ジクロロメタンのマウスを用いた吸入による2週間毒性試験報告書

試験番号:0230

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TABLE 1 EXPERIMENTAL DESIGN AND MATERIALS AND METHODS IN THE 2-WEEK INHALATION STUDIES OF DICHLOROMETHANE

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<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
               Crj:BDF<sub>1</sub>mouse
      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, 1000, 2000, 4000, 8000 or 16000ppm
<Duration of Dosing>
     5 d/wk for 2 wk
<Animal Maintenance>
     Feed
               CRF-1 (Oriental Yeast Co., Ltd.)
               Sterilized by \gamma-ray
               Available ad libitum
     Water
               Filtrated and sterilized by ultraviolet ray
               Automatic watering system
               Available ad libitum
     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 chamber air changes /h
<Type and Frequency of Observation>
     Clinical Sign
               Observed 2 per d (1 per d without Exposure day)
     Body Weight
               Weighed 0-0, 1-1, 1-7, and 2-7(wk-d)
     Food Consumption
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Weighed 1-7 and 2-7(wk-d)

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EXPERIMENTAL DESIGN AND MATERIALS AND METHODS IN THE 2-WEEK INHALATION STUDIES OF DICHLOROMETHANE

<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, White blood cell (WBC),

Differential WBC.

<Biochemistry>

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

Total protein, Albumin, A/G/ ratio,

Total bilirubin, Glucose, Total cholesterol,

Glutamic oxaloacetic transaminase (GOT),

Glutamic pyruvic transaminase (GPT),

Lactate dehydrogenase (LDH),

Creatine phosphokinase (CPK),

Urea nitrogen, 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;

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

<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, gall bladder, pancreas, kidney, urinary bladder, pituitary, thyroid, parathyroid, 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 MICE IN THE 2-WEEK INHALATION STUDY OF DICHLOROMETHANE

	Control		1000ppm			2000ppm			4000ppm			8	000ppm	,	16		
Week-Day on Study	Au.Wt.	Na.of Surviv. <10>	Au.Wt.	% of cont. <10>	No.of Surviv.	Av.Wt.	% of cont. <10>	Na.of Surviv.									
0-0	22.8 (1	0) 10/10	22.5 (10)	99	10/10	22.4 (10)	98	10/10	22.6 (10)	99	10/10	22.7 (10)	100	10/10	22,5 (10)	99	5/10
1-1	23.6 (1	0) 10/10	22.9 (10)	97	10/10	22.6 (10)	96	10/10	22.8 (10)	97	10/10	21.9 (10)	93	10/10	20.4 (5)	86	5/1
1-7	24.6 (1	0) 10/10	23.7 (10)	96	10/10	23.9 (10)	97	10/10	24.4 (10)	99	10/10	23.9 (10)	97	10/10	21.5 (5)	87	5/1
2-7	25,7 (1	•	24.6 (10)	96	10/10	24.5 (10)	95	10/10	25.2 (10)	98	10/10	25.4 (10)	99	10/10	22.4 (5)	87	5/1

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

	Control		1000ppm			2000ppm				4000ppm			8000ppm			16000ppm		
Week-Day on Study	Au.Wt.	No.of Surviv. <10>	Au.Wt.	% of cont. <10>	Na.of Surviv.	Au.Wt.	% of cont. <10>	No.of Surviv.	Au.Wt.	% af cont. <10>	No.of Surviv.	Au.Wt.	% of cont. <10>	No.of Surviv.	Au.Wt.	% of cont. <10>	No.of Surviv.	
0-0	18.4 (1	0) 10/10	18.2 (10)	99	10/10	18.3 (10)	99	10/10	18.1 (10)	98	10/10	17.9 (10)	97	10/10	17.9 (10)	97	9/10	
1-1	18.7 (1	0) 10/10	18.8 (10)	101	10/10	18.5 (10)	99	10/10	18.2 (10)	97	10/10	17.4 (10)	93	10/10	14.8 (8)	79	0/10	
1-7	19.4 (1	0) 10/10	19.6 (10)	101	10/10	19.2 (10)	99	10/10	20.1 (10)	104	10/10	19.0 (10)	98	10/10	~ (-)	_	0/10	
2-7	20.8 (1	0) 10/10	21.1 (10)	101	10/10	20.5 (10)	99	10/10	20.2 (10)	97	10/10	19.9 (9)	96	10/10	- (-)		0/10	

TABLE 4 FOOD CONSUMPTION CHANGES OF MALE MICE IN THE 2-WEEK INHALATION STUDY OF DICHLOROMETHANE

	Control		1000ppm		2000ppm			4000ppm			8	mqq000		160			
Week-Day on Study	Au.FC.	No.of Surviv. <10>	Au.FC.	% of cont. <10>	No.of Surviv.	Au.FC.	% of cont. <10>	No.of Surviv.									
1-7	4.4 (10)) 10/10	4.2 (10)	95	10/10	4.3 (10)	98	10/10	4.3 (10)	98	10/10	4.0 (10)	91	10/10	3.4 (5)	77	5/10
2-7) 10/10	4.2 (10)	98	10/10	4.3 (10)	100	10/10	4.2 (10)	98	10/10	4.6 (10)	107	10/10	4.1 (5)	95	5/10

TABLE 5 FOOD CONSUMPTION CHANGES OF FEMALE MICE IN THE 2-WEEK INHALATION STUDY OF DICHLOROMETHANE

	Control		1000ppm		. 20	. 2000ppm			4000ppm			8000ppm			16000ppm		
Week-Day on Study	Au.FC.	No.of Surviv. <10>	Au.FC.	% of cont. <10>	No.of Surviv.	Au.FC.	% of cont. <10>	No.of Surviv.	Au.FC.	% of cont. <10>	No.of Surviv.	Au.FC.	% of cont. <10>	No.of Surviv.	Au.FC.	% of cont. <10>	No.of Surviv.
1-7	3,6 (1	0) 10/10	3.7 (10)	103	10/10	3.7 (10)	103	10/10	3.9 (10)	108	10/10	3.5 (10)	97	10/10	- (-)		0/10
2-7	3.7 (1		3.7 (10)	100	10/10	3.8 (10)	103	10/10	3.5 (10)	95	10/10	3.6 (9)	97	10/10	- (-)		0/10