World Health Organization

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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	Sanit & Sons Co., Ltd
Corporate address of manufacturer	Callington Haven Pty Ltd 30 South Street, Rydalmere, NSW, 2116 Australia
Inspected site	
Name & address of inspected manufacturing site(s)	Sanit & Sons Co., Ltd: 177 Moo 6, Pakha Banna, Nakhon Nayok 26110 Thailand
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	17 -19 April 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.
Introduction	
Brief description of the manufacturing activities	The manufacturer manufactured aerosols. The activities related to the manufacture of the insecticides (aerosols) involved mixing, filling, crimping, and packaging.
General information about the company and site	This was the first WHO inspection. The manufacturer had the following certifications: **ISO 9001:2015** Certificate number:TH15/8398 Valid from 3 February 2021 until 3 February 2024 Scope: ‘‘Manufacturing and packing service providing of Aerosol and Non Aerosol products(Chemical used in household insecticide, Air care, Disinfectant) and industries (Contact cleaner, Spray lubricant)’’. The certificate was issued by SGS.

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	ISO 14001: 2015 Certificate number: TH18/11222 Valid from 20 July 2021 until 20 July 2024 Scope: ‘‘Manufacturing and packing service providing of Aerosol and Non Aerosol products(Chemical used in household insecticide, Air care, Disinfectant) and industries (Contact cleaner, Spray lubricant)’’. The certificate was issued by SGS. The manufacturer also had a GMP certificate, reference number 1-5-04-17-20-0140. Issued on 25 December 2020. Valid until 24 December 2023. The manufacturing site was found to be compliant with current Cosmetics Good Manufacturing Practice. The certificate was issued by Food and Drug Administration, Cosmetics and Hazardous Substances Control Division, Thailand.
History	This was the first WHO inspection of the site.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	**Document review included but was 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 were not applicable as the site was not involved in design and development.
Out of scope	The manufacture of other aerosols and other products not submitted to PQ were not included in the scope of this inspection.

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Restrictions	None
WHO products covered by the inspection	• Callington 1-Shot Aircraft Insecticide (2% Permethrin, 2% d-Phenothrin) – P-09038 • Callington Pre-Spray Aircraft Insecticide (2% Permethrin) - P09039 • Callington Aerosafe Aircraft Insecticide (2% d-Phenothrin) - P09040
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 manufacturer had an established quality policy and quality objectives. The quality policy was stated as follows: ‘‘We strive to produce quality products that satisfy customer requirements, deliver on time, meet legal standards and effective resource allocation for continuous development and improvement.’’ The quality objectives were measured and monitored. Key performance indicators (KPIs) had been defined for each quality objective. The KPIs were reviewed monthly. The extent to which quality objectives were met was discussed in management review. The quality policy was displayed within the facility at various location and was available of the manufacturer’s website.

2. Management review

Management review minutes for year 2022 were reviewed. The agenda for the meeting included: Context, external and internal interested parties, Actions from previous review, internal audits, external audits, customer satisfaction, complaints, KPI review, Corrective actions and preventive actions, nonconformities, performance of externa providers, Changes, Quality policy, improvements, and feedback. Opportunities for improvements had been identified. This was found satisfactory.

3. Organizational roles, responsibilities, and authorities

An organogram was in place. The job description of the QA Manager and Production Manager were reviewed. Among other responsibilities the QA Manager was responsible for approving test results while the Production Manager was responsible for supervising and monitoring the operations of each production line. The QA manager reported to the Managing Director while the Production Manager reported to the Plant Manager. The Plant manager reported to the Managing Director.

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4. Control of documented information

The procedure for document control was reviewed. The procedure applied to every management system of the organization. The objective of the procedure was to ensure that issuance, retrieval, storage, changes were controlled and to ensure that all documents in system were always up to date and the latest document was in use. Documents related to Quality and Environmental management had to be approved prior being used and had to be approved if there any revisions were made. The procedure described the document issuance and retrieval and control of changes among others. It also stated that pencils were not to be used to record data. Changes were documented on the 'Document Action Request form'. Documents were reviewed yearly.

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

5. Personnel competence and training

The Training and Development procedure was reviewed. The purpose of the procedure was to train and transfer knowledge and improve level of understanding to the required level. Training was categorized into:

- Orientation basic training
- On the job training
- In-house training
- External training

Trainings were evaluated. The roles for the Supervisors, Coaches, Head of Department (HOD), Quality Management Representative and Environmental Management Representative were defined. Training records were maintained. On-the-Job-training records for mixing and filling were reviewed.

