グリシドールのマウスを用いた
吸入による 13 週間毒性試験報告書

試験番号：０３１７

APPENDIX

APPENDIXES

APPENDIXES (CONTINUED)

APPENDIX A

CLINICAL OBSERVATION : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1 13

CLINICAL OBSERVATION (SUMMARY)
ALL ANIMALS

SEX : MALE

Clinical sign	Group Name	Administration Week-day 1-7	2-7	3-7	4-7	5-7	6-7	7-7	8-7	9-7	10-7	11-7	12-7	13-7
		1	1	1	1	1	1	1	1	1	1	1	1	1
DEATH	0ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	5ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	1	1	1	1	1	1	1	1	1	1	1
	40ppm	0	0	1	1	1	1	1	1	1	1	1	1	1
	80ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
LOCOMOTOR MOVEMENT DECR	0ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	5ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	40ppm	0	1	0	0	0	0	0	0	0	0	0	0	0
	80ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
ABNORMAL RESPIRATION	0ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	5ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	40ppm	0	1	0	0	0	0	0	0	0	0	0	0	0
	80ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
BRADYPNEA	0ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	5ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	40ppm	0	1	0	0	0	0	0	0	0	0	0	0	0
	80ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
SUBNORMAL TEMP	0ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	5ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	10ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	20ppm	0	0	0	0	0	0	0	0	0	0	0	0	0
	40ppm	0	1	0	0	0	0	0	0	0	0	0	0	0
	80ppm	0	0	0	0	0	0	0	0	0	0	0	0	0

APPENDIX B 1

BODY WEIGHT CHANGES :SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day 0-0	1-7	2-7	3-7	4-7	5-7	6-7
0ppm	22.5± 0.7	23.9± 0.9	24.9± 1.3	26.1± 1.5	26.9± 1.6	27.8± 1.8	28.8± 2.1
5ppm	22.5± 0.7	23.7± 0.9	24.7± 1.0	25.6± 1.0	26.2± 1.4	26.7± 1.3	27.6± 1.5
10ppm	22.5± 0.7	23.5± 0.8	24.9± 1.0	25.7± 1.1	26.7± 1.1	26.9± 1.3	27.5± 1.5
20ppm	22.5± 0.7	23.7± 1.6	24.7± 2.1	25.8± 1.1	26.7± 1.0	27.2± 1.0	27.9± 1.1
40ppm	22.5± 0.7	23.1± 1.4	23.7± 2.9	24.9± 1.3	26.1± 1.3	26.3± 1.6	26.9± 1.7
80ppm	22.5± 0.7	22.4± 0.9*	23.6± 0.7	23.5± 0.8**	24.3± 0.7**	25.2± 0.9**	24.9± 0.6**

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day 7-7	8-7	9-7	10-7	11-7	12-7	13-7
0ppm	29.3± 2.3	29.6± 2.5	30.4± 2.8	31.7± 3.1	32.5± 3.0	32.9± 3.4	33.8± 3.0
5ppm	28.4± 1.4	28.6± 1.8	28.9± 1.9	30.5± 2.0	31.4± 1.9	31.7± 2.6	33.0± 1.9
10ppm	28.3± 1.6	29.0± 1.6	29.9± 1.7	30.5± 1.8	31.3± 1.9	31.8± 1.9	32.0± 2.2
20ppm	29.0± 1.6	28.9± 1.6	29.5± 1.6	30.3± 1.8	30.9± 2.4	31.7± 2.1	32.1± 2.2
40ppm	27.7± 1.7	27.9± 1.6	27.8± 1.9*	28.8± 2.3	29.1± 1.9	29.6± 2.2	30.0± 1.8**
80ppm	25.6± 0.8**	26.3± 0.7**	25.6± 0.9**	26.9± 0.6**	27.1± 0.7**	27.3± 0.8**	27.3± 1.2**

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

APPENDIX B 2

BODY WEIGHT CHANGES : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day 0-0	1-7	2-7	3-7	4-7	5-7	6-7
0ppm	18.7± 0.7	19.5± 0.6	20.6± 0.6	21.3± 0.4	22.4± 1.1	22.5± 0.9	23.2± 1.2
5ppm	18.7± 0.7	19.2± 0.8	20.5± 0.8	21.4± 0.8	22.2± 0.9	23.2± 1.2	24.1± 1.4
10ppm	18.7± 0.7	19.5± 1.0	21.2± 1.0	21.3± 1.2	22.3± 1.2	22.3± 1.1	23.3± 1.3
20ppm	18.7± 0.7	19.3± 0.3	20.9± 0.7	21.3± 0.6	22.1± 0.8	22.8± 0.8	23.6± 1.1
40ppm	18.7± 0.7	18.7± 2.7	20.8± 1.4	21.2± 1.4	22.2± 1.1	22.5± 1.3	23.2± 1.1
80ppm	18.7± 0.7	19.3± 0.6	20.6± 0.4	20.7± 0.5	21.7± 0.5	21.7± 1.0	22.2± 0.7

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

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

BODY WEIGHT CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day 7-7	8-7	9-7	10-7	11-7	12-7	13-7
0ppm	23.5± 0.6	24.2± 1.7	24.2± 1.2	24.7± 0.8	24.9± 1.0	25.0± 1.2	25.5± 1.0
5ppm	24.1± 1.2	24.2± 1.2	24.5± 1.2	25.9± 1.5	25.8± 1.9	26.1± 1.8	26.8± 2.4
10ppm	23.4± 1.5	23.5± 1.6	24.2± 1.5	24.9± 2.0	24.5± 0.8	24.9± 1.3	25.1± 2.2
20ppm	23.4± 1.2	24.0± 0.8	24.3± 1.2	24.8± 1.5	24.9± 1.6	25.5± 1.3	25.3± 1.7
40ppm	24.4± 1.7	24.3± 1.1	24.3± 1.3	24.9± 1.2	24.4± 1.4	25.4± 1.3	26.0± 2.0
80ppm	22.6± 0.8	23.3± 0.6	22.7± 0.9*	24.1± 1.0	23.7± 0.8	24.2± 1.1	24.0± 0.8*

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

APPENDIX C 1

FOOD CONSUMPTION CHANGES : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day(effective) 1-7(6)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
0ppm	4.0± 0.4	4.0± 0.2	4.0± 0.3	4.2± 0.3	4.3± 0.3	4.4± 0.4	4.2± 0.3
5ppm	4.1± 0.2	4.0± 0.2	4.1± 0.3	4.2± 0.3	4.2± 0.3	4.4± 0.3	4.3± 0.3
10ppm	4.0± 0.2	4.2± 0.2	4.2± 0.3	4.3± 0.3	4.4± 0.3	4.4± 0.4	4.4± 0.3
20ppm	3.9± 0.7	4.1± 0.5	4.3± 0.4	4.5± 0.4	4.6± 0.4	4.6± 0.5	4.6± 0.5
40ppm	3.8± 0.5	4.0± 0.6	4.1± 0.3	4.3± 0.3	4.3± 0.4	4.3± 0.3	4.4± 0.3
80ppm	3.4± 0.4**	3.8± 0.2	3.7± 0.3*	4.0± 0.2	4.1± 0.2	3.8± 0.2**	4.1± 0.2

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

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : MALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day(effective) 8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)
0ppm	4.3± 0.4	4.4± 0.3	4.7± 0.3	4.5± 0.2	4.6± 0.2	4.5± 0.2
5ppm	4.4± 0.3	4.2± 0.4	4.9± 0.3	4.7± 0.4	4.6± 0.5	4.8± 0.3
10ppm	4.6± 0.3	4.5± 0.3	4.6± 0.4	4.6± 0.3	4.6± 0.3	4.5± 0.3
20ppm	4.6± 0.4	4.6± 0.4	4.8± 0.4	4.7± 0.4	4.8± 0.4	4.7± 0.4
40ppm	4.4± 0.3	4.3± 0.4	4.6± 0.4	4.3± 0.3	4.4± 0.4	4.4± 0.3
80ppm	4.0± 0.2	3.9± 0.2**	4.1± 0.2**	3.9± 0.2**	4.0± 0.1**	3.9± 0.2**

