

ACA Industry Labeling Guide, Sixth Edition

CHAPTER 8 – PESTICIDES

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I. Introduction

This chapter provides general guidance on the regulations issued by the U.S. Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (codified at 7 USC 136 et. seq.). Manufacturers of paints and coatings who determine that their products may be subject to FIFRA regulations should *not* rely solely on this general overview as a means of compliance.

FIFRA regulations can be found at [40 CFR Parts 150 189](#). Manufacturers should take care to ensure that they know and have conformed to current EPA requirements.

EPA's online [Pesticide Registration Manual](#) provides a comprehensive guide for registering pesticide products, complete with references to additional EPA guidance and links to registration forms.

[Pesticide Registration and Certification Forms](#) are also available on EPA's website.

Additional information is available on [EPA's Office of Pesticides](#) website and its [Pesticide Registration](#) site.

EPA also maintains an online archive of [Pesticide Registration Notices](#) addressing specific registration issues.

II. Labeling and Packaging Requirements

A. Prototype Labeling Requirements

Pesticide product labels are required to contain extensive information. Guidance in preparing label text for pesticide products appears at the end of this chapter, including regulatory citations specifying requirements for each portion of the label. As required at 40 CFR 156.10(a)(1), a pesticide label must show clearly and prominently the following label elements:

- a. Name, brand, or trademark under which the product is sold
- b. Name and address of the producer, registrant, or person for whom produced
- c. Net contents
- d. Product registration number
- e. Producing establishment number
- f. An ingredient statement
- g. Warning or precautionary statements
- h. Directions for use
- i. Use classification(s)

B. Packaging Requirements

A pesticide product must be distributed and sold in a child resistant package if all of the following criteria apply [[40 CFR 157.22](#)]:

- The product meets one or more of the toxicity criteria in [40 CFR 157.22\(a\)](#);
- Labeling either directly recommends residential use or can be interpreted to permit residential use; and
- The product does not qualify for an exemption under [40 CFR 157.24](#).

The regulations also specify the data necessary to justify an exemption, the standards and protocols for effectiveness and compatibility, certification procedures, and recordkeeping requirements [[40 CFR 157.24](#)].

Pesticide products for application on marine pleasure craft (antifouling) are subject to this rule. All other special packaging requirements for consumer products are issued by the Consumer Product Safety Commission pursuant to its authority under the *Poison Prevention Packaging Act* of 1970.

III. Summary of Pesticide Registration for a New Pesticide Product

As discussed below, paint and coatings products that serve a pesticidal purpose must be registered as a pesticide under FIFRA, including antifouling coatings. An overview of the registration process follows:

1. Obtain and complete appropriate application ([Part 152.50](#)).
2. Include a list and a summary of the data being submitted with the application ([Part 152.50](#)).
3. Identify the pesticide product (use product name and trade name(s), if different).
4. Identify physical, chemical, and technical properties of pesticide product.
5. Include product performance/application data (field of use; effects on harmful organisms; intended use; application rate; concentration of active ingredients; method of application; number/timing of application and duration of effectiveness; special instruction/precautions; and instructions for use).
6. Include additional information on use and handling of pesticide product.
7. Justification for the classification and labeling of the pesticide product.
8. Include required copies of the proposed label for the pesticide product.
9. Include efficacy data and related information (effectiveness and resistance).
10. Include a description of studies conducted, analytical methods used and results of the studies (see Part 158).
11. Include data on toxicological studies and exposure information; residues in or on treated products, food, or feed (if applicable); fate and behavior of pesticide product in the environment.

The registration process varies slightly for the following applications:

- Registration for alternate formulations (see [Part 152.43](#))
- Amendments to a previously approved registration (see [Part 152.44](#))
- Notification and non-notification changes to registration (see [Part 152.46](#))

IV. Procedure for Product Registration

A. Determining Whether FIFRA Requires Product Registration

Paints and other formulated products containing an antimicrobial designed to protect a substrate and with related label, product literature, or advertising claims require FIFRA registration as a pesticide. Paints and other formulated products treated with an antimicrobial to protect the dried coating itself, not intended for antimicrobial protection of a substrate, do not require registration as a pesticide. Such products fall under the “treated articles” exemption in the FIFRA. **An antimicrobial pesticide added to the paint or coating to impart protection is itself, however, a pesticide, and must be currently registered with EPA.**

