グリシドールのラットを用いた 吸入による2週間毒性試験報告書

試験番号:0307

# **APPENDIX**

#### **APPENDIXES**

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## APPENDIX A 1

CLINICAL OBSERVATION: SUMMARY, RAT: MALE

STUDY NO. : 0307 ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 2

SEX : MALE CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

	aroup wante	Adminis	stration	Week-day	7						
Clinical sign	Group Name	1-2	1-4	1-7	2-3	2-7	 	 	· · · · · · · · · · · · · · · · · · ·	 	 
		1-2	1	1	1	1					
		1	1	Ţ	1	1					
DEATH	Oppm	0	0	0	٥	. 0					
PLATII	оррш 37.5ppm	0	0	0	0 0	0					
	75.0ppm			0		-					
		0	0 0		0 0	0					
	150.0ppm	0		0	U	0					
	300.0ppm	0	10		-						
	600.0ppm	2(10)	-	-	-	-					
PILOERECTION	Oppm	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	0	0	-	-	_					
	600.0ppm	8	-	-	-	-					
IDDDAW ID DDBIMUING											
IRREGULAR BREATHING	mqq0	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	0	0	-	-	-					
	600.0ppm	8	-	-	-	-					
ADMODMAL DESCRIPTION			_		_	_					
ABNORMAL RESPIRATION	mqq0	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	0	0	-	-	-					
	600.0ppm	8	-	-	-	-					
RESPIRATORY SOUND ABNORMAL	Oppm	0	0	٥	0	0					
TALLADARA AROUG THOTALL ROLL	оррт 37.5ppm	0	0	0	0	0					
		•	0	0	0	0					
	75.0ppm	0	0	0	0	0					
	150.0ppm	0	0	0	0	0					
	300.0ppm	0	0	-	-	-					
	600.0ppm	3	-	-	_	-					

( ):after exposure

## APPENDIX A 2

CLINICAL OBSERVATION: SUMMARY, RAT: FEMALE

STUDY NO. : 0307 ANIMAL : RAT F344/DuCrj REPORT TYPE : A1 2

CLINICAL OBSERVATION (SUMMARY) ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Admin	istration	Week-day	,		 	
•	•	1-2 1	1-4	1-7 1	2-3 1	2-7 1		
				_ ,=/			 	
NOSE HEMORRHAGIC DISCHAGE	mqq0	0	0	0	0	0		
	37.5ppm	0	0	0	0	0		
	75.0ppm	0	0	0	0	0		
	150.Оррш	0	0	0	0	0		
	300.0ppm	0	0	-	-	-		
	600.0ppm	8	-	_	-	_		

## APPENDIX B 1

BODY WEIGHT CHANGES :SUMMARY, RAT : MALE (2-WEEK STUDY)

ANIMAL : RAT F344/DuCrj

UNIT : g

REPORT TYPE : A1 2

SEX : MALE

BODY WEIGHT CHANGES (SUMMARY) ALL ANIMALS

PAGE: 1

Name	Admin	stration	week-day	·		•							
	0-0		1-2		1-4		1-7		2-3		2-7		
0ppm	115±	3	124±	4	129±	5	138±	6	150±	7	166±	8	
37.5ppm	115±	3	123±	3	126±	4	136±	5	145±	7	159±	9	
75.0ppm	115±	3	121±	5	122±	5**	133±	7	140±	8*	154±	10**	
150.0ppm	115±	3	114±	4**	109±	4**	120±	4**	117±	5**	129±	6**	
300.0ppm	115±	4	106±	3**	-		~		-		-		
600.0ppm	115±	3	99±	4**			-		-		-		
Significant differenc	e; *:P≦	0.05	**: P ≤ 0.0	)1			Test of Du	ınnett					-

(HAN260)

BAIS 3

## APPENDIX B 2

BODY WEIGHT CHANGES: SUMMARY, RAT: FEMALE

ANIMAL : RAT F344/DuCrj

UNIT : g

REPORT TYPE: A1 2

SEX : FEMALE

BODY WEIGHT CHANGES ALL ANIMALS

(SUMMARY)

Group Name Administration week-day

Group Name	Administration	week-day					
	0-0	1-2	1-4	1-7	2-3	2-7	
0ppm	93± 3	98± 3	100± 4	104± 4	108± 5	116± 6	
37.5ppm	93± 3	97± 3	99± 3	104± 4	108± 4	114± 5	
75.0ppm	93± 3	96± 3	96± 4*	101± 4	103± 4*	110± 3*	
150.0ppm	93± 3	92± 3**	87± 4**	95± 4**	93± 5**	102± 5**	
300.0ppm	93± 3	86± 5**	-		<b></b>	-	
600.0ppm	93± 3	-	-	-	<b>-</b>	-	

Significant difference;  $*:P \le 0.05$   $**:P \le 0.01$ Test of Dunnett (HAN260)

BAIS 3

## APPENDIX C 1

FOOD CONSUMPTION CHANGES : SUMMARY, RAT : MALE (2-WEEK STUDY)

ANIMAL : RAT F344/DuCrj UNIT : g

REPORT TYPE : A1 2 SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)

ALL ANIMALS

: MALE				PAGE :
up Name	Administration 1-7(6)	week-day(effective)2-7(7)		
Oppm	15.2± 0.8	15.2± 0.9		
37.5ppm	14.4± 0.5*	14.3± 0.8		
75.0ppm	13.0± 0.8**	14.0± 1.3		
150.0ppm	9.9± 0.8**	10.7± 0.4**		
300.0ppm	-	-		
Mqq0.008	-	· <u>-</u>		
Significant difference	ce; *: P ≤ 0.05	** : P ≤ 0.01	Test of Dunnett	
N260)				ВАІ

## APPENDIX C 2

FOOD CONSUMPTION CHANGES: SUMMARY, RAT: FEMALE

ANIMAL : RAT F344/DuCrj UNIT : g

REPORT TYPE : A1 2

SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY) ALL ANIMALS

PAGE: 2

oup Name	Administration 1-7(6)	week-day(effective) 2-7(7)
Oppm	11.5± 0.6	10.9± 0.7
37.5ppm	11.3± 0.8	10.7± 0.6
75.0ppm	11.0± 0.7	10.3± 0.5
150,0ppm	8.2± 0.7**	9.3± 0.6**
300.0ppm	-	-
600.0ppm	-	<del></del>
Significant differen	ce; *:P≦0.05 *	**: P ≤ 0.01

(HAN260)

BAIS 3

## APPENDIX D 1

HEMATOLOGY: SUMMARY, RAT: MALE

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1 SEX: MALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY) ALL ANIMALS ( 3W)

Name	NO. of Animals	RED BLO	OOD CELL µl	g ∕dl HEMOGLO	BIN	HEMATOC %	RIT	MCV f Q		MCH pg		g/dl MCHC		PLATELE 1 Ο³ / μ.	
0ppm	5	8.17±	0.41	15.5±	0.8	44.0±	2.2	53.9±	0.3	19.0±	1.8	35.2±	3.4	907±	45
37.5ppm	5	8.54±	0.18	15.7±	0.6	45.6±	1.2	53.4±	0.6	18.4±	0.4	34.4±	0.8	879±	55
75.0ppm	5	8.52±	0.11	15.7±	0.4	45.7±	0.6	53.6±	0.3	18.4±	0.5	34.4±	0.9	, 894±	59
150.0ppm	5	8.25±	0.14	15.3±	0.3	44.0±	1.0	53.4±	0.6	18.6±	0.5	34.7±	1.2	776±	79**
300.0ppm	0	-						-		-		-			
600.0ppm	0	-		-		<del>+</del>		<del></del>		<del>-</del>		<del></del>		-	

(HCL070)

BAIS 3

ANIMAL : RAT F344/DuCrj

HEMATOLOGY (SUMMARY) ALL ANIMALS ( 3W)

