|  |  |  |  |
| --- | --- | --- | --- |
| **Primary Reviewer:** |  |  | **Date:** |
|  | ***[ Name, title, and aff*** | ***iliation]*** |  |
| **Secondary Reviewer:** |  |  | **Date:** |
|  | ***[Name, title, and affi*** | ***liation]*** |  |
| **[FOR JOINT REVIEWS ONLY- *otherwise delete*]** |
| **Approved by:** |  |  | **Date:** |
|  | ***[Name, title, and affi*** | ***liation]*** |  |

**DATA EVALUATION RECORD**

***[*NOTE TO REGISTRANT/APPLICANT: PLEASE DISREGARD *the header, footer, and reviewer information; reviewers’ comments in the conclusion section; and study classification statement. These sections are for EPA, PMRA, and OECD data entry only and will be populated upon Agency review.]***

— **THIS DER TEMPLATE SHOULD ONLY BE USED FOR EPA DATA SUBMISSIONS** —

### **STUDY TYPE:** Product Identity, Manufacturing Process, Discussion of Formation of Unintentional Ingredients, Analysis of Samples, Certification of Limits, and Physical and Chemical Properties

U.S. EPA OCSPP Guideline: 885.1100, 885.1200, 885.1300, 885.1400, 885.1500,

830.6302, 830.6303, 830.6304, 830.6313, 830.6317,

830.6319, 830.6320, 830.7000, 830.7100, 830.7300

PMRA Data Code: M2.1M2.12

OECD Data Code: IIM 1, IIM 2, IIM 3, IIM 4, IIM 5.3.5, IIIM 1, IIIM 2,

IIIM 3, IIIM 4, IIIM 5

**TEST MATERIAL (PURITY):** *[use name of material tested as referred to in the study and include its*

*potency, biological activity or concentration per unit weight or volume (% active ingredient name in parenthesis)]*

**SYNONYMS:** *[other names, code names and acronyms]*

**CITATION(S):** Author(s). *[Year]*. Study Title. Laboratory name and address. Laboratory report number, full study date. Unpublished *[OR if published, list Journal name, vol.:pages]*. MRID No. *[no hyphen],* PMRA *[number if applicable]*.

*[NOTE: If multiple study reports were submitted, insert individual citation for each MRID No. here and under the title heading for each portion of data with a different citation. Use the same format as above]*

**SPONSOR:** *[Name and address of Study Sponsor - indicate if different from Applicant]*

**EPA DER Template Version 2.1 (October 2011)**

**COMPLIANCE:** Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided. The study was *[not]* conducted in compliance with GLP [40 CFR § 160]. *[Discuss deviations from regulatory requirements]*.

*[If no CBI data is submitted]:* This DER does not contain FIFRA CBI.

*[If CBI data is submitted:* This DER contains FIFRA CBI, however, the data claimed as CBI are excerpted from the DER and placed in ***Appendix A. Confidential Business Information***.

**EXECUTIVE SUMMARY:** [Provide a brief, concise summary of the product identity and chemistry data (with the exception of CBI)]

The product identity and chemistry studies are classified as *[acceptable, unacceptable (why)]*. The studies were *[not]* conducted in accordance with the recommendations for product identity and chemistry *[Differentiate which study types did not follow guideline recommendations and if it does not satisfy the requirement. Concisely list only major deficiencies or refer to deficiency section. Do not include any CBI in listing deficiencies.]*

**CLASSIFICATION: [ACCEPTABLE / UNACCEPTABLE / SUPPLEMENTAL, but UPGRADEABLE]**

***(Use the following headings if a study report was submitted, otherwise delete. Specific headings for alternative data (i.e. waiver request, published study, and published literature, mini literature review) are available on the last section of the template. If a combination of study reports or alternative data is submitted then include the alternative data in the applicable sections to fulfill the respective data requirement requested to be waived.)***

# (NOTE: Guidance on populating the DER are reflected as [red italics]- please replace this text with requested data. The guidance language should be deleted upon completion of the DER template. For best preparation of data submission- refer to respective OSCPP Guideline and use both the DER template and guideline criteria. However, the overall structure of the templates should not be altered and data evaluation elements reflected in black text should not be deleted (i.e. headings, test parameters, tables, results section). Also- for data elements of the template that are not applicable- insert “not applicable.” For unavailable information- insert “not available” with a brief explanation for the omission of data.)

