

WHO Prequalification Programme / Vector Control Product Assessment

WHO Public Assessment Report: WHOPAR Part 2

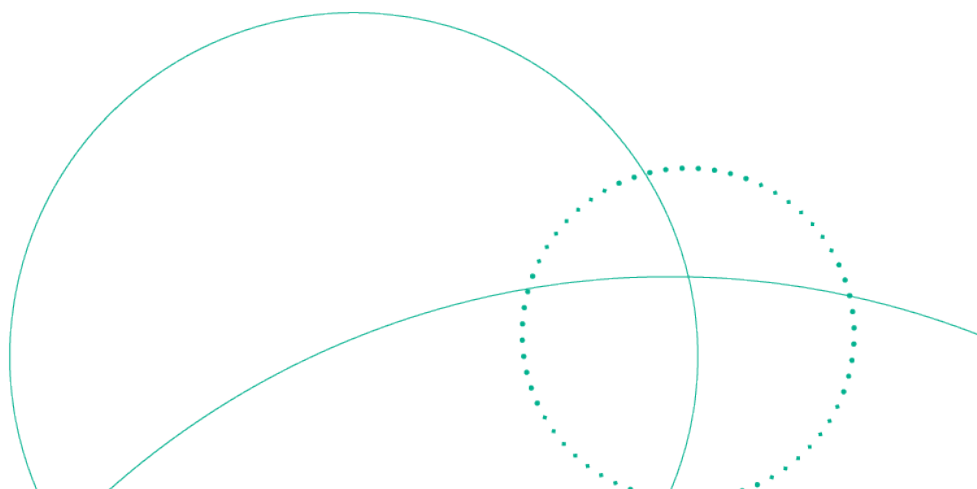
Optica ULV

(Clarke International)

P-11637

Executive Summary

Summary of prequalification status for Optica ULV initial acceptance	Date	Outcome
Status on PQ list	May 2025	PQ
Quality, safety, efficacy	May 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 Optica ULV (P-11637) manufactured by Clarke International, the product has been found to meet the requirements for WHO prequalification.

2. Product identification

Optica ULV is a formulated liquid containing 1% (w/w) of the active ingredient Broflanilide (10.8 g a.i./L) for use as an indoor or outdoor space spray. Broflanilide (Cas No. 1207727-04-5) is a meta-diamide, insecticide. Broflanilide produces an insecticidal effect by binding to the gamma aminobutyric acid (GABA) receptor, thereby inhibiting the neurotransmission in insects.

The product is intended to be used as an ultra-low volume (ULV) non-thermal aerosol mist space spraying insecticide to control of adult *Aedes aegypti* and adult *Aedes albopictus* mosquitoes. Optica ULV is meant to be sprayed via handheld, electric, or gas powered ULV cold aerosol application equipment for both indoor and outdoor uses. Additionally, the assessment supports outdoor application via a vehicle-mounted sprayer. The maximum application rate for indoor uses is 11mL Optica ULV/1000m² (equivalent to 0.118 g a.i./1000 m²). The maximum application rate for outdoor uses is 110 mL OPTICA ULV/ha (equivalent to 1.18 g a.i./ha).

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)	May 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	V1
Publication date (current version)	May 2025

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)	May 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 Optica ULV 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.