



Tel. direct: +41 22 791 2916
Fax direct: +41 22 791 4730
Email : pqvectorcontrol@who.int

In reply please
refer to: V2-447-3/ML/DS/2

Your reference: 005-002, PQC-VCP-2022-006

Vestergaard Sàrl
Ms Melinda Hadi
Place St-François 1
1003 Lausanne
Suisse

7 March 2022

**WHO Prequalification Unit – Vector Control Product Assessment Team (PQT/VCP)
Post-Prequalification Change (PPQC)
Product PQ Reference Number: 005-002
Application number: PQC-VCP-2022-006**

Dear Ms Hadi,

Thank you for submitting your company's Post-Prequalification Change (PPQC) application on 4 March 2022 for the following product:

- **PermaNet 3.0 – PQ Ref # 005-002**

Your submission to identify an alternative construction of the prequalified product PermaNet 3.0 which includes the additional barrier panel has been reviewed and found acceptable. The complete change assessment is attached to this acceptance letter.

Our files have been updated accordingly and the PQT Inspections group has been notified of the change.

Yours sincerely,

Marion Law
Group Lead, Vector Control Products Assessment
Prequalification Team
Regulation of Medicines and other Health Technologies

Change Assessment

Case: PQC-VCP-2022-0006

Product: PermaNet 3.0 (005-002)

Applicant: Vestergaard Sàrl

Description of the submission

Vestergaard Sàrl submitted a PPQC application to WHO PQT/VCP proposing an alternative construction of the prequalified insecticide treated net, PermaNet 3.0 (PQ Ref # 005-002). The intent of the submission is to present the alternate construction of PermaNet 3.0, referred to as **PermaNet 3.0 with Barrier** which would include an additional panel of the same fabric design and production as the roof, oriented in an upright position along the length of the product in the middle of the roof panel.

The submission included a description of the intended use of the product and an analysis of the potential considerations related to the Quality, Safety, and Efficacy of the alternate construction.

Context of the intended use

As indicated in the submission, the intended use of the alternate construction is within the context of a larger distribution campaign of standard PermaNet 3.0 products in the Democratic Republic of the Congo (DRC). 300,000 PermaNet 3.0 products which include the additional panel were produced to be included in a large-scale antenatal clinic based randomized control trial. The trial was developed in partnership between Vestergaard Sàrl, the Liverpool School of Tropical Medicine (LSTM) and the Against Malaria Foundation (AMF).

Classification of the ITN including proposed change

In accordance with the established procedures, the submission was assessed by WHO PQT/VCP. In order to guide the assessment, initial considerations were identified regarding the context of the change and the nature of the alternate construction. PermaNet 3.0 is already available in various constructed forms. The type (incorporated polyethylene roof and coated polyester sides) remains consistent. The construction of the finished product incorporates fabric designs which have been used in the manufacture of previously prequalified products. The 100 denier deltamethrin and PBO incorporated polyethylene roof panel is always the same in the construction of the PermaNet 3.0 product. The deltamethrin coated polyester side panels can be constructed of one of five fabric designs.

- 75 Denier
- 100 Denier
- 150 Denier
- 75 Denier with reinforced border
- 100 Denier with reinforced border

The available assessments of PermaNet 3.0 support the various alternate constructions of the product. Regardless of the final construction, the intended entomological effect (i.e. mode and mechanism of action) of the product remains the same.

The proposed additional panel oriented in an upright position along the length of the product in the middle of the roof panel has been presented as an extension of this concept. Its formulation and production are the same as that of the existing PermaNet 3.0 roof and therefore is intended to impart the same entomological effect as the roof. The applicant has not proposed any additional or enhanced claims associated with the additional panel.

Conclusions

The assessment included the review of submitted information pertaining to Modules 1, 3, 4, and 5.

The proposed change is an alternate construction of PermaNet 3.0 and therefore supported by the existing prequalification decision for PermaNet 3.0.

Note: The applicant should ensure that alternate constructions of PermaNet 3.0 are identifiable on the label, which may include the outer packaging and/or the sewn-on label tag.

Assessment by Module

Module 1

The applicant provided the necessary documentation in Module 1 to support the assessment of the change. A rendering of the sewn-on label tag was included for those products intended to be included in the planned trial. This has been included as an appendix to this report.

Module 3

Declaration of Product Formulation – There is no difference in the formulation of the barrier panel and the roof.

Description of Manufacturing process – The manufacturing process is the same, except that PermaNet 3.0 roof knitted fabric is cut into the dimensions of the barrier panel (190 cm x 40 cm) and sewn onto a precut roof panel. The barrier/roof combination is then sewn to the precut side panels. The product is then folded and packaged in the same manner as standard PermaNet 3.0.

