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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Vector Control Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Agricultural Chemicals (M) Sdn. Bhd.
Corporate address of manufacturer	Sumitomo Chemical Company Limited 2-7-1 Nihonbashi, Chuo-ku, Tokyo 103-6020, Japan
Inspected site	
Name & address of inspected manufacturing site(s)	Agricultural Chemicals (M) Sdn. Bhd. 962, Lorong Perusahaan 8, Taman Perindustrian Perai, 13600 Perai, Pulau Pinang, Malaysia Malaysia
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	12 -14 April 2023
Type of inspection	Initial inspection. The inspection was to establish that the applicable requirements to ISO 9001:2015 as well as WHO specific requirements were met.
Introduction	
Brief description of the manufacturing activities	Agricultural Chemicals (M) Sdn. Bhd manufactured herbicides, fungicides, fertilizers, rodenticides and insecticides. The activities related to the manufacture of Gokilaht-S 5EC included formulation, filling, labelling and packaging.
General information about the company and site	This was the first WHO inspection. The site also held several ISO certifications as indicated below: **ISO 9001: 2015: Quality Management System** Certificate Number: QMS 00795 Issue Date: 2 June 2021 Expiry Date: 13 July 2024 Scope: 1. Development, Formulation, Manufacture and Sales of Agricultural Chemicals

	2.Sales of Farm Machineries This was issued by SIRIM QAS International Sdn. Bhd. **ISO 14001: 2015: Environmental Management System** Certificate Number: EMS 00664 Issue Date: 21 December 2022 Expiry Date: 26 December 2025 Scope: 1. Development, Formulation, Manufacture and Sales of Agricultural Chemicals 2.Sales of Farm Machineries This was issued by SIRIM QAS International Sdn. Bhd. **ISO 45001: 2018: Occupational Health & Safety Management System** Certificate Number: OH S 00545 Issue Date: 21 December 2022 Expiry Date: 26 December 2025 Scope: 1. Development, Formulation, Manufacture and Sales of Agricultural Chemicals 2.Sales of Farm Machineries This was issued by SIRIM QAS International Sdn. Bhd. **ISO 17025:2017:** Certificate Number: SAMM 1053 Issue Date: 1 March 2022 Expiry Date: 1 March 2025 The quality control laboratory was accredited by Standards Malaysia.
History	This was the first WHO inspection of the site.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	**Document review including but not limited to:** • Quality Manual • Training • Risk management • Management review • Job descriptions and responsibilities of key personnel • Customer complaint handling • Non-conforming products • Product release • Batch processing records

	• Management of Change • Internal audits • Calibration and equipment maintenance **Physical areas:** • Raw material and finished goods warehouse • Production areas • Quality control laboratory
Exclusions and Non-applications of requirements in the QMS	None.
Out of scope	The manufacture of herbicides, fungicides, fertilizers, rodenticides, and other products not submitted to PQ were not included in the scope of this inspection.
Restrictions	None
WHO products covered by the inspection	Gokilaht-S 5EC (5% d, d, trans-Cyphenothrin) - 001-003
Abbreviations	**Meaning**
CoA	Certificate of Analysis
FMEA	Failure Modes and Effects Analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
MR	Management Review
MRM	Management Review Meeting
QMS	Quality Management System

Part 2	**Brief summary of the findings and comments (where applicable)**

1. Quality policy and quality objectives

Quality policy and quality objectives were in place. Key performance indicators for each of the quality objectives were monitored and reviewed in the management review meeting. The current quality objectives related to customer satisfaction, technology and expertise, and quality products were on track. The quality policy and quality objectives were displayed at various locations within the facility.

2. Management review

Management review meeting was held once every year. Management review meeting dated 12 July 2022 was reviewed. The agenda items included among others:

- Status of actions from previous management reviews
- Report on the status of corrections and preventive actions
- Process performance and product conformity
- Environmental performance, measurement, and monitoring
- Occupational safety and health

- Vendor monitoring and evaluation results
- Customer satisfaction
- Audit results
- Evaluations of compliance with legal and other relevant requirements

Opportunities for improvement were discussed. Management review was found satisfactory.