## PRODUCT IDENTITY (OCSPP 885.1100)

**CITATION(S):** Author(s). *[Year]*. Study Title. Laboratory name and address. Laboratory report number, full study date. Unpublished *[OR if published, list Journal name, vol.:pages]*. MRID No. *[no hyphen],* PMRA *[number if applicable]*.

**Deviations from guideline:** *[Indicate if there were any deviations from the test procedures and reporting requirements stated in guideline(s).This information is usually stated in the Good Laboratory Practices (GLP) and Quality Assurance (QA) statements in the introductory section of the study report. State the reasons for such deviations and its overall effect on the validity of the study.]*

1. **PRODUCT INFORMATION:**

**Product Name: Trade Name:**

## Name and Address of Applicant:

**Name and Address of Manufacturing Plant: Name and Address of Formulating Plant:**

**Active Ingredient: [include *genus, species, subspecies, isolate, strain ID No.]*** *[MCPAs should be expressed percentage of weight and as viable organisms per unit weight or volume (e.g. colony forming units/gram or cfu/g) or international units of potency per unit weight.]* **Chemical name:**

**Common Names:**

## Deposition number in a recognized culture collection:

**CAS No.: *[if applicable]* Molecular Weight: *[if applicable]* Chemical Formula: *[if applicable]***

**Regulatory Status:** *[Is the a.i. currently registered with EPA (include EPA Reg. No.) or registered in other country (include country’s regulatory registration number/code)? Is there an existing FFDCA exemption from the requirement of a tolerance for residues? Codex MRL ?]*

1. **INTENTIONALLY ADDED INERT INGREDIENTS: *[if applicable]***

***See Appendix A. Confidential Business Information — Section I. Product Identity***

1. **CHARACTERIZATION OF THE MPCA:**
	1. **Taxonomic designation:** *[the taxonomic designation (taxonomic position, serotype, strain, or any other appropriate designation) should be based on current international standards and be supported by technical data, including test methods, rationale, criteria (i.e., the morphological, biochemical, analytical (physical, chemical), serological, or other identification means) for identification of the MPCA in order to substantiate this designation. It is recognized that the level of sophistication of taxonomic methodology varies with the type of microorganism. The methods used to identify and classify the microorganism should reflect the best technology and*

methodology available for members of that particular group of microorganisms. Assurance that the methods used and the data submitted are capable of demonstrating that the microbial pesticide used in the field is the same as that which was tested for safety. Identification should be made to the lowest epithetic level possible (e.g., strain, subspecies, forma specialis]

## Alternatives / synonyms / superseded names associated with the microorganism:

[required information]

**iv) Strain origin:** [such as environmental, clinical, food isolate and culture collection; description of isolation procedure, including exact geographical origin of the MPCA isolate; and history of the strain during its development]

1. **Natural occurrence of the microorganism:** *[include information on its geographical distribution, preferred or obligate hosts, habitats, ecological niches and level of natural occurrence in the environment]*
2. **Mode of Action:** *[Its toxicity, pathogenicity, type of antagonism to target hosts, infective/toxic dose, transmissibility, etc. (if known). Any known or potential hazard (such*

as infectivity) to mammals (including humans), the environment, and nontarget species should be discussed.]

1. **Pest host range:** *[Include spectrum of pests susceptible to MPCA]*
2. **Life cycle:** *[If applicable- include the various forms of the MPCA that may occur and any significant differences in pesticidal, pathogenic or toxigenic characteristics of the various forms]*
3. **Differences in morphological, physiological, biochemical, pesticidal or resistance characteristics from naturally occurring microorganism:** *[If applicable- describe if such characteristics are different from the classical description of the species or microorganism]*

[NOTE: For guidance in compiling relevant information from multiple references/scientific literature- see format in “Review of Literature” section on last page on template. Include all reference citations.]

1. **History of use:** *[MPCA and/or closely related strains or species]*

## MANUFACTURING PROCESS (OCSPP 885.1200)

**CITATION(S):** Author(s). *[Year]*. Study Title. Laboratory name and address. Laboratory report number, full study date. Unpublished *[OR if published, list Journal name, vol.:pages]*. MRID No. *[no hyphen],* PMRA *[number if applicable]*.

