| | |
|---|---|
| **C Number:** | MOG003B |
| **Study Gender:** | Both |
| **PWG Approval Date** | See web page for date of PWG Approval |

**Study Number:** MOG003B
**Test Type:** MOG
**Route:** Dosing in Feed
**Species/Strain:** Rat/Sprague-Dawley

**R10: Fetal Defects**
**Test Compound:** 2-Ethylhexyl p-Methoxycinnamate
**CAS Number:** 5466-77-3

**Date Report Requested:** 01/14/2020
**Time Report Requested:** 12:17:23
**Lab:** RTI

**F1 Female: Prenatal Female**

| | Classification | Treatment Groups (ppm) 0 | 1000 | 3000 | 6000 |
|---|---|---|---|---|---|
| Total number of fetuses examined | | 283 | 229 | 183 | 218 |
| | **External** | | | | |
| No. Fetuses examined | | 283 | 229 | 183 | 218 |
| No. Litters examined | | 19 | 17 | 12 | 16 |
| **limbs** | | | | | |
| Limb, left hind, Clubbed limb | Malformation | 1 (0.35) | 0 (0.00) | 0 (0.00) | 0 (0.00) |
| | | 1 (5.26) | 0 (0.00) | 0 (0.00) | 0 (0.00) |
| Limb, right hind, Clubbed limb | Malformation | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.46) |
| | | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (6.25) |
| **placenta** | | | | | |
| Placenta, Fused | Gross Finding | 0 (0.00) | 2 (0.87) | 0 (0.00) | 0 (0.00) |
| | | 0 (0.00) | 1 (5.88) | 0 (0.00) | 0 (0.00) |

**F1 Female: Prenatal Female**

| | Classification | Treatment Groups (ppm) 0 | 1000 | 3000 | 6000 |
|---|---|---|---|---|---|
| | **Visceral** | | | | |
| No. Fetuses examined | | 283 | 229 | 183 | 218 |
| No. Litters examined | | 19 | 17 | 12 | 16 |
| **abdomen** | | | | | |
| Kidney, Hydronephrosis | Malformation | 1 (0.35) * | 0 (0.00) | 1 (0.55) | 4 (1.83) |
| | | 1 (5.26) | 0 (0.00) | 1 (8.33) | 1 (6.25) |
| Kidney, bilateral, Hydronephrosis | Malformation | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.46) |
| | | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (6.25) |
| Kidney, left, Hydronephrosis | Malformation | 0 (0.00) | 0 (0.00) | 1 (0.55) | 0 (0.00) |
| | | 0 (0.00) | 0 (0.00) | 1 (8.33) | 0 (0.00) |
| Kidney, right, Hydronephrosis | Malformation | 1 (0.35) | 0 (0.00) | 0 (0.00) | 3 (1.38) |
| | | 1 (5.26) | 0 (0.00) | 0 (0.00) | 1 (6.25) |
| Renal pelvis, Dilated | Variation | 3 (1.06) | 0 (0.00) | 2 (1.09) | 0 (0.00) |
| | | 1 (5.26) | 0 (0.00) | 1 (8.33) | 0 (0.00) |
| Renal pelvis, left, Dilated | Variation | 1 (0.35) | 0 (0.00) | 0 (0.00) | 0 (0.00) |
| | | 1 (5.26) | 0 (0.00) | 0 (0.00) | 0 (0.00) |
| Renal pelvis, right, Dilated | Variation | 2 (0.71) | 0 (0.00) | 2 (1.09) | 0 (0.00) |
| | | 1 (5.26) | 0 (0.00) | 1 (8.33) | 0 (0.00) |
| **pelvis** | | | | | |
| Testis, left, Malpositioned | Malformation | 1 (0.35) | 0 (0.00) | 0 (0.00) | 0 (0.00) |
| | | 1 (5.26) | 0 (0.00) | 0 (0.00) | 0 (0.00) |
| Ureter, Distended | Variation | 30 (10.60) | 19 (8.30) | 10 (5.46) * | 19 (8.72) |
| | | 10 (52.63) | 9 (52.94) | 6 (50.00) | 10 (62.50) |
| Ureter, Hydroureter | Malformation | 8 (2.83) | 1 (0.44) * | 4 (2.19) | 5 (2.29) |
| | | 4 (21.05) | 1 (5.88) | 2 (16.67) | 2 (12.50) |
| Ureter, bilateral, Distended | Variation | 6 (2.12) | 4 (1.75) | 0 (0.00) * | 5 (2.29) |
| | | 4 (21.05) | 3 (17.65) | 0 (0.00) | 4 (25.00) |
| Ureter, bilateral, Hydroureter | Malformation | 3 (1.06) | 0 (0.00) | 0 (0.00) | 1 (0.46) |

