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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	PT Sari Agro Solutions
Corporate address of manufacturer	BASF AGRO B.V. Arnhem (NL) Freienbach Branch Huobstrasse 3, 8808 Pfäffikon SZ Switzerland
Inspected site	
Name & address of inspected manufacturing site(s)	PT Sari Agro Solutions Building: Production Building A Line: Liquid Production Line 2 Jalan Raya Mojoagung, Sumobito, Desa Betek, Kecamatan Mojoagung, Kabupaten Jombang, Jawa Timur, 61482, Indonesia
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	03-05 July 2024
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	PT Sari Agro Solutions was established in 1994. The site is engaged in the manufacture of the following agrochemical product types: EC, SL, WP, SC, and wax block. The site was also engaged in the repackaging of EC, SL, SC, CS and WP agrochemical product types. The agrochemical products manufactured by the site included Herbicides, fungicides, and insecticides. The herbicides were manufactured in a separate and dedicated building. The activities related to the manufacture of Abate EC included: formulation, labelling, packaging, release testing and storage.

General information about the company and site	The site was certified as indicated below: **ISO 9001: 2015: Quality Management System** Scope: ‘‘Manufacturing of Agrochemical and Fertilizer Product’’ Certificate Number: 01 100 1735181 Valid from: 21/12/2023 Valid until: 20/12/2026 The certificate was issued by TUV Rheinland Cert GmbH. **ISO 45001: 2018: Occupational Health and Safety** Scope: ‘‘Manufacturing of Agrochemical and Fertilizer Product’’ Certificate Number: 01 100 1735181 Valid from: 21/12/2023 Valid until: 20/12/2026 The certificate was issued by TUV Rheinland Cert GmbH.
History	This was the first WHO inspection 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 • 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	The facility did not engage in design and development activities. The requirements for Design and development were excluded from the QMS.
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	Abate 500 EC (Temephos 500 g/L) – 002-003
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**

1. Quality policy and quality objectives

An integrated quality policy was documented in the Integrated Management System Manual. The quality policy included a commitment to satisfy applicable requirements. It also included a commitment to the continual improvement of the quality management system. The quality policy and quality objectives were displayed in various areas throughout the facility including production areas and the administration building (offices). The quality policy and quality objectives were communicated to staff through training. Training records on the quality policy and quality objectives were maintained. The quality objectives were measurable and monitored. Key performance indicators had been defined for each objective. The quality objectives were reviewed annually.

2. Management review

The relevant procedure for management review was reviewed. Management reviews were conducted once annually. Weekly meetings were also held to discuss planning, achieving production targets, occupation and health issues, operational issues, and quality problems. Management review meetings were attended by top management. The agenda of the annual management review meeting held in 2023 was reviewed. Information on the performance and effectiveness of the quality management system included trends in audits, production conformance, complaints, formulation/repack yield. Opportunities for improvement had been identified and documented.

3. Organizational roles, responsibilities, and authorities
An organizational structure showing the hierarchical and reporting lines was in place. The leadership commitment was described in the Integrated Management System Manual. Top management demonstrated leadership and commitment to the quality management system by ensuring that the quality policy and objectives were established and aligned with the organization's context. They also promoted improvement through internal audits, training, and other measures. The roles and responsibilities of the key personnel QC/QA Manager and Production manager were reviewed.

4. Change and Control of documented information
The relevant procedure for document control was in place. Documents were identified as per the procedure. The procedure also described how changes were initiated, reviewed, and approved. The retention period for different documents was defined. A master list of all controlled documents was in place. Changes were reviewed and impact assessments conducted. Changes were reviewed and found satisfactory.

5. Personnel competence and training
The procedure for training was reviewed. It described the different types of training, how and when training was to be conducted and who could conduct the training. The 2024 training plan was available. Training records on packaging were reviewed. The effectiveness of the trainings was assessed using questionaries. The training records and questionnaires were maintained.

6. Risks Management
The procedure for risk management was reviewed. Risks were categorized into Low, Medium, High, Extreme, and Disaster. The criteria for evaluation of risks were defined. Different actions were taken depending on the category assigned to the risk. A risk register was also in place. The risk assessment covered production, warehouse, quality control, personnel, and safety among others.

7. Internal Audits
The procedure for internal audits was reviewed. The procedure described how internal audits were to be conducted and managed. Internal audits were to be conducted annually. The procedure also described the competencies and qualification requirements of internal auditors. The 2024 audit schedule, check list, internal audit follow-up form, and internal audit summary were also in place.

