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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	Sunshine World Net 2003 Co. Ltd
Corporate address of manufacturer	BASF AGRO B.V. Arnhem (NL) Zürich Branch Im Tiergarten 7 8055 Switzerland
Inspected site	
Name & address of inspected manufacturing site(s)	Sunshine World Net 2003 Co. Ltd 18/2 Moo 7 Rattanatibet Rd, Nonthaburi, Muang district, 1100, Thailand
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	03-07 May 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	Sunshine World Net 2003 Co. Ltd manufactures Long Lasting Insecticide Nets (LLINs) on contract for BASF. The site only manufactured two brands of LLINs – Interceptor and Interceptor G2. Due to Market forces and demand it was stated that the facility currently manufacturers Interceptor G2 mainly. It was also stated that Interceptor was last manufactured more than three years ago. The manufacture of Interceptor G2 commenced in 2018. The manufacturing process including the process and quality controls related to the production of Interceptor and Interceptor G2 were inspected.

General information about the company and site	The manufacturer held the following ISO certificate: **ISO 9001: 2015: Quality Management System** Scope: ‘‘Manufacture Long Lasting Insecticide Mosquito Nets (LLINs) for Local Market and Export World-wide.’’ Registration Number: QMS/15/R66/0008 Recertification date: 01 November 2022 Expiry Date: 10 October 2025 The certificate was issued by Certification Partner Global (CPG).
History	This site was last inspected by WHO in September 2018. The manufacture had scaled up the production of Interceptor G 2 since the last inspection. The nonconformities raised in the previous inspection were verified and found satisfactory.
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	• 002-001 – Interceptor (Alpha-cypermethrin - 200 mg/m^2) • 002-002 - Interceptor G2 (200 mg/m^2 Chlorfenapyr, 100 mg/m^2 Alpha-cypermethrin).

Abbreviations	**Meaning**
CoA	Certificate of analysis
FMEA	Failure Modes and Effects Analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
LLIN	Long Lasting Insecticide Nets
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 manufacturer had established quality objectives and quality policy in place. The quality policy included a commitment to comply with regulatory requirements and to maintain the effectiveness of the QMS. The quality objectives were measurable and had defined targets. The quality policy was displayed in various areas within the facility. Staff interviewed during the inspection were aware of the manufacturer's quality priorities. Key performance indicators had been defined for each of the quality objectives and the level and extent to which the quality objectives were achieved was monitored and measured. The level and extent to which the quality objectives were achieved was discussed in management review meetings.

2. Management review

Documented requirements for management review were implemented and the review meetings were to be held regularly every 6 months according to the relevant procedure. The manufacturer monitored and measured the ability of the quality management system processes to meet planned results. It was evident from most of the information reviewed during the inspection that Top Management was committed to the development and implementation of the QMS. The minutes of the most recent management review meeting were reviewed. The minutes included review of the following: Internal audits, external audits, customer complaints, customer satisfaction and feedback, quality objectives and change control etc.

3. Organizational roles, responsibilities, and authorities

The manufacturer had an organogram in place with independent reporting of the quality and production to the Managing Director. Job description and roles of the production manager included preparation of the key performance indicators (KPIs) and monitoring of the performance of production to achieve objectives. The production manager was also responsible for production planning. The responsibilities of the Quality Control manager/Quality Assurance Head included investigation of quality issues and participation in preparation and review of KPIs. The Quality Assurance Head was responsible for product release.

4. Control of documented information

The quality and environmental management systems manual described the interaction between the processes of the Quality Management System (QMS) and defined the structure of the documentation system. Documents were prepared, reviewed, approved, and distributed in accordance with the document control manual. Documents were issued, revised, distributed, and retrieved in accordance with the procedures described in the document control manual. Electronic data was backed-up on a server and then transferred weekly to another supplementary server.

5. Personnel competence and training

The training procedure was reviewed. The necessary competence of personnel performing work affecting product quality had been determined. The 2024 annual training plan was in place. Training needs were reviewed annually. Training records of both practical and written tests were conducted to assess the effectiveness of trainings.

