6.15 **EMULSIFIABLE GRANULES** **(EG)**

# Introduction

#### A water emulsifiable granule is a formulation consisting of granules to be applied as a conventional O/W emulsion of the active ingredient(s), either solubilized or diluted in an organic solvent, after disintegration and dissolution in water.

Water emulsifiable granules comprise one or several active ingredient(s), either solubilized or diluted in a suitable organic solvent which is (are) absorbed in a water soluble polymeric shell or some other type of soluble or insoluble matrix. The formulation may contain other formulants as necessary.

#### Water emulsifiable granules are treated in a similar fashion to water dispersible granules (WG) and emulsifiable concentrates (EC) as they disintegrate and emulsify on dilution into water.

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] EMULSIFIABLE GRANULES**

(CIPAC No.)/EG (month & year of publication)

6.15.1 **Description**

The material shall consist of granules (Note 1) containing technical ...... [ISO common name] in the form of ……. (see Section 4.2), complying with the requirements of FAO/WHO specification ......, which may be dissolved in an organic solvent, together with other suitable formulants. The material shall be homogeneous, dry, free-flowing, free from visible extraneous matter and hard lumps and provide an emulsion upon dilution in water.

6.15.2 **Active ingredient**

6.15.2.1 **Identity tests** (Note 2)

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

6.15.2.2 **...... [ISO common name] content** (Note 2)

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**

6.15.3.1 **By-products of manufacture or storage** (Notes 2 & 3), if required

Maximum: ......% of the …… [ISO common name] content found under 6.15.2.2.

6.15.3.2 **Water** (MT 30.5), if required

Maximum: ...... g/kg.

6.15.4 **Physical properties**

6.15.4.1 **Acidity** and/or **Alkalinity** (MT 191) or **pH range** (MT 75.3) (Note 4), 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 5)

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

6.15.4.3 **Dispersion stability** (MT 180)

The formulation, when diluted at 30 ± 2 °C with CIPAC Standard Waters A and D, shall comply with the following:

|  |  |
| --- | --- |
| Time after allowing the dispersion to stand | Limits of stability |
| 0 h | initial dispersion complete |
| 0.5 h | “cream”, maximum: ...... ml |
|  | “free oil”, maximum: ...... ml |
|  | sediment, maximum: ...... ml |
| 24 h | re-dispersion complete |
| 24.5 h | “cream”, maximum: ...... ml |
|  | “free oil”, maximum: ...... ml |
|  | sediment, maximum: ...... ml |

6.15.4.4 **Wet sieve test** (MT 185) (Note 6)

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

6.15.4.5 **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.

6.15.4.6 **Attrition resistance** (MT 178.2)

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

6.15.4.7 **Persistent foam** (MT 47.3) (Note 7)

Maximum ...... ml after 1 min.

6.15.4.8 **Flowability** (MT172.1)

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

## 6.15.5 Storage stability

6.15.5.1 **Stability at elevated temperature** (MT 46.3)

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

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

- acidity, alkalinity or pH range (6.15.4.1),

- dispersion stability (6.15.4.3),

- wet sieve test (6.15.4.4),

- dustiness (6.15.4.5),

- attrition resistance (6.15.4.6),

as required.

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

Note 2 Methods of analysis for the active ingredient must be CIPAC, AOAC. Methods of analysis for relevant impurities must be peer validated. If the methods have not yet been published then full details, with appropriate validation data, must be submitted to FAO/WHO by the proposer.

Note 3 This clause should only include relevant impurities.

Note 4 In case of drifting pH values, the reading on the pH-meter is taken as constant and valid if the deviation in value is less than 0.1 pH unit over a period of 10 min (without stirring).

Note 5 The method to be used shall be stated, either without or with swirling (MT 53.3.1 or MT 53.3.2).

Note 6 The test will detect any coarse particle which could cause blockage of nozzles and filters.

Note 7 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.

Note 8 Unless other temperatures and/or times are specified. Refer to Section 4.6.2 of this Manual for alternative storage conditions.

Note 9Analysis of the formulation before and after storage stability test may be carried out at the same time (i.e. after storage) to reduce the analytical error.