UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Inert Ingredient Frequently Asked Questions

Subject List:

For more information on the following subjects, please see the specific questions listed under each heading.

1. What is an "inert ingredient"?

An inert ingredient is 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. It is important to note, the term "inert" does not imply that the chemical is nontoxic.

Inert ingredients play a key role in the effectiveness of a pesticidal product. For example, inert ingredients may serve as a solvent, allowing the pesticide's active ingredient to penetrate a plant's outer surface. In some instances, inert ingredients are added to extend the pesticide product's shelf-life or to protect the pesticide from degradation due to exposure to sunlight. Pesticide products may contain more than one inert ingredient; however, federal law does not require that these ingredients be identified by name or percentage on the label. In general, only the total percentage of inert ingredients is required to be on the pesticide product label, certain exceptions apply.

All inert ingredients in pesticide products, including those in an inert mixture, must be approved for use by the EPA. For those inert ingredients applied to food, a tolerance or tolerance exemption is required. Impurities are not included in the definition of inert ingredient (see Question 17 for more information on impurities).

2. Where can I find a list of approved inert ingredients?

e-CFR

For the most current list of inert ingredients approved for **food use** pesticide products see the Electronic Code of Federal Regulations (e-CFR) at Electronic Code of Federal Regulations (e-CFR)

The majority of inert ingredients can be found in 40 CFR 180.910-180.960. 40 CFR part 180 also contains a number of sections that include tolerances/ tolerance exemptions for specific inert ingredients where their use is usually significantly limited. An example is § 180.1065 which is a tolerance exemption for 2-amino-4,5-dihydro-6-methyl-4-propyl-s-triazolo(1,5-alpha)pyrimidin-5-one when used as an emetic at not more than 0.3 percent in formulation of paraquat dichloride.

InertFinder

InertFinder is an online searchable database that allows pesticide formulators and other interested parties to easily identify chemicals approved for use as inert ingredients in pesticide products (for trade names and/or mixtures please see "Trade Name Inert Ingredients" below and Question 14). Users can search for inert ingredients by chemical name or CAS Reg. No. to determine whether inert ingredients are approved in pesticide products used on food or solely for nonfood uses, as well as being provided with any applicable use limitations. The system does not include information about ingredients in individual pesticide products.

Trade Name Inert Ingredients

This voluntary database contains a listing of trade name inert ingredients for which the manufacturer of the trade name inert ingredient has volunteered to participate in the development of a publicly available list of trade name inert ingredients, along with the uses for which they are approved, and the manufacturer's name. The public listing does not include the composition of trade name inert ingredients, nor products in which they are used. In addition, the posting of the trade name inert ingredient list does not imply any endorsement by EPA of one trade name inert ingredient over another. The database is intended solely to enhance public access to information related to the EPA approval status of trade name inert ingredients used in pesticide products. Please see the Trade Name Inert Ingredient Database.

Nonfood Inert Ingredients

EPA previously maintained a PDF file listing nonfood use inert ingredients, including those that also have food uses. That list has been folded into InertFinder as appropriate, and is no longer being updated. Please see the old list of "Inert Ingredients Permitted for Use in Nonfood Use Pesticide Products".

Fragrances

Please see the InertFinder mentioned above for approved fragrances. For additional information on the Pesticide Program's Pilot Fragrance Notification Program and Fragrance Ingredient Database, please see Questions 26-28 and the Fragrance Notification Program.

FIFRA 25(b)

For information on inert ingredients in FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) 25(b) pesticide products see Question 15.

3. Why do I need to know the approval status of my inert ingredient before submitting a formulation to the Agency?

All Confidential Statements of Formula (CSF) submitted with a covered pesticide registration application are screened to ensure that all inert ingredients are either approved or pending with the Agency for the labeled use of the pesticide formulation. If a covered registration application is associated with and dependent upon an already pending application for an inert ingredient action, the dependent application must identify the pending inert action with its inert approval tracking number assigned by the Agency, the name of the inert ingredient that is pending, and the name of the inert ingredient's applicant's name. The decision review time for the dependent application could be affected by the inert ingredient's decision review time. If an inert ingredient is not currently approved for the intended use of the pesticide formulation nor is one pending before the Agency for the intended use, then the application may be rejected and a portion of the Pesticide Registration Improvement Act (PRIA) 3 fee (at least 25%) will be retained. See Question 18 for information on PRIA 3 fees related to inert ingredients.

