World Health Organization

WHO Prequalification Programme / Vector Control Product Assessment

# WHO Public Assessment Report: WHOPAR Part 2

## Optica ULV

## (Clarke International)

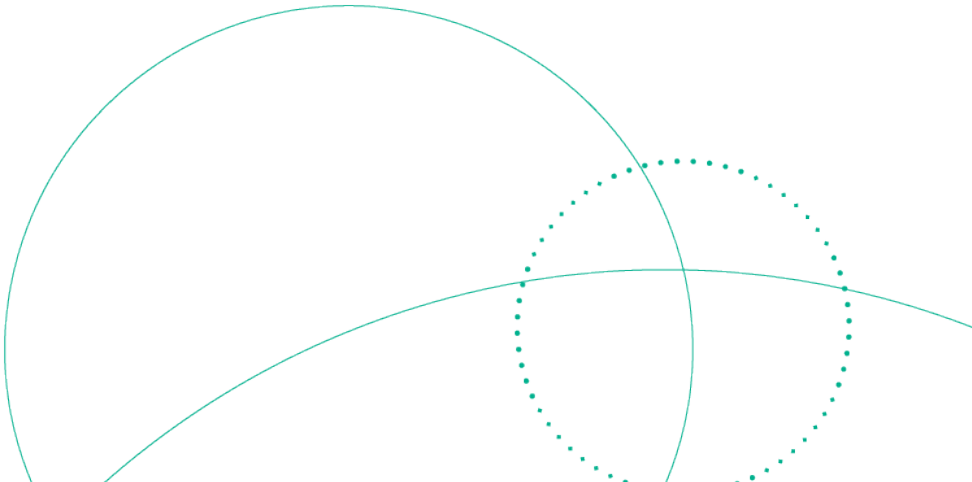
## P-11637

## 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



# Contents

# 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/1000m$^2$ (equivalent to 0.118 g a.i./1000 m$^2$). 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.