



Environment Protection Act (CAP. 549)

Permit number
EP 0102/20

The Environment and Resources Authority (hereinafter the Authority; the Competent Authority) in exercise of its powers under the Environment Protection Act (CAP. 549), hereby authorises:

Dr. Dino Mangion o.b.o.

Combino Pharm (Malta) Ltd. (hereinafter “the Operator” or “the Permit Holder”),

Of / Whose Registered Office (or principal place of business) is at
HHF60

Hal Far Industrial Park


Biržebbuğa BBG 3000

(Company registration number: C 34302)

to operate an installation at:

Combino Pharm (Malta) Ltd.
HHF60, Hal Far Industrial Park
Birżebbuġa BBG 3000

This permit is valid for six (6) months from the date of issue below.

<p>Signed</p>  <p>Prof. Victor Axiak Chairman</p>	<p>Date</p> <p>28/07/2020</p>
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Authorised to sign on behalf of the Competent Authority

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Conditions

1 General

The Permitted Installation shall, subject to the conditions of this Permit, be managed, controlled and operated as described in the EP Application, or as otherwise previously agreed in writing by the Authority.

1.1 Status Log

Detail	Date
<i>EP application</i>	11 September 2009
<i>Permit Issued</i>	19 July 2010
<i>Variation Request</i>	22 March 2013
<i>Permit Variation Issued</i>	06 May 2013
<i>Renewal Requested</i>	21 January 2014
<i>Renewal Issued</i>	17 December 2014
<i>Renewal Request</i>	17 July 2020
<i>Renewal determined by ERA board</i>	26 July 2020

1.2 Permitted Activities

1.2.1 The Operator is authorised to carry out the activities and the associated activities specified in Table 1.2.1.

Table 1.2.1		
Activity	Description of specified activity	Limits of specified activity
Manufacture of pharmaceutical preparations	Manufacture of pharmaceutical products (non-sterile solid dosage forms: tablets and capsules)	<p>From receipt of raw materials and associated chemicals to dispatch of finished product (including packing and testing). Includes the manufacture of cytostatic/cytotoxic products.</p> <p>Does not include the preparation of any APIs (including intermediates) using a chemical/biological reaction.</p> <p>Does not include the manufacture of hormones or injectables.</p>
Associated activity of utilities	<p>LPG boiler to produce steam and hot water.</p> <p>Emergency diesel generator to produce energy.</p>	<p>From receipt of fuel to delivery of utility.</p> <p>From receipt of fuel to delivery of energy.</p>

	Reverse osmosis for water purification.	From receipt of water to delivery of utility.
Associated activity of storage, treatment and disposal/recycling of waste materials	Handling, storage, treatment and containment of wastes from installation prior to disposal.	From generation of waste to disposal or recycling (including recovery) offsite at permitted facilities.

1.3 Site

- 1.3.1 The activities authorised under condition 1.1.1 shall not extend beyond the Site, as shown on the Site Map in Schedule 2 to this Permit.

1.4 General Conditions

- 1.4.1 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, the Occupational Health and Safety Authority, Transport Malta, the Regulator for Energy and Water Services (REWS) and the Environmental Health Directorate.
- 1.4.2 This permit is granted saving third party rights. The Permit Holder is not excused from obtaining any other permission required by law.
- 1.4.3 A copy of this Permit shall be available at all times on site at the permitted facility, including any Variation Notices or amendments to it.
- 1.4.4 In these conditions and their interpretation, all terms shall have the same meaning as that assigned to them in CAP 549 the Environment Protection Act and its subsidiary legislation.
- 1.4.5 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.
- 1.4.6 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.
- 1.4.7 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. The Permit Holder shall keep maintenance records as per Section 2.8 of this Permit.
- 1.4.8 The Permitted Installation shall be managed, controlled, supervised and operated by staff who are aware of the importance of environmental protection and suitably trained on the requirements of this Permit. All staff shall be provided with adequate training and written operating instructions to enable them to effectively carry out their duties. Such training shall be recorded and maintained in line with conditions in section 3.3. Subcontractors who enter the site shall also be made aware of any obligations arising from the permit which might affect their duties.
- 1.4.9 The permit is valid for a period of six months from the date of the granting. The permit will be considered renewed once the official renewed permit is granted by

the Authority.

