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

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OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Charles A. O'Connor III  
McKenna, Long, and Aldridge, LLP  
1900 K Street, N.W.  
Washington, DC 20006

Dear Mr. O'Connor:

Thank you for your letter expressing your concern with regards to the use of surface safety claims on antimicrobial product labeling. Your September 16, 2003, letter indicated that you were representing the Consumer Specialty Products Association (CSPA) and other registrants in asking the Agency to amend its policy to allow the use of the term "safe" as it relates to "true statements regarding the products' safety with respect to those recommended surfaces" as stated on product labeling.

After conducting an analysis and evaluation of your request and reviewing certain federal policies and practices relating to safety claims, the EPA's Office of Pesticide Programs has decided it cannot act favorably on your request. The Agency is, however, suggesting an alternate approach which should enable you to make comparable statements about use of affected products on certain surfaces.

#### CSPA REQUEST AND RATIONALE

CSPA requested that "EPA permit very narrow statements reflecting only that a particular pesticide is "safe" (i.e., will not damage a particular type of surface)," if used on that surface or comes into contact with that inanimate surface.

#### According to CSPA:

"Safe and proper use of antimicrobial products is paramount to both EPA and industry. Users must be able to apply antimicrobial products with confidence and without harm to themselves or the surfaces upon which the products are used. Apart from product safety, it is important to educate users about all the aspects of the product including where the product may be safely used. User intuition regarding product use is not always correct. Many users base their decisions on the habits and practices used in their home or passed down from mother to child. Frequently this information is good but product technologies do evolve and users should be

educated. Examples of past surface safety education includes: color safe bleaches and non-scratch "abrasive" cleaners."

"In addition, it is expected that new surface types will be created and registered products must address the cleaning and disinfecting needs of these new surfaces. For example, conductive floors are critical to the computer industry. Inappropriate cleaning of these surfaces may cause damage that is very costly to replace and may cause disruption to the workplace."

"Antimicrobial manufacturers need to be able to explain product benefits to users in a language they best understand. Frequently the product compatibility question users most want answered is: Is the product safe for use on \_\_\_\_\_? As long as the user is asking about an inanimate object, industry should be able to answer the question."

Lastly, CSPA stated, "it is important to instruct users about product compatibility, both acceptable and unacceptable scenarios, for product liability reasons. Without such instructions manufacturers may be required to replace damaged materials if the user was not properly instructed by the labeling."

## **EPA RESPONSE AND ANALYSIS**

EPA agrees that consumers need to know what products are compatible for use on various surfaces. Furthermore, the Agency encourages manufacturers to provide clear product use information so that consumers do not use products that are not suitable for specific surface types. However, the Agency believes this information can be provided on a pesticide label without confusing consumers about pesticide product safety.

In addressing the concerns outlined by CSPA, the Agency wanted to not only evaluate its own regulations, but also evaluate how other federal agencies approach "safety claims." Therefore, the Agency also reviewed the policies and practices of the Federal Trade Commission (FTC) and the Consumer Product Safety Commission (CPSC).

### **How Does CPSC Deal with Safety Claims?**

"CPSC is an independent Federal Regulatory Agency that works to save lives and keep families safe by reducing the risk of injuries and deaths associated with consumer products. They do this by:

- developing voluntary standards with industry
- issuing and enforcing mandatory standards or banning consumer products if no feasible standard would adequately protect the public

- obtaining the recall of products or arranging for their repair
- conducting research on potential product hazards
- informing and educating consumers through the media, state and local governments, private organizations, and by responding to consumer inquiries”<sup>1</sup>

The CPSC has jurisdiction over more than 15,000 kinds of consumer products used in and around the home, in sports, recreation and schools – this includes cleaning products.<sup>2</sup> The CPSC does not regulate cleaning products or safety claims in the same way EPA regulates pesticide products and safety claims. However, CPSC does publish a Manufacturer’s Guide to help manufacturers to provide appropriate safety information.

