*	176±	9*
10000 ppm	154±	11*	157±	12**	161± 12**	165±	12**	169± 13*	170±	13**	173±	15**
Significant differe	ence; *:P≦0	.05	**: P ≤ 0.01			Test of Dur	nnett					

(IIAN260)

APPENDIX B 2-3

BODY WEIGHT CHANGES :SUMMARY, MOSUE : MALE

STUDY NO. : 0167

ANIMAL : MOUSE BDF1
UNIT : g

REPORT TYPE : A1 13 SEX : MALE

BODY WEIGHT CHANGES (SUMMARY) ALL ANIMALS

PAGE: 1

up Name	Administration	week-day					
	0-0	1-7	2-7	3-7	4-7	5-7	6-7
Control	23.7± 0.8	25.1± 0.9	25.9± 0.8	26.6± 1.0	27.5± 0.9	28.4± 1.1	29.4± 1.1
3000 ppm	23.7± 0.8	25.0± 1.2	25.6± 1.1	25.8± 1.4	26.0± 1.3*	27.0± 1.3*	27.5± 1.5**
4400 ppm	23.7± 0.8	24.6± 0,9	25.9± 0.8	26.4± 0.9	26.8± 1.0	27.7± 1.0	28.2± 1.1
6700 ppm	23.7± 0.8	23.4± 1.0**	25.1± 0.8	25.9± 0.7	26.3± 0.8*	27.2± 1.0	27.8± 0.9**
10000 ppm	23.7± 0.8	22.1± 1.2 ?	-	-	-		-
15000 ppm	23.7± 0.8	-		-	-	-	-
Significant differe	nce; *:P≦0.05	**: P ≤ 0.01		Test of Dunnett			

^{?:} Significant test is not applied, because No. of data in this group is less than 3.

(HAN260)

STUDY NO.: 0167

ANIMAL : MOUSE BDF1

UNIT : g
REPORT TYPE : A1 13

SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)

ALL ANIMALS

roup Name	Administration	week-day					
	7-7	8-7	9-7	10-7	11-7	12-7	13-7
Control	30.1± 1.2	30.9± 1.5	31.4± 1.5	32.4± 1.9	33.3± 1.7	34.4± 1.8	34.9± 1.8
3000 ppm	27.7± 1.4**	28.6± 1.5**	29.2± 1.4**	29.9生 1.5**	30.7± 1.4**	31.2± 1.3**	32.2± 1.3**
4400 ppm	28.5± 1.2*	29.3± 1.3*	30.0± 1.5	30.8± 1.7	31.2± 1.6**	32.2± 1.7**	32.4± 1.8**
6700 ppm	28.3± 1.2**	28.9± 1.0**	29.6± 0.8*	29.9± 0.9**	30.4± 1.2**	31.2± 1.3**	31.4± 1.4**
10000 mag 00001	-	-	-	-	-	<u></u>	-
15000 ppm		-	~	-	<u>.</u>	-	-

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

(HAN260)

BAIS 2

PAGE: 2

APPENDIX B 2-4

BODY WEIGHT CHANGES: SUMMARY, MOSUE: FEMALE

STUDY NO.: 0167

ANIMAL : MOUSE BDF1

UNIT : g
REPORT TYPE : A1 13

SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY) ALL ANIMALS

PAGE: 3

roup Name	Administration	week-day					
	0-0	1-7	2-7	3-7	4-7	5-7	6-7
Control	19.1± 0.6	20.8± 0.7	21.8± 1.1	22.0± 1.1	22.8± 0.6	23.1± 0.8	24.4± 1.1
3000 ppm	19.1± 0.6	20.3± 0.5	21.2± 1.6	22.1± 0.7	22.9± 0.8	23.7± 0.9	24.4± 0.5
4400 ppm	19.1± 0.6	20.1± 0.7	21.5± 0.7	22.1± 1.0	22.5± 0.7	23.3± 0.9	23.7± 1.0
6700 ррт	19.1± 0.6	19.7± 0.7**	21.2± 1.0	22.5± 1.1	23.4± 0.9	24.0± 1.1	24.6± 1.1
10000 ppm	19.1± 0.6	-	-	-	-	-	-
15000 ppm	19.1± 0.6	-	-	-	-	- .	-
Significant differe	ence; $*:P \leq 0.05$	** : P ≤ 0.01		Test of Dunnett			

(HAN260)

STUDY NO. : 0167

ANIMAL : MOUSE BDF1

UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

PAGE: 4

oup Name	Administration	week-day						
	7-7	8-7	9-7	10-7	11-7	12-7	13-7	
Control	24.3± 0.9	25.0± 0.8	25.4± 1.4	25.5± 1.0	26.3± 1.3	26.4± 0.7	26.9± 1.3	
3000 ppm	24.6± 0.9	24.9± 1.0	25.2± 1.0	25.7± 1.1	26.5± 1.2	27.0± 1.0	26,9± 1.3	
4400 ppm	24.6± 0.6	25.0± 1.0	25.5± 1.2	25.9± 1.3	25.9± 1.2	26.8± 1.1	26.9± 1.2	
6700 ppm	25.0± 1.3	25.5± 1.2	26.1± 0.8	26.5± 1.0	27.2± 1.0	27.1± 1.4	27.4± 1.1	
10000 ppm	-	-	-	-	-	-	-	
15000 ppm	-	-	-	-	-	- .	-	
Significant differenc	e; *:P≦0.05	**: P ≤ 0.01		Test of Dunnett				
IAN260)	9, ↑,Γ⊒ 0,00	** · r \(\sigma \) 0.01		rest of buillett				

APPENDIX B 3-1

FOOD CONSUMPTION CHANGES: SUMMARY, RAT: MALE

STUDY NO.: 0166
ANIMAL: RAT F344
UNIT: g
REPORT TYPE: A1 13

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

SEX : MALE

PAGE: 1

roup Name	Administration (1–7(7)	ueek-day(effective) 2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7–7 (7)
Control	16.0± 1.1	17.7± 1.2	18.8± 1.3	18.0± 1.2	17.6± 1.1	18.1± 1.6	18.1± 1.4
2000 ppm	15.2± 0.8	17.1± 1.2	18.7± 1.8	18.6± 1.7	18.5± 1.4	18.1± 1.1	17.6± 0.9
3000 ppm	15.5± 1.0	17.3± 1.0	19.4± 1.3	18.6± 1.1	18.6± 1.4	18.0± 1.3	18.2± 1.1
4400 ppm	14.3± 0.6**	16.5± 1.0	17.9± 0.9	16.9± 0.8	17.2± 0.7	17.2± 0.3	17.2± 0.6
6700 ppm	12.7± 0.5**	15.2± 1.3**	16.6± 1.2**	16.8± 1.6	17.2± 1.4	16.4± 1.0*	16.9± 1.2
10000 ppm	10.7± 0.6**	12.1± 0.7**	13.0± 0.9**	13.5± 1.3**	14.3± 1.5**	13.9± 1.7**	14.2± 1.5**
Significant differen	ice; *:P≦0.05 *	* : P ≤ 0.01	. , ,	Test of Dunnett			

(IIAN260)

STUDY NO. : 0166 ANIMAL : RAT F344

UNIT : g

REPORT TYPE : A1 13 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 2

Group Name	Administration 8-7(7)	week-day(effective) 9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	
Control	18.2± 1.6	18.1± 1.2	18.3± 1.0	18.3± 1.0	17.5± 1.3	18.2± 0.9	
2000 ppm	17.9± 1.0	17.9± 1.0	18.1± 1.3	17.9± 1.2	17.0± 1.5	17.8± 1.3	
3000 ppm	18.5± 1.5	18.6± 1.9	18.5± 1.5	18.2± 1.7	17.7± 1.9	17.7± 1.7	
4400 ppm	17.1± 0.9	17.0± 0.9	17.6± 1.0	17.0± 0.7	16.6± 0.8	16.7± 0.6	
6700 ppm	16.6± 1.0*	16.6± 1.0	17.1± 1.1	16.7± 1.0*	16.6± 1.2	16.6± 1.3*	
10000 ppm	14.6± 1.8**	14.6± 1.9**	14.7± 2.0**	14.7± 1.4**	15.2± 1.3**	14.8± 1.6**	
Significant differe	ence; *:P≦0.05 ×	**: P ≤ 0.01		Test of Dunnett			

(HAN260)

APPENDIX B 3-2

FOOD CONSUMPTION CHANGES: SUMMARY, RAT: FEMALE

STUDY NO.: 0166
ANIMAL: RAT F344

UNIT : g
REPORT TYPE : A1 13

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

; g

Group Name Administration week-day(effective)_ 5-7(7) 1-7(7) 2-7(7) 3-7(7) 4-7(7)6-7(7)7-7(7) Control 12.5± 0.7 12.9± 0.6 12.4± 0.8 12.7± 0.5 12.7 ± 0.6 12.4± 0.7 12.4士 0.8 2000 ppm 11.9± 0.8 12.7 ± 0.9 13.0± 1.0 13.5 ± 1.3 13.2± 1.4 12.4± 1.1 12.4± 1.0 3000 ppm 11.9± 0.6 12.5± 0.9 13.1 ± 1.0 12.6± 0.8 12.2 ± 1.0 11.7± 1.3 11.8± 0.9 4400 ppm 11.6± 0.6* 12.7 ± 0.7 13.1± 1.0 12.2± 0.8 12.7 ± 0.5 12.0± 0.6 11.7± 0.7 6700 ppm 10.6± 0.3** 12.0 ± 0.6 12.5± 0.9 12.1± 0.6 12.2± 0.6 12.0 ± 0.6 11.9± 0.5 10000 ppm 9.7± 0.8** 10.7± 1.0** 11.4 ± 1.2 11.7± 0.7 11.8± 1.0 11.8± 0.8 11.8± 0.7

PAGE: 3

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

(HAN260) BAIS 2

STUDY NO.: 0166
ANIMAL: RAT F344
UNIT: g
REPORT TYPE: A1 13

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

PAGE: 4

Group Name	Administration 8–7(7)	n week-day(effective) 9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	
Control	12.9± 1.0	12.7± 0.8	12.3± 1.3	12.9± 1.7	12.4± 0.6	13.1± 1.4	
2000 ppm	12.3± 1.1	12.4± 1.4	12.1± 1.1	12.3± 1.3	12.5± 1.3	12.1± 1.3	
3000 ppm	12.0± 1.2	11.9± 1.1	11.7± 1.3	11.7± 1.4	11.7± 1.5	10.9± 1.3*	
4400 ppm	11.8± 0.6*	12.0± 0.7	12.3± 0.8	11.7± 0.9	11.7± 0.7	11.2± 0.6*	
6700 ppm	12.0± 0,4	11.8± 0.5	12.1± 0.5	11.3± 0.8	11.7± 0.9	11.6± 0.6	
10000 ppm	11.8± 0.6*	11.5± 0.5**	11.9± 0.7	11.8± 0.7	11.6± 0.9	11.2± 0.9**	
Significant difference;	*: P ≤ 0.05	**: P ≤ 0.01		Test of Dunnett			

(HAN260)

APPENDIX B 3-3

FOOD CONSUMPTION CHANGES: SUMMARY, MOSUE: MALE

STUDY NO. : 0167

ANIMAL : MOUSE BDF1

UNIT : g REPORT TYPE : A1 13

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

Group Name Administration week-day(effective)_ 3-7(7) 4-7(7) 5-7(7) 6-7(7) 7-7(7) 1-7(7)2-7(7)Control 4.5± 0.2 4.3± 0.2 4.4± 0.2 4.6± 0.3 4.7± 0.2 4.8± 0.2 4.7 ± 0.3 4.7± 0.3 3000 ppm 4.5± 0.3 4.4 ± 0.3 4.4 ± 0.3 4.6± 0.4 4.6 ± 0.3 4.9± 0.4 4400 ppm 4.6± 0.3 4.5 ± 0.3 4.4± 0.3 4.6± 0.3 4.7 ± 0.2 4.6± 0.1 4.6± 0.2 4.4 ± 0.3 6700 ppm 4.1± 0.3* 4.4± 0.1 4.4± 0.2 4.5± 0.2 4.6 ± 0.3 4.5± 0.1* 10000 ppm 4.7± 0.9 5.6± 0.7 ?

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

(HAN260)

15000 ppm

BAIS 2

PAGE: 1

^{?:} Significant test is not applied, because No. of data in this group is less than 3.

STUDY NO. : 0167

ANIMAL : MOUSE BDF1
UNIT : g

UNIT : g
REPORT TYPE : A1 13

SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 2

	week-day(effective)			10.7(7)		
8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	
4.8± 0.3	4.9± 0.2	5.0± 0.3	4.9± 0.2	5.0± 0.2	4.9± 0.3	
4.8± 0.5	5.2± 0.4	5.3± 0.5	5.2± 0.4	5.2± 0.4	5.1± 0.4	
4.7± 0.2	5.1± 0.2	5.2± 0.4	5.1± 0.8	5.2± 0.2	5.0± 0.2	
4.6± 0.1	4.9± 0.2	4.9± 0.2	4.8± 0.2	4.9± 0.2	4.7± 0.2	
-		-	-	-	-	
-	-	-	-		-	
	8-7(7) 4.8± 0.3 4.8± 0.5 4.7± 0.2 4.6± 0.1	8-7(7) 9-7(7) 4.8± 0.3 4.9± 0.2 4.8± 0.5 5.2± 0.4 4.7± 0.2 5.1± 0.2 4.6± 0.1 4.9± 0.2	8-7(7) 9-7(7) 10-7(7) 4.8 \pm 0.3 4.9 \pm 0.2 5.0 \pm 0.3 4.8 \pm 0.5 5.2 \pm 0.4 5.3 \pm 0.5 4.7 \pm 0.2 5.1 \pm 0.2 5.2 \pm 0.4 4.6 \pm 0.1 4.9 \pm 0.2 4.9 \pm 0.2	8-7(7) 9-7(7) $10-7(7)$ $11-7(7)$ 4.8 ± 0.3 4.9 ± 0.2 5.0 ± 0.3 4.9 ± 0.2 4.8 ± 0.5 5.2 ± 0.4 5.3 ± 0.5 5.2 ± 0.4 4.7 ± 0.2 5.1 ± 0.2 5.2 ± 0.4 5.1 ± 0.8 4.6 ± 0.1 4.9 ± 0.2 4.9 ± 0.2 4.8 ± 0.2 - - - -	8-7(7) 9-7(7) $10-7(7)$ $11-7(7)$ $12-7(7)$ 4.8± 0.3 $4.9\pm$ 0.2 $5.0\pm$ 0.3 $4.9\pm$ 0.2 $5.0\pm$ 0.2 4.8± 0.5 $5.2\pm$ 0.4 $5.3\pm$ 0.5 $5.2\pm$ 0.4 $5.2\pm$ 0.4 4.7± 0.2 $5.1\pm$ 0.2 $5.2\pm$ 0.4 $5.1\pm$ 0.8 $5.2\pm$ 0.2 4.6± 0.1 $4.9\pm$ 0.2 $4.9\pm$ 0.2 $4.8\pm$ 0.2 $4.9\pm$ 0.2 - - - - -	8-7(7) 9-7(7) 10-7(7) 11-7(7) 12-7(7) 13-7(7) 4.8 \pm 0.3 4.9 \pm 0.2 5.0 \pm 0.3 4.9 \pm 0.2 5.0 \pm 0.2 4.9 \pm 0.3 4.8 \pm 0.5 5.2 \pm 0.4 5.3 \pm 0.5 5.2 \pm 0.4 5.2 \pm 0.4 5.1 \pm 0.4 4.7 \pm 0.2 5.1 \pm 0.2 5.2 \pm 0.4 5.1 \pm 0.8 5.2 \pm 0.2 5.0 \pm 0.2 4.6 \pm 0.1 4.9 \pm 0.2 4.9 \pm 0.2 4.8 \pm 0.2 4.9 \pm 0.2 4.7 \pm 0.2

Significant difference;	* : P ≤ 0.05	** : P ≤ 0.01	Test of Dunnett	

(HAN260)

APPENDIX B 3-4

FOOD CONSUMPTION CHANGES: SUMMARY, MOSUE: FEMALE

STUDY NO. : 0167

ANIMAL : MOUSE BDF1

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	4.0± 0.3	4.1± 0.3	4.2± 0.4	4.6± 0.3	4.7± 0.3	4.8± 0.4	4.9± 0.3
3000 ppm	4.2± 0.2	4.0± 0.4	4.3± 0.3	4.5± 0.4	4.6± 0.3	4.8± 0.4	4.8± 0.4
4400 ppm	4.1± 0.1	4.0± 0.2	4.0± 0.2	4.3± 0.2	4.4± 0.2	4.5± 0.3	4.6± 0.2
6700 ppm	3.8± 0.7	4.1± 0.3	4.2± 0.2	4.4± 0.2	4.5± 0.2	4.5± 0.3	4.5± 0.2*
10000 ppm	4.5± 0.5	-	-	-	-	-	-
15000 ppm	-	-	-	-		-	-

Significant difference;	*: P ≤ 0.05	**: P ≤ 0.01	Test of Dunnett
(HAN260)			PALCO

STUDY NO. : 0167

ANIMAL : MOUSE BDF1

UNIT : g
REPORT TYPE : A1 13

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 4

Group Name	Administration	week-day(effective)_					
	8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)	
Control	4.9± 0.4	5.1± 0.4	5.1± 0.3	5.0± 0.3	4.8± 0.3	5.0± 0.3	
3000 ppm	4.9± 0.3	5.2± 0.5	5.1± 0.4	5.0± 0.5	5.2± 0.6	5.1± 0.6	
4400 ppm	4.7± 0.2	5.0± 0.4	5.2± 0.4	4.9± 0.4	5.1± 0.4	5.0± 0.3	
6700 ppm	4.5± 0.3*	5.0± 0.3	5.0± 0.2	5.0± 0.3	4.9± 0.4	4.7± 0.3	
10000 ppm	-	_	-	-	-		
15000 ppm	-	-			<u></u>	-	

