



PQT/VCP Executive Summary of Prequalification Decision

Reliefnet Reverte

(Deltamethrin 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 Reliefnet Reverte (PQ Ref# 036-002) 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.

The composition of Reliefnet Reverte includes a formulant which is intended to accelerate the degradation of the product after its useful life. This formulant, referred to as a pro-degradant additive, is intended to facilitate oxo-biodegradation of the polyethylene yarn after disposal of the product. The application was assessed based on supporting data generated using the product formulated with the pro-degradant additive.

The scope of the WHO evaluation of VCPs for the purpose of prequalification does not include the assessment of post-disposal claims. Therefore PQT/VCP has not assessed, the claim that the inclusion of the pro-degradant additive in the product composition will facilitate the degradation of the product in the environment following its use as a VCP.

This pro-degradant additive represents the first of its kind submitted to WHO and was therefore considered in the assessment even though its intended effect falls outside the scope of the WHO evaluation.

2 Product Identification

Reliefnet Reverte is an insecticide treated net (ITN) incorporated with deltamethrin. The insecticidal treatment is incorporated into the polyethylene monofilament yarn during the extrusion process by the addition of a proprietary deltamethrin masterbatch. The product is available in 120D yarn and has a declared fabric weight of 34 GSM. The product has a declared deltamethrin concentration of 1.8 g/kg net which corresponds to 61.2 mg/m².

The product Reliefnet Reverte was assessed based on the claim of equivalence to the prequalified product PandaNet 2.0 (PQ Ref #026-001).

3 Assessment of Quality

3.1 Chemical and Physical Properties

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

The source of active ingredient is supported by existing WHO specifications.

Data on the manufacturing process and product composition for Reliefnet Reverte have been provided and are adequate. The product is formulated in Jiangsu, China.

The information provided demonstrated that the product, with the pro-degradant additive included, possessed physical/chemical properties meeting established standards.

The identified reference method(s) in Table 2 are appropriate for the determination of the active ingredient 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 claim of equivalence and prequalification of the product.

Table 1. Chemical & Physical Properties - Reliefnet Reverte			
Title	Study Number	Test method ID	Result
Active ingredient content deltamethrin (samples kept at room temperature, before the storage stability test)	IIBAT Study No.:19245	CIPAC 333/LN/(M2)/3 (Handbook N, p. 34)	Sample S1 1.90 g/kg Sample S2 1.85 g/kg Sample S3 1.87 g/kg Sample S4 1.89 g/kg Sample S5 1.92 g/kg Average of five samples: 1.89 g/kg Nominal deltamethrin content: 1.8 g/kg ± 25% (range: 1.35-2.25 g/kg) All results were within the nominal range.
Active ingredient content deltamethrin (after accelerated storage stability, 54±2 °C for 14 days)	IIBAT Study No.:19245	CIPAC 333/LN/(M2)/3 (Handbook N, p. 34)	Sample S1 1.81 g/kg Sample S2 1.79 g/kg Sample S3 1.83 g/kg Sample S4 1.86 g/kg Sample S5 1.85 g/kg Average of five samples: 1.83 g/kg Nominal deltamethrin content: 1.8 g/kg ± 25% (range: 1.35-2.25 g/kg) All results were within the nominal range and above 95% of the initial concentration (before the storage stability test).
Deltamethrin R-isomer content	IIBAT Study No.:19180 Study Report Amendment	CIPAC 333/LN/(M2)/3 (Handbook N, p. 34)	Deltamethrin R-isomer content before wash: Sample code 1001: 0.16; 0.16; 0.16, 0.18; 0.18 Average value: 0.17 g/kg

