

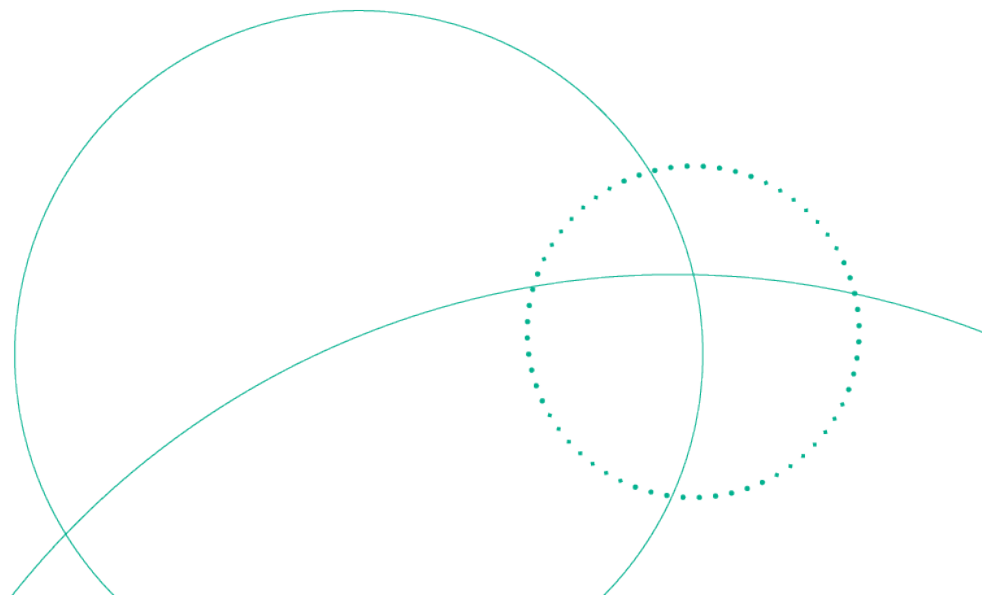
WHO Prequalification Programme / Vector Control Product Assessment

WHO Public Assessment Report: WHOPAR Part 2

Axient 440EW (Tagros Chemicals India Private
Limited) 004-017

Executive Summary

Summary of prequalification status for Axient 440EW initial acceptance	Date	Outcome
Status on PQ list	March 2023	PQ
Quality, safety, efficacy	February 2023	MR
PQ: prequalification MR: meets requirements		



Contents

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

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 Axient 440EW manufactured by Tagros Chemicals India Private Limited (PQ Ref# 004-017), the product has been found to meet the requirements for WHO prequalification.

2. Product identification

Axient 440EW is an emulsion, oil in water (EW), formulation containing malathion (CAS No. 121-75-5; 440g/l; 44.63%). Malathion is the ISO common name for diethyl (dimethoxythiophosphorylthio)succinate or S-1,2-bis(ethoxycarbonyl)ethyl O,O-dimethyl phosphorodithioate (IUPAC). The technical material is a racemic mixture of R-malathion [butanedioic acid, [(dimethoxyphosphinothioyl)thio]-, diethyl ester (2R)-(9CI)] and S-malathion [butanedioic acid, [(dimethoxyphosphinothioyl)thio]-, diethyl ester (2S)-(9CI)]. Malathion belongs to the class of organothiophosphate acaricides and to the class of aliphatic organothiophosphate insecticides and is acting as a cholinesterase inhibitor.

Tagros Chemicals India Private Limited submitted an application claiming equivalence of the proposed product to the prequalified product Fyfanon EW (PQ Ref# 013-002) manufactured by FMC Corporation.

The product, Axient 440EW, is intended to be used for *Aedes* and *Culex* mosquito vector control as an outdoor space spray. This EW product is intended to be applied exclusively by means of ground applications (vehicle or handheld foggers). The dilution and application rate per hectare is dependent upon the use of cold or thermal fogging machines. The product should not be applied at a rate higher than 319 ml product per hectare.

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)	January 2024

Revision history

Document version	Date	Identification of changes	Notes
Version 1	January 2024		Current version

4. Assessment of safety

Safety information is not required to be submitted for space spray products claiming equivalence.

5. Assessment of efficacy

Efficacy information is not required to be submitted for space spray products claiming equivalence.

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 additional post-prequalification commitments associated with this decision of prequalification.

8. Pre-qualification listing decision

The review of the dossier submitted for the product Axient 440EW has been completed by PQT/VCP. The results of the assessments show the product meets the claim of equivalency when used according to the directions for use on the label. The product is allowed inclusion on the list of prequalified vector control products.