

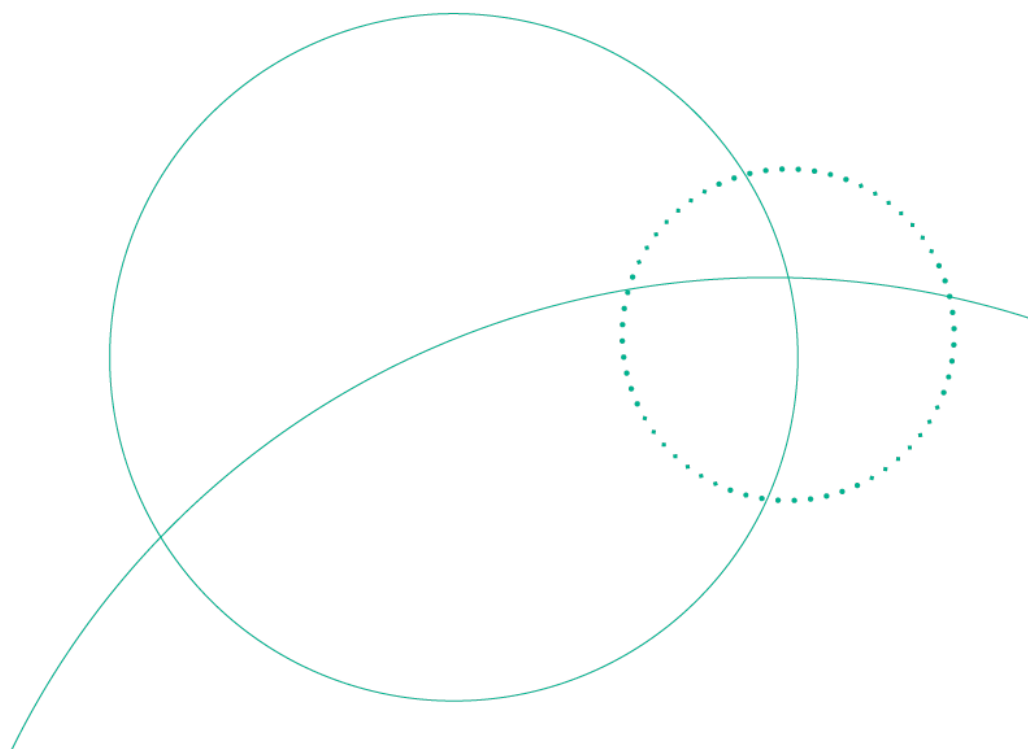
WHO Prequalification Programme / Vector Control Product Assessment

WHO Public Assessment Report: WHOPAR Part 4

UNET G3 LN
(Sino Africa Medical Devices Company Ltd.)

P-13228

Safety Assessment



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1 Risk assessment summary

1.1 Introduction

The applicant, Sino Africa Medical Devices Company Ltd. (Kampala, Uganda) submitted to the World Health Organization (WHO) Prequalification Unit Vector Control Product Assessment Team (PQT-VCP) a dossier containing supporting data on the product UNET G3 LN and requested WHO assessment for the purpose of prequalification. UNET G3 LN is an insecticide treated net (ITN) product intended for use in malaria endemic regions. The fabric is made from polyethylene yarn incorporated with Deltamethrin (CAS No. 52918-63-5) and Piperonyl butoxide (PBO) (CAS No. 51-03-6).

1.2 Active ingredient statement

1. Deltamethrin

Deltamethrin (1R,3R)-R-cyano (3-phenoxyphenyl) methyl 3-(2,2-dibromoethenyl)-2,2-dimethylcyclopropanecarboxylate (CAS No. 52918-63-5) is a broad-spectrum pyrethroid insecticide that is registered for direct application to a wide variety of food/feed crops, for use on stored grains, for use in food/feed handling establishments and as a wide-area mosquito adulticide.

2. 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 database

The toxicology database for Deltamethrin and PBO is adequate to address the health hazard and to assess the risks associated with the proposed uses of UNET G3 LN as an ITN.

The human health risk assessments, including hazard, exposure, and risk characterization for Deltamethrin and PBO are presented in the “*Generic Risk Assessment – Human Health – Deltamethrin (CAS No. 52918-63-5). An active ingredient in insecticide-treated nets*” 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, 2nd edition*” (GRAM)(WHO, 2018) and points of reference for the assessment of new products which are formulated with these active ingredients. Sino Africa Medical Devices Company Ltd. presented a proposed risk assessment which followed the GRAM (WHO, 2018).

1.4 Assessment

Comparison of the UNET G3 LN characteristics vs. GRA selected representative values				
	Deltamethrin		Piperonyl butoxide	
Attribute	UNET G3 LN	Deltamethrin GRA	UNET G3 LN	PBO GRA
Concentration by weight	3.0 g/kg net	3.0 g/kg net	11.0 g/kg net	25 g/kg net
Fabric weight	40 g/m ²	40 g/m ²	40 g/m ²	40 g/m ²
Concentration by net area	120 mg/m ²	120 mg/m ²	440 mg/m ²	1000 mg/m ²
Wash resistance index	93%	90%	90%	90%

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 UNET G3 LN 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 – Deltamethrin (CAS No. 52918-63-5). An active ingredient in insecticide-treated nets*” 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, 2nd 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 UNET G3 LN 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 Deltamethrin and PBO in the respective GRAs (WHO, 2021a,b).

The product characteristic values for UNET G3 LN which differ from the representative values (Deltamethrin WRI and PBO concentration) both result in a decrease in the calculated risk ratios meaning that the product does not pose any additional risk to human health beyond the assessment provide in the GRAs (WHO, 2021a, b).

Therefore, it can be concluded that the ITN UNET G3 LN can be used safely for its intended purpose.

Assessment of the submitted information supports the prequalification of the product UNET G3 LN.

2 References

WHO (World Health Organization), 2018. A Generic Risk Assessment Model for Insecticide-Treated Nets, 2nd Edition. Available at: <http://www.who.int/whopes/resources/9789241513586>.

WHO (World Health Organization), 2021a. Generic Risk Assessment – Human Health – Deltamethrin (CAS No. 52918-63-5). An active ingredient in insecticide-treated nets. Available at: https://extranet.who.int/prequal/sites/default/files/document_files/WHO_VCP_GRA%20ITN-DELTAMETHRIN.pdf.

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>.