グリシドールのマウスを用いた 吸入による2週間毒性試験報告書

試験番号:0308

APPENDIX

APPENDIXES

- APPENDIX A 1 CLINICAL OBSERVATION : SUMMARY, MOUSE : MALE (2-WEEK STUDY)
- APPENDIX A 2 CLINICAL OBSERVATION : SUMMARY, MOUSE : FEMALE (2-WEEK STUDY)
- APPENDIX B 1 BODY WEIGHT CHANGES : SUMMARY, MOUSE : MALE (2-WEEK STUDY)
- APPENDIX B 2 BODY WEIGHT CHANGES : SUMMARY, MOUSE : FEMALE (2-WEEK STUDY)
- APPENDIX C 1 FOOD CONSUMPTION CHANGES : SUMMARY, MOUSE : MALE (2-WEEK STUDY)
- APPENDIX C 2 FOOD CONSUMPTION CHANGES : SUMMARY, MOUSE : FEMALE (2-WEEK STUDY)
- APPENDIX D 1 HEMATOLOGY : SUMMARY, MOUSE : MALE (2-WEEK STUDY)
- APPENDIX D 2 HEMATOLOGY : SUMMARY, MOUSE : FEMALE (2-WEEK STUDY)
- APPENDIX E 1 BIOCHEMISTRY : SUMMARY, MOUSE : MALE (2-WEEK STUDY)

)

- APPENDIX E 2 BIOCHEMISTRY : SUMMARY, MOUSE : FEMALE (2-WEEK STUDY)
- APPENDIX F 1GROSS FINDINGS : SUMMARY, MOUSE : MALE :
DEAD AND MORIBUND ANIMALS (2-WEEK STUDY)APPENDIX F 2GROSS FINDINGS : SUMMARY, MOUSE : MALE :
SACRIFICED ANIMALS (2-WEEK STUDY)
- APPENDIX F 3 GROSS FINDINGS : SUMMARY, MOUSE : FEMALE : DEAD AND MORIBUND ANIMALS (2-WEEK STUDY)
- APPENDIX F 4 GROSS FINDINGS : SUMMARY, MOUSE : FEMALE : SACRIFICED ANIMALS (2-WEEK STUDY)

APPENDIXES (CONTINUED)

- APPENDIX G 1 ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOUSE : MALE (2-WEEK STUDY)
- APPENDIX G 2 ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOUSE : FEMALE (2-WEEK STUDY)
- APPENDIX H 1 ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : MALE (2-WEEK STUDY)
- APPENDIX H 2 ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : FEMALE (2-WEEK STUDY)
- APPENDIX I 1 HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY, MOUSE : MALE : DEAD AND MORIBUND ANIMALS (2-WEEK STUDY)
- APPENDIX I 2 HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY, MOUSE : MALE : SACRIFICED ANIMALS (2-WEEK STUDY)
- APPENDIX I 3 HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY, MOUSE : FEMALE : DEAD AND MORIBUND ANIMALS (2-WEEK STUDY)
- APPENDIX I 4 HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY, MOUSE : FEMALE : SACRIFICED ANIMALS (2-WEEK STUDY)

)

- APPENDIX J 1 IDENTITY OF GLYCIDOL IN THE 2-WEEK INHALATION STUDY APPENDIX J 2 STABILITY OF GLYCIDOL IN THE 2-WEEK INHALATION STUDY
- APPENDIX K 1 CONCENTRATION OF GLYCIDOL IN THE INHALATION CHAMBER OF THE 2-WEEK INHALATION STUDY APPENDIX K 2 ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER
 - IN THE 2-WEEK INHALATION STUDY OF ALLYL CHLORIDE

APPENDIXES (CONTINUED)

APPENDIX L 1 METHODS FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-WEEK INHALATION STUDY OF GLYCIDOL

APPENDIX L 2 UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-WEEK INHALATION STUDY OF GLYCIDOL

)

)

APPENDIX A 1

CLINICAL OBSERVATION : SUMMARY, MOUSE : MALE

STUDY NO. : 0308 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

 \sim

,

SEX : MALE

PAGE : 1

Clinical sign	Group Name	Adminis	stration W	eek-day				
· · · · · ·		1-2	1-4	1-7	2−3	2-7		
		1	1	1	1	1	 	
DEATH	0ppm	0	0	0	0	0		
	37.5ppm	0	0	0	0	0		
	75.0ppm	0	0	0	0	0		
	150.0ppm	0	3	4	7	8		
	300.0ppm	3	-			-		
	600.0ppm	10	-	-		-		
LOCOMOTOR MOVEMENT DECR	mqq0	0	0	0	0	0		
	37.5ppm	0	0	0	0	0		
	75.0ppm	0	0	0	0	0		
	150.0ppm	0	1	0	1	0		
	300.0ppm	7	-	-	-	-		
	600.0ppm	0	-	-	-	-		
PILOERECTION	0ppm	0	0	0	0	0		
	37.5ppm	0	0	0	0	0		
	75.0ppm	0	0	0	· 0	0		
	150.0ppm	0	0	0	1	0		
	300.0ppm	0	-	-		-		
-	600.0ppm	0	-	-	-	-		
FROG BELLY	0ppm	0	0	0	0	0		
	37.5ppm	0	0	0	0	0		
	75.0ppm	0	0	0	0	0		
	150.0ppm	0	1	0	Ö	0		
	300.0ppm	9	_	-	-	-		
	600.0ppm	10	-	-	-	-		
GASPING	mado	0	0	0	0	0		
and and	37.5ppm	ŏ	0	Õ	0	0 0		
	75.0ppm	õ	0	ŏ	0	0		
	150.0ppm	0	0	0	0	0		
	300.0ppm	7	-	-	-	-		
	SVU.UPPM				-			
	600.0ppm	0	-	-	-	-		
ABNORMAL RESPIRATION	0ppm	0	0	0	0	0		
	37.5ppm	0	0	0	0	0		
	75.0ppm	0	0	0	0	0		
	150.0ppm	0	1	0	0	0		
	300.0ppm	7	-	-	-	-		
	600.0ppm	0	-	-		-		

STUDY NO. : 0308 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

-

 \smile

.

SEX : MALE

PAGE: 2

Clinical sign	Group Name	Admini	stration We	eek-day		
-		1-2	1-4	1-7	2-3	2-7
		1	1	1	1	1
RADYPNEA EEP BREATHING	0ppm	0	0	0	0	0
	37.5ppm	0	0	0	0	0
	75.0ppm	0	0	0	0	0
DEEP BREATHING	150.0ppm	0	0	0	0	0
	300.0ppm	4	_	_	_	_
	600.0ppm	0		-	-	-
		-				
DEEP BREATHING	0ppm	0	0	0	0	0
EEP BREATHING	37.5ppm	0	0	0	Ō	Ō
	75.0ppm	0	Õ	Ō	Ō	Ő
	150.0ppm	0	1	0	Ō	Ó
	300.0ppm	3	-	-	-	-
	600.0ppm	0	-	-		_
	0000 PPM	·				
ABNORMAL RESPIRA.SOUND	0ppm	0	0	0	0	0
	37.5ppm	0	0	0	0	0
	75.0ppm	0	0	Ó	Ō	0
	150.0ppm	2	3	0	Ō	0
	300.0ppm	7	-	~	•	-
	600.0ppm	0	-	-	-	_
		v				
SUBNORMAL TEMP	0ppm	0	0	0	0	0
	37.5ppm	0	0	0	0	0
	75.0ppm	0	0	0	0	0
	150.0ppm	0	1	0	0	0
	300.0ppm	7	_	_	_	
	600.0ppm	0	-	-	-	-
		-				

(HAN190)

