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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	Chemark ZRT
Applicant/ Corporate address of manufacturer	Syngenta Crop Protection AG Rosentalstrasse 67 4058 Basel, Switzerland
Inspected site	
Name & address of inspected manufacturing site(s)	06/75 hrsz., H-8182 Berhida, Peremarton-Gyartelep, Veszprém 8182, Hungary
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	16 – 17 January 2025
Type of inspection	Re-Inspection The inspection was to establish that the applicable requirements to ISO 9001:2015 as well as WHO specific requirements continue to be met.
Introduction	
Brief description of the manufacturing activities	Chemark ZRT was established in 1991. The facility manufactures herbicides, fungicides, insecticides, adjuvants, plant Growth regulator products (PGR) and liquid fertilizers. There were dedicated manufacturing areas for herbicides and non-herbicides. Chemark ZRT is a contract manufacturer for Syngenta Crop Protection AG.
General information about the company and site	The manufacturer held the following ISO certificates: **ISO 9001: 2015** **Scope:** ‘‘Contract manufacture of pesticides and liquid fertilizers limited to formulation and packaging.’’ Certificate number: HU98/13378 Valid from: 07 October 2024 Valid until: 06 October 2027 The certificate was issued by SGS.

	ISO 14001:2015 **Scope:** ‘‘Contract manufacture of pesticides and liquid fertilizers limited to formulation and packaging.’’ Certificate number: HU10/5272 Valid from: 18 October 2024 Valid until: 17 October 2027 The certificate was issued by SGS. **ISO 45001:2018** **Scope:** ‘‘Contract manufacture of pesticides and liquid fertilizers limited to formulation and packaging.’’ Certificate number: CH20/1003 Valid from: 02 October 2024 Valid until: 01 October 2027 The certificate was issued by SGS.
History	The site was last inspected by WHO in March 2021.
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	This site was not involved in design and development activities.
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	• Actellic EC - 012-002 – (Pirimiphos-methyl 500g/L) - 012-002

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	**Summary of the findings and comments**

1. Management Review

The facility had an integrated quality management system. Management review meetings satisfied the requirements of the ISO 9001 standard. The quality objectives and key performance indicators (KPIs) were defined in the management review meeting. The extent to which KPIs were met was monitored monthly.

2. Leadership, responsibilities, and authorities

The manufacturer had an organogram in place. The analytical laboratory manager and the Formation manager reported independently to the Head of business development director and the Director – Production, respectively. The job descriptions of the Formulation manager, Analytical laboratory manager, Quality, Health, Safety, and Environment (HSEQ) manager and Fill and Pack manager were reviewed and found satisfactory.

3. Personnel competence and training

All employees, including cleaning staff and contractors, received induction training. A training schedule was in place. The manufacturer had in place annual training sessions including refresher trainings on the Quality Management System (QMS). The manufacturer also had in place a government-funded soft skills program that was attended by selected personnel. The effectiveness of the trainings were evaluated. If an employee failed a training evaluation, they underwent retraining and retesting. Personnel returning from extended leave (e.g., maternity leave) were required to undergo re-training before resuming duties. The manufacturer also had in place a structured trainer-training program.

4. Risk Management

The relevant procedure for Management of Risks and Opportunities was reviewed. The purpose of the procedure was to determine the methods by which the manufacturer identified external and internal factors that could compromise the performance of the integrated management system and determine the appropriate risk control measures. The manufacturer conducted the risk assessment using the Failure Mode and Effects Analysis (FMEA) approach. The procedure applied to internal and external factors related to Chemark's operations. The procedure in general defined the persons responsible for handling the different risk categories and approach to assessment of risk and

determination of risk control measures. The different risk categories included: QMS risks, Environmental risks, OHS (Occupational Health and Safety) process risks and energy management risks. The procedure also described the general approach to assessment of opportunities.

5. Internal Audits

The procedure for internal audits number was reviewed. The Environmental Engineer and Quality Assurance Officer and the Quality Assurance Engineer were responsible for preparation of the annual internal audit plan. The internal audit plan was approved by the HSEQ Director. The procedure provided for root cause determination, corrections, and corrective actions. Internal audits were performed by trained inspectors, in compliance with procedural requirements. The HSEQ Director reported the results of the audits at the management review to management.

6. Control of Changes

The procedure for management of changes was reviewed. Changes were categorised into major and minor changes. The procedure applied to changes in technology, test methods, products, raw materials, machinery, and equipment etc. The procedure provided for impact assessment prior to implementation of the change. The manufacturer maintained records of the changes. Selected changes were reviewed.

7. Design and development of products

This site was not involved in design and development of Actellic EC. This area was therefore not inspected.

8. Support

Infrastructure and work environment

The infrastructure was well maintained. A maintenance schedule was in place. Maintenance records for the equipment used for selected were reviewed. The personnel were gowned in appropriate personal protective equipment.

Monitoring and measuring resources

A calibration schedule and records were maintained. Calibration records of selected equipment were verified.

9. Production and service provisions

Control of Production

The major changes since that last inspection included:

- Formulation of Actellic EC
- Commissioning of a new building in 2022 for the manufacture of non-herbicides

The manufacture of Actellic 500 EC involved mixing of the solvent with different co-formulants and Pirimiphos-methyl for a defined period. The mixing time was monitored and recorded. A documented recipe was in place. The batch records for the manufacture of Actellic 500 EC were reviewed. The mixing tank had calibrated load cells. The in-process process parameters such as flow rate and pressure were monitored using a customized production software. The procedure for cleaning was reviewed. In-process tests were verified. One bottle of every batch was retained.

The Product Introduction Summary provided a brief on the laboratory test results of the trial batches, batch sizes, manufacturing instructions including process controls and product specifications was checked.

The quality control performed both chemical and physical tests. The laboratory was well equipped. Standard testing procedure for determination on Pirimiphos-methyl in Actellic EC and test reports were reviewed. Primary reference standards for Pirimiphos-methyl were appropriately stored. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

10. Preservation

The warehouse followed a First-Expired-First-Out (FEFO) approach, and in cases where expiration dates are unavailable, First-Production-Date-Out (FPDO) was applied. The warehouse was temperature controlled. The temperatures of the warehouse were recorded and maintained using a customised software. Pest control was conducted monthly. Access to the warehouse was restricted to authorized personnel. All materials were assigned a material code. The manufacturer used the SAP software for control of inventory including labels. Upon receipt materials the packing list and quantities were verified, and the relevant information was entered into the SAP system. The manufacturer relied on the COA of the raw material to ascertain the quality of the raw materials. Sampling of the raw materials was only performed under exceptional circumstances. Any nonconforming materials were labelled accordingly in red and blocked in SAP. The relevant personnel are then informed of the nonconformity. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

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

The selection and evaluation of the suppliers of the all the raw materials including labels and packaging materials was performed by Syngenta. The manufacturer however provided feedback to Syngenta in the event of any nonconforming raw materials.

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 by **Chemark ZRT** located at **06/75 hrsz., H-8182 Berhida, Peremarton-Gyartelep, Veszprém 8182, Hungary** 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/