

Experiment Number: A21919

Test Type: **Genetic Toxicology - Bacterial  
Mutagenicity**

**G06: Ames Summary Data**

Test Compound: **Bisacodyl**

CAS Number: **603-50-9**

Date Report Requested: **09/16/2018**

Time Report Requested: **10:13:21**

**NTP Study Number:**

A21919

**Study Result:**

Negative

Experiment Number: A21919  
Test Type: Genetic Toxicology - Bacterial  
Mutagenicity

G06: Ames Summary Data  
Test Compound: Bisacodyl  
CAS Number: 603-50-9

Date Report Requested: 09/16/2018  
Time Report Requested: 10:13:21

Strain: TA100

Dose (ug/Plate)	Without S9	Without S9	With 10% Rat S9	With 30% Rat S9	With 10% Hamster S9
Vehicle Control <sup>1</sup>	126 ± 17.7	85 ± 9.0	107 ± 3.2	163 ± 5.3	98 ± 10.7
100.0	143 ± 2.0	95 ± 8.6	122 ± 14.0	145 ± 9.3	108 ± 6.2
333.0	155 ± 3.3 <sup>p</sup>	96 ± 2.1 <sup>p</sup>	120 ± 4.7	141 ± 19.3	114 ± 1.3
1000.0	126 ± 9.6 <sup>p</sup>	103 ± 4.3 <sup>p</sup>	115 ± 6.4	167 ± 3.8	108 ± 8.0
3333.0	133 ± 9.8 <sup>p</sup>	119 ± 15.7 <sup>p</sup>	125 ± 6.6 <sup>p</sup>	105 ± 2.3 <sup>p</sup>	83 ± 13.9 <sup>p</sup>
10000.0	134 ± 6.0 <sup>p</sup>	99 ± 16.7 <sup>p</sup>	113 ± 6.7 <sup>p</sup>	134 ± 7.6 <sup>p</sup>	85 ± 3.5 <sup>p</sup>
Trial Summary	Negative	Negative	Negative	Negative	Negative
Positive Control <sup>2</sup>					544 ± 7.8
Positive Control <sup>3</sup>			433 ± 10.1		
Positive Control <sup>4</sup>	999 ± 31.5	572 ± 42.4			
Positive Control <sup>5</sup>				1031 ± 50.8	

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Date Report Requested: 09/16/2018  
Time Report Requested: 10:13:21

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Strain: TA100

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Dose (ug/Plate)	With 30% Hamster S9
Vehicle Control <sup>1</sup>	150 ± 9.0
100.0	171 ± 5.4
333.0	167 ± 8.0
1000.0	160 ± 4.8
3333.0	120 ± 12.3 <sup>P</sup>
10000.0	95 ± 10.9 <sup>P</sup>
Trial Summary	Negative
Positive Control <sup>2</sup>	
Positive Control <sup>3</sup>	1313 ± 55.4
Positive Control <sup>4</sup>	
Positive Control <sup>5</sup>	

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Strain: TA1535

Dose (ug/Plate)	Without S9	Without S9	With 10% Rat S9	With 30% Rat S9	With 10% Hamster S9
Vehicle Control <sup>1</sup>	9 ± 1.2	9 ± 1.2	11 ± 1.2	11 ± 1.9	11 ± 0.3
100.0	14 ± 3.3	9 ± 2.6	10 ± 1.5	15 ± 2.3	6 ± 0.3
333.0	8 ± 1.2 <sup>p</sup>	12 ± 3.5 <sup>p</sup>	9 ± 1.8	12 ± 2.0	6 ± 2.0
1000.0	7 ± 1.9 <sup>p</sup>	7 ± 3.2 <sup>p</sup>	7 ± 1.3	9 ± 2.0	5 ± 0.3
3333.0	10 ± 2.1 <sup>p</sup>	9 ± 0.3 <sup>p</sup>	5 ± 0.7 <sup>p</sup>	6 ± 1.0 <sup>p</sup>	9 ± 0.3 <sup>p</sup>
10000.0	8 ± 1.7 <sup>p</sup>	5 ± 0.6 <sup>p</sup>	6 ± 0.3 <sup>p</sup>	7 ± 0.9 <sup>p</sup>	7 ± 1.3 <sup>p</sup>
Trial Summary	Negative	Negative	Negative	Negative	Negative
Positive Control <sup>3</sup>					131 ± 3.8
Positive Control <sup>4</sup>	572 ± 14.4	719 ± 13.9			
Positive Control <sup>5</sup>			63 ± 7.4		
Positive Control <sup>6</sup>				132 ± 3.9	

