**Confidential data** (Proposer’s data entry template)

Where a specification is proposed jointly by manufacturers who produce separate technical materials (MPCAs/MPCPs, each manufacturer must submit a separate file of confidential data.

**Non-confidential data** (Proposer’s data entry and specification templates)

Where a specification is proposed jointly, non-confidential data may also be submitted jointly but the source(s) of data or information must be attributed to the appropriate Proposer(s).

Where the **proposed specifications** deviate from the guidelines given in the FAO/WHO Manual[[1]](#footnote-1), or include a clause which requires justification, the Proposer must enter the supporting data and/or arguments in appropriate sections of the data entry template.

**Tiered data submission for equivalence determination**

Data for equivalence determination may be submitted in two tiers. Tier-1 is essentially the chemical + mutagenicity data and Tier-2 the toxicological data. See FAO/WHO Manual1, Section 3.2 E.

**General**

Entries should be made where indicated in [red]. Replace the template text given in red (presented as instructions or examples) with appropriate entries in red. The brackets and quotes, [ ] and “ “, should be deleted but do not reformat the inserted text to black. Notes for information only are indicated in **[blue]**. Notes and any inappropriate text should be deleted before submission.

Template entries should be adapted or extended as required. Where an entry is not applicable, state “not applicable”. Where information is not available, state “not available”. Omission of data or information should be explained, briefly, by a note, in red, in the appropriate section.

It is not essential to adjust the pagination, this will be done by FAO/WHO before publication.

**SECTION 1. CONFIDENTIAL DATA ON [insert A.I. species *subspecies* strain]**

The information in this section is the property of [insert company name(s)] and must be kept secret

**Date of submission**

[Insert dd/mm/yyyy]

**Comparability of data with those submitted for registration**

Either The confidential data presented here are identical to those submitted for registration in [insert country/countries].

Or The confidential data presented here differ from those submitted for registration in [insert country/countries]. The differences are [insert differences]. The reasons for these differences are [rationalise the differences].

**Identity**

Scientific name of the MPCA up to strain level or a level sufficient to demonstrate unique identity in regard to taxonomic relation with known microorganisms (e.g., other known strain/species, pathogens etc.). The accession number of sample in a recognized culture collection should be provided where possible. The MPCA description, wild type/mutant/genetically modified etc., genetic stability and growth status (e.g., vegetative etc.) should be documented. The MPCA composition e.g., if MPCA is an isolated pure strain, mixture of isolated strains or unpurified strain/(s) in manufacturing media (e.g., fermentation slurry etc.), contains added agents (modifying or stabilizing) or not should be documented. used and results to identify the microorganism at the strain level should be described and documented in detail.

**Manufacturing process**

[Insert comprehensive description, including starting materials (with % purity where critical) and their sources, all media compositions, stages and conditions, solvents, intermediates, catalysts, extraction and purification steps of the MPCA/MPCP]. Maintenance of seed culture (where applicable) should be described. The selection pressure (e.g., selective media, growth conditions etc.) used (if any) for growing the nominated strain during manufacturing process or purification process should be described. The measures taken to inhibit or reduce other microorganisms especially pathogens during culture or fermentation should be described.

Include a flow diagram of the process.

Indicate the location(s) of the manufacturing plant(s).

The information in this section is the property of [insert company name(s)] and must be kept secret

