WHO Prequalification of Vector Control Products

Declaration of manufacturing sites

|  |  |
| --- | --- |
| Company | [Company name] |
| Product name | [Product name] |
| PQ ref # | [PQ Product Ref Number] (if not yet assigned, leave blank) |
| Product type[[1]](#footnote-2) | [Product Type] |

**Instructions:**

Instructions and guidance for completing the Declaration of Manufacturing Sites (DMS) are included in this template in red text. All red text should be deleted from the DMS prior to submission.

Text in [square brackets] should be replaced by appropriate descriptive language.

Refer to the implementation guidance for Product Manufacturing Details for further guidance for ITNs.

Lines may be added to the tables if more space is needed.

The list of manufacturing sites for each prequalified product published on the WHO website is developed based on the information provided on this form. Please ensure that all information is accurate and complete.

Identification of manufacturing sites

The manufacturers and addresses for production of the AI source materials must be identified in the table below. The address provided must be the actual address of the manufacturing site. A non-manufacturing HQ/office address should not be provided.

Active ingredients and synergists

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Active ingredient/ synergist name | Owner of site | Name of site | Address[[2]](#footnote-3) (including blocks/units) | Country | Supporting WHO specification[[3]](#footnote-4) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

The manufacturers and addresses for production of the VCP must be identified in the table below. The address provided must be the actual address of the manufacturing site. A non-manufacturing HQ/office address should not be provided.

If a third-party manufacturing facility is contracted for use in the production of the VCP, the information provided must reflect the legal name of the contracted company. The company name of the applicant must not be provided in place of the name of the contracted company.

The information provided in the Activities field must rely on the established terminology found below in the Appendix [Terminology for Describing Activities of Manufacturing Sites for VCPs.](#Appendix1)

The information provided in the Supporting SMF field should reflect the file name of the submitted SMF. This may be the file name of a compressed file (e.g. .zip, .7z, or .rar) with compiled documents or the primary file in the SMF. The version number and effective date of the SMF should also be provided.

End use vector control product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Owner of site | Name of site | Address (including blocks/units) | Country | Activities[[4]](#footnote-5) | Supporting SMF[[5]](#footnote-6) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

|  |
| --- |
| Name of authorized contact person for the manufacturer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of authorized contact person for the manufacturer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|

Appendix 1. Terminology for describing activities of manufacturing sites for VCPs

| Terms | Definition/guidance | Related terms |
| --- | --- | --- |
| Cutting | The process of cutting ITN fabric into defined sizes in preparation for sewing. |  |
| Formulation | Any activity related to the process of creating the end use vector control product. For ITNs, this includes the treatment, coating or incorporation, of knitted fabric or extrusion of yarn respectively. If an ITN contains untreated PE yarn, the extrusion of this component is considered part of the formulation. | Blending, extrusion, fabric impregnation, fabrication, granulating, heat setting, manufacturing, material mixing, molding, stenting, treatment of the net fabric, yarn extrusion |
| Knitting | The method by which yarn is manipulated to create a textile or fabric. In the case of coated ITN products, knitting would typically take place prior to the treatment (formulation) of the fabric. In the case of incorporated ITN products knitting would take place after the treatment (formulation) of the yarn. |  |
| Labelling | The process of affixing a label to the unit packaging or multi-packed container. For pre-printed packaging, the activities of labelling and packaging may be the same and both should be selected. |  |
| Masterbatch formulation | The process of creating a masterbatch intermediate mixture of concentrated target ingredient(s) for the purpose of conveying the ingredients, by means of formulation, into the finished product. |  |
| Packaging | The process of containerizing the formulated product individually and/or in multi-unit containers. | Baling, filling, packing |
| Release testing | Any testing, quality control, or compliance monitoring of finished products for the purpose of ensuring that the finished product complies with applicable specifications and order requirements. | Analytical testing, checking, QA/QC, testing |
| Sewing | The process of connecting cut fabric into the shape and size of the finished ITN product. This includes affixing a label tag to the product. | Stitching |
| Storage | Refers to the activity of storing finished product(s) prior to release/shipping, up until the point when the declared site is no-longer in direct control of the product(s). | Transit storage, warehousing |

1. Examples: ITN, IRS, Space Spray, Larvicide, Molluscicide, Rodenticide, or other description. [↑](#footnote-ref-2)
2. Provide the actual address of manufacturer, not the HQ/Office address of the source provider. [↑](#footnote-ref-3)
3. Identify the WHO specification code (ex. 333/TC, 454/SC). [↑](#footnote-ref-4)
4. See Appendix 1 [↑](#footnote-ref-5)
5. Identify the file name and version of the supporting SMF. [↑](#footnote-ref-6)