



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

<b>Part 1</b>	<b>General information</b>
<b>Manufacturers details</b>	
Name of manufacturer	Yorkool Chemicals (Cangzhou) Co., Ltd. – Cangzhou.
Corporate address of manufacturer	Tianjin Yorkool International Trading Co., Ltd F-721, Hi-Tech Information Plaza, #8, Huatian Avenue Huayuan Industrial Park, Tianjin
<b>Inspected site</b>	
Name & address of inspected manufacturing site(s)	Yorkool Chemicals (Cangzhou) Co., Ltd South of Chemical Avenue, West of Jing 4th Road, Coastal-port Economic and Technological Development Zone, Cangzhou China
Unit/Block/Workshop	Not applicable
<b>Inspection details</b>	
Dates of inspection	19, 22 and 23 May 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.
<b>Introduction</b>	
Brief description of the manufacturing activities	The activities related to the manufacture of Yorkool LN at the site included formulation, coating, release testing, storage, labelling. The greige fabric was coated, tested and released to other subsidiary sites for further processing at Bazhou and Gaotang subsites.
General information about the company and site	There was a change in the ownership of the site 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. Yorkool Chemicals (Cangzhou) Co., Ltd – Cangzhou is one of the new sites at which Yorkool LN was manufactured.  This was the first WHO inspection.



	<p>The site was certified as indicated below:</p> <p>ISO 9001: 2015: Quality Management System</p> <p>Certificate Number: 30722Q20579R1M</p> <p>Reissue Date: 20 October 2022</p> <p>Expiry Date: 23 September 2025</p> <p><b>Scope:</b> Manufacture of Long Lasting Insecticidal Net.</p> <p>The certificated was issued by BAC</p>
History	This was the first WHO inspection of the site.
<b>Brief report of inspection activities undertaken – Scope and limitations</b>	
Areas inspected	<p><b>Document review including but not limited to:</b></p> <ul style="list-style-type: none"> <li>• Quality Manual</li> <li>• Training</li> <li>• Risk management</li> <li>• Management review</li> <li>• Job descriptions and responsibilities of key personnel</li> <li>• Complaints</li> <li>• Non-conforming products</li> <li>• Product release</li> <li>• Batch processing records</li> <li>• Control of changes</li> <li>• Internal audits</li> <li>• Calibration and equipment maintenance</li> </ul> <p><b>Physical areas:</b></p> <ul style="list-style-type: none"> <li>• Raw material and finished goods</li> <li>• Production areas</li> <li>• Quality control laboratory</li> </ul>
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 WHO Prequalification were not included in the scope of this inspection.
Restrictions	None
WHO products covered by the inspection	Yorkool LN (Deltamethrin -55mg/m <sup>2</sup> ±25%)



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)
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### 1. Quality policy and quality objectives

A quality policy and quality objectives described in the quality manual. The quality objectives were measurable and monitored. Quality indicators had been defined for each of the quality objectives. The extent to which the quality objectives were achieved was monitored monthly and these were discussed in the management review meeting. The quality policy and objectives were communicated through trainings and meetings. They were also displayed on walls throughout the facility including production areas. The relevant training records on quality policy and objectives were reviewed.

### 2. Management review

The procedure for management review was discussed. Management reviews were held once every year. Management review meetings could also be held in 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 General Manager was responsible for chairing the meetings. The management review minutes were reviewed and found satisfactory.

### 3. Organizational roles, responsibilities, and authorities

Leadership commitment to establish a quality policy and quality objectives for the quality management system, promote improvement and support management roles in their areas of responsibility. The Leadership commitment was described in the quality manual. An organogram showing the organizational reporting structure was in place. The roles and responsibilities of key personnel were reviewed. The job descriptions of the Quality Assurance in-charge, Quality Control Manager, the production in-charge. Quality Control Manager was responsible of the product release.

### 4. Control of documented information

The record control procedure was reviewed. The record procedure described the creation, storage and control of records. A document distribution list was in place.

### 5. Personnel competence and training



The relevant procedures for training of staff and training of the management team were reviewed. A training plan was also available. The training plan was populated with information on the different topics, timelines, trainers etc. Training evaluation forms were in place. Other information on training retained included training notices which indicated the topics, the trainers' names, the dates of the training, and the list of participants. Induction training records were reviewed and found adequate.

## **6. Risks Management**

The procedure for risk management was reviewed. The scope included internal and external factors affecting products and related activities. The different types of risks were defined, and these included direct product quality risks, environmental risks, indirect quality risks and opportunities, business risks, market risks, financial risks etc. The criteria for identification and evaluation was defined. A risk matrix was in place.

## **7. Control of changes**

The relevant change control procedure was in place. Changes were approved by the Management Representative. A change request form was in place. Change control records related to change of SOP for inspection of packaging process was reviewed and found satisfactory.

## **8. Internal Audits**

The internal audit procedure was reviewed. Internal audits were conducted at least once every year. The purpose of the procedure was to assess whether the quality system was effectively implemented and maintained and to ensure the continuous improvement of the system. The audit criteria was based on GB/T19001-2016 and ISO 9001:2015 QMS. An annual audit plan was in place. The annual audit plan was approved by the Manager Representative and developed by the QA In-charge. Templates of the audit checklist, Report and Corrective/preventive Action plan were in place.