It is also important to ensure that the labeled uses of the pesticide product do not fall outside the use limitation of the inert ingredients. Some inert ingredients are approved for nonfood use only (e.g. ornamental plants, lawns, use in swimming pools, etc.) while others may be given a tolerance or tolerance exemption for a limited food use application such as the example provided in Question 2.

4. What is the difference between 40 CFR 180.910, 180.920, 180.930, 180.940, etc.?

The Federal Food Drug and Cosmetic Act (FFDCA) requires that all inert ingredients used in pesticide products applied to food sites must have an applicable tolerance/tolerance exemption in the Code of Federal Regulations under 40 CFR 180. These tolerance/tolerance exemptions often contain limitations on how the inert ingredient can be used in food-use pesticide products. It is important to keep this in mind when selecting an inert ingredient for use in a pesticide formulation.

Please note: In addition to the general limitations of the sections (e.g. 180.920, 180.940, etc.) each tolerance exemption may have a chemical-specific limitation that affects its approval status. For example, 3,6-dimethyl-4-octyn-3,6-diol is approved under § 180.920 for use on growing crops, however, it is limited to applications to "soil prior to planting or to plants before the edible parts form" when used as a surfactant or related adjuvants of surfactants. These limitations are listed in the CFR citation.

40 CFR 180 organizes inert ingredients into sections by general limitation as follows:

- § 180.910 "Inert ingredients used **pre- and post-harvest**; exemptions from the requirement of a tolerance."
- § 180.920 "Inert ingredients used **pre-harvest**; exemptions from the requirement of a tolerance."
- § 180.930 "Inert ingredients applied to **animals**; exemptions from the requirement of a tolerance."
- § 180.940 "Tolerance exemptions for active and inert ingredients for use in **antimicrobial formulations** (Food-contact surface sanitizing solutions)."
- § 180.950 "Tolerance exemptions for **minimal risk** active and inert ingredients."
- § 180.960 "**Polymers**; exemptions from the requirement of a tolerance."

NOTE- Inert Ingredients approved under 40 CFR 180.950 and 180.960 can be used for any food and nonfood use pesticide product.

5. How do I get approval for the use of a new inert ingredient?
To assist you in this process, IIAB has created three comprehensive guidance documents for food use, nonfood use, and Low Risk Polymer submissions. Please see these guidance documents for a more in depth explanation of the inert approval process including tips and templates to assist you in compiling your submission package. The guidance documents can be found on our website at the Inert Ingredients Overview and Guidance page. For instructions on how to get a trade name/mixture approved see Question 12.

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

6. I want to add a use to an already approved chemical, do I need to submit a new petition?
All changes/amendments regarding food use pattern (e.g. having a tolerance exemption under 180.920 and wanting to include use patterns under 180.910 or revisions to any limitation associated with an existing tolerance exemption) require a new petition. This petition must include a discussion on how the new proposed use pattern will affect the risk of adverse effects to human health and the environment. Make sure to summarize the data even if this submission is relying on a previous EPA assessment. Simply referencing a previous risk assessment without summarizing the data is not acceptable. Further details are provided in the guidance documents on our Inert Ingredients Overview and Guidance website.

A new submission is also required to add a new nonfood use to an already approved nonfood use inert ingredient. Please contact IIAB prior to your submission to discuss your request; IIAB will assist in determining what additional information, if any, would be necessary for a complete petition/submission.

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

7. Are there instructions or templates for how to do a Notice of Filing (NOF)?
NOF templates can be found at the Registrant Summary of Pesticide Petitions for EPA's Notice of Filing. Be sure to choose the NOF for the Registration Division. Instructions for filling out the NOF for food use inert ingredients and Low Risk Polymers can be found in the respective guidance documents for food use and polymer petitions discussed in Question 5. Nonfood submissions do not require a NOF.

8. What data is required for a complete submission?
Unlike active ingredients, inert ingredients do not have a specific "required" data set in 40 CFR Part 158; however, the Agency must have sufficient data to make a safety determination regarding human dietary risk under the FFDCA in connection with the establishment of a tolerance or tolerance exemption and to determine that whafathe ingredient will not present unreasonable adverse effects to the environment in connection with EPA's approval under FIFRA of pesticide products containing the ingredient. For detailed information please see the Food Use, Nonfood Use, and Polymer Guidance Documents on the Inert Ingredients Overview and Guidance website. We encourage you to contact us prior to submitting your petition to determine if additional information is necessary. These presubmission meetings can be conducted by telephone or in person. To set up a meeting please contact us at InertsBranch@epa.gov.

