



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

Part 1		General information
Manufacturers details		
Name of manufacturer	Aerolub	
Corporate address of the manufacturer	Produits Sanitaires Aeronefs - PSA 1 rue de Lamirault, ZAE de Lamirault Collegien, 77090, France	
Inspected site		
Name & address of inspected manufacturing site(s)	Aerolub ZA du Moulin D'Angean – Rue Paul Journée, Chaumont en Vexin, 60240, France	
Unit/Block/Workshop	Not applicable	
Inspection details		
Dates of inspection	17 -21 November 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 activities related to the manufacture of the insecticides (aerosols) involved mixing, filling, crimping, and packaging. Aerolub manufactured aerosols (Non-Flammable Aircraft Insecticide Phenothrin) on contract for PSA.	
General information about the company and site	Aerolub was ISO certified. ISO 9001:2015 Certificate number: FR070700-1 Valid from 31 March 2022 until 30 March 2025 Scope stated as follows: “Design and filling aerosols technical products, industrial maintenance, household, cleaning, hygiene, disinfection, Aero ’vert brand, bag on valve aerosol. Cosmetics and perfumes. Contracts and for stock manufacturing. Supply customized,	



	<p>technical and regulation support”. The certificate was issued by Bureau Veritas Certification France.</p> <p>ISO 22 000: 2018</p> <p>Certificate number: FR079429-1</p> <p>Valid from 10/02/2022 until 09/02/2025</p> <p>Scope stated as follows: “Packaging aerosols (filling, crimping, filling with propellant gas) of release agents intended for pastry and bakery”. The certificate was issued by Bureau Veritas Certification France.</p>
History	This was the first WHO inspection of the site.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	<p>Document review including but not limited to:</p> <ul style="list-style-type: none"> • 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 <p>Physical areas:</p> <ul style="list-style-type: none"> • Raw material and finished goods • Production areas • Quality control laboratory
Exclusions and Non-applications of requirements in the QMS	None
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	<ul style="list-style-type: none"> • Non-Flammable Aircraft Insecticide Phenothrin (2% w/w 1R-transphenothrin) – P-09041



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

The quality policy was displayed throughout the facility including production areas. The quality policy was appropriate to the purpose and context of the organization. The quality policy was signed by the Managing Director of Aerolub. The quality objectives for the year 2023 were in place. The key performance indicators for the established quality objectives were defined and monitored. The established quality objectives were related to the following: HSE (Health, Safety and Environment), maintenance, production, logistics, resources, and continuous improvement. The quality objectives were discussed in the management review.

2. Management review

Management reviews were held once a year. The 2023 management review report was reviewed. The agenda for the meeting included: the status of actions from previous management review, changes, nonconformities, audit results, complaints, performance of external providers, quality objectives etc. The analysis and evaluation of the conformity of products, as well as the degree of customer satisfaction, were discussed. Opportunities for improvements had been identified and documented. This was found satisfactory.

3. Organizational roles, responsibilities, and authorities

An organogram was in place. According to the organizational chart provided in the site master file the Lab manager and Production Manager reported independently to the Factory Director. The Factory director reported to the Vice President of Operations (Europe). The job description of the Lab manager was reviewed.

4. Control of documented information

The relevant procedure for document control was in place. The procedure described the creation, identification, approval, and review of documents. Documented information including records maintained in customized software systems were backed up daily to a third-party company and internally saved on a server.

5. Personnel competence and training

The training plan for 2023 was in place. A database with details of the skills and training of each employee was in place. Training needs were identified by the persons in charge of the department. The records for training conducted in 2023 included were checked. Training evaluation records were maintained.



6. Risks Management

Risk assessment was conducted each year. A SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis was in place. The SWOT analysis of the following was performed: management, security, production and packaging, maintenance, purchases, commercial, laboratory, continuous improvement, and work execution (expeditions). The actions and approaches to be taken were defined.

7. Control of changes

Procedure for the management of documents and records was available. Control of changes related to documentation were described in this procedure. Changes together with the implementation of new products were handled according to the procedure - “Conception for product development”. Selected change controls were reviewed.

8. Internal Audits

The relevant procedure for internal audits and external audits was reviewed. A three-year audit schedule (2021-2023) was available. Every area was to be audited years at least every three. An overview of the audits carried out to date was in place. Audit reports were reviewed. Corrective actions and corrections (CAPA) were documented and monitored. Two external audits were planned every year taking into consideration non-conformities identified in the previous audits.