**Names, codes and structures of impurities and methods of analysis**

**Microbiological impurities:**

[Notes. (i) Insert additional rows for all applicable microbial impurities (microbial activity and objectionable microorganisms) mentioned in OECD issue paper series on pesticides No. 65[[1]](https://euc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en-GB&rs=en-US&wopisrc=https%3A%2F%2Fworldhealthorg.sharepoint.com%2Fsites%2FWHOJMPS%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F767f48f247b14912877785fcbb99a4a9&wdenableroaming=1&mscc=1&hid=0FE88BA1-B0F0-C000-286F-B612362EACF0.0&uih=sharepointcom&wdlcid=en-GB&jsapi=1&jsapiver=v2&corrid=982f53e2-fa3b-3ca3-1739-46400441bc98&usid=982f53e2-fa3b-3ca3-1739-46400441bc98&newsession=1&sftc=1&uihit=docaspx&muv=1&cac=1&sams=1&mtf=1&sfp=1&sdp=1&hch=1&hwfh=1&dchat=1&sc=%7B%22pmo%22%3A%22https%3A%2F%2Fworldhealthorg.sharepoint.com%22%2C%22pmshare%22%3Atrue%7D&ctp=LeastProtected&rct=Normal&wdorigin=Other&csc=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush#_ftn1) (ii) Provide the method identification number as stated in the study on the batch analyses.]

[[1]](https://euc-word-edit.officeapps.live.com/we/wordeditorframe.aspx?ui=en-GB&rs=en-US&wopisrc=https%3A%2F%2Fworldhealthorg.sharepoint.com%2Fsites%2FWHOJMPS%2F_vti_bin%2Fwopi.ashx%2Ffiles%2F767f48f247b14912877785fcbb99a4a9&wdenableroaming=1&mscc=1&hid=0FE88BA1-B0F0-C000-286F-B612362EACF0.0&uih=sharepointcom&wdlcid=en-GB&jsapi=1&jsapiver=v2&corrid=982f53e2-fa3b-3ca3-1739-46400441bc98&usid=982f53e2-fa3b-3ca3-1739-46400441bc98&newsession=1&sftc=1&uihit=docaspx&muv=1&cac=1&sams=1&mtf=1&sfp=1&sdp=1&hch=1&hwfh=1&dchat=1&sc=%7B%22pmo%22%3A%22https%3A%2F%2Fworldhealthorg.sharepoint.com%22%2C%22pmshare%22%3Atrue%7D&ctp=LeastProtected&rct=Normal&wdorigin=Other&csc=1&instantedit=1&wopicomplete=1&wdredirectionreason=Unified_SingleFlush#_ftnref1) OECD ISSUE PAPER ON MICROBIAL CONTAMINANT LIMITS FOR MICROBIAL PEST CONTROL PRODUCTS Series on Pesticides No. 65

|  |  |  |  |
| --- | --- | --- | --- |
| Scientific Name | Code | CAS number (if known) | Method of analysis |
| [insert name] | [insert code] | [insert CAS number] | [insert method identification number] |
| [insert name] | [insert code] | [insert CAS number] | [insert method identification number] |
| [insert name] | [insert code] | [insert CAS number] | [insert method identification number] |

**Chemical impurities (where applicable):**

[Notes. (i) Insert additional rows for all impurities at or above 1 g/kg and additional rows for any impurities <1 g/kg considered to be relevant[[2]](#footnote-2). (ii) Provide the method identification number as stated in the study on the batch analyses.]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name | IUPAC name | Code | CAS number | Structure (Note) | Method of analysis |
| [insert name] | [insert IUPAC name] | [insert code] | [insert CAS number] | [insert structure] | [insert method identification number] |
| [insert name] | [insert IUPAC name] | [insert code] | [insert CAS number] | [insert structure] | [insert method identification number] |
| [insert name] | [insert IUPAC name] | [insert code] | [insert CAS number] | [insert structure] | [insert method identification number] |

[Note: Structure is not needed for water, sulphated ash, etc.]

**5 batch analysis data**

[Notes. (i) Insert data in the same order as the table of names, codes and structures. (ii) Insert additional rows as required, insert additional columns for additional batch data. (iii) Do not insert “not detected”, insert < LOD[[3]](#footnote-3).]