- 1.4.10 The Authority may request monitoring and/or review of operational practices and/or commission audits on the installation as deemed necessary to address any circumstances that may affect quality of the surrounding environment.
- 1.4.11 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 deemed if necessary.
- 1.4.12 Without prejudice to condition 1.4.10, the Authority may take any action deemed necessary including but not limited to the suspension of any activity/operation until investigations are concluded.
- 1.4.13 The Authority may carry out pre-set or unannounced compliance checks that vary in frequency according to the site's compliance with the permit conditions. Any such checks and audits carried out by the Authority are to be made at the Permit Holder's financial expense at the rate and arrangement communicated by ERA's Compliance and Enforcement Directorate.
- 1.4.14 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.
- 1.4.15 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.
- 1.4.16 The Authority may suspend or revoke this environmental permit in line with the provisions of CAP 549.
- 1.4.17 The Permit Holder shall undertake all reasonable measures and precautions to prevent spillage of raw materials, intermediates, products, waste and any other materials.

1.5 Operational Changes

- 1.5.1 The Permit Holder may apply for a variation in permit and shall seek the Authority's written agreement prior to any operational changes, by sending to the Authority;
 - a. 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 from the Permitted installation
 - b. Any relevant supporting information (e.g. chemical/fuel consumption, technical details, changes in the type/use of substances/mixtures, etc.);
 - c. Any relevant supporting assessments and drawings, and;
 - d. The proposed implementation date

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

- 1.5.2 The Permit Holder shall notify the following matters to the Authority in writing at

least within 10 working days prior to their occurrence:

- a) Any change in the Permit Holder's trading name, registered name or registered office address;
- b) Any change to particulars of the Permit Holder's corporate identity

1.6 Improvement Programme

1.6.1 There are no improvement programme conditions

2 Operating Conditions

2.1 Emissions to Air

- 2.1.1 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 a local nuisance effect.
- 2.1.2 The exhaust from general building ventilation (e.g. extractors or fans in walls or roofs) shall be vented in such a way as to avoid adverse environmental effects and in accordance with applicable legislation in this regard.
- 2.1.3 The Operator shall prevent or where that is not practicable reduce fugitive emissions of substances to air from the Permitted Installation.
- 2.1.4 Emissions to air shall only arise from the emission points specified in Table 2.1.4, as described Schedule 3.

Table 2.1.4 : Emission points to air	
Emission point references (Schedule 3)	Source
PS1	Boiler
PS2	Generator
PS3	Fluid-bed drier
PS4	Coater
PS5	HVAC exhausts

- 2.1.5 Should the Permit Holder intend to install equipment, which could lead to additional emissions to air (e.g. an additional boiler, etc.), a variation of this Permit must be secured prior to installation and operation of this equipment

API Handling areas

- 2.1.6 Emissions to air from all areas where active pharmaceutical ingredients are handled (including weighed, processed, compacted and dried) shall be exhausted through abatement equipment having at least 99.9% efficiency.
- 2.1.7 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 to operators working on the equipment such that an out of range incident can be easily and immediately identified.

Combustion Plants

- 2.1.8 ERA recommends that diesel (gas oil) used for generators or boilers shall have a sulphur content not greater than 0.1%.
- 2.1.9 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.
- 2.1.9 The Authority may request monitoring of emissions to air listed in table 2.1.4 which shall be undertaken in accordance to the terms of reference provided by the Authority.
- 2.1.10 During each measurement, as specified in condition 2.1.9, the plant shall be operating under stable conditions at a representative even load. In this context, start-up and shut-down periods shall be excluded.
- 2.1.11 The Permit Holder shall submit certification for the combustion equipment (PS1 and PS2) referred to in table 2.1.4, by an independent warranted engineer showing that the generator is in good working condition every four (4) years. The certification shall be submitted as part of the Environmental Report (ER) in Schedule 1. The certification and the monitoring results shall be submitted as part of the Annual Environmental Report. The Authority may request the right to require an increase in the frequency of such measurements

