

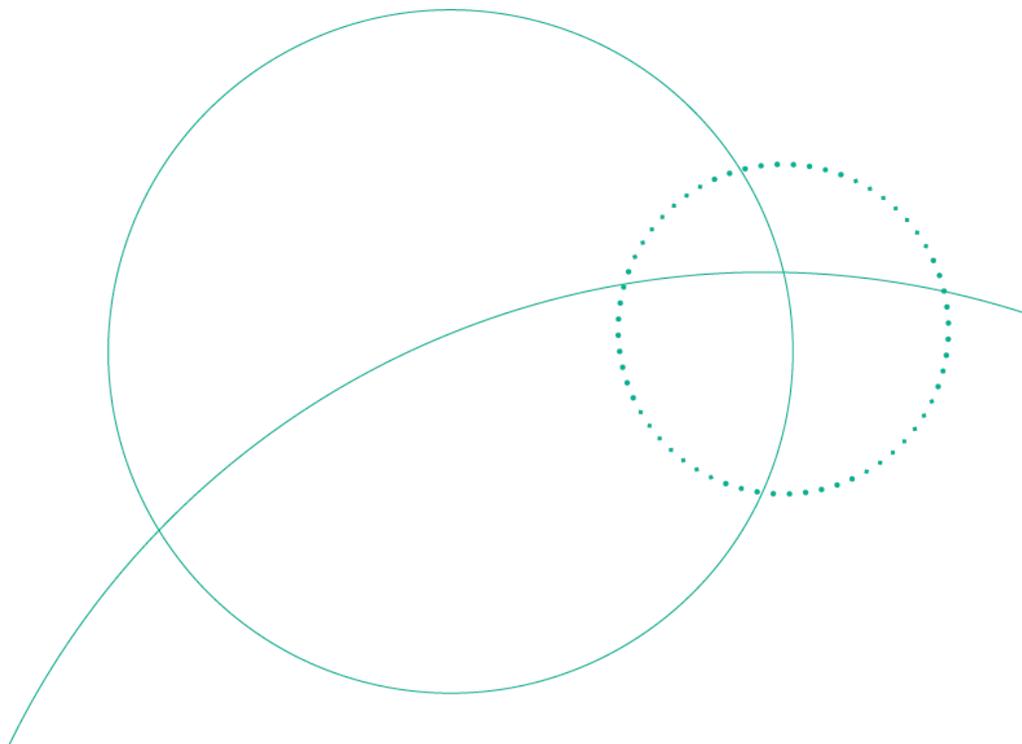
WHO Prequalification Programme / Vector Control Product Assessment

WHO Public Assessment Report: WHOPAR Part 4

Synera DuoForte
(GDM Health Product Ltd.)

P-13215

Safety Assessment



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1 Risk assessment summary

1.1 Introduction

The applicant, GDM Health Products Ltd. (Guangzhou, China) submitted to the World Health Organization (WHO) Prequalification Unit Vector Control Product Assessment (PQT-VCP) a dossier containing supporting data on the product, Synera DuoForte, and requested WHO assessment for the purpose of prequalification. Synera DuoForte is an insecticide treated net (ITN) product intended for use in malaria endemic regions. The fabric is made from synthetic polymer filaments coated 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 Synera DuoForte 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. GDM Health Products Ltd presented a proposed risk assessment which followed the GRAM (WHO, 2018).

1.4 Assessment

Comparison of the Synera DuoForte ITN characteristics vs. GRA selected representative values				
Attribute	Alpha-cypermethrin		Chlorfenapyr	
	Synera DuoForte	Alpha-cypermethrin GRA	Synera DuoForte	Chlorfenapyr GRA
Concentration by weight	3.75 g/kg net	5.8 g/kg net	5.60 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	150 mg/m ²	203 mg/m ²	224 mg/m ²	260 mg/m ²
Wash resistance index	96%	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 Synera DuoForte would be different from that of each ingredient or from the combined toxicity of the ingredients. Therefore, the waivers were granted. The textile matrix of the ITN consists of synthetic polymer fiber which is considered toxicologically inert and can be considered as safe for contact with humans, animals, and the environment. This PET 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, 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 Synera DuoForte 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 proposed ITN product Synera DuoForte can be used safely for its intended purpose. Assessment of the submitted information supports the prequalification of the product Synera DuoForte.

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>.