



October 20, 1999

Marcia E Mulkey
7501 C
USEPA Headquarters
401 M Street, S.W.
Washington, DC 20460

Dear Ms.Mulkey:

Under the exemption authority of section 25(b) of FIFRA, the Environmental Protection Agency issued a final rule in the *Federal Register* of March 6, 1996 (61 FR 9976), exempting certain minimum risk pesticides from regulation. As such, Section 25(b) pesticide labels are now in the marketplace.

The American Association of Pesticide Safety Educators (AAPSE) requests the Environmental Protection Agency modify the above mentioned final rule (61 FR 9976) and existing draft pesticide registration notice on Section 25(b) pesticide labels and establish a minimal approval process before such labels are available in the marketplace.

The establishment and usage of Section 25(b) pesticide labels has initiated issues of concern in three areas: 1) state lead agency activities in pesticide registration, compliance and enforcement, 2) consumer exposure to Section 25(b) pesticides, consumer perceptions and recognition of such pesticides and 3) Cooperative Extension educational programs for certified applicators and consumers.

State lead agencies and their pesticide registration functions are severely at risk under current Section 25(b) regulatory guidance. A FIFRA pesticide label must be registered with the state lead agency before sale and use in each state. According to a 1996 APPCO survey, most states require all pesticides, including Section 25(b) labels, to be registered by the state. Some state laws require each pesticide label to bear an EPA registration number and a signal word; those that do not bear the registration number or signal word are considered misbranded in those states and therefore, illegal.

Without EPA registration numbers, no means of identification unique to each product label is available to these agencies. While state lead agencies may assign an internal identification number to such products, that does not allow state agencies to compare records with other states or the EPA on

products which have no mutually agreed upon registration number.

Occasionally, pesticide products formulated in a specific lot must be recalled by the manufacturer and removed from market shelves. The additional absence of EPA establishment numbers prevents university researchers and commercial businesses from determining the formulation source when this issue is brought to their attention. There is no means of tracking the distribution of the product in marketing channels if EPA or a state lead agency determines that a Section 25(b) label is to be removed from the market.

A second serious concern is the impact of Section 25(b) labels upon the consumer. Labels are on the market with illegal ingredient statements, little or no guidelines for the use of personal protective equipment, and no assurance that the product has had a cursory review before entering the marketplace. No pesticide label signal word is present to guide users on toxicity, protective clothing and equipment. False and misleading statements now occur on pesticide labels that confuse consumers. Labels providing the impression that the product is non-toxic are a grave concern as by default they encourage unnecessary human and environmental exposure.

According to CFR guidance, in order to be exempted from FIFRA a pesticide product must not include any false or misleading labeling statements. See Appendix A concerning labeling guidance as per 40CFR 156.10(a)(5)(i)-(viii).

There are Section 25(b) labels in the marketplace that do mislead consumers and provide false statements. See Appendices B and C for excerpts from two Section 25(b) labels. The labels cannot be specifically identified for your reference because neither has an EPA registration number. Examples of misleading and/or false statements are:

1. Concern Weed Prevention Plus manufactured by Necessary Organics, Inc.

This label provides conflicting health statements. It makes reference that the product is "safe" and exempted from "herbicide regulations." In contrast, another reference on the same label states "possible allergic reaction to inhalation of dust." No PPE is recommended or required. No reference is made to the possible use of respirators or dust masks. According to a draft Pesticide Registration Notice on Section 25(b) labels, "This kind of statement leads the consumer to believe that the Federal Government has made such a determination for a particular product..." and would be considered as misleading.

2. Concern Weed Prevention Plus manufactured by Necessary Organics, Inc.

A fundamental rationale in the use of pesticides is to always follow the application rate on the label and never apply more than the labeled rate. This label undermines this principle by encouraging the applicator to "use twice the recommended rate for better control."

3. Tree Tanglefoot Pest Barrier manufactured by The Tanglefoot Company

This Section 25 (b) label states "E.P.A. Est. 1621-MI-1" and provides the strong impression that this is a valid EPA establishment number. No EPA registration number is on the label. The apparent counterfeit number is similar to the EPA establishment number on another FIFRA pesticide product by the same company (Tanglefoot Bird Repellent, EPA Reg. No. 1621-17, EPA Est. No. 1621-MI-1). The placement of a fictional establishment number implies the Environmental Protection Agency has reviewed the Section 25(b) label.

