

アリルクロリドのラットを用いた
吸入による 13 週間毒性試験報告書

試験番号 : 0340

TABLES

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- TABLE 1 EXPERIMENTAL DESIGN AND MATERIALS AND METHODS IN THE 13-WEEK INHALATION STUDY OF ALLYL CHLORIDE
- TABLE 2 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES OF MALE RATS IN THE 13-WEEK INHALATION STUDY OF ALLYL CHLORIDE
- TABLE 3 SURVIVAL ANIMAL NUMBERS AND BODY WEIGHT CHANGES OF FEMALE RATS IN THE 13-WEEK INHALATION STUDY OF ALLYL CHLORIDE
- TABLE 4 FOOD CONSUMPTION CHANGES OF MALE RATS IN THE 13-WEEK INHALATION STUDY OF ALLYL CHLORIDE
- TABLE 5 FOOD CONSUMPTION CHANGES OF FEMALE RATS IN THE 13-WEEK INHALATION STUDY OF ALLYL CHLORIDE

TABLE 1 EXPERIMENTAL DESIGN AND MATERIALS AND METHODS
IN THE 13-WEEK INHALATION STUDY OF ALLYL CHLORIDE

<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(Fisher)rat	
Animal Source	
Charles River Japan, Inc.	
Duration Held Before Study	
2 wk	
Age When Placed on Study	
6 wk	
Age When Killed	
19 wk	
<Doses>	
Male and Female	
0, 25, 50, 100, 200 or 400ppm	
<Duration of Dosing>	
6 h/d, 5 d/wk for 13 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	: $21 \pm 2^{\circ}\text{C}$
Humidity	: $55 \pm 15\%$
Fluorescent light 12 h/d	
15~17 room air changes /h	
Chamber Environment	
Barrier system	
Temperature	: $20 \sim 24^{\circ}\text{C}$
Humidity	: $30 \sim 70\%$
15 ± 1 air changes /h	
<Type and Frequency of Observation>	
Clinical Sign	
Observed 1 per day for mortality, Detailed clinical observation performed on once weekly before exposure.	
Body Weight	
Weighed 1 per wk	
Food Consumption	
Weighed 1 per wk	

TABLE 1 EXPERIMENTAL DESIGN AND MATERIALS AND METHODS
(Continued) IN THE 13-WEEK INHALATION STUDY OF ALLYL CHLORIDE

<Urinalysis>

Urinalysis performed on all animals that survived to end of dosing period using fresh urine collection.

The following measurement parameters were examined;
pH, Protein, Glucose, Ketone body, Bilirubin,
Occult blood, Urobilinogen.

<Hematology>

Hematological examination performed on scheduled 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>

Biochemistrical examination performed on scheduled 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 scheduled sacrificed animals.

The following organs were weighed;
thymus, adrenal, testis, ovary, heart, lung, kidney, spleen, liver, brain.

<Histopathologic Examination>

Histopathologic examination performed on all animals.

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 13-WEEK INHALATION STUDY OF ALLYL CHLORIDE