8. Control of nonconforming products
The procedure for control of nonconforming products was reviewed. The procedure described the handling of customer complaints, nonconforming goods from suppliers, non-conformities/abnormal conditions in field, products not complying with specifications, work accidents etc. The root cause determination, corrections and preventive actions were documented on the Corrective and Preventive action form. The nonconformities were monitored and tracked using the nonconformity monitoring form. QA was responsible for handling investigations. There were no registered nonconformities related to Abate. The nonconformities related to this section were adequately addressed by the manufacturer.

9. Design and development of products

Design and development of this product was not undertaken at this facility. This site was not involved in design and development activities. This area was therefore not inspected.

10. Support

Infrastructure and work environment

The facility comprised of production buildings, warehouses for the raw materials and finished products, and the administrative building, in which the quality control laboratory was housed.

The personnel were appropriately gowned. Material safety data sheets were in place. The production facilities were equipped with fire extinguishers, spill kits and eye wash stations.

Monitoring and measuring resources

The procedure for calibration and maintenance was reviewed. It described the maintenance actions to be taken and defined calibration and maintenance schedules. A calibration master list and 2024 calibration schedule were in place. The calibration certificates for selected balances were verified.

11. Production and service provisions

Control of Production

Abate 500 EC was specifically manufactured on a MT-A line in the fungicide and insecticide building. The raw materials were weighed and mixed following a documented recipe and mixing instructions. The mixing time was monitored. The hoses used to transfer Abate 500 EC from the mixing tank to the packaging containers were dedicated.

The batch production records for Abate were reviewed. The batch numbers of the raw materials were documented. The weighing was carried on a calibrated weighing scale. Line clearance was documented. Cleaning records were also maintained. The volume of the cleaning solution was documented. A matrix with values of the acceptable contamination limits from BASF was in place. The bulk solution was sampled prior to filling and tested for Active Ingredient content and density. A sample of the finished product was sampled from the filing line and tested for appearance, Active Ingredient content, density, pH, water content, emulsion stability and re-emulsification, D water 1% v/v, and persistent form 1% v/v. Label and packaging material issuance records were also available. Label reconciliation records were also in place. The bulk solution was filled in steel drums. The drums were manually closed and crimped. The weight of each filled drum was checked.

Product release was performed by the QA manager following review of the production and analytical data. The release was performed using the ERP software.

Process Validation

The process validation report was reviewed. Critical process parameters and product attributes had been determined.

Quality control laboratory

The analytical method verification protocol and analytical method verification report for Abate 500 EC were reviewed. The parameters verified included selectivity/specificity, precision, repeatability, accuracy. The results demonstrated that the method was robust, accurate, and precise. The standard testing procedure for Abate 500 EC was also reviewed. Analytical test reports for Abate batch were verified. The analysis was performed using HPLC. The date and time were locked. The users had unique passwords and log-in IDs. The raw data was backed up once every month on a hard disk and on the cloud.

The Temephos primary standard were store as per the label instructions from the manufacturer. The certificates of analysis for the Temephos primary standard were available.

Retention samples

Inventory records for the retention samples were maintained. The retention samples were stored in a dedicated area in the laboratory. They were stored at ambient temperatures for 3 years (shelf life plus one year). The temperature of the retention sample storage area was monitored.

Waste management.

The generated waste was segregated into solid and liquid waste. This was collected and stored in a central collection point. The generated waste was then collected by a third-party company for treatment and disposal. The nonconformities related to this section were adequately addressed by the manufacturer.

12. Preservation

Inventory records of materials was managed by ERP. The materials in the warehouse had materials status labels. Personnel accessing the ERP software had unique IDs and passwords. The ERP software also provided information on the product names, stock movement and quantities etc. Materials were stored at ambient temperatures. A QR coding system was used to trace and track materials in the warehouse. A stability study report on 3 batches of Temephos technical material was reviewed.

The raw materials were all supplied from sources approved by BASF. The raw materials were received along with certificates of analysis, delivery note, airway bill, packing list etc. Every batch of the raw materials was sampled and tested by the laboratory prior to approval and use of the raw materials. The quantity, names, batch numbers, physical appearance of the material containers were verified upon receipt and a material receiving report generated.

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

The procedure for supplier assessment was reviewed. It described the guidance for assessment of suppliers. The categorization of suppliers into groups A, B C and D and E were defined. The criteria for evaluation of suppliers were also defined. The assessment report of selected suppliers was 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 **PT Sari Agro Solutions** located at: **Building: Production Building A Line: Liquid Production Line 2 Jalan Raya Mojoagung, Sumobito, Desa Betek, Kecamatan Mojoagung, Kabupaten Jombang, Jawa Timur, 61482, Indonesia** 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/