

US EPA ARCHIVE DOCUMENT

**Appendix 5-1:
Pesticide Labeling Under the Federal Insecticide,
Fungicide and Rodenticide Act (FIFRA)**

Pesticide Labeling Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), first enacted in 1947 and subsequently amended, requires the registration of pesticides and pesticide producers with the US Environmental Protection Agency. Pesticides, as defined by FIFRA, are substances designed to prevent, destroy, repel, or mitigate any pests, or to regulate, defoliate, or desiccate plants.

Each of the 600-odd pesticide active ingredients in use today must pass a set of health and safety standards in order to be approved for registration, or in the case of chemicals registered before 1984, a re-registration. (Tweedy et al., 1991). As part of registration or reregistration, the labeling of each product is reviewed and approved by the Agency.

Program Summary

Under EPA's Consumer Labeling Initiative (CLI), EPA and several stakeholders are evaluating the need for improvements to FIFRA labels for pesticides and household cleaners. See the write-up on CLI in this section for details.

FIFRA requires labels to appear on the containers of every pesticide product sold in the US, and imposes standards and restrictions regarding the wording and format (40 CFR §156.10). As outlined in the Code of Federal Regulations (CFR), a pesticide label must clearly and prominently display the following information:

- a) The name, brand, or trademark under which the product is sold;
- b) The name and address of the producer, registrant, or person for whom produced;
- c) The net contents (weight or measure);
- d) The product registration number;
- e) The producing establishment number;
- f) An ingredient statement;
- g) Warnings and precautionary statements;
- h) The directions for use; and
- i) The use classification(s) (restricted use).

All required label text must be set in 6-point type or larger, and must appear in English. The Agency, however, may require additional text in other languages if it is considered necessary in protecting the public health.

The Office of Pesticide Programs (OPP) at EPA reviews each pesticide label individually to ensure appropriateness and accuracy. (Frane, 1993) The particular environmental or health effects of a pesticide may prompt EPA to require additional warnings or messages to be included on its label (e.g., groundwater advisory statements, chronic hazard warnings).

The various components of the label are discussed in more detail below. Label requirements as described

below are taken from the 40 CFR §156.10. The regulations set only broad guidance on label content. In practice, the Agency has wide latitude to require, or accept, statements that deviate from the regulations, and many statements that are accepted reflect variations based on product type and use.

- A. Name, brand, or trademark: The name that appears on the label must be registered with the EPA, and not be false or misleading.
- B. Name and address of the producer, registrant, or person for whom produced: If the registrant's name that appears on the label is not the producer of the pesticide, it must be qualified by appropriate wording such as "*Packed for ****," "*Distributed by ****," etc.
- C. Net contents (weight or measure): The net weight or measure, exclusive of wrapping materials, must be stated as an average content unless explicitly stated as a minimum quantity.
- D. Product registration number: The EPA registration number (often abbreviated to "EPA Reg. No.") assigned to the pesticide product at the time of registration must appear on the label.
- E. Producing establishment number: The producing establishment number, preceded by the phrase "EPA Est.," must appear on the label or on the immediate container.
- F. Ingredients statement: The ingredients statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the label cannot be read, then the ingredient statement must also appear on that container or wrapper.

The label of each pesticide product must bear a statement that contains the name and percentage by weight of each active ingredient, and the total percentage by weight of all inert ingredients. Each ingredient may be referred to by its accepted common name, if there is one. If no common name has been established, then the chemical name must be used. Trademarked names not accepted as common names are not allowed.

Pesticide products that contain one or more chemical components that change significantly over time must also include a statement that reads: "*Not for sale after [date]*."

G. Warning and precautionary statements:

Required warning and precautionary statements regarding toxicological hazards to humans fall into two groups: those required on the front panel and those that may appear elsewhere. The child hazard warning and the appropriate human hazard signal word (see below) must appear on the front panel of a pesticide label. The human hazard signal word also appears elsewhere on the label. Other warnings and messages, including the first aid or statements of practical treatment (except in cases of extremely toxic products), health and environmental precautionary statements, and physical and chemical hazard statements, may appear elsewhere on the label.

1. *Child hazard warning*

Except for those products deemed safe for use on children or infants, or where the possibility of contact with children is exceedingly small, all pesticide product labels must bear on the front panel the warning "*Keep Out of Reach of Children*."

