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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	Shanghai Gongtai Textile Co. Ltd
Corporate address of manufacturer	No.2, Fada Road, Taicang City, Jiangsu Province, China
Inspected site	
Name & address of inspected manufacturing site(s)	Same as above.
Unit/Block/ Workshop	Not applicable.
Inspection details	
Dates of inspection	26 March 2019
Type of inspection	Follow-up inspection The criteria for the inspection was based on ISO 9001:2015 standard.
Introduction	
Brief description of the manufacturing activities	The activities related to manufacture of the LLIN included warehousing (storage) of raw materials and finished products, processing of fabric (coating), cutting, sewing and stitching, labeling, packaging and quality control testing.
General information about the company and site	The site is a contract manufacturer for BASF Agro BV. The facility holds an ISO 9001:2015 certificate. Date of issue 27 August 2018, expiry date 17 September 2021. Registration number 03818Q06442R1M. Issued by WSF. Scope of certification: Processing of mosquito net cloth finishing; production and sale of textile products (mosquito nets).
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 not applicable as the site was not involved in design and development.
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.
Restrictions	None
WHO products covered by the inspection	Interceptor (*Alphacypermethrin* 200 mg/m^2) - 002-001 Interceptor G2 (*Alphacypermethrin* 100 mg/m^2 and *Chlorfenaypr* 200 mg/m^2) - 002-002
Abbreviations	**Meaning**
CoA	Certificate of Analysis
GSM	Grams per Square Meter
HPLC	High Performance Liquid Chromatography
LLIN	Long Lasting Insecticide treated Nets
PPE	Personal Protective Equipment
QMS	Quality Management System
SOP	Standard Operating Procedure

Part 2	Summary of the findings and comments

1. Organizational roles, responsibilities and authorities

Roles and responsibilities are fully described and were supported by an organogram detailed in the Quality Manual. Reporting lines for quality and production were independent of each other. Job descriptions were reviewed and found satisfactory.

2. Quality policy and quality objectives

The quality policy was described in the Quality Manual. The quality policy had been communicated to all staff during induction and regular internal training events. The quality policy was appropriate to the purpose of the organization and was displayed throughout the facility on notice boards. The objectives were documented and measurable with appropriate performance indicators. The objectives and performance indicators were reviewed in Management Review and records of the review maintained.

3. Management review

The procedure for management review was described in the Quality Manual. Management review minutes were reviewed. The minutes included the review of the quality objectives and performance of different departments. The report further included feedback from all departments on their performance. A new QMS had been implemented about a year ago. Management had strengthened the internal audit resources and capabilities to improve the overall application of the quality management system.

4. Leadership

The Quality Manual was reviewed. The factory manager was responsible for the implementation and maintenance of a working QMS. The Quality Manual further described management's commitment and understanding with respect to the quality management system.

5. Control of documented information

The procedure for document control was reviewed. Documented information included batch processing records, SOPs etc. The SOPs were readily available for reference. Documents were identified. The management representative was responsible for issuance and retrieval of documents. Documents were approved by the General Manager. Documents were maintained in both electronic and hard copy forms. The document master list was provided for review. The retention period of procedures and records such as training records, maintenance records, process inspection records was six years. The quality manual had been revised and the supporting documents were referenced. Electronic copies of procedures and the production record (excel sheet) were password protected. All the issues raised in relation to this section were satisfactorily addressed.

6. Personnel competence and training

A selection of job descriptions was reviewed. The job descriptions of the laboratory staff were reviewed including the list of duties to be performed and relevant educational requirements. Laboratory staff training records on the use of HPLC by the provider, Agilent were reviewed.

7. Risks and opportunities

Document titled "Risk and Opportunity Assessment analysis" was reviewed. It described how risks were to be identified, analysed and what mitigation measures were to be generated and implemented. The risks and opportunities were separated into specific business areas and appropriate responsible persons/owners had been assigned. A risk register had been developed. The identified risk and opportunities were relevant to the operations, purpose and strategic direction of the company. Mitigation of the top three risks had been implemented since October 2018. Evaluation of the implemented mitigation measures was ongoing at the time of the audit. Staff had been trained on risk and opportunities. Training records were reviewed. Trainings were evaluated, and records retained.