			<p>Sample code 1002: 0.17; 0.16; 0.17, 0.17; 0.16 Average value: 0.17 g/kg</p> <p>Sample code 1003: 0.17; 0.17; 0.17, 0.18; 0.17 Average value: 0.17 g/kg</p> <p>Sample code 1004: 0.17; 0.17; 0.18, 0.16; 0.16 Average value: 0.17 g/kg</p>
Wash resistance index deltamethrin (after 4 washings, 2 samples, regeneration time 22±2 hours)	IIBAT Study No.:19245	CIPAC MT195	<p>Deltamethrin content before wash: Sample S1R1 1.87 g/kg Sample S1R2 1.88 g/kg Average of two samples: 1.88 g/kg</p> <p>Deltamethrin content after the 4 washings: Sample S1R1 1.80 g/kg Sample S1R2 1.80 g/kg Average of two samples: 1.80 g/kg The average wash resistance index for samples kept at room temperature, after 4 washings was 98.98%. All results were above 95%.</p>
Wash resistance index deltamethrin (after 4 washings, 2 samples, after accelerated storage stability, 54±2 °C for 14 days, regeneration time 22±2 hours)	IIBAT Study No.:19245	CIPAC MT195	<p>Deltamethrin content before wash: Sample S1R1 1.84 g/kg Sample S1R2 1.83 g/kg Average of two samples: 1.83 g/kg Deltamethrin content after the 4 washings: Sample S1R1 1.74 g/kg Sample S1R2 1.75 g/kg Average of two samples: 1.75 g/kg The average wash resistance index for samples kept at room temperature, after 4 washings was 98.79%. All results were above 95%.</p>
Wash resistance index deltamethrin (after 4 washes, 3 samples, regeneration time two days)	IIBAT Study No.:20268	CIPAC MT195	<p>Deltamethrin content before wash: Sample S1 1.83 g/kg Sample S2 1.86 g/kg Sample S3 1.88 g/kg Average of samples: 1.86 g/kg Deltamethrin R-isomer content before wash: Sample S1 0.22 g/kg Sample S2 0.21 g/kg Sample S3 0.22 g/kg Average of samples: 0.22 g/kg Deltamethrin content after the 4 washings: Sample S1 1.82 g/kg Sample S2 1.80 g/kg Sample S3 1.77 g/kg Average of samples: 1.80 g/kg Deltamethrin R-isomer content before wash: Sample S1 0.27 g/kg Sample S2 0.26 g/kg Sample S3 0.25 g/kg Average of samples: 0.26 g/kg The average wash resistance index for samples after 4 washings was 99.18%. All results were above 95%.</p>
Fabric weight, mass per unit area	IIBAT Study No.:19245	ISO 3801/EN 12127	<p>Measured fabric weight values: 37.74; 35.67; 33.43; 34.45; 36.84 g/m²</p>

(samples kept at room temperature, 5 pieces, average of five pieces g/m ²)			Average value: 35.63 g/m ² Nominal fabric weight 34 g/m² Acceptable range (nominal value ±10%): 30.6 to 37.4 g/m ² . All results were in the acceptable range.
Netting mesh size (samples kept at room temperature, 5 pieces, average of five pieces)	IIBAT Study No.:19245	WHO Specification 333/LN/3	Measured fabric mesh size values: 20; 21; 20; 21; 21 holes/cm ² . Average value: 21 holes/cm ² . All results were above the acceptable value. Acceptable value: average shall be not less than 18 holes/cm²
Dimensional stability of netting to washing (samples kept at room temperature, 2 samples, two replicates)	IIBAT Study No.:19245	WHO Specification 333/LN/3	Measured percentage change in dimensions: Warp: -2.0; -2.6; -2.0; -2.7 Average shrinkage: -2.3 Measured percentage change in dimensions: Weft: -2.6; -2.7; -2.7; -2.0 Average shrinkage: -2.5 Shrinkage values less than 3 % in warp and weft directions. Acceptable values: extension not more than 5%, shrinkage not more than 10% in both directions.
Dimensional stability of netting to washing (two samples, two replicates, after accelerated storage stability, 54±2 °C for 14 days)	IIBAT Study No.:19245	WHO Specification 333/LN/3	Measured percentage change in dimensions: Warp: -2.7; -2.0; -2.0; -2.6 Average shrinkage: -2.3 Measured percentage change in dimensions: Weft: -2.0; -2.6; -2.0; -2.7 Average shrinkage: -2.3 Shrinkage values less than 3 % in warp and weft directions. Acceptable values: extension not more than 5%, shrinkage not more than 10% in both directions.
Bursting strength of fabric (samples kept at room temperature, 5 pieces, average of five pieces)	IIBAT Study No.:19245	ISO 13938-2:1999	Measured bursting strength values for fabric: 432.0; 445.6; 423.7; 418.6; 452.1 kPa Average value: 434.4 kPa Measured bursting strength values for seam: 534.1; 526.6; 550.9; 571.7; 545.2 kPa Average value: 545.7 kPa Acceptable value: minimum 400 kPa All values were above the acceptable value.
Flammability	IIBAT Study No.:19245	EN 1102:2016	No ignition, no propagation of the flame occurred.

