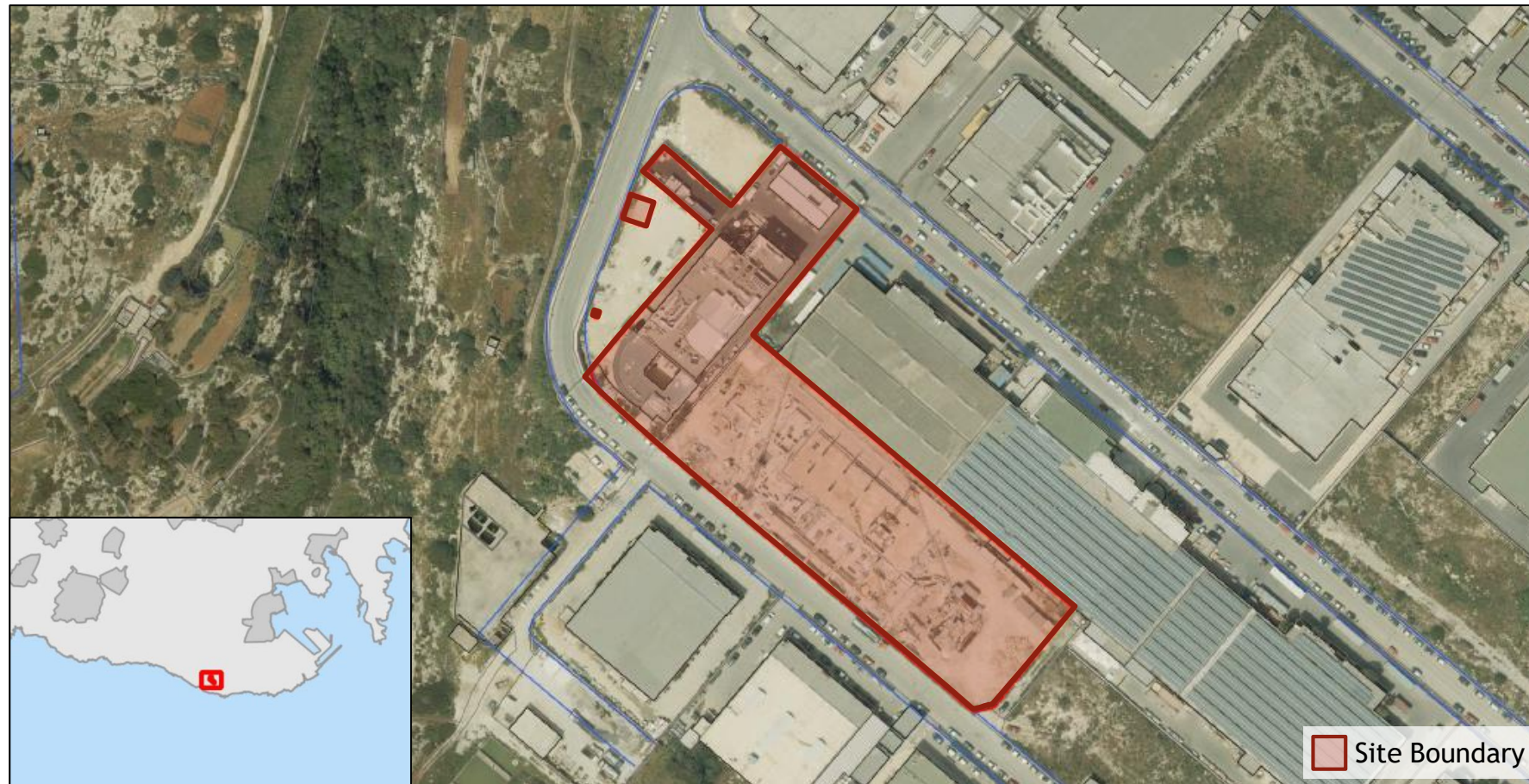


Renewal and Variation of IPPC Permit

Sterling Chemical Malta Ltd.
IP 0001/23

Environmental Permitting Unit
Environment and Resource Authority

Site Location



Sterling Chemical Malta Ltd.

Address: HF50, HF51 & HF53, Hal Far Industrial Estate, Birzebbuga BBG3000

Main Operations on Site

- ▶ Production by chemical or biological processing of pharmaceutical products including intermediates.
 - ▶ Research, development and synthesis of active pharmaceutical ingredients (APIs).
- ▶ Associated operations of utilities including:
 - ▶ Two (2) water purification plants
 - ▶ Sixteen (16) reactors
 - ▶ Two (2) LPG boilers to produce steam and hot water
 - ▶ One (1) cooling tower
 - ▶ Air handling units
 - ▶ Reverse Osmosis **NEW**
- ▶ Associated operations of storage, disposal and recycling of waste materials.

