*Last updated 1-22-2025*

Biochemical Technical Screen Tables

Responses to the following questions should be in the affirmative. If not, the submission may not pass the technical screen. Please note that there may be other deficiencies identified that are not specifically listed in these tables that may result in a failed technical screen.

Data Matrix

A separate data matrix for each active ingredient (unregistered source only) and product is needed.

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|  | Are all product chemistry data requirements appropriately listed on data matrix?  (Refer to [40 CFR 158.2030](https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-U/section-158.2030) for FIFRA section 3 applications (product registrations) or [40 CFR 158.2081](https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-U/section-158.2081) for FIFRA section 5 applications (experimental use permits)) |
|  | Are all human health (e.g., mammalian toxicology) data requirements appropriately listed on data matrix?  (Refer to [40 CFR 158.2050](https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-U/section-158.2050) for FIFRA section 3 applications (product registrations) or [40 CFR 158.2083](https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-U/section-158.2083) for FIFRA section 5 applications (experimental use permits)) |
|  | Are all nontarget organism/environmental fate data requirements appropriately listed on data matrix?  (Refer to [40 CFR 158.2060](https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-U/section-158.2060) for FIFRA section 3 applications (product registrations) or [40 CFR 158.2084](https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-U/section-158.2084) for FIFRA section 5 applications (experimental use permits)) |
|  | Are all residue data requirements appropriately listed on data matrix? (Refer to [40 CFR 158.2040](https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-U/section-158.2040) - N/A if not establishing/amending tolerance exemption) |
|  | If public health claims are made, are efficacy data requirements appropriately listed on data matrix?  (Refer to [40 CFR 158.2070](https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-158/subpart-U/section-158.2070) - N/A if no public health claims) |

Product Chemistry-CSF

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|  | CSF(s) complete, signed, and dated? |
|  | Units in all applicable boxes? |
|  | 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>) UNLESS pesticide product bears/will bear organic claims on the labeling. |
|  | CAS # for all ingredients (including inerts/impurities (as applicable)); CAS # match information in SDS? |
|  | Chemical names provided for all inerts/impurities (must list name of impurity)? |
|  | Do physical-chemical properties of product match information on the CSF (including units)? |
|  | Active ingredient (AI) cleared for food-use (N/A if not food-use)? Does the use of the AI meet the conditions of the exemption or tolerance? |
|  | 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 exemptions? |
|  | Are all inert ingredients properly included as inerts and not possibly active ingredients? |
|  | Are CSF and labeling consistent (ingredient statement, appropriate precautionary statements, etc.)? |
|  | Do the ingredients sum to 100%? |
|  | Are significant figures correct? |
|  | Are standard certified limits calculated correctly?  (Refer to [40 CFR 158.350(b)](https://www.ecfr.gov/current/title-40/part-158/section-158.350#p-158.350(b)), noting that are errors in the regulations (fixed errors are highlighted in yellow), i.e., the left column of the certified limits table should reflect the following: “N ≤1.0%,” “1.0% ˂N ≤20.0%,” and “20.0% ˂N ≤100.0%”) |
|  | If certified limits are outside recommended range, is an explanation provided?  (Refer to [40 CFR 158.350(c)](https://www.ecfr.gov/current/title-40/part-158/section-158.350#p-158.350(c))) |
|  | Are all alternate formulations substantially similar (i.e., actually alternates and not new products)?  (Refer to [40 CFR 152.43](https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-152/subpart-C/section-152.43)) |
|  | 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? |
|  | If the AI (unregistered source) is a blend of components, are all components identified and listed separately (to the extent that they can be identified)? |

