

March 6, 2000

PESTICIDE REGISTRATION (PR) NOTICE 2000 - 1*

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

ATTENTION: Persons Responsible for Registration of Pesticide Products

SUBJECT: Applicability of the Treated Articles Exemption to Antimicrobial Pesticides

This notice clarifies current EPA policy with respect to the scope of the "treated articles exemption" in 40 CFR 152.25(a). This exemption covers qualifying treated articles and substances bearing claims to protect the article or substance itself. EPA does not regard this exemption as including articles or substances bearing implied or explicit public health claims against human pathogens. This notice addresses the types of claims which are not permitted for antimicrobial pesticide products exempt from registration under this provision and gathers together in one place guidance the Agency has offered in recent years on labeling statements which it believes would or would not be covered under this provision. This notice also explains the requirement that the pesticide in a treated article be "registered for such use."

This notice provides guidance to producers and distributors of pesticide treated articles and substances, and to producers and distributors of pesticides used as preservatives to protect treated articles from microbial deterioration.

I. BACKGROUND

EPA regulations in 40 CFR 152.25(a) exempt certain treated articles and substances from regulation under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) if specific conditions are met. The specific regulatory language is:

Section 152.25 Exemptions for pesticides of a character not requiring FIFRA regulation

"(a) *Treated articles or substances.* An article or substance treated with, or containing, a pesticide to protect the treated article or substance itself (for example, paint treated with a pesticide to protect

* This version makes corrections to the February 3, 2000 PR Notice 2000-1. Corrections in bold/italics or editorial deletions were made on pages 3, 4, 7, and 9.

the paint coating, or wood products treated to protect the wood against insect or fungus infestation),
if the pesticide is registered for such use."

Known as the "Treated Articles Exemption," section 152.25(a) provides an exemption from all requirements of FIFRA for qualifying articles or substances treated with, or containing a pesticide, if:

- (1) the incorporated pesticide is registered for use in or on the article or substance, and;
- (2) the sole purpose of the treatment is to protect the article or substance itself.

The exemption gives two examples of treatments that are intended to protect only the treated article or substance itself. In the first case, paint is being protected from deterioration of the paint film or coating. In the second case, wood is being protected from fungus or insect infestations which may originate on the surface of the wood. Pesticides used in this manner are generally classified as preservatives. Other pesticides are incorporated into treated articles because of their ability to inhibit the growth of microorganisms which may cause odors or to inhibit the growth of mold and mildew. Because of this treatment, it is claimed that a fresher and more pleasing surface can be maintained.

To qualify for the treated articles exemption, both conditions stated above must be met. If both are not met, the article or substance does not qualify for the exemption and is subject to regulation under FIFRA.

In recent years, the marketplace has experienced a proliferation of products that are treated with pesticides and bear implied or explicit public health claims for protection against bacteria, fungi and viruses, as well as specific claims against pathogenic organisms which may cause food poisoning, infectious diseases or respiratory disorders. Examples of such articles include toothbrushes, denture cleansers, children's toys, kitchen accessories such as cutting boards, sponges, mops, shower curtains, cat litter, vacuum cleaner bags, pillows, mattresses and various types of finished consumer textiles. In many cases, these products have made public health claims that extend beyond the protection of the article itself, and thus, they do not qualify for the treated articles exemption.

II. TYPES OF ANTIMICROBIAL CLAIMS

A. Public Health Claims

Because consumers have long associated the following widely used claims and references to microorganisms harmful to humans with products providing public health protection, EPA considers an article or substance to make a public health claim if any of the following claims are made either explicitly or implicitly:

1. A claim for control of specific microorganisms or classes of microorganisms that are directly or indirectly infectious or pathogenic to man (or both man and animals). Examples of specific microorganisms include *Mycobacterium tuberculosis*, *Pseudomonas aeruginosa*, *E. coli*, *HIV*,

Streptococcus and *Staphylococcus aureus*.

2. A claim for the product as a sterilant, disinfectant, virucide or sanitizer, regardless of the site of use of the product, and regardless of whether specific microorganisms are identified.

3. A claim of “antibacterial,” “bactericidal,” or “germicidal” activity or references in any context to activity against germs or human pathogenic organisms implying public health related protection is made.