8. Control of changes

Changes were handled in accordance with the relevant procedure. Changes were reviewed and controlled. Changes were approved by the General Manager. Handling of changes was compliant with the requirements of the standard.

9. Internal Audits

The procedure for conducting internal audits was described in the Quality Manual. The internal audit covered all aspects of the quality management system and was conducted twice a year. The audit plan, implementation plan, audit meeting minutes, internal audit check list, internal audit report and corrective actions were reviewed. The company utilized qualified internal auditors. The report detailed the completed checklists and identified corrective actions. The report was reviewed at the Management Review.

10. Control of non-conforming products

The manufacturer inspected bed nets to ensure that defective bed nets were identified and controlled. The manufacturer had documented criteria for assessment of nonconformities such as holes, tears, etc. Repairable defects such as holes were repaired by stitching. The repaired bed nets were inspected again to ensure that they conform to the specified requirements. All nonconformities were documented.

11. Performance evaluation

All production data was recorded in an EXCEL Production Report, File reference "Updated Curing Report" which detailed all the relevant batch information such as batch number, the amount of material produced, batch size, batch numbers of the raw materials, the QC lab test results etc.

Weekly production reports were generated by the manufacturer and these were provided to BASF who then performed a detailed Statistical Process Control (SPC) analysis.

12. Complaint handling

The relevant procedure was reviewed. The procedure allowed for investigations, root cause analysis and corrective action. Complaints were reviewed and found satisfactory.

13. Design and development of products

Design and development were not applicable.

14. Support

Infrastructure and work environment

MSDSs were available in the warehouse. The environment was generally clean. The staff in the production and quality control laboratory were found wearing adequate PPE.

Monitoring and measuring resources

The calibration and preventive maintenance schedule were in place. Calibration reports for the balances were reviewed.

15. Production and service provisions

Control of Production

The manufacturing of Interceptor G2 involved heat setting of the fabric, chemical treatment (coating), stentering, cutting, sewing, stitching, labeling, packaging and baling. Records on the heat setting were available. The samples of the fabric collected after heat setting were identified with the lot number and date of sampling etc. The temperatures of the drying chambers were monitored and controlled. Temperature zones on the extruders were identified in a manner that allowed traceability to the temperature indicators on the control panel. The monitored in-process parameters included pressure included wet pick up, GSM, bursting strength etc. The procedure for mixing was reviewed. At the time of the inspection, manufacture of Interceptor bed nets was on going. Production records were maintained. It was possible to trace the batch number of the fabric used during production. At the time of the audit Interceptor G2 was being manufactured.

All tanks were graduated, and their volumes had been calibrated. Calibration certificates for all the tanks were available.

Laboratory testing records were reviewed. The analytical method for determination of the content for *Chlorfenaypr* and *Alphacypermethrin* was under validation at the time of the inspection. Chromatograms were available. The laboratory generated data was backed up at the end of every day. A UPS had been installed and could run for 6 hours. The excel sheets used for calculations were protected with a password. All the issues raised in relation to this section were satisfactorily addressed.

Identification and traceability

Material were identified, and status indicated.

Release of products and services

Completed batch manufacturing records bed nets were reviewed and approved for release by the General Manager.

16. Preservation

Raw materials and finished products were stored under ambient conditions. Inventory records for the fabric were reviewed. The fabric was inspected and sampled on receipt. Chemical raw materials were sampled at the port of entry, analysed and approved by the government authorities prior to release to the manufacturer. The manufacturer relied on the CoA provided by BASF Agro BV and the release of the chemicals by the government authorities. All the issues raised in relation to this section were satisfactorily addressed.

17. Post-delivery Activities

Stability studies for Interceptor and Interceptor G2 were conducted and submitted to WHOPES for approval. The report was not available on site at the time of the audit.

18. Control of externally provided processes and products

The procedure for control of external providers and supplier list were in place. BASF are the sole suppliers of the active ingredients and associated chemicals. Vendor reviews were conducted annually, and records retained.

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 ***Shanghai Gongtai Textile Co. Ltd*** located at ***No.2, Fada Road, Taicang City, Jiangsu Province, China*** 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/