



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2014-0558; FRL-9936-80]

Removal of Certain Inert Ingredients from the Approved Chemical Substance List for Pesticide Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is removing certain chemical substances from the current listing of inert ingredients approved for use in pesticide products because these chemical substances are no longer used as an inert ingredient in any registered pesticide product.

FOR FURTHER INFORMATION CONTACT: *For general information contact:*

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SUPPLEMENTARY INFORMATION:

I. General Information

A. *Does this Action Apply to Me?*

You may be potentially affected by this action if you engage in activities related to the registration of pesticide products, including but not limited to, the use of approved inert

ingredients used in registered pesticide products. Potentially affected entities may include, but are not limited to, engaging in the formulation and preparation of agricultural and household pest control chemical substances or pesticides and other agricultural and household pest control chemical substances or inert ingredient manufacturers and those who make proprietary inert ingredient formulations or pesticides and other agricultural chemical substance manufacturing generally identified by the North American Industrial Classification System (NAICS) code 325320.

This listing is not intended to be exhaustive, but rather provides a guide for readers to help determine whether this document applies to them and which entities are likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The NAICS code has been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult either person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's Authority for Taking this Action?

EPA is taking this action under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*

C. What Action is the Agency Taking?

EPA is removing 72 chemical substances from the current listing of inert ingredients approved for use in pesticide products because these chemical substances are no longer used as an inert ingredient in any registered pesticide product. The list of chemical substances that are no longer on the approved inert ingredient list is available in the docket for this action, under docket identifier EPA-HQ-OPP-2014-0558-0002 at <http://www.regulations.gov>. A

copy of the list will also be posted on the Agency's web site.

Removal of a chemical substance from the approved inert ingredient listing does not, by itself, restrict the use of the chemical substance in a pesticide product; it changes the way an application is processed. Once removed, the chemical substance would be considered a "new" inert ingredient. Any inert ingredient that is not on the approved list must be approved by EPA before the Agency will approve a registration for a formulation containing that chemical substance as an inert ingredient. EPA approval can be obtained by submitting a request, along with relevant data as instructed in applicable EPA guidance. The type of data needed to evaluate a new inert ingredient may include, among other things, studies to evaluate potential carcinogenicity, adverse reproductive effects, developmental toxicity, genotoxicity, as well as environmental effects associated with any chemical substance that is persistent or bioaccumulative. In addition, adding the chemical substance to the list of approved inert ingredients would also require payment of a fee in accordance with FIFRA section 33, 7 U.S.C. 136w-8.

Information regarding the inert ingredient request and approval process is available on the Agency's website at <http://www2.epa.gov/pesticide-registration/guidance-documents-inert-ingredients>.

D. How Can I Access the Docket for this Action?

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0558, is available online at <http://www.regulations.gov> or in person at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading

Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is: (202) 566-1744, and the telephone number for the OPP Docket is: (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

II. Background

A. What did EPA Propose?

On October 22, 2014 (79 FR 63120; FRL-9916-22), EPA published for comment a proposal to remove from the Agency's list of inert ingredients approved for use in pesticide products 72 chemical substances that are no longer being used as inert ingredients in pesticide products. In response to EPA's request for comments, no specific information regarding those 72 chemical substances or any products that may include them was provided to the Agency indicating that these chemical substances are being used in currently approved pesticide product formulations.

B. What Comments did EPA Receive and What is EPA Response?

EPA received approximately 50 public comments on the proposal. A summary of the significant areas of comment and EPA's responses is presented in this unit.

1. *Removal of inert ingredients no longer used in pesticide products.* Some commenters believe that EPA is banning certain chemical substances from pesticide products, stating that the chemical substances should remain on the approved list of inert ingredients because they are harmless.

EPA is not banning the chemical substances. This action does not change the fact that the chemical substances may be part of a formulation for which an application for a pesticide registration is submitted. All that changes is the process, which will now include an

application for approval of the inert ingredient. As before, each application for registration is evaluated pursuant to the unreasonable adverse effects on the environment standard in FIFRA section 3, which evaluation includes the inert ingredients in the formulation.

Another commenter requested that seven chemical substances: methyl ethyl ketone (CAS Reg. No. 78-93-3), tetrahydrofuran (CAS Reg. No. 109-99-9), 1-butanol, 3-methyl-, acetate (CAS Reg. No. 123-92-2), nitrous oxide (CAS Reg. No. 10024-97-2), ethane (CAS Reg. No. 74-84-0), turpentine oil (CAS Reg. No. 8006-64-2), and formaldehyde (CAS Reg. No. 50-00-0) not be removed from the list, stating that the chemical substances are currently being used in pesticide products formulations.