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

APPENDIX C 2

FOOD CONSUMPTION CHANGES : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day(effective) 1-7(6)	2-7(7)	3-7(7)	4-7(7)	5-7(7)	6-7(7)	7-7(7)
0ppm	3.5± 0.3	3.6± 0.2	3.7± 0.2	4.0± 0.2	4.0± 0.2	4.1± 0.3	4.1± 0.2
5ppm	3.4± 0.2	3.7± 0.2	4.0± 0.1**	4.3± 0.2**	4.5± 0.2**	4.6± 0.3**	4.5± 0.3**
10ppm	3.6± 0.3	3.8± 0.2	3.7± 0.2	4.0± 0.2	4.0± 0.2	4.2± 0.3	4.2± 0.2
20ppm	3.5± 0.2	3.8± 0.1	3.9± 0.1	4.1± 0.2	4.3± 0.2*	4.4± 0.2	4.5± 0.2**
40ppm	3.3± 0.6	3.8± 0.6	3.8± 0.3	4.1± 0.2	4.1± 0.3	4.2± 0.2	4.3± 0.4
80ppm	3.1± 0.3	3.7± 0.2	3.5± 0.2	3.7± 0.2*	3.8± 0.3	3.8± 0.2*	4.0± 0.2

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
UNIT : g
REPORT TYPE : A1 13
SEX : FEMALE

FOOD CONSUMPTION CHANGES (SUMMARY)
ALL ANIMALS

Group Name	Administration week-day(effective) 8-7(7)	9-7(7)	10-7(7)	11-7(7)	12-7(7)	13-7(7)
0ppm	4.1± 0.3	4.1± 0.3	4.3± 0.2	4.1± 0.4	4.1± 0.2	4.1± 0.3
5ppm	4.4± 0.2	4.3± 0.2	4.7± 0.2**	4.2± 0.2	4.4± 0.2*	4.3± 0.3
10ppm	4.3± 0.2	4.3± 0.1	4.3± 0.2	4.0± 0.2	4.3± 0.4	4.4± 0.4
20ppm	4.4± 0.2*	4.4± 0.2*	4.4± 0.3	4.1± 0.2	4.4± 0.3	4.2± 0.3
40ppm	4.3± 0.2	4.1± 0.3	4.2± 0.2	3.9± 0.1	4.2± 0.2	4.2± 0.3
80ppm	4.0± 0.3	3.9± 0.3	4.1± 0.3	3.7± 0.3	3.9± 0.2	3.6± 0.2**

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

APPENDIX D 1

HEMATOLOGY : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (14W)

Group Name	NO. of Animals	RED BLOOD CELL $10^6/\mu\ell$	HEMOGLOBIN g/dℓ	HEMATOCRIT %	MCV f ℓ	MCH p g	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
0ppm	10	10.75± 0.35	16.0± 0.5	50.1± 2.1	46.6± 0.9	14.9± 0.2	32.0± 0.8	1435± 100
5ppm	10	10.52± 0.31	15.9± 0.4	48.9± 1.2	46.5± 0.7	15.1± 0.5	32.5± 0.9	1456± 83
10ppm	10	10.79± 0.30	16.0± 0.6	50.1± 2.0	46.5± 0.8	14.8± 0.3	31.9± 0.5	1449± 93
20ppm	9	10.32± 0.25*	15.6± 0.3	47.9± 1.3*	46.3± 0.6	15.1± 0.5	32.7± 1.1	1441± 99
40ppm	9	10.54± 0.25	15.6± 0.2	48.7± 1.5	46.3± 0.7	14.8± 0.3	32.0± 0.8	1528± 75
80ppm	10	10.33± 0.38*	15.2± 0.5**	48.0± 1.9*	46.4± 1.1	14.7± 0.3	31.6± 0.7	1606± 95**

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

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (14W)

Group Name	NO. of Animals	WBC $10^3/\mu\ell$		Differential WBC (%) N-BAND		N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
0ppm	10	2.08±	1.27	0±	0	13±	3	2±	1	0±	0	3±	1	83±	3	0±	0
5ppm	10	1.88±	1.22	1±	1	14±	4	2±	1	0±	0	3±	1	80±	4	0±	0
10ppm	10	1.68±	1.08	0±	0	13±	3	1±	1	0±	0	2±	1	83±	4	0±	0
20ppm	9	1.35±	0.90	0±	0	14±	5	2±	1	0±	0	3±	1	81±	5	0±	0
40ppm	9	1.33±	1.08	0±	1	12±	2	2±	2	0±	0	2±	1	83±	4	0±	0
80ppm	10	1.12±	0.74	0±	0	14±	3	2±	1	0±	0	3±	1	82±	4	0±	0

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

APPENDIX D 2

HEMATOLOGY : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (14W)

Group Name	NO. of Animals	RED BLOOD CELL $10^6/\mu\ell$	HEMOGLOBIN g/dℓ	HEMATOCRIT %	MCV fℓ	MCH pg	MCHC g/dℓ	PLATELET $10^3/\mu\ell$
0ppm	10	10.39± 0.52	16.0± 0.5	48.1± 2.3	46.3± 0.6	15.4± 0.6	33.2± 1.1	1299± 84
5ppm	10	10.66± 0.28	16.1± 0.4	49.5± 1.4	46.5± 0.8	15.1± 0.2	32.5± 0.4	1265± 39
10ppm	10	10.62± 0.42	16.2± 0.5	49.7± 2.4	46.8± 0.6	15.3± 0.3	32.7± 0.7	1364± 97
20ppm	10	10.86± 0.19	16.2± 0.7	50.2± 1.1	46.2± 0.5	14.9± 0.5	32.3± 1.0	1382± 78
40ppm	10	10.55± 0.39	15.8± 0.5	48.8± 1.9	46.2± 0.6	15.0± 0.3	32.5± 0.6	1340± 118
80ppm	10	10.42± 0.27	15.7± 0.3	48.6± 1.5	46.6± 0.7	15.1± 0.4	32.4± 0.6	1370± 84

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

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

HEMATOLOGY (SUMMARY)
ALL ANIMALS (14W)

Group Name	NO. of Animals	WBC 10³/μℓ		Differential WBC (%) N-BAND		N-SEG		EOSINO		BASO		MONO		LYMPHO		OTHERS	
0ppm	10	1.85±	1.54	0±	0	14±	4	2±	1	0±	0	2±	1	82±	4	0±	0
5ppm	10	1.48±	1.25	0±	0	19±	7	2±	1	0±	0	2±	2	77±	7	0±	0
10ppm	10	1.57±	1.10	0±	0	15±	6	2±	1	0±	0	2±	1	81±	7	0±	0
20ppm	10	1.74±	0.99	0±	0	14±	5	2±	1	0±	0	3±	1	82±	5	0±	0
40ppm	10	1.58±	0.67	0±	0	14±	4	2±	2	0±	0	3±	1	81±	5	0±	0
80ppm	10	1.37±	0.43	0±	0	15±	4	3±	1	0±	0	2±	1	80±	4	0±	0

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

APPENDIX E 1

BIOCHEMISTRY : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (14W)

Group Name	NO. of Animals	TOTAL PROTEIN g/dℓ	ALBUMIN g/dℓ	A/G RATIO	T-BILIRUBIN mg/dℓ	GLUCOSE mg/dℓ	T-CHOLESTEROL mg/dℓ	TRIGLYCERIDE mg/dℓ
0ppm	10	5.2± 0.1	3.1± 0.1	1.5± 0.1	0.18± 0.02	162± 25	75± 13	23± 11
5ppm	10	5.2± 0.2	3.2± 0.1	1.6± 0.1	0.16± 0.01	169± 26	78± 11	20± 9
10ppm	10	5.3± 0.3	3.3± 0.2	1.6± 0.1	0.17± 0.02	169± 20	78± 8	19± 8
20ppm	10	5.2± 0.1	3.2± 0.1	1.6± 0.1	0.17± 0.01	189± 22	81± 4	17± 3
40ppm	10	5.2± 0.1	3.2± 0.2	1.6± 0.1	0.17± 0.03	187± 23	86± 11	18± 3
80ppm	10	5.2± 0.2	3.2± 0.1	1.6± 0.1	0.16± 0.01	173± 19	83± 6	14± 4**

Significant defference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (14W)

