

**Study Number:** C12011-01  
**Test Type:** TOX  
**Route:** Oral Gavage  
**Species/Strain:** Rat/Harlan Sprague Dawley

**PA43: Hematology Summary**  
**Test Compound:** Bumetrizole  
**CAS Number:** 3896-11-5

**Date Report Requested:** 05/20/2021  
**Time Report Requested:** 14:47:19  
**Lab:** Battelle

**Study Number:** C12011-01  
**Study Sex:** Male  
**PWG Approval Date:** See web page for date of PWG Approval  
**Version:** v1.2.0

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| Male                                      |       |                          |   |          |       |   |          |       |   |          |       |   |          |
|-------------------------------------------|-------|--------------------------|---|----------|-------|---|----------|-------|---|----------|-------|---|----------|
|                                           |       | Treatment Groups (mg/kg) |   |          |       |   |          |       |   |          |       |   |          |
| Phase Day                                 |       | 0                        |   |          | 30    |   |          | 100   |   |          | 300   |   |          |
| Hematocrit (%)                            | SD 14 | 50.1                     | ± | 0.9 (5)  | 50.0  | ± | 0.2 (5)  | 49.6  | ± | 0.8 (5)  | 50.2  | ± | 1.4 (4)  |
| Percent of Control                        |       |                          |   |          | 99.9  |   |          | 99.1  |   |          | 100.3 |   |          |
| Manual Hematocrit (%)                     | SD 14 | 48.8                     | ± | 0.9 (5)  | 48.4  | ± | 0.2 (5)  | 49.0  | ± | 0.7 (5)  | 48.5  | ± | 0.9 (4)  |
| Percent of Control                        |       |                          |   |          | 99.2  |   |          | 100.4 |   |          | 99.4  |   |          |
| Hemoglobin (g/dL)                         | SD 14 | 15.6                     | ± | 0.3 (5)  | 15.8  | ± | 0.0 (5)  | 15.9  | ± | 0.1 (5)  | 15.8  | ± | 0.3 (4)  |
| Percent of Control                        |       |                          |   |          | 101.3 |   |          | 101.5 |   |          | 100.7 |   |          |
| Erythrocytes (10 <sup>6</sup> /uL)        | SD 14 | 8.81                     | ± | 0.11 (5) | 8.80  | ± | 0.12 (5) | 8.73  | ± | 0.24 (5) | 8.77  | ± | 0.22 (4) |
| Percent of Control                        |       |                          |   |          | 99.8  |   |          | 99.0  |   |          | 99.5  |   |          |
| Reticulocytes (10 <sup>3</sup> /uL)       | SD 14 | 216.1                    | ± | 10.6 (5) | 220.1 | ± | 11.0 (5) | 213.8 | ± | 4.1 (5)  | 188.3 | ± | 9.9 (4)  |
| Percent of Control                        |       |                          |   |          | 101.8 |   |          | 99.0  |   |          | 87.1  |   |          |
| Mean Cell Volume (fL)                     | SD 14 | 56.8                     | ± | 0.7 (5)  | 56.9  | ± | 0.6 (5)  | 56.9  | ± | 0.9 (5)  | 57.3  | ± | 1.1 (4)  |
| Percent of Control                        |       |                          |   |          | 100.2 |   |          | 100.2 |   |          | 100.9 |   |          |
| Mean Cell Hemoglobin (pg)                 | SD 14 | 17.8                     | ± | 0.2 (5)  | 18.0  | ± | 0.2 (5)  | 18.2  | ± | 0.5 (5)  | 18.0  | ± | 0.2 (4)  |
| Percent of Control                        |       |                          |   |          | 101.2 |   |          | 102.5 |   |          | 101.1 |   |          |
| Mean Cell Hemoglobin Concentration (g/dL) | SD 14 | 31.3                     | ± | 0.1 (5)  | 31.7  | ± | 0.1 (5)  | 32.0  | ± | 0.5 (5)  | 31.4  | ± | 0.4 (4)  |
| Percent of Control                        |       |                          |   |          | 101.3 |   |          | 102.5 |   |          | 100.4 |   |          |
| Platelets (10 <sup>3</sup> /uL)           | SD 14 | 655                      | ± | 131 (5)  | 773   | ± | 27 (5)   | 663   | ± | 102 (5)  | 772   | ± | 38 (4)   |
| Percent of Control                        |       |                          |   |          | 118.0 |   |          | 101.2 |   |          | 117.8 |   |          |
| White Blood Cells (10 <sup>3</sup> /uL)   | SD 14 | 10.68                    | ± | 0.76 (5) | 13.27 | ± | 0.70 (5) | 13.74 | ± | 1.04 (5) | 12.49 | ± | 0.95 (4) |
| Percent of Control                        |       |                          |   |          | 124.3 |   |          | 128.7 |   |          | 117.0 |   |          |
| Neutrophils (10 <sup>3</sup> /uL)         | SD 14 | 1.45                     | ± | 0.03 (5) | 1.78  | ± | 0.16 (5) | 1.63  | ± | 0.19 (5) | 1.42  | ± | 0.23 (4) |
| Percent of Control                        |       |                          |   |          | 122.5 |   |          | 112.6 |   |          | 97.6  |   |          |

