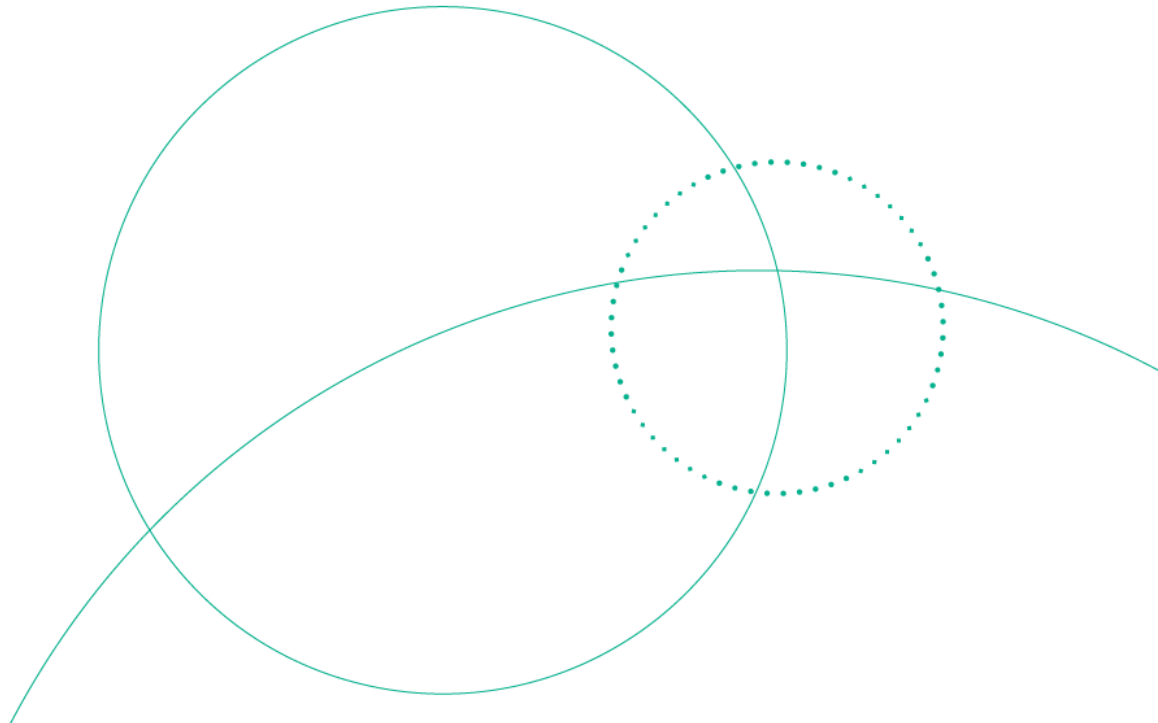
World Health Organization

WHO Prequalification Programme / Vector Control Product Assessment

WHO Public Assessment Report: WHOPAR Part 3

VECTRON T500 (Mitsui Chemicals Crop & Life Solutions, Inc.) P-03226

Quality Assessment



Contents

1 Chemical and physical data 3

1.1 Chemical and physical properties 3

1.2 Manufacturing, composition and formulant information 6

1.3 Enforcement analytical method 7

2 Entomological characterisation 7

2.1 Laboratory Studies 7

2.1.1 Characterisation of the VECTRON T500 AI 7

2.1.2 Residual efficacy 8

2.2 Entomological characterisation conclusions 11

3 Overall quality conclusions 11

4 Manufacturing release specifications 12

4.1 Summary of manufacturing release specifications 12

4.2 Storage 12

1 Chemical and physical data

1.1 Chemical and physical properties

Data on the chemical and physical properties of the active ingredient and the product VECTRON T500 were provided. These data were obtained from studies conducted according to established standards and/or Good Laboratory Practices (GLP) and are considered complete. The results are presented in Table 1.