In general, manufacturers must register individual formulations (not product lines). Manufacturers must carefully consider product formulation, use and accompanying statements made on labels, product literature and advertising when determining whether to register a product. The registration requirement applies to products intended to kill mildew organisms and products intended to kill or prevent mold in food-processing plants. Such products are considered pesticides [40 CFR 152.15]. Some examples of such products that are subject to FIFRA registration are:

- Anti-fouling paints and coatings for boat bottoms and underwater structures
- Wood preservatives
- Rot preservatives
- Food or beverage plant interior enamels, mildew resistant
- Anti-mildew paint additives

“Treated articles” are exempt from the FIFRA registration requirements, when treated with a registered antimicrobial. Treated articles (or substances) are defined as:

An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use. [40 CFR 152.25(a)].

Generally, public health claims — either explicit or implicit — that express protection beyond the treated article or substance itself will render a product ineligible for the treated articles exemption.

In other words, a manufacturer of paints or formulated products containing an antimicrobial pesticide does not need to register the product as a pesticide where:

1. The manufacturer treats the product with a pesticide, for the purpose of protecting the paint or other product from bacteria or other contamination, and
2. The product’s label and accompanying literature does not include statements about the pesticidal benefit of using the product, excluding statements related to pesticides added for protection of the product.

B. Procedures for Obtaining a FIFRA Registration

To register a pesticide, an applicant must demonstrate that the pesticide satisfies the statutory standard for approval. That standard requires, among other things, that the pesticide perform its intended function without causing “unreasonable” adverse effects on the environment [7 USC 136a(c)(5)(B)].

The term “unreasonable adverse effects on the environment” is defined as:

“any unreasonable risk to man or to the environment, taking into account the economical, social and environmental costs and benefits of the use of any pesticide” [7 USC 136(bb)].

EPA has interpreted this section to require a finding that the benefits of each use of the pesticide exceed the risks of use when the pesticide is used in compliance with the terms and conditions of registration or in accordance with commonly recognized practices.

For EPA to perform the risk/benefit analysis mandated under FIFRA, the agency must have sufficient data and information on a pesticide product. All applications for registration, re-registration or amended registration as covered under Section 3(c)(1)(D) of the act must include or cite data in support of such applications.

C. Application Procedures for Pesticide Registrations

EPA divides pesticide applications into three general categories: new chemical, new use and identical/substantially similar.

1. A “new chemical” application is for registration of a product containing a new pesticide that is not currently registered with EPA. The original Application for Pesticide Registration ([EPA Form 8570-1](#)) must be completed and submitted with each application for registration. EPA stipulates details at [40 CFR 152.50](#).
2. A “new use” application is for an active ingredient or formulation type that is not currently included in directions for use of any product that contains such an active ingredient or formulation type. New uses are defined in [40 CFR 152.3\(p\)](#).
3. An “identical/substantially similar” application is for registration of a pesticide product that is substantially similar or identical in its uses and formulation to products that are currently registered with EPA. In some cases, these applications are eligible for expedited review under 3(c)(3)(b) of FIFRA.

The three application procedures outlined above require use of [EPA Form 8570-1](#). The applicant must also submit a Confidential Statement of Formula ([EPA Form 8570-4](#)). [Instructions related to submitting forms](#) are available on EPA’s website. Applicants are advised not to fax or email forms containing confidential or sensitive information.

D. Data Submission Requirements

Applicants must include three copies of all applicable supporting data. This data submission must be formatted in accordance with the requirements set forth in [40 CFR Part 158](#) and [PR Notice 2011-3](#). Data requirements include such things as detailed specific chemistry data (particularly in “identical/substantially similar” applications), acute toxicity data (where the product is not substantially similar or identical to another registered product). Applicants/formulators who purchase and use an EPA registered product from another producer may be exempt from certain data submission requirements concerning safety of that ingredient. Such applicants may submit a Formulator’s Exemption Statement ([EPA Form 8570-27](#)).

Additionally, if the active ingredient used to formulate the product is not registered, applicants must provide chemistry data on the technical grade of the active ingredient as well as on the formulated product. Efficacy data is required for products designed to control pests of public health significance (such as rats, roaches, viruses, bacteria, etc.), and may be required on a case by case basis for other applications. In some limited circumstances, (e.g., an industry or NIOSH study might be used in lieu of specific inhalation toxicity data), EPA will waive data requirements (applicants who believe that a waiver is feasible should discuss that possibility with the appropriate EPA product manager).

