

40 C.F.R. § 158.500

Toxicology data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use the data table in paragraph (d) of this section to determine the toxicology data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test in the table are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) Food use patterns include products classified under the general use patterns of terrestrial food crop use, terrestrial feed crop use, aquatic food crop use, greenhouse food crop use, and indoor food use.

(2) Nonfood use patterns include products classified under the general use patterns of terrestrial nonfood crop use, aquatic nonfood use, greenhouse nonfood crop use, forestry use, residential outdoor use, and indoor nonfood use.

(c) *Key.* R = Required; CR = Conditionally required; NR = Not required; MP = Manufacturing-use product; EP = End-use product; TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; PAIRA = Pure active ingredient radio-labeled; Choice = Choice of several test substances depending on study required.

(d) *Table.* The following table lists the toxicology data requirements. The table notes are shown in paragraph (e) of this section.

Table—Toxicology Data Requirements

| Guideline Number | Data Requirements | Use Pattern | | Test substance to support | | Test Note No. |
|------------------|---------------------------------|-------------|---------|---------------------------|-----------------------------------|---------------|
| | | Food | Nonfood | MP | EP | |
| Acute Testing | | | | | | |
| 870.1100 | Acute oral toxicity - rat | R | R | TGAI and MP | TGAI, EP, and possibly diluted EP | 1, 2 |
| 870.1200 | Acute dermal toxicity | R | R | TGAI and MP | TGAI, EP | 1, 2, 3 |
| 870.1300 | Acute inhalation toxicity - rat | R | R | TGAI and MP | TGAI and EP | 4 |
| 870.2400 | Primary eye irritation - rabbit | R | R | TGAI and MP | TGAI and EP | 3 |

| | | | | | | |
|---|--|----|----|-------------|-------------|-----------------------|
| 870.2500 | Primary dermal irritation | R | R | TGAI and MP | TGAI and EP | 1, 3 |
| 870.2600 | Dermal sensitization | R | R | TGAI and MP | TGAI and EP | 3, 5 |
| 870.6100 | Delayed neurotoxicity (acute) - hen | CR | CR | TGAI | TGAI | 6 |
| 870.6200 | Acute neurotoxicity - rat | R | R | TGAI | TGAI | 7 |
| Subchronic Testing | | | | | | |
| 870.3100 | 90-day Oral - rodent | R | CR | TGAI | TGAI | 8, 9 |
| 870.3150 | 90-day Oral - non-rodent | R | CR | TGAI | TGAI | 36 |
| 870.3200 | 21/28-day Dermal | R | NR | TGAI | TGAI and EP | 10, 11 |
| 870.3250 | 90-day Dermal | CR | R | TGAI | TGAI and EP | 11, 12 |
| 870.3465 | 90-day Inhalation - rat | CR | CR | TGAI | TGAI | 13, 14 |
| 870.6100 | 28-day Delayed neurotoxicity-hen | CR | CR | TGAI | TGAI | 6, 15 |
| 870.6200 | 90-day Neurotoxicity - rat | R | R | TGAI | TGAI | 7, 16 |
| Chronic Testing | | | | | | |
| 870.4100 | Chronic oral - rodent | R | CR | TGAI | TGAI | 17, 18, 19 |
| 870.4200 | Carcinogenicity - two rodent species - rat and mouse preferred | R | CR | TGAI | TGAI | 9, 17, 18, 19, 20, 21 |
| Developmental Toxicity and Reproduction | | | | | | |
| 870.3700 | Prenatal Developmental toxicity - rat and rabbit, preferred | R | R | TGAI | TGAI | 22, 23, 24, 25, 26 |
| 870.3800 | Reproduction and fertility effects | R | R | TGAI | TGAI | 26, 27, 29 |
| 870.6300 | Developmental neurotoxicity | CR | CR | TGAI | TGAI | 27, 28, 29 |
| Mutagenicity Testing | | | | | | |
| 870.5100 | Bacterial reverse mutation assay | R | R | TGAI | TGAI | 30 |
| 870.5300 870.5375 | <i>In vitro</i> mammalian cell assay | R | R | TGAI | TGAI | 30, 31 |
| 870.5385 870.5395 | <i>In vivo</i> cytogenetics | R | R | TGAI | TGAI | 30, 32 |
| Special Testing | | | | | | |

| | | | | | | |
|----------|---------------------------------|----|----|--------------|--------------|----|
| 870.7485 | Metabolism and pharmacokinetics | R | CR | PAI or PAIRA | PAI or PAIRA | 33 |
| 870.7200 | Companion animal safety | CR | CR | NR | TGAI or EP | 34 |
| 870.7600 | Dermal penetration | CR | CR | Choice | Choice | 35 |
| 870.7800 | Immunotoxicity | R | R | TGAI | TGAI | |

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