Table 2. Details of the analytical method used to determine deltamethrin in Reliefnet Reverte	
Method ID	Deltamethrin CIPAC N 333/LN/(M2)/3 (Handbook N, p. 34) for quantification in LLIN

4 Assessment of Safety

PQT/VCP conducted its own hazard, exposure and risk assessments of the active ingredient deltamethrin when formulated as a bednet using the WHO "A Generic Risk Assessment Model for Insecticide Treated Nets, 2nd edition, 2018". This assessment was conducted using the highest concentration of deltamethrin found in a currently prequalified ITN (3 g/kg: 120 mg/m² assuming 40GSM). In line with the GRAM, the value used for assessing the exposure and risk was 125% of the target value:

"The concentration of the active ingredient in the net (TC) is derived from the WHO (2018) specification of the net (default variability of the concentration being +/- 25%).

TC = 125% X concentration of the a.i. mg/kg net X Weight of the net kg/m².

Since the highest concentration of Deltamethrin is 3.0 g/ kg or 120 mg/m² net and the weight of the net is 40 g/m², the TC is as follows:

TC = 125% X 3.0 g Deltamethrin/kg net X 40 g/m² = 150 mg/m²"

This assessment was considered supportive of the safe use of the product Reliefnet Reverte, based on the declared deltamethrin concentration of 1.8 g/kg.

The potential health risk is acceptable for all populations (adults, children, toddlers, and infants) sleeping under, for adults and children washing as well as for adults and children sleeping under and washing the treated nets. 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).

Table 4. Summary of Risk Characterization for Deltamethrin as ITN (up to 3 g/kg or 120 mg/m ² declared content)	
Activity/Population	Risk Acceptable / Not acceptable
Sleeping Under Net: Inhalation Exposure	
Adult	Acceptable
Children	Acceptable
Toddlers	Acceptable
Infants	Acceptable
Washing of Nets - Acute	
Adult	Acceptable
Children	Acceptable
Washing of Nets - Repeated Conditions	
Adult	Acceptable
Children	Acceptable
Sleeping Under and Washing of Nets - Acute Condition	
Adult	Acceptable
Children	Acceptable
Sleeping Under and Washing of Nets - Repeated Conditions	

Table 4. Summary of Risk Characterization for Deltamethrin as ITN (up to 3 g/kg or 120 mg/m² declared content)	
Activity/Population	Risk Acceptable / Not acceptable
Adult	Acceptable
Children	Acceptable
Exposures via Breast Milk from Mothers Exposed to Deltamethrin	
Infants (acute and chronic)	Acceptable
Newborns (acute and chronic)	Acceptable
Combined: Sleeping Under Net and Breast Milk	
Infants (acute and chronic)	Acceptable
Newborns (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 includes disease transmitting vectors. 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

In accordance with the established dossier requirements for the submission of applications for products claiming equivalence to a prequalified product, the applicant submitted data generated using the Reliefnet Reverte formulation from the lab setting in the efficacy Module of the dossier.

Assessment of all the submitted efficacy studies revealed that there is sufficient evidence to demonstrate that Reliefnet Reverte meets the efficacy requirements for prequalification. These efficacy studies were performed according to standard protocols for testing in laboratory conditions.

6 Labelling

The proposed Declaration of Labelling has been reviewed by PQT/VCP and found to be consistent with the supporting information.

7 Pre-Qualification Listing Decision

The review of the dossier submitted for the product Reliefnet Reverte 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.