9. Do I need to submit a MSDS with my petition?

Sources of information that may be submitted to the Agency include, but are not limited to, OSCPP guideline studies; publically available literature and data, including peer-reviewed assessments and journals (e.g. WHO, OECD SIDS, IUCLID, EPA HPV, IRSI, etc.); modeled data; and analog/surrogate data. 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, a copy of the study/data cited on the MSDS must be provided in order for the Agency to use this information in the risk assessment process.

10. How long does the review process take?

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

11. Will I be notified when a decision is made on my submission?

The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that for all food use tolerance petitions, the Agency must publish a determination in the form of a Final Rule in the Federal Register. Only after a Final Rule granting the use of the inert ingredient is published in the Federal Register is the chemical legally allowed to be used in a pesticide formulation.

Companies requesting the use of a nonfood inert ingredient will receive a letter regarding the Agency's safety determination and subsequent approval status of the chemical. Once a letter has been issued granting the nonfood use of the inert ingredient, the chemical may be used in nonfood use pesticide formulations.

Newly approved nonfood use chemicals will be added to InertFinder within a week of their approval.

12. How do I get a trade name/mixture approved?

The Agency evaluates trade name products based on the individual components of that product. Each component of the trade name/mixture must be approved for use as an inert ingredient. If all of the ingredients are approved for use then the trade name or mixture is permitted in pesticide products based on the component with the most restrictive use pattern. For example, Mixture A is made up of chemicals X, Y, and Z. If X and Y are approved for food use under 180.950 and Z is only approved for nonfood use, then Mixture A can only be used in nonfood products.

In order to determine the status of a trade name product or inert mixture the following information will need to be submitted to the attention of the Inert Ingredient Assessment Branch (see Question 24 for contact information) by the manufacturer **on company letterhead**:

1. The full product name
2. The chemical name/s and CAS Reg. No. of each ingredient
3. The % (by wt) in formulation of each component* of the **final** trade name product (not the starting materials used to make the final product)- **components must total 100%**.
4. If there are impurities remaining in the final product, those components should be listed as such along with their percentage in the final formulation (See Question 17 for more information on impurities). Compositional information should be submitted using the address in Question 24.

*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.

See Question 30 for more information on the public facing "Trade Name Inert Ingredient Database" and Question 13 regarding the acceptability of submitting an MSDS for the trade name review.

13. Is a MSDS acceptable to get a trade name product/inert mixture in Agency's database?

No, the Agency is no longer accepting an MSDS as proof of composition for a trade name/mixture product. Trade name/mixture compositional information must be submitted as outlined in Question 12 on the manufacturer's company letterhead.

14. How do I find out if an inert trade name and/or mixture is already approved?

We ask that you start by consulting the Trade Name Inert Ingredient database. If you are unable to find the trade name in the database please contact your supplier for the approval status. If the supplier is not able to provide the approval status please ask the supplier to contact IIAB directly so that we can discuss the trade name composition with them and inform the supplier of the overall approval status. If after consulting these two resources you are still unable to determine the approval status, please contact IIAB at inertsbranch@epa.gov. We are unable to confirm **any** of the components of the trade name/mixture; the Agency considers this information to be Confidential Business Information. We will, however, provide the overall approval status of the trade name product.

The Trade Name Inert Ingredients Database can be found on the Trade Name Database web page. This voluntary database contains a listing of trade name inert ingredients for which the manufacturer of the trade name inert ingredient has volunteered to participate in the development of a publicly available list of trade name inert ingredients, along with the uses for which they are approved, and the manufacturer's name. The public listing does not include the composition of trade name inert ingredients, nor products in which they are used. In addition, the posting of the trade name inert ingredient list does not imply any endorsement by EPA of one trade name inert ingredient over another. The database is intended solely to enhance public access to information related to the EPA approval status of trade name inert ingredients used in pesticide products.