MEASURE. TIME: 1

SEX : MALE

REPORT TYPE : A1

PAGE: 2 Group Name NO. of RETICULOCYTE PROTHROMBIN TIME APTT ‰ Animals sec sec 0ppm 5 43± 7 12.5± 1.2 22.2± 7.6 37.5ppm 5 41士 9 12.3± 0.6 21.8± 1.8 75.0ppm 5 40± 7 20.2± 4.8  $12.6 \pm$ 0.8 150.0ppm 5 20± 4\*\* 12.1± 0.9 22.5± 4.1 300.0ppm 0 600.0ppm 0 Significant difference;  $*:P \leq 0.05$ \*\* :  $P \le 0.01$ Test of Dunnett

(HCL070)

BAIS 3

SEX : MALE

ANIMAL : RAT F344/DuCrj MEASURE. TIME : 1

REPORT TYPE : A1

HEMATOLOGY (SUMMARY) ALL ANIMALS ( 3W)

Group Name	NO. of Animals	WBC 1 O³∕µશ	Dit N-BAND	fferentia	L WBC (% N-SEG	5)	EOSINO	·	BASO		МОМО		LYMPHO		OTHERS
0ppm	5	4.61± 0.93	0±	0	19±	3	1±	0	0±	0	4±	2	76±	4	-
37.5ppm	5	5.81± 1.80	0±	0	14±	2	1±	1	0±	0	3±	1	81±	3	-
75.0ppm	5	4.87± 0.73	0±	0	19±	4	1±	1	0±	0	4±	2	76±	5	-
150.0ppm	5	5.60± 0.27	0±	0	20±	6	0±	1	0±	0	5±	2	75±	7	_
300.0ppm	0	-	-		-				-		-		-		~
600.0ppm	0	-	-		-		-		-		-		-		-
Significant	difference :	*: P ≤ 0.05	**: P ≦	0.01			Test	of Duni	nett						

(HCL070)

BAIS 3

## APPENDIX D 2

HEMATOLOGY: SUMMARY, RAT: FEMALE

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1 SEX: FEMALE

REPORT TYPE : A1

HEMATOLOGY (SUMMARY) ALL ANIMALS ( 3W)

Group Name NO. of RED BLOOD CELL HEMOGLOBIN HEMATOCRIT MCV MCH MCHC PLATELE Animals 106/με g/dε % f. D pg g/dε 103/μ

Animals	1 0°/µl	a ∖qr Hewogrorin	HEMATOCRIT %	f Q	non Pg	MCHC g∕dl	PLATELET 1 O³ / μℓ
5	8.95± 0.19	16.7± 0.7	47.0± 1.1	52.5± 0.3	18.6± 0.5	35.5± 0.8	804± 32
5	9.07± 0.35	17.1± 0.5	47.9± 1.8	52.8± 0.3	18.8± 0.4	35.6± 0.8	810± 48
5	8.73± 0.56	16.9± 0.6	45.9± 3.0	52.6± 0.3	19.4± 1.5	36.9± 2.9	716± 85*
5	8.93± 0.20	16.2± 0.2	46.9± 1.2	52.5± 0.5	18.2± 0.3	34.6± 0.8	747± 26
0	-	-	-	-	-	-	-
0	-	-	-		-	-	-
	Animals 5 5 5 0	1 0°/με  5 8.95± 0.19  5 9.07± 0.35  5 8.73± 0.56  5 8.93± 0.20  0 -	Animals $10^6/\mu$ g/dl $9/d$ 5 $8.95\pm$ 0.19 $16.7\pm$ 0.7 5 $9.07\pm$ 0.35 $17.1\pm$ 0.5 5 $8.73\pm$ 0.56 $16.9\pm$ 0.6 5 $8.93\pm$ 0.20 $16.2\pm$ 0.2	Animals $10^6/\mu$ $g/d$ %  5 $8.95\pm 0.19$ $16.7\pm 0.7$ $47.0\pm 1.1$ 5 $9.07\pm 0.35$ $17.1\pm 0.5$ $47.9\pm 1.8$ 5 $8.73\pm 0.56$ $16.9\pm 0.6$ $45.9\pm 3.0$ 5 $8.93\pm 0.20$ $16.2\pm 0.2$ $46.9\pm 1.2$	Animals $10^{6}/\mu$ $g/d$ % $f$ 0.  5 $8.95\pm 0.19$ $16.7\pm 0.7$ $47.0\pm 1.1$ $52.5\pm 0.3$ 5 $9.07\pm 0.35$ $17.1\pm 0.5$ $47.9\pm 1.8$ $52.8\pm 0.3$ 5 $8.73\pm 0.56$ $16.9\pm 0.6$ $45.9\pm 3.0$ $52.6\pm 0.3$ 5 $8.93\pm 0.20$ $16.2\pm 0.2$ $46.9\pm 1.2$ $52.5\pm 0.5$	Animals $10^6/\mu$ $g/d$ $8/6$ $6/6$ $9/6$	Animals 10°/με g/dε % f Ω pg g/dε  5 8.95± 0.19 16.7± 0.7 47.0± 1.1 52.5± 0.3 18.6± 0.5 35.5± 0.8  5 9.07± 0.35 17.1± 0.5 47.9± 1.8 52.8± 0.3 18.8± 0.4 35.6± 0.8  5 8.73± 0.56 16.9± 0.6 45.9± 3.0 52.6± 0.3 19.4± 1.5 36.9± 2.9  5 8.93± 0.20 16.2± 0.2 46.9± 1.2 52.5± 0.5 18.2± 0.3 34.6± 0.8

PAGE: 4

(HCL070) BAIS 3

ANIMAL : RAT F344/DuCrj
MEASURE. TIME : 1
SEX : FEMALE REPOR

REPORT TYPE : A1

HEMATOLOGY (SUMMARY) ALL ANIMALS ( 3W)

oup Name	NO. of Animals	RETICULO ‰	CYTE	PROTHRON sec	MBIN TIME	APTT sec				
0ppm	5	23±	3	11.6±	0.5	18.6±	5.5			
37.5ppm	5	22±	4	11.1±	0.6	19.0±	4.9			
75.0ppm	5	20±	4	11.5±	0.3	17.0±	3.9			•
150.0ppm	5	19士	2	11.6±	0.4	17.2±				
300.0ppm	0	•~		-		-				
600.0ppm	0	-		-		-				
Significant o	difference;	*: P ≦ 0	.05	**: P ≤ 0.0	1			Test of Dunnett		
CL070)						***				 

ANIMAL : RAT F344/DLCrj MEASURE. TIME : 1

SEX : FEMALE

HEMATOLOGY (SUMMARY) ALL ANIMALS ( 3W)

REPORT TYPE : A1

oup Name	NO. of Animals	WBC 1 O³∕μℓ	Dif N-BAND	ferentia	L WBC (% N-SEG	ś)	EOSINO		BASO		MONO		LYMPHO		OTHERS
0ppm	5	4.07± 1.96	0±	0	19±	3	1±	1	0±	0	4±	1	76±	4	-
37.5ppm	5	3.59± 1.34	0±	0	18士	7	1±	1	0±	0	4±	2	77±	8	_
75.0ppm	5	3.21± 0.59	0±	0	18±	7	1±	1	0±	0	4±	2	77±	6	-
150.0ppm	5	4.78± 1.37	0±	0	18±	4	1±	1	0±	0	4±	2	77±	4	-
300.0ppm	0	-	-		-		-		-		-		-		-
600.0ppm	0	~	-		-		-		-		-		-		
Significant	difference :	*: P ≤ 0.05	** : P ≦	0.01			Test	of Dun	nett						
CL070)							*****								• • • • • • • • • • • • • • • • • • • •

## APPENDIX E 1

BIOCHEMISTRY: SUMMARY, RAT: MALE

ANIMAL : RAT F344/DuCrj MEASURE. TIME : 1 SEX : MALE REPOR

BIOCHEMISTRY (SUMMARY) ALL ANIMALS ( 3W)