Week-Day on Study	0ppm		25ppm			50ppm			100ppm			200ppm			400ppm		
	Av.Wt.	No.of Surviv. <10>	Av.Wt.	% of cont. <10>	No.of Surviv.	Av.Wt.	% of cont. <10>	No.of Surviv.	Av.Wt.	% of cont. <10>	No.of Surviv.	Av.Wt.	% of cont. <10>	No.of Surviv.	Av.Wt.	% of cont. <10>	No.of Surviv.
0-0	113 (10)	10/10	113 (10)	100	10/10	113 (10)	100	10/10	113 (10)	100	10/10	113 (10)	100	10/10	113 (10)	100	10/10
1-7	141 (10)	10/10	139 (10)	99	10/10	145 (10)	103	10/10	142 (10)	101	10/10	138 (10)	98	10/10	133 (10)	94	10/10
2-7	171 (10)	10/10	166 (10)	97	10/10	179 (10)	105	10/10	173 (10)	101	10/10	168 (10)	98	10/10	161 (10)	94	10/10
3-7	195 (10)	10/10	190 (10)	97	10/10	203 (10)	104	10/10	197 (10)	101	10/10	194 (10)	99	10/10	184 (10)	94	10/10
4-7	215 (10)	10/10	209 (10)	97	10/10	221 (10)	103	10/10	217 (10)	101	10/10	212 (10)	99	10/10	202 (10)	94	10/10
5-7	233 (10)	10/10	226 (10)	97	10/10	236 (10)	101	10/10	235 (10)	101	10/10	229 (10)	98	10/10	161 (8)	69	8/10
6-7	247 (10)	10/10	236 (10)	96	10/10	247 (10)	100	10/10	247 (10)	100	10/10	239 (10)	97	10/10	- (-)	-	0/10
7-7	259 (10)	10/10	248 (10)	96	10/10	260 (10)	100	10/10	259 (10)	100	10/10	253 (10)	98	10/10	- (-)	-	0/10
8-7	271 (10)	10/10	261 (10)	96	10/10	274 (10)	101	10/10	271 (10)	100	10/10	261 (10)	96	10/10	- (-)	-	0/10
9-7	279 (10)	10/10	268 (10)	96	10/10	279 (10)	100	10/10	281 (10)	101	10/10	269 (10)	96	10/10	- (-)	-	0/10
10-7	286 (10)	10/10	274 (10)	96	10/10	284 (10)	99	10/10	287 (10)	100	10/10	279 (10)	98	10/10	- (-)	-	0/10
11-7	287 (10)	10/10	275 (10)	96	10/10	287 (10)	100	10/10	287 (10)	100	10/10	277 (10)	97	10/10	- (-)	-	0/10
12-7	299 (10)	10/10	288 (10)	96	10/10	299 (10)	100	10/10	298 (10)	100	10/10	292 (10)	98	10/10	- (-)	-	0/10
13-7	304 (10)	10/10	291 (10)	96	10/10	298 (10)	98	10/10	304 (10)	100	10/10	298 (10)	98	10/10	- (-)	-	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 13-WEEK INHALATION STUDY OF ALLYL CHLORIDE

Week-Day on Study	0ppm		25ppm			50ppm			100ppm			200ppm			400ppm		
	Av.Wt.	No.of Surviv. <10>	Av.Wt.	% of cont. <10>	No.of Surviv.	Av.Wt.	% of cont. <10>	No.of Surviv.	Av.Wt.	% of cont. <10>	No.of Surviv.	Av.Wt.	% of cont. <10>	No.of Surviv.	Av.Wt.	% of cont. <10>	No.of Surviv.
0-0	97 (10)	10/10	97 (10)	100	10/10	97 (10)	100	10/10	97 (10)	100	10/10	97 (10)	100	10/10	97 (10)	100	10/10
1-7	110 (10)	10/10	110 (10)	100	10/10	114 (10)	104	10/10	112 (10)	102	10/10	111 (10)	101	10/10	108 (10)	98	10/10
2-7	123 (10)	10/10	124 (10)	101	10/10	129 (10)	105	10/10	128 (10)	104	10/10	125 (10)	102	10/10	121 (10)	98	10/10
3-7	133 (10)	10/10	134 (10)	101	10/10	139 (10)	105	10/10	138 (10)	104	10/10	134 (10)	101	10/10	129 (10)	97	10/10
4-7	139 (10)	10/10	142 (10)	102	10/10	145 (10)	104	10/10	144 (10)	104	10/10	139 (10)	100	10/10	132 (10)	95	10/10
5-7	149 (10)	10/10	149 (10)	100	10/10	153 (10)	103	10/10	152 (10)	102	10/10	145 (10)	97	10/10	104 (5)	70	5/10
6-7	154 (10)	10/10	155 (10)	101	10/10	159 (10)	103	10/10	156 (10)	101	10/10	148 (10)	96	10/10	- (-)	-	0/10
7-7	159 (10)	10/10	160 (10)	101	10/10	165 (10)	104	10/10	163 (10)	103	10/10	154 (10)	97	10/10	- (-)	-	0/10
8-7	163 (10)	10/10	164 (10)	101	10/10	172 (10)	106	10/10	164 (10)	101	10/10	157 (10)	96	10/10	- (-)	-	0/10
9-7	166 (10)	10/10	169 (10)	102	10/10	173 (10)	104	10/10	171 (10)	103	10/10	158 (10)	95	10/10	- (-)	-	0/10
10-7	171 (10)	10/10	170 (10)	99	10/10	178 (10)	104	10/10	171 (10)	100	10/10	163 (10)	95	10/10	- (-)	-	0/10
11-7	167 (10)	10/10	170 (10)	102	10/10	176 (10)	105	10/10	172 (10)	103	10/10	161 (10)	96	10/10	- (-)	-	0/10
12-7	175 (10)	10/10	175 (10)	100	10/10	184 (10)	105	10/10	178 (10)	102	10/10	167 (10)	95	10/10	- (-)	-	0/10
13-7	178 (10)	10/10	176 (10)	99	10/10	183 (10)	103	10/10	182 (10)	102	10/10	171 (10)	96	10/10	- (-)	-	0/10
< > : No.of effective animals, () : No.of measured animals Av.Wt. : g																	

