

WHO Prequalification Programme / Vector Control Product Assessment

# WHO Public Assessment Report: Change assessment

## SumiLarv 2MR (Sumitomo Chemical Co., Ltd) 001-006 PQC-VCP-2023-0006

WHO Prequalification of Vector Control Products Avenue Appia 20 1211 Geneva 27 Switzerland

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### **1. Introduction**

The primary purpose for the use of a pesticide is the control of a pest, including disease transmitting vectors. Vector control tools, including formulated pesticides, which provide effective management or control of vectors, may be used as part of a resistance management programme. Vector control products for use in public health are a component of Integrated Vector Management (IVM), which is a programme that relies on a suite of diverse interventions and implementations of best practices to manage the vector and chemical/behavioural resistance.

SumiLarv 2MR is a larvicide product formulated with 2% w/w pyriproxyfen in a controlled release polymer matrix. The product is intended to control container breeding mosquitoes in clean water used for drinking or other domestic purposes. The premise of the pyriproxyfen in the product is the action as a juvenile hormone analogue, which disrupts the transformation of late instar larvae to pupae and then to adult.

Evidence to support the request to revise the application rate of SumiLarv 2MR from one disc per 40 litres water to one disc in a range of water volumes between 40 and 500 litres of water was submitted.

## 2. Efficacy studies

Efficacy studies conducted for larvicide products include simulated field studies, in which large containers are used to simulate water bodies, and field studies, in which natural breeding sites are used. Based on the existing requirements and established decision framework, the inhibition of adult emergence is considered the primary endpoint for assessment.

#### 2.1 Simulated field studies

Data on the efficacy of SumiLarv 2MR in simulated field studies were provided. These data were obtained from studies conducted according to established standards. These summary results are based on studies using product batches AS-030315-W, AS280714G and ASA141015-W.

Three simulated field studies were presented to support the use of an application rate of one disc for a range of water volumes between 40 and 500 litres, conducted in 2017 - 2020 in Japan and Brazil (two studies were conducted in Brazil). In all three studies, water exchange was employed to mimic realistic water use conditions. The negative control in the simulated field studies was untreated water.

The endpoint used to evaluate bioavailability was the percentage reduction in adult emergence. The duration of efficacy in a range of water volumes was considered to be the duration of at least 80% inhibition of adult emergence.

The product was tested against pyrethroid susceptible colonised larvae of *Ae. aegypti* in Japan and Brazil. In the second study in Brazil, the product was tested against *Ae. aegypti* larvae reared from mosquitoes collected from the local populations at four field sites.



The results from the simulated field studies are presented in Tables 1-3. In simulated field studies, the percentage reduction in adult emergence was greater than 80% for up to:

- 25 weeks in Japan for doses up to 1 disc per 500 litres of water
- 330 days in Brazil for doses up to 1 disc per 500 litres of water with and without water exchange employed
- 420 days in four sites in Brazil for doses up to 1 disc per 1,000 litres of water

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Table 1. Inhibition of *Ae. aegypti* adult emergence by SumiLarv 2MR in volumes of clean water from 100 – 500 litres and SumiLarv 2MR dosages of 1 disc per 100L to 1 disc per 500L for 25 weeks in Japan.

		Study week														
Dose	Container	1	2	3	4	5	6	7	9	11	12	15	17	20	23	25
		Inhibition of adult emergence (%, SD)														
1 disc/ 100L	Polyethylene	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
1 disc/ 100L	Polyethylene + Polyethylene bag	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
1 disc/ 300L	Polyethylene + Polyethylene bag	100	100	100	100	100	100	85.7 (21.2)	100	100	100	100	100	100	100	97.0 (4.4)
1 disc/ 500L	Polyethylene + Polyethylene bag	100	100	100	100	100	97.2 (3.8)	100	100	100	100	100	100	100	91.2 (13.2)	87.6 (17.5)

Table 2. Inhibition of *Ae. aegypti* adult emergence by SumiLarv 2MR in volumes of clean water from 200 – 1,000 litres and SumiLarv 2MR dosages of 1 disc per 200L to 1 disc per 1,000L for 330 days in Brazil, both with and without water exchange.