9. Control of nonconforming products

The procedure for control of non-compliances together with the list of nonconformities were reviewed. The procedure described the handling of non-conformities including the conduct of root cause analysis and investigations, corrections, and corrective actions and verification of implemented actions. Changes to the manufacturing process of Non-Flammable Aircraft Insecticide Phenothrin (NFAI), if necessary, would be discussed and agreed upon with PSA. The documented non-conformity was reviewed. Only one non-conformity had been documented by the time of the inspection.

10. Design and development of products

Design and development of the Non-Flammable Aircraft Insecticide Phenothrin aerosol was undertaken by PSA. Aerolub was not responsible for the design and development of this product. This was therefore not audited.

11. Customer satisfaction

Customer satisfaction surveys were conducted every year. The data collected in the customer satisfaction survey was related to the clarity of the proposals/quotations, reactivity, purchasing support and technical documents, product functionality, lead times, labelling/packaging, and PSA brand visibility. The 2023 customer satisfaction survey was available.

12. Complaints

The manufacturer maintained a complaints database/register. Complaints were categorized as Major or Minor complaints depending on the impact of the complaint on the product and QMS and the probability of its occurrence. The root cause, the investigative team, corrective actions, and efficiency of the corrective actions were documented in the complaints database. Complaints were reviewed monthly by all managers. Complaints were reviewed.



13. Support

Infrastructure and work environment

The facilities were generally well maintained. The maintenance plan for 2023 was in place. All equipment were inspected every 3 months. Inspection records for filing line 4 were reviewed.

Monitoring and measuring resources

The calibration records of the selected equipment were reviewed.

14. Production and service provisions

Control of Production

The manufacture of the Non-Flammable Aircraft Insecticide Phenothrin included mixing, filling, crimping, labelling, and packaging. At the time of the inspection manufacture of Non-Flammable Aircraft Insecticide Phenothrin was ongoing. The master formula was reviewed. The production raw materials to be used in the manufacture of a batch were weighed on calibrated balance scales. It was only after approval of the in-process test results that filling was allowed to proceed. The bulk was transferred to filling room. The cans were filled with the propellant gas, actuator inserted and crimped. Defined in-process checks were performed and records were maintained. The filling line was equipped with online check weighers. The cans were labelled online. The cans were manually packaged into the cartons.

A report on hold time studies for the bulk in was reviewed. Selected batch records were reviewed. The batch numbers of the raw materials used for production were recorded. The cleaning instructions and records were also reviewed. Batches were released to PSA. PSA then released the batches to the customers/clients.

Quality control laboratory

Sample registries were entered in the customized software. The relevant and necessary analytical tests for the aerosol were conducted and records were maintained. Lab test records for One Shot reviewed. The relevant tests were demonstrated during the inspection to the inspectors. The procedure for sampling and release of raw materials by the laboratory was also reviewed. 2 samples of the finished product were collected at the beginning of each production run and tested.

Control of waste

Waste was collected and stored at a designated location at the facility. Third party companies later collected the wastes for treatment and disposal. The facility also had access to government software that allowed for tracking the status of the waste.

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

15. Preservation

The procedures for controlling labels, cartons, and caps and for “On-Site Reception Of raw materials, components, bulk materials / Incoming Flow” were reviewed. Inventory in the warehouse was managed by use of the ERP software which provided information on the quantities of the raw materials in the warehouse (received, issued and balance), suppliers etc. The raw material containers in the warehouse had status labels affixed to them. The warehouse had a designated area for storage



of rejected/nonconforming raw materials. All the materials were received along with a COA. Inventory records of the raw materials were verified.

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

The selection, evaluation and monitoring of the performance of external providers of raw materials was managed by PSA. Only the supplier of one solvent was selected and monitored by Aerolub.

The relevant procedure “Purchase Management” was reviewed. The procedure described the valuation of suppliers. Evaluation reports for the suppliers of the raw materials were reviewed.

Part 3	Conclusion – Inspection outcome
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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 **Aerolub** located at **ZA du Moulin D’Angean – Rue Paul Journée, Chaumont en Vexin, 60240, France** 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
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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/>