Specifications – The manufacturer declared release specifications for the alternate construction including the barrier are the same as the standard PermaNet 3.0. The additional attributes related to the barrier panel and the seam are highlighted below. The identified attributes below include the relevant WHO specifications as well as manufacturer declared information.

Section 1: PermaNet 3.0 Polyethylene Roof and Barrier Panels

Attribute	Declared Value/Clause	Method
Yarn composition	100% polyethylene	ISO 1833
Fabrication	Warpknitted	ISO 8388
Denier of yarn from unraveled fabric	100 D	ISO 2060
Flammability	After removing the ignition source the following fire phenomena should not occur: - ignition - propagation of the flame or glow - flaming debris - ignition of the filter paper	EN 1102
Deltamethrin content	Target 4.0 g/kg \pm 25%	CIPAC 333/LN/(M2)/3, CIPAC Handbook N, p.34, 2012
Piperonyl butoxide content	Target 25.0 g/kg \pm 25%	CIPAC 33/LN/(M)/3, CIPAC Handbook N, p.111, 2012
Deltamethrin Wash Resistance Index	88% - 100%	CIPAC MT 195
Piperonyl butoxide wash resistance index	81% - 100%	CIPAC MT 195
Netting meshsize	Min. 15.5 holes/cm ² or 100 holes/inch ²	WHO specification 333/LN/1, Note 9
Dimension stability of netting to washing	Max. 10% shrinkage Max. 5% expansion	ISO 3759; ISO 5077; ISO 6330 Type A, ballast type III, flat drying
Bursting strength – netting	Min. 300 kPa	ISO 13938-2, head area = 7.3 cm ²
Weight	32.0 g/m ² \pm 10%	ISO 3801

Section 2: PermaNet 3.0 Side Panels

(For use in alternate construction with barrier. 75 and 150 denier versions also available)

Attribute	Declared Value/Clause	Method
Yarn composition	100% polyester	ISO 1833
Fabrication	Warpknitted	ISO 8388
Denier of yarn from unraveled fabric	100D	ISO 2060
Flammability	After removing the ignition source the following fire phenomena should not occur: - ignition - propagation of the flame or glow - flaming debris - ignition of the filter paper	EN 1102
Deltamethrin content	2.1 g/kg \pm 25%	CIPAC 333/LN/M/2, CIPAC Handbook M, p 66,2009
Deltamethrin wash resistance index	80% - 98%	CIPAC MT195
Netting meshsize	Mean. 24.0 holes/cm ² or 156 holes/inch ² Min. 24.0 holes/cm ² or 156 holes/inch ²	WHO specification 333/LN/1, Note 9
Dimension stability of netting to washing	Max. 10% shrinkage Max. 5% expansion	ISO 3759; ISO 5077; ISO 6330 Type A, ballast type III, flat drying
Bursting strength –netting	Min. 350 kPa	ISO 13938-2, head area = 7.3 cm ²
Weight	40.0 g/m ² \pm 10%	ISO 3801

Section 3: PermaNet 3.0 – Finished Product

Attribute	Declared Value/Clause	Method
Storage stability	After storage the determined average Deltamethrin content (roof and side) and Piperonyl Butoxide content (roof) must not be lower than 95% of the average content found before storage and the netting shall continue to comply with the clauses for: • Wash resistance index • Dimensional stability • Bursting strength	Storage condition as defined in MT46.3.4, CIPAC Handbook O, p.176, 2017 • 54°C \pm 2°C, 2 weeks for polyethylene roof • 40°C \pm 2°C, 8 weeks for polyester side
Seam bursting strength/seam connecting PE andPET	Not less than that of the weaker fabric of the two	ISO 13938-2, head area = 7.3 cm ²
Seam bursting strength/seam connecting PET and PET	Not less than the stated value for the fabric	ISO 13938-2, head area = 7.3 cm ²
Barrier panel height	Target 40cm Min. 35cm	Flat measurement after relaxing and complete wrinkle removal

Module 4

The [Generic Risk Assessment-Human Health: ITNs formulated with Piperonyl-Butoxide](#) (GRA-PBO) was published by WHO to present a human health hazard and risk assessment for piperonyl butoxide-treated nets (incorporated). It is intended to be used by applicants, regulatory authorities and other stakeholders as an example of the implementation of the Generic risk assessment model for insecticide-treated nets, 2nd edition (GRAM) (WHO, 2018). The assessment assumes that the product is a uniformly treated PBO ITN with the following product characteristic values:

- Fabric weight: 40 g/m²
- Concentration by weight of net: 25 g PBO /kg net
- Concentration by net area: 1000 mg PBO /m²
- Wash resistance index: 90%
- The GRAM includes a default value of 15 m² for the maximal actual size of the net (SN) and assumes uniform treatment.

