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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 Termelo Es Kereskedo
Corporate address of manufacturer	Postafiok 31, 8182 Peremarton-Gyartelep, Hungary
Inspected site	
Name & address of inspected manufacturing site(s)	As above
Unit/Block/ Workshop	Building C
Inspection details	
Dates of inspection	16 – 17 March 2021
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	Chemark Termelo Es Kereskedo was established in 1991 and manufactures a range of herbicide and non-herbicide products in the following formulation types: Emulsifiable Concentrate (EC), Suspension Concentrate (SC), Suspo-emulsion (SE), Wettable powders (WP), Oil Dispersion (OD) and Emulsion in Water (EW). In relation to Actellic EC the site only carried out the filling, packaging and labelling of Actellic EC. Actellic EC was filled, packed and labelled in Building C (non-herbicide building). Actellic EC was packaged in bottles (1L), Cans (5L) and Drums (200L). Chemark manufactured Actellic EC on contract for Syngenta Crop Protection AG, Switzerland. Chemark was responsible for release the product to the market.

General information about the company and site	Chemark held the following ISO certificates: • ISO 9001:2015; Certificate number HU9813378; Validity 8th October 2018 to 7th October 2021. Scope: "Contract manufacture of pesticides and liquid fertilizers limited to formulation and packaging". Issued by SGS. • ISO 14001:2015; certificate number HU10/5272; Validity 19th October to 18th October 2021. Scope: "Contract manufacture of pesticides and liquid fertilizers limited to formulation and packaging''. Issued by SGS. • ISO 45001:2018; certificate number CH20/1003; Validity 7th November to 2nd October 2021. Scope: "Contract manufacture of pesticides and liquid fertilizers limited to formulation and packaging''. Issued by SGS. • ISO 50001:2018; Certificate number HU17/8125; Validity13th December 2020 to 12th December 2023 Scope: "Contract manufacture of pesticides and liquid fertilizers limited to formulation and packaging''. Issued by SGS.
History	This was the first WHO audit 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	Design and development were not applicable. The site was not involved in the design and development of the product.
Out of scope	Manufacture and testing of products not submitted to WHO for prequalification. The inspection was limited to the scope of products indicated in the section below (WHO products covered by the inspection).
Restrictions	None
WHO products covered by the inspection	Actellic EC (500 g/L Pirimiphos-methyl EC) Product number: 012-001
Abbreviations	**Meaning**
CoA	Certificate of analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
QMS	Quality Management System

Part 2	**Brief summary of the findings and comments**

1. Organizational roles, responsibilities and authorities

The job description of the Technical Director (TD) was discussed. He was mainly responsible for analytical and quality control functions. In his absence, the Chief Executive Officer (CEO) of the company was responsible for the technical operations.

The job description of the Quality and Environmental Manager was discussed. She was responsible for the management of the quality, environment, safety ensuring integrating systems, follow-up documents, preparation, approval and maintenance of documents, internal audit, supplier/customer assessment, complaint evaluation and corrective actions.

The job description of the filling/packaging plant director was discussed. In addition to other responsibilities, he was responsible for man-management, the fulfilment of orders received from clients, the safety of the packaging plant, follow-up the necessary number of operators, working with shift leaders, checking production efficacy and coordination of training program for operators.

2. Quality policy and quality objectives

The company had an integrated policy signed by the CEO; this company policy was prepared following ISO 9001 and other standards. The quality policy was documented in the Integrated management handbook (in the Hungarian language). Quality objectives were prepared each year and approved by the CEO. These were presented on a spreadsheet. Key Performance indicators had been defined.

3. Management review

Information related to Management Review was available in the integrated management manual. Management reviews were performed at least once annually and were headed by the Quality Head. The Management Review report for the meeting held on 01/10/2020 was discussed. The meeting was attended by the CEO and heads of all departments. The meeting discussed audits conducted by various parties (second, third and authority). In general, the detailed Management Review report was adequate.

4. Leadership

Leadership roles and commitment were described in the manual. An organogram was place.
From the discussions with management, it was demonstrated that top management was committed to the effective implementation of the QMS.

5. Control of documented information

The relevant procedure on documented information was reviewed. The SOPs were numbered by serial number and date. The SOPs were reviewed once every periodically or when there was any change required in the SOP. Documented information was retained for 5 years. Paper-based documents were retained in a library on-site whereas electronic documents were retained on a server maintained by an external IT company. It was indicated that a contract between an IT company and Chemark was in place. Documents were handled through the computer system and shared through emails using different folders such as under review, under approval process, approved and document withdrawal.

