

WHO Prequalification Programme / Vector Control Product Assessment

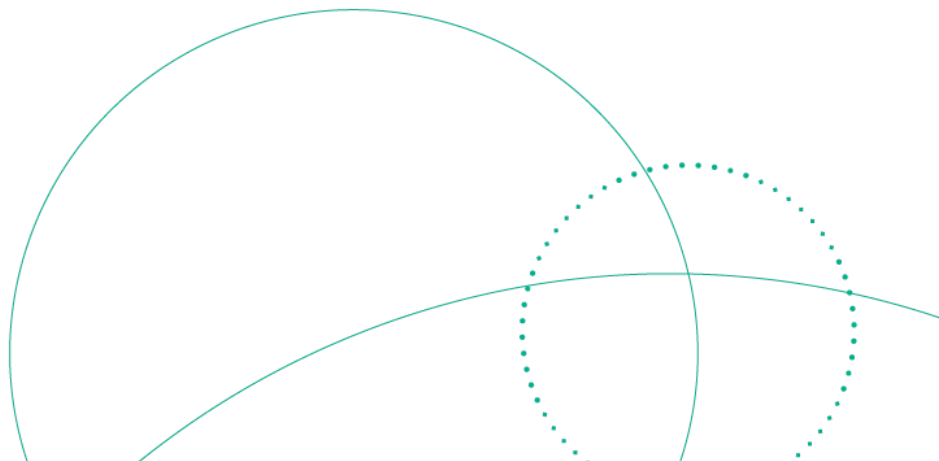
# WHO Public Assessment Report: WHOPAR Part 4

Vector Guard

(Disease Control Technologies LLC)

P-09284

Safety Assessment



## Contents

<b>1 Risk assessment summary</b>	<b>3</b>
1.1 Introduction	3
1.2 Active ingredient statement	3
1.3 Supporting data base	3
1.4 Assessment	4
1.5 Discussion and Conclusion	4
<b>2 References</b>	<b>5</b>

# 1 Risk assessment summary

## 1.1 Introduction

The applicant, Disease Control Technologies (DCT) (Greer, South Carolina, USA), submitted to the World Health Organization (WHO) Prequalification Unit Vector Control Product Assessment Team (PQT-VCP) a dossier containing supporting data on the product Vector Guard and requested WHO assessment for the purpose of prequalification. Vector Guard is an insecticide treated net (ITN) product intended for use in malaria endemic regions. The fabric used in the roof panel is made from polyethylene yarn incorporated with Alpha-cypermethrin (CAS No. 67375-30-8) and Piperonyl Butoxide (PBO) (CAS No. 51-03-6). The side panels of the constructed ITN are the same fabrics as produced for the prequalified product:

- Royal Sentry 2.0 (120 Denier) (PQ Ref 003-002)

## 1.2 Active ingredient statement

### Alpha-cypermethrin

Alpha-cypermethrin (CAS No. 67375-30-8) is a broad-spectrum insecticide, effective against target pests through contact and ingestion. Alpha-cypermethrin is a type II synthetic pyrethroid chemical. Pyrethroids disrupt the voltage-gated sodium channels in the nervous system, resulting in neurotoxicity.

### Piperonyl Butoxide

Piperonyl butoxide (CAS No. 51-03-6) is an insecticide synergist. PBO is commonly used in products containing pyrethrins and pyrethroids to increase the efficacy of the actual insecticide in ITNs.

## 1.3 Supporting data base

The toxicology database for Alpha-cypermethrin and PBO is adequate to address the health hazard and to assess the risks associated with the proposed uses of Vector Guard as an ITN.

The human health risk assessments, including hazard, exposure, and risk characterization for Alpha-cypermethrin and PBO are presented in the “*Generic Risk Assessment – Human Health – Alpha-cypermethrin (CAS No. 67375-30-8). A long-lasting mosquito net treated with Alpha-cypermethrin*” published by WHO (2021a) and the “*Generic Risk Assessment – Human Health – Piperonyl Butoxide (CAS No. 51-03-6). A synergist in insecticide-treated nets*” published by WHO (2021b). The generic risk assessments (GRA) published by WHO are intended to be used as an example of the implementation of the “*Generic Risk Assessment Model for Insecticide-Treated Nets, 2<sup>nd</sup> edition*” (GRAM)(WHO, 2018) and points of reference for the assessment of new products which are formulated with these active ingredients.