APPENDIX A 2

CLINICAL OBSERVATION : SUMMARY, MOUSE : FEMALE

STUDY NO. : 0308 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

~___

~~~

۲

#### SEX : FEMALE

PAGE: 3

| Clinical sign          | Group Name           | Adminis | stration We | ek-day |        |        |
|------------------------|----------------------|---------|-------------|--------|--------|--------|
|                        |                      | 1-2     | 1-4         | 1-7    | 2-3    | 2-7    |
|                        |                      | 1       | 1           | 1      | 1      | 1      |
|                        | ······               |         |             |        | ·····  |        |
| DEATH                  | 0ppm                 | 0       | 0           | 0      | 0      | 0      |
|                        | 37.5ppm              | õ       | ŏ           | 0<br>0 | Ő      | ŏ      |
|                        | 75.0ppm              | õ       | Õ           | õ      | õ      | Õ      |
|                        | 150.0ppm             | 0       | 3           | 3      | 8.     | 9      |
|                        | 300.0ppm             | 6       | -           | -      | -      | -      |
|                        | 600.0ppm             | 10      | -           | -      | -      | -      |
| OCOMOTOR MOVEMENT DECR | 0000                 | 0       | 0           | 0      | ٥      | ٥      |
| ACCHOICE NOVENENT DECK | 0ppm<br>37.5ppm      | 0<br>0  | 0           | 0      | 0      | 0<br>0 |
|                        | 75.0ppm              | õ       | 0           | 0      | 0      | 0      |
|                        | 150.0ppm             | 0       | 0           | 0      | 0      | 0      |
|                        | 300.0ppm             | 3       | U<br>~      | U<br>- | U<br>_ | U<br>_ |
|                        | 500.0ppm<br>600.0ppm | 3<br>0  | -           | -      | -      | -      |
|                        | 000.0000             | U       | -           | -      | -      | -      |
| ROG BELLY              | 0ppm                 | 0       | 0           | 0      | 0      | 0      |
|                        | 37.5ppm              | 0       | 0           | 0      | 0      | 0      |
|                        | 75.0ppm              | 0       | 0           | 0      | 0      | 0      |
|                        | 150.0ppm             | 0       | 0           | 0      | 0      | 0      |
|                        | 300.0ppm             | 9       | -           | -      |        | -      |
|                        | 600.0ppm             | 10      | -           | -      | -      | -      |
| GASPING                | mqq0                 | 0       | 0           | 0      | 0      | 0      |
|                        | 37.5ppm              | 0       | 0           | 0      | Ó      | 0      |
|                        | 75.0ppm              | 0       | 0           | 0      | 0      | 0      |
|                        | 150.0ppm             | 0       | 0           | 0      | 0      | 0      |
|                        | 300.0ppm             | 3       | -           | -      | -      | -      |
|                        | 600.0ppm             | 0       | -           | -      | -      | -      |
| IRREGULAR BREATHING    | 0ppm                 | 0       | 0           | 0      | 0      | 0      |
| IRREGULAR DREATHING    | 37.5ppm              | 0       | 0           | 0      | 0      | 0      |
|                        | 75 Oppm              | 0       | 0           | 0      | 0      |        |
|                        | 75.0ppm<br>150.0ppm  | 0       | 0           | 0      | 0      | 0      |
|                        | 300.0ppm             |         | U           | U      | -      | -      |
|                        |                      | 1       | _           | _      | -      | -      |
|                        | 600.0ppm             | 0       | -           | -      |        | -      |
| ABNORMAL RESPIRATION   | 0ppm                 | 0       | 0           | 0      | 0      | 0      |
|                        | 37.5ppm              | 0       | 0           | 0      | 0      | 0      |
|                        | 75.0ppm              | 0       | 0           | 0      | 0      | 0      |
|                        | 150.0ppm             | 0       | 0           | 0      | 0      | 0      |
|                        | 300.0ppm             | 4       | -           | -      | -      | -      |
|                        | 600.0ppm             | 0       |             | -      | -      | -      |

STUDY NO. : 0308 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 2

#### CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

.

SEX : FEMALE

PAGE: 4

| Clinical sign          | Group Name | Adminis | stration W | eek-day |     |     |
|------------------------|------------|---------|------------|---------|-----|-----|
|                        |            | 1-2     | 1-4        | 1-7     | 2-3 | 2-7 |
| <u></u>                |            | 1       | 1          | 1       | 1   | 1   |
|                        |            |         |            |         |     |     |
| BRADYPNEA              | 0ppm       | 0       | 0          | 0       | 0   | 0   |
|                        | 37.5ppm    | 0       | 0          | 0       | 0   | 0   |
|                        | 75.0ppm    | 0       | 0          | 0       | 0   | 0   |
|                        | 150.0ppm   | 0       | 0          | 0       | 0   | 0   |
|                        | 300.0ppm   | 3       | -          |         | -   | -   |
|                        | 600.0ppm   | 0       | -          | -       | -   | -   |
| ABNORMAL RESPIRA.SOUND | 0ppm       | 0       | 0          | 0       | 0   | 0   |
|                        | 37.5ppm    | 0       | 0          | 0       | 0   | 0   |
|                        | 75.0ppm    | 0       | 0          | 0       | 0   | 0   |
|                        | 150.0ppm   | 1       | 0          | 0       | 0   | 0   |
|                        | 300.0ppm   | 3       | -          | -       | _   | ~   |
|                        | 600.0ppm   | 0       | -          | -       | -   | -   |
| SUBNORMAL TEMP         | 0ppm       | 0       | 0          | 0       | 0   | 0   |
|                        | 37.5ppm    | 0       | 0          | 0       | 0   | 0   |
|                        | 75.0ppm    | 0       | 0          | 0       | 0   | 0   |
|                        | 150.0ppm   | 0       | 0          | 0       | 0   | 0   |
|                        | 300.0ppm   | 3       | -          | -       | -   | -   |
|                        | 600.0ppm   | 0       | -          | -       | -   |     |

(HAN190)

APPENDIX B 1

BODY WEIGHT CHANGES :SUMMARY, MOUSE : MALE

BODY WEIGHT CHANGES (SUMMARY) ALL ANIMALS  $\overline{\phantom{a}}$ 

-

.

STUDY NO. : 0308 ANIMAL : MOUSE Crj:BDF1 UNIT : g REPORT TYPE : A1 2 SEX : MALE

PAGE: 1

| o Name                   | Administratio | n week-day    |             |                 |             |             |
|--------------------------|---------------|---------------|-------------|-----------------|-------------|-------------|
| <sup>0,</sup>            | 0-0           | 1-2           | 1-4         | 1-7             | 2-3         | 2-7         |
| Oppm                     | 23.8± 0.8     | 25.0± 1.0     | 25.1± 1.0   | 25.3± 0.9       | 25.6± 1.0   | 26.4± 1.1   |
| 37.5ppm                  | 23.8± 0.8     | 24.4± 1.0     | 24.4± 0.8   | 24.7± 1.0       | 24.9± 0.8   | 25.2± 1.0*  |
| 75.0ppm                  | 23.9± 0.7     | 24.0± 0.8     | 23.8± 0.8*  | 24.2± 0.8       | 24.4± 0.9   | 25.0± 1.0*  |
| 150.0ppm                 | 23.8± 0.8     | 21.6± 1.3**   | 19.4± 1.6** | 20.6± 1.6**     | 20.3± 3.1** | 23.0± 0.5 ? |
| 300.0ppm                 | 23.9± 0.7     | 21.8± 0.4**   | -           | -               | -           | -           |
| 600.0ppm                 | 23.8± 0.8     | -             | -           | -               | -           | -           |
| Significant difference ; | *:P≦ 0.05     | ** : P ≦ 0.01 |             | Test of Dunnett |             |             |

(HAN260)

### APPENDIX B 2

### BODY WEIGHT CHANGES : SUMMARY, MOUSE : FEMALE

·.\_\_\_

~~~

~

STUDY NO. : 0308 ANIMAL : MOUSE Crj:BDF1 UNIT : g REPORT TYPE : A1 2 SEX : FEMALE

PAGE: 2

p Name	Administratio	n week-day				· · · · · · · · · · · · · · · · · · ·
	0-0	1-2	1-4	1-7	2-3	2-7
0ppm	19.3± 0.7	20.3± 0.7	20.6± 0.5	20.7± 0.8	21.2± 0.8	21.6± 0.8
37.5ppm	19.3± 0.6	19.4± 1.2	20.3± 0.5	20.6± 0.5	20.5± 0.6	20.6± 0.7**
75.0ppm	19.3± 0.6	19.0± 0.7**	19.7± 0.6*	20.3± 0.5	20.3± 0.8*	20.8± 0.7*
150.0ppm	19.3± 0.7	17.1± 0.9**	15.5± 1.7**	16.7± 1.2**	15.5± 3.6 ?	18.3± 0.0 ?
300.0ppm	19.3± 0.6	17.3± 0.4**	_	_	-	-
600.0ppm	19.3± 0.6	-	-	-	-	
Significant difference ;	*:P≦ 0.05	** : P ≦ 0.01		Test of Dunnett		

.

(HAN260)

APPENDIX C 1

FOOD CONSUMPTION CHANGES : SUMMARY, MOUSE : MALE

STUDY NO. : 0308 ANIMAL : MOUSE Crj:BDF1 UNIT : g		FOOD C All Ani	CONSUMPTION CHANGES (SUMMARY) MALS
REPORT TYPE : A1 2 SEX : FEMALE			PAGE : 2
Group Name	Administration 1-7(6)	week-day(effective) 2-7(7)	
0ppm	3.8± 0.3	3.7± 0.2	
37.5ppm	3.8± 0.3	3.4± 0.2**	
75.0ppm	3.7± 0.4	3.5± 0.2*	
150.0ppm	2.4± 0.6**	3.4± 0.0 ?	
300.0ppm	-	-	
600.0ppm	-	-	
Significant difference ;	*:P≦ 0.05	** : P ≤ 0.01	Test af Dunnett
?: Significant test is n	ot applied,because No.	of data in this group is la	ess than 3.

