**8.11** **AEROSOL DISPENSERS**

# Introduction

Not all characteristics which define the acceptability of aerosol dispensers (AE) are incorporated in the specification guideline given below.

The flammability and ignition distance of the spray produced by the dispenser and formulation are of potentially great importance to the user, but they must be dealt with by appropriate labelling of the dispensers.

The spray droplet size distribution is relevant to operator risk and may influence efficacy. At present, the measurement is complex and interpretation of the results is not straightforward, and therefore no clause is included.

Aerosol dispensers are expected to withstand corrosion for a minimum of 2 years from the date of release by the manufacturer. Ideally, specifications would include a clause to define the corrosion resistance of the dispenser. At present, no practical method is available to predict whether or not the structural integrity of dispenser could be compromised within 2 years and therefore a clause cannot be included. Manufacturers, users of aerosols and/or other interested parties are invited to develop and propose simple methods based on standard conditions, so that this important omission can be rectified.

*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. If two or more active ingredients are co-formulated, they should have separate specifications. From the “Notes” provided at the end of this guideline, incorporate only those which are applicable to the particular specification.*

**...... [ISO common name] AEROSOL DISPENSERS**

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

The material, sampled from any part of the consignment in accordance with the procedure described in Note 1 or any other acceptable procedure, shall comply with the specification.

**8.11.1** **Description**

The product shall consist of a liquid ‡formulation in a pressurised, non-refillable aerosol dispenser, containing propellant(s), synergist(s) and other formulants (see Note 2, for restrictions on solvents and propellants), as required, intended for release of the active ingredient into the air in the form of an aerosol. The technical (ISO common name(s)), in the form(s) of …… (see Section 4.2), used in the manufacture of the formulation shall comply with the requirements of WHO specification(s) ......

**8.11.2** **Active ingredient and synergist**

8.11.2.1 **Identity tests** (Notes 3 & 4)

 The active ingredient (and synergist, if required) shall (each) comply with an identity test and, where the identity remains in doubt, shall comply with at least one additional test.

8.11.2.2 **[Active ingredient ISO common name] content** (Notes 3 & 4)

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 tolerances, given in the table of tolerances, Section 4.3.2.

8.11.2.3 **[Synergist ISO common name] content** ( Notes 3 & 4), if required

The ...... [ISO common name] content shall be declared (g/kg) and, when determined, the average content measured shall not differ from those declared by more than the appropriate tolerances, given in the table of tolerances, Section 4.3.2.

**8.11.3** **Relevant impurities**

8.11.3.1 **By-products of manufacture or storage** (Notes 4 & 5), if required

Maximum: ..….% of the …… [active ingredient ISO common name] content found under 8.11.2.2.

**8.11.4**  **Physical properties**

8.11.4.1 **Net content of formulation**

The minimum net content shall be declared (g) and, when determined, the average net content shall not be lower than that declared.

8.11.4.2 **Internal pressure** (Note 6 and Figure 1)

 The pressure of the filled dispenser shall be declared on the label and, when measured at 30 ± 2°C, the internal pressure shall not exceed ...... MPa.

8.11.4.3 **Discharge rate** (MT 202) (Note 7)

The discharge rate of the filled dispenser shall be within the range .….. to …… g formulation/sec.

8.11.4.4 **pH range** (applicable to water-based formulations only) (MT 75.3) (Note 8)

pH range: ...... to ......

8.11.4.5 **Clogging of aerosol dispenser valves**

No clogging shall occur when the aerosol dispenser valves are tested in accordance with the procedure as described in Note 9 or any other acceptable method.

**8.11.5** **Storage stability**

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

After storage at 54 ± 2 ºC 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 clause for:

- by-products of manufacture or storage (8.11.3.1); and,

- the combined weight of the container and contents shall not be less than …% of the original weight,

s required.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Note 1 Sampling

*General requirements*

a) Samples shall be stored in such a manner that there is no deterioration of the material.

b) The sampling instrument shall be clean and dry.

c) Samples shall be protected against contamination.

*Sampling, testing and acceptance*

a) In any consignment, all the master cartons containing containers of the same type shall constitute a lot.

b) Samples shall be drawn from each lot and individually tested to ascertain whether the material complies with the specified requirements.

c) Any sample failing to comply with the specified requirements shall be termed as defective. The acceptance number shall be the maximum number of defective samples permissible for a lot to be accepted.

d) The number of containers to be drawn from the lot and the acceptance number shall be as shown in the following Table.

|  |  |  |
| --- | --- | --- |
| Total number of containers in lot | Number of containers to be tested | Acceptance number |
| 300 or less301 to 12001201 to 20002001 to 70007001 to 1500015001 to 2400024001 to 41000over 41000 | 361321294884126 | 012346913 |

e) Each of the containers to be tested shall be drawn from a different master carton which shall be selected at random. In order to ensure randomness of selection, random number tables shall be used. If such tables are not available, the following procedure may be adopted.

 Starting from any master carton, count the master cartons as 1, 2, 3...... r in a systematic manner. Every rth carton shall be drawn, r being the integral part of N/n, where N is the total number of master cartons in the lot and n the number of master cartons to be selected.