## DESCRIPTION OF PRODUCTION AND FORMULATION PROCESS:

***See Appendix A. Confidential Business Information — Section II. Manufacturing Process***

1. **QUALITY CONTROL/QUALITY ASSURANCE MEASURES:**

***See Appendix A. Confidential Business Information — Section II. Manufacturing Process***

1. **DISCUSSION OF FORMATION OF UNINTENTIONAL INGREDIENTS (OCSPP 885.1300):**

***See Appendix A. Confidential Business Information — Section III. Discussion of Formation of Unintentional Ingredients***

1. **ANALYSIS OF SAMPLES (OCSPP 885.1400)**

**CITATION(S):** Author(s). *[Year]*. Study Title. Laboratory name and address. Laboratory report number, full study date. Unpublished *[OR if published, list Journal name, vol.:pages]*. MRID No. *[no hyphen],* PMRA *[number if applicable]*.

**Deviations from guideline:** *[Indicate if there were any deviations from the test procedures and reporting requirements stated in guideline(s).This information is usually stated in the Good Laboratory Practices (GLP) and Quality Assurance (QA) statements in the introductory section of the study report. State the reasons for such deviations and its overall effect on the validity of the study.]*

***[Provide information on analysis of samples from five representative batches of product.]***

[The amount of active ingredient/MPCA will normally be expressed in recognized units of biological activity per unit weight or volume. The analytical methodologies used to determine the identity and verify biological activity must be described in detail, including standardization, sensitivity, reproducibility and statistical validity. Representative data to validate the assay must be submitted (e.g. SOPs, laboratory protocols, certificates of analysis, SOPs, QA/QC measures and results, manufacturer kit information].

[Claims concerning the nature and level of microbial contaminants must also be supported by data from five production batch analyses. Details and validation of methods used to assay for microbial contamination must be submitted. Since the nature of microbial formulations presents unique problems with respect to analysis for contaminating microorganisms, it is important that the validity, specificity, sensitivity and reliability of the detection method be reported.]

The validation data are shown in Table *[x]*. *[If applicable]*

|  |
| --- |
| **Table** *[x]***. Method validation data** |
| Component | Method Type / ID | Anal. Range (w %) | Retention time (min) | Recovery (%) | RSD (%) | LOD (%) | MA1 |
| Active |  |  |  |  |  |  |  |
| Impurity 1 |  |  |  |  |  |  |  |
| Impurity 2 |  |  |  |  |  |  |  |
| Impurity 3 |  |  |  |  |  |  |  |
| Impurity 4 |  |  |  |  |  |  |  |
| Impurity 5 |  | Validation data not required (level <0.1 in 5 batches of TGAI) |  |
| Solvent | GC/FID |  |  |  |  |  |  |
| Chloride ion | Ion chrom. | Validation data not required (well established method). |  |
| Sodium ion | atomic | Validation data not required (well established method). |  |

|  |
| --- |
| **Table** *[x]***. Method validation data** |
| Component | Method Type / ID | Anal. Range (w %) | Retention time (min) | Recovery (%) | RSD (%) | LOD (%) | MA1 |
|  | absorption |  |  |
| Water | Karl Fischer titration | Validation data not required (well established method). |  |
| 1 MA = Method acceptability; Y = acceptable; N = not acceptable (see deficiency).*[If method is not considered valid- enter explanations to table (if any) in this row.]* |

1. **CERTIFICATION OF LIMITS (OCSPP 885.1500)** *[Do not include any CBI data in this section]*

**CITATION(S):** Author(s). *[Year]*. Study Title. Laboratory name and address. Laboratory report number, full study date. Unpublished *[OR if published, list Journal name, vol.:pages]*. MRID No. *[no hyphen],* PMRA *[number if applicable]*.

The certifications of the upper and lower limits for the active and inert ingredient concentrations in *[product name or TGAI, MP, or EP name]* (expressed as weight percent) are presented in Table *[x]* in ***Appendix I. Confidential Business Information — Section V. Certification of Limits***.

## ENFORCEMENT ANALYTICAL METHOD (OCSPP 830.1800):

**CITATION(S):** Author(s). *[Year]*. Study Title. Laboratory name and address. Laboratory report number, full study date. Unpublished *[OR if published, list Journal name, vol.:pages]*. MRID No. *[no hyphen],* PMRA *[number if applicable]*.

**Deviations from guideline:** *[Indicate if there were any deviations from the test procedures and reporting requirements stated in guideline(s).This information is usually stated in the Good Laboratory Practices (GLP) and Quality Assurance (QA) statements in the introductory section of the study report. State the reasons for such deviations and its overall effect on the validity of the study.]*

[Detailed methodologies and validated data related to detection, identification, enumeration and/or quantification of the active ingredient, related metabolites, impurities, contaminants or other ingredients may be required. The registrant should consult with the Agency regarding the nature of specific tests that may be required for certain types of the microbial pesticides. These might include: methodologies to distinguish the MPCA from other closely related strains, monitoring of the active ingredient or relevant metabolite during production, quantification of doses for infectivity/ toxicity testing, and enumeration of viable forms of the MPCA in tissues.

