



PQT/VCP Executive Summary of Prequalification Decision

DuraNet Plus

(Alphacypermethrin and PBO Insecticide Treated Net)

Prequalification Unit – Vector Control Products Assessment (PQT/VCP)

Regulation and Prequalification Department (RPQ)

Access to Medicines and Health Products (MHP)

World Health Organization (WHO)

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 the decision for prequalification of the product DuraNet Plus (PQ Ref# 006-003) in conjunction with the Letter of Prequalification. The PQT/VCP Decision Document presents the complete assessment. In some cases, the PQT/VCP Executive Summary may be published in advance of the PQT/VCP Decision Document.

2 Product Identification

DuraNet Plus is an insecticide treated net (ITN) treated with alpha-cypermethrin and piperonyl butoxide (PBO). The insecticidal and synergist treatment is incorporated into extruded filaments by using a proprietary blend of HDPE and LDPE combined with alpha-cypermethrin and PBO master batches.

The product is available in a 150 denier (D) version and has a declared fabric weight of 45 grams per square meter (GSM). The product has a declared alpha-cypermethrin concentration of 270 mg/m² which corresponds to 6.0 g/kg net. The declared PBO concentration is 99 mg/m² which corresponds to 2.2 g/kg net.

3 Assessment of Quality

3.1 Chemical and Physical Properties

Data on the chemical and physical properties of the active ingredient and the product DuraNet Plus were provided. These data were obtained from studies conducted according to established standards and/or Good Laboratory Practices (GLP) and are considered complete. Product specific properties are summarized in Table 1. The information in this table should be relied upon as the WHO Specification for this product for the purpose of product identification and QA/QC testing.

The sources of active ingredient and synergist are supported by existing WHO specifications.

Data on the manufacturing process and product composition for DuraNet Plus have been provided and are adequate. The product is formulated in Karur, Tamil Nadu, India.

The identified reference methods in Table 2 are appropriate for the determination of the active ingredient and synergist content of the product. These methods were validated through the inter-laboratory CIPAC process.

The quality component of the dossier is considered complete, and the assessment of the submitted information on quality supports the prequalification of the product.

Table 1 Chemical and Physical Properties for DuraNet Plus

Data Requirement	Study Number	Test Method ID	Result
Active ingredient content alpha cypermethrin (samples kept on room temperature, before the storage stability test)	IIBAT Study No.:16059	CIPAC 454/LN/M/3.2 (Handbook M, p 41.)	Batch No. S6W0716 6.06 g/kg Batch No. S6W0716A 6.05 g/kg Batch No. S6W0716B 6.03 g/kg Batch No. S6W0716C 6.05 g/kg Batch No. S6W0716D 6.01 g/kg Nominal alpha cypermethrin content: 6.0 g/kg \pm 25% (range: 4.5-7.5 g/kg). All results were within the nominal range.
Active ingredient content piperonyl butoxide (samples kept on room temperature, before the storage stability test)	IIBAT Study No.:16059	CIPAC extension of 33/LN/M/3 (Handbook N, p 112.)	Batch No. S6W0716 2.21 g/kg Batch No. S6W0716A 2.21 g/kg Batch No. S6W0716B 2.20 g/kg Batch No. S6W0716C 2.23 g/kg Batch No. S6W0716D 2.20 g/kg Nominal piperonyl butoxide content: 2.2 g/kg \pm 25% (range: 1.65-2.75 g/kg) All results were within the nominal range.
Active ingredient content alpha cypermethrin (after accelerated storage stability, 54 \pm 2 °C for 14 days)	IIBAT Study No.:16059	CIPAC 454/LN/M/3.2 (Handbook M, p 41.)	Batch No. S6W0716 5.93 g/kg Batch No. S6W0716A 5.92 g/kg Batch No. S6W0716B 5.93 g/kg Batch No. S6W0716C 5.93 g/kg Batch No. S6W0716D 5.92 g/kg Nominal alpha cypermethrin content: 6.0 g/kg \pm 25% (range: 4.5-7.5 g/kg). All results were within the nominal range and above 95% of the initial concentration (before the storage stability test).
Active ingredient content piperonyl butoxide (after accelerated storage stability, 54 \pm 2 °C for 14 days)	IIBAT Study No.:16059	CIPAC 4941 extension of 33/LN/M/3 (Handbook N, p 112.)	Batch No. S6W0716 2.13 g/kg Batch No. S6W0716A 2.14 g/kg Batch No. S6W0716B 2.15 g/kg Batch No. S6W0716C 2.14 g/kg Batch No. S6W0716D 2.14 g/kg Nominal piperonyl butoxide content: 2.2 g/kg \pm 25% (range: 1.65-2.75 g/kg) All results were within the nominal range and above 95% of the initial concentration (before the storage stability test).
Wash resistance index: Alpha cypermethrin (after 4 washings, 5 batches) *****	IIBAT Study No.:16059	CIPAC MT195	Batch No. S6W0716 98.15 % Batch No. S6W0716A 98.67 % Batch No. S6W0716B 98.08 % Batch No. S6W0716C 98.29 % Batch No. S6W0716D 98.50 % The wash resistance index for samples kept at room temperature, after 4 washings was in the range 98.08 to 98.67%.