Significant difference; $*:P \leq 0.05$

**: P ≤ 0.01

Test of Dunnett

(HAN260)

APPENDIX B 4-1

HEMATOLOGY: SUMMARY, RAT: MALE

STUDY NO. : 0166 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : MALE

HEMATOLOGY(1) (SUMMARY) SURVIVAL ANIMALS (14)

PAGE: 1

Animals	1 06/με		HEMOGLOBIN g∕dl		HEMATOCRIT %		MCV f e		MCH pg		MCHC g∕dl		?
10	9.39± 0.20	16.0±	0.3	44.0±	1.0	46.8±	0.7	17.1±	0.4	36.5±	0.5	713±	37
10	9.48± 0.21	15.9±	0.3	43.8±	1.1	46.2±	0.5	16.8±	0.4	36.3±	0.7	740±	24
10	9.42± 0.15	15.8±	0.3	43.5±	0.8	46.1±	0.6*	16.8±	0.3	36.4±	0.8	764±	79
8	9.43± 0.28	16.0±	0.4	43.8±	1.4	46.4±	0.5	16.9±	0.5	36.4±	1.0	716±	59
10	9.40± 0.30	16.2±	0.4	44.3±	1.5	47.1±	0.6	17.2±	0.4	36.5±	0.7	733士	38
7	9.24± 0.23	16.0±	0.2	43.3±	0.7	46.9±	0.6	17.3±	0.4	36.8±	0.7	707±	46
difference;	*: P ≤ 0.05	**: P ≤ 0.	01			Test of Du	nnett						
_	10 10 8 10 7	10 9.48± 0.21 10 9.42± 0.15 8 9.43± 0.28 10 9.40± 0.30	10 $9.48\pm$ 0.21 $15.9\pm$ 10 $9.42\pm$ 0.15 $15.8\pm$ 8 $9.43\pm$ 0.28 $16.0\pm$ 10 $9.40\pm$ 0.30 $16.2\pm$ 7 $9.24\pm$ 0.23 $16.0\pm$	10 9.48 \pm 0.21 15.9 \pm 0.3 10 9.42 \pm 0.15 15.8 \pm 0.3 8 9.43 \pm 0.28 16.0 \pm 0.4 10 9.40 \pm 0.30 16.2 \pm 0.4 7 9.24 \pm 0.23 16.0 \pm 0.2	10 $9.48\pm$ 0.21 $15.9\pm$ 0.3 $43.8\pm$ 10 $9.42\pm$ 0.15 $15.8\pm$ 0.3 $43.5\pm$ 8 $9.43\pm$ 0.28 $16.0\pm$ 0.4 $43.8\pm$ 10 $9.40\pm$ 0.30 $16.2\pm$ 0.4 $44.3\pm$ 7 $9.24\pm$ 0.23 $16.0\pm$ 0.2 $43.3\pm$	10 9.48 \pm 0.21 15.9 \pm 0.3 43.8 \pm 1.1 10 9.42 \pm 0.15 15.8 \pm 0.3 43.5 \pm 0.8 8 9.43 \pm 0.28 16.0 \pm 0.4 43.8 \pm 1.4 10 9.40 \pm 0.30 16.2 \pm 0.4 44.3 \pm 1.5 7 9.24 \pm 0.23 16.0 \pm 0.2 43.3 \pm 0.7	10 9.48 \pm 0.21 15.9 \pm 0.3 43.8 \pm 1.1 46.2 \pm 10 9.42 \pm 0.15 15.8 \pm 0.3 43.5 \pm 0.8 46.1 \pm 8 9.43 \pm 0.28 16.0 \pm 0.4 43.8 \pm 1.4 46.4 \pm 10 9.40 \pm 0.30 16.2 \pm 0.4 44.3 \pm 1.5 47.1 \pm 7 9.24 \pm 0.23 16.0 \pm 0.2 43.3 \pm 0.7 46.9 \pm	10 9.48 \pm 0.21 15.9 \pm 0.3 43.8 \pm 1.1 46.2 \pm 0.5 10 9.42 \pm 0.15 15.8 \pm 0.3 43.5 \pm 0.8 46.1 \pm 0.6* 8 9.43 \pm 0.28 16.0 \pm 0.4 43.8 \pm 1.4 46.4 \pm 0.5 10 9.40 \pm 0.30 16.2 \pm 0.4 44.3 \pm 1.5 47.1 \pm 0.6 7 9.24 \pm 0.23 16.0 \pm 0.2 43.3 \pm 0.7 46.9 \pm 0.6	10 9.48 \pm 0.21 15.9 \pm 0.3 43.8 \pm 1.1 46.2 \pm 0.5 16.8 \pm 10 9.42 \pm 0.15 15.8 \pm 0.3 43.5 \pm 0.8 46.1 \pm 0.6* 16.8 \pm 8 9.43 \pm 0.28 16.0 \pm 0.4 43.8 \pm 1.4 46.4 \pm 0.5 16.9 \pm 10 9.40 \pm 0.30 16.2 \pm 0.4 44.3 \pm 1.5 47.1 \pm 0.6 17.2 \pm 7 9.24 \pm 0.23 16.0 \pm 0.2 43.3 \pm 0.7 46.9 \pm 0.6 17.3 \pm	10 9.48 \pm 0.21 15.9 \pm 0.3 43.8 \pm 1.1 46.2 \pm 0.5 16.8 \pm 0.4 10 9.42 \pm 0.15 15.8 \pm 0.3 43.5 \pm 0.8 46.1 \pm 0.6* 16.8 \pm 0.3 8 9.43 \pm 0.28 16.0 \pm 0.4 43.8 \pm 1.4 46.4 \pm 0.5 16.9 \pm 0.5 10 9.40 \pm 0.30 16.2 \pm 0.4 44.3 \pm 1.5 47.1 \pm 0.6 17.2 \pm 0.4 7 9.24 \pm 0.23 16.0 \pm 0.2 43.3 \pm 0.7 46.9 \pm 0.6 17.3 \pm 0.4	10 9.48± 0.21 15.9± 0.3 43.8± 1.1 46.2± 0.5 16.8± 0.4 36.3± 10 9.42± 0.15 15.8± 0.3 43.5± 0.8 46.1± 0.6* 16.8± 0.3 36.4± 8 9.43± 0.28 16.0± 0.4 43.8± 1.4 46.4± 0.5 16.9± 0.5 36.4± 10 9.40± 0.30 16.2± 0.4 44.3± 1.5 47.1± 0.6 17.2± 0.4 36.5± 7 9.24± 0.23 16.0± 0.2 43.3± 0.7 46.9± 0.6 17.3± 0.4 36.8±	10 9.48 \pm 0.21 15.9 \pm 0.3 43.8 \pm 1.1 46.2 \pm 0.5 16.8 \pm 0.4 36.3 \pm 0.7 10 9.42 \pm 0.15 15.8 \pm 0.3 43.5 \pm 0.8 46.1 \pm 0.6* 16.8 \pm 0.3 36.4 \pm 0.8 8 9.43 \pm 0.28 16.0 \pm 0.4 43.8 \pm 1.4 46.4 \pm 0.5 16.9 \pm 0.5 36.4 \pm 1.0 10 9.40 \pm 0.30 16.2 \pm 0.4 44.3 \pm 1.5 47.1 \pm 0.6 17.2 \pm 0.4 36.5 \pm 0.7 7 9.24 \pm 0.23 16.0 \pm 0.2 43.3 \pm 0.7 46.9 \pm 0.6 17.3 \pm 0.4 36.8 \pm 0.7	10 9.48± 0.21 15.9± 0.3 43.8± 1.1 46.2± 0.5 16.8± 0.4 36.3± 0.7 740± 10 9.42± 0.15 15.8± 0.3 43.5± 0.8 46.1± 0.6* 16.8± 0.3 36.4± 0.8 764± 8 9.43± 0.28 16.0± 0.4 43.8± 1.4 46.4± 0.5 16.9± 0.5 36.4± 1.0 716± 10 9.40± 0.30 16.2± 0.4 44.3± 1.5 47.1± 0.6 17.2± 0.4 36.5± 0.7 733± 7 9.24± 0.23 16.0± 0.2 43.3± 0.7 46.9± 0.6 17.3± 0.4 36.8± 0.7 707±

STUDY NO. : 0166 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : MALE

HEMATOLOGY(2) (SUMMARY) SURVIVAL ANIMALS (14)

PAGE: 1

Group Name Control	NO. of Animals	WBC 1 0 ³ /με		Differential N-BAND		al WBC (%) N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
	10	4.12±	1.50	0±	0	14±	4	2±	1	0±	0	2±	2	82±	5	0±	0
2000 ppm	10	4.41±	1.23	0±	0	14±	4	2±	1	0±	0	3±	1	82土	4	0±	0
3000 ppm	10	4.76±	1.72	0±	0	16±	5	1±	1	0±	0	4±	1	79±	5	0±	0
4400 ppm	8	3.60±	1.80	0±	0	15±	4	2±	2	0±	0	3±	0	80±	5	0±	0
6700 ppm	10	5.24±	1.94	0±	0	14±	4	1±	1	0±	0	2±	1	83±	4	0土	0
10000 ppm	7	3.29±	0.37	0±	0	23±	8**	1±	1	0±	0	3±	1	74±	9*	0±	0
Significan	it difference ;	*: P :	≦ 0.05	**: P ≦	0.01			Test	of Dunne	tt		·	<u> </u>				

(HCL071) BAIS 2

APPENDIX B 4-2

HEMATOLOGY: SUMMARY, RAT: FEMALE

STUDY NO. : 0166 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : FEMALE

HEMATOLOGY(1) (SUMMARY) SURVIVAL ANIMALS (14)

PAGE: 2

Group Name	NO. of Animals	RED BL	OOD CELL	g∕dl HEMOGLC	BIN	HEMATOC %	CRIT	MCV f e		MCH pg		MCHC g∕dl		PLATELE 1 O³/µ	
Control	10	8.60±	0.38	15.9±	0.6	43.4±	1.8	50.4±	0.9	18.5±	0.4	36.6±	0.8	695士	119
2000 ppm	10	8.67±	0.42	15.7±	0.5	43.0±	2.5	49.5±	8.0	18.1±	0.4	36.6±	1.1	748±	73
3000 ppm	9	8.69±	0.25	15.8±	0.4	42.4±	1.2	48.8±	0.6**	18.1±	0.5	37.2±	0.7	758±	56
4400 ppm	10	8.70±	0.22	15.9±	0.3	42.6±	1.1	49.0±	0.6**	18.3±	0.3	37.4±	0.5	758±	86
6700 ppm	9	8.80±	0.29	15.8±	0.4	42.8±	1.6	48.6±	0.6**	18.0±	0.3	37.0±	0.8	760±	88
10000 ppm	10	8.93±	0.34	15.7±	0.2	42.3±	0.7	47.4±	1.3**	17.6±	0.7**	37.1±	0.8	716±	126

(HCL070)

STUDY NO. : 0166 ANIMAL : RAT F344 REPORT TYPE : A1 SEX: FEMALE

HEMATOLOGY(2) (SUMMARY) SURVIVAL ANIMALS (14)

PAGE: 2

Group Name	NO. of Animals	WBC 1 O⁵	; 3 / με		fferentia BAND	L WBC (%		EO:	SINO	BAS	50	MOI	10	LYI	1P110	от	THERS
Control	10	2.33±	1.17	0±	0	15±	3	2±	1	0±	0	3±	1	81±	3	0±	0
2000 ppm	10	2.16±	0.76	0±	0	16±	5	2±	1	0±	0	3±	1	79±	5	0±	0
3000 ppm	9	2.85±	2.00	0±	0	13±	2	2±	1	0±	0	3±	2	82±	3	0±	0
4400 ppm	10	1.98±	0.63	0±	0	15±	7	2±	1	0±	0	3±	1	81±	8	0±	0
6700 ppm	9	2.11±	0.66	0±	0	17±	5	2±	1	0±	0	3±	1	78±	4	0±	0
10000 ppm	10	2.36±	0.82	0±	0	17±	5	2±	1	0±	0	3±	1	78±	5	0±	0
Significan	nt difference ;	* : P =	≦ 0.05	**: P ≦	0.01			Test	of Dunne	tt							
(IICL071)			· · · · · · · · · · · · · · · · · · ·														BAIS 2

APPENDIX B 4-3

HEMATOLOGY: SUMMARY, MOSUE: MALE

ANIMAL : MOUSE BDF1

REPORT TYPE : A1

HEMATOLOGY(1) (SUMMARY) SURVIVAL ANIMALS (14)

SEX : MALE

Group Name	NO. of Animals	RED BLOOD CELL 1 06/µl	HEMOGLOBIN g∕dl	HEMATOCRIT %	MCV f @	MCH pg	MCHC g∕dl	PLATELET 1 0³/µl
Control	9	11.15± 0.20	16.3± 0.3	49.2± 0.9	44.2± 0.7	14.6± 0.2	33.1± 0.5	1514± 91
mqq 0008	10	11.15± 0.44	16.4± 0.6	49.7± 2.3	44.6± 1.3	14.7± 0.1	33.0± 1.0	1497± 106
4400 ppm	10	11.13± 0.27	16.5± 0.4	49.4± 1.3	44.4± 0.6	14.8± 0.2	33.4± 0.2	1561± 123
6700 ppm	9	11.07± 0.21	16.4± 0.3	49.8± 1.3	45.0± 0.6	14.8± 0.2	33.0± 0.5	1527± 99
10000 ppm	0	-	-	-	-	-	-	-
15000 ppm	0	-	-	-	-	-	_	-
Significant	difference;	*: P ≤ 0.05	** : P ≤ 0.01		Test of Dunnett			
(IICL070)								BAI

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : MALE

HEMATOLOGY(2) (SUMMARY) SURVIVAL ANIMALS (14)

PAGE: 1

Group Name	NO. of Animals	WBC 1 0³∕μ¢	Diffe N-BAN	erential ND	WBC (%		EOS	INO	BAS	50	MON	0	LYY	PIIO	оті	IIERS
Control	9	1.47± 0.73	0±	0	18±	3	2±	1	0±	0	2±	1	78±	4	0±	0
3000 ppm	10	1.70± 0.88	0±	0	16±	3	2±	1	0±	0	3±	1	79±	2	0±	0
4400 ppm	10	1.64± 0.95	0±	0	17±	3	2±	1	0±	0	2±	2	79±	4	0±	0
6700 ppm	9	1.40± 0.62	0±	0	16±	4	2±	1	0±	0	2±	2	80±	5	0±	0
10000 ppm	0	-	-		-		•••		-		-		-		-	
15000 ppm	0	-			-		-		-		-		-		-	
Significant	t difference ;	*: P ≤ 0.05	** : P ≤ 0.	.01			Test	of Dunne	tt							

(HCL071)

APPENDIX B 4-4

HEMATOLOGY: SUMMARY, MOSUE: FEMALE

STUDY NO. : 0167 ANIMAL : MOUSE BDF1

REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(1) (SUMMARY) SURVIVAL ANIMALS (14)

PAGE: 2

Group Name	NO. of Animals	RED BLOOD 1 O ⁶ /μℓ	CELL	HEMOGLO g/dl	BIN	HEMATOC %	CRIT	MCV f e		MCH pg		MCHC g∕dl		PLATELE 1 0 ³ /1	
Control	10	10.84± 0.	26	16.2±	0.4	47.0±	1.1	43.4±	0.3	14.9±	0.3	34.4±	0.8	1357±	107
3000 ppm	10	10.99± 0.	29	16.3±	0.5	47.7±	1,5	43.4±	0.7	14.9±	0.2	34.3±	0.6	1324±	92
4400 ppm	10	10.81± 0.	33	16.5±	0.4	47.0±	1.9	43.5±	0.8	15.3±	0.3*	35.2±	0.9	1385±	80
6700 ppm	8	10.95± 0.	19	16.7±	0.3*	48.3±	1.1	44.1±	0.6	15.2±	0.2	34.6±	0.7	1320±	179
10000 ppm	0			-		-		-		_		-			
15000 ppm	0			-		-		-		-		-		-	
Significant	difference;	* : P ≤ 0.05	· **	: P ≤ 0.0	1			Test of Dur	nett						

(IICL070)

ANIMAL : MOUSE BDF1

REPORT TYPE : A1
SEX : FEMALE

HEMATOLOGY(2) (SUMMARY)
SURVIVAL ANIMALS (14)

PAGE: 2

up Name	NO. of Animals	WBC 1 Ο³/με		Differentia N-BAND	L WBC (% N-S		EOS	SINO	BAS	60	мом	√ 0	LYN	ІРНО	ОТ	HERS
Control	10	1.39± 0.8	2 0±	0	22±	6	1±	1	0±	0	2±	1	75±	6	0±	0
3000 ppm	10	1.66± 1.0	9 0±	0	18±	5	2±	1	0±	0	2±	1	79±	5	0±	0
4400 ppm	10	1.72± 1.0	2 0±	0	18±	5	2±	1	0±	0	2±	1	79±	6	0±	0
6700 ppm	8	1.51± 0.6	1 0±	0	19±	3	2±	1	0±	0	2±	2	77±	4	0±	0
Mqq 0000	0		-		-		-						-		-	
5000 ppm	0	-	-		-		-		-		-		-		-	
Significant o	difference ;	*: P ≤ 0.0	5 **: P	≤ 0.01		-	Test	of Dunne	tt							
Significant o	difference ;	*: P ≤ 0.0	5 **: P	≦ 0.01 ————			Test	of Dunne	tt							