Group Name	NO. of Animals	PHOSPHOLIPID mg/dℓ	GOT IU/ℓ	GPT IU/ℓ	LDH IU/ℓ	ALP IU/ℓ	G-GTP IU/ℓ	CPK IU/ℓ
0ppm	10	148± 30	62± 10	29± 5	227± 29	249± 34	2± 1	63± 38
5ppm	10	148± 26	67± 15	28± 5	261± 91	243± 49	2± 1	77± 64
10ppm	10	150± 18	55± 7	25± 4	231± 42	245± 28	2± 1	50± 12
20ppm	10	155± 8	51± 6	23± 3**	226± 27	252± 23	2± 1	44± 8
40ppm	10	162± 19	48± 9*	22± 5**	210± 55	219± 24	1± 1	40± 10
80ppm	10	152± 9	46± 6**	21± 4**	212± 46	240± 22	2± 1	39± 14

Significant defference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (14W)

Group Name	NO. of Animals	UREA NITROGEN mg/dℓ		SODIUM mEq/ℓ		POTASSIUM mEq/ℓ		CHLORIDE mEq/ℓ		CALCIUM mg/dℓ		INORGANIC PHOSPHORUS mg/dℓ	
0ppm	10	20.9±	2.6	149±	2	4.6±	0.4	118±	1	8.4±	0.7	6.8±	1.2
5ppm	10	21.4±	2.3	149±	2	4.7±	0.5	118±	1	8.8±	0.3	6.7±	1.6
10ppm	10	22.2±	1.6	149±	1	4.7±	0.4	118±	1	8.8±	0.3	6.7±	0.9
20ppm	10	21.2±	3.5	148±	2	4.8±	0.5	117±	2	8.9±	0.2	6.8±	1.3
40ppm	10	20.2±	3.4	148±	1	4.9±	0.4	116±	2**	8.7±	0.8	7.2±	0.5
80ppm	10	20.3±	3.6	148±	1	5.0±	0.3	115±	2**	8.7±	0.4	7.1±	1.3

Significant defference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX E 2

BIOCHEMISTRY : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (14W)

Group Name	NO. of Animals	TOTAL PROTEIN g/dℓ		ALBUMIN g/dℓ		A/G RATIO		T-BILIRUBIN mg/dℓ		GLUCOSE mg/dℓ		T-CHOLESTEROL mg/dℓ		TRIGLYCERIDE mg/dℓ	
0ppm	10	5.1±	0.1	2.9±	0.1	1.4±	0.0	0.18±	0.04	231±	33	82±	5	29±	10
5ppm	10	5.0±	0.1	2.8±	0.1	1.3±	0.0	0.17±	0.01	203±	37	81±	9	28±	9
10ppm	10	5.1±	0.3	2.9±	0.2	1.4±	0.1	0.17±	0.03	195±	35	77±	7	24±	7
20ppm	9	5.0±	0.1	2.9±	0.0	1.4±	0.1	0.17±	0.01	200±	29	77±	9	19±	7*
40ppm	9	5.0±	0.1	2.9±	0.1	1.4±	0.1	0.17±	0.01	219±	17	77±	7	19±	7*
80ppm	10	5.1±	0.2	3.0±	0.1	1.4±	0.1	0.18±	0.01	217±	23	83±	8	15±	4**

Significant defference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (14W)

Group Name	NO. of Animals	PHOSPHOLIPID mg/dℓ	GOT IU/ℓ	GPT IU/ℓ	LDH IU/ℓ	ALP IU/ℓ	G-GTP IU/ℓ	CPK IU/ℓ
0ppm	10	166± 16	47± 7	22± 6	216± 85	168± 12	2± 1	43± 14
5ppm	10	162± 18	49± 6	21± 3	196± 20	169± 8	2± 1	44± 8
10ppm	10	156± 16	48± 5	20± 3	212± 48	168± 9	1± 1	48± 14
20ppm	9	154± 21	47± 11	22± 3	225± 58	162± 11	1± 1	61± 45
40ppm	9	152± 15	41± 5	21± 5	210± 36	168± 13	2± 1	49± 41
80ppm	10	158± 11	38± 3**	19± 1	198± 25	164± 18	2± 1	37± 8

Significant defference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

BIOCHEMISTRY (SUMMARY)
ALL ANIMALS (14W)

Group Name	NO. of Animals	UREA NITROGEN mg/dℓ		SODIUM mEq/ℓ		POTASSIUM mEq/ℓ		CHLORIDE mEq/ℓ		CALCIUM mg/dℓ		INORGANIC PHOSPHORUS mg/dℓ	
0ppm	10	25.7±	3.7	150±	2	4.7±	0.3	119±	2	8.8±	0.3	7.3±	1.1
5ppm	10	23.5±	3.3	150±	1	4.8±	0.4	119±	1	8.8±	0.2	7.2±	0.8
10ppm	10	23.5±	3.5	150±	1	5.0±	0.5	120±	2	8.8±	0.3	7.6±	1.2
20ppm	9	24.2±	2.7	150±	1	4.7±	0.3	118±	2	8.7±	0.2	7.9±	0.6
40ppm	9	24.3±	2.6	149±	2	4.7±	0.3	117±	2	8.7±	0.2	7.2±	0.9
80ppm	10	23.9±	4.5	149±	1	4.8±	0.4	116±	2**	8.9±	0.3	7.6±	1.5

Significant defference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX F 1

URINALYSIS : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0317 URINALYSIS
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

Group Name	NO. of Animals	pH 5.0	6.0	6.5	7.0	7.5	8.0	8.5	CHI	Protein −	±	+	2+	3+	4+	CHI	Glucose −	±	+	2+	3+	4+	CHI	Ketone body −	±	+	2+	3+	4+	CHI	Occult blood −	±	+	2+	3+	CHI
0ppm	10	0	0	0	0	3	5	2		0	1	9	0	0	0		10	0	0	0	0	0		3	6	1	0	0	0		10	0	0	0	0	
5ppm	10	0	0	0	0	5	4	1		0	0	7	3	0	0		10	0	0	0	0	0		0	10	0	0	0	0		10	0	0	0	0	
10ppm	10	0	0	0	0	1	9	0		0	0	8	2	0	0		10	0	0	0	0	0		1	8	1	0	0	0		10	0	0	0	0	
20ppm	9	0	0	0	0	3	6	0		0	0	5	4	0	0	*	9	0	0	0	0	0		0	6	3	0	0	0		9	0	0	0	0	
40ppm	9	0	0	0	2	0	7	0		0	0	5	4	0	0	*	9	0	0	0	0	0		0	7	2	0	0	0		9	0	0	0	0	
80ppm	10	0	0	1	0	5	4	0		0	0	6	4	0	0		10	0	0	0	0	0		0	5	3	2	0	0		10	0	0	0	0	

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

STUDY NO. : 0317 URINALYSIS
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : MALE REPORT TYPE : A1

Group Name	NO. of Animals	Urobilinogen ±	+	2+	3+	4+	CHI
0ppm	10	10	0	0	0	0	
5ppm	10	10	0	0	0	0	
10ppm	10	10	0	0	0	0	
20ppm	9	9	0	0	0	0	
40ppm	9	9	0	0	0	0	
80ppm	10	10	0	0	0	0	

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

APPENDIX F 2

URINALYSIS : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)

STUDY NO. : 0317 URINALYSIS
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

Group Name	NO. of Animals	pH 5.0	6.0	6.5	7.0	7.5	8.0	8.5	CHI	Protein −	±	+	2+	3+	4+	CHI	Glucose −	±	+	2+	3+	4+	CHI	Ketone body −	±	+	2+	3+	4+	CHI	Occult blood −	±	+	2+	3+	CHI
0ppm	10	0	0	1	1	4	4	0		0	0	10	0	0	0		10	0	0	0	0	0		7	3	0	0	0	0		10	0	0	0	0	
5ppm	10	0	0	0	3	1	5	1		0	0	8	2	0	0		10	0	0	0	0	0		1	6	1	2	0	0	*	10	0	0	0	0	
10ppm	10	0	0	1	2	0	7	0		0	0	10	0	0	0		10	0	0	0	0	0		0	9	1	0	0	0	**	10	0	0	0	0	
20ppm	10	0	0	3	0	2	5	0		0	1	7	2	0	0		10	0	0	0	0	0		0	4	3	3	0	0	**	10	0	0	0	0	
40ppm	10	0	0	0	1	2	6	1		0	1	9	0	0	0		10	0	0	0	0	0		0	4	4	2	0	0	**	10	0	0	0	0	
80ppm	10	0	1	0	2	2	4	1		0	2	8	0	0	0		10	0	0	0	0	0		0	2	4	4	0	0	**	10	0	0	0	0	

