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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	Zobele Holding S.p.A
Applicant/ Corporate address of manufacturer	S.C. Johnson, Inc. 1525 Howe St Racine, Wisconsin, 53403-2236, USA
Inspected site	
Name & address of inspected manufacturing site(s)	Zobele Holding S.p.A Via Fersina 4 Trento, 38123 Italy
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	28-30 October 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	Zobele Holding S.p.A manufacturers insecticides, air fresheners, repellants. Mosquito shield was in a dedicated area. The manufacture of Mosquito shield involved mixing, filling, labelling, and packaging.
General information about the company and site	The manufacturer held the following ISO certificates: **ISO 9001: 2015** **Scope: ‘‘**Design, development and production of insecticides, air-care, and small electric devices.’’ Certificate Number: 526 Issued: 14/02/2023 Expiry date: 20/02/2026 The certificate was issued by CISQ. The inspected address and activities were covered by this certification. **ISO 14001:2015** **Scope:** ‘‘Production of insecticides and fragrances through mixing, filling, impregnation and packaging.’’

	Certificate Number: 5476 Issued: 08/02/2024 Expiry date: 08/02/2027 The certificate was issued by CISQ. **ISO 45001:2018** **Scope:** ''Design and development of insecticides, air freshener, housecleaning products, and small household appliances. Production and sale of insecticides and fragrances through mixing, filling, impregnation, and packaging.'' Certificate Number: 57596 Issued: 31/03/2023 Expiration date: 30/03/2026 The certificate was issued by CISQ.
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	Design and development activities of the WHO prequalified products under the scope of this inspection were not undertaken at this site.
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	• Mosquito Shield – (Transfluthrin 80%)- 024-003

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	**Summary of the findings and comments**

1. Management Review

The latest management review report was in place. The management review meeting was attended by top management, including the plant manager, HR manager, quality manager, process quality manager, quality director – home care, HSE manager, etc. The management review meeting inputs and outputs were found satisfactory.

2. Organizational roles, responsibilities, and authorities

Job descriptions of the key personnel were defined in the organization manual. The responsibilities of the following personnel were reviewed:

- Plant General Manager
- Group Quality Director
- Quality Manager

3. Quality policy and Quality objectives

The manufacturer had a management system policy in place. The quality policy included a commitment to continual improvement of the quality management system. The manufacturer had defined quality management objectives related to production, supply chain, HSE, quality and maintenance, and human resources. The defined KPIs for the different objectives were monitored. The extent to which the KPIs are achieved was discussed monthly. Action plans were developed in the event a KPI was not achieved.

4. Document control

The procedure for document and record management was reviewed. The procedure described the process for the creation, issue, distribution, control, and conservation of documents and records. The procedure also outlined how documents were to be prepared, updated, and reviewed. It specified that documents are prepared by relevant process owners and were subject to an approval process before release. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

5. Personnel competence and training

An organization Training Policy was available. It provided a framework for managing training and education activities to ensure that employees possessed the right skills and knowledge to deliver the organization's strategic and operational plans. This policy was applicable to all Zobele employees.

The procedure for training management was reviewed. The procedure described the different types of training given to employees. According to the procedure, training was given to new employees or to personnel that would change role or production line. Following that procedure, the organization defined a training plan.

Competency matrices (skill matrices) and technical profiles for production staff were in place. The company encouraged training through innovative learning methods, including e-learning, and the use of multimedia languages to ensure the use of IT tools as channels for disseminating training content. Training records were maintained. Training needs were identified by the manager.

It was also noted that weekly micro audits were arranged to assess knowledge and effectiveness of the operators' way of working in accordance with the company's principles and requirements relating to Quality, Safety, and the Environment. Micro audits were planned depending on the production agenda and were arranged by (HR manager, Quality and HSE). During such spot checks, the operator would have to demonstrate sufficient knowledge to perform the activity and in case of any gap, one would receive live training refresher by the assessors. A check list was used to this purpose.

6. Risk Management

The procedure for risk analysis defined the criteria for risk analysis. Risks were categorized into rare, low, medium, and high. A risk register was in place. Risk assessment had been conducted on the company environment, market, and competitors, macroeconomic and finance, technology, institutional laws, environment, and social and cultural environment. The risks were categorized into rare, low, medium, and high. Risk assessment had been conducted on the company environment, market, and competitors, macroeconomic and finance, technology, institutional laws, environment, social and cultural environment.

The manufacturer also had a business contingency plan that defined the different contingency plans, impact assessment in event of earth quakes, power disruption, fire, explosion, gas supply interruption, water supply interruption, flooding, heavy snow, legal compliance, pandemics, train and plane/helicopter incidents, staff strike, etc.

7. Internal Audits

The relevant procedure for internal audits described how audits were to be conducted and the roles and responsibilities of those involved in conducting internal audits. The annual audit program was created by the local management systems representatives. The nonconformities (NCs) were categorized into two: Simple NCs and Complex NCs.