For instructions on how to add your trade name or mixture to the database please see Guidance Documents for Inert Ingredients

15. Which inert ingredients are approved for use in FIFRA 25(b) products?

Please see the Inert Ingredients Approved for Use in Minimum Risk Pesticide Products for inert ingredients permitted in FIFRA 25(b) Pesticide Products. December 31, 2012 a proposed rule (77 FR 76979) was published in the Federal Register to more clearly describe the active and inert ingredients permitted in products eligible for the exemption from regulation for minimum risk pesticides. Until this regulatory process is completed and new regulations are established, no substances will be added or removed from the "Inert Ingredients Eligible for FIFRA 25(b) Pesticide Products."

For more information on FIFRA 25(b) Pesticide Products please see the Inert Ingredients Approved for Use in Minimum Risk Pesticide Products. If additional information is required please contact the Biopesticide and Pollution Prevention Division Ombudsperson Nicole Berckes at berckes.nicole@epa.gov or (703) 308-0152.

16. How do I get my chemical added to the "4A" Minimal risk inert ingredients list?

The List Category policy (i.e. the classification of inert ingredients as List 1, 2, 3, and 4A/4B), created in 1987, has now served its purpose as a tool for prioritizing the evaluation of inert ingredients. Now that reassessment of food tolerances/tolerance exemptions under the Food Quality Protection Act (FQPA) is complete, the approval determinations of inert ingredients are no longer classified as List 1, 2, 3, or 4A/4B and these lists are no longer being updated by the Office of Pesticide Programs.

17. Do I need to list impurities on the trade name / mixture formulations? How are they evaluated? Is there a de minimis level for which reporting is not necessary?

Impurities are not considered to be "pesticide chemicals" and are not subject to have a tolerance or tolerance exemption established under 40 CFR Part 180. Therefore, there is no formal petition process for impurities in inert ingredient formulations. However, all impurities in inert formulations need to be reported and are evaluated on a case by case basis. There is no "de minimis" level for impurities related to inert ingredients. The Agency looks at the amount in the formulation, the manufacturing information, and what steps are taken to limit or remove impurities. This information would be needed to make a determination regarding the need for further action.

Please note: As stated in Question 1, "An inert ingredient is 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." Therefore, intentionally added ingredients would not be considered impurities.

For more information on how to list impurities of a pesticide formulation on a **CSF** see OSCPP Harmonized Test Guideline Series 830.1700 and 40 CFR 158.340.

18. Is there a PRIA fee associated with inert ingredients?

Inert ingredient approvals are a covered application under PRIA 3 which took effect on October 1, 2012. See the Fee Determination Decision Tree for descriptions of the ten new inert categories, their PRIA 3 fees and corresponding decision review times. Additional information on fee waivers and a link to the "21-Day Initial Content Screen Worksheet" can be found at the Inert Ingredient 21-Day Content Screen Worksheet and the Pesticide Registration Manual: Chapter 5 - Registration Fees

19. What is a pesticide adjuvant and how is it regulated by EPA?

While there are a number of definitions for pesticide adjuvant, it is generally broadly defined as any substance separately added to a pesticide product (typically as part of a spray tank mixture), that will improve the performance of the pesticide product. Since pesticide adjuvant products don't make pesticidal claims, they are not pesticides and the components of adjuvants are therefore not pesticide inert ingredients. However, it should be noted that residues of pesticide adjuvants in or on food commodities are subject to the requirements of the Federal Food, Drug and Cosmetic Act, which means that a food additive regulation or exemption from the requirement of a tolerance is needed for any substance used as a pesticide adjuvant that is applied to food crops.

20. Are data submitted on inert ingredients subject to data protection and exclusive use rights? How are my data rights protected?

Under Section 408(i) of the Federal Food Drug and Cosmetic Act (FFDCA), data submitted to support tolerances or tolerance exemptions (i.e., food use data) for inert ingredients are entitled to data compensation and exclusive use data rights "to the same extent as provided by" [Section 3 of] the Federal Insecticide, Fungicide, and Rodenticide Act. Data protection rights for submitters of data for nonfood use inert ingredients are limited to certain cases for which data are submitted directly in response to test orders issued under FFDCA section 408(p) as part of the Endocrine Disruptor Screening Program (EDSP). Generally, data compensation is for 15 years from the date the data was submitted. Exclusive use, in general, is granted for 10 years from the time the final rule is published granting use of the chemical.