APPENDIX B 5-1

BIOCHEMISTRY: SUMMARY, RAT: MALE

STUDY NO. : 0166 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : MALE

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

PAGE: 1

Group Name	NO. of Animals	g/dl g/dl	ROTEIN	ALBUMIN g∕d%		A/G RAT	10	T-BILI mg/dl		GLUCOSE mg∕dl		T-CHOLE mg/dl	STEROL	TRIGLYC mg/dl	ERIDE
Control	10	7.0±	0.2	3.9±	0.1	1.3±	0.1	0.23±	0.04	187±	18	62±	5	109±	22
2000 ppm	10	6.9±	0.2	3.9±	0.1	1.3±	0.1	0.24±	0.05	180±	11	65±	4	110±	35
3000 ppm	10	7.0±	0.3	3.9±	0.1	1.3±	0.1	0.22±	0.03	170±	13	65±	8	94±	24
4400 ppm	8	7.0±	0.3	3.9±	0,2	1.3±	0.1	0.24±	0.02	175±	12	57±	5	85±	30
6700 ppm	10	7.1±	0.2	3.9±	0.1	1.2±	0.1	0.23±	0.02	175±	18	63±	6	80±	20
10000 ppm	7	6.9±	0.3	3.9±	0.1	1.3±	0.1	0.23±	0.05	158±	13**	67±	10	55±	11**

(IICL074)

STUDY NO. : 0166 ANIMAL: RAT F344 REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

SEX : MALE

Group Name PHOSPHOLIPID NO. of GOT GPT LDH ALP G-GTP CPK Animals mg/dl IU∕ℓ IU/e IU/l IU/e IU/e IU/l Control 10 $120\pm$ 8 10 78土 28土 5 $150 \pm$ 29 $301 \pm$ 21 1土 1 86± 15 2000 ppm 10 $122\pm$ 11 84± 16 $31\pm$ 10 $163 \pm$ 31 $279 \pm$ 15* 1± 84± 9 1 3000 ppm 10 119± 10 $75\pm$ 21 24± 7 $163 \pm$ 57 269± 14** 1± 1 86± 16 4400 ppm 8 106± 9* 69± 8 $23\pm$ 3 153± 30 $265 \pm$ 13** $1\pm$ ± 68 1 14 6700 ppm 10 114± 10 $57\pm$ 5** 19± 154± 62 2** $263 \pm$ 22** 1± 1 95± 22 10000 ppm 7 119± 15 56± 6** $19\pm$ 4* 154± 44 $273\pm$ 14** 1± · 1 94士 19 Significant difference; $*: P \leq 0.05$ **: $P \leq 0.01$ Test of Dunnett

(HCL074)

BAIS 2

STUDY NO. : 0166 ANIMAL : RAT F344 REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

SEX : MALE

Group Name	NO. of Animals	UREA NI mg∕dl	TROGEN	CREATIN mg∕d&	INE	SODIUM mEq∕ℓ		POTASSI mEq/6		CIILORIDE mEq∕ℓ		CALCIUM mg/dl		INORGAN mg∕dl	IIC PHOSPHORUS
Control	10	18.8±	1.1	0.5±	0.1	144±	2	3.6±	0.3	105±	1	10.4±	0.2	5.5±	1.2
2000 ppm	10	18.4±	2.2	0.5±	0.1	144±	1	3.8±	0.3	104±	1	10.5±	0.2	5.6±	0.8
3000 ppm	10	17.3±	1.1	0.5±	0.0	143±	1	3.7±	0.3	104±	1	10.5±	0.3	5.5±	0.7
4400 ppm	8	17.8±	1.5	0.5±	0.0	143±	1	3.6±	0.3	105±	1	10.3生	0.3	5.8±	0.9
6700 ppm	10	16.8±	1.4*	0.5±	0.0	144±	1	3.8±	0.3	106±	2	10.5±	0.2	6.1±	1.1
10000 ppm	7	15.9±	1.5**	0.4±	0.0	144±	1	3.9±	0.5	107±	1	10.4±	0.3	6.1±	0.8
Significan	t difference;	*: P ≦ ().05 *	*: P ≤ 0.0	1			Test of Dun	nett						
(IICL074)										· · · · · · · · · · · · · · · · · · ·					BAIS

APPENDIX B 5-2

BIOCHEMISTRY: SUMMARY, RAT: FEMALE

STUDY NO. : 0166 ANIMAL : RAT F344 REPORT TYPE : A1 SEX: FEMALE

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

PAGE: 4

iroup Name	NO. of Animals	TOTAL F g∕dl	PROTEIN	ALBUMIN g∕dl		A/G RAT	.10	T-BILI mg∕dl		GLUCOSE mg∕dl		T-CHOLE: mg∕dl	STEROL	TRIGLYCE mg/dl	ERIDE
Control	10	6.5±	0.3	3.6±	0.1	1.3±	0.1	0.27±	0.14	131±	13	78±	8	40±	6
2000 ppm	10	6.5±	0.3	3.6±	0.2	1.3±	0.1	0.25±	0.10	134±	11	80±	7	39±	5
3000 ppm	9	6.4±	0.1	3.5±	0.1	1.2±	0.1	0.24±	0.06	139±	9	73±	6	38±	7
4400 ppm	10	6.4±	0.2	3.5±	0.1	1.2±	0.1	0.24±	0.04	137±	6	72±	6	38±	6
6700 ppm	9	6.4±	0.2	3.5±	0.1*	1.2±	0.1	0.27±	0.07	133±	10	71±	7	36±	7
10000 ppm	10	6.4±	0.2	3.5±	0.1	1.2±	0.1	0.27±	0.10	129±	11	73±	14	35±	5

STUDY NO.: 0166
ANIMAL: RAT F344
REPORT TYPE: A1
SEX: FEMALE

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

PAGE: 5

Group Name	NO. of Animals	PHOSPHO mg/dl	LIPID	GOT IU/e		GPT IU/e		LDH I U / (?	ALP IU/0		G-GTP IU/e		CPK I U / 0	
Control	10	144±	17	71±	22	24±	13	270±	164	220±	23	1±	1	110±	35
2000 ppm	10	147±	11	65±	12	19±	6	273±	183	206±	22	1±	1	119±	49
3000 ppm	9	138±	13	63±	7	21±	5	194±	46	208±	20	2±	1	98±	14
4400 ppm	10	135±	9	57±	4	16±	2	164土	41	212±	19	1±	1	89±	16
6700 ppm	9	132±	13	54±	5*	15±	2*	190土	54	224±	25	1±	1	98±	23
10000 ppm	10	132±	25	56±	4	14±	1**	284±	90	226±	32	2±	1	123±	23

(HCL074)

STUDY NO. : 0166 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : FEMALE

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

Group Name	NO. of Animals	UREA N mg∕dl	TROGEN	CREATIN mg∕dl	INE	SODIUM mEq/l		POTASSI mEq/l		CHLORIDE mEq/l		mg/dl	1	INORGAN mg∕dl	IC PHOSPHORUS
Control	10	18.3±	1.9	0.5±	0.0	143±	2	3.7±	0.6	108±	2	10.0±	0.5	5.1±	1.6
2000 ppm	10	17.2±	1.6	0.5±	0.0	144±	2	3.6±	0.4	109±	2	9.9±	0.3	4.8±	0.8
3000 ppm	9	16.9±	1.9	0.4±	0.1	143±	1	3.6±	0.2	108±	1	9.8±	0.2	5.2±	0.8
4400 ppm	10	17.0±	2.1	0.5±	0.1	143±	1	3.5±	0.3	108±	1	9.8±	0.2	4.8±	0.8
6700 ppm	9	17.1±	2.2	0.5±	0.1	144±	1	3.8±	0.1	109±	1	9.9±	0.1	5.0±	1.0
10000 ppm	10	16.4±	2.5	0.4±	0.1	144±	2	4.0±	0.4	109±	2	9.9±	0.3	5.9±	1.2
Significan	t difference;	*: P ≦ ().05	** : P ≤ 0.0	1			Test of Dun	nett						
(IICL074)				·,,,,				1				·····		<u></u>	BAISS

APPENDIX B 5-3

BIOCHEMISTRY: SUMMARY, MOSUE: MALE

ANIMAL : MOUSE BDF1

REPORT TYPE : A1

SEX : MALE

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

PAGE: 1

Group Name	NO. of Animals	g∕dl TOTAL PR	ROTEIN	ALBUMIN g/dl		A/G RAT	10	T-BILI mg/dl		GLUCOSE mg/dl		T-CHOLE mg/dl	STEROL	TRIGLYCI mg/dl	ERIDE
Control	9	5.3±	0.2	2.8±	0.1	1.1±	0.1	0.33±	0.12	231±	42	81±	8	63±	14
3000 ppm	10	5.2±	0.3	2.8±	0.2	1.2±	0.1	0.30±	0.06	179±	45	72±	10	42±	6**
4400 ppm	10	5.3±	0.2	2.8±	0.1	1.2±	0.0	0.30±	0.05	206±	42	78±	7	49±	11*
6700 ppm	9	5.4±	0.1	2.9±	0.1	1.2±	0.0	0.33±	0.08	200±	37	80±	9	45±	7**
10000 ppm	0	-		-		-		_		-		-		=	
15000 ppm	0	-		-		-		-		-		-		_	

(IICL074)

STUDY NO. : 0167
ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

oup Name	NO. of Animals	GOT IU/4	?	GPT IU/e		LDII IU/e		ALP I U/4	?	CPK I U / 0		UREA N mg∕dl	TROGEN	SODIUM mEq/@	
Control	9	46±	4	10±	1	245±	71	183±	16	74±	45	28.1±	6.9	155±	3
3000 ppm	10	51±	9	12±	1	241±	45	195±	14	74±	50	29.1±	4.1	156±	2
4400 ppm	10	44±	4	11±	2	228±	36	183±	14	54士	21	26.8±	4.0	157±	4
6700 ppm	9	50±	17	12±	1	261 ±	46	181±	14	74±	28	27.4±	2.7	157±	3
Mqq 0000	0	-		-		-						-		-	
15000 ppm	0	-		-		-		-		-				-	
Significant	difference;	*: P ≤ 0.	.05	**: P ≤ 0.01				Test of Dunr	nett	<u></u>					

ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

PAGE: 3

Group Name	NO. of Animals	POTASSII meq/l		CHLORIDE mEq∕ℓ		mg∕d£		INORGAN mg∕dl	C PIIOSPIIO	RUS			
Control	9	4.8±	0.6	123±	1	8.7±	0.3	7.6±	1.2				
3000 ppm	10	4.7±	0.8	124±	2	8.8±	0.5	7.4±	1.6				
4400 ppm	10	4.5±	0.6	123±	3	8.6±	0.3	6.7±	1.2				
6700 ppm	9	4.5±	0.4	124±	2	8.6±	0.3	6.9±	1.1				
10000 ppm	0			-		_		-					•
15000 ppm	0	_		-		-		_					
Significant	difference;	*: P ≤ 0.	.05	**: P ≤ 0.01				Test of Dunr	ett		 		

(HCL074)

APPENDIX B 5-4

BIOCHEMISTRY: SUMMARY, MOSUE: FEMALE

STUDY NO. : 0167 ANIMAL : MOUSE BDF1

REPORT TYPE : A1
SEX : FEMALE

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

roup Name	NO. of Animals	g/dl PI	ROTEIN	ALBUMIN g∕dશ		∧/G RATI	0	T-BILII mg∕dl		GLUCOSE mg∕dl		T−CHOLES mg∕cll	STEROL	TRIGLYCI mg/dl	ERIDE
Control	10	5,4±	0.2	3.1±	0.1	1.3±	0.1	0.28±	0.09	167±	21	75±	8	46±	11
3000 ppm	10	5.3±	0.1	3.0±	0.1	1.4±	0.1	0.32±	0.08	164±	16	74±	12	51±	13
4400 ppm	10	5.4±	0.2	3.0±	0.1	1.3±	0.1	.0.29±	0.09	172±	21	84±	11	50±	10
6700 ppm	9	5.6±	0.3	3.2±	0.1	1.3±	0.1	0.32±	0.12	151±	31	81±	8	42±	10
10000 ppm	0			-				_		-		-		-	
15000 ppm	0	-		-		-		-				_		-	

(IICL074)

BAIS 2

ANIMAL : MOUSE BDF1
REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) SURVIVAL ANIMALS (14)

SEX : FEMALE

GOT I U	[U/@		GPT IU∕ℓ		LDH I U / 4	?	ALP IU/0		CPK I U / 0		UREA N mg∕dl		SODIUM mEq/0	
64:	l± :	18	15±	5	264±	42	285±	39	72±	17	20.5±	2,2	156±	3
61:	.±	14	14±	1	261±	42	289±	45	62±	27	21.2±	1.6	155±	2
58:	3± :	12	13±	2	256±	78	290士	36	62±	25	20.1±	2.2	155±	2
58:	3±	8	14±	2	299±	123	288±	29	63±	26	19.1±	2.2	156±	3
-	-		-		<u></u>		-		-		-		-	
-			-		-		-		-		-		-	
*:P:	≤ 0.05	*	* : P ≤ 0.01				Test of Dunr	nett						
*	: P	: P ≤ 0.05	: P ≤ 0.05 *	*: P ≤ 0.05	*: P ≤ 0.05	*: P ≤ 0.05	$*: P \le 0.05$ $**: P \le 0.01$::P ≤ 0.05 **: P ≤ 0.01 Test of Dunn	: P ≤ 0.05 **: P ≤ 0.01 Test of Dunnett	: P ≤ 0.05 **: P ≤ 0.01	: P ≤ 0.05 **: P ≤ 0.01 Test of Dunnett	: P ≤ 0.05 **: P ≤ 0.01 Test of Dunnett	: P ≤ 0.05 **: P ≤ 0.01	: P ≤ 0.05 **: P ≤ 0.01

BAIS 2

ANIMAL : MOUSE BDF1
REPORT TYPE : A1

SEX : FEMALE

BIOCHEMISTRY (SUMMARY)

SURVIVAL ANIMALS (14)

iroup Name	NO. of Animals	POTASSI mEq/		CIILORI DE mEq/l		CALCIUM mg/dl		INORGAN mg∕dl	IC PHOSPHORUS	
Control	10	4.6±	0.3	123±	3	8.7±	0.2	6.3±	1.0	
3000 ppm	10	4.3±	0.6	123±	3	8.8±	0.3	5.8±	1.1	
4400 ppm	10	4.5±	0.5	122±	2	8.7±	0.3	5.8±	0.8	
6700 ppm	9	4.9±	0.5	124土	2	9.0±	0.3	5.9±	1.1	
10000 ppm	0	-		-		-		-		
15000 ppm	0			-		-		-		
Significant	difference :	*: P ≤ 0),05	**: P ≤ 0.01				Test of Dun	nett	
ICL074)										BAI

APPENDIX B 6-1

URINALYSIS: SUMMARY, RAT: MALE

URINALYSIS

ANIMAL : RAT F344 SAMPLING DATE: 013-6

SEX : MALE

REPORT TYPE : A1

PAGE: 1

Group Name	NO. of	pll							Pr	ote	in					GL	JCOS	e			Ket	tone	bad	У			Bi	Liru	in	
	Animals		6.0	6.5	7.0	7.5	8.0	8.5 CHI			+	2+	3+	4+	CHI				2+ 3	+ 4+ CHI			+ 2		+ 4+	CHI	_	+ 2	3+ 3+	CHI
Control	10	0	0	0	0	2	7	1	0	0	6	4	0	0		10	0	0	0	0 0	4	6	0	0 () 0		10	0	0 (
2000 ppm	10	0	0	0	0	4	6	0	0	2	5	3	0	0		10	0	0	0	0 0	4	6	0	0 (0 (10	0	0 (
3000 ppm	10	0	0	0	0	2	8	0	0	4	4	2	0	0		10	0	0	0	0 0	6	4	0	0 (0 0		10	0	0 (1
4400 ppm	10	0	0	0	0	3	7	0	0	3	7	0	0	0	*	10	0	0	0	0 0	7	3	0	0	0 0		10	0	0 (ı
6700 ppm	10	0	0	0	1	2	7	0	0	3	7	0	0	0	*	10	0	0	0	0 0	7	3	0	0	0 0		10	0	0 (+
10000 ppm	7	0	0	0	0	3	4	0	0	4	3	0	0	0	*	7	0	0	0	0 0	5	2	0	0	0 0		7	0	0 (•

(JCL101)

URINALYSIS

ANIMAL : RAT F344 SAMPLING DATE : 013-6

SEX : MALE

REPORT TYPE : A1

Group Name NO. of Occult blood Vrobilinogen Animals $-\pm + 2 + 3 +$ CHI \pm + 2+ 3+ 4+ CHI Control 10 10 0 0 0 0 10 0 0 0 0 2000 ppm 10 10 0 0 0 0 10 0 0 0 0 3000 ppm 10 10 0 0 0 0 10 0 0 0 0 4400 ppm 10 9 0 0 0 1 10 0 0 0 0 6700 ppm 10 10 0 0 0 0 10 0 0 0 0 10000 ppm 7 7 0 0 0 0 7 0 0 0 0 Significent difference ; $*:P \leq 0.05$ Test of CHI SQUARE $**: P \leq 0.01$

PAGE: 2

(JCL101) BAIS 2

APPENDIX B 6-2

URINALYSIS: SUMMARY, RAT: FEMALE

URINALYSIS

ANIMAL : RAT F344 SAMPLING DATE : 013-6

SEX : FEMALE

REPORT TYPE : A1

PAGE: 3

TOUP Name	NO. of	pil								Pro	teir	١			C	lucc	SA				Kat	one l	oady.	• •		Βi	Lirub	in.		
	Animals	5.0	6.0	6.5	7.0	7.5	8.0	8.5	CIII				+ 3+	4+ CIII			-	2+ 3	3+ 4+	CIII			- 2+					111 - 3+ 	CHI	
Control	10	0	0	0	0	1	9	0		0	10	0	0 0	0	1	0 0	0	0	0 0		10	0 (0 0	0	0	10	0	0 0		
2000 ppm	10	0	0	. 0	0	2	7	1		0	10	0	0 0	0	1	0 0	0	0	0 0		10	0 (0 0	0	0	10	0	0 0		
3000 ppm	10	0	0	0	0	0	9	1		0	9	i	0 0	0	1	0 0	0	0	0 0		10	0 (0 0	0	0	10	0	0 0		
4400 ppm	10	0	0	0	0	2	7	1		0	8	2	0 0	0	1	0 0	0	0	0 0		10	0 (0 0	0	0	10	0	0 0		
6700 ppm	10	0	0	0	1	0	8	1	·	0	10	0	0 0	0	1	0 0	0	0	0 0		10	0 (0 0	0	0	10	0	0 0		
mqq 00001	10	0	. 0	0	0	5	5	0		0	10	0	0 0	0	1	0 0	0	0	0 0		10	0 (0 0	0	0	10	0	0 0		

