

WHO Prequalification Programme / Vector Control Product Assessment

WHO Public Assessment Report: WHOPAR Part 2

YAHE 4.0

(Fujian Yamei Industry & Trade Co. Ltd)

P-04983

Executive Summary

Summary of prequalification status for Yahe 4.0 initial acceptance	Date	Outcome
Status on PQ list	November 2024	PQ
Quality, safety, efficacy	October 2024	MR
PQ: prequalification MR: meets requirements		



Contents

1.	Introduction	3
2.	Product identification	3
3.	Assessment of quality	3
4.	Assessment of safety	4
5.	Assessment of efficacy	4
6.	Labelling	4
7.	Post-prequalification commitments	5
8.	Pre-qualification listing decision	5

1. Introduction

WHO's Prequalification Unit, Vector Control Product Assessment team (PQT/VCP) assesses vector control products and public health pesticide active ingredients to determine their acceptability and that they can be used safely, effectively and are manufactured to a high-quality standard. This is done by assessing product dossiers, inspecting manufacturing sites, and supporting quality-control testing of products. Products that meet prequalification requirements are added to the WHO list of vector control products.

WHO prequalification of vector control products primarily benefits populations most affected by vector-borne diseases by facilitating access to these prevention focused tools. The vector-borne diseases include malaria, and neglected tropical diseases such as Dengue, Chikungunya, Zika, Chagas, Lymphatic filariasis, Leishmaniasis, Human African trypanosomiasis, Onchocerciasis and Schistosomiasis.

This Executive Summary document conveys that, based on the application and product dossier supporting the product YAHE 4.0 manufactured by Fujian Yamei Industry & Trade Co. Ltd (PQ Ref# P-04983), the product has been found to meet the requirements for WHO prequalification.

2. Product identification

YAHE 4.0 is a homogenous ITN constructed from a single polyester multifilament fabric of 120 denier yarn incorporated with alpha-cypermethrin (CAS No. 67375-30-8) and piperonyl butoxide (CAS No. 51-03-6) at a nominal concentration of 6.25 g AI/kg and 2.2 g AI/kg respectively. The declared fabric weight is 38 g/m².

The premise of the combination of the pyrethroid insecticide with the PBO synergist is that the alpha-cypermethrin insecticidal activity provides knockdown and/or kill of mosquitoes and the PBO inhibits mixed function oxidases implicated in resistance in pyrethroid resistant *Anopheles spp.* malaria vectors.

3. Assessment of quality

Please see current WHOPAR Part 3 Quality Assessment.

Document information

Title	WHOPAR Part 3 Quality Assessment
Current version	V1
Publication date (current version)	October 2024

Revision history

Document version	Date	Identification of changes	Notes

4. Assessment of safety

Please see current WHOPAR Part 4 Safety Assessment.

Document information

Title	WHOPAR Part 4 Safety Assessment
Current version	V1
Publication date (current version)	October 2024

Revision history

Document version	Date	Identification of changes	Notes

5. Assessment of efficacy

Please, see current WHOPAR Part 5 Efficacy Assessment.

Document information

Title	WHOPAR Part 5 Efficacy Assessment
Current version	V1
Publication date (current version)	October 2024

Revision history

Document version	Date	Identification of changes	Notes

6. Labelling

The proposed Declaration of Labelling has been reviewed by PQT/VCP and found to be consistent with the supporting information.

7. Post-prequalification commitments

As per the existing WHO Guidelines on the testing of ITNs, the applicant is required to submit:

1. An updated dossier complying with the implementation plan following the 2023 publication of the WHO guideline for prequalification of ITNs including a new wash resistance study to further investigate the continuity of AI presentation over the wash series.
2. Community studies conducted in accordance with the available guidance to be published before the end of 2024.

8. Pre-qualification listing decision

The review of the dossier submitted for the product YAHE 4.0 has been completed by PQT/VCP. The results of the assessments show the product meets the requirements for prequalification when used according to the directions for use on the label. The product is allowed inclusion on the list of prequalified vector control products.