

Pesticide Registration Manual:

Chapter 8 – Inert Ingredients

Inert Ingredients

Many pesticide products contain substances in addition to the active ingredient(s) that are referred to as inert ingredients or sometimes as “other ingredients.” This chapter describes how EPA reviews inert ingredients as part of the pesticide product review process. For the most recent information and updates on this process, see the [Inert Ingredients](#) Web page.

This Web page provides information on and links to:

- [Inert Ingredient Frequently Asked Questions](#), which provides answers to commonly asked questions including guidance on finding approved food and nonfood inert ingredients and instructions for obtaining a trade name or mixture in the Agency database.
- Guidance documents for submitting a request for approval of a new or amended food use, nonfood use and Low Risk Polymer inert ingredient.

- Food - “[General Guidance for Petitioning the Agency for the Establishment of a New/Amended Food Use Inert Ingredient Tolerance or Tolerance Exemption](#)”
- Nonfood - “[General Guidance for Requesting a New Nonfood Use Inert Ingredient](#)”
- Low Risk Polymer - “[Guidance to Petitioners for Low Risk Polymer Submissions](#)”

- A page listing [inert ingredients permitted for use in pesticide products including a list of food-use, nonfood-use, 25\(b\) and organic inert ingredients](#).
- Completed [inert ingredient tolerance reassessment decision documents](#).
- [The Fragrance Ingredient List](#).

EPA plans to continue to post additional guidance and documents for inert ingredients on the Web page. Therefore, regular visits to the Web page are recommended.

Section 2(m) of FIFRA defines an inert ingredient as “an ingredient which is not active.” EPA further describes an inert ingredient in [40 CFR 152.3](#) as “any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product, except as provided by [40 CFR 174.3](#).” Inert ingredients may be, for example, solvents, carriers, aerosol propellants, fragrances, and dyes.

Regulation of Inert Ingredients

The registration and reregistration of pesticide products under FIFRA include a determination that the pesticide product formulation meets the registration standard under FIFRA section 3 (including the lack of unreasonable adverse effects on the environment). The entire formulation, including the inert ingredients, must meet this standard. In addition, the [Federal Food, Drug, and Cosmetic Act \(FFDCA\)](#) requires that inert ingredients in pesticide products used on food and feed crops, agricultural commodities, or livestock must have a tolerance or tolerance exemption under [40 CFR Part 180](#). Inert ingredient approval submissions are now covered categories under PRIA 3. See the PRIA 3 [Fee Schedule Tables](#) or the [Fee Determination Decision Tree](#) for descriptions of these inert categories, their PRIA 3 fees and corresponding decision review timeframes.

New Inert Ingredients under PRIA 3

Under PRIA 3 there are ten inert ingredient categories that cover new food, nonfood, low risk polymer inert ingredients as well as amendments to previously approved inert ingredients and nonfood inert ingredients that are substantially similar to approved inert ingredients. See the PRIA 3 [Fee Schedule Tables](#) or the [Fee Determination Decision Tree](#) for descriptions of these ten covered inert categories, their PRIA 3 fees and corresponding decision review timeframes.

PRIA 3 allows new inert ingredients to be submitted in conjunction with a new active ingredient or first food use application. Each component of such a joint application would be charged its appropriate PRIA fee, but the decision review timeframe for the joint application would be that of the PRIA category with the longer timeframe, which in most cases would be the new active ingredient or first food use.

PRIA 3 also allows for the submission of covered applications that are associated with and dependent upon a currently pending inert ingredient action. The decision review timeframe for the associated covered application will be extended to match the timeframe for the pending inert action unless the PRIA due date for the associated application is further out, in which case it will be subject to its own decision review timeframe.

For approval of a new inert ingredient intended for use in a food-use pesticide product, see [“General Guidance for Petitioning the Agency for the Establishment of a Tolerance or Tolerance Exemption under PRIA 3”](#). EPA recommends that parties interested in establishing

a tolerance or tolerance exemption for a new inert ingredient first consult with the Agency to determine the adequacy of available data and/or the need for additional data.

For approval of a new inert ingredient intended for use in a nonfood-use pesticide product, see [“General Guidance for requesting the Approval of a New Nonfood Use Inert Ingredient or Amending a Currently Approved Nonfood Use Inert Ingredient under PRIA 3”](#).

For approval of a new low risk polymer see [“General Guidance for Requesting the Establishment of a Tolerance Exemption for a Low Risk Polymer or Nonfood Use Approval of a Low Risk Polymer under PRIA 3”](#).

Inert Ingredient Review Process

The Agency screens all PRIA submissions during a 21-day Content Screen for adequacy/completeness upon receipt. Submission packages not deemed acceptable are returned to the applicant to correct the deficiency. The PRIA decision review time period begins 21 days after receipt of the application (i.e. after the 21-day Completeness Screen).

In addition to the 21-day Content Screen, under PRIA 3 the Agency also conducts a Preliminary Technical Screen of the application to determine if the data and information submitted in the application are accurate, complete and appear to be consistent with the request such that a full and complete assessment can be conducted. This screen is concluded no later than 45 days after the start of the decision review period for actions with decision review time periods less than or equal to six months and no later than 90 days after the start of the decision review period for actions with decision review periods greater than six months.

After the review and risk assessment are completed, a decision will be made regarding the safety of the inert ingredient in question. For food use inerts for which a tolerance or tolerance exemption will be granted, a final rule outlining IIAB’s decision will be published in the Federal Register. After the rule is published granting the use of the inert, the inert ingredient will be permitted for use under the appropriate use pattern. For nonfood use inerts a letter outlining IIAB’s decision will be emailed to the submitter. After issuance of this letter granting the use of the nonfood use inert, the inert will be permitted for use under the appropriate use pattern.