3. Organizational roles, responsibilities, and authorities

Among other duties, Top Managements and Management Representative were responsible for ensuring effective implementation of company policies, regulations, procedures and compliance with quality, occupational health, safety, and environmental management requirements in accordance with ISO 9001, ISO 14001, ISO 45001 and ISO 17025. The Head of Departments were responsible for the implementation, maintenance, improvement, and ensuring compliance with ISO 9001, ISO 14001 and ISO 45001; while Head, Quality Assurance was responsible for the implementation, maintenance, improvement, and ensuring compliance with ISO 17025 requirements. The Head, Toll Manufacturing was responsible in coordinating between customer and manufacturing site following to customer requirement. The job descriptions were signed by the respective job holders. An organogram was in place, depicting the Head, Quality Assurance, and Head, Toll Manufacturing reporting independently to the Chief Executive Officer (CEO).

4. Control of documented information

The Document and Data Control Procedure was reviewed. The purpose of the document was to provide adequate direction and reference to users and clarify interfaces at both departmental and interdepartmental level. The scope covered all standard operational procedures/work instructions and other support documents. The Management Representative and Heads of Departments were responsible for ensuring that all documents were reviewed and approved. The Central Document Controller (CDC) /Department Document Controller (DDC) was responsible for ensuring that all ISO procedures, work instructions and related support documents such as the Quality Manual, OH&S Manual, Environmental Manual, Laboratory Manual were identified and distributed to the relevant department.

The procedure for Control of Records was also reviewed. The SOP detailed the disposition and controls for recorded data. A document list was in place. Overwriting was not allowed as per procedure and staff were required to initial at the side of the amendment.

5. Personnel competence and training

The procedure for on the Job training (OTJT) was reviewed. The training covered ISO 9001 QMS, ISO 14001 EMS (Environmental), ISO45001 Occupational Health and Safety Management. Heads of Departments (HOD) were responsible for the effective planning and implementation of OTJT program. According to the SOP, it was compulsory for all new employees to undergo OTJT. Employees assigned to all verification activities such as inspection, testing, and monitoring of service were to be trained prior to being assigned to perform the function. Following identification of a training need, training of the new employee was conducted within 4 months and 3 months for existing employees. According to the procedure, employee job performance was to be monitored for 2 months after OTJT. A training schedule, evaluation and OTJT appraisal forms were in place.

Training and Development Needs Analysis (TNA) Procedure was also reviewed. The purpose was to identify the training needs of each employee and ensure that adequate training was performed.

The HODs were responsible for ensuring that the TNA was carried out yearly. Training records of personnel were in place.

6. Risks Management

The procedure for risk assessment was reviewed. The purpose was to enable a systematic methodology for conducting general risk assessments for all activities in operation under the control of the Agricultural Chemicals (M) Sdn. Bhd. The procedure had a flow diagram showing the steps followed when performing a risk assessment was available.

A risk register was in place. Risks related to environment, manufacturing among others were also assessed and evaluated. A risk assessment regarding the manufacturing of all different products in the same building as the Gokilaht -S-5EC presented. Risk Assessment categorized the risks by their likelihood of occurrence and the severity of their impact. The risk assessment was made up of Frequency (F), Likelihood (L), and Severity (S). The risk categories were determined, and control mechanisms were elaborated. The assessment also took into consideration solvent vapor and product leakage, and water pollution. Compliance with the applicable Environmental Act/Regulations was also assessed. A Hazard Identification, Risk Assessment and Determining Control (HIRADC) assessment had also been completed for areas of Production, Laboratory, FG warehouse, offices, and Farm Material Section among others.

7. Management of change

The Management of Change procedure was reviewed. The SOP was applicable to any modification to the operations, equipment changes involving engineering or design, organizational change to team structure, competence or staffing, procedural change to approval methods or agreed practices. Recent changes related to construction of the new warehouse and installation of a new granule plant were reviewed. The changes were recorded on the Management of Change request form.

8. Internal Audits

The Internal Audit Procedure was reviewed. The purpose of the procedure was to enable internal audits to be regularly performed and to ensure that the Quality, OH&S and Environmental Management Systems were implemented and adhered to requirements of ISO 9001:2015, ISO 14001:2015, ISO 45001:2018 and ISO/IEC 17025:2017 standards.
The Central Document Controller was responsible for drawing up the ISO audit schedule. The audit schedule was presented for 2022. The areas audited included: Purchasing and material control, Sales and Planning, Farm material assembly, service and repair, Human Resource, FG Warehouse, Product Development, Production Formulation and Laboratory, Management, and Raw Material Warehouse. Audit findings were categorized into major, minor and observation.