4. A claim for the product as a fungicide against fungi infections or fungi pathogenic to man, or the product does not clearly indicate it is intended for use against non-public health fungi.

5. A claim to control the spread of allergens through the inhibition or removal of microorganisms such as mold or mildew.

6. A non-specific claim that the product will beneficially impact or affect public health by pesticidal means at the site of use or in the environment in which applied.

7. An unqualified claim of “antimicrobial” activity. Refer to Unit IV.C.

B. Non-Public Health Claims

EPA considers a product to make a non-public health claim if any of the following applies:

1. A claim to inhibit the growth of mildew on the surface of a dried paint film or paint coating.

2. A claim to inhibit microorganisms which may cause spoilage or fouling of the treated article or substance.

3. A claim to inhibit offensive odors in the treated article or substance.

4. EPA considers terms such as “antimicrobial,” “fungistatic,” “mildew-resistant,” and “preservative,” as being acceptable for exempted treated articles or substances provided that they are properly, and very clearly, qualified as to their intended non-public health use. Refer to Unit IV.C. Use of these terms in product names or elsewhere in the labeling in bolder text than accompanying information may render such qualifications inadequate.

III. PAST EPA LABELING CLAIMS INTERPRETATIONS

A. Odor and Mildew-Resistant Properties May Be Claimed

Over the past twenty-five years the Agency has issued several interpretations concerning the

exemption from FIFRA regulations *of* certain types of antimicrobial treated article claims associated with mildew-resistant paint, films and coatings. In the same period, EPA has also issued other interpretations concerning certain types of odor-resistant antimicrobial treated article claims.

During this period there has been widespread dissemination and adoption by the antimicrobial pesticide product community of these EPA interpretations regarding mildew-resistant and odor-resistant claims under the “treated articles exemption.” Furthermore, the Agency continues to treat these general types of claims as covered by the term “to protect the treated article or substance itself” because mitigation of these non-public health related organisms can contribute to the protection of the appearance and maintenance of the intended useful life of the treated article or substance. Because during this period, there has also been widespread misinterpretation of EPA’s guidance, the Agency has developed a representative set of statements designed to clarify its position in this area. Consequently, if they otherwise qualify for the exemption, properly labeled treated articles and substances bearing claims such as those described under Unit IV.B. continue to be eligible for the treated articles exemption.

B. Product Names May Not Contain Public Health Claims

The Agency regards trademarked product names of treated articles or substances [or references to trademarked names of registered pesticides] as potential sources of public health claims that could render a product ineligible for the “treated articles exemption” just as could other direct or indirect public health claims on or in a product’s packaging or in its labeling or advertising literature. The Agency has maintained this position in enforcement actions against pesticide-treated articles, such as pesticide-treated cutting boards and other items, which bore names suggesting health or other benefits beyond mere preservation of the treated article itself. In determining the eligibility of a treated article or substance for the exemption, the Agency will examine the product name, its context, labeling claims and other related elements on a case-by-case basis

IV. TREATED ARTICLE LABELING CLAIMS

Products treated with antimicrobial pesticides with claims such as those described in Section A below are likely to not be acceptable under the “treated articles exemption” because they imply or express protection that extends beyond the treated article or substance itself. Products treated with antimicrobial pesticides registered for such use and which only bear claims for protection of the article or substance itself such as those described in Section B below are likely to be acceptable and eligible for the “treated articles exemption”, assuming all other conditions have been met. Section C below contains examples of appropriate qualifying and prominence statements which have been extracted from multiple enforcement proceedings dealing with claims that can be made for treated articles without obtaining registration.

A. Examples of Labeling Claims That the Agency is Likely to Consider Unacceptable Under the Exemption

The following examples are not intended to be an all-inclusive listing of unacceptable treated article labeling claims. If persons are not sure whether their antimicrobial pesticides are covered by the provisions of this section, the Agency encourages them to request a written opinion from the Antimicrobials Division at one of the addresses listed under Unit VII.

These examples represent claims or types of claims for a treated article that would lead to a requirement to register the article as a pesticide product.