## **9. Control of nonconforming products**

The procedure for control of nonconforming products was reviewed. The procedure described the different types of nonconformities, and action to be taken. The fabric was inspected for defects such as holes, stains tears etc. Records of identified defects during the manufacturing process were maintained. Records of collected unqualified fabric (nonconforming fabric) was to be disposed by a third-party company responsible for management of waste were in place.

## **10. Performance evaluation**

The relevant procedure for data analysis control was in place. The performance and effectiveness of the quality management system was assessed by evaluation the following data and information among others:

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

The data analytical report for finished products for 2022 was reviewed. The analysis was performed monthly. The data and trends from the above parameters were discussed in management review.

## **11. Design and development of products**

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

## **12. Customer satisfaction**

The relevant procedure for customer satisfaction was reviewed. Customer satisfaction surveys were conducted using questionnaires. The information collected from customers in the survey was related to the following: product quality, timeline for delivery, product packaging, service attitude and overall satisfaction. The customer satisfaction survey report was available. This was found satisfactory.

## **13. Complaints**

The customer quality complaint management system procedure was reviewed. Only one complaint had been received by the manufacturer. The complaint was related to sewing of nets to the packaging material was reviewed. Investigation and corrective actions were documented. Training records for the staff engaged in packaging at Bazhou and Gaotang sub-factories were also in place. List of attendees and evaluations forms were available.

## **14. Support**

### **Infrastructure and work environment**

The site comprised of 3 main buildings. One building housed the administration and laboratory, the next building housed the warehouse for the raw materials and the other building housed the formulation areas (mixing, weighing, fabric treatment). This was a new facility with newly constructed and installed infrastructure. The operators were gowned in appropriate personal protective equipment.

### **Monitoring and measuring resources**

An equipment maintenance plan was in place. Maintenance checklist for the mixing tanks was reviewed. Maintenance schedule was also in place. Calibration certificates for balances and the load cells in the mixing tanks were verified.

## **15. Production and service provisions**

### **Control of Production**

Only Yorkool LN was manufactured at the site. Production activities related to the manufacture of Yorkool LN at this site included preparation of coating solution (working liquid), coating, heat setting, labelling, release testing and storage. The coating solution was prepared in a closed system. The amounts of ingredients were controlled using a customized software. A documented recipe was in place. The software was used to monitor the different processing parameters such as mixing time. The coating solution was tested for deltamethrin content prior to the coating process. The pressure of the rollers, speed, and temperature of the stenter were monitored. The first piece of the coated fabric was sampled and tested. The coated fabric was inspected for defects such as holes, stains etc. and records maintained. A clean-in-place program was used to clean the production equipment.

The ‘Production verification report of the liquid dispensing process’ was reviewed. The purpose of the verification was to ensure stable and uniform coating process and that the process meets key process parameters such as stability, uniformity and deltamethrin content.



Production batch records for Yorkool LN were reviewed. The fabric was released by the QC in-charge to the Gaotang and Bazhou sub-factories for further processing.

Quality control lab

The laboratory was in a separate building from the production areas. Samples in the laboratory were adequately labelled and identified. Production samples were collected by the QC personnel. The standard operating procedure for inspection of working liquid and raw materials was reviewed. The procedure defined the sampling criteria for the raw materials, working liquid and coated fabric. The procedure for analysis of deltamethrin in coated was reviewed. The analytical test report for Yorkool LN was reviewed. The raw data was available. The excel sheet used for calculation of Active ingredient content was locked. The date and time on the computers in the laboratory were locked. Audit trails were activated. The analytical test reports were reviewed by the QC in-charge.

Waste management

The relevant procedure for production waste management was reviewed. The inventory record and the In/Out Warehouse receipt form were reviewed. A contract with third-party company responsible for safe disposal of the waste was available.

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

**16. Post-delivery Activities**

Each batch was sampled. The samples were stored at ambient temperatures. The sample management system procedure was reviewed. The sampling criteria were defined. The samples were stored for 6 years.

**17. Preservation**

The procedure for warehouse management was reviewed. Inventory records were in place. Material safety data sheets were in place. Upon receipt of the raw materials the quantity was verified. The raw materials containers were sampled following an established sampling plan. The warehouse was equipped with fire extinguishers.

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

The purchasing control procedure was reviewed. The management representative was responsible for approval of the qualified supplier list. The criteria for evaluation of suppliers was defined. The performance of suppliers was conducted yearly. The supplier evaluation records were reviewed and found satisfactory.

<b>Part 3</b>	<b>Conclusion – Inspection outcome</b>
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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. – Cangzhou.** located at: **South of Chemical Avenue, West of Jing 4th Road, Coastal-port Economic and Technological Development Zone, Cangzhou 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.

<b>Part 4</b>	<b>List of Standards and Guidelines referenced in the inspection report</b>
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1. Quality management systems – Requirements, International Standard (ICS 03.120.10), 5<sup>th</sup> 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/>