

EPA Definitions and Treatment of Inert Ingredients

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I. Inert Ingredient Definitions

Inert Ingredient Definitions

Inert Ingredient --

“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, except as provided by §174.3 of this chapter.”

40 CFR 152.3

Inert Ingredient Definitions

Adjuvant –

A substance added (typically to a tank mix) to a pesticide product prior to application. An adjuvant may impact the action of a pesticide or the physical characteristics of the mixture

Inert Ingredient Definitions

Adjuvants:

Substances used as adjuvants are not considered pesticide chemicals *per se*, but adjuvants used in conjunction with pesticide products applied to food **are** subject to the requirement of a tolerance (or tolerance exemption) under the Federal Food, Drug and Cosmetic Act (FFDCA).

Inert Ingredient Definitions

Polymers –

Inert ingredients meeting the definition of a polymer and the eligibility criteria given at 40 CFR §723.250.

A specific evaluation process is used for substances used as pesticide inert ingredients that meet the 40 CFR §723.250 definition and criteria.

Substances that are polymeric in nature but do not meet the 40 CFR §723.250 criteria are evaluated under the same general procedures as are used for all inert ingredients.

Inert Ingredient Definitions

Inert Ingredients in Antimicrobial Pesticides –

Inert ingredients in antimicrobial products are evaluated in the same manner as inert ingredients used in other types of pesticide products:

Food Use – e.g., food contact sanitizing solutions, certain hard surface disinfectants

Nonfood Use – e.g., metalworking fluids

Inert Ingredient Definitions

Safener –

A substance that protects a crop from the effects of a pesticide

Since safeners do not have pesticidal activity, they are considered inert ingredients, however, in almost all cases, the data requirements and evaluation process for safeners is equivalent to a pesticide active ingredient.



II. Fragrance Use in Pesticide Products

Fragrances in Pesticides

- Fragrances are used in pesticide products to impart a characteristic scent or odor to the pesticide product formulation
- The predominant usage of fragrances in pesticides is in antimicrobial products
- Fragrances are inert ingredients

Fragrances in Pesticides

- Fragrance products (“finished fragrances”) are typically mixtures of numerous components, which are referred to as fragrance ingredients
- Fragrance product composition information is generally considered proprietary by the fragrance manufacturer and, as such, is treated as Confidential Business Information (CBI) by EPA

Fragrances in Pesticides

- Pesticide registrants purchase fragrance products from fragrance manufacturers for formulation into pesticide products
- Pesticide registrants typically do not have information on the composition of the fragrances they use in their pesticide products

Fragrances in Pesticides

- Pesticide registrants list the fragrance product name and manufacturer on the Confidential Statement of Formula (CSF) form in which information on the composition of the pesticide product is provided to EPA.

U.S. Environmental Protection Agency, DC 20460				A. x • • Basic Formulation • • Alternative Formulation		B. Pg 1 • of 1 • •		See Instructions		
Biopesticides and Pollution Prevention Division (7511C)—Confidential Statement of Formula										
1. Name and Address of Applicant/Registrant (include ZIP code) XYZ Chemical Company, 1234 Water Street, Suite 555, City, State 00000-0000					2. Name and Address of Producer (include ZIP code) QXR Manufacturers, 5678 Raptor Road, Suite 543, City, State, 00000-0000					
3. Product Name Flyaway-Flee Sample: BIOCHEMICAL Active Ingredient					4. EPA Registration No./ File Symbol (if known) 00000-E		5. Team Leader/Team No. Sheryl Reilly-91		6. Country where Formulated United States	
					7. Density (wt/vol or wt/unit) 0.85 g/cc		8. pII 6-7		9. Flash Point/Flame Extension NA	
EPA Use Only	10. Components in Formulation *		11. Supplier Name and Address		12. EPA Registration No. (if there is one)	13. Each Component in Formulation		14. Certified Limits: % by Weight		15. Purpose in Formulation
	Component 1 (95% active ingredient) CAS No 0000-00-0/name		Company Name, Street Address, ZIP		00000-00	a. Amount 110.0 (104.5)**	b. % by Weight 11.0 (10.5)**	a. Upper Limit 11.55 (11.0)**	b. Lower Limit 10.45 (10.0)**	Active Ingredient
	Water: CAS No. 7732-18-5		Company Name (even if local source) Street Address, ZIP			60.0	6.0	6.3	5.7	Diluent
	Component 3 CAS No 00000-00-0 /name		Company Name, Street Address, ZIP			5.0	0.5	0.55	0.45	Antioxidant
	Component 4 CAS No 000-00-0/name		Company Name, Street Address, ZIP			825	82.5	85.0	80.0	Carrier
16. Typed Name of Approving Official Jesse Q. Smith					17. Total wt. 1000 gm		100%			
18. Signature of Approving Official <i>Jesse Q Smith</i>			19. Title of Approving Official Manager, Regulatory Affairs			20. Phone No. (include area code) 000-000-0000		21. Date April 1, 2002		
* Biochemical/Chemical: common chemical name; trade name; CAS No. and CAS name					** Values in () refer to the amount or percent of pure active ingredient in the product, e.g., Flyaway-Flee. The percent in () in column 13b will appear on the product's label as percent active ingredient.					
* Viable microbe: full identifying scientific name; ID No. in recognized collection; biological activity (e.g., CFU/gm)										