9. Control of nonconforming products

The procedure for control of nonconforming products was reviewed. The procedure was applicable to raw and packaging materials. The procedure provided for investigation, corrections, and corrective actions. Records of nonconforming products were maintained. Records related to nonconforming raw materials were reviewed.

10. Performance evaluation

The performance evaluation report for the year 2022 was in place. The report provided details on the quality objectives, performance targets and action plan. The quality objectives were related to the Customer satisfaction, Technology and expertise, Quality products and support functions. The target had been met.

11. Design and development of products

Not applicable. Design and development of Gokilaht-S 5EC was undertaken by Sumitomo Chemical Company Limited. Agricultural Chemicals (M) Sdn. Bhd was not responsible for the design and development of Gokilaht-S 5EC and therefore this was not inspected.

12. Customer satisfaction

The customer satisfaction measurement procedure was reviewed. Customer satisfaction surveys were conducted by use of questionnaires. The sales manager/assigned personnel was responsible for collection of questionnaires and analysis of the data. The customer satisfaction survey report for 2022 was in place. The customer satisfaction survey questions were related to cost, quality of products, branding, and after service care among others. The customers were satisfied with the products from Agricultural Chemicals (M) Sdn. Bhd.

13. Customer Complaint Handling

Market complaints were received by Sumitomo Chemical Company. Depending on the nature of the complaint, the complaint would then be communicated to Agricultural Chemicals (M) Sdn. Bhd. for investigation. The manufacture had a procedure for customer complaint handling in place. The procedure provided for root cause investigation, correction, and corrective actions. The HOD was responsible for carrying out the investigation. Records were maintained. Complaints were reviewed.

14. Support

Infrastructure and work environment

Personnel in production areas were appropriately gowned in PPE. The temperature in the laboratory was monitored and records maintained.

Monitoring and measuring resources

The Internal Maintenance Schedule for the plant was presented. The Maintenance schedule for the period January 2023 to December 2023 was reviewed. The plan was approved by the Head, Manufacturing. The Insecticide line (Sumitomo Liquid Plant) was scheduled for Feb 2023 and was completed in Feb 2023. The Machinery Maintenance Procedure was reviewed. It was noted that the packing equipment was not part of the Preventive Maintenance program.

The Equipment Calibration Procedure was reviewed. The purpose was to ensure that equipment used for inspection, measuring, and testing was accurate and in good working order. The scope was applicable to all inspection and testing equipment used in the laboratory, production, and workshops as well measurement equipment used in environment monitoring and impact and OH&S performance. The calibration schedule was in place. Calibration certificate for the balances were reviewed. The test performed included repeatability, eccentricity, and test for error of indication.

Calibration certificate for the calibration mass pieces 20 mg, 50 mg, and 100 mg used in the laboratory was verified. The mass pieces were labelled correctly and there was full traceability.

15. Production and service provisions

Control of Production

The inspectors inspected the insecticide line on which Gokilaht-S 5EC was manufactured. The manufacture of Gokilaht-S 5EC involved mixing, filtration, and packaging. The inspectors visited the dispensing area, mixing area, label control areas, filling and packaging areas. At the time of the inspection, the manufacture of Gokilaht-S 5EC was ongoing. The weighing balances were calibrated, and calibration status labels affixed to the balances. The mixing time was monitored.

The mixture was then filtered through a 100-mesh filter prior to filling. The bottles were sealed with an induction sealer. The sealed bottles were sampled for leak test. Each of the filled bottles was weighed to ensure that the correct amount had been filled in the bottles. The plastic bottles had labels affixed manually to them.

Batch production records for Gokilaht-S 5EC were reviewed. Technical service report for Gokilaht cleaning was reviewed. A cleaning procedure was in place.

Quality control laboratory

The quality control laboratory was carried out both physical and chemical tests. A sample receipt register (Daily Assignment Book) was in place. The in-process/product inspection procedure was reviewed. The procedure stated that the Head, Quality Assurance, Senior laboratory analyst, Assistant Manager Quality Assurance, Senior Chemist were authorized to release the product. The balances in the laboratory were calibrated.