REPORT TYPE : A1

oup Name	NO. of Animals	TOTAL P		g∕d%		A/G RAT	TIO	T-BILI mg/dl		GLUCOSE mg/dl		T-CHOLES	TEROL	TRIGLYCE mg/dl	RIDE
mada	5	5.6±	0.0	3.8±	0.1	2.0±	0.1	0.14±	0.01	158±	12	49±	4	32±	3
37.5ppm	5	5.6±	0.1	3.7±	0.1	2.0±	0.1	0.13±	0.01	141±	8	49±	4	26±	6
75.0ppm	5	5.6±	0.1	3.7±	0.0	2.0±	0.1	0.13±	0.00	136±	10*	49±	3	25±	4*
150.0ppm	5	5.6±	0.1	3.7±	0.1	2.0±	0.1	0.14土	0.01	133±	11**	53±	3	21±	3**
300.0ppm	0	-		-		-		-		-		-		-	
600.0ppm	0	-		-		-		-		_		-		-	
Significant o	defference ;	*: P ≤ 0	0.05	**: P ≤ 0.0	)1		,	Test of Du	nnett		<del>. , , , , , , , , , , , , , , , , , , ,</del>		_		
L074)	·													<u></u>	

STUDY NO. : 0307 ANIMAL : RAT F344/DuCrj MEASURE. TIME : 1 SEX : MALE REPOR

BIOCHEMISTRY (SUMMARY) ALL ANIMALS ( 3W)

REPORT TYPE : A1

PAGE: 2

roup Name	NO. of Animals	PHOSPHO mg/dl	LIPID	GOT IU/2		GPT IU/2		LDH IU/£		ALP IU/1	ļ	G−GTP IU∕£		CPK IU/Q	
mqq0	5	88±	4	70±	2	33±	1	231±	77	831±	38	1±	1	228±	24
37.5ppm	Б	88±	4	73±	4	35±	3	217生	53	806±	34	1±	1	199±	23
75.0ppm	5	88±	4	70±	3	34±	1	206士	28	812±	81	1±	1	203±	33
150.0ppm	5	92±	3	64±	1*	31±	2	184±	15	747±	43	2±	1	161±	20**
300.0ppm	0			-		<del></del>		-		-		-		-	
600.0ppm	0	-				-		-		-		-		-	
Significant o	defference ;	*: P ≤ 0	.05	**: P ≤ 0.01				Test of Dun	nett						
ICL074)						·		· · · · · · · · · · · · · · · · · · ·						-	р

BAIS3

SEX : MALE

ANIMAL : RAT F344/DuCrj

MEASURE. TIME: 1

REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (3W)

oup Name	NO. of Animals	UREA NI mg∕dl	TROGEN	CREATIN mg/dl	INE	SODIUM mEq/Q		POTASSI mEq/		CHLORIDE mEq∕ Q		mg∕dl mg∕dl		INORGAN mg/dl	IC PHOSPHORU
0ppm	5	16.9±	1.1	0.4±	0.1	140±	2	4.1±	0.2	104±	0	10.2±	0.1	8.7±	0.2
37.5ppm	5	16.0±	0.9	0.4±	0.0	140±	1	4.4±	0.3	104土	1	10.2±	0.1	9.0±	0.3
75.0ppm	5	16.0±	0.5	0.4±	0.0	140±	1	4.2±	0.2	104±	1	10.2±	0.1	8.7±	0.4
150.0ppm	5	14.4±	1.7**	0.4±	0.0	140±	2	4.2±	0.2	104±	1	10.2±	0.2	8.8±	0.3
300.0ppm	0	-		-		-		-		-		-		-	
600.0ppm	0	-		-		-		_		-		<del></del>		-	

(HCL074)

BAIS 3

## APPENDIX E 2

BIOCHEMISTRY: SUMMARY, RAT: FEMALE

ANIMAL : RAT F344/DuCrj
MEASURE. TIME : 1
SEX : FEMALE REPOR

BIOCHEMISTRY (SUMMARY) ALL ANIMALS ( SW)

REPORT TYPE : A1

PAGE: 4

NO. of Animals	TOTAL P	ROTEIN	g∕dl g∕dl		A/G RAT	.10	T-BILI mg/dl		GLUCOSE mg/dl		T-CHOLES mg∕dl	TEROL	TRIGLYCI mg/dl	ERIDE
5	5.6±	0.2	3.7±	0.1	2.0±	0.1	0.18±	0.04	128±	13	67±	5	16±	3
5	5.6±	0.1	3.7±	0.1	2.0±	0.1	0.15±	0.01	115±	6	64±	5	16±	2
5	5.6±	0.1	3.7±	0.1	1.9±	0.0	0.17±	0.02	116±	10	70±	5	17±	4
5	5.4±	0.2	3.5±	0.1	1.9±	0.1	0.17±	0.02	120±	13	74±	5	21 ±	3
0	-		-		-		-				-		-	
0	-		-		-		-		_		-		-	
	5 5 5 0	5 5.6± 5 5.6± 5 5.4± 0 -	5 5.6± 0.2 5 5.6± 0.1 5 5.6± 0.1 5 5.4± 0.2	5 5.6 $\pm$ 0.2 3.7 $\pm$ 5 5.6 $\pm$ 0.1 3.7 $\pm$ 5 5.6 $\pm$ 0.1 3.7 $\pm$ 5 5.4 $\pm$ 0.2 3.5 $\pm$ 0 -	5 5.6 $\pm$ 0.2 3.7 $\pm$ 0.1 5 5.6 $\pm$ 0.1 3.7 $\pm$ 0.1 5 5.6 $\pm$ 0.1 3.7 $\pm$ 0.1 5 5.4 $\pm$ 0.2 3.5 $\pm$ 0.1 0	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	5 5.6 $\pm$ 0.2 3.7 $\pm$ 0.1 2.0 $\pm$ 0.1 5 5.6 $\pm$ 0.1 3.7 $\pm$ 0.1 2.0 $\pm$ 0.1 5 5.6 $\pm$ 0.1 3.7 $\pm$ 0.1 1.9 $\pm$ 0.0 5 5.4 $\pm$ 0.2 3.5 $\pm$ 0.1 1.9 $\pm$ 0.1 0.1	5       5.6±       0.2       3.7±       0.1       2.0±       0.1       0.18±         5       5.6±       0.1       3.7±       0.1       2.0±       0.1       0.15±         5       5.6±       0.1       3.7±       0.1       1.9±       0.0       0.17±         5       5.4±       0.2       3.5±       0.1       1.9±       0.1       0.17±         0       -       -       -       -       -       -	5 5.6 $\pm$ 0.2 3.7 $\pm$ 0.1 2.0 $\pm$ 0.1 0.18 $\pm$ 0.04 5 5.6 $\pm$ 0.1 3.7 $\pm$ 0.1 2.0 $\pm$ 0.1 0.15 $\pm$ 0.01 5 5.6 $\pm$ 0.1 3.7 $\pm$ 0.1 1.9 $\pm$ 0.0 0.17 $\pm$ 0.02 5 5.4 $\pm$ 0.2 3.5 $\pm$ 0.1 1.9 $\pm$ 0.1 0.17 $\pm$ 0.02 0	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	5       5.6±       0.2       3.7±       0.1       2.0±       0.1       0.18±       0.04       128±       13         5       5.6±       0.1       3.7±       0.1       2.0±       0.1       0.15±       0.01       115±       6         5       5.6±       0.1       3.7±       0.1       1.9±       0.0       0.17±       0.02       116±       10         5       5.4±       0.2       3.5±       0.1       1.9±       0.1       0.17±       0.02       120±       13         0       -       -       -       -       -       -       -	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	5     5.6±     0.2     3.7±     0.1     2.0±     0.1     0.18±     0.04     128±     13     67±     5     16±       5     5.6±     0.1     3.7±     0.1     2.0±     0.1     0.15±     0.01     115±     6     64±     5     16±       5     5.6±     0.1     3.7±     0.1     1.9±     0.0     0.17±     0.02     116±     10     70±     5     17±       5     5.4±     0.2     3.5±     0.1     1.9±     0.1     0.17±     0.02     120±     13     74±     5     21±       0     -     -     -     -     -     -     -     -     -     -

