

**Study Number:** I20263

**Test Type:** TOX

**Route:** Dosing in Feed

**Species/Strain:** Rat/Harlan Sprague Dawley

**Study Number:**

**Study Gender:**

**PWG Approval Date:**

**Version:**

I20263

Both

See web page for date of PWG Approval

v1.1.8

**I05P: Pup Clinical Observations Summary**

**Test Compound:** Tris (chloropropyl) phosphate

**CAS Number:** 13674-84-5

**Date Report Requested:** 03/23/2021

**Time Report Requested:** 12:37:05

**Lab:** Burleson Research Technologies

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|  | F1 Pups                |            |            |            |
|--|------------------------|------------|------------|------------|
|  | Treatment Groups (ppm) |            |            |            |
|  | 0                      | 2500       | 5000       | 10000      |
| <b>Total Pups (PND 0)</b>                | <b>394</b>             | <b>394</b> | <b>379</b> | <b>394</b> |
| <b>No. pups post cull (PND 4)</b>        | <b>240</b>             | <b>232</b> | <b>228</b> | <b>211</b> |
| <b>Total Litters (PND 0)</b>             | <b>30</b>              | <b>29</b>  | <b>29</b>  | <b>30</b>  |
| <b>No. litters post cull (PND 4)</b>     | <b>30</b>              | <b>29</b>  | <b>29</b>  | <b>28</b>  |
| <b>Pup Clinical Observations PND 0-4</b> |                        |            |            |            |
| Breathing, labored                       | 0                      | 0          | 0          | 1 (0.3)    |
|  | 0                      | 0          | 0          | 1 (3.3)    |
|  |                        |            |            | PND 0-4    |
| Bruising                                 | 0                      | 2 (0.5)    | 2 (0.5)    | 0          |
| Abdomen                                  | 0                      | 2 (6.9)    | 2 (6.9)    | 0          |
|  |                        | PND 1-2    | PND 0-1    |            |
| Bruising                                 | 1 (0.3)                | 0          | 0          | 2 (0.5)    |
| Dorsum                                   | 1 (3.3)                | 0          | 0          | 2 (6.7)    |
|  | PND 0                  |            |            | PND 0-2    |
| Bruising                                 | 1 (0.3)                | 0          | 1 (0.3)    | 1 (0.3)    |
| Fore Limb                                | 1 (3.3)                | 0          | 1 (3.4)    | 1 (3.3)    |
|  | PND 1-4                |            | PND 1      | PND 2-4    |
| Bruising                                 | 10 (2.5)               | 27 (6.9)   | 11 (2.9)   | 28 (7.1)   |
| Fore Paw                                 | 7 (23.3)               | 9 (31.0)   | 6 (20.7)   | 10 (33.3)  |
|  | PND 0-4                | PND 2-4    | PND 2-4    | PND 2-4    |

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F1 Pups

Treatment Groups (ppm)

|                          | 0                   | 2500                | 5000                | 10000               |
|--------------------------|---------------------|---------------------|---------------------|---------------------|
| Bruising                 | 4 (1.0)             | 3 (0.8)             | 5 (1.3)             | 11 (2.8)            |
| Head                     | 3 (10.0)<br>PND 0-3 | 3 (10.3)<br>PND 0-1 | 5 (17.2)<br>PND 0-1 | 7 (23.3)<br>PND 0-2 |
| Bruising                 | 2 (0.5)             | 4 (1.0)             | 1 (0.3)             | 4 (1.0)             |
| Hind Paw                 | 2 (6.7)<br>PND 0-3  | 2 (6.9)<br>PND 0-2  | 1 (3.4)<br>PND 0-3  | 3 (10.0)<br>PND 0-2 |
| Bruising                 | 0                   | 0                   | 1 (0.3)             | 1 (0.3)             |
| Thorax                   | 0                   | 0                   | 1 (3.4)<br>PND 1    | 1 (3.3)<br>PND 1-2  |
| Cold To Touch            | 0                   | 2 (0.5)             | 3 (0.8)             | 19 (4.8)            |
|                          | 0                   | 2 (6.9)<br>PND 0    | 2 (6.9)<br>PND 0-4  | 3 (10.0)<br>PND 1-4 |
| Dehydrated               | 0                   | 1 (0.3)             | 1 (0.3)             | 0                   |
|                          | 0                   | 1 (3.4)<br>PND 3    | 1 (3.4)<br>PND 4    | 0                   |
| Discolored               | 0                   | 1 (0.3)             | 0                   | 0                   |
| Hind Paw; Left, Black    | 0                   | 1 (3.4)<br>PND 0    | 0                   | 0                   |
| Discolored               | 0                   | 1 (0.3)             | 0                   | 0                   |
| Nose/Snout; Black, Right | 0                   | 1 (3.4)<br>PND 1    | 0                   | 0                   |

