20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

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	BASF AGRO B.V. Arnhem (NL) Freienbach Branch Huobstrasse 3, 8808 Pfäffikon SZ Switzerland
Inspected site	
Name & address of inspected manufacturing site(s)	Shanghai Gongtai Textile Co Ltd No.2 Fada Road, Taicang City, Jiangsu Province, China
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	29th February to 1st March 2024
Type of inspection	Re-inspection The inspection was to establish that the applicable requirements of ISO 9001:2015 as well as WHO specific requirements were met.
Introduction	
Brief description of the manufacturing activities	Shanghai Gongtai Textile Co Ltd manufactured Interceptor and Interceptor G2 LLINs on contract for BASF. The activities related to the manufacture of the LLINs included storage, mixing, coating, cutting, sewing, stitching, labeling, packaging, and quality control testing. It was noted that the site was in the process of transferring its activities and equipment to a new site because the current site was to be repurposed for the manufacture of high-end products. A new site had been identified and the process of transfer to the new site was still ongoing. The site intended to maintain the same quality management system, personnel, and equipment at the new location.

General information about the company and site	The site had the following certifications: a) ISO 9001: 2015: Quality Management System Certificate registration Number: 03821Q07026R2M Issue Date: 4/8/2021 Expiry Date: 17/9/2024 **Scope:** ''Finishing of mosquito net cloth, production, and sales of textiles (mosquito nets)'' The certificate was issued by WSF. b) **Business License** Number: 27000000201601050216 Issue Date: 22 July 1995 Expiry Date: 22 July 2035
History	The site was last inspected in 2019 by WHO.
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 • Product release • Batch processing records • Control of changes • Internal audits • Calibration and equipment maintenance **Physical areas:** • Raw material and finished goods • Production areas • Quality control laboratory
Exclusions and Non-applications of requirements in the QMS	Design and development of products were not applicable as the site was not involved in the design and development activities.
Out of scope	The manufacture of other products not submitted to PQ were not included in the scope of this inspection.
Restrictions	None

WHO products covered by the inspection	• Interceptor (Alphacypermethrin 200 mg/m^2) 002-001 • Interceptor G2 (Alphacypermethrin 100 mg/m^2 and Chlorfenapyr 200 mg/m^2) 002-002

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
RPN	Risk Priority Number

Part 2	**Summary of the findings and comments**

1. Quality policy and quality objectives

The quality policy and quality objectives were documented in the quality manual. The extent to which the quality objectives were met was measured and monitored. The target for the different quality objectives had been defined. The quality objectives and quality policy were signed by the General Manager. The quality policy and quality objective were discussed in the management review. The quality objectives and policy were communicated to staff through trainings and departmental meeting.

2. Management review

The management meetings were held at least once every year. The most recent management review report was reviewed. The agenda of the management review meeting included discussions on the following: Quality policy, internal audits, Corrective and preventive measures, process performance and product quality analysis, resource allocation, analysis, and effectiveness of the measures to address risks and opportunities, improvement plan etc. The structure of the meeting was found to be compliant with the standard and structured according to the requirements of the standard. The meeting was attended by the General Manager, department heads and managers.

3. Organizational roles, responsibilities, and authorities

An organogram was in place. The heads of the quality department and production department reported independently to the Management Representative. The Management Representative reported to the General Manager. The roles and responsibilities of the Management Representative, Deputy General Manager and Head, Quality Control department were reviewed.

4. Document control and changes

The procedure for Document change control was reviewed. Documents were categorized into 3 levels, namely:

a) Quality Manual
b) Procedures
c) Supporting documents

The procedure described the numbering, creation, handling of changes related to documents, review, and approval of documents. The management representative was responsible for the review of documents. Documents were approved by the General Manager. The retention time for the different documents were defined.

Changes were also reviewed. The changes were approved by the General Manager. Changes were documented. The documented changes were sampled and reviewed by the inspectors.

5. Personnel competence and training

The relevant procedure for Human Resource control was reviewed. The procedure applied to all personnel engaged in work that affects product compliance including temporary employees and suppliers where applicable. Personnel competence took education, training, skills, and experience into consideration. Training plans were created every year and training records maintained. The training plan for the year 2024 was in place. Training records of the internal auditors and quality control analysts were reviewed. The training records on the following topics were checked: Quality Policy, quality objectives and targets, laws, and regulations. The effectiveness of the trainings was assessed by use of questionnaires.

6. Risk Management

The risk management procedure was reviewed. The manufacturer's approach to risk identification and assessment was described in the procedure. The different categories of risk were also defined. A SWOT analysis (SWOT – Strength, Weaknesses, Opportunities and Threats) was one of the methods used for risk analysis of risks. The risk categories included: Strategic risks, market risks, financial risks, legal risks, operational risk etc. A risk register was also in place. The risk assessment included risks related to production, quality control among others.

