Product Chemistry Data
Requirements for Biochemical Pesticides

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Product Chemistry Data Requirements

- First, most important step in science review
- Required for ALL products
- Integrated System vs. Non-integrated System
- Biochemical Pesticide Product Analysis Data Requirements [Table in 40 CFR 158.690 (b)]
**Product Chemistry Data Requirements**

- Product Identity and Composition
- Manufacturing Process
- Discussion of the Formation of Impurities
- Five-batch Preliminary Analysis
- Certified Ingredient Limits
- Analytical Methods
- Physical and Chemical Properties

**NOTE:** ***Read the Footnotes***
Product Identity and Composition

- Data/Information regarding the active ingredient (a.i.) formulated product (TGAI, MP, EP)
  - Chemical Name (IUPAC and synonyms)
  - Structure, CAS No., Source, Manufacturer
  - MSDS, Other literature sources

- Other (inert) Ingredients*
  *present in the formulated product
Manufacturing Process

- Information of ALL Starting Materials - MSDS, Source/Manufacturer
- Amounts of each ingredients (lbs, kg) used in a typical batch
- Complete description of the manufacturing process, including all chemical reactions (if any)
- Flow chart
- QA/QC procedures
Discussion of the Formation of Impurities

- Identify and discuss impurities present in formulated product (TGAI & EP) ≥ 0.1% by weight
  - carryover from starting materials
  - side reactions amongst a.i. and other ingredients
  - degradation products
  - migration from packaging or formulating equipment

- Any impurities of potential/actual toxicological significance
Five-batch Preliminary Analysis

- Required for each TGAI in the formulated product
- Identify and quantify a.i.(s) and other/impurities
- Conducted at point in production/formulation process at which no further chemical reactions are intended.
Certified Ingredient Limits

- Legally-binding range of concentrations for each ingredient in formulated product
- Based upon five-batch analysis
- May also be proposed by registrant based on wt %s of added ingredients
  - must consider variability due to manufacturing process, stability of product on storage
  - include an explanation/rationale for proposed limits
**Certified Ingredient Limits**

Certified limits should be within the ranges established in the table found in 40 CFR 158.175 (b)(2)

<table>
<thead>
<tr>
<th>Nominal Concentration</th>
<th>Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>N &lt;= 0.1%</td>
<td>+/- 10%</td>
</tr>
<tr>
<td>N &gt;=1% to &lt;20%</td>
<td>+/- 5%</td>
</tr>
<tr>
<td>N &gt;=20 to 100%</td>
<td>+/- 3%</td>
</tr>
</tbody>
</table>
Analytical Methods

- Not an “Enforcement Method”
- Method Used to Conduct Five-batch Preliminary Analysis
- Required Data:
  - Complete description of method
  - Precision and Accuracy Data
  - Representative chromatograms/GC-MS
  - Some validating data
# Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Property</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>pH</td>
</tr>
<tr>
<td>Physical State</td>
<td>Stability</td>
</tr>
<tr>
<td>Odor</td>
<td>Oxidizing/Reducing Action</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Flammability</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>Explodability</td>
</tr>
<tr>
<td>Density, Bulk Density, Specific Gravity</td>
<td>Storage Stability</td>
</tr>
<tr>
<td>Solubility</td>
<td>Viscosity</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>Miscibility</td>
</tr>
<tr>
<td>Dissociation Constant</td>
<td>Corrosion Characteristics</td>
</tr>
</tbody>
</table>
Physical and Chemical Properties

Table in 40 CFR 158.190 (a) *

*Read the Footnotes
Guidelines/Protocols

- Subdivision M vs. OPPTS Harmonized Guidelines
- GLN 151 Series vs. OPPTS 810 Series


- 830.1000 Background for Product Properties Test Guidelines
QUESTIONS?