

BPPD New Product/Registered AI Source Readiness Screen

Date:

Review Date:

File Symbol No.:

Reviewers:

BPB/MPB:

Comments: *note if any calls to the registrant were made*

Pass/Fail:

Hours Worked:

| | Checklist Item | Yes | No | N/A | Comments |
|----|---|-----|----|-----|-----------------------|
| 1. | <u>Forms</u> | | | | |
| a. | 8570-1: Application for Registration | | | | |
| b. | 8570-4: CSF | | | | |
| c. | 8570-27: Formulator's Exemption | | | | |
| d. | 8570-34: Certification with Respect to Data | | | | |
| e. | 8570-35: Data Matrix | | | | |
| 2. | <u>Confidential Statement of Formula (CSF)-review for alternate formulations too</u> | | | | |
| a. | Signed and dated | | | | |
| b. | Food-use? (If no, skip to 1e.) | | | | |
| c. | All inerts cleared for food-use | | | | |
| d. | Active cleared for food-use | | | | <i>List exemption</i> |
| e. | All inerts cleared for nonfood-use (skip if food-use) | | | | |
| f. | Conventional or antimicrobial actives present? | | | | |
| g. | CSF accurately reflects label | | | | |
| h. | Active(s) + Inert(s) = 100% | | | | |
| i. | CAS #s for all inerts | | | | |
| j. | Chemical names provided for inerts | | | | |
| k. | Units in all applicable boxes | | | | |
| l. | Proprietary inerts? If so, is info. on file with the Agency? | | | | |

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| m. | Supplier information adequately listed | | | | |
| n. | Certified limits correct? | | | | |
| o. | If certified limits are outside recommended range, explanation provided? | | | | |
| p. | Microbial: culture collection reference | | | | |
| q. | Microbial: strain designation for a.i. | | | | |
| r. | Microbial: potency provided with a.i. | | | | |
| s. | Alternate formulations? | | | | |
| t. | Are alternate formulations actually alternate and not a new product? | | | | |
| u. | Is Reg. No. of source of AI on CSF? | | | | |
| 3. | <u>Data Matrix-MP or EP</u> | | | | |
| a. | Separate data matrix for the product | | | | |
| b. | All product chemistry/product analysis data requirements addressed (guideline by guideline) | | | | |
| c. | All mammalian/human health toxicology/ pathogenicity data requirements addressed (guideline by guideline) | | | | |
| d. | All Tier 1 nontarget organism toxicology/ pathogenicity data requirements addressed (guideline by guideline) | | | | |
| e. | Efficacy data (if public health pests on label) | | | | |
| f. | HSRB review required? | | | | |
| 4. | <u>Data Requirements-Guideline Studies</u> | | | | |
| Note: This section is for submitted guideline studies only. See below for waivers and rationales. | | | | | |
| a. | Product chemistry: do all submitted studies appear to satisfy the data requirements? | | | | |
| b. | Toxicology: do all submitted studies appear to satisfy the data requirements? | | | | |
| c. | Nontargets: do all the submitted studies appear to satisfy the data requirements? | | | | |

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| d. | Other (residue data, special studies, etc.) | | | | |
| 5. | <u>Data Requirements- Waivers</u> | | | | |
| Note: This section is for waivers only. This does not apply to rationale submitted to satisfy the data requirements. | | | | | |
| a. | Are there any requests for waivers? Please note. | | | | |
| b. | For each applicable data requirement, does the waiver request have a separate scientific rationale justifying why testing is not applicable? | | | | |
| c. | Does each waiver request seem reasonable and justified? | | | | |
| 6. | <u>Data Requirements- Rationales/Literature</u> | | | | |
| Note: This section is for rationales only. This does not apply to requests submitted to waive the data requirements. | | | | | |
| a. | Have rationales been submitted in lieu of guideline studies? Please note. | | | | |
| b.. | Does each rationale have scientific literature citations where applicable? | | | | |
| c. | Are the rationale and scientific citations organized in reasonable order to facilitate timely review and is each guideline addressed individually? | | | | |
| d. | Are copies of cited scientific literature included in the package? | | | | |
| e. | Does the rationale appear to be reasonable and scientific? | | | | |
| 7. | <u>Label</u> | | | | |
| a. | Restricted Use Pesticide statement (If applicable) | | | | |
| b. | Product name, brand or trademark | | | | |
| c. | Ingredient statement correct? Microbial: strain designation Microbial: potency designation | | | | |
| d. | "Keep Out of Reach of Children" (KOOROC) Statement | | | | |
| e. | Signal word | | | | |
| f. | First aid statement | | | | |

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| g. | Net contents/net weight | | | | |
| h. | EPA Reg. No. and Establishment No. | | | | |
| i. | Company name and address | | | | |
| j. | Precautionary statement: hazards to human and domestic animals Microbial: dusk mask statement | | | | |
| k. | Environmental hazards | | | | |
| l. | Physical and chemical hazards (if app.) | | | | |
| m. | Directions for use | | | | |
| m. | Storage and disposal | | | | |
| o. | Warranty statement | | | | |
| p. | Worker protection | | | | |
| q. | Batch code | | | | |