



STERLING CHEMICAL MALTA LTD, HAL FAR

**APPLICATION FOR VARIATION OF IPPC PERMIT
VOLUME 1: IPPC APPLICATION FORMS**



Version 5: April 2024



Report Reference:

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Quality Assurance

Sterling Chemical Malta Ltd, Hal Far
Application for Variation of IPPC Permit: Volume 1
 April 2024

Report for: Sterling Chemical Malta Ltd

Revision Schedule

Rev	Date	Details	Prepared by	Reviewed by	Approved by
00	Oct. 2022	Submission to client	Collette Lynch Environmental Consultant	Rachel Xuereb Director	Adrian Mallia Managing Director
01	June 2023	Updates to include Generators & 22-MR Warehouse changes. Submission to client	Collette Lynch Environmental Consultant	Rachel Xuereb Director	Adrian Mallia Managing Director
02	Aug 2023	Updates to Section C3.3.1 following ERA's review.	Collette Lynch Environmental Consultant	Rachel Xuereb Director	Adrian Mallia Managing Director
03	Aug 2023	Updates to Section C3.3.2 following ERA's comments.	Collette Lynch Environmental Consultant	Rachel Xuereb Director	Adrian Mallia Managing Director
04	Apr 2024	Updates following Public Consultation	Collette Lynch Environmental Consultant	Rachel Xuereb Director	Adrian Mallia Managing Director

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FORM A

**Form IPPC Part A – application for a permit, variation, transfer or surrender
For Environment & Resources Authority Use Only**

Data received

Fee received: Yes No

Amount received

Name assigned to installation

**Application for a permit, variation, transfer or
surrender
Integrated Pollution Prevention and Control (IPPC)
Industrial Emissions (IPPC) Regulations 2013**

Introduction to Part A

When to use this form

Use this form if you are sending an application to the ERA under the Industrial Emissions (IPPC) Regulations, 2013.

The form is to be used for applications made in respect of both 'installations' and 'mobile plant' (and in the rest of the form, the term 'installation' also covers 'mobile plant' where appropriate).

Before you start to fill in this form

There may be two or more operators in a single installation. Each operator will need a permit, each obtained by a separate application. Your applications will principally relate to the part of the installation under your control, but will also need to include some information on the rest of the installation. This will help us to assess the operation of the whole installation. The term "installation", when used in this application form (and elsewhere) may refer to either the whole or part of the installation, depending on the nature of the information we are seeking to obtain.

Which parts of the form to fill in

The form is in five parts but we usually only send you the parts you need to fill in. Everyone has to fill in Part A, and prepare and sign a covering letter at the end of their application.

The other parts you need to fill in depends on the type of application you are making:

- To apply for a new permit – fill in Parts A and B;
- To vary an existing permit – fill in Parts A and C;
- To transfer all or part of an existing permit to

someone else – fill in Parts A and D. This should be a joint application by the transferor and the transferee;

- To surrender all or part of an existing permit – fill in Parts A and E.

Other documents we need to see

There are a number of other documents you will need to send us with your application. Each time a request for documents is made in the application form you will need to record a document reference number for the document or documents that you are submitting in the box provided on the form for this purpose.

Please also mark the document(s) clearly with this reference number and either the application reference number if you know it or your existing permit number. If you do not have either of these, please use the name of the installation.

If you know your Application Reference Number, please enter it into the box below:

Using continuation sheets

In the case of questions required to be answered on the application form itself, please use a continuation sheet if you need extra space; but please indicate clearly on the form that you have done so by stating a document reference number for that continuation sheet. Please also mark the continuation sheet itself clearly with the information referred to above.

Copies

Please submit 1 hard copy and 1 soft copy of the application form and all supporting information. A soft copy of the application form must also be submitted to the consultees identified in Regulation 19(2) of Legal Notice 10 of 2013. A signed delivery note must be enclosed with the application to ERA.

If you need help and advice

We have made the application form as straightforward as possible, but please get in touch with us on tel: 2292 3500 or email: ippc@era.org.mt if you need any advice on how to set out the information we need.

A1 About your application

A1.1 What type of application are you making?

- new permit
- variation of an existing permit
- transfer of an existing permit
- surrender of an existing permit

A1.2 Name of the installation

Sterling Chemical Malta Ltd

Please tell us if this name is:

- already agreed with the ERA; or
- one that you are proposing.

A1.3 Please give the address of the site of the installation, and a map or plan showing the site of the installation and the location of the installation on the site

Street Address	HF50, HF51, HF53	
	Hal Far Industrial Estate	
Locality	Birżebbuġa	Post Code BBG3000

A site plan is included in: **Appendix 1**

A1.4 Give details of any existing permit(s) for the installation.

Please give details of any applicable waste management licences, planning permits, environmental permits or sewer discharge permits. Include permit number(s), type(s) and date(s) of issue, and submit copies.

- IPPC permit: IP 0001/19 (issued November 2019), variation (IP 0004/21) granted September 2021.
- Relevant development permits:
 - PA 04236/08 (issued April 2010)
 - PA 03033/12 (June 2013)
 - PA 8089/19 (November 2020)
 - DN 0624/16 (September 2016)
 - DN 23/17 (January 2017)
 - DN 617/17 (July 2017)
 - DN 810/17 (October 2017)
 - PA 3638/18 (March 2019)
 - DN 1094/18 (November 2018)
 - DN 0259/20 (April 2020)
 - PA 04688/23 (Awaiting Recommendation – April 2024)

- LPG secondary storage permit issued by REWS, licence no. LPG-00110-SS (SS110) *(the renewal was paid in November 2020, but the latest permit has not been received yet; it will be forwarded to ERA once received).*

A2 Authorised contacts

It will help us to have someone who we can contact directly with any questions about your application. The person you name should have the authority to act on your behalf.

A2.1 Who can we contact about your application?

This could be an agent rather than the operator.

Name

Roberto Tumbiolo

Position

Director

Address

Street Address	HF51	
	Hal Far Industrial Estate	
Locality	Birżebbuġa	Post Code BBG3000

Phone Number +356 20908700

Fax Number n/a

Email address

rtumbiolo@sterlingchemicalmalta.com

A2.2 Operational contact

If different to the above, please identify the person we should contact to discuss operational matters on an ongoing basis.

Name

Andrea Caneponi

Position

Project Coordinator

Address

Street Address	HF 51	
	Hal Far Industrial Estate	
Locality	Birżebbuġa	Post Code BBG3000

Phone Number +356 99054582

Fax Number n/a

- Sewer discharge permit WSC DMU 6745 (January 2023).

Copies of all approved permits have been included in **Appendix 2**.

A3 About the operator

Please provide the information requested below about the 'operator', which means:

- for applications for a new permit – the person who it is proposed will have control over the installation in accordance with the permit (if granted),
- for applications for a variation, transfer or surrender – the person who currently has control over the installation in accordance with the permit.

If you are applying for a transfer, we will ask for more information relating to the proposed new operator (transferee) in Part D.

Legal status of operator

A3.1 Is the operator an individual, a group of individuals, a partnership or a company/corporate body?

- Individual (sole trader) or group of individuals: go to question A3.2.
- Partnership: go to question A3.3.
- Company or corporate body: go to question A3.5.

Individual applicants

A3.2 Please give us the following details.

Where more than one person is applying (other than as a partnership) we need details of each person.

Continue on separate sheets if necessary.

Full Name	
<input type="text"/>	
ID Card/Passport No.	
<input type="text"/>	
Trading/business name (if any)	
<input type="text"/>	
Business address	
Street Address	<input type="text"/>
	<input type="text"/>
	<input type="text"/>
Locality	Post Code
<input type="text"/>	<input type="text"/>

Email address
<input type="text"/>

Fax Number
<input type="text"/>

Email address
<input type="text"/>

Now go to question A4, What to do next.

Applications from partnerships

A3.3 Who is applying?

We can only issue permits to named individuals, not to a partnership name. We therefore need details of each person in the partnership.

Continue on separate sheets if necessary.

Person

Full Name	
<input type="text"/>	
ID Card/Passport No.	
<input type="text"/>	
Principal place of business	
Street Address	<input type="text"/>
	<input type="text"/>
	<input type="text"/>
Locality	Post Code
<input type="text"/>	<input type="text"/>

Contact Numbers

Phone Number
<input type="text"/>

Fax Number
<input type="text"/>

Email address
<input type="text"/>

Person

Full Name	
<input type="text"/>	
ID Card/Passport No.	
<input type="text"/>	
Principal place of business	
Street Address	<input type="text"/>
	<input type="text"/>
	<input type="text"/>
Locality	Post Code
<input type="text"/>	<input type="text"/>

Phone Number

Contact Numbers

Phone Number

Fax Number

Email address

Person

Full Name

--

ID Card/Passport No.

--

Principal place of business

Street Address		
Locality		Post Code

Contact Numbers

Phone Number

Fax Number

Email address

A3.4 Please give us the following details about the partnership.

Name of partnership (if there is one)

--

Principal place of business

Street Address		
Locality		Post Code

Contact Numbers

Phone Number

Fax Number

Now go to question A4, What to do next.

Companies or other corporate applicants

A3.5 Please give us the following details.

Full name of company or corporate body.

Sterling Chemical Malta Ltd

Trading/business name (if different)

--

Registered office address

Street Address	HF51	
	Hal Far Industrial Estate	
Locality	Birżebbuġa	Post Code BBG3000

Company registration number

C32508

Date of formation of company

9 th February 2006

- For applications from companies, please provide a copy of the certificate of incorporation or registration and any certificates of subsequent name changes.

Document reference number

Appendix 3

- For applications from other corporate bodies, please provide evidence of status.

Document reference number

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Email address

A3.6 Is the operator a subsidiary of a holding company?

No

Yes name of ultimate holding company

S.N.I.F.F. ITALIA S.P.A.

Registered office address

Street Address	Via della Carboneria 30/32	
	Corciano (PG)	
Locality	Italy	Post Code 06073

Principal office address (if different)

Street Address		
Locality		Post Code

Company registration number

PG 112595

A4 What to do next

Now you need to fill in the other Parts of this form available online.

If you are applying for

- A new permit – fill in IPPC Form Part B;
- A variation – fill in IPPC Form Part C;
- A transfer – submit a letter to the Authority
- A surrender – fill in IPPC Form Part E.

FORM C

Form IPPC Part C: Application for a Variation



For ERA use only
Application reference:

Use this part of the form if you are applying to vary the conditions or any other provision contained in your permit.
Please read carefully Appendix I attached with this application.

C1 About the installation

Please fill in the installation table below with details of all the activities and operators at the whole installation, even if you are applying for a permit in respect of only part of the installation.

In **Column 1: Activities in “the stationary technical unit”**, please describe all activities listed in Annex I to the Industrial Emissions Directive that are proposed to be carried out.

For **Directly associated activities**, please identify any directly associated activities proposed to be carried out on the same site which:

- have a technical connection with the activities in the stationary technical unit; and
 - could have an effect on pollution.
- These could include, for example, boilers, generators, water purification systems, scrubbers and other air purification systems.

In **Column 2: Schedule 1 references**, write the category the installation falls under in Schedule 1 of the Industrial Emissions (IPPC) Regulations (S.L. 549.77) e.g. 1.1, 5.3(b)(i).

In **Column 3: Operator**, write the name of the operator for each activity (if you are the operator yourself, write “Applicant”).

In **Column 4: Variations**, indicate how the proposed changes would affect the activities.

C1.1 Installation details

COLUMN 1 Permitted activities in the “stationary technical unit”	COLUMN 2 Schedule 1 references	COLUMN 3 Operator	COLUMN 4 Proposed variations
Production by chemical or biological processing of pharmaceutical products including intermediates	4.5	Applicant	No changes.

Directly associated activities

Associated activity of utilities: 1. Two water purification plants. 2. Operation of 16 reactors 3. Operation of two LPG boilers to produce steam and hot water.	-	Applicant	No changes.
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4. Operation of a cooling tower 5. Operation of air handling units			
Associated activity of waste management: • Handling and storage of waste generated from installation prior to dispatch offsite	-	Applicant	No changes.

C1.2 Non-technical description

Please provide a non-technical description of the proposed changes.

Document reference number:

Volume 2: Chapter 2

C1 About the installation *continued*

C1.3 The proposed variations

Please provide a summary of the variations which you are applying for.

This should include:

- a description of the change in operation requiring the variation;
- an indication of the variations to the conditions of the permit that you wish to apply for.

Document reference number for the summary:

Volume 2: Chapter 2

C1.4 Site maps and reports

Are you proposing any change in operation that would result in additional land being included within the site of the installation?

Yes No

If yes, please provide:

C1.4.1

A site report, describing the condition of the site of that part of the installation in respect of which you are applying for a variation, and, in particular, identifying any substance in, on or under the land which may constitute a pollution risk. A baseline report assessing the state of the groundwater and land may also be required by the Authority.

Document reference number for the report:

**Volume 2: Chapter 2; Volume 3:
Addendum 4 to Land and Groundwater**

C1.4.2

A suitable map (or maps) showing the location of the site of the installation, and the area for which a variation of the IPPC permit is being applied for. The outline of the site and the area requiring the variation should be clearly marked in colour, and the surroundings of the site should be included in the map.

Document reference number for map(s):

Appendix 1

C1.4.3

Suitable block plans, properly labelled, showing any changes to the location and nature of the various activities being proposed on that site.

Document reference number for plans:

**Volume 3: Addendum 4 to
Land and Groundwater**

All maps and plans submitted shall be to scale, using a scale rule. Soft copies of plans should be submitted in .pdf format only.

C2 Your proposed techniques

C2.1 Environmental Management System

Provide details of any changes to environmental management techniques resulting from your proposals.

Document reference number:

No changes are proposed

C2.2 Proposed activities

C2.2.1 Describe any proposed changes to the installation activities.

Document reference number:

Volume 2: Chapter 3

C2.2.2 Describe the proposed techniques and measures to prevent and reduce waste and emissions of substances and heat (including during periods of start-up or shut-down, momentary stoppage, leak or malfunction) as a result of your proposals.

Document reference number:

Volume 2: Chapter 3

C2.2.3 Submit a flow diagram summarising the proposed installation activities and indicating the changes.

Document reference number:

Volume 2: Chapter 3

C2.2.4 Include a comparison of the proposed changes to the activities with relevant BAT conclusions published by the European Commission, where these have been published.¹

Document reference number:

WGC (BAT) Conclusions comparison assessment is ongoing.

C2.2.5 Include an outline of the main alternatives considered to the proposed changes to the technology, techniques and measures.

Document reference number:

Volume 2: Chapter 3

¹ Available from <http://eippcb.jrc.es/reference/> and/or <http://ec.europa.eu/environment/air/pollutants/stationary/ied/implementation.htm>

C2 Your proposed techniques *continued*

C2.3 Raw materials

Identify any changes to the raw and auxiliary materials, and any other substances (including fuels) proposed to be used as a result of your proposals.

If any changes are proposed, give details of quantities proposed to be used annually and submit respective MSDS sheets.

In addition, identify the storage location of these materials on a site layout plan and give details on:

- Maximum storage capacity;
- Containment measures (including bunding capacity, where applicable);
- Protective measures (including security).

Document reference number:

No Changes are proposed.

C2.4 Ozone depleting substances and fluorinated greenhouse gases

Identify any changes to the equipment using ozone depleting substances and fluorinated greenhouse gases, with a fluid charge of 3 kg or more.

For each such equipment, identify the type of equipment (hermetically-sealed systems, fixed systems or mobile systems), its use (firefighting, refrigeration/air-conditioning or high-voltage switchgear), charge (in kg) and the type of substance (e.g. R22, R407c, R134a).

Document reference number:

No changes are proposed.

C2.5 Maintenance

Describe any changes to the maintenance programme for the installation.

Document reference number:

Volume 2: Chapter 3

C2.6 Energy

C2.6.1: Describe any changes to the annual energy consumption, highlighting the main energy-consuming equipment, and generation by source and end-use (including information on energy generated on site, if applicable).

C2.6.2: Describe any changes to the proposed basic measures for improvement of energy efficiency.

Document reference number:

No changes are proposed.

C2.7 Water

Provide a breakdown of any changes to the proposed annual water consumption by source and end-use.

Document reference number:

No changes are proposed.

C2.8 Risk assessment

Describe any changes to the documented system used to identify, assess and minimise the environmental risks and hazards of accidents and their consequences.

Include any changes to emergency plans in case of fire, actions to be taken in case of failure of abatement equipment and other environmentally relevant incidents (e.g. spillages, gas leakage).

Document reference number:

Volume 2: Chapter 3

C2.9 Training

Please indicate whether any changes to the staff training programme will be required. Please submit the name of the technically competent person on site who will be responsible for such training.

Document reference number:

No changes are proposed

C2.10 Cessation

Describe any changes to the outline decommissioning plan describing the draft proposed measures upon definitive cessation of activities, to avoid any pollution risk and return the site of the installation to a satisfactory state (including relevant measures for the design and construction of the installation).

This plan shall include a draft waste management strategy, and a qualitative assessment of the potential for contamination of land and groundwater pollution which might

arise from the historical and current processes carried out at the installation.

C2 Your proposed techniques *continued*

Document reference number:

No changes are proposed.

C2.11 Multi-operator installations

Where you are not the only operator of the installation, describe any change to the techniques and measures (including those to be undertaken jointly by yourself and other operators) for ensuring satisfactory operation of the whole installation resulting from your proposals.

Document reference number:

Not applicable.

C3 Your proposed emissions

C3.1 Waste²

C3.1.1: Characterise (using the European Waste Catalogue code, in accordance with Commission Decision 2014/955/EU) and quantify any changes to each waste stream from the installation.

Document reference number:

Volume 2: Chapter 4

C3.1.2: Describe any changes to the proposed measures for waste management, storage and handling. If any are identified, also indicate the storage location of wastes on a site layout plan and give details on:

- Maximum storage capacity;
- Containment measures (including bunding capacity, where applicable);
- Protective measures (including security).

Document reference number:

Volume 2: Chapter 4

C3.1.3: Describe how each waste stream identified in C3.1.1 is prepared for re use, recycled, recovered or disposed of. If you propose any disposal, explain why recovery is technically and economically impossible and describe the measures planned to avoid or reduce any impact on the environment.

² For installations carrying out waste management activities (activities listed in "Section 5: Waste management" of

C3 Your proposed emissions *continued*

For these wastes, give details on authorised disposal/recovery facilities proposed to be used for each waste. If any on-site recovery of waste is proposed, provide details.

For each of these wastes, give details on off-site transportation, including registered waste carriers/brokers to be used.

Document reference number:

Volume 2: Chapter 4

C3.2 Emissions to Groundwater

Could there be changes to groundwater discharges from the installation?

Yes No

If yes, explain how the requirements of the Protection of Groundwater against Pollution and Deterioration Regulations (S.L.549.53) have been addressed, and submit a map showing the proposed location of such emissions.

Document reference number:

C3.3 Emissions to Sewer

C3.3.1: Is a new sewer connection envisaged as a result of your proposal?

Yes No

If yes, please submit a block plan of the site, showing the proposed layout of sewer connections and any other drains (colour-coded), as well as the proposed discharge point(s).

Document reference number:

Volume 2: Chapter 4

C3.3.2: If a new sewer connection is envisaged, does the installation have a Sewer Discharge Permit?

Yes No

Please submit a copy of the permit, or of the submitted application if the permit has not yet been issued.

Document reference number:

Appendix 2

Annex I of the Industrial Emissions Directive), please use this section to document both incoming and outgoing waste.

C3 Your proposed emissions *continued*

C3.3.3: Could the proposal involve the release of any Schedule A or Schedule B substance into the sewers, or changes to releases?

Yes No

If yes, explain how the requirements of Sewage Discharge Control Regulations (S.L.545.08) have been addressed.

Document reference number:

C3.3.4: Are new or changes to cesspit/s being proposed?

Yes No

If yes, please provide certification by an independent, warranted engineer showing that each cesspit is in line with the requirements of Schedule 1 Activity 43 of S.L. 549.45 Waste Management Activity (Registration) Regulations.

Document reference number:

C3.4 Emissions to the Sea

Identify if the proposal may result in changes to direct discharges to coastal (up to 1 nautical mile from the coast line) or territorial waters.

Yes No

If any changes are identified, explain how the requirements of the Pollution caused by Certain Dangerous Substances discharged into the Aquatic Environment Regulations (S.L.549.10) and the Water Policy Framework Regulations (S.L.549.100) have been addressed.

Include details of the source, any treatment proposed prior to discharge, composition and maximum volumes (in m³/day) discharged.

Document reference number:

In addition, please submit a block plan of the site, showing the proposed discharge point to the sea. Indicate the geo-referenced coordinates for discharge to sea.

Document reference number:

C3.5 Rainwater

Describe any changes to how rainwater is handled on site. If any changes are proposed, attach a site drainage map indicating rainwater capture and harvesting/discharge.

Document reference number:

No changes are proposed.

C3.6 Emissions to Air

Identify if there may be any changes in emissions of substances to air.

Yes No

If any are identified, submit details of each emission point, the nature and the proposed quantities of substances emitted from each point and treatment/abatement measures. A block plan of the site showing each emission point should be submitted.

For each new boiler/generator, submit the following details: rated thermal input, energy output, date of manufacture, stack height, fuel type and annual fuel consumption.

Document reference number:

Volume 2: Chapter 4

C3.7 Odour emissions

Identify if there may be changes in emissions of odour.

Yes No

If any are identified, submit details of the main sources of odour, and the proposed techniques and measures for control of odour.

Document reference number:

C3.8 Emissions to Land

Identify if there may be any changes in emissions of substances to land.

Yes No

If any are identified, submit details of the nature and the proposed quantities of substances emitted to land, as well as a map showing the proposed location of such emissions.

Document reference number:

C3 Your proposed emissions *continued*

C3.9 Noise

Describe:

C3.9.1: The main sources of noise and vibration (including infrequent sources) of the new proposal;

C3.9.2: The proposed techniques and measures for control of noise;

C3.9.3: The nearest noise sensitive locations and distance away from the site (a site map may be submitted for this purpose); and

C3.9.4: Relevant environmental noise measurement surveys which have been undertaken (monitoring shall be according to the latest revisions of ISO1996 and the rating of industrial noise affecting residential areas shall be according to BS 4142; monitoring shall be carried out exclusively using type 1 sound level meter).

Document reference number:

Volume 2: Chapter 4

C3.10 Monitoring

Describe the proposed measures for monitoring emissions arising from the proposal, including any environmental monitoring. The following must be specified:

C3.10.1: The location of each proposed monitoring point (plotted on a suitably-labelled block plan of the site);

C3.10.2: The substances (in each environmental medium) which are proposed to be monitored;

C3.10.3: The frequency with which monitoring is proposed to take place;

C3.10.4: The proposed measurement methodology, which should be a standard methodology, such as EN or ISO standard, or equivalent;

C3.10.5: The proposed procedure for evaluation of the results.

Document reference number:

Volume 2: Chapter 4

C3.11 Emissions & waste summary

By means of a mass flow diagram, summarise the emissions and waste described in sections C3.1, C3.2, C3.3, C3.4, C3.6, and C3.8 of this application.

Document reference number:

**Flow charts have been included in
Volume 2: Chapter 2.**

C4 Impact on the environment

C4.1 Environmental effects

Provide an assessment of the potential significant environmental effects (including transboundary effects) of the foreseeable emissions from the proposal.

Document reference number:

Volume 2: Chapter 5

C4.2 Effects on other sites

Provide an assessment of whether the proposal is likely to have a significant effect on another site in Malta and, if it is, provide an assessment of the implications of the installation for that site.

Document reference number:

Volume 2: Chapter 5

C5 Environmental statements

C5.1 Environmental statement

Has this proposal required an EIA Report under the Environmental Impact Assessment Regulations (S.L. 549.46)?

Yes No

The waste warehouse was already included in the EIA Update for the entire site, prepared as part of PA 8089/19, which was already submitted to ERA as part of a previous IPPC variation application. The new emission points to air did not require an EIA report.

If yes, please supply a copy of the EIA Report submitted and details of any decision made.

Document reference number:

C6 Statutory consultees

We will use the information in this section to identify who we must consult about your proposals.

C6.1 Local council

In which area is the installation located? If premises are on a boundary please give the names of all the relevant authorities.

Birżebbuġa

C6.2 Other sites

Are there any other sites which may be affected by emissions from the proposal? (Refer also to your answer to C4.2).

Yes No

If yes, please give the names of the sites:

C6.3 Port Authority

Could the installation involve the release of any substance into a harbour managed by a port authority?

Yes No

If yes, please name the port authority:

C7 Planning status

C7.1 Planning status

Which of the following applies to the proposed installation activities?

We cannot issue a permit unless one of the following applies. Please tick the applicable answer and submit a copy of the relevant documents.

You have planning permission.

Document reference number:

Appendix 2

You have a certificate of lawful existing use or development.

Document reference number:

Planning permission is not required - please say why and enclose written confirmation from the Planning Authority.

Document reference number:

If you have submitted an application for planning permission which has not yet been determined, please provide a copy of the application.

Document reference number:

C8 Technically competent person

Technically competent person

We need to make sure that whoever holds the permit is a 'technically competent person'. This includes consideration of relevant offences, technical competence and financial provision.

C8.1 Technically competent management

Are any changes to the technically competent management of the activities proposed?

Yes No

If yes, please give details for each person and provide the written evidence requested.

An additional Technically Competent Person is proposed, as described below.

Responsible person 1:

Full Name: Andrea Caneponi
Position: HSE Manager
Date of employment: 30/10/2016
Mobile number: +35699054582

Document reference number for copies of CV, relevant qualifications and recent police conduct certificate:

Appendix 4

Responsible person 2:

Full Name:
Position:
Date of employment:
Mobile number:

Document reference number for copies of CV, relevant qualifications and recent police conduct certificate:

Responsible person 3:

Full Name:
Position:
Date of employment:
Mobile number:

Document reference number for copies of CV, relevant qualifications and recent police conduct certificate:

C8 Technically competent person cont.

C8.2 Management of other installations

Is any of the technically competent management already providing the technically competent management at other IPPC installations or at sites licensed under the Environment Protection Act, 2016?

Yes No

If yes, please use a separate sheet to give details of these people. For each person we need to know the:

- site/installation name and address;
- licence/permit reference number.

Document reference number for this information:

C9 Expenditure plan

C9.1 Expenditure plan

Please provide a plan of the estimated expenditure for each phase of the following specified activities arising from your proposal.

The plan should include the likely costs of:

- monitoring (emission/discharge and ambient monitoring);
- clearing the installation (including drainage systems) of all wastes;
- remedial action in the event of the failure of pollution control systems.

We recognise that this plan may need to be revised before the issue of the final permit.

Document reference number for expenditure plan:

Appendix 5

C10 What to do next

Please read Appendix I, then prepare and sign a covering letter to attach to your application form.

Appendix I Data Protection Clause

In terms of the Data Protection Act (Chapter 586 of the Laws of Malta), we will process any personal and/ or sensitive data supplied on/ in this submission or subsequently supplied by yourself, whether orally or in writing, for all or any of the following purposes:

1. The proper processing of your submission;
2. internal management, research and statistics;
3. the protection and promotion of our legitimate interests and the proper conduct of our obligations arising under any law or statutory instrument; and
4. to make public the necessary information as specified in the relevant law and/or instrument.

Relevant data will be disclosed or shared as appropriate with all our employees and with other third parties if pertinent to any of the purposes listed above.

You have the right to require that we provide you with access to your **personal data** as well as the right to rectify, or, in appropriate circumstances, erase/edit any inaccurate, incomplete or immaterial personal data which is being processed. However, you are required to inform us immediately of any alterations relating to your personal data which we are processing.

By sending your submission, you confirm that you are giving your explicit consent, in terms of the Data Protection Act, on behalf of yourself and all the other persons specified in this submission for the Authority to process your respective personal information as outlined above and you confirm that you have brought this Data Protection notice to the attention of these other persons and obtained their respective consents.

We undertake to implement appropriate measures and safeguards for the purpose of protecting the confidentiality, integrity and availability of all personal data processed.

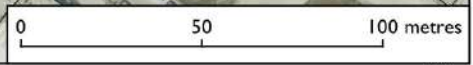
Appendix 1: Site plan



Location of site

- Legend**
- Site boundary
 - Proposed extension to existing site boundary

Sterling IPPC Micronisation Variation



Map by:
ensure monitoring
Client: Sterling Chemical Ltd
Ref: ES_STG013
Date: 5 / 2023

Appendix 2: Existing permits

Permit with introductory note

Environment Protection Act (CAP. 549)

Industrial Emissions (Framework) Regulations (S.L. 549.76).

Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L. 549.77).

Sterling Chemical Malta Ltd.
HF 50, HF 51 & HF53
Hal Far Industrial Estate,
Birzebbuga
BBG 3000

Permit number
IP 0004/21

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Introductory note

The following Permit is issued under Regulation 7 of the Industrial Emissions (Framework) Regulations, S.L.549.76 to operate an installation carrying out activities covered by the description in Section 4.5 in Schedule 1 of the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations S.L.549.77 (“the Industrial Emissions (IPPC) Regulations”), to the extent authorised by the Permit, i.e.

