



**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		SC Environmental Science Co. Ltd
Corporate address of manufacturer		Tokyo Nihombashi Tower 2-7-1, Nihonbashi, Chuo-ku, Tokyo 103-6020, Japan
Manufacturing site(s) under assessment		
Name & address of inspected manufacturing site(s) if different from that given above		SC Environmental Science Co. Ltd 312 Aza-Hirose, Aoyama, Yoka- Cho, Yabu, Hyogo 667 - 001, Japan
Unit/Block/Workshop		Not applicable
Desk assessment details		
Dates of review		28 March 2023, 30 October 2023
Products covered by this desk assessment		SumiShield 50 WG – 001-001 Sumilarv 0.5 G – 001-002
List of documents submitted		<ul style="list-style-type: none"> • Site Master File • Appendix of the Site Master File • Site floor plans • Quality Manual – SC Environmental • Staff organogram • List of current QMS procedures • Management procedure for handling product quality information and quality defects • Deviation control procedure • Change control procedure • Risk register • ISO 9001 certificate • Current full inspection report • List of products using common equipment • SLV 0.5 G process flow chart (Sumilarv) • Sumi shield process flow chart • Management review minutes • Sumilarv 0.5 G packaging records • Sumishield packaging record



	• Master batch record SLV 0.5 G	
Abbreviations	Meaning	
NC	Non-conformity	
NCR	Non-conformity Report	
OOS	Out-of-specification	
QC	Quality control	
QMS	Quality management system	
Part 2	Summary of the assessment of ISO audits	
Name of ISO certification body Japan Chemical Quality Assurance Ltd (JCQA)	Dates of Audit	22-23 April 2021
	Type of Audit	Recertification
	Inspected areas/documents	Top management and organizational capacity, QMS response to internal and external issues and stakeholder needs, determination of risks and opportunities, monitoring, measuring and evaluation of key performance indicators, complaints, nonconformities and status of corrective actions, Internal audits, adequacy of management review operations
	Product covered	Not indicated in the report.
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
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1. Quality Manual:

The English translated quality manual described the roles and responsibilities of key personnel, document management, internal communication, training, maintenance of facilities and equipment, internal and external audits, improvement, product development, production planning and control, evaluation of manufacturing subcontractors, selection and evaluation of suppliers, sales, and handling of quality information.

2. List of current quality management procedures:

List of current quality procedures was provided.

3. Standard operating procedures for:

i. Complaint handling, vigilance and recalls:

The “Management Procedure for Handling Product Quality Information and Quality Defects” was provided. The procedure described the handling of complaints. Complaints were evaluated by the



Quality Control Group Leader. The procedure provided for investigations, corrections, corrective actions, and maintenance of the relevant records.

ii. Control of nonconforming goods/processes:

The “Deviation control procedure” described the handling of deviations and their investigation. The scope of this procedure covered deviations in manufacturing facility, manufacturing control, quality control, raw materials, packaging materials, labelling materials, storage and logistics etc. The procedure also defined and categorized deviations. The procedure described the handling of rejected, returned, and recalled materials.

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

The change control procedure was provided. The Quality Control Group Leader and the Manufacturing manager were responsible for review of changes. Changes were approved by the Factory Manager. Changes were categorized into 3 levels, namely: Level I (Major Changes), Level II (Minor changes) and Level III (Other changes). The procedure provided for evaluation of the impact of the changes prior to their implementation.

iv. Risk management:

The quality manual referred to the “procedure for investigation of danger or harm”. The Sector General Manager was responsible for approval of the risk evaluation. A risk register was provided.

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

Raw material suppliers were selected in accordance with “procurement rules”. Raw material suppliers were evaluated by field audit and/or document audit. The criteria for evaluation of suppliers were provided. The criteria included price, turnaround time, quality, reliability, technical strength, and level of cooperation etc.

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

The Site Master File provided an overview of the QMS, activities, processes, and procedures.

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

A valid ISO 9001:2015 was provided.

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

It was stated that no inspections were planned in the next 6 months.

7. Process flowchart including in-process control points:

Process flow charts for SumiShield 50 WG and Sumilarv 0.5 G were provided.

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

List of all products and formulations manufactured on site was provided.

9. Most recent management review report/minutes:

Minutes of the latest management review meeting were provided. The agenda of the meeting included: Accidents (Disasters), Teams (Personnel), Production status, Changes, Audits,



Improvements, Health and safety, Equipment inspection, Compliance with legal mandates among others.

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

11. Completed batch manufacturing and/or packaging records:
The completed batch manufacturing record for Sumilarv 0.5 G and batch packing records for SumiShield 50 WG were provided.

12. List of any recalls/returns:
It was declared that there were no recalls or 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:
The list of shared equipment was provided. Cleaning procedures were also provided.

14. Name and address of sites to which any related activities are outsourced:
There were no outsourced activities related to the manufacture of SumiShield 50 WG and Sumilarv 0.5G.

15. Additional documents submitted:
None.

Part 5	Desk assessment conclusion
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Based on the inspection by Japan Chemical Quality Assurance Ltd (JCQA) 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 **SC Environmental Science Co. Ltd** located **312 Aza-Hirose, Aoyama, Yoka-Cho, Yabu, Hyogo 667 -001, 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 **30 October 2026** 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
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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. 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