EPA screens all new pesticide registration/registration amendment applications to ensure that for all inert ingredients for which data rights have been asserted, the applicant has done one or more of the following: 1) made an offer to pay for the use of data; 2) obtained authorization for the use of data; 3) purchased the chemical from the data owner; 4) purchase the chemical from a

company that has made an offer to pay to the data submitter or 5) submitted its own data to satisfy the data obligation.

21. If I am sending in a petition/submission for an inert ingredient and another company is submitting data on my behalf can they send it to the Agency prior to the submission of the petition?

Provided that the submitted data have been assigned a Master Record Identification Number (MRID) by the EPA, which is cited in your petition/submission, these data would be acceptable.

22. Are aromatic solvents acceptable for use as inert ingredients in food use pesticide formulations?

On June 22, 2011, an exemption from the requirement of a tolerance (i.e., a food use approval) was established for C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons (76 FR 36356). Any new registration action submitted to the Agency after June 22, 2011, that includes as a component of the product formulation an aromatic solvent that falls under the tolerance exemption descriptors C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons will be considered to be exempt from the requirement of a tolerance under 40 CFR 180.910 and will therefore be acceptable for use as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest.

Registrants that may be using or are contemplating using aromatic solvents as well as those companies that may be manufacturing and/or supplying such products to pesticide formulators should be aware that the establishment of tolerance exemptions for these specific aromatic solvents may result in data protection rights being asserted by the original data submitter for C_9 rich aromatic hydrocarbons, C_{10-11} rich aromatic hydrocarbons, and C_{11-12} rich aromatic hydrocarbons. Such rights would be in the form of data compensation rights that require that registrants seeking a registration for a pesticide product containing an inert ingredient for which data protection rights are claimed, to, as appropriate, 1) make an offer to pay for the use of data, 2) obtain authorization for the use of data prior to the Agency granting a registration 3) purchase the chemical from the data owner, or 4) purchase the chemical from a company that has made an offer to pay to the data submitter. Alternatively, registrants or other interested parties may seek to establish other tolerance exemptions for aromatic solvents. The Agency practice of allowing certain aromatic solvents to be permitted to be used in food use pesticide formulations based on the extant exemptions from the requirement of a tolerance for xylene under 40 CFR 180.910, 40 CFR 180.920 and 40 CFR 180.930 has been discontinued—the tolerance exemption for xylene will apply only to xylene.

23. Are fertilizers permitted in pesticide formulations applied to food?

Fertilizers meeting the definition of a fertilizer as given by the American Association of Plant Food Control Officials (AAPFCO), containing AAPFCO recognized plant nutrients, and used in pesticide products solely for their plant nutrient value are acceptable for use in pesticide formulations applied food crops. Fertilizers not meeting the AAPFCO definition or containing other components not recognized by AAPFCO as acceptable fertilizer components would be evaluated on a case-by-case basis by EPA.

24. How do I contact the Inert Ingredient Assessment Branch (IIAB)?

Please submit all questions and comments to the Inert Ingredient Assessment Branch email at InertsBranch@epa.gov. This email is maintained by members of IIAB and it allows us to keep track of the types of questions we are getting and areas that may need further clarification. Once a question is received it is answered by one of the members of the IIAB Team. If you need further assistance please contact IIAB Chief, PV Shah at shah.pv@epa.gov or (703)308-1846.

General correspondence (e.g., trade name information) can be submitted to the mailing address listed below. The mailing address for submitting petitions and/or nonfood submission and associated data can be found in Question 25.

(1) By USPS mail

Attn: Inert Ingredient Assessment Branch
Registration Division (7505P)
Office of Pesticide Programs
U.S. EPA
1200 Pennsylvania Ave. N.W.
Washington D.C. 20460-0001

(2) By courier

Attn: Inert Ingredient Assessment Branch
Registration Division
Office of Pesticide Programs
U.S. EPA, Room S-4400
One Potomac Yard (South Bldg)
2777 S. Crystal Drive
Arlington, VA 22202-4501

25. How do I submit my petition/submission/data to the Agency?

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 Electronic Submissions of Pesticide Applications.

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 Fee Payments (Paying PRIA Application Fees) for more information. The applicant must attach documentation that the fee has been paid with the application package. For more information on what should be contained in the submission and formatting requirements please see the Guidance Documents on our webpage Inert Ingredients Overview and Guidance.

