



**Prequalification Team Vector Control Decision Document**

**Aquatain AMF**

Prequalification Team–Vector Control Group (PQT-VC)

Access to Medicines, Vaccines and Pharmaceuticals (MVP)

World Health Organization

# Prequalification Team Vector Control Decision Document

## Aquatain AMF

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# 1 Introduction

WHO's Prequalification Team Vector Control Group (PQT-VC) ensures that vector control products and public health pesticide active ingredients are safe, effective and manufactured to a high-quality standard. This is done by assessing product dossiers and inspecting manufacturing sites. Products and manufacturing sites that meet prequalification requirements are added to (a) the WHO list of prequalified vector control products; (b) the WHO list of manufacturing sites for public health pesticide active ingredients.

WHO prequalification of vector control products primarily benefits populations most affected by major vector-borne diseases such as malaria, dengue fever and other arboviral diseases (Chikungunya, Zika virus), Chagas disease, lymphatic filariasis, visceral leishmaniasis, and human African trypanosomiasis.

This document presents the results of the safety, efficacy and quality (product chemistry and manufacturing process) assessments for the product Aquatain AMF which provide the basis for the prequalification listing decision.

## 2 Product Identification

Aquatain AMF is a liquid containing polydimethylsiloxane (78-89%). It acts as a physical barrier when applied to water bodies to control mosquito larvae and pupae. There is no chemical action against the mosquito larvae.

The product is intended to be applied to standing water bodies and can be poured or sprayed onto water at an application rate of 1 ml/m<sup>2</sup> of water surface and 1-5 ml per manhole/water trap/catch basin. It will then spread to cover the surface. The low surface tension of the silicone film prevents mosquito larvae and pupae from attaching at the surface to breath – causing them to drown. The product also deters gravid females from laying eggs on treated surfaces.

The applicant, Aquatain Products Pty Ltd, 19 Shepherds Hill Road, Lauriston, Victoria 3444, Australia, submitted a dossier containing supporting data to PQT-VC on 28 March 2018 and requested a PQ listing for the product.

The product is currently registered in 25 countries, and registration is pending in multiple countries. In addition, it has been exempted from registration in 38 countries due to its entirely physical action.

### 3 Assessment of Quality

#### 3.1 Chemical and Physical Properties

Data on the chemical and physical properties of the active ingredients and the product Aquatain AMF were provided and are summarized in Table 1 and 2. These data were obtained from studies conducted according to Good Laboratory Practices (GLP) and are complete.

Table 1: Aquatain AMF, AI Chemical and Physical Properties			
Title	Study Number	Test method ID	Result
Active ingredient content	R 475	NA	80.0 % PDMS, acceptable range: 78-89 % PDMS
Colour	R 475	ASTM D 1209	slightly cloudy
Physical State	NA	NA	silicon based liquid
Odour	NA	NA	almost odourless
Density or Specific Gravity	R 475	ASTM D 1298	0.95g/cm <sup>3</sup> , acceptable range: 0.94-0.97 g/cm <sup>3</sup>
Viscosity	R460	NA	390 centistokes, acceptable range: 300-550 cst
Storage Stability Data (shelf-life)	R 475	NMR method	stable for at least 2 years under normal conditions
Flammability	NA	NA	not flammable
Flash point	NA	NA	>101 °C
Corrosion Characteristics	NA	NA	non-corrosive
Volatility	NA	NA	not volatile

Table 2: Aquatain AMF, Product Chemical and Physical Properties		
Data Requirement	Study Number	Details
Description of Starting Material	R486	polydimethylsiloxane inert components
Production / Formulation Process	R486	blending process of polydimethylsiloxane and inert components
Discussion of Impurities	R 404	The purity of the polydimethylsiloxane was checked for lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls and polybrominated biphenyl ethers. No impurities of concern were detected.
Control Product Specification Form / Confidential Statement of Formula	NA	NA
Certification of Limits	NA	NA
Preliminary Analysis	NA	NA
Enforcement Analytical Method	NA	NA

## **3.2 Manufacturing, Composition and Formulant Information**

Data on the manufacturing process and product composition have been provided and are adequate. The product is obtained during a blending process of polydimethylsiloxane and inert components.