 \smile

.

(HAN260)

APPENDIX C 2

FOOD CONSUMPTION CHANGES : SUMMARY, MOUSE : FEMALE

FUDY NO. : 0308 NIMAL : MOUSE Crj:BDF1 NIT : g			O CONSUMPTION CHANGES (SUMMARY) ANIMALS		
EPORT TYPE : A1 2 EX : MALE			PAGE	::	
oup Name	Administration 1-7(6)	week-day(effective) 2-7(7)			
0ppm	4.3± 0.2	4.2± 0.2			
37.5ppm	4.1± 0.2	4.1± 0.3			
75.0ppm	3.9± 0.3**	3.9± 0.2			
150.0ppm	2.4± 0.5**	3.9± 0.2 ?			
300.0ppm	-				
600.0ppm	-	-			
Significant difference ;	*:P≦ 0.05	** : P ≤ 0.01	Test of Dunnett		
?: Significant test is n	ot applied,because No.	of data in this group i		RAIS	

 \sim

.

(HAN260)

APPENDIX D 1

HEMATOLOGY : SUMMARY, MOUSE : MALE

STUDY NO. : 0308		HEMATOLOGY (SUM
ANIMAL : MOUSE (Crj:BDF1	ALL ANIMALS (3
MEASURE. TIME : 1		
SEX : MALE	REPORT TYPE : A1	

Group Name	NO. of Animals	RED BLOOD CELL 1 0 ⁵ /µl	HEMOGLOBIN g⁄dl	HEMATOCRIT %	MCV f l	NCH Pg	MCHC g /dl	PLATELET 1 03/µl
0ppm	5	10.99± 0.17	16.8± 0.3	51.8± 1.6	47.0± 0.8	15.3± 0.2	32.6± 0.6	1251± 103
37.5ppm	5	10.99± 0.17	16.5± 0.2	51.5± 0.5	46.8± 0.5	15.0± 0.3	32.0± 0.6	1255± 57
75.0ppm	5	11.04± 0.39	16.6± 0.9	$51.3\pm$ 1.9	46.5± 0.4	15.0± 0.3	32.3± 0.6	1265 ± 51
150.0ppm	2	10.56± 0.62 ?	15.5± 0.9 1	48.7± 2.3 ?	46.1± 0.6 ?	14.6± 0.0 ?	31.7± 0.4 ?	1282± 147 ?
300.0pm	0	-	-	-	-	-	-	_
600.0ppm	0	-	-	-	-	-	-	-

Test of Dunnett

 \sim

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

** : P ≦ 0.01

Significant difference ; $*: P \leq 0.05$

(HCL070)

BAIS 3

JMMARY) 3W)

PAGE: 1

STUDY NO. : 0308 ANIMAL : MOUSE Crj:BDF1 MEASURE. TIME : 1 SEX : MALE REPORT TYPE : A1 HEMATOLOGY (SUMMARY) ALL ANIMALS (3W)

 \sim

. TIME : 1 ALE REPORT TYPE : A1

PAGE	:	2
------	---	---

iroup Name	NO. of Animals	WBC 1 0³∕		Dif N-BAND	fferential	WBC (%) N-SEG	}	EOSINO		BASO		MONO		LYMPHO		OTHERS	
Oppm	5	0.73±	0.37	0±	0	14±	5	1±	1	0±	0	3±	2	82±	6	0±	0
37.5ppm	5	0.97±	0.09	0±	0	8土	2*	0±	1	0±	0	2±	2	89±	4*	0±	0
75.0ppm	5	0.96±	0.38	0±	0	9±	2*	0±	0	0±	0	2±	1	89±	3*	0±	0
150.0ppm	2	0.68±	0.18 ?	0±	0 ?	11±	2?	$2\pm$	0 ?	0±	0 ?	$2\pm$	0 ?	86±	2 ?	0±	0 ?
300.0ppm	0			-		-		-		-		-		-		-	
600.0ppm	0	-		-		-		-		-		-		-		-	
Significant	difference :	*:P	≦ 0.05	**:P≦	0.01	<u></u>		Test	of Dunnet	t							

 ~ -1

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

,

(HCL070)

APPENDIX D 2

HEMATOLOGY : SUMMARY, MOUSE : FEMALE

STUDY NO. : 0308 ANIMAL : MOUSE Cr	j:BDF1	HEMATOLOGY (SUMMARY) ALL ANIMALS (3W)
MEASURE, TIME : 1		
SEX : FEMALE	REPORT TYPE : A1	

PAGE :	3
--------	---

oup Name	NO. of Animals	RED BL 1 06/	00D CELL µl	HEMOGLO g / dl		HEMATOO %	CRIT	MCV f Q		MCH Pg	•	MCHC g⁄dl		PLATELE 1 0³⁄µ	
000m	5	10.65±	0.25	15.9±	0.6	50.0±	1.3	46.9±	0.5	14.9±	0.4	31.8±	1.0	1103±	34
37.5ppm	5	10.53±	0.33	15.9±	0.6	49.5±	1.5	46.9±	0.3	15.1±	0.4	32.1±	0.8	$1077\pm$	124
75.0ppm	5	10.64±	0.29	15.9±	0.2	50.2±	1.1	47.2±	1.1	15.0±	0.5	31.6±	0.6	1064±	114
150.0ppm	1	10.04±	0.00 ?	14.7±	0.0 ?	45.7±	0.0 ?	45.5±	0.0 ?	14.6±	0.0 ?	32.2±	0.0 ?	$1390\pm$	0 ?
300.0ppm	0	-		-		-		-		-		-		-	
600.0ppm	0	-		-		-		-		-		-		-	

• ----

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

,

(HCL070)

STUDY NO. : 0308 ANIMAL : MOUSE Crj:BDF1 MEASURE. TIME : 1 SEX : FEMALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY) ALL ANIMALS (3W)

 \sim

Group Name NO. of WBC Differential WBC (%) Animals 1 0³/μl N-BAND EOSINO N-SEG BASO MONO LYMPHO OTHERS 0ppm 5 0.81± 0.36 0± 0 $12\pm$ 3 0± 1 0± 0 $2\pm$ 1 $85\pm$ 0± 4 37.5ppm 5 0.62± 0.21 0± $13\pm$ 3 1 0± 0 $0\pm$ 0 $3\pm$ 2 84± 0± 4 75.0ppm 5 0.81± 0.32 0± 0 $11\pm$ 2 0 $1\pm$ 1 0± $2\pm$ 1 86± 3 0± 1 150.0ppm 0.95± 0.00 ? 0± 0 ? $19\pm$ 0 ? 0土 0 ? 0± 0 ? $2\pm$ 0 ? $79\pm$ 0 ? 0± 300.0ppm 0 _ ---_ --_ _ _ _ 600.0ppm 0 _ ---_ _ _ Significant difference ; $*: P \leq 0.05$ ** : P ≦ 0.01 Test of Dunnett

~

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

(HCL070)

BAIS 3

PAGE: 4

0

0

0

0 ?

APPENDIX E 1

BIOCHEMISTRY : SUMMARY, MOUSE : MALE

STUDY NO. : 0308 ANIMAL : MOUSE Crj:BDF1 MEASURE. TIME : 1 SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (3W)

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

.

(HCL074)

BAIS 3

PAGE: 1

STUDY NO. : 0308 ANIMAL : MOUSE Crj:BDF1 MEASURE. TIME : 1 SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (3W)

 $\overline{}$

Dup Name	NO. of Animals	PHOSPHO mg⁄dl	LIPID	GOT IU∕₽		GPT IU∕ℓ		LDH IU⁄.	Q)	G-GTP IU∕₽		CPK IU/Q	
0ppm	5	178±	12	46±	7	23±	8	388±	149	$285\pm$	24	1±	1	96±	44
37.5ppm	5	$153\pm$	8**	42±	3	16±	2	$291\pm$	44	$301\pm$	6	2±	1	92±	32
75.0ppm	5	167±	11	41±	2	15±	2	$252\pm$	43	288±	10	$1\pm$	1	72±	44
150.0ppm	2	154±	1 ?	37±	0 ?	17±	2 ?	$249\pm$	119 ?	$296\pm$	28 ?	1±	1 ?	43±	4 ?
300.0ppm	0	-	,			-		-		-		-		-	
600.0ppm	0	-		-		-		-		-		-		_	

 \sim

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

.