Allowable active ingredients for Section 25(b) labels may be of a toxicological concern for consumers. Eugenol is an example. It is one of the active ingredients in EcoPRO D Dust Insecticide produced by EcoSmart Technologies, Inc. of Roswell, GA. See Appendix D for additional information. A material data safety sheet on eugenol available on the Internet at <http://MSDS.PDC.CORNELL.EDU/msds/siri/q246/ql88.html> indicates eugenol has a LD₅₀ of 2.68 mg/kg and that "eugenol is irritating to eyes. Repeated contact may cause allergic dermatitis." Such statements from a MSDS raises questions about its inclusion in the approved EPA active ingredient list for Section 25(b) pesticides.

The advent of Section 25(b) labels encourages illegal business practices. Because these labels have no minimum advance approval, a manufacturer may formulate and begin sale of a pesticide product without EPA oversight. Hence, pesticide labels can be in the marketplace formulated with illegal active and/or inert ingredients and the consumer is at risk. According to draft Pesticide Registration Notice on Section 25(b) labels, active ingredients must be listed by name and percentage by weight. An example of an illegal ingredient statement is below:

Tree Tanglefoot Pest Barrier manufactured by The Tanglefoot Company

The ingredient statement reads "Ingredients: Castor oil, Natural Gum Resins, Vegetable Wax."

In the above example, no distinction is made between active or inert ingredients. No active ingredient concentration is provided. Neither natural gum resins or vegetable wax are included in the allowed EPA active or inert ingredient lists for Section 25(b) pesticides.

Other flawed Section 25(b) labels exist. For your reference, several examples of these labels were provided to Sheryl Reilly, EPA by Ed White, Indiana State Chemist and EPA Region 5 representative to SFIREG.

Cooperative Extension and land grant universities began pesticide applicator training in 1976. Since that time, certain fundamental principles relative to pesticide labels have been incorporated into these educational programs. For example, a pesticide label must be approved in advance by the EPA before sale in the marketplace. The product review and subsequent approval is indicated by the presence of the EPA registration number on the label.

In addition, an EPA establishment number has identified (in code) the formulator of the product. Both certified applicators and consumers appreciate the presence of these two numbers and have realized a

level of confidence that products must be approved before sale. Existing guidance for Section 25(b) labels provide no assurance to Cooperative Extension, certified applicators, consumers or state lead agencies that minimum standards have been met before the product is on the market.

Section 25(b) labels rarely have personal protective equipment statements. To our knowledge, none have a pesticide signal word such as caution. Cooperative Extension educational programs promote the importance of effective pest management and safe pesticide handling practices, both for the user and the environment. The Section 25(b) labels hinder fundamental recognition of these principles associated with pesticide usage and impede efforts to educate the consumer on how to read and understand labels or use these products safely and effectively.

Because Section 25(b) pesticide products are allowed onto the market without an advance minimal approval, the potential for liability as incurred by the Environmental Protection Agency is heightened. As in the examples presented above, consumers can easily be misled by the label and wooed into a false sense of security because of incomplete active ingredient statements, the lack of a "caution" signal word, and no recommendations (or requirements) for personal protective equipment. Consumer health is at risk. A minimal EPA approval of the label, would assure no illegal active or inert ingredients enter the marketplace and jeopardize consumers.

We hereby request the Environmental Protection Agency modify final rule (61 FR 9976) and the draft Section 25(b) Pesticide Registration (PR) notice by establishing the following minimum standards:

1. The assignment of a recognizable EPA Registration Number (for example, EPA Reg. No. 25B - XXX-XXXX-XX) on all Section 25(b) pesticide labels *before* distribution and sale of the product in the marketplace.
2. The issuance of a Section 25(b) EPA Registration Number shall be based on minimum established criteria:
 - a. That the active and inert ingredients in a given product are determined to be allowed as per 40 CFR 152.25(g)(1) and (3)
 - b. The label contain an ingredient statement listing active ingredient(s) by common chemical name and percent by weight plus the concentration of the inert ingredients
 - c. No false or misleading statements are present on the label
 - d. The label contain an appropriate signal word, such as "caution"
 - e. The label include a statement of required minimum personal protective equipment
 - f. A statement appears on the label that indicates the product has not been subject to full testing by the Environmental Protection Agency or the Food and Drug Administration.
3. The use of an EPA establishment number is strongly encouraged on Section 25(b) labels.

