

Kind of data required	(b) Notes	General use patterns										Test substance		Guide- lines ref- erence No.			
		Terrestrial		Aquatic		Food crop	Nonfood crop	Greenhouse	Forestry	Domestic outdoor	Indoor	Data to sup- port MP	Data to sup- port EP				
		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]	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]	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]	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]	MP	EP*	81-4	
Primary dermal irritation ...	(1), (2)	[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]	MP	EP*	81-6	
Acute delayed neurotoxicity—hen.	(4)	[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]	TGAI	TGAI	82-1	
21-day dermal	(18)	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	TGAI	TGAI	82-3	
90-day inhalation—rat	(6)	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	TGAI	TGAI	82-5	
Mammal	(8)	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]	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	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]	TGAI	TGAI	83-3	
Mutagenicity testing																	
Gene mutation	(22)	[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]	TGAI	TGAI	84-2	
Other genotoxic effects	(22)	[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) The use requires a tolerance for the pesticide or exemption from the requirement to obtain a tolerance, or requires the issuance of a food additive regulation.
 - (iii) 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.

Environmental Protection Agency

§ 158.340

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