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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	Decotex Co. Ltd
Corporate address of manufacturer	Decotex Co Ltd: Lot II-2A, Road CN13, Tan Binh Industrial Park, Tan Phu District, Ho Chi Minh City, Vietnam
Inspected site	
Name & address of inspected manufacturing site(s)	**Site Name:** Decotex Co. Ltd **Address 1:** Lot 26 Road No. 7, Tan Duc Industrial Park, Duc Hoa Ha Community, Duc Hoa District, Long An Province, Vietnam **Address 2:** Texina Lot 21, Road 9, Tan Duc Industrial Park, Duc Hoa Ha Community, Duc Hoa District. Long An Province, Vietnam **Address 3:** Lot A8B, Road No. 4A, Hai Son Industrial Park, Duc Hoa Ha Community Du Hoa District, Long An Province, Vietnam
Unit/Block/ Workshop	Not applicable.
Inspection details	
Dates of inspection	06-07 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	Decotex Co. Ltd manufactures knitted decorative fabrics such as window curtains and bed nets. Decotex manufactures Interceptor and interceptor G2 on contract for BASF Agro BV. Below are the activities carried out at the inspected sites: Warping, Knitting and curing were carried out in adjacent buildings as indicated in a) and b) below: a) Decotex Co. Ltd: Lot 26 Road No. 7, Tan Duc Industrial Park, Duc Hoa Ha Community, Duc Hoa District, Long An Province, Vietnam.

	Activities related to the manufacture of LLIN included ware housing of the yarn, warping and knitting. b) Decotex Co. Ltd: Texina Lot 21, Road 9, Tan Duc Industrial Park, Duc Hoa Ha Community, Duc Hoa District. Long An Province, Vietnam Activities carried out included curing and warehousing of the bed nets. c) Decotex Co. Ltd: Lot A8B, Road No. 4A, Hai Son Industrial Park, Duc Hoa Ha Community Du Hoa District, Long An Province, Vietnam. This site was located about 2 Km from the above indicated addresses. Activities carried out at this site included cutting, sewing and stitching, labeling and packaging.
General information about the company and site	Decotex Co. Ltd was ISO 9001 certified. ISO 9001:2015 certificate number VN19/00373, Valid from 09 December 2019 to 09 December 2022. Issued by SGS. Scope: Manufacturing and distribution of mosquito net products for public health and domestic and decorative use, forest protection, covering agricultural, horticultural and forestry crops and other industrial and domestic application. Decotex Co. Ltd also held an investment certificate number 412043000215 issued by the Export Processing and Industrial Zones Authority, 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	Interceptor (200 mg/m^2 Alphacypermethrin) Product number: 002-001 Interceptor G2 (200mg/m^2 Chlorfenapyr 100mg/m^2 Alphacypermethrin Product number: 002-002
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 (where applicable)**

1. Organizational roles, responsibilities and authorities

The organizational chart approved by the General manager was reviewed. The organizational chart adequately reflected the reporting hierarchy of the company. The quality control and production departments were independent of each other with different reporting lines. The job descriptions of the Plant Manager and QC/QA Manager were reviewed. Roles and responsibilities were adequately defined. The QC/QA Manager was responsible for product release.

2. Quality policy and quality objectives

The quality policy included a commitment for continual improvement of the quality management system and was appropriate to the purpose of the organization. The quality objectives and respective key performance indicators were clearly defined. The quality objectives were monitored and measured. The quality objectives and policy were displayed throughout the facility.

3. Management review
Management review meeting were conducted in accordance with the established procedure. Management review meetings were held annually. Only one meeting had been held as the QMS had been implemented in mid-2019. Management review took into consideration information on the performance and effectiveness of the quality management system.

4. Leadership
The quality policy and quality objectives were approved by top management. The quality objectives were consistent with the quality policy. Top management ensured integration and implementation of the quality management system through internal audits and management review meetings. The manufacturer determined and provided the resources needed to implement the QMS, to maintain its effectiveness, and to meet regulatory and customer requirements.

5. Control of documented information
The relevant procedure for document and record control was reviewed. The procedure described the creation, distribution and retrieval of documents. Documented information was available in hard copy. The supervisors of each department were responsible for the distribution and retrieval of hard copies. The master list of documented information and distribution lists were available. The retention period for documents, records and forms was defined.

6. Personnel competence and training
The relevant procedure for training was reviewed. The necessary competences of personnel had been determined. Training plans for the year 2019 and 2020 were available. Records for the induction training, on-job trainings and external trainings were available. Training evaluation and effectiveness were assessed. Staff involved in auditing had been adequately trained by an external company and all training certificates were available.

7. Risks and opportunities
The relevant procedure for Risk Management was reviewed. The procedure had a well-documented risk matrix that was followed. The risk analysis covered the following areas among others; planning, knitting, Quality control, Production-cut and sew, inventory, import and export, maintenance etc.