BAIS3

ANIMAL : RAT F344/DuCrj

MEASURE, TIME: 1 SEX : FEMALE

BIOCHEMISTRY (SUMMARY) ALL ANIMALS ( 3W)

p Name	NO. of Animals	mg/dl	LIPID	GOT IU/&		GPT IU/Q		LDH IU/	Q	ALP IU/S	,	G−GTP I U∕ℓ		CPK IU/.	2
0ppm	5	115±	5	74±	5	31±	2	539±	334	601±	30	2±	1	268±	114
37.5ppm	5	112±	4	76±	6	34±	5	380±	72	618±	37	2±	2	217±	25
75.0ppm	5	122±	8	75±	3	33±	2	376±	83	663±	30	2±	1	214±	24
150.0ppm	5	138±	8**	72±	6	32±	4	498±	144	676±	59*	3±	1	196±	47
300.0ppm	0			-		-		-		-		-		-	
600.0ppm	0	-		-		_		-		-		-		_	

(HCL074)

BAIS3

ANIMAL : RAT F344/DuCrj

MEASURE, TIME: 1

SEX: FEMALE REPORT TYPE : A1 BIOCHEMISTRY (SUMMARY) ALL ANIMALS ( 3W)

roup Name	NO. of Animals	UREA NI' mg∕dl	TROGEN	CREATIN mg/dl	INE	SODIUM mEq/Q		POTASSI mEq/		CHLORIDE mEq∕£		mg/dl CALCIUM		INORGAN mg/dl	IC PHOSPHORU
0ppm	5	16.9±	1.0	0.4±	0.1	139±	1	4.0±	0.1	107±	1	9.8±	0.2	7.9±	0.6
37.5ppm	5	15.6±	1.8	0.4±	0.1	140±	1	3.8±	0.2	106±	1	10.0±	0.1	7.9±	0.4
75.0ppm	5	16.8±	0.8	0.4±	0.1	139±	1	3.7±	0.2	106±	1	10.0±	0.1	7.5±	0.5
150.0ppm	5	14.5±	2.2	0.4±	0.1	137±	1*	4.0±	0.4	105±	1*	9.9±	0.2	8.0±	0.6
300.0ppm	0	-		~~		-		<del></del>		-		-		-	
600.0ppm	0	-		-		-		-		-		-			

PAGE: 6

(HCL074) BAIS3

### APPENDIX F 1

GROSS FINDINGS: SUMMARY, RAT: MALE

DEAD AND MORIBUND ANIMALS

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1 SEX

: MALE

Organ	Findings	Group Name Oppm NO. of Animals 0 (%)	37.5ppm 0 (%)	75.0ppm 0 (%)	150.0ppm 0 (%)
stomach	gas	- ( -)	- ( -)	- ( -)	- ( -)
small intes	gas	- ( -)	- ( - <u>)</u>	- ( -)	- ( -)
large intes	gas	- ()	- ( -)	- ( -)	- ( -)
thoracic ca	pleural fluid	- ( -)	- ( -)	- ( -)	- ( -)

(HPT080)

BAIS3

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : MALE

Organ	Findings	Group Name NO. of Animals	10	300.0ppm (%)	1(	600.0ppm 0 (%)
stomach	gas		10	(100)	10	0 (100)
small intes	gas			(100)		2 (20)
large intes	gas		10	(100)	2	2 ( 20)
thoracic ca	pleural fluid		0	( 0)	2	2 (20)
(HPT080)						BAIS 3

## APPENDIX F 2

GROSS FINDINGS : SUMMARY, RAT : MALE : SACRIFICED ANIMALS

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS ( 3W)

0rgan	Findings	Group Name NO. of Animals	0ppm 10 (%)	37.5ppm 10 (%)	75.0ppm 10 (%)	150.0ppm 10 (%)
.iver	herniation		1 (10)	0 ( 0)	1 (10)	0 ( 0)
HPT080)						BA

ANIMAL : RAT F344/DuCrj

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS ( 3W)

REPORT TYPE : A1
SEX : MALE

Organ	Findings	Group Name NO. of Animals	300.0ppm 0 (%)	600.0ppm 0 (%)	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
liver	herniation		- ( -)	- ( -)	
(HPT080)					BAIS 3

## APPENDIX F 3

GROSS FINDINGS: SUMMARY, RAT: FEMALE

DEAD AND MORIBUND ANIMALS

(2-WEEK STUDY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

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

SEX : FEMALE

PAGE: 3

Organ	Findings	Group Name NO. of Animals	mqq0 (%) 0	37.5ppm 0 (%)	75.0ppm 0 (%)	150.0ppm 0 (%)
tomach	gas		- ( -)	- ( -)	~ ( -)	- ( -)
all intes	gas		- ( -)	- ( -)	- ( -)	- ( -)
rge intes	gas		- ( -)	- ( -)	- ( -)	- ( -)
oracic ca	pleural fluid		- ( -)	- ( -)	- ( -)	- ( -)

(IIPT080)

ANIMAL : RAT F344/DuCrj

GROSS FINDINGS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0- 3W)

REPORT TYPE : A1

SEX

EX :	: FEMALE	PAGE:	4

Organ	Findings	Group Name NO. of Animals	10	300.0ppm (%)	10	600.0ppm (%)	
			10	(100)		. ( 00)	
stomach	98S		10	(100)	(	3 (80)	
small intes	gas		9	(90)	;	3 (90)	
large intes	gas		10	(100)	;	3 (80)	
thoracic ca	pleural fluid		0	( 0)		( 10)	
(HPTORO)							BAISS

(HPT080)

## APPENDIX F 4

GROSS FINDINGS : SUMMARY, RAT : FEMALE : SACRIFICED ANIMALS

(2-WEEK STUDY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS ( 3W)

SEX : FEMALE

Organ	Findings	Group Name NO. of Animals	Оррт 10 (%)	37.5ppm 10 (%)	75.0ppm 10 (%)	150.0ppm 10 (%)
liver	herniation		2 (20)	0 ( 0)	1 (10)	1 ( 10)
(HPT080)		-				BAIS

ANIMAL : RAT F344/DuCrj

GROSS FINDINGS (SUMMARY) SACRIFICED ANIMALS ( 3W)

REPORT TYPE : A1
SEX : FEMALE

Organ	Findings	Group Name NO. of Animals	0	300.0ppm (%)	600.0ppm 0 (%)	
liver	herniation			( -)	- ( -)	
(HPT080)			<del></del>			 BAIS 3

# APPENDIX G 1

ORGAN WEIGHT, ABSOLUTE: SUMMARY, RAT: MALE (2-WEEK STUDY)

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

UNIT: g

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

PAGE: 1

0.283± 0.015 0.056± 0.288± 0.039 0.061± 0.290± 0.035 0.055±	0.015 2.235±	0.160 0.	.619± 0.041 , .611± 0.038	0.726± 0.045 0.726± 0.041
				0.726± 0.041
0.290± 0.035 0.055±	0.010 2.348+			
	0.010 2.040 I	0.113 0.	.638± 0.062	0.747± 0.010
0.224± 0.021* 0.055±	0.016 2.097±	0.094** 0.	529± 0.015*	0.680± 0.037
	~		-	-
-	-		-	-

(HCL040)