Volatile Organic Compounds

- 2.1.12 In the event that the VOC solvent consumption threshold exceeds 50 tonnes/year as per Activity 20 in Schedule II of S.L.549.79 (the Industrial Emissions (Limitation of Emissions of Volatile Organic Compounds) Regulations), the operator is to notify the Authority, and the provisions of S.L.549.79 shall apply.
- 2.1.13 The Permit Holder shall inform the Authority in advance should there be an intention to use any VOC solvents as per S.L. 549.79 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 (or the risk phrases R40, R45, R46, R49, R60, R61 or R68). In this case, the Authority may set emission limits for these substances and monitoring requirements.

Emergency Considerations

- 2.1.14 In the event of malfunction or breakdown leading to abnormal emissions from equipment, the Permit Holder must:
- a. Investigate immediately and undertake corrective action,
 - b. Adjust the process or activity to minimise those emissions, and
 - c. Record the events and actions taken
- 2.1.15 Further to condition 2.1.14, 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.
- 2.1.16 All abatement equipment and ducting shall be maintained on a regular basis (as per manufacturer specifications). Records of such maintenance shall be kept in line with Section 3.3 of this Permit.
- 2.1.7 Under abnormal operating conditions such as in the case of breakdown, the Operator shall reduce or close operations as soon as practical until normal operation can be restored.

- 2.1.18 Operation of the fluid bed drier emergency stack may only take place if the fluid bed drier is in an operational state that might otherwise cause danger to human beings or severe damage to the plant, e.g. acute danger of explosion. In the case of installation of new fluid bed driers, the operator shall endeavour to install and utilise alternative techniques, which in the case of an emergency, do not require use of an emergency stack.
- 2.1.19 The operator shall take all possible precautions (including maintenance, risk assessment, use of suitable materials in relation to the limitations of the fluid bed drier, etc.) to ensure that the likelihood of emergency stack use is minimised.
- 2.1.20 In case of emergency stack operation, the process occurring in the fluid bed drier must be stopped immediately and automatically. The duration of emergency stack operation must be reduced to the utmost minimum.
- 2.1.21 The Permit Holder shall maintain an emergency procedure that is specific to the use of the fluid bed drier emergency stack. The procedure shall include actions to be taken to minimise the release, and immediate notification of ERA, the Civil Protection Department and neighbours in case of an incident.
- 2.1.22 In the event of emergency stack operation, a report shall be submitted to ERA within two working days describing:
- a) the cause of emergency stack operation;
 - b) the duration of emergency stack operation;
 - c) the quantity of emissions resulting from emergency stack operation;
 - d) measures being implemented by the operator to minimise the probability of recurrence of such an incident.
- 2.1.23 The emergency stack vent shall be directed in such a way as to minimise impact to the surroundings in case of emissions.
- 2.2 Effluent discharges**
- 2.2.1 No discharges to surface water or groundwater shall take place from the permitted installation.
- 2.2.2 Foul sewer drains must be strictly segregated from stormwater drains.
- 2.2.3 Rainwater shall be segregated from all process areas that are potentially contaminated with raw materials, intermediates and/or products. If this is not possible, rainwater from areas where contamination by oil or chemicals is likely (such as loading/unloading and bunded areas) shall pass through an adequately sized interceptor.
- 2.2.4 All discharges to the foul sewer (other than from domestic sewage or equivalent), including reverse osmosis reject water, shall comply with the requirements of a Water Services Corporation Sewer Discharge Permit
- 2.2.5 Process effluents shall not be diluted prior to discharge to sewer or transfer off-site.
- 2.2.6 The Operator is allowed to discharge process water to the wastewater treatment plant and second reservoir of Medichem Manufacturing (Malta) Ltd (of HF-61, Hal Far Industrial Estate, Malta), provided that:
- a) Wastewaters from Combino Pharm are treated in Medichem's on-site wastewater treatment plant prior to discharge, except where the wastewaters from Combino Pharm are in conformity with the limits set in the Water Services Corporation Sewer Discharge Permit for Medichem and do not require treatment prior to discharge.

