World Health Organization

WHO Prequalification Programme / Vector Control Product Assessment

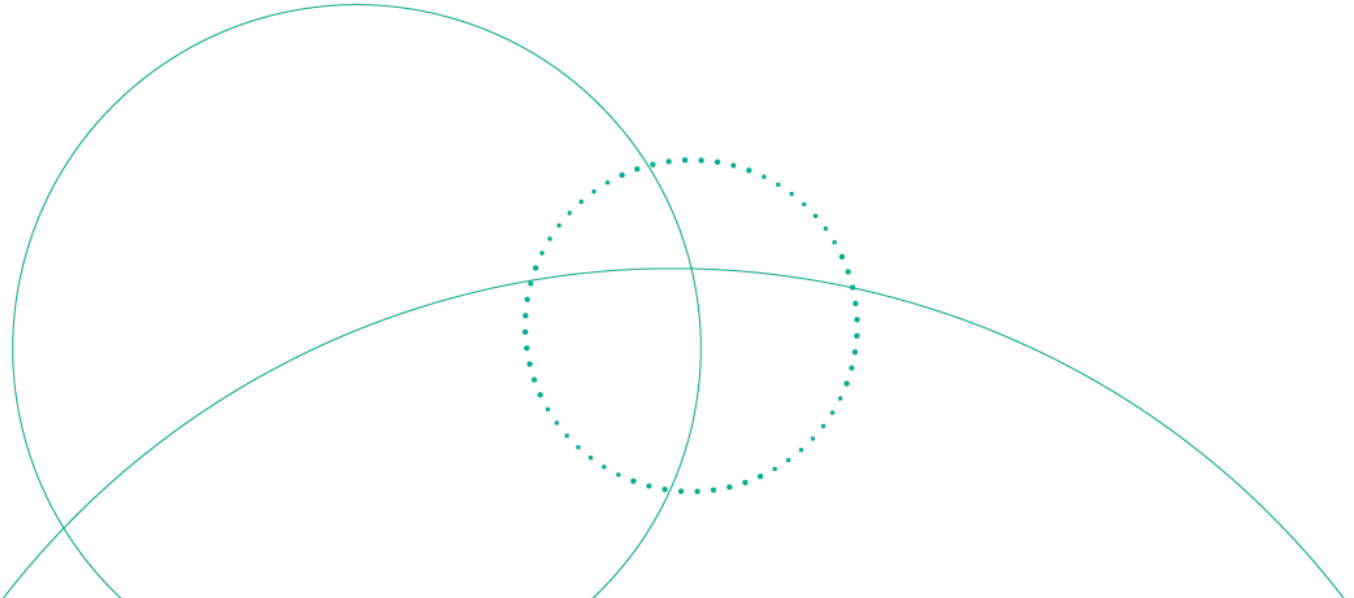
WHO Public Assessment Report: WHOPAR Part 4

UNET G1 LN

(Sino Africa Medical Devices Company Ltd.)

P-13227

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 G1 LN and requested WHO assessment for the purpose of prequalification. UNET G1 LN is an insecticide treated net (ITN) product intended for use in malaria endemic regions. The fabric is made from multifilament polyester yarn knitted fabric coated with Deltamethrin (CAS No. 52918-63-5).

1.2 Active ingredient statement

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.

1.3 Supporting data base

The toxicology database for Deltamethrin is adequate to address the health hazard and to assess the risks associated with the proposed uses of UNET G1 LN as an ITN.

The human health risk assessment, including hazard, exposure, and risk characterization for Deltamethrin is presented in the "*Generic Risk Assessment – Human Health – Deltamethrin (CAS No. 52918-63-5). An active ingredient in insecticide-treated nets*" published by WHO (2021). 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 G1 LN characteristics vs. GRA selected representative values		
Attribute	**UNET G1 LN**	**Deltamethrin GRA**
Concentration by weight	1.4 g/kg net	3.0 g/kg net
Fabric weight	40 g/m^2	40 g/m^2
Concentration by net area	56 mg/m^2	120 mg/m^2
Wash resistance index	≥ 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 G1 LN would be different from that of each ingredient or from the combined toxicity of the ingredients. Therefore, the waivers were granted. The carrier, knitted polyester fabric, 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 active ingredient is available in "*Generic Risk Assessment – Human Health – Deltamethrin (CAS No. 52918-63-5). An active ingredient in insecticide-treated nets*" published by WHO (2021).

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 G1 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 in the respective GRA (WHO, 2021).

The product characteristic values for UNET G1 LN, which differ from the representative values, 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 provided in the GRAs. (WHO, 2021)

Therefore, it can be concluded that the ITN proposed product UNET G1 LN can be used safely for its intended purpose.

Assessment of the submitted information supports the prequalification of the product UNET G1 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), 20211. 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%20_ITN-DELTAMETHRIN.pdf