

DEPARTMENT OF PESTICIDE REGULATION

1220 N Street, P.O. Box 942871
Sacramento, California 94271-0001



January 1, 1994

California Notice 94-1

TO: ECONOMIC POISON REGISTRANTS AND DATA SUBMITTERS

SUBJECT: GUIDELINES REGARDING FORMAT OF ALL DATA SUBMISSIONS FOR PESTICIDE REGISTRATION IN CALIFORNIA

The following are the Pesticide Registration Branch guidelines for applications for registration of economic poisons which include data, and data submissions that support currently registered products. The guidelines are specific to format and organization of each study volume, and include specifications for folders, covers, and labels. Submissions received that conform to these guidelines will be given highest priority for processing.

Many of the submissions received by the Pesticide Registration Branch are not bound together in any fashion. Many other submissions are received bound, but are not fit for a long shelf life. Our staff spends an inordinate amount of time binding and labeling submissions. All submissions must be bound and labeled in order for us to process, shelve, and track data submissions. Our time spent on binding and labeling can be better spent on processing applications and data. Adhering to these guidelines will allow us to process your submissions in a more timely manner.

These guidelines are based in large part on the federal regulations, 40 CFR, 158.32, with some specific prohibitions and recommendations for California only. Any submissions accompanied by data should have the data submitted according to the format specified below. Do not bind applications for registration, labels, proof of federal registration, cover letter (original copy) and letters authorizing use of another firm's data. Bind only data and a copy of the cover letter. Examples of specific exceptions to these format guidelines are listed following the suggested specifications of format, binding and labeling.

SPECIFICATIONS OF FORMAT FOR DATA SUBMISSION TO CALIFORNIA:

- Use uniform 8 1/2 by 11 inch white paper, printed in black ink, with high contrast and good resolution.
- Do not include frayed or torn pages, carbon copies, or copies in other than black ink.
- Be sure that photocopies are clear, complete, and fully readable.
- Be sure that all pages are present, numbered, and in order.

- Do not include oversized computer printouts or fold-out pages.
- If the original report is not in English, be sure to provide a complete translation in English.
- Separate each study or section of study by use of labeled tabs. Identify each study by the U.S. Environmental Protection Agency's (USEPA) guideline reference number.
- For large submissions, include a table of contents or itemize the volume titles in your cover letter.
- Your cover letter should address at least the following four points:
 1. Name and address of data submitter(s);
 2. Reason for which the package is submitted;
 3. Date of this submission;
 4. List of submitted studies.
- Place a copy of the cover letter in the very front of each volume of the submission.
- Multiple small studies of similar type (i.e. acute toxicology, product chemistry, efficacy) may be bound together in one volume with tabs and divider pages between each study. Include a table of contents and bind to a maximum thickness of two inches.
- Any studies conducted on other than pesticide active ingredients or product formulations (i.e., inert ingredients, precursors, impurities, degradation products, etc.) need to be clearly identified as to the kind of study (i.e., acute oral LD 50), the compound on which the study was conducted, and the reason for its inclusion in the submission (i.e., to support the application for registration of product name and EPA Reg. No.).
- Any studies which are to be considered confidential business information according to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 10 (d)(1) should be so designated by use of a red-ink stamp indicating "Trade Secret Information" or "Confidential Business Information" or similar words to the same effect. This should be stamped on the title page of the study only. Do NOT separate out confidential business information from nonconfidential information. The entire study, if designed confidential business information, will be treated accordingly.

- If your submission is in response to the requirements of a specific data call-in or reevaluation or is for a risk assessment or is an adverse effects disclosure, please label it prominently, identifying the specific reason for the submission, and do not include any data in the submission that does not relate to the purpose of your submission.
- If a single study consists of several volumes, clearly identify each volume in order (i.e. 1 of 5, 2 of 5, 3 of 5, etc.) and place a copy of the cover letter in the front of each volume.

RECOMMENDED FORMAT FOR EACH STUDY VOLUME: (in sequence listed)

Front cover;
Copy of cover (transmittal) letter to the Department of Pesticide Regulation
Title page;
Abstract (no confidential information);
Introduction;
Materials and methods;
Results and discussion;
Summary of study;
Data, tables, appendices;
Analytical methods, feed analysis, etc.;
Back cover.

SPECIFICATIONS FOR FOLDERS AND COVERS:

- Please do not use the following: plastic or vinyl covers of any sort (they slide, tear, and generally do not have long shelf life); 3-ring binders; folders with "pockets"; folders with comb-type, spiral or "velo" type bindings (they do not allow insertion of additional pages).

The Pesticide Regulation Library Staff recommend the following:

- "ACCO-PRESS" (or equivalent) pressboard folders for submissions of over 50 pages in length. (NOT plastic or vinyl). Have folder prongs open in the front of the submission and do not put tape on the prongs or bend them.
- If a submission exceeds two inches in thickness, for ease of handling please divide it into an appropriate number of ACCO-PRESS type folders with a copy of the cover letter in each. Allow one-half inch of length on each of the vertical arms of the ACCO-PRESS type folders to allow for the addition of route sheets, evaluation memos, etc.

- Please have ACCO-PRESS folder prongs open in front of the submission; do NOT bend the prongs back; do NOT tape them shut. Library staff need to be able to add route sheets in front of each document.

SPECIFICATIONS FOR LABELING:

Please clearly label each folder/binder including at least the following information: Name of submitter, product brand name and EPA registration number, name of primary active ingredient; type of data in the submission; and number of volumes in the submission. Examples follow:

For a specific registration action:

XYZ Corporation
XYZ PEST KILLER CONCENTRATE
EPA Reg. No. _____
AI= _____
Application for registration
Volume 1 of 1

For an active ingredient data call-in:

ABC, Incorporated
Technical _____
EPA Reg. No. _____
AI= _____
SB 950 Data Submission Chronic feeding
study in rats
Volume 1 of 5

SUBMISSIONS NOT REQUIRING BINDING:

- An application for registration with labels, cover letter, proof of federal registration and letter of authorization for use of data on file. NO DATA SUBMITTED.
- Request for registration of an amended label. NO DATA SUBMITTED.
- Request for registration of an alternate or revised formula. NO DATA SUBMITTED.
- Copies of correspondence.
- Copies of material safety data sheets and/or technical bulletins.
- Supplemental submissions of only a FEW PAGES OF DATA (i.e., less than 25) to be inserted into a submission already being processed. PLEASE identify the document to which these pages belong as completely as possible (i.e., product name, EPA registration number, chemical, study title and section of study, California ID number, etc.), in your letter.

Our review of data can proceed more quickly if the applicant includes a comprehensive summary of all data submitted, divided by the major categories of data (i.e., chemistry, efficacy, toxicology, environmental fate, wildlife and aquatic organisms, etc.), and the summary is substantiated by the actual data.

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This summary would be in addition to the summary statement contained in each complete report. Such a summary is particularly appropriate for new active ingredients and provides the applicant the opportunity to present a case that the use of the product, considering the data and use patterns, will not produce adverse effects.

Your cooperation in using these guidelines is very much appreciated. If you have any questions regarding these guidelines, you may call Jacquelyn Rivers at (916) 654-1202.

Sincerely,



Barry Cortez, Chief
Pesticide Registration Branch
(916) 654-0567

