World Health Organization

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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Desk Assessment of Vector Control Product Manufacturer

Part 1	**General information**
Company information	
Name of manufacturer	Clarke Mosquito Control Products, Inc.
Corporate address of manufacturer	Clarke Mosquito Control Products, Inc. 675 Sidwell Court St. Charles, IL 60174 United States of America
Manufacturing site(s) under assessment	
Address of manufacturing site if different from that given above	610 Lunt Ave Schaumburg Illinois 60193, U.S. A
Unit/Block/ Workshop	Not applicable
Desk assessment details	
Dates of review	15-21 March 2023
Products covered by this desk assessment	Spinosad 7.48% DT - 020-001 Spinosad 20.6% EC - 020-002 Spinosad 25 Extended-release GR - 020-003 Spinosad 0.5% GR - 020-004 Spinosad Monolayer DT - 020-005 Cielo ULV - 020-006 (Only release testing)
List of documents submitted	• Site Master File • Site Floor Plan • Location of site • Clarke Quality Manual • Staff Organogram • QMS SOPs • SOPs -Control of changes, risk, supplier evaluation • ISO audits -Internal and external • ISO 9001:2015 Certificate • ISO 17025:2017 Certificate • ISO 9001:2015 - 2020 report • ISO 17025: 2017 - 2020 report • ISO 9001:2015 - 2021 report • ISO 17025: 2017 - 2021 report • ISO 9001:2015 - 2022 report • ISO 17025: 2017 - 2022 report • Declaration – No NC observed in 9001 audits

	• Contamination control • List of products manufactured on site • Authorized contacts • Process flow chart – Natular 20EC • Process flow chart – Natular DT • Process flow chart – Natular G • Process flow chart – Natular G30 • Process flow chart - NatularT30 • Annex 6 – Flow charts • Q 3 2022 MRM Agenda and Minutes • Natular and Cielo Recent Batch Records • Natular XRT Template • Natular EC Template • Natular G or Granules template • Natular G30 Template • Natular T30 Template • Cielo Template • Product recalls • Contract manufacturer • Next expected manufacture date
Abbreviations	**Meaning**
NC	Non-conformity
NCR	Non-conformity Report
OOS	Out-of-specification
QA	Quality Assurance
QC	Quality control
QMS	Quality management system
Part 2	**Summary of the assessment of ISO audits**

Name of ISO certification body Eagle Registrations Inc.	Dates of Audit	2-3 June 2022
	Type of Audit	Surveillance
	Inspected areas/documents	Quality Manual, interested parties matrix, Risk Management, Management Review, Internal Audits, Nonconformities/Complaints/ Corrective Actions, Shipping, Receiving, Production records, Supplier performance monitoring, M3 ERP system, Improvement Plan, Calibration trails, QC release, QC process, test results, Maintenance, Analytical lab process, Training, Documented information.

Eagle Registrations Inc	Product covered	Natular DT (Spinosad 7.48% DT), Natular G30 (Spinosad 25 Extended Release GR)

Date of Audit	17-21 May 2021
Type of Audit	Recertification
Inspected areas/documents	Quality Manual, Interested Parties matrix, SWOT analysis, Risk mitigation, Management review, Customer satisfaction, Production, Supplier performance, Corrective actions, Complaints, Innovation, Internal audits, purchasing products and services, Maintenance of machinery and equipment, Calibration, Analytical process (Schaumburg), Receiving, Shipping, Documented information
Products covered	Cielo, Natular SC (Suspension concentrate), Biomist 4+4 ULV, Natular G30 (Spinosad 25 Extended Release GR), Natular DT (Spinosad 7.48% DT)

Date of Audit	2-3 June 2020
Type of Audit	Surveillance (Remote Audit)
Inspected areas/documents	Management review, Internal audits, quality process conformance, KPI reviews, Corrective actions, Improvement, external providers, Receiving, Shipping, Manufacturing batch records, design and development, Risk updates, international customer care and domestic sales.

Eagle Registrations Inc

	Products covered	Cielo, Natular G30 (Spinosad 25 Extended-Release GR)
Part 3	**Summary of the last WHO inspection**	
	The site has never been inspected by WHO.	

Part 4	**Summary of the assessment of supporting documentation**

1. Quality Manual:
The Quality Manual described the quality policy, planning, external and internal issues, interested parties, and system procedures. The QMS process map was also described.

