World Health Organization

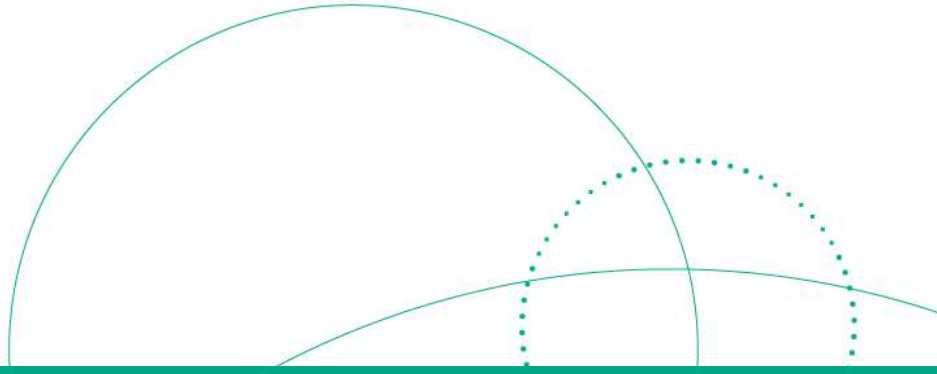
WHO Prequalification Programme / Vector Control Product Assessment

WHO Public Assessment Report:

Change assessment

FastM
(Saerfu (Henan) Agrochemical Co. Ltd)
035-001
PQC-VCP-2025-0011

There have been no changes to the WP-SB presentation of the FastM product. The WP-SB presentation of the FastM product has been considered according to the 2018 assessment and WHOPES recommendation.



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Contents

1. Introduction

FastM, formulated as wettable powder in water soluble bag (WP-SB), is an indoor residual spray which received a prequalification decision in September 2019 on the basis of conversion from a WHOPES recommendation. Moreover, the request for inclusion in the JMPS procedures for the extension of an established specification to include this product formulation was completed as part of the 2018 JMPS meeting in June 2018.

The applicant, Saerfu (Henan) Agrochemical Co. Ltd, has now submitted a Post-Prequalification Change Application to include FastM, formulated as wettable powder (WP), as another presentation of the product.

The formulation of both FastM product presentations (WP-SB and WP) is the same, but the packaging differs (WP being packaged without the water-soluble bag).

The change application does not require a review of the safety (Module 4) and efficacy (Module 5) data as the reference product was assessed previously with the consideration for presentation of the product in both WP and WP-SB forms.

2. Chemical and physical data

2.1 Chemical and physical properties

Data on the chemical and physical properties of the product FastM, formulated as wettable powder (WP), were provided. These data were obtained from studies conducted according to established standards and/or Good Laboratory Practices (GLP) and are considered complete. Five batches were tested in accordance with WHO requirements for testing physical/chemical properties. The results are presented in Table 1. These summary results are based on the analysis of batches EWP20250401, EWP20250402, EWP20250403, EWP20250404, EWP20250405 for active ingredient content and batch EWP20250405 for all physical chemical properties tested before and after storage stability at elevated temperature.

Table 1. Chemical and physical properties for FastM (formulated as WP)

Data requirement	Study number	Test method ID	Results
Bendiocarb content (test item stored at room temperature)	PQ-SN-25-005	232/WP/(M)/3, CIPAC Handbook D, p.12, 1988	Five batches and two samples/batch were tested: Mean value Batch No. EWP20250401: 82.18 % w/w Mean value Batch No. EWP20250402: 81.96 % w/w Mean value Batch No. EWP20250403: 81.69 % w/w Mean value Batch No. EWP20250404: 82.16 % w/w Mean value Batch No. EWP20250405: 81.60 % w/w
Bendiocarb content (after accelerated storage stability, 2 weeks at 54 °C)	PQ-SN-25-005	232/WP/(M)/3, CIPAC Handbook D, p.12, 1988	One batch and two samples/batch were tested: Mean value Batch No. EWP20250405: 81.60 % w/w
Wet sieve test (test item stored at room temperature) 75 µm sieve	PQ-SN-25-005	CIPAC MT 185.1, Handbook K, p. 149, 2003	One batch and two replicates/batch were tested: Mean value Batch No. EWP20250405: residue 75 µm: <0.1%
Wet sieve test (after accelerated storage stability test) 75 µm sieve	PQ-SN-25-005	CIPAC MT 185.1, Handbook K, p. 149, 2003	One batch and two replicates/batch were tested: Mean value Batch No. EWP20250405: residue 75 µm: <0.1%

