7.41 **SUSPO-EMULSIONS (SE)**

**Introduction**

A suspo-emulsion (SE) is a fluid heterogeneous formulation consisting of a stable dispersion of active ingredient(s) in the form of solid particles and of water-non-miscible fine globules in a continuous water phase. The formulation is intended for dilution into water prior to spray application. Mixtures of active ingredients are often used to provide a broader spectrum of pest control. Formulating the active ingredients together eliminates the need for tank mixing (which can lead to incompatibilities). Like other aqueous liquid formulations, suspo-emulsions are easy to handle and measure, dust free, non-flammable and offer good miscibility with water.

Suspo-emulsions are not stable indefinitely and therefore it is necessary to ensure that, after transportation and storage, the formulation remains suitable for use. Quantification of the following parameters, particularly after high and low temperature stability tests, serves this purpose.

- Active ingredient identity tests and active ingredient content determination (related to biological efficacy);

- Impurities;

- Pourability test (to ensure that the SE can be poured from its container);

- Dispersion stability and wet sieve tests (to ensure the sprayability of the diluted suspo-emulsion).

Information about other properties may also be given, but these parameters do not normally constitute essential parts of the specification.

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] SUSPO-EMULSION**

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

7.41.1 **Description**

The material shall consist of a suspension of fine particles of technical ...... [ISO common name] complying with the requirements of the FAO/WHO specification ......, in the form of ....... (see Section 4.2), combined with an emulsion of fine droplets of technical ...... [ISO common name] complying with the requirements of the FAO/WHO specification …..., in the form of ...... (see Section 4.2), in an aqueous phase together with suitable formulants. After gentle agitation the material shall appear homogeneous (Note 1) and be suitable for further dilution in water.

7.41.2. **Active ingredients**

7.41.2.1 **Identity tests** (Note 2)

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

7.41.2.2 **…… and …… [ISO common names] content** (Note 2)

The …… and …… [ISO common names] content shall be declared (g/kg or g/l at 20 ± 2 ºC, Note 3) and, when determined, the average contents measured shall not differ from those declared by more than the appropriate tolerances, given in the table of tolerances, Section 4.3.2.

7.41.3 **Relevant impurities**

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

 Maximum: ..….% of the …… [ISO common name] content found under 7.41.2.2.

7.41.4 **Physical properties**

 7.41.4.1 **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 ......

7.41.4.2 **Pourability** (MT 148.1)

 Residue : ......%.

If required: Rinsed residue ......%.

7.41.4.3 **Dispersion stability** (MT 180) (Note 6)

 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 |

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

 Maximum: ......% of the formulation shall be retained on a ...... µm test sieve.

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

 Maximum ......ml after 1 min.

7.41.5 **Storage stability**

7.41.5.1 **Stability at 0 °C** (MT 39.3)

 After storage at 0 ± 2 °C for 7 days, the formulation shall continue to comply with the clauses for:

- dispersion stability (7.41.4.3),

- wet sieve test (7.41.4.4),

as required.

7.41.5.2 **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 (7.41.3.1),

- acidity/alkalinity/pH range (7.41.4.1),

- pourability (7.41.4.2),

- dispersion stability (7.41.4.3),

- wet sieve test (7.41.4.4),

as required.

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Note 1 All the physical and chemical tests must be carried out on a sample taken after the recommended homogenization procedure. Before sampling to verify formulation quality, inspect the commercial container carefully. On standing, suspo-emulsions usually develop a concentration gradient which may result in the appearance of a clear layer at either the top or the bottom of the container. A sediment layer may also form at the bottom of the container, which can be detected by probing with a glass rod. Before sampling, homogenize the formulation according to the instructions given by the manufacturer or, in the absence of such instructions, by gentle shaking of the commercial container (for example by inverting the closed container several times). After this procedure the container should not contain a sticky layer of non-dispersed matter at the bottom (if the suspo-emulsion has flocculated it may not be possible to re-disperse this sticky layer).

Note 2 Method(s) of analysis must be CIPAC, AOAC or equivalent. Where methods have not yet been published, full details and appropriate method validation data must be submitted to FAO/WHO by the proposer.

Note 3 Unless homogenization is carried out carefully, it is possible for the sample to become aerated. This can lead to errors in the determination of the active ingredient content in g/l. It is preferable, therefore, to determine the content in g/kg and, if necessary, to determine the mass per millilitre, to calculate the active ingredient content in g/l.

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.

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 2% dilution.

Note 7 The mass of sample to be used in the test should be at the highest rate of use 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 storage stability test may be analysed concurrently after the test in order to reduce the analytical error.