

Experiment Number: A44526

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

G06: Ames Summary Data

Test Compound: **Annatto**

CAS Number: **1393-63-1**

Date Report Requested: **09/17/2018**

Time Report Requested: **00:51:01**

NTP Study Number:

A44526

Study Result:

Positive

Experiment Number: A44526

G06: Ames Summary Data

Date Report Requested: 09/17/2018

Test Type: Genetic Toxicology - Bacterial
Mutagenicity

Test Compound: Annatto

Time Report Requested: 00:51:01

Strain: TA100

| Dose (ug/Plate) | Without S9 | Without S9 | With 5% Rat S9 | With 10% Rat S9 | With 10% Rat S9 |
|-------------------------------|------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Vehicle Control ¹ | 100 ± 4.5 | 154 ± 3.3 | 124 ± 9.4 | 157 ± 3.5 | 108 ± 7.9 |
| 10.0 | | | | | |
| 16.0 | | | | | |
| 33.0 | | | | | |
| 66.0 | | | | | |
| 100.0 | 110 ± 4.3 ^p | 142 ± 8.8 ^p | 115 ± 2.7 ^p | 156 ± 4.0 ^p | 150 ± 13.3 ^p |
| 333.0 | 109 ± 6.7 ^p | 136 ± 15.7 ^p | 104 ± 3.7 ^p | 161 ± 7.8 ^p | 137 ± 21.1 ^p |
| 1000.0 | 98 ± 0.9 ^p | 139 ± 13.7 ^p | 118 ± 10.3 ^p | 193 ± 11.2 ^p | 134 ± 8.8 ^p |
| 3333.0 | 103 ± 5.0 ^p | 148 ± 13.3 ^p | 100 ± 3.3 ^p | 216 ± 3.3 ^p | 130 ± 5.2 ^p |
| 10000.0 | 108 ± 3.7 ^p | 137 ± 12.4 ^p | 131 ± 17.8 ^p | 221 ± 15.3 ^p | 134 ± 7.2 ^p |
| Trial Summary | Negative | Negative | Negative | Equivocal | Negative |
| Positive Control ² | | | | | |
| Positive Control ³ | | | 845 ± 19.6 | 629 ± 9.9 | 748 ± 25.8 |
| Positive Control ⁴ | 843 ± 13.0 | 930 ± 17.2 | | | |
| Positive Control ⁵ | | | | | |

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G06: Ames Summary Data

Date Report Requested: 09/17/2018

Test Type: Genetic Toxicology - Bacterial
Mutagenicity

Test Compound: Annatto

Time Report Requested: 00:51:01

Strain: TA100

| Dose (ug/Plate) | With 30% Rat S9 | With 10% Hamster S9 | With 30% Hamster S9 | With 30% Hamster S9 |
|-------------------------------|------------------------|-------------------------|------------------------|-------------------------|
| Vehicle Control ¹ | 119 ± 6.7 | 147 ± 7.1 | 114 ± 3.6 | 145 ± 6.7 |
| 10.0 | | | | |
| 16.0 | | | | |
| 33.0 | | | | |
| 66.0 | | | | |
| 100.0 | 128 ± 2.0 ^p | 165 ± 8.7 ^p | 178 ± 3.8 ^p | 166 ± 11.3 ^p |
| 333.0 | 126 ± 1.7 ^p | 174 ± 13.4 ^p | 173 ± 4.9 ^p | 175 ± 4.4 ^p |
| 1000.0 | 128 ± 4.6 ^p | 158 ± 11.2 ^p | 124 ± 7.1 ^p | 192 ± 13.7 ^p |
| 3333.0 | 109 ± 5.5 ^p | 151 ± 9.0 ^p | 135 ± 6.8 ^p | 175 ± 2.4 ^p |
| 10000.0 | 124 ± 4.8 ^p | 141 ± 10.5 ^p | 116 ± 5.5 ^p | 191 ± 4.3 ^p |
| Trial Summary | Negative | Negative | Equivocal | Negative |
| Positive Control ² | | 650 ± 30.6 | | |
| Positive Control ³ | | | 644 ± 18.9 | 656 ± 10.7 |
| Positive Control ⁴ | | | | |
| Positive Control ⁵ | 568 ± 17.6 | | | |