Table 1. Chemical and physical properties for FastM (formulated as WP)			
Data requirement	**Study number**	**Test method ID**	**Results**
Wettability (test item stored at room temperature) (without swirling)	PQ-SN-25-005	CIPAC MT 53.3, CIPAC Handbook F, p.164, 1995	One batch and two replicates/batch were tested: Mean value Batch No. EWP20250405: 32 s
Wettability (after accelerated storage stability test) (without swirling)	PQ-SN-25-005	CIPAC MT 53.3, CIPAC Handbook F, p.164, 1995	One batch and two replicates/batch were tested: Mean value Batch No. EWP20250405: 30 s
Persistent foam 5.0 %w/v CIPAC water D (test item stored at room temperature)	PQ-SN-25-005	CIPAC MT 47.3, CIPAC Handbook O, p. 177, 2017	One batch and two replicates/batch were tested: Mean value Batch No. EWP20250405: 50 ml after 0 min. Mean value Batch No. EWP20250405: 42 ml after 1 min. Mean value Batch No. EWP20250405: 28 ml after 12 min.
Persistent foam 5.0 %w/v CIPAC water D (after accelerated storage stability test)	PQ-SN-25-005	CIPAC MT 47.3, CIPAC Handbook O, p. 177, 2017	One batch and two replicates/batch were tested: Mean value Batch No. EWP20250405: 50 ml after 0 min. Mean value Batch No. EWP20250405: 42 ml after 1 min. Mean value Batch No. EWP20250405: 32 ml after 12 min.
Suspensibility (chemical assay, test item stored at room temperature)	PQ-SN-25-005	CIPAC MT 184.1, CIPAC Handbook P, p. 245, 2021	One batch and two replicates/batch were tested at 6.2% w/v: Mean value Batch No. EWP20250405: 96.2% in suspension after 30 minutes in CIPAC Standard Water D at 25 ± 5°C.
Suspensibility (chemical assay, after accelerated storage stability test)	PQ-SN-25-005	CIPAC MT 184.1, CIPAC Handbook P, p. 245, 2021	One batch and two replicates/batch were tested at 6.2% w/v: Mean value Batch No. EWP20250405: 96.8% in suspension after 30 minutes in CIPAC Standard Water D at 25 ± 5°C.

No significant differences were recorded among the properties of the product kept at ambient temperature and after accelerated storage stability test conditions.

2.2Manufacturing, composition and formulant information

Data on the manufacturing process and product composition for FastM (WP and WP-SB) have been provided and are adequate. A summary is presented in Table 2. Detailed information on the manufacturing process and product formulation is considered Confidential Business Information (CBI).

Table 2. Manufacturing process and product composition data submitted for FastM (WP and WP-SB)	
Description of starting material	Bendiocarb technical
Declaration of product formulation	Included in the confidential business information.
Production / formulation process	Bendiocarb technical active substance is mixed with the other formulation components such dispersing agents, wetting agents, antifoaming agents and carriers. The mixture is milled to the desired particle size. After this step the obtained material is packed into containers with approved labels. - FastM (formulated as WP) finished product is directly packed in aluminium foil bags. - FastM (formulated as WP-SB) finished product.is contained in a sealed water-soluble bag and then packed in aluminium foil bags. The packed products are organized and arranged for delivery.

Table 2. Manufacturing process and product composition data submitted for FastM (WP and WP-SB)	
Discussion of impurities	No relevant impurities are present in the product.
Certification of limits	Bendiocarb: 800 g/Kg, acceptable limits 775 to 825 g/Kg

2.3 Enforcement analytical method

Table 3. Details of the analytical method used to determine bendiocarb in FastM (WP and WP-SB)	
Quantification of bendiocarb	Bendiocarb: 232/WP/(M)/3, CIPAC Handbook D, p.12, 1988

The method is appropriate for the determination of the active ingredient content of the product.

3. Change assessment conclusions

The data submitted supports the inclusion of wettable powder (WP) as another presentation of the FastM product.

The applicant has submitted the necessary Module 3 data to expand the presentation of the product to WP formulation, which includes physical/chemical characterization (GLP data on minimum one batch of the WP to show compliance with the product manufacturing release specifications, declaration of product formulation, description of manufacturing process, declaration of manufacturing sites, product manufacturing release specifications and declaration of labelling).

The methods for assessing the physical properties of the product were appropriate CIPAC methods and/or validated methods.

Table 4. List of studies submitted to WHO as part of the post-prequalification change application dossier	
Studies that were relied upon for decision making	
Study number	**Study title**
PQ-SN-25-005	Physical-chemical Analysis of Bendiocarb 80 % WP
Studies that were not used to inform decision making	
Study number	**Study title**
	None

4. Manufacturing release specifications

4.1 Summary of manufacturing release specifications

For the purposes of product prequalification, the manufacturer submitted as part of the PPQC application the FastM (formulated as WP) product manufacturing release specifications and confirmed that the FastM properties' declared values in the manufacturing release specifications are applicable to both FastM product presentations (WP and WP-SB), except for persistent foam, wettability and dissolution of the bag, which are properties specific to the formulation type.