Note 2 Solvents not permitted for use in aerosols:

• benzene

• 2-butoxyethanol (ethylene glycol monobutyl ether)

• 2-butoxyethylacetate (ethylene glycol monobutyl ether acetate)

• carbon tetrachloride

• chlorobenzene

• chloroform

• 1,2-dichloroethane (ethylene dichloride)

• 2-ethoxyethanol (ethylene glycol monoethyl ether)

• 2-ethoxyethylacetate (ethylene glycol monoethyl ether acetate)

• *n*-hexane

• 2-hexanone (methyl *n*-butyl ketone)

• 2-methoxyethanol (ethylene glycol monomethyl ether)

• 2-methoxyethylacetate (ethylene glycol monomethyl ether acetate)

• tetrachloroethylene

• trichloroethylene.

• Propellants. The Montreal Protocol and European Union1 directive on the withdrawal of chlorofluorocarbons (CFCs) from aerosols were noted. Hydrocarbon propellants are recommended for insecticide aerosols, provided international safety standards are met by the aerosol producer. Industry should be encouraged to develop alternative and safer propellants and delivery systems.

 Note 3 Method(s) of analysis must be CIPAC or AOAC. If the methods have not yet been published then full details, with appropriate method validation data, must be submitted to WHO by the proposer.

Note 4 To remove the contents of the dispenser it should be weighed (to ± 0.01 g, at room temperature so that it is dry on the outside) and either immersed in dry ice (solid carbon dioxide) for a minimum of 1 h or placed in deep freeze (-18 ºC or below) overnight. The container should then be removed to a fume hood and, using a suitable shield, the container should be punctured towards the top with a sharp implement, making a hole or holes that will be sufficiently large for the subsequent introduction and removal of extraction solvent. Allow the propellent to evaporate by allowing the contents to rise to room temperature without applying additional warming. Using a suitable solvent (appropriate to the active ingredient and synergist), thoroughly rinse the contents of the dispenser into a volumetric flask, make to volume with the solvent. If possible, use a solvent that will not remove paint or other external coatings. Using a suitable analytical method, determine the mass of active ingredient and synergist in the rinsate. Dry the rinsed dispenser and re-weigh it to determine the mass of formulation it contained. Use this value to express the content of active ingredient and synergist on a g/kg basis.

Note 5 This clause should include only relevant impurities and the title should be changed to reflect the name of the relevant impurity. The method(s) of analysis must be peer validated/ILV.

Note 6 Determination of pressure in finished aerosol packs[[1]](#footnote-2)2.

*Introduction*

The determination of the pressure existing in the finished aerosol packs is necessary to verify that the true pressure is compatible with the pressure limitations of the pack, and in accordance with the regulations in force.

True pressure is the relative pressure given by an accurate manometer, at a given temperature.

*Objective*

The determination of the true pressure in the finished aerosol pack:

1. in such a way that the measurement affects as little as possible the value of the real pressure;
2. in such a way that the manometer will not be polluted by the product under pressure present in the pack.

*Scope*

The method is recommended for determination of the true pressure of all filled aerosol packs.

*Apparatus*

The following are required:

1. a source of reference gas (nitrogen for instance) from which the pressure can be regulated by means of a control valve;
2. a manometer of high accuracy, if possible cushioned by an oil-bath and adapted to fit the aerosol container on which the measurement will be effected (Figure 1).

The apparatus must be assembled in such a way that, in the state of rest, the manometer is connected to the reference gas (the pressure of this gas being slightly higher than the actual pressure in the pack) and, for taking the measurement, the manometer is connected to the interior of the pack to show the actual pressure.

*Working operation*

1. Make sure that the aerosol dispenser is thoroughly equilibrated to 30 ± 2 ºC.
2. The measuring apparatus must be fitted with an appropriate adaptor for the valve employed.
3. The pressure of the reference gas must be regulated to a value slightly higher than the anticipated pressure of the dispenser.
4. Apply the measuring apparatus to the valve and press lightly in order to open the valve and the slide of the apparatus.
5. Read the true pressure on the manometer, when the needle has stabilized.

*Accuracy of measurement*

The measurement of the true pressure will be the more accurate:

1. with larger aerosol dispenser sizes;
2. with only a small difference in pressure between the reference gas and the true pressure of the dispenser (if required, measurements can be made on additional dispensers after adjusting the reference gas pressure to a value very close to the true pressure);
3. if the dead volume of the manometer is small (less than 2 ml).

*Test report*

The test report must indicate, in addition to the results and test conditions, any relevant working details not specified in the method, especially if they are suspected of having influenced the results.

*Notes*

1 It is necessary to recalibrate the manometer frequently, for example with the aid of a manometric balance.

2 A non-return valve can be inserted in the apparatus to avoid the aerosol product penetrating the manometer if the pressure of the reference gas is inadvertently much lower than the true pressure in the dispenser.

Note 7 The method is applicable for non-lockable aerosol dispensers. Note 8 The pH may be determined by any acceptable method.

Note 9 Testing of valves of filled aerosol dispensers for clogging

*Apparatus*

a) Fume hood

b) Protective clothing and mask.

*Procedure*

Shake the aerosol dispensers thoroughly and, keeping them in an upright position, disperse the contents of each into the fume hood. Actuate the valve in a series of cycles (30 sec on, 30 sec off) until the dispenser is emptied. Examine the valves for clogging.

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 analyzed concurrently after the test in order to reduce the analytical error.

**Figure 1. Manometric measurement of internal pressure.**

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1. 2 European Aerosol Federation, (49 Square Marie-Louise, 1000 Brussels, Belgium). [↑](#footnote-ref-2)