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Code or name | Batch 1  [insert date] CFU/g or CFU/mL or OB/PIBs/g or OB/PIBs/mL or ITU/mg or ITU/mL etc. | Batch 2  [insert date] CFU/g or CFU/mL or OB/PIBs/g or OB/PIBs/mL or ITU/mg or ITU/mL etc. | Batch 3  [insert date] CFU/g or CFU/mL or OB/PIBs/g or OB/PIBs/mL or ITU/mg or ITU/mL etc. | Batch 4  [insert date] CFU/g or CFU/mL or OB/PIBs/g or OB/PIBs/mL or ITU/mg or ITU/mL etc. | Batch 5  [insert date] CFU/g or CFU/mL or OB/PIBs/g or OB/PIBs/mL or ITU/mg or ITU/mL etc. | Mean  CFU/g or CFU/mL or OB/PIBs/g or OB/PIBs/mL or ITU/mg or ITU/mL etc. | Standard deviation  CFU/g or CFU/mL or OB/PIBs/g or OB/PIBs/mL or ITU/mg or ITU/mL etc. | Manufacturing QC limit (technical specification), CFU/g or CFU/mL or OB/PIBs/g or OB/PIBs/mL or ITU/mg or ITU/mL etc. |
| [insert code] | [insert value] | [insert value] | [insert value] | [insert value] | [insert value] | [insert value] | [insert value] | [insert value] |
| [insert code] | [insert value] | [insert value] | [insert value] | [insert value] | [insert value] | [insert value] | [insert value] | [insert value] |
| [insert code] | [insert value] | [insert value] | [insert value] | [insert value] | [insert value] | [insert value] | [insert value] | [insert value] |
| [Insert “unknowns”, if appropriate] | [insert value] | [insert value] | [insert value] | [insert value] | [insert value] | [insert value] | [insert value] | [insert value] |

**References** **Section 1. Confidential data** (sorted by study number)

|  |  |  |  |
| --- | --- | --- | --- |
| Study number | Author(s) | year | Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study. |
| XX-nnn | Analyst BD and Chemist EF | 2020 | Determination of active ingredient and impurities in technical grade xoo6. Study XX-nnn. Report XX-nnn.05. GLP. XYZ Contract Laboratories, XXland. Unpublished. |
|  |  |  |  |
|  |  |  |  |

[Notes. (i) Insert additional rows as required. (ii) Data provided in Section 1 of the Proposer’s data entry template are confidential and will not be published in the appraisal or the supporting information of the evaluation report. However, the table of references will be published.]

**SECTION 2. NON-CONFIDENTIAL DATA ON [insert A.I. species *subspecies* strain] (CIPAC number xxx)**

**Explanation**

The data for [insert A.I. species subspecies strain] were evaluated in support of [insert “new” or “extension” or “review of existing”] FAO or WHO specifications [insert numbers and dates of existing specifications, if appropriate].

Either [insert A.I. species subspecies strain] is under patent in [insert countries] until [insert date(s)]. Or [insert a.i.] is not under patent.

[Insert a.i.] [insert was/has not been] evaluated by the FAO/WHO JMPR and WHO/IPCS [insert dates]. [If appropriate, insert, “It was evaluated/reviewed by the European Commission / US EPA, etc., in [year] or is currently under evaluation/review by the European Commission / US EPA, etc”].

The draft specification and the supporting data were provided by [insert company or companies] in [insert year].

**Uses**

[Insert a.i.] is [insert, e.g., “an insecticide”], [insert mode of action, systemic activity, etc.]. It is used in [insert agriculture/horticulture/viticulture/forestry/public health, or list typical crops] against [insert list typical pests/diseases]. [Insert literature reference if appropriate].

**Identity of the active ingredient**

*Scientific name*

[insert A.I. species subspecies strain]

**Taxonomy**

Kingdom:

Division:

Phylum:Class:

Order:

Family:

Genus:

Species:

Strain:

*any previous name/previous classification/other names*

If applicable

*Structural formula*

Not applicable

*Molecular formula*

Not applicable

*Relative molecular mass*

Not applicable

*CAS Registry number*

[insert number]

*CIPAC number*

[insert number]

[Insert any other internationally recognised system of numbering or coding]

[insert number/code]

*Identity tests*

[Insert identity tests, phenotypic and genotypic characterisation.