2. Toxicity Categories

The text required on the front panel of the label is determined by the Toxicity Category of the pesticide product. A pesticide is assigned a Toxicity Category based on its highest hazard potential in any of the following indicators listed in Table 1:

Table 1: Toxicity Category Definition				
Hazard Indicators	Toxicity Categories			
	I	II	III	IV
Oral LD ₅₀	up to and including 50 mg/kg	from 50 thru 500 mg/kg	from 500 thru 5000 mg/kg	greater than 5000 mg/kg
Inhalation LC ₅₀	up to and including 0.05 mg/liter	from 0.05 thru 2 mg/liter	from .5 thru 2 mg/liter	greater than 2 mg/liter
Dermal LD ₅₀	up to and including 200 mg/kg	from 200 thru 2000 mg/kg	from 2000 thru 20,000 mg/kg	greater than 5,000 mg/kg
Eye Effects	Corrosive (irreversible destruction of ocular tissue) or corneal involvement or irritation persisting for more than 21 days	Corneal involvement or irritation clearing in 8-21 days	Corneal involvement or irritation clearing in 7 days or less	Minimal effects clearing in less than 24 hours
Skin Effects	Corrosive (tissue destruction into the dermis and/or scarring)	Severe irritation at 72 hours (severe erythema or edema)	Moderate irritation at 72 hours (moderate erythema)	Mild or slight irritation (no irritation or slight erythema)
NOTES: LD ₅₀ is the lethal dose at which 50 percent of the animals in lab testing die. LD ₅₀ is measured in mg pesticide per kg bodyweight. LC ₅₀ is the lethal concentration at which 50 percent of the animals in lab testing die. LC ₅₀ is measured in mg pesticide per liter of air. SOURCE: <i>Consumer's Research</i> , July 1992; 40 CFR §156.10				

3. Human Hazard Signal Words

Pesticide labels must bear specific signal words, depending on the pesticide's assigned Toxicity Category.

A pesticide that meets the criteria of Toxicity Category I must bear the signal word "*Danger*" on the front panel of its label. In addition, if the product was assigned to Toxicity Category I based on its oral, inhalation, or dermal toxicity, the label must also bear the word "*Poison*" in red on a background of distinctly contrasting color and the skull and crossbones symbol must appear in close proximity to the word "*Poison*."

A pesticide meeting the criteria of Toxicity Category II must bear the signal word "*Warning*" on the front panel of its label.

A pesticide meeting the criteria of Toxicity Category III or IV must bear the signal word “*Caution*” on the front panel of its label.

4. *First Aid (Statements of Practical Treatment)*

For pesticides in Toxicity Category I, a first aid statement (or statement of practical treatment) is normally required on the front panel, although in practice reasonable variations are permitted by EPA. For other pesticides, first aid statements are not required on the front panel, but must appear elsewhere on the label.

5. *Other Required Warnings and Precautionary Statements*

Other appropriate warnings and precautionary statements must appear on the label under the general heading of “Precautionary Statements,” and under the subheadings of “Hazard to Humans and Domestic Animals,” “Environmental Hazard,” and “Physical or Chemical Hazard.”

Typical precautionary statements indicating hazard to humans and domestic animals are listed in Tables 2 through 8 below, and are arranged by Toxicity Category. Other statements are also used -- there is considerable variability in hazard statements.

If a pesticide is found to be potentially hazardous to non-target organisms (excluding humans and domestic animals), the text on its label must include precautionary statements describing the nature of the hazards and the appropriate precautions to avoid problems. For example, for a pesticide intended for outdoor use, which contains an agent with an acute oral LD₅₀ of 100 or less, the label must read, “*This Pesticide is Toxic to Wildlife.*” Other statements address toxicity to birds, fish, and aquatic organisms.

Finally, for chemical or physical hazards, the required precautionary statements are listed below in Table 9.

H. Directions for use

All pesticide labels must have printed on them detailed use instructions or references to accompanying instruction leaflets.

Table 2: Hazard to Humans and Domestic Animal Precautionary Statements		
Toxicity Category	Precautionary statement by Toxicity Category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe [vapor, dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, or skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed thru the skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Appropriate first aid statements required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed thru the skin]. Avoid breathing vapor [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statements required.]	Avoid contact with skin, eyes, or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

SOURCE: 40 CFR §156.10.

Table 3: Acute Oral Toxicity Study*		
Toxicity Category	Signal Word	Precautionary Statements and Personal Protective Equipment
I	DANGER Skull & Crossbones required	Fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco.
II	WARNING	May be fatal if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco.
III	CAUTION	Harmful if swallowed. Wash thoroughly with soap and water after handling.
IV	CAUTION	No statements are required. However, if the registrant chooses to use category III labeling that is acceptable.

*Products Containing 4% or more of methanol: Add the following to the precautionary statements:
"Methanol may cause blindness."

Table 4: Acute Dermal Toxicity Study

Toxicity Category	Signal Word	Precautionary Statements and Personal Protective Equipment
I	DANGER Skull & Crossbones required	Fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective clothing and gloves (specify protective clothing and type of gloves). Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.
II	WARNING	May be fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear protective clothing and gloves (specify protective clothing and type of gloves). Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse.
III	CAUTION	Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.
IV	CAUTION	No statements are required. However, if the registrant chooses to use category III labeling that is acceptable.