Experiment Number: A44526

G06: Ames Summary Data

Date Report Requested: 09/17/2018

Test Type: Genetic Toxicology - Bacterial
Mutagenicity

Test Compound: Annatto

Time Report Requested: 00:51:01

Strain: TA1535

| Dose (ug/Plate) | Without S9 | Without S9 | With 10% Rat S9 | With 30% Rat S9 | With 10% Hamster S9 |
|-------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Vehicle Control ¹ | 13 ± 2.4 | 12 ± 1.7 | 12 ± 2.9 | 20 ± 2.3 | 13 ± 1.2 |
| 10.0 | | | | | |
| 16.0 | | | | | |
| 33.0 | | | | | |
| 66.0 | | | | | |
| 100.0 | 10 ± 0.3 ^p | 9 ± 0.6 ^p | 14 ± 2.7 ^p | 13 ± 3.2 ^p | 11 ± 1.5 ^p |
| 333.0 | 11 ± 1.8 ^p | 10 ± 1.7 ^p | 9 ± 0.6 ^p | 17 ± 3.7 ^p | 12 ± 0.9 ^p |
| 1000.0 | 9 ± 2.0 ^p | 13 ± 1.8 ^p | 8 ± 2.6 ^p | 19 ± 5.0 ^p | 17 ± 1.2 ^p |
| 3333.0 | 12 ± 2.3 ^p | 8 ± 0.6 ^p | 11 ± 0.7 ^p | 17 ± 1.2 ^p | 11 ± 1.5 ^p |
| 10000.0 | 15 ± 2.0 ^p | 9 ± 1.2 ^p | 9 ± 1.2 ^p | 14 ± 1.2 ^p | 10 ± 0.3 ^p |
| Trial Summary | Negative | Negative | Negative | Negative | Negative |
| Positive Control ³ | | | | | 126 ± 8.0 |
| Positive Control ⁵ | | | 107 ± 18.2 | | |
| Positive Control ⁴ | 865 ± 17.3 | 961 ± 23.6 | | | |
| Positive Control ⁶ | | | | 106 ± 5.2 | |

Experiment Number: A44526
Test Type: Genetic Toxicology - Bacterial
Mutagenicity

G06: Ames Summary Data
Test Compound: Annatto
CAS Number: 1393-63-1

Date Report Requested: 09/17/2018
Time Report Requested: 00:51:01

Strain: TA1535

| Dose (ug/Plate) | With 30% Hamster S9 |
|-------------------------------|-----------------------|
| Vehicle Control ¹ | 11 ± 1.5 |
| 10.0 | |
| 16.0 | |
| 33.0 | |
| 66.0 | |
| 100.0 | 13 ± 3.0 ^p |
| 333.0 | 14 ± 1.2 ^p |
| 1000.0 | 11 ± 0.9 ^p |
| 3333.0 | 9 ± 0.9 ^p |
| 10000.0 | 9 ± 1.5 ^p |
| Trial Summary | Negative |
| Positive Control ³ | |
| Positive Control ⁵ | 120 ± 10.5 |
| Positive Control ⁴ | |
| Positive Control ⁶ | |

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G06: Ames Summary Data

Date Report Requested: 09/17/2018

Test Type: Genetic Toxicology - Bacterial
Mutagenicity

Test Compound: Annatto

Time Report Requested: 00:51:01

CAS Number: 1393-63-1

Strain: TA97

| Dose (ug/Plate) | Without S9 | Without S9 | With 10% Rat S9 | With 30% Rat S9 | With 10% Hamster S9 |
|-------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Vehicle Control ¹ | 148 ± 5.8 | 145 ± 8.7 | 154 ± 18.0 | 179 ± 10.8 | 185 ± 5.8 |
| 100.0 | 138 ± 5.8 ^p | 140 ± 8.3 ^p | 145 ± 12.2 ^p | 169 ± 16.2 ^p | 164 ± 10.6 ^p |
| 333.0 | 147 ± 9.5 ^p | 137 ± 6.7 ^p | 152 ± 18.0 ^p | 174 ± 11.0 ^p | 173 ± 12.7 ^p |
| 1000.0 | 147 ± 5.5 ^p | 154 ± 8.5 ^p | 137 ± 0.3 ^p | 194 ± 13.9 ^p | 190 ± 10.8 ^p |
| 3333.0 | 164 ± 8.4 ^p | 153 ± 17.1 ^p | 165 ± 9.0 ^p | 198 ± 6.7 ^p | 199 ± 9.8 ^p |
| 10000.0 | 151 ± 16.8 ^p | 151 ± 8.6 ^p | 164 ± 1.5 ^p | 178 ± 10.0 ^p | 170 ± 6.2 ^p |
| Trial Summary | Negative | Negative | Negative | Negative | Negative |
| Positive Control ² | | | | | 624 ± 27.2 |
| Positive Control ³ | | | 548 ± 16.5 | | |
| Positive Control ⁵ | | | | 686 ± 21.0 | |
| Positive Control ⁷ | 665 ± 15.9 | 576 ± 28.0 | | | |