8. Control of changes
The procedure for control of changes was reviewed. The procedure described the review and control of changes. The procedure allowed for the evaluation and impact assessment of the change. The QA in-charge was responsible for authorizing changes. No changes had been registered since the implementation of the QMS mid-2019. Changes were to be discussed in management review meetings.

9. Internal Audits
The procedure for internal audits was reviewed. The internal audit report for the year 2019 was reviewed. Internal audits were conducted by a team of qualified internal auditors who did not audit their own area. Findings from the internal audits were discussed at management review meetings. Appropriate corrections and corrective actions were taken and documented.

10. Control of non-conforming products

The procedure for non-conforming output control was in place. The procedure described how non-conforming products were to be handled and controlled. The procedure allowed for investigations. The QA department was responsible for investigating, analyzing and determining the root cause. Corrective actions following the investigations were performed following the procedure for corrective actions. BASF; the contact provider; was responsible for performing recalls.

11. Performance evaluation

Parameters to be monitored and measured included amount of waste material, staff and client satisfaction among others. The process of data analysis began in June 2019 and was still in its infancy stage. The results of the analysis were discussed in management review. This section will be reviewed further at the next inspection.

12. Complaint handling

The customer satisfaction evaluation and complaint handling procedure was reviewed. The procedure was followed. Complaints were adequately reviewed and investigated. Record were maintained.

13. Design and development of products

Design and development were excluded from applications and requirements of the ISO 9001: 2015 standard.

14. Support

Infrastructure and work environment

The facility was well maintained and clean. Staff were wearing PPE appropriate to the manufacturers requirements as specified in the gowning procedures. There was no sign of pests within the buildings.

Monitoring and measuring resources

Maintenance and repair procedure was reviewed. A maintenance schedule was in place. Weekly and annual maintenance records were in place. Maintenance records for Knitting machines were reviewed.

15. Production and service provisions

Control of Production

The manufacture of Interceptor involved warping, knitting, preparation of the chemical solution, impregnation (coating), stentering, cutting, sewing and packaging. Yarn was warped into bobbins. The bobbins were adequately labelled with information on denier, length and width etc. These were then transferred to the knitting section. Knitting records were maintained. Information on RPM, GSM, mesh size, and other material specification was documented in the knitting records. The equipment numbers were also documented to enable traceability. The knitted fabric was then transferred to the chemical treatment area. A master formula for the preparation of chemical solution was available. Graduated mixing tanks were used to determine the volumes used in the preparation of the chemical solution. The stenters were uniquely identified. The roll pressures, speed, temperature at which the fabric was dried, pH of the chemical solution and wet pick up were

monitored. Batch numbers of the chemical raw materials used to prepare the chemical solution and machine numbers of the stenters were recorded to enable traceability. 100% of the coated fabric was inspected for defects such as holes, tears, presence of extraneous material etc. The inspected fabric was then cut, sewed and labelled according to customer requirements. Labels were adequately controlled. Records of issuance of labels and usage were in place. Label information was verified and approved by the quality assurance department. The measuring tapes used to measure the length and width of the fabric to be cut were calibrated. 100 % of the sewed bed nets were inspected for workmanship and defects such as holes and tears. Records were retained.

The bed nets were then packaged and baled according to customer requirements. Completed batch production records were reviewed. The process for the manufacture of Interceptor G2 was similar to that of Interceptor. No commercial batch of Interceptor G2 had been manufactured at the site at the time of the inspection. The production of bed nets was segregated from the other general products such window curtains.

Each batch of the bed nets were then sampled and sent to an external laboratory, TUV Rheinland Vietnam Co. Ltd laboratory for physical and chemical analysis. TUV Rheinland Vietnam Co. Ltd laboratory is located at 1st Floor No 10 Street No 4. Quang Trung Software City Dist 12 Ho chi Minh City Vietnam.

Identification and traceability
Material were identified, and status indicated.

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 and finished products were stored in separate warehouses. Yarn was sourced from approved vendors. Chemical raw materials were supplied by BASF. All the raw materials were supplied along with the certificates of analysis, packing list and delivery note. The quantities of the raw materials were verified upon receipt. The raw materials were store at ambient temperatures. Inventory control records were in place. Inventory records provided details of the names of the materials, quantities received, expiry dates, quantities issued etc. MSDS were in place.

17. Post-delivery Activities
Storage stability studies had been performed by BASF. There was no available documentation on site. The relevant procedure for retention of samples was in place. Samples were retained for 4 years. Retention samples were stored at ambient temperatures, away from direct sunlight. The samples were adequately labelled. Inventory records were available.

18. Control of externally provided processes, products and services
The Supplier Evaluation Procedure was reviewed. The procedure described assessment, evaluation and approval of suppliers. Assessment of suppliers was performed by use of questionnaires. Onsite audits could be performed with the approval of the General Director. The approved supplier list was available. Supplier evaluation records 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, the following sites

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were 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/