6. Personnel competence and training

Training (preparedness, competency and awareness) was described in the integrated management manual. A training plan was prepared annually. Usually, training was imparted through lectures whereas in 2020/2021, it was organized virtually. Various training was provided and was assessed as follows:

- Cross-contamination training (RI)
- Emergency preparedness plan (BVT)
- Work safety (MTV)
- Quality management (MIR)
- Environmental management system (KIR)
- Safety and fire protection (MEBIR)
- Energy management system (EIR)

7. Risks and opportunities

The relevant procedure for managing risk and opportunity was briefly discussed. A risk matrix was in place. The risk was assessed using RPN (probability, severity and detectability). Chemical substance safety risk assessment report for Actellic EC dated 20th May 2020 was in place. Various risks were identified such as risk related to personnel (formulation, packaging, and logistic operator), risk related to material property, risk due to storage and transportation and risk due to usage and handling of materials (accidental) and hygiene. Other risk assessments performed by the company included the Cross-contamination matrix which detailed the maximum permissible carryover limits for the different active substances.

8. Control of changes

Change management procedure was discussed. The objective of the procedure was to determine responsibilities and procedure for handling changes and the technical director was responsible for the implementation of this procedure. The changes were categorized into minor and major changes. The spreadsheet was used to rank changes as minor or major during the weekly meeting.

9. Internal Audits

The internal audit procedure was reviewed. The SOP stipulated the procedure for the planning, preparation and reporting of internal audits to the senior management. The procedure stated that identified internal auditors will not audit their department or area of work. Internal audits were carried out once every year. It was indicated that identified auditors received training from an external company. A list of qualified internal auditors was available in a spreadsheet. Training records were in place. The internal audit report for the internal audit performed in September 2020 was discussed. The internal audit findings were categorized as "ok", "not ok" and "for improvement".

10. Control of nonconforming products

Nonconformance and corrective action procedure was discussed. The procedure described handling of nonconforming products detected due to manufacturing issues, non-conforming finished products, recalls and complaints. Complaints were received by the Customer Care team. The procedure provided for investigation to determine the root cause. A complaints register was in place. A complaint from Syngenta Crop Protection AG was discussed. An investigation was performed, and corrections and corrective actions taken.

11. Performance evaluation

The parameters monitored included label information (name of product, batch number, description) fill weight, appearance, closure integrity among others. The information was analyzed, and records maintained. Review of the records indicated that the parameters were within limits and the process was under control.

12. Design and development of products

Design and development were not applicable. The site was not involved in design and development activities.

13. Support

Infrastructure and work environment

The facility was generally well maintained and clean. Appropriate personnel protective equipment (PPE) was worn by staff. Rodent traps were in place.

Monitoring and measuring resources

The calibration and maintenance schedule for 2021 was in place. Maintenance records for the filling machine were reviewed. Calibration records for the balances were also reviewed.

14. Production and service provisions

Control of Production

Only the filling, packaging, and labelling of Actellic EC were performed. Bottles and Cans were fed through a conveyor belt to where the mechanical system positioned them under the filling machine. The automatic filling machine was equipped with checkweighers. The bulk was pumped to the filling machine. The filled bottled were then capped and labelled. The batch number was printed online using an Ink Jet printer. In-process checks performed included weight check, closure integrity check, print and label check. Records were maintained. At the time of the audit the filling, packaging and labelling of a different product into 1L bottles was ongoing.

The laboratory was located in Building A. The laboratory had appropriate equipment and utilities. Equipment was uniquely identified. The laboratory was well maintained. The date and time on workstations were locked. The analysts had unique login passwords.

Production records for Actellic EC were reviewed. Line clearance was performed prior to production of another batch. Cleaning was performed whenever there was a product changeover. The issues raised under this section were addressed by the manufacturer to a satisfactory level.

Identification and traceability

Materials were identified, and status indicated. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

Release of products and services

The batch release was performed through Flak Program (in-house developed software) based on the results of cross-contamination test. The issues raised under this section were addressed by the manufacturer to a satisfactory level.

15. Preservation

The weight and appearance of the bulk Actellic EC was verified upon receipt of the material from FMC Agricultural Solutions. The received materials were staged in an open/uncontrolled environment outside the warehouse awaiting verification. Inventory control was managed by use of SAP. The Logistics and goods receipt work instructions were reviewed. The temperatures in the warehouses were monitored. Material Safety Data Sheets (MSDS) were in place.

16. Post-delivery Activities

The temperature of retention samples rooms was monitored. The retention samples were adequately labelled. Inventory records were available. The samples were retained for 5 years.

17. Control of externally provided processes, products and services

A supplier evaluation reports was discussed. Assessment of suppliers was based on the following parameters: quantity, quality, price, lead time/deadline and complaints. A customer satisfaction report for Syngenta Crop Protection AG was in place. The criteria for assessment of customer satisfaction (Syngenta Crop Protection AG) were based on number of complaints and the quantity of the product received.

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 ***Chemark Termelo Es Kereskedo*** *located at* ***Postafiok 31, 8182 Peremarton-Gyartelep, 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. 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/