[Note. Identification and naming of the MPCA at the strain level should be performed using the best available technology. Currently whole genome DNA sequencing and/or phylogenetic analysis based on DNA/RNA protein sequence from marker or house-keeping genes are considered the most appropriate methods. Information should be provided whether the strains consist of single or multiple genotypes. Method details including the rationale for choosing the identification method, specific gene and primers should be provided. Where the identity test is based on DNA/RNA/protein sequence, the sequence/(s) and the NCBI accession number/(s) of the sequence/(s) and where applicable phylogenetic analysis details should be provided. ]

Add information on host organism for viruses, as appropriate

**Table 1. Physico-chemical properties of pure [insert A.I. species *subspecies* strain]**

[In the table below, insert additional rows for other characteristics. Provide information on the composition of the pure compound if it is a mixture]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter | Value(s) and conditions | Purity % | Method reference (and technique if the reference gives more than one) | Study number[[4]](#footnote-4) [[5]](#footnote-5) |
| pH value | [n.n] at [n.n] ±[n.n]]℃ | [n]  ITU/mg | [Insert e.g.CIPAC MT 75.3, , not in-house method] | XX-nnn |
| Density | [n.n] g/mL at [n.n] ±[n.n] ℃ | [n]  ITU/mg | [Insert e.g CIPAC MT 3.2, , not in-house method] | XX-nnn |
|  |  |  |  |  |
|  |  |  |  |  |

**Table 2. Chemical composition and properties of [insert A.I. species *subspecies* strain] technical materials (MPCA and or MPCP)**

[Notes. (i) In the table below, insert additional rows for MPCA/MPCPs. (ii) Unless the a.i. can exist only in one form, identify the form of a.i. to which the data refer.]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Manufacturing process, maximum limits chemical and microbiological impurities, 5 batch analysis data | | Confidential information supplied and held on file by FAO or WHO. Mass balances were [nn.n – nnn.n] % and percentages of unknowns were [n.n – n.n] % (where applicable). | | | |
| Declared minimum [a.i.] and maximum [a.i.] content | | [nnn] CFU/g or ITU/mg etc. | | | |
| Relevant Microbiological impurities (CFU/g etc) | | Insert data | | | |
| Relevant Microbiological impurities (CFU/g etc) | | Insert data | | | |
| Relevant chemical impurities **³** 1 g/kg and maximum limits for them | | [insert data or None, as appropriate]. | | | |
| Relevant chemical impurities **<** 1 g/kg and maximum limits for them: | | [insert data and additional rows, or enter None, as appropriate]. | | | |
| Stabilisers or other additives and maximum limits for them: | | [insert data and additional rows, or enter None, as appropriate]. | | | |
| Parameter | Value and conditions | | Purity % | Method reference | Study number |
|  |  | |  |  |  |
|  |  | |  |  |  |

[Insert additional information, brief conclusions or explanatory notes on the above data, if applicable. Insert additional information and data in support of specification clauses for water in MPCA/MPCPs or formulations, if required.]

**Toxicological summaries**

Notes.

(i) The proposer confirmed that the toxicological and ecotoxicological data included in the summary below were derived from [insert A.I. species *subspecies* strain] having impurity profiles similar to those referred to in the table above. [If there are differences, briefly describe them.]

(ii) The conclusions expressed in the summary below are those of the proposer, unless otherwise specified.

[(iii) State if the data relate to more than one form of the a.i. and whether the different forms have similar or dissimilar tox./ecotox. profiles.]