Product Chemistry-Data

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|  | Are all product chemistry data requirements addressed? |
|  | If literature is cited, was a copy of the reference document included? It is helpful when relevant information is highlighted in the reference document. |
|  | Is the product identity present and described? |
|  | If the AI is a plant extract or oil, is the source of the extract characterized adequately (e.g., location, harvest information, part of the plant)? |
|  | If an ingredient is food-grade, has adequate certification been provided? |
|  | Are Safety Data Sheets (SDS) provided for every inert or starting ingredient, and are the company names/addresses from the SDS for the inert ingredient supplier companies listed on the CSF? Does the name of the ingredient on the CSF match that on the SDS?  (Also refer to “c” of “Product Chemistry-CSF” above with regard to commodity inert ingredients) |
|  | Is the manufacturing process fully described (i.e., not just a flow chart) to the degree that it could be replicated by following the description? |
|  | Does the manufacturing process include quality control procedures? **Note:** The guideline does not recommend packaging information be described in the manufacturing process. If packaging information is needed to review storage stability, corrosion characteristics, or other data, see Section III of [EPA Form 8570-1 (Application Form)](https://www.epa.gov/sites/default/files/2013-07/documents/8570-1.pdf). |
|  | For (5-batch) preliminary analysis, is there a sufficient number of samples? Did results include both TGAI and impurity analysis? Are impurities of toxicological concern addressed? |
|  | Are all physical-chemical properties listed, and do they make sense? Were the data sufficiently reported (e.g., methodology included)? **Note:** We generally do not accept data derived using estimation software for the 158.2030 physical/chemical properties. Also, there is an apparent typographical error in test note #15 relating to particle size, fiber length, and diameter distribution (830.7520) in the regulations. This test note should read as follows (fixed error is highlighted in yellow): “15. Required for water insoluble test substances (˂10−6g/l) and fibrous test substances with diameter ≥0.1 µm.” |
|  | Were physical-chemical properties tests performed on the same material, and if not, has adequate bridging information been provided? |
|  | Are the relevant studies GLP-compliant? If not, does the GLP statement clearly describe what the deviations are and reasonably explain how the lack of GLP compliance does not affect the results?  (Refer to [40 CFR Part 160](https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-160?toc=1)) |
|  | For PRIA Codes where substantial similarity to another product is required, is the registered product  identified? If so, is the proposed product substantially similar to the registered product? |