(HCL074)

STUDY NO. : 0308		BIOCHEMISTRY (SU
ANIMAL : MOUSE Cr	j:BDF1	ALL ANIMALS (3
MEASURE. TIME : 1		
SEX : MALE	REPORT TYPE : A1	

up Name	NO. of Animals	UREA NI mg/dl		SODIUM mEq⁄Q		POTASS mEq/		CHLORIDE mEq 🖊 l		CALCIUN mg⁄dl	[INORGAN mg∕dl	NIC PHOSPHORUS
0ppm	5	26.8±	2.3	150±	1	4.6±	0.6	122±	3	9.0±	0.2	8.3±	0.9
37.5ppm	5	24.6±	2.6	150±	1	4.3±	0.8	121±	1	8.8±	0.2	8.4±	0.4
75.0ppm	5	22.2±	3.1	$150\pm$	1	4.7±	0.5	120±	1	8.8±	0.2	8.1±	0.8
150.0ppm	2	16.6±	2.4 ?	149±	0 ?	4.4±	0.4 ?	120±	1 ?	8.8±	0.3 ?	8.2±	0.2 ?
300.0ppm	0	-		-		-		-		-		-	
600.0ppm	0	-		-		-		-		-		-	

 \sim

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

.

(HCL074)

BAIS 3

(SUMMARY) 3W)

 \sim

PAGE: 3

APPENDIX E 2

BIOCHEMISTRY : SUMMARY, MOUSE : FEMALE

STUDY NO. : 0308 ANIMAL : MOUSE C MEASURE. TIME : 1	cj:BDF1	BIOCHEMISTRY (SUMMARY) ALL ANIMALS (3W)
SEX : FEMALE	REPORT TYPE : A1	

-

PAGE	:	4
1 1100		

oup Name	NO. of Animals	TOTAL I g⁄dl		ALBUMIN g⁄dl		A/G RAT	FIO	T-BILI mg∕dl		GLUCOSE mg∕dl		T-CHOLES mg∕dl	STEROL	TRIGLYCE mg⁄dl	RIDE
0ppm	5	5.2±	0.3	3.3±	0.1	1.7±	0.1	0.17±	0.04	213±	35	72±	5	17±	4
37.5ppm	5	5.4±	0.2	3.3±	0.0	1.6±	0.1	0.18±	0.06	197±	10	77±	5	$18\pm$	2
75.0ppm	5	5.3±	0.2	$3.3\pm$	0.2	1.7±	0.1	0.18±	0.05	198±	32	83±	7*	19±	4
150.0ppm	1	5.5±	0.0 ?	$3.4\pm$	0.0 ?	1.6±	0.0 ?	0.14±	0.00 ?	190±	0 ?	115±	0 ?	$22\pm$	0 ?
300.0ppm	0	-		-		-		-		-		-		-	
600.0ppm	0	-		-		-		-		-		-		-	
Significant c	lefference;	*:P≦().05 **	: P ≦ 0.0)1			Test of Du	nnett						

·----

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

.

(HCL074)

BAIS 3

.

STUDY NO. : 0308 ANIMAL : MOUSE Crj:BDF1 MEASURE. TIME : 1 SEX : FEMALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY) ALL ANIMALS (3W)

-

up Name	NO. of Animals	PHOSPHO mg/dl	LIPID	GOT IU/1	;	GPT IU∕Q	,	LDH IU/	Q	ALP IU/G	,	G-GTP IU∕ℓ		CPK IU/I	2
Oppm	5	143±	10	57±	19	20±	8	323±	182	420±	26	1±	1	113±	101
37.5ppm	5	145±	9	54±	9	20±	6	$312\pm$	74	$456\pm$	20*	1±	1	$104\pm$	23
75.0ppm	5	149±	10	56±	14	22±	12	400±	294	420±	20	1±	1	$128\pm$	132
150.0ppm	1	190±	0 ?	56±	0 ?	20±	0 ?	$285\pm$	0 ?	$346\pm$	0 ?	3±	0 ?	37±	0 ?
300.0ppm	0	-		-		-		-		_		-		-	
600.0ppm	0	-		-		-		-		_		-		-	

 \sim

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

(HCL074)

STUDY NO. : 0308		BIOCHEMISTRY (
ANIMAL : MOUSE Crj	:BDF1	ALL ANIMALS (
MEASURE. TIME : 1		
SEX : FEMALE	REPORT TYPE : A1	

UREA NITROGEN

mg/dl

BI	OCHEMIST	'RY (S	SUMMARY)
AL	I ANTMAT	5 (3W)

POTASSIUM

mEq∕Q

Significant defference ; $*: P \leq 0.05$ $**: P \leq 0.01$ Test of Dunnett														
600.0ppm	0	_		-		-		-				-		
300.0ppm	0	-		-		-		-		-		-		
150.0ppm	1	18.4±	0.0 ?	149±	0 ?	4.1±	0.0 ?	116±	0 ?	9.1±	0.0 ?	10.2±	0.0 ?	
75.0ppm	5	19.7±	2.6	149±	2	4.6±	0.5	119±	2	9.1±	0.3	7.8±	1.2	
37.5ppm	5	23.2±	2.0	, 150±	1	4.3±	0.5	119±	3	9.0±	0.2	8.1±	0.9	
0ppm	5	25.0±	4.6	149±	2	4.2±	0.4	$120\pm$	1	9.0±	0.2	6.8±	1.2	

CHLORIDE mEq∕Q

CALCIUM

mg/dl

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

.

(HCL074)

Group Name

NO. of

Animals

BAIS 3

PAGE: 6

INORGANIC PHOSPHORUS

mg/dl

3W)

.

SODIUM

mEq∕l

APPENDIX F 1

GROSS FINDINGS : SUMMARY, MOUSE : MALE

DEAD AND MORIBUND ANIMALS

STUDY NO. : 0308 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 SEX : MALE

GROSS FINDINGS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 3W)

-

SEX :	MALE					PAGE : 1	
Organ	Findings	Group Name NO. of Animals	0ppm 0 (%)	37.5ppm 0 (%)	75.0ppm 0 (%)	150.0ppm 8 (%)	
thymus	atrophic		- (-)	- (-)	- (-)	4 (50)	
spleen	black zone		- (-)	- (-)	- (-)	0 (0)	
stomach	gas		- (-)	- (-)	- (-)	4 (50)	
small intes	gas		- (-)	- (-)	- (-)	3 (38)	
large intes	gas		- (-)	- ()	- (-)	2 (25)	

 \smile

(HPT080)

STUDY NO. : 0308 ANIMAL : MOUSE Crj:BDF1 REPORT TYPE : A1 SEX : MALE

GROSS FINDINGS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 3W)

_

.

Group Name 300.0ppm 600.0ppm 0rgan___ Findings_ NO. of Animals 10 (%) 10 (%) thymus atrophic 0 (0) 0 (0) black zone spleen 1 (10) 0 (0) stomach gas 10 (100) 10 (100) small intes gas 10 (100) 10 (100) large intes gas 9 (90) 10 (100)

(HPT080)

BAIS 3

PAGE: 2

APPENDIX F 2

GROSS FINDINGS : SUMMARY, MOUSE : MALE : SACRIFICED ANIMALS (2-WEEK STUDY)

ANIMAL REPORT TYPE	: 0308 : MOUSE C-j:BDF1 : A1 : MALE	GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (3W)				PAGE : 1
0rgan	Findings	Group Name NO. of Animals	0ppm 10 (%)	37.5ppm 10 (%)	75.0ppm 10 (%)	150.0ppm 2 (%)
spleen	black zone		1 (10)	0 (0)	0 (0)	0 (0)
(HPT080)						BAIS 3

 \smile

 $\overline{}$

.

STUDY NO. : 0308 ANIMAL : MOUSE C-j:BDF1 REPORT TYPE : A1 SEX : MALE	GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS (3W)	PAGE : 2
Organ Findings	Group Name 300.0ppm 600.0ppm NO. of Animals 0 (%) 0 (%)	
spleen black zone	- (-) - (-)	
(HPT080)		BAIS 3

.

APPENDIX F 3

GROSS FINDINGS : SUMMARY, MOUSE : FEMALE

DEAD AND MORIBUND ANIMALS

(2-WEEK STUDY)

GROSS FINDINGS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 3W)

· ____

.

