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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	Yorkool Chemicals (Cangzhou) Co., Ltd. – Lixian.
Corporate address of manufacturer	Tianjin Yorkool International Trading Co., Ltd F-721, Hi-Tech Information Plaza, #8, Huatian Avenue Huayuan Industrial Park, Tianjin P. R. China
Inspected site	
Name & address of inspected manufacturing site(s)	Yorkool Chemicals (Cangzhou) Co., Ltd Lixian county Sangyuan Industrial Zone, Baoding City, Hebei, P. R. China.
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	04 -06 March 2024
Type of inspection	Re-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	The activities related to the manufacture of Yorkool LN and Yorkool G1 LN at the site included preparation of the coating solution, coating, release testing, storage of treated netting fabric, The activities related to the manufacture of Yorkool G3 LN included production of the master batch, extrusion, knitting, heat setting, storage of treated netting fabric, and release testing. The fabric was tested and released to other subsidiary sites (Bazhou and Gaotang subsites) for further processing. All the manufacturing sites shared the same quality management system. The major change since the last inspection was the commissioning of a new manufacturing line for the production of incorporated bed nets – Yorkool G3 LN. This production of Yorkool G3 LN commenced in June 2023.

General information about the company and site	There was a change in the ownership, the top management, and the organizational structure of the site in 2021. Under the new management, Tianjin Yorkool International Trading Co., Ltd and Yorkool Chemicals (Cangzhou) Co., Ltd were both subsidiaries of Yorkool Group. The ownership of all the manufacturing sites under the management of Tianjin Yorkool International Trading Co., Ltd were transferred to Yorkool Chemicals. The site was certified as indicated below: ISO 9001: 2015: Quality Management System **Scope:** ‘‘Manufacture of Long-Lasting Insecticidal Net’’ Certificate Number: 30722Q20579R1M Reissue Date: 20 October 2022 Expiry Date: 23 September 2025 The certificated was issued by BAC
History	The site was last inspected by WHO in 2019.
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 activities were not undertaken at this site.
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	• Yorkool LN (Deltamethrin -55mg/m^2±25%) - 021-001 • Yorkool G3 LN (3.0g±25% deltamethrin AI/kg + 11.0g ±25%Piperonyl butoxide AI/kg) – 021-003 • Yorkool G1 LN (Deltamethrin - 55mg/m^2) – P11664
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	**Brief summary of the findings and comments (where applicable)**

1. Quality policy and quality objectives

The quality policy and quality objectives were adequately defined in the Quality Manual. The quality policy and quality objectives were displayed at various areas with the production areas. The quality policy and quality objectives were also communicated through trainings. Evidence of training on quality policy, quality objectives, and the company's requirements was reviewed. The quality objectives were measurable. The key performance indicators were defined.

2. Management review

The procedure for management review was discussed. The general manager was responsible for presiding over the management review meeting. The Management representative, in-charge quality department, in-charge sales department other department managers were to participate in the management review meetings. Management reviews were held once every year. Management review meetings could also be held in the event of the following circumstances:

- Major changes in the company's organizational structure
- Major quality incidents or serious customer complaints
- Changes in laws, regulations, and other requirements
- Changes in market demand
- Critical nonconformity found in an external audit

The 2023 management review meeting report was reviewed and found satisfactory. The agenda of the meeting included a review of the following:

- status of actions from previous management reviews
- Performance and effectiveness of the QMS
- Trends in customer satisfaction, performance and conformity of products and services, nonconformities, and corrective actions, monitoring and measuring results, audit results, performance of external suppliers.

3. Organizational roles, responsibilities, and authorities

Leadership and commitment with respect to the quality management system were demonstrated by establishing a quality policy and quality objectives, promoting improvement, and supporting management roles in their areas of responsibility. The commitment was documented in the Quality Manual. The quality manual was signed and approved by the General Manager. An organizational structure indicating the hierarchical and reporting lines was in place. The job descriptions were also available. Job descriptions and responsibilities of key personnel were well defined. The roles and responsibilities of the Quality Control in-charge, Quality Assurance Manager and Production in-charge were described in the quality manual.

4. Control of documented information

The procedure for control of documented information was available. Documents were identified, issued, reviewed, retrieved, and approved in accordance with the established procedure. Documents were approved by the Manager representative. Documents were maintained in hard copy formats. A document distribution and control list was available. The nonconformities related to this section were adequately addressed by the manufacturer.

5. Personnel competence and training

The procedure for training of staff training of staff was available. The 2023 and 2024 training plans were also available. Training records were reviewed. The effectiveness of the trainings was assessed by using questionnaires.

6. Risks Management

The risk management procedure was reviewed. The procedure described the different types of risks including product quality risks, environmental risks, business risks, market risks, financial risks, and opportunities. A risk register was in place. Risks related to the following had been assessed and evaluated: Fire safety, resource management, planning and process control, identification and traceability, labor protection, organizational and environmental risks etc.

7. Control of changes

The procedure for change control was reviewed. Documented information on changes was retained. Changes related to the change in management were reviewed. Change request forms with descriptions of the reviewed changes, the person authorizing the change and actions to be taken were in place. Changes were approved by the Management Representative.