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?  (Refer to [PRN 95-3](https://www.epa.gov/pesticide-registration/prn-95-3-reduction-worker-protection-standard-wps-interim-restricted-entry) – Rationale should cover the active ingredient and the product) |
|  | Were the studies conducted under GLP standards? If the study is not GLP compliant, does the GLP statement clearly describe what the deviations are and reasonably explain how the lack of GLP compliance does not affect the results?  (Refer to [40 CFR Part 160](https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-160?toc=1)) |
|  | 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? |
| [**Acute Oral Toxicity (870.1100)**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0156-0003) | |
|  | Identification of the test animal strain and source included? |
|  | Animals fasted prior to substance administration (for rats, overnight)? |
|  | Animals dosed by gavage? |
|  | Were body weights reported shortly before the test substance is administered, weekly thereafter, and at death or just before terminal sacrifice (which would usually be on day 14)? |
|  | Were animals observed (and results reported) at least once during the 30 minutes after dosing, periodically during the first 24 hours and daily for at least 14 days or until all test animals appeared 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, if applicable? |
| [**Acute Dermal Toxicity (870.1200)**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0156-0004) | |
|  | Identification of the test animal strain and source included? |
|  | Are solids ground and test substance moistened with water or saline solution or (with justification) 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, weekly thereafter, and at death or just before terminal sacrifice (which would usually be on day 14)? |
|  | Were animals observed (and results reported) daily for at least 14 days, or until all test animals appeared 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**)](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0156-0005) | |
|  | 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 the test substance is administered, weekly thereafter, and at death or just before terminal sacrifice (which would usually be on day 14)? |
|  | Were animals observed (and results reported) daily for at least 14 days, or until all test animals appeared 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)**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0156-0006) | |
|  | 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 not washed for at least 24 hours following administration of test material? OECD allows for washing after 1 hour, which will be accepted. |
|  | Eyes examined and graded for irritation before dosing and at 1, 24, 48 and 72 hrs? |
|  | 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)**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0156-0007) | |
|  | 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)? |
| [**Dermal Sensitization (870.2600)**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0156-0008) **Note:** Different methods can be used to assess dermal sensitization. The Local Lymph Node Assay (LLNA) and Buehler assay are covered in this document. | |
| *Buehler* | |
|  | Identification of the test animal strain and source provided? |
|  | At least 20 animals exposed to the test material, and at least 10 naïve controls? |
|  | Submission must include a description and results of a positive control study with a known sensitizer, conducted within 6 months of the study on the test material. |
|  | Was the induction dose concentration high enough to cause mild irritation (where relevant)? |
|  | At least 3 induction treatments, one week apart? |
|  | Challenge dose used the highest non-irritating concentration? |
|  | Challenge on a previously untreated area two weeks after last induction? |
|  | 6-hour exposure periods for both induction and challenge? |
|  | Dry test material moistened with water or physiological saline before application? |
|  | Removal of the test material following exposure should be accomplished with the use of water or other appropriate solvent that does not alter the response. |
|  | Challenge readings at 24 and 48 hours after removal of the challenge dose? |
|  | If equivocal challenge results, is re-challenge performed one week later? |
|  | Comparison of challenge results with naïve controls? |
|  | Brief description of grading system provided? |
|  | Tabulation of individual animal data (e.g., erythema and edema, induction results, challenge results)? |
| *LLNA* | |
|  | Identification of the test animal strain and source provided? |
