

Product Safety Guidance

Determining the TSCA Status of Antimicrobial Containing Products

Background:

Many chemical products containing pesticidal products termed generically as “antimicrobials” are imported into the U.S. These antimicrobials are added to protect the product from biological degradation, becoming fouled with algal or other fungal growths, or bacteria that may be harmful to animal or human health. This Product Safety Guidance explains the current legal analysis of the TSCA compliance of products treated with antimicrobials.

Under TSCA a “chemical substance” does not include “any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide.” 40 CFR 720.3(e). Discussions with persons within the EPA OPPT office have indicated that EPA considers antimicrobial status to be a FIFRA issue rather than falling under the jurisdiction of TSCA. Specifically, products containing antimicrobials are governed by 40 CFR 152.25(a), which is a FIFRA regulation relating to *Treated articles or substances*.

An article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), is exempt from FIFRA if the pesticide is registered for such use. While there are those in the Pesticide branch of EPA who believe that if no pesticidal claim is made, there is no pesticide present, this is not the stated position of EPA.

On February 11, 2000, EPA issued a document, PR Notice No. 2000-1 which offers guidance on statements or claims that can be made for antimicrobial containing articles or substances without subjecting the product itself to FIFRA registration. The Notice also addresses specific requirements for pesticides used to manufacture a treated article or substance. The EPA states that any pesticide present in a treated article or substance must be present solely as the result of incorporation of a pesticide that is registered under FIFRA for treating the specific article or substance at issue. Further, the FIFRA registration for the treating pesticide must include specific listings

of the articles or substances that may be treated; general or broad categories of listing are not acceptable.

EPA has allowed a period of time for affected parties to come into compliance with the Notice, the initial date being extended until April 30, 2001.

Recommended Compliance Options:

1. USE OF A FIFRA REGISTERED ANTIMICROBIAL

Any pesticide product used as an antimicrobial must be (1) specifically registered by product name and (2) be used only for the protection of the specific type of substance for which it is registered. At this time we cannot indicate how specific the "use" description for the pesticidal product must be, however it should be as specific as possible. Registration terms such as "protection of polymer emulsions" are expected to be too general. The label of the pesticide product is the best source of the "permitted uses" of the pesticide. Guidance can also be obtained from the supplier of the pesticidal product. The EPA approved product label should be consulted for additional product information and the recommended dosage range.

Certain claims can be made such as - that the substance is protected against microbial activity. The statements that can be made are fairly well described in the PR 2000-1 document. Please note the EPA does not regard this exemption as including articles or substances bearing implied or explicit public health claims against human pathogens.

2. TSCA COMPLIANCE WITHOUT FIFRA REGISTRATION.

All chemicals present in the formulation, including the antimicrobial, are included in the TSCA Chemical Substances Inventory. The antimicrobial chemical substance should be included in the Inventory. 40 CFR 720(h)(3) excludes any chemical substance which results from a chemical reaction that occurs incidental to exposure of another chemical substance, mixture, or article to environmental factors such as air, moisture, microbial organisms, or sunlight. Thus the antimicrobial is the chemical intended to be added, and any resulting chemical substance is excluded from any notification requirement. **If this choice is elected, absolutely no claim can be made for the added chemical possessing any pesticidal activity.** If questioned whether any antimicrobial agents have been added, the response must be that it does not. In order to keep the chemicals exclusively under the TSCA requirements; no pesticidal statements or claims can be made.

A caution should be made that if this option is elected and the sales product is to be sold with a claim for FDA compliance, any such components must have a separate FDA listing for purposes other than antimicrobial protection.

3. **MULTI-REGULATION COMPLIANCE**

Antimicrobials which are registered under FIFRA for the specific use with the specific type of protected product and are registered by FDA, and whose components are all included in the TSCA Chemical Substance Inventory are very desirable.

4. **IMPORT PRODUCTS**

The EPA clearly states in the PR that in order to qualify for the exemption a specifically labeled EPA registered pesticide product must be used.

Recognizing that the odds of finding a FIFRA labeled antimicrobial pesticidal outside the U.S. are exceedingly low, the use of a product identified by a different product name, but containing all the components of a U.S. registered pesticidal product, and being manufactured by the same company holding a U.S. FIFRA registration, may be allowed, but could be challenged by EPA. In this instance it may be best to import and sell the article under Option 2, above, if the pesticidal substance is TSCA listed.

5. **GENERIC ANTIMICROBIALS**

In the same manner, it can be argued that “me too” antimicrobial pesticidal products which contain identical formulations to those registered under FIFRA and having an appropriate registered use for inclusion in the product, but which are manufactured or distributed by persons who do not possess the FIFRA registration, may also be allowed because EPA has reviewed all of the pertinent effects of the active and inert ingredients and determined that they have an acceptable risk. However, given the statements contained in the PR, there is a definite risk that EPA may well not agree with this interpretation and it is a choice of last resort, only to be utilized if none of the above options are available. This may also be an instance in which Option 2, above, is used.