“Installations carrying out an industrial scale the production by chemical or biological processing of pharmaceutical products including intermediates”.

Aspects of the operation of the installation which are not specifically regulated by conditions in the Permit may also be subject to the condition implied by Regulation 8 of the Industrial Emissions (IPPC) Regulations, which require the Operator to use the best available techniques for preventing or, where that is not practicable, reducing emissions from the installation.

Conditions marked with a “∞” shall be construed as conditions which are to be enforced by the Authority responsible for such an issue.

Techniques include both the technology used and the way in which the installation is designed, built, maintained, managed, operated and decommissioned.

In some sections, the Permit conditions require the Operator to use Best Available Techniques (BAT), in each of the aspects of the management of the installation, to prevent and where that is not practicable to reduce emissions. These conditions do not explain what BAT is.

A non-technical description of the installation is given in the original application dated 28 May 2014 and supported by the application for renewal and variation dated 11 October 2017, but the main activity of the installation is as follows:

- **Production of basic pharmaceutical products (Active Pharmaceutical Ingredients – APIs).**

Note that the Permit requires the submission of certain information to the Competent Authority. In addition, the Competent Authority has the power to seek further information at any time under regulation 11 of the Industrial Emissions (Framework) Regulations, provided that it acts reasonably.

Other IPPC Permits relating to this installation

Operator	Permit Number	Date of Issue
<i>Not applicable</i>		

Superseded Licences/Authorisations/Consents relating to this installation

Holder	Reference Number	Date of Issue
<i>Sterling Chemical (Malta) Ltd.</i>	<i>IP0001/14/A</i>	<i>13 August 2015</i>
<i>Sterling Chemical (Malta) Ltd.</i>	<i>IP0001/14/B</i>	<i>5 April 2019</i>

Public Registers

This IPPC Permit and application is available to the public through the Competent Authority in accordance with the requirements of the Industrial Emissions (IPPC) Regulations. Certain information may be withheld from the public where it is commercially confidential or contrary to national security. This clause has not been applied to this application and the relevant documentation and permit.

Variations to the Permit

This Permit may be varied by the Authority at any time in the future. If the Permit Holder wants any of the Conditions of the Permit to be changed, a formal application must be submitted to the Competent Authority.

The **Status Log** within the Introductory Note to any such Variation Notice will include summary details of this Permit, variations issued up to that point in time and state whether a consolidated version of the Permit has been granted.

Any change in operations shall only be implemented following the granting of a variation of the permit by the Authority.

Surrender of the Permit

Before this Permit can be wholly or partially surrendered, an Application to surrender the Permit has to be made to the Competent Authority by the Permit Holder. For the application to be successful, the Permit Holder must be able to demonstrate to the Competent Authority that there is no pollution risk and that no further steps are required to return the site to a satisfactory state.

Transfer of the Permit or part of the Permit

Upon the joint application of a Permit Holder and a proposed transferee, the Permit Holder may request to transfer an environmental permit. The permit shall not be transferred from the Permit Holder without prior approval from the Authority. Upon the Authority's decision to transfer the permit to the transferee, all rights, obligations, liabilities shall subsist onto the transferee.

Status Log

Detail	Date	Comment
<i>Application IP 0001/04</i>	<i>Received 28 May 2014</i>	<i>Not 'Duly Made'</i>
<i>Request for further information and Response</i>	<i>Request dated 17 February 2015</i>	<i>Response dated 18 March 2015</i>
<i>Internal Consultation and Consultation with statutory consultees.</i>	<i>Commenced on 17 February 2015</i>	<i>Concluded on 19 March 2015</i>
<i>Request for further information and Response</i>	<i>Request dated 15 April 2015</i>	<i>Response dated 28 May 2015</i>
<i>Request for further information and Response</i>	<i>Application regarded as 'Duly Made' on 6th June 2015 and 12 June 2015.</i>	<i>Consolidated application submitted on 18 June 2015</i>
	<i>Request for consolidated version for commencement of public consultation</i>	
<i>Public consultation</i>	<i>Commenced on 19 June 2015</i>	<i>Concluded on 19 July 2015</i>
<i>Permit determined</i>	<i>30 July 2015</i>	
<i>Permit issued</i>	<i>13 August 2015</i>	<i>Permit expires 13 August 2019</i>
<i>Application IP 0001/04/B</i>	<i>11 October 2017</i>	<i>variation</i>

<i>Regulatory consultation</i>	<i>6 April till 4 May 2018</i>	
<i>Application considered duly made</i>	<i>2 October 2018</i>	
<i>Public consultation</i>	<i>Commenced on 5 October 2018</i>	<i>Concluded on 19 October 2018</i>
<i>Permit Determined</i>	<i>23 November 2018</i>	
<i>Permit Issued</i>	<i>5 April 2019</i>	<i>Permit expires: 13 August 2019</i>
<i>Application IP0001/19</i>	<i>25 March 2019</i>	<i>variation and renewal</i>
<i>Regulatory consultation</i>	<i>between 12 April 2019 – 26 April 2019 and 19th June – 26th June 2019</i>	
<i>Application considered duly made</i>	<i>28 June 2019</i>	
<i>Public Consultation</i>	<i>Commenced on 6 July 2019</i>	<i>Concluded on 20 July 2019</i>
<i>Permit Determined</i>	<i>6 September 2019</i>	
<i>Permit Issued</i>	<i>29 November 2019</i>	
<i>Application for variation IP 0004/21</i>	<i>26 February 2021</i>	
<i>Regulatory Consultation</i>	<i>1 April 2021 till 22 April 2021</i>	
<i>Application considered duly made</i>	<i>3 June 2021</i>	
<i>Public Consultation</i>	<i>Commenced on 19 June 2021</i>	<i>Concluded on 03 July 2021</i>
<i>Variation Application Determined</i>	<i>3rd September 2021</i>	

End of Introductory Note

Permit

Industrial Emissions (Framework) Regulations, S.L. 549.76;

Industrial Emissions (Integrated Pollution Prevention and Control) Regulations, S.L. 549.77.

Permit number

IP 0004/21

Approved Documents:

IP 0004/21/DOC1

IP 0004/21/DOC2

The Environment and Resources Authority (hereinafter the Authority; the Competent Authority or ERA) in exercise of its powers under Regulation 7 of the Industrial Emissions (Framework) Regulations, (S.L.549.76) ("the Industrial Emissions (Framework) Regulations"), hereby authorises:

Mr. Roberto Tumbiolo obo Sterling Chemical (Malta) Ltd. (hereinafter "the Permit Holder")
(Company registration number: **C3250B/6**)

Of / Whose Registered Office (or principal place of business) is at:

**HF 50, HF 51 & HF53,
Hal Far Industrial Estate, Birzebbuga,
BBG 3000**

to operate an installation at:

**HF 50, HF 51 & HF53,
Hal Far Industrial Estate, Birzebbuga,
BBG 3000**

This variation is valid until the expiry of the permit IP 0001/19 which is 4 year/s from the 'permit granted' date below. An application for renewal is to be submitted at least nine (9) months prior to expiry of IP 0001/19.

Environment and Resources Authority	
APPROVAL	
Board No.141	Held on 3/09/21
Chairman _____	Secretary _____
	Permit Granted: 29/11/2019
	Variation Granted: 22/09/2021

Authorised to sign on behalf of the Competent Authority

Conditions

1. General

The Permitted Installation shall, subject to the conditions of this Permit, be managed, controlled and operated as described in the IPPC Application, or as otherwise previously agreed in writing by the Authority. This Permit shall be interpreted in accordance with Section 7 or as otherwise defined in S.L. 549.76 and S.L. 549.77.

1.1 Permitted Activities

1.1.1 The Operator is authorised to carry out the activities and the associated activities specified in Table 1.1.1

Table 1.1.1		
Activity listed in Schedule 1 of the Industrial Emissions (IPPC) Regulations / Associated Activity	Description of specified activity	Limits of specified activity
Section 4.5: Production by chemical or biological processing of pharmaceutical products including intermediates.	Synthesis of active pharmaceutical ingredients (APIs). Research & Development of active pharmaceutical ingredients (APIs).	From receipt of raw materials and associated chemicals to dispatch of finished product (including packaging and storage). Includes manufacture of high potency cytotoxic/cytostatic drugs. Does not include the preparation of any radioactive APIs
Associated activity of utilities	Two water purification plants. Operation of 16 reactors Operation of two LPG boilers to produce steam and hot water. Operation of a cooling tower Operation of air handling units	From receipt of water to delivery of utility. This does not include the discharge of any foul water generated from the high potency line into the sewerage network. As described in the consolidated IPPC applications. From receipt of fuel to delivery of utility. From intake of water, to treatment and final discharge. From the intake of outside air to filtration prior to extraction from the facility
Associated activity of waste management	Handling and storage of waste generated from	From generation of waste to dispatch for disposal or recovery (including recycling) offsite.

	installation prior to dispatch offsite.	Includes separation of solvent mixture from industrial process for recovery and re-use where possible, storage of rejected products.
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1.2 Site

- 1.2.1 The activities authorised under condition 1.1.1 shall not extend beyond the Site, as shown on the Site Plan in Schedule 3A and the layouts in **Approved Document IP0004/21/DOC1** to this Permit.
- 1.2.2 Site security systems shall be implemented at all times during the subsistence of this Permit, the objective of which shall be to prevent access, which is not authorised either by the Permit Holder or under legal powers of entry. These shall be installed, operated and maintained, and shall be fully documented and recorded.

1.3 Overarching Management Condition

- 1.3.1 The operator shall endeavour to implement and maintain the EMS and allocate resources that are sufficient to achieve compliance with the limits and conditions of this Permit
- 1.3.2 The Operator shall submit (including as part of the EMS) the following reports annually as part of the Annual Environmental Report of the site, according to the timeframe specified in Condition 5.2:
- i. Environmental Policy containing the installation's environmental objectives and targets;
 - ii. Environmental Management Programme report (for the reporting year);
 - iii. Environmental Management Programme proposal (for the following year);
- 1.3.3 The Permitted Installation shall, subject to the conditions of this Permit, be managed, controlled and operated as described in the application and subsequent responses to requests for information submitted as per the Status Log above, or as otherwise previously agreed in writing by the Authority.

1.4 Improvement Programme

- 1.4.1 The Operator shall complete the improvements specified in Table 1.4.1 by the date specified in that table, and shall send written notification of the date of completion of each requirement to the Authority within 10 working days of the completion of each such requirement.

Table 1.4.1: Improvement programme		
Reference	Requirement	Date
20	Emissions to air monitoring in accordance with condition 2.2.1.21 for emission points: EM4A, EM4B, EM10A, EM11	By December 2021

1.5 Operational Changes

- 1.5.1 The Operator shall seek the Authority's written agreement prior to any operational changes as defined by S.L 549.77 by sending to the Authority: written notice of the details of the proposed change, including an assessment of its possible effects (including changes in emissions and waste production) on risks to the environment and public health from the Permitted Installation; any relevant

supporting assessments and drawings; and the proposed implementation date. Operational changes shall include but not be limited to:

- a) Installation of new reactors, centrifuges, driers and other equipment;
- b) Inclusion of new production lines or process areas

1.5.2 Any such change shall not be implemented until agreed to in writing by the Authority. As from the agreed implementation date, the Operator shall operate the Permitted Installation in accordance with that change, and relevant provisions in the Application shall be deemed to be amended.

1.5.3 The Director of Environment and Resources and any officials to whom this role is delegated are hereby authorised to make decisions on variations to this permit that do not constitute a substantial change in the operations, permit or approved documents. No variations may be undertaken under this clause should these require any statutory consultation or further studies.

1.6 Approval procedure for new production processes

1.6.1 Prior to the production of any new Active Pharmaceutical Ingredient other than those approved by the Authority, the Operator shall notify the Authority 1 month prior to the start of production and submit the following documentation:

- i. Safety Data Sheets for the raw materials, intermediates and final product.
- ii. An Emission Diagram detailing the production process and associated mitigation measures for the identified emissions.
- iii. A mass flow calculation in the case of the use of solvents carrying the hazard statements indicated in conditions 2.2.18 and 2.2.19.

1.7 Pre-operational Conditions

1.7.1 There are no pre-operational conditions

1.8 Off-site Conditions

1.8.1 The Permit holder shall ensure that no chemicals or waste escape to the environment especially when transporting such materials offsite or onsite.

1.9 General Conditions

1.9.1 The conditions and obligations of this permit are without prejudice to any other regulation, code of practice, conditions or requirements requested by other Authorities or entities, including but not limited to the Planning Authority, Occupational Health and Safety Authority, Transport Malta, the Regulator for Energy and Water Services (REWS), the Environmental Health Directorate and the Malta Competition and Consumer Affairs Authority (MCCAA).

1.9.2 This permit is granted saving third party rights. The Permit Holder is not excused from obtaining any other permission required by law.

1.9.3 The validity of this permit is until 4 years from the date of the Permit Granted. The Permit Holder is able to renew the permit upon application with the Authority expressing his/her intention at least nine (9) months prior to the expiry of this permit. The permit will be considered renewed once the official renewed permit is issued by the Authority.

1.9.4 The permit is issued against a Bank Guarantee of €25,350 which shall be renewed annually. This guarantee will have to be maintained throughout the

validity of the permit. Following renewal and/or variations to this permit, the Authority may require amendments to the Bank Guarantee.

- 1.9.5 The Bank Guarantee shall remain in place for the duration of validity of this permit and shall only be released upon confirmation of full compliance with the permit conditions by the Authority.
- 1.9.6 The Authority may take part or all of the bank guarantee if the Permit Holder fails to take the necessary action, or fails to fulfil his legal obligations under the Act or its subsidiary legislation thereof, in cases of non-compliance with these permit conditions, or in cases where environmental integrity is threatened. This bank guarantee is without prejudice to any environmental liabilities incurred by the Permit Holder through failure to adhere with permit conditions or any other works/activity carried out on site. Should the Authority forfeit the Bank Guarantee either in part or in full, the permit holder shall ensure that this is replenished without undue delay, in any case not exceeding 2 months from the date of forfeiture.
- 1.9.7 In cases where the bank guarantee does not cover the expenses incurred by the Authority to take any remedial action on the Permit Holder's behalf, the Permit Holder is to financially reimburse the Authority of all the expenses incurred within.
- 1.9.8 The operator shall submit a fixed annual fee of €1,500 and a variable addition reflecting ERA's cost for inspections. The latter variable component depends on the actual number of site inspections, which is determined by the performance of the operator. The total annual contribution has to be paid before the anniversary of the date of issue of this permit.
- 1.9.9 A copy of this permit shall be available at all times at the site office, including any variation notices of amendments to it.
- 1.9.10 The Permitted Installation shall be managed, controlled, supervised and operated by staff that are aware of the importance of environmental protection and suitably trained on the requirements of this Permit, in particular on those permit conditions relevant to their duties. All staff shall be provided with adequate training and written operating instructions to enable them to effectively carry out their duties. Training records shall be maintained in line with Condition 2.19.3.
- 1.9.11 The company shall maintain a register of third party complaints. The register shall record the name and address of the complainant(s), the date, location, source and nature of the complaint and the corrective action undertaken, where such action proves necessary.
- 1.9.12 All plant, equipment and technical means used in operating the Permitted Installation shall be maintained in a good operating condition and maintenance records of the above shall be kept by the operator in line with Section 2.11 of this Permit.
- 1.9.13 In case of any monitoring requirements specified in this permit, there shall be provided safe means of access to enable sampling/monitoring to be carried out by the Authority or by a third party if necessary.
- 1.9.14 All persons have a duty of care to protect the environment. The Permit Holder shall become familiar with his legal obligations and good environmental practice.
- 1.9.15 The Authority may request additional monitoring and/or review of the operational practices and commission any audits/reports as deemed necessary to address any circumstances that may affect the quality of the surrounding environment, at the expense of the permit holder.

- 1.9.16 Without prejudice to condition 1.9.8, the Authority may take any action deemed necessary including but not limited to the suspension of any activity/operation until investigations are concluded.
- 1.9.17 The site shall be maintained in a tidy condition, free from litter and waste (whether arising from own activities or external sources).
- 1.9.18 The site must be well secured at all times.
- 1.9.19 The Permit Holder is to be fully liable and responsible for managing the site in all its various aspects and to supervise the full adherence with all the conditions of this permit.
- 1.9.20 The Authority may carry out regular pre-set or unannounced compliance or monitoring checks that vary in frequency according to the site's compliance with the permit conditions and safeguarding of natural assets. Any checks or audits carried out by the Authority may be made at the Permit Holder's financial expense at rate and arrangement communicated by ERA's Compliance and Enforcement Directorate.
- 1.9.21 The Authority's representatives may inspect and photograph any part of the site and ask for any closed or locked areas to be opened and may demand to be provided with any proof, documentation, plans, receipts or any other records.
- 1.9.22 The Authority may add, amend, delete or substitute any of the conditions of this permit after notifying the Permit Holder of its intention and after describing the changes to the Permit Holder. This is without prejudice to any prevailing circumstances that would preclude the Authority from following such a procedure.
- 1.9.23 The Authority may suspend or revoke this permit or part of this permit in cases of fraud, where public safety or significant environmental damage or risk is concerned, where there is an error on the face of the record or where there is a breach of one or more permit conditions after a written warning is given by the Authority or in any eventuality that gives the Authority enough reason to suspend or revoke this permit.
- 1.9.24 Any incident including accidental release of liquid, solid or gaseous materials from the site that could be regarded as causing environmental damage, or as posing a threat of environmental damage, shall be reported as soon as possible and not later than within 24 hours to ERA, without prejudice to the emergency plan for the installation and Health and Safety.
- 1.9.25 The Permit Holder has the sole responsibility to ascertain compliance with legal obligations, permit conditions and to undertake activities on and off site in line with good environmental practices at all times.

2 Operating Conditions

2.1 In-Process Controls

- 2.1.1 Only non-flammable waste shall be stored in the waste storage warehouse in the HF53 block. These shall consist of the waste streams described in the following table, in accordance to the European Waste Catalogue codes as published in Council Directive 2000/532/EC and as may be amended from time to time shall be stored on site.

Waste Location Code	EWC Code	Description
10	06 01 06*	Other acids
	07 07 01*	Aqueous washing liquids and mother liquors
	07 07 03*	Organic halogenated solvents, washing liquids, and mother liquors – dichloromethane
	16 10 01*	Aqueous liquid wastes containing hazardous substances

Emissions

2.2 Emissions to Air (excluding Odour, Noise or Vibration) from Specified Points

2.2.1 All processes which generate significant levels of airborne contaminants (such as dusts, toxic gases, odorous chemicals) shall have effective local collection and shall discharge (after treatment where necessary) through a stack or vent located and/or designed in such a way as to avoid local environmentally detrimental effects.

2.2.2 Emissions to air shall only arise from the emission points specified in Table 2.2.1, as per Schedule 3B.

Table 2.2.1 : Emission points to air

Emission point reference	Source	Location of emission point
EM1	Production area	Scrubber stack
	Weighing Room	
	Finished Goods area (clean room)	
	Microniser	
EM2	HVAC (General ventilation and air-conditioning) – H51 block	Fabric filter
EM3A	HVAC Production Line 2 clean rooms	HEPA filter (HF1)
EM3B	HVAC Production Line 1 clean rooms	HEPA filter (HF2)
EM3C	Micronisation plant clean rooms	HEPA filter (HF3)
EM4A	Laboratories	Fume Hood Extraction vent
EM4B	Laboratories	Fume Hood Extraction vent
EM4C	QC lab fume hoods	Carbon filter
EM4D	QC lab fume hoods	Carbon filter
EM4E	QC lab fume hoods	Carbon filter
EM5	Boiler	Boiler stack
EM6	Boiler	Boiler stack
EM7	Cooling Tower	Cooling tower stack
EM8A	AMS (Quality Control) lab fume hoods	Carbon filter
EM8B	AMS (Quality Control) lab fume hoods	Carbon filter
EM8C	AMS (Quality Control) lab fume hoods	Carbon filter
EM8D	AMS (Quality Control) lab fume hoods	Carbon filter
EM10A	R&D laboratory	Fume Hood Extraction vent
EM10B	R&D lab fume hoods	Carbon filter

EM10C	R&D lab fume hoods	Carbon filter
EM10D	R&D lab fume hoods	Carbon filter
EM11	Micronization laboratory	Fume Hood Extraction vent
EM12	Cold Rooms	Vent
EM13A	Production area	Scrubber
EM13B	Production area	Scrubber backup fan
EM14	General ventilation	HVAC
EM15	Clean rooms	HVAC- HEPA filter
EM16	laboratory	Fume Hood Extraction vent
EM17	laboratory	Fume Hood Extraction vent
EM18	laboratory	Fume Hood Extraction vent
EM19	laboratory	Fume Hood Extraction vent
EM20	laboratory	Fume Hood Extraction vent
EM22	Waste Warehouse	None

2.2.3 The limits for emissions to air for the parameters and emission points set out in Table 2.2.2 shall not be exceeded.

Table 2.2.2 : Emission limits to air and monitoring				
Emission point reference	Parameter	Limit		Frequency
EM1, EM13	VOC (Total Organic Carbon)	20	mgC/Nm ³	Annually
EM4A, EM4B, EM4C, EM4D, EM4E, EM8A, EM8B, EM8C, EM8D, EM10A, EM10B, EM10C, EM10D, EM11				Every four years subject to condition 2.2.1.21
EM1, EM13, EM3A, EM3B, EM3C	Total Particulate Matter	<1	mg/Nm ³	Annually
EM4A, EM4B, EM4C, EM4D, EM4E, EM8A, EM8B, EM8C, EM8D, EM10A, EM10B, EM10C, EM10D, EM11				Once subject to condition 2.2.1.21
EM1, EM13	HCl	7.5	mg/m ³	Annually
EM1, EM13	HBr	<1	mg/m ³	Annually

API Handling

- 2.2.4 There shall be no storage or handling of APIs in dry powder form in the storage areas unless storage is carried out in double polyethylene bags, closed with seals and re-packaged in polyethylene UN approved Drums. These shall only be handled and stored outside of such storage arrangements in the enclosed process rooms having dedicated extraction and room filtration as per condition 2.2.5.
- 2.2.5 Emissions to air from all areas where active pharmaceutical ingredients in dry powder form are handled (including weighed, processed, compacted and dried) shall be exhausted through abatement equipment having at least 99.9% efficiency.
- 2.2.6 The operational effectiveness of filters (such as HEPA filters) for the control of particulate emissions of pharmaceutical raw materials intermediates and products shall be monitored by means of a pressure differential recorder or equally effective means. Such recorders shall be visible and audible to operators working on the equipment such that an out of range incident can be easily and immediately identified.
- 2.2.7 When filters are found to have reached the pressure alert limit indicated by filter manufacturer, these shall be immediately replaced as per approved Standard Operating Procedure and where applicable, damaged filters shall be treated as hazardous waste as per S.L.549.63. Records of filter changes should be kept in line with Section 4 of the Permit.

- 2.2.8 Further to condition 2.2.6, the Permit Holder shall carry out and document HEPA filter integrity monitoring for exhaust filters indicated in Schedule 3C on a weekly basis in line with the approved Standard Operating Procedure. The results of the monitoring shall be submitted on a quarterly basis to the Authority and the Birzebbuga local council electronically. Such results shall also be submitted as part of the Annual Environmental Report, in the format specified in Schedule 2.
- 2.2.9 HEPA Filter efficiency certification for exhaust filters is to be submitted on an annual basis as part of the Annual Environmental Report, in the format specified in Schedule 2.

Combustion Plants

- 2.2.10 Industrial combustion plants (e.g. boilers, generators, etc.) shall be compliant with the provisions of S.L.549.50, Ambient Air Quality Regulations and S.L.549.122 Limitation of Emissions of Certain Pollutants into the air from Medium Combustion Plant Regulations.
- 2.2.11 Only LPG shall be utilised as a source of fuel for the boilers and other combustion plants on site. The co-incineration of any material or additional fuel including engine or other waste oil is strictly prohibited. Any change in fuel type shall require the notification and approval of the Authority prior to commencement of its utilisation.
- 2.2.12 The Permit Holder shall keep the periods of start-up and shut-down of the combustion plant as short as possible.
- 2.2.13 The Permit Holder shall submit certification for the boilers (EM5 & EM6) referred to in table 2.2.1, by an independent warranted engineer showing that the boilers are in good working condition every four years. The certifications shall be submitted as part of the Annual Environmental Report (AER).
- 2.2.14 Should the Permit Holder intend to install equipment which could lead to additional emissions to air (e.g. boiler, etc.), a variation of this Permit must be secured prior to installation and operation of this equipment.

Emissions from the Scrubbers

- 2.2.15 Regarding emissions of VOCs from organic solvents, the installation shall comply with the emission limit value for waste gases as defined in Table 2.2.2 for point sources EM1 and EM13A or EM13B, whichever one is active at the time of monitoring and a fugitive emission value of 5% of the solvent input.
- 2.2.16 Compliance with the fugitive emission value is to be demonstrated in accordance with the guidance provided in Schedule IV of the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (S.L. 549.79) and as may be subsequently amended, and, the VOC Reporting Template in Schedule 4. The calculations shall take account of all organic solvents used within the installation, including raw materials used in the process and solvent used for cleaning the equipment.
- 2.2.17 Compliance with the waste gas emission limit value in Table 2.2.2 shall be demonstrated through a monitoring exercise carried out in accordance with Regulations 7 and 8 of the industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (S.L. 549.79).
- 2.2.18 Discharges-of VOCs which are assigned or need to carry the hazard statements H340, H350, H350i, H360D or H360F (or the risk phrases R45, R46, R49, R60, or R61), where the mass flow of the sum of the compounds causing the risk labelling (H340, H350, H350i, H360D or H360F) is greater or equal to 10 g/hour,

an emission limit value of 2 mg/Nm³ shall be complied with. The emission limit value refers to the mass sum of the individual compounds causing the risk labelling and these limits relate to dry gas and volume flows without dilution. Where the Permit Holder has not used such substances during a particular year, he shall notify the Authority as part of the Annual Environmental Report, and such monitoring shall not be required during that year.

- 2.2.19 Without prejudice to the emission limit for total VOC as carbon specified in Table 2.2.2, discharges from the scrubber of halogenated VOCs which are assigned or need to carry the hazard statements H341 or H351 (or the risk phrases R40 or R68), and where the mass flow of the sum of the compounds causing the labelling is greater than or equal to 100 g/hour, shall comply with an emission limit value of 20 mg/Nm³. The emission limit value refers to the mass sum of the individual compounds and these limits relate to dry gas and volume flows without dilution. Where the Permit Holder has not used such substances during a particular year, he shall notify the Authority as part of the Annual Environmental Report, and such monitoring shall not be required during that year.
- 2.2.20 The Permit Holder shall monitor EM1 and EM 13A or EM13B as listed in Table 2.2.2 and subject to Conditions 2.2.15 – 2.2.16 annually provided that the limits detected are within the emission limit values specified in Table 2.2.2 and Conditions 2.2.15 – 2.2.16. Otherwise, monitoring shall be carried out at six-monthly intervals. Monitoring from the scrubber shall be carried out during production, while monitoring from the boiler shall be carried out during its operation. Measurements for the parameters shall be carried out according to Regulations 7 and 8 of the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (549.79).

Monitoring Provisions and Emergency considerations

- 2.2.21 Within the first year of commissioning of the laboratories generating the emissions listed in Table 2.2.2, the Permit Holder shall monitor the parameters listed in Table 2.2.2 as per defined frequency provided that the limits detected are within the emission limit values specified in Table 2.2.2. Otherwise, monitoring shall be carried out annually until compliance with the emission limit values is achieved for 2 years in a row. Measurements for VOC shall be carried out according to Regulations 7 and 8 of the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (549.79).
- 2.2.22 Sampling and analysis of polluting substances and measurements of process parameters shall be based on methods enabling reliable, representative and comparable results. Methods complying with harmonised EN standards shall be presumed to satisfy this requirement.
- 2.2.23 The Permit Holder shall keep a record of and process all monitoring results in such a way as to enable the verification of compliance with the emission limit values set out in Tables 2.2.2.
- 2.2.24 In the event of, malfunction or breakdown leading to abnormal emissions, the Permit Holder must:
- i Investigate immediately and undertake corrective action, and
 - ii Adjust the process or activity to minimise those emissions, and
 - iii Record the events and actions taken

2.2.1.25 Further to condition 2.2.23, the Permit Holder shall provide ERA with details of the specific cause of the malfunction and the remedial steps taken or to be taken to address the malfunction:

2.2.1.26 All abatement equipment and ducting shall be cleaned and maintained on a regular basis (as per manufacturer specifications and approved SOPs) in line with Section 2.11 of the Permit.

Fugitive emissions of substances to air

2.2.27 The Permit Holder shall use BAT so as to prevent or were not practicable to reduce fugitive emissions of substances to air from the Permitted Installation, in particular from the:

- process areas
- storage areas, including solvent storage, raw materials storage and waste storage
- buildings
- pipes, valves and other transfer systems
- open surfaces

provided always that the techniques used by the Permit Holder shall be no less effective than those described in the Application, where relevant and approved by the Authority prior to their implementation.

