

WHO Prequalification Programme / Vector Control Product Assessment

WHO Public Assessment Report: WHOPAR Part 2

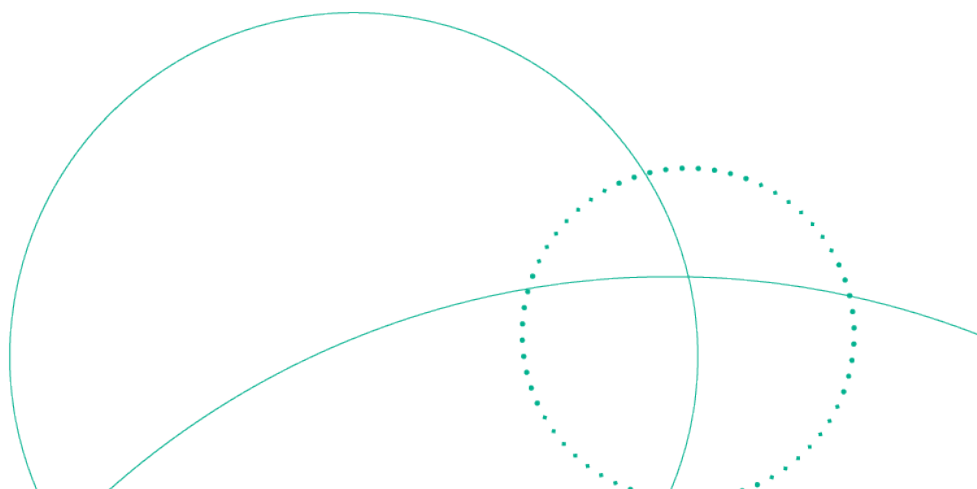
SOVRENTA 15WP

(Syngenta Crop Protection AG)

P-11568

Executive Summary

Summary of prequalification status for Sovrenta 15WP initial acceptance	Date	Outcome
Status on PQ list	April 2025	PQ
Quality, safety, efficacy	April 2025	MR
PQ: prequalification MR: meets requirements		



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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 SOVRENTA 15WP manufactured by Syngenta Crop Protection AG (WHO Product ID: P-11568), the product has been found to meet the requirements for WHO prequalification.

2. Product identification

SOVRENTA 15WP is formulated as a wettable powder packaged in water-soluble bags containing Isocycloseram (CAS No: 2061933-85-3; 15% w/w). Isocycloseram is an insecticide and acaricide in the isoxazoline chemical group which produces an insecticidal effect by binding to the gamma aminobutyric acid (GABA) receptor, thereby inhibiting the neurotransmission followed by hyperexcitation and death of insects.

The product is intended to be used for the control of Anopheline mosquitoes within malaria control initiatives as an indoor residual spray. The WP product is meant to be sprayed on indoor walls, eaves, ceilings, and other surfaces (not used for food preparation/consumption) on which mosquitoes may rest, at a target dosage/rate of 120 mg active ingredient (AI) per square meter.

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)	April 2025

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	V2
Publication date (current version)	August 2025

Revision history

Document version	Date	Identification of changes	Notes
V1	April 2025	Update Acute Toxicity – Dermal Toxicity Classification	

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)	April 2025

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

There are no post-prequalification commitments associated with this decision of prequalification.

8. Pre-qualification listing decision

The review of the dossier submitted for the product SOVRENTA 15WP 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.