Inert Mixture Products

Pesticide applicants typically include individual inert ingredients in their pesticide products. In addition, applicants often purchase products containing a mixture of inert ingredients and add them to their pesticide products. For example, applicants may buy surfactants and anti-foaming agents made by other companies. These products may be mixtures containing multiple inert ingredients. Just as with individual inert ingredients, each component in a mixture must be approved for use by the Agency. It is the applicant's responsibility to ensure that EPA has sufficient information about the inert mixture the applicant wishes to use.

When the composition of a mixture product is held as proprietary by the company that sells the mixture to the applicant, the Agency establishes a Master File for the mixture that contains the complete compositional information. If an applicant wishes to use a proprietary inert mixture as part of its product formulation, the following information should be submitted on the letterhead of the manufacturing company:

- The full product name and, for each component* in the mixture, its chemical name, CAS Registry Number, and percentage by weight.
- The total percentage by weight for all components must total 100%.

Items submitted for inclusion in the Master File may be claimed as confidential business information (CBI). Information claimed as confidential will be treated in accordance with established procedures for handling FIFRA CBI. To assure proper routing and processing, the cover letter should identify the submission as inert ingredient mixture information.

*Please note - If the product contains a component that is itself a mixture or trade name product, EPA needs to receive the above information for all of the proprietary products. If there are impurities remaining in the final product, those components should be listed as such along with their percentage in the final formulation.

Formulators sometimes have difficulty determining whether a trade name product is permitted for use as an inert ingredient. EPA is offering companies an opportunity to add their trade name product to a list for posting on EPA's web page, along with the uses for which it is approved, and possibly the manufacturer's name. The public listing will **not** include any information related to the composition of trade name inert ingredients, **nor** products they are used in.

Pesticide Product Registration and Inert Ingredients

Pesticide applicants who would like to use a chemical or substance as an inert ingredient in their pesticide product should first ensure that it has been approved by EPA or is currently pending before the Agency for approval. As part of the Agency's review of an application for the registration of a pesticide product, the product's composition information will be examined to verify that all of the inert ingredients proposed for use in the pesticide formulation have been approved by the Agency or are currently pending before the Agency for approval.

All Confidential Statements of Formula (CSF) submitted with a new or amended pesticide registration application for conventional pesticides, antimicrobial pesticides, and biopesticides are screened to ensure that all inert ingredients are approved for the labeled use of the pesticide product or are currently pending before the Agency for approval. If an inert ingredient is not currently approved for the intended use of the pesticide formulation nor currently pending before the Agency for approval and the application is covered by [PRIA](#) (FIFRA section 33) but does not contain the data necessary for the Agency to make a decision on the inert ingredient, then the submission will be rejected and a portion of the PRIA fee will be retained.

If a new inert ingredient is part of an application for registration of a new conventional chemical product, the PRIA 3 fee category will be [I001 or I008 for a food use](#) and I004 or I009 for a nonfood use product. If a new conventional product is submitted and it requires an amendment to an existing inert tolerance exemption (e.g. adding post-harvest use) it will fall under the PRIA 3 fee category I002, I003 or I010. If a new product is submitted and it requires an amendment to an approved inert use pattern, it would fall under the PRIA 3 fee category of I005 or I006. Another category of pesticide application involving a request to approve an inert ingredient that is covered by PRIA 3 is a request to approve a Plant Incorporated Protectant inert ingredient such as a marker protein with a fee category of [B903](#).

The Agency's current process for confirming the approval status of an inert ingredient included within other types of applications covered by PRIA are described in Footnote A of the [21 Day Content Screen Review Worksheet](#). To avoid unnecessary delays and possible loss of fees, it is strongly recommended that applicants confirm the approval status of all components in their new product before submitting a registration application. Approved inert ingredient tolerances and tolerance exemptions are found in the Code of Federal Regulations (CFR) under [40 CFR Part 180](#). [Links to inert ingredients approved for nonfood uses are listed on the Inert Ingredients Web page](#).

Contacting the Chemistry, Inerts, and Toxicology Branch

The staff of the Chemistry, Inerts, and Toxicology Assessment Branch (CITAB) (formerly the Inert Ingredient Assessment Branch) is available to assist you with your questions. The Branch's e-mail address is: [Inert Ingredient Assessment Branch](mailto:inertsbranch@epa.gov) (inertsbranch@epa.gov).

[Information is also available on the Inert Ingredients Web page](#). If you need further assistance contact CITAB Chief, [PV Shah](mailto:shah.pv@epa.gov) at shah.pv@epa.gov or (703) 308-1846.

References Cited in Chapter 8

Refer to [Chapter 19](#) for information on how to obtain these documents.

[Code of Federal Regulation, Title 40](#)

- Part 152 - Pesticide Registration and Classification Procedures
- Part 174 - Procedures and Requirements for Plant-Incorporated Protectants
- Part 180 - Tolerances and Exemptions from Tolerances for Pesticide Chemicals in Food

[Federal Insecticide, Fungicide, and Rodenticide Act](#), as amended by the Food Quality Protection Act of August 3, 1996

- Section 2 Definition

[Federal Food, Drug and Cosmetic Act](#)

- Section 408 - Tolerances and Exemptions for Pesticide Chemical Residues

[Inert Ingredients Web page](#).