## **3.3 Enforcement Analytical Method**

An enforcement method is not required due to the non-chemical mode of action of the product.

## **3.4 Specifications**

Specifications have not been established for Aquatain AMF due to the non-chemical mode of action of the product.

## **3.5 Impurities of Toxicological Concern**

No impurities of toxicological concern were found in the technical active ingredient or the inert ingredients.

## **3.6 Quality conclusion**

The quality component of the dossier is complete. The assessment of the submitted information supports the prequalification of the product.

# **4 Assessment of Safety**

The existing toxicology database is adequate to support the proposed labelled uses of Aquatain AMF. Supporting toxicology data submitted by the sponsor consist of mammalian and ecotoxicology studies conducted at independent contract laboratories. The authors indicated that the studies were conducted according to Good Laboratory Practices and were designed based on OECD guidelines. However, some deficiencies in study design and procedure were noted such as: recording; data reporting and analytical measurements. Overall, only the studies conducted at JAI Research Foundation, India meet the OECD guidelines. All other studies provide supplemental information (e.g. two studies on acute dermal and acute inhalation conducted in China, for which the assessment was based on an English translation). Collectively, the data can be used to support the safety assessment of Aquatain AMF as a vector control product. Based on the studies submitted in the dossier and relevant data available in the open literature, Aquatain AMF is not acutely toxic to mammalian species, does not produce skin or eye irritation upon contact and is not a skin sensitizer. Chronic exposure to polydimethylsiloxane (PDMS), the active

ingredient in Aquatain AMF, in the diet up to 1000 mg/kg bw (milligrams per kilogram of body weight) is not expected to result in systemic toxicity (NOEL > 1000 mg/kg bw/day). There is no evidence that the active ingredient (PDMS) is a developmental toxicant, mutagen or carcinogen. PDMS has been evaluated by the joint FAO/WHO Expert Commission on Food Additives, which concluded that PDMS presented no significant toxicity.

## **4.1 Human Safety Assessment**

### **4.1.1 Product Specific Acute Toxicity**

Several acute toxicology studies were conducted with Aquatain AMF. These studies demonstrate that Aquatain AMF is non-toxic by the oral administration (oral LD50 > 2000 mg/kg bw in mice) and non-toxic by dermal application (LD50 > 2000 mg/kg bw in rats). In an inhalation study with rats, the LC50 is 7.3 mg/L/4 hours based on the highest nominal aerosol concentration generated. Topical application of the test material did not result in skin irritation. Aquatain AMF was not an eye irritant based on the results of a study in rabbits. The test substance demonstrated, Aquatain AMF is not a skin sensitizer.

Using the Global Harmonization System of Classification and Labelling (GHS), Aquatain AMF is:

- Category 5: acute oral toxicity and acute dermal toxicity;
- Category 3: acute inhalation toxicity.
- Not classified: skin irritation; eye irritation; skin sensitization.

### **4.1.2 Summary of Available Toxicity on Polydimethylsilicone from the Open Literature**

To evaluate the possible long-term toxic and carcinogenic effects, PDMS fluid was administered in the diet of Fischer 344 rats for 12 and 24 months at dose levels of 0, 100, 300 or 1000 mg/kg bw. Each group consisted of 90 males and 90 females.

Based on the results of this study, the NOEL for systemic toxicity was 1000 mg/kg bw after 12 months. There was no indication of carcinogenicity potential after 24 months of feeding up to 1000 mg/kg bw (EPA, 2003; Dow Chemical; WHO and UN Food and Agriculture Organization Report on PDMS as food additive, 2009).

*In vitro* genotoxicity studies did not indicate that PDMS has mutagenic activity. PDMS studies with rabbits did not show any evidence of teratogenic effects. Studies with rats and rabbits did not demonstrate any adverse effects of PDMS on fertility, gestation, peri- or post-natal development (JACC Report NO. 55, ECETOC, 2011).