**F1 Female: Prenatal Female**

| | Classification | Treatment Groups (ppm) 0 | 1000 | 3000 | 6000 |
|---|---|---|---|---|---|
| | | 3 (15.79) | 0 (0.00) | 0 (0.00) | 1 (6.25) |
| Ureter, left, Distended | Variation | 15 (5.30) | 8 (3.49) | 4 (2.19) | 8 (3.67) |
| | | 7 (36.84) | 4 (23.53) | 3 (25.00) | 4 (25.00) |
| Ureter, left, Hydroureter | Malformation | 1 (0.35) | 0 (0.00) | 1 (0.55) | 1 (0.46) |
| | | 1 (5.26) | 0 (0.00) | 1 (8.33) | 1 (6.25) |
| Ureter, right, Distended | Variation | 9 (3.18) | 7 (3.06) | 6 (3.28) | 6 (2.75) |
| | | 8 (42.11) | 6 (35.29) | 4 (33.33) | 6 (37.50) |
| Ureter, right, Hydroureter | Malformation | 4 (1.41) | 1 (0.44) | 3 (1.64) | 3 (1.38) |
| | | 1 (5.26) | 1 (5.88) | 1 (8.33) | 1 (6.25) |
| **pelvis/abdomen** | | | | | |
| Kidney/ureter, Hydronephrosis and/or hydroureter | Malformation | 8 (2.83) | 1 (0.44) * | 4 (2.19) | 5 (2.29) |
| | | 4 (21.05) | 1 (5.88) | 2 (16.67) | 2 (12.50) |
| Ureter/renal pelvis, Dilated renal pelvis and/or distended ureter | Variation | 32 (11.31) | 19 (8.30) | 12 (6.56) | 19 (8.72) |
| | | 10 (52.63) | 9 (52.94) | 7 (58.33) | 10 (62.50) |
| **thorax (excluding heart)** | | | | | |
| Innominate artery, Agenesis | Variation | 4 (1.41) * | 0 (0.00) | 5 (2.73) | 6 (2.75) |
| | | 4 (21.05) | 0 (0.00) | 4 (33.33) | 3 (18.75) |
| | **Head** | | | | |
| No. Fetuses examined | | 142 | 116 | 94 | 107 |
| No. Litters examined | | 19 | 17 | 12 | 16 |

