

**Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Vector Control Product Manufacturer**

Part 1	General information
Manufacturers details	
Name of manufacturer	TJC Chemical Co Ltd
Corporate address of manufacturer	TJC Chemical Co Ltd Thailand Mueang Samut prakarn, Samut prakarn 185 M.2 Sukhumvit Rd., Bangpoo-mai, Thailand
Inspected site	
Name & address of inspected manufacturing site(s) if different from that given above	As above
Unit/Block/Workshop	Building SG-3
Inspection details	
Dates of inspection	17 – 18 September 2018
Type of inspection	Initial inspection. The criteria for the inspection was the ISO 9001:2015 standard.
Introduction	
Summary of the manufacturing activities	TJC Chemical Co Ltd manufactures insecticides and herbicides in the form of liquids and granules. Activities related to the manufacture of the larvicide Abate 1 Sand Granules (Temephos 1%) included warehousing of raw and finished products, in-process testing, labelling and packaging.
General information about the company and site	This was the first WHO inspection. ISO 9001:2015 Date of issue 27th January 2018 Expiry date 27th January 2021 Certificate number TH00/2347. Issued by SGS United Kingdom Ltd. Scope of certification by SGS United Kingdom Ltd: Manufacture of pesticides and other agro-chemical products (hormones, fertilizers) for agriculture. In addition, the site had a GMP certificate number 1-6-04-90-16-00002, issued 21st January 2016, valid until 20th January 2019. Issued by FDA,

	Ministry of Public Health, Hazardous substances control division, Thailand. Scope of GMP certification by FDA: Manufacturing of Pesticides
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 • Data integrity • Product release • Batch processing records • Sampling and laboratory test reports • Control of changes • Internal audits • Calibration and equipment maintenance Physical areas: • Quality control laboratory • Raw material and finished goods warehouses • Production areas
Exclusions and Non-applications of requirements in the QMS	Design and development of products and services was not applicable. TJC Chemical Co. Ltd was not involved in the activities of design and development of products submitted to WHO for prequalification. Design and development of Abate 1 Sand Granules was performed by BASF.
Out of scope	Products not submitted to WHO for prequalification.
Restrictions	None
WHO products covered by the inspection	Abate 1 Sand Granules (Temephos 1%) 002-004
Abbreviations	Meaning
HPLC	High performance liquid chromatography (or high-performance liquid chromatography equipment)
MSDS	Material safety data sheet
NC	Non-conformities
PPE	Personal Protective Equipment
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory

QMS	Quality management system
RA	Risk assessment
SOP	Standard operating procedure
WHOPES	World Health Organization Pesticides Evaluation Scheme

Part 2	Brief summary of the findings and comments
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1. Organizational roles, responsibilities and authorities

The organogram was reviewed, and it reflected the current structure of the company. Reporting lines for Quality Control and production were independent of each other. A selection of job descriptions was reviewed. The job descriptions included the relevant requirements for the jobs including educational requirements for technical posts.

2. Quality policy and quality objectives

The quality policy was adequately described in the quality manual and was appropriate to the purpose of the organization. The policy was communicated to all employees by training, regular internal communications and reinforcement during annual employee performance reviews.

The quality objectives were documented, measurable and consistent with the quality policy.

3. Management review

A procedure for management review was in place. Agenda items listed in the procedure were compliant with the requirements of the standard. The review was conducted twice a year with reporting periods of Jan-June and July to December.

Minutes of the Management Review meeting were reviewed. Minutes included the following discussion topics; risk assessments, change management, Internal Audit, External audit report, Performance reports from each section including production, product quality, performance of external providers etc. The Quality policy was also reviewed. The performance of 52 suppliers was evaluated and an overview of the evaluation was discussed during the management review meeting.

4. Leadership

The Quality Manual was reviewed and a commitment of the factory manager to implement and maintain a working QMS was documented therein. Section 4 of the quality manual further described managements` commitments and understanding with respect to the quality management system.

5. Control of documented information

Documented information included batch processing records, SOPs etc. The SOPs were readily available for reference. Documents were identified. Quality control was responsible for issuance and retrieval of documents. The documentation system was paper-based, and records were readily available. Documents were retained for more than 2 years. The shelf life of Abate 1 Granules was 2 years. Issues raised in relation to this section were satisfactorily addressed by the manufacturer.

6. Personnel competence and training

The relevant procedure was reviewed. Training needs were discussed with staff every October to obtain training requirements for each staff member, if any. A five-year training schedule was reviewed. All new staff underwent a standard induction and orientation training package. The topics on the trainings included factory rules and regulations, Safety, QA including ISO9001, 14001, GMP, quality policy and job specific training from the section chief. Each function in the organization had an approved job description and related minimum educational requirements. Training records were reviewed.

7. Risks and opportunities

The manufacturer presented a draft risk management plan with timelines to identify opportunities and fully implement the plan. At the time of the audit no procedure on risk and opportunities existed. It was planned to introduce the procedure in Dec 2018, with the activity recorded on the project plan timeline.

A full assessment of the company had been carried out based on the SWOT method of analysis. All identified strengths, weakness, opportunities and threats have been recorded in the draft register. The analysis of these is classified according to Low, Medium and High-risk mapping matrix. Mitigations for weaknesses and threats had been recorded along with responsible persons to action the mitigation. The progress and monitoring of the action plan and mitigation was reviewed at the bi-annual management review meetings.