Findings	Group Name NO. of Animals	0ppm 0 (%)	37.5ppm 0 (%)	75.0ppm 0 (%)	150.0ppm 9 (%)
atrophic		- (-)	- (-)	- (-)	6 (67)
gas		- (-)	- (-)	- (-)	1 (11)
gas		- (-)	- (-)	- (-)	0 (0)
gas		- (-)	- (-)	- (-)	0 (0)
	atrophic gas gas	Findings NO. of Animals atrophic gas gas	Findings NO. of Animals 0 (%) atrophic - (-) gas - (-) gas - (-)	Findings NO. of Animals 0 (%) 0 (%) atrophic - (-) - (-) - (-) gas - (-) - (-) - (-) gas - (-) - (-) - (-)	Findings NO. of Animals 0 (%) 0 (%) 0 (%) atrophic - (-) - (-) - (-) - (-) gas - (-) - (-) - (-) - (-) gas - (-) - (-) - (-) gas - (-) - (-) - (-)

 \sim

BAIS 3

STUDY NO.	;	0308
ANIMAL.	:	MOUSE Crj:BDF1
REPORT TYPE	:	A1
SEX	:	FEMALE

GROSS FINDINGS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 3W)

~___

PAGE: 4

0rgan	Findings	Group Name NO. of Animals	10	300.0ppm (%)	10	600.0ppm (%)
thymus	atrophic		0	(0)	0	(0)
stomach	Sac		10	(100)	10	(100)
small intes	gas		10	(100)	10	(100)
Large intes	gas		8	(80)	9	(90)

 \sim

(HPT080)

BAIS 3

APPENDIX F 4

GROSS FINDINGS : SUMMARY, MOUSE : FEMALE : SACRIFICED ANIMALS (2-WEEK STUDY)

STUDY NO. : 0308	GROSS FINDINGS (SUMMARY)
ANIMAL : MOUSE Crj:BDF1	SACRIFICED ANIMALS (3W)
REPORT TYPE : A1	
SEX : FEMALE	

.

.

~

Organ Findings	Group Name	Оррт	37.5ppm	75.0ppm	150.0ppm
	NO. of Animals	10 (%)	10 (%)	10 (%)	1 (%)
thymus atrophic		0 (0)	0 (0)	0 (0)	1 (100)
spleen black zone		0 (0)	1 (10)	3 (30)	0 (0)

(HPT080)

BAIS 3

STUDY NO. : 0308	GROSS FINDINGS (SUMMARY)
ANIMAL : MOUSE Crj:BDF1	SACRIFICED ANIMALS (3W)
REPORT TYPE : A1	
SEX : FEMALE	

~

Organ	Findings	Group Name NO. of Animals		600.0ppm 0 (%)	
thymus	atrophic		- (-)	- (-)	
spleen	black zone		- (-)	- (-)	
(115/10000)			/		
(HPT080)					BAIS 3

 \sim

BAIS 3

.

APPENDIX G 1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOUSE : MALE

(2-WEEK STUDY)

ORGAN WEIGHT:ABSOLUTE (SUMMARY) SURVIVAL ANIMALS (3W)

- سيب

up Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS	
0ppm	5	22.1± 0.6	0.048± 0.004	0.013± 0.002	0.195± 0.010	0.126± 0.009	0.152± 0.013	
37.5ppm	5	21.5± 0.9	0.048± 0.012	0.012± 0.002	0.202± 0.028	0.124± 0.012	0.152± 0.012	
75.0ppm	5	21.6± 0.8	0.051± 0.007	0.011± 0.002	0.187± 0.014	0.117± 0.004	0.157± 0.004	
150.0ppm	2	19.8± 0.4 ?	0.038± 0.006 ?	0.012± 0.002 ?	0.195± 0.008 ?	0.114± 0.004 ?	0.158± 0.010 ?	
300.0ppm	0	-	-	-	-	-	-	
600.0ppm	0	-	-	**	_	-	_	

-

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

.

(HCL040)

BAIS 3

ORGAN WEIGHT: ABSOLUTE (SUMMARY) SURVIVAL ANIMALS (3W)

~

> Name	NO. of Animals	KID	NEYS	SPL	EEN	LIV	ER	BRA	IN
Oppm	5	0.358±	0.023	0.041±	0.006	0.991±	0.075	0.448±	0.023
37.5ppm	5	0.356±	0.019	0.041±	0.005	0.901±	0.032*	0.439±	0.017
75.0ppm	5	0.373±	0.021	0.043±	0.002	0.961±	0.036	0.438±	0.016
150.0ppm	2	0.348±	0.017 ?	0.033±	0.000 ?	0.880±	0.035 ?	0.429±	0.016 ?
300.0ppm	0	-		-		-			
600.0ppm	0	-		-				-	

~

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

(HCL040)

BAIS 3

APPENDIX G 2

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOUSE : FEMALE

(2-WEEK STUDY)

ORGAN WEIGHT:ABSOLUTE (SUMMARY) SURVIVAL ANIMALS (3W)

 \sim

 \sim

roup Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
0ppm	5	17.7± 0.8	0.066± 0.005	0.012± 0.003	0.017± 0.003	0.109± 0.003	0.146± 0.004
37.5ppm	5	17.3± 0.5	0.061± 0.006	0.012± 0.001	0.014± 0.004	0.109± 0.005	0.146± 0.006
75.0ppm	5	17.6± 0.7	0.062± 0.006	0.011± 0.001	0.019± 0.004	0.106± 0.003	0.148± 0.008
150.0ppm	1	15.7± 0.0 ?	0.013± 0.000 ?	0.010± 0.000 ?	0.014± 0.000 ?	0.099± 0.000 ?	0.143± 0.000 ?
300.0ppm	0	-	-	-	-	-	-
600.0ppm	0	-	-	-	-	-	-

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

(HCL040)

BAIS 3

ORGAN WEIGHT: ABSOLUTE (SUMMARY) SURVIVAL ANIMALS (3W)

~

PAGE: 4 Group Name NO. of KIDNEYS SPLEEN LIVER BRAIN Animals 0ppm 5 0.271± 0.016 0.047± 0.006 0.808± 0.026 0.448± 0.018 5 37.5ppm 0.271± 0.016 0.042± 0.004 0.782± 0.024 0.454± 0.005 75.0ppm 5 0.268± 0.013 0.044± 0.004 0.777 ± 0.035 0.441± 0.015 150.0ppm 1 0.259± 0.000 ? 0.026 ± 0.000 ? 0.744± 0.000 ? 0.433 ± 0.000 ? 300.0ppm 0 --_ -600.0ppm 0 _ _ Significant difference ; $*: P \leq 0.05$ ** : P ≦ 0.01 Test of Dunnett

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

.

(HCL040)

BAIS 3

APPENDIX H 1

ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : MALE (2-WEEK STUDY)

ORGAN WEIGHT:RELATIVE (SUMMARY) SURVIVAL ANIMALS (3W)

~

Group Name NO. of Body Weight THYMUS ADRENALS TESTES HEART LUNGS Animals (g) 0ppm 5 22.1± 0.6 0.216 ± 0.018 0.058 ± 0.009 0.882 ± 0.045 0.572 ± 0.046 0.685 ± 0.053 37.5ppm 5 21.5± 0.9 0.221 ± 0.052 0.055 ± 0.010 0.939 ± 0.108 0.579 ± 0.049 0.705 ± 0.038 75.0ppm 5 21.6± 0.8 0.239 ± 0.035 0.053 ± 0.007 0.868 ± 0.076 0.542 ± 0.011 0.730 ± 0.030 2 150.0ppm 19.8± 0.4 ? 0.189 ± 0.028 ? 0.059± 0.012 ? 0.983 ± 0.061 ? 0.574 ± 0.030 ? 0.798± 0.033 ? 300.0ppm 0 _ _ _ _ _ ---600.0ppm 0 _ _ -----Significant difference ; $*: P \leq 0.05$ ** : P ≦ 0.01 Test of Dunnett

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

(HCL042)

BAIS 3

•----

p Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN	
0ppm	5	1.617± 0.111	0.187± 0.025	4.476± 0.257	2.027± 0.088	
37.5ppm	5	1.660± 0.105	0.193± 0.019	4.195± 0.128	2.047± 0.136	
75.0ppm	5	1.730 ± 0.094	0.199± 0.013	4.452± 0.051	2.034± 0.140	
150.0ppm	2	1.757± 0.048 ?	0.167± 0.004 ?	4.442± 0.080 ?	2.167± 0.032 ?	
300.0ppm	0	-	-	-	-	
600.0ppm	0	-	~		_	

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

(HCL042)

BAIS 3

PAGE: 2

ORGAN WEIGHT: RELATIVE (SUMMARY) SURVIVAL ANIMALS (3W)

 \sim

APPENDIX H 2

ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : FEMALE (2-WEEK STUDY)

ORGAN WEIGHT:RELATIVE (SUMMARY) SURVIVAL ANIMALS (3W)