Experiment Number: A44526
Test Type: Genetic Toxicology - Bacterial
Mutagenicity

G06: Ames Summary Data
Test Compound: Annatto
CAS Number: 1393-63-1

Date Report Requested: 09/17/2018
Time Report Requested: 00:51:01

Strain: TA97

| Dose (ug/Plate) | With 30% Hamster S9 |
|-------------------------------|-------------------------|
| Vehicle Control ¹ | 166 ± 16.8 |
| 100.0 | 186 ± 0.3 ^p |
| 333.0 | 183 ± 12.3 ^p |
| 1000.0 | 188 ± 5.8 ^p |
| 3333.0 | 138 ± 15.3 ^p |
| 10000.0 | 165 ± 23.3 ^p |
| Trial Summary | Negative |
| Positive Control ² | |
| Positive Control ³ | 748 ± 13.9 |
| Positive Control ⁵ | |
| Positive Control ⁷ | |

Experiment Number: A44526
 Test Type: Genetic Toxicology - Bacterial
 Mutagenicity

G06: Ames Summary Data
 Test Compound: Annatto
 CAS Number: 1393-63-1

Date Report Requested: 09/17/2018
 Time Report Requested: 00:51:01

Strain: TA98

| Dose (ug/Plate) | Without S9 | Without S9 | With 10% Rat S9 | With 30% Rat S9 | With 10% Hamster S9 |
|-------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Vehicle Control ¹ | 11 ± 0.9 | 16 ± 2.2 | 26 ± 2.3 | 20 ± 4.3 | 22 ± 3.0 |
| 100.0 | 9 ± 1.0 ^p | 12 ± 3.3 ^p | 20 ± 1.0 ^p | 19 ± 0.3 ^p | 23 ± 3.2 ^p |
| 333.0 | 7 ± 0.9 ^p | 15 ± 1.2 ^p | 24 ± 0.6 ^p | 17 ± 3.5 ^p | 18 ± 2.7 ^p |
| 1000.0 | 11 ± 2.0 ^p | 11 ± 2.7 ^p | 27 ± 2.3 ^p | 19 ± 4.7 ^p | 17 ± 3.8 ^p |
| 3333.0 | 10 ± 0.7 ^p | 13 ± 2.8 ^p | 23 ± 3.2 ^p | 19 ± 0.7 ^p | 25 ± 4.5 ^p |
| 10000.0 | 9 ± 1.0 ^p | 10 ± 0.9 ^p | 29 ± 1.7 ^p | 23 ± 2.6 ^p | 21 ± 4.8 ^p |
| Trial Summary | Negative | Negative | Negative | Negative | Negative |
| Positive Control ² | | | | | 655 ± 23.7 |
| Positive Control ³ | | | 563 ± 16.8 | | |
| Positive Control ⁸ | 450 ± 21.2 | 451 ± 17.8 | | | |
| Positive Control ⁵ | | | | 459 ± 17.8 | |

Experiment Number: A44526
Test Type: Genetic Toxicology - Bacterial
Mutagenicity

G06: Ames Summary Data
Test Compound: Annatto
CAS Number: 1393-63-1

Date Report Requested: 09/17/2018
Time Report Requested: 00:51:01

Strain: TA98

| Dose (ug/Plate) | With 30% Hamster S9 |
|-------------------------------|-----------------------|
| Vehicle Control ¹ | 20 ± 1.9 |
| 100.0 | 22 ± 3.5 ^p |
| 333.0 | 22 ± 1.2 ^p |
| 1000.0 | 21 ± 2.3 ^p |
| 3333.0 | 22 ± 0.9 ^p |
| 10000.0 | 21 ± 2.9 ^p |
| Trial Summary | Negative |
| Positive Control ² | |
| Positive Control ³ | 547 ± 11.8 |
| Positive Control ⁸ | |
| Positive Control ⁵ | |