6. Risks Management

The relevant procedure for risk management was documented in the Quality Manual. The tools used for identification, analysis and evaluation of risks and opportunities included PESTLE, (Political, Economic, Social, Technological, Legal, Environmental), SWOT (Strengths, Weaknesses, Opportunities, Threats) and FMEA (Failure Modes and Effects Analysis). Risk registers were in place. The risk assessment considered the severity of risk/impact, likelihood of occurrence, probability of detection among others. Risk mitigation measures/actions were defined.
All the issues raised related to this section were addressed satisfactorily by the manufacturer.

7. Control of changes

The relevant procedure for control of changes was reviewed. The objective of the standard was to establish a standard for control of changes that affect product quality or facility management. The responsibilities of the different departments/teams were defined. For example, the Quality Control (QC) was responsible for inspections and tests, provide samples, control plans, evaluate process capability, evaluate the measurement processes and issuing a certificate of Analysis (CoA). Manufacturing and other departments create work standards and check sheets in alignment with the control plan. The procedure provided for review of the impact of the change prior to approval. Changes were documented on the Change Control Form. Changes related to adjustment of specification for bulk filling and gassing were reviewed.

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8. Internal Audits

The internal audit procedure was reviewed. The procedure was applicable to all departments. The objective of the procedure was to evaluate the Quality and Environmental management Systems and determine the company's compliance to ISO 9001, GMP and ISO 14001 standards. And additionally, to also ensure continuous improvement to the Quality and Environmental management systems. Responsibilities of the Auditee, Auditor and Quality Management Representative/Environment Management Representative were defined.

The Audit plan for 2023 was in place. The departments to be audited included: Departments included Quality Management System, QC, Mixing Production, Planning, Warehouse including FG, Logistics, Document Control, HR and Training, Calibration, Engineering, Maintenance, Information Technology and Customer Services. The procedure provided for root cause investigation, corrections, corrective actions and follow up. The follow up was done by original auditor within 5 days of implementation.

9. Control of nonconforming products

The procedure for handling on nonconforming products was reviewed. The procedures applied to all processes that do not meet requirements including raw materials, packaging materials or products. The procedure provided for root cause investigation, corrective, and corrective actions. Nonconforming products were to be identified to prevent their use. Records related to nonconforming products were documented on a Nonconformity report.

10. Performance evaluation

The manufacturer evaluated the performance of external providers, the degree of customer satisfaction, complaints and the performance and effectiveness of the quality management system. These were analysed by use of graphs and 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

Customer satisfaction surveys were conducted using questionnaires yearly. The customer satisfaction score/criteria was/were defined. If any of the metrics scored below 80%, the concerned department would then need to put in place actions for improvement. Customer satisfaction survey report for the year 2022 was reviewed. The data collected was related quality of the product, communication, delivery, and service. The customers were all satisfied with the products from Sanit and Sons Co. Ltd.

13. Complaints

Callington was responsible for receipt of market complaints related to WHO product. Callington was also responsible for product recalls. The procedure for customer complaints was discussed. The sales department was responsible for receiving the complaints. The complaints were the communicated to the Quality Management Representative that instituted an interdepartmental team to investigate the complaint. The procedure provided for root cause investigation, corrective, and corrective actions. Complaints were documented on the Non conformity report. A compliant register was in place. Complaints were reviewed.

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14. Support

Infrastructure and work environment

The infrastructure was generally well maintained. A house keeping program was in place

Monitoring and measuring resources

A calibration schedule was in place. The calibration schedule for the year 2023 was reviewed. Maintenance records for the filling machine were also reviewed. The maintenance was performed as scheduled. Calibration certificates for the balances and Hydrometer were in place.

15. Production and service provisions

Control of Production

Callington 1-Shot Aircraft Insecticide, Callington Pre-Spray Aircraft Insecticide or Callington Aerosafe Aircraft Insecticide were manufactured on a line that was dedicated to the manufacture of insecticides. The manufacture of aerosols involved mixing, filling, crimping, and packaging. The inspectors visited the weighing areas, mixing area, filling, and packaging line. At the time of the inspection the manufacture of Callington Aerosafe Aircraft Insecticide was ongoing. A master formula was in place. The mixing time was monitored. The mixture was sampled and tested by Quality Control for density and appearance prior to filling. Empty cans were loaded into molded holders. The bulk was transferred to the filling room and via an adaptor and tube manifold to the filling needles. The tubes and needles were primed prior to the filling process. The cans were filled with the propellant valves inserted and secured. In process checks included crimp width and crimp depth. Weight checks were done to ensure correct mass was added. The filled and crimped cans were checked for leaks by passing them through a water bath. The filling line was equipped with a checker weigher. The cans were labelled online with the batch number, date of manufacture and expiry date. The cans were then manually capped and packaged. The packaged cans were weighed.

