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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	Minh Hung Tien Giang Co. Ltd.
Corporate address of manufacturer	Kinh 2A, Phuoc Lap, Tan Phuoc, Tien Giang, Vietnam.
Inspected site	
Name & address of inspected manufacturing site(s)	As above
Unit/Block/ Workshop	Not applicable.
Inspection details	
Dates of inspection	10-12 February 2020
Type of inspection	Initial inspection. The criteria for the inspection was based on the ISO 9001:2015 standard.
Introduction	
Brief description of the manufacturing activities	Minh Hung Tien Giang Co. Ltd (MHTG Co. Ltd) was established in 2008. The facility is a contract manufacturer for Sumitomo Chemical, Japan. It manufactured Long Lasting Insecticide Nets (LLIN) and Sumilarv 2MR. The activities related to manufacture of the LLIN included warehousing, production of the master batch, manufacture of the fabric (Incorporation), warping, knitting, cutting, sewing, labelling and packaging. The activities related to manufacture of Sumilarv 2 MR included production of the master batch, molding, labelling and packaging.
General information about the company and site	MHTG Co. Ltd held an ISO 9001:2015 certificate. ISO 9001:2015 certificate number VN10/00092, Valid from 29 September 2019 to 29 September 2022. Issued by SGS. Scope: “Manufacturing and distribution of long-lasting insecticidal nets (LLIN), manufacture of plastic products (SLV 2MR) for control of mosquitoes.

	MHTG Co. Ltd also held a business certificate number 1200748517 issued by the Department of Planning and Investment of Tien Giang Province, Vietnam.
History	This was the first WHO audit 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 • Complaints • Non-conforming products • Data integrity • Product release • Batch processing records • Laboratory test reports • Control of changes • Internal audits • Calibration and equipment maintenance **Physical areas:** • Quality control laboratory • Raw material and finished goods • Production areas
Exclusions and Non-applications of requirements in the QMS	Design and development were excluded from applications of the ISO 9001: 2015 standard.
Out of scope	Manufacture and testing of products not submitted to WHO for prequalification. The inspection was limited to the scope of products indicated in the section below (WHO products covered by the inspection).
Restrictions	None
WHO products covered by the inspection	Olyset Net (2% w/w Permethrin) Product number: 001-004 Olyset Plus (2% w/w Permethrin, 1% w/w Piperonyl butoxide) Product number: 001-005 Sumilarv 2MR (2% w/w Pyriproxyfen) - Product number: 001-006

Abbreviations	Meaning
CoA	Certificate of analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
QMS	Quality Management System
LLIN	Long Lasting Insecticide treated Nets

Part 2	Brief summary of the findings and comments

1. Organizational roles, responsibilities and authorities
The job descriptions of the Quality Control manager and the Quality Assurance manager were reviewed. Products were released by the Quality Assurance manager. An organizational chart was in place and was found adequate.

2. Quality policy and quality objectives
The quality policy and quality objectives were in place. The quality objectives were consistent with the quality policy. The quality policy and quality objectives were communicated to the staff through trainings. The quality policy and quality objectives were displayed throughout the facility. Key performance indicators had been defined for each quality objective and were being monitored.

3. Management review
Management reviews were held every year. The minutes of the management review held on 17/01/2020 were reviewed. The management review meeting input and outputs met the requirements of the standard. Information on performance and effectiveness of the quality management system including trends in process performance and conformity of products, audit results, customer satisfaction etc. were in place. Management review out puts included decisions and actions related to opportunities for improvement and resource needs.

4. Leadership
The quality policy and quality objectives had been approved and signed by top management. Top management ensured that an effective quality management system was implemented through internal audits and management reviews. The Quality Assurance manager was responsible for controlling and maintaining the quality management system.

5. Control of documented information
The relevant procedure for the control of documents was reviewed. The procedure described the review and approval of documents. The document distribution list was provided. Document retention period was defined. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

6. Personnel competence and training
The relevant training procedure was reviewed. Detailed training was conducted annually for all staff on safety, hygiene, the quality policy and environmental policy. Evidence of competence of the internal auditors and staff member in charge of training were available. The training records of the internal auditors were available.