URINALYSIS

ANIMAL : RAT F344 SAMPLING DATE : 013-6

SEX : FEMALE

REPORT TYPE : A1

Group Name	NO. of Animals	Occult blood — ± + 2+ 3+ CHI	Urabilinagen ± + 2+ 3+ 4+ CHI		
Control	10	10 0 0 0 0	10 0 0 0 0		
2000 ppm	10	10 0 0 0 0	10 0 0 0 0		
3000 ppm	10	10 0 0 0 0	10 0 0 0 0		
4400 ppm	10	10 0 0 0 0	10 0 0 0 0		
6700 ppm	10	10 0 0 0 0	10 0 0 0 0		
10000 ppm	10	10 0 0 0 0	10 0 0 0 0		
Significen	nt difference	; *: P ≤ 0.05 **	$: P \leq 0.01$	Test of CHI SQUARE	
(JCL101)					DATEO

BAIS 2

APPENDIX B 6-3

URINALYSIS: SUMMARY, MOSUE: MALE

URINALYSIS

ANIMAL : MOUSE BDF1
SAMPLING DATE : 013-5

SEX : MALE

REPORT TYPE : A1

PAGE: 1

roup Nam	10	NO. of	lla								Protein	Glucose	Ketane bady	Occult blood
	1	Animals	5.0	6.0	6.5	7.0	7.5	8.0	8.5	CHI	- ± + 2+ 3+ 4+ CHI	- ± + 2+ 3+ 4+ CIII	- ± + 2+ 3+ 4+ CHI	- ± + 2+ 3+ CHI
Contro	ıl	10	0	0	0	1	6	3	0		0 0 9 1 0 0	10 0 0 0 0 0	0 10 0 0 0 0	10 0 0 0 0
3000	ppm	10	0	0	1	6	3	0	0	*	0 0 10 0 0 0	10 0 0 0 0 0	0 4 6 0 0 0 **	10 0 0 0 0
4400	ppm	10	0	0	3	0	5	2	0		0 0 9 1 0 0	10 0 0 0 0 0	0 2 4 3 1 0 **	10 0 0 0 0
6700	ppm	10	0	0	0	0	7	3	0		0 0 7 3 0 0	10 0 0 0 0 0	0 0 2 7 1 0 **	10 0 0 0 0
10000	ppm	0	-	-	-	-	-	-	-					
15000	ppm	0	-	-	-	-	-	-	-					
Signi	ficent	difference	; *:	P ≦	0.05	ı	** :	P ≦	0.01		Test	of CHI SQUARE		

(JCL101)

URINALYSIS

ANIMAL : MOUSE BDF1 SAMPLING DATE: 013-5

SEX : MALE

REPORT TYPE : A1

Group Name NO. of Urabilinagen ± + 2+ 3+ 4+ CIII Animals 10 0 0 0 0 Control 10 3000 ppm 10 10 0 0 0 0 4400 ppm 10 10 0 0 0 0 6700 ppm 10 10 0 0 0 0 10000 ppm 15000 ppm

Significent difference ; $*: P \leq 0.05$

 $** : P \leq 0.01$

Test of CHI SQUARE

(JCL101)

BAIS 2

APPENDIX B 6-4

URINALYSIS: SUMMARY, MOSUE: FEMALE

URINALYSIS

ANIMAL : MOUSE BDF1 SAMPLING DATE: 013-5

SEX : FEMALE

REPORT TYPE : A1

PAGE: 3

	Animals								Protein	Glucose	Ketone body	Occult blood
		5.0	6.0	6.5	7.0	7.5	8.0	8.5 CHI	- ± + 2+ 3+ 4+ CHI	- ± + 2+ 3+ 4+ CHI	- ± + 2+ 3+ 4+ CHI	- ± + 2+ 3+ CIII
Control	10	0	0	1	1	5	3	0	0 1 8 1 0 0	10 0 0 0 0 0	2 6 2 0 0 0	10 0 0 0 0
3000 ppm	10	0	0	0	5	4	1	0	0 5 5 0 0 0	10 0 0 0 0 0	1 9 0 0 0 0	10 0 0 0 0
4400 ppm	10	0	0	0	4	4	2	0	0 2 8 0 0 0	10 0 0 0 0 0	0 10 0 0 0 0	10 0 0 0 0
6700 ppm	9	0	0	1	1	4	3	0	0 1 6 2 0 0	9 0 0 0 0 0	1 7 1 0 0 0	9 0 0 0 0
10000 ppm	0	-	_	-	-	_		-				
15000 ppm	0	-	-	-	-	_	-	-				·
15000 ppm		-	-		-	-	-	-				

(JCL101)

ANIMAL : MOUSE BDF1

SAMPLING DATE: 013-5

SEX : FEMALE

REPORT TYPE : A1

URINALYSIS

SEX : FEMALE	REPORT	TYPE: A1		PAGE: 4
Group Name	NO. of Animals	Urabilinogen ± + 2+ 3+ 4+ CHI		
Control	10	10 0 0 0 0	·	
3000 ppm	10	10 0 0 0 0		
4400 ppm	10	10 0 0 0 0		
6700 ppm	9	9 0 0 0 0		
10000 ppm	0			
15000 ppm	0			
Significent	difference	$*: P \le 0.05$ $**: P \le 0.01$	Test of CHI SQUARE	
(JCL101)				RAIS 2

APPENDIX B 7-1

GROSS FINDINGS: SUMMARY, RAT: MALE: SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

ANIMAL : RAT F344

REPORT TYPE : A1

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (14W)

SEX : MALE

rgan	Findings	Group Name NO. of Animals	Control 10 (%)	2000 ppm 10 (%)	3000 ppm 10 (%)	4400 ppm 10 (%)
hymus	red zone		1 (10)	1 (10)	0 (0)	0 (0)
iver	herniation		0 (0)	2 (20)	0 (0)	0 (0)
iver	herniation		0 (0)	2 (20)	0 (0)	U
)						В

STUDY NO. : 0166
ANIMAL : RAT F344
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (14W)

Organ	Findings	Group Name NO. of Animals	6700 ppm 10 (%)	10000 ppm 7 (%)	
thymus	red zone		0 (0)	0 (0)	
liver	herniation		0 (0)	1 (14)	
(HPT080)					BAIS 2

APPENDIX B 7-2

GROSS FINDINGS: SUMMARY, RAT: FEMALE: SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166 ANIMAL : RAT F344
REPORT TYPE : A1

SEX : FEMALE

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (14W)

PAGE: 3

0rgan	Findings	Group Name NO. of Animals	Control 10 (%)	2000 ppm 10 (%)	3000 ppm 10 (%)	4400 ppm 10 (%)
al stomach	ulcer		0 (0)	0 (0)	0 (0)	0 (0)
ver	herniation		0 (0)	1 (10)	0 (0)	0 (0)
ary	fluid:red		1 (10)	0 (0)	0 (0)	0 (0)
ain	deformed		0 (0)	0 (0)	0 (0)	0 (0)

(IIPT080)

STUDY NO. : 0166 ANIMAL : RAT F344 REPORT TYPE : A1

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (14W)

: FEMALE

SEX

6700 ppm 10000 ppm Group Name Organ____ Findings_ 10 (%) 10 (%) NO. of Animals gl stomach ulcer 0 (0) 1 (10) liver herniation 0 (0) 0 (0) ovary fluid:red 0 (0) 0 (0) brain deformed 0 (0) 1 (10) (IIPT080) BAIS 2

APPENDIX B 7-3

GROSS FINDINGS : SUMMARY, RAT: MALE : DEAD AND MORIBUND ANIMALS (THIRTEEN - WEEK STUDY)

: RAT F344 ANIMAL

REPORT TYPE : A1 : MALE SEX

GROSS FINDINGS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0- 14W)

. 4400 ppm 0 (%) Group Name Control 0 (%) 2000 ppm 3000 ppm 0rgan__ Findings_ 0 (%) 0 (%) NO. of Animals - (-) - (-) - (-) - (-) lung voluminus (HPT080)

BAIS 2

STUDY NO. : 0166 ANIMAL : RAT F344 REPORT TYPE : A1

GROSS FINDINGS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0- 14W)

SEX : MALE PAGE: 2 10000 ppm 3 (%) Group Name 6700 ppm Findings_ 0 (%) Organ__ NO. of Animals lung voluminus - (-) 1 (33) (IIPT080) BAIS 2

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APPENDIX B 7-4

GROSS FINDINGS: SUMMARY, MOSUE: MALE: SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

ANIMAL : MOUSE BDF1

REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)

SACRIFICED ANIMALS (14W)

Organ	Findings	Group Name NO. of Animals	Control 10 (%)	3000 ppm 10 (%)	4400 ppm 10 (%)	6700 ppm 10 (%)
spleen	black zone		1 (10)	0 (0)	0 (0)	0 (0)
(HPT080)						BAIS

ANIMAL

: MOUSE BDF1

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (14W)

REPORT TYPE : A1

: MALE SEX

PAGE: 2 15000 ppm 0 (%) Group Name 10000 ppm Findings__ 0 (%) Organ____ NO. of Animals - (-) - (-) spleen black zone (HPT080) BAIS 2

APPENDIX B 7-5

GROSS FINDINGS: SUMMARY, MOSUE: FEMALE: SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : FEMALE GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (14W)

PAGE: 3

Organ	Findings	Group Name NO. of Animals	Control 10 (%)	3000 ppm 10 (%)	4400 ppm 10 (%)	6700 ppm 9 (%)
spleen	black zone		1 (10)	1 (10)	1 (10)	0 (0)
IPT080)						

ANIMAL : MOUSE BDF1

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (14W)

REPORT TYPE : A1

SEX : FEMALE PAGE: 4 10000 ppm 15000 ppm Group Name Findings_ 0 (%) Organ____ NO. of Animals 0 (%) - (-) black zone - (-) spleen (HPT080) BAIS 2

APPENDIX B 7-6

GROSS FINDINGS : SUMMARY, MOUSE: MALE :DEAD AND MORIBUND ANIMALS (THIRTEEN - WEEK STUDY)

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : MALE GROSS FINDINGS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0- 14W)

Organ	Findings	Group Name NO. of Animals	Control 0 (%)	mqq 0008 (%) 0	4400 ppm 0 (%)	6700 ppm 0 (%)
ung	red zane		- (-)	- (-)	- (-)	- (-)
IPT080)						

ANIMAL : MOUSE BDF1
REPORT TYPE : A1

GROSS FINDINGS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0- 14W)

ganFindings	Group Nam NO, of An	e 10000 ppm imals 10 (%)	15000 ppm 10 (%)	
		······································		
ung red zone		0 (0)	1 (10)	

APPENDIX B 7-7

GROSS FINDINGS : SUMMARY, MOUSE: FEMALE : DEAD AND MORIBUND ANIMALS (THIRTEEN - WEEK STUDY)

: MOUSE BDF1 ANIMAL

REPORT TYPE : A1 : FEMALE SEX

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

Group Name Control 3000 ppm 4400 ppm 6700 ppm Organ__ Findings_ NO. of Animals 0 (%) 0 (%) 0 (%) 1 (%) lung red zane - (-) - (-) - (-) 0 (0) BAIS 2

PAGE: 3

(HPT080)

ANIMAL : MOUSE BDF1

GROSS FINDINGS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0- 14W)

REPORT TYPE : A1 SEX : FEMALE

0rgan	Findings	Group Name NO. of Animals	10000 ppm 10 (%)	15000 ppm 10 (%)	
lung	red zone		1 (10)	2 (20)	
(IIPT080)					BAIS

APPENDIX B 8-1

ORGAN WEIGHT, ABSOLUTE: SUMMARY, RAT: MALE
(THIRTEEN-WEEK STUDY)

STUDY NO. : 0166 ANIMAL : RAT F344 REPORT TYPE : A1

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

SEX : MALE UNIT: g

Group Name	NO. of Animals	Body V	Veight	ТНҮМ	JS	ADRE	NALS	TEST	ES	HEAR'	Г	LUNG	S
Control	10	323±	18	0.339±	0.131	0.057±	0.009	2.974±	0.051	0.943±	0.045	1.006±	0.040
2000 ppm	10	311±	15	0.276±	0.030	0.052±	0.006	2.781±	0.662	0.926±	0.050	1.007±	0.038
3000 ppm	10	312±	30	0.278±	0.053	0.054±	0.006	3.010±	0.108	0.950±	0.107	1.026±	0.079
4400 ppm	10	280±	14**	0.243±	0.037*	0.062±	0.012	3.006±	0.093	0.895±	0.042	0.967±	0.048
6700 ppm	10	269±	22**	0.208±	0.026**	0.059±	0.005	2.804±	0.275	0.848士	0.064*	0.955±	0.037
10000 ppm	7	227±	18**	0.185±	0.030**	0.064±	0.005	2.809±	0.119	0.783±	0.060**	0.885±	0.037**
Significar	nt difference;	*: P ≤ 0.0	05 **	: P ≤ 0.01			Tes	t of Dunnett					
(IICL040)													

STUDY NO. : 0166 ANIMAL : RAT F344 REPORT TYPE : A1 ORGAN WEIGHT: ABSOLUTE (SUMMARY)
SURVIVAL ANIMALS (14)

SEX : MALE UNIT: g

PAGE: 2

Group Name	NO. of Animals	KID	NEYS	SPL	EEN	LIV	ER	BRA		
Control	10	1.947±	0.076	0.531±	0.030	8.451±	0.605	1.902±	0.027	
2000 ppm	10	1.970±	0.116	0.527±	0.031	8.348±	0.488	1.885±	0.046	
3000 ppm	10	2.008±	0,205	0.534±	0.039	8,238±	0.884	1.884±).052	
4400 ppm	10	1.863±	0.046	0.496±	0.031	7.630±	0.456*	1.865±).024	
6700 ppm	10	1.800±	0.129*	0.474±	0.045**	7.269±	0.449**	1.844±).033**	
10000 ppm	7	1.609±	0.083**	0.413±	0.037**	6,266±	0.525**	1.788±).032**	

(HCL040)

APPENDIX B 8-2

ORGAN WEIGHT, ABSOLUTE: SUMMARY, RAT: FEMALE
(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166 ANIMAL : RAT F344 REPORT TYPE : A1 SEX : FEMALE

UNIT: g

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

PAGE: 3

Group Name	NO. of Animals	Body V	leight	ЈМ ҮНТ	JS	ADRE	NALS	OVAR	IES	HEAR	Γ	LUNG	S	
Control	10	182±	10	0.219±	0.020	0.061±	0.007	0.128±	0.056	0.622±	0.026	0.778±	0.052	
2000 ppm	10	178±	15	0.204±	0.026	0.065±	0.008	0.100±	0.013	0.611±	0.044	0.753±	0.053	
3000 ppm	10	171±	14	0.204±	0.013	0.060±	0.011	0,097±	0.019	0.591±	0.055	0.766±	0.046	
4400 ppm	10	170±	13	0.199±	0.036	0.059±	0.005	0.107±	0.015	0.602±	0.047	0.757±	0.044	
6700 ppm	10	165±	9*	0.179±	0.020**	0.062±	0.006	0.114±	0.027	0.594±	0.041	0.744±	0.029	
10000 ppm	10	162±	13**	0.179±	0.028**	0.067±	0.006	0,103±	0.023	0,591±	0.035	0.741±	0.049	
Significan	at difference ;	*: P ≤ 0.0	05 **	: P ≤ 0.01			Tes	t of Dunnett						DA

BAIS 2 (HCL040)

STUDY NO.: 0166 ANIMAL : RAT F344 REPORT TYPE : A1

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

SEX : FEMALE UNIT: g

PAGE: 4 Group Name NO. of KIDNEYS SPLEEN LIVER BRAIN Animals Control 10 1.219± 0.063 0.369± 0.021 4.379± 0.249 1.728± 0.034 2000 ppm 10 1.236± 0.082 0.366± 0.039 4.405± 0.325 1.764± 0.029 3000 ppm 10 1.239± 0.071 0.363± 0.039 4.227± 0.426 1.745± 0.043 4400 ppm 10 1.230± 0.077 0.365± 0.046 4.195± 0.318 1.737± 0.049 6700 ppm 10 1.233± 0.050 0.350± 0.024 4.214± 0.257 1.704± 0.033 10000 ppm 10 1.208± 0.084 0.336± 0.033 4.294± 0.287 1.670± 0.066* Significant difference; $*:P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett

(IICL040) BAIS 2

APPENDIX B 8-3

ORGAN WEIGHT, ABSOLUTE: SUMMARY, MOSUE: MALE

(THIRTEEN - WEEK STUDY)

ANIMAL : MOUSE BDF1

REPORT TYPE : A1

SEX : MALE UNIT: g ORGAN WEIGHT: ABSOLUTE (SUMMARY) SURVIVAL ANIMALS (14)

PAGE: 1

roup Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
Control	10	30.9± 2.1	0.040± 0.007	0.011± 0.004	0.208± 0.022	0.153± 0.010	0.158± 0.010
3000 ppm	10	28.1± 1.2**	0.034± 0.004*	0.010± 0.003	0,215± 0.023	0.154± 0.008	0.161± 0.009
4400 ppm	10	28.7± 1.8*	0.035± 0.004	0.009± 0.002	0.210± 0.025	0.149± 0.010	0.160± 0.008
6700 ppm	10	27.9± 1.3**	0.033± 0.003*	0.010± 0.002	0.216± 0.018	0.153± 0.010	0.156± 0.007
10000 ppm	0	-	-	-	-	-	-
15000 ppm	0	- .	-	-	-	~	-

(HCL040)

