**APPENDIX 1-11: Multi-A.I. Formulation Analysis for Malathion**

|  |
| --- |
| This analysis is based on the acute oral rat studies submitted to EPA by registrants. The analysis includes data for technical grade active ingredient (TGAI) and typical end-use products (TEP). If there are multiple studies with the technical formulation for which confidence intervals (CI) are provided for the LD50, then the CI with the smallest lower CI for the LD50 (*i.e*., most toxic LD50,) after correcting for %AI, is compared to the LD50 upper CI for each formulation, after correcting for %AI. If these confidence intervals do not overlap, then the formulated mixture is considered to be more toxic to mammals on an acute exposure basis.  |
| "Percent Active Ingredient" (column I) and the "Oral LD50 Lower/Upper CIs" must be numeric values for the toxicity comparison to be done. If any of these values are non-numeric (e.g., "<50", "N/A", "highest dose"), the corresponding study will not be included in the comparison. The conclusion will be “Insufficient data to establish different toxicity”.If the CIs overlap, the conclusion will be “Formulation not more toxic than single a.i.”. If CIs are not available, the conclusion will be “Insufficient data to establish different toxicity”. If the results are from an up-and-down study (OECD Test Guideline 425 Acute Oral Toxicity-Up-and-Down Procedure), there is lower confidence in the results due to the lower number of animals used in testing. Therefore, the conclusion for any differences in the CIs based on up-and-down studies will also be “Insufficient data to establish different toxicity”. If a mixture formulation is more toxic than the technical formulation (i.e., CIs do not overlap), then the conclusion "Formulation more toxic than single AI" will be highlight red with red text. **Table B 1-11.1** presents the comparison between the studies using technical grade and multi-ai formulations. Tables **B 1-11.2** and **B 1-11.3** present intermediate calculations for the comparisons.  |

**Table B 1-11.1. Rat LD50 comparison for technical grade malathion and multi-A.i. formulations that contain malathion.**

| **Current Registration No.** | **Name** | **Percent Active Ingredient** | **Active Ingredient** | **MRID(s) for Acute Oral Study** | **Male Oral LD50 (mg/kg) (CI)1** | **Female Oral LD50 (mg/kg) (CI)1** | **Combined Oral LD50 (mg/kg) (CI)1** | **Is Formulation more toxic to males** | **Is Formulation more toxic to females** | **Is formulation more toxic to combined sexes** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **LD50 Information on Technical** |
| 4787-5 | FYFANON TECHNICAL | 96.5 | Malathion | 46761609 | 1778 (1485-2128) | 1938 (1614-2357) | 1857 (1677-2057) |  |  |  |
| 66330-219 (51036-103) | MALATHION ULV | 92 | Malathion | 00158056 | 1522 (1156-2005) | 1546 (1336-1788) | NA |  |  |  |
| 4787-5 | FYFANON TECHNICAL | 97.4 | Malathion | 00159876 | 5400 (4100-6900) | 5700 (4300-7600) | 5500 (4600-6700) |  |  |  |
| NA | NA | 95.6 | Malathion | 48153112 | 2687 (2122-3471) | 2098 (1608-2550) | 2382 |  |  |  |
| **LD50 Information for Multi-AI Formulations** |
| 4-122 | BONIDE A COMPLETE FRUIT TREE SPRAY | 6 | Malathion | 45269101 | >30- <300 | >30- <300 | >30- <300 | Insufficient data to establish different toxicity | Insufficient data to establish different toxicity | Insufficient data to establish different toxicity |
|  | BONIDE A COMPLETE FRUIT TREE SPRAY | 0.3 | Carbaryl |  |  |  |  |  |  |  |
|  | BONIDE A COMPLETE FRUIT TREE SPRAY | 11.76 | Captan |  |  |  |  |  |  |  |
| 67760-108 | Fyfanon Plus ULV | 92.2 | Malathion | 481093032 | NA | 1614 (995-3439) | NA |  | Insufficient data to establish different toxicity |  |
|  | Fyfanon Plus ULV | 1.47 | Gama cyhalothrin |  |  |  |  |  |  |  |
| 829-175 | SA-50 BRAND MALATHION-OIL CITRUS & ORNAMENTAL SPRAY | 5 | Malathion | 47627901 | NA | >250 | NA |  | Insufficient data to establish different toxicity |  |
|  | SA-50 BRAND MALATHION-OIL CITRUS & ORNAMENTAL SPRAY | 75 | Mineral Oil |  |  |  |  |  |  |  |

1 Endpoints in formulation are based on percent a.i. of malathion.

2 The results are from an up-and-down study (OECD Test Guideline 425 Acute Oral Toxicity-Up-and-Down Procedure).

**Table B 1-11.2. Intermediate calculations used to compare rat LD50 values for technical grade (TGAI) malathion and multi-A.i. formulations that contain malathion – TGAI data.**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Male LD50 Lower CI** | **%AI CorrectedMale LD50 Lower CI** | **Female LD50 Lower CI** | **%AI CorrectedFemale LD50 Lower CI** | **Combined LD50 Lower CI** | **%AI CorrectedCombined LD50 Lower CI** | **% ai** |
| **Single AI Studies** | 1485.00 | 1433.03 | 1614.00 | 1557.51 | 1677.00 | 1618.31 | 96.5 |
| 1156.00 | 1063.52 | 1336.00 | 1229.12 |   |   | 92.0 |
| 4100.00 | 3993.40 | 4300.00 | 4188.20 | 4600.00 | 4480.40 | 97.4 |
| 2122.00 | 2037.12 | 1608.00 | 1543.68 |   |   | 96.0 |
| **Minimum** | 1156.00 | 1063.52 | 1336.00 | 1229.12 | 1677.00 | 1618.31 |  |

**Table B 1-11.3. Intermediate calculations used to compare rat LD50 values for technical grade (TGAI) malathion and multi-A.i. formulations that contain malathion – formulated product data.**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Male LD50 Upper CI** | **%AI CorrectedMale LD50 Upper CI** | **Female LD50 Upper CI** | **%AI CorrectedFemale LD50 Upper CI** | **Combined LD50 Upper CI** | **%AI CorrectedCombined LD50 Upper CI** | **Reg No. & AI** | **%AI** | **%AI for Correction** |
|   |   | 3730 | 3439 |  |  | 67760-108Fyfanon Plus ULV  | 92.2 | 92.2 |