## **4.2 Environmental Safety Assessment**

### **4.2.1 Product Specific Toxicity Data**

The ecotoxicity potential of Aquatain AMF or PDMS is negligible to non-target aquatic vertebrate and invertebrate species. The only concern noted is that aquatic microorganisms may become trapped and immobilized if a surface film of insoluble Aquatain AMF (or PDMS) is present.

The ecotoxicity potential of Aquatain AMF was investigated in fish, daphnia and algae. A short -term reproduction study in fish is also available.

The EC50 at 72h for algae was greater than 10 mg/L. Exposure to Aquatain AMF up to 100 mg/L did not result in mortality in fish (Guppy sp.). The 24h survival EC50 (Half maximal effective concentration) for daphnia was greater than 100 mg/L and the reproductive NOEC (No Observed Effect Concentration) for daphnia was 5 mg/L.

Using the GHS classification, Aquatain AMF is classified as Category 3 (practically non-toxic) for acute ecotoxicity.

In a 21-day short term reproductive study in guppies, the NOEC for survival, fecundity and reproduction was reported as 10 mg/L (highest dose tested).

#### **4.2.2 Summary of Available Ecotoxicity on Polydimethylsilicone from the Open Literature**

An ecotoxicity study with Aquatain AMF on selected fish and aquatic plant was conducted at the National Aquatic Resources Research and Development in Sri Lanka. Aquatain AMF was applied at the manufacturer's labelled rate, and fish were monitored for mortality and abnormal behavior for up to 30 days. The tank set-up was designed to have 3 replicates for each treatment and control. Aquatain AMF had no effects on fish mortality or abnormal behavior after 30 days. No impact on aquatic plants (ex. African violet, Golden Pothos, Rice) was observed in non-target analyses conducted within multiple efficacy studies.

There are numerous studies in the open literature summarizing the impact of Aquatain AMF on non-target species and aquatic life. In summary, the available ecotoxicity data showed there are no significant differences between treated and control guppies, shrimps, snails, bloodworms, etc. These data support that PDMS is harmless for non-target organisms and does not cause any disturbance to aquatic life (Ref R590 in dossier: Impacts on nontarget species).

### **4.3 Safety conclusion**

The use of Aquatain AMF does not present any unacceptable risk to human safety or the environment.

The safety component of the dossier is complete. The assessment of the submitted information supports the prequalification of the product.

## 5 Assessment of Efficacy

The primary intention for the use of a pesticide is for the control of a pest or vector, whether resistant or susceptible, rather than for resistance management. Tools which provide effective management of pests or vectors can be used as part of a resistance management plan. For public health pesticides, this is a component of Integrated Vector Management (IVM) which relies on a suite of diverse interventions and implementation of best practices to manage the vector and chemical/behavioral resistance.

For larvicides, products must demonstrate  $\geq 80\%$  larval mortality or  $\geq 90\%$  adult emergence inhibition.

A series of studies and scientific papers were provided in the submitted dossier including laboratory and field scale. These studies were conducted in several locations and with appropriate mosquito strains. All studies were evaluated individually and a summary of the results are provided in the next section.

Aquatain AMF is a monomolecular film (MMF). In the supporting studies it is referred to as Aquatain, Aquatain AMF, AMF, Aquatain MMF, or MMF. The formulation used in these studies is the same as that submitted for prequalification, 78-89% polydimethylsiloxane.

