6.3 **GRANULES** **(GR)**

**Introduction**

These specifications are intended for granular products to be applied in dry form by machine. Granules formulated on commercially available fertilizers as carriers are excluded, if they are to be applied at full fertilizer rate.

Granules are formulated in many different ways depending on the physico-chemical properties of the active ingredient(s), the manufacturing equipment available and the nature of the carriers used. This can lead to products of differing physical properties. Furthermore, a wide range of application equipment is available in different parts of the world. In consequence, the establishment of internationally agreed specifications for granules is relatively more difficult than is the case for some other types of formulation.

*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] GRANULES**

[CIPAC number]/GR (month & year of publication) (Note 1)

6.3.1 **Description**

The material shall consist of granules containing technical ...... [ISO common name], complying with the requirements of FAO/WHO specification [......], in the form of ...... (see Section 4.2), together with suitable carriers and any other necessary formulants. It shall be dry, free from visible extraneous matter and hard lumps, free-flowing, nearly dust-free or essentially non-dusty and intended for application by machine.

6.3.2 **Active ingredient**

6.3.2.1 **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.

6.3.2.2 **...... [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.

6.3.2.3 **Release rate of active ingredient** (applicable only for slow- or controlled release formulations), if required

The release rate measured shall comply with the following criteria: …….

6.3.3 **Relevant impurities**

6.3.3.1 **By-products of manufacture or storage** (Note 3), if required

Maximum: ......% of the …… [ISO common name] content found under 6.3.2.2.

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

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

6.3.4 **Physical properties**

6.3.4.1 **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 ......

6.3.4.2 **Pour and tap density** (MT 186), if required

Pour density: ...... to ...... g/ml.

Tap density: ...... to ...... g/ml.

6.3.4.3 **Nominal size range** (MT 170)

The nominal size range of the formulation shall be declared (Note 5). Normally, the ratio of the lower to the upper limit should not exceed 1:4 (Note 6). Not less than 850 g/kg of the formulation shall be within the nominal declared size range.

6.3.4.4 **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 (Note 7).

6.3.4.5 **Flowability** (MT 172.2)

At least ……% of the formulation shall pass through a 5 mm test sieve after 20 drops of the sieve (Note 8)

6.3.4.6 **Attrition resistance** (MT 178)

Minimum ......% attrition resistance.

6.3.5 **Storage stability**

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

After storage at 54 ± 2 °C for 14 days (Note 9), the determined average active ingredient content must not be lower than ......% relative to the determined average content found before storage (Note 10) and the formulation shall continue to comply with the clauses for:

- by-products of manufacture or storage (6.3.3.1),

- acidity/alkalinity/pH range (6.3.4.1),

- dustiness (6.3.4.4),

- attrition resistance (6.3.4.6),

as required.

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Note 1 Where the specification does not include certain types of granule, the exclusions should be noted in the description.

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

Note 5 e.g. 250 to 500 µm, 500 to 1,200 µm.

Note 6 Higher ratios increase the risk of segregation and adverse effects on the flow rate. This should be checked with the machine to be used. The purchaser should check that the nominal size range is suitable for his requirements, since different size ranges may affect biological activity.

Note 7 The optical method of MT 171.1, usually shows good correlation with the gravimetric method, and can, therefore, be used as an alternative where the equipment is available. Where the correlation is in doubt, it must be checked with the formulation to be tested. In case of dispute the gravimetric method shall be used.

Note 8 The flowability test (MT 172.2) includes the accelerated storage conditions to be used

Note 9 Unless other temperatures and/or times are specified. Refer to Section 4.6.2 of this manual for alternative storage conditions.

Note 10 Samples of the formulation taken before and after the accelerated storage stability test may be analyzed concurrently after the test in order to reduce the analytical error.