2.3 Cooling Tower Registration [∞]

2.3.1 Any new cooling tower on site shall be registered with the Environmental Health Directorate, within a timeframe agreed with the Environmental Health Directorate.

2.3.2 The installation shall comply with the conditions set by the Environmental Health Directorate and with the provisions of the Control of Legionella Regulations, (S.L.465.03).

2.3.3 The Permit Holder shall abide to the following Minimum Disinfection and water monitoring conditions for cooling towers.

- a) Water of the cooling tower should be continuously treated with one or more biocides to effectively control the growth of micro-organisms including Legionella and with chemical or other agents to minimise scale formation, corrosion and fouling.
- b) A chlorine-compatible bio-dispersant is added to the recirculating water of the cooling tower system and, that the system is then disinfected, cleaned and re-disinfected;
 - i immediately prior to initial start-up following commissioning, or any shut down period of greater than one month;
 - ii at intervals not exceeding 6 months;
- c) At least every 6 months a sample of the recirculating water of the cooling tower system shall be tested for *Legionella* and at least every month for heterotrophic colony count, at a laboratory accredited for such tests (or other laboratory providing the equivalent performance and reliability). The results of such tests shall be submitted as part of the Annual Environmental Report of the installation in the format specified therein (Table S2.4.3).

2.4 Discharges to surface water

2.4.1 There shall be no discharges to surface waters.

2.5 Discharges to the sewer [∞]

2.5.1 The Permit Holder shall ensure the Sewer Discharge Permit from the Water Services Corporation (WSC) is obtained and updated every year and shall supply all the information requested by the WSC and take all the necessary actions as instructed by the WSC and/or the Authority. The Permit Holder shall forward to the Authority a copy of any Sewer Discharge Permit issued by the Water Services Corporation within 10 days of its issue. No emissions of trade effluent to sewer shall be discharged from this premises unless the entity asks for and obtains a modification of the existing Public Sewer Discharge Permit from the Water Services Corporation.

2.5.2 The Permit Holder shall follow the conditions of the Sewer Discharge Permit, as may be updated from time to time by the Water Services Corporation and the provisions of the Sewer Discharge Control Regulations (S.L.545.08).

2.5.3 Rainwater shall be segregated from all process areas that are potentially contaminated with raw materials, intermediates and/or products.

2.5.4 Foul sewer drains must be strictly segregated from storm water drains.

2.5.5 Emissions shall only arise from the emission point specified in Table 2.2.3, as described in the IPPC application and shall only constitute emissions from sanitary facilities.

2.5.6 Emissions of trade effluent to sewer shall only arise from the emission point specified in Table 2.2.3, and Schedule 3B:

Emission point reference	Source	Location of emission point
EM9	Sewer discharge connection	Sewer discharge point
EM21	Sewer discharge connection	Sewer discharge point

2.5.7 The Permit Holder shall monitor emissions to the sewer as may be directed by the Water Services Corporation from time to time. The Permit Holder shall inform the Authority of any changes to the Sewer Discharge Permit of the installation or changes made by the Water Services Corporation to monitoring requirements or frequency of monitoring-

2.5.8 Any accidental release of substances shall be duly reported to the Waster Services Corporation and effluents treated/contained prior to discharge into the sewers (subject to clearance from the WSC), or disposed as waste. Records shall be kept of such discharges, including the volume discharged and other parameters, as agreed with the Water Services Corporation, as per the Sewer Discharge Permit.

2.6 Discharges to groundwater[∞]

- 2.6.1 The Permit Holder shall not allow the introduction into groundwater of any substance included in the Regulations for the Protection of Groundwater against Pollution and Deterioration (S.L.549.63).
- 2.6.2 Further to conditions 2.6.1 the Permit Holder shall not allow any discharges to groundwater.
- 2.6.3 The operations of the installation shall not hinder the achievement of good chemical and quantitative status of groundwater as prescribed under the Water Policy Framework Regulations, S.L.549.100.

2.7 Fugitive emissions of substances to water and sewer

- 2.7.1 The operations of the installation shall not hinder the achievement of good chemical and quantitative status of surface waters as prescribed under the Water Policy Framework Regulations, S.L. 549.100.
- 2.7.2 The Permit Holder shall use BAT so as to prevent or where that is not practicable to reduce fugitive emissions of substances to water (including to groundwater) and sewer from the Permitted Installation, in particular from:
- All structures under or over ground
 - Surfacing
 - Storage areas
 - Bunded areas
- 2.7.3 Catchment pits and bunds on site must be tested and certified to be leak-proof by an independent, warranted civil engineer or engineer before any renewal of this IPPC permit. Such certification shall be also submitted as part of the AER by end of March after the end of each year when testing has occurred.
- 2.7.4 All rainwater runoff from the temporary waste management area shall be diverted to the sump which is fitted with a lockable valve. This valve shall remain locked in the closed position at all times other than when clean rainwater is discharged and shall be carried out under supervision. In the case of spillages, the collected material shall be discarded as hazardous waste.
- 2.7.5 Brine reject from the water softening system shall be disposed of as waste, unless agreed otherwise with the Authority.

2.8 Emission to Land

- 2.8.1 No emission from the Permitted Installation shall be made to land.
- 2.8.2 In the event of spillages or incidents which could have led to contamination of land, the Permit Holder shall notify the Authority within 24 hours, forward a decontamination plan for the Authority's approval and execute it within an agreed time frame.

2.9 Odour

- 2.9.1 The Permit Holder shall use BAT so as to prevent or where that is not practicable to reduce odorous emissions from the Permitted Installation, in particular by:
- limiting the use of odorous materials;
 - restricting odorous activities;
 - controlling the storage conditions of odorous materials;

- controlling processing parameters to minimise the generation of odour;
- optimising the performance of abatement systems;
- timely monitoring, inspection and maintenance;
- employing, where appropriate, an approved odour management plan

provided always that the techniques used by the Permit Holder shall be no less effective than those described in the Application, and where relevant approved by the Authority prior to their implementation.

2.9.2 There shall be no significant offensive odour, as perceived by an Authorised Officer of the Competent Authority, outside the boundary of the permitted installation.

2.9.3 In case of complaints regarding odours which upon investigations are verified, the Authority may require the Permit Holder to submit an odour management plan, which would include recommendations for abatement of the odour and timeframes for implementation.

2.10 Noise

2.10.1 The Permit Holder shall use BAT so as to prevent or where that is not practicable to reduce emissions of noise and vibration from the Permitted Installation, in particular by:

- i Equipment maintenance, e.g. circulating pumps, extraction fans, compressors.
- ii Use and maintenance of appropriate attenuation, ex. silencers, barriers, enclosures
- iii Appropriate timing and location of noisy activities and vehicle movements
- iv Periodic checking of noise emissions, either qualitatively or quantitatively; and
- v Maintenance of building fabric

Provided always that the techniques used by the Permit Holder shall be no less effective than those described in the Application, where relevant and approved by the Authority prior to their implementation.

2.10.2 Emergency generators/alarms/sirens/release valves shall only be tested between the hours of 10.00 and 17.00 Monday to Friday and not on any Public Holiday.

2.10.3 The level of noise emitted from the installation at all operational times shall not exceed the background noise level by 5dB.

Noise Monitoring

2.10.4 Noise monitoring is to be carried out every 5 years to ensure that the above limits are not exceeded. Noise monitoring shall also be carried out upon commissioning of any new equipment which in the opinion of the Authority has the potential to significantly increase noise emissions from the installation. The locations shall be chosen and the measurements and assessment made according to BS 4142:2014.

- 2.10.5 As part of the AER, records of noise monitoring of the previous year shall be submitted to the Competent Authority by not later than end of March after the end of each reporting year, in the format specified in Schedule 2 of this permit. A detailed report shall also accompany such results.

2.11 Maintenance

- 2.11.1 All plant, equipment and technical means used in operating the Permitted Installation shall be maintained in good operating condition and without causing polluting emissions, leaks and spillages.

- 2.11.2 The Permit Holder shall maintain a record of plant and equipment covered by condition 2.11.1, and for such plant and equipment:

- i. a written or electronic maintenance programme; and
- ii. records of its maintenance.

- 2.11.3 The Permit Holder shall maintain appropriate access to standby and/or spares of HEPA Filters to ensure the operation of the abatement system.

2.12 Solvents

- 2.12.1 A monthly inventory of solvent usage shall be maintained on site, and be available for review by an authorised officer of the Competent Authority where requested.

- 2.12.2 This permit does not authorise the use of substances and preparations which because of their content of volatile organic compounds, are classified as carcinogens, mutagens, or toxic to reproduction, and are assigned or need to carry the hazard statements H340, H341, H350, H350i, H351, H360D or H360F other than those notified to the Authority.

- 2.12.3 The Permit Holder shall submit to the Competent Authority, a plan for the replacement, as far as reasonably practicable for the process & relevant installation, of substances or preparations that are used in the installation and which, because of their content of VOCs are classified as carcinogens, mutagens or toxic to reproduction and are assigned or need to carry the hazard statements H340, H350, H350i, H360D or H360F, shall be replaced by less harmful substances / preparations. Details of the substances that shall be used as replacements and timeframes for substitution shall be submitted to the Competent Authority for approval prior to substitution. A reduction programme shall be submitted to the Competent Authority on an annual basis together with the submission of the Annual Environmental Report.

- 2.12.4 The Permit Holder shall and examine options to replace substances or preparations listed in condition 2.12.2, a report of which shall be submitted to the Authority annually, together with the AER.

- 2.12.5 The Permit Holder shall, annually as part of the Annual Environmental Reports submit an updated list of the raw materials being produced.

2.13 Waste

Waste storage and handling

- 2.13.1 The Permit Holder shall use BAT in the design, maintenance and operation of all facilities for the storage and handling of waste on site such that there are no

- releases to water or land during normal operation and that emissions to air and risk of accidental release to water or land are minimised.
- 2.13.2 All operations concerning the management of waste are subject to the Waste Management Regulations (S.L.549.63) and the Waste Management (Activity Registration) Regulations (S.L.549.45).
- 2.13.3 The Permit Holder shall be committed to reduce waste generation where possible.
- 2.13.4 Waste produced at the Permitted Installation shall be reused, recycled or recovered unless technically and/or economically unfeasible.
- 2.13.5 All wastes shall be stored within a designated and controlled storage area(s) prior to ultimate disposal. Wastes to be recycled shall be stored in a designated container or area and shall not be mixed with other wastes.
- 2.13.6 The Permit Holder is to prevent litter or other wastes escaping from the site boundaries, particularly during loading/unloading. Any such escape of waste shall be collected immediately upon detection.
- 2.13.7 Unless approved in writing by the Authority, the Permit Holder is prohibited from mixing a hazardous waste of one category with a hazardous waste of another category or with any other waste, substances or materials.
- 2.13.8 End-of-waste criteria must be met for any waste to be classified as a product. In such cases, the Permit Holder shall comply with relevant criteria set by legislation. In the absence of any relevant legislation, the Permit Holder shall follow the procedure laid down in Regulation 6 of S.L.549.63.
- 2.13.9 Liquid and hazardous wastes shall be stored in a labelled, closed container(s) within a designated and controlled storage area(s) prior to ultimate disposal which shall be appropriately contained to ensure no contamination of the environment in case of spillage. Wastes of different natures and having different European Waste Catalogue codes as established by Commission Decision 2000/532/EC and any subsequent amendments should not be mixed in the same container.
- 2.13.10 Packaging and containers which came into contact with hazardous substances shall be regarded as hazardous waste and shall be disposed of in an appropriate manner.
- 2.13.11 Permit Holder shall renew their registration with ERA as a producer of packaging and provide the required information as set out in Subsidiary Legislation 549.43, the Packaging and Packaging Waste Regulations unless putting less than 100kgs of packaging on the market annually. In case the Permit Holder opts to be self-compliant for transport packaging, the targets as set out in Subsidiary Legislation 549.43, the Packaging and Packaging Waste Regulations, shall also be achieved. Documentation in relation to the Permit Holder's obligations pertaining to S.L 549.43, the Packaging and Packaging Waste Regulations shall be maintained for a period of 5 years and be made available, upon request by ERA.
- 2.13.12 On-site disposal of wastes by any means including burning, disposal to drain or surface water, burying or deposition on land is prohibited. This excludes treated waste water discharged into sewer in line with the Sewer Discharge Permit.
- 2.13.13 No storage of waste, equipment or materials is permitted on property outside the site premises.

- 2.13.14 All storage of materials or waste shall take place only in locations where thorough clean-up and site reinstatement can be readily undertaken.
- 2.13.15 All wastes leaving the site after storage and/or processing must only be sent to facilities licensed to accept the individual waste stream, either locally or abroad.
- 2.13.16 No storage of waste destined for recovery is permitted for a period exceeding 3 years.
- 2.13.17 No storage of waste destined for disposal is permitted for a period exceeding 12 months.
- 2.13.18 The Permit Holder shall ensure that waste transferred to another person is packaged and labelled in accordance with national, European and any other standards which are in force in relation to such labelling. While awaiting collection, recovery or disposal all waste shall be stored in designated areas protected, as may be appropriate, against spillage, leachate run-off and accidental damage. The waste is to be clearly labelled and appropriately segregated.
- 2.13.19 No wastes other than those which are categorized in **Approved Document IP 0004/21/DOC2** in accordance to the European Waste Catalogue codes as published in Council Directive 2000/532/EC and as may be amended from time to time shall be stored on site.

Transport

- 2.13.20 In the case of waste that is sent for treatment or recovery to another facility locally or abroad, the audit trail shall cover all waste from the point of generation or collection to the end recovery or disposal facility.
- 2.13.21 the transboundary movement of waste shall be carried out in accordance with the following regulations, as amended from time to time:
- i. Regulation (EC) N° 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste as implemented through S.L. 549.65;
 - ii. Commission Regulation (EC) N° 1418/2007 of 29 November 2007 concerning the export for recovery of certain waste listed in Annex III or IIIA to Regulation (EC) N° 1013/2006 of the European Parliament and of the Council to certain countries to which the OECD Decision on the control of transboundary movements of waste does not apply; and
 - iii. Any other applicable legislation
- 2.13.22 Waste sent off-site for recovery or disposal shall be conveyed only by an authorised waste carrier as per Activity 38 of Schedule 1 of S.L.549.45. The waste shall be transported only from the site of the activity to the site of recovery/disposal in a manner which shall not adversely affect the environment and in accordance with all relevant National and European legislation.
- 2.13.23 Transport of hazardous waste within the Maltese Islands shall be accompanied by the necessary waste transfer permits issued by the Authority. Applications for such permits are made through the hazardous waste consignment permit procedure available from the Authority's Offices.
- 2.13.24 Permit Holder shall ensure to keep records for every consignment of wastes removed from the Site indicating the EWC Code, description, quantities, date of removal, contractor name (including for transport), consignment note number

(where applicable) and manner and place of final disposal/recovery. Waste receipts should be made available upon request.

2.13.25 Should the operator require the services of a waste broker, it shall be ensured that any such broker is a duly registered waste broker in accordance with S.L. 549.45.

2.13.26 Conditions related to the transport of chemicals and hazardous wastes on land are included in section 2.17

Waste Records

2.13.27 Disposal and/or recovery certificates and any documentation related to transfer of waste to and from the site and/or related to its end disposal and/or recovery shall be kept on record and made available for inspection for a period of at least 5 years from date of their issue. Copies of such certificates shall be submitted on an annual basis as part of the AER.

2.13.28 As part of the AER, the Permit Holder shall submit the name of each carrier used in the transport of the substances specified in Conditions 2.13.22 and 2.13.23, in the format specified in Schedule 2, by end of March after the end of each reporting year.

2.13.29 As part of the Annual Environmental Report for the installation, the Permit Holder shall produce a report on the off-site transfers of waste and wastes recycled/recovered at the Permitted Installation over the previous calendar year, providing the information listed in Schedule 2.

2.13.30 Without prejudice to Condition 2.13.4, disposal of wastes including rejects, expired products, and other wastes are to be managed in accordance with the legal obligations of the Waste Regulations (S.L. 549.63). Off-site disposal or recovery of wastes may only take place at a facility licensed for that purpose.

2.14 Energy Efficiency

2.14.1 As part of the Annual Environmental Report, the Permit Holder shall produce a report on the energy consumed at the Permitted Installation over the previous calendar year, by the end of March of each year, providing the information listed in Schedule 2.

2.14.2 The Permit Holder shall maintain and operate the Permitted Installation so as to secure energy efficiency, in particular by:

- i. ensuring that the appropriate operating and maintenance systems are in place;
- ii. ensuring that all the plant is adequately insulated to minimise energy loss or gain;
- iii. ensuring that the type of lighting used is energy-efficient;
- iv. ensuring that all appropriate containment methods (e.g. seals) are employed and maintained to minimise energy loss;
- v. maintaining and implementing an energy efficiency plan which identifies energy-saving techniques that are applicable to the activities and their associated environmental benefit, and prioritises them.

2.15 Monitoring

2.15.1 The Permit Holder shall maintain and implement an emissions monitoring programme which ensures that emissions are monitored as specified in this Permit, and the results of such monitoring shall be assessed. The programme

shall ensure that monitoring is carried out under an appropriate range of operating conditions, and that measurements for the determination of concentrations of substances specified in this Permit shall be carried out representatively.

- 2.15.2 Sampling and analysis of all pollutants, as well as reference measurement methods to calibrate automated, continuous measurement systems shall be carried out as specified by the appropriate CEN standards. If CEN standards are not available, ISO standards, national or international standards, which will ensure the provision of data of an equivalent scientific quality, as agreed in writing with the Authority, shall apply. In addition, VOC emissions shall be measured and assessed according to Regulation 8(2) of the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations.
- 2.15.3 Monitoring equipment, techniques, personnel and organisations employed for the monitoring requirements in condition 2.15.1 of this Permit shall be from a certified or accredited laboratory or laboratory in the process of accreditation, as confirmed by the National Accreditation Body (NAB-Malta). As part of the Annual Environmental Report, the Permit Holder shall provide evidence of certification or accreditation of laboratories used.
- 2.15.4 The Permit Holder shall maintain records of all monitoring taken or carried out (this includes records of the taking and analysis of samples, instrument measurements (periodic and continual), calibrations, examinations, tests and surveys) and any assessment or evaluation made on the basis of such data, for at least a period of 5 years. Such records may be requested at any time by the Authority.
- 2.15.5 The Permit Holder shall provide ERA with monitoring reports as indicated in Section 4 of this permit.

2.16 Storage

- 2.16.1 All bulk oil and liquid fuel storage tanks, with the exception of gaseous fuels, shall be provided with an adequately designed bund system with an impermeable base and walls, as per relevant REWS standards. The capacity of the bund shall be a minimum of 110% of the largest tank within the bund or 25% of the total volume of all the tanks within the bund. Filling and off-take points shall be located within the bund. The Permit Holder shall also ensure and take all precautions to avoid any leakages or spills from liquid or solid material.
- 2.16.2 Containers for bulk storage of chemicals shall be properly designed, located, labelled, banded and maintained so as to prevent accidental spillage. Incompatible chemicals shall not be stored within the same bund.
- 2.16.3 The construction of fuel tanks shall comply with relevant REWS standards.
- 2.16.4 Drums and containers of solvents, oils or any other chemicals shall be stored in designated and secure storage areas. Storage areas shall be banded or otherwise designed so that surface and ground waters cannot be contaminated by spillages.
- 2.16.5 Chemicals of different properties shall be stored and handled as specified in respective SDS sheets. Such sheets shall be made available and accessible to personnel responsible for the management of the storage areas and for inspection by the Competent Authority.
- 2.16.6 Bulk storage tanks for chemicals and associated bunding and pipe work shall be visually inspected at least once a month. Such records should be kept and made available to the Authority upon request.

2.16.7 Drainage systems (including catchment pits, bunds) shall be designed, constructed, inspected, validated and maintained; and shall be fully documented and recorded to be fit for purpose while meeting the following construction quality assurance standards. All areas are to:

- i. Be fully impermeable;
- ii. Be kept free from cracks which could increase permeability;
- iii. Be leak-proof and resistant to physical and chemical stresses to which they may be subjected;
- iv. Be laid to fall towards the drainage system to prevent pond formation.

Such systems shall be certified by an independent, warranted civil engineer or engineer as being leak-proof and resistant to physical and chemical stresses to which they may be subjected. Such testing and certification shall be carried out in the year prior to any renewal of this IPPC permit. The certification shall be submitted as part of the AER in the format specified in Schedule 2. This is without prejudice to the Authority requesting such testing and certification should there be reason to believe that the interceptor may not be in good working order.

2.17 Transport [∞]

2.17.1 Independent of any Environment Management System, the Permit Holder shall be responsible for making use of the services of an ADR (The European Agreement concerning the International Carriage of Dangerous Goods by Road) certified carrier for transport of chemicals and hazardous wastes on land.

2.18 Ozone Depleting Substances and Fluorinated Greenhouse Gases[∞]

2.18.1 All installation, maintenance and servicing of equipment containing Fluorinated Greenhouse Gases shall abide by the requirements of EC Regulation No. 517/2014 on Fluorinated Greenhouse Gases, and L.N. 143 of 2018 on Fluorinated Greenhouse Gases (Implementing) Regulations.

2.18.2 The use of HCFCs in the maintenance and servicing, in particular refilling, or products and equipment whose function relies on such substances shall be prohibited.

2.18.3 Maintenance and servicing of equipment containing ozone depleting substances and fluorinated greenhouse gases shall be carried out in accordance with the legal provisions of Regulation (EU) No 517/2014 on fluorinated greenhouse gases and L.N. 143 of 2018 on Fluorinated Greenhouse Gases (Implementing) Regulations and Regulation (EC) No. 1005/2009 on substances that deplete the Ozone Layer. All maintenance and servicing shall be reported in the AER as per template in Schedule 2.

2.18.4 For all equipment installed on site utilising Ozone Depleting Substances or Fluorinated Greenhouse Gases, information pertaining to installation, maintenance and servicing shall be provided as prescribed in Schedule 2. When any equipment is replaced by new equipment, The Authority shall be notified in this regard and details provided on the new equipment installed.

2.18.5 Upon decommissioning of all equipment containing refrigerant, foam and insulation panels containing substances falling within the scope of EC Regulation No. 1005/09 on substances that deplete the Ozone Layer, together with EC Regulation No. 517/2014 on Fluorinated Greenhouse Gases, and L.N. 143 of 2018 on Fluorinated Greenhouse Gases (Implementing) Regulations. The waste gas should be treated as hazardous waste and any foam containing components

need to be disposed of at specialised facilities where possible ODS/F gas can be extracted prior to disposal.

2.18.6 No new equipment or components containing substances falling within the scope of EC Regulation No. 1005/2009 on substances that deplete the Ozone Layer on substances that deplete the ozone layer, shall be installed within the site.

2.18.7 Where required, leak detection systems as per the legal provisions of Regulation (EU) No 517/2014 on fluorinated greenhouse gases shall be installed and well maintained.

2.19 Management and Technically Competent Person

Training

2.19.1 The Permitted Installation shall be supervised and controlled by staff who are suitably trained and fully conversant with the requirements of this Permit.

2.19.2 All staff shall be fully conversant with those aspects of the Permit conditions which are relevant to their duties and shall be provided with adequate professional technical development and training and written operating instructions to enable them to effectively carry out their duties.

Attendance of Technically Competent Person(s)

2.19.3 The TCP is responsible for the implementation of all the obligations stipulated in this permit, must supervise the rest of the staff on site and shall be the Permit Holder's technical focal point for the implementation of the conditions of this permit including during inspections.

2.19.4 Attendance of the technically competent person(s) at the Site shall be recorded on arrival and departure.

2.19.5 For the whole operational hours permitted for the Site under this Permit, the Technically Competent Person/s or their delegate/s shall be physically in attendance at the Site. The Technically Competent Person/s or their delegate/s has to be permanently present on site during the manufacture of APIs. The permit holder is to provide details as to how he intends to provide this coverage in order to take into account unavoidable absences due to continuous operation, vacation or sick leave.

2.19.6 Where the Authority has been notified that the site is either non-operational or closed, the TCP or delegate TCP shall be capable of attending the Site within one hour.

Changes in Technically Competent Persons

2.19.7 In the event of any short or long periods of leave of absence taken by the TCP or the delegate for a period exceeding 10 days, the Permit Holder is obliged to find a replacement for that member of staff without delay.

2.19.8 In the event of the death, dismissal, resignation, leave, or of extended sick leave of the Technically Competent Management of the Site, the Permit Holder shall immediately inform the Authority, and prove to the Authority that the Permit Holder is actively seeking a replacement.

Incidents and Complaints

- 2.19.9 The Permit Holder shall maintain and implement written procedures for:
- i Taking prompt remedial action, investigating and reporting to the Competent Authority actual or potential non-compliance with operating procedures or emission limits and if such events occur.
 - ii Investigating incidents, (including any malfunction, breakdown or failure of plant, equipment or techniques, down time, any short-term and long-term remedial measures and near-misses) and prompt implementation of appropriate actions; and
 - iii Ensuring that detailed records are made of all such actions and investigations.
- 2.19.10 The Permit Holder shall record and investigate complaints concerning the Permitted Installation's effects or alleged effects on the environment and public health. The record shall give the date and nature of complaint, time of complaint, name of complainant (if given), a summary of any investigation and the results of such investigation and any actions taken.
- 2.19.11 As part of the Annual Environmental Report of the Permitted Installation, the Permit Holder shall provide the information specified in Schedule 2 by not later than end of March after the end of each reporting year.

2.20 Accident prevention and control

- 2.20.1 In the case of an accident, the Permit Holder shall follow the Emergency Plan submitted as part of the IPPC application, as may be updated from time to time
- 2.20.2 The plan shall be updated whenever necessary and the updated version sent by the Permit Holder to the Civil Protection Department for their perusal/clearance.
∞
- 2.20.3 The plan shall be reviewed at least every 2 years or as soon as practicable after an accident, whichever is the earlier, and the Authority notified of the results of the review within 2 months of its completion.
- 2.20.4 The Permit Holder shall maintain and implement all occupational health and safety measures in compliance with Act XXVII of 2000 (Occupational Health and Safety Authority Act, 2000 (Chapter 424)) and all relevant subsidiary legislation.∞
- 2.20.5 The Permit Holder shall have sufficient employees trained to deal with any emergency that may arise, e.g. fire-fighting, spills and first aid.
- 2.20.6 The Permit Holder is to keep the Authority updated on any major changes in operations that may impact on the health and safety of the employees.
- 2.20.7 The Permit Holder is to make available Health and Safety documentation freely available.
- 2.20.8 Spillages of chemicals or other hazardous material shall receive immediate attention to prevent escape to drain, surface water or land. Spilled material shall be disposed of in an appropriate manner. Kits for the collection of liquid and powder spills shall be available on site at strategic locations.
- 2.20.9 In the case of an accident (including fire, chemical spills, etc.), the Permit Holder shall follow the Emergency Response Plan or the standard operating procedures related to spill response (whichever may be applicable) and, in the case that such accident could cause environmental damage, the Permit Holder shall notify the Authority within 24 hours.

- 2.20.10 Small leaks or spills shall be cleared up immediately by the application of absorbent materials. All sand and other material shall be disposed of as approved by the responsible authority.
- 2.20.11 The Permit Holder shall have in storage an adequate supply of suitable absorbent material to absorb any spillage.
- 2.20.12 The Permit Holder is to carry out monitoring of the head space of the wash water reservoirs for potential fire hazards. The monitoring results shall be submitted as part of the AER in the format specified in Schedule 2.

3 Closure and Decommissioning

- 3.1 The Permit Holder shall endeavour to carry out a full review of the *Plan* at least every 4 years and shall include all the following information.
- 3.1.1 A draft waste management plan which shall include:
- i. The identification and characterisation of sources and types of wastes;
 - ii. Criteria for segregation of wastes;
 - iii. Proposed treatment, conditioning, transport, storage and disposal/ recovery methods;
 - iv. Potential reuse/recycling of such wastes
 - v. Details on decommissioning and disposal of equipment
- 3.1.2 A list of materials which will not be disposed of but transferred to third parties for re-use including any unprocessed raw materials and finished products.
- 3.1.3 A qualitative assessment of the potential for contamination of land and groundwater pollution which might arise from the historical and current processes carried out at the installation.
- 3.2 The Permit Holder shall maintain and operate the Permitted Installation so as to prevent or minimise any pollution and public health risk, including the generation of waste, on closure and decommissioning in particular by: -
- i. Attention to the design of new plant or equipment;
 - ii. The maintenance of a record of any events which have, or might have, impacted on the condition of the site along with any further investigation or remediation work carried out; and
 - iii. The maintenance of the preliminary site closure plan to demonstrate that the installation can be decommissioned avoiding any pollution and public health risk and returning the site of operation to a satisfactory state.
- 3.3 The Permit Holder shall notify the Authority immediately upon a decision being taken to decommission all or part of the site, or planned cessation for a period greater than 6 months, of all or part of the permitted activities. The Authority may impose further requirements in the case of planned cessation for a period greater than 6 months.
- 3.4 In the event of cessation of operations on the site, all wastes, equipment and hazardous materials (including fuels and chemicals) must be removed from the site such that any pollution risk is avoided and the site is returned to a satisfactory state. The Permit Holder shall notify the Authority immediately upon a decision

being taken to cease business activity. In the case of full decommissioning, applicant shall submit a decommissioning plan in accordance with the terms of reference provided by the Authority for approval by the relevant Authorities. The obligations arising from the permit shall subsist until the Authority confirms in writing that the implementation of the decommissioning plan has been implemented to its satisfaction.