ANIMAL : MOUSE BDF1
REPORT TYPE : A1

SEX : MALE

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

UNIT: g

PAGE: 2

roup Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN	
Control	10	0.468± 0.019	0.044± 0.005	1.190± 0.070	0.443± 0.013	
3000 ppm	10	0.461± 0.020	6 0.046± 0.005	1.150± 0.060	0.450± 0.014	
4400 ppm	10	0.466± 0.02	0.043± 0.005		0.437± 0.010	
6700 ppm	10	0.449± 0.02	9 0.042± 0.004	1.172± 0.057	0.444± 0.010	
10000 ppm	0	-	-	-	-	
15000 ppm	0	-		- '	-	

(IICL040)

APPENDIX B 8-4

ORGAN WEIGHT, ABSOLUTE: SUMMARY, MOSUE: FEMALE

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167 ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

UNIT: g

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

1171	•	•
'AGE	٠	•

Group Name	NO. of Animals	Bady Weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS	
Control	10	22.3± 1.1	0.039± 0.006	0.012± 0.002	0.025± 0.005	0.138± 0.005	0.156± 0.008	
3000 ppm	10	22.7± 1.5	0.042± 0.008	0.014± 0.002	0.023± 0.007	0.135± 0.007	0.158± 0.013	
4400 ppm	10	22.7± 0.8	0.043± 0.006	0.013± 0.001	0,026± 0,003	0.133± 0.006	0.157± 0.008	
6700 ppm	9	22.7± 1.3	0.042± 0.006	0.012± 0.001	0.026± 0.004	0.140± 0.007	0.157± 0.010	
10000 ppm	0	-	-	-	-	-	-	
15000 ppm	0	-	-	-	-	-	-	
Significant	difference;	*: P ≤ 0,05 **	: P ≤ 0.01	Test	of Dunnett			

(IICL040)

ANIMAL : MOUSE BDF1

REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

PAGE: 4

NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN	
10	0.326± 0.009	0.054± 0.005	0.994± 0.064	0.465± 0.010	
10	0.322± 0.025	0.056± 0.010	1.026± 0.123	0.463± 0.017	
10	0.326± 0.012	0.053± 0.004	1.058± 0.053	0.455± 0.013	
9	0.325± 0.023	0.050± 0.009	1.036± 0.080	0.456± 0.012	
0	-	-		_	
0	-	-		-	
	10 10 10 9 0	10 0.326± 0.009 10 0.322± 0.025 10 0.326± 0.012 9 0.325± 0.023 0 -	10 0.326± 0.009 0.054± 0.005 10 0.322± 0.025 0.056± 0.010 10 0.326± 0.012 0.053± 0.004 9 0.325± 0.023 0.050± 0.009 0	10	10

(IICL040)

APPENDIX B 9-1

ORGAN WEIGHT, RELATIVE: SUMMARY, RAT: MALE

(THIRTEEN - WEEK STUDY)

ANIMAL : RAT F344

REPORT TYPE : A1

SEX : MALE UNIT: %

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

PAGE: 1

roup Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS	
Control	10	323± 18	0.105± 0.041	0.018± 0.004	0.925± 0.054	0.293± 0.015	0.312± 0.012	
2000 ppm	10	311± 15	0.089± 0.008	0.017± 0.002	0.893± 0.211	0.298± 0.017	0.324± 0.015	
3000 ppm	10	312± 30	0.089± 0.009	0.018± 0.002	0.971± 0.072	0.304± 0.006	0.330± 0.015	
4400 ppm	10	280士 14**	0.087± 0.011	0.022± 0.004**	1.076士 0.049**	0.320± 0.015**	0.346± 0.015**	
6700 ppm	10	269土 22**	0.077土 0.009**	0.022主 0.003*	1.046士 0.119*	0.315± 0.014**	0.356± 0.023**	
10000 ppm	7	227± 18**	0.082± 0.016	0.029± 0.003**	1.241± 0.102**	0.344± 0.010**	0.390± 0.021**	

REPORT TYPE : A1

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

SEX : MALE UNIT: %

Group Name NO. of KIDNEYS SPLEEN LIVER BRAIN Animals Control 10 0.605 ± 0.018 0.165 ± 0.009 2.619 ± 0.073 0.591 ± 0.034 2000 ppm 10 0.634 ± 0.026 0.170 ± 0.007 2.687 ± 0.075 0.608 ± 0.028 3000 ppm 10 0.644± 0.022* 0.172 ± 0.008 2.640 ± 0.076 0.608± 0.045 4400 ppm 10 0.667± 0.037** 0.177士 0.008** 2.727 ± 0.133 0.668± 0.038** 6700 ppm 10 0.670± 0.035** 0.176± 0.009* 2.703± 0.087 0.688± 0.054** 10000 ppm 7 0.709生 0.026** 0.182± 0.007** 2.757± 0.121* 0.791± 0.069** Significant difference; $*:P \leq 0.05$ ** : $P \leq 0.01$ Test of Dunnett (IICL042)

BAIS 2

APPENDIX B 9-2

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : FEMALE

(THIRTEEN - WEEK STUDY)

REPORT TYPE: A1
SEX: FEMALE
UNIT: %

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

PAGE: 3

NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS	
10	182± 10	0.120± 0.007	0.034± 0.004	0.071± 0.032	0.342± 0.016	0.428± 0.027	
10	178± 15	0.115± 0.011	0.037± 0.005	0.057± 0.010	0.345± 0.016	0.425± 0.023	
10	171± 14	0.120± 0.013	0.035± 0.005	0.056± 0.008	0.345± 0.010	0.449± 0.023	
10	170± 13	0.116± 0.013	0.035± 0.004	0.063± 0.008	0.355± 0.012	0.446± 0.021	
10	165± 9*	0.108± 0.008	0.038± 0.004	0.069± 0.016	0.360± 0.015	0.452± 0.020	
10	162土 13**	0.110± 0.012	0.042± 0.005**	0.064± 0.013	0.367± 0.029	0.460± 0.022*	
_	10 10 10 10 10 10	10 182± 10 10 178± 15 10 171± 14 10 170± 13 10 165± 9*	Animals (g) 10 182± 10 0.120± 0.007 10 178± 15 0.115± 0.011 10 171± 14 0.120± 0.013 10 170± 13 0.116± 0.013 10 165± 9* 0.108± 0.008	Animals (g) 10 182± 10 0.120± 0.007 0.034± 0.004 10 178± 15 0.115± 0.011 0.037± 0.005 10 171± 14 0.120± 0.013 0.035± 0.005 10 170± 13 0.116± 0.013 0.035± 0.004 10 165± 9* 0.108± 0.008 0.038± 0.004	Animals (g) 10 182 \pm 10 0.120 \pm 0.007 0.034 \pm 0.004 0.071 \pm 0.032 10 178 \pm 15 0.115 \pm 0.011 0.037 \pm 0.005 0.057 \pm 0.010 10 171 \pm 14 0.120 \pm 0.013 0.035 \pm 0.005 0.056 \pm 0.008 10 170 \pm 13 0.116 \pm 0.013 0.035 \pm 0.004 0.063 \pm 0.008 10 165 \pm 9* 0.108 \pm 0.008 0.038 \pm 0.004 0.069 \pm 0.016	Animals (g) 10 182 ± 10 0.120 ± 0.007 0.034 ± 0.004 0.071 ± 0.032 0.342 ± 0.016 10 178 ± 15 0.115 ± 0.011 0.037 ± 0.005 0.057 ± 0.010 0.345 ± 0.016 10 171 ± 14 0.120 ± 0.013 0.035 ± 0.005 0.056 ± 0.008 0.345 ± 0.010 10 170 ± 13 0.116 ± 0.013 0.035 ± 0.004 0.063 ± 0.008 0.355 ± 0.012 10 $165\pm 9*$ 0.108 ± 0.008 0.038 ± 0.004 0.069 ± 0.016 0.360 ± 0.015	Animals (g) 10 182± 10 0.120± 0.007 0.034± 0.004 0.071± 0.032 0.342± 0.016 0.428± 0.027 10 178± 15 0.115± 0.011 0.037± 0.005 0.057± 0.010 0.345± 0.016 0.425± 0.023 10 171± 14 0.120± 0.013 0.035± 0.005 0.056± 0.008 0.345± 0.010 0.449± 0.023 10 170± 13 0.116± 0.013 0.035± 0.004 0.063± 0.008 0.355± 0.012 0.446± 0.021 10 165± 9* 0.108± 0.008 0.038± 0.004 0.069± 0.016 0.360± 0.015 0.452± 0.020

REPORT TYPE: A1 SEX: FEMALE UNIT: % ORGAN WEIGHT: RELATIVE (SUMMARY) SURVIVAL ANIMALS (14)

PAGE: 4

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	0.670± 0.017	0.203± 0.010	2.409± 0.087	0.952± 0.050
2000 ppm	10	0.698± 0.038	0.206± 0.014	2.484± 0.092	0.999± 0.078
3000 ppm	10	0.726± 0.036**	0.212± 0.013	2.469± 0.098	1.025± 0.071
4400 ppm	10	0.725± 0.027**	0.214± 0.015	2.470± 0.084	1.026± 0.054
6700 ppm	10	0.748± 0.022**	0.212± 0.008	2.555± 0.078**	1.036± 0.050
10000 mag	10	0.749± 0.024**	0.208± 0.018	2.662± 0.106**	1.042± 0.113
Significan	t difference ;	*: P ≤ 0.05 **:	P ≤ 0.01	Test	of Dunnett

(IICL042)

BAIS 2

APPENDIX B 9-3

ORGAN WEIGHT, RELATIVE: SUMMARY, MOSUE: MALE

(THIRTEEN - WEEK STUDY)

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : MALE UNIT: %

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

PAGE: 1

Group Name	NO, of Animals	Body Weight (g)	TIIYMUS	ADRENALS	TESTES	HEART	LUNGS	
Cantrol	10	30.9± 2.1	0.128± 0.015	0.034± 0.012	0.673± 0.071	0.496± 0.031	0.511± 0.046	
3000 ppm	10	28.1± 1.2**	0.119± 0.014	0.035± 0.009	0.768± 0.097*	0.549± 0.039**	0.575± 0.039**	
4400 ppm	10	28.7± 1.8*	0.124± 0.015	0.030± 0.007	0.731± 0.070	0.519± 0.020	0.560± 0.050*	
6700 ppm	10	27.9± 1.3**	0.119± 0.012	0.034± 0.007	0.775± 0.075*	0.548± 0.043**	0.560± 0.042*	
10000 ppm	0	~	-	· ••	-	-	-	
15000 ppm	0	-	-	-	-	-	-	
Significant	difference;	*: P ≤ 0.05 **	: P ≤ 0.01	Tes	t of Dunnett			
(HCL042)							···· · · · · · · · · · · · · · · · · ·	В

ANIMAL : MOUSE BDF1

REPORT TYPE : A1
SEX : MALE
UNIT: %

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

PAGE: 2

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	1.515± 0.072	0.144± 0.013	3.852± 0.171	1.436± 0.073
3000 ppm	10	1.645± 0.067**	0.163± 0.018*	4.101± 0.110**	1.606± 0.092**
4400 ppm	10	1.626± 0.076*	0.150± 0.013	4.145± 0.108**	1.526± 0.101
6700 ppm	10	1.611± 0.107*	0.149± 0.016	4.207± 0.171**	1.595士 0.075**
10000 ppm	0	-	-	-	~
15000 ppm	0	-	-	-	~
Significan	t difference ;	* : P ≤ 0.05 **:	P ≤ 0.01	Test	of Dunnett

(IICL042)

BAIS 2

APPENDIX B 9-4

ORGAN WEIGHT, RELATIVE : SUMMARY, MOSUE : FEMALE

(THIRTEEN - WEEK STUDY)

ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : FEMALE UNIT: % ORGAN WEIGHT: RELATIVE (SUMMARY) SURVIVAL ANIMALS (14)

PAGE: 3

roup Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
Control	10	22.3± 1.1	0.173± 0.027	0.056± 0.010	0.111± 0.020	0.619± 0.033	0.700± 0.038
3000 ppm	10	22.7± 1.5	0.184± 0.022	0.060± 0.009	0.103± 0.034	0.595± 0.033	0.698± 0.044
4400 ppm	10	22.7± 0.8	0.191± 0.027	0.055± 0.006	0.114± 0.014	0.587± 0.041	0.691± 0.038
6700 ppm	9	22.7± 1.3	0.185± 0.020	0.055± 0.004	0.112± 0.017	0.618± 0.029	0.693± 0.049
10000 ppm	0	-	-	-	-	-	-
15000 ppm	0	-	-	-	-	-	-

(IICL042)

BAIS 2

ANIMAL : MOUSE BDF1

REPORT TYPE: A1
SEX: FEMALE
UNIT: %

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

PAGE: 4

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
Control	10	1.464± 0.064	0.244± 0.016	4.448± 0.176	2.083± 0.097
3000 ppm	10	1.422± 0.060	0.246± 0.026	4.514± 0.273	2.047± 0.109
4400 ppm	10	1.436± 0.059	0.235± 0.021	4.657± 0.183	2.006± 0.086
6700 ppm	9	1.429± 0.055	0.219± 0.030	4.561± 0.176	2.014± 0.137
10000 ppm	0	-	-		-
15000 ppm	0	-	-	-	-

(HCL042)

BAIS 2

APPENDIX B 10-1

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

RAT: MALE: SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

: MALE

REPORT TYPE : A1

SEX

MISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (14W)

PAGE: 1

Organ	•	Group Name No. of Animals on Study Grade I (%)	Contro 10 2 (%)		<u>4</u> (%)	<u>1</u> (%			3	4 (%)	<u>1</u> (%		000 pr 10 2 (%)		<u>4</u> (%)	,	<u>1</u> (%)	4400 1 2 (%)	PPM 10 3 (%)	4) (%	
[Respiratory :	system]																				
nasal cavit	squamous cell metaplasia	0 (0)	<10 0 (0) (0	0	0 (0		<10> 0 0) (0 0) (0 0)	0)		<10 0 0) (0	0	(0	0	10> 0 (0)	() (
	respiratory metaplasia	(0)	0 (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:foreign body	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)
	inflammation:squamous epithelium	(0)	0 (0) (0	0 (0)	0)		0 (0 0) (0	(20		0	0	0 (0)	(1 10) /	0 (0)	0 (0)	(0 0)
	inflammation:respiratory epithelium	(0)	0 (0) (0 (0)	0 (0)	0)		0 0) (0 (0 0)	((0	0	0 (0)	(0	0 (0)	0 (0)	(0 0)
	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)
	nuclear enlargement:olfactory epitheli		0 (0) (0 (0)	0 (0)	(0		0 0) (0 0) (0 0)	((0	0 0)	0	(0	0 (0)	0 (0)	(0 0)
	nuclear enlargement:respiratory epithe		(0) (0 (0)	0 (0)	(0		0 0) (0 0) (0 0)	(0		0 (0	0 (0)	(0	0 (0)	0 (0)	() 0)

(c) Significa (HPT150)

Grade

< a >

b

1: Slight

c:b/a*100

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

2 : Moderate

a: Number of animals examined at the site

b: Number of animals with lesion

3 : Marked

4 : Severe

: MALE

REPORT TYPE : A1

SEX

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (14W)

Organ	, No.	Oup Name 6700 ppm . of Animals on Study 10 ade 1 2 3 4 (%) (%)	10000 ppm 7 1 2 3 4 (%) (%) (%) (%)	
Respiratory	system]			
nasal cauit	squamous cell metaplasia	(10) 0 0 0 0 (0) (0) (0) (0)	3 1 0 0 * (43) (14) (0) (0)	
	respiratory metaplasia	0 0 0 0 0 0 (0) (0)	1 0 0 0 (14) (0) (0) (0)	
	inflammation:foreign body	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	
	inflammation:squamous epithelium	2 0 0 0 0 (20) (0) (0) (0)	1 0 0 0 0 (14) (0) (0) (0)	
	inflammation:respiratory epithelium	0 0 0 0 0 0 (0) (0)	5 0 0 0 ** (71) (0) (0) (0)	
	atrophy:olfactory epithelium	0 0 0 0 0 (0) (0)	2 5 0 0 ** (29) (71) (0) (0)	
	nuclear enlargement:olfactory epithelium	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	6 0 0 0 *** (86) (0) (0) (0)	
	nuclear enlargement:respiratory epitheli	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	4 0 0 0 * (57) (0) (0) (0)	
irade (a) b	1: Slight 2: Moderate 3: a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100	Marked 4: Severe		

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (14W)

REPORT TYPE : A1 SEX

Organ____

: MALE

Group Name Control 2000 ppm 3000 ppm 4400 ppm No. of Animals on Study 10 10 10 10 Findings (%) (%) (%) (%)

[Respiratory	system]				
Lung	granulation	<10> 0 0 0 0 0 0 0 0 0 0 0	<10> 0 0 0 0 (0) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)	<10> 0 0 0 0 (0) (0) (0) (0)
	accumulation of foamy cells	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
[Circulatory	system]				
heart	granulation	2 0 0 0 (20) (0) (0) (0)	<10> 0 0 0 0 (0) (0) (0) (0)	(0) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)
[Digestive sy	ystem]				
liver	herniation	<10> 0 0 0 0 0 0 0 0 0 0 0	2 0 0 0 (20) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)	<10> 0 0 0 0 (0) (0) (0) (0)

[Urinary system]

kidney

basophilic change

<10> <10> <10> <10> 1 0 0 0 3 0 0 0 2 0 0 0 2 0 0 0 (10) (0) (0) (0) (30) (0) (0) (0) (20) (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

(IIPT150)

BAIS2

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

ANIMAL : RAT F344
REPORT TYPE : A1

SEX : MALE

Organ		oup Name 6700 ppm of Animals on Study 10 de 1 2 3 4 (%) (%) (%) (%)	10000 ppm 7 1 2 3 4 (%) (%) (%) (%)	