8. Control of changes

A change control procedure was in place. Change request related to a change of the secondary packaging material for the Abate from fiber to plastic was reviewed. The reason for the change was to improve product integrity and to allow easier warehouse handling and transportation. Risk assessment for the change was conducted. The review and approval of the change was adequately documented.

9. Internal Audits

The relevant procedure was reviewed. Internal audits were conducted twice a year. These had been planned for April and October 2018. The internal audit complied with the requirements of the ISO 9001 standard and other standards including ISO 14001 and GMP.

A list of trained and approved internal auditors was provided. The external training records and certificates were reviewed. The report for the internal audit conducted in April 2018 was presented for review. Verification of the implemented corrective actions was performed during the next internal audit. The ISO 9001 audit was conducted and reported using a checklist. Internal audits were discussed in management review meetings. An audit plan for October 2018 was in place.

10. Control of non-conforming products

No reworking was permitted at the facility. If a product did not meet the specifications for content of active ingredient the non-conforming results were to be documented and communicated to BASF. The product would then be destroyed. No non-conforming products had been encountered.

11. Performance evaluation

The manufacturer monitored and analyzed key process and product quality parameters for every batch such as flowability, particle size, pH, Temephos content, dryness, dust, active ingredient content. The data was evaluated by use of graphs. The data for the month of January to September 2018 was reviewed. The results of the evaluation indicated that the process and product quality parameters were within control.

12. Complaint handling

The relevant procedure was reviewed. The scope of the procedure encompassed both internal and external complaints. Complaints were broadly categorized as quality related complaint and non-quality related complaints. Complaints were received by the QC chief and safety and environment chief and forwarded to the General Manager. The General manager was responsible for composing an investigation team to investigate the root-cause. Complaints from the market were received by BASF and then forwarded to TJC for further investigation. No complaint on Abate had been received by the time of the audit.

13. Design and development of products

Design and development of products and services was not applicable. TJC Chemical Co. Ltd was not involved in the activities of design and development. Design and development of Abate 1 Sand granules was performed by BASF.

14. Support

Infrastructure and work environment

MSDSs were available in the warehouse. The environment was generally clean. The staff in the quality control laboratory were found wearing adequate PPE.

Monitoring and measuring resources

A calibration and preventive maintenance schedule was in place. Calibration reports for HPLC and weighing balances were reviewed. Preventive maintenance report for the drum blender was also reviewed.

15. Production and service provisions

Control of Production

Abate was manufactured in a dedicated building; SG-3. The manufacturing process involved premixing, blending, shifting and packaging. The dispensing of the liquid materials (Temephos and emulsifier) was performed in a dedicated area. Blending was carried out in a drum blender. The production equipment was made of stainless steel. No manufacturing was ongoing at the time of inspection. Records of production activities were maintained within the batch processing records. Batch processing records for Abate were reviewed. The documented information included incoming raw material report, production schedule, recipe, raw material orders from the warehouse, dispensing records, batch processing records, label issue records and packaging material check sheet. In-process checks included appearance, dryness, dust, flowability, particle size, pH and Temephos active ingredient content. Laboratory equipment was uniquely identified. Following intimation from production or warehouse, samples were collected by QC staff. Established sampling criteria for the raw materials, intermediates and finished product were in place. Samples were adequately identified. A sample of the blend was only collected from the outlet of the hopper during filling. The validation

report for in-house analytical method used in the determination of Temephos active ingredient content (Assay) was reviewed. The validation characteristics evaluated included accuracy, linearity, precision, range, limit of quantitation and limit of detection.

Laboratory test reports for the determination of the Temephos active ingredient were reviewed. The issues raised related to this section were satisfactorily addressed by the manufacturer.

Identification and traceability

Materials were uniquely identified, and the status clearly indicated. Records were maintained to enable traceability. Issues raised related to identification and traceability were satisfactorily addressed by the manufacturer.

Release of products and services

Upon review of the production and quality control reports production batches were released by the Deputy factory manager. Abate was marketed by BASF. The released batches were transported to BASF.

16. Preservation

Raw materials and finished products were stored under ambient conditions. The relevant procedure for receipt, storage and movement of materials was reviewed. Raw materials were checked upon receipt and an incoming material report issued. Abate granules were filled in polythene bags (25Kg) and then packaged in secondary plastic containers.

17. Post-delivery Activities

Storage stability

Due to time constraints, this was not reviewed at the time of inspection.

Retention samples

Retention samples were retained for a minimum of 3 years. The shelf life of Abate was 2 years. Records of the samples retained were maintained.

18. Control of externally provided processes and products

The vendor lists were provided. Vendor reviews were conducted twice a year and records maintained. Performance evaluation records of external providers were reviewed. this was conducted as per the procedure. If a supplier scored below a specified level/score they are removed from the approved vendors list. Vendors were approved by the purchasing deputy manager at head office and the details passed to TJC. Initially any new product is tested as a demo production sample for suitability prior to final acceptance onto the vendor lists. Vendor reports were reviewed.

Part 3	Conclusion – Inspection outcome
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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 ***TJC Chemical Co Ltd*** located at ***A Thailand Mueang Samut prakarn, Samut prakarn 185 M.2 Sukhumvit Rd., Bangpoo-mai, Thailand*** 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
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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, GHTE/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/>