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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	Shree Dutt Agrochem
Corporate address of manufacturer	Tagros Chemicals India Private Limited Tagros House, No.4, Club House Road, Anna Salai, Chennai 600002, Tamilnadu -India
Inspected site	
Name & address of inspected manufacturing site(s)	1. Shree Dutt Agrochem Shed No: A2/625, unit 3, Hickcal Road, G.I.D.C, Panoli, 394116, Gujarat, India. 2. Tagros Chemicals India Pvt Ltd. (Quality Control Laboratory), Plot No.2901-2906 and 2806, GIDC, Ankleshwar, Bharuch District, Panoli, Gujarat 394116 India
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	21 -22 September 2023
Type of inspection	Re-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	a) Shree Dutt Agrochem: Shed No: A2/625, unit 3, Hickcal Road, G.I.D.C, Panoli, 394116, Gujarat, India Shree Dutt Agrochem manufactured 2GARD and Klypson 500 WG on contract for Tagros Chemicals India Private Limited. The manufacture of 2GARD involved pre-blending, milling, post-blending and packaging. The manufacture of Klypson 500 WG involved premixing, milling, post blending, dough making, extrusion, drying, sieving and packaging. There were two blocks. Klypson 500 WG and 2GARD were manufactured in a block that was dedicated to the manufacture of Tagros products. b) Tagros Chemicals India Pvt Ltd. (Quality Control Laboratory): Plot No.2901-2906 and 2806, GIDC, Ankleshwar, Bharuch District, Panoli, Gujarat 394116 India.

	Only the quality control laboratory was inspected. The laboratory performed both physical and chemical tests on the in-process samples and finished products from Shree Dutt Agrochem.
General information about the company and site	The manufacturer had a valid license to manufacture insecticides from Government of Gujarat, Directorate of Agriculture. The manufacturing site also held a valid 'License to Work a Factory' issued by the Directorate of Industrial Safety and Health, Gujarat State. The manufacturer did not have ISO certifications. The site adopted and implemented the QMS from Tagros Chemicals India Pvt Ltd. Tagros Chemical India Pvt Ltd is ISO 9001 certified.
History	The site was last inspected by WHO in February 2019.
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 of products were not applicable as the site was not involved in the 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	• 2GARD (Clothianidin 50% + Deltamethrin 6.25% WP) - 004-018 • Klypson 500 WG (Clothianidin 50% WG) - 004-019

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 (where applicable)**

1. Quality policy and quality objectives

There were no changes to the quality policy or objectives since the last WHO inspection in February 2019. The quality policy was displayed throughout the facility and available in both English and local language.

2. Management review

Management reviews meetings were carried out in accordance with an established procedure. The meetings covered all 4 sites that were affiliated with Tagros including Shree Dutt AgroChem. The last meeting was held on 15/02/2023 at the Tagros Chemicals India Pvt.Ltd -Cuddalore site. The attendance sheets were available.

3. Organizational roles, responsibilities, and authorities

Roles and responsibilities were clearly defined between the two sites with Tagros personnel being on site to oversee production when required. The technology transfer agreement between the Tagros Chemicals India Pvt Ltd and Shree Dutt Agrochem was available. The agreement between Shree Dutt Agrochem and Tagros was reviewed. As per the agreement Tagros was responsible for ordering and providing all raw materials and performing the QC release on these items before sending to Shree Dutt Agrochem. Shree Dutt was responsible for providing material samples to Tagros for QC testing. Tagros was responsible for product release.

Tagros as well as site management were committed and dedicated to improvement of the quality management system and processes. A representative from Tagros oversaw the production activities at the site.

4. Control of documented information

Tagros were responsible for the control of documents and distribution to Shree Dutt Agrochem. According to the procedure for document control the Quality Assurance department was responsible for issuing the necessary controlled documents to authorized personnel. Tagros staff would physically hand over the documents to top management of Shree Dutt Agrochem. All templates of Batch Manufacturing Records were distributed by Tagros for each production.

5. Personnel competence and training

Tagros had a well-established procedure for the training of staff. Tagros were responsible for training Shree Dutt Agrochem staff. Training records were available. The following trainings had been conducted:

- Material receipt, storage and handling procedure
- Cross contamination prevention
- Good document practice BMR writing
- Guidelines for cross contamination prevention
- Blender cleaning for solid product

Training for managers was conducted monthly at all 4 affiliated sites. Training records were in place.

6. Risk Management

The procedure for Hazard identification and risk assessment was in place. A Hazard identification and risk assessment matrix was reviewed. The document titled ‘‘Internal and external Issues and Risk and opportunities” was reviewed.

7. Control of changes

Any changes to documents and processes at Shree Dutt were approved by Tagros prior to implementation. The procedure for change authorization was reviewed. The procedure applied to process changes, document changes, changes concerning engineering modifications, supplier changes, specification and analysis methods of raw materials and finished products. Process changes were reviewed by an expert team and approved by the Site Head, Tagros. Document change request template and process change request template were in place. The change request templates provided for impact assessment of the proposed change. No changes had been registered since the last inspection. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

8. Internal Audits

Tagros had a process for internal audits and had audited Shree Dutt Agrochem in August 2023. The internal audit report was provided.

9. Control of nonconforming products and complaint handling

Market complaints were received by Tagros (Marketing department). No market complaints had been received at the time of the inspection. The relevant procedure for customer complaints was reviewed. Complaints were categorized into 3:

- Critical – high probability of causing adverse consequences to the consumer
- Major – could have possibility/potentially cause adverse consequences to the customer
- Minor- can’t be classified as major or critical.

