

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

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TABLE 1 EXPERIMENTAL DESIGN AND MATERIALS AND METHODS
IN THE 2-WEEK INHALATION STUDY OF GLYCIDOL

<Method of Administration>	Inhalation
<Number of Groups>	Male 6, Female 6
<Size of Groups>	10 males and 10 females of each group
<Animals>	Strain and Species F344/DuCrj(Fischer)rat
	Animal Source Charles River Japan, Inc.
	Duration Held Before Study 2 wk
	Age When Placed on Study 6 wk
	Age When Killed 8 wk
<Doses>	Male and Female 0, 37.5, 75, 150, 300 or 600ppm
<Duration of Dosing>	6 h/d, 5 d/wk for 2 wk
<Animal Maintenance>	Feed CRF-1 (Oriental Yeast Co., Ltd.) Sterilized by γ -ray Available <i>ad libitum</i>
	Water Filtrated and sterilized by ultraviolet ray Automatic watering system Available <i>ad libitum</i>
	Animal per Cage Single (stainless steel wire)
	Animal Room Environment Barrier system Temperature : 21±2°C Humidity : 60±10% Fluorescent light 12 h/d 15~17 room air changes /h
	Chamber Environment Barrier system Temperature : 20~24°C Humidity : 30~70% 12±1 air changes /h (6±0.5 air changes /h during exposure)
<Type and Frequency of Observation>	Clinical Sign Observed 1 or 2 per day for mortality, Detailed clinical observation performed on 1-2, 1-4, 1-7, 2-3 and 2-7 (wk-d) before exposure.
	Body Weight Weighed 0-0, 1-2, 1-4, 1-7, 2-3 and 2-7 (wk-d)
	Food Consumption Weighed 1-7 and 2-7 (wk)

TABLE 1 EXPERIMENTAL DESIGN AND MATERIALS AND METHODS
(Continued) IN THE 2-WEEK INHALATION STUDY OF GLYCIDOL

<Hematology>

Hematological examination performed on five animals per sex per groups.
(schedule sacrificed animals)

The following measurement parameters were examined;

Red blood cell (RBC), Hemoglobin, Hematocrit,
Mean Corpuscular Volume (MCV),
Mean Corpuscular hemoglobin (MCH),
Mean Corpuscular hemoglobin concentrate (MCHC),
Platelet, Reticulocyte,
Prothrombin time (PT),
Activated partial thromboplastin time (APTT).
White blood cell (WBC), Differential WBC.

<Biochemistry>

Biochemical examination performed on five animals per sex per groups.
(schedule sacrificed animals)

The following measurement parameters were examined;

Total protein, Albumin, A/G ratio,
Total bilirubin, Glucose, Total cholesterol,
Triglyceride, Phospholipid,
Glutamic oxaloacetic transaminase (GOT),
Glutamic pyruvic transaminase (GPT),
Lactate dehydrogenase (LDH),
Alkaline phosphatase (ALP),
 γ -Glutamyl transpeptidase (γ -GTP),
Creatine phosphokinase (CPK),
Urea nitrogen, Creatinine,
Sodium, Potassium, Chloride,
Calcium, Inorganic phosphorus.

<Necropsy>

Necropsy performed on all animals.

<Organ Weight>

Organ weight measurement performed on five animals per sex per groups.
(schedule sacrificed animals)

The following organs were weighed;

thymus, adrenal, testis, ovary, heart, lung, kidney, spleen, liver, brain.

<Histopathologic Examination>

Histopathologic examination performed on at least two animals per sex per groups.

The following organs were examined;

skin, nasal cavity, nasopharynx, larynx, trachea, lung,
bone marrow, lymph node, thymus, spleen, heart, tongue,
salivary gland, esophagus, stomach, small intestine,
large intestine, liver, pancreas, kidney, urinary bladder,
pituitary, thyroid, parathyroid, adrenal, testis, epididymis, seminal vesicle,
prostate, ovary, uterus, vagina, mammary gland,
brain, spinal cord, peripheral nerve, eye, Harderian gland, muscle, bone.

