**Microbial Technical Screen Tables**

Data Matrix

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|  | Are all product chemistry data requirements appropriately listed on data matrix? (Refer to 40 CFR 158.2120) |
|  | Note that a separate data matrix for each active ingredient (unregistered source only) and product is needed. |
|  | Are all human health (e.g., mammalian toxicology) data requirements appropriately listed on data matrix? (Refer to 40 CFR 158.2140) |
|  | Are all nontarget organism/environmental fate data requirements appropriately listed on data matrix? (Refer to 40 CFR 158.2150) |
|  | If public health claims are made, are efficacy data requirements appropriately listed on data matrix? (N/A if no public health claims) |

Product Chemistry - CSF

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|  | Is CSF(s) complete, signed, and dated? |
|  | Are units in all applicable boxes? |
|  | Is supplier information adequately listed? Note: supplier information is not required on the CSF for commodity inert ingredients (https://www.epa.gov/pesticide-registration/commodity-inert-ingredients) |
|  | CAS # for all inert ingredients included that match information in submitted SDS? |
|  | Chemical names provided for all inerts? |
|  | Do physical-chemical properties of product match information on the CSF (including units)? |
|  | Does the use of the AI meet the conditions of the exemption or tolerance (https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180/subpart-D/section-180.900)? |
|  | All other ingredients (e.g., inerts and proprietary mixtures) cleared (and for food-use, if food-use)? Are inerts compliant with any restrictions listed in the respective inert exemptions? https://www.epa.gov/pesticide-registration/inert-ingredients-overview-and-guidance |
|  | Are all inert ingredients properly included as inerts and not possibly active ingredients? |
|  | Are CSF and labeling consistent (ingredient statement, appropriate precautionary statements, etc.)? |
|  | Are culture collection reference number and strain designation correct? |
|  | Is the potency/viability claim correct? Is the product potency/viability clearly identified on the CSF (not just the AI source potency)? |
|  | If a food-use product formulation contains peanuts, tree nuts, milk, soybeans, eggs, fish, crustacea and/or wheat, do the product uses comply with any restrictions listed in 40CFR 180.1071? |
|  | If certified limits are outside recommended range, is a rationale provided to support this request as a necessary deviation? |
|  | Are all alternate formulations substantially similar? |
|  | If the product has a registered source, does the MP label have any restrictions? Does the MP label support the uses on the proposed EP label? |

Product Characterization Data

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|  | Are all product characterization data requirements addressed? |
|  | If literature is cited, is a copy of the reference document included with the relevant sections highlighted? |
|  | Is the culture collection ID provided? |
|  | Has current taxonomic literature on the subject species been identified as a basis for the AI identity/classification methodology? |
|  | Are appropriate test results provided that confirm identity including complete phenotypic and genomic analysis/characterization (with phylogenetic analysis)? |
|  | Are Safety Data Sheets (SDS) provided for every inert ingredient, and are the SDS from the supplier company(ies)? |
|  | Is the entire manufacturing process fully described (i.e., not just a flow chart), such that an outside party could replicate it if need be? |
|  | If the manufacturing process (e.g., growth media) includes the use of allergens (such as peanuts, tree nuts, milk, soybeans, eggs, fish, crustacea and/or wheat), do the product uses comply with any restrictions listed in 40CFR 180.1071? Alternatively, is the potential for these allergens to remain in the final product fully characterized with supporting analyses? |
|  | Does the manufacturing process include packaging information and full quality control procedures? |
|  | Is an acceptable active ingredient identification/quantification method included? |
|  | Does the analysis of samples include potency analysis using the active ingredient quantification method employed in the manufacturing process? |
|  | If food-use, do the analysis of samples testing and the manufacturing process QA/QC standards include the current contaminant analysis standard defined as absence of *Salmonella*, *Listeria monocytogenes* in 25 grams of product and (pathogenic) *E. coli* in 1 or 25 grams of product using validated (standard) methods of analysis for these pathogens? |
|  | Are the relevant studies fully GLP compliant? If not, does the GLP statement clearly describe how GLP compliance was deficient and address any potential effects on the study results from this non-compliance? |