Batch records for the following products were reviewed:

- Callington 1-Shot Aircraft Insecticide
- Callington Pre-Spray Aircraft Insecticide
- Callington Aerosafe Aircraft Insecticide

The batch numbers of the raw materials used for production were recorded. The Procedure for cleaning of equipment was reviewed. The equipment train included among others equipment in the mixing room such as Mixing tank 150 and 200 L drum and 400 and 100 L mixing tank.

Confidence in manufacturing checks and processes

The current manufacturing checks and processes for all insecticide aviation aerosol products were considered suitable to ensure the integrity of the finished product active content to specification.
This included the following: Agreed Specification of purity and isomer ratio between Callington and the Raw Material Supplier of the active, Regular audits of the Raw Material Supplier, Certificate of Analysis provided for each batch of active provided, Quality checks of key specifications of active material at the manufacturer on receipt, Accurate weighing of active material into production batches, Accurate weighing of all excipients into production batches, Accurate weighing of concentrate and product into the final can, Check weights of concentrate dosage at regular intervals, 100% check weigh for every can, 100% check weigh for every carton.

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Consistency of manufacturing process as measured by density of bulk concentrates

Callington and Sanit had conducted an extensive study of bulk concentrate densities for each aircraft insecticide product over a period of six to twelve months. Based on this data, Callington updated the density specifications for each product. The results also demonstrate high precision and repeatability achieved during manufacturing each of the products, giving high confidence that the correct amount of insecticide active was consistently and accurately added to every batch of each product.

Margin of uncertainty allowed by the WHO specification

The WHO specifications allowed a tolerance of ± 15%, which for a product containing 2% w/w of actives, gives an allowable range of 1.7 %w/w – 2.3% w/w. All data supplied by Callington met the specifications.

Quality Control laboratory

The laboratory was neat and clean. The analytical tests conducted included bulk weight, propellant weight, Clinch diameter, Clinch depth, Odor, Spray Pattern, Temperature, Leak test etc. These tests were as indicated on the Certificate of analysis.

An electronic sample register was in place. In-process test reports for the Callington Aerosafe Aircraft Insecticide mixture were reviewed. The products were released by the QA Manager. The balances in the laboratory were calibrated and records maintained.

Waste management

Waste was collected at the stored at the scrap area. The waste material at the scrap area was later collected by a third-party company for treatment and disposal.

Stability studies

The following stability study reports were reviewed:

- Accelerated Storage Stability and Container Content Compatibility of Callington pre-spray (2% Permethrin aerosol)
- An accelerated Storage Stability Study for Callington 1-Shot Aircraft Insecticide

The studies were conducted at 40°C for 8 weeks. The studies supported the assigned shelf life of 4 years.

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

16. Post-delivery Activities

A sample of every batch was retained. The samples were stored at ambient temperatures. Information on the name, batch number, date of manufacture, expiry date and date of receipt was retained.

17. Preservation

Inventory was managed by use of the ERP software and stock cards. The Status of the materials (Approved, quarantine or rejected) were indicated in the ERP. The ERP software also indicated the approved suppliers and product codes for the different materials. The temperature in the finished goods warehouse and components/packaging material warehouse was ambient. The temperature in

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the raw materials warehouse was controlled and monitored. Materials under quarantine were identified as so and stored in a segregated area. Ethanol was stored in bulk in a tank. The Ethanol was contained in 2 tanks which shared common pipework. Materials were received along with the certificate of Analysis (CoA) at receipt.

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

The raw materials were supplied from manufacturers approved by Callington Haven Pty Ltd. Callington was responsible for the evaluation and approval of suppliers of raw materials. Packaging materials and other components such as valves were purchased by Sanit and Sons Co. Ltd. The procedure titled - Criteria for selection of suppliers was reviewed. The procedure described the evaluation, selection, monitoring of performance of suppliers. The review of the performance of suppliers was carried out yearly. The criteria for evaluation of suppliers included Quality, Price, Delivery time, Service and Support. The evaluation report of supplier of valves was reviewed.
All the issues raised related to this section were addressed satisfactorily by the manufacturer.

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 **Sanit & Sons Co., Ltd.** located at: **177 Moo 6, Pakha Banna, Nakhon Nayok 26110 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. 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/

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