World Health Organization

WHO Prequalification Programme / Vector Control Product Assessment

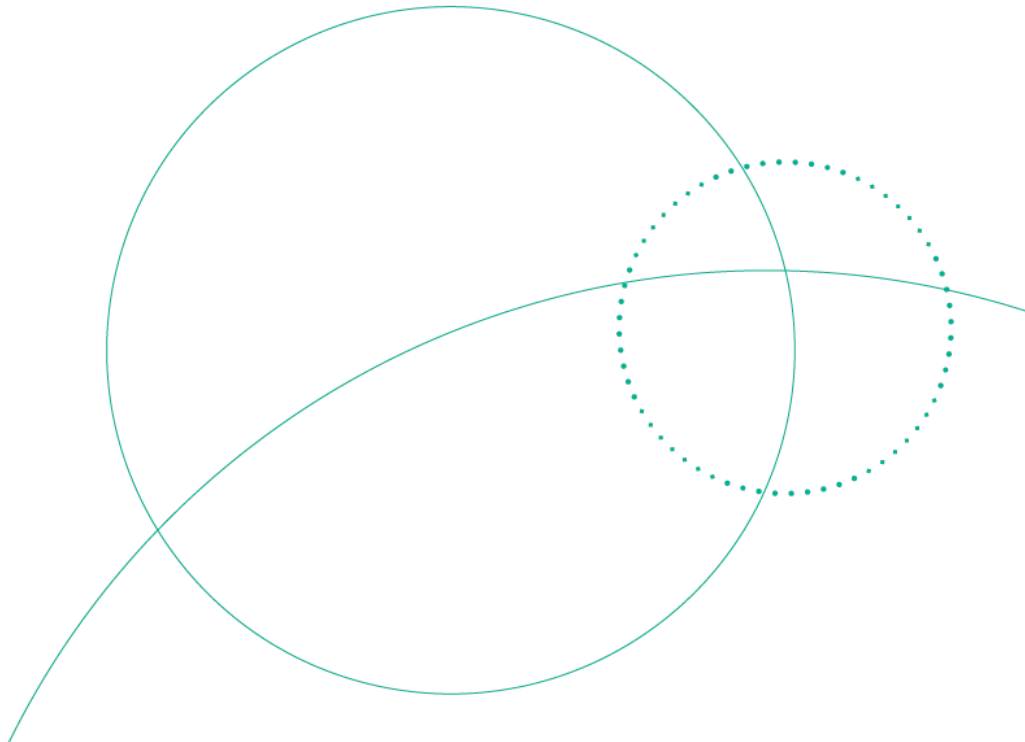
WHO Public Assessment Report: WHOPAR Part 4

Yorkool G5 LN

(Tianjin Yorkool International Trading Co., Ltd)

P-12507

Safety Assessment



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1 Risk assessment summary

1.1 Introduction

The applicant, Tianjin Yorkool International Trading Co., Ltd (Tianjin, China) submitted to the World Health Organization (WHO) Prequalification Unit Vector Control Product Assessment Team (PQT-VCP) a dossier containing supporting data on the product Yorkool G5 LN and requested WHO assessment for the purpose of prequalification. Yorkool G5 LN is an insecticide treated net (ITN) product intended for use in malaria endemic regions. The fabric is made from polyethylene yarn incorporated with Alpha-cypermethrin (CAS No. 67375-30-8) and Chlorfenapyr (CAS No. 122453-73-0).

1.2 Active ingredient statement

1. **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.

2. **Chlorfenapyr**
   Chlorfenapyr (CAS No. 122453-73-0) is an N-substituted halogenated pyrrole. It is a pro-insecticide that is converted to its active metabolite by P450 monooxygenases mechanisms.

1.3 Supporting database

The toxicology database for Alpha-cypermethrin and Chlorfenapyr is adequate to address the health hazard and to assess the risks associated with the proposed uses of Yorkool G5 LN as an ITN.

The human health risk assessments, including hazard, exposure, and risk characterization for Alpha-cypermethrin and Chlorfenapyr 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 (2021) and the "*Generic Risk Assessment – Human Health – Chlorfenapyr (CAS No. 122453-73-0) An active ingredient in insecticide-treated nets*" published by WHO (2024). 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. Tianjin Yorkool International Trading Co., Ltd presented a proposed risk assessment which followed the GRAM (WHO, 2018).

1.4 Assessment

Comparison of the Yorkool G5 LN characteristics vs. GRA selected representative values				
	Alpha-cypermethrin		Chlorfenapyr	
Attribute	Yorkool G5 LN	Alpha-cypermethrin GRA	Yorkool G5 LN	Chlorfenapyr GRA
Concentration by weight	2.4 g/kg net	5.8 g/kg net	4.8 g/kg net	6.5 g/kg net
Fabric weight	40 g/m^2	35 g/m^2	40 g/m^2	40 g/m^2
Concentration by net area	96 mg/m^2	208 mg/^{m2}	192 mg/m^2	260 mg/m^2
Wash resistance index	93%	90%	91%	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 Yorkool G5 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 –Alpha-cypermethrin (CAS No. 67375-30-8). A long-lasting mosquito net treated with Alpha-cypermethrin*" and the "*Generic Risk Assessment – Human Health – Chlorfenapyr (CAS No. 122453-73-0) An active ingredient in insecticide-treated nets*" published by WHO (2021, 2024).

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 Yorkool G5 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 Alpha-cypermethrin and Chlorfenapyr in the respective GRAs (WHO, 2021, 2024).

Therefore, it can be concluded that the ITN proposed product Yorkool G5 LN can be used safely for its intended purpose. Assessment of the submitted information supports the prequalification of the product Yorkool G5 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), 2021. 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), 2024. Generic Risk Assessment – Human Health, Chlorfenapyr (CAS No. 122453-73-0). An active ingredient in insecticide-treated nets. 13 September 2024. Available at: https://extranet.who.int/prequal/vector-control-products/who-guideline-prequalification-assessment-insecticide-treated-nets.