Human Health Data

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| **General** | |
| a. | If there are studies conducted according to alternative methodology (e.g., in vitro studies), have they been conducted according to their respective OECD guideline? |
| b. | Has a rationale been provided if the Restricted Entry Interval (REI) on the proposed product label is less than 12 hours? |
|  | Are the relevant studies fully GLP compliant? |
|  | Full identification of the test material or certificate of analysis provided (needs to be linked back to the actual material intended for testing)? If the latter, does the batch/lot number on the CoA match the description in the study report? |
|  | If the test substance is identified by a name other than the active ingredient or product name used, is there verification that the test substance is the actual active ingredient or product and not a variation or other material? |
|  | Does the test substance description (e.g., potency) and physical/chemical properties match those given in the product chemistry data? |
| **Acute Oral Toxicity (870.1100)** | |
|  | Identification of the test animal strain and source included? |
|  | Animals fasted prior to substance administration (for rats, overnight)? |
|  | Animals dosed by gavage? |
|  | Body weights reported (shortly before the test substance is administered and weekly thereafter, including just before terminal sacrifice which would usually be on day 14)? |
|  | Individual observations for at least 14 days, or until all test animals appear normal (whichever is longer). |
|  | Gross necropsy performed on all animals dying during the test, as well as all others following terminal sacrifice and results reported. |
|  | Doses tested sufficient to determine a toxicity category or a limit dose (which may be 2000 or 5000 mg/kg). |
|  | Were statistical methods and results reported, if applicable? |
| **Acute Dermal Toxicity (870.1200)** | |
|  | Identification of the test animal strain and source included? |
|  | Are solids ground and test substance moistened with water or saline solution or (with justification) or other suitable vehicle to ensure good contact with skin? |
|  | Was the application site clipped or shaved at least 24 hours before dosing? |
|  | Was the application site at least 10% of body surface area (except for highly toxic substances)? |
|  | Were the animals exposed for 24 hours? |
|  | Were body weights reported shortly before the test substance is administered and weekly thereafter, including just before terminal sacrifice (which would usually be on day 14)? |
|  | Were there individual observations, noting irritation if needed, for at least 14 days, or until all test animals appear normal (whichever is longer)? |
|  | Was gross necropsy performed on all animals dying during the test, as well as all others following terminal sacrifice? Were the results reported? |
|  | Were the doses tested sufficient to determine a toxicity category or a limit dose (which may be 2000 or 5000 mg/kg)? |
|  | Were statistical methods and results reported? |
| **Acute Inhalation Toxicity (870.1300**) | |
|  | Was the chamber air flow dynamic with at least 10 air changes/hour and at least 19% oxygen content? |
|  | Was the chamber temperature 22o (+2o); with relative humidity 40-60%? |
|  | Was the rate of chamber air flow measured or monitored at least 3 times during the exposure? |
|  | Were the test substance concentrations measured in the breathing zone? |
|  | If the test substance is a formulation (i.e., EP), was a discussion provided that the mixture at the animal’s breathing zone was analogous to the formulation? |
|  | Were the MMAD and GSD determined for relevant substances? Were they within the appropriate ranges (MMAD: 1-4 µm; GSD: 1.5-3)? |
|  | Were at least 5 young (8-12 weeks old) adult rats per sex tested per exposure level? |
|  | Was the dose concentration described? |
|  | Was dosing at least 4 hours by inhalation? |
|  | Were doses tested and findings sufficient to determine a toxicity category? |
|  | Were body weights reported (shortly before exposure to the test substance and weekly thereafter, including just before terminal sacrifice)? |
|  | Did individual observations occur for at least 14 days, or until all test animals appear normal (whichever is longer)? |
|  | Was gross necropsy performed on all animals dying during the test, as well as all others following terminal sacrifice, with particular attention to organs of respiration? Were results reported? |
|  | Were statistical methods and results reported? |
| **Primary Eye Irritation (870.2400)** | |
|  | At least three adult rabbits are required, except when irreversible eye damage is demonstrated in a single animal, in which case the test material will be assigned to Toxicity Category I in terms of eye hazard potential. |
|  | Identification of the test animal strain and source provided? |
|  | Dose: 0.1 mL if a liquid, 0.1 mL or not more than 100 mg if a solid, paste or particulate substance? |
|  | If test material is solid or granular, it must be ground to a fine dust or powder and weight of test substance administered to the eye must be reported. |