### 5.1 Summary of Efficacy Study Results

Laboratory Studies	
Study Number:	Results
R310	Bukhari, T & Knols, B. (2009). Efficacy of Aquatain AMF, a monomolecular surface film, against malaria vectors <i>Anopheles stephensi</i> and <i>Anopheles gambiae s.s.</i> in the laboratory. The American Journal of Tropical Medicine and Hygiene
	<p>This scientific paper presented information on the larvicidal efficacy of Aquatain AMF against <i>Anopheles coluzzii</i> and <i>Anopheles stephensi</i> larvae and ovipositions effect on gravid females in laboratory conditions.</p> <p><b>Results:</b></p> <ul style="list-style-type: none"> <li>• 100% mortality of pupae of both test strains was observed within two hours.</li> <li>• &gt;90% mortality of larvae of both test strains occurred progressively over 10 days.</li> <li>• Deterrence of oviposition was observed when gravid females were given the option of egg laying in treated or untreated cups.</li> </ul>
R323	Ngrenngarmert, W, Sukkanon, C, Yaicharoen, R & Chareonviriyaphap, T. (2016). Physical influence on larvicidal and pupicidal activity of the silicone-based monomolecular film. Acta Tropica
	<p>This scientific paper presented information on the effects of Aquatain MMF on:</p> <ul style="list-style-type: none"> <li>• larvicidal and pupicidal effects on <i>Aedes aegypti</i></li> <li>• larvicidal and pupicidal activity after the product was exposed to drastic conditions such as: high temperature, ultraviolet light and acid or base pH</li> <li>• oviposition of <i>Aedes aegypti</i></li> <li>• non-target organisms <i>Poecilia reticulata</i> (guppy), and water planted ornamental plants <i>African violet</i> and <i>Golden pothos</i></li> </ul>



	<p><b>Results:</b></p> <ul style="list-style-type: none"> <li>• The treatment of Aquatain MMF resulted in 100% emergence inhibition of <i>Aedes aegypti</i> larvae. In terms of mortality, the product was most effective on pupae and older (3<sup>rd</sup> and 4<sup>th</sup> instar) larvae. Pupation inhibition rate was 100% and larval length was significantly reduced versus the control.</li> <li>• Emergence inhibition was ≥90% under scenarios of elevated temperature (42°C), UV radiation, and a various pH levels. Emergence inhibition was ≥90% for prepared treatment cups stored at elevated temperature (42°C) for 7d, 14d, 21d, and 28d. Emergence inhibition was &lt;90% for prepared treatment cups stored at elevated temperature (42°C) for 56d.</li> <li>• The numbers of eggs laid treated oviposition cups was significantly less than in untreated cups (p-value = 0.0041 and 0.0039 for choice and no choice, respectively) indicating a deterrent oviposition effect of Aquatain MMF.</li> <li>• No mortality was observed in fish and no significant effect was detected on plants.</li> </ul>																														
R305	Webb, C & Russell, R. (2007). A laboratory assessment of Aquatain AMF mosquito formula as a potential mosquito control agent.																														
	<p><b>Laboratory study:</b> The study presented information on the larvicidal efficacy of Aquatain AMF against <i>Culex quinquefasciatus</i> and <i>Aedes aegypti</i> 4<sup>th</sup> instar larvae and pupae in laboratory conditions. In addition, this study evaluated the Aquatain AMF deterrence level, as oviposition medium, for gravid female egg laying.</p> <p><b>Results:</b></p> <table border="1" data-bbox="418 1056 1417 1325"> <thead> <tr> <th colspan="5">Table 1: Larvicidal efficacy of Aquatain AMF against <i>Culex quinquefasciatus</i> and <i>Aedes aegypti</i> 4th instar larvae.</th> </tr> <tr> <th>Species mortality</th> <th>instars</th> <th>mean</th> <th>max mortality (time)</th> <th>Mean control</th> </tr> </thead> <tbody> <tr> <td><i>Cx quinquefasciatus</i></td> <td>4th</td> <td>94.6%</td> <td>48h</td> <td>1.2%</td> </tr> <tr> <td><i>Cx quinquefasciatus</i></td> <td>pupa</td> <td>100%</td> <td>2h</td> <td>0%</td> </tr> <tr> <td><i>Ae. aegypti</i></td> <td>4th</td> <td>54.8%</td> <td>48h</td> <td>0.4%</td> </tr> <tr> <td><i>Ae. aegypti</i></td> <td>pupa</td> <td>100%</td> <td>3h</td> <td>0%</td> </tr> </tbody> </table> <p>Aquatain AMF was efficacious against immature stages of larvae and pupae of <i>Culex quinquefasciatus</i> (94.6% &amp; 100% respectively) and <i>Aedes aegypti</i> (54.8% &amp; 100% respectively).</p> <p>Concerning the oviposition deterrence, no egg rafts were present in treatments, and an average of 7.7 dead adults was found compared to an average of 2 egg rafts for the controls. However, based on the review of the study, it was determined that no conclusions can be obtained concerning oviposition deterrence, as the study presents vague results and lacks supporting statistical analysis.</p>	Table 1: Larvicidal efficacy of Aquatain AMF against <i>Culex quinquefasciatus</i> and <i>Aedes aegypti</i> 4th instar larvae.					Species mortality	instars	mean	max mortality (time)	Mean control	<i>Cx quinquefasciatus</i>	4th	94.6%	48h	1.2%	<i>Cx quinquefasciatus</i>	pupa	100%	2h	0%	<i>Ae. aegypti</i>	4th	54.8%	48h	0.4%	<i>Ae. aegypti</i>	pupa	100%	3h	0%
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R340	Webb, C & Russell, R. (2012). Does the monomolecular film Aquatain AMF mosquito formula provide effective control of container-breeding mosquitoes in Australia. The Journal of the American Mosquito Control Association.																														
	This scientific paper presented information on the efficacy of Aquatain AMF in field conditions against immature stages of <i>Aedes notoscriptus</i> and <i>Culex quinquefasciatus</i> in domestic artificial breeding sites. The study was conducted in Sydney, New South																														

