

**Experiment Number:** 88073-03  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Mouse/B6C3F1

**P08: STATISTICAL ANALYSIS OF PRIMARY TUMORS**

**Test Compound:** 2',3'-Dideoxycytidine

**CAS Number:** 7481-89-2

**Date Report Requested:** 10/22/2014

**Time Report Requested:** 02:48:58

**First Dose M/F:** NA / NA

**Lab:** SRI

<b>C Number:</b>	C88073B
<b>Lock Date:</b>	02/05/1993
<b>Cage Range:</b>	All
<b>Date Range:</b>	All
<b>Reasons For Removal:</b>	All
<b>Removal Date Range:</b>	All
<b>Treatment Groups:</b>	All
<b>Study Gender:</b>	Female
<b>PWG Approval Date</b>	NONE

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**HISTORICAL CONTROL STUDIES**

**From NA 1997 report**

**SAME ROUTE**

89006-06 -- 3'-Azido-3'-deoxythymidine (AIDS) (GAVAGE METHYLCELLULOSE)

**ALL ROUTES**

05067-10 -- Theophylline (GAVAGE CORN OIL)

05068-10 -- Codeine (ORAL FEED)

05069-07 -- 1,2-Dihydro-2,2,4-trimethylquinoline (monomer) (SKIN ACETONE)

05103-04 -- 2,2-bis(Bromomethyl)-1,3-propanediol (ORAL FEED)

05136-08 -- Chloroprene (INHALATION AIR)

05156-06 -- Cobalt sulfate heptahydrate (INHALATION AIR)

05158-04 -- Molybdenum trioxide (INHALATION AIR)

05160-06 -- 1-Chloro-2-propanol, technical (ORAL WATER)

05162-10 -- Diethanolamine (SKIN ETHANOL)

05181-04 -- Tetrahydrofuran (INHALATION AIR)

05182-04 -- Phenolphthalein (ORAL FEED)

05188-06 -- Sodium xylenesulfonate (SKIN ETHANOL)

05200-06 -- Nitromethane (INHALATION AIR)

05201-06 -- Furfuryl alcohol (INHALATION AIR)

05210-04 -- Ethylbenzene (INHALATION AIR)

05212-03 -- Oxazepam (ORAL FEED)

05217-05 -- t-Butylhydroquinone (ORAL FEED)

55301-04 -- Pyridine (ORAL WATER)

55312-04 -- Coconut oil acid diethanolamine condensate (SKIN ETHANOL)

55323-04 -- Lauric acid diethanolamine condensate (SKIN ETHANOL)

60968-02 -- Isobutyraldehyde (INHALATION AIR)

88034-04 -- Ozone (INHALATION AIR)

88035-06 -- Primidone (primaclone) (ORAL FEED)

88066-01 -- Polyvinyl alcohol (VAGINAL DEIONIZED WATER)

88070-04 -- Isobutene (INHALATION AIR)

89006-02 -- Interferon AD + 3'-azido-3'-deoxythymidine (AIDS Initiative) (GAVAGE SERUM|0.5 % AQUEOUS METHYLCELLULOSE)

89006-04 -- Interferon AD + 3'-azido-3'-deoxythymidine (AIDS Initiative) (GAVAGE SERUM|0.5 % AQUEOUS METHYLCELLULOSE)

89006-06 -- 3'-Azido-3'-deoxythymidine (AIDS) (GAVAGE METHYLCELLULOSE)

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**HISTORICAL CONTROL STUDIES**

**From NA 1997 report**

89006-08 -- Interferon A (AIDS Initiative) (SUBCUTANEOUS SERUM)

91014-04 -- Oleic acid diethanolamine condensate (SKIN ETHANOL)

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**FOR ALL DOSES THE TUMOR RATES IN THE FOLLOWING TISSUES/ORGANS ARE BASED ON NUMBER OF TISSUES  
IN OTHER TISSUES/ORGANS RATES ARE BASED ON THE NUMBER OF ANIMALS NECROPSIED.**

NA

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**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF 2',3'-DIDEOXYCYTIDINE**

**FEMALE MOUSE**

**Organ**

All Organs

**Morphology**

Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type

Malignant and Benign Tumors

Malignant Tumors

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**STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MOUSE(B6C3F1)  
LAST REMOVAL AT 25 WEEKS**

DOSE	FEMALE		
	VEHICLE CONTROL	500 MG/KG	1000 MG/KG
<b>Uterus</b>			
<b>Polyp Stromal</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL(a)	1/50 (2%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	1/50.00	0/50.00	3/48.04
POLY-3 PERCENT (g)	2%	0%	6.2%
TERMINAL (d)	1/50 (2%)	0/50 (0%)	3/44 (7%)
FIRST INCIDENCE	183(T)	---	183(T)
HC TUMORS SAME ROUTE	1/50 (2%)		
HC TUMORS ALL ROUTES	52/1653 (3%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.173	P=0.500N	P=0.292
POLY 1.5	P=0.174	P=0.500N	P=0.298
POLY 6	P=0.172	P=0.500N	P=0.284
COCH-ARM / FISHERS	P=0.176	P=0.500N	P=0.309
MAX-ISO-POLY-3	P=0.079	P=0.159N	P=0.151
HISTCONT SAME RTE	P=0.177	P=1.000	P=0.305
HISTCONT ALL RTEs	P=0.217	P=1.000	P=0.169
CURR VS HC SAME RTE	P=1.000		
CURR VS HC ALL RTEs	P=0.636		

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 First Dose M/F: NA / NA  
 Lab: SRI

