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(d) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (c) of this section.

1. The Agency has waived the requirement to submit efficacy data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment, or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However each registrant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

2. [Reserved]

[72 FR 60957, Oct. 26, 2007, as amended at 73 FR 75596, Dec. 12, 2008]

§ 158.230 Experimental use permit data requirements for toxicology.

All toxicology data, as described in paragraph (c) of this section, must be submitted to support a request for an experimental use permit.

(a) *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 crop use, aquatic nonfood outdoor use, greenhouse nonfood crop use, forestry use, residential outdoor use, indoor nonfood use, and indoor residential use.

(b) *Key.* CR=Conditionally required; NR=Not required; R=Required; EP=End-use product; MP=Manufacturing-use product; PAIRA=Pure active ingredient radiolabeled; TGAI=Technical grade of the active ingredient.

(c) *Table.* The following table shows the experimental use data requirements for toxicology. The test notes are shown in paragraph (d) of this section.

TABLE—EXPERIMENTAL USE PERMIT TOXICITY DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern		Test substance to support		Test Note No.
		Food	Nonfood	MP	EP	
Acute Testing						
870.1100	Acute oral toxicity - rat	R	R	MP and TGAI	TGAI, EP	1
870.1200	Acute dermal toxicity	R	R	MP and TGAI	TGAI, EP	1, 2
870.1300	Acute inhalation toxicity - rat	R	R	MP and TGAI	TGAI and EP	3
870.2400	Primary eye irritation - rabbit	R	R	MP	TGAI and EP	2
870.2500	Primary dermal irritation	R	R	MP	TGAI and EP	1, 2
870.2600	Dermal sensitization	R	R	MP	TGAI and EP	2, 4
870.6100	Delayed neurotoxicity (acute) - hen	CR	CR	TGAI	TGAI	5
Subchronic Testing						
870.3100	90–day Oral - rodent	R	NR	TGAI	TGAI	--
870.3150	90–day Oral - non-rodent	R	NR	TGAI	TGAI	--
Chronic Testing						

TABLE—EXPERIMENTAL USE PERMIT TOXICITY DATA REQUIREMENTS—Continued

Guideline Number	Data Requirement	Use Pattern		Test substance to support		Test Note No.
		Food	Nonfood	MP	EP	
870.4100	Chronic oral - rodent	R	NR	TGAI	TGAI	6
Developmental Toxicity and Reproduction						
870.3700	Prenatal Developmental toxicity - rat and rabbit, preferred	R	NR	TGAI	TGAI	7, 8
870.3800	Reproduction	R	NR	TGAI	TGAI	6
Mutagenicity Testing						
870.5100	Bacterial reverse mutation assay	R	NR	TGAI	TGAI	9
870.5300 870.5375	*In vitro* mammalian cell assay	R	NR	TGAI	TGAI	9, 10
870.5385 870.5395	*In vivo* cytogenetics	R	NR	TGAI	TGAI	9, 11

(d) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (c) of this section.

1. Not required if test material is a gas or a highly volatile liquid.

2. Not required if test material is corrosive to skin or has a pH of less than 2 or greater than 11.5.

3. Required if the product consists of, or under conditions of use will result in, a respirable material (e.g., gas, vapor, aerosol, or particulate).

4. Required if repeated dermal exposure is likely to occur under conditions of use.

5. Required if the test material is an organophosphorus substance, which includes uncharged organophosphorus esters, thioesters, or anhydrides of organophosphoric, organophosphonic, or organophosphoramidic acids, or of related phosphorothioic, phosponothioic, or phosphorothioamidic acids, or is structurally related to other substances that may cause the delayed neurotoxicity sometimes seen in this class of chemicals.

6. These studies are seldom required to support EUPs. They may be required if the dietary exposure for these EUPs occupies a large part, e.g., greater than 50%, of the reference dose.

7. The oral route, by oral intubation, is preferred unless the chemical or physical properties of the test substance or the pattern of exposure suggests a more appropriate route of exposure.

8. May be combined with the 2–generation reproduction study in rodents by utilizing a second mating of the parental animals in either generation.

9. At a minimum, an initial battery of mutagenicity tests with possible confirmatory testing is required. Other relevant mutagenicity tests that may have been performed, plus a complete reference list must also be submitted.

10. Choice of assay using either:

i. Mouse lymphoma L5178Y cells, thymidine kinase (tk) gene locus, maximizing assay conditions for small colony expression or detection;

ii. Chinese hamster ovary (CHO) or Chinese hamster lung fibroblast (V79) cells, hypoxanthine-guanine phosphoribosyl transferase (hgprt) gene locus, accompanied by an appropriate *in vitro* test for clastogenicity; or

iii. CHO cells strains AS52, xanthine-guanine phosphoribosyl transferase (xprt) gene locus.

11. The micronucleus rodent bone marrow assay is preferred; however, rodent bone marrow assays using metaphase analysis (aberrations) are acceptable.

[72 FR 60957, Oct. 26, 2007, as amended at 73 FR 75596, Dec. 12, 2008]

§ 158.240 Experimental use permit data requirements for ecological effects.

All data for terrestrial nontarget organisms and aquatic nontarget organisms as described in § 158.243 must be submitted to support a request for an experimental use permit. No data for nontarget plant protection must be submitted to support a request for an experimental use permit.