

# Challenges in EPA's Inert Ingredient Approval Process under FIFRA

**CPDA Annual Meeting**

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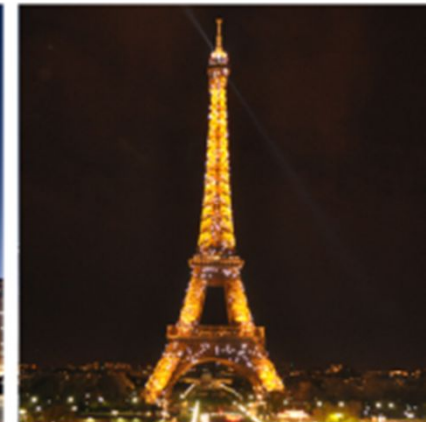
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# Statutory Jurisdiction Over Products

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- Adjuvants and Inerts (Before Pesticide)
- Regulated Under TSCA and OSHA *not* FIFRA
- Adjuvants Require State Registration
- Inerts in Pesticide Products Regulated under FIFRA
- FIFRA Requires Inert Approvals

# Pesticide Ingredients



- **Active Ingredient** – Functions as a Pesticide (*i.e.*, Controls the Pest)
- **Inert (“Other”) Ingredient** – Any purpose other than controlling a pest (*i.e.*, surfactants, solvents, carriers, stabilizers, foaming agents, buffers, dyes, and preservatives)

## ACTIVE INGREDIENT:

Bifenthrin..... 2.0%

OTHER INGREDIENTS:..... 98.0%

TOTAL:..... 100.0%

# Definition of “Inert Ingredient”

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- **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”

- 40 C.F.R. § 152.3

- **Not “unreactive” or “non-toxic”**
- **Not impurities**

# General Characteristics of Inerts

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- Part of the delivery system
- No direct pesticidal affect
- *Can* affect efficacy
- Wide degree of biological activity, including toxicity, ecotoxicity
  - *If an “Active” in one product, can it be an “Inert” in another product?*

# EPA's Regulation of Inerts



- **Listed on Pesticide “CSF”**
  - Chemical Identity/CAS # or Trade Name
  - Supplier Information and Function in Pesticide
  - Supplier Discloses Ingredients Only to EPA for Trade Name
- **Food use inerts require a tolerance or exemption from a tolerance**
- **EPA Inert Lists**
  - Published database of inerts (“**Inert Ingredient Finder**”)
    - <https://iaspub.epa.gov/apex/pesticides/f?p=INERTFINDER:1:0::NO:1::>
  - Categorized Lists of Inert Ingredients (old “lists A, B...”)
    - <https://www.epa.gov/pesticide-registration/categorized-lists-inert-ingredients-old-lists>
  - Previously reviewed trade name ingredients
    - <http://www2.epa.gov/sites/production/files/2014-02/documents/tradenames.pdf>

40 C.F.R. Part 180

## ■ General Approval Categories

- Food and Non-food Use
- Non-food Use Only
- Fragrance Ingredient List (FIL)
  - Pilot program:  
<http://www.epa.gov/opprd001/inerts/fragrancenote.pdf>
  - The list:  
<http://www.epa.gov/opprd001/inerts/fmaingredient.pdf>

# Fragrance Ingredient List

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## ■ Fragrance Ingredient List (FIL)

- Ingredients for use as fragrances
- Non-food use only
- 1,531 ingredients
- Quick link to Fragrance Ingredient List:

<https://iaspub.epa.gov/apex/pesticides/f?p=INERTFINDER:1:::NO:1::>



# Other Inert Ingredient Lists

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- **Minimum Risk**
  - FIFRA Section 25(b)
  - List of minimum risk inert ingredients
    - Old list 4A
- **USDA's National Organic Program (NOP) Ingredients List**
- **Trade Name Inert Ingredients**
  - Adding trade names
    - <http://www2.epa.gov/sites/production/files/2014-02/documents/tradenames.pdf>

# Tolerance Exemptions



## ■ Inert Ingredient Categories

- Subject to Limits and Uses

- § 180.910 **Pre- and post-harvest**

- § 180.920 **Pre-harvest**

- § 180.930 **Applied to animals**

- § 180.940 **Antimicrobial formulations** (Food-contact surface sanitizing solutions)