The FastM (formulated as WP-SB) product manufacturing release specifications have been adopted from the Bendiocarb WHO specification 232/WP-SB (November 2018), as the quality data for this product were initially assessed through JMPS.

Table 5 presents the FastM (formulated as WP) product manufacturing release specifications (consistent with Bendiocarb WHO specification 232/WP (November 2018) and Table 6 presents the FastM (formulated as WP-SB) product manufacturing release specifications.

Table 5. Summary of manufacturing release specifications for FastM (formulated as WP)

Description
The formulation shall consist of a homogeneous mixture of technical bendiocarb, complying with the requirements of WHO specification 232/TC (current), together with filler(s) and any other necessary formulants. It shall be in the form of a fine powder, free from visible extraneous matter and hard lumps.

ID	Property	Method	Declared value
1*	Sampling	See Appendix 2	
2	Bendiocarb identity	232/WP/(M)/2, CIPAC Handbook D, p.12, 1988	
3	Bendiocarb content	232/WP/(M)/3, CIPAC Handbook D, p.12, 1988	800 g/Kg ±25%
4	Wet sieve test	CIPAC MT 185.1, Handbook K, p. 149, 2003	Maximum: 1% retained on a 75 µm test sieve.
5*	Persistent foam	CIPAC MT 47.3, CIPAC Handbook O, p. 177, 2017	Maximum: 50 ml after 1 min.
6	Wettability	CIPAC MT 53.3, CIPAC Handbook F, p.164, 1995	The formulation shall be completely wetted in 1min. seconds without swirling in CIPAC Standard water D.
7*	Suspensibility	CIPAC MT 184.1, CIPAC Handbook P, p. 245, 2021	A minimum of 70% shall be in suspension after 30 minutes in CIPAC Standard Water D at 25 ± 5°C.

*Indicates that additional information is available in Appendix 2.

Table 6. Summary of manufacturing release specifications for FastM (formulated as WP-SB)

Description
The formulation shall consist of a homogeneous mixture of technical bendiocarb, complying with the requirements of WHO specification 232/TC (current), together with filler(s) and any other necessary formulants. It shall be in the form of a fine powder, free from visible extraneous matter and hard lumps, contained in a sealed water-soluble bag.

ID	Property	Method	Declared value
1*	Sub-sampling	See Appendix 2	
2	Bendiocarb identity	232/WP/(M)/2, CIPAC Handbook D, p.12, 1988	
3	Bendiocarb content	232/WP/(M)/3, CIPAC Handbook D, p.12, 1988	800 g/Kg ±25%
4	Wet sieve test	CIPAC MT 185.1, Handbook K, p. 149, 2003	Maximum: 1% retained on a 75 µm test sieve.
5*	Persistent foam	CIPAC MT 47.3, CIPAC Handbook O, p. 177, 2017	Maximum: 50 ml after 12 min (for WP-SB formulation).
6	Wettability	CIPAC MT 53.3, CIPAC Handbook F, p.164, 1995	The formulation shall be completely wetted in 4min. seconds without swirling in CIPAC Standard water D.
7*	Suspensibility	CIPAC MT 184.1, CIPAC Handbook P, p. 245, 2021	A minimum of 70% shall be in suspension after 30 minutes in CIPAC Standard Water D at 25 ± 5°C.
8*	Dissolution of the bag	CIPAC MT 176, CIPAC Handbook F, p.440, 1995	Flow time of the suspension: maximum 30 sec. in CIPAC Standard water D.

*Indicates that additional information is available in Appendix 2.

Manufacturers are expected to rely on the information above as part of a QC management plan and for validation of product quality when released. To the extent required, Certificates of Analysis to support the release of products should present results for the attributes identified in the above table.

4.2 Storage

Accelerated storage stability data were generated as per CIPAC MT 46.3 on FastM (WP and WP-SB). Test samples were stored for 2 weeks at 54°C. No significant differences were recorded among the tested properties of the product kept at ambient temperature and after accelerated storage stability test conditions.

Products should be stored and transported in appropriate conditions in accordance with the recommendations of the manufacturer.

Where products have been subjected to prolonged storage, adverse conditions, or in opened/damaged packaging/containers, analysis and testing are recommended to assess changes in characteristics and their suitability for use.