	<p>Wales, Australia.</p> <p><b>Results:</b>  <u>Efficacy on larvae:</u>  The results demonstrated a significantly lower mean abundance of larvae in Aquatain AMF treated containers compared with controls. Overall, either in containers with plants and without plants, there was a significant reduction between the mean abundance of all immature stages (i.e., larvae and pupae) of both species combined, between the pretreatment and posttreatment periods.</p> <p>a) <i>Culex quinquefasciatus</i></p> <ul style="list-style-type: none"> <li>• Mortality in containers without plants: 100% (from 7-42d);</li> <li>• Mortality in containers with plants: 100% (from 7-28d).</li> </ul> <p>b) <i>Aedes notoscriptus</i></p> <ul style="list-style-type: none"> <li>• Mortality in containers without plants: 100% (from 7-35d);</li> <li>• Mortality in containers with plants: 100% (from 14-28d).</li> </ul> <p><u>Effect on oviposition:</u>  Very few egg rafts were collected over the 8-week sampling period, although there was a distinct difference in the abundance of egg rafts in treatment tubs pre- and post-application of Aquatain AMF, with egg rafts only collected in treated tubs on one occasion, 5-week post application.</p>
R367	Almalik, A., Reeves, G., & Azrag, R. (2015). Laboratory report on larval bioassays using Aquatain AMF. University of Khartoum, Max Planck Institute.
	<p><b>Laboratory study:</b>  The study presented information on the efficacy of Aquatain AMF in laboratory conditions against <i>Anopheles arabiensis</i> and <i>Aedes caspius</i> mosquitoes. Bioassays were performed in twelve glass boxes with different height and surface area. Glass boxes were designed to have three water depths; 9cm, 7cm and 5cm. Each glass box contained 1000 ml tap water. Aquatain AMF was added to each glass box according to the recommended concentration of 1ml/m<sup>2</sup> and left for 18 hours before the start of the experiment.</p> <p><b>Results:</b></p> <ul style="list-style-type: none"> <li>• For <i>Aedes caspius</i> ≥90% mortality was recorded after 6 hours for all three box types (water depths).</li> <li>• For <i>Anopheles arabiensis</i> ≥90% mortality was recorded after 3 days in the boxes with 9 cm water depth. ≥90% mortality was recorded after 4 days in the boxes with 7 and 5 cm water depth.</li> </ul>