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

STUDY NO. : 0317 URINALYSIS
ANIMAL : MOUSE Crj:BDF1
MEASURE. TIME : 1
SEX : FEMALE REPORT TYPE : A1

Group Name	NO. of Animals	Urobilinogen ±	+	2+	3+	4+	CHI
0ppm	10	10	0	0	0	0	
5ppm	10	10	0	0	0	0	
10ppm	10	10	0	0	0	0	
20ppm	10	10	0	0	0	0	
40ppm	10	10	0	0	0	0	
80ppm	10	10	0	0	0	0	

Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of CHI SQUARE

APPENDIX G 1

GROSS FINDINGS : SUMMARY, MOUSE : MALE

DEAD AND MORIBUND ANIMALS

(13 - WEEK STUDY)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name	0ppm	5ppm	10ppm	20ppm
		NO. of Animals	0 (%)	0 (%)	0 (%)	1 (%)
kidney	hydronephrosis		- (-)	- (-)	- (-)	1 (100)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name	40ppm	80ppm
		NO. of Animals	1 (%)	0 (%)
kidney	hydronephrosis		0 (0)	- (-)

APPENDIX G 2

GROSS FINDINGS : SUMMARY, MOUSE : MALE : SACRIFICED ANIMALS

(13 - WEEK STUDY)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

Organ	Findings	Group Name / NO. of Animals	0ppm 10 (%)	5ppm 10 (%)	10ppm 10 (%)	20ppm 9 (%)
spleen	black zone		0 (0)	0 (0)	0 (0)	2 (22)
kidney	hydronephrosis		0 (0)	0 (0)	0 (0)	1 (11)
urin bladd	urine:marked retention		0 (0)	0 (0)	0 (0)	0 (0)
testis	atrophic		0 (0)	0 (0)	0 (0)	0 (0)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

Organ	Findings	Group Name	40ppm	80ppm
		NO. of Animals	9 (%)	10 (%)
spleen	black zone		0 (0)	2 (20)
kidney	hydronephrosis		1 (11)	2 (20)
urin bladd	urine:marked retention		0 (0)	1 (10)
testis	atrophic		0 (0)	1 (10)

APPENDIX G 3

GROSS FINDINGS : SUMMARY, MOUSE : FEMALE : SACRIFICED ANIMALS

(13 - WEEK STUDY)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

Organ	Findings	Group Name / NO. of Animals	0ppm 10 (%)	5ppm 10 (%)	10ppm 10 (%)	20ppm 10 (%)
spleen	black zone		1 (10)	1 (10)	0 (0)	0 (0)
kidney	hydronephrosis		0 (0)	0 (0)	0 (0)	1 (10)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE

GROSS FINDINGS (SUMMARY)
SACRIFICED ANIMALS (14W)

Organ	Findings	Group Name / NO. of Animals	40ppm 10	(%)	80ppm 10	(%)
spleen	black zone		1	(10)	0	(0)
kidney	hydronephrosis		1	(10)	0	(0)

APPENDIX H 1

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	TESTES	HEART	LUNGS
0ppm	10	30.1± 3.0	0.036± 0.007	0.012± 0.002	0.237± 0.024	0.154± 0.009	0.166± 0.013
5ppm	10	29.1± 2.0	0.036± 0.006	0.011± 0.002	0.232± 0.036	0.155± 0.011	0.163± 0.012
10ppm	10	28.5± 1.9	0.034± 0.006	0.012± 0.002	0.222± 0.031	0.153± 0.012	0.164± 0.009
20ppm	9	28.6± 2.3	0.033± 0.005	0.011± 0.002	0.221± 0.042	0.167± 0.011*	0.164± 0.007
40ppm	9	26.3± 1.7**	0.032± 0.004	0.011± 0.002	0.219± 0.019	0.151± 0.013	0.163± 0.009
80ppm	10	24.2± 1.0**	0.028± 0.005**	0.010± 0.002	0.199± 0.058	0.143± 0.007	0.157± 0.010

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

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: g

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

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
0ppm	10	0.431± 0.033	0.046± 0.004	1.155± 0.072	0.439± 0.014
5ppm	10	0.464± 0.035	0.049± 0.005	1.158± 0.086	0.439± 0.007
10ppm	10	0.463± 0.029	0.047± 0.003	1.138± 0.076	0.437± 0.015
20ppm	9	0.512± 0.069**	0.050± 0.005	1.171± 0.071	0.447± 0.016
40ppm	9	0.525± 0.178	0.045± 0.007	1.109± 0.054	0.443± 0.014
80ppm	10	0.538± 0.219*	0.042± 0.006	1.051± 0.058**	0.431± 0.016

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX H 2

ORGAN WEIGHT, ABSOLUTE : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

Group Name	NO. of Animals	Body Weight	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
0ppm	10	21.7± 0.9	0.045± 0.005	0.014± 0.002	0.033± 0.004	0.126± 0.005	0.162± 0.008
5ppm	10	22.4± 2.1	0.044± 0.006	0.014± 0.002	0.031± 0.009	0.129± 0.006	0.163± 0.010
10ppm	10	21.4± 1.8	0.039± 0.008	0.014± 0.002	0.036± 0.006	0.125± 0.007	0.164± 0.011
20ppm	10	21.5± 1.5	0.041± 0.010	0.014± 0.002	0.031± 0.006	0.130± 0.005	0.159± 0.014
40ppm	10	22.2± 1.6	0.041± 0.005	0.013± 0.002	0.032± 0.004	0.127± 0.008	0.164± 0.012
80ppm	10	20.5± 0.9	0.040± 0.005	0.013± 0.002	0.030± 0.005	0.120± 0.008	0.153± 0.008

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: g

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

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
0ppm	10	0.300± 0.012	0.061± 0.006	0.943± 0.066	0.454± 0.014
5ppm	10	0.328± 0.013	0.060± 0.008	1.002± 0.122	0.454± 0.017
10ppm	10	0.319± 0.022	0.055± 0.008	0.956± 0.109	0.460± 0.017
20ppm	10	0.353± 0.056**	0.055± 0.008	0.955± 0.050	0.452± 0.024
40ppm	10	0.387± 0.124**	0.055± 0.009	0.994± 0.066	0.452± 0.020
80ppm	10	0.355± 0.015**	0.048± 0.004**	0.934± 0.055	0.442± 0.018

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

APPENDIX I 1

ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : MALE

(13 - WEEK STUDY)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	TESTES	HEART	LUNGS
0ppm	10	30.1± 3.0	0.118± 0.013	0.040± 0.008	0.790± 0.090	0.513± 0.033	0.556± 0.048
5ppm	10	29.1± 2.0	0.123± 0.020	0.039± 0.004	0.802± 0.148	0.534± 0.061	0.561± 0.044
10ppm	10	28.5± 1.9	0.120± 0.018	0.041± 0.007	0.780± 0.110	0.537± 0.052	0.576± 0.035
20ppm	9	28.6± 2.3	0.114± 0.010	0.039± 0.005	0.779± 0.173	0.587± 0.065**	0.575± 0.042
40ppm	9	26.3± 1.7**	0.121± 0.021	0.042± 0.007	0.837± 0.094	0.573± 0.027*	0.620± 0.049**
80ppm	10	24.2± 1.0**	0.114± 0.018	0.042± 0.006	0.825± 0.245	0.593± 0.042**	0.648± 0.037**

Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Dunnett

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE
UNIT: %

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

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
0ppm	10	1.439± 0.125	0.155± 0.013	3.857± 0.255	1.470± 0.135
5ppm	10	1.596± 0.119	0.169± 0.017	3.985± 0.206	1.515± 0.122
10ppm	10	1.627± 0.109	0.165± 0.013	3.992± 0.185	1.538± 0.119
20ppm	9	1.805± 0.360**	0.177± 0.022	4.097± 0.142*	1.567± 0.123
40ppm	9	2.005± 0.708**	0.170± 0.022	4.220± 0.147**	1.689± 0.090**
80ppm	10	2.231± 0.927**	0.173± 0.025	4.344± 0.128**	1.787± 0.105**

