

Revised January 2012



# Label Review Manual

## Chapter 6: Use Classification



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## I. Introduction

End-use pesticide products (as opposed to products solely for further formulation into other pesticides) (See *40 CFR 152.166*) may be classified as Restricted Use Pesticides (RUP), or general use, or may be unclassified. *40 CFR 152.160(a)*. The Agency does not normally classify products for general use; products that are not restricted remain unclassified.

*40 CFR 152.160(a)*. If the Agency determines that the pesticide, when applied in accordance with the label's directions for use, warning and cautions, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects, the Agency will classify the pesticide as an RUP. *FIFRA 3(D)(1)(c)*.

It is the Agency's policy that when labeling cannot sufficiently mitigate the risk, special training in handling and applying the pesticide product is necessary to ensure the safe use of the product. The sale and distribution of RUPs must meet the regulations set out at *40 CFR 152.167*, or those restrictions established through Agency regulation. *FIFRA 3(d)(1)(C)(i)&(ii)*. The use of RUPs is limited to certified applicators or persons under their direct supervision. *FIFRA 3(d)(1)(C)(i)&(ii)*; *40 CFR 152.175*. Users of unclassified products are not limited in any manner unless the labeling limits use to a specific definable group, (e.g., veterinarians). See *Chapter 11* for further explanation of this issue.

## II. Unclassified products

### A. Criteria

If the label under review meets any of the criteria below, then the product may remain unclassified.

1. **Identical or Substantially Similar.** The product under review is an identical or substantially similar registration, and the product cited as substantially similar is unclassified.
2. **Data Supported.** The product under review is a new product for which data were submitted and none of the following data reviews indicates that the product should be considered for restricted-use classification.
  - (a) Environmental Effects, Fate and Groundwater reviews assess the toxicity to fish, birds and mammals, and endangered species and assess the possibility of groundwater contamination and persistence in soil.
  - (b) Chemistry and Exposure reviews assess the degree of human health exposure.
  - (c) Toxicity reviews assess the acute and chronic toxicity of the product, and the acute and chronic human health hazards.

(d) Note that under *40 CFR 152.170(d)*, there may be other evidence such as field studies or monitoring data that would result in the Agency determining that a pesticide should be restricted use.

3. **Manufacturing Use Products.** The product under review is a manufacturing use product (MP). MPs are not subject to the *40 CFR 152.166* restricted use labeling requirements.
4. **Active Ingredients Have not Previously Been Classified Restricted Use.** The product under review contains no active ingredient(s) or use(s) which have been previously classified as restricted use. To check: Refer to *40 CFR 152.175*. Another reference source for this information is the Webpage: <http://www.epa.gov/opprd001/rup/>.

If the label under review does not meet one of the above criteria, then the product may be classified as an RUP.

### III. Restricted use pesticides (RUP)

#### A. Determination of Classification.

Review the criteria below to determine whether the product should be classified as an RUP.

1. If the product under review is an identical or substantially similar registration and the cited product is classified as an RUP, then the product label under review must bear the Restricted Use classification. Go to section B below on “*Labeling Requirements for RUPs*”.
2. Based on a review of the data that support the product registration, the pesticide may be classified as RUP if its toxicity exceeds the specific hazard criteria set out at *40 CFR 152.170*. Even if the RUP criteria are triggered, the Agency must determine if the potential risk can be adequately mitigated through additional labeling restrictions. The label reviewer should check with the Product Manager/team leader to determine if this is the case. See *40 CFR 152.170(e)*. If not, the product must be classified as an RUP. Go to Section B. below on “*Labeling Requirements for RUPs*”.

MITIGATION OPTION: If the PM/team leader determines that the product should not be classified as an RUP because additional label language can mitigate the risk, then the label reviewer must include a memo to the file noting this decision. The memo must specify the basis for the decision under *40 CFR 152.170(e)*, including the alternative labeling language required. The label reviewer must sign and date the memo, place it in the registration jacket, and ensure the product label under review does not bear any use classification.

**B. Labeling Requirements for RUPs.**

Restricted use pesticides are subject to the labeling requirements specified in *40 CFR Part 156*, including the requirements set out in *40 CFR 156.10(j)(2)* described further in *PR Notice 93-1*. The product may have both general and restricted uses. If there is a restricted use, the labeling requirements for restricted use must be followed. Check the label under review to make certain that the label meets the RUP labeling requirements listed below:

1. The statement “Restricted Use Pesticide” must appear at the very top of the label's front panel. *40 CFR 156.10(j)(2)(i)(A)*. No other wording or symbols should appear above the RUP statement. *PR Notice 93-1*. The phrase “Restricted Use Pesticide” on the front panel must meet the minimum type size requirements of the human hazard signal words. *40 CFR 156.10(j)(2)(i)(A)*. If type size is too small, the label reviewer must notify the registrant in writing of the type size requirements specified in the Code of Federal Regulations at *40 CFR 156.60(b)(1)* for the signal word.
2. A briefly stated reason for the restricted use classification should directly follow “Restricted Use Pesticide”. *PR Notice 93-1*.
3. A summary statement of the terms of the restrictions must follow. *40 CFR 156.10(j)(2)(i)(B)*. (See the next section below for examples of chemical-specific RUP statements and reasons for RUP classification).
4. The RUP statement should be enclosed in a box to enhance its visibility on the label. *PR Notice 93-1*.
5. The RUP statement must appear with sufficient prominence in relation to other label text and graphics so as not to be overlooked. *40 CFR 156.10(j)(2)(i)(A)*.
6. The label must bear the phrase “Restricted Use Pesticide” under the heading “Directions for Use”. *40 CFR 156.10(i)(2)(i)*.
7. The label must not bear any designation indicating that certain uses are restricted and other uses are not restricted. If the registrant wants to include unrestricted uses on a product with restricted uses then the entire product must be labeled restricted. This is to avoid the general public obtaining access to products with restricted uses. If the registrant desires to market uses as unrestricted, then the registrant should seek a separate registration only for those unrestricted uses. *40 CFR 156.10(j)*.

**C. Wording of the RUP Terms of Restriction.**

The label must bear the general summary statement of the terms of restriction at top of the front panel. *40 CFR 156.10(j)(2)(i)(B)*; see *Chapter 3* for correct formats.

1. If use is restricted to certified applicators, the general RUP statement listed at [40 CFR 156.10\(j\)\(2\)\(i\)\(B\)](#) must appear as follows: “For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator’s certification”.
2. Some pesticides require a specific RUP statement, based on specific case-by-case risk management decisions. The Agency in some cases has determined that particular RUP statements are applicable to specific products or to the active ingredient(s). Check the appropriate science review, and consult your Product Manager or Team Leader to determine if a specific RUP statement has been applied to particular products or active ingredients. Then evaluate whether the particular product at issue requires that same or similar language based on risk management issues and the FIFRA statutory standard of unreasonable adverse effects. Also, check in OPPIN or the Chemical Review Manager/Team Leader for the status of the Reregistration Eligibility Decision (RED) document for the chemical. If a RED document has been issued, check it for any specific guidance for Restricted Use Pesticide classification and/or associated labeling. Following is an example of an RUP statement.

*“Restricted Use Pesticide (Same minimum type size as signal word)”*

*“Due to (reason for restricted use)”*

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator’s Certification.