

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Office of Chemical Safety and Pollution Prevention  
Office of Pesticide Programs  
Registration Division  
Inert Ingredient Assessment Branch  
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1/8/13

**General Guidance for Petitioning the Agency for the Establishment of a New/Amended Food Use Inert Ingredient Tolerance or Tolerance Exemption<sup>1</sup> under PRIA 3**

The general process for submitting a food use petition to the Environmental Protection Agency, herein referred to as the EPA or the Agency, for the establishment of a new/amended inert ingredient tolerance or tolerance exemption under PRIA 3 is provided below.

The following topics are outlined in this guidance document:

- Presubmission Consultation
- Applicable PRIA 3 Fees
- Petition Contents
  - Transmittal Document
  - Form 8570-1
  - Notice of Filing
  - Petition Summary
  - Data
- Sources of Data
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  - Petition Layout
  - Study Profile Templates
  - Submission of Data
- Inert Ingredient Review Process
- How to Submit a Petition
- Questions and Additional Information

**Presubmission Consultation**

The Agency recommends that a submitter request a presubmission conference call or meeting with the Inert Ingredient Assessment Branch (IIAB) prior to submitting the petition. This is an informal discussion to determine if the petitioner has enough information to proceed with the petition process. The petitioner will need to provide a brief summary of the information they have regarding the chemical, including use information, limitations, sections of the CFR that

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<sup>1</sup> For low risk polymer exemption submissions, please see the document titled "Guidance to Petitioners for Low Risk Polymer Submissions."

apply, and toxicity and environmental fate data. IIAB will determine if additional information is needed in order to make a safety finding regarding the chemical before submitting a formal petition to the Agency.

### **Applicable PRIA 3 Fees**

Inert ingredient approvals are now a covered application under PRIA 3, which took effect on October 1, 2012. See the PRIA 3 [Fee Schedule Tables](#) or the [Fee Determination Decision Tree](#) for descriptions of the ten inert categories, their PRIA 3 fees and corresponding decision review times.

The food use inert ingredient PRIA 3 codes covered in this document are I001, I002, I003, and I010. Additional information regarding PRIA 3 (e.g., fee waivers, exemptions, reductions, and refunds and Q and A's) can be found at <http://www.epa.gov/pesticides/fees>.

### **Petition Contents**

The submission package should include a transmittal document, Form 8570-1, a Notice of Filing, an informative summary of the petition, and a complete copy of all data used to support your request. See "Data Formatting" section of this document for data formatting requirements.

1. **Transmittal document** (often submitted as a cover letter) should include:
  - a. Identity and contact information of the Submitter/Applicant and Agent (if applicable). If an agent is representing the applicant then a letter from the company granting permission to act on their behalf needs to accompany the submission.
  - b. Transmittal Date
  - c. Subject line that reads one of the following.
    - i. "Petition for Approval of a New Food Use Inert Ingredient: PRIA 3 category I001" [Insert your chemical name and CAS Reg. No.] or
    - ii. "Petition to amend a currently approved inert ingredient tolerance or tolerance exemption (new data): PRIA 3 category I002" [Insert your chemical name and CAS Reg. No.] or
    - iii. "Petition to amend a currently approved inert ingredient tolerance or tolerance exemption (no new data): PRIA 3 category I003"[Insert your chemical name and CAS Reg. No.],
  - d. Brief summary of your request including the regulatory action being requested (e.g. CFR description 180.XXX, proposed use, purpose in formulation, any limits in formulation, other known uses, etc.)
  - e. A list of the data/information you are attaching to your package in support of your request
2. **Form 8570-1** can be found at <http://www.epa.gov/opprd001/forms/>. For instructions on how to complete this form for an inert ingredient please see Appendix A
3. **Notice of Filing:** The Notice of Filing (NOF) is a summary of your request for an exemption from tolerance for an inert ingredient and includes a summary of all supporting data. It will be published in the Federal Register and made available for public

comment for 30 days<sup>2</sup>. Please make sure to include an electronic Word version of your NOF.