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

APPENDIX I 2

ORGAN WEIGHT, RELATIVE : SUMMARY, MOUSE : FEMALE

(13 - WEEK STUDY)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

Group Name	NO. of Animals	Body Weight (g)	THYMUS	ADRENALS	OVARIES	HEART	LUNGS
0ppm	10	21.7± 0.9	0.207± 0.024	0.067± 0.011	0.151± 0.019	0.580± 0.033	0.749± 0.048
5ppm	10	22.4± 2.1	0.196± 0.017	0.063± 0.008	0.140± 0.032	0.578± 0.029	0.733± 0.050
10ppm	10	21.4± 1.8	0.180± 0.031	0.066± 0.008	0.167± 0.030	0.587± 0.047	0.771± 0.078
20ppm	10	21.5± 1.5	0.190± 0.034	0.064± 0.006	0.142± 0.021	0.605± 0.038	0.738± 0.030
40ppm	10	22.2± 1.6	0.184± 0.024	0.060± 0.008	0.142± 0.016	0.576± 0.031	0.742± 0.048
80ppm	10	20.5± 0.9	0.196± 0.022	0.061± 0.007	0.147± 0.022	0.583± 0.031	0.746± 0.029

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

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : FEMALE
UNIT: %

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

Group Name	NO. of Animals	KIDNEYS	SPLEEN	LIVER	BRAIN
0ppm	10	1.383± 0.059	0.281± 0.021	4.345± 0.183	2.095± 0.104
5ppm	10	1.476± 0.109	0.266± 0.022	4.472± 0.218	2.042± 0.178
10ppm	10	1.496± 0.103	0.256± 0.024	4.459± 0.194	2.160± 0.161
20ppm	10	1.650± 0.314**	0.257± 0.022	4.449± 0.149	2.110± 0.148
40ppm	10	1.743± 0.514**	0.248± 0.034*	4.492± 0.143	2.050± 0.173
80ppm	10	1.731± 0.060**	0.231± 0.018**	4.552± 0.156	2.156± 0.084

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

APPENDIX J 1

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : MALE : DEAD AND MORIBUND ANIMALS

(13 - WEEK STUDY)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name	0ppm				5ppm				10ppm				20ppm			
		No. of Animals on Study	0				0				0				1			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]																		
thymus			< 0>				< 0>				< 0>				< 0>			
	atrophy		-	-	-	-	-	-	-	-	-	-	-	-	0	0	0	0
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(0)	(0)	(0)	(0)
spleen			< 0>				< 0>				< 0>				< 1>			
	atrophy		-	-	-	-	-	-	-	-	-	-	-	-	0	0	0	0
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(0)	(0)	(0)	(0)
[Circulatory system]																		
heart			< 0>				< 0>				< 0>				< 1>			
	necrosis:focal		-	-	-	-	-	-	-	-	-	-	-	-	0	1	0	0
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(0)	(100)	(0)	(0)
	fibrosis		-	-	-	-	-	-	-	-	-	-	-	-	0	1	0	0
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(0)	(100)	(0)	(0)
[Urinary system]																		
kidney			< 0>				< 0>				< 0>				< 1>			
	vacuolization of proximal tubule		-	-	-	-	-	-	-	-	-	-	-	-	1	0	0	0
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(100)	(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

Organ	Findings	Group Name	40ppm				80ppm			
		No. of Animals on Study	1				0			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Hematopoietic system]										
thymus			< 1>				< 0>			
	atrophy		0	1	0	0	-	-	-	-
			(0)	(100)	(0)	(0)	(-)	(-)	(-)	(-)
spleen			< 1>				< 0>			
	atrophy		0	1	0	0	-	-	-	-
			(0)	(100)	(0)	(0)	(-)	(-)	(-)	(-)
[Circulatory system]										
heart			< 1>				< 0>			
	necrosis:focal		0	1	0	0	-	-	-	-
			(0)	(100)	(0)	(0)	(-)	(-)	(-)	(-)
	fibrosis		0	1	0	0	-	-	-	-
			(0)	(100)	(0)	(0)	(-)	(-)	(-)	(-)
[Urinary system]										
kidney			< 1>				< 0>			
	vacuolization of proximal tubule		0	0	0	0	-	-	-	-
			(0)	(0)	(0)	(0)	(-)	(-)	(-)	(-)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100

Organ	Findings	Group Name	0ppm				5ppm				10ppm				20ppm			
		No. of Animals on Study	0				0				0				1			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
[Urinary system]																		
kidney			< 0>				< 0>				< 0>				< 1>			
	hydronephrosis		-	-	-	-	-	-	-	-	-	-	-	-	0	1	0	0
			(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(0)	(100)	(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

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name	40ppm				80ppm			
		No. of Animals on Study	1				0			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Urinary system]										
kidney			< 1>				< 0>			
	hydronephrosis		0	1	0	0	-	-	-	-
			(0)	(100)	(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

APPENDIX J 2

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : MALE: SACRIFICED ANIMALS

(13 - WEEK STUDY)

STUDY NO. : 0317
ANIMAL : MOUSE Crj:BDF1
REPORT TYPE : A1
SEX : MALE

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

Organ	Findings	Group Name	0ppm				5ppm				10ppm				20ppm			
		No. of Animals on Study	10				10				10				9			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
nasal cavit			<10>				<10>				<10>				< 9>			
	eosinophilic change:olfactory epithelium		0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	eosinophilic change:respiratory epithelium		0	0	0	0	1	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	respiratory metaplasia:olfactory epithelium		0	0	0	0	0	0	0	0	2	0	0	0	7	0	0	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(78)	(0)	(0)	(0)
	desquamation:olfactory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(11)	(0)	(0)	(0)
	squamous cell metaplasia:respiratory epithelium		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	atrophy:olfactory epithelium		0	0	0	0	0	0	0	0	4	0	0	0	9	0	0	0 **
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(40)	(0)	(0)	(0)	(100)	(0)	(0)	(0)
[Hematopoietic system]																		
spleen			<10>				<10>				<10>				< 9>			
	deposit of hemosiderin		0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(22)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	40ppm				80ppm			
		No. of Animals on Study	9				10			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]										
nasal cavit			< 9>				<10>			
	eosinophilic change:olfactory epithelium		1	0	0	0	0	0	0	0
			(11)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	eosinophilic change:respiratory epithelium		2	0	0	0	6	0	0	0 *
			(22)	(0)	(0)	(0)	(60)	(0)	(0)	(0)
	respiratory metaplasia:olfactory epithelium		8	0	0	0 **	10	0	0	0 **
			(89)	(0)	(0)	(0)	(100)	(0)	(0)	(0)
	desquamation:olfactory epithelium		0	0	0	0	7	0	0	0 **
			(0)	(0)	(0)	(0)	(70)	(0)	(0)	(0)
	squamous cell metaplasia:respiratory epithelium		0	0	0	0	2	0	0	0
			(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
	atrophy:olfactory epithelium		6	3	0	0 **	3	7	0	0 **
			(67)	(33)	(0)	(0)	(30)	(70)	(0)	(0)
[Hematopoietic system]										
spleen			< 9>				<10>			
	deposit of hemosiderin		0	0	0	0	2	0	0	0
			(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	0ppm				5ppm				10ppm				20ppm			
		No. of Animals on Study	10				10				10				9			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																		
liver			<10>				<10>				<10>				< 9>			
	granulation		0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
pancreas			<10>				<10>				<10>				< 9>			
	atrophy		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)
[Urinary system]																		
kidney			<10>				<10>				<10>				< 9>			
	vacuolization of proximal tubule		9	0	0	0	10	0	0	0	10	0	0	0	9	0	0	0
			(90)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	(100)	(0)	(0)	(0)
	hydronephrosis		0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(11)	(0)	(0)
urin bladd			<10>				<10>				<10>				< 9>			
	dilatation		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)
[Reproductive system]																		
testis			<10>				<10>				<10>				< 9>			
	atrophy		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)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	40ppm				80ppm			
		No. of Animals on Study	9				10			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]										
liver			< 9>				<10>			
	granulation		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
pancreas			< 9>				<10>			
	atrophy		1	0	0	0	0	0	0	0
			(11)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Urinary system]										
kidney			< 9>				<10>			
	vacuolization of proximal tubule		4	0	0	0	0	0	0	0 **
			(44)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	hydronephrosis		0	1	0	0	0	2	0	0
			(0)	(11)	(0)	(0)	(0)	(20)	(0)	(0)
urin bladd			< 9>				<10>			
	dilatation		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
[Reproductive system]										
testis			< 9>				<10>			
	atrophy		0	0	0	0	0	1	0	0
			(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	0ppm				5ppm				10ppm				20ppm			
		No. of Animals on Study	10				10				10				9			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Reproductive system]																		
testis			<10>				<10>				<10>				< 9>			
	germ cell necrosis		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(11)	(0)	(0)	(0)
epididymis			<10>				<10>				<10>				< 9>			
	decreased:sperma		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)
	debris of spermatic elements		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(11)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	40ppm				80ppm			
		No. of Animals on Study	9				10			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Reproductive system]										
testis			< 9>				<10>			
	germ cell necrosis		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
epididymis			< 9>				<10>			
	decreased:sperma		0	0	0	0	0	0	1	0
			(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)
	debris of spermatic elements		0	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