Applicable Legislation

Environment Protection Act (CAP. 549)

- ▶ Industrial Emissions (Framework) Regulations (S.L. 549.76)
- ▶ Industrial Emissions (Integrated Pollution Prevention & Control) Regulations (S.L. 549.77)
 - ▶ **Schedule I, Activity 4.5** - Production of pharmaceutical products including intermediates
- ▶ Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (S.L. 549.77)
 - ▶ **Schedule I, Activity 7** - Manufacturing of pharmaceutical products

BREF Documents

- ▶ BAT for Manufacture of Organic Fine Chemicals (August 2006);
- ▶ BAT for Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector (May 2016);
- ▶ BAT for Common Waste Gas Management and Treatment Systems in the Chemical Sector (December 2022) **NEW**

Permit History

Permit Number	Details	Date of Issue
IP 0001/14/A	New Application	13 th August 2015
IP 0001/14/B	Variation	5 th April 2019
	Extension Request (6 months)	9 th August 2019
	Extension Request (3 months)	29 th November 2019
IP 0001/19	Renewal and Variation	29 th November 2019
IP 0004/21	Variation	22 nd September 2021
	Extension Request (6 months)	10 th November 2023
IP 0001/23	Renewal and Variation	(received 6th June 2023) Being Processed

Proposed Variations

The variation covers the following changes:

- ▶ Two additional air emission points in the HF51 block, originating from:
 - ▶ Micronisation plant
 - ▶ Fire safety cabinets for the storage of raw materials
- ▶ Inclusion of an existing air emission point emanating from the diesel emergency fire pump;
- ▶ Monitoring of existing air emission point EM15 from Production Line 7;
- ▶ Relocation of a few raw materials from the warehouse to the Quality Control lab;
- ▶ Discharge of reverse osmosis (RO) reject effluent to sewer; and
- ▶ Changes to the use and layout of the 22-MR Warehouse.

Additional Emission Points

The proposed additional emission points are the following:

Emission Point Reference	Source	Abatement
EM23	Microniser (Nitrogen Outlet)	Cyclone & HEPA Filters
EM24	Fire Safety Cabinet	Extraction Vent & Carbon Filter

Internal Consultation

Environmental Assessment Unit

- ▶ Proposed variation is not environmentally significant, however an additional variation application is required to address interventions proposed through PA 4688/23 that are currently not reflected in IP 0001/23.

Air Quality & Water Unit (Noise Team)

- ▶ Since initial variation proposal included the installation of 3 generators, there was an inquiry regarding their inclusion in the upcoming noise monitoring study. This is however no longer relevant since the generators are no longer part of this variation.

Compliance and Enforcement Unit

- ▶ All AERs were submitted and all previous IP items were addressed. During inspections the site was found to be largely compliant.

Regulatory Consultation

(30th August - 30th September 2023)

Regulator	Feedback
Malta Resources Authority Water Services Corporation Civil Protection Department Environmental Health Directorate Planning Authority Energy & Water Agency	No objections
Regulatory for Energy & Water Services	Applicant to submit relevant documents prior to installation of generators <i>- No longer relevant</i>
Malta Competition & Consumer Affairs Authority Occupational Health & Safety Authority	No feedback

Public Consultation

(9th September - 23rd September 2023)

No feedback was received.

Site Visit

Conducted on
Tuesday 30th April 2024



Fire Safety Cabinets storing small amounts of raw material



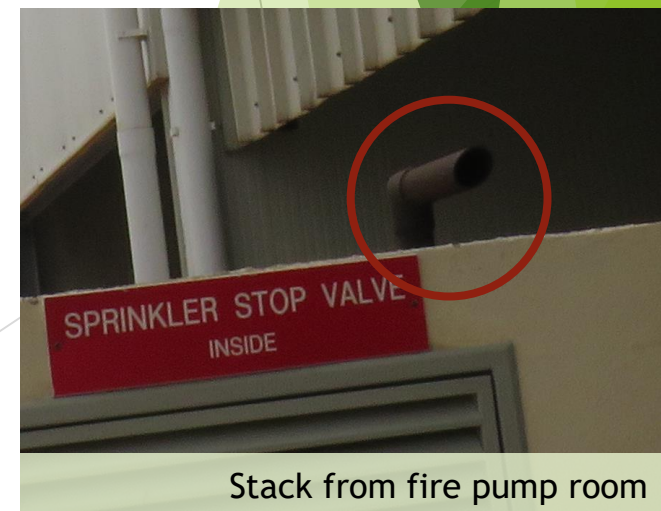
RO for cleaning glassware



22-MR Warehouse with ample space for raw material storage



Microniser used for particle size reduction



Stack from fire pump room

Proposed Changes to the Permit

The amendments to the permit being recommended include:

- ▶ The permitted emission points to air (to include the proposed additional emission points);
- ▶ The ‘Emissions to Air’ monitoring programme to include monitoring from the new emission points, and monitoring of parameters to reflect the current APIs being produced at the facility;
- ▶ Standardisation of certain conditions;
- ▶ Updating the Improvement Programme Items to include further assessment of the BAT conclusions specified in BREF for Common Waste Gas Management and Treatment Systems in the Chemical Sector; and
- ▶ Updating of site layout plans to include new emission points.

Proposed Improvement Programme

Reference	Requirement	Deadline
21	Submission of Best Available Techniques (BAT) comparison, under Directive 2010/75/EU of the European Parliament and the Council on industrial emissions, for common waste gas management & treatment systems in the chemical sector, in accordance with Condition 7.1.4.	Within 4 months from granting of permit.
22	Good working order certificate for diesel fire pump (EM25), in accordance with Condition 2.2.16.	Within 4 months from granting of permit.

Permit Fees

The following application fees were duly made:

- ▶ Renewal Fee of €7,500 **PAID**
- ▶ Variation Fee of €1,500 **PAID**

All other annual fees (amounting to 5% of the original application fee due to ISO Accreditation) and inspection fees (€200 per inspection) have also been paid.

Updates since Submission of the COR

There have been no updates to the case officer report to date.

Feedback from the Applicant

There has been no feedback from the applicant to date.

Recommendation

The Environment Resources Directorate
is recommending the

GRANTING

of this Renewal and Variation, for a period of 10 years,
subject to:

The submission of an updated Bank Guarantee of **€22,000**
(as compared to the current Bank Guarantee of €25,350)