Complaints were submitted to the Head QA/QC for investigation. The procedure provided for investigations, corrections, and corrective actions. Feedback was to be provided to the customer within 30 days. The template of the customer complaints register was in place. The procedure for control of nonconforming products was briefly checked. At the time of inspection no nonconforming product had been detected.

10. Recalls

Tagros was responsible for product recalls. The relevant procedure for product recall was reviewed. The purpose of the procedure was to ensure a prompt and effective recall of finished products known or suspected to be defective from the market. Recalls were classified as follows:

- Class I – recall of products which could cause serious safety issues or process failure or
- deviation
- Class II – Recall of products which could cause serious injury/temporary illness
- Class III – recall of products that are unlikely to cause injury or illness

In case of a recall the Head Marketing/Head logistics would inform all customers and regulators of the recall. At the time of the inspection no product recall had been initiated yet. A mock recall was performed every 4 years. The template of the product recall circular was in place.

11. Design and development of products

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

12. Customer satisfaction

The relevant procedure for customer satisfaction was reviewed. The purpose of the procedure was to obtain customer feedback, analyse and identify opportunities for improvement. The procedure applied to all customers. The Head, Sales was responsible for obtaining customer feedback. The Head, QA was responsible for analysis the data. The data analysed was collected from customer satisfaction surveys and complaints. This was discussed in the management review meetings. Customer satisfaction surveys were conducted biannually. The customer feedback form was in place. The customer satisfaction survey included the following metrics: quality of the products, consistency, delivery on time, price worthiness, quality of the packaging materials, availability of documents, communication, response to queries/complaints, solutions to queries or complaints. Customer satisfaction survey report performed in April 2023 was in place.

13. Support

Infrastructure and work environment

The infrastructure at the manufacturing site was well maintained. The Quality Control Laboratory was also well maintained and clean, with appropriate equipment that was fit for purpose. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

Monitoring and measuring resources

Maintenance records for January 2023 and July 2023 were available for the following equipment:

• Pre-blender
• Post-blender
• Dough Mixer
• Extruder
• Continuous sealing machine
• Balances

External service report for the following were available:

• LT panel
• Thermohygrometer

14. Production and service provisions

Control of Production

The manufacture of Klypson 500 WG involved the weighing and mixing of the different

ingredients in a pre-blender, milling, dough making, extrusion, drying, sieving, and packaging. The granules were dried in a Fluid Bed Drier. The granules were sampled and tested. The defined in-process tests were performed, and records maintained.

The manufacture of 2GARD involved pre-mixing, milling, blending, and packaging. The powder was sampled after post-blending and defined in-process tests performed.
The ingredients were weighed using a calibrated balance. Master formulas were in place. Batch manufacturing records for Klypson 500 WG and 2GARD were reviewed. The times for the jet milling and post-blending were monitored and recorded.

The procedure for cleaning of solid products was reviewed. The procedure described the instructions for cleaning of the equipment of the WP and WG production lines. Cleaning was done whenever there was a product changeover. Cleaning records were available.

The process validation protocol and report were reviewed. The validation was carried out using three batches. No deviations were noted. The critical process parameters and critical quality attributes were identified.

Quality Control Laboratory
The Quality Control laboratory was situated in newly constructed premises. The Quality Control laboratory was well maintained and clean with appropriate equipment that was fit for purpose.

An inward sample register was in place. The laboratory performed both physical and chemical tests. The analytical test reports for Klypson 500 WG and 2GARD were reviewed. The standard testing procedures were also reviewed. The date and time of the computer linked to the HPLC was locked. Audit trails were available. Each of the users accessed the software using unique passwords. Data was backed up on hard disks on a regular basis. Standards used in the QC laboratory were stored within a refrigerator.

The procedure for sampling of raw materials and retention samples was reviewed. The sampling plan for the different materials was defined. The procedure for Handling of Out of Specifications was reviewed. The cleaning instructions for the glassware in the Quality Control Laboratory was available.

Control of waste
The manufacturer had a procedure available for the control of waste. The scope of this procedure only included the Tagros - Cuddalore site. There were clear waste disposal processes at Shree Dutt Agrochem with waste management agreements in place. The site was regulated by local and national waste disposal rules and regulations.

All the issues raised related to this section were addressed satisfactorily by the manufacturer.

15. Preservation

The raw materials were supplied along with a requestion slip, packing list, invoice, and Certificate of Analysis etc. Upon receipt of the raw materials a goods received note (GRN) was generated and an intimation (for sampling) was sent to the QC laboratory. Raw materials were sampled by Quality Control Laboratory personnel. A spill kit was available in the warehouse. Material safety data sheets were in place. Finished products were stored in a separate warehouse from that of the raw materials. The Inventory records were in place.

16. Retention samples

A retention sample storage area was available in the Quality Control laboratory at the Tagros site. A sample of each batch was retained. The procedure for sampling of raw materials and retention samples defined the quantity of retention samples to be drawn and stored. Inventory records for the retention samples were available. Samples were retained for 5 years.

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

Raw materials were all received from Tagros Chemicals India Pvt Ltd. The suppliers of the raw materials were selected and evaluated by Tagros. This will be assessed further during an inspection of Tagros Chemicals India Pvt Ltd.

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 **Shree Dutt Agrochem** located at **Shed No: A2/625, unit 3, Hickcal Road, G.I.D.C, Panoli, 394116, Gujarat, India** 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/