2. List of current quality management procedures:
A list of current quality procedures was provided.

3. Standard operating procedures for:

i. Complaint handling, vigilance and recalls:
The procedure for product complaints and returns processing was reviewed. Quality Assurance (QA) was responsible for the review and investigation of complaints. Corrective actions were handled in accordance with the procedure for corrective actions. In the event of a recall, the QA department together with the Regulatory Affairs department determined the market impact and took the necessary actions.

ii. Control of nonconforming goods/processes:
The procedure for Control of nonconforming products and processes was reviewed. Nonconformities were documented in the Quality Action log by QA. The quality action log included among others, records on Facility impact, products/process impact, product lots, salesforces case, nonconformance description, corrective action. Nonconforming products could be reworked, accepted as is, with customer authorization, repaired, scrapped, or returned to the vendor. Reworked products were inspected for conformance to product specifications and requirements before release.

Change control/change notifications (product and processes):
The procedure for Engineering change control was reviewed. The procedure applied to manufacturing process, equipment, tooling, and manufacturing documents. The procedure provided for impact assessment of the changes.

iv. Risk management:
The procedure titled 'Risk and opportunity process' was reviewed. The procedure described the identification, assessment, and evaluation of risks. The Risk Matrix scoring tool was also described.

v. Supplier evaluation and control, verification of purchased product:
The supplier standards manual described the process for qualification, assessment, and evaluation of suppliers. The process included on-site assessment to determine the effectiveness of the suppliers'

systems including procurement and information systems. Suppliers are categorized into three types of approval levels: Full, Conditional or Unsatisfactory. The criteria of evaluation of suppliers were also described.

4. Site Master File (SMF) and site floor plan
The Site Master File provided an overview of the QMS, activities, processes, and procedures. The site floor plan was also provided.

5. Quality management system certificate(s) and scope of certification: (e.g., ISO 13485/ISO 9001):
The manufacturer provided a valid ISO 9001: 2015 certificate.

6. List of notifications of upcoming inspections by the regulatory authorities or ISO 9001:2015 certification bodies in the next 6 months:
The list of upcoming inspections was provided.

7. Process flowchart including in-process control points:
Process flow charts for the following were provided:
• Natular 20EC (Spinosad 20.6% EC)
• Natular DT (Spinosad 7.48% DT)
• Natular G (Spinosad 0.5% GR)
• Natular G30 (Spinosad 25 Extended-Release GR)
• Natular T30 (Spinosad Monolayer DT)

8. List of all the products and formulation types manufactured at this site:
The list of products manufactured on site was provided.

9. Most recent management review report/minutes:
The most recent management review minutes were provided. The agenda of the meeting included among others: changes in external and internal issues that are relevant to the quality management system, status of actions items, information on performance and effectiveness of the quality management system, customer satisfaction and feedback from all relevant interested parties, monitoring & measuring results, adequacy of resources, opportunities for improvement and review of action items.

10. Master batch manufacturing, and/or packaging records of the WHO product of interest:
The following master batch manufacturing records were submitted and reviewed.
• Natular 20EC
• Natular DT
• Natular G
• Natular G30
• Natular T30
• Cielo
• Natular XRT

11. Completed batch manufacturing and/or packaging records:
The following production records were submitted and reviewed:
• Natular DT (Spinosad 7.48% DT)
• Natular EC (Spinosad 20.6% EC)

• Natular G (Spinosad 0.5% GR)
• Natular G30 (Spinosad 25 Extended-Release GR)
• Natular T30 (Spinosad Monolayer DT)

12. List of any recalls/returns:
A declaration was submitted. No recalls or returns were registered in the last 3 years.

13. Name and address of sites to which any related activities are outsourced:
There are no outsourced activities.

Part 5	**Desk assessment conclusion**

Based on the inspection by Eagle Registrations Inc and on the QMS evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site ***Clarke Mosquito Control Products, Inc*** located at ***610 Lunt Ave Schaumburg Illinois 60193, U.S.A*** is considered to be operating at an acceptable level of compliance with *ISO 9001:2015 standard* and WHO compliance guidelines as per *Overview of the WHO Prequalification Assessment of Vector Control Products, June 2021*. This compliance status shall be valid until **24th July 2024** or when another inspection is conducted by WHO or by a reliable certification body.

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/

3. Overview of the WHO Prequalification Assessment of Vector Control Products, June 2021
   https://extranet.who.int/prequal/sites/default/files/document_files/WHO_PQT_VectorControlProducts_June2021.pdf