[Respirator	y system]			
lung	granulation	(0) (0) (0) (0)	<pre></pre>	
	accumulation of foamy cells	1 0 0 0 (10) (0) (0) (0)	0 0 0 0 0 (0) (0)	•
[Circulator	y system]			
heart	granulation	1 0 0 0 (10) (0) (0) (0)	<pre></pre>	
[Digestive	system]			
liver	herniation		7> 1 0 0 0 (14) (0) (0) (0)	
[Urinary sy	vstem]			
kidney	basophilic change	(0) (0) (0) (0) 0 0 0 0 0 0 0 0	<pre></pre>	
Grade < a > b (c)	1: Slight 2: Moderate 3: a: Number of animals examined at the site b: Number of animals with lesion c: b/a * 100	Varked 4 : Severe		

(IIPT150)

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

ANIMAL : RAT F344 REPORT TYPE : A1

SEX

: MALE

Group Name Control 2000 ppm 3000 ppm 4400 ppm

Organ	Findings	No. of Animals on Study 10 Grade 1 2 3 (%) (%) (%)	2000 ppm 10 10 (%) (%) (%) (%) (%)	10 10 1 2 3 4 (%) (%) (%) (%)	10 10 1 2 3 4 (%) (%) (%) (%)
[Urinary sys	stem]				
kidney	easinaphilic bady	(10> 7 3 0 (70) (30) (0) (0 7 3 0 0 0) (70) (30) (0) (0)	<10> 8 2 0 0 (80) (20) (0) (0)	9 1 0 0 (90) (10) (0) (0)
[Endocrine:	system]				
pituitary	Rathke pouch	(11) (0) (0) (0 1 0 0 0 0) (10) (0) (0) (0)	(10> 0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
thyroid	ultimibranchial body remanet	<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)	\(\lambda 10 \rangle \) \(1 0 0 0 \\ (10) (0) (0) (0) \)
adrenal	mineralization	0 0 0 (0) (0) (0) (0 0 0 0 0 0) (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
[Reproducti	ue system]				
testis	atrophy	(0) (0) (0) (0 0 0 1 0 0 0 0 1 0 0 0 0 1 0	(10) 0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
Grade <a> b (c) Significant	1: Slight 2: Moderate a: Number of animals examined at th b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **:				

(HPT150)

BAIS2

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

REPORT TYPE : A1

SEX : MALE

Organ	· · ·	Froup Name 6700 ppm No. of Animals on Study 10 Frade 1 2 3 4 (%) (%) (%) (%)	10000 ppm 7 1 2 3 4 (%) (%) (%) (%)	
[Urinary sy	vstem]			
kidney	eosinophilic body	<10> 8 2 0 0 (80) (20) (0) (0)	7 0 0 0 (100) (0) (0) (0)	
[Endocrine	system]			
pituitary	Rathke pouch	1 0 0 0 (10) (0) (0) (0)	7> 1 0 0 0 (14) (0) (0) (0)	
thyroid	ultimibranchial body remanet	10> 1 0 0 0 (10) (0) (0) (0)	7> 1 0 0 0 (14) (0) (0) (0)	
adrenal	mineralization	1 0 0 0 (10) (0) (0) (0)	<pre></pre>	
[Reproducti	i∪e system]			
testis	atrophy	<10> 0 0 1 0 (0) (0) (10) (0)	<pre></pre>	
Grade <a>> b (c) Significant	1: Slight 2: Moderate 3: a: Number of animals examined at the sit b: Number of animals with lesion c: b / a * 100 t difference; *: P ≤ 0.05 **: P ≤			

(HPT150)

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (14W)

REPORT TYPE : A1

SEX : MALE

(IIPT150)

Group Name Control 2000 ppm 3000 ppm 4400 ppm No. of Animals on Study 10 10 10 10 2 3 Findings_ (%) (%) (%) (%) (%) (%) (%) (%) [Reproductive system] prostate <10> <10> inflammation 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) [Special sense organs/appandage] еуе <10> <10> <10> <10> 0 0 0 0 retinal atrophy 0 0 0 0 1 0 0 0 0 0 0 0 (0)(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 * 100Significant difference : $*: P \le 0.05$ $**: P \le 0.01$ Test of Chi Square

BAIS2

ANIMAL : RAT F344

REPORT TYPE : A1 : MALE HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (14W)

PAGE: 8 Group Name 6700 ppm 10000 ppm No. of Animals on Study 10 7 1 2 3 (%) (%) (%) (%) Organ____ Findings_ (%) (%) (%) (%) [Reproductive system] prostate <10> inflammation 1 0 0 0 1 0 0 0 (10) (0) (0) (0) (14) (0) (0) (0) [Special sense organs/appandage] еуе <10> retinal atrophy 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 b (c) c:b/a*100Significant difference; * : P \leq 0.05 ** : P \leq 0.01 Test of Chi Square (HPT150) BAIS2

APPENDIX B 10-2

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

RAT: FEMALE: SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0166 ANIMAL : RAT F344 REPORT TYPE : A1

: FEMALE

SEX

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (14W)

PAGE: 9

Organ	Findings	Group Name Control No. of Animals on Study 10 Grade 1 2 3 4 (%) (%) (%) (%) (%)	2000 ppm 10 1 2 3 4 (%) (%) (%) (%)	3000 ppm 10 1 2 3 4 (%) (%) (%) (%)	4400 ppm 10 1 2 3 4 (%) (%) (%) (%)
or Sart	1 mungs	(%) (%) (%)	(%) (%) (%)	(%) (%) (%)	(%) (%) (%) (%)
[Respiratory	system]				
nasal cavit	squamous cell metaplasia	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	<10> 0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
	respiratory metaplasia	0 0 0 0 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:foreign body	0 0 0 0 0 (0) (0)	1 0 0 0 0 (10) (10) (10)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)
·	inflammation:squamous epithelium	2 1 0 0 (20) (10) (0) (0)	3 1 0 0 (30) (10) (0) (0)	2 1 0 0 (20) (10) (0) (0)	3 0 0 0 0 (30) (0) (0) (0)
	inflammation:respiratory epithelium	0 0 0 0 0 (0) (0)	1 0 0 0 (10) (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)
	nuclear enlargement:olfactory epithel	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0) (0)
	ณuclear enlargement:respiratory epith	0 0 0 0 0 (0) (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe (a) a : Number of animals examined at the site

b b: Number of animals with lesion

(c) c:b/a * 100 Significant difference ; * : $P \le 0.05$ ** : $P \le 0.01$ Test of Chi Square

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (14W)

REPORT TYPE : A1

SEX : FEMALE

> Group Name 6700 ppm 10000 ppm

Organ		No. of Animals on Study Grade 1 (%)	10 2 (%) (%)	3 4 (%)	1 2 (%) (%)	3 (%) (S	4/6)
[Respiratory	system]						
nasal cavit	squamous cell metaplasia	(0)	<10> 0 ((0) (0		4 3 (40) (30)		0 **
	respiratury metaplasia	0 (0)	0 (0 0	3 0 (30) (0)	0 (0) (0
	inflammation:foreign body	0 (0)	0 (0 0 0) (0)	0 0 (0)	0 (0) (
·	inflammation:squamous epithelium	3 (30)	0 (0 0 0) (0)	4 0 (40) (0)	0 (0) (0
	inflammation:respiratory epithelium	0 (0)	0 (0 0 0) (0)	5 0 (50) (0)	0 (0) (0 *
	atrophy:olfactory epithelium	0 (0)	0 (0) (0 0 0) (0)	4 5 (40) (50)	0 (0) (0 **
	nuclear enlargement:olfactory epitheliu		0 (0) (0 0 0) (0)	7 0 (70) (0)	0 (0) (0 **
	nuclear enlargement:respiratory epithe		0 (0) (0 0 0) (0)	8 0 (80) (0)		0 **

< a >

a: Number of animals examined at the site

b b: Number of animals with lesion (c)

c : b / a * 100

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

(IIPT150)

BAIS2

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (14W)

ANIMAL : RAT F344 REPORT TYPE : A1 SEX : FEMALE

Organ		Group Name Control No. of Animals on Study 10 Grade 1 2 3 4 (%) (%) (%) (%)	2000 ppm 10 1 2 3 4 (%) (%) (%) (%)	3000 ppm 10 1 2 3 4 (%) (%) (%) (%)	$\begin{array}{cccccccccccccccccccccccccccccccccccc$
[Respiratory	system]				
lung	granulation	<10> 0 0 0 0 0 0 0 0 0 0 0	0 0 0 0 (0) (0) (0) (0)	<10> 0 0 0 0 (0) (0) (0) (0)	<10> 0 0 0 0 (0) (0) (0) (0)
	accumulation of foamy cells	I 0 0 0 0 (10) (10) (10)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 0 (10) (0) (0)
[Hematopoieti	c system]				
bone marrow	granulation	1 2 0 0 (10) (20) (0) (0)	2 3 0 0 (20) (30) (0) (0)	3 0 0 0 (30) (0) (0) (0)	0 1 0 0 (0) (10) (0) (0)
[Circulatory	system]				
heart	granulation	10> 1 0 0 0 (10) (0) (0) (0)	(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)
[Digestive sy	ystem]				
liver	herniation	(10) 0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	<10> 0 0 0 0 (0) (0) (0) (0)	<10> 0 0 0 0 (0) (0) (0) (0)
Grade <a> b (c) Significant d	1: Slight 2: Moderate 3 a: Number of animals examined at the si b: Number of animals with lesion c: b / a * 100 lifference; *: $P \le 0.05$ **: $P \le 0.05$				

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

ANIMAL : RAT F344 REPORT TYPE : A1

SEX : FEMALE

	Group N. No. of A Grade	ame 6700 ppm Animals on Study 10 1 2 3 4	10000 ppm 10 1 2 3 4	
Organ	Findings	(%) (%) (%) (%)	(%) (%) (%) (%)	
[Respiratory	system]			
lung	granulation	<pre></pre>	<10> 0 0 0 0 0 0 0 0 0 0 0	
	accumulation of foamy cells	2 0 0 0 0 (20) (0) (0)	1 0 0 0 0 (10) (0) (0)	
[Hematopoieti	ic system]			
bone marrow	granulation	1 0 0 0 (10) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)	
(Circulatory	system]			
heart	granulation	<10> 0 0 0 0 0 0 0 0 0 0 0	<10> 0 0 0 0 (0) (0) (0) (0)	
[Digestive sy	ystem]			
liver	herniation	<10> 0 0 0 0 (0) (0) (0) (0)	<10> 0 0 0 0 (0) (0) (0) (0)	
Grade <a>a> <a>b <a>c <a>c<	1: Slight 2: Moderate 3: Marke a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; *: $P \le 0.05$ **: $P \le 0.01$			

(IIPT150)

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

STUDY NO. : 0166 ANIMAL : RAT F344 REPORT TYPE : A1 SEX

: FEMALE

Organ	Findings	Group Name Control No. of Animals on Study 10 Grade 1 2 3 4 (%) (%) (%) (%) (%)	2000 ppm 10 10 (%) (%) (%) (%)	3000 ppm 10 1 2 3 4 (%) (%) (%) (%)	4400 ppm 10 1 2 3 4 (%) (%) (%) (%)
[Digestive	system]				
liver	granulation	1 0 0 0 (10) (0) (0) (0)	3 0 0 0 (30) (0) (0) (0)	<10> 2 0 0 0 (20) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
[Urinary sy	vstem]				
kidney	basophilic change	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
·	mineralization:cortico-medullary junc	3 0 0 0 (30) (0) (0) (0)	2 0 0 0 0 (20) (0) (0) (0)	2 0 0 0 0 (20) (0) (0) (0)	0 0 0 0 0 (0) (0)
[Endocrine	system]				
thyroid	ultimibranchial body remanet	\(\lambda 10 \rangle \) \(1 0 0 0 \\ (10) (0) (0) (0) \)	1 0 0 0 (10) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)
[Special se	ense organs/appandage]				
өуө	retinal atrophy	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	2 0 0 0 (20) (0) (0) (0)
Grade <a> b (c) Significant	1: Slight 2: Moderate 3 a: Number of animals examined at the s b: Number of animals with lesion c: b / a * 100 t difference; *: P ≤ 0.05 **: P ≤				

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (14W)

REPORT TYPE : A1

SEX : FEMALE

Group Name 6700 ppm 10000 ppm No. of Animals on Study 10 10 Findings [Digestive system] liver <10> granulation 2 0 0 0 2 0 0 0 (20) (0) (0) (0) (20) (0) (0) (0) [Urinary system] kidney <10> <10> 0 0 0 0 basophilic change 0 0 0 0 (0)(0)(0)(0) (0)(0)(0)(0) mineralization:cortico-medullary junction (10) (0) (0) (0) (20) (0) (0) (0) [Endocrine system] thyroid <10> <10> ultimibranchial body remanet 1 0 0 0 0 0 0 0 (10) (0) (0) (0) (0)(0)(0)(0) [Special sense organs/appandage] еуе <10> retinal atrophy 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

(HPT150)

(c)

c:b/a*100

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

REPORT TYPE : A1 SEX : FEMALE HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS (14W)

[Special sense organs/appandage] Special sense organs/appandage] Significant difference; **: P \leq 0.05 ***: P \leq 0.01 Test of Chi Square C10>	0rgan	Findings	Group Name No. of Animal Grade	s on Study	ontrol 10 2 3 (%) (%)	<u>4</u> (%)	<u>1</u> (%)	2000 pp 10 2 (%)	3 4 (%) (%)	<u>1</u> (%)	3000 p 10 2 (%)		<u>4</u> (%)	<u>1</u> (%)	2	00 ppm 10 2 3		<u>4</u> (%)
Lymphocytic infiltration	[Special ser	nse organs/appandage]																
<pre>(a) a: Number of animals examined at the site b b: Number of animals with lesion (c) c:b/a * 100</pre>	Harder gl	lymphocytic infiltration		1 (10) (0 0		1 (10)	0	0 0		0	0		0 (0)	() ())) (0
	(a) b (c)	a: Number of animals examined at the b: Number of animals with lesion c: b / a * 100	ne site				<u>:</u>											

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (14W)

REPORT TYPE : A1 : FEMALE

Group Name 6700 ppm 10000 ppm No. of Animals on Study 10 10 2 3 2 3 (%) (%) (%) (%) (%) (%) (%) Findings_ [Special sense organs/appandage] Harder gl <10> <10> lymphocytic infiltration 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 b (c) c:b/a*100Significant difference; *: $P \le 0.05$ **: $P \le 0.01$ Test of Chi Square (HPT150) BAIS2

APPENDIX B 10-3

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

RAT: MALE: DEAD AND MORIBUNDANIMALS

(THIRTEEN - WEEK STUDY)

ANIMAL : RAT F34 REPORT TYPE : A1

SEX

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0- 14W)

TYPE: AI:

Group Name Control 2000 ppm 3000 ppm 4400 ppm No. of Animals on Study 0 0 0 0 Grade Organ_ Findings (%) (%) (%) (%) (%) (%) (%) (%) [Respiratory system] nasal cavit squamous cell metaplasia (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) inflammation:respiratory epithelium (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) atrophy:olfactory epithelium (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) nuclear enlargement:olfactory epithelium (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) lung < 0> < 0> < 0> congestion (-) (-) (-) (-) (-) (-) (-) (-) (-) (-) .(-) (-) (-) Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe (a) a: Number of animals examined at the site b: Number of animals with lesion b (c) c : b / a * 100(HPT150)

BAIS2

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

ANIMAL : RAT F344 REPORT TYPE : A1 SEX : MALE

Organ	The state of the s	Dip Name 6700 ppm of Animals on Study 0 de 1 2 3 4 (%) (%) (%) (%)	10000 ppm 3 1 2 3 4 (%) (%) (%) (%)	
[Respiratory	system]			
nasal cauit	squamous cell metaplasia	(-) (-) (-) (-)	3> 1 2 0 0 (33) (67) (0) (0)	
	inflammation:respiratory epithelium	(-) (-) (-)	2 0 0 0 0 (67) (0) (0) (0)	
·	atrophy:olfactory epithelium	(-) (-) (-)	1 1 0 0 (33) (33) (0) (0)	
	nuclear enlargement:olfactory epithelium	(-) (-) (-) (-)	3 0 0 0 0 (100) (0) (0) (0)	
lung	congestion	(-) (-) (-)	<pre></pre>	
Grade <a> b (c)	1: Slight 2: Moderate 3: Ma a: Number of animals examined at the site b: Number of animals with lesion c: b/a * 100	arked 4: Severe		
(IIPT150)				BAIS2

APPENDIX B 10-4

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOUSE: MALE: SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

SEX

: MALE

ANIMAL : MOUSE BDF1 REPORT TYPE : A1

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

Organ	ı	Group Name No. of Animals on Study Grade 1 (%)	Control 10 2 3 4 (%) (%) (%)	3000 ppm 10 10 1 2 3 4 (%) (%) (%) (%)	4400 ppm 10 10 (%) (%) (%) (%)	$\begin{array}{cccccccccccccccccccccccccccccccccccc$
[Respiratory	system]					
nasal cauit	nuclear enlargement:olfactory epitheli		<10> 0 0 0 (0) (0) (0		<10> 0 0 0 0 (0) (0) (0) (0)	<10> 2 0 0 0 (20) (0) (0) (0)
[Nematopoieti	ic system]					
spleen	deposit of melanin	1 (10)	<10> 0 0 0 (0) (0) (0		0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
[Digestive sy	vstem]					
stomach	hyperplasia:forestomach	0 (0)	<10> 0 0 0 (0) (0) (0		0 0 0 0 (0) (0) (0) (0)	3 0 0 0 (30) (0) (0) (0)
liver	granulation		(0) (0) (0		4 0 0 0 (40) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)
[Urinary syst	tem]					
kidney	basophilic change	2 (20)	<10> 0 0 0 (0) (0) (0		1 0 0 0 (10) (10) (0) (0)	0 0 0 0 (0) (0) (0) (0)
Grade <a>> b (c)	1: Slight 2: Moderate 3 a: Number of animals examined at the si b: Number of animals with lesion c: b/a * 100	: Marked 4 : Severe te				

