

- (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.
 - (ii) And if: end-use product is to be registered for:
 - (A) Application to growing crops, such as to or around horticultural and agronomic crops that are field- or orchard-grown.
 - (B) Application to outdoor tree nursery and forestry operations.
 - (C) Application to turf crops and commercial applications to turf.
 - (D) Application to parks and arboreums; or (E) application to aquatic crops.
 - (iii) And if: human exposure to residues of the pesticide can be reasonably foreseen. This applies primarily to pesticides that will be used on crops where human tasks will involve substantial exposure to residues of the pesticide.
- (2) Data required if appropriate surrogate data are not available.
- (3) Data required if the applicant chooses to use the allowable exposure level method for proposal of a reentry interval.
- (4) Soil dissipation data required if agricultural practice involves human tasks that would cause substantial exposure to residues sorbed to soil.

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

§ 161.440 Spray drift data requirements.

(a) *Table.* Sections 161.100 through 161.102 describe how to use this table to determine the aerial spray drift data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns										Test substance		Guide-lines reference No.			
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP					
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood										
Droplet size spectrum	(1)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	201-1
Drift field evaluation	(1)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	202-1

Key: CR=Conditionally required; TEP=Typical end use product.
 (b) NOTES: The following are referenced in column two of the table contained in paragraph (a) of this section.
 (1) This study is required when aerial applications (rotary and fixed winged) and mist/blower or other methods of ground application are proposed and it is estimated that the detrimental effect level of those nontarget organisms expected to be present would be exceeded. The nontarget organisms include humans, domestic animals, fish and wildlife, and nontarget plants. This requirement may be satisfied by submittal of published or unpublished information regarding spray drift patterns that would be expected to be similar to the proposed product.
 (2) [Reserved]

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

§ 161.490 Wildlife and aquatic organisms data requirements.

(a) *Table.* Sections 161.100 through 161.102 describe how to use this table to determine the wildlife and aquatic organisms data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns										Test substance		Guidelines reference No.		
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP				
		Food crop	Nonfood	Food Crop	Nonfood	Food crop	Nonfood									
Avian and mammalian testing																
Avian oral LD ₅₀ (preferably mallard or bobwhite).	(1)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	CR	[R]	CR	TGAI	TGAI	71-1
Avian dietary LC ₅₀ (preferably mallard and bobwhite).	(1)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	CR	[R]	CR	TGAI	TGAI	71-2
Wild mammal toxicity	(2)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	71-3
Avian reproduction (preferably mallard and bobwhite).	(3)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	71-4
Simulated and actual field testing—mammals and birds.	(2)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TEP	TEP	71-5
Aquatic organism testing																
Freshwater fish LC ₅₀ (preferably rainbow and bluegill).	(1), (7)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	CR	[R]	CR	TGAI	TGAI	72-1
Acute LC ₅₀ freshwater invertebrates (preferably <i>Daphnia</i>).	(1), (7)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	CR	[R]	CR	TGAI	TGAI	72-2
Acute LC ₅₀ estuarine and marine organisms.	(4), (7)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	72-3
Fish early life stage and aquatic invertebrate life-cycle.	(5)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	72-4
Fish—life-cycle	(6)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	72-5
Aquatic organism accumulation.	(8)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI, PAI, or degradation product.	TGAI, PAI, or degradation product.	72-6
Simulated or actual field testing—aquatic organisms.	(2)	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	CR	TEP	TEP	72-7

Key: R=Required; CR=Conditionally required; []=Brackets (ie, [R], [CR]) indicate data requirements that apply when an experimental use permit is being sought; TGAI=Technical grade of the active ingredient; TEP=Typical end-use product; PAI="Pure" active ingredient.

(b) NOTES: The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1)(i) Data are required as follows to support manufacturing use products and those end-use products for indoor use for which there is no registered manufacturing use product:

(A) Solid formulation indoor use products require avian oral LD₅₀ (bobwhite), avian dietary LC₅₀ (bobwhite), freshwater fish LC₅₀ (rainbow trout), and acute LC₅₀ freshwater invertebrate (*Daphnia*).

- (B) Liquid formulation indoors use products require all tests listed under (b)(1)(i) of this section except the avian oral LD₅₀.
- (ii) Data are not required to support:
- (A) Indoor end-use products consisting of a gas/highly volatile liquid or a highly reactive solid.
 - (B) Indoor end-use products for which there is a manufacturing use product registration.
- (2) Tests required on a case-by-case basis depending on the results of lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics.
- (3) Data required if one or more of the following criteria are met:
- (i) Birds may be subjected to repeated or continued exposure to the pesticide or any of its major metabolite degradation products, especially preceding or during the breeding season.
 - (ii) The pesticide or any of its major metabolites or degradation products are stable in the environment to the extent that potentially toxic amounts may persist in avian feed.
 - (iii) The pesticide or any of its major metabolites or degradation products are stored or accumulated in plant animal tissues, as indicated by its octanol/water partition coefficient, accumulation studies, metabolic release and retention studies, or as indicated by structural similarity to known bioaccumulative chemicals.
 - (iv) Any other information, such as that derived from mammalian reproduction studies that indicates the reproduction in terrestrial vertebrates may be adversely affected by the anticipated use of the pesticide product.
- NOTE: Prior to conducting this test to support the registration of an avicide, the applicant should consult the Agency.
- (4) Data required if the product is intended for direct application to the estuarine or marine environment, or the product is expected to enter this environment in significant concentrations because of its expected use or mobility pattern.
- (5) Data from fish early life-stage tests or life-cycle tests with aquatic invertebrates (on whichever species is most sensitive to the pesticide as determined from the results of the acute toxicity tests) are required if the product is applied directly to water or expected to be transported to water from the intended use site, and when any one or more of the following conditions apply:
- (i) If the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity.
 - (ii) If any LC₅₀ or EC₅₀ value determined in acute toxicity testing is less than 1 mg/l, or
 - (iii) If the estimated environmental concentration in water is equal to or greater than 0.01 of any EC₅₀ or LC₅₀ determined in acute toxicity testing.
 - (iv) If the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any EC₅₀ or LC₅₀ determined in acute toxicity testing and any of the following conditions exist:
- (A) Studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected.
 - (B) Physicochemical properties indicate cumulative effects.
 - (C) The pesticide is persistent in water (e.g., half-life in water greater than 4 days).
 - (D) Data are required if end-use product is intended to be applied directly to water or expected to transport to water from the intended use site, and when any of the following conditions apply:
- (i) If the estimated environmental concentration is equal to or greater than one-tenth of the no-effect level in the fish early life-stage or invertebrate life-cycle test.
 - (ii) If studies of other organisms indicate the reproductive physiology of fish may be affected. NOTE: The applicant should consult the Agency prior to these tests to support the registration of a pesticide.
- (7) Data from testing with the applicant's end-use product or a typical end-use product is required to support the registration of each end-use product which meets any one of the following conditions:
- (i) The end-use pesticide will be introduced directly not an aquatic environment when used as directed.
 - (ii) The LC₅₀ or EC₅₀ of the technical grade of active ingredient is equal to or less than the maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment when the end-use pesticide is used as directed.
 - (iii) An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms.
 - (8) Required if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments and may accumulate in aquatic organisms.

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§ 161.540 Plant protection data requirements.

(a) *Table.* Sections 161.100 through 161.102 describe how to use this table to determine the plant protection data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns								Test substance		Guide-lines reference No.	
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP		Data to support EP
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Target area phytotoxicity ..	(1)	121-1