- a. The NOF template can be found on the following website:  
<http://www.epa.gov/oppts/pubs/frs/home/rules1.html>. Please make sure to choose the “Registration Division Notice of Filing of Pesticide Petitions” template. All fields of the template need to be addressed. In the first paragraph of the template you must choose one of two options. Choose #2 (if this is your intent) and include the following information (see example below):
    - i. Chemical name- Please make sure to use the most current name provided by the American Chemical Society’s CAS. Trade names and mixture names should not be included.
    - ii. CAS Reg. Number
    - iii. Specific section of the CFR for which you are seeking an exemption (e.g., 40 CFR 180.920)
    - iv. Purpose in formulation (e.g. solvent, emulsifier, etc.)
    - v. Use limitations, if any
  - b. An example of the first paragraph of the NOF could be as follows:  
#2) to establish an exemption from the requirement of a tolerance for *(insert chemical name and CAS Reg. No. XXXXX-XX-X)* under *40 CFR 180.XXX* when used as an inert ingredient *(insert purpose in formulation, make sure to include any use limitations as appropriate)* in pesticide formulations. EPA has determined that the petition contains data or information regarding the elements set forth in section 408 (d)(2) of FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.
4. **Petition Summary:** Your submission should contain a summary of your request; a summary of the data, information, and arguments submitted or cited in support of the petition submitted; and a justification for why the submitted data is appropriate and sufficient to make a safety finding.
- a. Summary of your request
    - i. Name, chemical identity and composition of the inert ingredient.
    - ii. Indicate the proposed purpose in formulation and a full description of the use pattern. Include any proposed limitations.
    - iii. Current uses of the chemical including any existing tolerance or tolerance exemptions for the chemical
  - b. Summary of the data- It is not acceptable to just provide results from literatures searches, studies, modeled data, etc. without summarizing the information. Please give clear explanations as to:
    - i. Relevancy of each submitted study- This should include a rationale of how the submitted data support the proposed tolerance/exemption and a discussion on the adequacy of the data.
    - ii. Study results and conclusions

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<sup>2</sup> Federal Register website <https://www.federalregister.gov>; Docket website <http://www.epa.gov/dockets/regulations.htm>

- iii. A discussion of any data gaps and a justification as to why this information is not needed to make a safety finding for your chemical.
      - c. Summarize how, based on the toxicity, expected exposure, and environmental fate properties of the chemical; the proposed use of the chemical would be considered safe for human health and the environment. Make sure to include a discussion of the “reasonable certainty of no harm” and address the risk to infants and children as required under the Food Quality Protection Act<sup>3</sup>.
      - d. Key Studies- Identify the key studies used to support your submission. A pre-submission meeting or conference call, as noted above, may be helpful in identifying the key studies you will be using to support your request.
5. **Data:** Information/data typically used by the Agency to make a decision for a new food use inert ingredient include: physical/chemical properties, toxicity data from animal studies, metabolism data, ecotoxicity, exposure studies, and environmental fate and effects data. Please see the “Data Formatting” section of this document for information on how to arrange your petition.
  - a. **Physical/chemical properties** (Series 830 Group B type data)-Make sure to include a statement indicating whether or not the material is a nano material. If it is a particulate, give the particle size.
  - b. **Toxicity Data:** Toxicological information that should be addressed(proposed use of chemical will dictate data needs):
    - i. Acute
      1. Oral
      2. Dermal
      3. Inhalation
      4. skin irritation
      5. eye irritation
      6. skin sensitization
    - ii. Chronic/repeat dose toxicity data
    - iii. Reproduction/Developmental
    - iv. Mutagenicity
    - v. Carcinogenicity- if data is not included the petitioner should provide the results of a predictive Quantitative Structure Activity Relationship (QSAR) model (e.g.,the [OncoLogic™](#) Model, [OECD QSAR Toolbox](#), or equivalent predictive models) and/or provide a scientific explanation why it would not be carcinogenic
    - vi. Neurotoxicity
    - vii. Endocrine
    - viii. Immunotoxicity
  - c. **Human/animal metabolism-**
    - i. Is the chemical absorbed by the body
    - ii. How much of the chemical is excreted and how is it excreted (e.g. urine, feces)
    - iii. Will it bioaccumulate

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<sup>3</sup> More information can be found at [http://www.epa.gov/pesticides/regulating/laws/fqpa/fqpa\\_implementation.htm](http://www.epa.gov/pesticides/regulating/laws/fqpa/fqpa_implementation.htm)