**Table 3.** **Toxicology profile of the [insert A.I. species subspecies strain] technical material, based on acute toxicity, irritation and sensitization.**

[Notes. (i) Only examples are given, insert additional rows for additional species and tests. (ii) Insert additional column(s) for different forms, etc.]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Species | Test | Purity % Note[[6]](#footnote-6) | Guideline, duration, doses and conditions | Result | Study number 2 |
| [insert species and sex] | oral | [nnn]  ITU/mg | [insert duration, etc] | LD50 = [nnn – nnn] mg/kg bw | XX-nnn |
| [insert species and sex] | dermal | [nnn]  ITU/mg | [insert duration, etc] | LD50 = [nnn – nnn] mg/kg bw | XX-nnn |
| [insert species and sex] | inhalation | [nnn]  ITU/mg | [insert duration, etc] | LC50 = [nnn – nnn] mg/m3 | XX-nnn |
| [insert species and sex] | skin irritation | [nnn]  ITU/mg | [insert duration, etc] | [insert assessment] | XX-nnn |
| [insert species and sex] | eye irritation | [nnn]  ITU/mg | [insert duration, etc] | [insert assessment] | XX-nnn |
| [insert species and sex] | skin sensitisation | [nnn]  ITU/mg | Guideline: OECD 406; Duration: 14 days; Dose: 13.51% w/v; | [insert assessment] | XX-nnn |

[Insert any necessary explanation, additional information and brief conclusions or interpretations, if applicable.]

**Table 4.** **Toxicology profile of the [insert A.I. species subspecies strain] technical material based on repeated administration (subacute to chronic)**

[Examples given, insert additional rows for additional species and tests. Insert additional column(s) for different forms, etc.]

| Species | Test | Purity % Note[[7]](#footnote-7) | Guideline, duration, doses and conditions | Result with recapitulation of findings at the LOAEL dose | Study number [[8]](#footnote-8) |
| --- | --- | --- | --- | --- | --- |
| [insert species and sex] | [e.g. oral] | [nn.n] | [insert duration, etc] | NOAEL = [n] mg/kg bw/d LOEL = [n] mg/kg bw/d | XX-nnn |
| [insert species and sex] | [e.g. inhalation, if applicable] | [nn.n] | [insert duration, etc] | NOAEL = [n.n] mg/m³ LOEL = [n.n] mg/m³ | XX-nnn |
| [insert species and sex] | [e.g. feeding, carcinogenicity] | [nn.n] | [insert duration, etc] | [insert assessment] | XX-nnn |
| [insert species and sex] | [e.g. feeding, [n] generation reproduction] | [nn.n] | [insert duration, etc] | NOAEL = [nn] mg/kg bw/d LOEL = [nn] mg/kg bw/d | XX-nnn |
| [insert species and sex] | [e.g. teratogenicity and developmental toxicity] | [nn.n] | [insert duration, etc] | [insert assessment] | XX-nnn |
| [insert species and sex] | [e.g. sub-chronic delayed neurotoxicity, if appropriate] | [nn.n] | [insert duration, etc] | [insert assessment] | XX-nnn |

[Insert any necessary explanation, additional information and brief conclusions or interpretations, if applicable.]

**Table 5.** **Mutagenicity profile of the [insert A.I. species subspecies strain] technical material based on *in vitro* and *in vivo* tests**

[Examples given, insert additional rows for additional species and tests. Insert additional column(s) for different isomers, salts, esters, etc.]

| Species | Test | Purity % Note[[9]](#footnote-9) | Guideline, duration, doses and conditions | Result | Study number[[10]](#footnote-10) |
| --- | --- | --- | --- | --- | --- |
| [Insert species and cells] | [insert test and define *in vitro* or *in vivo*] | [nn.n] | [insert conditions] | [insert assessment] | XX-nnn |

[Insert any necessary explanation, additional information and brief conclusions or interpretations, if applicable.]