APPENDIX J 3

HISTOLOGICAL FINDINGS : NON-NEOPLASTIC LESIONS : SUMMARY

MOUSE : FEMALE : SACRIFICED ANIMALS

(13 - WEEK STUDY)

Organ	Findings	Group Name	0ppm				5ppm				10ppm				20ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]																		
nasal cavit			<10>				<10>				<10>				<10>			
	eosinophilic change:olfactory epithelium		0	0	0	0	1	0	0	0	1	0	0	0	3	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(30)	(0)	(0)	(0)
	eosinophilic change:respiratory epithelium		1	0	0	0	3	0	0	0	7	0	0	0 *	10	0	0	0 **
			(10)	(0)	(0)	(0)	(30)	(0)	(0)	(0)	(70)	(0)	(0)	(0)	(100)	(0)	(0)	(0)
	respiratory metaplasia:olfactory epithelium		0	0	0	0	1	0	0	0	8	0	0	0 **	8	2	0	0 **
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(80)	(0)	(0)	(0)	(80)	(20)	(0)	(0)
	desquamation:olfactory epithelium		0	0	0	0	0	0	0	0	2	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
	squamous cell metaplasia:respiratory epithelium		0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
	atrophy:olfactory epithelium		0	0	0	0	2	0	0	0	10	0	0	0 **	10	0	0	0 **
			(0)	(0)	(0)	(0)	(20)	(0)	(0)	(0)	(100)	(0)	(0)	(0)	(100)	(0)	(0)	(0)
[Hematopoietic system]																		
spleen			<10>				<10>				<10>				<10>			
	deposit of hemosiderin		1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference : * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	40ppm				80ppm			
		No. of Animals on Study	10				10			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Respiratory system]										
nasal cavit			<10>				<10>			
	eosinophilic change:olfactory epithelium		9	0	0	0 **	10	0	0	0 **
			(90)	(0)	(0)	(0)	(100)	(0)	(0)	(0)
	eosinophilic change:respiratory epithelium		4	5	0	0 **	4	6	0	0 **
			(40)	(50)	(0)	(0)	(40)	(60)	(0)	(0)
	respiratory metaplasia:olfactory epithelium		10	0	0	0 **	10	0	0	0 **
			(100)	(0)	(0)	(0)	(100)	(0)	(0)	(0)
	desquamation:olfactory epithelium		2	0	0	0	2	0	0	0
			(20)	(0)	(0)	(0)	(20)	(0)	(0)	(0)
	squamous cell metaplasia:respiratory epithelium		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
	atrophy:olfactory epithelium		6	4	0	0 **	3	7	0	0 **
			(60)	(40)	(0)	(0)	(30)	(70)	(0)	(0)
[Hematopoietic system]										
spleen			<10>				< 9>			
	deposit of hemosiderin		1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	0ppm				5ppm				10ppm				20ppm			
		No. of Animals on Study	10				10				10				10			
		Grade	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]																		
liver			<10>				<10>				<10>				<10>			
	granulation		1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Urinary system]																		
kidney			<10>				<10>				<10>				<10>			
	hydronephrosis		0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)
[Nervous system]																		
brain			<10>				<10>				<10>				<10>			
	epidermal cyst		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)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

Organ	Findings	Group Name	40ppm				80ppm			
		No. of Animals on Study	10				10			
		Grade	1	2	3	4	1	2	3	4
			(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
[Digestive system]										
liver			<10>				<10>			
	granulation		1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Urinary system]										
kidney			<10>				<10>			
	hydronephrosis		1	0	0	0	0	0	0	0
			(10)	(0)	(0)	(0)	(0)	(0)	(0)	(0)
[Nervous system]										
brain			<10>				<10>			
	epidermal cyst		0	0	0	0	1	0	0	0
			(0)	(0)	(0)	(0)	(10)	(0)	(0)	(0)

Grade 1 : Slight 2 : Moderate 3 : Marked 4 : Severe
< a > a : Number of animals examined at the site
b b : Number of animals with lesion
(c) c : b / a * 100
Significant difference ; * : P ≦ 0.05 ** : P ≦ 0.01 Test of Chi Square

APPENDIX K 1

IDENTITY OF GLYCIDOL IN THE 13 - WEEK INHALATION STUDY

IDENTITY OF GLYCIDOL IN THE 13-WEEK INHALATION STUDY

A. Test Substance Lot No.: LER5803

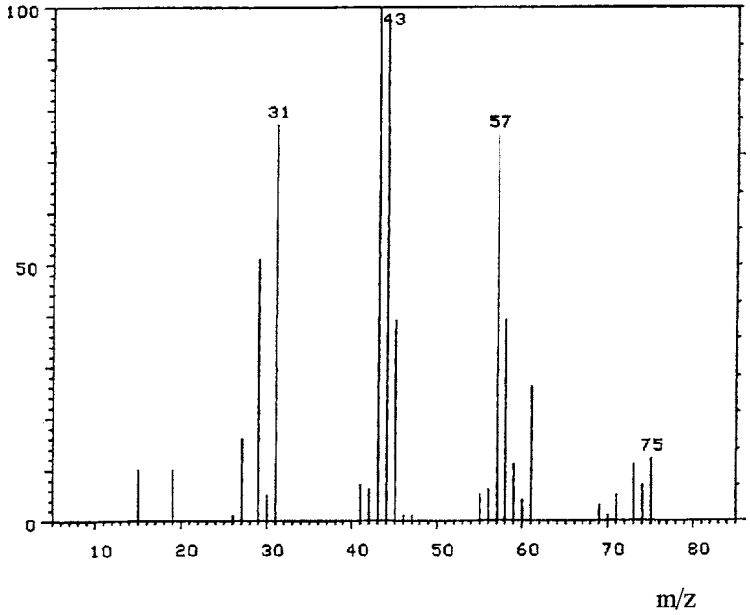
1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

Determined Peak(m/z)	Literature Value* Peak(m/z)
31	31
43	43
44	44
57	57
73	73
75	

Results: The mass spectrum was consistent with literature spectrum.

