

Environmental Protection Agency

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(c) *Contents of title page.* Each individual study must have a title page bearing the following identifying information:

(1) The title of the study, including identification of the substance(s) tested and the test name or data requirement addressed;

(2) The author(s) of the study;

(3) The date the study was completed;

(4) If the study was performed in a laboratory, the name and address of the laboratory and any laboratory project numbers or other identifying codes;

(5) If the study is a commentary on or supplement to another previously submitted study, full identification of the other study with which it should be associated in review; and

(6) If the study is a reprint of a published document, all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and date of publication.

(d) *EPA identification number.* EPA will assign each study an EPA Master Record Identification (MRID) number, and will promptly notify the submitter of the number assigned. This number should be used in all further communications with the Agency about the study.

(e) *Reference to previously submitted data.* Data which previously have been submitted need not be resubmitted unless resubmission is specifically requested by the Agency. If an applicant or registrant wishes the Agency to consider such data in the review of an Agency action, he should cite the data by providing:

(1) The title or adequate description of the study;

(2) The transmittal information required by paragraph (a) (1), (2), and (3) of this section; and

(3) The MRID number assigned in accordance with paragraph (d) of this section.

[53 FR 15991, May 4, 1988]

§ 158.33 Procedures for claims of confidentiality of data.

(a) *General.* A data submitter must clearly identify any information which he claims is entitled to confidential treatment under FIFRA sec. 10. The procedures in this section must be fol-

lowed to assert a claim of confidentiality.

(b) *Claims of confidentiality for information described by FIFRA sec. 10(d)(1) (A), (B), and (C).* Any information claimed to be confidential under FIFRA sec. 10(d)(1) (A) through (C) must be submitted in accordance with the following procedures:

(1) The information must be contained in a separate attachment to the study. If any information is included in the body of the study rather than in the confidential attachment, the submitter waives a claim of confidentiality for such information under FIFRA sec. 10(d)(1) (A), (B), or (C).

(2) The attachment must have a cover page which is clearly marked to indicate that the material contained in the attachment falls within the scope of FIFRA sec. 10(d)(1) (A), (B), or (C).

(3) Each item in the attachment must be numbered. For each item, the submitter must cite the applicable portion of FIFRA sec. 10(d)(1) (A), (B), or (C) on which the claim of confidentiality is based. In addition, for each item, the submitter must provide a list of page numbers in the study where the item is cited (i.e., identified by number).

(4) Each item in the attachment must be referenced in the body of the study by its number in the attachment.

(5) The following statement must appear on the Statement of Data Confidentiality Claims:

Information claimed confidential on the basis of its falling within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

The statement must bear the name, title, and signature of the submitter or his properly designated agent, and the date of signature.

(c) *No claim of confidentiality under FIFRA sec. 10(d)(1)(A), (B), or (C).* If no claim of confidentiality is being made for information described by FIFRA sec. 10(d)(1)(A), (B), or (C), or if such information is not contained in the body of the study, the Statement of Data Confidentiality Claims must include the following statement:

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No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C).

This statement must bear the name, title and signature of the submitter or his properly designated agent, and the date of signature.

(d) *Claim of confidentiality for information not described by FIFRA sec. 10(d)(1)(A), (B), or (C).* Any information not described by FIFRA sec. 10(d)(1)(A), (B), or (C) for which a claim of confidentiality is made must be submitted in accordance with the following procedures:

(1) The information must be clearly marked in the body of the study as being claimed confidential.

(2) A separate Supplemental Statement of Data Confidentiality Claims must be submitted identifying by page and line number the location within the study of each item claimed confidential, and stating the basis for the claim.

(3) The Supplemental Statement of Data Confidentiality Claims must bear the name, title, and signature of the submitter or his properly designated agent, and the date of signature.

[53 FR 15991, May 4, 1988]

§ 158.34 **Flagging of studies for potential adverse effects.**

(a) Any person who submits a study of a type listed in paragraph (b) of this section to support an application for new or amended registration, or to satisfy a requirement imposed under FIFRA sec. 3(c)(2)(B), must submit with the study a statement in accordance with paragraph (c) of this section.

(b) The following table indicates that study types and the criteria to be applied to each. Column 1 lists the study types by name. Column 2 lists the associated Pesticide Assessment Guideline number. Column 3 lists the criteria applicable to each type of study. Column 4 lists the reporting code to be included in the statement specified in §158.34(c) when any criterion is met or exceeded.

TABLE—FLAGGING CRITERIA

Toxicity studies	Pesticide assessment guidelines No.	Criteria	Reporting code
Oncogenicity [or combined oncogenicity/chronic feeding study] or Subchronic feeding study	83–2	Treated animals show any of the following:	
	82–1	An incidence of neoplasms in male or female animals which increases with dose;	1
		or A statistically significant ($p \leq 0.05$) incidence of any type of neoplasm in any test group (male or female animals at any dose level) compared to concurrent control animals of the same sex;	2
		or An increase in any type of uncommon or rare neoplasms in any test group (male or female animals at any dose level) compared to concurrent control animals	3
	or A decrease in the time to development of any type of neoplasms in any test group (male or female animals at any dose level) compared to concurrent control animals	4	
Teratogenicity	83–3	When compared with concurrent controls, treated animals show a dose-related increase in malformations (or deaths) on a litter basis in the absence of significant maternal toxicity at the same dose levels	5
Neurotoxicity	81–7	When compared with controls, treated animals show a response indicative of acute delayed neurotoxicity	6
Chronic feeding study or combined chronic feeding/ oncogenicity study	83–1	Cholinesterase inhibition NOEL less than 10 times the current existing ADI. or	7