**Table 6.** **Ecotoxicology profile of the[insert A.I. species *subspecies* strain] technical material**

[Examples given, insert additional rows for additional species and tests. Insert additional column(s) for different isomers, salts, esters, etc.]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Species | Test | Purity % Note[[11]](#footnote-11) | Guideline, duration, doses and conditions | Result | Study number[[12]](#footnote-12) |
| [insert species, e.g. *Daphnia magna*  (water flea)] | [e.g. acute toxicity] | [nn.n] | [insert duration, temperature and other test conditions] | EC50 = [n.n x]g/l | XX-nnn |
| [insert species, e.g. *Leuciscus idus melanotus*  (golden orfe)] | [e.g. short-term toxicity, flow-through] | [nn.n] | [insert duration, temperature and other test conditions] | LC50 = [n.n x]g/l | XX-nnn |
| [insert species, e.g. *Scenedesmus subspicatus*  (green alga)] | [e.g. effect on growth, static water] | [nn.n] | [insert duration, temperature and other test conditions] | EC50 = [n.n x]g/l  NOEC = [n.n x]g/l | XX-nnn |
| [insert species, e.g. Earthworm] | [e.g. acute toxicity] | [nn.n] | [insert duration, temperature and other test conditions] | LC50 = [n.n] mg/kg dry soil | XX-nnn |
| [insert species, e.g. *Apis mellifera* (honey bee)] | [e.g. acute oral toxicity] | [nn.n] | [insert duration, temperature and other test conditions] | LD50 = [n.n] µg/bee | XX-nnn |
| [insert species, e.g. Bobwhite quail] | [e.g. acute toxicity] | [nn.n] | [insert duration, temperature and other test conditions] | TEL = [nn] mg/kg bw | XX-nnn |
| [insert species, e.g. Mallard duck] | [e.g. short-term toxicity] | [nn.n] | [insert duration, temperature and other test conditions] | TEC = [nn] mg/kg diet | XX-nnn |

[Insert any necessary explanation, additional information, brief conclusions and/or interpretation, if applicable.]

[insert A.I. species *subspecies* strain] [was/has not been] evaluated by the WHO IPCS [insert years] [and/or] by the FAO/WHO JMPR [insert years]. [Insert brief summary of conclusions.]

[Insert published hazard statements and classifications of any other authority, together with any other relevant conclusions of that authority.]

**Formulations and co-formulated active ingredients**

The main formulation types available are [insert appropriate codes for formulations (as listed in appendix of each CIPAC Handbook) and differentiate between agricultural and public health formulations, if appropriate].

Either [insert a.i.] [is/may be] co-formulated with [insert other a.i.s]. Or [Insert a.i.] is not co-formulated with other pesticides.

These [define if necessary] formulations are registered and sold in [name the countries or, if more than a few, express as, e.g. “many countries in North, Central and South America”, or as “many countries throughout the world”, as appropriate.]

**Methods of analysis and testing**

The analytical method for the active ingredient (including identity tests) is [insert reference(s)]. The content of[insert A.I. species *subspecies* strain] is determined by [insert, for example, “bioassay that compare the mortality of A.I. species *subspecies* strain control mosquito larvae with standard.”]. [Insert any modifications required for existing published methods and any details required for additional identity tests.]

The method(s) for determination of impurities are based on [insert brief description of method(s)].

[Insert and describe briefly the methods for the determination of proposed relevant impurities, if applicable.]

[Note. If the validation of the methods or method extensions has not been published or adopted by CIPAC, AOAC or similar, indicate the intended date(s) of submission. If publication or adoption is not essential under the requirements of the FAO/WHO Manual, as in the case of methods for relevant impurities, a brief justification and critical summary of the validation data should be provided as a minimum.]

Test methods for determination of physico-chemical properties of the technical active ingredient were [insert, for example, OECD, EPA, EC], while those for the formulations were [insert, for example, CIPAC], as indicated in the specifications.

**Physical properties**

The physical properties, the methods for testing them and the limits proposed for the [insert codes for formulations[[13]](#footnote-13)] formulations, comply with the requirements of the FAO/WHO Manual (2024 first edition). [Identify any exceptions and insert justification for them.]

