6.18 **EMULSIFIABLE POWDERS (EP)**

# Introduction

An emulsifiable powder (EP) is applied as a conventional oil-in-water emulsion of the active ingredient(s), after dispersion in water. The active ingredient(s) may be solubilized or diluted in organic solvent(s).

Emulsifiable powders contain one or more active ingredient(s), either solubilized or diluted in suitable organic solvent(s) which is (are) absorbed in a water soluble polymer powder or some other type of soluble or insoluble powder. The formulation may contain other formulants, as necessary.

Emulsifiable powders are treated in a similar fashion to wettable powders (WP), emulsifiable granules (EG) and emulsifiable concentrates (EC), as they disperse and emulsify on dilution in 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 POWDER**

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

## 6.18.1 Description

The material shall consist of a homogeneous mixture of technical ...... [ISO common name], complying with the requirements of FAO/WHO specification [......], in the form of ...... (see Section 4.2), together with any other necessary formulants. The material shall be dry, free flowing, free from visible extraneous matter and hard lumps and provide an emulsion upon dilution in water.

6.18.2 **Active ingredient**

6.18.2.1 **Identity tests** (Note 1)

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

6.18.2.2 **...... [ISO common name]content** (Note 1)

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.

6.18.3 **Relevant impurities**

6.18.3.1 **By-products of manufacture or storage** (Note 2), if required

Maximum: ......% of the …… [ISO common name] content found under 6.18.2.2.

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

Maximum: ...... g/kg.

6.18.4 **Physical properties**

6.18.4.1 **Acidity** and/or **Alkalinity** (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 ......

6.18.4.2 **Wettability** (MT 53.3) (Note 4)

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

6.18.4.3 **Dispersion stability** (MT 180) (Note 5)

### The formulation, when diluted at 23 ± 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 |

6.18.4.4 **Wet sieve test** (MT 185.1) (Note 6)

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

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

Maximum ...... ml after 1 min.

6.18.5 **Storage stability**

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

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 (6.18.3.1),

- acidity, alkalinity or pH range (6.18.4.1),

- dispersion stability (6.18.4.3),

- wet sieve test (6.18.4.4),

as required.

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Note 1 Method(s) of analysis must be CIPAC, AOAC. Where methods have not yet been published, full details and appropriate 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.

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

Note 4 The method to be used shall be stated, either without or with swirling (MT 53.3.1 or MT 53.3.2).

Note 5 The formulation should be tested at 2% dilution.

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 at 25 ± 5 °C.

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

Note 9 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.