8. Internal Audits

The procedure for Internal Audits and the 2023 audit plan were reviewed. The purpose and scope of the audit were clearly described. The aim of the audit was to verify the suitability and effectiveness of the QMS. An internal audit checklist was also available. The internal audit report and corrective/preventive action plan were also in place.

9. Control of nonconforming products

The procedure for control of nonconforming products described different types of nonconformities, and corresponding actions to be taken. The fabric was inspected for defects such as holes, stains, tears etc. Records of the nonconformities identified during manufacture were maintained.

10. Design and development of products

Design and development of Yorkool LN, Yorkool G1 LN and Yorkool G3 LN were not undertaken at this facility. This site was not involved in design and development activities. This area was therefore not inspected.

11. Performance Evaluation

The performance and effectiveness of the quality management system was discussed in management review meetings. The manufacturer analyzed and evaluated the following to assess the performance of the quality management system

- Process performance and conformity of products and services
- Audit results
- Customer satisfaction and feedback from relevant parties
- Degree of realization of quality objectives
- Nonconformities and corrective measures
- Performance evaluation of external suppliers

12. Support

Infrastructure and work environment

The site comprised of two units; one for production of coated bed nets and the other for production of incorporated bed nets. The two units were separate and in the vicinity of each other. The equipment was relatively well maintained. The procedure for equipment maintenance was reviewed. The procedure described the manufacturer's approach to purchasing, verification, calibration, and disposal of equipment.

Monitoring and measuring resources

The equipment maintenance schedule was in place. The calibration certificates of selected equipment were reviewed.

13. Production and service provisions

Control of Production

The production of Yorkool LN and Yorkool G1 LN involved preparation of the coating solution, coating, release testing, storage of treated netting fabric.

The coating solution was prepared following an approved recipe. The instructions for preparation of the working liquid were described in the procedure for liquid dispensing process. The raw materials used for the preparation of the coating solutions were weighed on calibrated balances. Records of the amount and batch numbers of raw materials used in preparation of the coating solution were maintained in a customized software. Cleaning records were in place. This was followed by coating and heat setting of the greige fabric. The coating solution was pumped to the stenter. The temperature of the different zones of the stenter and pressure of the rollers were monitored. The first piece of the coated fabric was sampled and tested for width, mesh size, fabric weight, and active ingredient content. The coated fabric was then packaged.

The manufacture of Yorkool G3 involved preparation of the master batch, extrusion, knitting, heat setting, storage of treated netting fabric , and release testing. The procedure for the preparation of the master batch and the procedure for sampling were reviewed. The master batch was sampled and tested for active ingredient content, moisture content and appearance. The temperatures of the extruder and water baths were monitored. The yarn was sampled and tested for weight per meter. This was followed by knitting and packaging. The knitted fabric was inspected for defects such as holes and stains. The procedure for extrusion was also reviewed. The inspection records for the extrusion process, knitting record and the raw material weighting record for the extrusion process were maintained. The fabric was released by the QC in-charge to the Gaotang and Bazhou sub-factories for further processing.

Production batch records for Yorkool LN, Yorkool G1 LN and Yorkool G3 LN were reviewed. The extrusion verification and working liquid verification reports were reviewed. Key process parameters were defined and ascertained.

Quality control laboratory

The quality control laboratory was well equipped. The procedure for determination of deltamethrin in the working liquid and the procedure for determination of deltamethrin content in the coated mosquito net were reviewed. Analytical test results and raw data for selected batches were reviewed. The excel sheet used to calculate the deltamethrin was protected. The date and time on the HPLC computer were locked. Laboratory data was backed up on hard drive regularly. Audit trails were activated. The analytical method validation for determination of deltamethrin in mosquito bed nets was also reviewed.

Chemical analysis of Yorkool G3 LN was performed by a third-party company. The agreement between the third-party company and Yorkool Chemicals Co Ltd was checked. The roles of both Yorkool Chemicals Co Ltd and the third-party company were clearly defined.

Waste management

The relevant procedure for production waste management was checked. The waste was collected and disposed of by a third-party company. A contract between contracted third-party company and Yorkool Chemicals Co. Ltd was in place.

Retention samples

The sample management system procedure was reviewed. The sampling criteria were defined. Each batch of the master batch was sampled retained for 3 months. Each sample of the finished bed net was retained and stored for 6 years. The samples of the finished bed net were retained at the subsidiary located at Cangzhou.

The nonconformities related to this section were adequately addressed by the manufacturer.

14. Preservation

Inventory records were maintained. Upon receipt of the raw materials the certificate of analysis and quantity were verified. Materials safety data sheet were available. The liquid raw material inspection procedure was reviewed. The sampling criteria were defined. The warehouse was equipped with an eye wash and fire extinguishers.

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

The purchasing control procedure was reviewed. The performance evaluation of suppliers was conducted yearly. The procedure described the selection and evaluation of suppliers. The management representative was responsible for approval of the qualified supplier list. The criteria for evaluation of suppliers were defined. Suppliers were categorized into 3 namely:
Class A – suppliers of Critical materials
Class B – Suppliers of General materials
Class C – Suppliers of Auxiliary Materials

The supplier evaluation records for 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 **Yorkool Chemicals (Cangzhou) Co., Ltd. – Lixian** located at: **Lixian county Sangyuan Industrial Zone, Baoding City, Hebei, P. R. 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.

World Health Organization

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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/