Declaration of product formulation for spatial emanator products

1. Introduction

The applicant must submit the current and complete chemical composition of the spatial emanator product so it can be reviewed as part of the WHO Prequalification Assessment of Vector Control Products.

The available forms/templates and guidance information have been developed to support reporting of:

- the raw materials;
- the formulation of intermediates under the control of the applicant which are used in the production process, and
- the chemical composition of the formulated product.

For spatial emanator products, the Declaration of Product Formulation (DPF) template is used to clearly convey the chemical composition of the product.

2. DPF template 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 presented in the template documents. When replicating tables, a unique identifier must be given using the section letter and a number, for example, A1, A2, etc..

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, etc..

3. DPF template sections

3.1. Identification

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

Product Name – Name of the prequalified or proposed product.

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

Density – Expressed in g/ml for liquid formulations.

Version number – 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 nonproprietary name from a recognized reference, for example, 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.

Example

Ingredient	Amount
Transfluthrin TC (95%) (equiv. transfluthrin)	10.0 kg (9.5 kg)
Transfluthrin SC (9.5%) 20.0 kg (equiv. transfluthrin) (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 substrates in which the active ingredient may be impregnated.

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, for example, as a formulated intermediate, include the designated name and corresponding table number in which the composition is presented. For example, in the finished impregnated substrate table, reference may be made to the table in which a soluble concentrate (or other intermediate formulation) is defined.

3.2. 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.

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.

3.3. 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 the manufacturing process (DMP) (see IG – Product manufacturing details for details).

The quantity of ingredient introduced during production may vary or be different from the resulting quantity at the end of production, for example, where an excess of input is required to compensate for losses during the manufacturing process. If an elevated quantity is required, a note must be included in the DPF, and full details must be included in the DMP to describe the nature of the loss of ingredient.

3.4. 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 colouring agent has a purpose in the formulation beyond the appearance, this must be declared.

4. Related documents

- WHO PQT/VCP Declaration of product formulation for spatial emanator products – Template
- WHO PQT/VCP Implementation Guidance – Module 3. Data requirements table
- WHO PQT/VCP Implementation guidance – Product manufacturing details