Table 1. Chemical and physical properties for VECTRON T500

Data requirement	Study number	Test method ID	Results
Broflanilide content (test item stored at room temperature)	S21-06192 Physico-chemical Properties of Three Batches of Broflanilide 50 WP before and after Accelerated Storage for 2 weeks at 54°C (GLP Study)	Broflanilide HPLC method fully validated identical with Broflanilide 994/TC/(M) CIPAC method, Handbook P, p.21, 2021	Measured values: Three samples/batch were tested: Mean value Batch No.20I-4359: 50.9 % w/w Mean value Batch No.20T-001: 51.1 % w/w Mean value Batch No.20T-002: 51.0 % w/w Mean value of three batches: 51.0 % w/w The declared broflanilide content is 50 % w/w ± 2.5 % w/w
Broflanilide content (after accelerated storage stability)	S21-06192 Physico-chemical Properties of Three Batches of Broflanilide 50 WP before and after Accelerated Storage for 2 weeks at 54°C (GLP Study)	Broflanilide HPLC method fully validated identical with Broflanilide 994/TC/(M) CIPAC method, Handbook P, p.21, 2021 Storage stability CIPAC MT 46.4	Measured values: Three samples/batch were tested: Mean value Batch No.20I-4359: 50.7 % w/w Mean value Batch No.20T-001: 50.8 % w/w Mean value Batch No.20T-002: 51.2 % w/w Mean value of three batches: 50.9 % w/w The declared broflanilide content is 50 % w/w ± 2.5 % w/w No significant differences between broflanilide concentration values before and after storage stability test. After storage at 54 ± 2°C for 14 days, the determined average active ingredient content must not be lower than 95%, relative to the determined average content found before storage
Water Content (test item stored at room temperature)	S21-06192 (GLP Study)	CIPAC MT 30.5 Handbook J, p. 120, 2000	Measured values: Three samples/batch were tested: Mean value Batch No.20I-4359: 0.46 % w/w Mean value Batch No.20T-001: 0.47 % w/w Mean value Batch No.20T-002: 0.43 % w/w Mean value of three batches: 0.45 % w/w Maximum allowed concentration 20 g/kg (2 % w/w).
Water Content (after accelerated storage stability)	S21-06192 (GLP Study)	CIPAC MT 30.5 Handbook J, p. 120, 2000	Measured values: Three samples/batch were tested: Mean value Batch No.20I-4359: 0.48 % w/w Mean value Batch No.20T-001: 0.44 % w/w Mean value Batch No.20T-002: 0.44 % w/w Mean value of three batches: 0.45 % w/w

Table 1. Chemical and physical properties for VECTRON T500			
Data requirement	**Study number**	**Test method ID**	**Results**
			Maximum allowed concentration 20 g/kg (2 % w/w). No significant differences between the impurity concentration values before and after storage stability test.
Colour	S21-06192 (GLP Study)	visual inspection	White colour. Same colour before and after accelerated storage stability test.
Odour	ASW-2021-116 Physico-chemical Properties of Broflanilide 50WP before and after Accelerated Storage for 2 weeks at 54°C (non-GLP Study)	physical examination	Odourless. Same odour before and after accelerated storage stability test.
Physical state	S21-06192 (GLP Study)	visual inspection	Very fine powder. Same physical state before and after accelerated storage stability test.
pH (1% w/v aqueous dilution) (test item stored at room temperature)	S21-06192 (GLP Study)	MT 75.3, CIPAC Handbook J, p. 131, 2000	Measured values: Three samples/batch were tested: Mean value Batch No.20I-4359: 7.07 Mean value Batch No.20T-001: 7.12 Mean value Batch No.20T-002: 7.10 Mean value of three batches: 7.10 pH range should be: 5.5 to 8.5
pH (1% w/v aqueous dilution) (after accelerated storage stability test)	S21-06192 (GLP Study)	MT 75.3, CIPAC Handbook J, p. 131, 2000	Measured values: Three samples/batch were tested: Mean value Batch No.20I-4359: 7.16 Mean value Batch No.20T-001: 7.17 Mean value Batch No.20T-002: 7.06 Mean value of three batches: 7.13 pH range should be: 5.5 to 8.5 No significant differences between pH values before and after storage stability test.
Wet sieve test (test item stored at room temperature)	S21-06192 Physico-chemical (GLP Study)	MT 185, CIPAC Handbook K, p. 149, 2003	Measured values: Three samples/batch were tested: Mean value Batch No.20I-4359: residue 75 µm: ≤ 0.04 % Mean value Batch No.20T-001: residue 75 µm: ≤ 0.03 % Mean value Batch No.20T-002: residue 75 µm: ≤ 0.07 % Mean value of three batches: residue 75 µm: ≤ 0.05 % A maximum of 2 % retained on a 75 µm test sieve
Wet sieve test (after accelerated storage stability test)	S21-06192 (GLP Study)	MT 185, CIPAC Handbook K, p. 149, 2003	Measured values: Three samples/batch were tested: Mean value Batch No.20I-4359: residue 75 µm: ≤ 0.06 % Mean value Batch No.20T-001: residue 75 µm: ≤ 0.08 % Mean value Batch No.20T-002: residue 75 µm: ≤ 0.10 % Mean value of three batches: residue 75 µm: ≤ 0.08 % A maximum of 2 % retained on a 75 µm test sieve No significant differences between wet sieve test values