[Notes. In general, limits that are reasonably achievable should be proposed in preference to default values. Generally, it is not necessary to justify more stringent limits than those required by the Manual but expended limits must be justified. The following cases must also be justified:

(i) use of non-standard methods;

(ii) exclusion of standard clauses;

(iii) inclusion of non-standard clauses;

(iv) inclusion of clauses without specified limits;

(v) inclusion of clauses and limits for water.]

**Containers and packaging**

[insert , e.g., “No special requirements for containers and packaging have been identified”.]

**Expression of the active ingredient**

The [insert A.I. species *subspecies* strain] is expressed as [insert A.I. species *subspecies* strain, to define how the a.i. is to be quantified].

**References** **Section 2. Non-confidential data** (sorted by study number)

|  |  |  |  |
| --- | --- | --- | --- |
| Study number | Author(s) | year | Study title. Study identification number. Report identification number. GLP [if GLP]. Company conducting the study. |
|  | FAO/WHO | 2024 | Manual on the development and use of FAO and WHO specifications for microbial pesticides. First edition. Rome and Geneva. <https://www.fao.org/pest-and-pesticide-management/guidelines-standards/faowho-joint-meeting-on-pesticide-specifications-jmps/manuals-jmps/en/> and [Manuals on Development and Use of FAO/WHO Specifications for Pesticides | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)](https://extranet.who.int/prequal/vector-control-products/manuals-development-and-use-faowho-specifications-pesticides) |
| XX-nnn | Author AB and Writer CD | 2020 | Determination of melting point of pure and technical grade xoo6. Study XX-nnn. Report XX-nnn.03. GLP. XYZ Contract Laboratories, XXland. Unpublished. |
|  |  |  |  |

[Notes. Insert additional rows as required.]

1. FAO and WHO. 2024. Manual on the development and use of FAO and WHO specifications for microbial pesticides - First edition. Rome and Geneva.

   <https://www.fao.org/pest-and-pesticide-management/guidelines-standards/faowho-joint-meeting-on-pesticide-specifications-jmps/manuals-jmps/en/> and [Manuals on Development and Use of FAO/WHO Specifications for Pesticides | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)](https://extranet.who.int/prequal/vector-control-products/manuals-development-and-use-faowho-specifications-pesticides) [↑](#footnote-ref-1)
2. Relevant impurities are associated with manufacture or storage of the a.i. and comply with the requirements given in Section 4.4 of the “Manual on the development and use of FAO and WHO specifications for microbiall pesticides – First edition. Rome and Geneva. FAO and WHO. 2024.

   <https://www.fao.org/pest-and-pesticide-management/guidelines-standards/faowho-joint-meeting-on-pesticide-specifications-jmps/manuals-jmps/en/> and [Manuals on Development and Use of FAO/WHO Specifications for Pesticides | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)](https://extranet.who.int/prequal/vector-control-products/manuals-development-and-use-faowho-specifications-pesticides) [↑](#footnote-ref-2)
3. If an impurity is analysed but not detected (< LOD), the value of the LOD (limit of detection) has to be provided. [↑](#footnote-ref-3)
4. Copies of the full studies should be provided for evaluation. [↑](#footnote-ref-4)
5. Study numbers appearing in the data tables must match study numbers in the references section at the end of the document. [↑](#footnote-ref-5)
6. Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage. [↑](#footnote-ref-6)
7. Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage. [↑](#footnote-ref-7)
8. Note: Study numbers appearing in the data tables must match study numbers in the references section at the end of the document. [↑](#footnote-ref-8)
9. Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage. [↑](#footnote-ref-9)
10. Note: Study numbers appearing in the data tables must match study numbers in the references section at the end of the document. [↑](#footnote-ref-10)
11. Note: Purity is the content of pure active ingredient in the technical material, expressed as a percentage. [↑](#footnote-ref-11)
12. Note: Study numbers appearing in the data tables must match study numbers in the references section at the end of the document. [↑](#footnote-ref-12)
13. As listed in Appendix E the FAO/WHO Manual (FAO/WHO, 2022). Appendix E: CropLife International codes for technical & formulated pesticides. [↑](#footnote-ref-13)