|  | Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hours? |
|  | Tabulation of irritant/corrosive response data for each individual animal at each observation point (e.g., 1, 24, 48 and 72 hr and then until reversibility of lesions or termination of the test)? |
|  | Is the method used to score irritation described? |
| **Primary Dermal Irritation (870.2500)** | |
|  | At least three adult rabbits required, except when irreversible damage is demonstrated in a single animal, in which case the test material will be assigned to Toxicity Category I in terms of irritation potential. |
|  | Identification of the test animal strain and source provided? |
|  | Fur removed from test site approximately 24 hours before application? |
|  | Application site area was approximately 6 cm2? |
|  | Dose: 0.5 mL if a liquid, 500 mg if a solid or semisolid? |
|  | If test material is dry, water or physiological saline solution may be used to moisten it. There should be justification if other agents are used to moisten test material. |
|  | Test substance should be covered with a gauze patch, which would be held in place with non-irritating tape. |
|  | Exposure for 4 hours (recommended, except for corrosive or highly irritating substances)? |
|  | At the end of the exposure period, was the material removed and/or site washed with water? |
|  | Was the appropriate numerical grading system used? |
|  | Tabulation of irritant/corrosive response data for each individual animal at each observation point following the end of exposure (e.g. 30-60 min, 24, 48 and 72 hr) and then until reversibility of lesions or termination of the test)? |
| **Acute Oral Toxicity/Pathogenicity (OCSPP 885.3050)** | |
|  | Study conducted under GLP standards? |
|  | Are all control groups included as indicated in the guidelines? |
|  | Was the proper maximum hazard dose used (108 CFU/animal) with potency of dose verified concurrent with (or immediately prior to) testing? |
|  | Was the form of the MPCA tested equivalent to the material intended for registration (e.g., material as identified in tolerance/tolerance exemption)? To the extent possible, the test MPCA also should be equivalent to the MPCA intended for registration with respect to stage of growth and expression of phenotypic traits (e.g., secondary metabolites). |
|  | Was adequate interim sacrifice timeframe to establish pattern of clearance of at least 21 days or as long as needed used to demonstrate pattern of clearance from all tissues? |
|  | Were properly validated methods used for recovery of microbe in tissue homogenate including a correction factor? |
|  | Was the microbe recovery from feces, blood or organ homogenate at interim sacrifices (not organ surface smear) performed as noted in the guidelines? |
| **Acute Pulmonary Toxicity/Pathogenicity (OCSPP 885.3150)** | |
|  | Study conducted under GLP standards? |
|  | Are all control groups included as noted in the guidelines? |
|  | Was the proper maximum hazard dose used (108 CFU/animal in 0.3ml/100g body wt.) with potency of dose verified concurrent with or immediately prior to testing? |
|  | Was the form of the MPCA tested equivalent to the material intended for registration (e.g., material as identified in tolerance/tolerance exemption)? To the extent possible, the test MPCA also should be equivalent to the MPCA intended for registration with respect to stage of growth and expression of phenotypic traits (e.g., secondary metabolites). |
|  | Was adequate interim sacrifice timeframe to establish pattern of clearance of at least 21 days or as long as needed used to demonstrate pattern of clearance from all tissues? |
|  | Were properly validated methods used for recovery of microbe in tissue homogenate including a correction factor? |
|  | Was microbe recovery from feces, blood or organ homogenate at interim sacrifices (not organ surface smear) performed as noted in the guidelines? |
| **Acute Injection Toxicity/Pathogenicity (OCSPP 885.3200)** | |
| a. | Study conducted under GLP standards? |
| b. | Are all control groups included as noted in the guidelines? |
| c. | Was the proper maximum hazard dose used (107 CFU/animal in 0.3ml/100g body wt.) with potency of dose verified concurrent with or immediately prior to testing? |
|  | Was the form of the MPCA tested equivalent to the material intended for registration (e.g., material as identified in tolerance/tolerance exemption)? To the extent possible, the test MPCA also should be equivalent to the MPCA intended for registration with respect to stage of growth and expression of phenotypic traits (e.g., secondary metabolites). |
| d. | Was adequate interim sacrifice timeframe to establish pattern of clearance of at least 21 days or as long as needed used to demonstrate pattern of clearance from all tissues? |
| e. | Were properly validated methods used for recovery of microbe in tissue homogenate including a correction factor? |
| f. | Was microbe recovery from feces, blood or organ homogenate at interim sacrifices (not organ surface smear) performed as noted in the guidelines? |
| **Cell Culture (OCSPP 885.3500)** | |
| a. | Is a full cell culture study provided (rather than a waiver) if the active ingredient is a virus? |