- 3.5 A finalised version of the *Site Closure Plan* shall be submitted to the Authority for approval not later than 10 days after the Authority is notified of the intention to decommission the site.
- 3.6 The approved Decommissioning Plan shall be implemented within 12 months of final cessation of the Permitted activities or part thereof or according to a timeframe as may be agreed with the Authority.
- 3.7 When deemed necessary, the authority may require the permit holder to take such additional measures as it considers necessary with respect to after care obligations in relation, but not limited to the remedial action, rehabilitation, and monitoring of the site.

4 Records

- 4.1 The Permit Holder shall ensure that all records required to be made by this Permit and any other records made by it in relation to the operation of the Permitted Installation shall:-
- 4.1.1 be made available for inspection by the Authority upon request;
 - 4.1.2 be supplied to the Authority on demand and without charge and in the format requested;
 - 4.1.3 be legible
 - 4.1.4 indicate any amendments which have been made and shall include the original record wherever possible; and
 - 4.1.5 be retained at the Permitted Installation, or other location agreed by the Authority in writing, for a minimum period of 5 years from the date when the records were made, unless otherwise agreed in writing.
- 4.2 A daily operations log should be kept on site in which the following information shall be recorded on a daily basis:
- 4.2.1 Any incidents that took place on site such as mechanical faults in the machinery or equipment used on site, any spills, fires, etc and the remedial action taken.
 - 4.2.2 Any maintenance and inspections carried out on machinery and equipment.
 - 4.2.3 Any defects or damage to the Site Security System.

Each record shall be compiled within 24 hours of the relevant event. The records kept in the daily operations log shall be available for inspection at any time when the Authority representatives request to inspect them.

- 4.3 The Permit Holder shall maintain a record of the skills and training requirements for all staff whose tasks in relation to the Permitted Installation may have an impact on the environment and shall keep records of all relevant training.

5 Reporting

- 5.1 All reports and written and/or verbal notifications required by this Permit and notifications required by Regulation 7 of the Industrial Emissions (IPPC) Regulations shall be made and sent to the Authority using the contact details notified in writing to the Permit Holder by the Authority.
- 5.2 The Permit Holder shall submit to the Authority an Annual Environmental Report (AER) of the previous year to the Competent Authority by the end of March of each year. The AER shall contain all the information listed in Schedule 2 of this Permit. The AER shall be forwarded to the Authority in electronic format.
- 5.3 The European Pollutant Release and Transfer Register (E-PRTR) report for the installation shall be submitted as part of the Annual Environment Report, by end of March of each year, or as required by Legislation. All quantities shall be reported, even when these do not exceed the thresholds mentioned in EC Regulation 166/2006. The format used for reporting shall be that established by Legislation, notably S.L. 549.47 and Government Notice 138 of 2017 or as subsequently amended.
- 5.4 The Permit Holder shall, within 6 months of receipt of written notice from the Authority, submit to the Authority a report assessing whether all appropriate preventive measures continue to be taken against pollution, in particular through the application of the best available techniques, at the installation. The report shall consider any relevant published technical guidance current at the time of the notice which is either supplied with or referred to in the notice, and shall assess the costs and benefits of applying techniques described in that guidance, or otherwise identified by the Permit Holder, that may provide environmental improvement.

6 Notifications

- 6.1 The Permit Holder shall notify the Authority without delay of:-
- 6.1.1 the detection of an emission of any substance which exceeds any limit or criterion in this Permit specified in relation to the substance;
 - 6.1.2 the detection of any fugitive emission which has caused, is causing or may cause exceedances of the emission limit values stipulated in the permit;
 - 6.1.3 the detection of any malfunction, breakdown or failure of plant or techniques which has caused, is causing or has the potential to cause exceedances of the emission limit values stipulated in the permit; and
 - 6.1.4 any accident which has caused, is causing or has the potential to cause significant pollution and/or public health risk.
- 6.2 The Permit Holder shall submit written confirmation to the Authority of any notification under condition 6.1, by sending:
- 6.2.1 the information listed in Schedule 1 to this Permit within 24 hours of such notification; and

- 6.2.2 the information listed in Table S2.5.1 of Schedule 2 and such information shall be in accordance with that Schedule as part of the AER.
- 6.3 The Permit Holder shall give written notification as soon as practicable prior to any of the following:-
- 6.3.1 permanent cessation of the operation of part or all of the Permitted Installation;
 - 6.3.2 cessation of operation of part or all of the Permitted Installation for a period likely to exceed 1 year; and
 - 6.3.3 resumption of the operation of part or all of the Permitted Installation after a cessation notified under condition 6.3.2
- 6.4 The Permit Holder shall notify the Authority, as soon as practicable, of any information concerning the state of the site which affects or updates that provided to the Authority as part of the Site Report submitted with the application for this Permit.
- 6.5 The Permit Holder shall notify the following matters to the Authority in writing within 10 working days of their occurrence: -
- Where the Permit Holder is a registered company:-
- 6.5.1 Any change in the Permit Holder's trading name, registered name or registered office address;
 - 6.5.2 Any change to particulars of the Permit Holder's corporate identity; and
 - 6.5.3 Any steps taken with a view to the Permit Holder going into administration, entering into a company voluntary arrangement or being wound up.
- Where the Permit Holder is a corporate body other than a registered company: -
- 6.5.4 Any change in the Permit Holder's name or address; and
 - 6.5.5 Any steps taken with a view to the dissolution of the Permit Holder.
- In any other case: -
- 6.5.6 The death of any of the named Permit Holders (where the Permit Holder consists of more than one named individual);
 - 6.5.7 Any change in the Permit Holder's name(s) or address(es);
 - 6.5.8 Any steps taken with a view to the Permit Holder, or any one of them, going into bankruptcy, entering into a composition or arrangement with creditors, or, in the case them being in a partnership, dissolving the partnership
- 6.6 The Permit Holder is to notify the Civil Protection Department in the event that the fire hydrant system is not operational. The notification shall also include other measures which will be put in place until the fire hydrant system is rendered operational.[∞]

7 Interpretation

7.1 In this Permit, the following expressions shall have the following meanings:-

Malta means the Island of Malta, the Island of Gozo and the other islands of the Maltese Archipelago, including the territorial waters thereof.

“mg.Nm⁻³” or *“mg/Nm³”* means milligramme per normal metre cubed.

“Land” means the upper layer of the earth’s crust and shall include all the various components of the lithosphere to the rock-water and rock-air boundary, where the topmost 200 cm which is made up of inorganic and organic components and which serves as a habitat for micro- and macroorganisms is defined as soil.

“AER” means the Annual Environmental Report.

“Application” means the application for this Permit, together with any response to a notice served under Regulation 5 to the Industrial Emissions (IPPC) Regulations and any operational change agreed under the conditions of this Permit.

“Authorised Officer” means any officer of the Authority authorised in writing pursuant to the Environment Protection Act 2016 to exercise any of the powers specified therein.

“Background concentration” means such concentration of that substance as is present in:

- i. Where the Permitted Installation uses no significant amount of supplied or abstracted water, the precipitation onto the site. or
- ii. water supplied to the site; or
- iii. where more than 50% of the water used at the site is directly abstracted from ground or surface water on site, the abstracted water;

“BAT” means best available techniques, which means the most effective and advanced stage of development of activities and their methods of operation which indicates the practical suitability of particular techniques to prevent and where that is not practicable to reduce emissions and the impact on the environment as a whole. For these purposes: “available techniques” means “those techniques which have been developed on a scale which allows implementation in the relevant industrial sector, under economically and technically viable conditions, taking into consideration the cost and advantages, whether or not the techniques are used or produced in Malta, as long as they are reasonably accessible to the operator”; “best” means “in relation to techniques, the most effective in achieving a high general level of protection of the environment as a whole” and “techniques” “includes both the technology used and the way in which the installation is designed, built, maintained, operated and decommissioned.”

“VOC Solvents Regulations” means the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (S.L.549.79, as may be amended from time to time).

VOC means Volatile Organic Compound as defined by the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations (S.L. 549.77)

“Year” or *“reporting year”* means calendar year ending 31 December.

The Regulations” means the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L. 549.77) and any regulations amending or replacing them.

“The Operator” means a person who is in occupation of the Site and has responsibility for carrying out day to day activities at the Site.

“BREF” means the latest version of the BAT reference document published by the European Commission.

“Fugitive emission” means an emission to air or water (including sewer) from the Permitted Installation which is not controlled by an emission or background concentration limit under conditions 2.2.1 - 2.2.6 of this Permit.

Groundwater” means all water which is below the surface of the ground in the saturation zone and in direct contact with the ground or subsoil.

Industrial Emissions (IPPC) Regulations” means the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L.549.77) and words and expressions defined in the Industrial Emissions (IPPC) Regulations shall have the same meanings when used in this Permit save to the extent they are specifically defined in this Permit. It shall include any future amendments or superseding legislation.

“Monitoring” includes the taking and analysis of samples, instrumental measurements (periodic and continual), calibrations, examinations, tests and surveys.

“Permitted Installation” means the activities and the limits to those activities described in Table 1.1.1 of this Permit.

“Sewer” means *“Public sewerage system”* means the sewerage system owned by the Water Services Corporation.

“Staff” includes employees, directors or other officers of the Operator, and any other person under the Operator’s direct or indirect control, including contractors.

“Technically Competent Person” means a person possessing the qualifications, experience and technical competence to abide by the conditions of the Permit.

Technically Competent Management” means the Technically Competent Person or Persons in control of the day-to-day activities authorised by the Permit and carried on at the Site.

The Authority” or *“the Competent Authority”* or *“ERA”* means the Malta Environment and Resources Authority or such other body or person as the Minister responsible for the environment may by order in the Gazette prescribe.

The Permit Holder” means the Permit Holder specified in the Permit or other person to whom the Permit has been transferred in accordance with the Industrial Emissions (Integrated Pollution Prevention and Control) Regulations (S.L.549.77) and any statutory provisions or regulations amending or replacing them.

“The Site” means the land, structures, plant and equipment to which this Permit relates;

7.2

Where a minimum limit is set for pH, reference to exceeding the limit shall mean that the parameter shall not be less than that limit.

- 7.3 Unless otherwise stated, any references in this Permit to concentrations of substances in emissions into air means:-
- 7.3.1 in relation to gases from combustion processes, all emission limit values are defined at a temperature of 273.15K, a pressure of 101.3 kPa after correction for the water vapour content of the waste gases and at a standardised O₂ for 6% medium combustion plants using solid fuels, 3% for medium combustion plants, other than engines and gas turbines, using liquid and gaseous fuels and 15% for gas turbines.
 - 7.3.2 in relation to gases from non-combustion sources, the concentration at a temperature of 273K and at a pressure of 101.3 kPa, with no correction for water vapour content.
- 7.4 Where any condition of this Permit refers to the whole or parts of different documents, in the event of any conflict between the wording of such documents, the wording of the document(s) with the most recent date shall prevail to the extent of such.

Schedule 1

Notification of abnormal emissions and significant adverse environmental effects

This page outlines the information that the Operator must provide to satisfy conditions 6.1 and 6.2 of this Permit.

Units of measurement used in information supplied under Part A and B requirements shall be appropriate to the circumstances of the emission. Where appropriate, a comparison should be made of actual emissions and authorised emission limits.

If any information is considered commercially confidential, it should be separated from non-confidential information, supplied on a separate sheet and accompanied by an application for commercial confidentiality under the provisions of the Industrial Emissions (IPPC) Regulations.

Part A

Permit Number	
Name of Operator	
Location of Installation	
Location of the emission	
Time and date of the emission	

Substance(s) emitted	Media (e.g. air, groundwater)	Best estimate of the quantity or the rate of emission (include units)	Time between which the emission took place

Measures taken, or intended to be taken, to stop the emission	
--	--

Part B

Any more accurate information on the matters for notification under Part A.	
Measures taken, or intended to be taken, to prevent a recurrence of the incident.	
Measures taken, or intended to be taken, to rectify, limit or prevent any pollution of the environment or harm to human health which has been or may be caused by the emission.	
The dates of any unauthorised emissions from the installation in the preceding 24 months.	

Name ⁱ	
I.D. Card No./Passport No.	
Post	
Signature	
Date	

ⁱ Authorised to sign on behalf of Operator

Schedule 2

Annual Environmental Report

Important note

By this submission, you confirm that you give your explicit consent for the entire contents of this Annual Environment Report to be made available on the Authority's public website.

S2.1 Introduction

IPPC Permit Number	
Reporting Year	
Name and location of Site	
Brief description of activities at the site	

S2.2 Environment Management System & Reporting

Please attach a supporting document with the following:

1. Environmental Policy containing the installation's environmental objectives and targets;
2. Environmental Management Programme report (for the reporting year);
3. Environmental Management Programme proposal (for the following year);
4. European Pollutant Release and Transfer Register Report (as per Condition 4.3)ⁱ.

Tick (✓)

S2.3 Process Data**S2.3.1 Annual Summary**

	Units	Previous reporting year ⁱⁱ	Current reporting year
Quantity of product	Tonnes		
Total Annual Energy Consumption (from electricity and other sources)	MWh		
Electricity from renewable energy sources	MWh		
Energy consumption per unit product	MWh/tonne of product		
Annual water consumption	m ³		
Water consumption per unit product	m ³ /tonne of product		
Annual quantity of waste produced	Tonnes		
Waste produced per unit product	tonne waste/tonne product		

S2.3.2 Fuel consumption

	Units	Sulphur Content ⁱⁱⁱ	Consumption	
			Previous Year	Current Year
LPG	m ³			

ⁱ The format used for reporting shall be that published in the Government Gazette (<http://www.doi.gov.mt/EN/gazetteonline/2007/07/gazts/GG%2013.7.pdf>)

ⁱⁱ "Previous reporting year" is not applicable for the first reporting year (2015)

ⁱⁱⁱ Specify units (e.g. as percentage, or mg/kg)

S2.3.3 List of Raw Materials

Raw Material	Risk phrase	Annual Quantity Used (kg)

S2.3.4 Data on ozone depleting substances and fluorinated greenhouse gases

Table 1: Registration of equipment

Equipment code	Type of equipment	Use	Charge (kg) /CO ₂ (eq)	Type of substance
EQ 1				
EQ 2				
EQ 3				

Table 2: Maintenance Scheduleⁱ

Data Submitted for each scheduled inspection ⁱⁱ	Equipment Code							
	EQ 1	EQ 2	EQ 3	EQ 4	EQ 5	EQ 6	EQ 7	Continue as required
Date of inspection								
All amounts of leakages detected (in Kg/CO ₂ equiv ⁱⁱⁱ)								
Actions taken to eliminate such leakages								
Quantity and nature of the substances involved								
Serial number of the personnel involved								
Quantities added ^{iv} and/or recovered (in Kg/ CO ₂ equiv).								

ⁱ (a) for equipment that contains fluorinated greenhouse gases in quantities of 5 tonnes of CO₂ equivalent or more, but of less than 50 tonnes of CO₂ equivalent: at least every 12 months; or where a leakage detection system is installed, at least every 24 months; (b) for equipment that contains fluorinated greenhouse gases in quantities of 50 tonnes of CO₂ equivalent or more, but of less than 500 tonnes of CO₂ equivalent: at least every six months or, where a leakage detection system is installed, at least every 12 months; (c) for equipment that contains fluorinated greenhouse gases in quantities of 500 tonnes of CO₂ equivalent or more: at least every three months or, where a leakage detection system is installed, at least every six months.

ⁱⁱ Table to be repeated for every scheduled inspection as per 'footnote 1' above

ⁱⁱⁱ Carbon Dioxide equivalent – use annex 1 for calculation

^{iv} The quantities of added fluorinated greenhouse gases are from recycled or reclaimed stocks, please include the name and address of the recycling or reclamation facility and, where applicable, the certificate number

S2.4 Monitoring Data

S2.4.1 Emissions to air

Parameter	Emission point reference	Limit Value	Standard methodology used	Total annual number of exceedances ⁱ		Concentration (Annual Average)			Total Annual Load		
				Previous year	Present year	Unit	Previous year	Present year	Unit	Previous year	Present year
TVOC	1	20 mg/Nm ³				mg/Nm ³			kg		
	4A										
	4B										
	4C										
	4D										
	4E										
	8A										
	8B										
	8C										
	8D										
	10A										
	10B										
	10C										
	10D										
11											
13											
VOCs: R45, R46, R49, R60 or R61 (H340, H350, H350i, H360D, or H360F) where mass flow of sum of compounds ≥ 10 g/h ⁱⁱ	1	2 mg/Nm ³		iii		mg/Nm ³			kg		
	13										
Halogenated VOCs: R40 or R68 (H341 or H351) where mass flow of sum of compounds ≥ 100 g/h ^{iv}	1	20 mg/Nm ³				mg/Nm ³			kg		
	13										
HBR	1	1 mg/Nm ³				mg/Nm ³			Kg		
	13										
HCl	1	7.5 mg/Nm ³				mg/Nm ³			kg		
	13										
Total Particulate Matter	1	<1 mg/Nm ³				mg/Nm ³			kg		
	3A										
	3B										
	3C										
	4A										
	4B										
	4C										
	4D										
	4E										
	8A										
	8B										
	8C										
	8D										
	10A										
	10B										
	10C										
10D											
11											
13											

ⁱ If the total number of exceedances exceeds 0, the value of these exceedances (for the reporting year) must be submitted in a separate report, together with the action taken to regularize the situation. Where only one measurement was required to be made during the year, the total annual number of exceedances is taken to be zero if the measurements indicates compliance with the limit value.

ⁱⁱ Where mass flow is <10g/h, appropriate calculations are required to confirm this.

ⁱⁱⁱ For those VOCs only, do any of the hourly averages exceed the emission limit value by more than a factor of 1.5? Only such values are considered as exceedances

^{iv} Where mass flow is <100g/h, appropriate calculations are required to confirm this.

Name of laboratory where tests in this section have been carried out	
Is this laboratory accredited (certified) for the above tests?	Yes <input type="checkbox"/> No <input type="checkbox"/>

Additional documentation to be submitted:

Accreditation certificate(s) of laboratory
 Calculations showing mass flow of VOCs with risk phrases H340, H350, H350i, H360D, or H360F where mass flow of sum of compounds < 10 g/h
 Calculations showing mass flow of halogenated VOCs with risk phrases H341 or H351 where mass flow of sum of compounds < 100 g/h

Tick
(✓)

S2.4.2 HEPA Filter Integrity Monitoring

Date of Inspection	Differential Pressure						Continued as required
	HF1	HF2	HF3	HF4	HF5	HF6	
Week 1							
Week 2							
Week 3							
Week 4							
Continued as required							

Additional documentation to be submitted:

Efficiency certification	Tick (✓)
HF1	
HF2	
HF3	
HF4	
HF5	
HF6	

S2.4.3 Cooling tower monitoring

Parameter	Timeframe	Standard methodology used	Result	
			Previous year ⁱ	Present year
Heterotrophic colony count	1 st month			
	2 nd month			
	3 rd month			
	4 th month			
	5 th month			
	6 th month			
	7 th month			
	8 th month			
	9 th month			
	10 th month			
	11 th month			
	12 th month			
<i>Legionella</i>	1 st six months			
	2 nd six months			

Name of laboratory where tests in this section have been carried out	
Is this laboratory accredited (certified) for the above tests?	Yes <input type="checkbox"/> No <input type="checkbox"/>

Additional documentation to be submitted:

Accreditation certificate(s) of laboratory Tick (✓)

S2.4.4 Noise monitoringⁱⁱ

Year when noise monitoring was last carried out	
Testing due in (year)	

Additional documentation to be submitted if test was carried out during previous reporting year:

Noise monitoring report according to BS 4142:2014 Tick (✓)

ⁱⁱ Noise monitoring shall be carried out according to BS 4142:2014, all the series of ISO1996 and any other standard methodology stipulated by the Authority.

S2.4.7 Testing of catchment pits and bunds

	Number on site	Date of last test	Testing due on (date)
Catchment pits			
Bunds			
Others: (specify)			

Additional documentation to be submitted if test was carried out during previous reporting year:

Certification by warranted engineer Tick (✓)

S2.4.8 Testing of the wash water reservoirs

Reservoir Identifier	Test Date	% Lower Explosive Limit	% O ₂

S2.5 Incidents and Complaints**S2.5.1 Non-Compliance Incidents during Reporting Year**

Date of incident	Brief description of Incident	Cause	Corrective action

Total number of non-compliance incidents for previous year:ⁱ

Total number of non-compliance incidents for current reporting year:

S2.5.2 Complaints made by the public

Date of Complaint	Description of complaint	Actions taken

Total number of complaints for previous year:ⁱ

Total number of complaints for current reporting year:

ⁱ "Previous year" data is not required in the first reporting year (2015).

S2.6 Transport

Name of registered waste carrier used during reporting year	Waste type(s) transported

S2.7 Submission of Certification and Documentation

Submission	Tick (✓)
Improvement Programme Items as per Table 1.4.	<input type="checkbox"/>
Certification that the boilers (EM5 & EM6) are in good working condition. ⁱ	<input type="checkbox"/>
HEPA filter integrity monitoring for exhaust filters indicated in Schedule 3C, on a weekly basis in line with the approved Standard Operating Procedure. The results of the monitoring shall be submitted on a quarterly basis to the Authority and the Birzebbuga local council electronically. Such results shall also be submitted as part of the Annual Environmental Report, in the format specified in S2.4.2	<input type="checkbox"/>
HEPA Filter efficiency certification for exhaust filters is to be submitted on an annual basis in the format specified in S2.4.2	<input type="checkbox"/>
Calculations showing the mass flow of VOCs with the hazard statements H340, H350, H350i, H360D or H360F (or risk phrases R45, R46, R49, R60 or R61), where the mass flow of the sum of the compounds < 10g/h.	<input type="checkbox"/>
Calculations showing the mass flow of VOCs with the hazard statements H341 or H351 (or the risk phrases R40 or R68) where the mass flow of the sum of the compounds < 100 g/h.	<input type="checkbox"/>
Catchment pits and bunds on site must be tested and certified to be leak-proof by an independent, warranted civil engineer or engineer before any renewal of this IPPC permit.	<input type="checkbox"/>
Submission of replacement/substitution plan for substances or preparations that are used in the installation and which, because of their content of VOCs are classified as carcinogens, mutagens or toxic to reproduction and are assigned or need to carry the hazard statements H340, H350, H350i, H360D or H360F.	
Monitoring of the head space of the wash water reservoir for potential fire hazards.	<input type="checkbox"/>

ⁱ To be submitted by March 2023

Applicant's declaration

I declare that, to the best of my knowledge, all the above information is correct and substantiated.

.....
Name
(in block letters)

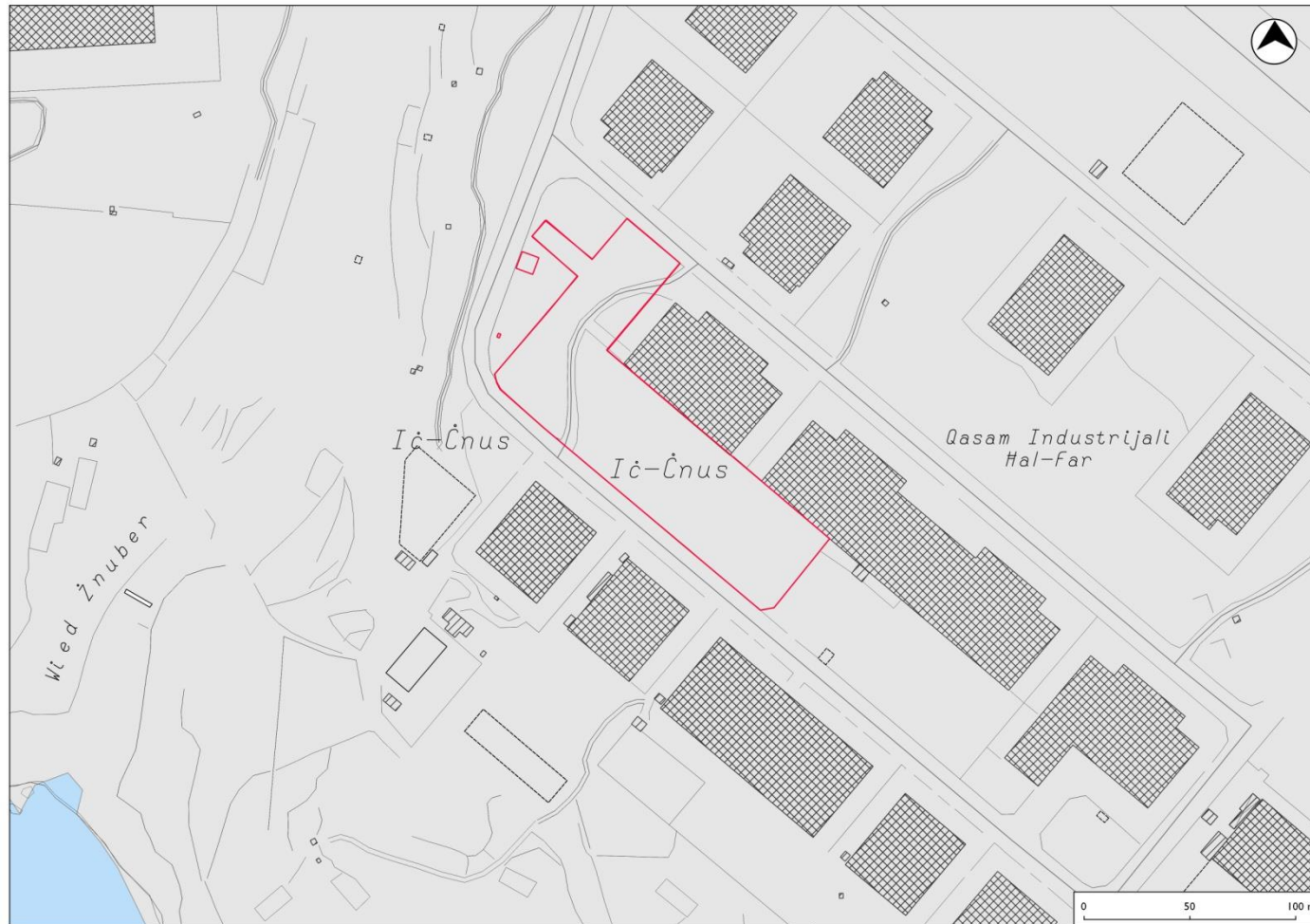
.....
ID Card Number

.....
on behalf of / in my own name
(in block letters)

.....
Signature

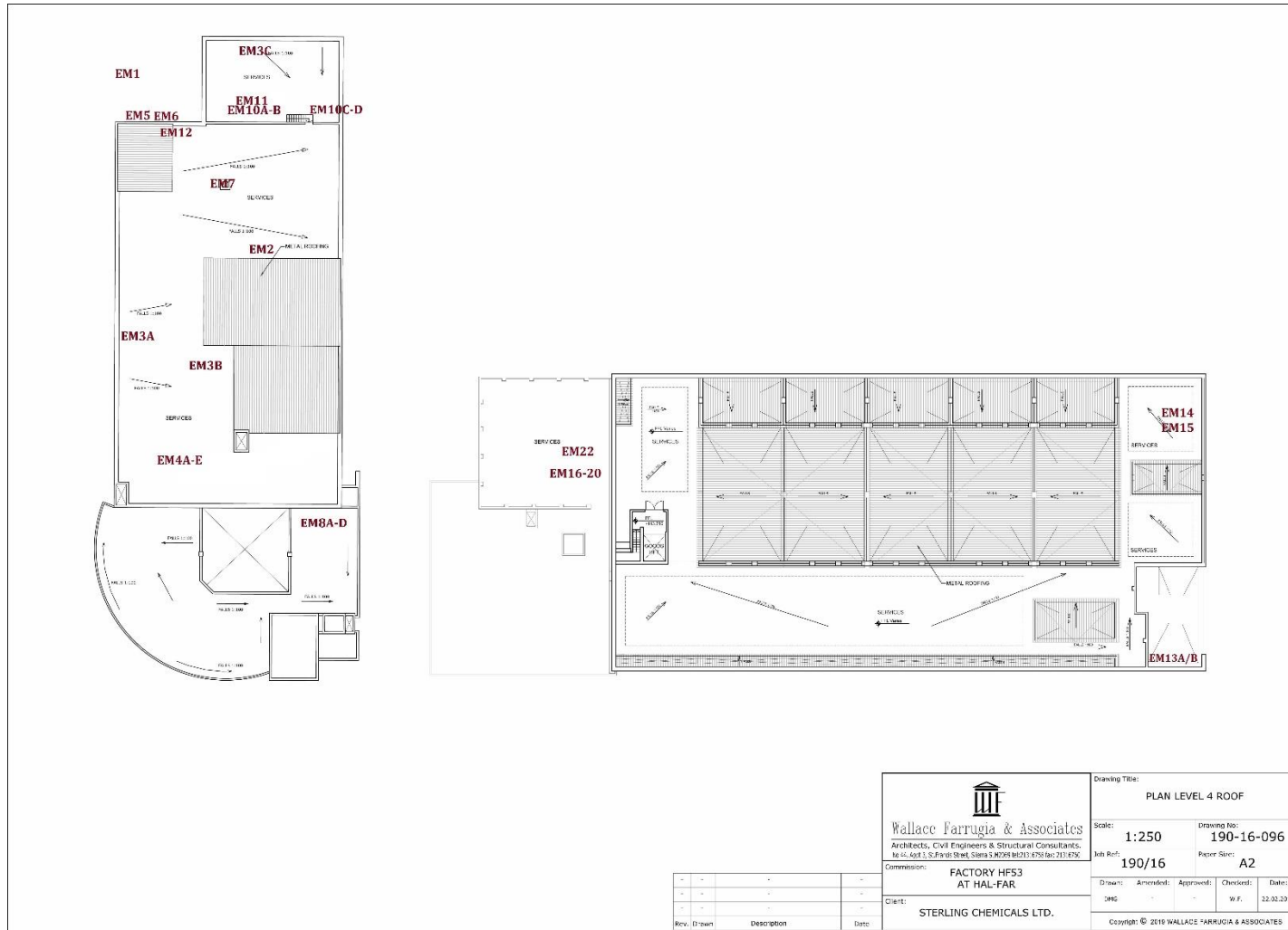
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Schedule 3A
Site Plan