### An analytical method was provided for the determination of the *[TGAI] [and/or] [impurities of concern]*. The method was [not] assessed to be specific, precise and accurate for use as an enforcement analytical method.

1. **SUMMARY OF PHYSICAL AND CHEMICAL PROPERTIES (OCSPP 830.6302, 830.6303, 830.6304, 830.6313, 830.6317, 830.6319, 830.6320, 830.7000, 830.7100, 830.7300)**

**CITATION(S):** Author(s). *[Year]*. Study Title. Laboratory name and address. Laboratory report number, full study date. Unpublished *[OR if published, list Journal name, vol.:pages]*. MRID No. *[no hyphen],* PMRA *[number if applicable]*.

**Deviations from guideline:** *[Indicate if there were any deviations from the test procedures and reporting requirements stated in guideline(s).This information is usually stated in the Good Laboratory Practices (GLP) and Quality Assurance (QA) statements in the introductory section of the study report. State the reasons for such deviations and its overall effect on the validity of the study.]*

[The following physical and chemical properties, as applicable, for technical active ingredients and EPs are required:

The physical and chemical characteristics for *[TGAI, MP, or EP]* are presented in Table *[x]*.

|  |
| --- |
| **TABLE** *[x]***. Description of Chemical and Physical Properties for *[Product formulation, TGAI, MP, or EP]*** |
| **OCSPP****Guideline No.** | **Property** | **Result** | **Method/Reference** |
| 830.6302 | Color |  |  |
| 830.6303 | Physical State |  |  |
| 830.6304 | Odor |  |  |
| 830.6313 | Stability to normal and elevated temperatures, metals, and metal ions |  |  |
| 830.6317 | Storage Stability |  |  |
| 830.6319 | Miscibility |  |  |
| 830.6320 | Corrosion characteristics |  |  |
| 830.7000 | pH | *[#] (include range)* |  |
| 830.7100 | Viscosity | *[#] (include range)* |  |
| 830.7300 | Density/relative density (specific gravity) | *[#] (include range)* |  |

*[Refer to 40 CFR §158.2120(d) test notes to determine when data requirements might not apply. If a data requirement does not apply- include why (based on test note justification) and include CFR citation .] [Include the method used (such as a SOP or ASTM number) or the reference used. If published references are used as a source, they should be included in an attachment.]*

## CONCLUSION

1. **STUDY AUTHOR CONCLUSION:** *[Summarize the study author’s conclusions]*
2. **REVIEWER’S COMMENTS:** *[Note if in agreement with study author. Provide a few brief concluding statements on the overall acceptability of the study report(s) and list any data gaps or deficiencies and note whether they are considered “minor” or “major”.] Do not include any CBI data in this section. If reviewer comments on any specific CBI data must be made or if data deficiencies are found in CBI claimed data, include the following statement:* ***For any reviewer comments and/or data deficiencies that contain CBI- See Appendix A. Confidential Business Information — Section VIII. Conclusion***
3. **DEFICIENCIES:** *[List each deficiency with the required data to resolve the deficiency OR if no data can be provided to satisfy the deficiency.]*
4. **CLASSIFICATION: [ACCEPTABLE / UNACCEPTABLE / SUPPLEMENTAL, but UPGRADEABLE]**
5. **REFERENCES** *[Provide references that were cited in the study report: methods, studies in the open literature, references to other study reports in the submission or other studies conducted by the applicant. Submission of these documents as an appendix to the study report is recommended, however relevant data and supporting statements for conclusions (especially scientific rationales) made for each data requirement should be excerpted and cited from those documents and inserted into the DER. Examples of information in appendices would be MSDS for intentionally added inert ingredients, or company SOPs referenced in manufacturing process or QC descriptions.].*

**APPENDIX A. CONFIDENTIAL BUSINESS INFORMATION**

[If applicable- otherwise delete appendix]

## PRODUCT IDENTITY (OCSPP 885.1100):

**CITATION(S):** Author(s). *[Year]*. Study Title. Laboratory name and address. Laboratory report number, full study date. Unpublished *[OR if published, list Journal name, vol.:pages]*. MRID No. *[no hyphen],* PMRA *[number if applicable]*.

