**6.15 WATER DISPERSIBLE GRANULES IN SEALED WATER SOLUBLE BAG**

**Introduction**

Water dispersible granules in sealed water soluble bag (WG-SB) are intended for application after disintegration and dispersion in water by conventional spraying equipment. A defined quantity of the granules are included in a closed bag which dissolves quickly once applied in water allowing the granules to be disintegrated and dispersed in water.

WGs are formulated in many different ways depending on the physico-chemical properties of the active ingredient and the manufacturing equipment available. This can lead to products of differing appearances and differing particle size ranges. Products with a wide particle size range may give rise to some segregation in the containers. However, since the mixture from which WGs are formed is homogeneous, it is possible to allow a wider particle size range than typically used for GRs.

In order to check the properties of a WG according to a given specification, it is essential that the sample taken is representative. A method of sample preparation of WG is available (CIPAC MT 166: “Sample preparation for analytical determination of WG”) which should be applied.

Samples of intact bags for analysis and testing should be taken from a *freshly* opened commercial container, if practicable.

The properties specified in this guideline are considered to be essential for good field performance. In addition to the properties usually considered for WP, these are dispersibility in water, dustiness, flow properties and attrition resistance.

Note for preparation of draft specifications. Do not omit clauses or insert additional clauses, nor insert limits that are more lax than those 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] WATER DISPERSIBLE GRANULES
IN SEALED WATER SOLUBLE BAG**

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

6.15.1 **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 carriers and any other necessary formulants. It shall be in the form of granules (Note 1), contained in a sealed water soluble bag (Note 2), for application after disintegration and dispersion in water. The formulation shall be dry, free-flowing, nearly dust free or essentially non-dusty, and free from visible extraneous matter and hard lumps.

6.15. 2 **Active ingredient**

6.15. 2.1 **Identity tests** (Notes 3 & 4)

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

6.15. 2.2 **...... [ISO common name] content** (Note 3 & 4)

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.

6.15. 3 **Relevant impurities** (Note 3)

6.15.3.1 **By-products of manufacture or storage** (Note 5), if required

Maximum: ......% of the …… [ISO common name] content found under 6.15. 2.2.

6.15.3.2 **Water** (MT 30.6) (Note 6 ), if required

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

6.15.4 **Physical properties** (Note 3)

6.15.4.1 **Acidity** and/or **alkalinity** (MT 191) or **pH range** (MT 75.3) (Note 7),
if required

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

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

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

6.15.4.2 **Wettability** (MT 53.3) (Note 8)

The formulation shall be completely wetted in ...... min.

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

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

6.15.4.4 **Dispersibility** (MT 174)

Dispersibility: minimum ......% after 1 min of stirring.

6.15.4.5 **Suspensibility** (MT 184.1) (Notes 9 & 10)

The suspensibility shall be tested on a suspension containing the WG and the bag material in the actual ratio of application, prepared according to the procedure described in Note 11.

Suspensibility: minimum ......% s after 30 min in CIPAC Standard Water D at 25 ± 2°C (Note 12).

6.15.4.6 **Persistent foam** (MT 47.3) (Note 13 )

The persistent foam shall be tested on a suspension containing the WG and the bag material in the actual ratio of application, prepared according to the procedure described in Note 11.

Maximum: …… ml after 1 min.

6.15.4.7 **Dustiness** (MT 171) (Note 14)

Nearly dust free or essentially non-dusty. The formulation shall have a maximum collected dust of 30 mg by the gravimetric method or a maximum dust factor of 25 by the optical method.

6.15.4.8 **Flowability** (MT 172.2)

At least ......% of the formulation shall pass through a 5 mm test sieve after 20 drops of the sieve (Note 15).

6.15.4.9 **Attrition resistance** (MT 178.3)

Minimum: ......% attrition resistance.

6.15.4.10 **Dissolution of the bag** (MT 176) (Notes 3 & 16)

The dissolution of the bag shall be tested on a sample of the emptied and cleaned bag together with an appropriate proportion of the WG in CIPAC Standard Water D taken according to the procedure described in Note 16.

Flow time of the suspension: maximum …… sec.

6.15.5 **Storage stability**

6.15.5.1 **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 (Notes 17 & 18). The determined average active ingredient content must not be lower than ……% relative to the determined average content found before storage (Note 19) and the formulation shall continue to comply with the clauses for:

* by-products of manufacture or storage (6.15.3.1),

- acidity/alkalinity/pH range (6.15.4.1),

- wet sieve test (6.15.4.3),

- dispersibility (6.15.4.4),

- suspensibility (6.15.4.5),

* persistent foam (6.15.4.6),
* dustiness (6.15.4.7),
* attrition resistance (6.15.4.9),

- dissolution of the bag (6.15.4.10),

as required.

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

Note 1 Depending on the manufacturing conditions, WGs may have different forms and particle size ranges. To describe specific formulations, it is recommended that information about the form (e.g. irregular shape, nearly spherical, cylindrical...) is added and the nominal size range stated.

Note 2 For record keeping purposes, the suffix “SB” should be added to the formulation code (WG-SB).

Note 3 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),
- dispersibility (4.4),
- suspensibility (4.5),
- persistent foam (4.6),
- dustiness (4.7),
- flowability (4.8),
- attrition resistance (4.9),
- dissolution of the bag (4.10).

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. Aliquots of an aqueous solution of the bag material shall be used in the suspensibility (4.5) and persistent foam (4.6) 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 4 Method(s) of analysis must be CIPAC, AOAC or equivalent. If the methods have not yet been published, full details and appropriate method validation data must be submitted to FAO/WHO by the proposer.

Note 5 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.

Note 6 There may be cases where a minimum water content has to be specified.

Note 7 The method to be used shall be stated. If several methods are available, a referee method shall be selected.

Note 8 The method to be used shall be stated, either with or without swirling.

Note 9 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 10 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 11 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) . 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 WG contained in the bag

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

Note 12 Unless another temperature is specified.

Note 13 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 ± 5oC.

 Note 14 Measurement of dustiness must be carried out on the sample “as received” and, where practicable, the sample should be taken from a newly opened container, because changes in the water content of samples may influence dustiness significantly. The optical method of MT 171.1, usually shows good correlation with the gravimetric method and can, therefore, be used as an alternative where the equipment is available. Where the correlation is in doubt, it must be checked with the formulation to be tested. In case of dispute the gravimetric method shall be used.

Note 15 The flowability test (MT 172.2) included the accelerated storage conditions to be used.

Note 16 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 17 Unless other temperatures and/or times are specified. Refer to Section 4.6.2 of this Manual for alternative storage conditions.

Note 18 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 19 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.