ANIMAL : RAT F344/DuC-j REPORT TYPE : A1 SEX : NALE

UNIT: g

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

PAGE: 2

Group Name	NO. of Animals	KIDI	NEYS	SPLI	EEN	LIV	ER	BRA	IN
mqq0	5	1.228±	0.040	0.370±	0.015	4.709±	0.158	1.656±	0.026
37.5ppm	5	1.228±	0.052	0.359±	0.038	4.319±	0.227**	1.621±	0.036
75.0ppm	5	1.272±	0.018	0.353±	0.016	4.423±	0.188	1.653±	0.031
150.0ppm	5	1.201±	0.024	0.298±	0.013**	3.822±	0.125**	1.562±	0.034**
300.0ppm	0	-		-		-		-	
600.0ppm	0	-		-		. <del></del>		***	
Significant o	lifference;	*: P ≤ 0.0	05 *:	*: P ≤ 0.01			Te	st of Dunnet	t

(HCL040)

## APPENDIX G 2

ORGAN WEIGHT, ABSOLUTE: SUMMARY, RAT: FEMALE (2-WEEK STUDY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE: A1
SEX: FEMALE
UNIT: g

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

PAGE: 3

OUP Name	NO. of Animals	Body (	Veight	ТНҮМ	US	ADRE	NALS	OVAR	IES	HEAR	T	LUNG	S	
mqq0	5	104±	6	0.233±	0.009	0.064±	0.014	0.076±	0.012	0.471±	0.029	0.590±	0.041	
37.5ppm	5	101±	3	0.219±	0.016	0.052±	0.007	0.068±	0.004	0.440±	0.024	0.557±	0.019	
75.0ppm	5	98主	2	0.235±	0.021	0.062±	0.007	0.072±	0.009	0.465±	0.027	0.578±	0.012	
150.0ppm	5	90±	5**	0.199±	0.029*	0.058±	0.009	0.064±	0.005	0.448±	0.020	0.585±	0.035	
300.0ppm	0	-		-		-		-		-		-		
600.0ppm	0	-		-		~~		-		-		_		
Significant	difference;	*: P ≤ 0.0	)5 **	: P ≤ 0.01			Test	t of Dunnett						<u></u>

(HCL040)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

PAGE: 4

oup Name	NO. of Animals	KIDNEY	S SF	PLEEN	LIV	ER	BRA	N		
Mqq0	5	0.913± 0	.039 0.274±	0.017	3.139±	0.225	1,548±	0.036		
37.5ppm	5	0.925± 0	.049 0.257±	0.013	3.117±	0.099	1.495±	0.061		
75.0ppm	5	0.912± 0	.013 0.268±	0.020	3.039±	0.126	1.539±	0.021		
150.0ppm	5	0.990± 0	.066 0.239±	0.025*	3.007±	0.097	1.488±	0.050		
300.0ppm	0	-	-		-		-			
600.0ppm	0	-	-				-			

(HCL040)

## APPENDIX H 1

ORGAN WEIGHT, RELATIVE : SUMMARY, RAT : MALE

(2-WEEK STUDY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

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

SEX : MALE UNIT: % PAGE: 1

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS	
mad0	5	151± 6	0.187± 0.008	0.037± 0.006	1.555± 0.093	0.410± 0.026	0.480± 0.025	
37.5ppm	5	140± 6**	0.206± 0.023	0.044± 0.012	1.600± 0.087	0.438± 0.020	0.520± 0.018*	
75.0ppm	5	143± 5*	0.203± 0.019	0.038± 0.006	1.644± 0.052	0.447± 0.033	0.524± 0.023*	
150.0ppm	5	115± 3**	0.195± 0.022	0.047± 0.013	1.828± 0.091**	0.461± 0.012**	0.592± 0.018**	
300.0pm	0	<del>-</del>	-	~	-	-	-	
600.0ppm	0	-	-	-	-	-	-	
Significant	difference;	*: P ≤ 0.05 **	: P ≤ 0.01	Tes	t of Dunnett			
(HCL042)								BAISS

ANIMAL : RAT F344/DuC-j REPORT TYPE : A1 SEX : MALE UNIT: %

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

PAGE: 2

p Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN	
0ppm	5	0.813± 0.024	0.245± 0.008	3.115± 0.058	1.096± 0.035	
37.5ppm	5	0.880± 0.019**	0.257± 0.020	3.093± 0.079	1.163± 0.052*	
75.0ppm	5	0.892± 0.032**	0.247± 0.011	3.097± 0.071	1.159± 0.042	
150.0ppm	5	1.047± 0.017**	0.259± 0.009	3.329± 0.038**	1.361± 0.023**	
300.0ppm	0	-	-	-	-	
600.0ppm	0	-	-	-	-	

(HCL042)

# APPENDIX H 2

ORGAN WEIGHT, RELATIVE: SUMMARY, RAT: FEMALE

(2-WEEK STUDY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

PAGE: 3

oup Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS	
Mqq0	5	104± 6	0.226± 0.017	0.061± 0.013	0.073± 0.009	0.454± 0.017	0.569± 0.016	
37.5ppm	5	101± 3	0.218± 0.018	0.051± 0.007	0.067± 0.004	0.437± 0.016	0.553± 0.014	
75.0ppm	5	98± 2	0.241± 0.019	0.064± 0.007	0.074± 0.009	0.477± 0.030	0.592± 0.025	
150.0pm	5	90± 5**	0.222± 0.028	0.064± 0.011	0.072± 0.005	0.499± 0.016**	0.652± 0.037**	
300.0pm	0	-	-	-	-	-	-	
600.0pm	0	-	-	-	-	-	-	
Significant	difference;	*: P ≤ 0.05 *:	*: P ≤ 0.01	Tes	t of Dunnett	,		
CL042)								B/

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : FEMALE UNIT: %

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

PAGE: 4

up Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN	
0ppm	5	0.881± 0.019	0.265± 0.010	3.024± 0.098	1.495± 0.082	
37.5ppm	5	0.917± 0.030	0.255± 0.006	3.092± 0.030	1.486± 0.106	
75.0ppm	5	0.935± 0.026*	0.275± 0.020	3.113± 0.055	1.578± 0.054	
150.0ppm	5	1.102± 0.041**	0.265± 0.020	3.353± 0.137**	1.659± 0.075*	
300.0ppm	0	-	-	-	-	
600.0ppm	0	-	-	-	-	

(HCL042)

## APPENDIX I 1

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

RAT: MALE: DEAD AND MORIBUND ANIMALS

(2-WEEK STUDY)

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

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

: MALE SEX

Group Name 37.5ppm 75.0ppm 150.0ppm 0ppm No. of Animals on Study

Organ	Findings	Grade 1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)	1 2 3 4 (%) (%) (%) (%)
[Respiratory	system]				
nasal cavit	ulcer	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	< 0>  ( -) ( -) ( -) ( -)
	inflammatory infiltration	( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -)	( -) ( -) ( -) ( -)
	necrosis:olfactory epithelium	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)
	necrosis:respiratory epithelium	( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)
nasopharynx	necrosis:epithelium	( -) ( -) ( -) ( -)	( o) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)
Larynx	inflammatory infiltration	( -) ( -) ( -) ( -)	< 0>  ( -) ( -) ( -) ( -)	< 0>  ( -) ( -) ( -) ( -)	( -) ( -) ( -)
	necrosis:epithelium	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)
Grade <a> b (c)</a>	1: Slight 2: Moderate a: Number of animals examined at the b: Number of animals with lesion c: b / a * 100	3 : Marked 4 : Severe site			

(HPT150)

BAIS3

: RAT F344/DuCrj

HISTOLOGICAL FINDINGS :NON-NEOPLASTIC LESIONS (SUMMARY)

PAGE: 2

BAIS3

REPORT TYPE : A1 SEX : MALE

ANIMAL

(HPT150)

DEAD AND MORIBUND ANIMALS (0- 3W)