**Deviations from guideline:** *[Indicate if there were any deviations from the test procedures and reporting requirements stated in guideline(s).This information is usually stated in the Good Laboratory Practices (GLP) and Quality Assurance (QA) statements in the introductory section of the study report. State the reasons for such deviations and its overall effect on the validity of the study.]*

## B. INTENTIONALLY ADDED INERT INGREDIENTS:

*[Use the following format for each inert ingredient]*

## Chemical Name: Trade Name:

**CAS No.:** *[Verify correct CAS No.]*

## Common Names: Molecular Formula: Molecular Weight:

**Name and Address of Manufacturing Plant:**

**Purpose in Formulation:** *[e.g.:* surfactant, emulsifier, preservative, diluent)

**Regulatory Status:** *[Is the inert ingredient approved by EPA? If this product is for feed or food use, all inert ingredients* ***MUST*** *have appropriate clearance; verify in 40 CFR part 180 (the majority are found in sections 180.910 – 960). Is there an existing FFDCA exemption from the requirement of a tolerance for residues of the inert ingredient? Is there an existing Codex MRL? NOTE: Many food-use inert ingredients have use limitations and restrictions.]*

**Toxicological Information:** *[Note any toxicological information disclosed in catalog, supplier, % purity, and impurities of toxicological concern are identified appropriately.]*

*[If the toxicological characteristics of an ingredient in the formulation suggest a potential for human health or environmental hazard, a rationale should be submitted as to why its use in the formulation is not considered to pose a significant risk.]*

*[NOTE: check for the presence of food allergen inert ingredients in products for direct application to food crops.]*

Corresponding MSDS sheets were *[not]* provided for each inert ingredient.

*[The Applicant should provide Material Safety Data Sheets (MSDS) with manufacturer's specifications and related technical information on all intentionally added inert ingredients as an attachment to the study.]*

## MANUFACTURING PROCESS (OCSPP 885.1200)

**CITATION(S):** Author(s). *[Year]*. Study Title. Laboratory name and address. Laboratory report number, full study date. Unpublished *[OR if published, list Journal name, vol.:pages]*. MRID No. *[no hyphen],* PMRA *[number if applicable]*.

**Deviations from guideline:** *[Indicate if there were any deviations from the test procedures and reporting requirements stated in guideline(s).This information is usually stated in the Good Laboratory Practices (GLP) and Quality Assurance (QA) statements in the introductory section of the study report. State the reasons for such deviations and its overall effect on the validity of the study.]*

## DESCRIPTION OF PRODUCTION AND FORMULATION PROCESS:

[Describe process step-wise, including:

General characterization of the process (whether it is batch or continuous) and quantity produced.

The individual steps in the process should be clearly outlined, A flow chart of the chemical reactions at each step of the process is recommended.

Identities of the reactants, solvents, and catalysts used to product the product, the amounts and the order in which they are added.

Description of the equipment used that may influence the composition of the product.

Description of the conditions (temp, pressure, pH, humidity) that are controlled during each step and the limits that are maintained.]

[Description of the purification steps. Include QC/QA measures taken to limit extraneous contamination, both chemical and biological. These steps would include, preparation of culture media and inocula, scale up of culture to production volume, pilot and/or commercial scale cultivation, harvest and concentration of active ingredient, processing of final culture, formulation methods, packaging and storage steps.]

[Description of production methods should also incorporate details of the manufacturing facilities, including the approach used for good sanitary state of the production unit, equipment and instrumentation employed, procedures for cleaning and sterilizing equipment, production vessels, transfer lines, etc., and time frames for each step.]

## QUALITY CONTROL/QUALITY ASSURANCE MEASURES:

[Description of the procedures used to assure consistent composition of the product (calibration

of equipment, sampling regimens, analytical methods and other QC measures). This description shall include the procedures used by the manufacturer to establish the identity and purity of the culture from which the unformulated MPCA is produced, the method of manufacture, and techniques used to ensure a uniform or standardized product.

As an integral part of the production process, the QA program should be outlined. QA programs would normally incorporate elements, such as appropriate QC of raw materials and ingredients; effective process controls during manufacture to limit introduction of extraneous organisms and deleterious substances; and valid, reliable methodology to monitor the integrity of the active ingredient during production and to ensure consistent quality and safety of the final product.