<b>Field Studies</b>	
R366	Mbare, O., Lindsay, S., & Fillinger, U. (2014). Aquatain AMF mosquito formulation (AMF) for the control of immature <i>Anopheles gambiae sensu stricto</i> and <i>Anopheles arabiensis</i> : dose-responses, persistence and sub-lethal effects. BioMed Central – Parasites and Vectors
	This scientific paper presented information on the efficacy of Aquatain AMF on <i>An. gambiae sensu stricto</i> and <i>An. arabiensis</i> in Laboratory & Semi field studies following

	<p>WHO standardized procedures. The study was conducted in Homa Bay County, Kenya.</p> <p><b>Results:</b></p> <ul style="list-style-type: none"> <li>• Both vector species were highly susceptible to Aquatain AMF. An application rate of 0.5 ml/m<sup>2</sup> resulted in ≥ 90% larval mortality</li> <li>• The estimated LC<sub>99</sub> was: <ul style="list-style-type: none"> <li>○ <i>An. gambiae</i> s.s: 1.23 ml/m<sup>2</sup> (95% confidence interval-CI; 0.99-1.59 ml/m<sup>2</sup>)</li> <li>○ <i>An. arabiensis</i>: 1.35 ml/m<sup>2</sup> (95% CI 1.09-1.75 ml/m<sup>2</sup>)</li> </ul> </li> <li>• In field studies ≥90% larval mortality was observed for 6 weeks</li> <li>• A single dose of AMF at 1 ml/m<sup>2</sup> inhibited emergence by 85% (95% CI 82-88%) for 6 weeks compared to the control group. Actual emergence was ≤10% for 6 weeks.</li> <li>• Females exposed as larvae to a sub-lethal dose of AMF were 2.2 times less likely (Odds ratio (OR) 0.45, 95% CI 0.26-0.78) to lay eggs compared to those from untreated ponds. However, exposure to sub-lethal doses neither affected the number of eggs laid by females nor the proportion hatching.</li> </ul>
R365	<p>Bukhari, T., Takken, W., Githeko, A., &amp; Koenraadt, C. (2011). Efficacy of Aquatain AMF, a monomolecular film, for the control of malaria vectors in rice paddies. PLoS ONE</p>
	<p>This scientific paper presented information on the efficacy of Aquatain AMF on <i>anopheline</i> and <i>culicine</i> mosquito larvae in field conditions (rice paddies) at the Ahero Irrigation Research Station in western Kenya and the potential effects on non-target organisms and rice plants. An initial application of 1ml/m<sup>2</sup> was made. Once, upon visual inspection, it appeared that the film had dissipated, a second application of 2 ml/m<sup>2</sup> was made.</p> <p><b>Results:</b></p> <ul style="list-style-type: none"> <li>• There was a 93.2% reduction in emergence of <i>anopheline</i> adults and a 69.5% reduction in emergence of <i>culicine</i> adults compared to pretreatment rates.</li> <li>• After the second application there was an 88% reduction in emergence of <i>anopheline</i> adults and an 82% reduction in emergence of <i>culicine</i> adults compared to pretreatment rates.</li> <li>• No difference was reported (GEE, p&gt;0.05) in the densities of non-target organisms (e.g. Ephemeroptera, Odonata, Orthoptera, Mollusks, etc.) in the control and treatment paddies after Aquatain AMF application apart from backswimmers.</li> <li>• The study indicated that Aquatain AMF film had no adverse effects on the growth and development of rice plants in treatment paddies. The crop yield was similar in the control and treatment plots.</li> </ul>
R395	<p>Kioulos, I. &amp; Koliopoulos, G. (2013). Impact of Aquatain AMF mono-molecular surface film on mosquito larvae in rice paddies.</p>
	<p><b>Field study:</b></p> <p>The study presented information on the efficacy of Aquatain AMF in rice paddies in Central Greece. Aquatain AMF was poured into a 1.2 hectare rice paddy along one side of the field. Laboratory reared larvae of <i>Culex pipiens</i> were introduced in plastic cages placed in 3 different positions along a transect in the paddy. Larval mortality was assessed at 3, 6, 15 and 25-days post treatment. The mortality percentage of L1-</p>

