8.22 **MATRIX RELEASE FORMULATION (MR)**

**Introduction**

Matrix release formulation in this guideline is mainly for public health protection uses but could potentially also be used in agricultural applications in the future. This formulation type can be classified into the following two basic forms;

1. One or more active ingredient(s) are either incorporated into a polymer, or coated onto the surface of a polymer.
2. In some cases, both methods (coating and incorporation) are applied for the preparation of a finished MR formulation (combination type).

“Combination matrix formulation is composed of different types of formulations such as coated and incorporated, which are produced by different preparation methods.”

For combination type MR formulations it is advisable to split the specification into one specification for each polymer preparation type and another for the finished product. The specifications and footnotes should be modified accordingly to cover the clauses properly. For such a product, two specifications which refer to each preparation method are then combined into a specification for a finished product.

A matrix release formulation consists of one or more active ingredients, polymer and formulants if appropriate. Its size and weight is defined by manufacturing and/or use requirements. It is intended for direct application into a body of water.

Generally, for public health protection, this formulation shall realize long lasting pest efficacy by controlled release of active ingredient(s) after application into the habitat of harmful pests, for example, a water source, pond, water jar or well.

Therefore, selection of active ingredient(s), content of active ingredient(s), product design (shape or size) and retention/release rate of active ingredient(s) are important parameters for defining the quality of this formulation type.

These parameters can be optimized by the manufacturing process and/or customer needs.

*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. For combination MR, specifications must be separated into one specification for each material and one for the finished product.**From the “Notes” provided at the end of this guideline, incorporate only those which are applicable to the particular specification.*

**… [ISO common name] MATRIX RELEASE FORMULATION**

[CIPAC number]/MR (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.

8.22.1 **Description**

The product shall be formed mainly from polymer treated with, technical/formulated … [ISO common name] complying with the requirements of FAO/WHO specification … [CIPAC number/technical or formulation code (date)], and … [ISO common name and/or chemical name and CAS number] (synergist, if required) complying with the requirements of FAO/WHO specification … [CIPAC number/technical or formulation code (date)], together with any necessary other formulants. The product shall appear clean and shall be free from visible extraneous matter, visible damage (such as splitting or tearing) and visible manufacturing defects, and shall be suitable for use as/in a pesticidal formulation with controlled release activity. (Note 2)

8.22.2 **Active ingredient**

8.22.2.1 **Identity tests** (Note 3)

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.

8.22.2.2 … **[ISO common name] content** (Notes 3 and 4)

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

8.22.2.3 … **[ISO common name] isomer ratio** (Notes 3 and 5), if required

The ratio of … isomers shall be in the range … to ….

8.22.2.4 … **[ISO common name] content (synergist)** (Notes 3, 4 and 5), if required

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

8.22.2.5 **Retention/release rate of** … **[ISO common name]** (Notes 3 and 4)

The retention/release rate of … [ISO common name] from the polymer, when measured, shall comply with the following criteria:

8.22.3 **Relevant impurities**

8.22.3.1 **By-products of manufacture or storage** (Notes 4, 5 and 6), if required

Maximum: …% of the … [ISO common name] content found under 8.22.2.2.

8.22.4 **Physical properties**

8.22.4.1 **Floating or sinking ability** (Note 7)

The product, when used, should [sink or float] in water.

8.22.5 **Storage stability**

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

After storage at 54 ± 2 °C for 2 weeks (Note 8), the determined total active ingredient content shall not be lower than …%, and the determined total synergist content shall not be lower than …% (Note 5), relative to the determined average content found before storage (Notes 9 and 10) and the product shall continue to comply with the clauses for:

- isomer ratio (8.22.2.3),

- retention/release rate (8.22.2.5),

- by-products of manufacture or storage (8.22.3.1) (Note 11),

as required.

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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 matrix formulation products of the same type shall constitute a lot. Each master carton contains several containers.

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/samples to be drawn from the lot and the acceptance number shall be as shown in the following Table.

|  |  |  |
| --- | --- | --- |
| Total number of containers/samples in lot | Number of containers/samples to be tested | Acceptance number |
| 300 or less  301 to 1200  1201 to 2000  2001 to 7000  7001 to 15000  15001 to 24000  24001 to 41000  Over 41000 | 3  6  13  21  29  48  84  126 | 0  1  2  3  4  6  9  13 |

e) Each of the containers/samples 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 The product weight and shape should be described in a Note to distinguish from others.

Note 3 Method(s) of analysis must be CIPAC or 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 4 Samples must be sufficiently large to conduct all tests required and representative of the product. A sufficient quantity of samples must be selected by taking at random and in some cases the total amount of product must be used. Where a final product is made from more than one type of polymer preparation method (e.g. coating and incorporation), then each type should be sampled and tested separately.

Use sharp scissors, or equivalent, to minimize damage to the product and thus avoid any consequential bias in the results of certain tests. Put the small portion in a labelled, new, clean screw glass bottle prior to analysis. Samples should be kept cool, avoiding heat sources (including sun heat) or freezing, and analyzed/tested with minimum delay.

For the purposes of chemical analysis, the analytical method and the number and size of test portions analyzed should be designed to provide applicable results. Test portion and replication requirements for physical test methods should be defined in the methods or Notes referenced.

Methods for determination of retention/release rate and the criteria to be met for product retention/release rate may be product specific.

Note 5 This clause or sub-clause is required only if appropriate to the product specified. Isomer ratio is specified only where the active ingredient is defined as a particular isomer ratio. A synergist is specified only where required. An impurity is specified only where it is relevant, as defined in the glossary of terms (Appendix C).

Note 6 The method of analysis must be peer-validated, as a minimum. If it is not published, full details of the method and the peer-validation data must be provided.

Note 7 Whether a final product, when used, sinks or floats on water depends on the type of polymer. It closely relates to application method and must be specified.

Drop one piece of the product in a sufficiently-large beaker containing CIPAC standard water D. Stir thoroughly using a glass rod to ensure complete wetting. Check to confirm that air bubbles are completely removed. After 1 min, state the test result. Possible results are: “sinking” or “floating”.

Note 8 Unless other temperatures and/or times are specified. Alternative conditions are: 6 weeks at 45 ± 2 °C; 8 weeks at 40 ± 2 °C; 12 weeks at 35 ± 2 °C or 18 weeks at 30 ± 2 °C. Whole product must be stored.

Note 9 Samples of the product taken before and after the storage stability test should be analysed concurrently in order to reduce the analytical error.

Note 10 When the whole product is used to analyse the active ingredient/synergist, the tolerance of the product should be examined and described.

Note 11 This sub-clause is required only if the relevant impurity concentration is capable of increasing during storage.