6. Risks Management

The procedure for Risk analysis and assessment was reviewed. The failure modes and effects analysis (FMEA) was used to identify of risks. The criteria for determination of the impact and likelihood were described. The procedure also defined the criteria for determination of the RPN and categorization of risks were also defined. A risk register was in place. Risks and opportunities to the company, stakeholders, objectives and goals, processes and products were reviewed. Risk analysis was performed using the 4M approach (Material, Method, Machine, Man).

7. Internal Audits

The procedure for internal audits was reviewed. An internal audit schedule was in place. Internal audits were conducted twice a year taking into consideration the importance of the area to be audited and status and results of previous audits. The internal audits were conducted by appropriately qualified auditors independent of the areas being audited. Records of internal audits were available.

8. Control of nonconforming products

The procedure for handling of non-conforming products was in place. Nonconformities were reviewed. Investigations were performed and the actions taken documented.

9. Design and development of products

Design and development activities of were not undertaken at this site.

10. Support

Infrastructure and work environment

The facility was well maintained. The personnel were appropriately gowned. The preventive maintenance plan for 2024 was reviewed. The maintenance report for the mixing tanks were checked.

Monitoring and measuring resources.

The 2023 calibration plan for laboratory equipment and instruments was in place. The calibration records for the GC were checked. The GC was calibrated annually by an external company. Calibration records of selected balances were also checked.

11. Production and service provisions

Control of Production

The untreated fabric from approved suppliers was inspected for defects such as holes, dirt etc. The physical test performed on the untreated fabric included GSM, size, number of holes per square meter, bursting strength etc. The fabric inspection records were maintained.

The manufacture of Interceptor and Interceptor G2 involved the weighing and dispensing of raw materials, mixing, curing, cutting, sewing, labelling, and packaging. The manufacturer had software that recorded the amount of the raw materials introduced into the mixing tank. The mixer had inbuilt load cells. Selected parameters including pressure of the rollers, temperatures of the stenter zones etc were monitored. The fabric was sampled for chemical analysis by quality control lab and then cut, sewed, labelled, and packed. The sewed nets were sampled for defects such as holes, dirt, burst seams, missing hooks, and labels etc. A sewing inspection record was maintained. Label control was verified. The label artwork was verified by QA. Production records were maintained. Batch production records were reviewed. Batch numbers of the raw materials used in production of the bed nets were traceable.

The QC laboratory was separated from production areas. The laboratory has been designed and equipped with facilities for chemical and physical testing. The laboratory had adequate space for the orderly placement of equipment and materials and to perform tests. Appropriate specifications were established.

Waste management.

The procedure for waste management was reviewed. The safety officer was responsible for management of waste. The objective of the procedure was to ensure appropriate control and separation of liquid from solid waste and to ensure that all the production activities are properly controlled, and waste disposed according to the relevant standard and laws of the country.

The solid and liquid waste was collected and stored at a central location. This was later collected by an approved third-party waste treatment company for treatment and disposal.

Retention samples

Retention samples were stored separately at ambient temperatures. Adequate quantities of the retention samples were retained. The samples were appropriately labelled.

12. Preservation

There were separate warehouses for storage for raw materials and finished products. The working instructions for receipt of chemicals were reviewed. Material safety data sheets were in place. A checklist for receipt of materials was in place. Inventory records were maintained. Materials were stored at ambient temperatures. The temperatures of the chemical warehouse were monitored. Dedicated areas for storage of nonconforming materials were in place.

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

The selection and evaluation of the performance of suppliers of the chemical raw materials was performed by the BASF. The manufacturer only selected and evaluated the performance of the suppliers of fabric and other accessories.

The procedure for selection and evaluation of suppliers was reviewed. The criteria for selection and evaluation of suppliers were defined. The managing director was responsible for approval of suppliers. The evaluation of suppliers was conducted every six months. An approved supplier list was in place. The supplier evaluation reports of selected suppliers 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 **Sunshine World Net 2003 Co. Ltd** located at: **18/2 Moo 7 Rattanatibet Rd, Nonthaburi, Muang district, 1100, Thailand** 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/