E. Amended Applications

Certain modifications of a registered product’s composition, labeling or packaging make it subject to amended application requirements. Manufacturers must obtain prior approval from EPA by using [EPA Form 8570-1](#) for proposed alterations. Generally, amendments are characterized as either a “identical/substantially similar” amendment or a “new use” amendment. Refer to [40 CFR 152.50](#) for details. on the information required in applications for amended registration

Some modifications to a registered product may not require a formal application and agency approval; however, EPA must be notified of these changes [[40 CFR 152.46\(a\)](#)]. These changes include labeling revisions concerning such things as brand name changes, bilingual labeling, warranty changes, etc., or certain limited product chemistry changes. The notification procedure also requires use of [EPA Form 8570-1](#).

F. Data Compensation Requirements

In complying with the extensive data submission requirements under FIFRA, some applicants submit data that is developed and submitted to the agency in support of another person’s application for registration. Applicants who use such secondary data may be required to comply with the data compensation requirements of FIFRA Section 3(c)(1)(F).

EPA provides details related to data compensation in [Chapter 10 of the Pesticides Registration Manual](#).

V. Standard Treated Article Labeling Claims for Paints and Other Formulated Coatings

[EPA’s Pesticide Registration Notice 2000-1](#), titled *Applicability of the Treated Articles Exemption to Antimicrobial pesticides*, provides guidance about the scope of the treated articles exemption, specified at [40 CFR 152.25\(a\)](#). In this notice, EPA provides examples of labeling claims eligible for the treated articles exemption. Generally, public health claims, either explicit or implicit, that express protection beyond the treated article or substance itself will render a product ineligible for the treated articles exemption. In addition, EPA regards trademarked product names of treated articles or substances and a product’s packaging and advertising literature as potential sources of public health claims that would render the product ineligible for the exemption. EPA encourages requests for written opinions regarding antimicrobial claims when there is a question about exemption applicability.

False or misleading claims or comparison may not be used on the label. Also disallowed are other claims such as “safe,” “nonpoisonous,” “harmless,” etc., or claims such as “pollution approved” and “all natural ingredients” [[40 CFR 156.10\(a\)\(5\)](#)]. Furthermore, EPA does not allow antimicrobial claims that are part of the name of the product or not properly qualified as to their intended non-public health use. All references to the pesticidal properties and the required qualifying statements should be located together, printed in same size, color, and style of type, and given equal prominence to each other as well as any other described feature of the product.

VI. Assignment of Registration to Private Labeler or Distributor

EPA permits a private labeler or distributor to market a pesticide product under that company's own brand name, provided an application for supplemental registration is submitted [[40 CFR 152.132](#)]. Such registration and sale are called "supplemental distribution."

The application may be submitted by the manufacturer/registrant of the previously registered product or by an applicant for new or amended registration (such as the private labeler or distributor). No application for supplemental registration will be approved until the application for new registration has been approved.

EPA specifies that applicants for supplemental registration must provide the agency with certain information (using [EPA Form 8570 5](#)). These required notification elements include:

1. The name and address of the basic registrant and the registration number of the registered product.
2. The name and address of the distributor, the distributor's company number (if desired, EPA will assign a name upon written request), and the name to be used on the product to be distributed.
3. There are also specific requirements concerning packaging and labeling with which the distributor must be familiar.

VII. State Registration Requirements

The states (except for Alaska) also register pesticides to meet special local needs, as allowed by EPA regulation at [40 CFR Part 162](#). Most will accept products that are EPA registered without further requirements. All charge fees and all require periodic renewal, some on an annual basis.