|  | Dose preparation/vehicle selection consistent with guideline? |
|  | At least 5 animals/dose level? |
|  | At least 3 dose levels selected in accordance with guideline criteria. **Note:** One dose level may be used if using the “reduced LLNA” method. |
|  | Test material applied on days 1, 2, and 3? |
|  | Radioisotope administered on day 6; is radioisotope material used consistent with guideline? |
|  | Lymph nodes excised 5 hours after radioisotope injection? |
|  | Lymph node cells prepared and measured in accordance with guideline methodology? |
|  | DPMs measured and reported for each mouse? |
|  | Negative/vehicle control acceptable? |
|  | Calculation of final stimulation index scores? |
|  | Positive control substance appropriate and demonstrates a proper response? |
|  | Statistical analysis reported? |
|  | Tabulation of results (e.g., solvent/vehicle control data, dosing, dpm/mouse, group mean dpm/mouse with error term, SI, etc.)? |
| [**90-Day Oral**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0156-0010)**,** [**90-Day Dermal**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0156-0013)**,** [**90-Day Inhalation**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0156-0014)**, and** [**Developmental Toxicity**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0156-0017) **(870.3100, 870.3250, 870.3465 and 870.3700)** | |
|  | Identification of the test animal strain and source provided? |
|  | Was dose preparation/vehicle selection consistent with guideline? |
|  | Is the dosing methodology adequately described and are test levels appropriate? |
|  | 90-Day inhalation only: were the test and exposure conditions sufficiently reported (description of exposure apparatus, equipment, airflow rates, environmental conditions, concentration of the test substance in the breathing zone, nominal concentration of the test substance, MMAD, GSD, etc.)? |
|  | Were appropriate controls included? |
|  | Did they provide individual animal data? |
|  | Were all of the recommended parameters assessed according to the guideline (including (as applicable), clinical pathology, clinical chemistry, body weight, food consumption, survival, hematology, clinical chemistry, urinalysis, histopathology, necropsy findings, and study-specific parameters such as developmental toxicity, etc.)? |
|  | Are statistical analyses of the results reported? |
| [**Bacterial Reverse Mutation Test (870.5100)**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0156-0022) | |
|  | Was the highest amount of test substance used taking into consideration cytotoxicity and solubility? |
|  | Was the assay conducted with and without metabolic activation? |
|  | Were cultures used in the assay in the late exponential or early stationary phase of growth (~ 109 cells/mL)? |
|  | Were at least 5 strains of bacteria used? |
|  | Were concurrent strain-specific positive and negative controls included? |
|  | If conducted, were statistical analyses of the results reported? |
| **Mammalian Cell Assays**  **Note:** Both 870.5300 and 870.5375 must be addressed as they are used to assess different endpoints (chromosome aberration and gene mutation). The mouse lymphoma assay with colony sizing can be used to satisfy both requirements. | |
| [***In Vitro* Mammalian Cell Gene Mutation Test (870.5300)**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0156-0028) | |
|  | Was the assay conducted with and without metabolic activation for all necessary parameters? |
| b. | Was an appropriate vehicle or solvent used (if necessary)? Were fresh preparations of the test substance used? |
| c. | Were at least 4 analyzable concentrations tested and were they appropriate considering cytotoxicity and solubility? |
| d. | Did the test include concurrent positive and negative (solvent or vehicle) controls? |
| e. | Was the test procedure conducted according to the guideline? |
| f. | If conducted, are statistical analyses of the results reported? |
| [***In Vitro* Mammalian Chromosome Aberration Assay (870.5375)**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0156-0029) | |
| a. | Was the assay conducted with and without metabolic activation for all necessary parameters? |
| b. | Was an appropriate vehicle or solvent used (if necessary)? Were fresh preparations of the test substance used? |
| c. | Were at least 3 analyzable concentrations tested and were they appropriate considering cytotoxicity and solubility? |
| d. | Did the test include concurrent positive and negative (solvent or vehicle) controls? |
| e. | Was the test procedure conducted according to the guideline? |
| f. | If conducted, are statistical analyses of the results reported? |