Tolerance/Exemption/Nonfood Determination

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|  | If food-use, is there a petition for a tolerance, tolerance exemption, or nonfood determination? |
|  | Is there sufficient information to conduct a drinking water assessment, even if a non-food use? |
|  | If there are adverse effects reported in the hazard data, is a tolerance exemption appropriate (if not see data requirements for establishing a numeral tolerance)? |
|  | Are the hazard data adequate for full science review (refer to tables above)? |
|  | Are all tolerance exemption/tolerance petition sections addressed/provided? |
|  | Do all sections appear provide adequate information to cover the tolerance/exemption request? |
|  | Are references cited provided with the petition or MRIDs? |

Nontarget Organisms

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| **General** | |
|  | Are the relevant studies fully GLP compliant? If not, does the GLP statement clearly describe how GLP compliance was deficient and address any potential effects on the study results from this non-compliance? |
|  | Are all data requirement addressed with a guideline study (if not, see rationale section belowfor further guidance)? |
|  | Full identification of the test material or certificate of analysis provided (needs to be linked back to the actual material intended for testing)? If the latter, does the batch/lot number on the CoA match the description in the study report? If the test substance is identified by a name other than the active ingredient or product name used, is there verification that the test substance is the actual active ingredient or product and not a variation or something else? |
|  | Does the test substance description (e.g., potency) and physical/chemical properties match those given in the product chemistry data? |
| **Avian Oral Toxicity/Pathogenicity (OCSPP 885.4050)** | |
|  | Were Northern bobwhite quail species used? If not, justification needed. |
|  | Were at least 10 birds per treatment and control used, or 30 birds in a limit test, provided test material? |
|  | Was control mortality under 10% for the duration of the study? |
|  | Was an attenuated or sterile filtrate control included? |
|  | Did the birds receive a dose consistent with the maximum hazard dose as described in the guideline? |
|  | Were the birds observed for 30 days after initial dose? |
|  | Is raw data reported? |
|  | Is there a certificate of analysis? Does it provide viability information on the test substance, was the lot/batch analyzed the same as the test substance used? |
|  | If pathogenic symptoms or significant signs of toxicity were observed, were sequentially lower doses tested? |
| **Avian Inhalation Toxicity/Pathogenicity (OCSPP 885.4100)** | |
|  | Were Northern bobwhite or Japanese quail species used? If not, justification needed. |
|  | Was the study performed in accordance with the test guidelines? |
| **Wild Mammal Toxicity/Pathogenicity (OCSPP 885.4150)** | |
| a. | Were appropriate test species used? |
| b. | Was the study performed in accordance with the test guidelines? |
| **Freshwater Fish Toxicity/Pathogenicity (OCSPP 885.4200)** | |
|  | Was the species used appropriate? |
|  | Were all test vessels identical with treatments and fish randomly assigned to test vessels? |
|  | Was a dilution water control (and vehicle (solvent) control, if a vehicle was used) included in the test,  along with at least 5 definitive concentrations (including the Maximum Hazard Dose) or was the test a limit test at 1000X the maximum calculated pesticide concentration in a 6 inch layer of water performed? |
|  | Was the dosing of the test material performed simultaneously with feeding? |
|  | Were at least 10 individuals per controls and treatment or 30 in a limit test used? Were the test fish juveniles between 0.5 and 5 grams? |
|  | Was the test duration 30 days? |
| **Freshwater Aquatic Invertebrate Toxicity/Pathogenicity (OCSPP 885.4240)** | |
|  | Were all test vessels identical with treatments and daphnids randomly assigned to test vessels? |
|  | Was a dilution water control (and vehicle (solvent) control, if a vehicle was used) included in the test along with at least 5 definitive concentrations (including the maximum hazard dose) or was the test a limit test at 1000X the maximum calculated pesticide concentration in a 6 inch layer of water performed? |
|  | Were at least 20 daphnids (<24 hours old) tested in each treatment level, with at least 2 replicate vessels at each concentration? |
|  | Was the test duration 21 days? |
|  | If significant deleterious effects, due either to toxicity or pathogenicity, were observed, were sequentially lower doses tested? |
