

Module 4. Data requirements table

DR code	Requirement	Description/notes	Method ¹ /reference	Form/template
4.0	Module 4 index	Identification of supporting information included within Module 4 to address the data requirements.		<ul style="list-style-type: none"> Template Module 4 index
4.1	Identification of applicable hazard assessments	Identification of the available authoritative hazard evaluations and justification for selection of endpoints.		
4.2	Product-specific risk assessment	Complete product risk assessment based on the WHO generic risk assessment model (GRAM) and other internationally accepted assessment methodologies integrated as needed.	GRAM for insecticide-treated clothing, skin-applied repellents and household insecticides for insecticide-treated nets	

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.

Spatial emanators guidance

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4.3	Acute 6-pack	<p>The short-term toxicity testing battery consists of the following six acute toxicity studies, commonly referred to as the acute 6-pack:</p> <ul style="list-style-type: none"> • Acute oral LD₅₀ – rat • Acute dermal LD₅₀ – rat or rabbit • Acute inhalation LC₅₀ – rat • Primary eye irritation – rabbit • Primary dermal irritation – rat or rabbit • Dermal sensitization (local lymph node assay, guinea pig maximization test or Buehler test). 		
4.4	Other related information	To be proposed by applicant as necessary.		