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

December 10, 2020

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

FROM: Alexandra Dapolito Dunn, Esq.
Assistant Administrator

ALEXANDRA DAPOLITO DUNN Digitally signed by ALEXANDRA DAPOLITO DUNN Date: 2020.12.10 08:38:20 -05'00'

TO: Ed Messina, Acting Director
Office of Pesticide Programs

SUBJECT: Voluntary Antimicrobial Pesticide Inert Ingredient Disclosure Process

The U.S. Environmental Protection Agency (EPA) is allowing registrants of antimicrobial pesticides to voluntarily disclose all inert ingredients on their product labels and/or through a company website for their products which can be linked on product labeling. EPA is taking this step to increase transparency and provide the regulated community with a tool to meet the market needs in light of recent consumer transparency initiatives. By implementing this new policy, EPA is being responsive to external stakeholders' request to disclose all ingredients – active and inert – on EPA-registered antimicrobial product labels. EPA will continue to work with registrants to ensure that pesticide labels meet the statutory and regulatory requirements.

This memorandum describes how EPA's Office of Pesticide Programs (OPP) intends to review applications beginning December 15, 2020 for voluntary inert ingredient disclosure for such antimicrobial pesticide products. Currently, the scope of this voluntary inert ingredient disclosure process is limited to antimicrobial pesticide products; however, the Agency may consider expanding its process to conventional pesticides and biopesticide product in the future.

Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and its implementing regulations, a pesticide label must have a clear and prominent ingredient statement that contains the name and the percentage of each active ingredient, and the total percentage of all "inert" or "other" ingredients in the pesticide. The ingredient statement must be presented clearly and cannot be obscured or crowded by surrounding text.[1] Except where it has been required on a case-by-case basis, there is no statutory or regulatory requirement at the federal level to identify inert ingredients in the ingredient statement or anywhere else (*e.g.*, on the label, on registrants' website).

Active ingredient means any substance (or group of structurally similar substances, if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, defoliant, or nitrogen stabilizer, within the definition at FIFRA Section 2(b). Inert ingredient means any substance other than the active ingredient, which is intentionally included in a pesticide product.[2]

[1] 40 C.F.R. § 156.10(a)(2).
[2] 40 C.F.R. § 158.300.

In order to provide consumers with inert ingredient information for antimicrobial products, some registrants of these products asked EPA to allow them to disclose pesticidal inert ingredients on their EPA-approved labels. However, there are challenges associated with on-package inert ingredient disclosure, including the potential for misbranded products if the information required by FIFRA is not displayed prominently, the fact that numerous alternate formulations make it difficult to list all inert ingredients accurately, and the limited space available on product labels.

Relevant Legal Requirements and EPA Policy

FIFRA Section 2(q)(1)(A), 7 U.S.C. 136(q)(1)(A), states that a pesticide is misbranded if its labeling bears any statement that is false or misleading. That includes statements related to the pesticide's ingredients.

Inert ingredients are not required to be identified in the ingredient statement except when EPA determines that such inert ingredients may pose a hazard to man or the environment.[3] In such a situation, EPA may determine that the name of the inert ingredient must be listed in the ingredient statement on a case-by-case basis for either risk-based or hazard-based reasons. Examples include the following ingredients:

- Petroleum distillates, xylene, or xylene range aromatic solvents $\geq$ 10%;
- Sodium nitrate > 0.1%; or
- Inert ingredients of toxicological concern (formerly known as "List 1 Inerts").

EPA's long-standing policy per the Label Review Manual has been that "if a registrant wants to list a particular inert ingredient in the ingredient statement, the registrant should list **all** inert ingredients directly below the ingredient statement in descending order by weight. A partial listing on the label could be misleading."[4] This new policy applies to voluntary identification of inert ingredients using alternate nomenclature, not cases where EPA directs registrants to list particular inert ingredients, as discussed above.

New Antimicrobial Pesticide Voluntary Inert Ingredient Disclosure Process

EPA is allowing voluntary inert ingredient disclosure on currently registered antimicrobial product labels as set forth in this memorandum. Under this new process, if registrants choose to utilize alternate chemical nomenclature on their product labeling, they must resubmit the corresponding Confidential Statement(s) of Formula (CSF) containing the inert ingredients as approved on the existing formulation as well as the alternate chemical nomenclature. A crosswalk between the approved nomenclature of the CSF and the alternate nomenclature should be provided to the Agency with these registrants' non-Pesticide Registration Improvement Act (PRIA) amendment application (90-day review). EPA's website provides additional information about the application process and a template for the crosswalk document. EPA strongly encourages registrants who choose to use alternate nomenclature, to use the following sources:

- U.S. Environmental Protection Agency Inerts List;[5]
- International Union of Pure and Applied Chemistry (IUPAC);

[3] 40 C.F.R. § 156.10(g)(7).
[4] EPA's Label Review Manual, Chapter 5: Ingredient Statement (revised May 2012), available at https://www.epa.gov/sites/production/files/2017-10/documents/chap-05-may-2012.pdf.
[5] Available online at https://www.epa.gov/pesticide-registration/inert-ingredients-overview-and-guidance.