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F1 Pups

Treatment Groups (ppm)

|                  | 0                  | 2500                | 5000                | 10000               |
|------------------|--------------------|---------------------|---------------------|---------------------|
| Milk Band Absent | 0                  | 7 (1.8)             | 5 (1.3)             | 33 (8.4)            |
| Abdomen          | 0                  | 4 (13.8)<br>PND 0-3 | 5 (17.2)<br>PND 1-4 | 4 (13.3)<br>PND 2-4 |
| Missing          | 1 (0.3)            | 0                   | 0                   | 0                   |
| Tail             | 1 (3.3)<br>PND 0-1 | 0                   | 0                   | 0                   |
| Missing          | 2 (0.5)            | 1 (0.3)             | 1 (0.3)             | 2 (0.5)             |
| Tip of Tail      | 2 (6.7)<br>PND 0-4 | 1 (3.4)<br>PND 0    | 1 (3.4)<br>PND 1-4  | 2 (6.7)<br>PND 0-4  |
| Pale             | 1 (0.3)            | 2 (0.5)             | 3 (0.8)             | 1 (0.3)             |
|                  | 1 (3.3)<br>PND 0-3 | 2 (6.9)<br>PND 0-1  | 3 (10.3)<br>PND 1-2 | 1 (3.3)<br>PND 2    |
| Scab             | 1 (0.3)            | 0                   | 0                   | 0                   |
| Dorsum; Left     | 1 (3.3)<br>PND 4   | 0                   | 0                   | 0                   |
| Scab             | 1 (0.3)            | 0                   | 1 (0.3)             | 0                   |
| Dorsum           | 1 (3.3)<br>PND 1   | 0                   | 1 (3.4)<br>PND 1-4  | 0                   |
| Scab             | 0                  | 1 (0.3)             | 0                   | 0                   |
| Face             | 0                  | 1 (3.4)<br>PND 1    | 0                   | 0                   |

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F1 Pups

Treatment Groups (ppm)

|                      | 0                  | 2500             | 5000               | 10000              |
|----------------------|--------------------|------------------|--------------------|--------------------|
| Scab                 | 0                  | 0                | 0                  | 1 (0.3)            |
| Fore Limb; Bilateral | 0                  | 0                | 0                  | 1 (3.3)<br>PND 4   |
| Scab                 | 0                  | 0                | 0                  | 1 (0.3)            |
| Fore Limb; Left      | 0                  | 0                | 0                  | 1 (3.3)<br>PND 4   |
| Scab                 | 0                  | 0                | 0                  | 1 (0.3)            |
| Fore Limb; Right     | 0                  | 0                | 0                  | 1 (3.3)<br>PND 4   |
| Scab                 | 3 (0.8)            | 0                | 0                  | 0                  |
| Head                 | 2 (6.7)<br>PND 1-4 | 0                | 0                  | 0                  |
| Scab                 | 2 (0.5)            | 1 (0.3)          | 1 (0.3)            | 1 (0.3)            |
| Tip of Tail          | 2 (6.7)<br>PND 1-4 | 1 (3.4)<br>PND 0 | 1 (3.4)<br>PND 1-4 | 1 (3.3)<br>PND 0-4 |
| Sore                 | 1 (0.3)            | 0                | 0                  | 0                  |
| Dorsum; Bilateral    | 1 (3.3)<br>PND 0   | 0                | 0                  | 0                  |
| Sore                 | 0                  | 0                | 1 (0.3)            | 0                  |
| Head; Bilateral      | 0                  | 0                | 1 (3.4)<br>PND 0   | 0                  |