The analytical test reports for Gokilaht-S 5EC were reviewed and verified. The analytical tests carried out included pH, appearance, specific gravity, persistent form, emulsion stability, water content and active ingredient content. The active ingredient content was determined by the use of Gas Chromatography.

Analytical method verification

Document procedure for method Verification on the determination of Gokilaht-S content in Emulsifiable Concentrate (EC) by GC with Flame Ionization Detector (GC-FID) was reviewed. The analytical method was adopted from the CIPAC method 804/EC/(M). The determination of the active ingredient (AI) in Gokilaht-S-5EC was collaboratively tested with a technical mixture of isomers enriched with S,1R-trans isomer as specified by the WHO specification for d,d-trans-cyphenothrin. The parameters verified included selectivity, linearity, repeatability, intermediate precision, and accuracy. The Injection Sequence was defined. From the data reviewed and presented, the verification study on the determination of Gokilaht-S content in Gokilaht-S 5EC was accurate and precise over the specified concentration. LOD and LOQ were specified.

Stability studies

Stability study reports for Gokilaht-S 5EC in plastic bottle (COEX bottle), and metal bottle respectively were in place. The studies had been conducted at 40^{o}C ± 2^{o}C for six months and at 54^{o}C ±2^{o}C for one month. The product met specifications for active ingredient content, pH, specific gravity, emulsion stability and appearance. Stability studies were also conducted at ambient conditions (28-32^{o}C) for 3 years. The product had been assigned a shelf-life of 3 years.

Waste management

Waste generated during production was treated at the site. The waste was tested by a certified external laboratory and sent results to the relevant Government regulatory body prior to releasing the waste to the environment. The waste run off was chemically treated and the sludge was pumped to a filter press and then dried. The dried waste was discarded as chemical waste. The company was ISO 14001 certified. Instructions for wastewater treatment and Scheduled Waste Management procedure were in place.

16. Post-delivery Activities

A sample of every batch was retained. The samples were stored at ambient temperatures. The retention samples were kept for 4 years.

17. Preservation

Inventory control was managed by both ERP and stock cards. Only finished products that have been released were allowed into the finished goods warehouse. A conformity slip was affixed to all materials that had been tested and released. The information on the conformity slip included product name, packaging size, quantity, in-charge, and batch number.

Raw materials were housed in the raw material warehouse. Documentation verified at receipt of the raw materials included purchase order, packing list, certificate of analysis, and delivery note among others. The quantities of the received raw materials were verified at receipt.

Labels were stored in a separate room in the production area. Access to the label storage room was controlled.

18. Control of externally provided processes, products, and services

Raw materials were purchased and supplied by Sumitomo Chemical Company Limited. Agricultural Chemicals (M) Sdn. Bhd. purchased the bottles, caps, and seals locally. The specifications were defined. The Vendor Selection and Monitoring Procedure was reviewed. The purpose of the SOP was to source and monitor suitable vendors who were able to meet Agricultural Chemicals (M) Sdn. Bhd. requirements. The criteria for evaluation of suppliers was defined. The performance evaluation reports of the suppliers were reviewed.

Part 3	Conclusion – Inspection outcome

Based on the areas inspected, the people met, and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, as well as the corrective actions taken and planned **Agricultural Chemicals (M) Sdn. Bhd.** located at: **962, Lorong Perusahaan 8, Taman Perindustrian Perai, 13600 Perai, Pulau Pinang, Malaysia** was considered to be operating at an acceptable level of compliance with the ISO 9001: 2015 Standard.

All the non-conformances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 4	List of Standards and Guidelines referenced in the inspection report

1. Quality management systems – Requirements, International Standard (ICS 03.120.10), 5th edition (2015), ISO/FDIS 9001: 2015 ***Short name: ISO 9001:2015***
   https://www.iso.org

2. Manual on the Development and Use of FAO and WHO Specifications for Pesticides, First edition -third revision. Pesticide specifications. FAO plant production and protection paper (228), FAO/WHO Joint Meeting on Pesticide Specifications (JMPS), Rome 2016
   http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmps/manual/en/