WHO Decision Document: SumiShield 50WG

1. Introduction

SumiShield 50WG is a water dispersible granule indoor residual spray (IRS) product containing 50% clothianidin. The final product is packaged in sachets (120g and 150g). According to the product label, the product is intended to be diluted and applied as a suspension to walls inside of dwellings, eaves and other indoor surfaces that serve as resting places for mosquitoes.

Clothianidin is a neonicotinoid compound classified in Group 4A by the Insecticide Resistance Action Committee (IRAC)[1]. This group of chemicals are known as nicotinic acetylcholine receptor (nAChR) competitive modulators which act on the central nervous system of insects.

SumiShield 50WG was submitted to WHO for evaluation through the WHO Pesticide Evaluation Scheme (WHOPES) on 14 August 2014 by Sumitomo Chemical Co., LTD. The 20th WHOPES Working Group was held in March of 2017. The full efficacy data package for SumiShield 50WG was not available in time for this Working Group and thereby, the responsibility for evaluation of the SumiShield 50WG was transferred within WHO from WHOPES to the Prequalification Team – Vector Control Group (PQT-VC).

2. Quality

Specifications

Specifications for clothianidin TC and WG formulations were evaluated by the Joint Meeting on Pesticide Specifications (JMPS) in 2009 and 2013 respectively, and recommended for adoption by the UN Food and Agriculture Organization (FAO). The existing specifications have been extended to WHO specifications to support the public health uses of these formulations and will be published separately.

Inspections

Site master files (SMF) have been submitted to WHO for the active ingredient and end use vector control product manufacturing sites. The SMFs have been screened for completeness and onsite inspections will be scheduled for 2018.

Conclusion

The quality part of the dossier is accepted.

3. Efficacy

Supporting data was generated under the oversight of WHOPES. These data were generated between 2014 and 2017 as part of the WHOPES process. The WHOPES management of efficacy data generation was based on WHOPES *Guidelines for testing mosquito adulticides for indoor residual spraying and treatment of mosquito nets*[2] - Phase 1, 2 and 3, and included approval of all protocol/study design, selection of 2 out of 3 field study facilities, and oversight of studies at those 2 facilities. Sumitomo

[1] http://www.irac-online.org/documents/moa-classification/
[2] http://apps.who.int/iris/bitstream/10665/69296/1/WHO_CDS_NTD_WHOPES_GCDPP_2006.3_eng.pdf

Chemical Co., LTD contracted directly with the third testing facility. Additional efficacy data generated outside of the WHOPES process were submitted by Sumitomo Chemical Co., LTD.

Phase 1

Laboratory entomological efficacy trials were conducted by IRD in Montpellier, France. These studies were used to establish the dosage of 300 mg ai/m^2 as the optimum application target dose on cement, mud, wood surfaces.

Phase 2 and 3

Experimental hut, small scale village and large scale village trials were conducted to assess the efficacy and duration of residual effect of SumiShield 50WG.

Site	Trials	Study Sponsor
India - National Institute of Malaria Research Field Unit, Bengaluru	Phase 2 and 3 - Almatti Catchment area, District Bagalkot in Karnataka state, India	WHOPES
Tanzania - Ifakara Health Institute, Bagamoyo Research and Training Centre, India Street, PO Box 74, Bagamoyo, Pwani, United Republic of Tanzania	Phase 2 and 3 - Ulanga District, south-eastern Tanzania	WHOPES
Cote d'Ivoire - Tiassalé Field Trials Site, CSRS	Phase 2 - Tiassale Phase 3 - Agboville	Sumitomo Chemical Co., LTD (WHOPES approved protocol)
Benin - Anopheles Biology & Control (ABC)	Phase 2 - Malanville	Sumitomo Chemical Co., LTD
Benin - Centre de Recherche Entomologique de Cotonou (CREC)	Phase 2 - Covè	Sumitomo Chemical Co., LTD
Tanzania	Moshi District	Sumitomo Chemical Co., LTD

The submitted data were assessed by independent experts to review the integrity of the data, its scientific validity, and the performance of the product. These experts completed a *Declaration of interest for WHO experts* prior to their work and their interests were not found to be directly related to the work requested by WHO.

The performance of SumiShield 50WG was assessed based on the standards for efficacy and duration of effect established in the WHOPES *Guidelines for testing mosquito adulticides for indoor residual spraying and treatment of mosquito net.*

Conclusion

The efficacy part of the dossier is accepted based on established WHO IRS standards.

The duration of residual bio-efficacy is variable depending on the quality of treatment, effective application to meet target dosage, and surface substrate. Based on mosquito mortality rates in cone tests measured at 24 and 72 hours after exposure, the expected duration of residual efficacy is between 3-8 months. In certain situations residual efficacy may extend beyond this period. Implementing partners should monitor the residual bio-efficacy of the product post-application in order to inform decision making for additional spray campaigns[3].

4. Safety Assessment

Sumitomo Chemical Co., LTD performed a risk assessment which was submitted as part of the product dossier. An independent risk assessment was performed at the request of WHO in order to validate the findings of the manufacturer generated risk assessment. The risk assessments were conducted using the Generic Risk Assessment Model (GRAM) for indoor residual spraying of insecticides (First Revision - February 2011)[4]. The hazard endpoints for clothianidin were established as part of the 2010 Joint Meeting on Pesticide Residues (JMPR)[5].

Conclusion

When used for IRS as instructed, S-1752 [SumiShield 50] WG granule sachets do not pose undue hazards to the spray operators or residents of the treated dwellings.

5. Benefit Risk Assessment and Overall Conclusion

Quality

Sumishield 50 WG is considered to be of acceptable quality provided it conforms to the relevant WHO specifications for the active ingredient and end use formulation.

Efficacy and Safety

Sumishield 50 WG is considered to be efficacious and not pose undue risk to applicators or bystanders when used in accordance with its label.

Benefit Risk Assessment

Based on the WHO assessment of available data and application of a weight of evidence based approach for decision making, SumiShield 50WG should be included in the list of prequalified vector control products. Sumishield 50WG utilizes a different chemical class, based on IRAC groupings, than those products previously evaluated by WHO. A diverse toolbox of products enables vector borne disease programs access to products which meet their specific needs.

6. Supporting Policy Recommendation

The WHO Global Malaria Program (GMP) has confirmed that SumiShield 50WG is covered by the existing policy recommendations for IRS intervention.

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[3] http://www.who.int/malaria/publications/atoz/9789241508940/en/

[4] http://apps.who.int/iris/bitstream/10665/44676/1/9789241502177_eng.pdf

[5] http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Report10/JMPR_2010_contents.pdf