NO VISIBLE LESIONS PRESENT

**F1 Female: Prenatal Female**

| | Classification | Treatment Groups (ppm) 0 | 1000 | 3000 | 6000 |
|---|---|---|---|---|---|
| **Skeletal - Body** | | | | | |
| No. Fetuses examined | | 283 | 211 | 183 | 218 |
| No. Litters examined | | 19 | 17 | 12 | 16 |
| **ribs** | | | | | |
| Rib, Lumbar I rudimentary | Variation | 12 (4.24) ** | 8 (3.79) | 7 (3.83) | 22 (10.09) ** |
| | | 5 (26.32) | 5 (29.41) | 2 (16.67) | 7 (43.75) |
| Rib, bilateral, Lumbar I rudimentary | Variation | 4 (1.41) | 4 (1.90) | 4 (2.19) | 8 (3.67) |
| | | 2 (10.53) | 3 (17.65) | 2 (16.67) | 5 (31.25) |
| Rib, left, Lumbar I rudimentary | Variation | 0 (0.00) ** # | 4 (1.90) * | 0 (0.00) | 8 (3.67) ** |
| | | 0 (0.00) | 4 (23.53) * | 0 (0.00) | 4 (25.00) * |
| Rib, right, Lumbar I rudimentary | Variation | 8 (2.83) | 0 (0.00) * | 3 (1.64) | 6 (2.75) |
| | | 5 (26.32) | 0 (0.00) * | 1 (8.33) | 4 (25.00) |
| **sternebrae** | | | | | |
| Sternebra V, Incomplete ossification | Variation | 0 (0.00) | 1 (0.47) | 3 (1.64) | 2 (0.92) |
| | | 0 (0.00) | 1 (5.88) | 2 (16.67) | 1 (6.25) |
| **thoracic vertebrae** | | | | | |
| Thoracic centrum, Bipartite ossification | Variation | 3 (1.06) | 1 (0.47) | 0 (0.00) | 3 (1.38) |
| | | 2 (10.53) | 1 (5.88) | 0 (0.00) | 2 (12.50) |
| Thoracic centrum, Bipartite ossification, Bipartite cartilage | Malformation | 1 (0.35) | 0 (0.00) | 0 (0.00) | 0 (0.00) |
| | | 1 (5.26) | 0 (0.00) | 0 (0.00) | 0 (0.00) |
| Thoracic centrum, Bipartite ossification, Dumbbell cartilage | Variation | 3 (1.06) | 1 (0.47) | 0 (0.00) | 2 (0.92) |
| | | 2 (10.53) | 1 (5.88) | 0 (0.00) | 1 (6.25) |
| Thoracic centrum, Bipartite ossification, Normal cartilage | Variation | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (0.46) |
| | | 0 (0.00) | 0 (0.00) | 0 (0.00) | 1 (6.25) |
| Thoracic centrum, Dumbbell or Bipartite ossification | Variation | 11 (3.89) | 3 (1.42) | 3 (1.64) | 6 (2.75) |
| | | 4 (21.05) | 2 (11.76) | 2 (16.67) | 3 (18.75) |
| Thoracic centrum, Dumbbell ossification | Variation | 8 (2.83) | 3 (1.42) | 3 (1.64) | 4 (1.83) |
| | | 4 (21.05) | 2 (11.76) | 2 (16.67) | 2 (12.50) |

**F1 Female: Prenatal Female**

| | | Treatment Groups (ppm) | | | |
|---|---|---|---|---|---|
| | **Classification** | **0** | **1000** | **3000** | **6000** |
| Thoracic centrum, Dumbbell ossification, Dumbbell cartilage | Variation | 2 (0.71) | 3 (1.42) | 1 (0.55) | 2 (0.92) |
| | | 2 (10.53) | 2 (11.76) | 1 (8.33) | 2 (12.50) |
| Thoracic centrum, Dumbbell ossification, Normal cartilage | Variation | 6 (2.12) | 0 (0.00) * | 2 (1.09) | 2 (0.92) |
| | | 4 (21.05) | 0 (0.00) | 1 (8.33) | 2 (12.50) |
| **Skeletal - Skull** | | | | | |
| No. Fetuses examined | | 141 | 104 | 89 | 111 |
| No. Litters examined | | 19 | 17 | 12 | 16 |

NO VISIBLE LESIONS PRESENT

LEGEND

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Upper row denotes number of affected fetuses (%) and lower row the number of affected litters (%)

Trend and pairwise significance levels are determined using one-sided tests.

Statistical analysis for litter data and for fetal data ignoring the litter effects were performed by Cochran-Armitage (trend) and Fisher Exact (pairwise) tests.

* Statistically significant at P <= 0.05

** Statistically significant at P <= 0.01

Statistical analysis for fetal data including litter effects were performed by using a Rao-Scott modification to the Cochran-Armitage test where the Dam ID was the random effect for both trend and pairwise analysis.

# Statistically significant at P <= 0.05 (litter based analysis)

## Statistically significant at P <= 0.01 (litter based analysis)

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

** END OF REPORT **