- Chemical Abstracts Service (CAS); or
- Consumer Product Ingredients Database's Directory.[6]

Generally, antimicrobial consumer products have small containers with limited space for labeling. Including inert ingredient information on product labeling could result in crowding of the FIFRA-required text.

As specified in FIFRA Section 2(q)(1)(E), 7 U.S.C. 136(q)(1)(E), the product could be considered misbranded if the information required by FIFRA is not prominently placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) that it will be likely to be read and understood by the ordinary individual under customary conditions of purchase and use. If a registrant chooses to voluntarily disclose inert ingredients on the label, if space allows, they should list all of the inert ingredients directly below the ingredient statement in descending order by weight, so that it does not interfere with the required labeling information. However, if space is limited, to avoid crowding of required labeling information, a referral statement may be used directing the reader to the back or side panel for the full list of inert ingredients in descending order by weight. The referral statement should be placed directly below the ingredient statement with an asterisk or some other equivalent symbol connecting the "Inert Ingredients" or "Other Ingredients" heading in the ingredient statement with the full list of inert ingredients placed on the back or side panel of the label. For example, an acceptable referral statement is "*See back panel for complete inert ingredient statement.", and acceptable corresponding text on the back panel is "*Inert Ingredients: Inert A, Inert B, etc.".

In addition, inert ingredient information may be disclosed on company websites. Although registrants are not required to identify company websites on their labels, when websites are indeed referenced on product labels, they become labeling under FIFRA and are subject to Agency review.[7] When registrants choose to add a website address or QR code to their labeling that leads to inert ingredient information, EPA asks that they, in a cover letter transmitting the labeling amendment application to the Agency, self-certify (using the statement below) that the inert ingredient information provided on their website(s) and other marketing materials is consistent with the information provided on the latest approved CSF. Including on a company website false or misleading information or claims that substantially differ from what EPA approved may result in their product(s) being in violation of FIFRA.

Elements of Inert Ingredient Disclosure Applications

As EPA begins to implement this new policy, please note that no other actions should be included with the inert ingredient disclosure application. The following information should be included as part of the application:

- For applications to add alternative nomenclature to the labels:
  - ✓ Crosswalk linking the current CSF nomenclature to any alternate inert ingredient nomenclature, CAS number, reference database name and website link for alternate nomenclature as confirmation that the current CSF nomenclature and alternate nomenclature are synonyms of each other (*i.e.*, the exact same inert ingredient). See attached spreadsheet as an example.

[6] Available online at http://productingredients.com/ingredients/browse.

[7] Labeling is defined in FIFRA Section 2(p)(2), 7 U.S.C. 136(p)(2), in part, as meaning labels and all other written, printed, or graphic material accompanying a pesticide or device at any time or to which reference is made on the label or in accompanying literature.

- ✓ Cover letter identifying the proposed change(s) to the alternate nomenclature on product labels and CSFs, the revised CSF (which includes the current and alternate nomenclature) and master label with changes highlighted.

- For applications to add currently approved nomenclature to the labels:
  - ✓ Cover letter identifying the proposed change(s) on product labels and master label with changes highlighted including the following self-certification statement: "The inert ingredients voluntarily disclosed in the labeling for EPA Registration No. [add registration number], are accurate for the EPA-registered product listed above. No changes to the product formulation have been made. I certify that no other changes have been made to the labeling of this product. I understand that it is a violation of 18 U.S.C. 1001 to willfully make any false statement to EPA. I further understand that if the information I have provided is misbranded as defined in section 2(q) of FIFRA, 7 U.S.C. 136(q), this product may be in violation of FIFRA and EPA may pursue enforcement actions under sections 12 and 14 of FIFRA, 7 U.S.C. 136(j) and 136(l)."

- For applications to add or change a website or QR code to include inert information:
  - ✓ Cover letter identifying the proposed change(s) on product labels and master label with changes highlighted including the following self-certification statement: "The inert ingredients voluntarily disclosed in the labeling for EPA Registration No. [add registration number], are accurate for the EPA-registered product listed above. No changes to the product formulation have been made. I certify that no other changes have been made to the labeling of this product. I understand that it is a violation of 18 U.S.C. 1001 to willfully make any false statement to EPA. I further understand that if the information I have provided is misbranded as defined in section 2(q) of FIFRA, 7 U.S.C. 136(q), this product may be in violation of FIFRA and EPA may pursue enforcement actions under sections 12 and 14 of FIFRA, 7 U.S.C. 136(j) and 136(l)."

In light of the process for voluntary inert ingredient disclosure described above, the Agency has decided to discontinue the 2011 pilot project allowing for disclosure of inert ingredients for antimicrobial products. EPA's website has been updated with the information presented in this memorandum.

cc:

Michael Goodis, Acting Deputy Director, Office of Pesticide Programs
Anita Pease, Director, Antimicrobials Division
Kimberly Nesci, Director, Biological and Economic Analysis Division
Billy Smith, Acting Director, Biopesticide and Pollution Prevention Division
Marietta Echeverria, Acting Director, Registration Division
Dana Vogel, Director, Health Effects Division
Elissa Reaves, Acting Director, Pesticide Re-evaluation Division
Jan Matuszko, Acting Director, Environmental Fate and Effects Division