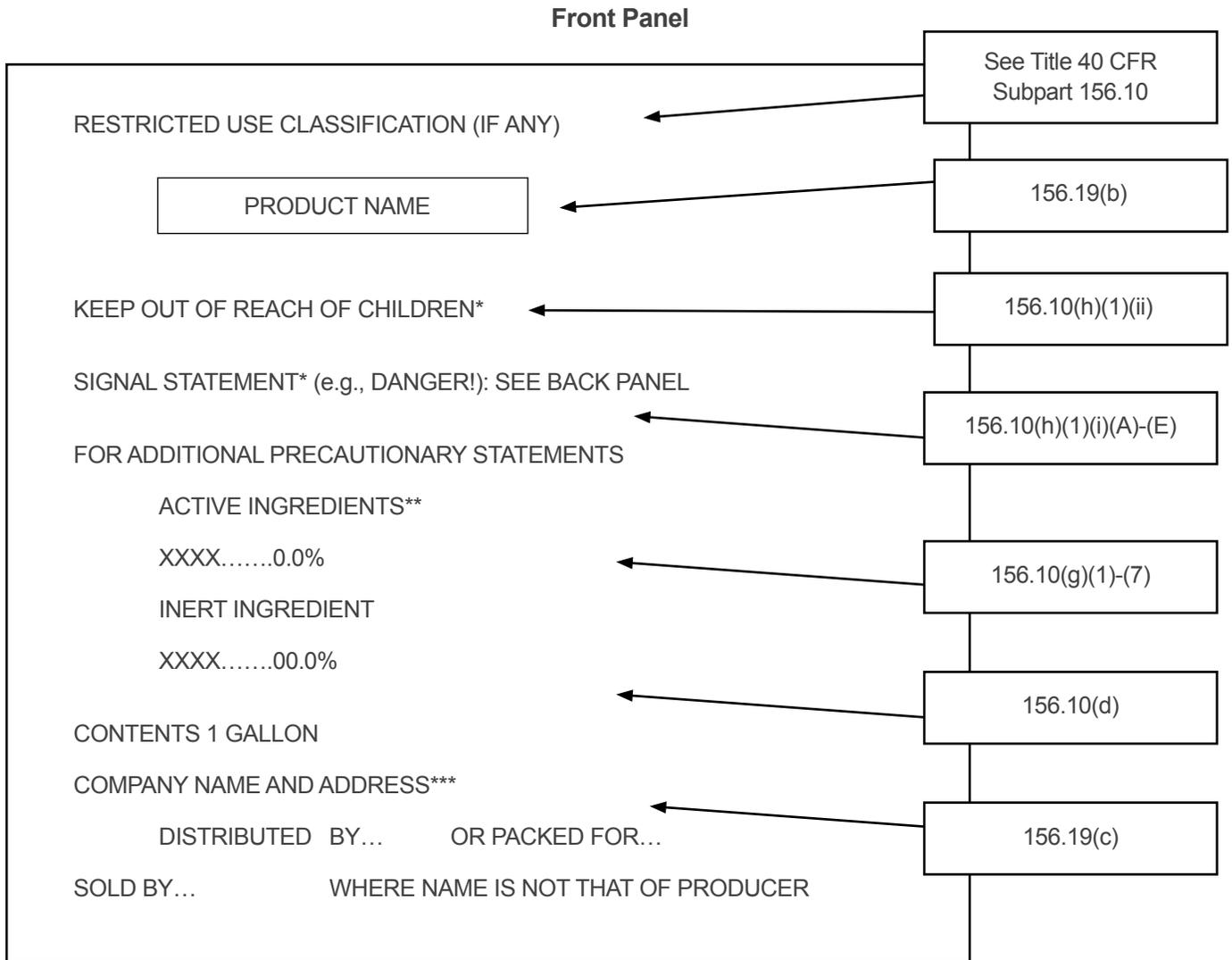
Applicants should note that the state agencies handling pesticide registrations and the primary pesticide control official in each state are listed in the official publication of the [Association of American Pesticide Control Officials](#).

Information about the Association of American Pesticide Control Officials (AAPCO) is available on the [AAPCO website](#).

AAPCO also maintains a [list of official publications](#), with each document accessible online.

EPA Prototype Sales Label

[See 40 CFR 156.10]



*Required front panel placement

**Waiver may be obtained for back panel placement

***Front or back panel placement

NOTE: Consult 40 CFR 156.10(a)(2) for prominence and legibility requirements.
Signal statement is determined by toxicity categories [40 CFR 156.10(h)]

Back Panel

Directions for Use:

It is a violation of Federal Law to use this Product in a manner inconsistent with its labeling

Consult 156.10(i) for specific instruction for directions for use.

Precautionary Statements

[Repeat Signal Statement]

Hazard to Humans and Domestic Animals

[156.10(h)(2)(i)]

Practical Treatment

[156.10(h)(1)(iii)]

Environmental Hazards

[156.10(h)(2)(ii)]

Physical and Chemical Hazard

[156.10(h)(2)(iii)]

Storage and Disposal

[Consult Storage and Disposal Notice, PR-83-3]

NOTE: Consult 40 CFR 156.10(a)(2) for prominence and legibility requirements. Signal statement is determined by toxicity categories. [40 CFR 156.10(h)]