- b) Wastewaters from Combino Pharm do not result in any exceedance of the limits set in the Water Services Corporation Sewer Discharge Permit for Medichem.

2.3 Emissions to Land

- 2.3.1 No emission from the Permitted Installation shall be made to land.

2.4 Odour

- 2.4.1 The Operator shall prevent or where that is not practicable 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.

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

2.5 Noise and Vibration

- 2.5.1 The Operator shall prevent or where that is not practicable reduce emissions of noise and vibration from the Permitted Installation.

- 2.5.2 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.

- 2.5.3 The Authority shall reserve the right to request noise monitoring analysis, at the expense of the Permit Holder. In this regard, the locations, measurements and assessment must be made according to BS 4142:2014 and Terms of Reference issued by the Authority.

2.6 Waste

Waste storage and handling

- 2.6.1 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).

- 2.6.2 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.

- 2.6.3 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. Wastes of different natures and having different European Waste Catalogue codes as established by Commission Decision 2000/532/EC shall not be mixed in the same container.

- 2.6.4 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.
- 2.6.5 No storage of waste, equipment or materials permitted on property outside the site boundary referred to in condition 1.3.1
- 2.6.6 All storage of materials or waste shall take place only in locations where thorough clean-up and site reinstatement can be readily undertaken.
- 2.6.7 No storage of waste destined for disposal is permitted for a period exceeding 12 months. No storage of waste destined for recovery is permitted for a period exceeding 3 years.
- 2.6.8 The Operator 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.

Waste recovery or disposal

- 2.6.9 No treatment, dismantling or recovery of waste is allowed on site.
- 2.6.10 The Permit Holder shall be committed to reduce waste generation where possible.
- 2.6.11 The operator 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.
- 2.6.12 On-site disposal of wastes by any means including burning, disposal to drain or surface water, burying or deposition on land is prohibited.
- 2.6.13 Off-site disposal or recovery of wastes may only take place at a facility licensed for that purpose.

Transport

- 2.6.14 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.
- 2.6.15 The Operator shall ensure that no waste escape to the environment especially when transporting such materials offsite or onsite.
- 2.6.16 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.
- 2.6.17 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 SL 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.

- 2.6.18 The Permit Holder shall make use of the services of a registered waste carrier for the transport of waste from the site in accordance activity 38 of schedule 1 of Subsidiary Legislation 549.45, the Waste Management (Activity Registration) Regulations. Where the company removes wastes using its own transport the vehicle(s) must also be registered as a waste carrier in accordance with S.L. 549.45 or any statutory provisions or regulations amending or replacing them.
- 2.6.19 Movement of hazardous waste to authorised facilities shall be covered by a valid consignment permit obtainable from the Competent Authority. Each movement shall also be covered by a consignment note obtainable from the Authority.
- 2.6.20 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.
- 2.6.21 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.

Waste Records

- 2.6.22 The Permit Holder shall ensure to keep records for every consignment of hazardous wastes, or other wastes, as deemed necessary by the Authority, 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.
- 2.6.23 Disposal certificates shall be kept on record and made available for inspection for a period of at least 3 years from date of their issue.

2.7 Storage

- 2.7.1 All bulk oil storage tanks shall be provided with an adequately designed bund system with an impermeable base and walls. The capacity of the bund shall be at least 110% of the largest tank within the bund or 25% of the total volume of all the tanks within the bund, whichever is the greater. Filling and off-take points shall be located within the bund.
- 2.7.3 Containers for bulk storage of liquids (including waste liquids) shall be properly designed, located, labelled, banded and maintained so as to prevent accidental spillage. The capacity of retention pallets shall be a minimum of 110% of the largest container within the bund or 25% of the total volume of all the containers within the bund, whichever is the greater. Incompatible chemicals shall not be stored within the same bund.
- 2.7.4 Drums and containers of solvents, oils or any other chemicals shall be stored in designated and secure storage areas. Storage areas shall be designed so that surface and ground waters cannot be contaminated by spillages.
- 2.7.5 The storage of flammable, toxic and hazardous substances shall be in line with the measures specified in the Material Safety Data Sheets (SDS) for that substance and the maintenance of safety critical equipment shall correspond to manufacturer specifications.
- 2.7.6 Chemicals of different properties shall be stored 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. Incompatible chemicals shall not be stored within the same bund.

