



US Environmental Protection Agency Office of Pesticide Programs

Pesticide Fragrance Notification Pilot Program

Revised December 2012

Guidance for the Office of Pesticide Program's Pilot Fragrance Notification Program

This document provides guidance for EPA's Office of Pesticide Programs (OPP) Pilot Fragrance Notification Program (PFNP) for registrants seeking to add new or modify existing fragrances in new or currently registered pesticide products. In addition, registrants seeking new registrations can now participate. The Pilot will be conducted for two years and started on September 19, 2011. The PFNP is a process improvement effort to streamline the current process used to amend registrations when fragrance ingredients are added, removed, or modified. This guidance document includes the eligibility criteria for participation, submission requirements and submission instructions. Certification forms and the audit procedure are also included.

I. Eligibility for Participation in the Pilot Fragrance Notification Program

Registrants seeking to add or modify fragrances in new or currently registered, products have the option of using the OPP Pilot Fragrance Notification Program. Participation in the OPP Pilot Fragrance Notification Program is subject to the following requirements and limitations:

- 1) Registrants must certify (see Attachment 1) that all fragrance component ingredients in the newly proposed fragrance are included on the Fragrance Ingredient List (FIL): <http://www.epa.gov/opprd001/inerts/fmaingredient.pdf>.
- 2) The concentration of the fragrance being added or changed must not exceed 1.0% (by weight) of the total pesticide product composition.
- 3) Individual fragrance component ingredients that would exceed 0.1% (by weight) of the total pesticide product composition must have existing approval for use as pesticide product inert ingredients.
- 4) Fragrances for antimicrobial aerosol products making public health claims can be added by notification provided the new fragrance(s) is within the certified limits established for fragrances already approved for the product. Fragrances cannot be added by notification to antimicrobial aerosol products if: a) a fragrance has not been previously approved for the product or b) the new fragrance exceeds the upper certified limit for fragrances already approved for the product. These changes must be made by submitting an amendment and confirmatory efficacy data.
- 5) Fragrance actions involving pesticide products that are insect repellents or baits are not eligible for the OPP Pilot Fragrance Notification Program.

- 6) This notification program is for non-food use pesticide products only. Food-use products are ineligible.
- 7) Requests for inclusion of individual fragrance ingredients that are not on the FIL should be submitted directly to the Inert Ingredient Assessment Branch in the Registration Division for evaluation and a determination of appropriateness for inclusion on the FIL.
- 8) Newly proposed fragrances that contain ingredients not listed on the FIL are not eligible for the OPP Pilot Fragrance Notification Program. All ingredients of a fragrance must be listed on the FIL and/or approved by the Agency before a notification or amendment can be submitted for that fragrance under the Pilot Fragrance Notification Program.
- 9) It is the responsibility of the registrant to contact the fragrance supplier to ensure that the fragrance composition is submitted to the Agency. The fragrance composition consists of the complete listing of all components that make up the fragrance. The approved identity of new fragrances is to be submitted to the Agency as outlined in Section II (B) below.
- 10) OPP will audit the program yearly. As part of this process, OPP will use composition data for a random sampling of the new fragrances.

II. Pilot Fragrance Notification Program Requirements

A. Registrants filing a Fragrance Notification are required to submit the following:

1. EPA Form 8570-1 identifying the submission as an addition of a fragrance or identifying new or modified fragrances eligible for the Pilot Fragrance Notification Program. The form is available at www.epa.gov/opprd001/forms.
2. Fragrance Supplier Certification Letter (See Attachments I and II) certifying that all fragrance ingredients in the newly proposed fragrance are on the FIL.
3. Confidential Statement of Formula (CSF). The form is available at www.epa.gov/opprd001/forms.

B. The fragrance supplier agrees to submit the composition of approved fragrances to the Inert Ingredient Assessment Branch in the Registration Division of the Office of Pesticide Programs by June 30 of the year it is approved. If approved after this date, then it should be submitted no later than June 30 of the following year.

III. Submission instructions

1. Registrants submitting the information identified above for Fragrance Notifications should follow the instructions for submitting various types of applications to OPP found in Pesticide Registration (PR) Notice 2006-1, April 12, 2006, entitled “New Instructions for Transmitting Information to the Office of Pesticide Programs”.
www.epa.gov/PR_Notices/. Submissions would be sent to:

Document Processing Desk (Code)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Submissions via Hand Delivery or Courier Delivery: Deliveries by you or a commercial courier should be directed to:

Document Processing Desk (Code)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

2. The fragrance supplier or registrant is responsible for ensuring that the information related to the fragrance identity is submitted to the Agency for delivery to the Inert Ingredient Assessment Branch in the Registration Division. This information should be titled as “Fragrance Identity” and submitted by hard copy or in an excel format on a CD or similar media. Submissions should be sent to:

