

Challenges in EPA's Inert Ingredient Approval Process under FIFRA

CPDA Annual Meeting

July 17, 2018

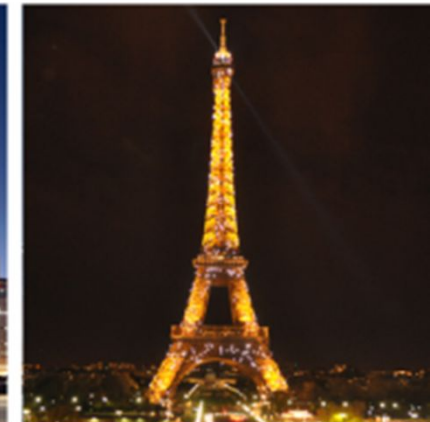
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Statutory Jurisdiction Over Products



- 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”



- **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



- 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



■ 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



- **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



- 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



- **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

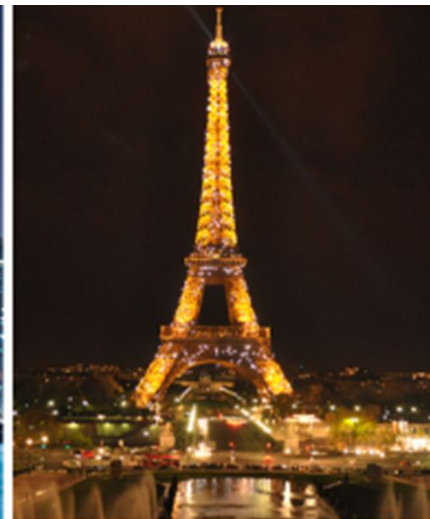
▪ Available tools to determine status of inert

- “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



- 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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