



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SEP 11 1997

PR NOTICE 97-6

NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS, AND
REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for the Registration of
Pesticides

SUBJECT: Use of Term "Inert" in the Label Ingredients Statement

This notice announces a change in EPA policy regarding the label ingredients statement. Effective immediately, the phrase "Inert ingredients," may be replaced by the term "Other ingredients." Although no registrant is required to make this change, EPA encourages registrants to do so. Provided the term "Other ingredients" is used, the change may be made at any time without notification to the Agency.

I. BACKGROUND

The terms "active ingredient" and "inert ingredient" have been defined in FIFRA since 1947 and pesticide labeling regulations require that the ingredients statement use the terms "Active ingredients" and "Inert ingredients" as the headings for the ingredients statement information. An active ingredient is one that prevents, destroys, repels or mitigates a pest, and each active ingredient must be identified by name on the label together with its percentage by weight. An inert ingredient is simply any ingredient in the product that is not pesticidally active. Unless an inert ingredient is determined to be highly toxic, it is not required to be identified by name or percentage on the label, but the total percentage of such ingredients must be declared. Neither FIFRA nor the regulations define the term "inert ingredient" on the basis of toxicity, hazard or risk to humans, non-target species, or the environment.

Most "inert" ingredients are not known to pose health or environmental concerns; however, EPA has long known and acknowledged that some inert ingredients are not

benign to human health or the environment. The "inert" ingredients in some products may be more toxic or pose greater risks than the active ingredient. Since 1987, EPA has been actively evaluating new and existing inert ingredients for their toxicity before allowing their use in pesticide products. EPA will also be reassessing food tolerances for existing inert ingredients in pesticide products. EPA has not taken the additional step, however, of departing from its traditional use of the term "inert ingredient" on pesticide labeling.

In 1996, EPA began a Consumer Labeling Initiative (CLI), which has as its goal the improvement of consumer labeling (focussing on pesticide products). In the first phase of the CLI, one-on-one interviews were conducted with users of household pesticides (indoor insecticides, outdoor pesticides, and household hard surface cleaners) and non-pesticide cleaning agents. Among other things, the interviews demonstrated that many consumers have a misleading impression of the term "inert ingredient," believing it to indicate water or other harmless ingredients. A number of comments from the public and the consumer interviews recommended that EPA discontinue the use of the term. By this notice, EPA is implementing that recommendation with respect to pesticide labeling.

II. POLICY

Effective immediately, EPA will permit (and encourages) registrants and applicants for registration to substitute the more neutral term "Other ingredients" on their pesticide labels and in other materials describing the pesticide product. EPA will initiate rulemaking to revise its labeling regulations in 40 CFR 156.10 to make this change binding; however, EPA believes that it should proceed immediately to permit registrants to make this change voluntarily.

Accordingly, any registrant or applicant for registration may revise product labels to substitute the phrase "Other ingredients" as the heading for the "inert" ingredients in the product ingredients statement.

This change affects only the heading "Inert ingredients" used in the label ingredients statement. It does not affect the status of any ingredient in a product as an "inert ingredient" under FIFRA sec. 2(m). It does not affect an Agency determination as to whether an ingredient is an "active" or pesticidally inert ingredient under 40 CFR 153.125. Nor does it relieve the registrant of other requirements of FIFRA or the Federal Food, Drug and Cosmetic Act pertaining to "inert ingredients" as defined by FIFRA.

III. PROCEDURE

Provided that the term "Other ingredients" is used, a registrant may revise its label at any time without notification to the Agency. The format, type style and size of the heading "Other ingredients" must be the same as is currently approved by EPA for "Inert

ingredients." All other requirements pertaining to the label ingredients statements remain the same.

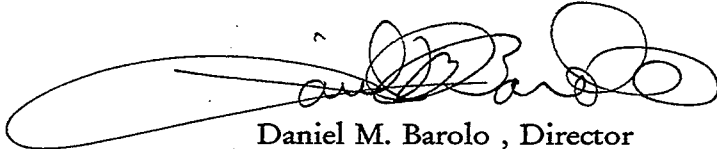
At this time, EPA is not considering other terms to substitute for "inert ingredients"; however, when EPA revises its regulations, it may consider other terms.

IV. COMPLIANCE

No registrant is required to make this change. However, EPA strongly encourages registrants to make this change as labels are routinely revised. EPA will not consider a product bearing the term "Other ingredients" instead of "Inert ingredients" to be misbranded within the meaning of FIFRA sec. 12 solely because of that change.

V. FOR FURTHER INFORMATION

If you wish further information on this notice, you may contact Jean M. Frane, Field and External Affairs Division, at 703-305-5944, or by e-mail to Frane.Jean@epamail.epa.gov.

A handwritten signature in black ink, appearing to read "Daniel M. Barolo", is written over a horizontal line.

Daniel M. Barolo , Director
Office of Pesticide Programs