Fragrances in Pesticides

- Information on the fragrance product composition is provided directly to EPA by the fragrance manufacturer

Example of Fragrance Composition

Acme Fragrance Company
123 Anywhere St. USA

Pine Scent 123 Compositional Information

<u>Ingredient</u>	<u>% by weight</u>
Ingredient "A"	50
Ingredient "B"	20
Ingredient "C"	10
Ingredient "D"	10
Ingredient "E"	5
Ingredient "F"	1
Ingredient "G"	1
Ingredient "H"	1
Ingredient "I"	1
Ingredient "J"	1

Fragrances in Pesticides

Evaluation of Fragrance

- Factors Considered:
 - Use Pattern of Pesticide Product
 - Concentration of Finished Fragrance in Pesticide Product
 - Composition of Finished Fragrance

Fragrances in Pesticides

Evaluation of Fragrance

Based on the:

- 1) concentration of finished fragrance in pesticide product and
- 2) composition of finished fragrance,

the resultant concentration of each fragrance ingredient in the pesticide product is determined.

Fragrances in Pesticides

Evaluation of Fragrance

Example:

Pine Scent 123 is listed as component on CSF of pesticide product (Flyaway-Free) at a concentration of 2%.

Ingredient “A” of Pine Scent 123 is 50% of finished fragrance.

Ingredient “A” is therefore present (2% x 50%) or 1% in the pesticide product

Fragrances in Pesticides

- The concentration of each fragrance ingredient in the pesticide product is determined as in the above example
- Those fragrance ingredients that are determined to be present in the pesticide product at **0.1%** or greater are treated as discrete inert ingredients

Fragrances in Pesticides

What about those fragrance ingredients that are present in the pesticide product at less than **0.1%** ?

Fragrance ingredients at these levels are deemed acceptable provided they are not of known toxicological concern

Fragrances in Pesticides

Fragrance Ingredient List (FIL):

- FMA Fragrance Ingredient Database (April 16, 2007), referred to as “FIL” is on EPA Web

<http://www.epa.gov/opprd001/inerts/fmaingredient.pdf>

- EPA has conducted an evaluation of the ingredients listed on the FIL to determine their safety for use as fragrance ingredients in pesticides and will soon be issuing an EPA version of the “FIL” list

Fragrances in Pesticides

Fragrance Notification Program:

- Being developed by the Antimicrobial Division of OPP
- Fragrances meeting certain use criteria that contain fragrance ingredients that are all listed on the FIL would be considered acceptable for use in certain antimicrobial products without any additional review.

Contact the Inert Ingredient Assessment Branch

The Inert Ingredient Assessment Branch has a Branch e-mail address to assist in answering questions regarding evaluation and use of fragrances in pesticides and other inert ingredient related inquires:

InertsBranch@epa.gov