TABLE 2 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES OF MALE RATS IN THE 2-WEEK INHALATION STUDY OF GLYCIDOL

Week-Day on Study	0ppm		37.5ppm			75.0ppm			150.0ppm			300.0ppm			600.0ppm		
	Av.Wt.	No.of Surviv.	Av.Wt.	% of cont.	No.of Surviv.	Av.Wt.	% of cont.	No.of Surviv.	Av.Wt.	% of cont.	No.of Surviv.	Av.Wt.	% of cont.	No.of Surviv.	Av.Wt.	% of cont.	No.of Surviv.
		<10>		<10>			<10>			<10>			<10>		<10>		<10>
0-0	115 (10)	10/10	115 (10)	100	10/10	115 (10)	100	10/10	115 (10)	100	10/10	115 (10)	100	10/10	115 (10)	100	10/10
1-2	124 (10)	10/10	123 (10)	99	10/10	121 (10)	98	10/10	114 (10)	92	10/10	106 (10)	85	10/10	99 (10)	84	0/10
1-4	129 (10)	10/10	126 (10)	98	10/10	122 (10)	95	10/10	109 (10)	84	10/10	- (-)	-	0/10	- (-)	-	0/10
1-7	138 (10)	10/10	136 (10)	99	10/10	133 (10)	96	10/10	120 (10)	87	10/10	- (-)	-	0/10	- (-)	-	0/10
2-3	150 (10)	10/10	145 (10)	97	10/10	140 (10)	93	10/10	117 (10)	78	10/10	- (-)	-	0/10	- (-)	-	0/10
2-7	166 (10)	10/10	159 (10)	96	10/10	154 (10)	93	10/10	129 (10)	78	10/10	- (-)	-	0/10	- (-)	-	0/10

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

TABLE 3 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES OF FEMALE RATS IN THE 2-WEEK INHALATION STUDY OF GLYCIDOL

Week-Day on Study	0ppm		37.5ppm			75.0ppm			150.0ppm			300.0ppm			600.0ppm		
	Av.Wt.	No.of Surviv.	Av.Wt.	% of cont.	No.of Surviv.	Av.Wt.	% of cont.	No.of Surviv.	Av.Wt.	% of cont.	No.of Surviv.	Av.Wt.	% of cont.	No.of Surviv.	Av.Wt.	% of cont.	No.of Surviv.
		<10>		<10>			<10>			<10>			<10>		<10>		<10>
0-0	93 (10)	10/10	93 (10)	100	10/10	93 (10)	100	10/10	93 (10)	100	10/10	93 (10)	100	10/10	93 (10)	100	10/10
1-2	98 (10)	10/10	97 (10)	99	10/10	96 (10)	98	10/10	92 (10)	94	10/10	86 (10)	88	10/10	- (-)	-	0/10
1-4	100 (10)	10/10	99 (10)	99	10/10	96 (10)	96	10/10	87 (10)	87	10/10	- (-)	-	0/10	- (-)	-	0/10
1-7	104 (10)	10/10	104 (10)	100	10/10	101 (10)	97	10/10	95 (10)	91	10/10	- (-)	-	0/10	- (-)	-	0/10
2-3	108 (10)	10/10	108 (10)	100	10/10	103 (10)	95	10/10	93 (10)	86	10/10	- (-)	-	0/10	- (-)	-	0/10
2-7	116 (10)	10/10	114 (10)	98	10/10	110 (10)	95	10/10	102 (10)	88	10/10	- (-)	-	0/10	- (-)	-	0/10

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

TABLE 4 FOOD CONSUMPTION CHANGES OF MALE RATS IN THE 2-WEEK INHALATION STUDY OF GLYCIDOL

Week-Day on Study	0ppm		37.5ppm		75.0ppm		150.0ppm		300.0ppm		600.0ppm						
	Av.FC.	No.of Surviv.	Av.FC.	% of cont.	No.of Surviv.	Av.FC.	% of cont.	No.of Surviv.	Av.FC.	% of cont.	No.of Surviv.	Av.FC.	% of cont.	No.of Surviv.			
		<10>		<10>		<10>		<10>		<10>		<10>		<10>			
1-7	15.2 (10)	10/10	14.4 (10)	95	10/10	13.0 (10)	86	10/10	9.9 (10)	65	10/10	- (-)	-	0/10	- (-)	-	0/10
2-7	15.2 (10)	10/10	14.3 (10)	94	10/10	14.0 (10)	92	10/10	10.7 (10)	70	10/10	- (-)	-	0/10	- (-)	-	0/10

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

TABLE 5 FOOD CONSUMPTION CHANGES OF FEMALE RATS IN THE 2-WEEK INHALATION STUDY OF GLYCIDOL

Week-Day on Study	0ppm		37.5ppm		75.0ppm		150.0ppm		300.0ppm		600.0ppm						
	Av.FC.	No.of Surviv.	Av.FC.	% of cont.	No.of Surviv.	Av.FC.	% of cont.	No.of Surviv.	Av.FC.	% of cont.	No.of Surviv.	Av.FC.	% of cont.	No.of Surviv.			
		<10>		<10>		<10>		<10>		<10>		<10>		<10>			
1-7	11.5 (10)	10/10	11.3 (10)	98	10/10	11.0 (10)	96	10/10	8.2 (10)	71	10/10	- (-)	-	0/10	- (-)	-	0/10
2-7	10.9 (10)	10/10	10.7 (10)	98	10/10	10.3 (10)	94	10/10	9.3 (10)	85	10/10	- (-)	-	0/10	- (-)	-	0/10

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