- iv. Are the degradates/metabolites of the chemical more toxic than the parent chemical? If no metabolism information is available, registrants are asked to provide potential metabolic/degradation products based on currently available scientific information.
- d. **Exposure**- Identify all anticipated exposure pathway/s (e.g., dietary, residential, and occupational) for both pesticidal and nonpesticidal uses of the chemical.
  - i. Dietary for food use chemicals with PRIA codes I001, I002, I003: An Inert Dietary Exposure Evaluation Model (I-DEEM ; which includes drinking water)- will be run for all food use chemical. If there are toxicity issues or if the petitioner wants to modify the I-DEEM, the petitioner will need to provide information on:
    - 1. % crop treated, application rate, and % in formulation- use maximum anticipated values when possible
    - 2. Intended food use crop/s to be treated
    - 3. Drinking water-Models (if applicable)
      - a. [PRZM](#) (Pesticide Root Zone Model) -surface water model that stimulates chemical movement in soil within and immediately below the plant root zone.
      - b. [SCI-GROW](#) (Screening Concentration in Ground Water) - used to estimate the pesticide concentration in ground water
  - ii. Residential-dermal, inhalation, and incidental oral from residential uses such as personal care products, home use, handler exposure and post application exposure, pet use, etc. Approximate or high end value of the percentage in non pesticidal formulations
  - iii. Occupational-what is the anticipated exposure to workers mixing, loading, and applying the inert to the treatment area. Make sure to also include a discussion of post-application exposure.
- e. **Environmental Fate and Effects**-(Series 835 Group A & B type information) if there is no data on the chemical provide the Estimation Program Interface model([EPI Suite™](#)) model data for the chemical.
  - i. Biodegradation/Persistence in the environment
  - ii. Expected fate of the chemical-may use the physical/chemical properties or fugacity models to describe the anticipated fate
- f. **Ecotoxicity**- Please provide a rationale for why ecotoxicity is not expected to be of concern. Submit all available studies. If no data is available the results of the [EPI Suite™](#) or the Ecological Structural Activity Relationship model ([ECOSAR](#)) should be provided.
  - i. Aquatic
  - ii. Avian
  - iii. Invertebrate

## Sources of Data

Sources of information that may be submitted to the Agency include, but are not limited to, OCSPP guideline studies<sup>4</sup>; publically available literature and data, including peer-reviewed assessments and journals (e.g. WHO, OECD SIDS, IUCLID, EPA HPV, IRSI, etc.); modeled data<sup>5</sup>; and analog/surrogate data.

If sufficient data does not exist on the submitted chemical and analog/surrogate data (e.g. Structural Activity Relationship (SAR) data) is being submitted, please include a scientific discussion as to why the surrogate data is relevant/adequate for read across/bridging to the subject chemical. If sufficient explanation and rationale is not provided then the petition will be rejected and the data will not be considered for review.

Unacceptable sources of data include:

1. **MSDS sheets:** A MSDS is only useful if the product contains 100% of the chemical in question and it clearly states this on the MSDS. In addition, in order for the toxicity data to be used by the Agency in the risk assessment process it must come from an acceptable accessible source and the source must be cited on the MSDS and a copy of the study must also be provided.
2. Unpublished studies that are submitted without the full study report.

## Data Formatting

1. **PR Notice 2011-3:** there are standard data format requirements for all study data submitted to the Agency under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA). These requirements are outlined in (PR) Notice 2011-3. Submitted data packages that do not conform to these requirements may be rejected by the Agency's Document Processing Desk and returned to you for revision. (PR Notice 86-5 was replaced by 2011-3 on January 12, 2012.)
2. **Petition Layout:** Chapter 11 of [EPA's Blue Book](#) provides additional information about the format of the petition. In particular, the section entitled "[Filing a Petition](#)" gives guidance on how the information should be presented. We encourage you to use these formatting guidelines for your inert ingredient submission.
3. **Study profile templates:** These templates describe the layout and scope of information that should be contained within a study profile and can serve as a guide for the preparation of study documents. While these templates are not required they can be used by the Agency to efficiently develop its own review of the study. The templates can be found at [http://www.epa.gov/pesticides/regulating/studyprofile\\_templates/studyprofile\\_templates.htm](http://www.epa.gov/pesticides/regulating/studyprofile_templates/studyprofile_templates.htm)

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<sup>4</sup> OCSPP Harmonized Test Guidelines: <http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm>

<sup>5</sup> Models: [http://www.epa.gov/pesticides/science/models\\_pg.htm](http://www.epa.gov/pesticides/science/models_pg.htm)

#### 4. **Submission of Data:**

- a. Independent/Company studies that have not been peer reviewed or previously reviewed by the Agency will need to be submitted in their entirety.
- b. MRID #s of previously submitted studies cited in support of your petition.
- c. A complete bibliography of all studies/documents cited and other supporting material.
- d. If the chemical has already been reviewed (e.g. chemical is also registered as an active ingredient or it has another exemption as an inert ingredient) then the company should provide a copy of the EPA assessment that summarized the data.