The commenter did not submit any evidence (*e.g.* a confidential statement of formula form or other record) indicating that the chemical substances were in fact being used as inert ingredients in currently approved pesticide product formulas.

2. Inert ingredient strategy. Some commenters believe that the action does not improve public access to inert ingredient information and suggested that EPA proceed with the rest of the inert ingredient strategy as expressed in the EPA May 22, 2014, letter to Kamala Harris, Attorney General of the State of California (see document in Docket EPA-HQ-OPP-2014-0558-0003).

This action is not intended to address public access to inert ingredient information but to facilitate EPA review of inert ingredients not currently used in pesticide formulations. Removing ingredients no longer used in pesticide products from the list of approved inert ingredients is one of the actions discussed in the May 22, letter. The Agency continues to develop and implement the other concepts outlined in that letter.

3. Administrative decision to remove chemical substances. Some commenters stated

that FIFRA requires that the Agency decision to remove chemical substances from the approved inert ingredient list must be based on risk.

FIFRA does not state a standard for approval of an inert ingredient, specifying only the fee category and review time. While the statute incorporates the risk of unreasonable adverse effects on the environment as one of the factors in granting a registration for an individual pesticide product under FIFRA section 3, no such criteria apply to approval of an inert ingredient. Addition of an inert ingredient to the approved inert list is a prerequisite to approval of applications for registration of specific pesticide formulations that contain the inert ingredient.

4. Regulation of pesticide adjuvants. Some commenters asked the Agency to clarify the impact of this removal action on the use of tank-mix adjuvants, including with respect to tolerances and exemptions under the Federal Food, Drug and Cosmetic Act.

An adjuvant is a chemical substance separately added to a pesticide product (typically as part of a spray tank mixture). Since pesticide adjuvant products do not make pesticidal claims, they are not pesticides, and the components of adjuvants are therefore not pesticide inert ingredients. Adjuvants are not included in the inert ingredient approval process and are therefore unaffected by this policy. While adjuvants may need tolerances or tolerance exemptions in some cases, tolerances and exemptions are separate from the inert ingredient approval process.

5. No impact to the fragrance ingredient listing. One commenter noted that a few inert ingredients proposed for removal from the chemical substance list appear on the EPA Fragrance Ingredient List (FIL).

The EPA FIL comprises more than 1,500 fragrance component ingredients that have

undergone Agency evaluation to determine their suitability for safe use as components of fragrances in nonfood-use pesticide product formulations in accordance with the Fragrance Notification Program. Removal of an inert ingredient from the approved inert ingredient listing does not preclude use as a fragrance ingredient as part of the Fragrance Notification Program provided that inert ingredient is listed on the FIL and use in a pesticide formulation is consistent with the Fragrance Notification Process. The inert ingredients no longer used in registered pesticide products will be removed from the approved inert ingredient listing but these same ingredients will not be removed from the FIL.

6. Impurities. Some commenters want EPA to clarify that removing the chemical substances from the list does not prohibit the use of these chemical substances being classified as residual impurities in approved inert ingredients.

The definition of inert ingredient as given in 40 CFR 152.3 applies to chemical substances used as inert ingredients that are “intentionally included in a pesticide product” and as such the removal of a chemical substance from the approved inert ingredient list does not apply to circumstances where the chemical substance may be present as an impurity. Impurities in pesticide products are considered on a case-by-case basis as part of the Agency’s pesticide product registration process. As part of that evaluation, the Agency looks at the identity and amount of an impurity in the product manufacturing information, and the steps taken to limit or remove impurities.

7. Confirming the ingredient use in current pesticide products. Some commenters suggested that EPA provide them more time to investigate whether any of the 72 chemical substances are used in currently registered products.

EPA records include no Confidential Statements of Formula for any currently

registered pesticide product that list any of these chemical substances. However, if a registrant or a producer of proprietary mixtures identifies an active registration that contains one of the chemical substances that has now been removed from the approved inert ingredient listing, that registrant or producer should contact the Agency directly, using the contact for listing inquiries that is provided under **FOR FURTHER INFORMATION CONTACT**. If EPA confirms that the chemical substance is contained in a currently registered product, the Agency will restore the chemical substance to the list of approved inert ingredients.

Authority: 7 U.S.C 136 *et seq.*

Dated: December 7, 2016.

James J. Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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