WHO Prequalification of Vector Control Products

Data requirements table – Module 3

DR code	Requirement	Description/notes	Method[1]/reference	Form/template	Number of batches to test
3.0	Module 3 index	Identification of supporting information included within Module 3 to address the data requirements.		• Template Module 3 index	
3.1	Declaration of product formulation (DPF)	The complete product composition and purpose of all formulants in intermediates and finished fabrics.	Implementation guidance (IG) – DPF for insecticide-treated net (ITN) fabric	• Template DPF for incorporated ITN fabric • Example template DPF for single active ingredient (AI) incorporated fabric • Example template DPF for dual AI incorporated fabric • Template DPF for coated ITN fabric • Example template DPF for single AI coated ITN fabric	
3.2	Product manufacturing details	A key difference between the manufacturing details in Module 3 and the information required in Sites Master Files for Module 6 is that the description of	IG – Product manufacturing details - ITNs		

[1] Methods identified should be used for the generation of data. Additional and/or alternative methods may be proposed by applicants provided that complete description of the method and validation is included.

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		manufacturing process defines all equipment, settings/ranges, speeds, temperatures which must be followed to produce the product as intended. The SMF and QMS are the system by which a manufacturer, ensures that the declared process is followed.			
3.2.1	Declaration of manufacturing sites (DMS)	Identification of the manufacturing sites where source AIs are produced and the manufacturing sites (including their function(s)) for production and storage of the end-use products prior to release.		• Template DMS	
3.2.2	Control of starting materials	Presentation of the acceptance criteria for use of starting materials in the formulation of the product.			
3.2.3	Batch delineation and formula	Presentation of how batches are defined/delineated for the product/fabric and a formula with applicable volumes for a typical batch.			
3.2.4	Description of manufacturing process (DMP)	Complete narrative of the manufacturing process including the necessary equipment/settings to produce the product as intended			

DR code	Requirement	Description/notes	Method[1]/reference	Form/template	Number of batches to test
3.3	Declaration of ITN construction and sampling procedure (DIC)	Declare the product construction including sizes and shapes and establish defined sampling procedures which ensure appropriate representation of the fabric(s) which comprise ITN in its declared forms.	IG – Declaration of ITN construction and sampling procedure	• Template DIC	
3.4	Physical characteristics				
3.4.1	Integral components (e.g. yarn)				3
3.4.1.1	Verification of denier	Supporting data to verify the declared yarn denier and determine the potential inter-/intra-batch variability.	IG – Verification of denier and tensile strength ISO 2060:1994		3
3.4.1.2	Tensile strength	Determination of yarn tensile strength based on the declared formulation and manufacturing process.	IG – Verification of denier and tensile strength ISO 2062:2009/ ASTM D2256/D2256 M-21		3
3.4.1.3	Other representative attributes relevant to the	To be proposed by applicant as necessary.			

DR code	Requirement	Description/notes	Method[1]/reference	Form/template	Number of batches to test
	integral component(s)				
3.4.2	Fabric				5
3.4.2.1	Description of fabric formation (e.g. knitting pattern)	Should include a narrative description and image(s) of the formed fabric.			
3.4.2.2	Fabric weight	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability.	ISO 3801 / EN 12127		5
3.4.2.3	Mesh size	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability.	IG – Determination of mesh size		5
3.4.2.4	Flammability	Verification of product being classified as “not flammable.”	IG – Flammability EN 1102		5
3.4.2.5	Bursting strength	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability.	ISO 13938 part 2: 2019		5
3.4.2.6	Snag strength	Supporting data to verify the declared value and determine the	IG –Snag strength		5

DR code	Requirement	Description/notes	Method[1]/reference	Form/template	Number of batches to test
		potential inter-/intra-batch variability.			
3.4.2.7	Abrasion	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability.	IG - Abrasion		5
3.4.2.8	Resistance to hole formation	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability.	IG -Resistance to hole formation		5
3.4.2.9	Dimension stability to washing	Supporting data to verify compliance with limits of shrinkage and expansion.	ISO 6330: 2021		5
3.4.3	Constructed ITN				5
3.4.3.1	Bursting strength – seam	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability.	ISO 13938 part 2: 2019		5
3.4.3.2	Dimensional stability to compression packing	Supporting data to verify compliance with limits of shrinkage and expansion.	Identified as future requirement. Proposal for consultation in development.		

DR code	Requirement	Description/notes	Method[1]/reference	Form/template	Number of batches to test
3.5	Chemical and entomological characteristics – fabric	The chemical characteristics of the treated fabric(s), and the integral components, using established sample preparation, analytical chemistry, and bioassay methods for the purpose of assessing the following and informing product testing activities by procurers/users.			
3.5.1	Verification of the target dose, homogeneity of the treated fabric, and consistency of production	Chemical analysis of total AI, conducted in a manner to capture heterogeneity of fabric treatment. Includes identification of the enforcement analytical method.	CIPAC, AOAC or equivalent		5
3.5.2	Regeneration study	The time required for the reestablishment of observable intended effect(s) of a washed fabric sample using chemical analysis, an established bioassay method(s) and appropriate strain(s) of test system(s).	IG - Regeneration study for ITN fabric IG – Cone test IG – Tunnel test IG – IACT IG – Control selection IG - Thresholds IG – Novel bioassays		3

DR code	Requirement	Description/notes	Method[1]/reference	Form/template	Number of batches to test
3.5.3	Determination and selection of appropriate wash interval for artificial aging	Applicable supporting analytical chemistry and/or bioassay data which characterizes the translocation of AI(s) over time and analysis to justify the selection of a wash interval to be used in artificial aging of fabric/product samples.	IG - Regeneration study for ITN fabric		
3.5.4	Determination of Wash resistance – chemical and bioefficacy	Analytical chemistry and bioassay data generated on fabric samples over a series of washes using the selected wash interval. Pilot under consideration for characterization of the physical presentation of AI(s) on the surface via imaging methods.	IG – Wash resistance study for ITN fabric IG – Control selection IG – Cone test IG – Tunnel test IG – IACT		3
3.5.5	Determination of wash resistance index (WRI)	WRI is based on a standardized method for sample preparation and chemical analysis to determine the rate of AI loss per wash from 0 to 4 washes.	IG – Determination of wash resistance index for ITN fabric CIPAC MT 195		5
3.5.6	Declaration of strains	Declaration of vector strains used in laboratory bioassays.	IG – Strain selection IG – Matrix of selected mosquito strains (MSMS)	• Template MSMS	

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3.6	Storage stability	Storage stability data should be generated using samples which have been subjected to accelerated storage conditions as well as real-time storage conditions. Data from real-time storage samples may be submitted post-prequalification.	IG – Storage stability MT 46.4		3
3.7	Manufacturing release specifications	A set of attributes and QC tests relying on validated methods and established limits that the product needs to meet to be considered of acceptable quality.	IG – Manufacturing release specifications		
3.7.1	Post-storage and In-use tolerances in relation to the manufacturing release specifications	Proposed tolerances for certain characteristics for those products which have been in storage or in operational use for the purpose of investigating product fitness.	Identified as future requirement. Proposal for consultation in development.		
3.8	Other related information	To be proposed by applicant as necessary.			