WHO PQT/VCP Implementation Guidance –

Declaration of Product Formulation (DPF) for ITN Fabric

Introduction

The applicant must submit the current and complete chemical composition of each fabric used in the construction of an insecticide-treated net (ITN) so it can be reviewed as part of the WHO Prequalification Assessment of Vector Control Products.

The available forms/templates, examples and guidance information have been developed to support reporting of the raw materials, the formulation intermediates under the control of the applicant which are used in the production process and the chemical composition of the treated fabric.

Separate templates have been developed for fabrics which are produced by means of incorporation via extrusion versus coating of pre-knitted fabric.

For ITNs, the Declaration of Product Formulation (DPF) form is used to clearly convey the chemical composition of a particular fabric. In the cases where multiple fabrics may be interchangeable or used in combination in the construction of an ITN, each fabric must be supported by a completed DPF (see Formulation Code).

DPF Templates – Instructions

Instructions and guidance for completing the DPF are included in the templates in red text. All red text should be deleted from the DPF prior to submission.

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

Within the guidance and templates, active ingredient (AI) includes those ingredients which are included in the formulation as synergists.

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, where there are two AI masterbatches with a different AI in each, the tables may be titled A1 – [AI Masterbatch] and A2 – [2nd AI Masterbatch].

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.).

Identification

Company – Name of responsible owner of the prequalified or proposed product.

Product Name – Name of the prequalified or proposed product.

PQ Ref # – WHO PQT/VCP assigned reference number; if not yet assigned, leave blank.

Formulation Code – A single product may require multiple DPFs to be submitted in order to clearly define separate versions of the fabric(s) which have differing formulations/characteristics. For example,

separate DPFs must be submitted for each denier version of the product and unique formulation codes provided.

In order to avoid unnecessary replication of documentation, a single formulation code may be submitted which includes appendices for the following:

- Replacement/substitute ingredients, which are identical/substantially similar, and their respective suppliers, including but not limited to:
    - Sources of AI, including technical materials (TC) or other source formulations – In identifying the various declared sources of AI, the nominal purity must be identified, and any augmentations of the formulation to account for different purities in the source materials must be clearly described.
    - Colorants – In the relevant formulation tables for the formulated intermediates and the finished product, a single line for colorant may be provided. A range for the Amount may be identified. In the appendix, the coloring agents which may be included in the formulation (e.g., dyes or masterbatch) must be listed along with the suppliers/addresses and product codes. ***A separate DPF for each color version is not required.***

Upon review of the submitted information, WHO may determine that a separate formulation code and DPF are required.

Version number – For each DPF and the respective formulation code, a version number must be identified. When submitting updates/changes to an established formulation, the version number must be adjusted sequentially. The past versions must be identified in the Version Tracking table at the end of the DPF. The purpose of the version number and version tracking is to ensure that the applicable formulation can be identified based on the date of manufacturing.

Ingredient and Grade/CAS#/Other Fields

For pure chemical substances, identify the chemical name or a non-proprietary name from a recognized reference (e.g., American National Standards Institute [ANSI], British Standards Institute [BSI], International Standards Organization [ISO] or other).

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

Ex.

Ingredient	Amount
Deltamethrin TC (95%) (equiv. deltamethrin)	10.0 kg (9.5 kg)
Deltamethrin MB (9.5%) 20.0 kg (equiv. deltamethrin) (1.9 kg)	20.0 kg (1.9 kg)

Where an ingredient is commercially available in different grades, the grade used must be stated in the DPF. This is especially important for key raw material ingredients such as the polymer matrix and binder(s).

For known mixtures not produced as part of the manufacturing process of the product, include either details of the individual chemical substances as described above or a name from a recognized reference that unambiguously identifies the composition of the mixture.

For proprietary mixtures, the brand name and supplier's product code must be identified. The material safety data sheet (MSDS) should also be provided in Module 3. Manufacturers are responsible for ensuring that necessary steps and agreements are established with suppliers to ensure that they are alerted to changes in the composition of the mixture(s).

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. For example, the formulation table for a yarn would refer to the table in which the masterbatch is fully defined.

Supplier Name(s) and Address(es)

Identification of the supplier names and addresses is required. Multiple suppliers and addresses may be listed for each ingredient. See section on Formulation Codes.

The information provided should reflect the actual manufacturer of the respective ingredient. In cases where an ingredient is purchased through a third party distributor, the name and address of the distributor should also be provided and identified clearly as a distributor.

Amount

The Amount value should be provided using metric units of mass.

The Amount value declared should be the nominal quantity of the ingredient in the relevant formulation table. The nominal quantity means the amount of an ingredient which is expected to be present in a typical sample of a product at the time the product is produced, expressed as mg/g, g/kg or a percentage by weight.

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 required, full details must be included in the Description of the Manufacturing Process to describe the nature of the loss of ingredient.

Purpose in formulation

An unambiguous description of the function of the ingredient in the formulation must be provided.

In cases where an ingredient's purpose is limited to a formulation intermediate, this should be clearly denoted.

If the coloring agent has a purpose in the formulation beyond the appearance, this must be declared.