7. Risks and opportunities
The relevant procedure titled "Risk Evaluation and Management" was reviewed. The procedure had a matrix on how to score risks and the departments or committees responsible for reviewing each risk were clearly defined The Process/Product Failure modes and Effect Analysis for 2019 and 2020 were reviewed. The full life cycle of the product had been considered. There was evidence that the risk evaluation and analysis was reviewed annually, and that the effectiveness of the mitigating actions had been evaluated.

8. Control of changes
The change control procedure was reviewed. The procedure allowed for the evaluation and impact assessment of the change prior to implementation of the change. Only one change had been registered in the last 3 years. The change was related to installation of the Master Batch feeder in April 2018. Related performance qualification and validation reports were in place.

9. Internal Audits
The procedure for internal audits was reviewed. Internal audits were performed once annually. The internal audit program, and internal audit reports for 2018 and 2019 were in place. Internal audits were conducted with a team of internal auditors who had all received training on the process by a competent trained staff member. Internal auditors did not audit their own areas of work. Internal audit findings were signed by the General Manager and discussed at management review meetings. The identified non-conformities had been addressed and closed.

10. Control of nonconforming products
The procedure for control of non-conforming products and records was reviewed. Within the production area, the manufacturer had segregated areas for storage of nonconforming goods. Information related to the nonconforming products was adequately documented and retained including information on the investigation that had been conducted and actions to be taken.

The manufacturer had in place a procedure for recalls. The manufacturer had not instituted any recalls at the time of the inspection. Sumitomo Chemicals was responsible for product recall from the market. The manufacturer performed a mock recall annually. The report for the mock recall was reviewed and found satisfactory.

11. Performance evaluation
Parameters to be monitored and measured had been determined. The performance evaluation report was available. The permethrin content, trans isomer ratio, Piperonyl Butoxide content etc were some of the parameters monitored for the bed nets. Parameters monitored and measured for Sumilarv 2MR included Pyriproxifen content, retention rate, weight etc. Upper and lower control limits had been set and the monitored parameters were all within set specifications. The results of the analysis and evaluation were discussed in management review.

12. Complaint handling
The relevant procedure titled "Customer Complaints Feedback and resolving" was reviewed. Complaints were adequately documented. Investigations were performed and records maintained. All the reviewed complaints had been closed. All complaints related to WHO prequalified products were to be directed to Sumitomo Chemical, Japan. In liaison with Sumitomo Chemical an investigation would be performed.

13. Design and development of products

Design and development were not applicable. The site was not involved in design and development activities.

14. Support

Infrastructure and work environment

The facility was well maintained and clean. The external grounds were clean and free of litter. Several rodent traps were placed within the building. These were identified as being checked regularly. All staff observed were wearing appropriate PPE (mask, hair net, ear plugs, company dust coat and appropriate foot wear).

Monitoring and measuring resources

The manufacturer had in place a well-documented procedure for the maintenance and calibration of equipment. All equipment observed within the facility was labelled with a unique identifier and a sticker with calibration information was available. A calibration and maintenance schedule was available. The frequency of maintenance/calibration was determined from the individual equipment manuals. The calibration equipment list included unique identifier, serial number and acceptance range of the equipment. Maintenance records were discussed. Temperature mapping of the QC laboratory was performed twice a year. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

15. Production and service provisions

Control of Production

The manufacture of Olyset Nets involved the production of the master batch and fabric, warping, knitting, cutting sewing, labelling and packaging.

The production of the Permethrin master batch involved mixing of Permethrin with other ingredients, extrusion, cooling of the filaments and cutting of the filaments into pellets. The manufacture of the master batch was carried out in a dedicated area. At the time of the inspection the production of a master batch was ongoing. The weighing scales used to weigh the raw materials were calibrated. The temperature at which extrusion was performed was monitored. Productions records for the manufacture of the master batch were retained. The test for permethrin content was performed on each lot of the master batch.