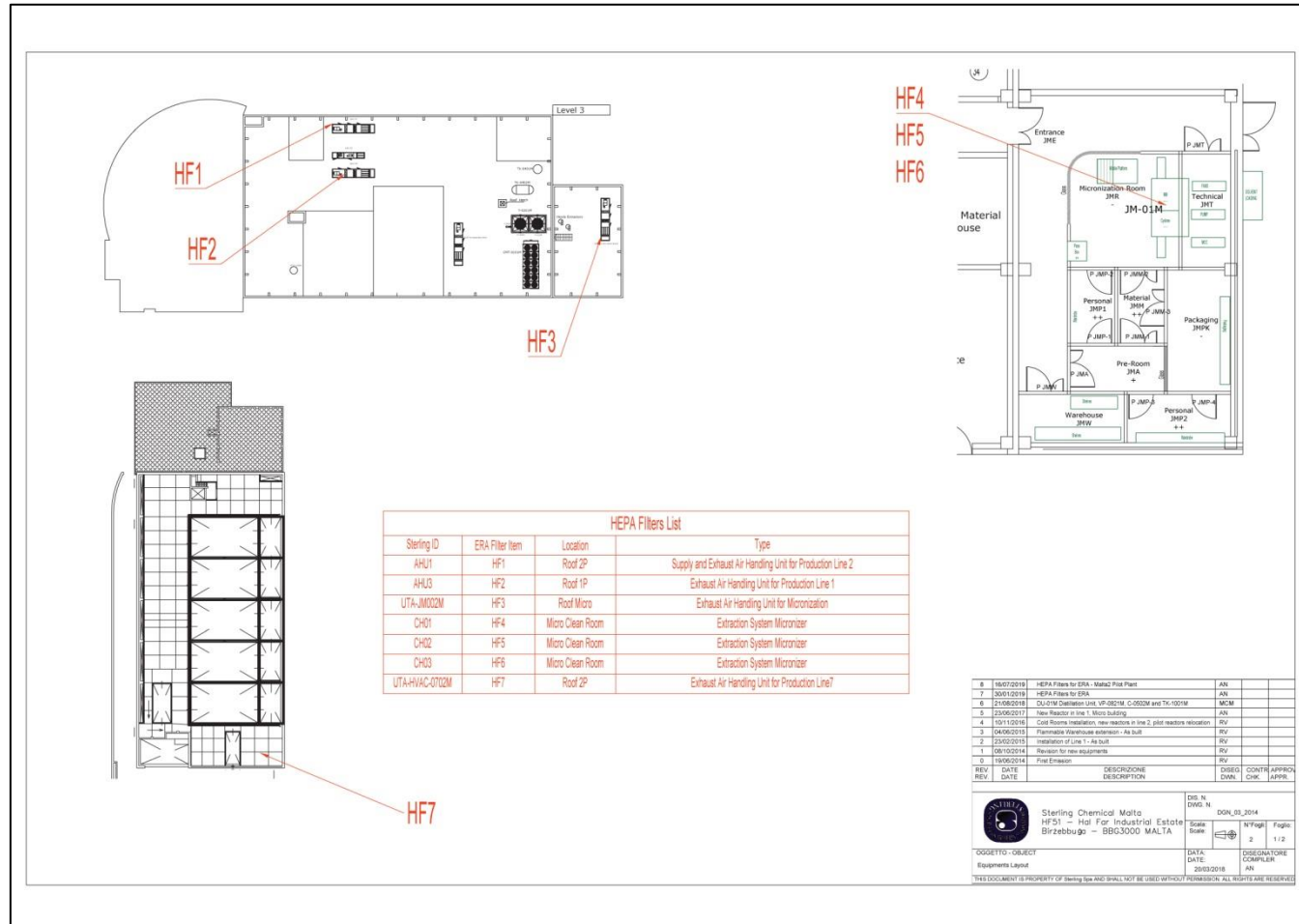
INDICATIVE ONLY - Not to be used for direct interpretation

Schedule 3B Effluent and Air Emission Points



Schedule 3C

Location of exhaust HEPA Filters installed on site on-site



Schedule 4
VOC Report

Kindly fill in the questionnaire with the information requested below. This information is being requested for the reporting period detailed below, in accordance with the installation's IPPC permit.

Permit Number	IP 0004/21
Installation	Sterling Chemical Malta Ltd.
Activity	Manufacturing of Pharmaceutical Products
Reporting Period	Day Month Year – Day Month Year

Solvents VOC emissions calculation is based on the guidance provided in the Solvent Management Plan in Schedule IV of S.L.549.79)

1	Solvent Input and Consumption calculation			
a	New Solvent Input = The quantity of organic solvents or their quantity in mixtures purchased which are used as input into the process in the time frame over which the mass balance is being calculated	I		Kg VOC
2	Fugitive Emissions calculation			
	Fugitive Emissions (F) is determined by subtraction of other measured emissions (i.e. $F = I - O1 - O5 - O6$):			
a	Quantity of organic solvents in Waste gases (annual load) <i>Information / calculation to be submitted as part of ER – Section 1.5 Table 2.</i>	O1		Kg VOC
b	Quantity of organic solvents and/or organic compounds lost due to chemical or physical reactions (including those that are destroyed by incineration or other waste gas or waste water treatments, or captured, as long as they are not counted under O6, O7 or O8).	O5		Kg VOC
c	Quantity of organic solvents contained in disposed waste <i>Only solvents in waste that was produced and disposed of during the reporting period should be included as O6. VOC content in waste needs to be verified by sampling and analysis in an accredited lab and copy of test result to be submitted together with this reportⁱ.</i>	O6		Kg VOC
d	Sum of above Emissions (Total output of organic solvents) <i>(cells 2a+2b+2c)</i>	$\Sigma O =$ O1+O5+O6		Kg VOC
e	Fugitive Emissions = Input – (Total output of organic solvents) <i>(cells 1a – 2d)</i>	F = I - ΣO		Kg VOC

ⁱ In case waste load (and type) can be considered to be constant, a one-time sampling and analysis would be sufficient.

Schedule 5

Terms of Reference for Noise Monitoring

1. Introduction

The noise monitoring shall be carried out by the Operator. A consultant that is either an accredited Acoustic expert or qualified professional Engineer and is approved by ERA according to the following criteria shall be commissioned who will propose a monitoring procedure for measuring noise levels within and around the installation as described in section 2 below.

The person(s) undertaking the “on field monitoring” shall be in possession of a certification for the collection of data.

The noise monitoring and impact study report shall be compiled and reviewed by a person who is in possession of a:

- (a) Bachelors degree in Acoustics, **or**
- (b) Bachelors degree in any of the following: Physics, Architecture, Civil Engineering or Engineering, Environmental Health, Environmental Science/Management, Occupational Health and Safety, **and** an MQF Level 7 specialisation in Acoustics, **or**
- (c) Bachelors degree in any of the following: Physics, Architecture, Civil Engineering or Engineering, Environmental Health, Environmental Science/Management, Occupational Health and Safety **and** in addition the consultant must be at least an associate member of the Institute of Acoustics or be employed by an organization who are members of the Association of Noise Consultants or equivalent grade of Membership of a professional body for those working in acoustics and noise in any one of the EU member states or any other reputable professional body to the satisfaction of ERA, **or**
- (d) Certification for the collection of data, such as “Certificate of Competence in Environmental Noise Measurement” issued by the Institute of Acoustics (IoA) or any other equivalent qualification issued by a comparable Professional Association dealing with acoustics in any one of the EU and EEA Member States or any qualifications issued by an educational institution to the satisfaction of ERA **and** five (5) years experience in noise measurements and assessments.

Copies of such qualifications and certification shall be submitted to ERA prior to the monitoring proposal.

The consultant, in collaboration with ERA, may, where applicable need to consult and seek advice from the Local Council during the selection of the sensitive receptors.

2. Content of monitoring study

The monitoring study should address the following issues:

1. A description of the installation – this shall include a description of all processes carried out on site and related equipment and infrastructures.
2. A description of the surrounding areas – this shall include identification of the types of activities, whether residential or commercial, roads and other amenities. These shall be location-specific taking into account their location with respect to the site.
3. Identification of the main sources of noise and vibration – this shall include all processes on site, including aspects such as transport noise on site, plant equipment, mechanical operations, etc (amongst others) and their times of operation.

4. Identification of the closest noise sensitive receptors – this shall be carried out after assessing the noise levels in the plant's perimeter and in the other locations identified in point 2 above under normal operating conditions of the plant. The various monitoring points shall be identified with a unique code and an analyses of the ambient noise to which each monitoring point is subjected to.

5. Environmental Noise Study – this shall include details of the standards used for measurements, equipment used including calibration details and certificates, resultant measurement data, assessment methods and complaints significance scale. The study is to be carried out according to the latest revisions of ISO1996 and the rating of industrial noise affecting residential areas shall be according to the latest revisions of BS4142. The study should include perimeter noise levels, baseline noise study of sensitive receptor sites, noise impact on site sensitive receipts including day and night background levels.

The data compiled for both day and night is a typical representation of the current situation at all receptor points and the measurement time interval is sufficient enough to obtain representative value of a typical background when the specific noise source will be operating. For facilities that operate continuously for 24 hours, it may be appropriate to measure at a time when all other noises have subsided. If it is possible 'specific noise' is estimated by measuring the noise level with and without the facility running.

6. The monitoring shall be performed exclusively using a calibrated type 1 sound level meter conforming to BS 6698/IEC 61672 Class 1. The use of type 2 sound level meters or less is not considered acceptable and will not be considered. The sound level meter, calibrator and microphone must hold a valid current calibration certificate from an accredited laboratory (ex. UKAS)

7. Prior to the initial data collection and at the end of the monitoring day, all acoustic instrumentation system such as the sound level meters are calibrated, and checked immediately before and after each series of monitoring readings. Results must be within $\pm 1.0\text{dB}$, otherwise discarded and read again.

8. As a basis for the collection of background data, monitoring shall be carried out during a period when there are no operations at the facility. If this is not possible, operations are to be temporarily suppressed during readings. If this is still not possible, a measurement at an alternative location where the residual sound is comparable to the assessment location(s) with justifications shall be provided.

In case that operating conditions of the site are significantly different during the day, evening or night periods, the measurement procedure will be repeated for those periods of day/evening or night. Therefore, information from the operator is requested prior to the commencement of the measurements. If the information requested is not provided in time, the Consultants will assume that the site operates uniformly during the day, evening and night periods and measure during the daytime only. However, baseline noise levels would still need to be measured at the nearest noise sensitive locations at night in order to determine the impact.

9. The background noise measurements shall be accompanied by a critical listening of all the other noise sources present in the background. Due to certain acoustic features such as tonality, impulsivity and intermittency the inclusion of specific noise level plus any adjustment for the different noise characteristic features, the rating level, $L_{Ar,Tr}$ should be reported in accordance with BS 4142:2014, and any revision thereof, depending on the subjective assessment made while taking the readings.

10. Monitoring shall consider seasonal variations including but not limited to the occurrence of the fireworks and any other similar typical seasonal predominant noise sources. The recommended time periods over a twenty-four hour period are categorized in terms of daytime, from 0700-2300 hrs ($L_{Aeq, [16\text{hrs}]}$) and night-time period from 2300 – 0700 hrs ($L_{Aeq, [8\text{hrs}]}$).

11. For the propagation of noise from the power plant, the use of ISO 9613, ISO 8297: 1994, ISO 3744:2010 and ISO 3746:2010; and any revision thereof (as per the interim methods of the

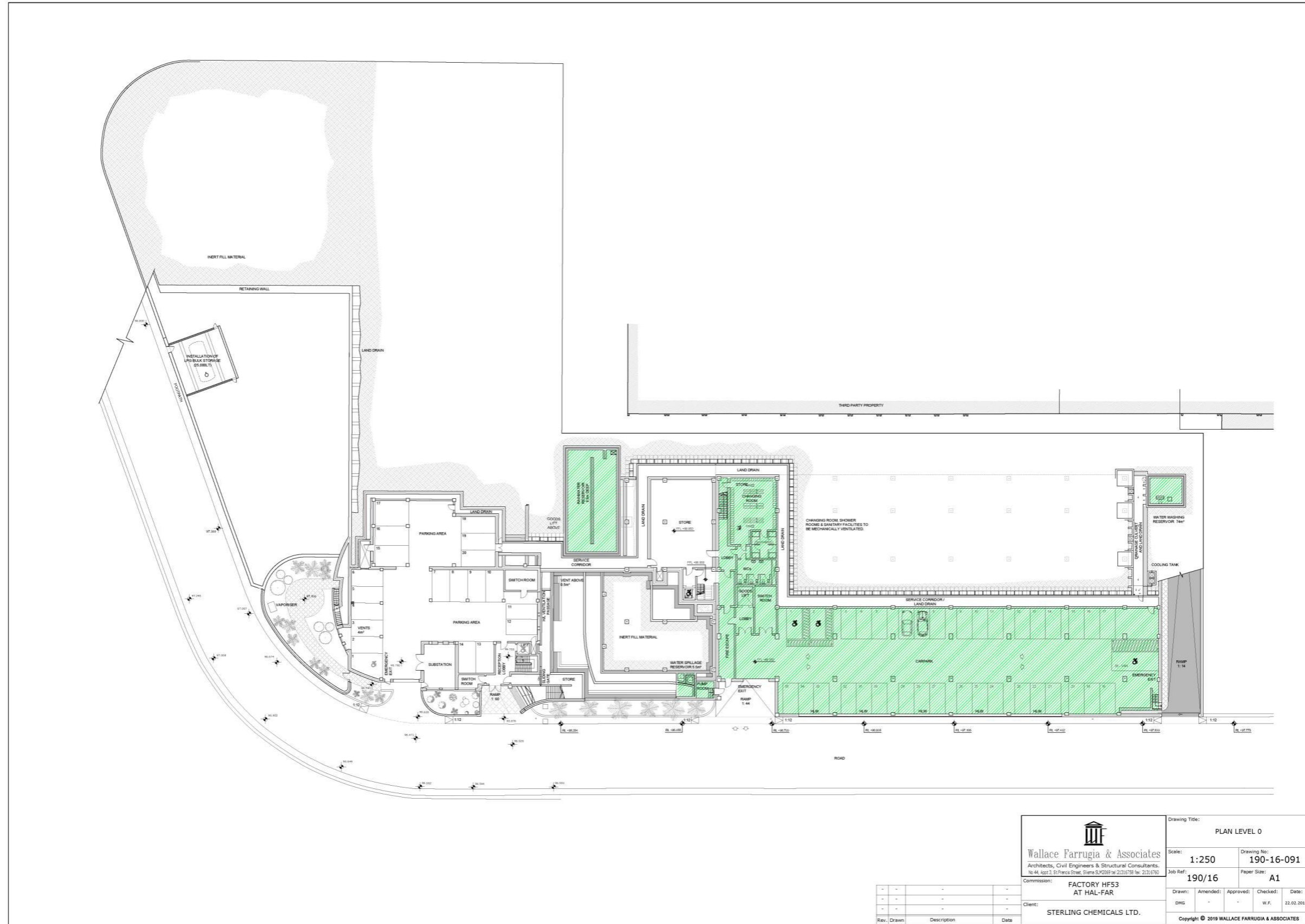
Environmental Noise Directive 2002/49/EC) is strongly recommended.

12. In the case of multioperator installations where the evaluation and monitoring needs to distinguish between the impact caused by different or interconnected operators within the same installation, the application of the following standards is deemed necessary: standard ISO8297:1994 and any revision thereof, and ISO37XX series or specifically ISO 9614-2:1996.

13. Impact assessment of noise events on noise sensitive receptor site – this shall include an assessment according to the guidelines BS 4142:2014, ISO1996 and ISO9613 or any other standard and any other standard methodology stipulated by the Authority. A summary of the data obtained after the study has been carried out in relation to the noise sensitive receptors identified above shall be submitted.

14. Conclusions and Mitigation measures – this shall include a summary report of findings from the noise monitoring study including the impact assessment of noise events on noise receptors sites and any remedial action and/or mitigation measures to be implemented by the operator in order to reduce impacts resulting from the site of operation.

END OF PERMIT

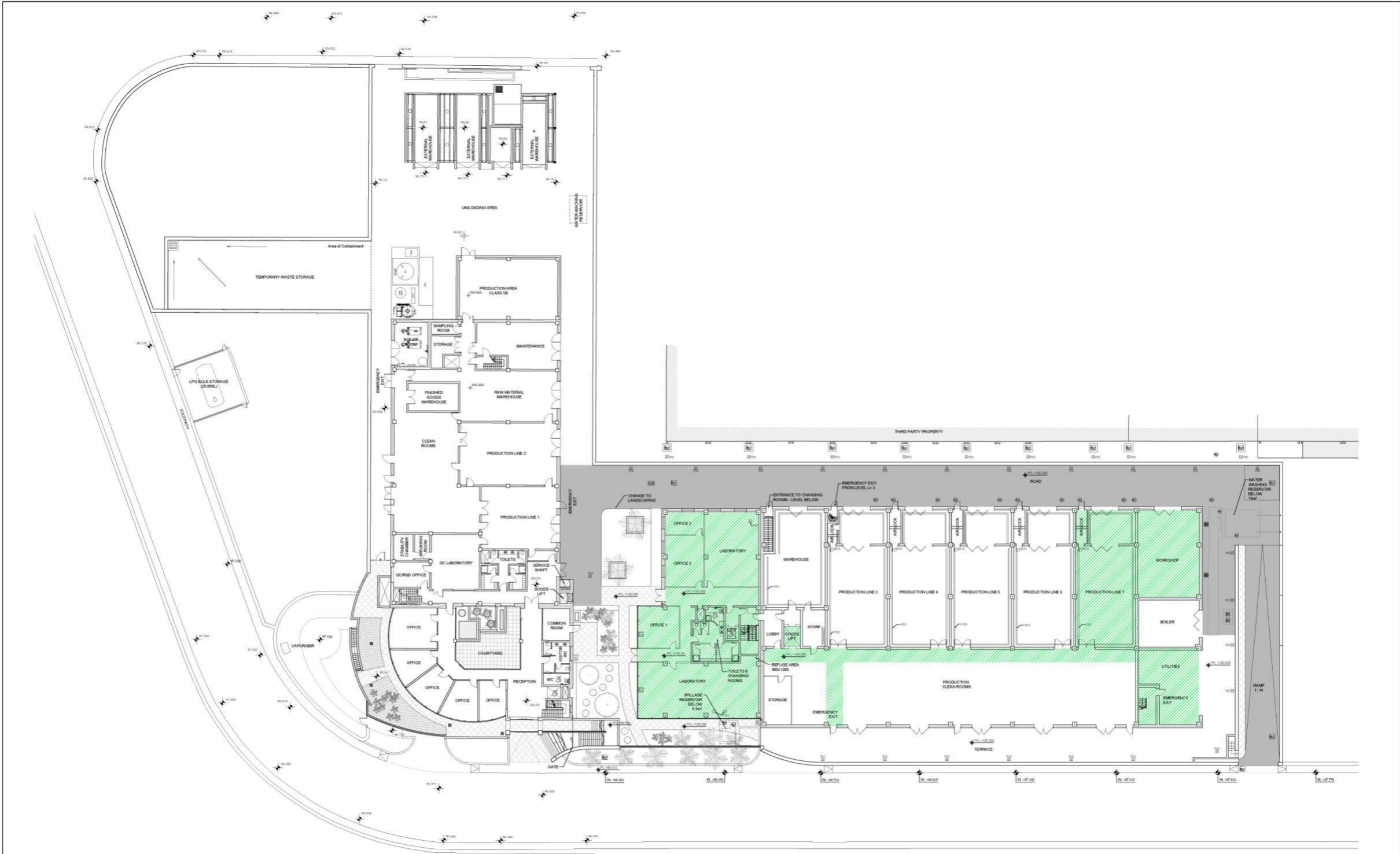


Scheme Layout (Level 0)

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	Scale: 1:250	Drawing No: 190-16-091		
	Job Ref: 190/16	Paper Size: A1		
	Drawn: DMG	Amended: -	Approved: W.F.	Checked: W.F.

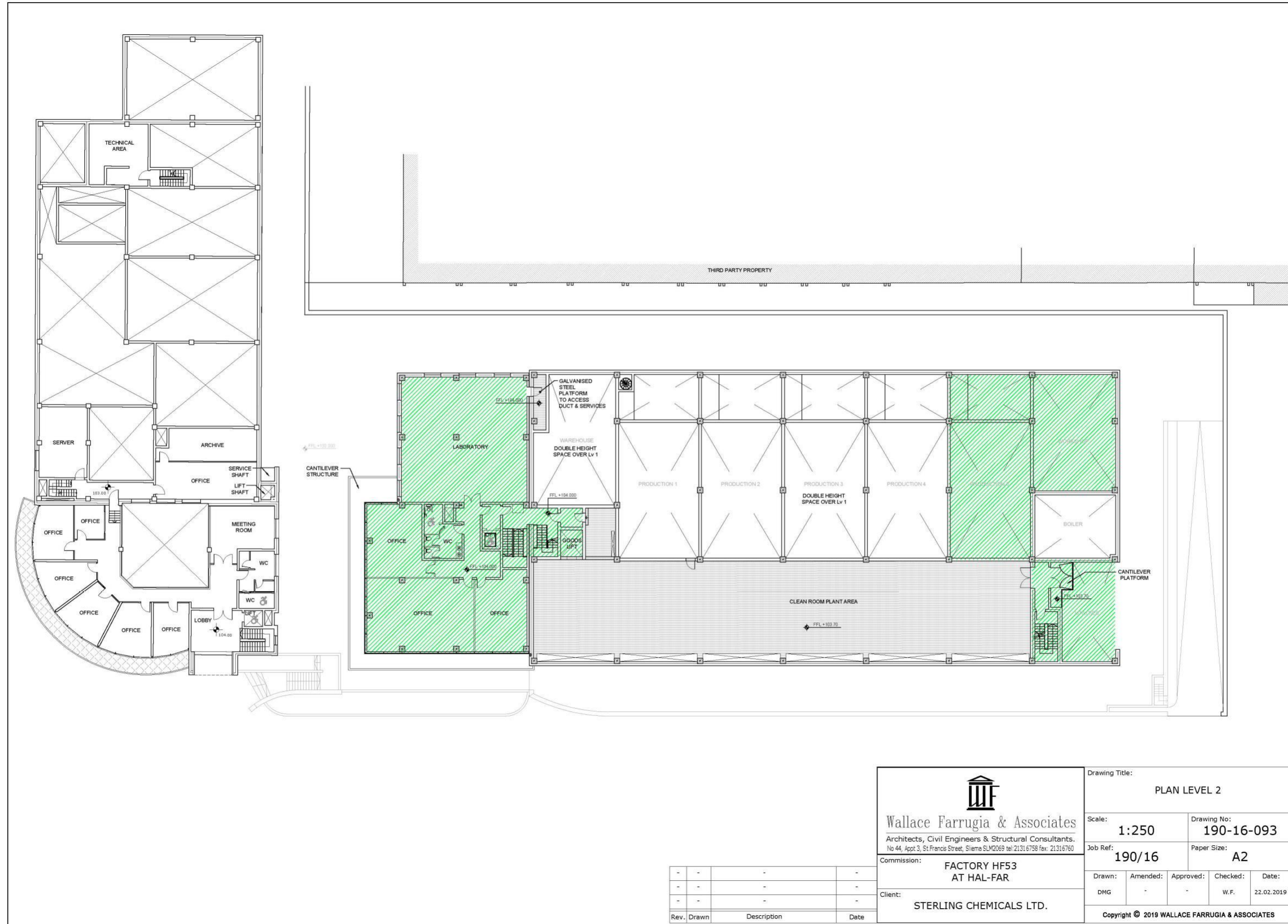
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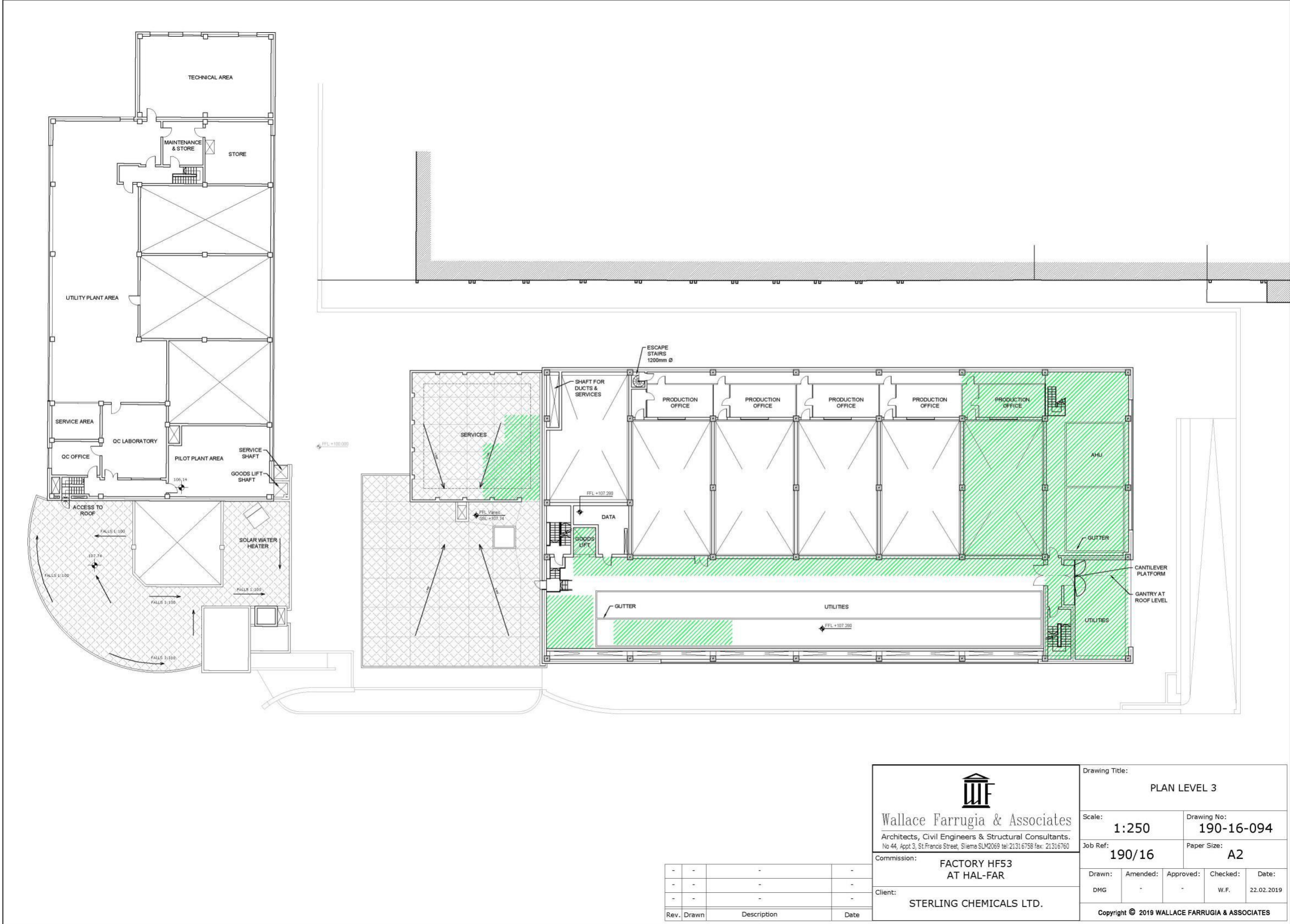


