



**Prequalification Team Inspection Services  
WHO PUBLIC INSPECTION REPORT  
(WHOPIR)**

**Desk Assessment of Vector Control Product Manufacturer**

| <b>Part 1</b>  |  | <b>General information</b> |
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| <b>Company information</b>   |  |                            |
| Name of manufacturer   | Utsunomiya Chemical Industry Co., Ltd.<br>Shinshiro Factory  |                            |
| Corporate address of manufacturer  | Utsunomiya Chemical Industry Co., Ltd – Head quarters<br>1215 Iwazo-machi, Utsunomiya-shi, Tochigi, Japan  |                            |
| <b>Manufacturing site(s) under assessment</b>  |  |                            |
| Name & address of inspected manufacturing site(s) if different from that given above | Utsunomiya Chemical Industry Co., Ltd.<br>11-4 Ihara, Oomi, Shinshiro-shi, Aichi,<br>Japan   |                            |
| Unit/Block/Workshop  | Not applicable.  |                            |
| <b>Desk assessment details</b>   |  |                            |
| Dates of review  | 6 - 9 March 2023   |                            |
| Products covered by this desk assessment   | Vectron 10EW 016-001<br>Vectron 20WP 016-002   |                            |
| List of documents submitted  | 1) Site Master File<br>2) Site floor plans<br>3) Full address of manufacturing site<br>4) Quality Manual<br>5) Staff Organogram<br>6) List of current Quality Management Procedures<br>7) Complaint Handling guideline –only a list of contents submitted in English<br>8) Deviation Control Guideline<br>9) Guideline for Quality Change Control<br>10) Risk Management<br>11) Regulation of Purchasing Management<br>12) List of ISO 9001:2015 Certification and Surveillance audits<br>13) Management System Audit Planning<br>14) ISO 9001 Management System Certificate<br>15) Current Full inspection reports<br>16) Product list<br>17) Name and contact details of responsible persons at the manufacturing facility |                            |



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|   | 18) Process flow chart of Vectron 10 EW and Vectron 20 WP in Japanese<br>19) Most recent management review minutes<br>20) Most recent management review report<br>21) Completed batch record for the most recently released batch<br>22) Master batch records (Template)<br>23) List of any recalls and returns |  |
| <b>Abbreviations</b>  | <b>Meaning</b>  |  |
| CAPA  | Corrective Action and Preventive Action   |  |
| NC  | Non-conformity  |  |
| NCR   | Non-conformity Report   |  |
| OOS   | Out-of-specification  |  |
| QC  | Quality Control   |  |
| QMS   | Quality Management System   |  |
| <b>Part 2</b>   | <b>Summary of the assessment of ISO audits</b>  |  |
| <b>Name of ISO certification body</b><br><br>Japan Quality Assurance Organization | Dates of Audit  | 18-20 May 2021   |
|   | Type of Audit   | Surveillance audit   |
|   | Inspected areas/documents   | Business Environment, Status of system, Internal Audits, Operation management, corrective and preventive actions, response to complaints, compliance with laws and regulations, Management review, publication of registration, vendor evaluation, and use of registration marks, continual improvement. |
|   | Product covered   | Not mentioned  |
| <b>Part 3</b>   | <b>Summary of the last WHO inspection</b>   |  |
|   | The site has never been inspected by WHO.   |  |

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| <b>Part 4</b> | <b>Summary of the assessment of supporting documentation</b> |
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**1. Quality Manual:**

A copy of the quality manual was reviewed. The quality manual provided an overview of the quality management system.

**2. List of current quality management procedures:**



A list of the current quality management procedures was provided.

### **3. Standard operating procedures for:**

#### **i. Complaint handling, vigilance and recalls:**

A document titled “Complaint Handling Guideline” was provided. Complaints were handled by a committee that comprised of the Head of Quality Assurance, Factory Manager of each Factory, General Manager of Management, and General Management Representative among others. The committee was chaired by the President. The ‘guideline’ provided for investigations and implementation, verification of CAPA, quarantining of nonconforming and returned products.

The flow chart in the SMF indicated that complaints were received by Mitsui Chemicals Agro, Inc. and submitted to the manufacturer’s QC Manager for investigation. A report with proposed corrective measures was approved by Mitsui Chemicals Agro, Inc prior to implementation. Complaints were categorized into Critical, Major and Minor.

