

NAFTA Technical Working Group on Pesticides
Grupo de Trabajo Técnico del TLCAN sobre plaguicidas
Groupe de travail technique de l'ALENA sur les pesticides

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) $>$ or $= 0.1\%$ 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 TGA I 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 wgt %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)

<u>Nominal Concentration</u>	<u>Limits</u>
$N \leq 0.1\%$	+/- 10%
$N \geq 1\%$ to $< 20\%$	+/- 5%
$N \geq 20$ to 100%	+/- 3%



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

Color

Physical State

Odor

Melting Point

Boiling Point

Density, Bulk Density,
Specific Gravity

Solubility

Vapor Pressure

Dissociation Constant

Oct/Water Part. Coeff.

pH

Stability

Oxidizing/Reducing Action

Flammability

Explodability

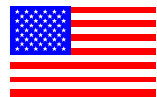
Storage Stability

Viscosity

Miscibility

Corrosion Characteristics

Dielectric Breakdown Volt.



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

www.epa.gov/docs/OPPTS_Harmonized/830_Product_Properties_Test_Guidelines/Series/

- 830.1000 Background for Product Properties Test Guidelines



QUESTIONS?