Group Name 300.0ppm 600.0ppm No. of Animals on Study 2 2 0rgan\_ Findings (%) [Respiratory system] nasal cavit < 2> < 2> ulcer 0 2 0 0 0 1 0 (0)(0)(100)(0) (0)(0)(50)(0) inflammatory infiltration (0)(0)(100)(0) (0)(0)(100)(0) necrosis:olfactory epithelium 0 0 2 0 0 0 2 0 ( 0) ( 0) (100) ( 0) (0)(0)(100)(0) necrosis:respiratory epithelium 0 0 2 0 0 0 2 0 (0)(0)(100)(0) (0)(0)(100)(0) < 2> nasopharynx < 2> 0 2 0 0 necrosis:epithelium 0 1 0 0 (0)(100)(0)(0) (0)(50)(0)(0) larynx < 2> < 2> inflammatory infiltration 0 0 0 0 1 0 0 (0)(0)(0)(0) (0)(50)(0)(0) necrosis:epithelium 1 1 0 (0)(0)(0)(0) (50) (50) (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

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

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

SEX : MALE

PAGE: 3

0rgan	Group Na No. of A Grade Findings	me Oppm animals on Study 0 1 2 3 4 (%) (%) (%) (%)	37.5ppm 0 1 2 3 4 (%) (%) (%) (%)	75.0ppm 0 1 2 3 4 (%) (%) (%) (%)	150.0ppm 0 1 2 3 4 (%) (%) (%) (%)
[Respirator	y system]				
trachea	necrosis:epithelium	< 0>  ( -) ( -) ( -) ( -)	< 0>  ( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)
lung	congestion	< 0>  ( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)
	edema	( -) ( -) ( -) ( -)	( -) ( -) ( -)	( -) ( -) ( -)	( -) ( -) ( -) ( -)
[Hematopoi	etic system]				
thymus	karyorrhexis	< 0>  ( -) ( -) ( -) ( -)	( -) ( -) ( -)	< 0>  ( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)
[Digestive	system]				
liver	congestion	< 0>  ( -) ( -) ( -) ( -)	< 0>  ( -) ( -) ( -) ( -)	< 0>  ( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)
Grade <a> b (c)</a>	1: Slight 2: Moderate 3: Marked a: Number of animals examined at the site b: Number of animals with lesion c: b / a * 100	d 4 : Severe			

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

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : MALE

Group Name 300 Oppm 600 0ppm

Organ	No	Dup Name 300.0ppm  of Animals on Study 2  ade 1 2 3 4  (%) (%) (%) (%)	600.0ppm 2 1 2 3 4 (%) (%) (%) (%)	
[Respirator	ry system]			
trachea	necrosis:epithelium	\( \lambda 2 \rangle \) 1	0 0 2 0 ( 0) ( 0) (100) ( 0)	
lung	congestian	( 2> 1	<pre></pre>	
	edema	1 0 0 0 (50) (0) (0) (0)	1 0 0 0 0 (50) ( 0) ( 0) ( 0)	
[Hematopoi	etic system]			
thymus	karyorrhexis ,	<pre></pre>	2> 1 0 1 0 (50) (0) (50) (0)	
[Digestive	system]			
liver	congestion	0 0 0 0 ( 0) ( 0) ( 0) ( 0)	2	
Grade <a>&gt; b (c)</a>	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)				BAISS

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1

SEX : MALE

Organ	Findings	Group Name No. of Animals on Study Grade 1 (%)	0 0 2 3 4 (%) (%) (%)	37.5ppm 0 1 2 3 4 (%) (%) (%) (%)	75.0ppm 0 1 2 3 4 (%) (%) (%) (%)	150.0ppm 0 1 2 3 4 (%) (%) (%) (%)
[Endocrine	system]					
adrenal			< 0>	< 0>	< 0>	< 0>
	necrasis	( -)	( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)
[Special se	ense organs/appandage]					
өуө	1		< 0>	< 0>	< 0>	< 0>
	keratitis	( -)	( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)
Grade <a> b (c)</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				
(HPT150)						BAI

ANIMAL : RAT F344/DuCrj

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

DEAD AND MORIBUND ANIMALS (0- 3W)

Group Name 300.0ppm 600.0ppm No. of Animals on Study 2 2 Grade Findings\_ [Endocrine system] adrenal < 2> < 2> 0 0 0 0 necrosis ( 0) ( 0) ( 0) ( 0) (0)(50)(0)(0) [Special sense organs/appandage] өуө < 2> keratitis 0 0 0 0 1 0 0 0 ( 0) ( 0) ( 0) ( 0) (50) (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) BAIS3

## APPENDIX I 2

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

RAT: MALE: SACRIFICED ANIMALS

(2-WEEK STUDY)

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

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

Organ	No	oup Name o, of Animals on Study rade 1 (%)	0ppm 2 2 3 4 (%) (%) (%)	37.5ppm 2 1 2 3 4 (%) (%) (%) (%)	75.0ppm 2 1 2 3 4 (%) (%) (%)	150.0ppm 2 1 2 3 4 (%) (%) (%)
[Respiratory	system]					
nasal cavit	ulcer	0 ( 0)	< 2> 0 0 0 ( 0) ( 0) ( 0)	<pre></pre>	<pre></pre>	<pre></pre>
	inflammatory infiltration	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)
	squamous cell metaplasia:respiratory ep	thelium 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 2 0 ( 0) (100) ( 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)	2 0 0 0 (100) ( 0) ( 0) ( 0)
	necrosis:olfactory epithelium	( 0)	0 0 0 0 ( 0) ( 0)	0 0 0 0 0 ( 0) ( 0) ( 0)	0 0 0 0 0 ( 0) ( 0)	0 1 0 0 (0) (50) (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 0 0	0 0 0 0 0 0 ( 0) ( 0)	1 0 0 0 (50) (0) (0) (0)
[Reproductiv	e system]					
prostate	inflammation	0 ( 0)	2> 1 0 0 (50) (0) (0)	<pre></pre>	<pre></pre>	<pre></pre>
Grade <a>&gt; b (c)</a>	1: Slight 2: Moderate 3: a: Number of animals examined at the sit b: Number of animals with lesion c: b / a * 100	Marked 4: Severe	•			

ANIMAL : RAT F344/DuCrj

SACRIFICED ANIMALS ( 3W)

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

Group Name 300.0ppm 600.0ppm No. of Animals on Study Findings\_ [Respiratory system] nasal cavit ulcer ( -) ( -) ( -) ( -) ( -) ( -) ( -) ( -) inflammatory infiltration ( -) ( -) ( -) ( -) ( -) ( -) ( -) ( -) squamous cell metaplasia:respiratory epithelium ( -) ( -) ( -) ( -) ( -) ( -) atrophy:olfactory epithelium ( -) ( -) ( -) ( -) ( -) ( -) ( -) ( -) necrosis:olfactory epithelium ( -) ( -) ( -) ( -) ( -) ( -) ( -) ( -) necrosis:squamous epithelium ( -) ( -) ( -) ( -) ( -) ( -) [Reproductive system] prostate < 0> inflammation ( -) ( -) ( -) ( -) ( -) ( -) Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe <a>></a> a: Number of animals examined at the site b b: Number of animals with lesion (c) c:b/a\*100

(HPT150)

## APPENDIX I 3

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

RAT: FEMALE: DEAD AND MORIBUND ANIMALS

(2-WEEK STUDY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE

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

Organ		up Name	37.5ppm 0 1 2 3 4 (%) (%) (%) (%)	75.0ppm 0 1 2 3 4 (%) (%) (%) (%)	150.0ppm 0 1 2 3 4 (%) (%) (%) (%)
[Respiratory	system]				
nasal cavit	ulcer	< 0>  ( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)
	inflammatory infiltration	( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -)	( -) ( -) ( -) ( -)
	necrosis:olfactory epithelium	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -)	( -) ( -) ( -) ( -)
	necrosis:respiratory epithelium	( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)
nasopharynx	necrosis:epithelium	( -) ( -) ( -) ( -)	< 0>  ( -) ( -) ( -) ( -)	< 0>  ( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)
larynx	inflammatory infiltration	< 0>  ( -) ( -) ( -) ( -)	< 0>  ( -) ( -) ( -) ( -)	< 0>  ( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)
	necrosis:epithelium	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)
Grade (a) b (c)	1: Slight 2: Moderate 3: Na : Number of animals examined at the site b: Number of animals with lesion c: b / a * 100	farked 4 : Severe	·		

