

WHO Prequalification of Vector Control Products

Data requirements table – Module 4

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) or citation of applicable generic risk assessments with justification of the applicability.	<p>Generic risk assessment model for insecticide-treated nets, second edition</p> <p>Generic risk assessments for insecticide-treated nets</p>	<p>Spreadsheets for calculations:</p> <ul style="list-style-type: none"> Generic risk assessment model for insecticide-treated nets – empty worksheet Generic risk assessment model for insecticide-treated nets – example worksheet
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 	Advice to Manufacturers Series – Considerations for fulfilling the acute 6-pack requirement 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.

DR code	Requirement	Description/notes	Method ¹ /reference	Form/template
		<ul style="list-style-type: none"> • 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.		