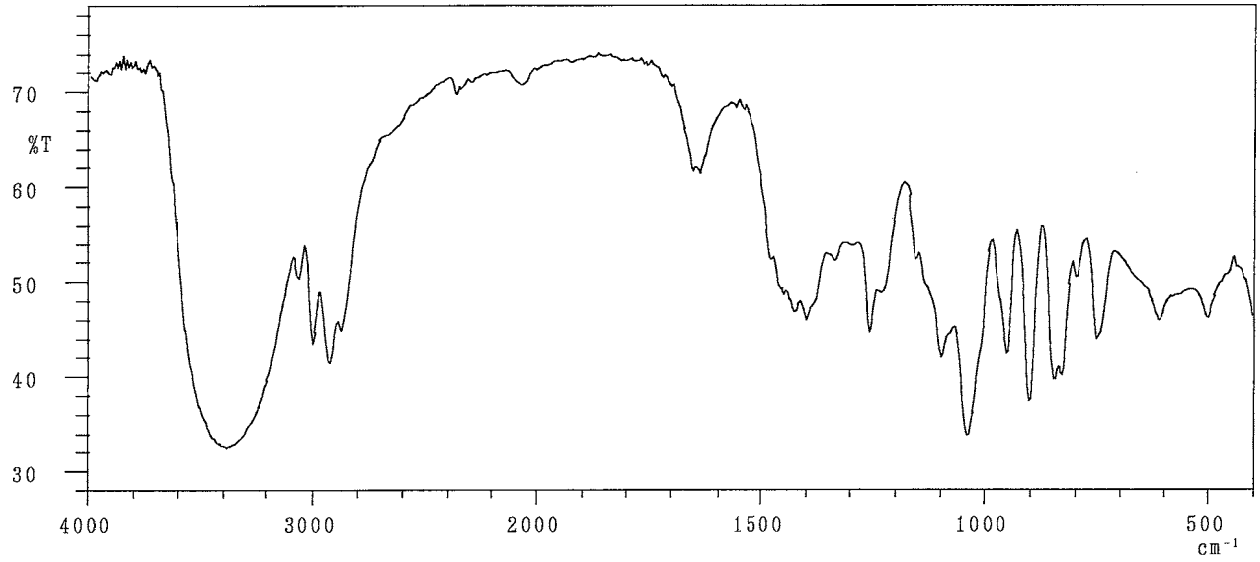
(*Fred W. McLafferty (1994) Wiley Registry of Mass Spectral Data, 6th edition. John Wiley and Sons, Inc. (U.S.), Entry Number 1733)

Infrared Spectrometry

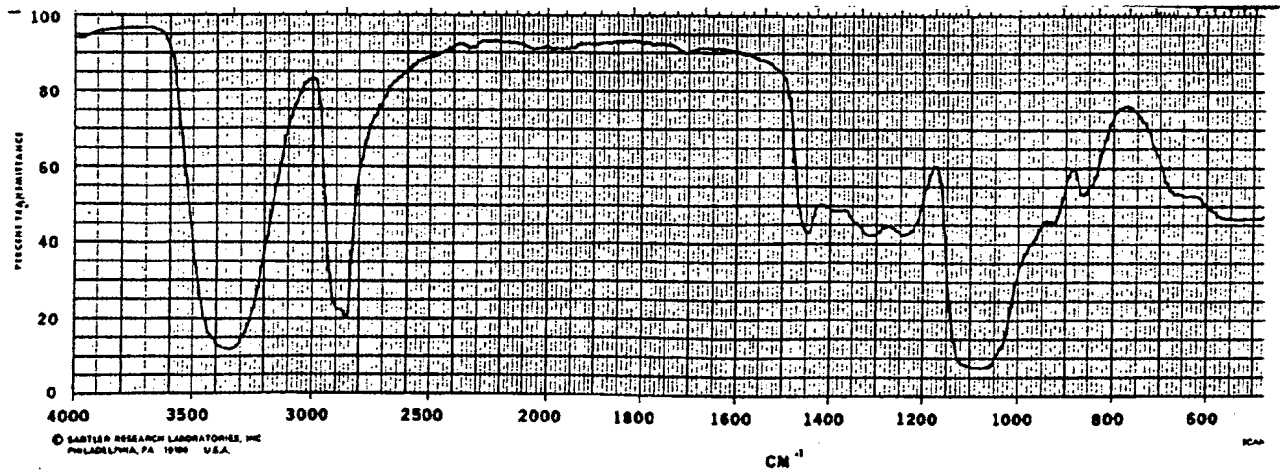
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

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.

(*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.

B. Test Substance Lot No.: LEQ5980

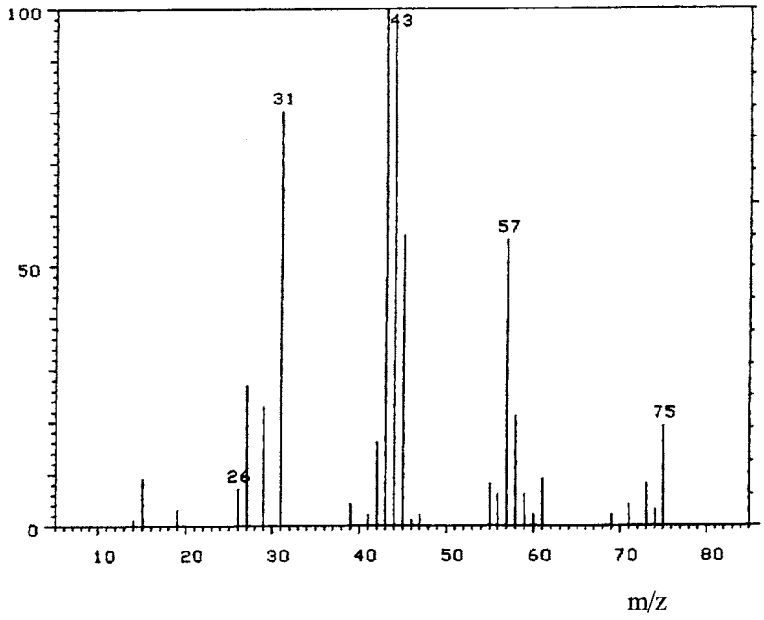
1. Spectral data

Mass Spectrometry

Instrument : Hitachi M-80B Mass Spectrometer

Ionization : EI (Electron Ionization)

Ionization Voltage : 70eV



Mass Spectrum of Test Substance

Determined Peak(m/z)	Literature Value* Peak(m/z)
31	31
43	43
44	44
57	57
73	73
75	

Results: The mass spectrum was consistent with literature spectrum.

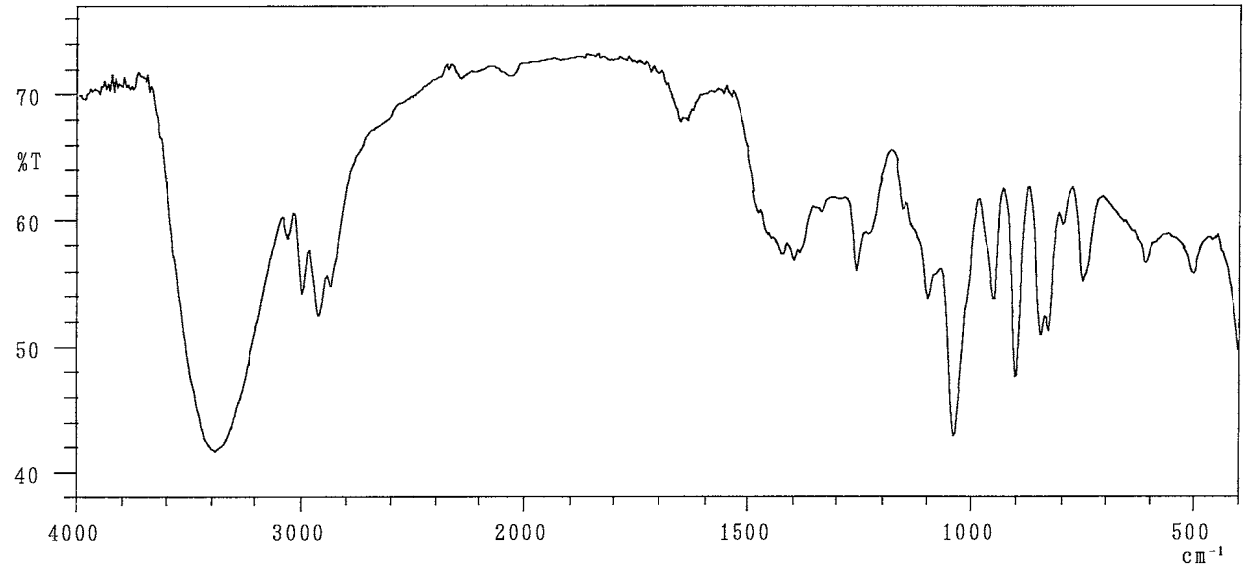
(*Fred W. McLafferty (1994) Wiley Registry of Mass Spectral Data, 6th edition. John Wiley and Sons, Inc. (U.S.), Entry Number 1733)