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE

#### HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0- 3W)

Group Name 300.0ppm 600.0ppm No. of Animals on Study 2 Findings\_ [Respiratory system] nasal cavit < 2> 1 1 0 0 1 0 0 ulcer (0)(50)(50)(0) (0)(50)(0)(0) inflammatory infiltration 0 1 1 0 (0)(100)(0)(0) (0)(50)(50)(0) 0 0 2 0 0 0 2 0 necrosis:olfactory epithelium (0)(0)(100)(0) (0)(0)(100)(0) necrosis:respiratory epithelium 0 0 2 0 0 2 ( 0) ( 0) (100) ( 0) (0)(0)(100)(0) 〈 2〉 nasopharynx 〈 2〉 necrosis:epithelium 1 1 0 0 0 1 0 0 (0)(50)(0)(0) (50) (50) (0) (0) larynx < 2> 0 0 0 0 0 0 0 inflammatory infiltration (50) (0) (0) (0) (0)(0)(0)(0) necrosis:epithelium 0 1 0 0 1 1 0 (0)(50)(0)(0) (0)(50)(50)(0) Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe <a>></a> a: Number of animals examined at the site b b: Number of animals with lesion (c) c:b/a\*100

(HPT150)

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE DEAD AND MORIBUND ANIMALS (0- 3W)

Organ	Group Na No. of A Grade Findings	ne Oppm nimals on Study 0  1 2 3 4 (%) (%) (%) (%)	37.5ppm 0 1 2 3 4 (%) (%) (%) (%)	75.0ppm 0 1 2 3 4 (%) (%) (%) (%)	150.0ppm 0 1 2 3 4 (%) (%) (%) (%)
[Respirator:	y system]				
trachea	necrosis:epithelium	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)
lung	congestion	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	( -) ( -) ( -)	( -) ( -) ( -)
	edema	( -) ( -) ( -) ( -)		( -) ( -) ( -)	( -) ( -) ( -) ( -)
[Hematopoie	tic system]				
thymus	karyorrhexis	< 0>  ( -) ( -) ( -) ( -)	< 0>  ( -) ( -) ( -) ( -)	< 0>  ( -) ( -) ( -) ( -)	< 0>  ( -) ( -) ( -) ( -)
Digestive	system]				
stomach	erosion:forestomach	( -) ( -) ( -)	( -) ( -) ( -) ( -)	< 0>  ( -) ( -) ( -) ( -)	( -) ( -) .( -)
Grade (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	4 : Severe			

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1

DEAD AND MORIBUND ANIMALS (0- 3W)

SEX : FEMALE

0rgan		0 Name 300.0ppm  of Animals on Study 2  of 1 2 3 4  of (%) (%) (%) (%)	600.0ppm 2 1 2 3 4 (%) (%) (%) (%)	
[Respirator	y system]			
trachea	necrosis:epithelium	0 1 1 0 ( 0) ( 50) ( 50) ( 0)	<pre></pre>	
lung	congestion		<pre></pre>	
	edema	1 0 0 0 (50) (0) (0) (0)	2 0 0 0 (100) ( 0) ( 0) ( 0)	
[Hematopoie	tic system]			
thymus	karyorrhexis	<pre></pre>	<pre></pre>	
[Digestive	system]			
stomach	erosion:forestomach	2> 1 0 0 0 (50) (0) (0) (0)	<pre></pre>	
Grade <a>&gt; b (c)</a>	1: Slight 2: Moderate 3: Ma a: Number of animals examined at the site b: Number of animals with lesion c: b/a * 100	rked 4 : Severe		
(HPT150)				

ANIMAL : RAT F344/DuCrj

REPORT TYPE : A1 SEX : FEMALE

#### HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

DEAD AND MORIBUND ANIMALS (0- 3W)

[Endocrine system]  adrenal  necrosis  (-)(-)(-)(-)(-)(-)(-)(-)(-)(-)(-)(-)(-)(		150.0ppm 0 3 4 (%) (%)
Congestion		
adrenal (0) (0) (0)  (-)(-)(-)(-)(-)(-)(-)(-)(-)(-)(-)(-)(-)(		
Crade   1 : Stight   2 : Moderate   3 : Marked   4 : Severe   5 : Moderate   5 : Moderate   5 : Moderate   5 : Moderate   6 : Moderate   6 : Moderate   6 : Moderate   7 : Modera		
(a) a: Number of animals examined at the site b: Number of animals examined at the site		0> ( -) ( -)
(c) c:b/a*100	е	

STUDY NO. : 0307

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

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX : FEMALE

PAGE: 12

Organ	Findings	Group Name 300.0ppm  No. of Animals on Study 2  Grade 1 2 3 4  (%) (%) (%) (%)	600.0ppm 2 1 2 3 4 (%) (%) (%)	
[Digestive	system]			
liver	congestion	( 2) 0 0 0 0 ( 0) ( 0) ( 0) ( 0)	<pre></pre>	
[Endocrine	system]			
adrenal	necrosis	<pre></pre>	<pre></pre>	
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	3 : Marked 4 : Severe site		
(HPT150)				BAIS

# APPENDIX I 4

HISTOLOGICAL FINDINGS: NON-NEOPLASTIC LESIONS: SUMMARY

RAT: FEMALE: SACRIFICED ANIMALS

(2-WEEK STUDY)

STUDY NO. : 0307

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS (SUMMARY)

SACRIFICED ANIMALS ( 3W)

ANIMAL : RAT F344/DuCrj REPORT TYPE : A1

SEX

: FEMALE

PAGE: 3

Organ		Group Name Oppm No. of Animals on Study 2 Grade 1 2 3 4 (%) (%) (%) (%)	37.5ppm 2 1 2 3 4 (%) (%) (%) (%)	75.0ppm 2 1 2 3 4 (%) (%) (%) (%)	150.0ppm 2 1 2 3 4 (%) (%) (%) (%)
[Respirator:	y system]				
nasal cavit	: ulcer	<pre></pre>	0 0 0 0 ( 0) ( 0) ( 0) ( 0)	0 0 0 0 ( 0) ( 0) ( 0) ( 0)	2> 1 0 0 0 (50) (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)	1 1 0 0 (50) (50) (0) (0)
	necrosis:olfactory epithelium	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 1 0 0 (50) (50) (0) (0)
	necrosis:respiratory epithelium	0 0 0 0 0 ( 0) ( 0)	0 0 0 0 0 (0) (0)	0 0 0 0 0 (0) (0)	1 0 0 0 (50) (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 0 0 0 0 0 0 0 0 0 0 0	0 1 0 0 ( 0) ( 50) ( 0) ( 0)
(Digestive	system]				
liver	herniation	<pre></pre>	<pre></pre>	<pre></pre>	2> 1 0 0 0 (50) (0) (0) (0)
Grade <a>&gt; b (c)</a>	1: Slight 2: Moderate 3 a: Number of animals examined at the s b: Number of animals with lesion c: b/a * 100	: Marked 4 : Severe ite			
(HPT150)					RAI

(HPT150)