 Wallace Farrugia & Associates Architects, Civil Engineers & Structural Consultants. No. 44, Appt 3, St. Francis Street, Sierra Square, London E15 2JF. Tel: 020 7461 6700		Drawing Title: PLAN LEVEL 1	
		Scale: 1:250	Drawing No: 190-16-092
Commission: FACTORY HF53 AT HAL-FAR		Job Ref: 190/16	Paper Size: A1
Client: STERLING CHEMICALS LTD.		Drawn: DMG	Approved: W.F. Checked: W.F. Date: 22.02.2019
Rev. Drawn Description Date - - - - - - - - - - - - - - -		Copyright © 2019 WALLACE FARRUGIA & ASSOCIATES	

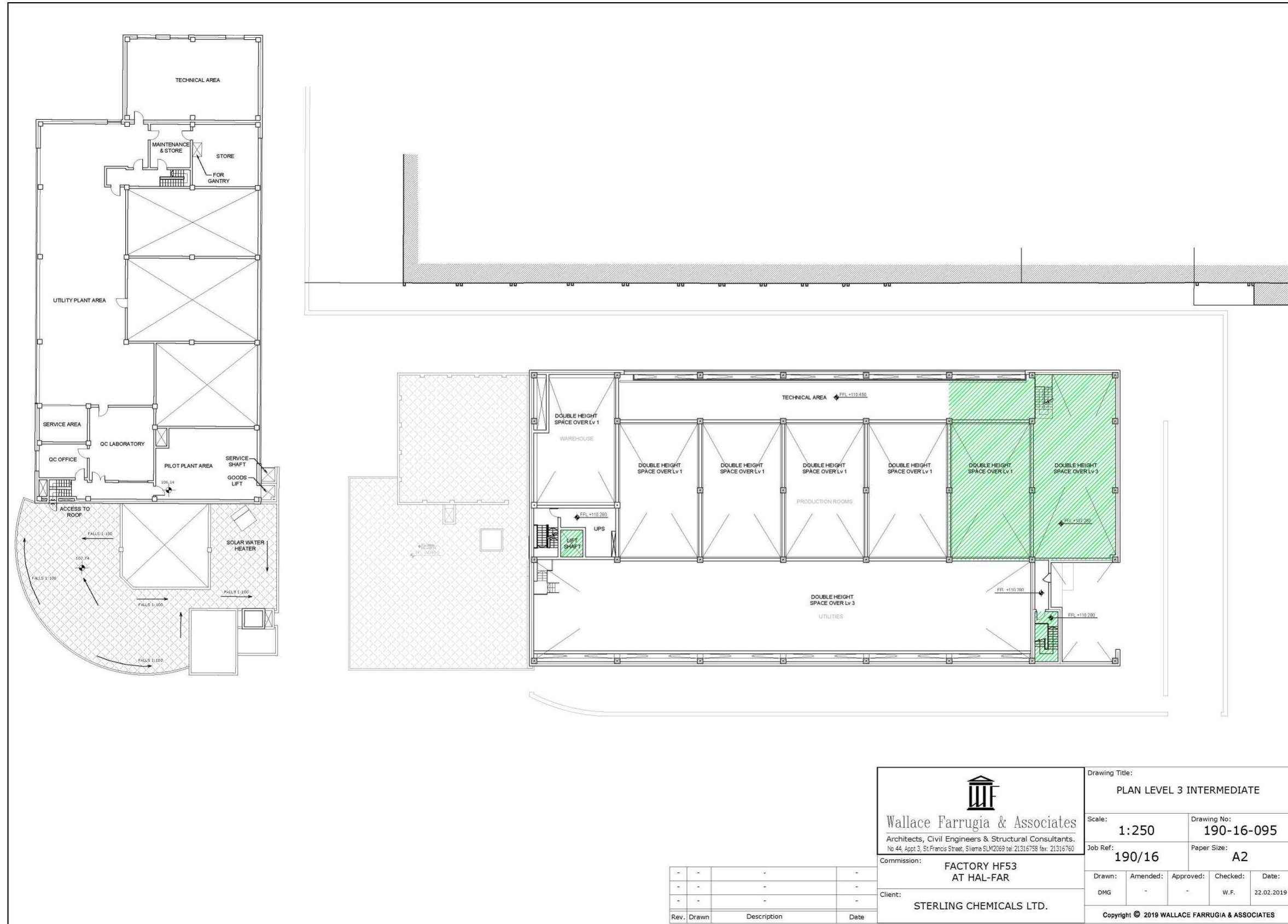
Scheme Layout (Level 1)



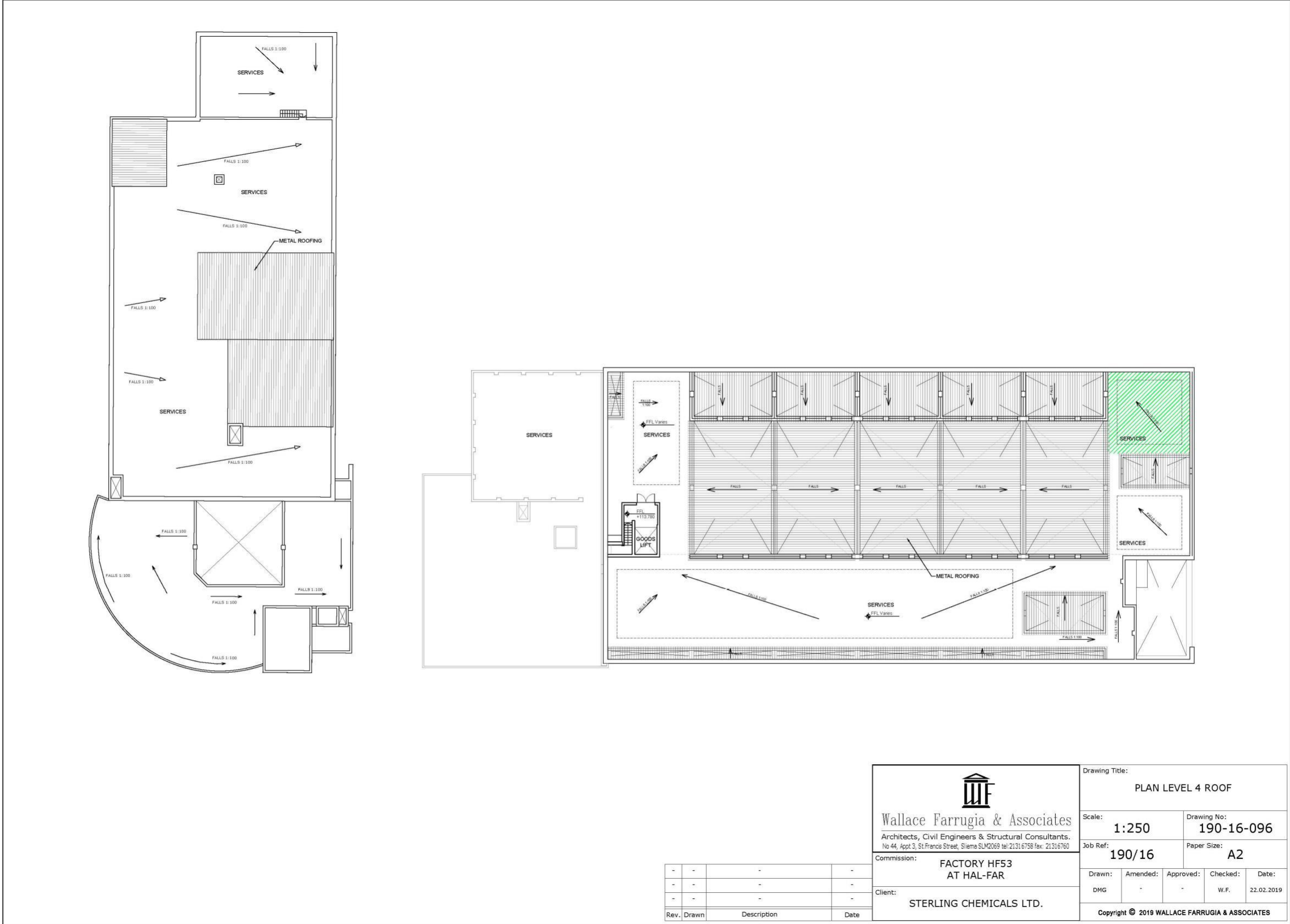
Scheme Layout (Level 2)



Scheme Layout (Level 3)




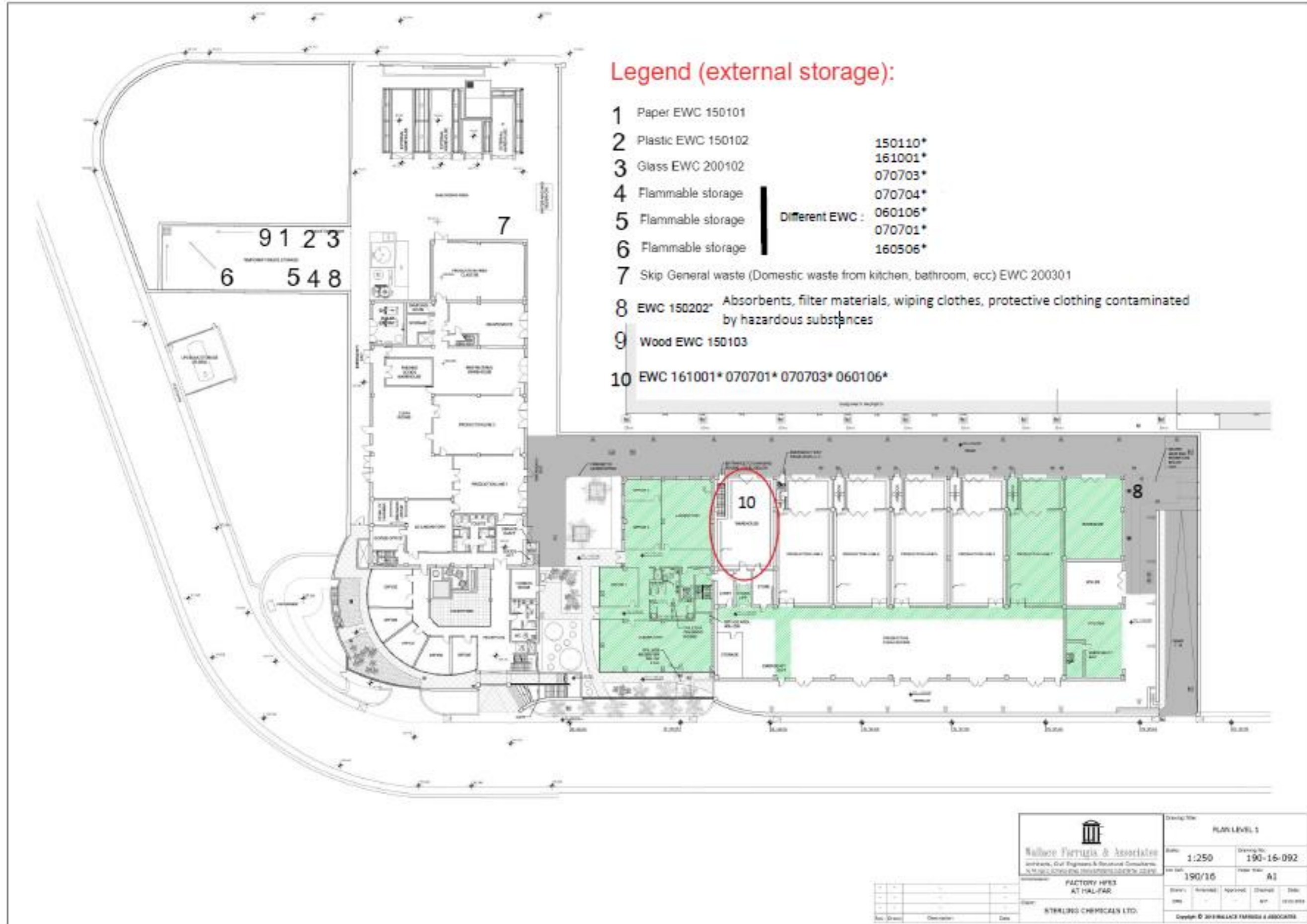
Scheme Layout (Level 3 Intermediate)



Scheme Layout (roof level)

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Client: STERLING CHEMICALS LTD.		Drawn: DMG	Amended: -
		Approved: -	Checked: W.F.
		Date: 22.02.2019	
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<p>Wallace Ferriss & Associates Architects, Civil Engineers & Structural Consultants 17 High Street, London EC1A 3BE</p>	Drawing Title: PLAN LEVEL 1	
	Scale: 1:250	Drawing No: 190-16-092
	Rev: 190/16	Rev: A1
	Drawn: [] Checked: [] Approved: [] Date: []	Date: []
PROJECT: FACTORY HPES AT HAL-FAR CLIENT: STERILISED CHEMICALS LTD.		Drawn: [] Checked: [] Approved: [] Date: []

Copy of Original Decision Notice



Mr. Gorg Cilia
obo MIP Ltd
UB8 San Gwann Industrial Estate
San Gwann

Date: 15 Oct 2010
Our Ref: PA/04236/08

Application Number: PA/04236/08
Application Type: Full development permission
Date Received: 29 August 2008
Approved Documents: PA4236/08/1C/55A/55B/55C/55D/55E/55F/29C/29D/29F/29I.
Accessibility Audit report PA 4236/08/61A
Fire Safety and Ventilation Report PA 4236/08/69
Location: Factory HF 51, Qasam Industrijali, Hal Far
Proposal: Factory at Hal Far for Sterling Chemicals Ltd. This excludes the installation of a plant and operation as an API for manufacturing which is subject to a separate permit.

Development Planning Act, 1992 Full Development Permission

The Malta Environment & Planning Authority hereby grants development permission in accordance with the application and plans described above, subject to the following conditions:

- 1 a) This permit is being issued exclusively for the construction of the factory premises and for the use of the site for research and development and administration only. The manufacturing of commercial quantities of APIs is not allowed, unless a separate development permit and IPPC permit has been obtained from the MEPA.
- b) The development permit is strictly without prejudice to any additional requirements (e.g. ancillary infrastructure & modifications to the approved development) as may be required in connection with the operational permit. Depending on the nature of the requirements in question, a new or amended development permit application may also be required.
- c) Any modifications to the approved development shall not be exempted from any EIA, IPPC permit or other legal requirement.
- d) A list of all chemicals used including quantities kept on premises together with production quantities shall be made available for inspection at any time upon request of MEPA.
- e) No discharge point for any type of effluent to land, storm drains or sea is allowed, unless specifically approved under a permit issued by MEPA.

PA/04236/08

Print Date: 15/10/2010

f) Foul sewer drains must be strictly segregated from storm water drains.

g) All discharges to the foul sewer, including process effluents and wash waters (e.g. Contaminated with industrial detergents etc.), shall comply with the requirements of a license issued by the Water Services Corporation. Any grease trap or sedimentation tank or other equipment specified by the WSC shall be adequately sized.

h) All operations concerning the management of waste during the construction phase are subject to the legal provisions of Legal Notice 337 Waste Management (Permit and Control) Regulations of 2001 and Legal Notice 106 Waste Management (Activity Registration) Regulations, 2007. Wastes are to be separated according to the different waste streams as per EWC codes and disposed of in facilities permitted to receive such waste as per provisions of Legal Notice 337 Waste Management (Permit and Control) Regulations of 2001.

i) Inert waste material resulting from excavations or from demolition may be reused as fill material or shall be deposited at facilities permitted by MEPA and in accordance with the legal provisions laid down in LN 337 Waste Management (Permit and Control) Regulations of 2001 and LN 106 Waste Management (Activity Registration) Regulations, 2007.

2 Prior to the issuing of this development permit the applicant shall submit a financial planning contribution of €4,467 which will be used in the EIPP Partnership Programme.

3 The following conditions are imposed by the Department of Environmental Health:

(a) All building and sanitary laws and regulations are complied with;

(b) Toilet rooms and anterooms are to be naturally or mechanically ventilated;

(c) Rainwater from reservoir may be used for the flushing of WCs but is not be used for personal hygiene;

(d) Floors are to be of an impervious material, and easy to clean and precautions are to be taken in the event of spillages of chemicals;

(e) Chemicals are to be kept segregated and in a bonded area;

(f) Water washing reservoirs are to be of an impervious material and of adequate size.;

(g) Any generated noxious fumes, gases, dusts, powders etc are to be controlled by means of an adequate ventilation system and are not to be discharged into the atmosphere.

(h) All necessary measures are to be taken to prevent the causing of nuisance to neighboring properties (factories) and their personnel by means of fumes, gases, dust, steam odour, noise and vibrations both during the construction phase and afterwards.

(i) If cooling towers are constructed, applicant is to abide by Legal Notice 5 of 2006 –

Control of Legionella Regulations and LN6 of 2006 - Registration of Cooling Towers and Evaporative Condensers.

The applicant shall consult Department of Environmental Health during the construction phase of the development hereby approved, to ensure that the development is carried out in conformity with the conditions imposed by the Department of Environmental Health.

4 The following conditions are imposed by the Malta Resources Authority:

a) There should be no direct or indirect discharges of effluents into the environment or groundwater in particular. These effluents will include all substances which have a deleterious effect on the physical and chemical composition of groundwater, and compounds liable to cause the formation of such substances in groundwater such as to render it unfit for human consumption; and

b) All necessary permits relating to discharge to the government sewers should be obtained from the Water Services Corporation.

c) The MRA reserves the right to inspect the premises as and when required; and take any action in case of any infringement of these conditions.

The applicant shall consult Malta Resources Authority during the construction phase of the development hereby approved, to ensure that the development is carried out in conformity with the conditions imposed by the Malta Resources Authority.

5 Landscaping of the site shall be implemented in its entirety within the first planting season following completion of the development hereby approved, in accordance with the details submitted with the application unless the prior approval in writing of the Malta Environment & Planning Authority has been obtained to depart from these details. No compliance certificate (partial or full) shall be issued on part, or the whole, of the development hereby approved prior to the implementation of the landscaping scheme in its entirety.

6 The development shall be constructed in conformity with the provisions set out in the accessibility audit report (approved document PA4236/08/61A).

7 There shall be no service pipes, cables or wires visible on the front elevation or on any other elevations of the building which are visible from the street.

8 Air conditioning units shall not be located on the facades of the building which are visible from a public space. Any such units located at roof level shall be set back from the facade by at least 1 metre.

9 a) This development permission is valid for a period of FIVE YEARS from the date of this notice but will cease to be valid if the development is not completed by the end of this five year period.

b) It should be noted that a third party may have the right of appeal against this

permission. Any development which is carried out when such an appeal has been made, or until the time limit for the submission of such an appeal has expired, is undertaken at the risk that this permission may be revoked by the Planning Appeals Board or quashed by the Court of Appeal.

c) This development permission does not remove or replace the need to obtain the consent of the land/building owner to this development before it is carried out. Furthermore, it does not imply that consent will necessarily be forthcoming nor does it bind the land/building owner to agree to this development. Where the land/building is owned or administered by the Government of Malta a specific clearance and agreement must be obtained for this development from the Land and/or Estate Management Departments.

d) All works shall be carried out strictly in accordance with the approved plans and the conditions of this permission. Where a matter is not specified on the plans then the conditions of this permission and of Development Control Policy and Design Guidance shall take precedence and modify the plans accordingly.

e) All building works shall be erected in accordance with the official alignment and proposed/existing finished road levels as set out on site by the Malta Environment & Planning Authority's Land Surveyor. The Setting Out Request Notice must be returned to the Land Survey Unit of the Malta Environment & Planning Authority when the setting out of the alignment and levels is required.

f) Before any part of the development hereby permitted commences, the enclosed green copy of the Development Permit shall be displayed on the site. This must be mounted on a notice board, suitably protected from the weather and located not more than 2 metres above ground level at a point on the site boundary where it is clearly visible and can be easily read from the street. The copy of the permit must be maintained in a good condition and it shall remain displayed on the site until the works are complete.

g) The enclosed Commencement Notice shall be returned to the Malta Environment & Planning Authority so that it is received at least five days prior to the commencement of the development hereby permitted.

h) Copies of all approved plans and elevations shall be available for inspection on site by Malta Environment & Planning Authority staff at all reasonable times.

i) Where the street bordering the site is unopened, it shall be opened up prior to the commencement of the building operations hereby permitted.

j) The Enforcement Unit of the Malta Environment & Planning Authority shall be notified prior to the commencement of the following stages of the development : construction of the foundations; roofing over the last basement level; roofing over the first level above ground level.

k) The height of the building shall not exceed the height as indicated on the approved drawings PA4236/08/55E

l) A water cistern with a volume in cubic metres of 60% of the total roof area (in square metres) of the building(s) shall be constructed to store rainwater run-off from the built-up area of the development. This cistern shall be completed and available for use prior to the development hereby permitted being first brought into use.

m) The development hereby permitted shall not be brought into use until the Final Compliance (Completion) Certificate, certifying that the development has been carried out in full accordance with the plans approved by this permission and with the other conditions imposed in this permission, has been issued by the Malta Environment & Planning Authority.

n) Apertures and balconies shall not be constructed of gold, silver or bronze aluminium.

o) The facade of the building shall be constructed in local stone, except where other materials, finishes and colours are indicated on the approved plans and drawings.

p) Where applicable hoarding should be erected in accordance with Schedule 2 of the Environmental Management Construction Site Regulations, LN 295 of 2007

q) The permit is issued on condition that, where applicable, any excavation shall be subject to the requirements of the Civil Code regarding neighbouring tenements.

r) Any soil on the site shall not be built over but shall be collected for reuse. A permit from the Director of Agriculture is required to remove the soil from the site. All soil shall be deposited at the place indicated by the Director of Agriculture; and authorisation by the Environment Protection Directorate shall also be required prior to any deposition on open or undeveloped land unless located within officially approved development zones. Contaminated soils (if any) are to be managed/disposed of in accordance with the legal provisions laid down in Legal Notice 337 Waste Management (Permit and Control), Regulations, 2001 and L.N. 168 Waste Management (Landfill) Regulations, 2002 and its amendments.

s) Where applicable, the development, hereby permitted, shall be carried out in accordance with the provisions of the Environmental Management Construction Site Regulations, LN 295 of 2007.

t) This permission relates only to the additions and alterations specifically indicated on the approved drawings. This permission does not sanction any illegal development that may exist on the site.

Should the site fall within areas designated as HOS and property originating from the Housing Authority, this permit does not exonerate the applicant from obtaining the necessary clearances from the same Authority.

This permit is granted saving third party rights. The applicant is not excused from obtaining any other permission required by law. The applicant should contact the following regarding the location and provision of services prior to commencing development:- Enemalta, Water Services Corporation and Cable Network Operators.

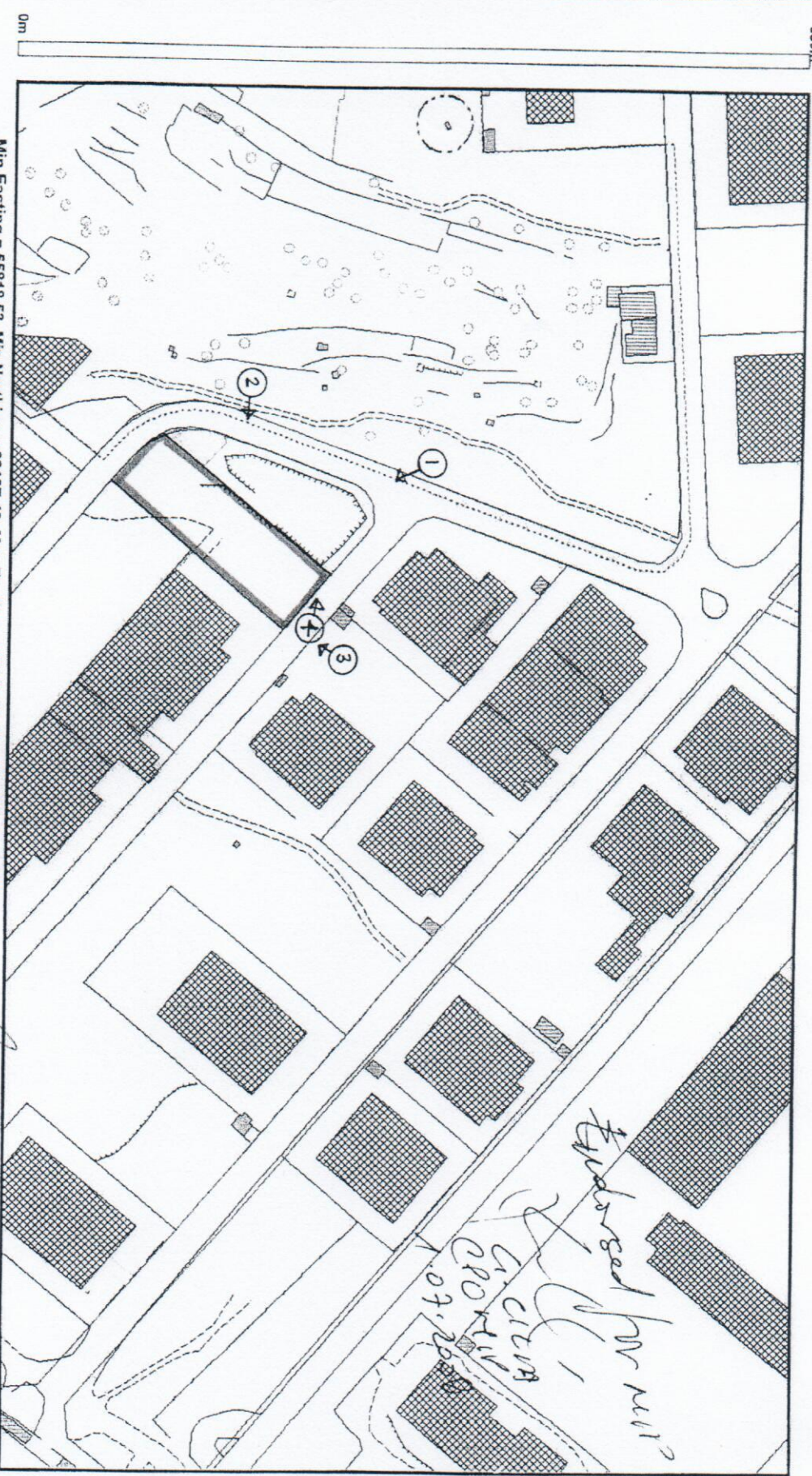


Sylvana De Bono
Board Secretary
MEPA

[PADCNCopy]

PA/04236/08

Print Date: 15/10/2010



350m

1c

0m

Min Easting = 55818.53, Min Northing = 63137.49, Max Easting = 56443.53, Max Northing = 63487.4

625m

MEPA

www.mepa.org.mt
 St. Francis Ravelin
 Floriana
 PO Box 200, Valletta, Malta
 Tel: +356 240976 Fax: +356 224846

Site Plan, Scale 1:2500

APPROVAL

Printed on: Saturday, December 06, 2008
 Not to be used for interpretation or scaling of scheme alignments
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Board No. PA4236/08 held on 20/12/08
 Chairman *[Signature]*
 Secretary *[Signature]*

Plan No: PA4236/08/1c

741805

Exchanged for null?
10.7.2008
PA4236/08/1c

Copy of Original Decision Notice



Mr. Simone Ferlin
Sterling Chemicals Malta Ltd.
C/O 44
Triq San Frangisk
Sliema SLM 2069

Date: 26 June 2013
Our Ref: PA/03033/12

Application Number: PA/03033/12
Application Type: Full development permission
Date Received: 17 October 2012
Approved Documents: Site Plan - PA3033/12/1A
Part existing and proposed Plan - PA3033/12/36a
Part existing and proposed Elevation - PA3033/12/36b
Civil Protection Directorate Conditions - PA3033/12/35

Location: Factory HF 51, Qasam Industrijali, Hal Far, Birzebbugia, Malta
Proposal: Installation of LPG bulk storage in a facility/factory already covered by permit PA/04236/08.

Environment and Development Planning Act, 2010 Full Development Permission

The Malta Environment & Planning Authority hereby grants development permission in accordance with the application and documents described above, subject to the following conditions:

1 Environmental Conditions:

a. Removal and re-use of soil, and management of waste generated by site preparation, excavation and construction operations:

(i) Any soil on the site shall not be built over but shall be collected for re-use in accordance with the Fertile Soil (Preservation) Act, 1973. A permit from the Director of Agriculture may be required to this effect.

(ii) The deposition and reuse of any soil removed from the site shall be approved in advance by MEPA's Environment Protection Directorate if it would involve deposition or re-use in any site which is located Outside Development Zones or within a scheduled or otherwise legally protected site.

(iii) Contaminated soils are to be managed and disposed of in accordance with the legal provisions laid down in Legal Notice 184 of 2011 [The Waste Management Regulations of 2011] as amended by Legal Notice 441 of 2011 and L.N. 168 of 2002 [Waste Management (Landfill) Regulations of 2002] and its amendments. (d) Inert waste material resulting from demolition may be reused as fill material within the site (as long as this is in

PA/03033/12

Print Date: 26/06/2013

line with the approved plans and other conditions of this permit), or shall be deposited at facilities permitted by MEPA and in accordance with the legal provisions laid down in Legal Notice 184 of 2011 [The Waste Management Regulations of 2011] as amended by Legal Notice 441 of 2011 and Legal Notice 106 of 2007 [Waste Management (Activity Registration) Regulations of 2007].