STUDY NO. : 0167 ANIMAL : MOUSE ANIMAL : MOUSE BDF1
REPORT TYPE : A1

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

: MALE

0rgan	Group Name No. of Anim Grade	10000 ppm als on Study 0 1 2 3 4 (%) (%) (%) (%)	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	
[Respiratory	system]			
nasal cauit	nuclear enlargement:olfactory epithelium	< 0> (-) (-) (-) (-)	< 0> (-) (-) (-) (-)	
[Hematopoieti	c system]			
spleen	deposit of melanin	< 0> (-) (-) (-) (-)	< 0> (-) (-) (-) (-)	
[Digestive sy	vstem]			
stomach	hyperplasia:forestomach	< 0> (-) (-) (-) (-)	(-) (-) (-) (-)	
liver	granulation	< 0> (-) (-) (-) (-)	< 0> (-) (-) (-) (-)	
[Urinary syst	cem]			
kidney	basaphilic change	< 0> (-) (-) (-) '(-)	< 0> (-) (-) (-) (-)	
<a>> b (c)	1: Slight 2: Moderate 3: Marked a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; $*:P \le 0.05$ **: $P \le 0.01$ Te	4 : Severe st of Chi Square		

(IIPT150)

ANIMAL : MOUSE BDF1 REPORT TYPE : A1

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

SEX : MALE

Organ	Findings	Group Name No. of Animals on Grade	Study 	Contra 10 2 (%)		<u>4</u> (%)	<u>1</u> (%)	3000 1 2 (%)) ppm 0 3 (%)	<u>4</u> (%)	1 (%)	440 2 (%)	10 3	4	1 (%)		0 ppm 10 3 (%)	4
[Urinary sys	stem]																	
kidney	vacuolization of proximal tubule		9 (90) (<10 0 0) (0	0 (0)	8 (80)	0	0 (0)	0 (0)	8 (80)	0	(10> 0 (0)	0 (0)	1 (10)	0	10> 0 (0)	0 * (0)
(Endocrine s	system]																	
adrenal	accesory cortical nodule		2 (20) (<10 0 0) (0	0	0 (0)		0 (0)	0 (0)	0 (0)		(10> 0 (0)	0 (0)	0 (0)	0	10> 0 (0)	0 (0)
Grade (a) b (c)	1: Slight 2: Moderate a: Number of animals examined at the b: Number of animals with lesion c: b / a * 100		: Severe															

ANIMAL : MOUSE BDF1 REPORT TYPE : A1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS (14W)

SEX : MALE PAGE: 4 Group Name 10000 ppm 15000 ppm No. of Animals on Study 0 0 2 3 2 3 4 Findings (%) (%) (%) (%) (%) (%) (%) [Urinary system] kidney < 0> vacuolization of proximal tubule (-) (-) (-) (-) (-) (-) (-) [Endocrine system] adrenal accesory contical nodule (-) (-) (-) (-) (-) (-) (-) Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe <a>> a: Number of animals examined at the site b: Number of animals with lesion b (c) c:b/a*100Significant difference; $*:P \le 0.05$ $**:P \le 0.01$ Test of Chi Square (HPT150)

BAIS2

APPENDIX B 10-5

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOUSE: FEMALE: SACRIFICED ANIMALS

(THIRTEEN - WEEK STUDY)

STUDY NO. : 0167 ANIMAL : MOUSE BDF1

REPORT TYPE : A1 SEX : FEMALE HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS (14W)

Organ	Group No. of Grade Findines	Name Control Animals on Study 10 1 2 3 4 (%) (%) (%) (%)	3000 ppm 10 1 2 3 4 (%) (%) (%) (%)	4400 ppm 10 1 2 3 4 (%) (%) (%) (%)	6700 ppm 9 1 2 3 4 (%) (%) (%) (%)
[Respiratory	system]				
nasal cauit	easinophilic change:respiratory epithelium	(10) 0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	(10) 1 0 0 0 (10) (0) (0) (0)	<pre></pre>
	nuclear enlargement: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	4 0 0 0 0 (44) (0) (0) (0)
[Hematopoiet	ic system]				
spleen	deposit of melanin	1 0 0 0 (10) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	(0) (0) (0) (0) (0)
[Digestive s	system]				
stomach	hyperplasia:forestomach	0 0 0 0 (0) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)	<10> 0 0 0 0 (0) (0) (0) (0)	<pre></pre>
liver	granulation	4 0 0 0 (40) (0) (0) (0)	3 0 0 0 (30) (0) (0) (0)	2 0 0 0 (20) (0) (0) (0)	<pre></pre>
Grade <a>> b (c) Significant	1: Slight 2: Moderate 3: Mark a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; $*: P \le 0.05$ **: $P \le 0.01$				

ANIMAL : MOUSE BDF1

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

REPORT TYPE : A1

SEX : FEMALE

Organ	Findings	Animals on Study 0 1 2 3 4 (%) (%) (%) (%)	15000 ppm 0 1 2 3 4 (%) (%) (%) (%)	
[Respiratory				
nasal cavit	eosinophilic change:respiratory epithelium	< 0> (-) (-) (-) (-)	< 0> (-) (-) (-) (-)	
	nuclear enlargement:olfactory epithelium	(-) (-) (-)	(-) (-) (-) (-)	
[Nematopoiet	cic system]			
spleen	deposit of melanin	(-) (-) (-)	(-) (-) (-) (-)	
[Digestive s	system]			
stomach	hyperplasia:forestamach	< 0> (-) (-) (-) (-)	(-) (-) (-) (-)	
liver	granulation	(-) (-) (-) (-)	(-) (-) (-) (-)	
Grade <a> b (c) Significant	1: Slight 2: Moderate 3: Mark a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 difference; *: P ≤ 0.05 **: P ≤ 0.01			
(HPT150)				 RAIS2

ANIMAL : MOUSE BDF1

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

REPORT TYPE : A1

SEX : FEMALE

Organ	. No	oup Name Control . of Animals on Study 10 ade 1 2 3 4 (%) (%) (%) (%)	3000 ppm 10 1 2 3 4 (%) (%) (%) (%)	4400 ppm 10 1 2 3 4 (%) (%) (%) (%)	6700 ppm 9 1 2 3 4 (%) (%) (%) (%)
[Endocrine	system]				
adrena l	accesory cortical nodule	1 0 0 0 (10) (0) (0) (0)	1 0 0 0 (10) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
[Reproduct	iue system]				
gvary	hyaline degeneration	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	(10) 0 0 0 0 (0) (0) (0) (0)	(9) 1 0 0 0 (11) (0) (0) (0)
Grade <a>> b (c) Significant	1: Slight 2: Moderate 3: a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100 t difference; $*: P \le 0.05$ **: $P \le 0$		·		
(IIPT150)					BAIS2

ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

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

[Endocrine system] adrenal accesory cortical nodule	
accesory cortical nodule	
Duary hyaline degeneration	
hyaline degeneration	
Grade 1: Slight 2: Moderate 3: Marked 4: Severe	
b b: Number of animals with lesion (c) c:b/a*100 Significant difference; *: $P \le 0.05$ **: $P \le 0.01$ Test of Chi Square	

APPENDIX B 10-6

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOSUE: MALE: DEAD AND MORIBUND ANIMALS

(THIRTEEN - WEEK STUDY)

ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name Control No. of Animals on Study 0 Grade 1 2 3 4 (%) (%) (%) (%)	3000 ppm 0 1 2 3 4 (%) (%) (%) (%)	4400 ppm 0 1 2 3 4 (%) (%) (%) (%)	6700 ppm 0 1 2 3 4 (%) (%) (%) (%)
[Digestive	system]				
liver	granulation	< 0> (-) (-) (-) (-)	< 0> (-) (-) (-) (-)	(-) (-) (-)	(-) (-) (-) (-)
[Endocrine	system]				
adrena l	accesory cortical nodule	(-) (-) (-) (-)	(-) (-) (-)	(-) (-) (-)	(-) (-) (-)
Grade <a> b (c)	1: Slight 2: Moderate a: Number of animals examined at th b: Number of animals with lesion c: b/a * 100	3 : Marked 4 : Severe me site			
(IIPT150)					BA

ANIMAL : MOUSE BDF1 REPORT TYPE : A1 SEX : MALE

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0- 14W)

Group Name 10000 ppm 15000 ppm No. of Animals on Study 10 10 2 3 4 2 3 Organ____ Findings__ (%) (%) (%) (%) (%) (%) [Digestive system] Liver <10> <10> 0 0 0 0 1 0 0 0 granulation (0)(0)(0)(0) (10) (0) (0) (0) [Endocrine system] adrenal <10> <10> 0 0 0 0 1 0 0 accesory cortical nodule (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 b

(c) c:b/a*100

(IIPT150)

BAIS2

APPENDIX B 10-7

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

MOSUE: FEMALE: DEAD AND MORIBUND ANIMALS

(THIRTEEN - WEEK STUDY)

ANIMAL : MOUSE BDF1
REPORT TYPE : A1
SEX : FEMALE

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

Organ	Findings	Group Name No. of Animals on Study Grade 1 (%)	Control 0 2 3 4 (%) (%) (%)	3000 ppm 0 1 2 3 4 (%) (%) (%) (%)	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$
[Respiratory:	system]					
nasal cavit	vacuolic change:olfactory epithelium	(-)	< 0> (-) (-) (-)	(0) (-) (-) (-) (-)	(-) (-) (-) (-)	(1) 0 0 0 0 (0) (0) (0) (0)
ung	congestion	· (-)	< 0> (-) (-) (-)	(-) (-) (-) (-)	< 0> (-) (-) (-) (-)	< 1> 0 0 0 0 (0) (0) (0) (0)
	hemorrhage	(-)	(-) (-)	(-) (-) (-) (-)	(-) (-) (-) (-)	0 1 0 0 (0) (100) (0) (0)
Digestive sy:	stem]					
tomach	erosion:forestomach	(-)	< 0> (-) (-) (-)	(-) (-) (-) (-)	(-) (-) (-) (-)	0 0 0 0 (0) (0) (0) (0)
iver	granulation	(-)	< 0> (-) (-) (-)	< 0> (-) (-) (-) (-)	< 0> (-) (-) (-)	(0) (0) (0) (0)
Endocrine sy	stem]					
idrenal :	accesory cortical nodule	(-)	< 0> (-),(-) (-)	< 0> (-) (-) (-) (-)	< 0> (-) (-) (-) (-)	0 0 0 0 (0) (0) (0) (0)
(a)	1: Slight 2: Moderate 3 a: Number of animals examined at the s b: Number of animals with lesion c: b/a * 100	3: Marked 4: Severe site	,			

ANIMAL : MOUSE BDF1

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

REPORT TYPE : A1

SEX : FEMALE

PAGE: 4 Group Name 10000 ppm 15000 ppm No. of Animals on Study 10 10 2 3 2 3 Findings_ (%) (%) (%) (%) (%) (%) [Respiratory system] nasal cavit <10> vacualic change:alfactory epithelium 0 0 0 0 6 0 0 0 (0)(0)(0)(0) (60) (0) (0) (0) lung <10> <10> congestion 1 0 0 0 2 0 0 0 (10) (0) (0) (0) (20) (0) (0) (0) hemorrhage 5 0 0 0 0 0 0 0 (50) (0) (0) (0) (0)(0)(0)(0) [Digestive system] stomach <10> <10> erosion:forestomach 0 0 0 0 (0) (0) (0) (0) (10) (0) (0) (0) Liver <10> <10> granulation 0 0 0 0 2 0 0 0 (0)(0)(0)(0) (20) (0) (0) (0) [Endocrine system] adrena l <10> 0 0 0 0 accesory cortical nodule 1 0 0 0 (0)(0)(0)(0) (10) (0) (0) (0) Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe (a) a: Number of animals examined at the site b b: Number of animals with lesion (c) c : b / a * 100

(IIPT150)

BAIS2

APPENDIX B 11-1 IDENTITY AND PURITY OF 1,1,1-TRICHLOROETHANE (THIRTEEN - WEEK STUDY)

IDENTITY OF 1, 1, 1-TRICHLOROETHANE (THIRTEEN-WEEK STUDIES)

A. Lot no. ECG7864

1. Spectral data

Mass Spectrometry

Instrument

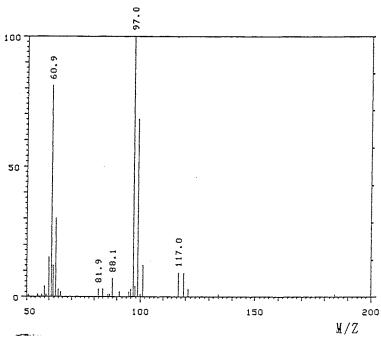
: Hitachi M-80B Mass Spectrometer

Ionization

: EI(Electron Ionization)

Ionization Voltage

: 70eV



Wass Spectrum of Test Substance

Results: <u>Determines</u>

Fragment Peak(M/Z)

60.9 97.0

117.0

Literature Values*

Fragment Peak($\frac{1}{2}$ /Z)

61 97

117

(*EPA/NIH Wass Spectral Data Base (1978) V. 1,

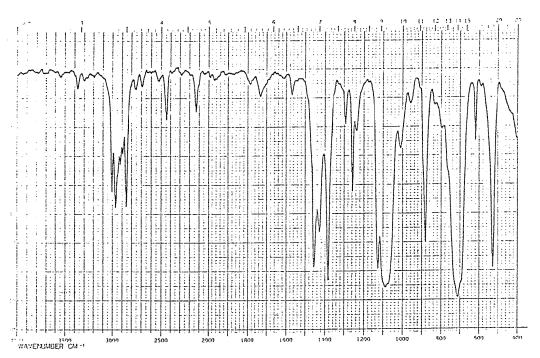
p. 278.)

Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr

Slit : Medium



Infrared Spectrum of Test Substance

Results:	Determined Value Wave Number(cm ⁻¹)	<u>Literature Values*</u> Wave Number(cm ⁻¹)
	$510 \sim 550$ $600 \sim 640$ $660 \sim 760$ $850 \sim 900$ $1040 \sim 1110$ $1120 \sim 1150$ $1240 \sim 1270$	$500 \sim 540$ $600 \sim 630$ $660 \sim 760$ $860 \sim 900$ $1040 \sim 1110$ $1110 \sim 1140$ $1240 \sim 1260$
	$1370 \sim 1400$ $1410 \sim 1440$ $1440 \sim 1480$ $2100 \sim 2170$ $2420 \sim 2480$ $2800 \sim 2880$ $2940 \sim 3050$	1370~1400 1410~1440 1440~1480 2100~2150 2400~2470 2800~2880 2940~3050 (*Performed by the WAKO PURE CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The result of the mass spectrum and the infrared spectrum agreed with the literature values.

Consequently, the test substance was identified as $l,\,l,\,l$ -Trichloroethane.

B. Lot no. DSP4087

1. Spectral data

Mass Spectrometry

Instrument

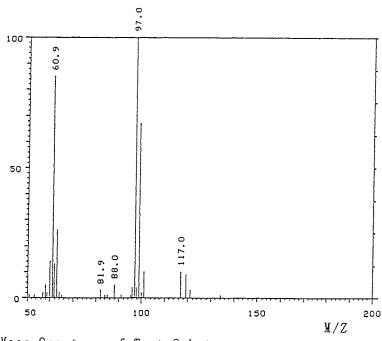
: Hitachi M-80B Mass Spectrometer

Ionization

: EI(Electron Ionization)

Ionization Voltage

: 70eV



Mass Spectrum of Test Substance

Results: <u>Determines</u>

Fragment Peak(M/Z)

60.9

97.0

117.0

<u>Literature Values*</u> Fragment Peak(M/Z)

61

97

117

(*EPA/NIH Mass Spectral Data Base (1978) V. 1, p. 278.)

Infrared Spectrometry

Instrument

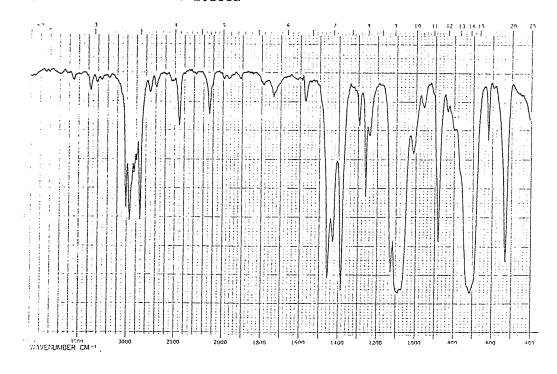
: Hitachi 270-30 Infrared Spectrometer

Cell

: KBr

Slit

: Medium



Infrared Spectrum of Test Substance

Results:	<u>Determined Value</u> Wave Number(cm ⁻¹)	<u>Literature Values*</u> Wave Number(cm ⁻¹)
	510~ 550	500~ 540
	600~ 640 660~ 760	600~ 630 660~ 760
	850~ 900	860~ 900
	$1040 \sim 1110$	1040~1110
	1120~1150	1110~1140
	$1240 \sim 1270$	1240 ~ 1260
	$1370 \sim 1400$	1370~1400
	$1410 \sim 1440$	1410~1440
	1440~1480	$1440 \sim 1480$
	2100~2170	2100~2150
	2420~2480	$2400 \sim 2470$
	2800~2880	2800~2880
	2940~3050	2940~3050
		(*Performed by the WAKO
		PURE CHEMICAL INDUSTRIES,
		LTD.)

2. Conclusions: The result of the mass spectrum and the infrared spectrum agreed with the literature values.

Consequently, the test substance was identified as 1, 1, 1-Trichloroethane.