	Study day																						
Dose	0	15	30	45	60	75	90	105	120	135	150	165	180	195	210	225	240	255	270	285	300	315	330
										Inhib	ition of a	dult eme	rgence (S	%, SD)									
With water exchange																							
1 disc/ 200L	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	97 (5)	96 (2)	88 (8)	96 (3)	91 (2)	96 (3)
1 disc/	4.00	100	4.00	400	4.00	100	400	400	400	100	100	100	100	100	100	4.00	99	97	96	90	98	87	96
250L	100 1	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	(1)	(2)	(1)	(9)	(2)	(11)	(4)
1 disc/	100	100	100	100	100	100	100	100	100	100	100	100	94	97	96	76	73	88	81	87	80	76	80
500L	100	100	100	100	100	100	100	100	100	100	100	100	(7)	(3)	(6)	(21)	(23)	(5)	(11)	(8)	(24)	(33)	(23)
1 disc/	31	99	92	87	96	93	81	74	63	59	NI/A	NI/A	NI/A	NI/A		NI/A	NI/A	NI/A	NI/A	NI/A	NI/A	N/A	NI/A
1,000L	(32)	(1)	(2)	(9)	(1)	(5)	(10)	(6)	(11)	(6)	11/7	11/1		11/7	N/A	11/7	11/7	11/7	11/7	11/7	11/7	19/7	11/7
										With	out wate	er excha	inge										
1 disc/	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	99	94	90	89	93	85
200L	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100 1	100	100	(1)	(2)	(7)	(14)	(6)	(19)
1 disc/	100	100	100	100	100	100	100	100	100	100	100	100	100	100	99	97	86	83	94	91	75	94	92
250L	100	100	100	100	100	100	100	100	100	100	100	100	100	100	(1)	(5)	(24)	(26)	(6)	(11)	(14)	(2)	(9)
1 disc/	100	100	100	100	100	100	100	100	100	100	100	100	100	100	96	98	91	93	94	86	96	94	96
500L	100	100	100	100	100	100	100	100	100	100	100	100	100	100	(8)	(4)	(9)	(9)	(4)	(14)	(4)	(6)	(4)
1 disc/	99	100	100	100	100	100	100	100	100	100	100	98	99	69	41	44	N/A	N/A	N/A	N/A	N/A	N/A	N/A
1,000L	(3)	-30	-30	-30	-30	-30	-30	-30	-30	-00	-30	(3)	(1)	(8)	(15)	(9)	,,,	,,,	,//	,,,	,,,	,,,	,,,

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Table 3.	Inhibi	tion of	Ae. ae	gypti a	dult en	ergeno	ce by Si	umiLarv	/ 2MR i	n volu	nes of	clean v	vater fr	om 25	0 – 1,00	00 litre	s and S	umiLar	v 2MR	dosage	s of 1 c	lisc per	250L
to 1 dis	c per 1	,000L f	or 420	days in	four si	tes in E	Brazil.																
Deres											9	Study day	y Lang										
Dose	1	14	28	42	56	70	84	98	112	126 Inhi	140 hition of	154 adult or	168	182	196	210	224	238	252	266	280	294	308
											Maca	adult en	leigence	(70)									
1 disc/ 250L	100	100	100	100	100	100	100	100	100	100	97.3	100	100	100	100	84.7	100	99.3	100	100	100	100	100
1 disc/ 500L	100	100	100	100	94.0	94.0	99.3	100	100	100	93.3	100	100	100	100	72.7	99.3	100	100	100	100	100	100
2 discs/ 500L	100	100	100	100	100	100	94.7	96.7	100	100	100	100	100	100	97.3	88.0	100	97.3	96.0	100	95.3	100	100
1 disc/ 1,000L	100	100	98.0	96.7	98.0	96.7	96.7	100	99.3	100	96.8	100	99.3	100	98.7	92.7	99.3	98.7	100	97.3	98.7	100	100
2 discs/ 1,000L	100	100	100	99.3	100	100	100	100	100	100	100	100	100	100	100	94.7	100	100	100	99.3	97.7	99.3	99.3
Dose	322	336	350	364	378	392	406	420															
1 disc/ 250L	100	98.0	100	100	99.3	100	100	100															
1 disc/ 500L	100	100	100	100	99.3	100	100	99.3															
2 discs/ 500L	100	99.3	100	99.3	100	97.3	92.7	100															
1 disc/ 1,000L	100	98.7	98.7	100	100	100	97.3	99.3															
2 discs/ 1,000L	100	98.7	99.3	98.0	100	98.0	87.3	100															
										I	Rio de Ja	aneiro											
1 disc/ 250L	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
1 disc/ 500L	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
2 discs/ 500L	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
1 disc/ 1,000L	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
2 discs/ 1000L	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
Dose	322	336	350	364	378	392	406	420															
1 disc/ 250L	100	100	100	100	100	100	100	100															
1 disc/ 500L	100	100	100	100	100	100	100	100															

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Table 3. Inhibition of Ae. aegypti adult emergence by SumiLarv 2MR in volumes of clean water from 250 – 1,000 litres and SumiLarv 2MR dosages of 1 disc per 250L to 1 disc per 1,000L for 420 days in four sites in Brazil. Study day Dose Inhibition of adult emergence (%) 2 discs/ 500L 1 disc/ 99.3 89.3 92.0 70.0 1,000L 2 discs/ 94.7 1000L Marilia 0.04mg 97.2 96.5 99.3 97.1 85.2 88.7 96.1 91.1 92.9 93.2 /L 0.08mg /L 0.16mg /L Dose 0.04mg 73.3 92.3 86.4 79.8 76.8 89.0 88.7 80.4 /L 0.08mg 96.9 99.3 /L 0.16mg /L Recife 0.04mg 71.0 80.0 77.0 92.0 76.0 77.0 59.0 81.0 81.0 69.0 59.0 33.0 -/L 0.08mg 89.0 99.0 87.0 92.0 83.0 95.0 88.0 91.0 89.0 76.0 91.0 /L 0.16mg /L Dose 0.04mg ------/L 0.08mg 78.0 52.0 55.0 ----/L

99.0

99.0

94.0

0.16mg

/L



#### 2.2 Simulated field studies conclusions

The submitted simulated field studies demonstrate that the bioavailability of SumiLarv 2MR was sustained for up to 420 days post-water treatment against pyrethroid susceptible *Ae. aegypti*.

## 3. Change assessment conclusions

The data presented support a change in application rate for SumiLarv 2MR from one disc per 40 litres of water to one disc up to 500 litres of water.