

马来西亚非专利农药产品登记材料要求_2017
Documents Required for Generic Pesticides Registration in Malaysia_2017

编号	材料要求	中文要求
a.	Support Documents from Company	
1	Letter of Authorization (Original Copy Required)	授权书
2	Letter of Authorization To Use Data (Original Copy Required)	使用数据的授权书
3	ICAMA Certificate for Technical Material and Formulated Product or Letter of Source for Technical Material and Export Certificate for Formulated Product	原药和制剂 ICAMA 证书
b.	About Technical Material	
12	Chemical Composition	化学成分
13	Manufacturing Process	生产工艺
14	Explanation / Route of Origin of Impurities, if applicable	杂质的来源的解释/路线
15	5 Batch Analysis Report (GLP)	5 批次
16	Validated Methods of Analysis for Active Ingredient	有效成分分析方法
17	Toxicology Report for Technical Product (GLP)	原药毒性报告
18	Specification (Original Copy Required)	规格
19	MSDS	MSDS
20	Residue Report [If Available]	残留报告
11	Storage Stability Report (GLP)	储存稳定性报告 (GLP)
c.	About Formulated Product	制剂产品

1	Physical & Chemical Properties Report (GLP)	理化性质报告 (GLP)
2	Recipe with CAS No (Must be actual recipe)	配方编号 (必须是实际配方)
3	Manufacturing Process and Quality Control Process	生产工艺和质量控制过程
4	Specification (Original Copy Required)	规格
5	MSDS (Included Inert Materials used in formulation)	MSDS
6	Toxicology Report for Formulated Product (GLP) [If Available]	毒性报告
7	5 Batch QC Report, with chromatogram	5BQC 报告, 包含色谱图
8	Storage Stability Report (GLP)	储存稳定性报告 (GLP)
9	Efficacy Report [If Available]	功效报告
d.	Sample [Send After Received Advice from Registrant]	样品
1	500ml / 500g sample based on actual recipe and must be able to pass accelerated storage stability test, with certificate of analysis (Original Copy)	500ml/500g 根据实际配方样品和必须能够通过加速储存稳定性测试, 和 COA
2	1g Analytical Standard with Certificate of Analysis (Original Copy Required)	1g 标样带分析单

说明： 以上信息， 仅作公司内部用， 非授权请勿外传。