Table 1. Chemical and physical properties for VECTRON T500			
Data requirement	**Study number**	**Test method ID**	**Results**
			before and after storage stability test.
Suspensibility (test item stored at room temperature)	S21-06192 (GLP Study)	MT 184.1, CIPAC Handbook K, p. 142, 2003	Measured values: Three samples/batch were tested at two use rate: Lowest use rate (0.25 % w/v): Mean value Batch No.20I-4359: 91.4 % Mean value Batch No.20T-001: 88.2 % Mean value Batch No.20T-002: 90.7 % Mean value of three batches: 90.1 % Highest use rate(1.33 % w/v): Mean value Batch No.20I-4359: 95.2 % Mean value Batch No.20T-001: 90.6 % Mean value Batch No.20T-002: 91.2 % Mean value of three batches: 92.3 % A minimum of 60 % should be in suspension after 30 min in CIPAC standard water D at 30±2°C
Suspensibility (after accelerated storage stability test)	S21-06192 (GLP Study)	MT 184.1, CIPAC Handbook K, p. 142, 2003	Measured values: Three samples/batch were tested at two use rate: Lowest use rate (0.25 % w/v): Mean value Batch No.20I-4359: 93.3 % Mean value Batch No.20T-001: 89.0 % Mean value Batch No.20T-002: 89.9 % Mean value of three batches: 90.7 % Highest use rate(1.33 % w/v): Mean value Batch No.20I-4359: 93.6 % Mean value Batch No.20T-001: 91.0 % Mean value Batch No.20T-002: 91.8 % Mean value of three batches: 92.1 % A minimum of 60 % should be in suspension after 30 min in CIPAC standard water D at 30±2°C No significant differences between the concentration values before and after storage stability test.
Persistent foam (test item stored at room temperature)	S21-06192 (GLP Study)	MT 47.3, CIPAC Handbook O, p. 177, 2017	Measured values: Three samples/batch were tested at the highest use rate: Highest use rate(1.33 % w/v): Mean value Batch No.20I-4359: 29 mL Mean value Batch No.20T-001: 33 mL Mean value Batch No.20T-002: 30 mL Mean value of three batches: 30.7 mL Maximum of 100 mL foam after 1 min
Persistent foam (after accelerated storage stability test)	S21-06192 (GLP Study)	MT 47.3, CIPAC Handbook O, p. 177, 2017	Measured values: Three samples/batch were tested at the highest use rate: Highest use rate(1.33 % w/v): Mean value Batch No.20I-4359: 30 mL Mean value Batch No.20T-001: 32 mL Mean value Batch No.20T-002: 38 mL Mean value of three batches: 33.3 mL Maximum of 100 mL foam after 1 min

Table 1. Chemical and physical properties for VECTRON T500			
Data requirement	**Study number**	**Test method ID**	**Results**
			No significant differences between foam volume values before and after storage stability test.
Wettability (test item stored at room temperature)	S21-06192 (GLP Study)	CIPC MT 53.3, CIPAC Handbook F p. 165, 1995	Measured values: Three samples/batch were tested without swirling: Mean value Batch No.20I-4359: 37 s Mean value Batch No.20T-001: 57 s Mean value Batch No.20T-002: 43 s Mean value of three batches: 45.7 s The formulation should be completely wetted in 2 min without swirling.
Wettability (after accelerated storage stability test)	S21-06192 (GLP Study)	CIPC MT 53.3, CIPAC Handbook F p. 165, 1995	Measured values: Three samples/batch were tested without swirling: Mean value Batch No.20I-4359: 17 s Mean value Batch No.20T-001: 26 s Mean value Batch No.20T-002: 23 s Mean value of three batches: 22.0 s The formulation should be completely wetted in 2 min without swirling. No significant differences between the wettability properties before and after storage stability test
Flammability	S20-07303 Flammability (Solids) of Broflanilide 50WP (GLP Study)	UN method N.1.	No independent burning or glowing of the formulation over the length of the pile was observed in the preliminary test, therefore the test item is not flammable solid.
Pour and tap density	S20-07304 Pour and Tap Density of Broflanilide 50WP (GLP Study)	CIPC MT 186, CIPAC Handbook K p. 151, 2003	Measured values: Lot No.20I-4359: pour density: 0.307 g/mL tap density: 0.396 g/mL

