**6.12**  **WETTABLE POWDERS IN SEALED WATER SOLUBLE BAG**

*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 referring to Section 4. From the “Notes” provided at the end of this guideline, incorporate only those which are applicable to the particular specification.*

**…… [ISO common name] WETTABLE POWDER**
**IN SEALED WATER SOLUBLE BAG**

(CIPAC Number)/WP-SB (month & year of publication)

**6.12.1** **Description**

The material shall consist of a defined quantity of a homogeneous mixture of technical ...... [ISO common name], complying with the requirements of the FAO/WHO ……, 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, contained in a sealed water soluble bag (Note 1).

**6.12.2** **Active ingredient**

6.12.2.1 **Identity tests** (Notes 2 & 3)

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

6.12.2.2.**..... [ISO common name] content** (Note 2 & 3)

The ...... [ISO common name] content shall be declared (g/kg) and, when determined, the average content measured shall not differ from that declared by more than the appropriate tolerance, given in the table of tolerances, Section 4.3.2.

**6.12.3** **Relevant impurities** (Note 2)

6.12.3.1 **By-products of manufacture or storage** (Note 4), if required

Maximum: ......% of the …… [ISO common name] content found under 6.12.2.2.

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

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

**6.12.4** **Physical properties** (Note 2)

6.12.4.1 **Acidity** and/or **alkalinity** (MT 191) or **pH range** (MT 75.3) (Note 5),
if required

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

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

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

6.12.4.2 **Wettability** (MT 53.3)

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

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

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

6.12.4.4 **Suspensibility** (MT 184.1) (Notes 6 & 7)

The suspensibility shall be tested on a suspension containing the WP and the bag material in the actual ratio of application, prepared according to the procedure described in Note 8.

Minimum ......% after 30 min in CIPAC Standard Water D at 25 ± 5°C

6.12.4.5 **Persistent foam** (MT 47.3) (Note 9)

The persistent foam shall be tested on a suspension containing the WP and the bag material in the actual ratio of application in CIPAC Standard Water D, prepared according to the procedure described in Note 8.

Maximum: …… ml after 1 min.

6.12.4.6 **Dissolution of the bag** (MT 176) (Notes 2 & 10)

The dissolution of the bag shall be tested on a sample of the emptied and cleaned bag together with an appropriate proportion of the WP in CIPAC Standard Water D taken according to the procedure described in Note 8.

Flow time of the suspension: maximum …… sec.

## 6.12.5 Storage stability

### 6.12.5.1 **Stability at elevated temperature** (MT 46.4)

The package should be enclosed in a watertight sachet, box or any other container at 54 °C for 14 days (Note 11 & 12). The determined average active ingredient content must not be lower than ……% relative to the determined average content found before storage (Note 13) and the formulation shall continue to comply with the clauses for:

- by-products of manufacture or storage (6.12.3.1),

- acidity/alkalinity/pH range (6.12.4.1),

- wettability (6.12.4.2),

- wet sieve test (6.12.4.3),

- suspensibility (6.12.4.4),

- persistent foam (6.12.4.5),

- dissolution of the bag (6.12.4.6),

as required.

None of the bags tested should show signs of leakage or rupture during normal handling, before and after storage.

Note 1 For record keeping purposes, the suffix “SB” should be added to the formulation code (WP-SB).

Note 2 Sub-sampling.

Lay the bag on a bench and carefully open one side of the bag with a cutter, taking care not to damage the seals. Transfer the contents of the bag into a suitable flask. This material shall be used to carry out the tests for:

- active ingredient identity (2.1),
- active ingredient content (2.2),
- by-products of manufacture or storage (3.1),
- water content (3.2),
- acidity/alkalinity/pH range (4.1),
- wettability (4.2),
- wet sieve test (4.3),
- suspensibility (4.4),
- persistent foam (4.5),
- dissolution of the bag (4.6).

The bag is then opened on three sides, completely cleaned from adhering powder by brushing or suction and weighed to the nearest 0.01 g. It shall be used to carry out the dissolution test (4.6). Aliquots of an aqueous solution of the bag material shall be used in the suspensibility (4.4) and persistent foam (4.5) tests.

In the case of delay of the above tests, the bag shall be stored in a watertight container (glass bottle or equivalent) to avoid any change in its properties.

Note 3 Method(s) of analysis must be CIPAC, AOAC or equivalent. 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 4 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 5 The method to be used shall be stated. If several methods are available, a referee method shall be selected.

Note 6 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 7 Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, the simpler gravimetric method may be used on a routine basis provided that it has been shown to give equal results to those of chemical assay. In case of dispute, chemical assay shall be the referee method.

Note 8 The procedure for adding the bag material to the solution for the suspensibility and persistent foam tests should be as follows:

Prepare a stock solution of the bag material (1 mg/ml) by weighing approximately a sample (n mg) of the bag (excluding sealed parts) to the nearest mg. Dissolve this sample by stirring in the standard water used for the tests to give a final volume of n ml. Store the stock solution in a stoppered bottle before use.

Calculate the volume (V ml) of the stock solution of the bag to be added to the test suspension of the water dispersible granule according to the following equation:

V(ml) = X *x* 1000B

W

Where: B (g) = weight of the emptied and cleaned bag

W (g) = nominal weight of the WP contained in the bag

X (g) = weight of the WP sample used in the test

Note 9 The mass of sample to be used in the test should be specified at the highest rate recommended by the supplier. The test is to be conducted in CIPAC standard water D at 25 ± 5 °C.

Note 10 The sampling of the bag for the dissolution test should be as follows:

Lay the empty cleaned bag in its original configuration (double layer). Delineate and then cut up a test sample including part of the upper seal (5 cm) and symmetrically including the vertical seal (10 cm). If the size of the bag is less than this dimension, use the whole bag.

Carry out the dissolution test immediately to avoid any modification of the sample.

Note 11 Unless other temperatures and/or times are specified. Refer to Section 4.6.2 of this Manual for alternative storage conditions.

Note 12 If irreversible changes in the characteristics of the bag material are known to occur when stored at elevated temperatures, refer to Section 4.6.2 of this Manual for alternative storage conditions.

Note 13 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.