	<p>L4 larvae was assessed using a Kruskal-Wallis H-Test and the mean by Mann-Whitney U-test. Transect 1 was closest to the point of application and transects 2 and 3 were progressively farther away.</p> <p><b>Results:</b>  Transect 1 (closest section to Aquatain AMF application): 100% mortality after 3 days and remained at 75% up to 25 days.  Transect 2: 80% mortality up to 15 days but declined after.  Transect 3: 42% mortality detected after 6 days.  Results indicated that the product was able to spread across the entire waterbody, however in areas of dense vegetation applications should be made at multiple sites around the periphery of the waterbody to ensure more equitable and faster dispersion.</p>
R397	<p>Drago, A. et al. (2017). Field trial to evaluate to different procedures for monitoring the efficacy of Aquatain against <i>Culex pipiens</i> and <i>Aedes albopictus</i>. Journal of the American Mosquito Control Association</p>
	<p>This scientific paper presented information on the efficacy of a novel method (floating system - FS) to monitor adult emergence in comparison to the standard dipper sampling method commonly used for estimating larval abundance after treatment with Aquatain AMF larvicide. <i>This component of the study not relevant to the efficacy of Aquatain AMF. However, this study also assessed the efficacy of the Aquatain AMF against Aedes albopictus and Culex pipiens found in urban catch basins in northeastern Italy.</i></p> <p><b>Results:</b></p> <ul style="list-style-type: none"> <li>• Both FS and dipper sampling methods recorded high percentages of adults and larvae reduction from the first treatment (1-3 week) supporting that Aquatain AMF is simultaneously active against all stages of mosquitoes.</li> <li>• The FS method recorded significantly lower adult emergence in treated basins even when monitoring of larvae was ineffective, suggesting that FS could be a good monitoring tool to assess the efficacy of monomolecular films such as Aquatain AMF.</li> <li>• ≥90% emergence inhibition was shown for 2 weeks for wild <i>Aedes</i> and <i>Culex</i></li> </ul>

In addition to the studies which were reviewed and the results summarized in this document, the submitted dossier also included published studies that supported the label claims for the following use sites:

- Polluted water (canals)
- Polluted drains
- Standing water which is polluted and heavily vegetated
- Standing water in residential areas

## 5.2 Efficacy Conclusion

Taking into account the entirety of the submitted efficacy studies in lab and field settings, there is sufficient information to demonstrate that Aquatain AMF meets the efficacy requirements for prequalification. At the labelled application rate, Aquatain AMF is a physical larvicide able to significantly reduce emergence of several mosquito species in both laboratory and field conditions through its larvicidal and pupicidal activity. It has also been shown to deter gravid females from depositing eggs on treated surfaces. The residual activity of the product appears to be 2-4 weeks depending on the nature of the aquatic site.

The product is appropriate for use in a variety of settings and may be useful in the development of IVM strategies.

The efficacy component of the dossier is complete. The assessment of the submitted information supports the prequalification of the product.

## 6 Labeling

The proposed Declaration of Labelling has been reviewed by PQT-VC and found to be consistent with the supporting information.

## 7 Pre-Qualification Listing Decision

The review of the dossier submitted for the product Aquatain AMF has been completed by PQT-VC. The results of the assessments show the product is safe and effective when used according to the directions for use on the label for the control of mosquito larvae and pupae. This product is allowed inclusion in the list of prequalified vector control products.

## 8 References

### Quality

1. SGS Thailand Ltd. Heavy Metals Report. 2012. R404.
2. Aquatain Products Pty Ltd. SDS for Aquatain AMF. April 2017. R405.
3. Aquatain Products Pty Ltd. Aquatain AMF Technical Data Sheet. 2017. R406.
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