The approved master batch (following the test for Permethrin content) was then blended with HDPE. The test for blend uniformity was performed on each bag of the blend. This was then followed by extrusion, cooling, warping, knitting, cutting of the fabric and sewing. Cooling of the filaments was done in a water bath. The cooling temperature, yarn diameter and denier were monitored. The equipment was identified. The temperature gauge was calibrated. Production records were retained. The yarn was warped into bobbins and then transferred to the knitting area. Each lot of the knitted fabric was sampled and tested for GSM, mesh size and hole density. Other parameters monitored during knitting included yarn feeding rate, width of the fabric roll, denier etc. The knitted fabric was then cut, sewed, labelled and packaged according to customer specifications. The tape measures used to measure the length of the fabric to be cut were calibrated All the fabric was inspected for defects such as holes, tears, stains etc. Inspection records were retained. Labels were adequately controlled. Records of label issuance and usage were available. 100% of the sewed bed nets were inspected for workmanship and other defects such as holes, tears, stains etc.

The process of manufacture of Olyset Plus was similar to that of Olyset. Completed batch production records were reviewed.

The production of SumiLarv 2MR involved the mixing of pyriproxyfen with other ingredients to produce the pyriproxyfen master batch. The pyriproxyfen master batch was produced using the same equipment as that to produce permethrin master batch. Each lot of the mater batch was sampled and tested for pyriproxyfen content. The production of the pyriproxyfen master batch was followed by molding, packaging and labeling. The molding, labelling and packaging were performed in a segregated area. The master batch was molded in a prescribed shape (discs). The temperature at which the master batch was melted, speed and pressure were monitored. The tests performed included weight of the SumiLarv 2MR discs, retention rate and pyriproxyfen content. The discs were packaged and labelled according to customer requirements. Production records were available.

Cleaning validation protocol and report and instructions for cleaning were reviewed. Cleaning was performed when there was a product change over or color change. The cleaning validation protocol and report, and cleaning instructions were found adequate.

The process validation reports for the manufacture of the master batch and extrusion process for Olyset, Olyset Plus and SumiLarv 2MR were reviewed. Critical process parameters and critical quality attributes had been identified and monitored. The validation process was found adequate.

The quality control laboratory located separate from production areas. The laboratory performed both physical and chemical tests. A sample register was in place. Laboratory equipment were calibrated. Some of the equipment in the laboratory included three GCs, weighing balances, bursting strength tester, GSM cutter etc. Standard testing procedures and test results were reviewed. The standard testing procedure for determination of the content in Olyset (following CIPAC method), Olyset Plus (In-house method) and SumiLarv 2MR (In-house method) were reviewed.

The analytical method validation protocols and reports for the determination of Permethrin, Piperonyl butoxide and Pyriproxyfen content were reviewed. The parameters verified included specificity, linearity, accuracy, precision, repeatability. The analytical method validation performed was found satisfactory.

The finished products were released by the Quality Assurance Manager following the review of production records and laboratory results. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

Identification and traceability

Material were identified, and status indicated. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

Release of products and services

Following the review of production records and laboratory results, the bed nets were released by the QA/QC Manager.

16. Preservation

The raw materials were supplied by Sumitomo Chemical. The raw materials and finished products were stored separately. Inventory records were available. MSDS were in place. Raw materials and finished products were stored at ambient temperatures. The raw materials were supplied along with a Certificate of Analysis (CoA) from the manufacturer. The physical appearance of the packaging and quantity were verified upon receipt. The manufacturer relied on the CoA from the manufacturer of the raw materials. No additional testing on the raw materials was performed.

17. Post-delivery Activities

Storage stability studies had been performed by Sumitomo Chemical. The results of the analysis for Olyset and Olyset Plus and SumiLarv 2MR complied with specifications. The results of analysis for also complied with specifications. The stability study protocol and reports were satisfactory.

A dedicated area for storage of retention samples was in place. They were clearly labelled, and inventory records were available. A sample of each batch of the finished products was retained. Samples were retained for 4 years. The samples were stored at ambient temperatures.

18. Control of externally provided processes, products and services

The relevant procedure was reviewed. The critical suppliers list was available. Chemical raw materials were supplied by Sumitomo Chemical. Critical suppliers were to be audited annually. Supplier evaluation reports and contracts 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 ***Minh Hung Tien Giang Co. Ltd*** *located at* ***Kinh 2A, Phuoc Lap, Tan Phuoc, Tien Giang, Vietnam*** 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. Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange, Final Document, Global Harmonization Task Force, November 2, 2012, GHTF/SG3/N19:2012
   https://www.imdrf.org

3. 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/