| **Estuarine/Marine Fish and Invertebrate Testing (OPPTS 885.4280)** | |
| a. | Is the study of sufficient duration to determine pathogenicity? |
| b. | Were the test animals exposed to the Maximum Hazard Dose? |
| c. | Were sufficient numbers of animals tested in both the test and control groups? |
| d. | Were appropriate controls included? |
| e. | If a surfactant or other “solvent” was used, is there a solvent control? |
| **Plant Testing (OCSPP 885.4300)** | |
|  | Was the test substance tested in at least one concentration level equal to or greater than the maximum label rate? |
|  | Was a rationale provided for the number and type of species tested? |
|  | If the MPCA is intended to control animals, including insects, did the plants that were tested include six spp of Dicots of at least four families and four spp of Monocots of at least two families? |
|  | If the MPCA is intended for aquatic uses, were additional aquatic plants used (e.g., *Selenastrum capricornutum* (a freshwater green alga), *Lemna gibba* (duckweed), *Skeletonema* *costatum* (a marine diatom), *Anabaena flos*-*aquae* (a blue-green bacterium), and a freshwater diatom)? |
|  | If the MPCA is intended to control plant growth and development, were the plants identified in section d. above tested? Additionally, were tests performed on plants that are important to economics and/or ecosystem maintenance and are closely related to the target plants? |
|  | Were both positive and negative (untreated) controls included in the test protocols? |
|  | Were environmental test conditions similar to those known or suspected to be optimal for penetration, infection, and disease development? |
|  | Were the test plants exposed to the MPCA by the route of exposure expected by the proposed use pattern (e.g., wounding of plants, insect vectors, seed treatment, root/soil application, foliar spray)? |
|  | Were the plant test spp treated at the time of most likely susceptibility or at the time when application is meant to be initiated? |
|  | Were observations recorded at least once per week until normal harvest or death, or if the test spp. were perennials, were observations made at regular intervals for at least 2 years? |
|  | If no obvious adverse effects were observed, were the roots, foliage, fruit, vascular tissues, etc. analyzed for the presence of the MPCA? |
|  | Was a description of the growth chambers, greenhouse, or other type of test facility provided? |
|  | Was information regarding the photoperiod and lighting provided? |
|  | Was temperature and humidity data provided? |
| **Insect Testing (OCSPP885.4340)** | |
|  | Was the test substance administered at 10-100X the EEC resulting from the maximum field application rate (MFAR)? |
|  | Were tests performed on at least three species of insects, including at least two from the following groups: parasitic dipterans, predaceous hemipterans, predaceous coleopterans, predaceous mites, predaceous neuropterans, or parasitic wasps? |
|  | Was the test duration appropriate according to the following standards?   1. Entomopathogenic fungi: 8-10 days 2. Bacteria: 21-30 days; or if cannot be cultured for this long, then at least until control mortality exceeds 20% 3. Protozoa: Determined case-by-case   Viruses: At least 30 days; if cannot be cultured for 30 days, then at least until control mortality exceeds 20% |
|  | Was the route exposure appropriate for the microbe? |
|  | Was the exposure duration sufficient to deliver a maximum hazard dose (prolonged [e.g., 10 days] and/or repeated exposure)? |
|  | Were appropriate concurrent controls included (negative control + non-viable/microbe-free)? |
|  | Was viability confirmed? |
|  | If pathogenic symptoms or significant signs of toxicity were observed, were sequentially lower doses tested? |
| **Honey Bee Testing (OPPTS 885.4380)** | |
|  | Was the test substance administered at 10-100X the EEC resulting from the maximum field application rate (MFAR)? |
|  | Did the study last at least 30 days? |
|  | Was the exposure duration sufficient to deliver a maximum hazard dose (prolonged [e.g., 10 days] and/or repeated exposure)? |
|  | Was the route exposure appropriate for the microbe? |
|  | Were appropriate concurrent controls included (negative control + non-viable/microbe-free)? |
|  | Note that honeybee studies should be conducted on adults unless the use significantly exposes bee larvae. |
|  | If food consumption is reported, are there any significant differences in the amount of food consumed between treatment groups? |
|  | Was test substance viability confirmed? |
|  | If pathogenic symptoms or significant signs of toxicity were observed, were sequentially lower doses tested? |