State regulators, consumers, applicators and the Environmental Protection Agency would benefit greatly from tighter Section 25(b) label requirements. With only the above minimal review of a Section 25(b) pesticide label and the assignment of an EPA registration number in advance of product

sale and usage, the EPA would:

- allow state lead agencies to be in compliance with their respective pesticide registration requirements
- allow specific identification of individual Section 25(b) labels to aid states' registration processes
- assure active and inert ingredients are correctly listed in ingredient statements for proper identification by regulators, consumers and applicators
- prevent illegal pesticide active or inert ingredients from entering the marketplace
- reduce its own liability by strengthening regulatory guidance to states and by taking necessary steps to protect consumers
- reduce unnecessary pesticide exposure to consumers through personal protective equipment requirements and the placement of the "caution" signal word on labels,
- eliminate false and misleading statements that confuse consumers
- allow ease of tracing a label in the marketplace during product recalls
- support long-established Cooperative Extension educational principles that the presence of EPA registration and establishment numbers are indicators of quality and health protection assurance
- support Cooperative Extension in its educational programs to promote the use of approved pesticide labels, to use PPE during pesticide applications, to use specific application rates according to the label and to accurately portray product "claims."

We request this action by EPA to correct the deficiencies in the Section 25(b) pesticide label regulatory criteria. The American Association of Pesticide Safety Educators submits this request with the support of the Association of American Pesticide Control Officials. Both organizations recognize the need for tighter criteria on Section 25(b) pesticide labels.

Sincerely,

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AAPSE ListServ

Appendix A

According to 40 CFR 156.10(a)(5)(i)-(viii) Labeling Statements:

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to 153.240, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non- pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

- (i) A false or misleading statement concerning the composition of the product;
- (ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;
- (iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;
- (iv) A false or misleading comparison with other pesticides or devices;
- (v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;
- (vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more, but not all such principal active ingredients, even though the names of the other ingredients are stated elsewhere in the labeling;
- (vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;
- (viii) Label disclaimers which negate or detract from labeling statements required under conditions of exemption:

Appendix B

Excerpts from Concern Weed Prevention Plus Section 25(b) label

"Corn gluten meal 100% "

"Hazards to Humans & Domestic Animals Caution: Possible allergic reaction to inhalation of dust in affected individuals"

"So Safe the U.S. Environmental Protection Agency Exempted it from Herbicide Regulations"

"Application Rate: Apply 5 lbs per 250 sq. ft. (25' x 10') to turf or garden soil. If you choose, you can use twice the recommended rate for even better control with no fear of burning your plants"

Container weight - 5 pounds

Manufacturer:

Necessary Organics, Inc.
One Natures' Way
New Castle, VA 24127-0305
concem@swva.net
www.concemgarden.com

Appendix C

Excerpts from Tree Tanglefoot Pest Barrier label

"Sticky Barrier Protects Trees
Gypsy Moths - Ants - Cankerworms - Other Crawling Insects"

"Ingredients: Castor oil, Natural Gum Resins, Vegetable Wax"

"E.P.A. Est. 1621-MI-I 1/96"

Manufacturer:

The Tanglefoot Company
Grand Rapids, MI 49504

Appendix D

Excerpts from EcoPRO D Dust Insecticide label

"Active Ingredient: Hexa-Hydroxyl'
from Plant Essential Oils:
Eugenol 7.0%
2-Phenethyl Proplonate 2.5%
Other Ingredients 90.5%"

"Other Ingredients: Vermiculite, Calcium Carbonate, Sodium Bicarbonate,
Hi-Sil 233, Fragrance"

"Quick Knockdown"

"Residual Protection"

"Non-staining & Non-Corrosive"

"EPA 25(b)(2) Exempt Product"

Manufacturer:

EcoSmart Technologies, Inc.
555 Sun Valley Drive, Ste F-3
Roswell, GA 30076