- § 180.950 **Minimal risk**

- § 180.960 **“Polymers”**

## ■ Inerts approved for food use *also* approved for non-food use unless stated

# Limits and Uses



- 40 CFR section 180.910
- Cetyl alcohol (CAS # 36653-82-4)
- Limit: Not more than 5.0% of pesticide formulation
- Use: Evaporation retardant
- Sodium alkyl naphthalenesulfonates (CAS Nos. 68909-83-1, 68909-84-2, 68909-82-0, 27213-90-7, 26264-58-4, 27178-87-6, 111163-74-7, 908356-16-1, 25417-20-3, ....etc.)
- Limited to no more than 30% by weight in pesticide end-use products
- Use: Surfactants, related adjuvants of surfactants

# Limits and Uses: Low Risk Polymers

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- 40 CFR section 180.960
- Meet definition of a polymer and the criteria specified for defining a low-risk polymer in 40 CFR section 723.50
- Butadiene-styrene copolymer, “None”
- Polyvinyl acetate - polyvinyl alcohol copolymer, minimum number average molecular weight (in amu), 50,000. CAS # 25213-24-5

# Submit Application If Inert Not Approved



- Pesticide Registration Improvement Extension Act (PRIA 3)
- Ten Inert PRIA 3 Categories (2016-17)

EPA No.	Action	Decision Review Time (Months)	FY'17 & FY'18 Registration Service Fee (\$)
I001	Approval of new food use inert ingredient	12	19,845
I002	Amend currently approved inert ingredient tolerance or exemption from tolerance; new data	10	5,513
I003	Amend currently approved inert ingredient tolerance or exemption from tolerance; no new data	8	3,308
I004	Approval of new non-food use inert ingredient	8	11,025
I005	Amend currently approved non-food use inert ingredient with new use pattern; new data	8	5,513
I006	Amend currently approved non-food use inert ingredient with new use pattern; no new data	6	3,308
I007	Approval of substantially similar non-food use inert ingredients when original inert is compositionally similar with similar use pattern	4	1,654
I008	Approval of new polymer inert ingredient, food use	5	3,749
I009	Approval of new polymer inert ingredient, non-food use	4	3,087
I010	Petition to amend a tolerance exemption descriptor to add one or more CASRNs; no new data	6	1,654

- **Same but Different than Actives**
  - Assumed less hazardous than active ingredients
  - Not necessarily intended to have biological activity
- **Flexible – “risk assessment objectives approach”**
  - Use existing data from the open literature
  - Approvals by other agencies (FDA, EPA TSCA PMN program, etc.)
  - Modeling, etc.

# Inert Ingredient Data Compensation

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- **Support tolerances or tolerance exemptions (*i.e.*, food use data)**
  - Data compensation (15 years)
  - Exclusive use data rights (10 years)
- **Non-food use**
  - Limited
  - Submitted in response to test orders as part of the Endocrine Disruptor Screening Program (EDSP)

# EPA Inert Group (in Registration Division)



## ▪ Guidance documents

- Establishment of a New/Amended Food Use Inert Ingredient Tolerance or Tolerance Exemption
- Low Risk Polymer Submissions
- Requesting New Non-food Use Inert Ingredients

## ▪ Available tools to determine status of inert

- “Inert Finder” searches by chemical name or CASRN
  - <http://iaspub.epa.gov/apex/pesticides/f?p=101:1>
- Trade Name – unfortunately limited
  - <http://iaspub.epa.gov/apex/pesticides/f?p=inertfinder:mixtures>
  - EPA reluctant to confirm if components of a trade name/mixture are approved (Confidential Business Information)

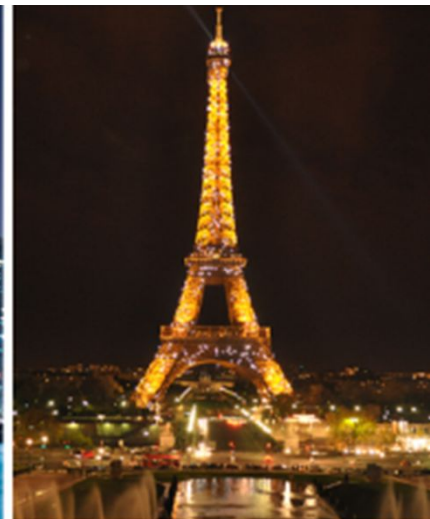


# Trade Name Submissions

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- Letters to EPA's Inert Branch
- Not Subject to PRIA
- Submit Trade Name, Approval Status of Ingredient(s) and CAS #s, Name of Manufacturer
- Takes 1-2 Months
- Listed Internally for CSF Reference and Publicly in Inert Finder?
  - Can Amend Trade Name
  - Can Amend Ingredient in Trade Name Mixture
  - Defined Mixture – Add Alternative CAS #?



# THANK YOU

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