#### **The CPSC Manufacturers Guide states:**

- “Safety messages must stand out from other messages and be immediately recognized as safety-critical”
- “If you include too many safety messages for highly unlikely and trivial hazards, you weaken the effectiveness of the more significant messages.”
- “Mixing marketing messages and up-beat statements with the safety message can undermine warnings”
- “If you want to list non-safety items such as notices or tips for more effective product use, keep these lists separate and clearly label each list.”<sup>3</sup>

These types of instructions and guidance coincide with the EPA’s concerns about the use of surface safety claims on pesticide products. EPA believes strongly that required warnings and product use directions must not be potentially undermined or confused by marketing messages and up-beat statements using terms such as “safe” or “safety.”

#### **How Does The Federal Trade Commission (FTC) Deal with Safety Claims?**

The FTC seeks to prevent deception and unfairness in the marketplace. The FTC Act gives the Commission the power to bring law enforcement actions against false or misleading marketing claims, including environmental or “green” marketing claims. The Commission looks at all advertising from the consumer’s perspective: what message does

<sup>1</sup> U.S. Consumer Product Safety Commission “Frequently Asked Questions” <http://www.cpsc.gov/about/faq.html>

<sup>2</sup> U.S. Consumer Product Safety Commission “Frequently Asked Questions: Jurisdiction” <http://www.cpsc.gov/about/faq.html#jur>

<sup>3</sup> Consumer Products Safety Commission; “Manufacturer’s Guide to Developing Consumer Product Instructions,” October 2003; Contract No. CPSC-S-02-1215

the advertising actually convey to consumers? Furthermore, the FTC seeks to ensure that all marketers making express or implied claims about the attributes of their product, package or service must have substantiation, that is, a *reasonable basis* for their claims.<sup>4</sup>

In evaluating this request, the EPA asked the same question: is there a reasonable basis for having to make a surface safety claim, when all that is needed is a clear statement which identifies upon what surfaces a specific product can be applied and states that the subject product is compatible with the particular surface?

### How Has EPA/OPP Historically Dealt with Safety Claims?

EPA has been very careful not to intentionally allow use of the term *safe* (including relating the term *safe* to inanimate surfaces being cleaned) due to concerns that consumers would misinterpret the safety claim and believe that the product itself had achieved some elevated level of safety.

Under 40 CFR 156.10(a)(5)(ix) label claims as to the safety of the pesticide or its ingredients are considered to be statements that are misbranding and thus are not allowed on pesticide labeling.<sup>5</sup>

<sup>4</sup> Federal Trade Commission – Facts for Businesses; “Complying with the Environmental Marketing Guides;” [www.ftc.gov](http://www.ftc.gov)

<sup>5</sup> 40 CFR 156.10(a)(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 Sec. 152.500, 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 under the Act and these regulations;
- (ix) Claims as to the safety of the pesticide or its ingredients, including statements such as “safe,” “nonpoisonous,” “noninjurious,” “harmless” or “nontoxic to humans and pets” with or without such a qualifying phrase as “when used as directed”; and (x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:
  - (A) “Contains all natural ingredients”;
  - (B) “Among the least toxic chemicals known”
  - (C) “Pollution approved”

Examples cited in the regulatory provision cited above include statements such as "safe," "harmless," "nonpoisonous," "non-injurious," or "nontoxic to humans and pets". Therefore, Agency regulations do not allow statements that contain the word safe or variations thereof to appear in pesticide labeling. The Agency has addressed such claims in several PR Notices<sup>6</sup> and this subject has been discussed in numerous labeling workshops held by the Registration Division, the Biopesticides Pollution Prevention Division, and the Antimicrobials Division. Such statements when found on labeling during the label review process are required to be removed from the labeling before label approval is granted.

Over the past 20-30 years, numerous letters have been written by the regulatory divisions within OPP requiring the word "safe" to be removed from labeling citing either the regulations or other supporting material such as the Label Review Manual (which restates 40 CFR 156.10). Current label review training programs for new reviewers for all three regulatory divisions emphasize that the term "safe" (or variants thereof) is not allowed on pesticide labeling.

FIFRA Section 2(q)(1) provides that a pesticide is misbranded if "its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular."