8. Control of nonconforming products

The procedure for nonconformity, problem solving, and complaint management was in place. The procedure described the process for management for nonconformities, customer complaints, and related corrective actions. The procedure took into consideration investigations, root cause analysis, corrective actions, and verification of corrective actions. All the nonconformities were documented and retained in SAP. The 5 whys or cause effect (Ishikawa) was used to identify root cause. Key Account Manager provided feedback to the complainant. The manufacturer had not received any complaints related to Mosquito shield. No reworking procedures were adopted for Mosquito Shield.

9. Control of Changes

The relevant procedure for changes (PRO-00074) was reviewed. The procedure described the scope, roles and responsibilities, and overall process to follow when initiating and implementing a change. Whenever a change was initiated, a formal request was drafted and submitted in the facility's customized software system. Prior to initiation of a change, a feasibility study (including impact assessment) was conducted to assess the technical feasibility and financial convenience associated with the change. The changes reviewed were found satisfactory. The roles and responsibilities of the personnel at which each phase of the process were clearly outlined.

10. Recalls

Zobele was not responsible for product recalls. SC Johnson was responsible for recalls. SC Johnson had in place a procedure for product incident management. The procedure included investigation, risk assessment, and determination of preventive actions. The product recovery protocol was also in place. Product recovery from the market was categorized into 3:

-Class 1 – emergency, immediate removal; the deficiency poses an immediate long-term threat to health or life. Depth of recovery complete and immediate removal from consumers, retail shelves, and all levels of the distribution chain

-Class II – product causes temporary or medically, possibility of serious adverse effect is remote. Depth of recovery: rapidly as possible from all levels of distribution chain and retail shelves.

-Class III – product deficiencies causing adverse effects are highly improbable. Product involving misbranding or due to adulteration. Recovery RDCs (warehouse). There had been no recalls.

11. Design and development of products

Design and development activities of the WHO prequalified products under the scope of this inspection were not undertaken at this site.

12. Support

Infrastructure and work environment

The facility was in good state of repair. The warehouse was equipped with sprinklers and spill kits were in place. The laboratory had eyewash stations. PPE was available in the production area. Material safety data sheets, including Transfluthrin, were also in place. Personnel in the laboratory were appropriately gowned.

Monitoring and measuring resources

An equipment maintenance schedule was in place. Mosquito shield was dosed, filled, and packed on three dedicated lines. The three lines were maintained every 3 months. Maintenance reports were maintained. Breakdowns were reported and recorded on the maintenance intervention request form.

The manufacturer also maintained an equipment calibration database. The calibration records of selected balances were checked. The calibration certificates of the selected standard weights were checked.

13. Production and service provisions

Control of Production

The manufacture of Mosquito Shield involved the mixing of Transfluthrin with a solvent and filling in sachets, labelling and packaging. Selected batch records for Mosquito Shield were reviewed. The mixing time and weight of the raw material used in production were recorded. The Transfluthrin mixture was sampled and analyzed prior to filling. The facility was equipped with a dosing line that had form, fill and seal components. Instructions for production were in place. The following were some of the parameters monitored during production: dosage weight, vacuum, integrity of the pouch, labelling. No commercial batches had yet been manufactured. The manufacturer had only produced batches for clinical trial purposes. The packaging was done manually.

The laboratory carried out both physical and chemical tests. The analytical method validation report for determination of Transfluthrin – Mosquito shield was reviewed. The validation parameters included linearity, repeatability, accuracy, specificity, and asymmetry. LOQ had been determined. Raw data and test reports for selected batches were verified. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

Process validation.

The procedure for product and process validation was in place. The relevant documentation, including formula, test plan, BOM scale up report and predetermined parameters were defined. The procedure also described the management of changes during the validation process. The process validation was report for the Mosquito shield was checked. The critical parameters to be monitored were defined.

Waste management.

The manufacturer had a procedure for waste management in place. The waste was collected by an authorized/certified third-party company. The procedure required that waste be collected, segregated, and stored appropriately as per the relevant Italian laws. The procedure also defined the relevant documentation to be maintained by the manufacturer.

14. Preservation

Inventory and material management was managed by SAP. Raw materials were received along with the Certificates of Analysis (CoA), delivery note, packing list, and other relevant documentation. The procedure for receipt of materials and the procedure for quality control and control processes were reviewed. Any nonconformities observed at receipt of materials were communicated to the quality department. The materials were issued to production following the FEFO principle.

15. Retention samples

A sample of every batch was retained. The samples were retained for 6 years. The samples were stored at ambient conditions.

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

The selection and performance evaluation of suppliers of the raw materials was carried out by SC Johnson. Zobele Holding S.p.A was not responsible for the selection and performance of the suppliers of the raw materials used in the manufacture of Mosquito shield.

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 **Zobele Holding S.p.A** located at **Via Fersina 4 Trento, 38123 Italy** 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/