7. Internal Audits

An internal audit program for 2023 was in place. The audit program included schedules for auditing of the quality management system covering all sectors and activities including production and laboratory. The internal audit plan for July 2023 was reviewed. The internal audit checklist was in place. The corrective actions and preventive actions were documented on the Improvement and corrective action report and Preventive action execution form respectively. The manufacturer had trained internal auditors. Training certificates of the internal auditors were in place. The Internal auditors had been trained on the requirements of ISO 9001 standard.

8. Control of nonconforming products and complaint handling

The manufacturer had documented criteria for assessment of nonconformities such as holes, tears, stains, missing hooks, missing label that were detected during production. Repairable defects such as missing label were corrected. The corrected/repaired bed nets were inspected again to ensure that they conformed to the specified requirements. All nonconformities were documented. Raw materials that did not meet specifications were quarantined and the supplier informed. The raw material was then returned to the supplier.

Complaints were received by BASF. Complaints were received by the customer service. The investigation procedure included registration of the complaint, investigation, correction, follow-up, and closure. In case of any complaint, the complaint is communicated to Shanghai Gongtai and an investigation conducted together with BASF to determine the root cause and implement corrections

and corrective actions. Complaints were reviewed. BASF was responsible for initiation and handling of recalls.

9. Design and development of products

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

10. Support

Infrastructure and work environment

Personnel were appropriately donned in personal protective equipment (PPE). The equipment were well maintained. The maintenance records of the equipment were in place Materials safety data sheets were also available.

Monitoring and measuring resources

The calibration schedule for equipment was in place. The calibrations records of selected equipment were reviewed.

11. Production and service provisions

Control of Production

The manufacture of Interceptor and Interceptor G2 included weighing and dispensing of raw materials, mixing, curing, cutting, sewing, labelling, and packaging. The raw materials were weighed on a calibrated balance following an approved manufacturing recipe. The manufacturer had a software that recorded the amount of the raw materials introduced into the mixed. The mixed had inbuilt load cells. A clean-in-place program was used to clean the mixer and adjoining pipework and equipment. Cleaning records were maintained. This was followed by coating and heat setting. The pressure of the rollers and temperatures of the different zones of the stenter were monitored. The fabric was sampled for chemical analysis by quality control lab. The fabric was quarantined awaiting approval by the quality control lab. The fabric was then cut, sewed, labelled, and packed. The sewed nets were sampled and analyzed for defects. The sampled nets were sampled for defects such as holes, hanging treads, burst seams, missing hooks, and labels etc. A stitching inspection record with details of the results was maintained. The criteria for sampling of the stitched bed nets for inspection was in place. Some of the labels were printed on site while others are pre-printed by a third party. The manufacturer information on the pre-printed labels was verified prior to use. Production was ongoing at the time of the inspection.

The quality control was well equipped. The balances in the lab were calibrated.
The standard test procedure (following CIPAC method) for determination of Alphacypermethrin and Chlorfenapyr in bed net fabric was reviewed. The test results and raw data for Interceptor G2 lot number 21249408 were reviewed. The calculations were performed using a formula in a protected and locked excel spread sheet. The time was locked. Audit trails were available. The tests for determination of the bursting strength and flammability in the fabric was demonstrated. The primary standards for Alphacypermethrin and Chlorfenapyr were stored as per the manufacturer's instructions. The certificates of analysis for the primary standards were available.

The batch manufacturing records of Interceptor G2 were reviewed. The batch numbers and quantities of the active raw materials used in production of the batch were documented. Samples of the finished net are sent to a third-party lab in Thailand for chemical analysis. The chemical results

from the third-party lab in Thailand were compared with those of the quality control laboratory at Shanghai Gongtai prior to authorizing release of the batch to the customer. The results obtained from Thailand were only for confirmation purposes. Batches were released by Shanghai Gongtai to the customer following approval of BASF.

Control of waste

The manufacturer had a procedure for waste management regulation in place. The records for waste collection were available. The waste was collected and treated by a third-party company.

All the issues raised related to this section were addressed satisfactorily by the manufacturer.

12. Preservation

All the chemical raw materials were supplied by BASF. Inventory records of the raw materials in the warehouse were in place. The greige fabric was inspected for defects upon receipt. The defects were documented in the raw materials quality report. Upon entry into the country, chemical raw materials were sampled at the port of entry, analyzed prior to release of the chemical raw materials to the manufacturer. The manufacturer relied on the Certificate of Analysis provided by BASF and the release of the chemicals by the government authorities. Certificates of Analysis were available. An area for storage of nonconforming materials was in place. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

13. Retention samples

Retention samples of the finished bed net were maintained by both BASF and Shanghai Gongtai. The retention samples were kept for 5 years by BASF.

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

The relevant procedure for supplier evaluation was reviewed. The evaluation of suppliers was performed by the supply and marketing department. The procedure described the criteria for selection and evaluation of suppliers. The list of approved suppliers was in available. Supplier evaluation reports 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 by **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. 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/