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|                     | F1 Pups                |                     |                     |                      |
|---------------------|------------------------|---------------------|---------------------|----------------------|
|                     | Treatment Groups (ppm) |                     |                     |                      |
|                     | 0                      | 2500                | 5000                | 10000                |
| Sore                | 0                      | 0                   | 0                   | 1 (0.3)              |
| Tip of Tail         | 0                      | 0                   | 0                   | 1 (3.3)<br>PND 0-1   |
| Swelling            | 0                      | 0                   | 1 (0.3)             | 2 (0.5)              |
| Fore Limb; Left     | 0                      | 0                   | 1 (3.4)<br>PND 2-3  | 2 (6.7)<br>PND 2-4   |
| Swelling            | 1 (0.3)                | 0                   | 3 (0.8)             | 0                    |
| Fore Paw; Left      | 1 (3.3)<br>PND 2       | 0                   | 2 (6.9)<br>PND 3    | 0                    |
| Swelling            | 1 (0.3)                | 5 (1.3)             | 3 (0.8)             | 29 (7.4)             |
| Fore Paw; Right     | 1 (3.3)<br>PND 2-3     | 4 (13.8)<br>PND 2-4 | 3 (10.3)<br>PND 3-4 | 10 (33.3)<br>PND 2-4 |
| Swelling            | 2 (0.5)                | 1 (0.3)             | 0                   | 1 (0.3)              |
| Hind Paw; Bilateral | 2 (6.7)<br>PND 2       | 1 (3.4)<br>PND 2    | 0                   | 1 (3.3)<br>PND 2     |
| Swelling            | 2 (0.5)                | 1 (0.3)             | 1 (0.3)             | 0                    |
| Hind Paw; Left      | 2 (6.7)<br>PND 2       | 1 (3.4)<br>PND 0    | 1 (3.4)<br>PND 2-4  | 0                    |
| Swelling            | 4 (1.0)                | 1 (0.3)             | 1 (0.3)             | 1 (0.3)              |
| Hind Paw; Right     | 2 (6.7)<br>PND 1-3     | 1 (3.4)<br>PND 2    | 1 (3.4)<br>PND 2    | 1 (3.3)<br>PND 2-4   |

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F1 Pups

Treatment Groups (ppm)

|   | 0                               | 2500                          | 5000                            | 10000                         |
|---|---------------------------------|-------------------------------|---------------------------------|-------------------------------|
| Thin                                      | 1 (0.3)<br>1 (3.3)<br>PND 3     | 2 (0.5)<br>2 (6.9)<br>PND 1-3 | 0<br>0                          | 1 (0.3)<br>1 (3.3)<br>PND 1-4 |
| Wound<br>Dorsum                           | 0<br>0                          | 0<br>0                        | 1 (0.3)<br>1 (3.4)<br>PND 0     | 0<br>0                        |
| Wound<br>Tail                             | 1 (0.3)<br>1 (3.3)<br>PND 0-1   | 0<br>0                        | 0<br>0                          | 0<br>0                        |
| <b>Pup Clinical Observations PND 5-28</b> |                                 |                               |                                 |                               |
| Alopecia<br>Dorsum; Left                  | 1 (0.4)<br>1 (3.3)<br>PND 11-13 | 0<br>0                        | 0<br>0                          | 0<br>0                        |
| Alopecia<br>Dorsum                        | 0<br>0                          | 0<br>0                        | 1 (0.4)<br>1 (3.4)<br>PND 14-20 | 0<br>0                        |
| Alopecia<br>Head                          | 0<br>0                          | 1 (0.4)<br>1 (3.4)<br>PND 12  | 0<br>0                          | 0<br>0                        |