 \smile

oup Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
0ppm	5	17.7± 0.8	0.372± 0.028	0.068± 0.017	0.098± 0.012	0.617± 0.026	0.826± 0.046
37.5ppm	5	17.3± 0.5	0.354 ± 0.031	0.067± 0.007	0.083± 0.023	0.629± 0.042	0.843± 0.029
75.0ppm	5	17.6± 0.7	0.350± 0.032	0.065± 0.007	0.107± 0.026	0.600± 0.015	0.841± 0.068
150.0ppm	1	15.7± 0.0 ?	0.083± 0.000 ?	0.064± 0.000 ?	0.089± 0.000 ?	0.631± 0.000 ?	0.911± 0.000 ?
300.0ppm	0	-	-	-	-	-	-
600.0ppm	0	-	-		. –	_	-

 \sim

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

•

(HCL042)

BAIS 3

ORGAN WEIGHT:RELATIVE (SUMMARY) SURVIVAL ANIMALS (3W)

~

Group Name NO. of KIDNEYS SPLEEN LIVER BRAIN Animals 5 0ppm 1.527 ± 0.078 0.263 ± 0.035 4.560 ± 0.085 2.526 ± 0.087 37.5ppm 5 1.562 ± 0.108 0.244 ± 0.020 4.509 ± 0.078 2.618 ± 0.090 75.0ppm 5 1.520 ± 0.066 0.247 ± 0.013 4.412± 0.164 2.508 ± 0.169 1 150.0ppm 1.650 ± 0.000 ? 0.166 ± 0.000 ? 4.739± 0.000 ? 2.758 ± 0.000 ? 300.0ppm 0 ---_ ••• _ 600.0ppm 0 _ _ ----Significant difference ; $*: P \leq 0.05$ ** : P ≦ 0.01 Test of Dunnett

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

(HCL042)

BAIS 3

APPENDIX I 1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : MALE : DEAD AND MORIBUND ANIMALS

(2-WEEK STUDY)

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 30)

PAGE: 1

0rgan	Findings	Group Name Oppm No. of Animals on Study O Grade <u>1 2 3 4</u> (%) (%) (%) (%)	$ \begin{array}{c} 37.5 \text{ppm} \\ 0 \\ \frac{1 2 3 4}{(\%) (\%) (\%) (\%)} \end{array} $	$\begin{array}{c} 75.0 \text{ppm} \\ 0 \\ \hline 1 & 2 & 3 & 4 \\ \hline (\%) & (\%) & (\%) & (\%) \end{array}$	$ \begin{array}{c} 150.0ppm \\ 1 \\ 1 \\ \hline (\%) (\%) (\%) (\%) \end{array} $
[Respiratory :	system]				
nasal cauit	ulcer	< 0> (-) (-) (-) (-)	< 0> 	< 0> (-) (-) (-) (-)	<pre> < 1> 0 0 1 0 (0) (0) (100) (0)</pre>
	inflammatory infiltration	(-) (-) (-) (-)	(-) (-) (-) (-)	(-) (-) (-) (-)	0 1 0 0 (0) (100) (0) (0)
	necrosis:olfactory epithelium	(-) (-) (-) (-)	(-) (-) (-) (-)	(-) (-) (-) (-)	0 0 1 0 (0) (0) (100) (0)
	necrosis:respiratory epithelium	(-) (-) (-) (-)	(-) (-) (-) (-)	(-) (-) (-) (-)	0 0 1 0 (0) (0) (100) (0)
	necrosis:squamous epithelium	(-) (-) (-) (-)	(-) (-) (-) (-)	(-) (-) (-) (-)	0 0 0 0 (0) (0) (0) (0)
trachea	inflammatory infiltration	< 0> 	< 0> 	< 0> (-) (-) (-) (-)	<pre> < 1> 1 0 0 0 (100) (0) (0) (0) (0)</pre>
	necrosis:epithelium	(-) (-) (-) (-)	(-) (-) (-) (-)	 (-) (-) (-) (-)	0 1 0 0 (0) (100) (0) (0)
ung	congestion	< 0> (-) (-) (-) (-)	< 0> 	< 0> (-) (-) (-) (-)	< 1> 1 0 0 0 (100) (0) (0) (0)

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

b b: Number of animals with lesion

(c) c:b/a*100

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 300)

Drgan	Findings	Group Name 300.0ppm No. of Animals on Study 2 Grade 1 2 3 4 (%) (%) (%) (%) (%)	$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	
Respiratory s	system]			
nasal cavit	ulcer	<pre></pre>	< 2> 0 0 0 0 (0) (0) (0) (0)	
	inflammatory infiltration	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	
	necrosis:olfactory epithelium	0 0 2 0 (0) (0) (100) (0)	0 0 2 0 (0) (0) (100) (0)	
	necrosis:respiratory epithelium	0 0 2 0 (0) (0) (100) (0)	0 0 2 0 (0) (0) (100) (0)	
	necrosis:squamous epithelium	1 0 0 0 (50)(0)(0)(0)	0 0 0 0 (0) (0) (0) (0)	
trachea	inflammatory infiltration	<pre>< 2> 0 0 0 0 (0) (0) (0) </pre>	< 2> 0 0 0 0 (0) (0) (0) (0)	
·	necrosis:epithelium	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	
lung	congestion	<pre></pre>	< 2> 2 0 0 0 (100) (0) (0) (0)	

rgan	Findings	Group Name Oppm No. of Animals on Study O Grade <u>1 2 3 4</u> (%) (%) (%) (%)	$ \frac{37.5ppm}{0} \\ \frac{1 & 2 & 3 & 4}{(\%) & (\%) & (\%) & (\%)} $	$ \begin{array}{c} 75.0 \text{ppm} \\ 0 \\ \underline{1 2 3 4} \\ (\%) (\%) (\%) (\%) \end{array} $	150.0ppm 1 <u>1 2 3 4</u> (%) (%) (%) (%) (%)
Hematopoie	etic system]				
hymus	karyorrhex is	< 0> 	< 0> 	< 0> (-) (-) (-) (-)	<pre> < 1> 0 0 1 0 (0) (0) (100) (0)</pre>
pleen	deposit of melanin	< 0> 	< 0> (-) (-) (-) (-)	< 0> (-) (-) (-) (-)	< 1> 0 0 0 0 (0) (0) (0) (0)
Jrinary s <u></u>	vstem]				
idney	tubular necrosis	< 0> 	< 0> (-) (-) (-) (-)	< 0> (-) (-) (-) (-)	< 1> 0 0 0 0 (0) (0) (0) (0)
Special se	onse organs/appandage]				
ye	keratitis	< 0> (-) (-) (-) (-	< 0> ,	< 0> 	$\langle 1 \rangle$ 1 0 0 0 (100) (0) (0) (0)

-

,

(c) c:b/a*100

(HPT150)

BAIS3

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 3W) ~

~~

.

PAGE: 4

Fgan		p Name 300.0ppm of Animals on Study 2 le <u>1 2 3 4</u> (%) (%) (%) (%)	$ \begin{array}{c} 600.0ppm \\ 2 \\ \underline{1 2 3 4} \\ (\%) (\%) (\%) (\%) \end{array} $	
Hematopoiet	tic system]			
hymus	karyorrhexis	< 2> 0 0 1 0 (0) (0) (50) (0)	< 2> 0 0 0 0 (0) (0) (0) (0)	
pleen	deposit of melanin	< 2> 1 0 0 0 (50) (0) (0) (0)	< 2> 1 0 0 0 (50) (0) (0) (0)	
Urinary sys	stem]			
tidney	tubular necrosis	$\langle 2 \rangle$ 0 1 0 0 (0) (50) (0) (0)	< 2> 0 0 0 0 (0) (0) (0) (0)	
Special ser	nse organs/appandage]			
эу ө	keratitis	< 2> 0 0 0 0 (0) (0) (0) (0)	< 2> 0 0 0 0 (0) (0) (0) (0)	
irade (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		

(HPT150)

APPENDIX I 2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : MALE: SACRIFICED ANIMALS

(2-WEEK STUDY)

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS (3W)