- 2.7.7 Storage and handling of cytotoxic/cytostatic materials shall be to the satisfaction of the Occupational Health and Safety Authority.

2.8 Maintenance

- 2.8.1 All plant and equipment used in operating the Permitted Installation shall be maintained in good operating condition.

- 2.8.2 The Permit Holder shall maintain a record of plant and equipment covered by section 3.3, and for such plant and equipment:

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

2.9 Ozone depleting substances and Fluorinated greenhouse gases

- 2.9.1 All installation, maintenance and servicing of equipment containing Fluorinated Greenhouse Gases shall abide by the requirements of Regulation (EU) No 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No. 842/06, Commission Regulation (EC) Nos 1516/07, 304/08, 306/08 and S.L.427.94, Fluorinated Greenhouse Gases (implementing) Regulations.

- 2.9.2 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.

- 2.9.3 All installation, maintenance and servicing of equipment containing Fluorinated Greenhouse Gases shall abide by the requirements of Regulation (EU) No 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No. 842/06, Commission Regulation (EC) Nos 1516/07, 304/08, 306/08 and S.L.427.94, Fluorinated Greenhouse Gases (implementing) Regulations.

- 2.9.4 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 1. When any equipment is replaced by new equipment, The Authority shall be notified in this regard and details provided on the new equipment installed.

- 2.9.5 Upon decommissioning of all equipment containing foam and insulation panels containing substances falling within the scope of EC Regulation No. 1005/09 on substances that deplete the Ozone Layer & S.L. 549.58 on substances that deplete the ozone Layer, together with Regulation (EU) No. 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No.842/2006, or containing foam and insulation panels utilising such substances 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.

- 2.9.6 No new equipment or components containing substances falling within the scope of EC Regulation No. 1005/2009 on Substances that Deplete the Ozone Layer & S.L. 549.58 on Substances that Deplete the Ozone Layer, shall be installed within the site.

- 2.9.7 Where required, leak detection systems as per the legal provisions of Regulation (EU) No 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No. 842/2006 shall be installed and well maintained.

3 Site Management

3.1 Staff obligations and Responsibilities

- 3.1.1 One member of the staff shall be nominated as the Technically Competent Person (TCP) of the site, whereby this person is to physically represent the Permit Holder during the times when the Permit Holder will not be available.
- 3.1.2 In the event of any short or long periods of leave of absence taken by the TCP for a period exceeding 10 days or change in the TCP, the Permit Holder is obliged to find a replacement for that member of staff without delay and the Authority informed accordingly.
- 3.1.3 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 is completely responsible to ascertain that all permit conditions are being adhered to.
- 3.1.4 All the staff on site shall be fully aware of the procedures to be taken in the event of an accidental spill of any liquids other than water and how to contain the environmental hazard.
- 3.1.5 Any changes in technically competent management (person/s) and the name of any incoming person together with evidence that such person has the required technical competence shall be submitted to the Authority in writing within 5 working days of the change in management.

3.2 Accident prevention and control

- 3.2.1 An Emergency Response Plan shall be maintained containing details of the location, nature and quantity of chemicals, oils and fuels stored, any special hazards, a drawing showing location of drains and the emergency phone numbers of the Permit Holder and relevant authorities. It shall also include actions to be taken in the case of incidents which could affect the environment, such as fires, chemical/fuel spills, failure of abatement equipment and use of the emergency stack. The emergency plan shall indicate that accidental releases of chemicals and fires caused by chemicals are to be managed as specified in the respective SDS sheets
- 3.2.2 In the case of an accident (including chemical spills, etc.), the Permit Holder shall follow the Emergency Response Plan referred to in Condition 3.2.1 and shall notify the Authority within 24 hours.
- 3.2.3 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.
- 3.2.4 Small leaks or spills shall be cleared up immediately by the application of absorbent materials. All used absorbent materials shall be disposed of as hazardous waste at facilities permitted to accept such waste. Transfer of this waste shall be carried out as per conditions specified in Section 2.6 of this permit.
- 3.2.5 The Permit Holder shall have in storage an adequate supply of suitable absorbent material to absorb any spillage.
- 3.2.6 The emergency procedure shall be updated whenever necessary and the updated version sent to ERA and the Civil Protection Department.