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|                     | F1 Pups                |                      |                      |                      |
|---------------------|------------------------|----------------------|----------------------|----------------------|
|                     | Treatment Groups (ppm) |                      |                      |                      |
|                     | 0                      | 2500                 | 5000                 | 10000                |
| Alopecia            | 0                      | 0                    | 1 (0.4)              | 0                    |
| Hind Limb; Right    | 0                      | 0                    | 1 (3.4)<br>PND 16-17 | 0                    |
| Breathing, gasping  | 0                      | 1 (0.4)              | 0                    | 0                    |
|                     | 0                      | 1 (3.4)<br>PND 15    | 0                    | 0                    |
| Bruising            | 0                      | 0                    | 0                    | 1 (0.5)              |
| Fore Limb           | 0                      | 0                    | 0                    | 1 (3.6)<br>PND 5-7   |
| Bruising            | 0                      | 11 (4.7)             | 6 (2.6)              | 8 (3.8)              |
| Fore Paw            | 0                      | 7 (24.1)<br>PND 5-10 | 4 (13.8)<br>PND 5-8  | 5 (17.9)<br>PND 5-10 |
| Cold To Touch       | 0                      | 0                    | 0                    | 1 (0.5)              |
|                     | 0                      | 0                    | 0                    | 1 (3.6)<br>PND 5     |
| Discharge           | 0                      | 0                    | 0                    | 1 (0.5)              |
| Eye; Bilateral, Red | 0                      | 0                    | 0                    | 1 (3.6)<br>PND 20-28 |
| Discharge           | 1 (0.4)                | 0                    | 0                    | 0                    |
| Eye; Brown, Right   | 1 (3.3)<br>PND 22      | 0                    | 0                    | 0                    |



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|                     | F1 Pups                |      |         |           |
|---------------------|------------------------|------|---------|-----------|
|                     | Treatment Groups (ppm) |      |         |           |
|                     | 0                      | 2500 | 5000    | 10000     |
| Discharge           | 1 (0.4)                | 0    | 0       | 0         |
| Eye; Clear, Left    | 1 (3.3)                | 0    | 0       | 0         |
|                     | PND 28                 |      |         |           |
| Discharge           | 1 (0.4)                | 0    | 0       | 0         |
| Eye; Clear, Right   | 1 (3.3)                | 0    | 0       | 0         |
|                     | PND 28                 |      |         |           |
| Discharge           | 0                      | 0    | 1 (0.4) | 0         |
| Eye; Left, Red      | 0                      | 0    | 1 (3.4) | 0         |
|                     |                        |      | PND 27  |           |
| Discharge           | 0                      | 0    | 0       | 1 (0.5)   |
| Eye; Red, Bilateral | 0                      | 0    | 0       | 1 (3.6)   |
|                     |                        |      |         | PND 21-27 |
| Discharge           | 0                      | 0    | 1 (0.4) | 0         |
| Eye; Red, Left      | 0                      | 0    | 1 (3.4) | 0         |
|                     |                        |      | PND 28  |           |
| Discharge           | 2 (0.8)                | 0    | 0       | 0         |
| Eye; Right, Brown   | 1 (3.3)                | 0    | 0       | 0         |
|                     | PND 21-22              |      |         |           |
| Discharge           | 1 (0.4)                | 0    | 0       | 0         |
| Eye; Right, Clear   | 1 (3.3)                | 0    | 0       | 0         |
|                     | PND 28                 |      |         |           |

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F1 Pups

Treatment Groups (ppm)

|                    | 0        | 2500    | 5000     | 10000    |
|--------------------|----------|---------|----------|----------|
| Discolored         | 1 (0.4)  | 0       | 0        | 0        |
| Tip of Tail; Black | 1 (3.3)  | 0       | 0        | 0        |
|                    | PND 7-15 |         |          |          |
| Limping            | 0        | 1 (0.4) | 0        | 0        |
| Hind Limb; Severe  | 0        | 1 (3.4) | 0        | 0        |
|                    |          | PND 27  |          |          |
| Missing            | 3 (1.2)  | 0       | 1 (0.4)  | 1 (0.5)  |
| Tip of Tail        | 3 (10.0) | 0       | 1 (3.4)  | 1 (3.6)  |
|                    | PND 5-28 |         | PND 5-28 | PND 5-28 |
| Scab               | 1 (0.4)  | 0       | 0        | 0        |
| Dorsum; Left       | 1 (3.3)  | 0       | 0        | 0        |
|                    | PND 5-10 |         |          |          |
| Scab               | 0        | 0       | 1 (0.4)  | 0        |
| Dorsum             | 0        | 0       | 1 (3.4)  | 0        |
|                    |          |         | PND 5-13 |          |
| Scab               | 0        | 0       | 0        | 1 (0.5)  |
| Fore Limb; Left    | 0        | 0       | 0        | 1 (3.6)  |
|                    |          |         |          | PND 5-8  |
| Scab               | 0        | 0       | 0        | 3 (1.4)  |
| Fore Limb; Right   | 0        | 0       | 0        | 3 (10.7) |
|                    |          |         |          | PND 5-13 |

