

Chloral Hydrate, NTP TR 503 B-1

TABLE B1

Summary of the Incidence of Neoplasms in Dietary-Controlled Male Mice in the 2-Year Gavage Study of Chloral Hydrate^a

	Vehicle Control	25 mg/kg	50 mg/kg	100 mg/kg
Disposition Summary				
Animals initially in study	60	60	60	60
15-Month interim evaluation				
Early deaths				
Moribund	1	1	1	
Natural deaths	2	3		7
Survivors				
Terminal sacrifice	45	44	47	41
Animals examined microscopically	60	60	60	60
15-Month Interim Evaluation				
Alimentary System				
Liver	(12)	(12)	(12)	(12)
2-Year Study				
Alimentary System				
Intestine large, colon	(47)	(4)	(1)	(45)
Histiocytic sarcoma		1 (25%)		
Intestine small, duodenum	(47)	(4)	(1)	(44)
Adenoma	1 (2%)			
Hemangiosarcoma		1 (25%)		
Intestine small, ileum	(48)	(4)	(1)	(44)
Histiocytic sarcoma		1 (25%)		
Lymphoma malignant	1 (2%)			
Intestine small, jejunum	(47)	(5)	(1)	(44)
Lymphoma malignant	1 (2%)	2 (40%)		
Liver	(48)	(48)	(48)	(48)
Hemangiosarcoma				2 (4%)
Hepatocellular adenoma, single	7 (15%)	7 (15%)	10 (21%)	9 (19%)
Hepatocellular adenoma, multiple	2 (4%)			1 (2%)
Hepatocellular carcinoma, single	2 (4%)	3 (6%)	3 (6%)	7 (15%)
Hepatocellular carcinoma, multiple		2 (4%)	1 (2%)	1 (2%)
Histiocytic sarcoma	2 (4%)	1 (2%)		2 (4%)
Leukemia granulocytic		1 (2%)		
Lymphoma malignant	1 (2%)	1 (2%)		2 (4%)
Pancreas	(48)	(4)	(1)	(48)
Lymphoma malignant	1 (2%)			
Salivary glands	(48)	(4)	(1)	(48)
Lymphoma malignant				1 (2%)
Cardiovascular System				
Blood vessel	(48)	(4)	(1)	(48)
Histiocytic sarcoma				1 (2%)
Lymphoma malignant		1 (25%)		1 (2%)
Heart	(48)	(4)	(1)	(48)
Histiocytic sarcoma				1 (2%)
Lymphoma malignant				1 (2%)

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2-Year Study (continued)				
Endocrine System				
Pituitary gland	(43)	(3)	(1)	(38)
Adenoma, pars distalis		1 (33%)		
General Body System				
None				
Genital System				
Epididymis	(48)	(4)	(1)	(48)
Fibroma				1 (2%)
Lymphoma malignant				1 (2%)
Prostate	(47)	(4)	(1)	(46)
Histiocytic sarcoma		1 (25%)		
Lymphoma malignant				1 (2%)
Hematopoietic System				
Bone marrow	(48)	(4)	(1)	(48)
Lymphoma malignant				1 (2%)
Lymph node	(47)	(8)	(3)	(48)
Histiocytic sarcoma, renal		1 (13%)		
Lymphoma malignant, axillary				1 (2%)
Lymphoma malignant, inguinal				1 (2%)
Lymphoma malignant, lumbar	1 (2%)			1 (2%)
Lymphoma malignant, popliteal				1 (2%)
Lymphoma malignant, renal		1 (13%)		1 (2%)
Lymph node, mandibular	(46)	(3)	(1)	(48)
Lymphoma malignant				1 (2%)
Lymph node, mesenteric	(44)	(8)	(3)	(48)
Histiocytic sarcoma		1 (13%)		3 (6%)
Lymphoma malignant	3 (7%)	4 (50%)	1 (33%)	3 (6%)
Spleen	(48)	(8)	(4)	(48)
Hemangiosarcoma	1 (2%)		1 (25%)	1 (2%)
Histiocytic sarcoma				2 (4%)
Leukemia granulocytic		1 (13%)		
Lymphoma malignant	6 (13%)	2 (25%)	1 (25%)	2 (4%)
Thymus	(39)	(2)	(1)	(30)
Lymphoma malignant	1 (3%)	1 (50%)		1 (3%)
Integumentary System				
Skin	(48)	(4)	(1)	(48)
Hemangiosarcoma	1 (2%)			
Lymphoma malignant				1 (2%)
Musculoskeletal System				
Skeletal muscle	(48)	(4)	(1)	(48)
Lymphoma malignant				1 (2%)

Chloral Hydrate, NTP TR 503 B-3

TABLE B1

Summary of the Incidence of Neoplasms in Dietary-Controlled Male Mice in the 2-Year Gavage Study of Chloral Hydrate

	Vehicle Control	25 mg/kg	50 mg/kg	100 mg/kg
2-Year Study (continued)				
Nervous System				
None				
Respiratory System				
Lung	(48)	(6)	(5)	(48)
Alveolar/bronchiolar adenoma	9 (19%)	1 (17%)	3 (60%)	5 (10%)
Alveolar/bronchiolar carcinoma	2 (4%)			
Carcinoma, metastatic, harderian gland		1 (17%)		1 (2%)
Hepatocellular carcinoma, metastatic, liver				1 (2%)
Histiocytic sarcoma	1 (2%)			1 (2%)
Lymphoma malignant	2 (4%)	1 (17%)		1 (2%)
Special Senses System				
Ear	(1)			
Fibrous histiocytoma		1 (100%)		
Harderian gland	(48)	(8)	(2)	(48)
Adenoma	4 (8%)	3 (38%)	1 (50%)	4 (8%)
Carcinoma		1 (13%)		1 (2%)
Lacrimal gland	(47)	(4)	(1)	(46)
Lymphoma malignant				1 (2%)
Urinary System				
None				
Total animals with primary neoplasms ^b				
2-Year study	27	24	16	29
Total primary neoplasms				
2-Year study	49	41	21	66
Total animals with benign neoplasms				
2-Year study	20	12	12	17
Total benign neoplasms				
2-Year study	23	12	14	20
Total animals with malignant neoplasms				
2-Year study	12	14	5	16
Total malignant neoplasms				
2-Year study	26	29	7	46
Total animals with metastatic neoplasms				
2-Year study		1		
Total metastatic neoplasms				
2-Year study		1		

^a Number of animals examined microscopically at the site and the number of animals with neoplasm

^b Primary neoplasms: all neoplasms except metastatic neoplasms