Experiment Number: A44526

G06: Ames Summary Data

Date Report Requested: 09/17/2018

Test Type: Genetic Toxicology - Bacterial
Mutagenicity

Test Compound: Annatto

Time Report Requested: 00:51:01

Strain: TA102

| Dose (ug/Plate) | Without S9 | Without S9 | With 10% Rat S9 | With 30% Rat S9 | With 30% Rat S9 |
|-------------------------------|------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Vehicle Control ¹ | 269 ± 9.5 | 247 ± 5.2 | 271 ± 12.7 | 315 ± 31.5 | 271 ± 9.0 |
| 10.0 | | | 276 ± 6.6 | | |
| 33.0 | | | 295 ± 30.1 | | |
| 100.0 | 285 ± 6.9 ^P | 252 ± 19.8 ^P | 346 ± 15.5 ^P | 376 ± 27.0 ^P | 427 ± 20.3 ^P |
| 333.0 | 242 ± 5.8 ^P | 257 ± 22.5 ^P | 388 ± 4.3 ^P | 383 ± 30.3 ^P | 421 ± 3.7 ^P |
| 1000.0 | 249 ± 8.6 ^P | 272 ± 13.7 ^P | 383 ± 8.6 ^P | 498 ± 9.0 ^P | 440 ± 30.1 ^P |
| 3333.0 | 288 ± 5.6 ^P | 268 ± 5.8 ^P | 422 ± 49.1 ^P | 491 ± 44.6 ^P | 498 ± 27.2 ^P |
| 10000.0 | 319 ± 4.0 ^P | 289 ± 11.6 ^P | 414 ± 5.7 ^P | 433 ± 22.3 ^P | 495 ± 4.4 ^P |
| Trial Summary | Negative | Negative | Weakly Positive | Weakly Positive | Positive |
| Positive Control ⁹ | 891 ± 37.4 | 800 ± 43.1 | | | |
| Positive Control ⁶ | | | 1110 ± 60.9 | 1013 ± 56.9 | 1038 ± 57.0 |

Experiment Number: A44526

G06: Ames Summary Data

Date Report Requested: 09/17/2018

Test Type: Genetic Toxicology - Bacterial
Mutagenicity

Test Compound: Annatto

Time Report Requested: 00:51:01

Strain: TA102

| Dose (ug/Plate) | With 30% Rat S9 | With 10% Hamster S9 | With 30% Hamster S9 | With 30% Hamster S9 | With 30% Hamster S9 |
|-------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Vehicle Control ¹ | 272 ± 11.3 | 286 ± 17.3 | 340 ± 27.3 | 363 ± 52.2 | 353 ± 23.1 |
| 10.0 | 333 ± 29.5 | 282 ± 15.3 | | | 345 ± 17.7 |
| 33.0 | 358 ± 25.2 | 251 ± 7.5 | | | 342 ± 14.5 |
| 100.0 | 430 ± 18.6 ^P | 305 ± 6.1 ^P | 524 ± 8.8 ^P | 439 ± 23.4 ^P | 403 ± 10.7 ^P |
| 333.0 | 441 ± 46.8 ^P | 315 ± 26.6 ^P | 617 ± 9.4 ^P | 487 ± 10.5 ^P | 461 ± 14.1 ^P |
| 1000.0 | 386 ± 14.1 ^P | 395 ± 10.3 ^P | 568 ± 11.3 ^P | 475 ± 14.7 ^P | 417 ± 33.5 ^P |
| 3333.0 | 481 ± 10.7 ^P | 373 ± 26.3 ^P | 685 ± 48.7 ^P | 497 ± 14.0 ^P | 456 ± 30.8 ^P |
| 10000.0 | 489 ± 18.9 ^P | 428 ± 54.3 ^P | 721 ± 14.8 ^P | 598 ± 70.0 ^P | 539 ± 29.9 ^P |
| Trial Summary | Positive | Weakly Positive | Positive | Weakly Positive | Weakly Positive |
| Positive Control ⁹ | | | | | |
| Positive Control ⁶ | 1210 ± 20.6 | 1211 ± 42.0 | 1105 ± 31.1 | 1135 ± 37.9 | 1147 ± 55.4 |