Tolerance/Exemption/Nonfood Determination

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|  | If food-use, is there a petition for a tolerance exemption, tolerance 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? |
|  | Are the hazard data adequate for full science review (refer to tables above)? If so, is there a likely endpoint? |
|  | If residue, environmental fate, etc. data are required, are they present and are adequate? |
|  | Are all tolerance exemption/tolerance petition sections provided? |
|  | Do all sections appear provide adequate information to cover the tolerance/exemption?  (Refer to [Chapter 11 of the Pesticide Registration Manual](https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-11-tolerance-petitions#petition) for a description of the sections of a petition) |
|  | Are references cited provided with the petition or MRIDs? It would be helpful if relevant information was highlighted in the reference document. |

Non-target Organisms

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| **General** | |
|  | Was the study conducted under GLP standards? If not, does the GLP statement clearly describe what the deviations are and reasonably explain how the lack of GLP compliance does not affect the results?  (Refer to [40 CFR Part 160](https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-160?toc=1)) |
|  | 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? |
|  | Is the biochemical introduced directly into an aquatic environment when used as directed?  (If yes, were there tests conducted in accordance with 850 Series guidelines?)  (If yes, test standards should meet and be reported according to applicable requirements outlined in 850 Series guidelines (e.g., 850.1000, 850.3000, and other sections))  (If not, **850.1010** test is sufficient) |
| [**Avian Acute Oral Toxicity (850.2100)**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0010) | |
|  | Are Northern bobwhite used? If not, justification is needed. |
|  | Did the birds receive a dose consistent with the guideline requirement (limit dose at 2,000 mg/kg or at least 5 definitive levels plus control)? |
|  | Were birds randomly assigned to test and control groups? |
|  | Were birds appropriately dosed orally with gavage or capsule? |
|  | Were at least 10 birds treated for each dose level (including control) and split evenly by sex? |
|  | Were the birds observed for a minimum of 14 days? |
|  | Did fewer than 10% of the control birds die during the test? |
|  | Are ages of birds similar among all test animals? |
|  | Are statistical analyses of the results reported according to the guideline? |
| [**Avian Dietary Toxicity (850.2200)**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0011) | |
|  | Were birds randomly assigned to treatment and control pens? |
|  | Did the birds receive dietary levels of the test substance consistent with the guideline requirement (at least 5 definitive levels plus control)? If the limit test was performed, was the highest dose 5000 ppm? |
|  | Were at least 10 young birds treated for each dietary concentration level (including control) and split evenly by sex? (Age of test organisms at start: Northern bobwhite, 10-14 days; Mallard, 5 days) |
|  | Was the test substance administered in the diet (in a period of 5 consecutive days at levels at least  80% of nominal concentration)? |
|  | Were the birds exposed for 5 days with a minimum of 3-day observation? |
|  | Did fewer than 10% of the control birds die during the test? |
|  | Are statistical analyses of the results reported according to the guideline? |
| [**Freshwater Fish Acute Toxicity (850.1075)**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0035) | |
|  | Was the species used appropriate as recommended in the guideline? |
|  | 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)? If a limit test was conducted, was the highest dose either 100 mg/L or the limit of water solubility/dispersion? |
|  | Were fish NOT fed during the test? |
|  | Did fewer than 10% show signs of disease, stress, and/or death? |
|  | Were at least 7 juvenile (<3.0 grams) fish tested in each treatment level? |
|  | Was the test duration 96 hours? |
|  | Are statistical analyses of the results reported according to the guideline? |
| [**Freshwater Aquatic Invertebrate Acute Toxicity (850.1010)**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0041) | |
|  | 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)? If a limit test was conducted, was the highest dose either 100 mg/L or the limit of water solubility/dispersion? |
|  | Were daphnids NOT fed during the test? |
|  | Did fewer than 10% show signs of disease, stress, and/or death in control group? |
|  | 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 48 hours? |
|  | Are statistical analyses of the results reported according to the guideline? |
| [**Terrestrial Plant Toxicity, Seedling Emergence (850.4100)**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0023) | |
|  | Were all test chambers (including soil medium) identical and all seeds used from the same source and lot number? |
|  | Was a negative (untreated) control [and solvent (or vehicle) control, when a solvent was used] included in the test with control seedlings free from visible phytotoxic symptoms? |
|  | Unless performing limit test, were a minimum of 5 treatment levels plus appropriate controls tested? |
|  | Was the lowest test concentration level lower than the most sensitive effect EC25 and IC25? Was a NOAEC or IC05 established? |
|  | Were at least 40 seeds tested in each treatment level, with at least 4 replicates per test treatment? |
|  | Was the test duration 14 days post-emergence of 50% of control plants? |
|  | Was the mean control seedling survival at least 90% at test termination? |
|  | Are statistical analyses of the results reported according to the guideline? |
| [**Terrestrial Plant Toxicity, Vegetative Vigor (850.4150)**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0024) | |
|  | Were all test chambers (including soil medium) identical and all seeds used from the same source and lot number? |
|  | Was a negative (untreated) control [and solvent (or vehicle) control, when a solvent was used] included in the test with control seedlings free from visible phytotoxic symptoms? |
|  | Unless performing limit test, were a minimum of 5 treatment levels plus appropriate controls tested? |
|  | Was the lowest test concentration level below both the shoot height and biomass IC25 for the species? |
|  | Were at least 30 plants with 6 replicates tested in each treatment level, or at least 40 seedlings with 4 replicates tested per treatment level? |
|  | Was the test duration at least 21 days after test substance application? |
|  | Was the mean control seedling survival at least 90% at test termination? |
|  | Was the test substance applied to the foliage? |
|  | Are statistical analyses of the results reported according to the guideline? |
| [**Honey-Bee Acute Contact Toxicity Test (850.3020)**](https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0154-0016) **(satisfies 880.4350)** | |
|  | Were test bees young adult workers of similar age and feeding status? |
|  | Was a negative (untreated) control [and solvent (or vehicle) control, when a solvent was used] included in the test? |
|  | Were there a minimum of 5 dose levels plus appropriate controls tested? If a limit test was conducted, was the highest dose 25 µg/bee (or higher if the expected environmental contact residue will be higher)? |
|  | Were there at least 25 bees per treatment and control and randomly assigned to test chambers? |
|  | Were there fewer than 20% of the test bees in any control treatment dead at end of test? |
|  | Was the test duration 48 hours (or 96 hours if mortality increased >10% between 24 and 48 hours)? |
|  | Are statistical analyses of the results reported according to the guideline? |

Rationales

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|  | 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 (reporting an LD50, NOAEL, LOAEL, etc., are ideal)? 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? It would be helpful if relevant information was highlighted in the reference document. |
|  | Does the rationale cite to data previously submitted to EPA directly or summarized in an EPA regulatory document (e.g., Decision Document or Biopesticides Registration Action Document)? If so, are the associated MRIDs cited on the appropriate data matrix? (**Note:** The Risk Manager should be alerted about this and asked to check for data compensation paperwork, if applicable, during his/her/their part of the preliminary technical screening) |

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”. The lack of reporting or data does not constitute a safety finding.
* Analog is not suitable (e.g., not structurally similar, metabolized differently, etc.) or the justification for using the analog 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.
* 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
  + FDA GRAS, use as a food additive, cosmetic, traditional medicine, etc.
  + Justification is not relevant to the route of exposure