The standard PermaNet 3.0 roof has the following product characteristic values:

- Fabric weight: 32 g/m²
- Concentration by weight of net: 25 g PBO /kg net
- Concentration by net area: 800 mg PBO /m²
- Wash resistance index: 81%
- SN: 3.42m² (assuming largest roof size available)

The PermaNet 3.0 roof with barrier panel has the following product characteristic values:

- Fabric weight: 32 g/m²
- Concentration by weight of net: 25 g PBO /kg net
- Concentration by net area: 800 mg PBO /m²
- Wash resistance index: 81%
- SN: 3.60 m² (area of roof + area of barrier)

Based on an analysis of the declared characteristics of the alternate construction, the increased area of PBO treated material associated with the inclusion of the barrier panel:

- Does not increase risks from dermal exposure while sleeping based on the location of the barrier panel away from the sleeper.
- Does not increase risks from oral exposure to toddlers and infants (hand to mouth or direct mouth contact) while sleeping based on the location of the barrier panel away from the sleeper.
- Does not increase acute or repeated risks from combined dermal and oral exposure to adults and children washing nets.
 - Compared to the GRA-PBO, the lower Wash resistance index causes an increase in the surface fraction from 10% in the GRA-PBO to 19% for the actual PermaNet 3.0 roof/barrier, in the worst-case scenario. The directionality of this change increases the calculated systemic doses and thereby increases the risk ratios.
 - Compared to the GRA-PBO, the actual size of net in the worst-case scenario of PermaNet 3.0 roof+barrier is 3.6 m² compared to the default maximal actual size of the net (SN) 15m² used in the GRA-PBO. The directionality of this change decreases the calculated systemic doses and thereby decreases the risk ratios.
 - Compared to the GRA-PBO, the concentration of the PBO in the worst-case scenario of PermaNet 3.0 roof/barrier is 1000 mg PBO/m² compared to the value of 1250 mg

PBO/m² used in the GRA-PBO. The directionality of this change decreases the calculated systemic doses and thereby decreases the risk ratios.

- The resulting exposure calculations for the declared characteristics of the roof+barrier is a >60% reduction in the calculated systemic doses for those relevant scenarios as compared to the GRA-PBO.
- Does not increase acute or repeated risks from combined (sleeping and consuming breast milk) exposures to infants as a result of the findings above.

In the same manner, when considering the additional deltamethrin included in the additional panel, there is an increase in calculated systemic doses for combined dermal and oral exposure to adults and children washing nets as compared to the [Generic Risk Assessment-Human Health: ITNs formulated with Deltamethrin](#) (GRA-Delta). However, all risk ratios are still below 1 and considered acceptable.

Module 5

The inclusion of the additional panel is not expected to negatively impact the assessed efficacy of PermaNet 3.0.

5mm 110mm 5mm

9mm

45mm

PermaNet® 

3.0 | by VESTERGAARD

Pyrethroid-PBO LLIN with barrier

1mm


 Wash with precaution Laver avec précaution	 Do not use bleach or chlorine Ne pas utiliser d'eau de javel ou de chlore	 Do not tumble dry Ne pas mettre dans le sèche-linge	 Do not iron or press Ne pas repasser ou presser	 Do not dry-clean Ne pas nettoyer à sec
--	---	---	---	--

5mm 110mm 5mm

9mm

45mm

1mm

Manufacturer/ Fabricant	: Vestergaard Sàrl	
Address of manufacturer/ Adresse du fabricant	: Place Saint-François 1, CH - 1003 Lausanne, Switzerland	
Size/ Taille	: W160 x L180 x H150 cm	
Insecticide (Deltamethrin)/ Insecticide (Deltaméthrine)	: Roof/Toit/Barrier/Barrière: 4.0 g/kg Sides/ Côté: 100D/150D: 2.1g/kg	
Synergist (Piperonyl Butoxide)/Synergiste	: Roof/Toit/Barrier/Barrière - 25.0 g/kg	
Fabric Composition/ Composition	: Roof/Toit/Barrier/Barrière: 100% Polyethylene Sides/ Côté - 100% Polyester	
Date of Release/ Date de Sortie	: 10/2021	
Date of expiration/ Date d'expiration	: 10/2023	
Batch No/ Numéro de Série	: 1 119 21 (1)	
Country of origin/ Pays d'origine	: Vietnam	
Lifetime/ Durée de vie	: 20 washes	

5mm 120 mm 5mm

3 mm


7 mm


55 mm


44 mm

1mm

AMF - DRC - 2021 - Batch Number 1 119 21







PAS À VENDRE

République Démocratique du Congo, 2021
AMF - DRC - 2021 - Batch Number 1 119 21