Infrared Spectrometry

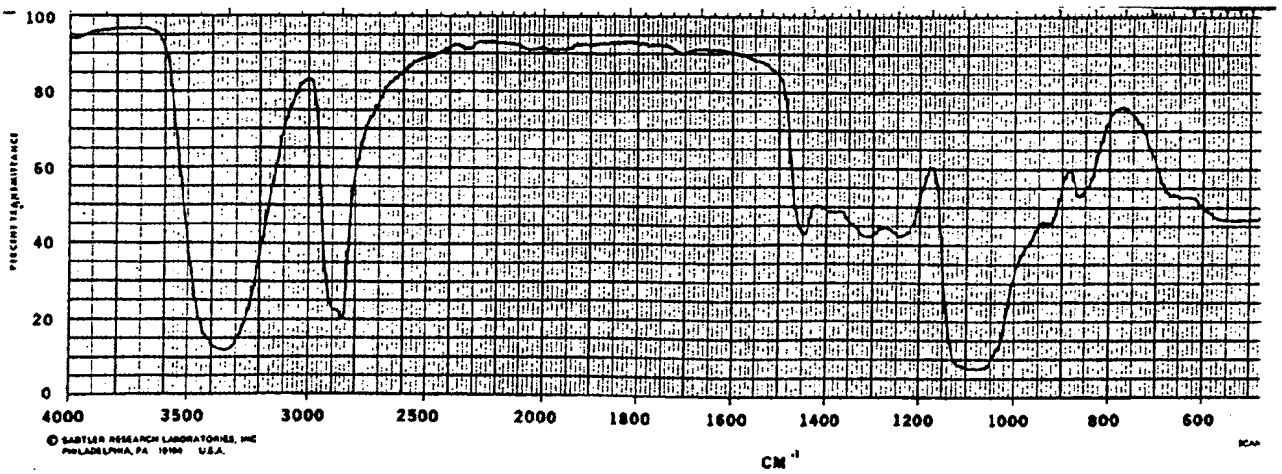
Instrument : Shimadzu FTIR-8200PC Infrared Spectrometer

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.

(*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 K 2

STABILITY OF GLYCIDOL IN THE 13 - WEEK INHALATION STUDY

STABILITY OF GLYCIDOL IN THE 13-WEEK INHALATION STUDY

A. Test Substance Lot No.: LER5803

1.Sample: This lot was used from 1996.9.11 to 1996.10.14. Test substance was stored at room temperature.

2. Gas Chromatography

Instrument	: Hewlett Packard 6890
Column	: Methyl Silicone (0.53 mmϕ × 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 1996.8.30 and one major peak (peak No.3) and two impurities (peak No.1,2 < 1% of total area) analyzed at 1996.10.15. No new trace impurity peak in the test substance analyzed at 1996.10.15 was detected.

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
1996.08.30	1	1.89	0.15
	2	2.12	0.23
	3	2.52	99.62
1996.10.15	1	1.90	0.14
	2	2.13	0.23
	3	2.52	99.63

4. Conclusions: The results indicated that the test substance did not change when stored at room temperature during this period (for about 2 months).

B. Test Substance Lot No.: LEQ5980

1.Sample: This lot was used from 1996.10.15 to 1996.12.10. Test substance was stored at room temperature.

2. Gas Chromatography

Instrument : Hewlett Packard 6890

Column : Methyl Silicone (0.53 mmϕ × 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 1996.10.11 and one major peak (peak No.3) and two impurities (peak No.1,2 < 1% of total area) analyzed at 1996.12.11. No new trace impurity peak in the test substance analyzed at 1996.12.11 was detected.

Date (date analyzed)	Peak No.	Retention Time (min)	Area (%)
1996.10.11	1	1.82	0.14
	2	2.12	0.23
	3	2.52	99.63
1996.12.11	1	1.89	0.14
	2	2.12	0.23
	3	2.52	99.63

4. Conclusions: The results indicated that the test substance did not change when stored at room temperature during this period (for about 2 months).

APPENDIX L 1

CONCENTMOUSEION OF GLYCIDL IN THE INHALATION CHAMBER

OF THE 13-WEEK INHALATION STUDY

CONCENTRATION OF GLYCIDOL IN THE INHALATION CHAMBER OF THE 13-WEEK INHALATION STUDY

Group Name	Concentration(ppm) Mean ± S.D.
Control	0.0 ± 0.0
5.0ppm	5.0 ± 0.1
10.0ppm	10.2 ± 0.1
20.0ppm	20.2 ± 0.2
40.0ppm	40.1 ± 0.5
80.0ppm	80.0 ± 0.9

APPENDIX L 2

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE

13 - WEEK INHALATION STUDY OF GLYCIDOL

ENVIRONMENTAL CONDITIONS OF INHALATION CHAMBER IN THE 13-WEEK INHALATION STUDY OF GLYCIDOL

Group Name	Temperature(℃) Mean ± S.D.	Humidity(%) Mean ± S.D.	Ventilation Rate(L/min) Mean ± S.D.	Air Change(time/h) Mean
Control	22.2 ± 0.2	55.9 ± 0.7	104.3 ± 0.5	12.0
25ppm	21.8 ± 0.2	55.9 ± 1.9	104.2 ± 0.8	12.0
50ppm	22.0 ± 0.1	53.1 ± 1.3	104.6 ± 0.8	12.1
100ppm	22.1 ± 0.2	52.7 ± 2.4	104.7 ± 0.5	12.1
200ppm	22.0 ± 0.3	52.1 ± 2.6	104.4 ± 0.9	12.0
400ppm	22.0 ± 0.1	51.1 ± 4.0	104.6 ± 0.5	12.1

APPENDIX M 1

METHODS FOR HEMATOLOGY, BIOCHEMISTRY AND URINALYSIS IN THE 13 - WEEK INHALATION STUDY OF GLYCIDOL

METHODS FOR HEMATOLOGY,BIOCHEMISTRY AND URINALYSIS IN THE 13-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 × MCV/10 [1]
Mean corpuscular volume (MCV)	Light scattering method [1]
Mean corpuscular hemoglobin (MCH)	Calculated as Hgb/RBC × 10 [1]
Mean corpuscular hemoglobin concentration (MCHC)	Calculated as Hgb/Hct × 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・Rate method [3]
Lactate dehydrogenase (LDH)	UV・Rate method [3]
Alkaline phosphatase (ALP)	p-Nitrophenylphosphate method [3]
γ-Glutamyl transpeptidase (γ-GTP)	L-γ-Glutamyl-p-nitroanilide method [3]
Creatine phosphokinase (CPK)	UV・Rate method [3]
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]
Urinalysis	
pH,Protein,Glucose,Ketone body,Occult Blood, Urobilinogen	Urinalysis reagent paper method [4]

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)

4) Ames reagent strips for urinalysis (Uro-Labstix : Bayer-Sankyo Co.,Ltd.,Japan)

APPENDIX M 2

UNITS AND DECIMARL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE

13 - WEEK INHALATION STUDY OF GLYCIDOL

UNITS AND DECIMAL PLACE FOR HEMATOLOGY AND BIOCHEMISTRY IN THE 13-WEEK INHALATION STUDY OF GLYCIDOL

Item	Unit	Decimal place
Hematology		
Red blood cell (RBC)	$\times 10^6/\mu L$	2
Hemoglobin	g/dL	1
Hematocrit	%	1
Mean corpuscular volume (MCV)	fL	1
Mean corpuscular hemoglobin (MCH)	pg	1
Mean corpuscular hemoglobin concentration (MCHC)	g/dL	1
Platelet	$\times 10^3/\mu L$	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 transaminase (GOT)	IU/L	0
Glutamic pyruvic transaminase (GPT)	IU/L	0
Lactate dehydrogenase (LDH)	IU/L	0
Alkaline phosphatase (ALP)	IU/L	0
γ-Glutamyl transpeptidase (γ-GTP)	IU/L	0
Creatine phosphokinase (CPK)	IU/L	0
Urea nitrogen	mg/dL	1
Sodium	mEq/L	0
Potassium	mEq/L	1
Chloride	mEq/L	0
Calcium	mg/dL	1
Inorganic phosphorus	mg/dL	1