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Test Type: Genetic Toxicology - Bacterial  
Mutagenicity

G06: Ames Summary Data  
Test Compound: Bisacodyl  
CAS Number: 603-50-9

Date Report Requested: 09/16/2018  
Time Report Requested: 10:13:21

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Strain: TA1535

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Dose (ug/Plate)	With 30% Hamster S9
Vehicle Control <sup>1</sup>	11 ± 1.2
100.0	10 ± 2.3
333.0	14 ± 1.2
1000.0	8 ± 0.6
3333.0	6 ± 1.9 <sup>p</sup>
10000.0	8 ± 1.5 <sup>p</sup>
Trial Summary	Negative
Positive Control <sup>3</sup>	
Positive Control <sup>4</sup>	
Positive Control <sup>5</sup>	245 ± 13.1
Positive Control <sup>6</sup>	

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 Time Report Requested: 10:13:21

Strain: TA97

Dose (ug/Plate)	Without S9	Without S9	With 10% Rat S9	With 30% Rat S9	With 10% Hamster S9
Vehicle Control <sup>1</sup>	122 ± 1.2	111 ± 7.7	122 ± 12.1	204 ± 2.3	126 ± 3.3
100.0	139 ± 9.4	101 ± 7.7	148 ± 10.4	167 ± 3.6	151 ± 2.9
333.0	130 ± 2.6 <sup>P</sup>	121 ± 2.4 <sup>P</sup>	161 ± 7.4	157 ± 5.0	144 ± 6.0
1000.0	153 ± 5.7 <sup>P</sup>	112 ± 10.1 <sup>P</sup>	148 ± 12.1	144 ± 9.8	140 ± 2.7
3333.0	143 ± 11.5 <sup>P</sup>	149 ± 27.1 <sup>P</sup>	156 ± 13.3 <sup>P</sup>	146 ± 6.0 <sup>P</sup>	132 ± 6.4 <sup>P</sup>
10000.0	136 ± 6.8 <sup>P</sup>	125 ± 0.7 <sup>P</sup>	195 ± 28.7 <sup>P</sup>	145 ± 30.7 <sup>P</sup>	133 ± 5.5 <sup>P</sup>
Trial Summary	Negative	Negative	Equivocal	Negative	Negative
Positive Control <sup>2</sup>					541 ± 10.9
Positive Control <sup>3</sup>			536 ± 6.5		
Positive Control <sup>5</sup>				452 ± 9.8	
Positive Control <sup>7</sup>	351 ± 15.7	366 ± 56.0			

Experiment Number: A21919  
Test Type: Genetic Toxicology - Bacterial  
Mutagenicity

G06: Ames Summary Data  
Test Compound: Bisacodyl  
CAS Number: 603-50-9

Date Report Requested: 09/16/2018  
Time Report Requested: 10:13:21

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Strain: TA97

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Dose (ug/Plate)	With 30% Hamster S9
Vehicle Control <sup>1</sup>	140 ± 5.3
100.0	137 ± 8.4
333.0	147 ± 11.0
1000.0	140 ± 7.0
3333.0	157 ± 7.7 <sup>P</sup>
10000.0	96 ± 11.7 <sup>P</sup>
Trial Summary	Negative
Positive Control <sup>2</sup>	
Positive Control <sup>3</sup>	602 ± 22.8
Positive Control <sup>5</sup>	
Positive Control <sup>7</sup>	

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Date Report Requested: 09/16/2018  
 Time Report Requested: 10:13:21

