



**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	Condivex
Corporate address of manufacturer	Produits Sanitaires Aeronefs - PSA 1 rue de Lamirault, ZAE de Lamirault Collegien, 77090, France
<b>Inspected site</b>	
Name & address of inspected manufacturing site(s)	Condivex ZI Porte Rouge, Etrepagny, 27150 France
Unit/Block/Workshop	Not applicable
<b>Inspection details</b>	
Dates of inspection	22 – 24 November 2023
Type of inspection	Initial inspection.  The inspection was to establish that the applicable requirements of ISO 9001:2015 as well as WHO specific requirements were met.
<b>Introduction</b>	
Brief description of the manufacturing activities	Condivex is part of the Fareva group and is a contract manufacturer for PSA. Condivex was founded in 1978. Condivex specializes in the manufacture of aerosols. Condivex manufactures different types of aerosols including Household, Industrial, Automotive and Plant Protection Products aerosols.  FAREVA is a group of 41 production sites including those that manufacture active pharmaceutical ingredients and medicinal products.  Products produced by Condivex were registered by PSA in several European countries.  The activities related to the manufacture of the insecticides (aerosols) involved mixing, filling, crimping, and packaging.
General information about	Condivex held an ISO 9001:2015 certificate.



the company and site	<p>Certificate number: 858841/r1</p> <p>Valid from 12/12/2021 until 11/12/2024</p> <p>Scope stated as follows: “Manufacturing, Custom Packaging and Delivery of Household, Industrial, Automotive and Plant Protection Products in Aerosol, Jugs or in Bulk”.</p> <p>The certificate was issued by Apave Certification.</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	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"> <li>• Non-Flammable Aircraft Insecticide Phenothrin (2% w/w 1R-transphenothrin) – P-09041</li> </ul>
<b>Abbreviations</b>	<b>Meaning</b>
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

<b>Part 2</b>	<b>Brief summary of the findings and comments (where applicable)</b>
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**1. Quality policy and quality objectives**

The manufacturer had an established quality policy and quality objectives in place. The quality policy had been signed by the Managing Director. The 2023 quality objectives were related to maintenance, production, logistics, continuous improvement and HSE (health, safety, and environment). The quality objectives were displayed in various areas throughout the facility. The quality objectives were also communicated to staff by respective department managers. Key performance indicators had been defined for each of the quality objectives. The extent to which the quality objectives had been met was monitored and measured.

**2. Management review**

The procedure for management review was reviewed. The management review aimed at analyzing the overall effectiveness of the site’s QMS and to establish new objectives and identifying areas for improvements for each process. The Quality, Health, Safety and Environment (QHSE) Manager organized the meeting each year. Occasional management review meetings could be triggered if Management or QHSE Manager deems necessary particularly if important decisions on the Quality Management System are to be taken to avoid nonconformities. The management review report for the year 2023 were reviewed and found satisfactory.

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

An organogram was in place. The laboratory quality manager and production and logistics Manager reported independently to the Factory Director. Job descriptions of the responsible personnel were available. The job descriptions of the responsible personnel including the QC Manager were reviewed.

**4. Control of documented information**

The relevant procedure for document control was reviewed. The procedure described the control of documents, instructions, and forms at Condivex. Documents were retained for 4 years. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

**5. Personnel competence and training**

The relevant procedure for Management of Human Resources was reviewed. A data base for Management of Certification and training with training status of the personnel was in place. A competence file for each employee was also available. Training record and Competence files of the employees were checked including employees in the laboratory.

**6. Risks management**

A risk management procedure was reviewed. Risk analysis was to be performed by a committee of personnel with multidisciplinary knowledge and experience. The committee comprised of at least

one person from the quality department and the person in charge of the relevant process, among others. The criteria for evaluation and assessment of risks were defined. A risk register was available.

## **7. Control of changes**

The procedure for change control was reviewed. The procedure ensured that changes were introduced in a planned and controlled manner. The procedure also ensured that any changes made to products and processes, equipment, environment, methods, and related documents are assessed, approved, and authorized by designated and competent personnel. Risk analysis, customer approval, technical validation if required and monitoring were part of the change control process. A database for changes was available. Changes were reviewed.

## **8. Internal audits**

The relevant procedure for internal audits was reviewed. A three-year audit schedule (2021-2023) was in place. Every area was audited at least once in three years. An overview of the audits carried out to date was available. The audit reports were in place.

