

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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General Guidance for Requesting the Approval of a New Nonfood Use Inert Ingredient¹ or Amending a Currently Approved Nonfood Use Inert Ingredient under PRIA 3

The general process for submitting a nonfood use request to the Environmental Protection Agency, herein referred to as the EPA or the Agency, under PRIA 3 is provided below.

The following topics are outlined in this guidance document:

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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 your request. This is an informal discussion to determine if the submitter has enough information to proceed with the review process. The submitter will need to provide a brief summary of the information they have regarding the chemical, including use information, limitations, 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 application to the Agency.

¹ For low risk polymer nonfood submissions, please see the document titled "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."

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 nonfood use inert ingredient PRIA 3 codes covered in this document are I004, I005, I006, and I007. 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>.

Submission Contents

The submission package should include a transmittal document, Form 8570-1, an informative summary of the submission, 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. "Request for approval of a new nonfood use inert ingredient: PRIA 3 category I004" [Insert your chemical name and CAS Reg. No.] or
 - ii. "Request to amend a currently approved nonfood inert ingredient with new use pattern (new data): PRIA 3 category I005" [Insert your chemical name and CAS Reg. No.] or
 - iii. "Request to amend a currently approved nonfood inert ingredient with new use pattern (no new data): PRIA 3 category I006" [Insert your chemical name and CAS Reg. No.] or
 - iv. "Request to approve a substantially similar nonfood use inert ingredient with similar use pattern: PRIA 3 category I007" [Insert your chemical name and CAS Reg. No.]
 - d. Brief summary of your request including the regulatory action being requested (e.g. 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. **Submission 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 submission; 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 supports the request and a discussion on the adequacy of the data.
 - ii. Study results and conclusions
 - 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.
 - 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.
4. **Data:** Information/data typically used by the Agency to make a decision for a new nonfood 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 submission.
- 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 (The 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 submitter should provide the results of a predictive Quantitative Structure Activity Relationship (QSAR) model (e.g., the [OncoLogic](#)TM 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?
 - 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., residential and occupational) for both pesticidal and nonpesticidal uses of the chemical.
- i. 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
 - ii. 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 studies²; publically available literature and data, including peer-reviewed assessments and journals (e.g. WHO, OECD SIDS, IUCLID, EPA HPV, IRSI, etc.); modeled data³; and analog/surrogate data.

² OCSPP Harmonized Test Guidelines: <http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm>

³Models: http://www.epa.gov/pesticides/science/models_pg.htm

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 application 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. **Submission Layout:** Chapter 11 of [EPA's Blue Book](#) provides additional information about the format of the submission. 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
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 submission.
 - 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 nonfood use inert (PRIA code- I004) is 8 months; for amending a currently approved nonfood inert ingredient with new use pattern with new data (PRIA code I005) is 8 months; to amend a currently approved nonfood inert ingredient with new use pattern without new data (PRIA code I006) is 6 months; and for the approval of a substantially similar nonfood use inert ingredient when the original inert is compositionally similar with similar use pattern (PRIA code I007) is 4 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 the request; 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 letter outlining IIAB's decision will be emailed to the submitter. After the issuance of the letter, granting the use of the chemical, the inert ingredient will be permitted for use under the appropriate use pattern.

How to Submit a Nonfood Request

All submissions to IIAB are received and processed by our Document Processing Desk. If you would like to submit your application 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 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