Table 5: Acute Inhalation Toxicity Study

Toxicity Category	Signal Word	Precautionary Statements and Personal Protective Equipment
I	DANGER Skull & Crossbones required	Fatal if inhaled. Do not breathe (dust, vapor, or spray mist).* [Identify specific respiratory protective device approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health.]** Remove contaminated clothing and wash clothing before reuse.
II	WARNING	May be fatal if inhaled. Do not breathe (dust, vapor or spray mist).* Wear a mask or pesticide respirator jointly approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health. Remove contaminated clothing and wash clothing before reuse.
III	CAUTION	Harmful if inhaled. Avoid breathing (dust, vapor or spray mist).* Remove contaminated clothing and wash clothing before reuse.
IV	CAUTION	No statements are required. However, if the registrant chooses to use category III labeling that is acceptable.

* Choose the word which appropriately describes the product during use.

** Refer to Section to determine the specific respiratory protective device. This section can be used for both WPS and Non-WPS products.

Table 6: Primary Eye Irritation Study		
Toxicity Category	Signal Word	Precautionary Statements and Personal Protective Equipment
I	DANGER	Corrosive.* Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses).** Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.
II	WARNING	Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses).** Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.
III	CAUTION	Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.
IV	CAUTION	No statements are required. However, if the registrant chooses to use category III labeling that is acceptable.

*The term "corrosive" is not required if only eye irritation (redness) was observed during the study and was still present at day 21.

**Use the term "safety glasses" in the precautionary labeling for residential use products.

Table 7: Primary Skin Irritation Study		
Toxicity Category	Signal Word	Precautionary Statements and Personal Protective Equipment
I	DANGER	Corrosive. Causes skin burns. Do not get in eyes or on clothing. Wear protective clothing and gloves (specify protective clothing and type of gloves)*. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.
II	WARNING	Causes skin irritation. Do not get on skin or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.
III	CAUTION	Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling.
IV	CAUTION	No statements are required. However, if the registrant chooses to use category III labeling that is acceptable.

*The need for rubber (homeowner products) or chemical-resistant gloves must be determined on an individual basis. Some products cause blistering if confined under clothing.

Table 8: Dermal Sensitization Study	
Study Results	Precautionary Statement
Product is a sensitizer or is positive for sensitization.	Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
Product is not a sensitive or is negative for sensitization.	No labeling is required for this hazard.

Table 9: Physical or Chemical Hazard Precautionary Statements	
Flash Point	Required Text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F, if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers.	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NON-PRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Combustible. Do not use or store near heat or open flame.
SOURCE: 40 CFR §156.10	

The directions must appear under the heading “*Directions for use,*” and include the following:

- a) the statement of use classification (see section I, below);
- b) the statement, “*It is a violation of Federal law to use this product in a manner inconsistent with its labeling;*”
- c) the sites of application (e.g., crops, lawns, etc.), or objects to be treated;
- d) the target pests;
- e) the dosage rate;
- f) the method of application;
- g) the proper frequency and timing of application;
- h) the reentry statement (if needed), which specifies the length of time that must pass before people can reenter a treated area;
- i) the disposal directions; and
- j) any use limitations or restrictions required to prevent unreasonable adverse effects.

I. Use classification

Every registered pesticide has one or more EPA-designated uses. Each of these uses is evaluated for hazard potential and may be classified for restricted use if necessary to protect human health or the environment.

1. *General Use Pesticides*

Unclassified products, with one exception, do not bear the term “General Use” as discussed in 40 CFR 15.160. The one exception involves products containing the active ingredient, chlorine gas. These products are the only products which bear the classification “General Use.”

2. *Restricted Use Classification*

Products designated for restricted use only must include the words “*Restricted Use Pesticide*” on the front panels of their labels. A statement describing the nature of the restrictions and the reason for the restriction must appear directly below the above statement. For example, “Due to oncogenicity,” “For retail sale and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator’s certification.” For each specific pesticide, other additional restriction statements may be required by EPA.

Enforcement

According to FIFRA Sec. 2(q) and 12 (Federal Environmental Laws, 1988), failure on the part of the pesticide producer or registrant to comply with labeling requirements may be considered “misbranding” of the pesticide. Sales or distribution of a misbranded pesticide constitutes an unlawful act. The Environmental Protection Agency may then cancel the registration, or bring criminal and/or civil charges against the registrant or producer of the pesticide.

References

Code of Federal Regulations, 40: PARTS 150 to 189. Revised as of July 1, 1992.

Committee on Scientific and Regulatory Issues Underlying Pesticide Use Patterns and Agricultural Innovation, Board on Agriculture, and the National Research Council (US), 1987. *Regulating Pesticides in Food: The Delaney Paradox*. National Academy Press, Washington D.C.

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