No significant differences were recorded among the properties of the product kept at ambient temperature and after accelerated storage stability test conditions.

1.2 Manufacturing, composition and formulant information

Data on the manufacturing process and product composition for VECTRON T500 have been provided and are adequate. A summary is presented in Table 2. Detailed information on the manufacturing process and product formulation is considered Confidential Business Information (CBI).

Table 2. Manufacturing process and product composition data submitted for VECTRON T500	
Description of starting material	Broflanilide technical, broflanilide content ≥99 % w/w. Manufacturer: Mitsui Chemical Agro, Inc. 1-19-1, Nihonbashi, Chuo-ku, Tokyo 103-0027, Japan The source of active ingredient is supported by a current evaluation report confirming compliance of the material with the established WHO specification.
Declaration of product formulation	Included in the confidential business information.

Table 2. Manufacturing process and product composition data submitted for VECTRON T500	
Production / formulation process	Broflanilide technical active substance is mixed with the other formulation components such as surfactants, antifoam agent and carrier. The mixing phase is followed by a milling phase where the required size distribution is achieved. This step is followed by filtering and mixing phases. After this step the obtained material is packed. The packed products are organized and arranged for delivery.
Discussion of impurities	Water is identified as a relevant impurity in the formulation and a maximum amount is identified in the manufacturing release specifications based on the potential for water to impact the storage stability of the product.
Certification of limits	Broflanilide: 50 % w/w, acceptable limits 47.5 to 52.5 % w/w

1.3 Enforcement analytical method

Table 3. Details of the analytical method used to determine broflanilide in VECTRON T500	
Quantification of broflanilide	Broflanilide 994/TC/(M) CIPAC method, Handbook P, p.21

The method is appropriate for the determination of the active ingredient content of the product.

2 Entomological characterisation

Laboratory studies to characterize the effect of the active ingredient in VECTRON T500 on Anopheline mosquito species and the residual efficacy on wall surface substrates were submitted to WHO as part of the prequalification dossier.

2.1 Laboratory Studies

Data on characterization of the active ingredient in VECTRON T500 and the residual efficacy on concrete, plywood and mud substrates were provided. These data were obtained from studies conducted according to established standards and/or Good Laboratory Practices (GLP).

2.1.1 Characterisation of the VECTRON T500 AI

One study was presented to characterize the properties of the active ingredient and determine the LC_{50}, LC_{99} and potential for cross-resistance with other public health insecticide classes, using technical grade broflanilide. The concentrations used in the study were determined from previous preliminary experiments and are presented in Table 4. The LC_{50} and LC_{99} results as determined using three *Anopheles gambiae* test systems and CDC bottle bioassays are presented in Table 5.

The test systems used in this study were *An. gambiae* s.s. Kisumu strain, a colonized strain that is susceptible to insecticides and is regularly characterized for phenotypic and genotypic resistance status, *An. gambiae* s.s. Muleba-Kis, a colonized strain that is homozygous for the L1014F *kdr* mutation and which expresses elevated levels of Cytochrome P450s, and *An. gambiae* s.l. wild type mosquitoes which were collected as larvae from the local area and reared to adults.

Logistic regression analyses were conducted to evaluate the potential for cross-resistance between pyrethroid insecticides and broflanilide. No indications of cross-resistance were observed. These results are presented in Table 6.