Appendix 1. Summary of available data considered

Batches used to generate the physical chemical data

Batch number	Date of production	Description
EWP20250401	2025.04.01	Off-white solid fine powder
EWP20250402	2025.04.02	Off-white solid fine powder
EWP20250403	2025.04.03	Off-white solid fine powder
EWP20250404	2025.04.04	Off-white solid fine powder
EWP20250405	2025.04.05	Off-white solid fine powder

Appendix 2. Manufacturing release specifications: Methods and notes

Sampling (for WP and WP-SB formulation)

Sampling conducted as per standard (GB/T 1605-2001 - GB/T 1605-2001 Sampling Method for Commodity Pesticides Foreword. The packaging units for sampling are determined by the random number as per the method. The final sampling quantity should be no less than 100g.

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.

Sub-sampling (for WP formulation)

Place the sample of the original packaging bag flat on a dry test bench. Carefully cut a corner of the packaging bag with scissors, being careful not to damage the sealing line of the bag. Transfer all the powder inside the bag to a sealed sample bottle and set it aside for later use.

Sub-sampling (for WP-SB formulation)

Lay the bag on a bench and carefully open one side of the bag with a cutter, taking care not to damage the seals. Transfer the contents of the bag into a suitable flask. This material shall be used to carry out the tests for:

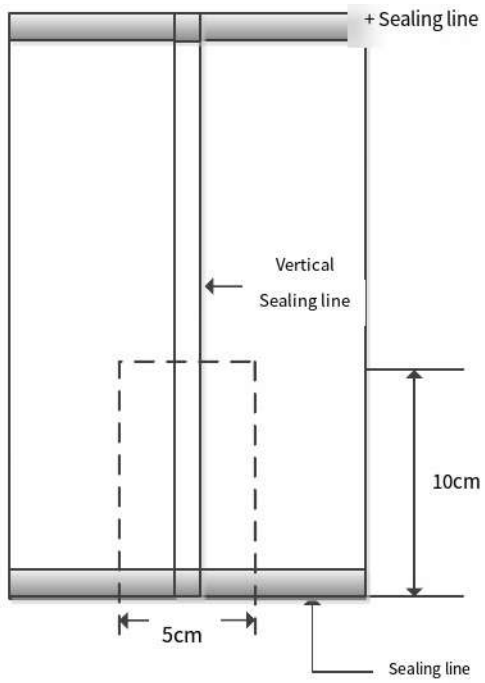
- active ingredient identity
- active ingredient content
- wet sieve test
- suspensibility
- persistent foam
- wettability
- dissolution of the bag

The bag is then opened on three sides, completely cleaned from adhering powder using a hair dryer and weighed to the nearest 0.01 g. Restore the empty water-soluble bag to its initial double-layered flat state. Cut out the test bag as shown in Figure 1, including 5 cm of the bottom sealing line and 10 cm of the sealing line perpendicular to it (if the bag size is insufficient for the required dimensions, use the entire bag) and test the

solubility. The remaining water-soluble bag is used to prepare the mother liquor for testing suspensibility and persistent foam.

In the case of delay of the above tests, the bag shall be stored in a watertight container (glass bottle or equivalent) to avoid any change in its properties.

Figure 1



Attributes 5 and 7: Suspensibility and persistent foam (for WP and WP-SB formulation)

The procedure for adding the bag material to the solution for the suspensibility and the persistent foam tests should be as follows:

Prepare a stock solution of the bag material (3 mg/ml) by weighing approximately a sample (1500 mg) of the bag (excluding sealed parts) to the nearest mg. Dissolve this sample by stirring in the standard water used for the tests to give a final volume of 500 ml. Store the stock solution in a stoppered bottle before use.

Calculate the volume (V ml) of the stock solution of the bag to be added to the test suspension of the wettable powder according to the following equation:

V(ml) = X x 1000B W

Where: B (g) = weight of the empty and cleaned bag

W (g) = nominal weight of the WP contained in the bag

X (g) = weight of the WP sample used in the test

Attribute 7 : Suspensibility (for WP and WP-SB formulation)

The WP and WP-SB formulation should be tested at the highest and lowest rates of use recommended by the supplier in accordance with method MT184.1.

Chemical assay is the only fully reliable method to measure the mass of active ingredient still in suspension. However, simpler methods such as gravimetric and solvent extraction determination may be used on a routine basis provided that these methods have been shown to give equal results to those of chemical assay. In case of dispute, chemical assay shall be the "referee method".

Attribute 8: Dissolution of the bag (WP-SB formulation)

The sampling of the bag for the dissolution test should be as follows (see Figure 1):

Lay the empty cleaned bag in its original configuration (double layer). Delineate and then cut up a test sample including part of the upper seal (5 cm) and symmetrically including the vertical seal (10 cm). If the size of the bag is less than this dimension, use the whole bag.

Carry out the dissolution test immediately to avoid any modification of the sample.