STUDY NO. : 0307

ANIMAL : RAT F344/DuCrj

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

REPORT TYPE : A1 SEX : FEMALE

PAGE: 4

Organ		Group Name 300.0ppm No. of Animals on Study 0 Grade 1 2 3 4 (%) (%) (%) (%)	600.0ppm 0 1 2 3 4 (%) (%) (%) (%)	
[Respirator	y system]			
nasal cavit	: ulcer	< 0>  ( -) ( -) ( -) ( -)	< 0>  ( -) ( -) ( -) ( -)	
	atrophy:olfactory epithelium	( -) ( -) ( -) ( -)	( -) ( -) ( -)	
	necrosis:olfactory epithelium	( -) ( -) ( -) ( -)	( -) ( -) ( -)	
	necrosis:respiratory epithelium	( -) ( -) ( -) ( -)	( -) ( -) ( -)	
	necrosis:squamous epithelium	( -) ( -) ( -) ( -)	( -) ( -) ( -) ( -)	
[Digestive	system]			
liver	herniation	( o> ( -) ( -) ( -) ( -)	( -) ( -) ( -)	
Grade <a> b (c)</a>	1: Slight 2: Moderate 3 a: Number of animals examined at the s b: Number of animals with lesion c: b/a*100	: Marked 4 : Severe ite		
(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

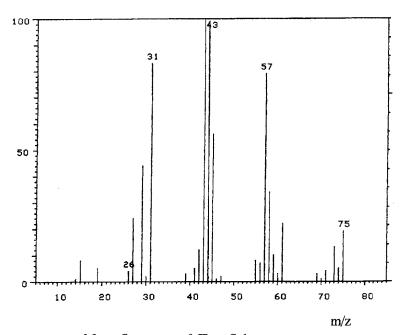
: Hitachi M-80B Mass Spectrometer

Ionization

: EI (Electron Ionization)

Ionization Voltage

: 70eV



Mass Spectrum of Test Substance

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

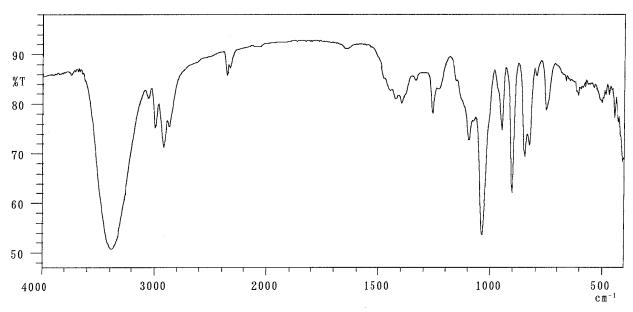
: Shimadzu FTIR-8200PC Infrared Spectrometer

Cell

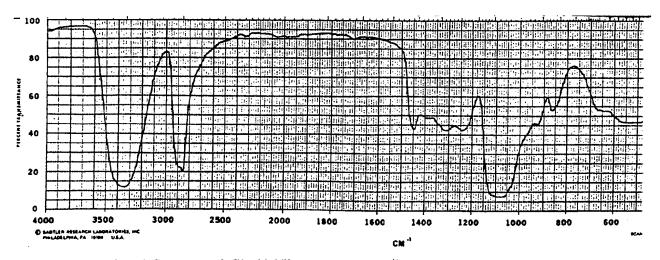
: KBr Liquid Cell

Resolution

: 4 cm<sup>-1</sup>



Infrared Spectrum of Test Substance



Infrared Spectrum of Glycidol(literature spectrum\*)

Results: The infrared spectrum was consistent with literature spectrum.

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

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.

# 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 1996.3.19 to 1996.4.1. 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	
1996.04.18	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

CONCENTRATION OF GLYCIDL IN THE INHALATION CHAMBER

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

Group Name	Concentration(ppm) Mean ± S.D.
Control	$0.0 \pm 0.0$
37.5ppm	$37.7 \pm 0.7$
75.0ppm	$75.2 \pm 1.3$
150.0ppm	$149.7 \pm 2.0$
300.0ppm	$301.4 \pm 1.4$
600.0ppm	$613.2 \pm 3.6$

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

## 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 ± S.D.	Air Change(time/h) Mean
Control	$22.2 \pm 0.1$	$54.2 \pm 0.3$	$212.2 \pm 2.2 \ (113.0 \pm 6.1)$	12.0 (6.4)
37.5ppm	$22.4 \pm 0.1$	$53.3 \pm 1.6$	$211.2 \pm 2.3 \ (114.1 \pm 5.9)$	12.0 (6.5)
75.0ppm	$22.3 \pm 0.1$	$52.8 \pm 2.0$	$209.8 \pm 2.1 \ (112.5 \pm 5.9)$	11.9 (6.4)
150.0ppm	$22.4 \pm 0.1$	$52.3 \pm 2.4$	$211.7 \pm 2.2 \ (112.8 \pm 5.8)$	12.0 (6.4)
300.0ppm	$22.3 \pm 0.6$	$49.1 \pm 3.4$	$209.8 \pm 2.2 \ (112.6 \pm 6.5)$	11.9 (6.4)
600.0ppm	$22.2 \pm 0.5$	$48.3 \pm 1.5$	$210.8 \pm 0.3 \ (108.0 \pm 2.7)$	11.9 (6.1)

( ): during 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 $ imes$ 100 $^{^{1)}}$
Platelet	Light scattering method 1)
Reticulocyte	Pattern recognition method (New methyleneblue staining)
Prothrombin time	Quick one stage method 2)
Activated partial thromboplastin time (APTT)	Ellagic acid activaterd method 2)
White blood cell (WBC)	Light scattering method 1)
Differential WBC	Pattern recognition method (May-Grunwald-Giemsa staining)
Biochemistry	
Total protein (TP)	Biuret method 4)
Albumin (Alb)	BCG method 4)
A/G ratio	Calculated as Alb/(TP-Alb)
T-bilirubin	Alkaline azobilirubin method 4)
Glucose	Enzymatic method (GLK·G-6-PDH)
T-cholesterol	Enzymatic method (CE·COD·POD)
Triglyceride	Enzymatic method (LPL·GK·GPO·POD) 4)
Phospholipid	Enzymatic method (PLD·COD·POD) 4)
Glutamic oxaloacetic transaminase (GOT)	UV·Rate method 4)
Glutamic pyruvic transaminase (GPT)	UV•Rate method 4)
Lactate dehydrogenase (LDH)	UV·Rate method 4)
Alkaline phosphatase (ALP)	p-Nitrophenylphosphate method 4)
$\gamma$ -Glutamyl transpeptidase ( $\gamma$ -GTP)	L- $\gamma$ -Glutamyl-p-nitroanilide method 4)
Creatine phosphokinase (CPK)	UV•Rate method 4)
Urea nitrogen	Enzymatic method (Urease · GLDH)
Creatinine	Jaffe method 4)
Sodium	Ion selective electrode method
Potassium	Ion selective electrode method 4)
Chloride	Ion selective electrode method 4)
Calcium	OCPC method 4)
Inorganic phosphorus	Enzymatic method (PNP·XOD·POD) 4)

- 1) Automatic blood cell analyzer (Technicon H·1: Technicon Instruments Corporation, USA)
- 2) Automatic coagulometer (Sysmex CA-5000 : Toa Medical Electronics Co.,Ltd.,Japan)
- 3) Automatic blood cell differential analyzer (Hitachi 8200: Hitachi, Ltd., Japan)
- 4) 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)	$\times 10^6/\mu L$	2
Hemoglobin	m g/dL	1
Hematocrit	%	1
Mean corpuscular volume (MCV)	$_{ m fL}$	1
Mean corpuscular hemoglobin (MCH)	pg	1
Mean corpuscular hemoglobin concentration (MCHC)	g/dL	1
Platelet	$\times 10^3 / \mu L$	0
Reticulocyte	%	0
Prothrombin time	sec	1
Activated partial thromboplastin time (APTT)	sec	1
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	${ m mg/dL}$	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
Creatinine	mg/dL	1
Sodium	mEq/L	0
Potassium	mEq/L	1
Chloride	mEq/L	0
Calcium	mg/dL	1
Inorganic phosphorus	$_{ m mg/dL}$	1