

Experiment Number: 00058 - 04
Test Type: CHRONIC
Route: GAVAGE
Species/Strain: MICE/B6C3F1/N

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Black Cohosh
CAS Number: 84776-26-1

Date Report Requested: 12/10/2020
Time Report Requested: 12:20:52
First Dose M/F: NA / 04/09/12
Lab: BAT

12 Month SSAC Mice_Final 1

NTP Study Number: C00058B
Lock Date: 10/02/2018
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: 08-Apr-2013 - 08-Apr-2013
Treatment Groups: Include ALL
Study Gender: Female
TDMSE Version: 3.0.2.3_002
PWG Approval Date: NONE

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SUMMARY OF STATISTICALLY SIGNIFICANT ($P \leq .05$) RESULTS IN THE ANALYSIS OF BLACK COHOSH

FEMALE MICE

Organ

Spleen

Morphology

Extramedullary Hematopoiesis Increased

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN MICE(B6C3F1/N)
 LAST REMOVAL AT 53 WEEKS**

DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Spleen					
Extramedullary Hematopoiesis Increased					
LESION RATES					
OVERALL (a)	2/10 (20%)	3/10 (30%)	8/10 (80%)	4/10 (40%)	6/10 (60%)
POLY-3 RATE (b)	2/10.00	3/10.00	8/10.00	4/10.00	6/10.00
POLY-3 PERCENT (g)	20%	30%	80%	40%	60%
INT SACRIFICE 1	2/10 (20%)	3/10 (30%)	8/10 (80%)	4/10 (40%)	6/10 (60%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	365 (I)				
STATISTICAL TESTS					
POLY 3	P=0.176	P=0.500	P=0.004**	P=0.318	P=0.077
POLY 1.5	P=0.176	P=0.500	P=0.004**	P=0.318	P=0.077
POLY 6	P=0.176	P=0.500	P=0.004**	P=0.318	P=0.077
COCH-ARM / FISHERS	P=0.188	P=0.500	P=0.012*	P=0.314	P=0.085
MAX-ISO-POLY-3	P=0.051	P=0.310	P<0.001**	P=0.171	P=0.029*

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DOSE	Females				
	0 mg/kg	30 mg/kg	100 mg/kg	300 mg/kg	1000 mg/kg
Spleen					
Hyperplasia Lymphocyte					
LESION RATES					
OVERALL (a)	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
POLY-3 RATE (b)	1/10.00	0/10.00	0/10.00	0/10.00	0/10.00
POLY-3 PERCENT (g)	10%	0%	0%	0%	0%
INT SACRIFICE 1	1/10 (10%)	0/10 (0%)	0/10 (0%)	0/10 (0%)	0/10 (0%)
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	365 (I)	---	---	---	---
STATISTICAL TESTS					
POLY 3	P=0.568N	P=0.500N	P=0.500N	P=0.500N	P=0.500N
POLY 1.5	P=0.568N	P=0.500N	P=0.500N	P=0.500N	P=0.500N
POLY 6	P=0.568N	P=0.500N	P=0.500N	P=0.500N	P=0.500N
COCH-ARM / FISHERS	P=0.569N	P=0.500N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.099N	P=0.158N	P=0.158N	P=0.158N	P=0.158N

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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 ***