~

~

PAGE	:	1
------	---	---

0rgan	Findings	Group Name Xo. of Animals on Study 2 Grade 1 2	0ppm 2 <u>3 4</u> (%) (%)	37.5ppm 2 <u>1 2 3 4</u> (%) (%) (%) (%)	$ \begin{array}{c} 75.0 \text{ppm} \\ 2 \\ \underline{1 2 3 4} \\ (\%) (\%) (\%) (\%) \\ \end{array} $	$ \begin{array}{c} 150.0 \text{ppm} \\ 2 \\ \hline \frac{1 2 3 4}{(\%) (\%) (\%) (\%)} \end{array} $
[Respiratory :	system]					
nasal cavit	inflammatory infiltration	<pre></pre>	0 0	< 2> 0 0 0 0 (0) (0) (0) (0)	< 2> 1 0 0 0 (50) (0) (0) (0)	< 2> 0 0 0 0 (0) (0) (0) (0)
	inflammatory polyp	0 0 (0) (0) (0 0 (0) (0)	0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (50)(0)(0)(0)	1 1 0 0 (50)(50)(0)(0)
	respiratory metaplasia:olfactory epi	thelium 000 (0)(0)(0 0 (0) (0)	1 0 0 0 (50)(0)(0)(0)	0 2 0 0 (0) (100) (0) (0)	1 1 0 0 (50)(50)(0)(0)
	atrophy:olfactory epithelium	0 0 (0) (0) (0 0 (0)(0)	1 0 0 0 (50)(0)(0)(0)	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)
	necrosis:olfactory epithelium	0 0 (0) (0) (0 0 (0) (0)	2 0 0 0 (100) (0) (0) (0)	2 0 0 0 (100) (0) (0) (0)	2 0 0 0 (100) (0) (0) (0)
	necrosis:respiratory epithelium	0 0 (0) (0) (0 0 (0) (0)	0 0 0 0 (0) (0) (0) (0)	1 0 0 0 (50)(0)(0)(0)	0 0 0 0 (0) (0) (0) (0)
	necrosis:squamous epithelium	0 0 (0) (0) (0 0 (0) (0)	0 0 0 0 (0) (0) (0) (0)	0 0 0 0 (0) (0) (0) (0)	2 0 0 0 (100) (0) (0) (0)

b b: Number of animals with lesion

(c) c:b/a*100

(HPT150)

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS (3W)

~~

0rgan	Findings	Group Name No. of Animals on Study Grade <u>1</u> (%)	300.0ppm 0 2 3 4 (%) (%) (%)	600.0ppm 0 <u>1 2 3 4</u> (%) (%) (%) (%)	
[Respiratory	system]				
nasal cavit	inflammatory infiltration	- (-)	< 0> () (-) (-)	< 0> (-) (-) (-) (-)	
	inflammatory polyp	(-)	(-) (-) (-)	(-) (-) (-)	
	respiratory metaplasia:olfactory epit		 (-) (-) (-)	(-) (-) (-) (-)	
	atrophy:olfactory epithelium	- (-)	 (-) (-) (-)	() () ()	
	necrosis:olfactory epithelium	(-)	(-) (-) (-)	(-) (-) (-) (-)	
	necrosis:respiratory epithelium	- (-)		() () ()	
	necrosis:squamous epithelium	- (-)	(-) (-) (-)	(-) (-) (-) (-)	

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

.

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

b b: Number of animals with lesion

(c) c:b/a*100

(HPT150)

BAIS3

APPENDIX I 3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : FEMALE : DEAD AND MORIBUND ANIMALS

(2-WEEK STUDY)

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 3W)

 \sim

PAGE	:	5
------	---	---

Drgan	N	TOUP Name Oppm p. of Animals on Study 0 rade 1 2 3 4 (%) (%) (%) (%) (%)	$ \begin{array}{c} 37.5ppm \\ 0 \\ \underline{1 2 3 4} \\ (\%) (\%) (\%) (\%) \end{array} $	$\begin{array}{c} 75.0 \text{ppm} \\ 0 \\ \hline 1 & 2 & 3 & 4 \\ \hline (\%) & (\%) & (\%) & (\%) \end{array}$	$ \begin{array}{c} 150.0ppm \\ 2 \\ \hline (\%) (\%) (\%) (\%) (\%) \end{array} $
Respiratory :	system]				
nasal cauit	ulcer	< 0> (-) (-) (-) (-)	< 0> (-) (-) (-) (-)	< 0> 	<pre> < 2> 1 0 1 0 (50) (0) (50) (0)</pre>
	inflammatory infiltration	(-) (-) (-) (-)	(-) (-) (-) (-)	(-) (-) (-) (-)	1 1 0 0 (50)(50)(0)(0)
	inflammatory polyp	(-) (-) (-) (-)	(-) (-) (-) (-)	(-) (-) (-) (-)	1 0 0 0 (50)(0)(0)(0)
	respiratory metaplasia:olfactory epithe	Lium	(-) (-) (-) (-)	(-) (-) (-) (-)	1 0 0 0 (50) (0) (0) (0)
	atrophy:olfactory epithelium	(-) (-) (-) (-)	(-) (-) (-) (-)	(-) (-) (-) (-)	0 .1 0 0 (0) (50) (0) (0)
	necrosis:olfactory epithelium	(-) (-) (-) (-)	(-) (-) (-) (-)	(-) (-) (-) (-)	0 1 1 0 (0) (50) (50) (0)
	necrosis:respiratory epithelium	(-) (-) (-) (-)	(-) (-) (-) (-)	() (-) (-)	1 0 1 0 (50)(0)(50)(0)
ung	congestion	< 0> 	< 0> 	< 0> (-) (-) (-) (-)	<pre></pre>

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

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

b: Number of animals with lesion c: b / a * 100 b

(c)

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 3W)

-

~----

Organ	Findings	Group Name No. of Animals on Study Grade <u>1</u> (%) (300.0ppm 2 2 3 4 %) (%) (%	<u>1</u> (%)	600.0pr 2 2 3 (%) (%)	
[Respiratory :	system]					
nasal cavit	ulcer	0 (0) (< 2> 0 0 0 0) (0) (0) (0)(< 2> 0 0 0) (0) (0 (0)
	inflammatory infiltration		2 0 0 0)(0)(0		0 0 0) (0) (0 (0)
	inflammatory polyp	0 (0) (0 0 0 0)(0)(0) (0) (0 0 0)(0)(0 (0)
	respiratory metaplasia:olfactory epi		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)
	necrosis:olfactory epithelium		0 2 0 0) (100) (0) (0) (0 2 0) (100) (0 (0)
	necrosis:respiratory epithelium		0 2 0 0) (100) (0		0 2 0) (100) (0 (0)
lung	congestion		< 2> 0 0 0 0) (0) (0		< 2> 2 0 00) (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

.

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 3W)

 \cdot

 \sim

PAGE: 7

Organ	Group No. of No. of Grade	Name Oppm Animals on Study 0 1 2 3 4 (%) (%) (%) (%)	$\begin{array}{c} 37.5 \text{ppm} \\ 0 \\ \hline 1 & 2 & 3 & 4 \\ \hline (\%) & (\%) & (\%) & (\%) \end{array}$	$\begin{array}{c} 75.0 \text{ppm} \\ 0 \\ \hline 1 & 2 & 3 & 4 \\ \hline (\%) & (\%) & (\%) & (\%) \end{array}$	$ \begin{array}{c} 150.0ppm \\ 2 \\ \hline (\%) (\%) (\%) (\%) \\ \hline (\%) (\%) (\%) \\ \hline (\%) (\%) (\%) \\ \end{array} $
[Hematopoid	ətic system]				
thymus	atrophy	(-) (-) (-) (-)	< 0> (-) (-) (-) (-)	< 0> (-) (-) (-) (-)	<pre></pre>
	karyorrhexis	(-) (-) (-) (-)	(-) (-) (-) (-)	(-) (-) (-) (-)	0 0 0 0 (0) (0) (0) (0)
Digestive	system]				
liver	fatty change	< 0> 	< 0> (-) (-) (-) (-)	< 0> 	<pre></pre>
Grade (a) b (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	ad 4 : Severe			

BAIS3

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) DEAD AND MORIBUND ANIMALS (0- 3W)

· ____

Organ		up Name 300.0ppm of Animals on Study 2 de <u>1 2 3 4</u> (%) (%) (%) (%)	$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	
[Hematopoid	etic system]			
thymus	atrophy	< 2> 0 0 0 0 (0) (0) (0) (0)	< 2> 0 0 0 0 (0) (0) (0) (0)	
	karyorrhexis	0 0 1 0 (0) (0) (50) (0)	0 0 0 0 (0) (0) (0) (0)	
[Digestive	system]			
liver	fatty change	< 2> 1 0 0 0 (50) (0) (0) (0)	< 2> 0 0 0 0 (0) (0) (0) (0)	
Grade くa> b (c)	1: Slight 2: Moderate 3: M a : Number of animals examined at the site b : Number of animals with lesion c : b / a * 100	arked 4 : Severe		

(HPT150)

BAIS3

APPENDIX I 4

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : FEMALE : SACRIFICED ANIMALS

(2-WEEK STUDY)

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS (3W)

 \sim

.

.