The applicant should provide a table summarizing the critical QC tests and criteria (i.e., product release standards, determination of whether a batch of technical active ingredient, MP, or EP will be released for commercial use, etc.). Details of sampling programs, including procedures, sample size, frequency and statistical validity should also be included in the description of quality assurance. Measures to be taken when product release standards are not met should be reported.

QC testing may include, but is not limited to, integrity of the MPCA, product guarantee, contaminant screening, pathogen screening and other tests appropriate to the nature of the product. Representative QC data from five production batches must be submitted.

QC data on commercial batches produced after registration must be maintained and submitted to the EPA upon request. Any significant variation in product release specifications or contamination problems must be reported immediately.]

## DISCUSSION OF FORMATION OF UNINTENTIONAL INGREDIENTS (OCSPP 885.1300):

**CITATION(S):** Author(s). *[Year]*. Study Title. Laboratory name and address. Laboratory report number, full study date. Unpublished *[OR if published, list Journal name, vol.:pages]*. MRID No. *[no hyphen],* PMRA *[number if applicable]*.

**Deviations from guideline:** *[Indicate if there were any deviations from the test procedures and reporting requirements stated in guideline(s).This information is usually stated in the Good Laboratory Practices (GLP) and Quality Assurance (QA) statements in the introductory section of the study report. State the reasons for such deviations and its overall effect on the validity of the study.]*

[A theoretical discussion regarding the formation and/or presence of unintentional ingredients (impurities, contaminants or extraneous materials) that are likely to occur in the particular TGAI preparation should be provided. The nature and incidence of contamination will depend on the type of MPCA, the production methods and the production environment.

Examples include: microbial contaminants (with particular reference to potentially infective or antagonistic forms), microbial toxins, allergens, pathogens, dermal sensitizers and other metabolic products; impurities in materials used in the manufacturing process; by-products from chemical reactions in the manufacturing process; fermentation residues; extraneous host residues from the production of intracellular parasites in cell cultures, whole animals or other living forms; and mutants, or alternate forms of the MPCA; residues of contaminants that remain following the purification or extraction process; and impurities in chemicals used in the manufacturing process.]

The names of the unintentional ingredients (impurities, contaminants or extraneous materials), company codes ***(if applicable)***, origin and description ***[OR chemical structure- if applicable]*** of unintentional ingredients are shown in Table 1.

|  |
| --- |
| **Table** *[x]***. Unintentional Ingredients, company codes *(if applicable)*, possible origin and description *[OR chemical structure- if applicable]* of impurities in *[Product formulation, TGAI, MP, or EP]*** |
| Name of Unintentional Ingredient and type | Codes ***(if applicable)*** | Possible origin | Description ***[OR chemical structure- if applicable]*** |
|  |  |  |  |
|  |  |  |  |

[NOTE: substances toxic or sensitizing to humans or other nontarget mammalian species are known or suspected to be present at any stage of the manufacturing process, include data to show that the substances do not exist in the final product or exist only in quantities too small to pose any hazard.]

[Include a discussion on how human or other nontarget animal pathogens such as (but not limited to) Shigella, Salmonella, and Vibrio will not be present at hazardous levels in the TGAI. If the production method can support the growth of human or animal pathogens, each production batch must be tested for their presence. Provide an analysis of all human or animal pathogens that might be present at potentially hazardous levels in the product before formulation, including proposed methodology for detecting and/or eliminating these from the product.

For example: the method prescribed in 40 CFR 180.1011 to monitor each production batch of Bacillus thuringiensis for the pathogen Bacillus anthracis involves subcutaneous injection of at least 1 million viable microorganisms or spores into each of 5 laboratory mice weighing 17 to 23

g. Such tests shall show no evidence of infection or injury in the test animals when observed for 7 days following injection.]

[Include proposed methods for controlling any hazardous contamination detected in the product (example: discarding of a contaminated production batch).]

[Distinguish discussions of impurities associated with TGAI vs. other impurities in the following separate sections.]

## IMPURITIES ASSOCIATED WITH TGAI:

1. **OTHER IMPURITIES:**

**V. CERTIFICATION OF LIMITS (OCSPP 885.1500)**

**CITATION(S):** Author(s). *[Year]*. Study Title. Laboratory name and address. Laboratory report number, full study date. Unpublished *[OR if published, list Journal name, vol.:pages]*. MRID No. *[no hyphen],* PMRA *[number if applicable]*.