TABLE 4 FOOD CONSUMPTION CHANGES OF MALE RATS IN THE 13-WEEK INHALATION STUDY OF ALLYL CHLORIDE

Week-Day on Study	0ppm			25ppm			50ppm			100ppm			200ppm			400ppm		
	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.	Av.FC.	% of cont.	No.of Surviv.
		<10>			<10>			<10>			<10>			<10>			<10>	
1-7	14.0 (10)	10/10		13.8 (10)	99	10/10	14.0 (10)	100	10/10	14.1 (10)	101	10/10	14.1 (10)	101	10/10	13.7 (10)	98	10/10
2-7	15.1 (10)	10/10		14.5 (10)	96	10/10	16.2 (10)	107	10/10	16.2 (10)	107	10/10	15.4 (10)	102	10/10	16.9 (10)	112	10/10
3-7	15.9 (10)	10/10		15.2 (10)	96	10/10	16.5 (10)	104	10/10	15.8 (10)	99	10/10	16.0 (10)	101	10/10	17.7 (10)	111	10/10
4-7	16.6 (10)	10/10		15.8 (10)	95	10/10	16.7 (10)	101	10/10	16.5 (10)	99	10/10	16.2 (10)	98	10/10	18.9 (10)	114	10/10
5-7	16.6 (10)	10/10		15.5 (10)	93	10/10	16.9 (10)	102	10/10	16.4 (10)	99	10/10	16.6 (10)	100	10/10	12.3 (8)	74	8/10
6-7	16.3 (10)	10/10		15.1 (10)	93	10/10	15.0 (10)	92	10/10	16.2 (10)	99	10/10	16.0 (10)	98	10/10	- (-)	-	0/10
7-7	16.4 (10)	10/10		15.4 (10)	94	10/10	14.9 (10)	91	10/10	16.3 (10)	99	10/10	16.5 (10)	101	10/10	- (-)	-	0/10
8-7	16.6 (10)	10/10		15.6 (10)	94	10/10	15.7 (10)	95	10/10	16.5 (10)	99	10/10	16.3 (10)	98	10/10	- (-)	-	0/10
9-7	16.1 (10)	10/10		15.3 (10)	95	10/10	15.6 (10)	97	10/10	16.5 (10)	102	10/10	16.4 (10)	102	10/10	- (-)	-	0/10
10-7	15.9 (10)	10/10		14.9 (10)	94	10/10	15.3 (10)	96	10/10	16.0 (10)	101	10/10	16.3 (10)	103	10/10	- (-)	-	0/10
11-7	15.4 (10)	10/10		14.4 (10)	94	10/10	15.3 (10)	99	10/10	15.6 (10)	101	10/10	16.1 (10)	105	10/10	- (-)	-	0/10
12-7	16.0 (10)	10/10		15.3 (10)	96	10/10	15.7 (10)	98	10/10	15.9 (10)	99	10/10	17.0 (10)	106	10/10	- (-)	-	0/10
13-7	15.6 (10)	10/10		14.8 (10)	95	10/10	14.7 (10)	94	10/10	15.6 (10)	100	10/10	16.4 (10)	105	10/10	- (-)	-	0/10
< > : No.of effective animals, () : No.of measured animals Av.FC. : g																		

