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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	Agroquimicos Versa, S.A. DE C.V
Corporate address of manufacturer	BASF AGRO B.V. Arnhem (NL) Zuerich Branch Im Tiergarten 7 8055 Switzerland
Inspected site	
Name & address of inspected manufacturing site(s)	Agroquimicos Versa, S.A. DE C.V Mexico Torreon, Coahila, C.P. 27019 Alfonso Gomez Torres No. 170 Mexico
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	27-29 July 2022
Type of inspection	Initial inspection. The criteria for the inspection were based on the ISO 9001:2015 standard.
Introduction	
Brief description of the manufacturing activities	The site manufactured different categories of products including herbicides, fungicides, insecticides, bactericides, nutrition (Fertilizers) etc. The manufacture of Abate 1 SG included mixing, filling, packaging, and labelling.
General information about the company and site	Agroquimicos Versa started its operations in 1980. Agroquimicos Versa, S.A. DE C.V is a contract manufacturer for BASF AGRO B.V. The site was ISO 9001 certified. ISO 9001:2015 certificate number MX02/2923. Valid from: 7th April 2020 until 6th April 2023. Scope: ‘‘Manufacture of Agrochemicals such as insecticides, fungicides and herbicides.’’ The certificate was issued by SGS.
History	This was the first WHO audit of the site

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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 were excluded from the requirements and applications of the quality management system.
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 1 SG (Temephos 1% w/w) - 002-004
Abbreviations	**Meaning**
CoA	Certificate of analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
QMS	Quality Management System

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Part 2	Brief summary of the findings and comments

1. Organizational roles, responsibilities, and authorities
The job descriptions of the R&D and Quality Control Manager and Quality Management System Manager were reviewed. The R&D and Quality Control Manager was responsible for the release of products. The Quality Management System Manager had been assigned the responsibility of ensuring that the quality management system meet the requirements of the ISO 9001 standard. The Quality Management System Manager also reported on the performance of the quality management system in management review meetings. An organogram was in place. The Director of Operation and the Quality Management System Manager reported independently to the Director General.

2. Quality policy and quality objectives
The manufacturer had established quality policy and quality objectives. The quality policy was appropriate to the purpose and context of the organization. The quality policy and quality objectives were displayed in various locations within the facility and were communicated in meetings. The quality objectives were measurable. Key performance indicators had been defined for each quality objective. The quality objectives were monitored. Meetings were held every six months to discuss the status and extent to which the quality objectives have been met. The quality objectives were also discussed in management review meetings.

3. Management review
The relevant procedure for management review was discussed. Management reviews were held once a year. The minutes of the last management review meeting held in February 2022 were in place. The management review inputs included infrastructure, human resource, organizational performance, external issues (i.e., political, economic, social, cultural, technological, legal, environmental issues), complaints, quality objectives, customer satisfaction, employee satisfaction, audits, external suppliers etc. Opportunities for improvements had been identified.

4. Leadership
An organogram was in place. Top management demonstrated leadership and commitment to the Quality Management System by taking accountability of the effectiveness of the quality management system and promoting improvement through management reviews and internal audits, corrections, and corrective actions among others.

5. Control of documented information
The procedure for document control described the creation, format, review, and approval of documents. Documented information was both in paper and electronic forms. Standard operating procedures were reviewed every two years. The document creation included the description of the company's logo, name, title, document identification number (code), review dates, scope, objective and responsible persons or departments etc. Access to documents such as procedures was controlled by used of a customized software. The software was access controlled with unique passwords for the different users. Each personnel was restricted to assessing documents that are of relevance to their area of work. Printing was also restricted. Only the Quality Management System Manager was allowed to print documents. Procedures were in place for the control of external documents in the possession of Versa. These procedures described the identification and control of

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customer information. A master register for all external documents was in place and only controlled copies could be made available for use. Obsolete documents were not accessible to all operations staffs. Production data was backed up regularly.

6. Personnel competence and training

The procedure for Training and Development of Competence. An annual training program outlining all training schedules for personnel was in place. Templates for identification and evaluation of training needs and evaluation of training/course undertaken were in place. Skills and training matrix was also available. The training records of personnel/staff were reviewed. Training records on new product development, marketing intelligence were also reviewed. The evaluation record of the personnel were available. Trainings provided included, General Induction into Versa Group, Quality System Management, Quality Control of products, etc. The process of engaging external trainers and assessing the competence of the trainer was reviewed.

7. Risks Management

Risk management procedure was reviewed. The procedure described the identification, evaluation, classification, and review of risks. Risk assessment/evaluation was performed every year. A process map was in place. Risk identification for each of the processes had been performed. A Failure mode and effects analysis (FMEA) approach was used for the identification and analysis of risks. A risk register was in place. Risks related to the manufacture of Abate 1 SG at each of the following processes: receipt of materials, storage of materials, delivery of materials, cleaning of process areas and equipment, preparation of the premix, mixing process, spraying, lab analysis, packaging, release of the product etc. had been identified, analyzed, and evaluated.

8. Control of changes

The relevant change control procedure was reviewed. The procedure provided for justification and impact analysis of the change. Changes were categorized into temporal, permanent and emergency. The procedure applied to production, new regulations, SAP, Quality Control, Risk management etc. Forms were used to document changes. A change related to the change in pH specification for Abate was reviewed.

9. Internal Audits

The internal audit procedure was reviewed. Audit program for year 2021-2022 was available Based on an established criterion some areas were audited annually, some bi-annually and others more frequently. The areas audited included commercial processes, supply chain and production among others.

