

Common deficiencies associated with product chemistry and acute toxicity submissions (10/2/24)

This document contains common deficiencies associated with product chemistry and acute toxicity data submissions used to support conventional and antimicrobial pesticide registration. The goal of this document is to identify these common issues for applicants to increase submission quality. The list is meant to communicate common data deficiencies the divisions encounter when reviewing product chemistry and acute toxicity data; see the [product chemistry](#) and [acute toxicity](#) guidelines for detailed information on study design and the 40 CFR part 158 data requirements tables [eCFR :: 40 CFR Part 158 Subpart D -- Product Chemistry](#) and [eCFR :: 40 CFR Part 158 -- Data Requirements for Pesticides](#).

Common deficiencies associated with product chemistry data submissions

Group A data

- OCSPP Harmonized Test Guideline 830.1550: Product Identity and Composition
 - Information is not provided on the active ingredient (*e.g.*, structure, Mol. Wt., etc.) (referencing the proposed CSF is not sufficient).
 - The EPA Reg # is not included on the CSF for antimicrobial preservatives.
- OCSPP Harmonized Test Guideline 830.1600: Description of Materials Used to Produce the Product
 - Safety Data Sheets (SDS's) are not submitted for the ingredients used in the formulation of the end use product and production of the technical active ingredient.
- OCSPP Harmonized Test Guideline 830.1620: Description of Production Process
 - A general description of the process is provided without inclusion of information on chemical reactions occurring in the process.
- OCSPP Harmonized Test Guideline 830.1650: Description of Formulation Process
 - Ingredients listed on the formulation process do not match with the proposed basic CSF.
 - Formulation process is not described and instead a statement like the following is included: "ingredients listed on the CSF are mixed and the process is proprietary information."
- OCSPP Harmonized Test Guideline 830.1670: Discussion on Formation of Impurities
 - In technical product/manufacturing use product submissions, the mechanism/origin of the impurity is not provided (*e.g.*, how the impurity is formed is not included).
 - The structure or the names of the impurities are not provided correctly.
 - The structure does not match with the chemical name of the impurity.
- OCSPP Harmonized Test Guideline 830.1700: Preliminary Analysis
 - Five batch analysis results do not match with the proposed CSF (basic /alternate).
 - Analytical validation with respect to accuracy data for technical/manufacturing use products is not provided.
 - The structure or the names of the impurities are not provided correctly.
 - The structure does not match with the chemical name of the impurity.
- OCSPP Harmonized Test Guideline 830.1750: Certified Limits
 - Non-standard certified limits are provided without justification.
- OCSPP Harmonized Test Guideline 830.1800: Enforcement Analytical Method
 - The submitted enforcement analytical method (EAM) is not properly validated for linearity, precision & accuracy.
 - Linearity curve is missing

- EAM is cited for a different product (the EAM is a product specific data requirement).

Group B data:

- OCSPP Harmonized Test Guideline 830.6313: Stability to Normal and Elevated Temperatures, Metals, and Metal Ions; OCSPP Harmonized Test Guideline 830.6317: Storage Stability; OCSPP Harmonized Test Guideline 830.6320: Corrosion Characteristics
 - Data are only submitted for one or two of these guidelines instead of addressing all three.
- OCSPP Harmonized Test Guideline 830.7000: pH
 - There is an excessive pH range (>1 pH unit or >2 pH units bracketing a neutral pH range ((i.e., pH 6.0 to 8.0)) given in Box #8 of the CSF.
- OCSPP Harmonized Test Guideline 830.6314: Oxidation/Reduction: Chemical Incompatibility
 - Data are submitted for oxidation only.
- OCSPP Harmonized Test Guideline 830.7300: Density/Relative Density/Bulk Density
 - A range is given instead of single value in Box #7 of the CSF.

Common deficiencies associated with acute toxicity data submissions

- OCSPP Harmonized Test Guideline 870.1100: Acute Oral Toxicity
 - A full explanation for the initial dose selection is not submitted when using the Up-And-Down Procedure.
- OCSPP Harmonized Test Guideline 870.1300: Acute Inhalation Toxicity
 - The mass median aerodynamic diameter (MMAD) for aerosol concentrations is not of a particle size range between 1–4 µm.
- OCSPP Harmonized Test Guideline 870.2400: Acute Eye Irritation
 - The *in vitro* rabbit study includes eye pre-treatment.
- R300 and R301 submissions
 - Data matrix for acute toxicity data do not match the MRIDs identified in the cited “me too” product.
- Data waivers for acute toxicity studies are not done on a guideline-by-guideline basis and do not include an MRID with the waiver and the full rationale/justification for the waiver.