1. Spectral data

Mass Spectrometry

Instrument

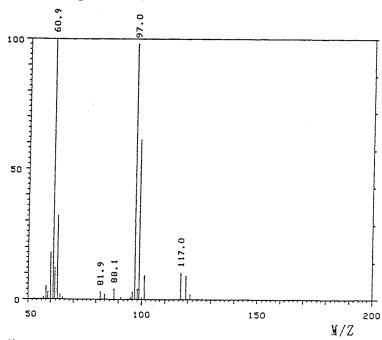
: Hitachi M-80B Mass Spectrometer

Ionization

: EI(Electron Ionization)

Ionization Voltage

: 70eV



Mass Spectrum of Test Substance

Results: <u>Determines</u>

Fragment Peak(M/Z)

60.9

97.0

117.0

Literature Values*
Fragment Peak(\(\M/Z\))

61

97

117

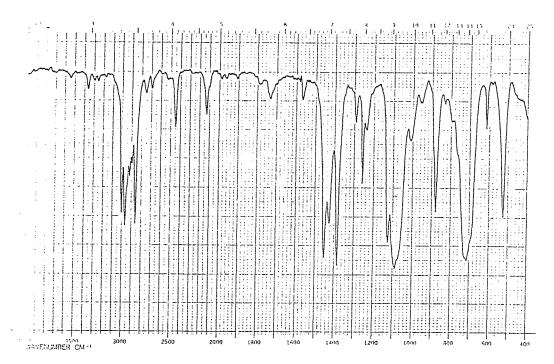
(*EPA/NIH Mass Spectral Data Base (1978) V. 1, p. 278.)

Infrared Spectrometry

Instrument : Hitachi 270-30 Infrared Spectrometer

Cell : KBr

Slit : Medium



Infrared Spectrum of Test Substance

Results:	Determined Value Wave Number(cm ⁻¹)	<u>Literature Values*</u> Wave Number(cm ⁻¹)
	510~ 550 600~ 640	500~ 540 600~ 630
	660~ 760 850~ 900 1040~1110	660~ 760 860~ 900 1040~1110
	$1120 \sim 1110$ $1120 \sim 1150$ $1240 \sim 1270$ $1370 \sim 1400$	$ \begin{array}{c} 1110 - 1110 \\ 1240 - 1260 \\ 1370 - 1400 \end{array} $
	1410~1440 1440~1480	$1410 \sim 1440 \\ 1440 \sim 1480$
	2100~2170 2420~2480 2800~2880	2100~2150 2400~2470 2800~2880
	2940~3050	2940~3050 (*Performed by the WAKO PURE CHEMICAL INDUSTRIES, LTD.)

2. Conclusions: The result of the mass spectrum and the infrared spectrum agreed with the literature values.

Consequently, the test substance was identified as 1, 1, 1-Trichloroethane.

APPENDIX B 11-2 STABILITY OF 1,1,1-TRICHLOROETHANE (THIRTEEN - WEEK STUDY)

STABILITY OF 1, 1, 1-TRICHLOROETHANE (THIRTEEN-WEEK STUDIES)

A. Lot no. ECG7864

1. Sample: This lot was used from 1991.4.11 to 1991.4.29. Test substance was stored at room temperature.

2. Infrared Spectrometry

Instrument

: Hitachi 270-30 Infrared Spectrometer

Cell

: KBr

Slit

: Medium

Results: Infrared spectrum of the test substance agreed with before use and after use.

1991.04.03(date analyzed) Wave Number(cm ⁻¹)	1991.05.01(date analyzed) Wave Number(cm ⁻¹)
naro wander (ea.	
510~ 550	510~ 550
600~ 640	600~ 640
660~ 760	660~ 760
850~ 900	850~ 900
1040~1110	1040~1110
1120~1150	1120~1150
$1240 \sim 1270$	$1240 \sim 1270$
1370~1400	1370~1400
1410~1440	1410~1440
1440~1480	1440~1480
2100~2170	2100~2170
2420~2480	2420~2480
2800~2880	2800~2880
2940~3050	2940~3050

3. Gas Chromatography

Instrument:

Hewlett Packard 5890A

Column:

Methyl Silicone(0.2mm $\phi \times 50$ m)

Column Temperature:

80°C

Flow Rate:

1 ml/min

Detector:

FID(Flame Ionization Detector)

Injection Volume:

 $1 \mu 1$

Results: Gas chromatography indicated one major peak(peak No. 4) and four impurities(peak No. 1, 2, 3, 5 < 5% of total area) analyzed at 1991. 4.3 and one major peak(peak No. 4) and four impurities(peak No. 1, 2, 3, 5 < 5% of total area) analyzed at 1991. 5.1. It was identified only by comparing its gas chromatograph with that of the 1, 4-Dioxane(peak No. 5) in the 1, 1.1-Trichloroethane, the amount in the test substance was 3.43% at 1991. 4.3. The new treace impurity peak in the test substance analyzed at 1991. 5.1 was not detected.

Date	Peak	No.	Retention Time(min)	AREA COUNT	
1991.04.	03	1	2.388	122	
(date an	alyzed)	2	2.455	73	
		3	2.54	1092	
		4	2.782	145248	
		5	3.093	5658	
1991.05.	01	1	2.387	121	
(date an	alyzed)	2	2.453	72	
		3	2.54	1090	
		4	2.78	144876	
		5	3.092	5646	

^{4.} Conclusions: The results indicated that the test substance did not change when stored in the dark at room temperature during this period(for about 4 weeks).

B. Lot no. DSP4087

1. Sample: This lot was used from 1991.4.29 to 1991.7.8. Test substance was stored at room temperature.

2. Infrared Spectrometry

Instrument

: Hitachi 270-30 Infrared Spectrometer

Cell

: KBr

Slit

: Medium

Results: Infrared spectrum of the test substance agreed with before use and after use.

$510 \sim 550$ $510 \sim 550$ $600 \sim 640$ $600 \sim 640$ $660 \sim 760$ $850 \sim 900$ $850 \sim 900$ $1040 \sim 1110$ $1040 \sim 1110$ $1120 \sim 1150$ $1240 \sim 1270$ $1240 \sim 1270$ $1370 \sim 1400$ $1370 \sim 1400$ $1410 \sim 1440$ $1440 \sim 1440$ $1440 \sim 1480$ $2100 \sim 2170$ $2120 \sim 2170$ $2420 \sim 2480$ $2800 \sim 2880$ $2940 \sim 3050$ $2940 \sim 3050$	1991.04.19(date analyzed) Wave Number(cm ⁻¹)	1991.07.08(date analyzed) Wave Number(cm ⁻¹)
	$600 \sim 640$ $660 \sim 760$ $850 \sim 900$ $1040 \sim 1110$ $1120 \sim 1150$ $1240 \sim 1270$ $1370 \sim 1400$ $1410 \sim 1440$ $1440 \sim 1480$ $2100 \sim 2170$ $2420 \sim 2480$ $2800 \sim 2880$	$600 \sim 640$ $660 \sim 760$ $850 \sim 900$ $1040 \sim 1110$ $1120 \sim 1150$ $1240 \sim 1270$ $1370 \sim 1400$ $1410 \sim 1440$ $1440 \sim 1480$ $2100 \sim 2170$ $2420 \sim 2480$ $2800 \sim 2880$

3. Gas Chromatography

Instrument:

Hewlett Packard 5890A

Column:

Methyl Silicone(0.2mm $\phi \times 50$ m)

Column Temperature: 80°C

Flow Rate:

1 ml/min

Detector:

FID(Flame Ionization Detector)

Injection Volume:

 $1 \mu 1$

Results: Gas chromatography indicated one major peak(peak No. 4) and four impurities(peak No. 1, 2, 3, 5 < 5% of total area) analyzed at 1991. 4.19 and one major peak(peak No. 4) and four impurities(peak No. 1, 2, 3, 5 < 5% of total area) analyzed at 1991. 7.8. It was identified only by comparing its gas chromatograph with that of the 1, 4-Dioxane(peak No. 5) in the 1, 1, 1-Trichloroethane, the amount in the test substance was 3.44% at 1991. 4.19. The new treace impurity peak in the test substance analyzed at 1991. 7.8 was not detected.

Date	Peak	No.	Retention Time(min)	Area Count	
1991.04.	19	1	2.388	129	
(date ana	alyzed)	2	2.455	94	
		3	2.54	1088	
		4	2.782	143663	
		5	3.093	5570	
1991.07.()8	1	2.387	130	
(date ana	alyzed)	2	2.453	95	
		3	2.538	1094	
		4	2.78	144718	
		5	3.092	5610	

^{4.} Conclusions: The results indicated that the test substance did not change when stored in the dark at room temperature during this period(for about 11 weeks).

C. Lot no. DSQ3398

1. Sample: This lot was used from 1991.7.8 to 1991.7.17. Test substance was stored at room temperature.

2. Infrared Spectrometry

Instrument

: Hitachi 270-30 Infrared Spectrometer

Cell

: KBr

Slit

: Medium

Results: Infrared spectrum of the test substance agreed with before use and after use.

1991.07.03(date analyzed) Wave Number(cm ⁻¹)	<pre>1991.07.30(date analyzed) Wave Number(cm⁻¹)</pre>
510~ 550 600~ 640	510~ 550 600~ 640
660~ 760 850~ 900 1040~1110	$660 \sim 760$ $850 \sim 900$
$1120 \sim 1110$ $1120 \sim 1150$ $1240 \sim 1270$	$1040 \sim 1110$ $1120 \sim 1150$ $1240 \sim 1270$
$1370 \sim 1400$ $1410 \sim 1440$	$1370 \sim 1400$ $1410 \sim 1440$
$1440 \sim 1480$ $2100 \sim 2170$ $2420 \sim 2480$	$1440 \sim 1480$ $2100 \sim 2170$ $2420 \sim 2480$
2800~2880 2940~3050	2800~2880 2940~3050

3. Gas Chromatography

Instrument:

Hewlett Packard 5890A

Column:

Methyl Silicone(0.2mm $\phi \times 50$ m)

Column Temperature: 80°C

Flow Rate:

1 ml/min

Detector:

FID(Flame Ionization Detector)

Injection Volume: $1 \mu 1$

Results: Gas chromatography indicated one major peak(peak No. 4) and four impurities(peak No. 1, 2, 3, 5 < 5% of total area) analyzed at 1991.7.3 and one major peak(peak No. 4) and four impurities(peak No. 1, 2, 3, 5 < 5% of total area) analyzed at 1991.7.30. It was identified only by comparing its gas chromatograph with that of the 1.4-Dioxane(peak No. 5) in the 1,1,1-Trichloroethane, the amount in the test substance was 3.49% at 1991.7.3. The new treace impurity peak in the test substance analyzed at 1990.7.30 was not detected.

Date	Peak	No.	Retention Time(min)	AREA COUNT	
1991.07.0	3	1	2.388	130	
(date analyzed)		2.	2.453	93	
		3	2.54	1083	
		4	2.78	143204	
		5	3.092	5544	
1991.07.30	0	1	2. 387	131	
(date ana)	lyzed)	2	2.453	93	
		3	2.54	1085	
		4	2.78	144147	
		5	3.092	5596	

^{4.} Conclusions: The results indicated that the test substance did not change when stored in the dark at room temperature during this period(for about 2 weeks).

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APPENDIX B 12-1

CONCENTRATION OF 1,1,1-TRICHLOROETHANE IN INHALATION CHAMBER (THIRTEEN - WEEK STUDY)

CONCENTRATION OF 1, 1, 1-TRICHLOROETANE IN INHALTION CHAMBER (RAT:THIRTEEN-WEEK STUDY)

	Concentration (ppm)
Group Name	Mean \pm S.D.
Control	0.0 ± 0.0
2000ppm	2001.6 ± 12.7
3000ppm	2994.8 ± 15.4
4400ppm	4380.3 ± 31.6
6700ppm	6665.2 ± 45.5
10000ppm	10003.7 ± 81.9

CONCENTRATION OF 1, 1, 1-TRICHLOROETANE IN INHALTION CHAMBER (MOUSE:THIRTEEN-WEEK STUDY)

Group Name	Concentration (ppm) $Mean \pm S.D.$
Control	0.0 ± 0.0
3000ppm	3006.0 ± 35.1
4400ppm	4388.1 ± 42.4
6700ppm	6696.1 ± 28.8
10000ppm	9997.4 ± 1.1
15000ppm	14972.9 ± 0.0

APPENDIX B 12-2 ENVIRONMENT OF INHALATION CHAMBER (THIRTEEN - WEEK STUDY)

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS

Item	Method	Unit
Hematology		
Red blood cell	Light scattering method 1)	\times 10 ⁶ / μ L
Hemoglobin	Cyanmethemoglobin method 1)	g/dL
Hematocrit	Calculated as RBC × MCV/10 1)	%
Mean corpuscular volume (MCV)	Light scattering method 1)	fL
Mean corpuscular hemoglobin (MCH)	Calculated as Hgb/RBC × 10 1)	pg
Mean corpuscular hemoglobin	Calculated as Hgb/Hct × 10 1)	g/dL
concentration (MCHC)		
Platelet	Light scattering method 1)	\times 10 ³ / μ L
White blood cell (WBC)	Light scattering method 1)	\times 10 3 / μ L
Differential WBC	Pattern recognition method 2)	%
	(May-Grunwald-Giemsa staining)	
Biochemistry		
Total protein	Biuret method 3)	g/dL
Albumin	BCG method 3)	g/dL
A/G ratio	Calculated as Alb/(TP-Alb) 3)	
T-bilirubin	Michaelson method 3)	mg/đL
Glucose	Enzymatic method (HK·G-6-PDH) 3)	mg/dL
T-cholesterol	Enzymatic method (CEH·COD·POD) 3)	mg/dL
Triglyceride	Enzymatic method (GK·GPO·POD) 3)	mg/dL
Phospholipid	Enzymatic method (PLD·COD·POD) 3)	mg/dL
Glutamic oxaloacetic transaminase (GOT)	Karmen method 3)	IU/L
Glutamic pyruvic transaminase(GPT)	Karmen method 3)	IU/L
Lactate dehydrogenase (LDH)	Wroblewski-LaDue method 3)	IU/L
Alkaline phosphatase (ALP)	GSCC method 3)	IU/L
γ -Glutamyl transpeptidase (G-GTP)	L- γ -Glutamyl-p-nitroanilide substrate	IU/L
	method ³⁾	
Creatine phosphokinase (CPK)	GSCC method 3)	IU/L
Urea nitrogen	Enzymatic method (Urease GLDH) 3)	mg/dL
Creatinine	Jaffe metod 3)	mg/dL
Sodium	Flame photometry 4)	mEq/L
Potassium	Flame photometry 4)	mEq/L
Chloride	Coulometric titration 4)	mEq/L
Calcium	OCPC method 3)	mg/dL
Inorganic phosphorus	Enzymatic method (SPL·PGM·G-6-PDH) 3)	mg/dL
Urinalysis pH,Protein,Glucose,Ketone body, Bilirubin, Occult Blood,Urobilinogen	Urinalysis reagent paper metod 5)	

- 1) Automatic blood cell analyzer (Technicon H·1: Technicon Instruments Corporation, USA)
- 2) Automatic blood cell differential analyzer (Hitachi 8200 : Hitachi ,Ltd.,Japan)
- 3) Automatic analyzer (Hitachi 705 : Hitachi ,Ltd.,Japan)
- 4) Flame photometer (Hitachi 750 : Hitachi ,Ltd.,Japan)
- 5) Ames reagent strips for urinalysis (Multistix, Uro-Labstix: Miles Sankyo Co., Ltd., Japan)

${\bf APPENDIX} \,\, {\bf C} \,\, {\bf 1}$ ${\bf METHODS} \,\, {\bf FOR} \,\, {\bf HEMATOLOGY}, \,\, {\bf BIOCHEMISTRY} \,\, {\bf AND} \,\, {\bf URINALYSIS}$

ENVIRONMENT OF INHALATION CHAMBER (RAT: THIRTEEN-WEEK STUDY)

Group Name	Temper Mean			Humid Mean			Ventilati Mean		. ,	Room Air Change(time/h) Mean
Control	22.6	±	0.2	60.2	±	3.1	208.6	土	11.5	11.8
2000ppm	22.5	\pm	0.2	55.4	\pm	2.4	208.9	\pm	11.0	11.8
3000ppm	22.8	\pm	0.2	57.7	\pm	1.7	208.1	\pm	11.0	11.8
4400ppm	22.2	\pm	0.2	55.0	土	1.6	207.9	±	10.4	11.8
6700ppm	22.8	\pm	0.3	51.3	\pm	1.0	207.9	土	10.7	11.8
10000ppm	22.6	土	0.2	53.0	±	1.3	208.8	土	10.3	11.8

ENVIRONMENT OF INHALATION CHAMBER (MOUSE: THIRTEEN-WEEK STUDY)

Group Name	Temper Mean			Humi o Mean			Ventilatio Mean		* * * *	Room Air Change(time/h) Mean
Control	21.2	土	0.2	60.5	±	2.6	102.3	土	5.8	11.8
3000ppm	21.2	\pm	0.2	60.0	土	2.9	104.1	\pm	0.6	12.0
4400ppm	21.3	\pm	0.2	55.2	\pm	2.9	104.7	\pm	0.7	12.1
6700ppm	21.3	\pm	0.4	56.0	土	3.0	102.7	\pm	5.2	11.9
10000ppm	20.9	\pm	0.6	54.4	\pm	5.8	103.6	±	0.7	12.0
15000ppm	21.5	\pm	0.0	48.0	\pm	0.0	103.3	\pm	0.0	11.9

APPENDIX C 2

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY

	TEST ITEM	DECIMAL PLACE	UNIT
HEMATOLOGY	Red blood cell	2	× 10 ⁶ / μ L
	Hemoglobin	1	g/dL
	Hematocrit	1	%
	MCV	1	fL
	мсн	1	pg
	MCHC	1	g/dL
	Platelet	0	$\times 10^3 / \mu L$
	White blood cell	2	$\times 10^3 / \mu L$
	Differential WBC	0	%
BIOCHEMISTRY	Total protein	1	g/dL
	Albumin	1	g/dL
	A/G ratio	1	_
	T-bilirubin	2	mg/dL
	Glucose	0	mg/dL
	T-cholesterol	0	mg/dL
	Triglyceride	0	mg/dL
	Phospholipid	0	mg/dL
	GOT	0	IU/L
	GPT	0	IU/L
	LDH	0	IU/L
	ALP	0	IU/L
	G-GTP	0	IU/L
	CPK	0	IU/L
	Urea nitrogen	1	mg/dL
	Creatinine	1	mg/dL
	Sodium	0	mEq/L
	Potassium	1	mEq/L
	Chloride	0	mEq/L
	Calcium	1	mg/dL
	Inorganic phosphorus	1	mg/dL