TABLE 5 FOOD CONSUMPTION CHANGES OF FEMALE RATS IN THE 13-WEEK INHALATION STUDY OF ALLYL CHLORIDE

Week-Day on Study	0ppm		25ppm			50ppm			100ppm			200ppm			400ppm		
	Av.FC.	No.of Surviv. <10>	Av.FC.	% of cont. <10>	No.of Surviv.	Av.FC.	% of cont. <10>	No.of Surviv.	Av.FC.	% of cont. <10>	No.of Surviv.	Av.FC.	% of cont. <10>	No.of Surviv.	Av.FC.	% of cont. <10>	No.of Surviv.
1-7	11.2 (10)	10/10	11.4 (10)	102	10/10	11.7 (10)	104	10/10	12.2 (10)	109	10/10	12.0 (10)	107	10/10	11.8 (10)	105	10/10
2-7	11.1 (10)	10/10	11.3 (10)	102	10/10	12.6 (10)	114	10/10	13.0 (10)	117	10/10	12.4 (10)	112	10/10	13.6 (10)	123	10/10
3-7	11.3 (10)	10/10	11.1 (10)	98	10/10	11.9 (10)	105	10/10	11.8 (10)	104	10/10	11.5 (10)	102	10/10	13.2 (10)	117	10/10
4-7	11.0 (10)	10/10	11.4 (10)	104	10/10	12.1 (10)	110	10/10	11.3 (10)	103	10/10	11.3 (10)	103	10/10	12.4 (10)	113	10/10
5-7	11.8 (10)	10/10	11.7 (10)	99	10/10	12.0 (10)	102	10/10	11.8 (10)	100	10/10	11.6 (10)	98	10/10	5.6 (5)	47	5/10
6-7	11.2 (10)	10/10	11.5 (10)	103	10/10	11.5 (10)	103	10/10	11.8 (10)	105	10/10	11.1 (10)	99	10/10	- (-)	-	0/10
7-7	11.2 (10)	10/10	11.3 (10)	101	10/10	11.5 (10)	103	10/10	11.9 (10)	106	10/10	11.8 (10)	105	10/10	- (-)	-	0/10
8-7	11.0 (10)	10/10	10.8 (10)	98	10/10	11.8 (10)	107	10/10	11.5 (10)	105	10/10	11.4 (10)	104	10/10	- (-)	-	0/10
9-7	11.2 (10)	10/10	10.7 (10)	96	10/10	11.6 (10)	104	10/10	11.9 (10)	106	10/10	11.2 (10)	100	10/10	- (-)	-	0/10
10-7	11.1 (10)	10/10	11.0 (10)	99	10/10	10.9 (10)	98	10/10	11.1 (10)	100	10/10	11.7 (10)	105	10/10	- (-)	-	0/10
11-7	10.7 (10)	10/10	10.6 (10)	99	10/10	11.2 (10)	105	10/10	11.4 (10)	107	10/10	11.1 (10)	104	10/10	- (-)	-	0/10
12-7	11.0 (10)	10/10	11.0 (10)	100	10/10	11.8 (10)	107	10/10	11.3 (10)	103	10/10	11.2 (10)	102	10/10	- (-)	-	0/10
13-7	11.4 (10)	10/10	10.8 (10)	95	10/10	11.3 (10)	99	10/10	11.8 (10)	104	10/10	11.8 (10)	104	10/10	- (-)	-	0/10
< > : No.of effective animals, () : No.of measured animals Av.FC. : g																	