Document Processing Desk (Code)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Submissions via Hand Delivery or Courier Delivery: Deliveries by you or a commercial courier should be directed to:

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Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

IV. Contact Information

For information regarding the Fragrance Ingredient List (FIL) contact:

Prakashchandra Shah
Inert Ingredient Assessment Branch (IIAB)
USEPA/OCSP/OPP, Registration Division
Shah.pv@epa.gov
703-308-1846

For information regarding the OPP Pilot Fragrance Notification Program, contact:

Dennis Edwards
Chief, Regulatory Management Branch I
USEPA/OCSP/OPP, Antimicrobials Division
Edwards.dennis@epa.gov
703-308-8087

ATTACHMENT I

Certification for the OPP Pilot Fragrance Notification Program

Version I: For use when the fragrance supplier knows the fragrance identities and the registrant does not

(Basic Product Name)
EPA Reg. No.

Statement of Fragrance Supplier

On behalf of [name of fragrance supplier], I certify that all of the ingredients found in fragrance formula _____ to be used in EPA Reg. No. _____ are listed in the Fragrance Ingredient List (FIL) at <http://www.epa.gov/opprd001/inerts/fmaingredient.pdf> and meet the other requirements of the Pilot Fragrance Notification Program. I understand that it is a violation of 18 U.S.C. §1001 to willfully make any false statement in this letter. I agree

- 1) to maintain records documenting the identities of the fragrances in this formula for a period of 5 years after I cease selling this formula to [name of registrant] and to provide this documentation to the U.S. Environmental Protection Agency (EPA) upon request,
- 2) to notify EPA and [name of registrant] if fragrance formula changes in a manner that makes the formula ineligible for the Pilot Fragrance Notification Program and
- 3) to certify that the composition of new fragrances will be submitted to the Agency.

I understand that the registrant will contact the fragrance suppliers to ensure that the submissions are made to the Agency.

Signature, Fragrance Supplier
(Name, Fragrance Supplier, Address, Phone)

Date

Statement of Registrant

As the registrant of EPA Reg. No. _____, I am aware that it is my responsibility to ensure that

- 1) this product meets the terms of the OPP Pilot Fragrance Notification Program and
- 2) EPA has access to complete and accurate formulation information for the pesticide.

I acknowledge that if this product does not meet the terms of the OPP Pilot Fragrance Notification Program, including the requirement that all fragrance ingredients are on the FIL, then the sale or distribution of this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.

Signature, Registrant Company
(Registrant Name)
(Registrant
Address)
(Registrant city, state, zip code)

Date

ATTACHMENT II
Certification Letter
for the OPP Pilot Fragrance Notification Program

Version II: for use when the registrant knows the fragrance identities

(Basic Product Name)
EPA Reg. No.

On behalf of [name of registrant], I certify that all of the fragrances in EPA Reg. No. _____ (or the new registration application) are listed in the Fragrance Ingredient List (FIL) at <http://www.epa.gov/opprd001/inerts/fmaingredient.pdf> and meet the other requirements of the OPP Pilot Fragrance Notification Program. I understand that it is a violation of 18 U.S.C. §1001 to willfully make any false statement in this certification. I further understand that if this product is not consistent with the terms of the OPP Pilot Fragrance Notification Program, 40 CFR 152.46, including the requirement that all fragrance ingredients are on the FIL, then the sale or distribution of this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.

Signature, Registrant Company
(Registrant Name)
(Registrant
Address)
(Registrant city, state, zip code)

Date

ATTACHMENT III

Fragrance Supplier Audit Procedure for the OPP Pilot Fragrance Notification Program

Recordkeeping /Audit Procedure

The **recordkeeping obligations** and the **audit procedure** are required elements of the OPP Pilot Fragrance Notification Program. Failure to comply with these voluntary Program elements means that any changes in fragrances from the most recent Confidential Statement of Formula filed with EPA require approval from the Agency. Sale or distribution of a formulation whose fragrances have neither been approved by EPA nor qualify for the OPP Pilot Fragrance Notification Program may result in enforcement action and penalties under Sections 12 and 14 of FIFRA.

The OPP Pilot Fragrance Notification Program recordkeeping and audit procedures are as follows:

- 1) **Certification Statement/Fines & Penalties:** In lieu of submitting composition data for each fragrance, registrants may sign and submit the “**Fragrance Supplier Certification Letter**” (attached) or ensure that the fragrance supplier does so. A false statement on the certification letter may violate **18 U.S.C. § 1001**
- 2) **Recordkeeping Requirements:** The fragrance supplier and/or registrant will maintain a **record of the composition data** for each fragrance in a registered pesticide product and agrees to make such records available upon request by EPA (**Note:** OPP uses a similar model for efficacy data for non-public health pesticides).
- 3) **Audit Procedure:** EPA, at its discretion, may conduct **periodic audits** of such records by requesting that **composition data** for a portion of the new fragrances registered by notification.