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**Male**

|                                             |       | Treatment Groups (mg/kg) |          |         |             |         |            |         |          |
|---------------------------------------------|-------|--------------------------|----------|---------|-------------|---------|------------|---------|----------|
|                                             |       | 0                        |          | 30      |             | 100     |            | 300     |          |
| Phase Day                                   |       |                          |          |         |             |         |            |         |          |
| Lymphocytes (10 <sup>3</sup> /uL)           | SD 14 | 8.66 ±                   | 0.70 (5) | 10.52 ± | 0.63 (5)    | 11.21 ± | 0.82 (5)   | 10.32 ± | 0.66 (4) |
| Percent of Control                          |       |                          |          | 121.4   |             | 129.4   |            | 119.1   |          |
| Monocytes (10 <sup>3</sup> /uL)             | SD 14 | 0.29 ±                   | 0.05 (5) | 0.55 ±  | 0.08 (5)    | 0.55 ±  | 0.05 (5) * | 0.41 ±  | 0.04 (4) |
| Percent of Control                          |       |                          |          | 192.4   |             | 191.7   |            | 143.2   |          |
| Basophils (10 <sup>3</sup> /uL)             | SD 14 | 0.04 ±                   | 0.00 (5) | 0.07 ±  | 0.01 (5)    | 0.07 ±  | 0.01 (5)   | 0.05 ±  | 0.01 (4) |
| Percent of Control                          |       |                          |          | 161.9   |             | 166.7   |            | 125.0   |          |
| Eosinophils (10 <sup>3</sup> /uL)           | SD 14 | 0.15 ±                   | 0.05 (5) | 0.20 ±  | 0.06 (5)    | 0.16 ±  | 0.05 (5)   | 0.17 ±  | 0.05 (4) |
| Percent of Control                          |       |                          |          | 127.3   |             | 103.9   |            | 112.0   |          |
| Large Unstained Cells (10 <sup>3</sup> /uL) | SD 14 | 0.08 ±                   | 0.01 (5) | 0.15 ±  | 0.02 (5) ** | 0.12 ±  | 0.02 (5)   | 0.13 ±  | 0.01 (4) |
| Percent of Control                          |       |                          |          | 202.6   |             | 157.9   |            | 164.5   |          |

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|                                           | Phase Day | Treatment Groups |
|-------------------------------------------|-----------|------------------|
|                                           |           | 1000             |
| Hematocrit (%)                            | SD 14     | 48.6 ± 1.4 (5)   |
| Percent of Control                        |           | 97.1             |
| Manual Hematocrit (%)                     | SD 14     | 48.6 ± 0.6 (5)   |
| Percent of Control                        |           | 99.6             |
| Hemoglobin (g/dL)                         | SD 14     | 15.7 ± 0.2 (5)   |
| Percent of Control                        |           | 100.4            |
| Erythrocytes (10 <sup>6</sup> /uL)        | SD 14     | 8.54 ± 0.22 (5)  |
| Percent of Control                        |           | 96.9             |
| Reticulocytes (10 <sup>3</sup> /uL)       | SD 14     | 212.8 ± 5.6 (5)  |
| Percent of Control                        |           | 98.5             |
| Mean Cell Volume (fL)                     | SD 14     | 56.9 ± 0.3 (5)   |
| Percent of Control                        |           | 100.2            |
| Mean Cell Hemoglobin (pg)                 | SD 14     | 18.4 ± 0.4 (5)   |
| Percent of Control                        |           | 103.5            |
| Mean Cell Hemoglobin Concentration (g/dL) | SD 14     | 32.4 ± 0.8 (5)   |
| Percent of Control                        |           | 103.5            |
| Platelets (10 <sup>3</sup> /uL)           | SD 14     | 723 ± 49 (5)     |
| Percent of Control                        |           | 110.3            |
| White Blood Cells (10 <sup>3</sup> /uL)   | SD 14     | 10.99 ± 0.83 (5) |
| Percent of Control                        |           | 103.0            |
| Neutrophils (10 <sup>3</sup> /uL)         | SD 14     | 1.36 ± 0.16 (5)  |
| Percent of Control                        |           | 93.8             |

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|                                             | Phase Day | Treatment Groups |
|---------------------------------------------|-----------|------------------|
|                                             |           | 1000             |
| Lymphocytes (10 <sup>3</sup> /uL)           | SD 14     | 8.99 ± 0.69 (5)  |
| Percent of Control                          |           | 103.8            |
| Monocytes (10 <sup>3</sup> /uL)             | SD 14     | 0.40 ± 0.06 (5)  |
| Percent of Control                          |           | 138.9            |
| Basophils (10 <sup>3</sup> /uL)             | SD 14     | 0.04 ± 0.01 (5)  |
| Percent of Control                          |           | 95.2             |
| Eosinophils (10 <sup>3</sup> /uL)           | SD 14     | 0.11 ± 0.01 (5)  |
| Percent of Control                          |           | 68.8             |
| Large Unstained Cells (10 <sup>3</sup> /uL) | SD 14     | 0.10 ± 0.01 (5)  |
| Percent of Control                          |           | 134.2            |

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## LEGEND

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Values given as mean  $\pm$  SEM (N) with Percent of Control calculated by (dosed group mean / control group mean) x 100

SD – Study Day

Statistical analysis were performed by Jonckheere (trend) and Shirley or Dunn (pairwise) tests.

Statistical significance for the control group indicates a significant trend test

Statistical significance for a treatment group indicates a significant pairwise test compared to the vehicle control group

\* Statistically significant at  $P \leq 0.05$

\*\* Statistically significant at  $P \leq 0.01$

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