6.1 **DUSTABLE POWDERS** **(DP)**

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] DUSTABLE POWDER**

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

6.1.1 **Description**

The material shall consist of an 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 carriers and any other necessary formulants. It shall be in the form of a fine, free-flowing powder, free from visible extraneous matter and hard lumps.

6.1.2 **Active ingredient**

6.1.2.1 **Identity tests** (Note 1)

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

6.1.2.2 **...... [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.

6.1.3 **Relevant impurities**

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

Maximum: ......% of the …… [ISO common name] content found under 6.1.2.2

6.1.3.2 **Water** (MT 30.5) (Note 3), if required

Maximum: ...... g/kg.

6.1.4 **Physical properties**

6.1.4.1 **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 ......

6.1.4.2 **Dry sieve test** (MT 170) (Note 4)

Maximum: 5% retained on a 75 µm test sieve. Not more than (0.005 x X)% of the formulation shall be retained on a test sieve of which the size must be specified.

Alternatively, not more than (0.005 x X)% of the mass of the sample used for the determination shall be present as ... [ISO common name] in the residue on the sieve, where X is the ... [ISO common name] content (g/kg) found under 6.1.2.2 (Note 5).

6.1.5 **Storage stability**

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

After storage at 54 ± 2 °C for 14 days (Note 6), the determined average active ingredient content must not be lower than ......% relative to the determined mean content found before storage (Note 7) and the formulation shall continue to comply with the clauses for:

- by-products of manufacture or storage (6.1.3.1),

- acidity/alkalinity/pH range (6.1.4.1),

- dry sieve test (6.1.4.2),

as required.

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Note 1 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 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 method.

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

Note 4 Method MT 170, together with relevant methods of analysis for active ingredient, see Note 1.

Note 5 If the formulation has a found content of 40 g/kg (X) of ...... [ISO common name] and 20 g of sample is used in the test, then the amount of ...... [ISO common name] in the residue on the sieve should not exceed 0.040 g, e.g. (0.005 x 40) x 20 / 100 g.

Note 6 Unless other temperatures and/or times are specified. Refer to Section 4.6.2 of this Manual for alternative storage conditions.

Note 7 Samples of the formulation taken before and after the storage stability test may be analyzed concurrently after the test in order to reduce the analytical error.