Table 4. Broflanilide concentrations tested in LC50 and LC99 experiments

Broflanilide concentration (µg/ml)	Dose A	Dose B	Dose C	Dose D	Dose E	Dose F	Dose G
Log scale	2.301	2.084	1.867	1.651	1.434	1.217	1.00
Normal scale	200.00	121.39	73.68	44.72	27.14	16.48	10.00

Table 5. LC50 and LC99 concentrations of broflanilide as determined using three *Anopheles gambiae* complex test systems in CDC bottle bioassays

Mosquito Strain	LC50 µg/ml (95% CI)	LC99 µg/ml (95% CI)
An. gambiae (Kisumu)	0.87 (0.33, 1.79)	66.73 (28.59, 242.32)
An. gambiae (Muleba Kis)	0.61 (0.12, 1.65)	160.67 (49.62, 1,309.50)
An. gambiae wild type	3.57 (0.92, 7.61)	451.86 (160.33, 3,759.20)

Table 6. Logistic regression results for comparisons between three *An. gambiae* complex test systems after exposure to concentrations of broflanilide

Broflanilide concentration (µg/ml)	*An. gambiae* strain					
	Kisumu vs wild type (reference group)		Muleba-Kis vs wild type (reference group)		Muleba-Kis vs Kisumu (reference group)	
	OR (95% CI)	p	OR (95% CI)	p	OR (95% CI)	p
0.00	5.32 (0.60, 47.45)	0.116	9.26 (0.94, 91.36)	0.055	1.74 (0.82, 3.68)	0.126
10.00	1.31 (0.23, 7.39)	0.726	1.72 (0.70, 4.23)	0.203	1.31 (0.18, 9.44)	0.761
16.48	18.9 (0.72, 500.23)	0.072	4.28 (0.25, 73.30)	0.272	0.23 (0.01, 3.59)	0.250
27.14	8.69 (0.29, 260.06)	0.181	7.52 (0.42, 135.82)	0.147	0.87 (0.04, 19.86)	0.918
44.72	N/A	N/A	N/A	N/A	N/A	N/A
73.68	N/A	N/A	N/A	N/A	N/A	N/A
121.39	N/A	N/A	0.84 (0.06, 10.82)	0.871	N/A	N/A
200.00	N/A	N/A	N/A	N/A	N/A	N/A

2.1.2 Residual efficacy

Two studies were presented to characterize the residual efficacy of the product on test surfaces under laboratory conditions. In the first study, prepared substrate blocks of concrete, plywood, and mud were treated with 100 mg AI/m^2, in the second, the treatment concentrations used were 50 mg AI/m^2, 100 mg AI/m^2, and 200 mg AI/m^2 and concrete and mud were used as the substrates. Residual efficacy was tested using WHO cone tests and three (Study 1) and two (Study 2) mosquito test systems, respectively.

In Study 1, the mosquito test systems were *An. gambiae* Kisumu strain, *An. gambiae* Muleba-Kis strain, and F1 wild type *An. gambiae* (*Anopheles arabiensis)* collected from the local area. Each test system was

characterized for insecticide resistance mechanisms using molecular techniques. The Kisumu strain and wild type mosquitoes were both susceptible to pyrethroid insecticides; the Muleba-Kis strain *kdr* gene frequencies were 48-52% homozygous resistant, 42-43% heterozygous resistant and 5-10% homozygous susceptible at the start and end of the testing period. In Study 2, the mosquito test systems were insecticide susceptible *An. gambiae* Kisumu strain and an insecticide resistant strain of *Anopheles coluzzii*.

The results for the residual efficacy studies are presented in Tables 7 and 8. In Study 1, mortality above 80% was observed on all substrates to 10 months post-treatment (12 months for concrete and plywood substrates) using the insecticide susceptible test system, eight months post-treatment (12 months for concrete and plywood) in the insecticide resistant test system and one month (nine months for concrete and eight months for plywood) using the wild type test system. In Study 2, mortality above 80% was observed on all substrates and at all AI concentrations to 12 months post-treatment (14 months for mud and 14 months for concrete treated at 200 mg AI/m^2) using the insecticide susceptible test system. In the insecticide resistant test system, mortality greater than 80% was observed on all substrates to 10 months at 200 mg AI/m^2 (14 months for mud), six months at 100 mg AI/m^2 (eight months for mud), and three months for 50 mg AI/m^2 (four months for mud).