#### **Inert Ingredient Review Process**

The Agency screens all PRIA submissions during a 21 Day Screen for adequacy/completeness upon receipt. Submission packages not deemed acceptable are returned to the applicant to correct the deficiency. The PRIA 3 decision review time for approval of a new food use inert (PRIA code I001) is 12 months; for amending a currently approved inert ingredient tolerance or tolerance exemption with new data (PRIA code I002) is 10 months; to amend a currently approved inert ingredient tolerance or tolerance exemption without new data (PRIA code I003) is 8 months; and to amend a tolerance exemption descriptor to add one or more CASRNs without new data (PRIA code I010) is 6 months. See the [Fee Determination Decision Tree](#) for more information. Once a more in depth review of the chemical is underway, deficiencies may arise and additional information may be requested.

In addition to the 21 Day Screen under PRIA 3 the Agency also conducts a preliminary technical screen of the application to determine if the application and the data and information submitted with the application are accurate and complete; and the application, data and information are consistent with any proposed tolerance or tolerance exemption; and the application, data and information are such that subject to full review could result in the granting of the application.

This screening is conducted no later than 45 days after the start of the decision review period for actions with decision review time periods equal to or less than 6 months and no later than 90 days after the start of the decision review period for actions with decision review time periods greater than 6 months. If the application fails the technical screen, and the deficiencies cannot be corrected by the applicant within 10 business days after receipt of the Agency's notification of the failure, the Agency will reject the application.

After the review and risk assessment are completed, a decision will be made regarding the safety of the inert ingredient in question. A Final Rule outlining IIAB's decision will be published in the Federal Register. After the rule, granting the use of the chemical is published, the inert ingredient will be permitted for use under the appropriate use pattern.

## **How to submit a petition**

All submissions to IIAB are received and processed by our Document Processing Desk. If you would like to submit your petition as an e-submission please see <http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm>.

Applicants must submit fee payments at the time of application, and EPA will reject any application that does not contain evidence that the fee has been paid. Payments may be made by check, bank draft, money order or online with a credit card or wire transfer. See the [Fee Determination Decision Tree](#) for more information. The applicant must attach documentation that the fee has been paid with the application package. The application should be sent to one of the following locations:

1) By USPS mail:

Document Processing Desk (REGFEE)  
Office of Pesticide Programs  
(Mail Code 7504P)  
U.S. EPA  
1200 Pennsylvania Avenue, NW  
Washington DC, 20460-0001

2) By Courier:

Document Processing Desk (REGFEE)  
Office of Pesticide Programs  
U.S. EPA, Room S-4900  
One Potomac Yard (South Bldg.)  
2777 South Crystal Drive  
Arlington, VA 22202-4501

**\*\*Note\*\*** the address is different depending on the type of delivery service you plan to use.

## **Questions and Additional Information**

Questions regarding an inert ingredient submission or requests to set up a presubmission meeting should be directed to IIAB. Please e-mail questions to [InertsBranch@epa.gov](mailto:InertsBranch@epa.gov) or contact PV Shah at (703) 308-1846.

Additional information on pesticide inert ingredients (e.g., FAQs, InertFinder, FIFRA 25 (b) inert ingredients) can be found on our website <http://www.epa.gov/opprd001/inerts>

## APPENDIX A

### **PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS**

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to **Director, Collection Strategies Division (2822T) U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460.**

**INSTRUCTIONS:** This form is to be used for all **inert ingredient** submission, (this form is also used for new registrations, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc). In order to process an application, the following material must accompany the application:

1. Transmittal Document;
2. Notice of Filing (Food Use Only);
3. Three copies of any data submitted;

**Submission of Data** -Data submitted in support of this application must be submitted in accordance with PR Notice 2011-3

**Block A** -Check "Other"

**Section I-** This section must be completed, as applicable, for all inert ingredient submissions.

1. **Company/Product Number** - Insert your company number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. Product Number- Leave Blank.
2. **EPA Product Manager** -Leave the first box blank and enter "8" under PM number
3. **Proposed Classification** -Check "None".
4. **Company/Product (Name)** - Enter the company name only.
5. **Name and Address of Applicant** -Enter the name and address of the company or person requesting the inert ingredient approval. If you are acting on behalf of another party, you must submit authorization from that party to act on their behalf. If applicable, the name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** -Leave Blank

**Section II-** Check "Other".

In the Explanation section write "Inert Ingredient" and provide a brief explanation of the regulatory action you are requesting. The Explanation Section should also be used for any additional information regarding Sections I and II.

**SECTION III** - Leave Blank

**SECTION IV** (Contact Point) -This section must be completed for all submissions.

- 1-5. Self-explanatory
6. EPA Use Only