The application should be sent to:

(1) By USPS mail

Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
U.S. EPA
1200 Pennsylvania Ave. N.W.
Washington D.C. 20460-0001

(2) By courier

Document Processing Desk (REGFEE)
Office of Pesticide Programs
U.S. EPA, Room S-4400
One Potomac Yard (South Bldg)
2777 S. Crystal Drive
Arlington, VA 22202-4501

*Please note the mailing address is different depending on the type of delivery service you intend to use.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Certain Provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), there are standard data format requirements for all study data submitted to the Agency. 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.

26. What is the Pesticide Fragrance Notification Pilot Program?

EPA's Office of Pesticide Programs (OPP) Pilot Fragrance Notification Program (PFNP) is a two year pilot program (commenced 9/19/11) for registrants seeking to add new or modify existing fragrances in new or currently registered nonfood use pesticide products. The PFNP is a process improvement effort to streamline the current process used to amend registrations when fragrance ingredients are added, removed, or modified. More information on the PFNP, including submission requirements and application forms, can be found at the Fragrance Notification Program.

All components of a fragrance formulation must be listed on the Fragrance Ingredient List (FIL) and/or approved by the Agency before a notification or amendment can be submitted for that fragrance under the Pilot Fragrance Notification Program. In order to qualify for the PFNP the concentration of the fragrance being added or changed must not exceed 1.0% (by weight) of the total pesticide product composition. In addition, the individual fragrance components must be less than or equal to 0.1% (by weight) of the total pesticide product composition **or**, for those individual fragrance component ingredients that exceed 0.1% (by weight) of the total pesticide product composition, have an existing approval for use as a pesticide product inert ingredient.

Under the PFNP, the fragrance composition is to be submitted once a year. OPP will audit the program yearly. As part of this process, OPP will use composition data from a random sampling of the new fragrances. Fragrance actions involving pesticide products that are insect repellents or baits are not eligible for the PFNP. Antimicrobial aerosol products that make public health claims are also not eligible because confirmatory efficacy data are required to support any change in an antimicrobial aerosol product formulation intended to control public health microorganisms.

27. What if my fragrance does not meet the requirements of the Pilot Fragrance Notification Program (PFNP)?

Fragrance formulations that are not eligible under the PFNP (e.g., fragrances used in food use pesticide products, fragrance formulations used at greater than 1%, fragrances used in insect repellents, etc.) are evaluated on a case-by-case basis. For those fragrance formulations intended for use in food use pesticide products, all components must have an exemption from tolerance in 40 CFR Part 180. For nonfood use fragrance formulations each fragrance component must have approval as a food use inert ingredient, a nonfood use inert ingredient, and/or be on the Fragrance Ingredient List (FIL).

28. How do I get a new fragrance ingredient on the Fragrance Ingredient List (FIL)? What kind of data/information is required?

Fragrance components that do not currently have an exemption from tolerance under 40 CFR Part 180, are not approved as nonfood inert ingredients, or do not appear on the FIL will need to be submitted for review and approved by the Agency prior to use in a fragrance formulation incorporated into pesticide products. Depending upon the proposed use of the fragrance, new fragrance components may be evaluated using either the conventional nonfood use or (when appropriate) food use review process. Guidance documents are available on our web site Inert Ingredients Overview and Guidance for both food use and nonfood use inert ingredient submissions. The data needed to support the request for approval will depend on the use pattern of

the fragrance. Requestors are encouraged to have a presubmission meeting with IIAB to determine the data necessary for a complete submission. To set up a meeting please contact us at InertsBranch@epa.gov.

29. I would like to use a chemical that is not listed as an approved inert ingredient; however, it falls under a chemical grouping that has been approved for use as inert ingredients. Does this mean that my chemical is also approved and can be used as an inert ingredient?

No, if a chemical is not specifically listed as an approved inert ingredient it cannot be used in pesticide formulation even if the chemical grouping has been approved. All inert ingredients must be reviewed by the EPA before they can be used in pesticide products. There are two PRIA 3 fee categories (I010 and I007) to address these types of requests.

An application that proposes to amend a tolerance exemption descriptor by adding one or more CAS Registry Numbers (CASRN) to an existing tolerance exemption expression in which the tolerance exemption descriptor is for grouping of closely related substances with associated CASRNs rather than a single chemical entity would be submitted under PRIA Fee Category I010 "Petition to amend a tolerance exemption descriptor to add one or more CASRNs; no new data".

