WHO Prequalification of Vector Control Products

Declaration of product formulation for coated ITN fabric

|  |  |
| --- | --- |
| Company | [Company name] |
| Product name | [Product name] |
| PQ ref # | [PQ Product Ref Number] (if not yet assigned, leave blank) |
| Formulation code | [Formulation code] Each fabric formulation must be identified by a unique alphanumeric code. |
| Version number | [Version number] Version numbers should be sequential. |
| Effective date | [Date of internal company approval for use in pilot and/or full production] |

Refer to the implementation guidance document on the PQT/VCP website for further guidance and to access example DPFs for ITNs.

Applicants may need to replicate tables which are presented in the template documents. When replicating tables, a unique identifier must be given using the section letter and a number. For example, if two different filaments are used in the production of the multi-filament yarn, the tables may be titled A1 – [Filament 1] and A2 – [Filament 2]. If various filaments are used, the proportion of the filaments in the yarn would need to be declared.

Lines may be added to the tables if more space is needed to fit all ingredients in the formulation.

Number the tables within each section sequentially (for example, A1, A2, A3, etc.).

For those mixture ingredients whose formulation is defined within the DPF (e.g., as a formulated intermediate) include the designated name and corresponding table number in which the composition is presented.

The Amount value declared should be the nominal quantity of the ingredient in the relevant formulation table.

In some cases, a range of an ingredient amount may be relied upon in the manufacturing process to compensate for environmental and process-based factors. The nominal quantity must still be reflected in the DPF. The range and considerations for adjustments of inputs must be presented in the Description of Manufacturing Process.

The quantity of ingredient introduced during production may vary or be different from the resulting quantity at the end of production (e.g., where an excess of input is required to compensate for losses during the manufacturing process). If an elevated quantity is declared in the field, full details must be included in the Description of the Manufacturing Process to describe the nature of the loss of ingredient.

1

For any ingredient which contains an active substance, the equivalent quantity of the pure substance should also be stated. For example, 10.0 g/kg of a 95% TC is equivalent to 9.5 g/kg of the pure active substance.

Section A. Chemical compositions and formation of fabric intermediates

If the filaments/multi-filament yarn is supplied by a third party, the supplier’s product code, the filament/multi-filament yarn denier, and respective filament count must be provided.

A[#]. [Filament]

Denier: [#] D

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Ingredient | Grade/CAS#/other | Supplier name(s) and address(es) | Amount | Purpose in formulation |
| [Ingredient name] | [Grade/CAS#/Product Code] | [Supplier name and address] | [#]g/kg | [Purpose] |
| [Ingredient name] | [Grade/CAS#/Product Code] | [Supplier name and address] | [#]g/kg | [Purpose] |
| [Ingredient name] | [Grade/CAS#/Product Code] | [Supplier name and address] | [#]g/kg | [Purpose] |
| Total | 1000g/kg |

A[#]: [Multi-filament yarn]

Filament count: [#]

Denier: [#] D

[Proportion of different filaments: IF NEEDED]

If the knitted fabric is supplied by a third party, grade of polyester, the filament/multi-filament yarn denier, respective filament count and fabric weight must be provided.

A[#]: [Fabric]

Fabric weight: [#]g/m2

This is the fabric weight of the knitted fabric prior to treatment

Section B. Chemical compositions of formulated intermediates

If an intermediate formulation of the AI used in the preparation of the treatment solution is produced in-house, the complete formulation and form (e.g., SC) must be provided. If an intermediate formulation is supplied by a third party, the supplier’s product code must be identified in the Coating table.

B[#]: [Formulation of AI source for use in treatment solution]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Ingredient | Grade/CAS#/other | Supplier name(s) and address(es) | Amount | Certified Limits | Purpose in formulation |
| Upper | Lower |
| [AI name TC/SC (#%)](*equiv. [AI 1 name]*)(*equiv. [AI 2 name]*) | [Product Code] | [Supplier name and address]  | [#]g/kg(*[#]g/kg*)(*[#]g/kg*) | [#](*[#]*)(*[#]*) | [#](*[#]*)(*[#]*) | AI |
| [Ingredient name] | [Grade/CAS#/Product Code] | [Supplier name and address] | [#]g/kg | [#] | [#] | [Purpose] |
| [Ingredient name] | [Grade/CAS#/Product Code] | [Supplier name and address] | [#]g/kg | [#] | [#] | [Purpose] |
| [Ingredient name] | [Grade/CAS#/Product Code] | [Supplier name and address] | [#]g/kg | [#] | [#] | [Purpose] |
| Total | 1000g/kg |

B[#]: Coating [treatment bath solution/suspension]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Ingredient | Grade/CAS#/other | Supplier name(s) and address(es) | Amount | Purpose in formulation |
| [AI name TC/SC (#%)](*equiv. [AI 1 name]*)(*equiv. [AI 2 name]*) | [Product Code] | [Supplier name and address]  | [#]g/kg(*[#]g/kg*)(*[#]g/kg*) | AI |
| [Ingredient name] | [Grade/CAS#/Product Code] | [Supplier name and address] | [#]g/kg | [Purpose] |
| [Ingredient name] | [Grade/CAS#/Product Code] | [Supplier name and address] | [#]g/kg | [Purpose] |
| [Ingredient name] | [Grade/CAS#/Product Code] | [Supplier name and address] | [#]g/kg | [Purpose] |
| Total | 1000g/kg |

Section C. Chemical composition of the coated fabric

C[#]: Wet fabric

Fabric weight: [#]g/m2

|  |  |  |  |
| --- | --- | --- | --- |
| Ingredient | Grade/CAS#/other | Amount by weight | Amount by area |
| Fabric | [Table number/ Product Code] | [#]g/kg | [#]g/m2 |
| [AI name] | [Table number] | [#]g/kg | [#]g/m2 |
| [Ingredient name] | [Table number] | [#]g/kg | [#]g/m2 |
| [Ingredient name] | [Table number] | [#]g/kg | [#]g/m2 |
| [Ingredient name] | [Table number] | [#]g/kg | [#]g/m2 |
| Total | 1000g/kg |

C[#] : Finished coated fabric

Fabric weight: [#]g/m2

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Ingredient | Grade/CAS#/other | Amount by weight | Amount by area | Certified Limits |
| Upper | Lower |
| Fabric | [Table number] | [#]g/kg | [#]g/m2 | [#] | [#] |
| [AI name] | [Table number] | [#]g/kg | [#]g/m2 | [#] | [#] |
| [Ingredient name] | [Table number] | [#]g/kg | [#]g/m2 | [#] | [#] |
| [Ingredient name] | [Table number] | [#]g/kg | [#]g/m2 | [#] | [#] |
| [Ingredient name] | [Table number] | [#]g/kg | [#]g/m2 | [#] | [#] |
| Total | 1000g/kg |

Note: [Identify formulants lost by evaporation during drying/curing or see the Module 2 Product Development section for a discussion of differences between the formulations of the wet and dry coated fabrics.]

All differences between the formulations of the wet and coated fabric should be identified either here or in the Module 2 Product Development section of the dossier, and any differences other than losses due to evaporation should be justified. The justification should include discussion of the chemical changes occurring during the adsorption and drying/curing processes that are responsible for the differences in formulation (for example, polymerisation of monomers).

Construction of the net from the fabric(s) should be detailed in the manufacturing process description. If the net is composed of more than one fabric, the fabric used for each panel should be identified in the manufacturing process by name and the formulation code for the respective DPF.

Version tracking

| Version number | Effective dates | Reason for replacement |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

Add rows to the table if required.

Confidentiality

All formulation information provided on this form is considered confidential business information.

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