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|                  | F1 Pups                |                    |                      |                      |
|------------------|------------------------|--------------------|----------------------|----------------------|
|                  | Treatment Groups (ppm) |                    |                      |                      |
|                  | 0                      | 2500               | 5000                 | 10000                |
| Scab             | 0                      | 0                  | 0                    | 1 (0.5)              |
| Fore Limb        | 0                      | 0                  | 0                    | 1 (3.6)<br>PND 9     |
| Scab             | 1 (0.4)                | 1 (0.4)            | 0                    | 0                    |
| Head             | 1 (3.3)<br>PND 5       | 1 (3.4)<br>PND 11  | 0                    | 0                    |
| Scab             | 0                      | 0                  | 1 (0.4)              | 0                    |
| Hind Limb; Right | 0                      | 0                  | 1 (3.4)<br>PND 14-15 | 0                    |
| Scab             | 0                      | 0                  | 0                    | 1 (0.5)              |
| Tail; Bilateral  | 0                      | 0                  | 0                    | 1 (3.6)<br>PND 10-13 |
| Scab             | 2 (0.8)                | 0                  | 1 (0.4)              | 1 (0.5)              |
| Tip of Tail      | 2 (6.7)<br>PND 5-9     | 0                  | 1 (3.4)<br>PND 5-6   | 1 (3.6)<br>PND 5-10  |
| Swelling         | 0                      | 1 (0.4)            | 0                    | 7 (3.3)              |
| Fore Paw; Right  | 0                      | 1 (3.4)<br>PND 5-6 | 0                    | 4 (14.3)<br>PND 5-6  |
| Swelling         | 0                      | 1 (0.4)            | 0                    | 0                    |
| Hind Limb; Left  | 0                      | 1 (3.4)<br>PND 27  | 0                    | 0                    |

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F1 Pups

Treatment Groups (ppm)

|                 | 0 | 2500    | 5000 | 10000     |
|-----------------|---|---------|------|-----------|
| Swelling        | 0 | 0       | 0    | 1 (0.5)   |
| Hind Paw; Right | 0 | 0       | 0    | 1 (3.6)   |
|                 |   |         |      | PND 5-28  |
| Thin            | 0 | 1 (0.4) | 0    | 0         |
|                 | 0 | 1 (3.4) | 0    | 0         |
|                 |   | PND 14  |      |           |
| Vocalization    | 0 | 1 (0.4) | 0    | 0         |
| Mild            | 0 | 1 (3.4) | 0    | 0         |
|                 |   | PND 15  |      |           |
| Wound           | 0 | 0       | 0    | 1 (0.5)   |
| Hind Paw; Right | 0 | 0       | 0    | 1 (3.6)   |
|                 |   |         |      | PND 10-28 |
| Wound           | 0 | 0       | 0    | 1 (0.5)   |
| Tail; Bilateral | 0 | 0       | 0    | 1 (3.6)   |
|                 |   |         |      | PND 9     |

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## LEGEND

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Animals exhibiting clinical observations "within normal limits" were recorded as scheduled but are omitted from the table for clarity.

Upper row denotes the pup incidence N (%)

Middle row denotes the litter incidence N (%)

Lower row denotes the range of postnatal days the finding was seen for the group

F1 litter incidence based on the number of F0 dams; F2 litter incidence based on number of F1 dams.

No. live litters includes litters with  $\geq 1$  live pup

Percent incidence calculated using number of live pups or litters on PND 0 (pre cull) or PND 4 (post cull)

PND - Postnatal Day, pups pre-weaning

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