An application that proposes a new nonfood use for an inert ingredient which is proposed to be compositionally similar with a similar use pattern to an approved nonfood use inert ingredient would fall under PRIA fee category I007, "Approval of substantially similar nonfood use inert ingredients when original inert is compositionally similar with similar use pattern"

A full description of the fee categories can be found at Interpretations of PRIA Fee Categories

30. Why aren't all approved trade name/mixtures in the "Trade Name Inert Ingredients" database?

While the Agency maintains a confidential database of all approved inert ingredient trade names and mixtures, the public facing "Trade Name Inert Ingredients" is a voluntary database and therefore, only trade name/mixtures that have specifically been submitted for inclusion by the manufacturer are presented in this database. If you are the manufacturer of a trade name inert ingredient and wish to have your trade name inert ingredient included in a publicly available list of trade name inert ingredients.

31. I am submitting a petition for the exemption from tolerance of a new inert ingredient, can I also have the trade names for this chemical simultaneously approved?

We ask that you submit your trade names only after the chemical has been approved by the Agency. Trade names that are submitted with a petition will not be added to the database. The petition review process or nonfood approval process is for the review of the chemical itself and not the trade name. For more information on how to have a trade name and/or mixture approved see Question 12

32. How do I find out if an inert ingredient approval application by another applicant is currently pending before the Agency and for what uses?

As stated in the Registrations Service Fee, Questions on Inert Ingredients, "Due to CBI concerns, the Agency, in general, cannot provide information regarding the status of a pending inert ingredient application. Information on whether an inert ingredient application is currently pending with the Agency and for what uses should come from the inert ingredient applicant. In cases where another covered application, such as a product registration application, intends to associate with and depend upon an already pending application for an inert ingredient approval, the applicant must identify the pending inert ingredient action in its application. To identify the inert, the applicant must provide the inert approval tracking number assigned by the Agency, name of the

inert ingredient(s) that is pending and the inert ingredient's applicant's name. This information can be requested from the pending inert ingredient applicant. The Agency will not provide information to the applicant of the dependent covered application regarding the status of the pending inert ingredient approval action beyond information that must be shared to adjust the decision review time due date for the dependent application at the start of the review. PRIA 3 requires that the decision review times for inert ingredient applications and applications associated with and dependent upon them be in sync."

33. What is the new Preliminary Technical Screen under PRIA 3?

FIFRA section 33(f)(4)(B), "Initial Content and Preliminary Technical Screenings" directs the Agency to conduct a preliminary technical screen 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. In conducting this technical screen, the Agency determines whether:

1. the application and the data and information submitted with the application are accurate and complete, and
2. the application, data and information are consistent with the proposed labeling and any proposed tolerance or tolerance exemption, and
3. the application, data and information are such that subject to full review could result in the granting of the application.

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. See Pesticide Registration Manual: Chapter 5 - Registration Fees for more information.

34. Is there a de minimis level for which inert ingredient do not have to be reported on a CSF and therefore, do not need a exemption from tolerance or a nonfood approval?

No. All intentionally added inert ingredients must be approved for the intended use and need to be listed on the CSF, regardless of their percentage in formulation. See Question 17 for information on impurities.

35. Our company is based in Europe, can we submit an inert ingredient petition and/or nonfood submission directly to the EPA or do we need to designate a U.S. agent as required under 40 CFR 152.50 for "all registration matters"?

Under PRIA 3, applications for approval of inert ingredients are considered "covered pesticide registration applications" (see FIFRA sec. 33(b)(3), Table 18). EPA interprets the requirement in 40 CFR 152.50(b) for applicants not residing in the U.S. to designate a U.S. agent to also apply to inert ingredient approval applications. Therefore, a U.S. agent must be designated as outlined in 40 CFR 152.50.

36. Are there data compensation rights associated with inert ingredients?

In 1996 Congress amended section 408(i) of the Federal Food, Drug and Cosmetic Act (FFDCA) to provide both exclusive use and data compensation protections for data that inert ingredient manufacturers and/or petitioners submit to EPA to establish or maintain tolerances or tolerance exemptions for these ingredients. More information on data rights protections for inert ingredients can be found at Protection of Proprietary Data Rights for Data Used to Support Tolerance Exemptions for Inert Ingredients.