6.12 **WATER DISPERSIBLE GRANULES**

#### **Introduction**

Water dispersible granules (WG) are intended for application after disintegration and dispersion in water by conventional spraying equipment.

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.

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, and flow properties.

*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*

**…… [*Taxon*] WATER-DISPERSIBLE GRANULES**

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

6.12.1 **Description**

The material shall consist of a homogenous mixture of technical…… [taxon] complying with the requirements of FAO / WHO specification [……], 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) 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.

In case there is no TK, the material shall contain ...... [taxon], 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) for application after disintegration and dispersion in water. The formulation shall be dry, free-flowing, essentially non-dusty, and free from visible extraneous matter and hard lumps.

6.12.2 **Active Ingredient**

6.12.2.1 **Identity tests** (Note 2)

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 **….[Taxon] content** (Note 2)

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 UI/g or UI/mL, etc. | | |
|  |  |  |

###### 6.12.3 **Relevant impurities**

6.12.3.1 **Microbial contaminants** (Note 3), if required

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

6.12.3.2 **Secondary compounds** (Note 3), if required

Insert name (any identification code, if exists).

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

6.12.3.3 **Chemical impurities from the manufacturing process)** (Note 3), if required

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

6.12.3.4 **Water** (MT 30.6) (Note 4), if required

Maximum …… g/kg

6.12.4. **Physical properties**

6.12.4.1  **Acidity and/or alkalinity** (MT 191) **or pH range** (CIPAC 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)(Note 6)

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

6.12.4.3 **Wet sieve test** (MT 185.1) (Note 7)

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

6.12.4.4 **Dispersibility** (MT 174)

Minimum ......% after 1 min of stirring.

6.12.4.5 **Suspensibility** (MT 184.1) (Note 8)

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

(Notes 9 and 10)

6.12.4.6 **Persistent foam** (MT 47.3) (Note 11)

Maximum: ...... ml after 1 minute.

6.12.4.7 **Dustiness** (MT 171.1)

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 (Note 12).

6.12.4.8 **Flowability** (MT 172.2)

At least % of the formulation shall pass through a 5 mm test sieve

after 20 drops of the sieve (Note 13).

6.12.4.9 **Attrition resistance** (MT 178.2)

Minimum ...... % attrition resistance.

# 6.12.5 Storage stability

# 6.12.5.1 Low temperature stability (MT 39.3) (Note 14), 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 than ...... % relative to the determined average content found before storage (Note 15).

# 6.12.5.1 Stability at elevated temperature (MT 46.4)

# After storage at 54 ± 2 °C for 14 days (Note 16), the determined average active ingredient content must not be lower than ...... % relative to the determined average content found before storage (Note 15) and the formulation shall continue to comply with the clauses for:

# – acidity/alkalinity/pH range (6.12.4.1),

# – wet sieve test (6.12.4.3)

# – dispersibility (6.12.4.4),

# – suspensibility (6.12.4.5),

# – dustiness (6.12.4.7),

# – attrition resistance (6.12.4.9),

as required.

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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 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 3 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 4 There may be cases where a minimum water content has to be specified.

Note 5 The method to be used shall be stated. If several methods are available, a referee method shall be selected.

Note 6 The method to be used shall be stated, either with or without swirling.

Note 7 The wet sieve test detects coarse particles that may block filters and nozzles.

Note 8 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 MT 184.1.

Note 9 MT 184.1 allows gravimetric determination and assay of the active ingredient in the remaining 25 ml. The assay of some microbial active ingredients may be complex, and therefore the gravimetric determination is generally considered acceptable.

Note 10 Unless another temperature is specified.

Note 11 The mass of sample to be used in the test should correspond to the highest rate recommended by the supplier. The test is to be conducted in CIPAC standard water D.

Note 12 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 13 The flowability test (MT 172.2) includes the accelerated storage conditions to be used.

Note 14 The cold temperature storage test is to be conducted in glass bottle or commercial packaging as for MT 46.4.

Note 15 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 16 Unless other temperatures and/or times are specified. Refer to Section 4.6.2 of this manual for alternative storage conditions.