6.11 **WETTABLE POWDERS (WP)**

Note for preparation of draft specifications. Do not omit clauses or insert additional clauses, nor insert limits that are more lax than those than given in the guidelines, without providing referring to Section 4.. From the “Notes” provided at the end of this guideline, incorporate only those which are applicable to the particular specification.

**…… [Taxon] WETTABLE POWDER**

[CIPAC number]/WP (month & year of publication)

**6.11.1** **Description**

The material shall consist of a homogeneous mixture of technical ...... [taxon], complying with the requirements of FAO/WHO specification [......], in the form of ...... (see Section 4.2), together with filler(s) and any other necessary formulants. It shall be in the form of a fine powder free from visible extraneous matter and hard lumps.

In case there is no TK, the material shall contain ...... [taxon], in the form of ....... (see Section 4.2) together with filler(s) and any other necessary formulants. It shall be in the form of a fine powder free from visible extraneous matter and hard lumps.

**6.11.2** **Active ingredient**

6.11.2.1 **Identity tests** (Note 1)

The active ingredient shall comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

6.11.2.2 **...... [Taxon] content** (Note 1)

The ...... [taxon] content shall be declared (g/kg, or for liquids only, g/l at 20 ± 2 °C, or CFU/g, CFU/ml or biopotency units or another appropriate microbial unit), and when determined, the average content measured shall be within the following declared tolerance range:

|  |  |  |
| --- | --- | --- |
| Declared content | Tolerance | |
|  | Minimum declared | Maximum declared |
| in g/kg or g/l or CFU/g or CFU/ml or IU/g or IU/ml, etc | | |
|  |  |  |

**6.11.3** **Relevant impurities**

6.11.3.1  **Microbial contaminants** (Note 2), if required

[Taxon] content: Absence in ...... g or ...... ml or a maximum value (with appropriate unit).

6.11.3.2 **Secondary compounds** (Note 2), if required

Insert name (any identification code, if exists).

Maximum: ...... (insert appropriate unit).

6.11.3.3 **Chemical impurities** **(from the manufacturing process)** (Note 2), if required

Maximum: ...... (insert chemical name) g/kg.

6.11.3.4 **Water** (MT 30.6), if required

Maximum: ...... g/kg.

**6.11.4** **Physical properties**

6.11.4.1 **Acidity** and/or a**lkalinity** (MT 191) or **pH range** (MT 75.3) (Note 3), if required

Maximum acidity: ...... g/kg calculated as H2SO4.

Maximum alkalinity: ...... g/kg calculated as NaOH.

pH range: ...... to ......

6.11.4.2 **Wet sieve test** (MT 185.1)

Maximum: ......% retained on a 75 µm test sieve.

6.11.4.3 **Suspensibility** (MT 184.1) (Note 4)

Minimum ......% after 30 min in CIPAC standard water D at 25 ± 5°C (Note 5 ).

6.11.4.4 **Persistent foam** (MT 47.3) (Note 6)

Maximum: ...... ml after 1 min.

6.11.4.5 **Wettability** (MT 53.3)

The formulation shall be completely wetted in ...... min without swirling.

**6.11.5** **Storage stability**

6.11.5.1 **Low temperature stability** (MT 39.3) (Note 7), if required

After storage at 0 ± 2 °C for 7 days, the determined average active ingredient content must not be lower than the specified minimum active ingredient content. After storage at 0 ± 2 °C for 7 days, the determined average active ingredient content must not be lower that ...... % relative to the determined average content found before storage (Note 8).

6.11.5.2 **Stability at elevated temperature** (MT 46.4)

After storage at 54 ± 2 °C for 14 days (Note 9), the determined average active ingredient content must not be lower than ......% relative to the determined average content found before storage (Note 8) and the formulation shall continue to comply with the clauses for:

- acidity/alkalinity/pH range (6.11.4.1),

- wet sieve test (6.11.4.2),

- suspensibility (6.11.4.3),

- wettability (6.11.4.5),

as required.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note 1 Method(s) of identification and quantitation must be peer validated/ILV. If the methods have not yet been published, then full details with appropriate method validation data must be submitted to FAO/WHO by the proposer.

Note 2 This clause should include only relevant impurities and the title should be changed to reflect the name of the relevant impurity. Method(s) of analysis must be peer validated/ILV.

Note 3 The method to be used shall be stated. If several methods are available, a referee method shall be selected.

Note 4 The formulation should be tested at the highest and lowest rates of use recommended by the supplier, provided this does not exceed the conditions given in method MT 184.1.

Note 5 MT 184.1 allows for gravimetric determination or assay of the active ingredient in the remaining 25 ml in the cylinder. As the assay of some microbial active ingredients may be complex, the gravimetric determination is considered acceptable.

Note 6 The mass of sample to be used in the test should be at the highest rate of use recommended by the supplier. The test is to be conducted in CIPAC standard water D at 25 ± 5°C.

Note 7 The cold temperature storage test is to be conducted in glass bottle or commercial packaging as for MT 46.4.

Note 8 Samples of the formulation taken before and after the accelerated storage stability test may be analysed concurrently after the test in order to reduce the analytical error.

Note 9 Unless other temperatures and/or times are specified. Refer to Section 4.6.2 of this manual for alternative storage conditions.