Table 1 Chemical and Physical Properties for DuraNet Plus

Piperonyl butoxide (after 4 washings, 5 batches)			<p>All results were above 95%.</p> <p>*****</p> <p>Batch No. S6W0716 97.27 % Batch No. S6W0716A 97.28 % Batch No. S6W0716B 97.48 % Batch No. S6W0716C 97.24 % Batch No. S6W0716D 97.61 %</p> <p>The wash resistance index for samples kept at room temperature, after 4 washings was in the range 97.24 to 97.61%.</p> <p>All results were above 95%.</p>
Wash resistance index: Alpha cypermethrin (after 4 washings, 5 batches, after accelerated storage stability, 54±2 °C for 14 days) ***** Piperonyl butoxide (after 4 washings, 5 batches, after accelerated storage stability, 54±2 °C for 14 days)	IIBAT Study No.:16059	CIPAC MT195	<p>Batch No. S6W0716 98.01 % Batch No. S6W0716A 98.14 % Batch No. S6W0716B 98.46 % Batch No. S6W0716C 98.39 % Batch No. S6W0716D 98.42 %</p> <p>The wash resistance index for samples kept at elevated temperature (54±2 °C for 14 days), after 4 washings was in the range 98.01 to 98.46%.</p> <p>All results were above 95%.</p> <p>*****</p> <p>Batch No. S6W0716 97.30 % Batch No. S6W0716A 97.37 % Batch No. S6W0716B 97.47 % Batch No. S6W0716C 97.30 % Batch No. S6W0716D 97.41 %</p> <p>The wash resistance index for samples kept at elevated temperature (54±2 °C for 14 days), after 4 washings was in the range 97.30 to 97.47%.</p> <p>All results were above 95%.</p>
Mass per unit area (samples kept at room temperature, 5 batches, average of five pieces g/m ²)	IIBAT Study No.:16059	ISO 3801/EN 12127	<p>Batch No. S6W0716 45.83 Batch No. S6W0716A 45.74 Batch No. S6W0716B 46.15 Batch No. S6W0716C 45.95 Batch No. S6W0716D 45.92</p> <p>Nominal weight 45 g/m². Acceptable range: 40.5 to 49.5 g/m². All results were in the acceptable range.</p>
Mass per unit area (5 batches, average of five pieces g/m ² , after accelerated storage)	IIBAT Study No.:16059	ISO 3801/EN 12127	<p>Batch No. S6W0716 45.91 g/m² Batch No. S6W0716A 45.82 g/m² Batch No. S6W0716B 46.08 g/m² Batch No. S6W0716C 45.85 g/m²</p>

Table 1 Chemical and Physical Properties for DuraNet Plus

stability, 54±2 °C for 14 days)			Batch No. S6W0716D 45.72 g/m ² Nominal weight 45 g/m ² . Acceptable range: 40.5 to 49.5 g/m ² . All results were in the acceptable range.
Netting mesh size (samples kept on room temperature, 5 batches, average of five pieces)	IIBAT Study No.:16059	WHO Specification 454+33/LN	Batch No. S6W0716 23 holes/cm ² Batch No. S6W0716A 23 holes/cm ² Batch No. S6W0716B 23 holes/cm ² Batch No. S6W0716C 24 holes/cm ² Batch No. S6W0716D 23 holes/cm ² Acceptable value: average shall be not less than 20 holes/cm ²
Netting mesh size (5 batches, average of five pieces, after accelerated storage stability, 54±2 °C for 14 days)	IIBAT Study No.:16059	WHO Specification 454+33/LN	Batch No. S6W0716 23 holes/cm ² Batch No. S6W0716A 24 holes/cm ² Batch No. S6W0716B 23 holes/cm ² Batch No. S6W0716C 23 holes/cm ² Batch No. S6W0716D 23 holes/cm ² Acceptable value: average shall be not less than 20 holes/cm ²
Dimensional stability of netting (samples kept on room temperature, 5 batches, two replicates)	IIBAT Study No.:16059	WHO Specification 454+33/LN	Batch No. S6W0716 Batch No. S6W0716A Batch No. S6W0716B Batch No. S6W0716C Batch No. S6W0716D Shrinkage values less than 3 % in warp and weft directions. Acceptable values: extension not more than 5%, shrinkage not more than 10%.
Dimensional stability of netting (five batches, two replicates, after accelerated storage stability, 54±2 °C for 14 days)	IIBAT Study No.:16059	WHO Specification 454+33/LN	Batch No. S6W0716 Batch No. S6W0716A Batch No. S6W0716B Batch No. S6W0716C Batch No. S6W0716D Shrinkage values less than 3 % in warp and weft directions. Acceptable values: extension not more than 5%, shrinkage not more than 10%.
Bursting strength of fabric (samples kept on room temperature, 5 batches, average of three replicates)	IIBAT Study No.:16059	ISO 13938-2:1999	Batch No. S6W0716 400.4 kPa Batch No. S6W0716A 401.8 kPa Batch No. S6W0716B 402.3 kPa Batch No. S6W0716C 400.0 kPa Batch No. S6W0716D 403.7 kPa Acceptable value: minimum 350 kPa All values were above the acceptable value.