(iv) All operations concerning the management of waste are subject to the legal provisions of Legal Notice 184 of 2011 [The Waste Management Regulations 2011] as amended by Legal Notice 441 of 2011 and Legal Notice 106 of 2007 [Waste Management (Activity Registration) Regulations of 2007].

b. All operations concerning the management of waste are subject to the legal provisions of Legal Notice 184 of 2011 [The Waste Management Regulations of 2011] as amended by Legal Notice 441 of 2011 and Legal Notice 106 of 2007 [Waste Management (Activity Registration) Regulations, 2007].

c. Inert waste material/rock resulting from excavations or from demolition may be reused as fill material on site or shall be deposited at facilities permitted by MEPA and in accordance with the legal provisions laid down in Legal Notice 184 of 2011 [The Waste Management Regulations of 2011] as amended by Legal Notice 441 of 2011 and Legal Notice 106 of 2007 [Waste Management (Activity Registration) Regulations, 2007].

2 a) This development permission is valid for a period of FIVE YEARS from the date of publication of the decision in the press but will cease to be valid if the development is not completed by the end of this validity period.

b) This permission relates only to the development as specifically indicated on the approved drawings. This permission does not sanction any other illegal development that may exist on the site.

c) Copies of all approved drawings and documents shall be available for inspection on site by MEPA staff at all reasonable times. All works shall be carried out strictly in accordance with the approved drawings, documents and conditions of this permission. Where a matter is not specified, then the conditions of this permission and of Development Control Policy and Design Guidance shall take precedence and shall modify the drawings and documents accordingly.

d) Where applicable, all building works shall be erected in accordance with the official alignment and official/existing finished road levels as set out on site by MEPA's Land Surveyor. The Setting Out Request Notice must be submitted to the Land Survey Unit of MEPA when the setting out of the alignment and levels is required.

e) Where an officially schemed street, within the development zone, bordering the site is unopened or unformed, it shall be opened up and brought up to its proper, approved and official formation levels prior to the commencement of any development hereby being permitted.

f) Before any part of the development hereby permitted commences, the enclosed green copy of this development permission shall be displayed on the site. This must be mounted on a notice board, suitably protected from the weather and located not more than 2 metres above ground level at a point on the site boundary where it is clearly visible and can be easily read from the street. The copy of the permission must be maintained in a good condition and it shall remain displayed on the site until the works are complete.

- g) The enclosed Commencement Notice shall be returned to MEPA so that it is received at least five days prior to the commencement of any works hereby permitted.
- h) Where applicable, the development hereby permitted shall be carried out in accordance with the provisions of the Environmental Management Construction Site Regulations, Legal Notice 295 of 2007 (or subsequent amendments). Any hoarding shall be erected in accordance with Schedule 2 of the same Regulations.
- i) The height of the development shall not exceed the permitted number of floors and the height in metres as indicated on the approved drawings.
- j) There shall be no service pipes, cables or wires visible on the front elevation or on any other elevations of the building which are visible from the street or public space.

3 The conditions imposed and enforced by the Civil Protection Department are at document PA3033/12/35. The architect/applicant are required to contact the Civil Protection Department, throughout all the construction phases of the development hereby approved, to ensure that the development is carried out in conformity with the conditions imposed by the Civil Protection Department].

Where the approved drawings and/or documents are dimensioned, then the declared dimensions shall prevail over the actual size as depicted on the approved drawings and/or documents.

Developers are advised to check the invert level to the sewer main with the Water Services Corporation as they would have to make their own arrangements where a gravity service connection is not possible. In these cases, the architect has to indicate the solutions envisaged and to indicate on the plan what needs to be carried out and obtain approval from WSC. Developers are further reminded that connection of storm water into main sewers is not allowed.

A third party may have the right of appeal against this permission. Any action taken on this permission when such an appeal has been made, or until the time limit for the submission of such an appeal has expired, is undertaken at the risk that this permission may be revoked by the Environment and Planning Review Tribunal or quashed by the Court of Appeal.

If the declaration of ownership, as contained in the application form, is determined as incorrect by a Court of Law, then the said Court of Law can declare this development permission as null and void. This development permission does not remove or replace the need to obtain the consent of the land/building owner to this development before it is carried out. Furthermore, it does not imply that consent will necessarily be forthcoming nor does it bind the land/building owner to agree to this development. Where the land/building is owned or administered by the Government of Malta a specific clearance and agreement must be obtained for this development from the Land and/or Estate Management Departments.

This development permission is granted saving third party rights. This permission does not exonerate the applicant from obtaining any other necessary permission, license, clearance or approval required from any Government department, local council, agency or authority (including MEPA), as required by any law or regulation.

This development permit does not authorise any storage of substances listed in Occupational Health and Safety Authority Act (Cap. 424) - Control of Major Accident Hazards Regulations, 2003, as amended, in quantities that would render this site an establishment within scope of these regulations.

The storage and handling of said substances may require a new or amended development permission in line with current policies and regulations.

For any non-residential uses hereby being approved, prior to commencement of any works on site or any eventual permitted change of use, the applicant shall be required to contact the Environment Protection Directorate (within MEPA) to obtain any necessary operational permit or registration. This requirement does not apply to Class 4, 5, 7 and 8 uses as listed in the Development Planning (Use Classes) Order (1994), or its subsequent amendments.

This decision is being published on 6 July 2013.



David Cassar
f/Head EPC Secretariat
Environment and Planning Commission

[PADCNCopy]

Sterling Chemicals Malta Attn: Mr Roberto Tumbiolo

Date: 23 November 2020
Our Ref: PA/08089/19

Application Number: PA/08089/19
 Application Type: Full development permission
 Date Received: 6 September 2019
 Approved Documents: PA 8089/19/1A - Site Plan
 PA 8089/19/1M - Level 1
 PA 8089/19/1O - Level 3 Intermediate
 PA 8089/19/1Q - Elevations 1/2/3
 PA 8089/19/1R - Elevations 4/5/8
 PA 8089/19/1S - Elevations 6/7
 PA 8089/19/1T - Sections A/B/C/F
 PA 8089/19/1U - Sections D/E
 PA 8089/19/1X - Level 3
 PA 8089/19/85C - Roof Plan
 PA 8089/19/120E - Level 0
 PA 8089/19/120F - Level 2; and

 PA 8089/19/24A-E - Fire Safety Report
 PA 8089/19/54A - Environmental Health Directorate (EHD)
 PA 8089/19/64B - Fire Safety Report (Addendum)
 PA 8089/19/80C - Environment and Resources Authority (ERA)
 PA 8089/19/86C - Medicines Authority
 PA 8089/19/110A - Water Services Corporation(WSC)
 PA 8089/19/120B - Ventilation and Light Report
 PA 8089/19/152A - Enemalta
 PA 8089/19/131B - Accessibility Audit Report

Location: Sterling Chemicals Malta, HF 53, Qasam Industrijali Hal-Far, Birzebbuga

Proposal: To sanction changes from approved permits PA04236/08, DN/01094/18, DN00624/16, including the increase in overall height; to change use approved in DN/01094/18 from general manufacturing (Class 5B) to production of Active Pharmaceutical Ingredients (API); to replace parking layout approved in PA03638/18 with waste containment area and including changes to landscaping; changes to boundary wall and access gates and extension of external warehouses.”

Development Planning Act, 2016
Full Development Permission

The Planning Authority hereby grants development permission in accordance with the application and documents described above, subject to the following conditions:

1 **Standard Conditions:**

- a) This development permission is valid for a period of FIVE YEARS from the date of publication of the decision in the press but will cease to be valid if the development is not completed by the end of this validity period.
- b) This permission relates only to the development as specifically indicated on the approved drawings. This permission does not sanction any other illegal development that may exist on the site.
- c) A Commencement Notice is to be submitted to the Planning Authority, by the permit holder on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, **if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised** - Article 72(4) of the Development Planning Act (2016).
- d) Copies of all approved drawings and documents shall be available for inspection on site by Planning Authority officers at all reasonable times.
- e) The development shall be carried out in complete accordance with the approved drawings, documents and conditions of this permission. Where a matter is not specified, then the conditions of this permission and of Development Control Design Policy, Guidance and Standards 2015 shall apply.
- f) Before any part of the development hereby permitted commences, the enclosed green copy of this development permission shall be displayed on the site. This must be mounted on a notice board, suitably protected from the weather and located not more than 2 metres above ground level at a point on the site boundary where it is clearly visible and can be easily read from the street. The copy of the permission must be maintained in a good condition and it shall remain displayed on the site until the works are completed.
- g) All building works shall be erected in accordance with the official alignment and official/existing finished road levels as set out on site by the Planning Authority's Land Surveyor. A Setting Out Request must be submitted to the Land Survey Unit of the Planning Authority, prior to the commencement of works on site, when the setting out of the alignment and levels is required.
- h) Where an officially schemed street, within the development zone, bordering the site is unopened or unformed, it shall be opened up and brought up to its proper, approved and official formation levels prior to the commencement of any development hereby being permitted.
- i) It is the responsibility of the permit holder to ensure that development is carried out in accordance with the provisions of the Environmental Management Construction Site Regulations, Legal Notice 295 of 2007 (or subsequent amendments). Any hoarding shall be erected in accordance with Schedule 2 of the same Regulations.

j) New development on vacant or redeveloped sites shall be provided with a water cistern to store rainwater run-off as required by the Energy Performance of Buildings Regulations (2012) [published through Legal Notice 376 of 2012 and any amendments thereto].

k) No steps, ramps or street furniture are to be constructed on or encroached onto the public pavement or road.

l) Any doors and windows, the lower edge of which is less than 2m above road level, and any gates shall not open outwards onto a public pavement or road.

m) Where present, window grilles (including 'pregnant' windows), sills, planters and other similar elements which are part of or fixed to the facade of buildings, the lower edge of which is less than 2 metres above road level, shall not project more than 0.15 metres from the facade over a public pavement or street.

n) Air conditioning units shall not be located on the facades of the building which are visible from the street or a public space.

o) There shall be no service pipes, cables or wires visible on the front elevation or on any other elevations of the building which are visible from the street or public space.

p) Any garages/parking spaces shall only be used for the parking of private cars and shall be kept available at all times for this purpose.

q) Any approved stores shall be used for domestic storage only and shall not be segregated from the rest of the building.

r) Any unit approved on more than one floor (duplex or more) shall remain physically interconnected as a single unit, and shall not be sub-divided into separate units without specific Planning Authority consent.

2 **Loading and unloading:**

Where a loading bay is indicated on the approved drawings, loading and unloading shall take place solely within the premises, and not from/on the public pavement or street.

3 **Condition by external agencies:**

The conditions imposed and enforced by the:

- Environmental Health Directorate (EHD) as per PA 8089/19/54A,
- Environment and Resources Authority (ERA) as per PA 8089/19/80C,
- Medicines Authority as per PA 8089/19/86C,
- Water Services Corporation (WSC) as per PA 8089/19/110A, and
- Enemalta as per PA 8089/19/152A.

The architect/applicant is required to contact the above throughout the implementation of the development hereby approved, to ensure conformity with the imposed conditions. A copy of the relative correspondence issued by the above Authorities / Departments shall be submitted to the Planning Authority accordingly.

4 **Final Compliance Certification:**

The development hereby permitted shall be subject to Final Compliance (Completion) Certification, verifying that the development has been carried out in full accordance with the approved drawings, documents and conditions imposed in this development permission, except where such conditions are enforced by other entities. Prior to the issue of any compliance certificate on any part of this development, the applicant shall submit to the Planning Authority, in relation to that part of the building:

(i) clearance from the Commission for the Rights of Persons with Disability verifying that the development fully satisfies the accessibility standards and/or any conditions imposed by the Commission in supporting document PA 8089/19/131B.

Note: Should a partial compliance certificate be requested, a Bank Guarantee of EUR 25,000 shall apply to ensure that CRPD clearance is obtained

(ii) certification from a qualified engineer confirming that the development fully satisfies the requirements specified in supporting documents PA 8089/19/24A-E - *Fire Safety Report*, PA 8089/19/64B - *Fire Safety Report (Addendum)* and PA 8089/19/120B - *Ventilation and Light Report*.

5 **Conditions imposed and enforced by other entities:**

A. Where construction activity is involved:

(a) the applicant shall:

(i) **Appoint a Project Supervisor for the Design Stage and a Project Supervisor for the Construction Stage** and any such appointment shall be terminated, changed or renewed as necessary. The same person may be appointed to act as project supervisor for both the design and construction stage, if that person is competent to undertake the duties involved and

(ii) **Keep a health and safety file** prepared by the Project Supervisor for the Design Stage.

(b) When the construction works related to this application are scheduled to last longer than thirty working days and on which more than twenty workers are occupied simultaneously, or on which the volume of work is scheduled to exceed five hundred person-days, the project supervisor **shall communicate a prior notice to the Occupational Health and Safety Authority (OHSA) at least four calendar weeks before commencement of works.**

(c) The Project Supervisor for the Design Stage shall **draw up a health and safety plan** which sets out the occupational health and safety rules applicable to the construction activities concerned, outlining the measures to ensure cooperation between different contractors and shall also include specific measures concerning occupational risks that may be present at this site.

B. Where the development concerns a change of use to a place of work, the applicant shall obtain a Perit's declaration that the building conforms to the requirements of LN 44 of 2002.

C. Where the development concerns a place of work:

The applicant shall:

- (i) obtain a Perit's declaration that the necessary requirements arising out of LN 44 of 2002 have been included in the plans and drawings; and
- (ii) obtain a Perit's declaration that the building conforms to the requirements of LN 44 of 2002.

D. The development is to strictly adhere to the 'Design Guidelines on fire safety for buildings in Malta' to ensure that all Fire Safety measures and provisions are addressed as indicated in the Design Guidelines on Fire Safety for Buildings in Malta, published by the DCID in 2004, (or other relevant standard, provided it is approved by the Civil Protection Department), Policies, and the Laws and Regulations of Malta.

E. Prior to laying of water and wastewater services in the road, the development shall comply with the requirements of Legal Notice 29/10 Part III (Roads in inhabited Areas) Clause 12.

F. In the event of an accidental discovery in the course of approved works, any cultural heritage feature discovered should not be damaged or disturbed and the Superintendence is to be immediately informed of such discovery. Any cultural heritage features discovered are to be investigated, evaluated and protected in line with the Cultural Heritage Act 2019 (CAP 445). The discovery of cultural heritage features may require the amendment of approved plans.

G. For new development, the following condition, imposed and enforced by Enemalta, applies:

A culvert measuring 0.8m wide by 0.75m deep should be prepared along the façade of the development in order that any overhead lines may be substituted by underground cables. The culvert is to be interconnected to an adequate space consisting of a **small room or recess** located near the **entrance**, provided for the purpose of housing the electricity meter. Another adequate space for the purpose of housing the electricity meters, consisting of a **small room or recess** located in the basement near the **entrance**, also interconnected to the culvert, is to be provided. The architect/applicant is required to contact Enemalta, throughout the implementation of the development hereby approved, to ensure conformity with the imposed conditions. A copy of the relative correspondence issued by Enemalta shall be submitted to the Planning Authority accordingly.

In terms of Article 72(3) of the Development Planning Act, 2016, the execution and validity of this permission is automatically temporarily **suspended** and no works as approved by the said development permission may commence before the lapse of the time period established in Article 13 of the Environment and Planning Review Tribunal Act and subsequently will remain so suspended if the Tribunal so decides in accordance with the Environment and Planning Review Tribunal Act.

Where the approved drawings and/or documents are dimensioned, then the declared dimensions shall prevail over the actual size as depicted on the approved drawings and/or documents.

Developers are advised to check the invert level to the sewer main with the Water Services Corporation as they would have to make their own arrangements where a gravity service connection is not possible. In these cases, the architect has to indicate the solutions envisaged and to indicate on the plan what needs to be carried out and obtain approval from WSC. Developers are further reminded that connection of storm water into main sewers is not allowed.

PA/08089/19

If the declaration of ownership, as contained in the application form, is determined as incorrect by a Court of Law, then the said Court of Law can declare this development permission as null and void. This development permission does not remove or replace the need to obtain the consent of the land/building owner to this development before it is carried out. Furthermore, it does not imply that consent will necessarily be forthcoming nor does it bind the land/building owner to agree to this development. Where the land/building is owned or administered by the Government of Malta a specific clearance and agreement must be obtained for this development from the Land and/or Estate Management Departments.

This development permission is granted saving third party rights. This permission does not exonerate the applicant from obtaining any other necessary permission, license, clearance or approval required from any Government department, local council, agency or authority, as required by any law or regulation.

This development permit does not authorise any storage of substances listed in Occupational Health and Safety Authority Act (Cap. 424) - Control of Major Accident Hazards Regulations, 2003, as amended, in quantities that would render this site an establishment within scope of these regulations. The storage and handling of said substances may require a new or amended development permission in line with current policies and regulations.

For any non-residential uses hereby being approved, prior to commencement of any works on site or any eventual permitted change of use, the applicant shall be required to contact the Environment and Resources Authority to obtain any necessary operational permit or registration. This requirement does not apply to Class 2B, 2C, 4A and 4B uses as listed in the Development Planning (Use Classes) Order 2014, or its subsequent amendments.

This decision is being published on 25 November 2020.

Yoanne Muscat
Board Secretary
Planning Board

Notes to Applicant and Perit

Right for reconsideration

Where applicable, you have a right to submit a request for reconsideration to the Authority in terms of regulation 14 of Legal Notice 162 of 2016.

Right for appeal

You have a right to submit an appeal, against the decision, to the Environment and Planning Review Tribunal in terms of Article 13 of the Environment and Planning Review Tribunal Act, 2016.

Time limits

Requests for reconsideration or appeals must be made within 30 days from the publication of the decision notification in the local press as required by regulation 14(1) of Legal Notice 162 of 2016.

Fees to submit a request for reconsideration or appeal

In either case, there is a fee to be paid which should accompany the request for reconsideration or the appeal. The fees are as follows:

For reconsideration - 3% of the Development Permit Fee paid in respect of the original application, subject to a minimum of €69.88.

For appeal - 5% of DPF (Development Permit Fee) paid in respect of the original application, subject to a minimum of €150 + €50 administrative fee (LN 112 of 2016).

Submission of request for reconsideration or appeal

With regards to requests for reconsideration, Form PA 4/16 must be used for submission. All fields of the Form must be filled in as appropriate. Requests for reconsideration can only be submitted electronically.

With regards to appeals, as required by Article 13 of the Environment and Planning Review Tribunal Act, 2016, the submission must include the detailed grounds for appeal and the requests being made by the appellant. Appeals must be submitted physically at the offices of the Environment and Planning Review Tribunal, St. Francis Ditch, Floriana.

Important Notice

In view of the provisions of Article 72(4) of the Development Planning Act (2016), a Commencement Notice is to be submitted to the Planning Authority, by the perit on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised.

-PADCN-



Perit Wallace Farrugia
No. 44, Apartment 3
St. Francis Street

Date : 16 September 2016
Your Ref : 165/15

Sliema SLM 2069

Dear Sir/Madam,

Notification Number: DN 00624/16
Proposal: Extension to factory.
Location: Factory HF 51, Qasam Industrijali, Birzebbugia, Malta

Permitted Development by the Development Notification Order, 2007.

We refer to your notification of intent to undertake the above mentioned works, validated on 7 April 2016.

In accordance with the Development Notification Order, 2007, the development as endorsed on the attached drawings and site plan **DN0624/16/1B/5B/5C/5D/5E/5F/5G/5H doc. 5A (KNPD Accessibility Audit Report), doc. 5i (Civil Protection Dept. Report) and doc. 5J (Fire Safety & Ventilation Report)** is permitted under the following class:

16(i) The construction, re-development, alteration or extension of an industrial unit.

This clearance is granted in relation to the proposed development **ONLY** as indicated in conventional colours on plans and **does not** cover any other development whether shown or not shown on plans, **does not** cover any CTB concession and **does not** sanction any illegal development which may exist on site, even if shown on plans.

This written notification is limited to the development as shown on the submitted plans and is issued without prejudice to sub-article 55(7) of the Development Planning Act, 2016.

This written notification is valid for a period of 12 Months from 14 September 2016 to 14 September 2017, but is rendered null in the event that the development is subsequently modified, extended or relocated in a manner which would result in the limitations set out in the Development Notification Order being exceeded.

The written notification is granted saving third party rights. This notification does not exonerate the applicant from obtaining any other necessary permission, license, clearance or approval required from any Government department, local council, agency or authority, as required by any law or regulation, including an environmental permit from the Planning Authority for the operation of the permitted development.

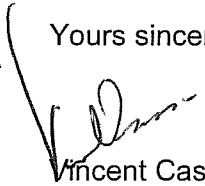
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A Commencement Notice is to be submitted to the Planning Authority, by the *perit* on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, **if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised** - Article 72(4) of the Development Planning Act (2016).

Where applicable, the development, hereby notified, shall be carried out in accordance with the provisions of the Environmental Management Construction Site Regulations, LN 295 of 2007.

If the declaration of ownership, as contained in the application form, is determined as incorrect by an Administrative Tribunal or by a Court of Law, then the said notification and its effects shall be considered as null and void.

Yours sincerely,



Vincent Cassar
Chairman
Planning Board



Perit Wallace Farrugia
No. 44, Apartment 3
St. Francis Street

Date : 25 January 2017
Your Ref : 128/16

Sliema SLM 2069

Dear Sir/Madam,

Notification Number: DN 00023/17
Proposal: Extension to external area and carpark.
Location: Sterling Chemicals Ltd., Factory HF50, Qasam Industrijali, Birzebbugia, Malta

Permitted Development by the Development Notification Order, 2016.

We refer to your notification of intent to undertake the above mentioned works, validated on 17 January 2017.

In accordance with the Development Notification Order, 2016, the development as endorsed on the attached drawings and site plan **DN00023/17/1A/1B/1C doc. 1D (CRPD Accessibility Audit Report)**

is permitted under the following class:

16(i) The construction, re-development, alteration or extension of an industrial unit.

This clearance is granted in relation to the proposed development **ONLY** as indicated in conventional colours on plans and **does not** cover any other development whether shown or not shown on plans, **does not** cover any CTB concession and **does not** sanction any illegal development which may exist on site, even if shown on plans.

This written notification is limited to the development as shown on the submitted plans and is issued without prejudice to sub-article 55(7) of the Development Planning Act, 2016.

This written notification is valid for a period of 12 Months from 25 January 2017 to 25 January 2018, but is rendered null in the event that the development is subsequently modified, extended or relocated in a manner which would result in the limitations set out in the Development Notification Order being exceeded.

The written notification is granted saving third party rights. This notification does not exonerate the applicant from obtaining any other necessary permission, license, clearance or approval required from any Government department, local council, agency or authority, as required by any law or regulation, including an environmental permit from the Planning Authority for the operation of the permitted development.

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A Commencement Notice is to be submitted to the Planning Authority, by the *perit* on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, **if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised** - Article 72(4) of the Development Planning Act (2016).

Where applicable, the development, hereby notified, shall be carried out in accordance with the provisions of the Environmental Management Construction Site Regulations, LN 295 of 2007.

If the declaration of ownership, as contained in the application form, is determined as incorrect by an Administrative Tribunal or by a Court of Law, then the said notification and its effects shall be considered as null and void.

Yours sincerely,



Vincent Cassar
Chairman
Planning Board

17/4/16
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PLANNING AUTHORITY

Perit Wallace Farrugia
No. 44, Apartment 3
St. Francis Street

Date : 18 July 2017
Your Ref : 174/16

Sliema SLM 2069

Dear Sir/Madam,

Notification Number: DN 00617/17
Proposal: Extension to offices.
Location: Sterling Chemicals Ltd., Factory HF51, Qasam Industrijali, Birzebbugia, Malta

Permitted Development by the Development Notification Order, 2016.

We refer to your notification of intent to undertake the above mentioned works, validated on 13 July 2017.

In accordance with the Development Notification Order, 2016, the development as endorsed on the attached drawings and site plan **DN617/1A/1C/1E doc. 1F (Fire Safety & Ventilation Report) doc.1G (Civil Protection Dept Report) doc. 1H (CRPD Accessibility Audit Report)** is permitted under the following class:

16(i) The construction, re-development, alteration or extension of an industrial unit.

This clearance is granted in relation to the proposed development **ONLY** as indicated in conventional colours on plans and does **Not** cover any other works or sanction any illegal development which may exist on site, even if shown on plans.

This written notification is limited to the development as shown on the submitted plans and is issued without prejudice to sub-article 55(7) of the Development Planning Act, 2016.

This written notification is valid for a period of for a period of 12 Months from 18 July 2017 to 18 July 2018, but is rendered null in the event that the development is subsequently modified, extended or relocated in a manner which would result in the limitations set out in the Development Notification Order being exceeded.

The written notification is granted saving third party rights. This notification does not exonerate the applicant from obtaining any other necessary permission, license, clearance or approval required from any Government department, local council, agency or authority, as required by any law or regulation, including an environmental permit from the Planning Authority for the operation of the permitted development.

A Commencement Notice is to be submitted to the Planning Authority, by the *perit* on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, **if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised** - Article 72(4) of the Development Planning Act (2016).

Where applicable, the development, hereby notified, shall be carried out in accordance with the provisions of the Environmental Management Construction Site Regulations, LN 295 of 2007.

If the declaration of ownership, as contained in the application form, is determined as incorrect by an Administrative Tribunal or by a Court of Law, then the said notification and its effects shall be considered as null and void.

Yours sincerely,



Vincent Cassar
Chairman
Planning Board

Malta Industrial Parks Ltd. Attn: Damian Whitehead
Malta Industrial Parks
Guardamangia Hill

Date : 9 October 2017
Our Ref: DN 00810/17

Pieta MEC0001

Dear Sir/Madam,

Notification Number: DN 00810/17
Proposal: Construction of factory.
Location: HF53, Qasam Industrijali, Birzebbugia, Malta

Development Planning Act, 2016
Development Notification Order, 2016.

We refer to your notification of intent to undertake the above mentioned works, validated on 11 September 2017.

In accordance with the Development Notification Order, 2016, the development as endorsed on the attached drawings and site plan **DN810/17/1A/1C/1D/E/1F/1G/1H/1I/1J/ 6A(CRPD Clearance),1M(Civil Protection),1L(Environment & Resources Authority),1N(Fire Safety & Ventilation Report)**

is permitted under the following class:

16(i) The construction, re-development, alteration or extension of an industrial unit.

This clearance is granted in relation to the proposed development **ONLY** as indicated in conventional colours on plans and does **Not** cover any other works or sanction any illegal development which may exist on site, even if shown on plans.

This written notification is limited to the development as shown on the submitted plans and is issued without prejudice to sub-article 55(7) of the Development Planning Act, 2016.

This written notification is valid from 09 October 2017 to 09 October 2018, but is rendered null in the event that the development is subsequently modified, extended or relocated in a manner which would result in the limitations set out in the Development Notification Order being exceeded.

The written notification is granted saving third party rights. This notification does not exonerate the applicant from obtaining any other necessary permission, license, clearance or approval required from any Government department, local council, agency or authority, as required by any law or regulation, including an environmental permit from the Planning Authority for the operation of the permitted development.

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A Commencement Notice is to be submitted to the Planning Authority, by the *perit* on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, **if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised** - Article 72(4) of the Development Planning Act (2016).

Where applicable, the development, hereby notified, shall be carried out in accordance with the provisions of the Environmental Management Construction Site Regulations, LN 295 of 2007.

If the declaration of ownership, as contained in the application form, is determined as incorrect by an Administrative Tribunal or by a Court of Law, then the said notification and its effects shall be considered as null and void.

Important Notice

In view of the provisions of Article 72(4) of the Development Planning Act (2016), a Commencement Notice is to be submitted to the Planning Authority, by the perit on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised.

-DocDNDcnApplicant-

Sterling Chemicals Malta Attn: Mr Roberto Tumbiolo

Date: 7 March 2019
Our Ref: PA/03638/18

Application Number: PA/03638/18
Application Type: Full development permission
Date Received: 23 March 2018
Approved Documents: PA 3638/18/10B/73B/73C/73D/81B
Supporting Documents:
PA 3638/18/42A (WSC conditions);
PA 3638/18/48A (EHD conditions);
PA 3638/18/50A (CRPD conditions);
PA 3638/18/53A (SCH conditions);
PA 3638/18/66B (Engineer's Report);
PA 3638/18/81C (REWS Clearance).

Location: HF 50, HF 51, HF 53, Hal-Far Industrial Estate, Hal Far, Birzebbuga, Malta
Proposal: Removal of existing LPG storage approved in PA/03033/12, and installation of new 25,000 Litre LPG storage tank, including all required ancillary equipment and pipework, minor amendments to parking area layout and construction of new boundary wall.