PAGE : 3

Organ		of Animals on Study 2		$ \begin{array}{c} 37.5 \text{ppm} \\ 2 \\ \hline 3 \\ (\%) \\ (\%) \\ \hline (\%) \\ \hline (\%) \\ \hline \end{array} $	75.0ppm 2 2 (%) (%) (%)	$\begin{array}{c} 150.0 \text{ppm} \\ 1 \\ \hline 1 \\ \hline (\%) \\ (\%$
[Respiratory	system]					
nasal cavit	inflammatory infiltration	< 2> 0 0 0 (0) (0) (0)	0 1 0 (0) (50) (0)	0 0 2		< 1> 0 0 0 0 (0) (0) (0) (0)
	inflammatory polyp	0 0 0 (0)(0)(0)	0 1 0 (0) (50) (0)	0 0 2 (0) (0) (100)	0 0 0 (0) (0) (0)	0 0 0 0 (0)(0)(0)(0)(0)
	rospiratory metaplasia:olfactory epithel	um 0 0 0 (0)(0)(0)	0 0 1 (0) (0) (50)	0 0 1 (0) (0) (50)	1 0 0 (50) (0) (0)	1 0 0 0 (100) (0) (0) (0)
	atrophy:olfactory epithelium	0 0 0 (0) (0) (0)	0 1 0 (0) (50) (0)	0 0 2 (0) (0) (100)	0 0 0 (0) (0) (0)	1 0 0 0 (100) (0) (0) (0)
	necrosis:olfactory epithelium	0 0 0 (0)(0)(0)	0 2 0 (0) (100) (0)	0 0 0 (0) (0) (0)	0 0 0 (0) (0) (0)	1 0 0 0 (100) (0) (0) (0)
[Hematopoiet	ic system]					
thymus	atrophy	< 2> 0 0 0 (0) (0) (0)	<pre></pre>	0 0 0		< 1> 1 0 0 0 (100) (0) (0) (0)
Grade ⟨a⟩ b (c)	1: Slight 2: Moderate 3: A a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100	arked 4 : Severe				

(HPT150)

BAIS3

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY) SACRIFICED ANIMALS (3W)

 \sim

~~

				FAGE • 4
Organ	No	oup Name 300.0ppm . of Animals on Study 0 ade <u>1 2 3 4</u> (%) (%) (%) (%)	$ \begin{array}{c} 600.0ppm \\ 0 \\ \frac{1}{(\%)} (\%) (\%) (\%) (\%) \end{array} $	
[Respiratory	v system]			
nasal cavit	inflammatory infiltration	< 0> (-) (-) (-) (-)	< 0> (-) (-) (-) (-)	
	inflammatory polyp	(-) (-) (-) (-)	(-)(-)(-)	
	respiratory metaplasia:olfactory epithel	ium	(-) (-) (-) (-)	
	atrophy:olfactory epithelium	() () ()	() () ()	
	necrosis:olfactory epithelium		(-) (-) (-) (-)	
[Hematopoiet	cic system]			
thymus	atrophy	< 0> 	< 0> 	
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	Marked 4 : Severe		
(HPT150)				

(HPT150)

BAIS3

APPENDIX J 1

IDENTITY OF GLYCIDOL IN THE 2-WEEK INHALATION STUDY

IDENTITY OF GLYCIDOL IN THE 2-WEEK INHALATION STUDY

Test Substance Lot No.: SKG5118

1. Spectral data

)

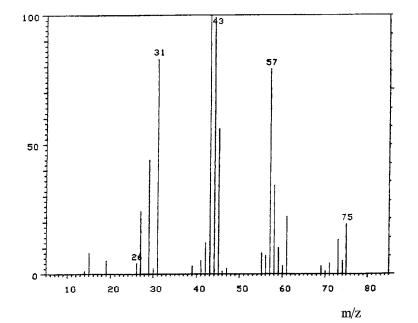
)

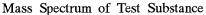
Mass Spectrometry

Instrument	:	Hitachi	M-80B	Mass	Spectrometer
------------	---	---------	-------	------	--------------

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV





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

Results: The mass spectrum was consistent with literature spectrum.

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

Infrared Spectrometry

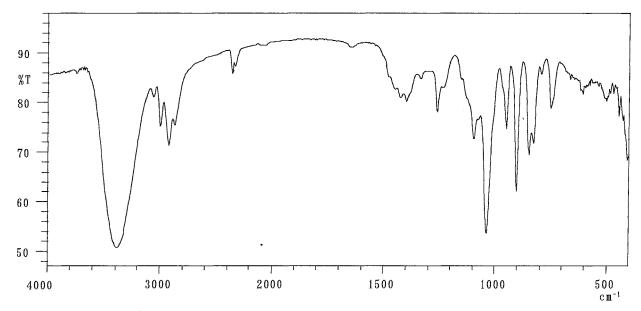
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

Cell : KBr Liquid Cell

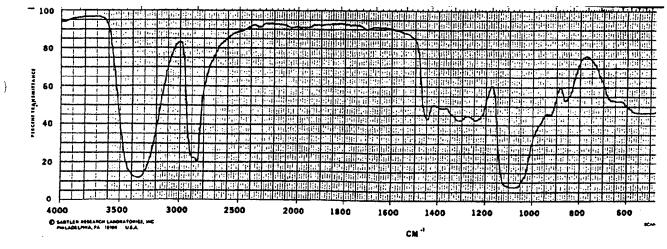
Resolution

)

: 4 cm⁻¹



Infrared Spectrum of Test Substance



Infrared Spectrum of Glycidol(literature spectrum*)

Results: The infrared spectrum was consistent with literature spectrum.

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

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

APPENDIX J 2

STABILITY OF GLYCIDOL IN THE 2-WEEK INHALATION STUDY

STABILITY OF GLYCIDOL IN THE 2-WEEK INHALATION STUDY

Test Substance Lot No.: SKG5118

1.Sample: This lot was used from 1996.4.3 to 1996.4.16. Test substance was stored at room temperature.

2. Gas Chromatography

)

)

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

Results: Gas chromatography indicated one major peak (peak No.3) and two impurities (peak No.1,2 < 1% of total area) analyzed at 1996.3.14 and one major peak (peak No.3) and two impurities (peak No.1,2 < 1% of total area) analyzed at 1996.4.18. No new trace impurity peak in the test substance analyzed at 1996.4.18 was detected.

Date (date analyzed)	Peak No.	Retention Time (min)	Area(%)
1996.03.14	1	1.89	0.15
	2	2.13	0.23
	3	2.52	99.62
996.04.18	1	1.89	0.15
	2	2.12	0.23
	3	2.52	99.62

4. Conclusions: The results indicated that the test substance did not change when stored at room temperature during this period (for about 1 month).

APPENDIX K 1

CONCENTMOUSEION OF GLYCIDL IN THE INHALATION CHAMBER

Group Name	Concentration(ppm) Mean \pm S.D.		
Control	0.0 ± 0.0		
37.5ppm	36.7 ± 0.9		
75.0ppm	73.7 ± 1.4		
150.0ppm	148.4 ± 3.4		
300.0ppm	304.7 ± 6.2		
600.0ppm	597.2 ± 0.0		

-

CONCENTRATION OF GLYCIDOL IN THE INHALATION CHAMBER OF THE 2-WEEK INHALATION STUDY

-

APPENDIX K 2

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 2-WEEK INHALATION STUDY OF GLYCIDOL

Group Name	Temperature(°C) Mean ± S.D.	Humidity(%) Mean ± S.D.	Ventilation Rate(L/min) Mean \pm S.D.	Air Change(time/h) Mean
Control	22.1 ± 0.1	52.6 ± 0.2	$103.4 \pm 1.1 (55.2 \pm 2.5)$	11.9 (6.4)
62.5ppm	21.8 ± 0.1	50.1 ± 1.8	$104.7 \pm 1.4 (54.5 \pm 2.9)$	12.1 (6.3)
125.0ppm	21.9 ± 0.1	50.7 ± 2.1	$103.9 \pm 1.5 (55.6 \pm 2.7)$	12.0 (6.4)
250.0ppm	21.6 ± 0.2	49.0 ± 2.9	$104.3 \pm 1.3 (55.6 \pm 2.7)$	12.0 (6.4)
500.0ppm	21.7 ± 0.3	49.7 ± 4.8	$104.9 \pm 1.1 (53.3 \pm 1.1)$	12.1 (6.2)
1000.0ppm	21.6 ± 0.5	52.5 ± 8.0	$104.9 \pm 0.6 (52.7 \pm 0.0)$	12.1 (6.1)

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 2-WEEK INHALATION STUDY OF GLYCIDOL

(): durig exposure

APPENDIX L 1

METHODS FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-WEEK INHALATION STUDY OF GLYCIDOL

METHODS FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-WEEK INHALATION STUDY OF GLYCIDOL

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

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

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

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

)

APPENDIX L 2

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-WEEK INHALATION STUDY OF GLYCIDOL

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 2-WEEK INHALATION STUDY OF GLYCIDOL

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

)

)