Experiment Number: A44526

G06: Ames Summary Data

Date Report Requested: 09/17/2018

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

Time Report Requested: 00:51:01

Strain: TA104

| Dose (ug/Plate) | Without S9 | Without S9 | With 10% Rat S9 | With 30% Rat S9 | With 30% Rat S9 |
|--------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Vehicle Control ¹ | 434 ± 23.2 | 328 ± 25.9 | 398 ± 8.5 | 275 ± 4.7 | 445 ± 44.7 |
| 10.0 | | | 418 ± 15.5 | | |
| 33.0 | | | 412 ± 42.5 | | |
| 100.0 | 425 ± 13.3 ^p | 344 ± 14.0 ^p | 401 ± 43.0 ^p | 312 ± 37.5 ^p | 422 ± 7.9 ^p |
| 333.0 | 410 ± 47.0 ^p | 315 ± 1.5 ^p | 380 ± 16.6 ^p | 298 ± 11.3 ^p | 415 ± 24.9 ^p |
| 1000.0 | 428 ± 18.9 ^p | 356 ± 30.2 ^p | 425 ± 55.4 ^p | 312 ± 23.6 ^p | 448 ± 54.5 ^p |
| 3333.0 | 526 ± 6.4 ^p | 390 ± 14.5 ^p | 422 ± 23.2 ^p | 332 ± 27.6 ^p | 439 ± 7.5 ^p |
| 10000.0 | 464 ± 24.2 ^p | 369 ± 29.9 ^p | 419 ± 19.7 ^p | 380 ± 4.4 ^p | 508 ± 62.8 ^p |
| Trial Summary | Equivocal | Negative | Negative | Weakly Positive | Negative |
| Positive Control ⁶ | | | 1266 ± 29.0 | 1094 ± 37.5 | 1228 ± 34.3 |
| Positive Control ¹⁰ | 944 ± 19.1 | 1090 ± 73.5 | | | |

Experiment Number: A44526

G06: Ames Summary Data

Date Report Requested: 09/17/2018

Test Type: Genetic Toxicology - Bacterial
Mutagenicity

Test Compound: Annatto

Time Report Requested: 00:51:01

Strain: TA104

| Dose (ug/Plate) | With 30% Rat S9 | With 10% Hamster S9 | With 30% Hamster S9 | With 30% Hamster S9 | With 30% Hamster S9 |
|--------------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| Vehicle Control ¹ | 442 ± 17.5 | 393 ± 18.9 | 384 ± 11.1 | 448 ± 14.0 | 391 ± 10.7 |
| 10.0 | 449 ± 16.9 | 449 ± 10.9 | | | 364 ± 24.6 |
| 33.0 | 402 ± 18.9 | 458 ± 10.9 | | | 434 ± 21.3 |
| 100.0 | 438 ± 22.1 ^P | 458 ± 11.3 ^P | 496 ± 64.7 ^P | 574 ± 9.9 ^P | 529 ± 9.3 ^P |
| 333.0 | 437 ± 5.3 ^P | 511 ± 10.0 ^P | 613 ± 24.8 ^P | 588 ± 6.5 ^P | 579 ± 28.7 ^P |
| 1000.0 | 452 ± 47.3 ^P | 556 ± 16.0 ^P | 584 ± 27.8 ^P | 627 ± 19.9 ^P | 628 ± 16.0 ^P |
| 3333.0 | 422 ± 30.2 ^P | 585 ± 6.7 ^P | 681 ± 3.3 ^P | 747 ± 36.4 ^P | 659 ± 8.1 ^P |
| 10000.0 | 429 ± 17.7 ^P | 646 ± 17.3 ^P | 818 ± 2.7 ^P | 693 ± 38.9 ^P | 622 ± 26.2 ^P |
| Trial Summary | Negative | Positive | Positive | Weakly Positive | Positive |
| Positive Control ⁶ | 1165 ± 68.3 | 1254 ± 25.9 | 1214 ± 16.8 | 1237 ± 21.7 | 1276 ± 32.8 |
| Positive Control ¹⁰ | | | | | |

Experiment Number: A44526

Test Type: Genetic Toxicology - Bacterial
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G06: Ames Summary Data

Test Compound: Annatto

CAS Number: 1393-63-1

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LEGEND

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 ****