#### **ii. Control of nonconforming goods/processes:**

The “Deviation Control Guidelines” was reviewed. It defined the procedure for root cause investigation, handling of non-conformities and corrective actions. The procedure applied to all the Utsunomiya Chemical Industry Co Ltd sites including the Shinshiro, Funaoka and Utsunomiya sites. It applied to raw materials, intermediate products, and finished products.

#### **iii. Change control/change notifications (product and processes):**

A document titled “Guidelines for Quality Change Control” was reviewed. The procedure applied to changes that affect or were likely to affect the quality of products. The procedure included the impact assessment of the change. Changes were implemented by the manager of the concerned department.

#### **iv. Risk management:**

A general overview of the application of risk management was provided. Risk management applied to deviation control, change control, complaints, product defects, recalls, product quality review, internal audits, and supplier management among others.

#### **v. Supplier evaluation and control, verification of purchased product:**

Document titled ‘Regulations of Purchasing Management’ was reviewed. The criteria for selection of supplier and evaluation were defined. The criteria for selection of suppliers included quality, quantity, price, and long-term stability. The SCM (Supply Chain Management) department was responsible for the evaluation of suppliers.

### **4. Site Master File (SMF) and site floor plan**

The Site Master File provided a brief overview of the manufacturing activities and QMS. The organogram showed relationship between the different departments. The quality unit was independent of production and that fulfilled both Quality Assurance (QA) and Quality Control (QC) functions. The Quality unit was responsible for product release. The suppliers of critical materials were audited by Mitsui Chemicals Agro, Inc. A brief layout of the site was provided.

### **5. Quality management system certificate(s) and scope of certification: (e.g., ISO 13485/ISO 9001):**



A valid ISO 9001:2015 certificate was provided.

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

No information on upcoming inspections was provided. The site has previously been inspected by FAMIC (Incorporated Administrative Agency Food and Agricultural Materials Inspection Center) in 2021 and by the Japan Quality Assurance Organization in 2017, 2019 and 2020. The site complied with the relevant requirements.

**7. Process flowchart including in-process control points:**

A process flow chart was submitted and reviewed.

**8. List of all the products and formulation types manufactured at this site:**

The list of products formulated and packaged on site was submitted and reviewed.

**9. Most recent management review report/minutes:**

The management review meeting minutes were reviewed. The agenda of the meeting included the management review inputs specified by the ISO 9001:2015 standard.

**10. Master batch manufacturing, and/or packaging records of the WHO product of interest:**

The templates of the manufacturing records were provided.

**11. Completed batch manufacturing and/or packaging records:**

It was declared that no batch of WHO PQ products, namely Vectron 10 EW and Vectron 20 WP had been manufactured in the last 5 years. Therefore, no batch manufacturing records were provided. There were no plans to manufacture the WHO PQ products in the next two years.

**12. List of any recalls/returns:**

Declaration provided: There have been no recalls or returns.

**13. List of equipment that is shared and measures in place to ensure that this sharing of equipment is managed appropriately:**

The list of shared equipment used for the manufacture of both Vectron 10 EW and Vectron 20 WP was provided. A cross contamination matrix was also provided.

**14. Name and address of sites to which any related activities are outsourced:**

No information was provided.

**15. Additional documents submitted:**

None.

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| <b>Part 5</b> | <b>Desk assessment conclusion</b> |
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Based on the latest inspection by Japan Quality Assurance Organization (JQA) 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 **Utsunomiya Chemical Industry Co., Ltd, Shinshiro Factory** located at **11-4 Ihara, Oomi, Shinshiro-shi, Aichi, Japan** is considered to be operating at an acceptable level of



compliance with *ISO 9001:2015 standard* and WHO guidelines as per *Overview of the WHO Prequalification Assessment of Vector Control Products, June 2021*. This compliance status shall be valid until **9 July 2025** or when another inspection is conducted by WHO or by a reliable certification body.

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| <b>Part 6</b> | <b>List of Standards and Guidelines referenced in the inspection report</b> |
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1. Quality management systems – Requirements, International Standard (ICS 03.120.10), 5<sup>th</sup> 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](https://extranet.who.int/prequal/sites/default/files/document_files/WHO_PQT_VectorControlProducts_June2021.pdf)