The internal audit report on manufacturing, supply chain, Human Resource departments was reviewed. The audit had been scheduled and conducted according to schedule. An audit plan and audit checklist were in place. Non-conformities, observations and corresponding corrections and corrective actions were documented. The corrections and corrective actions were reviewed prior to implementation. The effectiveness of the corrections and corrective actions had been evaluated prior to closure of the nonconformities.

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10. Control of nonconforming products

The procedure for handling nonconforming products was reviewed. The procedure provided for root cause investigation and risk analysis. The manufacturer retained documented information on nonconforming products. Non-conformities were reviewed. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

11. Complaints and customer satisfaction

The procedure for customer satisfaction was reviewed. Customers were categorized into 3 namely: Final consumer, manufacturer, distributor. Customer satisfaction surveys were conducted at least once a year. The survey into account the following areas: quality, distribution, sales, payments, services, production, and warehousing. The customer satisfaction survey were conducted using an electronic platform – Survey monkey or forms. The customer satisfaction survey conducted in 2021 was reviewed and found satisfactory.

Market complaints related to Abate 1 SG were received by BASF and communicated to Agroquimicos Versa. Recall of Abate 1 SG from the market was the responsibility of BASF. The procedure for handling complaints was reviewed. Complaints could be received by call, email, and intranet website audits. A form was also in place for sales representative to route complaints from customers to customer service Complaints were classified into low, medium, high, and critical. Depending on the type and nature of the complaint a team would be selected to investigate a complaint. After investigation the necessary corrective and preventive measures are put in place and monitored. Following a period of non-recurrence, the CAPA would be deemed effective, and complaint closed. Complaints were reviewed.

12. Performance evaluation

Key performance indicators had been defined for the following parameters: supply chain, quality, operations, finance, human resource, commercial, customer satisfaction etc. An evaluation and trend analysis was performance for each of the parameters. Additionally, production and laboratory data was reviewed weekly. The monthly reports for 2021 were in place. These were reviewed and found satisfactory.

13. Design and development of products

Design and development were excluded from the requirements and applications of the quality management system.

14. Support

Infrastructure and work environment

The infrastructure at the facility was generally well maintained. The site was equipped with rodent traps. Personnel were appropriately dressed in PPE which included gas mask, overall suit, safety googles, helmet and boots. The facility had eye washes and emergency showers situated at appropriate locations.

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Monitoring and measuring resources

Records and schedules of equipment maintenance and calibration were tracked using a customized software. Equipment breakdowns were communicated to the maintenance department using the same software. The maintenance records for the pressure pump, drum blender on the insecticide production line and sieves were in place. Calibration and maintenance records for the HPLCs were reviewed. The calibration certificate for the pH meter and balances were also in place.

15. Production and service provisions

Control of Production

Abate 1 SG was produced on a line dedicated to the manufacture of insecticides. The product was packaged in bags (20Kg/50Kg pack) and labelled. All the raw materials were weighed using calibrated balances. The weight of the bags was verified prior to labelling. Samples of the final mixture were collected from the drum blender ('spinning tank') and tested for active ingredient content. In-process controls included particle size (silica) and pH of the final blend. Batch production records for Abate batch were reviewed. Line clearance was documented. Batch numbers of the raw materials used in production were indicated in the batch records. The batch records were reviewed and verified prior to release of the batch.

Cleaning instructions and cross contamination matrix were in place. Cleaning was performed whenever there was a change of product. The samples of the final rinse were collected from various points along the equipment train on the production line. In addition, first-fill analysis (i.e., cross contamination analysis of first filled bottle) was also performed.

The laboratory was headed by the R&D and Quality Control Manager. Samples were adequately labelled with information on the product name, lot number, date sampled etc. A sample register was in place. The analytical method for determination of Temephos was reviewed. Temephos content in Abate 1 SG was determined by use of HPLC. Test reports and raw data for Abate 1 SG were verified. The analytical method validation report for Abate was also reviewed. Access to the software used for HPLC analysis was protected by use of unique passwords. The secondary standard for Temephos was appropriately stored.

Waste generated during production was collected in a general waste disposal collection area on site. This was then later collected by the National waste disposal body for treatment. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

Identification and traceability

There was adequate traceability of the raw materials, samples, and finished products in the production records. Equipment were uniquely identified.

Post-delivery activities

The stability studies were undertaken by BASF. The stability study report was not available on for review at the time of the inspection. The procedure for retention of samples (PRO-CC- 009 Rev 13 Implemented 25/05/2022 Review date 25/05/2024) was in place. A sample of each lot was retained. The retention samples were kept for 3 years. The shelf life of the product was 2 years. The retention samples were appropriately stored and labelled.

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16. Preservation

The procedure for receipt of materials. A checklist for receipt of materials was in place. Upon receipt of materials the purchase order, Certificate of Analysis (COA), bill of lading, invoice, quantity were verified. Temephos technical material (active ingredient) was supplied by BASF. Inventory management was managed by use of a software system. Access to the software was controlled by use of unique passwords. The status of the materials in the warehouse were indicated as using different codes. The procedure for sampling was in place. All the containers of silica were sampled while other materials were sampled as per the sampling plan provided in the procedure for sampling.

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

The procedure for selection, evaluation, performance monitoring and re-evaluation of suppliers was reviewed. Suppliers were qualified based on the quality of their products, delivery time and quantity delivered. A list of approved suppliers was in place. The supplier evaluation reports were reviewed and found satisfactory.

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 ***Agroquimicos Versa, S.A. DE C.V*** located at ***Mexico Torreon, Coahila, C.P. 27019 Alfonso Gomez Torres No. 170 Mexico.*** 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/