Strain: TA98

Dose (ug/Plate)	Without S9	Without S9	With 10% Rat S9	With 30% Rat S9	With 10% Hamster S9
Vehicle Control <sup>1</sup>	37 ± 1.9	17 ± 0.6	18 ± 1.5	30 ± 3.8	21 ± 0.9
100.0	34 ± 4.0	16 ± 3.2	24 ± 4.2	29 ± 1.2	17 ± 0.6
333.0	32 ± 6.1 <sup>P</sup>	17 ± 1.8 <sup>P</sup>	21 ± 1.5	37 ± 5.8	19 ± 2.6
1000.0	34 ± 4.9 <sup>P</sup>	13 ± 1.7 <sup>P</sup>	21 ± 1.0	31 ± 1.7	16 ± 2.3
3333.0	28 ± 3.8 <sup>P</sup>	13 ± 2.3 <sup>P</sup>	12 ± 1.0 <sup>P</sup>	20 ± 1.2 <sup>P</sup>	13 ± 1.5 <sup>P</sup>
10000.0	24 ± 2.6 <sup>P</sup>	9 ± 1.7 <sup>P</sup>	14 ± 2.3 <sup>P</sup>	17 ± 4.7 <sup>P</sup>	9 ± 1.9 <sup>P</sup>
Trial Summary	Negative	Negative	Negative	Negative	Negative
Positive Control <sup>2</sup>					329 ± 3.3
Positive Control <sup>3</sup>			223 ± 0.6		
Positive Control <sup>8</sup>	466 ± 15.6	391 ± 32.2			
Positive Control <sup>5</sup>				1037 ± 137.8	



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G06: Ames Summary Data  
Test Compound: Bisacodyl  
CAS Number: 603-50-9

Date Report Requested: 09/16/2018  
Time Report Requested: 10:13:21

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Strain: TA98

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Dose (ug/Plate)	With 30% Hamster S9
Vehicle Control <sup>1</sup>	33 ± 3.3
100.0	32 ± 3.4
333.0	28 ± 2.6
1000.0	32 ± 8.6
3333.0	28 ± 5.8 <sup>P</sup>
10000.0	21 ± 2.3 <sup>P</sup>
Trial Summary	Negative
Positive Control <sup>2</sup>	
Positive Control <sup>3</sup>	1041 ± 65.0
Positive Control <sup>8</sup>	
Positive Control <sup>5</sup>	

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 CAS Number: 603-50-9

Date Report Requested: 09/16/2018  
 Time Report Requested: 10:13:21

Strain: TA102

Dose (ug/Plate)	Without S9	Without S9	With 10% Rat S9	With 30% Rat S9	With 10% Hamster S9
Vehicle Control <sup>1</sup>	192 ± 1.0	222 ± 9.4	286 ± 10.0	220 ± 5.3	305 ± 9.3
100.0	189 ± 1.3	243 ± 2.3	277 ± 6.9	199 ± 0.7	309 ± 3.3
333.0	204 ± 18.1 <sup>P</sup>	272 ± 13.1 <sup>P</sup>	273 ± 16.8	208 ± 6.4	275 ± 11.7
1000.0	161 ± 3.8 <sup>P</sup>	265 ± 28.2 <sup>P</sup>	293 ± 14.9	207 ± 11.7	294 ± 13.4
3333.0	202 ± 14.7 <sup>P</sup>	210 ± 4.3 <sup>P</sup>	277 ± 9.2 <sup>P</sup>	238 ± 3.0 <sup>P</sup>	288 ± 22.9 <sup>P</sup>
10000.0	168 ± 14.0 <sup>P</sup>	221 ± 7.0 <sup>P</sup>	229 ± 12.9 <sup>P</sup>	252 ± 9.2 <sup>P</sup>	261 ± 13.5 <sup>P</sup>
Trial Summary	Negative	Negative	Negative	Negative	Negative
Positive Control <sup>9</sup>	929 ± 26.9	837 ± 39.6			
Positive Control <sup>6</sup>			721 ± 14.3	547 ± 124.9	683 ± 20.8