**Deviations from guideline:** *[Indicate if there were any deviations from the test procedures and reporting requirements stated in guideline(s).This information is usually stated in the Good Laboratory Practices (GLP) and Quality Assurance (QA) statements in the introductory section of the study report. State the reasons for such deviations and its overall effect on the validity of the study.]*

[Information required includes: type of formulation, nature and percent composition of each ingredient, including identity and purpose in formulation, chemical name, trade name and CAS No.] [Since the production of the MPCAs is by nature a variable process, any variation in percent composition of the MPCA preparation and other formulation ingredients should be presented and explained.]

The certifications of the upper and lower limits for the active and inert ingredient concentrations in *[product name or TGAI, MP, or EP name]* (expressed as weight percent) are presented in Table *[x]*.

The certified limits were derived from the CSF (Dated [*month/day/year]*) for the active ingredient and intentionally added inerts for all ingredients have *[not]* been set according to EPA's table of standard certified upper and lower limits given in 40 CFR § 158.175(b)(2) *[If applicable include:* with the exception of the *[active and/or inert ingredient (identify)].*

### Supporting data on five (5) representative batches to demonstrate the alternative proposed upper and lower limits were [not] provided.

The expanded certified limits of the active *[OR inert (include name)]* ingredient were due to

[provide reason/justification].

|  |
| --- |
| **TABLE** *[x]***. Description of Ingredients and Certification of Limits for***[product name or TGAI, MP, or EP name]* **(EPA Reg. No.** ######**)** |
| **Trade Name (Chemical description)****EPA Reg. No. or CAS No.** | **Purpose in Formulation** | **Concentration (% by weight)** |
| **Nominal** | **Upper Limit** | **Lower Limit** |
| **Active Ingredient** |
| *[Name of Product]**(containing #% active ingredient (scientific name- include subspecies and strain)**[Include the number of units per unit volume or weight; viability data in terms of PFU, CFU, or other expression of biological activity]**Example:*Contains a minimum of [#  10#] cfu/g*[Include deposition Number from nationally recognized culture collection Depository example*: ATTC *####* or NRRL *####*]EPA Reg. No. ###### | TGAI | *[#]*% | *[#]*% | *[#]*% |
| **Inert Ingredients** |
| *[Trade Name]**[(chemical name/description)] CAS No. ###### or N/A* | *[purpose of insert] (example:* surfactant, emulsifier, preservative, antifoam, diluent) | *[#]*% | *[#]*% | *[#]*% |
| *[insert additional rows for each additional inert ingredient in format presented above]* |  |  |  |  |
| **Total** | 100 |  |  |

## CONCLUSION

1. **REVIEWER’S COMMENTS:** *[For CBI specific comments- provide brief concluding statements on the overall acceptability of those data and list any data gaps or deficiencies and note whether they are considered “minor” or “major”.] [Note- Do not include any comments or data deficiencies that are CBI data in the executive summary].*
2. **DEFICIENCIES:** *[For CBI specific data deficiencies- list each deficiency with the required data to resolve the deficiency OR if no data can be provided to satisfy the deficiency.]*
3. **REFERENCES** *[Provide references that were cited in the study report: methods, studies in the open literature, references to other study reports in the submission or other studies conducted by the applicant. Submission of these documents as an appendix to the study report is recommended, however relevant data and supporting statements for conclusions (especially scientific rationales) made for each data requirement should be excerpted and cited from those documents and inserted into the DER. Examples of information in appendices would be MSDS for intentionally added inert ingredients, or company SOPs referenced in manufacturing process or QC descriptions.].*

# (This section of the DER represent the format for submitting alternative data for satisfying data requirement and supporting scientific rationale to justify the use of alternative data Alternative data include: waiver request(s), published study, and/or mini-literature review.

***(Formatting instructions: Use cover page (first page of template) and include a brief executive summary of the waiver request/published study/OR mini- literature review and its classification. Delete study template and proceed to the following sections)***

***NOTE: If a combination of studies and alternative data are submitted- use the following format and insert the applicable text directly into the respective section of the DER representing the specific data requirement to be waived. Any CBI data should be placed in the Confidential Appendix A. )***

***(For a waiver request, otherwise delete)***

1. **WAIVER RATIONALE** *[Summarize the information and/or data presented by the author justifying why the required data element should be waived for the MPCA, TGAI or EP.]*
2. **CONCLUSION**

**[*NOTE: All statements used as justification to support the scientific rationale for the waiver rationale should be individually supported by a reference (i.e. MSDS sheets, studies in the open literature, references to other study reports in the submission and/ or other studies conducted by the registrant/applicant). Include specific details and/or excerpts of relevant data/information from individual references. Supporting data include: background information of MPCA (e.g. previously reported characterization data related to its identity, mode of action, its nature, prevalence and/or interactions in the environment), history of safe use, and/or significant similarities to other microbial strains.*]**