Table 7. Control corrected 72-hour mortality (%) for WHO cone tests conducted on prepared substrate blocks treated with 100 mg AI/m^2 of VECTRON T500

Substrate	Month												
	0.25	1	2	3	4	5	6	7	8	9	10	11	12
***An. gambiae* (Kisumu)**													
Concrete	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	99.2	100.0	100.0	98.0	100.0
Plywood	100.0	100.0	100.0	100.0	96.9	100.0	100.0	100.0	99.0	100.0	100.0	94.3	98.5
Mud	100.0	97.8	100.0	98.6	81.3	98.0	90.9	90.7	91.7	94.4	90.0	74.3	75.7
***An. gambiae* (Muleba-Kis)**													
Concrete		98.2	100.0	100.0	100.0	100.0	100.0	99.3	100.0	97.5	96.2	98.7	98.6
Plywood		100.0	93.3	97.7	94.5	98.1	98.7	95.5	95.7	98.1	99.6	97.9	96.3
Mud		96.6	97.2	83.1	79.2	82.4	85.6	69.3	81.8	60.3	67.2	63.2	61.4
***An. gambiae* (wild type)**													
Concrete		100.0	91.2	98.3			98.7	98.3	98.6	81.8		71.3	
Plywood		98.2	93.2	69.7			71.6	92.9	84.7	61.8		67.8	
Mud		81.6	72.0	24.2					53.2	41.9		25.0	

Table 8. 72-hour mortality (%) for WHO cone tests conducted on prepared substrate blocks treated with 50, 100 and 200 mg AI/m2 of VECTRON T500

Substrate and target application	Month											
	0.25	1	2	3	4	5	6	8	10	12	13	14
***An. gambiae* (Kisumu)**												
Concrete												
Control					1.9 (1.2)			1.7 (1.3)	6.0 (2.0)	0	4.4 (2.1)	4.0 (2.0)
50 mg/m^2					43.6 (9.1)			100	100	100	34.0 (7.3)	59.5 (8.5)
100 mg/m^2					98.1 (1.8)			100	100	100	77.7 (6.2)	79.5 (6.9)
200 mg/m^2					100			100	100	100	94.4 (3.1)	100
Mud												
Control					3.9 (2.4)			1.9 (1.1)	2.13 (2)	0	0	4.8 (2.9)
50 mg/m^2					100			100	100	100	97.1 (1.5)	100
100 mg/m^2					100			100	100	100	100	100
200 mg/m^2					100			100	100	100	100	100
An. coluzzii												
Concrete												
Control	4.7 (2.2)	2.9 (1.4)	2.9 (1.7)	1.0 (1.0)	1.9 (1.3)	6.3 (3.8)	5 (4.4)	3.5 (2.2)	4.8 (2.4)	1.9 (1.7)	2.5 (1.5)	1.9 (1.8)
50 mg/m^2	91.8 (2.7)	100	81 (6.3)	76.2 (6.9)	63.1 (7.7)	100	30.1 (8.4)	20.9 (4.3)	45.7 (12.6)	3.9 (3.6)	2.5 (1.5)	7.1 (3.4)
100 mg/m^2	100	100	99.0 (0.9)	100	99 (0.9)	100	86.5 (6.3)	34.0 (5.1)	89.8 (5.0)	0	19.8 (7.7)	21.4 (3.8)
200 mg/m^2	100	100	100	100	100	100	100	100	100	51.0 (14.1)	63.4 (12.5)	62.3 (4.9)
Mud												
Control	6.6 (2.1)	4.1 (2.0)	6.9 (3.5)	3.9 (2.4)	4.5 (3.0)	6.6 (3.7)	0	3.5 (2.6)	11.8 (3.6)	0	3.9 (2.0)	5.8 (3.8)
50 mg/m^2	95.2 (2.3)	96.9 (2.3)	100	97.0 (2.0)	99.1 (0.9)	42.9 (5.0)	97.3 (1.9)	98.5(1.4)	49.1 (13.5)	64.2 (15.9)	23.2 (6.1)	86.3 (3.7)
100 mg/m^2	100	100	100	98.0 (2.0)	100	90.5 (3.0)	100	100	67.0 (10.6)	92.5 (3.7)	53.9 (6.6)	98.1 (1.9)
200 mg/m^2	100	100	100	100	100	100	100	100	100	100	100	100