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 25 WEEKS

DOSE	FEMALE		
	VEHICLE CONTROL	500 MG/KG	1000 MG/KG
<b>All Organs</b>			
<b>Benign Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL(a)	2/50 (4%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	2/50.00	0/50.00	3/48.04
POLY-3 PERCENT (g)	4%	0%	6.2%
TERMINAL (d)	2/50 (4%)	0/50 (0%)	3/44 (7%)
FIRST INCIDENCE	183(T)	---	183(T)
HC TUMORS SAME ROUTE	30/50 (60%)		
HC TUMORS ALL ROUTES	1000/1653 (60%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.386	P=0.237N	P=0.482
POLY 1.5	P=0.388	P=0.237N	P=0.490
POLY 6	P=0.384	P=0.237N	P=0.471
COCH-ARM / FISHERS	P=0.390	P=0.247N	P=0.500
MAX-ISO-POLY-3	P=0.178	P=0.077N	P=0.312
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.000**		
CURR VS HC ALL RTEs	P=0.000**		

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STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 25 WEEKS

DOSE	FEMALE		
	VEHICLE CONTROL	500 MG/KG	1000 MG/KG
<b>All Organs</b>			
<b>Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL(a)	0/50 (0%)	3/50 (6%)	15/50 (30%)
POLY-3 RATE (b)	0/50.00	3/50.00	15/50.00
POLY-3 PERCENT (g)	0%	6%	30%
TERMINAL (d)	0/50 (0%)	3/50 (6%)	9/44 (20%)
FIRST INCIDENCE	---	183(T)	126
HC TUMORS SAME ROUTE	5/50 (10%)		
HC TUMORS ALL ROUTES	261/1653 (16%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.000**	P=0.119	P=0.000**
POLY 1.5	P=0.000**	P=0.119	P=0.000**
POLY 6	P=0.000**	P=0.119	P=0.000**
COCH-ARM / FISHERS	P=0.000**	P=0.121	P=0.000**
MAX-ISO-POLY-3	P=0.000**	P=0.039*	P=0.000**
HISTCONT SAME RTE	P=0.145	P=1.000	P=0.180
HISTCONT ALL RTEs	P=0.064	P=1.000	P=0.011*
CURR VS HC SAME RTE	P=0.016*		
CURR VS HC ALL RTEs	P=0.002**		



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STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MOUSE(B6C3F1)  
 LAST REMOVAL AT 25 WEEKS

DOSE	FEMALE		
	VEHICLE CONTROL	500 MG/KG	1000 MG/KG
<b>All Organs</b>			
<b>Malignant Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL(a)	0/50 (0%)	3/50 (6%)	15/50 (30%)
POLY-3 RATE (b)	0/50.00	3/50.00	15/50.00
POLY-3 PERCENT (g)	0%	6%	30%
TERMINAL (d)	0/50 (0%)	3/50 (6%)	9/44 (20%)
FIRST INCIDENCE	---	183(T)	126
HC TUMORS SAME ROUTE	26/50 (52%)		
HC TUMORS ALL ROUTES	782/1653 (47%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.000**	P=0.119	P=0.000**
POLY 1.5	P=0.000**	P=0.119	P=0.000**
POLY 6	P=0.000**	P=0.119	P=0.000**
COCH-ARM / FISHERS	P=0.000**	P=0.121	P=0.000**
MAX-ISO-POLY-3	P=0.000**	P=0.039*	P=0.000**
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.000**		
CURR VS HC ALL RTEs	P=0.000**		

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DOSE	FEMALE		
	VEHICLE CONTROL	500 MG/KG	1000 MG/KG
<b>All Organs</b>			
<b>Malignant and Benign Tumors</b>			
<b>TUMOR RATES</b>	#	#	#
OVERALL(a)	2/50 (4%)	3/50 (6%)	17/50 (34%)
POLY-3 RATE (b)	2/50.00	3/50.00	17/50.00
POLY-3 PERCENT (g)	4%	6%	34%
TERMINAL (d)	2/50 (4%)	3/50 (6%)	11/44 (25%)
FIRST INCIDENCE	183(T)	183(T)	126
HC TUMORS SAME ROUTE	41/50 (82%)		
HC TUMORS ALL ROUTES	1335/1653 (81%)		
<b>STATISTICAL TESTS</b>			
POLY 3	P=0.000**	P=0.500	P=0.000**
POLY 1.5	P=0.000**	P=0.500	P=0.000**
POLY 6	P=0.000**	P=0.500	P=0.000**
COCH-ARM / FISHERS	P=0.000**	P=0.500	P=0.000**
MAX-ISO-POLY-3	P=0.000**	P=0.324	P=0.000**
HISTCONT SAME RTE	(h)	(h)	(h)
HISTCONT ALL RTEs	(h)	(h)	(h)
CURR VS HC SAME RTE	P=0.000**		
CURR VS HC ALL RTEs	P=0.000**		

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**LEGEND**

- (a) Number of tumor-bearing animals/number of animals examined at site.
  - (b) Number of tumor-bearing animals/Poly-3 number
  - (d) Observed incidence at terminal kill.
  - (e) Value of statistic cannot be computed.
  - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
  - (g) Poly-3 adjusted lifetime tumor incidence.
  - (n) No statistics are calculated if all dose groups have fewer than two tumors.
  - (I) Interim sacrifice
  - (T) Terminal sacrifice
  - # Tumor rates based on numbers of animals necropsied.
  - \* To the right of any statistical result, indicates significance at ( $P \leq 0.05$ ).
  - \*\* To the right of any statistical result, indicates significance at ( $P \leq 0.01$ ).
  - N Indicates a negative trend for all tests
- The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

**\*\* END OF REPORT \*\***