- o Antibacterial
- o Bactericidal
- o Germicidal
- o Kills pathogenic bacteria.
- o Effective against E. coli and Staphylococcus.
- o Reduces the risk of food-borne illness from bacteria.
- o Provides a germ-resistant surface.
- o Provides a bacteria-resistant surface.
- o Surface kills common gram positive and negative bacteria.
- o Surface controls both gram positive and negative bacteria.
- o Surface minimizes the growth of both gram positive and negative bacteria.
- o Reduces risk of cross-contamination from bacteria.
- o Controls allergy causing microorganisms.
- o Improves indoor air quality through the reduction of microorganisms.

B. Examples of Labeling Claims the Agency is Likely to Consider Acceptable Under the Exemption

The following examples are not intended to be an all-inclusive listing of acceptable treated article labeling claims. If persons are not sure whether their antimicrobial pesticides are covered by the provisions of this section, the Agency encourages them to request a written opinion from the

Antimicrobials Division at one of the addresses listed under Unit VII.

1. Mold and Mildew Resistant Claims

- o This article has been treated with a fungistatic agent to protect the product from fungal growth.
- o Mildew Resistant - treated with a fungistatic agent to protect the paint itself from the growth of mildew.
- o Mildew Resistant - This paint contains a preservative which inhibits the growth of mildew on the surface of this paint film.
- o Mildew Resistant - Extends useful life of article by controlling deterioration caused by mildew.
- o Algae Resistant - This article contains a preservative to prevent discoloration by algae.
- o A fungistatic agent has been incorporated into the article to make it resistant to stain caused by mildew.
- o Article treated to resist deterioration by mold fungus.
- o Article treated to resist deterioration from mildew.
- o The fungistatic agent in this article makes it especially useful for resisting deterioration caused by mildew.
- o Dry coating of this paint mildew resistant.
- o Dried paint film resists mold fungus.
- o Dry enamel coating resists discoloration from mildew.
- o Cured sealant is mildew resistant.
- o Dried film resists stains by mold.
- o A mold or mildew resisting component has been incorporated in this article to make its dry film mildew resistant.
- o Specially formulated to resist mildew growth on the paint film.
- o Gives mildew-resistant coating.

- o The mildew resistance of this outside house paint film makes it especially useful in high humidity areas.
- o Retards paint film spoilage.
- o Resists film attack by mildew.

2. Odor Resistant Claims

- o This product contains an antimicrobial agent to control odors.
- o This product contains an antimicrobial agent to prevent microorganisms from degrading the product.
- o Resists Odors - This product has been treated to resist bacterial odors.
- o Inhibits the growth of bacterial odors.
- o Resists microbial odor development.
- o Retards the growth and action of bacterial odors.
- o Guards against the growth of odors from microbial causes.
- o Guards against degradation from microorganisms.
- o Reduces odors from microorganisms.
- o Odor-resistant.
- o Acts to mitigate the development of odors.

C. Antimicrobial Qualifying and Prominence Considerations

EPA does not believe that claims such as “antimicrobial,” “fungistatic,” “mildew-resistant,” and “preservative” or related terms are consistent with the intent of 40 CFR 152.25(a) if they are: (1) part of the name of the product; or (2) not properly qualified as to their intended non-public health use. Examples of *permissible* statements would include, but not be limited to: “Antimicrobial properties built in to protect the product” and “Provides mildew-resistant dried paint coating.” All references to the pesticidal properties and the required qualifying statements should be located together, should be printed in type of the same size, style, and color, and should be given equal prominence. Moreover, such references should not be given any greater prominence than any other described product feature.

In addition, treated articles or substances intended for microbial odor control or article preservation in areas where food-borne or disease-causing organisms may be present have the potential to create the impression that the article provides protection against food-borne and disease-causing bacteria. This potential should be addressed through very careful narrowing and qualification of the non-public health claims. A complete assurance that there is no misleading impression could be achieved through use of language like: “This product does not protect users or others against food-borne (or disease-causing) bacteria. Always clean this product thoroughly after each use.” or “This product does not protect users or others against bacteria, viruses, germs or other disease organisms. Always clean this product thoroughly after each use.”