2.2 Entomological characterisation conclusions

The submitted laboratory studies characterize the residual efficacy of the AI on prepared substrate blocks treated with a single application of VECTRON T500 against four strains of *An. gambiae* complex mosquitoes. Following an application of 100 mg AI/m^2, the laboratory results demonstrate the bioavailability of broflanilide for up to ten months on concrete, mud, and plywood blocks against insecticide susceptible *An. gambiae* s.s. Kisumu, up to six months on concrete and plywood blocks against pyrethroid resistant *An. gambiae* s.l. and up to one month on mud against pyrethroid resistant *An. gambiae* s.l. There were no indications of cross resistance between pyrethroid insecticides and broflanilide.

3 Overall quality conclusions

Based on the studies and information provided, all data requirements for the prequalification assessment of product quality have been satisfied. These data have been relied upon to assess the formulation, manufacturing process, physical/chemical characteristics, LC_{50}, LC_{99}, cross-resistance to other insecticides and bioavailability of the proposed product for the purpose of establishing the identity of the product and assuring that the product can be produced consistently.

The methods for assessing the physical/chemical properties of the product were CIPAC methods and/or validated methods.

The quality component of the dossier is considered complete, and the assessment of the submitted information on quality supports prequalification of the product.

Table 9. List of efficacy studies submitted to WHO as part of the prequalification dossier

Studies that were relied upon for decision making	
Study number	**Study title**
26A003-P	Impact of pyrethroid resistance in *An. gambiae* test systems on the efficacy of broflanilide
26A009-P	GLP laboratory evaluation of a novel IRS formulation, VECTRON™ T500, against three test systems in Moshi, Tanzania
2016/04	Evaluation of VECTRON™ T500 efficacy as indoor residual spraying (IRS) product against malaria vectors, in Burkina Faso
Studies that were not used to inform decision making	
Study number	**Study title**
LITE-P26-01	Laboratory studies on the efficacy and potency of Tenebenal™ against mosquito vectors of disease
ASR-2021-066	Efficacy comparison of VECTRON™ T500 using two different sources of kaolin as carrier

4 Manufacturing release specifications

4.1 Summary of manufacturing release specifications

Description	The material shall consist of a homogeneous mixture in the form of powder, together with filler and any other necessary formulants. It shall be in the form of an off-white, very fine and slightly dusty powder, free from visible extraneous matter and hard lumps.	
Property	**Method**	**Value and tolerance/Minimum/Maximum**
Broflanilide identity	994/TC/(M)/2.1 994/TC/(M)/2.2 CIPAC Handbook P, p.21, 2021	
Broflanilide content	994/WP/M/3, CIPAC Handbook P, p.21, 2021	500 g/kg (± 5% average content measured)
Water content	MT 30.5, CIPAC Handbook J, p.120, 2000	Maximum: 20 g/kg (2% w/w)
pH range	MT 75.3, CIPAC Handbook J, p.131, 2000	5.5 to 8.5
Wet sieve test	MT 185, CIPAC Handbook K, p.149, 2003	Maximum: 2% retained on a 75 µm test sieve
Suspensibility	MT 184, CIPAC Handbook K, p.142, 2003	Minimum of 60% of the broflanilide content found in suspension after 30 min in CIPAC Standard Water D at 30 ± 2 °C
Persistent foam	MT 47.3	Maximum: 100 ml after 1 min
Wettability	MT 53.3, CIPAC Handbook F, p.165, 1995	The formulation shall be completely wetted in 2 min without swirling

Manufacturers are expected to rely on the information above as part of a QC management plan and for validation of product quality when released. To the extent required, Certificates of Analysis to support the release of products should present results for the attributes identified in the above table.

4.2 Storage

Accelerated storage stability data were generated as per CIPAC MT 46.3 on VECTRON T500. Test samples were stored for 2 weeks at 54 °C. No significant differences were observed and recorded among the properties of the product after accelerated storage stability test conditions.

Products should be stored and transported in accordance with the conditions recommended by the manufacturer. Products which have been stored in accordance with these recommendations are expected to maintain their declared physical/chemical properties for up to 2 years.

Where products that have been subjected to prolonged storage (>2 years), adverse conditions, or in opened/damaged packaging/containers, product testing is recommended to assess its suitability for use.