Development Planning Act, 2016 Full Development Permission

The Planning Authority hereby grants development permission in accordance with the application and documents described above, subject to the following conditions:

- 1 a) This development permission is valid for a period of FIVE YEARS from the date of publication of the decision in the press but will cease to be valid if the development is not completed by the end of this validity period.

b) This permission relates only to the development as specifically indicated on the approved drawings. This permission does not sanction any other illegal development that may exist on the site.

c) A Commencement Notice is to be submitted to the Planning Authority, by the perit on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall

invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, **if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised** - Article 72(4) of the Development Planning Act (2016).

d) Copies of all approved drawings and documents shall be available for inspection on site by Planning Authority officers at all reasonable times.

e) The development shall be carried out in complete accordance with the approved drawings, documents and conditions of this permission. Where a matter is not specified, then the conditions of this permission and of Development Control Design Policy, Guidance and Standards 2015 shall apply.

f) Before any part of the development hereby permitted commences, the enclosed green copy of this development permission shall be displayed on the site. This must be mounted on a notice board, suitably protected from the weather and located not more than 2 metres above ground level at a point on the site boundary where it is clearly visible and can be easily read from the street. The copy of the permission must be maintained in a good condition and it shall remain displayed on the site until the works are completed.

g) All building works shall be erected in accordance with the official alignment and official/existing finished road levels as set out on site by the Planning Authority's Land Surveyor. The Setting Out Request Notice must be submitted to the Land Survey Unit of the Planning Authority when the setting out of the alignment and levels is required.

h) It is the responsibility of the permit holder to ensure that development is carried out in accordance with the provisions of the Environmental Management Construction Site Regulations, Legal Notice 295 of 2007 (or subsequent amendments). Any hoarding shall be erected in accordance with Schedule 2 of the same Regulations.

i) No steps, ramps or street furniture are to be constructed on or encroached onto the public pavement or road.

j) Any doors and windows, the lower edge of which is less than 2m above road level, and any gates shall not open outwards onto a public pavement or road.

k) There shall be no service pipes, cables or wires visible on the front elevation or on any other elevations of the building which are visible from the street or public space.

l) Any parking spaces shall only be used for the parking of private cars and shall be kept available at all times for this purpose.

- 2 The development hereby permitted shall be subject to Final Compliance (Completion) Certification, verifying that the development has been carried out in full accordance with the approved drawings, documents and conditions imposed in this development permission, except where such conditions are enforced by other entities. Prior to the issue

of any compliance certificate on any part of this development, the applicant shall submit to Planning Authority, in relation to that part of the building:

- (i) Certification from a qualified engineer confirming that the development fully satisfies the requirements specified in supporting document PA 3638/18/66B

- 3 The conditions imposed and enforced by the Environmental Health Directorate are at supporting document PA/3638/18/48A. The architect / applicant is required to contact the Environmental Health Directorate, throughout the implementation of the development hereby approved, to ensure conformity with the imposed conditions. A copy of the relative correspondence issued by the Environmental Health Directorate shall be submitted to the Planning Authority accordingly.
- 4 The conditions imposed and enforced by the Commission for the Rights of Persons with Disability are at supporting document PA/3638/18/50A. The architect / applicant is required to contact the Commission for the Rights of Persons with Disability, throughout the implementation of the development hereby approved, to ensure conformity with the imposed conditions. A copy of the relative correspondence issued by the Commission for the Rights of Persons with Disability shall be submitted to the Planning Authority accordingly.
- 5 The conditions imposed and enforced by the Superintendence for Cultural Heritage are at supporting document PA/3638/18/53A. The architect / applicant is required to contact the Superintendence for Cultural Heritage, throughout the implementation of the development hereby approved, to ensure conformity with the imposed conditions. A copy of the relative correspondence issued by the Superintendence for Cultural Heritage shall be submitted to the Planning Authority accordingly.
- 6 The conditions imposed and enforced by the Regulator for Energy and Water Services (REWS) are at supporting document PA/3638/18/81C. The architect / applicant is required to contact the Regulator for Energy and Water Services, throughout the implementation of the development hereby approved, to ensure conformity with the imposed conditions. A copy of the relative correspondence issued by the Regulator for Energy and Water Services shall be submitted to the Planning Authority accordingly.
- 7 The operational changes to the site approved by the development permit shall not commence until such time that the variation / renewal of the Environmental Registration / Environmental Permit is issued by ERA.

8 **Conditions imposed and enforced by other entities**

A. Where construction activity is involved:

(a) the applicant shall:

- (i) **Appoint a Project Supervisor for the Design Stage and a Project Supervisor for the Construction Stage** and any such appointment shall be terminated, changed or renewed as necessary. The same person may be appointed to act as project supervisor

for both the design and construction stage, if that person is competent to undertake the duties involved and

(ii) **Keep a health and safety file** prepared by the Project Supervisor for the Design Stage.

(b) When the construction works related to this application are scheduled to last longer than thirty working days and on which more than twenty workers are occupied simultaneously, or on which the volume of work is scheduled to exceed five hundred person-days, the project supervisor **shall communicate a prior notice to the Occupational Health and Safety Authority (OHSA) at least four calendar weeks before commencement of works.**

(c) The Project Supervisor for the Design Stage shall **draw up a health and safety plan** which sets out the occupational health and safety rules applicable to the construction activities concerned, outlining the measures to ensure cooperation between different contractors and shall also include specific measures concerning occupational risks that may be present at this site.

B. Where the development concerns a place of work:

The applicant shall:

(i) obtain a Perit's declaration that the necessary requirements arising out of LN 44 of 2002 have been included in the plans and drawings; and

(ii) obtain a Perit's declaration that the building conforms to the requirements of LN 44 of 2002.

C. The development is to strictly adhere to the 'Design Guidelines on fire safety for buildings in Malta' to ensure that all Fire Safety measures and provisions are addressed as indicated in the Design Guidelines on Fire Safety for Buildings in Malta, published by the DCID in 2004, (or other relevant standard, provided it is approved by the Civil Protection Department), Policies, and the Laws and Regulations of Malta.

D. In the event of an accidental discovery in the course of approved works, any cultural heritage feature discovered should not be damaged or disturbed and the Superintendence is to be immediately informed of such discovery. Any cultural heritage features discovered are to be investigated, evaluated and protected in line with the Cultural Heritage Act 2002 (CAP 445). The discovery of cultural heritage features may require the amendment of approved plans.

In terms of Article 72(3) of the Development Planning Act, 2016, the execution and validity of this permission is automatically temporarily **suspended** and no works as approved by the said development permission may commence before the lapse of the time period established in Article 13 of the Environment and Planning Review Tribunal Act and subsequently will remain so suspended if the Tribunal so decides in accordance with the Environment and Planning Review Tribunal Act.

Where the approved drawings and/or documents are dimensioned, then the declared dimensions shall prevail over the actual size as depicted on the approved drawings and/or documents.

Developers are advised to check the invert level to the sewer main with the Water Services Corporation as they would have to make their own arrangements where a gravity service connection is not possible. In these cases, the architect has to indicate the solutions envisaged and to indicate on the plan what needs to be carried out and obtain approval from WSC. Developers are further reminded that connection of storm water into main sewers is not allowed.

If the declaration of ownership, as contained in the application form, is determined as incorrect by a Court of Law, then the said Court of Law can declare this development permission as null and void. This development permission does not remove or replace the need to obtain the consent of the land/building owner to this development before it is carried out. Furthermore, it does not imply that consent will necessarily be forthcoming nor does it bind the land/building owner to agree to this development. Where the land/building is owned or administered by the Government of Malta a specific clearance and agreement must be obtained for this development from the Land and/or Estate Management Departments.

This development permission is granted saving third party rights. This permission does not exonerate the applicant from obtaining any other necessary permission, license, clearance or approval required from any Government department, local council, agency or authority, as required by any law or regulation.

This development permit does not authorise any storage of substances listed in Occupational Health and Safety Authority Act (Cap. 424) - Control of Major Accident Hazards Regulations, 2003, as amended, in quantities that would render this site an establishment within scope of these regulations. The storage and handling of said substances may require a new or amended development permission in line with current policies and regulations.

For any non-residential uses hereby being approved, prior to commencement of any works on site or any eventual permitted change of use, the applicant shall be required to contact the Environment and Resources Authority to obtain any necessary operational permit or registration. This requirement does not apply to Class 2B, 2C, 4A and 4B uses as listed in the Development Planning (Use Classes) Order 2014, or its subsequent amendments.

This decision is being published on 20 March 2019.

Marthese Debono
Secretary Planning Commission
Within Development Scheme

Notes to Applicant and Perit

Right for reconsideration

Where applicable, you have a right to submit a request for reconsideration to the Authority in terms of regulation 14 of Legal Notice 162 of 2016.

Right for appeal

You have a right to submit an appeal, against the decision, to the Environment and Planning Review Tribunal in terms of Article 13 of the Environment and Planning Review Tribunal Act, 2016.

Time limits

Requests for reconsideration or appeals must be made within 30 days from the publication of the decision notification in the local press as required by regulation 14(1) of Legal Notice 162 of 2016.

Fees to submit a request for reconsideration or appeal

In either case, there is a fee to be paid which should accompany the request for reconsideration or the appeal. The fees are as follows:

For reconsideration - 3% of the Development Permit Fee paid in respect of the original application, subject to a minimum of €69.88.

For appeal - 5% of DPF (Development Permit Fee) paid in respect of the original application, subject to a minimum of €150 + €50 administrative fee (LN 112 of 2016).

Submission of request for reconsideration or appeal

With regards to requests for reconsideration, Form PA 4/16 must be used for submission. All fields of the Form must be filled in as appropriate. Requests for reconsideration can only be submitted electronically.

With regards to appeals, as required by Article 13 of the Environment and Planning Review Tribunal Act, 2016, the submission must include the detailed grounds for appeal and the requests being made by the appellant. Appeals must be submitted physically at the offices of the Environment and Planning Review Tribunal, St. Francis Ditch, Floriana.

Important Notice

In view of the provisions of Article 72(4) of the Development Planning Act (2016), a Commencement Notice is to be submitted to the Planning Authority, by the perit on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised.

-PADCN-

Sterling Chemicals Malta Attn: Roberto Tumbiolo

Date : 12 November 2018
Our Ref: DN 01094/18

Dear Sir/Madam,

Notification Number: DN 01094/18
Proposal: Construction of factory
Location: HF53, Qasam Industrijali Hal-Far, Birzebbugia, Malta

Development Planning Act, 2016
Development Notification Order, 2016.

We refer to your notification of intent to undertake the above mentioned works, validated on 16 October 2018.

In accordance with the Development Notification Order, 2016, the development as endorsed on the attached drawings and site plan **DN001094/18/1A/5A/5B/5C/5D/5F/G/5H/5I/5J**

DO NOT PRINT - For ease of reference only:-
doc.1L (CPD)
doc.1M (Fire Safety and Ventilation Report)
doc.1N (CRPD clearance letter)
doc. 7B (Malta Industrial Parks clearance letter)
is permitted under the following class:

16(i) The construction, re-development, alteration or extension of an industrial unit.

This clearance is granted in relation to the proposed development **ONLY** as indicated on plans in conventional colors and does **Not** cover any other works or sanction any illegal development which may exist on site, even if shown on plans.

written notification is limited to the development as shown on the submitted plans and is issued without prejudice to sub-article 55(7) of the Development Planning Act, 2016.

This written notification is valid from 12 November 2018 to 12 November 2019, but is rendered null in the event that the development is subsequently modified, extended or relocated in a manner which would result in the limitations set out in the Development Notification Order being exceeded.

The written notification is granted saving third party rights. This notification does not exonerate the applicant from obtaining any other necessary permission, license, clearance or approval required from any Government department, local council, agency or authority, as required by any law or

-

regulation, including an environmental permit from the Planning Authority for the operation of the permitted development.

A Commencement Notice is to be submitted to the Planning Authority, by the *perit* on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, **if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised** - Article 72(4) of the Development Planning Act (2016).

Where applicable, the development, hereby notified, shall be carried out in accordance with the provisions of the Environmental Management Construction Site Regulations, LN 295 of 2007.

If the declaration of ownership, as contained in the application form, is determined as incorrect by an Administrative Tribunal or by a Court of Law, then the said notification and its effects shall be considered as null and void.

Perit Vincent Cassar
Chairman Planning Baord

c.c.: Perit Wallace Farrugia

Important Notice

In view of the provisions of Article 72(4) of the Development Planning Act (2016), a Commencement Notice is to be submitted to the Planning Authority, by the perit on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised.

-DocDNDcnApplicant-

Sterling Chemicals Malta Attn: Roberto Tumbiolo

Date : 13 April 2020
Our Ref: DN 00259/20

Dear Sir/Madam,

Notification Number: DN 00259/20
Proposal: Construction of external stores and security room, and alterations to boundary wall and site entrance.
Location: HF50 & HF51, Qasam Industrijali Hal-Far, Birzebbuga

Development Planning Act, 2016
Development Notification Order, 2016.

We refer to your notification of intent to undertake the above mentioned works, validated on 11 March 2020.

In accordance with the Development Notification Order, 2016, the development as endorsed on the attached drawings and site plan **DN00259/20/1a/1d/1e/1g/1i doc.1i (Engineer's Report), doc.1k(Civil Protection Dept Report), doc.1j (CRPD) & docs. 10a (Malta Industrial Parks)** is permitted under the following class:

16(i) The construction, re-development, alteration or extension of an industrial unit.

This clearance is granted in relation to the proposed development **ONLY** as indicated on plans in conventional colors and does **Not** cover any other works or sanction any illegal development which may exist on site, even if shown on plans.

This written notification is limited to the development as shown on the submitted plans and is issued without prejudice to sub-article 55(7) of the Development Planning Act, 2016.

This written notification is valid from 13 April 2020 to 13 April 2021, but is rendered null in the event that the development is subsequently modified, extended or relocated in a manner which would result in the limitations set out in the Development Notification Order being exceeded.

The written notification is granted saving third party rights. This notification does not exonerate the applicant from obtaining any other necessary permission, license, clearance or approval required from any Government department, local council, agency or authority, as required by any law or regulation, including an environmental permit from the Planning Authority for the operation of the permitted development.

-

A Commencement Notice is to be submitted to the Planning Authority, by the *perit* on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, **if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised** - Article 72(4) of the Development Planning Act (2016).

Where applicable, the development, hereby notified, shall be carried out in accordance with the provisions of the Environmental Management Construction Site Regulations, LN 295 of 2007.

If the declaration of ownership, as contained in the application form, is determined as incorrect by an Administrative Tribunal or by a Court of Law, then the said notification and its effects shall be considered as null and void.

Vincent Cassar

Chairman Planning Baord

c.c.: Perit Wallace Farrugia

Important Notice

In view of the provisions of Article 72(4) of the Development Planning Act (2016), a Commencement Notice is to be submitted to the Planning Authority, by the perit on behalf of the applicant, at least FIVE DAYS prior to the date of commencement of works or utilisation of the permission. Failure to submit the Commencement Notice (with all fields correctly completed) or failure to submit it within the required timeframe shall invalidate the Notice and shall result in the imposition of fines according to Schedule D of Legal Notice 277 of 2012, or its amendments, or its replacements. In addition, if the applicant fails to submit the Commencement Notice or the Commencement Notice submitted is invalid, the relative permission shall be considered as never having been utilised.

-DocDNDcnApplicant-

15th June 2020
MR. ROBERTO TUMBILO
STERLING CHEMICALS MALTA LTD
HF 51, HAL-FAR INDUSTRIAL ESTATE,
HAL-FAR

Dear Mr. Tumbiolo,

Re: Issue of Public Sewer Discharge Permit

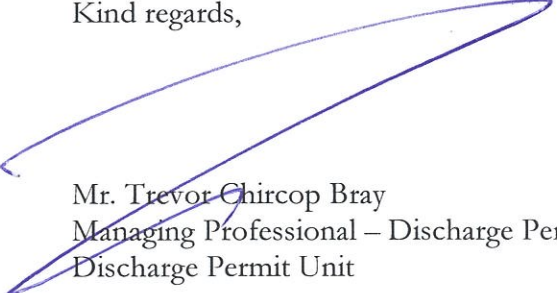
With reference to the above, please find enclosed the Public Sewer Discharge Permit for **STERLING CHEMICALS MALTA LTD.**

Permit is valid for one year.

We kindly appreciate that for next year's renewal, you call at our offices one month prior to the expiry date. A fresh data analysis will once more be required.

If you have any queries, please do not hesitate to inform us.

Kind regards,



Mr. Trevor Chircop Bray
Managing Professional – Discharge Permitting
Discharge Permit Unit

PUBLIC SEWER DISCHARGE PERMIT

<p>SUBJECT</p> <p>STERLING CHEMICALS MALTA LTD HF 51, HAL-FAR INDUSTRIAL ESTATE, HAL-FAR</p>
--

<p>OUR REFERENCE: DMU 6745</p> <p>YOUR REFERENCE:</p>	<p>ACTIVITY: PHARMACEUTICAL FACTORY</p>
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To whom it may concern

Applicant, **Mr. Roberto Tumbiolo** has submitted an application to discharge trade effluent into the Public Sewer in terms of S.L. 545.08.

This application has been accepted and the necessary permit is hereby being issued to the applicant for the discharge from the following trade effluent source/s: (i) Softener reject excluding regeneration of catalyst.

Permit is valid for one (1) year from date of issue.

Mr. Trevor Chircop Bray
Managing Professional – Discharge Permitting
Discharge Permit Unit

15 June 2020

Conditions printed overleaf

Conditions for Permit

The Water Services Corporation would have no objection to this application provided that S.L. 545.08 is adhered, in particular (but without prejudice to all other sections of the regulation):

1. Applicant shall not discharge any prohibited effluent (directly or indirectly) into the public sewerage system.
2. Applicant shall not discharge (directly or indirectly) into the public sewer any effluent containing material which alone, or in combination with the contents of the sewer, is likely:
 - ❑ To damage the sewage system, including pipe work, sumps and equipment, or block, cause overflows or in any other way interfere with the free flow of the contents of the sewer.
 - ❑ To constitute a health hazard to sewer maintenance personnel by emission of flammable, explosive, toxic, irritating or asphyxiating gases or vapours. Such material includes; volatile organic compounds (including solvents) and substances rich in sulphur and sulphur containing compounds.
 - ❑ To interfere with treatment and recovery of liquid and solid waste. Such material includes: substances that create a high oxygen demand, non-biodegradable organic matter, surfactants, salts and biocides, nitrification inhibitors, heavy metals, boron and other substances which render the recovered material unfit for re-use.
 - ❑ To bring about adverse aesthetic or other objectionable effects on the marine ecosystem upon discharge into the marine environment; floating material, settable solids which smother benthic marine life, substances which are toxic to marine life.
3. The discharge of any substance, including such substance as is listed in Schedule B to these regulations, shall be restricted according to the provisions of regulation 5. Guideline maximum discharge concentration values for selected substances are shown in Schedule C to these regulations.
4. Applicant is to indicate suitable effluent inspection and sampling points, which points must be to the satisfaction of Managing Professional – Discharge Permitting, Water Services Corporation.
5. Applicant is to record related discharge parameters and records are to be made available to the, Managing Professional – Discharge Permitting, Water Services Corporation.
6. Maximum component discharge concentrations shall not be reached by dilution of effluent by tap water, ground water, storm water or sewage.

Applicant has **one (1) year** to present sound scientific evidence, to the satisfaction of the Managing Professional – Discharge Permitting that they are adhering to S.L. 545.08.

The above-mentioned conditions are without prejudice to all other sections laid down in S.L. 545.08.

Failure to comply with the above mentioned conditions or any other article in S.L. 545.08 shall nullify such permit.



Appendix 3: Company registration certificate

Registrar of Companies

MALTA

Our Ref: C 32508

8th May 2017

TO WHOM IT MAY CONCERN

This is to certify that Sterling Chemical Malta Limited of HF51, Hal-Far Industrial Estate, Birzebbugia BBG3000, Malta was registered under the Laws of Malta on the 20th November 2003 and is still so registered.

According to our records the present shareholders of the company are:

Name	Number of Shares
S.N.I.F.F. Italia SPA (Company Reg. No. 112595)	3,499 Ordinary Shares of EUR 0.8393 each
Osiris Trust Limited (Company Reg. No. C 36502)	1 Ordinary Share of EUR 0.8393

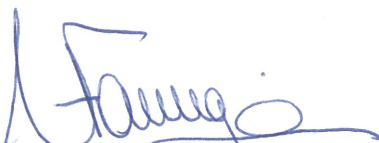
The present directors of the company are:

Simone Ferlin (Italian Passport No. 009477W)
Alessandro Bianchi (Italian I.D. Card No. AT8871126)
Roberto Tumbiolo (Italian Passport No. AA4260020)

The present secretary of the company is:

Alessandro Bianchi (Italian I.D. Card No. AT8871126)

This information is provided on the basis of the documents registered in respect of the company.



Natalie Farrugia

f/Registrar of Companies

Registry of Companies, MFSA Building, Notabile Road, Attard - BKR 3000, Malta.

Tel: (+356) 2144 1155 • Fax: (+356) 2144 1195

E.mail: info@rocmalta.com.mt • Web: <http://rocmalta.com.mt>

Appendix 4: Technically competent person

CURRICULUM VITAE

Introduction

Name & Surname **Andrea Caneponi**

Nationality Italian

Marital status Married

Mobile numbers + 356 99054582 +39 371 1545403

@ work acaneponi@sterlingchemicalmalta.com

@ personal andreacaneponi@gmail.com

Address Triq M.Spir Penza, Anfield Flats FL 1 - Birzebbuga (Malta)

Gender Male

Date of birth 15/05/62

Birth place Marsciano (PG)

Education and Training

Degree University of Perugia in Geological Science

Qualification Doctor in Geological Sciences

Qualification exam (1992) State exam for the practice of the free profession

Diploma (1982) Arnolfo di Cambio Technical Institute for Surveyors of Perugia

Qualification Surveyor

Diploma (1982) Arnolfo di Cambio Technical Institute for Surveyors of Perugia

October 2020 Training course on the risks deriving from work carried out in environments with an explosive atmosphere

Work experience

Date 29/05/2020 - ongoing

Company Sterling Chemical Malta

Sector Chemical – Pharmaceutical

Designation Health, Safety & Environment (HSE Manager)

Date 30/10/2016 – 29/05/2020

Company Sterling Chemical Malta

Sector Chemical – Pharmaceutical

Duties performed Project Coordinator for the expansion of the company, supervision of construction sites, maintenance organizer, relation with suppliers

Date 1996 – 30/10/2016
Company SO.GEO sas – Castiglione del Lago (PG)
Sector Geognostic investigations, special foundations, drilling for water research, structural consolidation, reinforced concrete works
Duties performed Administrator, relations with customers and suppliers, work planning, site manager, operator of operating machines, instructor in the use of operating machines, maintenance organizer, management of equipment and raw material purchases

Date 1994 - 1996
Company Geoprogram Associated Studio - Perugia
Sector Geological consultancy, on-site geotechnical tests
Duties Performed Geological consultancy, site manager, planning geognostic investigations on site

Date 1982 - 1983
Company CIEMME 1 Studio - Perugia
Sector Design studio
Duties Performed Draftsman, topographic surveys

Mother language Italian
Foreign language Basic English level A1

IT Skills

Knowledge of the most common Windows programs

Additional Information

Driving License B - Driving of tracks and forklifts

Attitude

Friendly with colleagues, polite, punctual, tidy, attentive to the needs of the company and customers, willing to collaborate with management and colleagues to achieve common goals, work-oriented by objectives

Availability

Willing to work in a group with peers and younger colleagues, ready to work shifts even during the weekend, available for eventual work trips

Interests

Photography, music, singing, basketball

Sports

Mountain excursions, scuba diving (level I certification), enduro, MTB, basketball

Birzebbuga 19.11.2020

Andrea Caneponi

"I authorize the processing of my personal data, pursuant to Legislative Decree no. 196 of 30 June 2003"



REPVBBLICA ITALIANA

IN NOME DELLA LEGGE

NOI PROF. Giancarlo Dotta
RETTORE DELLA VNIVERSITA' DEGLI STVDI DI PERGVIA
VEDVTI GLI ATTESTATI DEGLI STVDI COMPIVTI

DAL SIG. Andrea Canepini
NATO A Montesciano (Perugia) IL 14 maggio 1902
VEDVTO IL RISVLTA TO DELL' ESAME DI LAVREA DA LVI SVPERATO
IN QUESTA VNIVERSITA' IL GIORNO 10 luglio 1921
GLI CONFERIAMO LA LAVREA DI DOTTORE IN Scienze Geologiche

IL PRESENTE DIPLOMA VIENE RILASCIATO A TVTTI GLI EFFETTI DI LEGGE
DATO IN QUESTA VNIVERSITA' DEGLI STVDI DI PERGVIA ADDI 11 dicembre 1921

IL RETTORE

IL DIRETTORE AMMINISTRATIVO

IL PRESIDE DELLA FACOLTA

STVDIVM
GENERAE
CIVITATIS
PERVSII
AD
MCCCVIII

BALDVS

AJRACI

00.39201



MINISTERO DELLA PUBBLICA ISTRUZIONE

ISTITUTO TECNICO GEOMETRI

(tipo di istituto)

“ (denominazione) ” di PERUGIA (sede)

ANNO SCOLASTICO 1981 - 1982

MATURITÀ TECNICA

DIPLOMA DI GEOMETRA

(Legge 15 giugno 1931, n. 889; D. L. 15 febbraio 1969, n. 9, convertito con modificazioni nella legge 5 aprile 1969, n. 119)

*conferito a Caneponi Andrea
nato a Marsciano (prov. di Perugia)
il giorno 14 maggio 1962*

con il seguente voto *quarantaquattro* / sessantesimi
(in lettere)

Perugia addì 28 luglio 1982

IL PRESIDENTE DELLA COMMISSIONE

IL PRESIDE

(Prof. Luigi Italo Carcione)

N° 0010510 * 1983

Si certifica che

CANEPONI ANDREA

Codice Fiscale: CNPNDR62E14E975J

Addetto ufficio HSE

per conto di

STERLING CHEMICAL MALTA Ltd.

ha frequentato in data 28.09.20, 01.10.20, 05.10.20, 16.10.20,
26.10.20, 02.11.20, 11.11.20 e 16.11.20 il:

**Corso di formazione su rischio
Atmosfere esplosive (ATEX)**

Programma del corso

1. Il fenomeno Atex e le proprietà delle sostanze.
2. Classificazione delle zone Atex per la presenza di gas, vapori e nebbie.
3. Classificazione delle zone Atex per la presenza di polveri.
4. Misure tecniche ed organizzative per la prevenzione della formazione di Atex.
5. Sorgenti di accensione.
6. Misure tecniche ed organizzative per la prevenzione dell'innesco di Atex.
7. Sistemi di protezione contro le esplosioni e riparazioni componenti Atex.
8. Il documento sulla Protezione contro le Esplosioni.

Certificato n. **CFESM01/2020**

Durata del corso: 16 h

Docente: Massimo Bonci

Firma: 



MALTA RED CROSS

THIS IS TO CERTIFY THAT

Andrea Caneponi
164775 A

HAS SUCCESSFULLY COMPLETED A 14 HOUR COURSE IN

Basic First Aid at Work

ON THE **24th November 2020** [COURSE 201123A],

UNDER THE INSTRUCTION OF

Albert Tolner

CERTIFICATION IS VALID FOR THREE YEARS

f/PAULETTE FENECH
DIRECTOR GENERAL

In accordance with European Red Cross and Red Crescent Guidelines on

In accordance with European Resuscitation Council Guidelines (2015) on Basic Life Support

Certificate Number 5396

www.redcross.org.mt



This is to certify that:

Andrea Caneponi

Successfully completed a:

Fire Warden Course
(Ref: 10.030)

Held on: 22nd October, 2020

Certificate No. : 44407

Validity: 3 years / Expiry 21st October, 2023

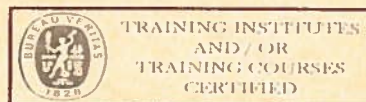

International Safety Training College (Malta) Ltd.

Hal Far Road, Hal Far BBG 3000, Malta.

Tel. No. +356-21658281/2/3

E-Mail: info@istcollege.com.mt Website: www.istcollege.com.mt

Private School Licence No. 230 issued by the Ministry of Education – Malta.





This is to certify that:

Andrea Caneponi

Successfully completed a:

Working At Heights Course
(Ref: 94.045.01)

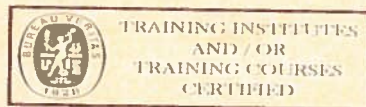
Held on: 12th November, 2020

Certificate No. : 44512

Validity: 3 years / Expiry: 11th November, 2023


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Appendix 4: Expenditure Plan

1. A monitoring programme for emissions to air is included in section C3.10 of the IPPC application (**Volume 2**). The estimated cost is as shown in **Table 1**.

Table 1: Cost of emissions monitoring to air

Emission point reference	Source	Parameters	Estimated cost per monitoring point
EM23	Microniser (nitrogen exhaust)	Total particulate matter	€250

2. The type of pollution control systems at the installation (including for abatement of air emissions, and containment systems), will also remain the same. It is therefore considered that the types of emissions (and associated expenses) in the event of a failure of the pollution control systems will remain approximately the same as in the current scenario.