1. **STUDY AUTHOR CONCLUSION:** *[Summarize the study author’s conclusions]*
2. **REVIEWER’S COMMENTS:** *[Note if in agreement with study authors.]*
3. **DEFICIENCIES:** *[List each deficiency with the required data to resolve the deficiency or if no data can be provided to satisfy the deficiency.]*
4. **CLASSIFICATION: [ACCEPTABLE / UNACCEPTABLE / SUPPLEMENTAL, but UPGRADEABLE]**
5. **REFERENCES** *[List references that were cited in the study report]*

***[NOTE: Depending on the level of relevance- copies of published literature and any other supporting literature that support the use of alternative data/waiver rationale (including other studies reporting similar findings) should be provided as an appendix and attached to the study report for the reviewer’s reference and verification of rationale.]***

# (For a published study, otherwise delete)

1. **PURPOSE** *[Indicate the purpose of the study]*
2. **METHOD** *[Describe the experimental procedure]*
3. **RESULTS** *[Summarize the results using appropriate headers*

*e.g.,* ***A. METHOD OF DETERMINING MODE OF ACTION:***

***B. INSECTICIDAL SPECTRUM:]***

1. **CONCLUSION**
2. **STUDY AUTHOR CONCLUSION:** *[Summarize the study author’s conclusions]*
3. **REVIEWER’S COMMENTS:** *[Note if in agreement with study authors.]*
4. **DEFICIENCIES:** *[List each deficiency with the required data to resolve the deficiency or if no data can be provided to satisfy the deficiency.]*
5. **CLASSIFICATION: [ACCEPTABLE / UNACCEPTABLE / SUPPLEMENTAL, but UPGRADEABLE]**
6. **REFERENCES** *[Provide references that were cited in the study report: methods, studies in the open literature, references to other study reports in the submission or other studies conducted by the applicant.].*

**[*NOTE: Include a copy of the published study and/or previously conducted unpublished study in the study report as an appendix attached to the study report for the reviewer’s reference and verification of study details. Any additional statements used as justification to support the use of alternative data should be individually cited- including the specific background information, details and/or excerpts of relevant data/information from individual references. Depending on the level of relevance- copies of published literature and any other supporting literature that support the use of a published study or previously conducted study as alternative data (including other studies reporting similar findings) should also be provided in the appendix.*]**

# (For a mini literature review, otherwise delete)

**I. REVIEW OF PUBLISHED LITERATURE** *[Summarize the background information and published studies covered in this mini literature review. Grouping related papers for discussion under specific subheadings may be useful.*

* 1. *.,* ***A. DISCUSSION OF FORMATION OF UNINTENTIONAL INGREDIENTS:***
		1. ***Article 1:*** *(summarize and report findings)*
		2. ***Article 2:*** *(summarize and report findings)*
	2. ***CHRARCTERIZATION OF THE ACTIVE INGREDIENT:***
		1. ***Article 1:*** *(summarize and report findings)*
		2. ***Article 2:*** *(summarize and report findings)*
	3. ***MSDS SHEETS:***

|  |  |  |
| --- | --- | --- |
| ***1.*** | ***Article 1:*** | *(summarize and report findings)* |
| ***2*** | ***Article 2:*** | *(summarize and report findings)]* |
| **II.** | **CONCLUSION** |  |
| **A.** | **LITERATURE REVIEW CONCLUSION:***literature results/ findings]* | *[Summarize overall conclusion based on compilation of* |

1. **REVIEWER’S COMMENTS:** *[Note if in agreement with study authors.]*
2. **DEFICIENCIES:** *[List each deficiency with the required data to resolve the deficiency or if no data can be provided to satisfy the deficiency.]*
3. **CLASSIFICATION: [ACCEPTABLE / UNACCEPTABLE / SUPPLEMENTAL, but UPGRADEABLE]**

**III. REFERENCES** *[Provide references that were cited in the study report: methods, studies in the open literature, references to other study reports in the submission or other studies conducted by the applicant.].*

**[*NOTE: Depending on the level of relevance- copies of published literature, previously conducted unpublished study and any other background literature that support the use of a literature review as alternative data (including other studies reporting similar findings) should be provided as an appendix attached to the study report for the reviewer’s reference and verification of study details.*]**