Module 2. Guidance on submitting the product summary

1. Purpose

The prequalification assessment of vector control products relies on information provided by the legal manufacturer on the design of the product and its intended deployment/use. The document submitted to address this data requirement should include, at a minimum, the following sections with adequate supporting information to inform the assessment process.

2. Description of the product

A narrative description of the product, including any individual components used to finish the product in its final form.

If a deployment device or specialized application equipment is required, the device/equipment should be clearly described, including, but not limited to, structural design, refill instructions, power source, and device settings/modes, for example, fan speed(s) and/or temperature(s).

Pictures and diagrams may be included.

3. Description of product use pattern

3.1 Use pattern/application rate

A narrative description of how the product is intended to be used, in which parts of a dwelling/room, the number of units per room (based on room volume) and, for active emanators, the intended number of hours per day the product should be “on.”

This should include a presentation of the range of measured emanation rates, description of factors which may impact emanation rate, for example, temperature, humidity, device setting, etc., and declaration of the target/nominal emanation rate to be used for assessment purposes.

Pictures and diagrams may be included.

3.2 Deployment

A narrative description of how the product is intended to be deployed. Information should be provided if the product is intended to be deployed by an "operator" who may be installing/opening multiple products a day, and, if so, a description of the deployment process and estimation of the number of products deployed per day should be provided.

Alternatively, or in addition to the above, if the product is intended to be distributed to end users, a description of the form in which the product is distributed, for example, packaging, and the guidance provided to users for storage, handling and deployment is required. In cases where end users may be responsible for storing replacement products and/or refills for active emanators, the intended guidance for storing/handling the product and precautionary language, such as "Keep out of reach of children," should be described here.

Pictures and diagrams may be included.

4. Summary of Module 3

The summary of Module 3 must be provided using this template: Template quality dossier summary

5. Summary of Module 4

5.1 Acute toxicity

Acute toxicity 6-pack studies for the product should be summarized in tabular format in the product summary and presented in full in Module 4. The table below can be used as an example for presenting the summary.

If waiver(s) to any of these studies are requested, or if studies from other formulations are proposed to be bridged to this product, please identify this in the row relating to the applicable study(ies). The full waiver/bridging rationale must be included in Module 4.

Table x. Acute toxicity of [Product Name]				
Route of exposure	**Species**	**Toxicity**	**GHS category**	**Reference**
Acute oral toxicity	Rat			[If waiver/bridging approach is used, identify here along with any reference(s).]
Acute dermal toxicity	Rat			
Acute inhalation toxicity	Rat			
Primary dermal irritation	Rabbit			
Primary eye irritation	Rabbit			
Skin sensitization, Buehler	Guinea Pigs			

5.2 Selection of tolerable systemic dose (TSD)

To ensure alignment between available toxicity information on the active ingredient (AI) and product-specific risk assessment, please identify acute and chronic TSDs utilized in the risk assessment. These values are used to calculate risk ratios in the exposure assessment. The table below can be used as an example for presenting the summary.

Table x. TSD of [Active Ingredient]		
Exposure	**Reference dose**	**Value**
Acute (maximal) TSD	[Include reference from selected dose]	[value] mg/kg/bw
Long-term (TWA) TSD	[Include reference from selected dose]	[value] mg/kg/bw

5.3 Values to conduct exposure assessment

A summary table of the product specific inputs to the risk assessment model must be included. The following table provides an example that can be used in the submitted document. Justification for the selected input should be described in the Notes column.

Table x. Exposure model inputs for [Product Name]

Parameter	Unit*	Value	Notes
Identification of [AI name] (and synergist, or second AI)	w/w%		
Molecular weight of AI	g/mol		
Vapor pressure of AI	Pa at 20°C		
Maximum emanation rate of product in the first 24 hours	Mg/day		
Nominal/mean emanation rate of product spanning duration of intended useful life	Mg/day		
Amount of AI/product unit	Mg		
Exposure duration (applicator during deployment)	Hours per day		
Exposure duration (resident)	Hours per day		
Room volume (default value or selected to align with efficacy testing)	m^3		
Number of emanators deployed per room (based on declared room volume)			

*Units may be adjusted as necessary based on product design and formulation type

5.4 Risk assessment conclusion and mitigation of identified risks

Provide a summary of the calculated risk ratios and provide a narrative justification for any scenario wherein risk ratios may exceed the level of concern.

If any mitigative approaches are recommended/required to reduce potential risks, they should be clearly described in this section.

6. Summary of Module 5

6.1 Efficacy endpoints

Provide a clear statement on the selected primary and secondary endpoint(s) upon which the product is tested and assessed. The same primary endpoint must be used consistently across all studies.

7. Justification for the claim of duration of intended useful life

The claim, or setting-dependent claims, for duration of intended useful life should be developed based on the AI content/reservoir, emanation rate at various temperatures, active emanator duration per day and supporting efficacy data on artificially/operationally aged products.

8. Related documents

- Generic Risk Assessment Models for Insecticide-Treated Clothing, Skin-Applied Repellents and Household Insecticides
- WHO PQT/VCP Implementation guidance – Template quality dossier summary