Table 1 Chemical and Physical Properties for DuraNet Plus			
Bursting strength of fabric (5batches, average of three replicates after accelerated storage stability, 54±2 °C for 14 days)	IIBAT Study No.:16059	ISO 13938-2:1999	Batch No. S6W0716 406.0 kPa Batch No. S6W0716A 408.1 kPa Batch No. S6W0716B 409.9 kPa Batch No. S6W0716C 404.7 kPa Batch No. S6W0716D 408.2 kPa Acceptable value: minimum 350 kPa All values were above the acceptable value.
Flammability (one batch, three replicates)	TRP/T(H)/20/0 09863	EN 1102:2016	no ignition, no propagation of the flame occurred.

Table 2. Details of the analytical method used to determine alpha-cypermethrin and PBO in DuraNet Plus	
Quantification alpha-cypermethrin	CIPAC 454/LN/M/3.2 (Handbook M, p 41.)
Quantification piperonyl butoxide	CIPAC extension of 33/LN/M/3 (Handbook N, p 112.)

4 Assessment of Safety

The applicant submitted an exposure and risk assessment for DuraNet Plus, conducted by an independent consultant. The submitted risk assessment was conducted according to the WHO "A Generic Risk Assessment Model for Insecticide Treated Nets, 2nd edition, 2018".

PQT/VCP conducted its own hazard, exposure and risk assessments of DuraNet Plus and the active ingredient alpha-cypermethrin and synergist PBO using the WHO "A Generic Risk Assessment Model for Insecticide Treated Nets, 2nd edition, 2018".

4.1 Safety Conclusions

The potential health risk is acceptable for all individual and combined scenarios for both alpha-cypermethrin and PBO:

- For all populations (adults, children, infants and toddlers) sleeping under the nets
- For adults and children washing the treated bednets
- For adults and children sleeping under and washing the treated bednets.
- For infants and children exposed to alpha-cypermethrin and PBO via breast milk from mothers sleeping under and washing DuraNet Plus LN nets (worst case scenario).

The risk ratios are < 1 for all populations, routes of exposure (inhalation, dermal and oral) and all activities (sleeping under, washing and sleeping under and washing).

The safety component of the dossier is complete. The assessment of the submitted information on safety supports the prequalification of the products DuraNet Plus.

Table 4. Summary of Risk Characterization for DuraNet Plus	
Activity/Population	Risk Acceptable / Not acceptable
Sleeping Under DuraNet Plus: Inhalation Exposure	
Adult	Negligible
Children	Negligible
Toddlers	Negligible
Infants	Negligible
Washing DuraNet Plus: Acute Conditions	
Adult	Acceptable
Children	Acceptable
Washing DuraNet Plus: Repeated Conditions	
Adult	Acceptable
Children	Acceptable
Sleeping Under and Washing DuraNet Plus Acute Conditions	
Adult	Acceptable
Children	Acceptable
Sleeping Under and Washing DuraNet Plus Repeated Conditions	
Adult	Acceptable
Children	Acceptable
Exposures via Breast Milk from Mothers Exposed to DuraNet Plus	
Newborn (acute and chronic)	Acceptable
Infants (acute and chronic)	Acceptable

5 Assessment of Efficacy

5.1 Background

The primary purpose for the use of a pesticide is the control of a pest, which can include a disease transmitting vector. Vector control tools, including formulated pesticides which provide effective management/control of vectors, may be used as part of a resistance management program. Vector control products for use in public health are a component of an Integrated Vector Management program (IVM). IVM relies on a suite of diverse interventions and implementation of best practices to manage the vector and chemical/behavioral resistance.

5.2 Efficacy Conclusions

Assessment of all the submitted efficacy studies performed in lab and semi-field settings revealed that there is sufficient evidence to demonstrate that DuraNet Plus LN meets the efficacy requirements for prequalification. These efficacy studies were performed according to standard protocols for testing in laboratory and semi-field conditions. Various mosquito species and strains exhibiting varying levels of pyrethroid resistance were tested in the studies.

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

The product, DuraNet Plus, has been included in the “Non pyrethroid-only ITN Product Review” initiated by WHO PQT/VCP. The applicant has responded to the initial call for information issued to support this review. The applicant will be required to comply with any future requests for information or data generation requirements identified as part of this review and pertaining to DuraNet Plus.

As per the existing “WHO Guidelines for laboratory and field testing of long-lasting insecticidal nets” (2013), the applicant is required to submit results from long-term field trials.

8 Pre-Qualification Listing Decision

The review of the dossier submitted for the product DuraNet Plus has been completed by PQT/VCP. The results of the assessments show the product is safe and effective when used according to the directions for use on the label. The product is allowed inclusion on the list of prequalified vector control products.