FIFRA Section 3(c)(9) pertains to certain additional statements on antimicrobial products. It allows such additional statements to be made if they consist of "relevant information on product efficacy, product composition, container composition or design,

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<sup>6</sup> Pesticide Registration Notice 2001-3 "Insect Repellents: Labeling Restrictions for Use on Infants and Children and Restrictions on Food Fragrances and Colors":

"A statement that a repellent offers specific protection for infants and children would also not be acceptable because it may be construed as an implied safety claim. EPA regulations specify that safety claims for pesticides are false or misleading [40 CFR 156.10(a)(5)(ix)]. The Agency believes there is no factual basis to support a claim that implies that certain products pose significantly lower risk to infants and children than products without such statements. If parents believe that such products are safer than adult products, they may, for example, allow children to use them without adequate supervision or may overuse the products on their infants and children."

**PRN 92-2 – "Permissible Label Claims Regarding Ozone Depleting Substances:"**

EPA's concern with safety claims is the overall effect such claims have on consumers of pesticides. If a claim leads users to believe that a product is safe for humans and the environment to the extent that the label directions and precautions may be disregarded, then EPA considers the claim to be misleading. Examples of such claims are "safe," "non-injurious," "harmless," etc. Similarly, claims such as "ozone friendly," "safe for the ozone layer" and "environmentally friendly" may give users the misleading impression that a product is totally safe for the environment when it is not.

**PRN 98-10 – "Notifications, Non-Notifications and Minor Formulation Amendments:"**

"Safety related claims or other false or misleading claims are not permitted (e.g., "less toxic," "worker safe")."

or other characteristics that do not relate to any pesticidal claim or pesticidal activity." In order to be a permissible statement under this provision, the information must not be "false or misleading, shall not conflict with or detract from any statement required by law or the Administrator as a condition of registration and shall be substantiated on the request of the Administrator." The section provides a procedure for such statements to be submitted to the Agency and for the Administrator to disapprove a particular statement, if the statement is deemed inappropriate.

FIFRA Section 12(a)(1)(E) makes it unlawful for any person to distribute or sell "any pesticide which is adulterated or misbranded." Such an act could then serve as the basis for an enforcement action pursuant to FIFRA enforcement authority.

40 CFR 156.10(a)(5) includes some examples of statements or representations in the labeling that constitute misbranding. Those potentially relevant to claims of "safe" or "safety" are:

- (iv) A false or misleading comparison with other pesticides or devices;
- (vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;
- (ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe", non-poisonous," "noninjurious," "harmless" or non-toxic to humans and pets" with or without such a qualifying phrase as "when used as directed."<sup>7</sup>

Based upon statutory interpretation, regulations, and guidance per FIFRA section 2(q)(1), 3(c)(9), and 12 (a)(1)(E); 40 CFR 156.10(a)(5)(ix); PRN 2001-3, 92-2, and 98-10; and the Label Review Manual, OPP cannot allow registrants to place the word "safe" on pesticide labels.

To ensure that such misunderstandings do not occur, the Agency will continue to disallow the use of safety claims on pesticide product labeling. However, pesticide registrants wishing to provide clear information about a product's applicable use sites without confusing the consumer about product safety may use the terms "Compatible with..." or "Suitable for use on..." on non-food contact surfaces (that is, surfaces that will not come in contact with food). Such statements may not be made with respect to food contact surfaces. This limitation is necessary so that the impression is not given through labeling statements that a particular product's compatibility or suitability with the surface upon which it may be used also extends to the food that may be prepared on or come in contact with such surface. It is our belief that the use of such terms meets your initial request to assist consumers by "provid[ing] [them] with useful information that would help them select the appropriate disinfectant product for the surface that they wish to disinfect."

<sup>7</sup> Note that in contrast with other provisions, ix does not hinge claims as to safety on a false and misleading finding in order to amount to misbranding. The mere existence of a "safety" claim is enough to trigger a misbranding situation.

Thank you for your letter and request. I hope this information is helpful.

Sincerely,

A handwritten signature in black ink, appearing to read 'James J. Jones', with a long horizontal flourish extending to the right.

James J. Jones, Director  
Office of Pesticide Programs