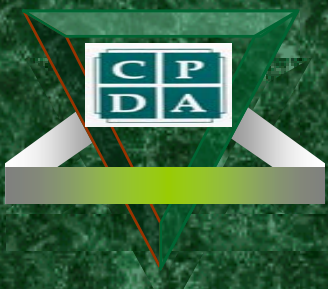




# 2010 EPA/CPDA Symposium on Inert Ingredients

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## Formulator/distributor perspective

*I. Definition*

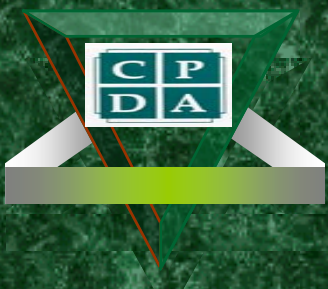
*II. Regulatory Importance*

*III. Detail/Function in Formulation*

*IV. Supply Chain*

*V. Compliance Approval for Purchase/Use*





## Definition as per EPA

### A. *Inert Ingredient:*

An inert ingredient means 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. 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 can contain more than one inert ingredient, but federal law does not require that these ingredients be identified by name or percentage on the label. Only the total percentage of inert ingredients is required to be on the pesticide product label.

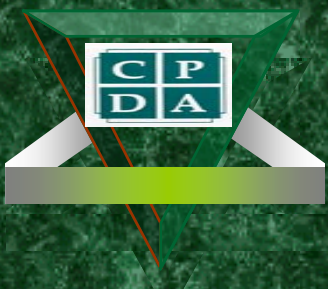
### B. *Non-Food Use Inert Ingredients:*

Inerts permitted for use in pesticide products applied to non-food use sites, such as ornamental plants, highway right-of-ways, rodent control, etc.

### C. *Food-Use Inert Ingredients* —

*The only inert ingredients approved for use in pesticide products applied to food are those that have either tolerances or tolerance exemptions in the Code of Federal Regulations (CFR), 40 CFR part 180 (the majority are found in sections 180.910 – 960). The most up-to-date tolerances and tolerance exemptions are found in the [electronic CFR \(e-CFR\)](#). Please note that many food-use inert ingredients have use limitations and restrictions.*





**C. Minimal Risk Section 25(b) List 4(a):**

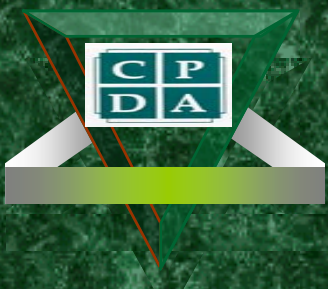
*Are approved for use in minimal risk pesticide products under FIFRA Section 25(b); they are called “4A” inert ingredients.*

**D. USDA’s National Organic Program (NOP) Inert List:**

*Stakeholders interested in finding inert ingredients that are eligible for use in USDA’s NOP program. Here is a brief overview of [EPA’s role in USDA’s National Organic Program](#).*

**E. Note:** *The List Category policy, created in 1987, has now served its purpose as a tool for prioritizing the evaluation of chemicals. Now that [reassessment of food tolerances/tolerance exemptions](#) under the Food Quality Protection Act (FQPA) is complete, there are no longer inerts classified as List 1, 2, or 3. All-food use inert ingredient tolerances and tolerance exemptions are considered to be safe when used according to the conditions set forth in the CFR's text and tables. As noted above, the “4A” category is still being used for the purposes of FIFRA Section 25(b), and USDA is still utilizing “List 4” for their National Organic Program. For non-food inert ingredients, the 1987 List Category policy remains pertinent (including labeling) for those identified as “List 1” (toxicological concern). For informational purposes you can still access [EPA’s old inert list categories](#).*





# Regulatory Importance

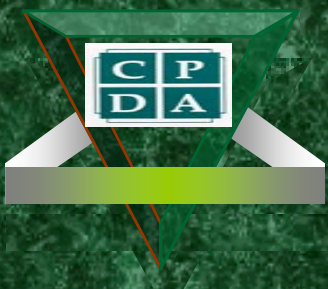
## *Toxicological Characteristics*

- 1. Eye Irritation*
- 2. Inhalation*
- 3. Dermal Exposure*
- 4. Oral*
- 5. Cleared for Food or Non Food uses or both*
- 6. Signal Word*
- 7. Flammable/Combustible*
- 8. MSDS*
- 9. Approval Status from the Inerts Branch >>LOA*

## *Function and Behavior in Formulation*

- 1. Class of Chemistry*
- 2. History of development, use ( U.S. & Intl'L)*
- 3. Details of composition makeup ( mole, %, etc)*
- 4. Function of wide variety of active ingredients*





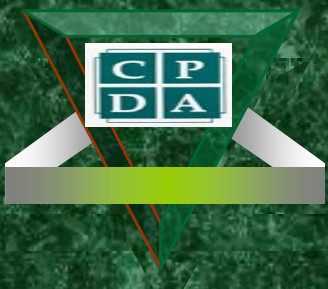
## Supply Chain

- A. Where Produced*
- B. Package Size*
- C. Order/Response Time ( FOB Plant)*
- D. Price and Terms*
- E. Sample for evaluation in formulation and product testing*

## Compliance Approval for Purchase/use:

- A. Approved for use formulation*
- B. Submit to EPA for use in ALT CSF*
- C. Upon approval from EPA purchase and use in formula*





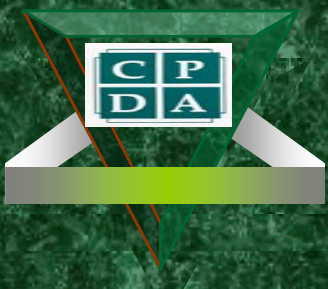
## Helpful Inert Websites

*Inert Ingredient Assessment Branch (IIAB) at  
[inertsbranch@epa.gov](mailto:inertsbranch@epa.gov)*

*Inert Ingredients Permitted in Pesticide Products*

- <http://www.epa.gov/opprd001/inerts/lists.html>





***Thank You!!***