V. ADDITIONAL INFORMATION

A. Registration of Treated Articles Making Public Health Claims

Treated articles or substances with implied or explicit public health claims or which otherwise fail to qualify for exemption are pesticide products subject to all requirements of FIFRA. They may not be legally sold or distributed unless they are registered with EPA or unless such claims have been removed and the article otherwise qualifies for exemption. To obtain a registration, an applicant must submit acceptable data supporting all the proposed claims under which the product will be marketed and meet all other applicable registration requirements. Refer to 40 CFR Parts 152, 156, and 158.

The Agency currently has no established protocols for the development of data to support public health claims on treated articles for which registration is sought. Acceptable protocols for product testing reflecting actual use conditions need to be submitted and approved by EPA prior to the development of these data. As part of this review process, the Agency will require that these protocols be independently validated for accuracy and reproducibility. Antimicrobial treated articles requiring registration must meet the same efficacy performance standards that are required for corresponding antimicrobial public health products. For any questions regarding the need for registration or the registration requirements for specific treated articles or substances, contact the Antimicrobials Division at the address listed under Unit VII.

B. The Term “Registered for Such Use”

In order to qualify for the treated articles exemption, 40 CFR 152.25(a) specifies that an article or substance must be treated with, or contain, a pesticide to protect the treated article or substance itself. The terms “treated with, or containing, a pesticide” and “if the pesticide is registered for such use” in 40 CFR 152.25(a) refer to actual incorporation or adding of an antimicrobial pesticide specifically registered for that use. To qualify under the “treated articles exemption” (assuming the article or substance otherwise qualifies), it is not sufficient that the antimicrobial pesticidal substance in the treated article merely resemble or have activity like a registered pesticide. The antimicrobial pesticide in the treated article or substance must be present in the article or substance solely as the result of

incorporating an antimicrobial pesticide which is registered for treating the specific article or substance.

Because of the wide range of exposure scenarios associated with the use of treated articles such as cutting boards and conveyor belts used in the food processing industry, and the wide range of household consumer uses, the Agency has interpreted 40 CFR 152.25(a) to mean that the registration and the labeling of the antimicrobial pesticide intended for incorporation into the treated article or substance needs to include specific listings of the articles or substances that may be treated. Accordingly, in registration actions over the past several years, EPA has not permitted broad general use patterns, such as the preservation of hard surfaces, plastics, adhesives or coatings for the registered pesticide. Instead, it has required that specific listings such as toys, kitchen accessories and clothing articles be reflected in the product registration and labeling as a prerequisite for incorporation of the pesticide into an article or substance under 40 CFR 152.25(a).

VI. EFFECTIVE DATE AND PROCEDURES

In order to remain in compliance with FIFRA and avoid regulatory or enforcement consequences as described here and below, it is the Agency's position that producers, distributors, and any other person selling or distributing pesticide treated articles and substances not in compliance with the Agency's interpretation of 40 CFR 152.25(a), as clarified by this notice, need to bring their products, labeling and packaging, any collateral literature, advertisements or statements made or distributed in association with the marketing (*sale or distribution*) of the treated article or substance into full compliance with the regulation as clarified by this notice as soon as possible.

Because some of the elements of this interpretation may not have been well understood by the regulated community, the Agency expects that some companies may need up to a year in order to comply with those elements that have been clarified by this notice. Therefore, for the present, the Agency is following the approach set forth in the April 17, 1998 **Federal Register** (63 FR 19256). Although non-public health claims for microbial odor control and mold and mildew claims associated with deterioration, discoloration, and staining were not specifically mentioned in the April 17, 1998 **Federal Register**, such claims are also consistent with the enforcement approach set forth in that notice, as well as with this guidance, provided that they are properly, and very clearly, qualified as to their non-public health use. The Agency will begin to rely on the guidance provided in this Notice on February 11, 2001. Products in commerce after that date *which make statements, etc. that do not reflect the clarification offered in this notice* would risk being considered out of compliance with 40 CFR 152.25(a).

VII. ADDRESSES

By mail:

Antimicrobials Division (7510C)
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D. C. 20460-0001

By courier:

Antimicrobials Division (7510C)
U. S. Environmental Protection Agency
Room 300, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

VIII. FOR FURTHER INFORMATION CONTACT

If you have questions about the content of this notice, you should contact Debra Edwards at (703) 308-7891.

/signed/

Marcia E. Mulkey, Director
Office of Pesticide Programs