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Mutagenicity

G06: Ames Summary Data  
Test Compound: Bisacodyl  
CAS Number: 603-50-9

Date Report Requested: 09/16/2018  
Time Report Requested: 10:13:21

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Strain: TA102

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Dose (ug/Plate)	With 30% Hamster S9
Vehicle Control <sup>1</sup>	234 ± 8.8
100.0	241 ± 9.2
333.0	241 ± 5.5
1000.0	219 ± 10.6
3333.0	258 ± 8.1 <sup>P</sup>
10000.0	201 ± 7.5 <sup>P</sup>
Trial Summary	Negative
Positive Control <sup>9</sup>	
Positive Control <sup>6</sup>	1902 ± 109.5

Experiment Number: A21919

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G06: Ames Summary Data

Test Compound: Bisacodyl

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## Strain: TA104

Dose (ug/Plate)	Without S9	Without S9	With 10% Rat S9	With 30% Rat S9	With 10% Hamster S9
Vehicle Control <sup>1</sup>	247 ± 2.1	281 ± 9.1	354 ± 13.5	356 ± 10.4	344 ± 5.5
100.0	256 ± 8.1	270 ± 15.8	345 ± 7.4	357 ± 12.6	363 ± 12.9
333.0	267 ± 6.8 <sup>p</sup>	302 ± 18.4 <sup>p</sup>	353 ± 4.9	346 ± 7.5	362 ± 13.6
1000.0	271 ± 7.9 <sup>p</sup>	305 ± 17.8 <sup>p</sup>	333 ± 9.8	331 ± 3.8	346 ± 8.4
3333.0	256 ± 27.9 <sup>p</sup>	273 ± 11.6 <sup>p</sup>	355 ± 20.7 <sup>p</sup>	345 ± 23.2 <sup>p</sup>	341 ± 17.8 <sup>p</sup>
10000.0	224 ± 3.1 <sup>p</sup>	237 ± 14.4 <sup>p</sup>	337 ± 11.8 <sup>p</sup>	336 ± 19.7 <sup>p</sup>	311 ± 17.7 <sup>p</sup>
Trial Summary	Negative	Negative	Negative	Negative	Negative
Positive Control <sup>6</sup>			923 ± 195.9	910 ± 27.1	988 ± 28.2
Positive Control <sup>10</sup>	723 ± 9.4	679 ± 56.7			

Experiment Number: A21919  
Test Type: Genetic Toxicology - Bacterial  
Mutagenicity

G06: Ames Summary Data  
Test Compound: Bisacodyl  
CAS Number: 603-50-9

Date Report Requested: 09/16/2018  
Time Report Requested: 10:13:21

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Strain: TA104

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Dose (ug/Plate)	With 30% Hamster S9
Vehicle Control <sup>1</sup>	318 ± 5.4
100.0	350 ± 17.5
333.0	337 ± 9.5
1000.0	320 ± 5.4
3333.0	354 ± 15.2 <sup>P</sup>
10000.0	345 ± 19.0 <sup>P</sup>
Trial Summary	Negative
Positive Control <sup>6</sup>	1008 ± 13.1
Positive Control <sup>10</sup>	

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## LEGEND

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Values given as Mean or Mean  $\pm$  Standard Error Mean

The number of samples = 3, unless samples marked toxic or contaminated were excluded from mean and SEM calculations

CAS Number = Chemical Abstracts Service registry number

- 1: Vehicle Control: Dimethyl Sulfoxide
- 2: 1.0 ug/Plate 2-Aminoanthracene
- 3: 2.0 ug/Plate 2-Aminoanthracene
- 4: 5.0 ug/Plate Sodium Azide
- 5: 5.0 ug/Plate 2-Aminoanthracene
- 6: 10.0 ug/Plate 2-Aminoanthracene
- 7: 50.0 ug/Plate 9-Aminoacridine
- 8: 2.5 ug/Plate 4-Nitro-O-Phenylenediamine
- 9: 0.5 ug/Plate Mitomycin-C
- 10: 250.0 ug/Plate Methyl Methane Sulfonate
- p: Precipitate

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