

Kind of data required	(b) Notes	General use patterns										Test substance		Guide- lines ref- erence No.			
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to sup- port MP	Data to sup- port EP					
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood										
Acute testing																	
Acute oral toxicity—rat	(1)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* or EP dilution* and TGAI.	81-1
Acute dermal toxicity	(1), (2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* or EP dilution* and TGAI.	81-2
Acute inhalation toxicity— rat.	(16)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* and TGAI.	81-3
Primary eye irritation— rabbit.	(2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	81-4
Primary dermal irritation	(1), (2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	81-5
Dermal sensitization	(3)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	81-6
Acute delayed neurotoxicity—hen.	(4)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	81-7
Subchronic testing																	
90-day feeding studies— rodent and nonrodent.	(17)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	82-1
21-day dermal	(18)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI and EP*	82-2
90-day dermal	(5), (19)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82-3
90-day inhalation—rat	(6)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82-4
90-day neurotoxicity: Hen	(7)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82-5
Mammal	(8)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82-5
Chronic testing																	
Chronic feeding—2 spp. rodent and nonrodent.	(9), (13), (20)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	83-1
Oncogenicity study—2 Spp. rat and mouse preferred.	(9), (21)	R	R	R	R	R	R	R	R	R	R	R	R	R	TGAI	TGAI	83-2
Teratogenicity—2 species Reproduction, 2-genera- tion.	(10), (15) (11), (14)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	83-3 83-4
Mutagenicity testing																	
Gene mutation	(22)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	84-2
Structural chromosomal aberration.	(22)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	84-2
Other genotoxic effects	(22)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	84-4

- (ii) The use requires a tolerance for the pesticide or an exemption from the requirement to obtain a tolerance, or requires issuance of a food additive regulation.
- (21) Required if any of the following criteria are met:
 - (i) The active ingredient(s) or any of its (their) metabolites, degradation products, or impurities:
 - (A) is structurally related to a recognized carcinogen.
 - (B) is a substance that cause mutagenic effect as demonstrated by *in vitro* or *in vivo* testing.
 - (C) Produces in subchronic studies a morphologic effect (e.g., hyperplasia, metaplasia) in any organ that may lead to neoplastic change.
 - (ii) Use of the pesticide product is likely to result in human exposure over a portion of the human lifespan which is significant in terms of either the time the exposure occurs or the duration of exposure (for example; pesticides used in treated fabrics for wearing apparel, diapers, or bedding; insect repellents applied directly to human skin; swimming pool additives; constant-release indoor pesticides which are used in aerosol form).
 - (22)(i) The required battery of mutagenicity tests must include tests appropriate to address the following three categories in accordance with the objectives set forth in §158.202:
 - (A) Gene mutations.
 - (B) Structural chromosomal aberrations.
 - (C) Other genotoxic effects as appropriate for the test substance, e.g., numerical chromosome aberrations, direct DNA damage and repair, mammalian cells transformation, target organ/cell analysis.
 - (ii) Currently recognized tests for each of these categories are listed with the National Technical Information Service (NTIS). Applicants shall explain their reasons for selecting specific tests from the battery of currently recognized tests. Because of the rapid improvements in this field, applicants are encouraged to discuss with the Agency: test selection, protocol design and results of preliminary testing.
 - (iii) Not required if the pesticide use pattern precludes human exposure (e.g., nonvolatile pesticides packaged and used in enclosed bait boxes).
- (23) Required if chronic feeding or oncogenicity studies are required.
- (24) Dermal absorption studies required for compounds having a serious toxic effect as identified by oral or inhalation studies, for which a significant route of human exposure is dermal and for which the assumption of 100 percent absorption does not produce an adequate margin of safety. Registrants should work closely with the Agency in developing an acceptable protocol and performing dermal absorption studies.

[49 FR 42881, Oct. 24, 1984. Redesignated and amended at 53 FR 15993, 15999, May 4, 1988; 58 FR 34203, June 23, 1993]

§ 158.390 Reentry protection data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the reentry protection data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns										Test substance			Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	Guideline reference No.		
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood								
Foliar dissipation	(1)	CR	CR	CR	CR	TEP	TEP	132-1		
Soil dissipation	(1), (4)	CR	CR	CR	CR	TEP	TEP	132-1		
Dermal exposure	(1), (2), (3)	CR	CR	CR	CR	TEP	TEP	133-3		
Inhalation exposure	(1), (2), (3)	CR	CR	CR	CR	TEP	TEP	133-4		

Key: CR=Conditionally required; TEP=Typical end-use product.
 (b) NOTES: The following notes are referenced in column two of the table contained in paragraph (a) of this section.
 (1) Data are required if the following conditions are met:
 (i)(A) The acute dermal toxicity of the technical grade of active ingredient is less than 200 mg/kg (body weight); or
 (B) The acute inhalation toxicity of the technical grade of active ingredient is less than 200 mg/m³ (for a one-hour exposure); or
 (C) The acute oral toxicity of the technical grade of active ingredient is less than 50 mg/kg (body weight); or
 (D) Neurotoxic, teratogenic, or oncogenic effects or other adverse effects as evidenced by subchronic, chronic, and reproduction studies would be expected from entry of persons into treated sites; or
 (E) The Agency receives other scientifically validated toxicological or epidemiological evidence that a pesticide or residue of a pesticide could cause adverse effects on persons entering treated sites. In the last situation, reentry intervals and supporting data may be required on a case-by-case basis.