3.3 Records

3.3.1 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:

- a) Be made available for inspection by the Authority at any reasonable time;
- b) Be supplied to the Authority on demand and without charge and in the format requested;
- c) Be legible;
- d) Be made as soon as reasonably practicable;
- e) Indicate any amendments which have been made and shall include the original record wherever possible; and
- f) Be retained at the Permitted Installation, or other location agreed by the Authority in writing, for a minimum period of 3 years from the date when the records were made, unless otherwise agreed in writing.

3.3.2 A site operations log shall be made in a legible manner and kept on site and be made available for inspection by the Authority at any reasonable time. The following information shall be recorded and retained for 5 years:

- i. Total amount of waste in kilos removed from site for disposal or further treatment
- ii. 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
- iii. Any other incidents that the Permit Holder deems important to record in the Site operations log.

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

3.4 Closure and Decommissioning

3.4.1 The Permit Holder shall notify the Authority prior to ceasing operations permanently in part or full, whereby an application for cessation of operations shall be made to the Authority and shall include a decommissioning plan.

3.4.2 In the event of cessation of operations on the site, the Permit Holder shall remain responsible for all wastes and hazardous materials on site, which shall be removed from the site in accordance to good environmental practice and in such a manner that minimises environmental risks

3.4.3 The Decommissioning Plan shall be implemented once approved by the Authority and within 12 months of final cessation of operations or as agreed with the Authority in writing.

3.4.4 The obligations arising from this permit shall subsist until the Authority confirms in writing that the decommissioning plan has been implemented to its satisfaction.

3.4.5 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 waste management or waste production site.

4 Reporting

- 4.1 The Permit Holder shall submit to the Authority an Annual Environmental Report (AER) of the previous year by not later than end of March of each year, providing the information listed in Schedule 1 of this Permit and in the format specified therein. It shall also be ensured that all certification and documentation as per Schedule 3 are submitted.
- 4.2 In the event where operations cease temporarily (2 weeks or more), the TCP or Permit Holder are obliged to notify the Authority within two (2) days and are also to inform the Authority with regards to when the works are intended to resume.

Schedule 1
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.

S1.1 Introduction

Environmental Permit Number	
Name and locality of Site	
Brief description of activities at the site	
Reporting Year (Calendar Year: 1 January to 31 December)	

S1.2 Fuel Consumption Data

Equipment ¹	Fuel type	Sulphur Content of Fuel ²	Fuel Consumption	Units
				tonnes
				tonnes

S1.3 Off-site transfers and exports of hazardous waste

Date of transfer	EWC Code ³	Quantity of waste (in kg)	Consignment note number and/or TFS (Transfrontier Shipment of waste) reference number	Ultimate destination

S1.4 Off-site transfers of non-hazardous Waste

Date of transfer	EWC Code ³	Quantity of waste (in kg)	Ultimate destination	Name(s) of registered waste carrier used during reporting year

¹ E.g. Boiler, generator, vehicles, etc.

² Specify units (e.g. as percentage, or mg/kg)

³ European Waste Catalogue Code (Reference: Commission decision 2000/532/EC establishing a list of wastes)

S1.5 Data on Ozone depleting substances and Fluorinated greenhouse gases**S1.5.1 registration of equipment**

Equipment code	Type of equipment	Use	Charge		Type of substance
			Kg	CO ₂ (eq)	
EQ 1					
EQ 2					
EQ 3					
EQ 4					
Continue as required					

S1.5.2. Maintenance Schedule¹

Data Submitted for each scheduled inspection ²	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 ³)								
Actions taken to eliminate such leakages								
Quantity and nature of the substances involved								
Serial number of the personnel involved								
Quantities added ⁴ and/or recovered (in Kg/ CO ₂ equiv).								

¹ (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.

² Table to be repeated for every scheduled inspection as per 'footnote 1' above.