## 1.4 Assessment

A Comparison of the Vector Guard characteristics vs. GRA selected representative values				
Attribute	Alpha-Cypermethrin		Piperonyl Butoxide	
	Vector Guard	Alpha-Cypermethrin GRA*	Vector Guard	PBO GRA*
Concentration by weight	Roof and Sides: 5.8 g/kg net	5.8 g/kg net	Roof: 20.3 g/kg net	25 g/kg net
Fabric weight	Roof: 35 g/m <sup>2</sup> Sides: 35 g/m <sup>2</sup> (120D)	35 g/m <sup>2</sup>	Roof: 35 g/m <sup>2</sup>	40 g/m <sup>2</sup>
Concentration by net area	Roof: 203 mg/ m <sup>2</sup> Sides: 203 mg/m <sup>2</sup> (120D)	203 mg/m <sup>2</sup>	Roof: 710 g/m <sup>2</sup>	1000 g/m <sup>2</sup>
Wash resistance index	Roof: 90% Sides: 90% (120 D)	90%	Roof: 90%	90%

\* In the GRA for alpha-cypermethrin and PBO, it is assumed that the roof and side panels of the ITN are uniformly treated at the identified concentration.

Acute 6-pack toxicity data for the proposed ITN were not submitted and a waiver was requested. Based on the low acute toxicity profile of the components, it is not expected that the acute toxicity of Vector Guard would be different from that of each ingredient or from the combined toxicity of the ingredients. Therefore, the waivers were granted. The carrier, high density polyethylene (HDPE), is a non-toxic, non-hazardous material and can be considered as safe for contact with humans, animals, and the environment. This carrier is not subject to evaluation in this human health risk assessment. The toxicity profile of the two active ingredients is available in “*Generic Risk Assessment – Human Health –Alpha-cypermethrin (CAS No. 67375-30-8). A long-lasting mosquito net treated with Alpha-cypermethrin*” published by WHO (2021a) and the “*Generic Risk Assessment – Human Health – Piperonyl Butoxide (CAS No. 51-03-6). A synergist in insecticide-treated nets*” published by WHO (2021b).

## 1.5 Discussion and Conclusion

The risk assessment was conducted according to the guidance provided in the most recent “*Generic Risk Assessment Model for Insecticide-Treated Nets, 2<sup>nd</sup> edition*” (GRAM) (WHO, 2018). In support of new product applications or change applications submitted to the WHO Prequalification Unit – Vector Control Product Assessment Team, applicants may include reference to the GRAs as part of the product dossier.

Based on the proposed product characteristics and the use pattern, it was determined that the risk ratios for Vector Guard are acceptable (i.e., less than 1) for all population subgroups (adults, children, toddler, infants and newborn), for all exposure scenarios (sleeping under the net, washing the net, sleeping under and washing the net) and the exposure routes (oral, dermal and inhalation) similar to those obtained for Alpha-cypermethrin and PBO in the respective GRAs (WHO, 2021a,b).

Therefore, it can be concluded that the ITN proposed product Vector Guard can be used safely for its intended purpose. Assessment of the submitted information supports the prequalification of the product Vector Guard.

## 2 References

WHO (World Health Organization), 2018. A Generic Risk Assessment Model for Insecticide-treated Nets, 2<sup>nd</sup> Edition. Available at: <http://apps.who.int/iris/bitstream/10665/260305/1/9789241513586-eng.pdf?ua=1>

WHO (World Health Organization), 2021a. Generic Risk Assessment – Human Health, Alpha-cypermethrin (CAS No. 67375-30-80). A long-lasting mosquito net treated with Alpha-cypermethrin. 16 June 2021. Available at: <https://extranet.who.int/pqweb/key-resources/documents/generic-risk-assessment-human-health-itns-formulated-alpha-cypermethrin>.

WHO (World Health Organization), 2021b. Generic Risk Assessment – Human Health, Piperonyl Butoxide (CAS No. 51-03-6). A synergist in insecticide-treated nets. 8 June 2021. Available at: <https://extranet.who.int/pqweb/key-resources/documents/generic-risk-assessment-human-health-itns-formulated-piperonyl-butoxide>.