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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1/23/13

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

The general process for submitting a petition to the Environmental Protection Agency, herein referred to as the EPA or the Agency, for the establishment of a new inert ingredient tolerance exemption for a food use Low Risk Polymer under 40 CFR 180.960 or for the approval of a nonfood use Low Risk Polymer is provided below.

The following topics are outlined in this guidance document:

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Presubmission Consultation

The Agency recommends that the 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 in which the submitter would provide a brief summary of the information they have regarding the chemical as it relates to the criteria outlined in 40 CFR 723.250 for a Low Risk Polymer. IIAB will determine if there is sufficient information to proceed with a formal application.

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 inert ingredient PRIA 3 codes covered in this document are I008 and I009. 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, a Notice of Filing (food use only), an informative summary of the petition/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. "Petition for approval of a new food use inert ingredient Low Risk Polymer Exemption: PRIA 3 category I008" [insert your chemical name, number average molecular weight (in amu) and CAS Reg. No.] or
        ii. "Request for approval of a new nonfood use Low Risk Polymer inert ingredient: PRIA 3 category I009" [Insert your chemical name, number average molecular weight (in amu), and CAS Reg. No.].
    d. Brief summary of your request including the regulatory action being requested (e.g. CFR description 180.960, nonfood use approval. proposed use, purpose 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 (Food Use Only):** 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[1]. Please make sure to include an electronic Word version of your NOF.

[1] Federal Register: https://www.federalregister.gov; Docket: http://www.epa.gov/dockets/regulations.htm

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 (CAS). Trade names and mixture names should not be included.
    ii. Number average molecular weight (in amu)
    iii. CAS Reg. Number
    iv. Specific section of the CFR for which you are seeking an exemption (i.e., 40 CFR 180.960)
    v. Purpose in formulation (e.g. solvent, emulsifier, etc.)
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, number average molecular weight (in amu), and CAS Reg. No. XXXXX-XX-X)* under 40 CFR 180.960 when used as an inert ingredient *(insert purpose in formulation)* 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.

The NOF for a Low Risk Polymer must address all of the exemption criteria listed in 40 CFR 723.250

4. **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 petition/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 and iInclude any proposed use 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
        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 the chemical meets ALL of the criteria for a Low Risk Polymer under 40 CFR 723.250
d. Studies- Identify the studies used to support your submission and how they support the criteria for a Low Risk Polymer.

5. **Data**: In order for the Agency to determine if a polymer meets the criteria for a Low Risk Polymer exemption under 40 CFR 180.960, the following information will need to be included in your submission:
    a. Representative structure (Diagram of polymer)
    b. Number average molecular weight of polymer (Mn)
    c. Method used to determine the number average molecular weight (e.g. Gel permeation chromatography) AND
    d. A representative chromatogram
    e. % oligomer material below molecular weight 1000 and % oligomer material below molecular weight 500
    f. Submission must clearly state why the polymer conforms to the definition of a polymer given in 40 CFR 723.250(b) AND a scientific rationale for how the chemical meets all of the criteria used to identify Low Risk Polymers described in 40 CFR 723.250. Please address any exclusion criteria that may apply. (e.g. reactive functional groups, potentially cationic polymers)
    g. Studies to support 40 CFR 723.250 criteria (e.g., biodegradation studies)

Low Risk Polymer Criteria

To meet the criteria for a polymer tolerance exemption under 40 CFR 180.960 or be approved as a nonfood use Low Risk Polymer the chemical must meet the definition of a polymer given in 40 CFR 723.250(b) and meet ALL of the criteria used to identify Low Risk Polymers under 40 CFR 723.250. A summary is provided below; however, we recommend you consult 40 CFR 723.250 in the Code of Federal Regulations for a more comprehensive explanation of the criteria as this supersedes the description below.

Definition of a polymer given in 40 CFR 723.250 (b) is:

"Polymer means a chemical substance consisting of molecules characterized by the sequence of one or more types of monomer units and comprising a simple weight majority of molecules containing at least 3 monomer units which are covalently bound to at least one other monomer unit or other reactant and which consists of less than a simple weight majority of molecules of the same molecular weight. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. In the context of this definition, sequence means that the monomer units under consideration are covalently bound to one another and form a continuous string within the molecule, uninterrupted by units other than monomer units."

The criteria used to identify Low Risk Polymer exemption under 40 CFR 723.250 (d) are:

1. The polymer is not a cationic polymer nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment. (Please see 723.250 for exceptions to this criteria)
2. The polymer must contain as an integral part of its composition at least two of the atomic elements carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur.
3. The polymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723 .250(d)(2)(ii).
    a. The elements listed in paragraph (d)(2)(i) which are: carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur.
    b. Sodium, magnesium, aluminum, potassium, calcium, chlorine, bromine, and iodine as the monatomic counter ions Na^{+}, Mg^{+2}, Al^{+3}, K^{+}, Ca^{+2}, $C1^{-}$, Br^{-}, or I
    c. Fluorine, chlorine, bromine, and iodine covalently bound to carbon.
    d. Less than 0.20 weight percent of any combination of the atomic elements lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin, and zirconium.
4. The polymer is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize.
5. The polymer is manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption. Please list all monomers and/or reactants and their CAS Reg. No.
6. The polymer is not a water-absorbing polymer with a number average molecular weight greater than or equal to 10,000 daltons.
7. The polymer does not contain, as an integral part of its composition, except as impurities, one or more of the following perfluoroalkyl moieties consisting of a CF3- or longer chain length:
    a. Perfluoroalkyl sulfonates (PFAS),
    b. Perfluoroalkyl carboxylates (PFAC),
    c. Fluorotelomers,
    d. Perfluoroalkyl moieties that are covalently bound to either a carbon or sulfur atom where the carbon or sulfur atom is an integral part of the polymer molecule.
8. The polymer must meet one of the exemption criteria specified in 40 CFR 723.250(e):
    a. Option 1. The polymer's number average molecular weight is greater than 1,000 and less than 10,000 daltons. The polymer contains less than 10% oligomeric material below MW 500 and less than 25% oligomeric material below MW 1,000 and the polymer does not contain any reactive functional groups. (See 40 CFR 723.250 (e) for more information on reactive functional groups.)
    b. Option 2. The polymer's number average molecular weight is greater than or equal to10,000 daltons. The polymer contains less than 2% oligomeric material belowMW 500 and less than 5% oligomeric material below MW 1,000.
    c. Option 3. *Polyester polymers.* The polymer is a polyester as defined in § 723.250(b) and is manufactured solely from one or more of the reactants in Table 1 of § 723.250.

If the polymer does not meet ALL of the above criteria, it does not meet the requirements to qualify as a Low Risk Polymer.

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/Submission 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 all of your inert ingredient submissions.

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_templatelist.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/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 food use polymer inert ingredient (PRIA code- I008) is 5 months and for a new nonfood polymer inert ingredient (PRIA code I009) 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. 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 is completed, a decision will be made regarding the safety of the inert ingredient in question. For food use polymers 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 is permitted for use under the appropriate use pattern. For nonfood use polymers 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 Petition or Nonfood Polymer Request

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. 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 USPD 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

Additional information on the polymer exemption rule (40 CFR 723.250) and the Polymer Exemption Guidance Manual can be found at http://www.epa.gov/oppt/newchems/pubs/guideman.htm

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