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	Sumika Agro Manufacturing Co., Ltd
Corporate address of manufacturer	Sumitomo Chemical Co. Ltd 2-7-1 Nihonbashi, 2-chome Chuo-Ku, Tokyo, 104-8260 Japan
Manufacturing site(s) under assessment	
Name & address of inspected manufacturing site(s) if different from that given above	Sumika Agro Manufacturing Co., Ltd 1-3 Higashi-kaigan-dori Kudamatsu-shi Yamaguchi 744-002 Japan
Unit/Block/ Workshop	Not applicable
Desk assessment details	
Dates of review	6 - 10 February 2023
Products covered by this desk assessment	SumiShield 50 WG 001-001
List of documents submitted	1) Site master mile 2) Site floor plans 3) Full address of manufacturing site 4) Quality manual 5) List of current Quality Management Procedures 6) Procedure for control of nonconforming products 7) Procedure for control of changes 8) Procedure for supplier evaluation and verification of purchased products 9) List of ISO 9001:2015 surveillance audits 10) List of upcoming inspections 11) ISO 9001 certificate 12) ISO 14001 certificate 13) Audit reports 14) List of latest inspection findings 15) List of all products and formulations 16) Most recent management review report 17) Operations standard for previous products at time of Sumi Shield 50 WG production

<table>
<tr><td></td><td>18) Name and contact details of responsible person
19) Process flow chart
20) Most recent management review minutes
21) Batch records
22) Master batch records
23) Production schedule</td></tr>
<tr><td>Abbreviations</td><td>Meaning</td></tr>
<tr><td>NC</td><td>Non-conformity</td></tr>
<tr><td>NCR</td><td>Non-conformity Report</td></tr>
<tr><td>OOS</td><td>Out-of-specification</td></tr>
<tr><td>QC</td><td>Quality Control</td></tr>
<tr><td>QMS</td><td>Quality Management System</td></tr>
<tr><td>Part 2</td><td>Summary of the assessment of ISO audits</td></tr>
<tr><td>Name of ISO certification body

The High-Pressure Gas Safety Institute of Japan</td><td>
<table>
<tr><td>Dates of Audit</td><td>13 - 15 June 2022</td></tr>
<tr><td>Type of Audit</td><td>Surveillance audit</td></tr>
<tr><td>Inspected areas/documents</td><td>Internal audits, statutory and other requirements, evaluation of compliance, evaluation and status of conformity to contractual requirements and applicable statutory requirements, complaints, objectives, leadership, planning, the effectiveness of corrective actions for nonconformities in previous audit and status, operation, support, performance evaluation, improvement, management reviews, and quality control.</td></tr>
<tr><td>Products covered</td><td>Blastin -Joker Flowable 500ml, Dantotsu (Clothianidin) granule, Sumithion Emulsion.</td></tr>
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<tr><td>Dates of Audit</td><td>1 - 4 June 2021</td></tr>
<tr><td>Type of Audit</td><td>Recertification audit</td></tr>
<tr><td>Inspected areas/documents</td><td>Improvement, Internal audits, Statutory and other requirements and evaluation of compliance, evaluation, and status of conformity to contractual requirements and applicable statutory requirements, complaints, objectives of the organization,</td></tr>
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The High-Pressure Gas Safety Institute of Japan
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		leadership, planning, effectiveness of corrective actions for nonconformities in previous audit and status, operation, support, performance evaluation, quality control, and management reviews.
	Products covered	Ares Boxed granules, Stout Ares boxed granules, Varidasin liquid 5

The High-Pressure Gas Safety Institute of Japan	Dates of Audit	8 - 10 June 2020
	Type of Audit	Surveillance audit
	Inspected areas/documents	Internal audits, statutory and other requirements and evaluation of compliance, evaluation, and status of conformity to contractual requirements and applicable statutory requirements, complaints, objectives, leadership, planning, the effectiveness of corrective actions for nonconformities in previous audit and status, operation, support, performance evaluation, improvement, management reviews, and quality control.
	Product covered	Sumithion Emulsion

Part 3	**Summary of the last WHO inspection**
	The site has not been inspected by WHO before.

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

1. Quality Manual:
A copy of the quality and environmental manual was provided. The manual was applicable to Head Office and Kudamatsu Plant, Koriyama Plant, and Shobara Plant. The quality manual described the policies and practices established by the manufacturer to achieve the requirements of ISO 9001 and ISO 14001.

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:

Complaint handling was described in the Quality Manual and Site Master File. A relevant procedure titled 'Rules for product information control' was in place. Complaints related to the quality were handled by the responsible care department, while the other complaints are handled by the Product Planning Department. Complaints were investigated, and CAPA put in place. Records of complaints were maintained for 5 years

ii. Control of nonconforming goods/processes:

The procedure for "Nonconforming products handling rules" was reviewed. The procedure described handling nonconforming products that do not meet in-process tests, finished product analytical tests, customer requirements, packaging, and labeling requirements, etc. The procedure also applied to raw materials that do not meet the acceptance criteria.

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

A procedure titled 'New Product Introduction/ Control of 4M Change Rules' was provided. The procedure described the introduction of a new formulation and trial manufacturing, including contract manufacturing. The procedure also took into consideration changes to equipment. The changes were assessed using the 4 M approach (Man, Machine, Machinery, and Method).

iv. Risk management:

The quality manual required the manufacturer to define risks and opportunities and maintain the relevant documentation. The manufacturer had a risk map in place.

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

The procedure titled 'Supplier Evaluation Rules' was reviewed. The procedure described supplier selection and evaluation. The procedure made reference to an approved supplier/vendor list. The performance review of the suppliers was conducted annually.

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

The Site Master File described the site's quality management system policies and activities. The site floor plans were also provided.

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

A valid ISO 9001:2015 certificate was submitted.

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

List of upcoming inspections provided. Two upcoming inspections slated for June 2022 and June 2023 respectively were indicated.

7. Process flowchart including in-process control points:

The process flow chart for the manufacture of wettable powders was submitted and reviewed.

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 minutes of the management review meeting were provided. The agenda included output from building a culture of safety, compliance initiatives, environmental conservatives, Sumika group initiatives, Health management, risk assessment conservation, abnormalities in raw materials, and promotion of anti-smoking activities among others.

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

11. Completed batch manufacturing and/or packaging records:
Batch manufacturing and packaging records for Sumi Shield bulk powder batch 4001 were submitted and reviewed. A production schedule was provided.

12. List of any recalls/returns:
It was declared that there had been no recalls/returns in the last 3 years.

13. List of equipment that is shared and measures in place to ensure that this sharing of equipment is managed appropriately:
A list of shared equipment was provided. A matrix showing the cleaning approach was provided.

14. Name and address of sites to which any related activities are outsourced:
No information was provided.

15. Additional documents submitted:
None

Part 5	Desk assessment conclusion

Based on the inspection by the High Pressure Gas Safety Institute of Japan and on the QMS evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. **Sumika Agro Manufacturing Co., Ltd** located at **1-3 Higashi-kaigan-dori Kudamatsushi, Yamaguchi 744-002, 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 5th August 2024 or when another inspection is conducted by WHO or by a reliable certification body.

Part 6	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