Rationale

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|  | If a study was addressed with rationale, does the rationale address the data requirement and the route of exposure (human health) or test organism (non-targets) specifically? |
|  | Does the rationale address each data requirement separately (guideline by guideline)? |
|  | Does the rationale address potential exposure and/or hazard? In addressing exposure, are all relevant scenarios addressed (e.g., human health: dietary (food and drinking water), incidental oral, occupational and residential handler dermal and inhalation, occupational and residential post-application; non-targets: all uses/potential exposure scenarios based on the label)? |
|  | If there are studies in the public literature indicating that the proposed AI could be toxic to non-target organisms, is rationale provided to explain why these effects would not be expected as a result of the proposed uses? |
|  | Are copies of cited literature included with relevant sections highlighted? |

Other Rationale Deficiencies Resulting in Tech Screen Failure

Deficiencies include but are not limited to the following:

* Data dump (e.g., a data volume submitted that solely contains copies of scientific literature; no rationale is provided indicating how the data in the literature satisfies the data requirement).
* Conclusions or statements that are unsubstantiated (e.g., “no exposure”, “degrades rapidly in the environment”, etc., with no supportive information).
* Justifications primarily based on statements such as “no reported effects in the literature” or “no available data” or “ubiquitous in the environment”. The lack of reporting or data does not constitute a safety finding.
* Analog is not suitable/strain is not equivalent (e.g., not structurally similar/genetically equivalent, produces different metabolites, etc.) or the bridging rationale is not provided or is insufficient.
* Test substance identity and/or composition in the cited study is not adequately described.
* For EP acute toxicity data requirements, toxicity profiles of inert ingredients are not addressed.
* Request to bridge data from a registered product or active ingredient that is not substantially similar to the proposed product or active ingredient.
* Lack of rationale to describe why the data requirement should be waived (e.g., “not relevant” is inadequate)
* Data obtained from estimation software to satisfy product chemistry data requirements are unacceptable.
* Non-target organism data requirements cannot be waived simply because the target pest can also be the non-target organism (i.e. herbicides/insecticides need definitive plant/insect endpoints in order to evaluate potential risks to endangered species)
* Rationale is limited to ONLY one of the following:
  + Small clinical trials and/or case studies in the human population
  + Lack of acute toxicity
  + Lack of exposure argument is generalized and not supported
  + Anecdotal information (e.g., “I’ve applied this to my skin for years and I’m fine”)
  + Natural occurrence and/or ubiquitous in the environment
  + Use as a food additive, cosmetic, traditional medicine, etc.
  + Justification is not relevant to the route of exposure