**7.31**  **SUSPENSION CONCENTRATES**

**Introduction**

Suspension concentrate (SC) is the designation for a stable suspension of active ingredient(s) in an aqueous continuous phase, intended for dilution with water before use.

The parameters which best describe the performance characteristics are:

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

- Water dispersibility (spontaneity of dispersion), suspensibility, wet sieve and persistent foam tests (to ensure the sprayability of the diluted suspension).

Some other physical properties, especially particle size range and viscosity, however, are excluded from the specification for the following reasons:

- Particle size range: There is no internationally accepted, simple method for determination of the particle size range of SCs. Moreover, particle size range is described and limited in the specification by a number of easily quantifiable parameters which are influenced by it. These parameters are the wet sieve analysis, suspensibility, pourability and water dispersibility;

- Viscosity: Although viscosity is also an important property, it cannot readily be determined by simple means. Since most SCs show non-Newtonian flow characteristics, viscosity is only one part of a much more complex rheology. Pourability and water dispersibility parameters included in the specification adequately describe the flow (rheological) properties.

*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] SUSPENSION CONCENTRATE**

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

**7.31.1** **Description**

The material shall consist of a suspension of fine particles of technical ...... [ISO common name], complying with the requirements of 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 be homogeneous (Note 1) and suitable for further dilution in water.

**7.31.2** **Active ingredient**

7.31.2.1 **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.

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

The ...... [ISO common name] content shall be declared (g/kg or g/l at 20 ± 2 ºC, Note 3) 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.

**7.31.3** **Relevant impurities**

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

Maximum: ......% of the …… [ISO common name] content found under 7.31.2.2.

**7.31.4** **Physical properties**

7.31.4.1 **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 ......

7.31.4.2 **Pourability** (MT 148.2)

 Residue : ......%.

7.31.4.3 **Spontaneity of dispersion** (MT 160.1) (Note 6)

Minimum of ......% after 5 min in CIPAC Standard Water D at 25 ± 5 °C.

7.31.4.4 **Suspensibility** (MT 184.1) (Note 6)

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

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

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

7.31.4.6 **Persistent foam** (MT 47.3) (Note 8)

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

7.31.4.7 **Particle size distribution** (MT 187), if required

…% of particles shall be in the range … to … (Note 9)

**7.31.5** **Storage stability**

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

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

- suspensibility (7.31.4.4),

- wet sieve test (7.31.4.5),

as required.

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

After storage at 54 ± 2 °C for 14 days (Note 10), the determined average active ingredient content must not be lower than ......% relative to the determined average content found before storage (Note 11) and the formulation shall continue to comply with the clauses for:

- by-products of manufacture or storage (7.31.3.1),

- acidity/alkalinity/pH range (7.31.4.1),

- pourability (7.31.4.2),

- spontaneity of dispersion (7.31.4.3),

- suspensibility (7.31.4.4),

- wet sieve test (7.31.4.5),

as required.

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Note 1 Before sampling to verify the formulation quality, inspect the commercial container carefully. On standing, suspension concentrates usually develop a concentration gradient from the top to the bottom of the container. This may even result in the appearance of a clear liquid on the top and/or of sediment on the bottom. Therefore, 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). Large containers must be opened and stirred adequately. After this procedure, the container should not contain a sticky layer of non-dispersed matter at the bottom. A suitable and simple method of checking for a non-dispersed sticky layer (“cake”) is by probing with a glass rod or similar device adapted to the size and shape of the container. All the physical and chemical tests must be carried out on a sample taken after the recommended homogenization procedure.

Note 2 Method(s) of analysis must be CIPAC, AOAC or equivalent. 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 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 mass per millilitre and in calculation of the active ingredient content (in g/l) if methods other than OECD 109 or MT 3.3 are used. If the buyer requires both g/kg and g/l at 20 °C, then in case of dispute the analytical results shall be calculated as g/kg.

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/ILV.

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

Note 6 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 7 This test detects coarse particles (e.g. caused by crystal growth) or agglomerates (crust formation) or extraneous materials which could cause blockage of spray nozzles or filters in the spray tank.

Note 8 The mass of sample to be used in the test should correspond to 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 9 Percentages may be specified in one or more ranges, as appropriate to the product. The determination of particle size range by laser diffraction is not an ideal criterion to ensure the suitability of liquid formulations. This should be evaluated by Wet sieve test (MT 185.1) and Suspensibility (MT 184.1) or Dispersion stability (MT 180).

Note 10 Unless other temperatures and/or times are specified. Refer to Section 4.6.2 of this Manual for alternative storage conditions.

Note 11 Samples of the formulation taken before and after the storage stability test should be analysed concurrently after the test in order to reduce the analytical error.