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

The procedure for Non-Conformity Management was reviewed. As required by the procedure, all nonconformities were assigned a registration number. The register for nonconformities was managed using a customized software. Several nonconformities were selected and discussed with the inspection team.

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

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

## **11. Customer satisfaction**

The customer satisfaction procedure was reviewed. Customer satisfaction surveys were conducted using questionnaires. The Quality group (RAQ group) received the questionnaires from customers and assessed them. A report was then sent to the export sales directors and support services for action. Customer satisfaction surveys were conducted every year. The customer satisfaction survey for the first quarter of 2023 was reviewed. The customer satisfaction survey covered the following: product quality, complaints, R&D service, site relations (communication and availability), décor service, sales service, and general impression of the services.

## **12. Customer complaints**

Market complaints were received by PSA. Depending on the nature of the complaints, relevant ones were communicated to Condivex. The procedure for customer complaints was reviewed. Feedback to the complainant on the progress of the complaint was provided by the Quality Manager. A register (Complaint Tracking File) was in place. The Product Quality Manager together with departments managers were responsible for the analysis of the complaint, root cause identification, and proposed corrections and corrective actions. Complaints were categorised as Critical, Major, and Minor. Major complaints were reported to the corporate group via monthly quality reporting form. The complaints were registered into and tracked using a customised software. There was no complaint related to Non-Flammable Aircraft Insecticide Phenothrin (NFAI) by the time of the inspection.



### 13. Support

#### **Infrastructure and work environment**

There were two buildings used for production. One building housed the raw material warehouse and bulk preparation area including solvents dispensing area. The other housed warehouses for components and finished products, final filling / packaging of products, gas storage area with dedicated tanks for gases.

The facilities were well maintained. The staff gowned in appropriate Personal Protective Equipment (PPE). The maintenance plan for 2023 was in place. The maintenance plan for the formulation area was reviewed.

The quality manual provided a brief overview of the hygiene, safety, and environment principles (HSE Process). The QHSE Manager was responsible for Hygiene, safety, and environment of the facility. HSE reports were compiled every three months following a meeting with all Condivex managers. The latest HSE report (November 2023) was available.

#### **Monitoring and measuring resources**

A calibration schedule was in place. 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 (NFAI) included mixing, filling, crimping, labelling, and packaging. The raw materials were weighed on calibrated balances and mixed in the formulation area. The mixing tanks were dedicated. The master formula was in place. There were 3 filling lines. The volume of the bulk was checked prior to filling, with the propellant gas. The cans were then filled with the propellant gas, actuator inserted and crimped. The filling line was equipped with an online check weigher. At the time of the inspection, the manufacture of Non-Flammable Aircraft Insecticide Phenothrin was ongoing. Defined in process checks were performed and records maintained. The cans were labelled online and packaged into cartons. Cleaning instructions and records were reviewed.

A report on hold time studies for the bulk was reviewed. Batch records were also reviewed. Batches were released to PSA. PSA then released the batches to the customers/clients.

#### **Quality control laboratory**

The laboratory verified the documentation received along with the incoming raw materials in the warehouse. The supplier, order number, delivery number, batch number, certificates of analysis (CoA) were verified. A sample registry (data base) was in place. The procedure for production control was reviewed. The procedure described the sampling criteria and approach for the bulk, finished product etc. The manufacturer relied on Certificate of Analysis from the supplier for all raw materials received.

Analytical test records for the NFAI were reviewed.

#### **Control of waste**



Waste Management / Monitoring Waste procedure was provided. The spill management procedure was also in place. Absorbent materials and appropriate equipment were available at relevant areas. Waste and solvent residues were collected by a third party for treatment and disposal.

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

**15. Preservation**

There were two raw material warehouses. One for solvents and chemical raw materials, and another one for storage of packaging materials and components. Inventory control was managed by use of a customized software. The software provided information on the quantities of the raw materials received, issued to production, suppliers, etc... The materials were identified with status labels. The warehouse had designated areas for storage of quarantine and nonconforming materials.

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

The selection, evaluation, and monitoring of performance of external providers of raw materials was managed by PSA apart from the supplier of one solvent that was selected and monitored by Condivex. The relevant procedures “Qualification for new direct suppliers” and “Supplier and subcontractor assessment” procedure were reviewed. Supplier evaluation reports of the suppliers of the raw materials were reviewed.

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

<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 **Condivex** located at: **ZI Porte Rouge, Etrepagny, 27150 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.

<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/>