³ Carbon Dioxide equivalent – use Annex 1 and Annex IV of EC517/2014 for calculation.

⁴ 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

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

.....
Date

Schedule 2
Site Map

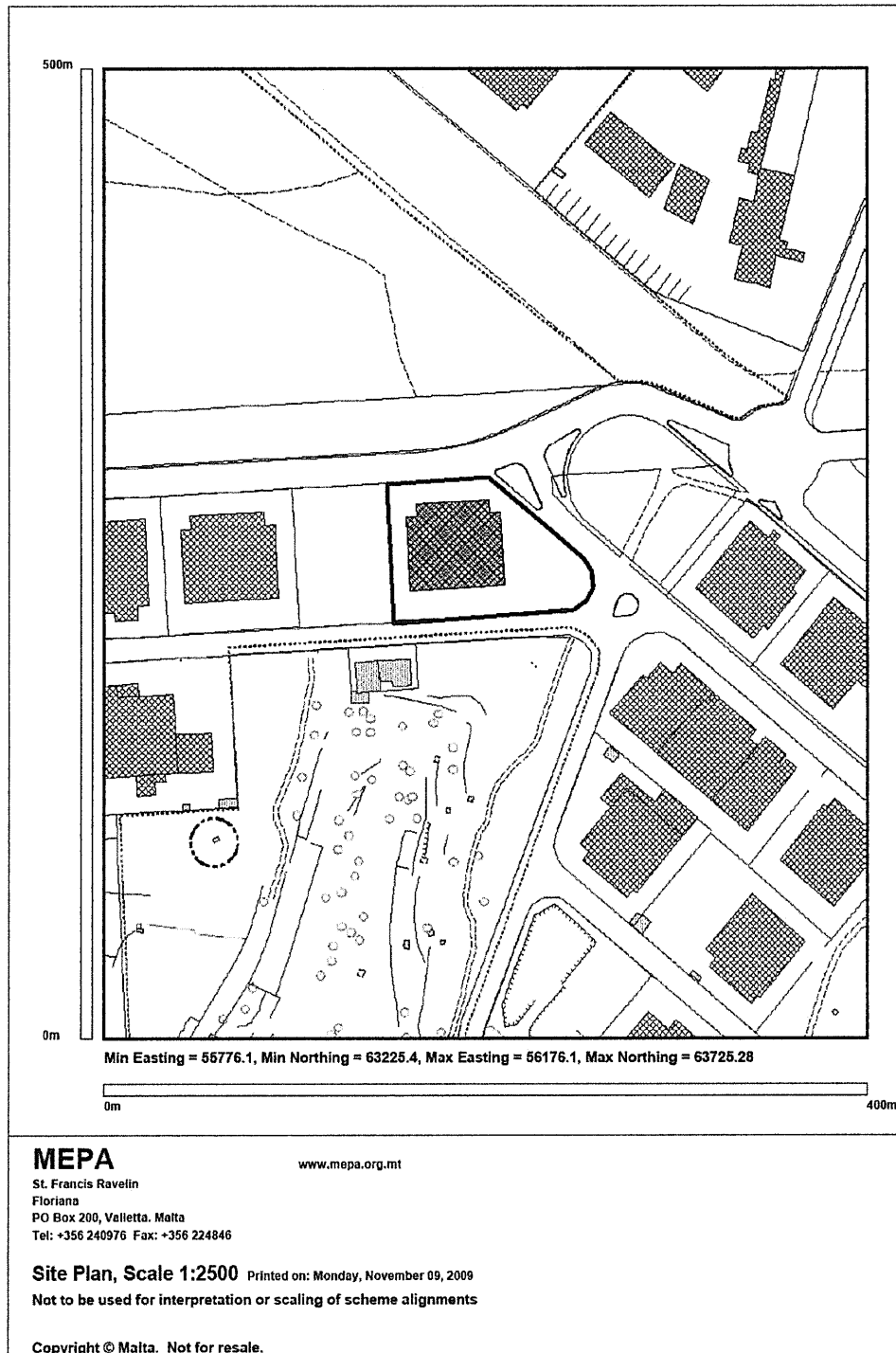
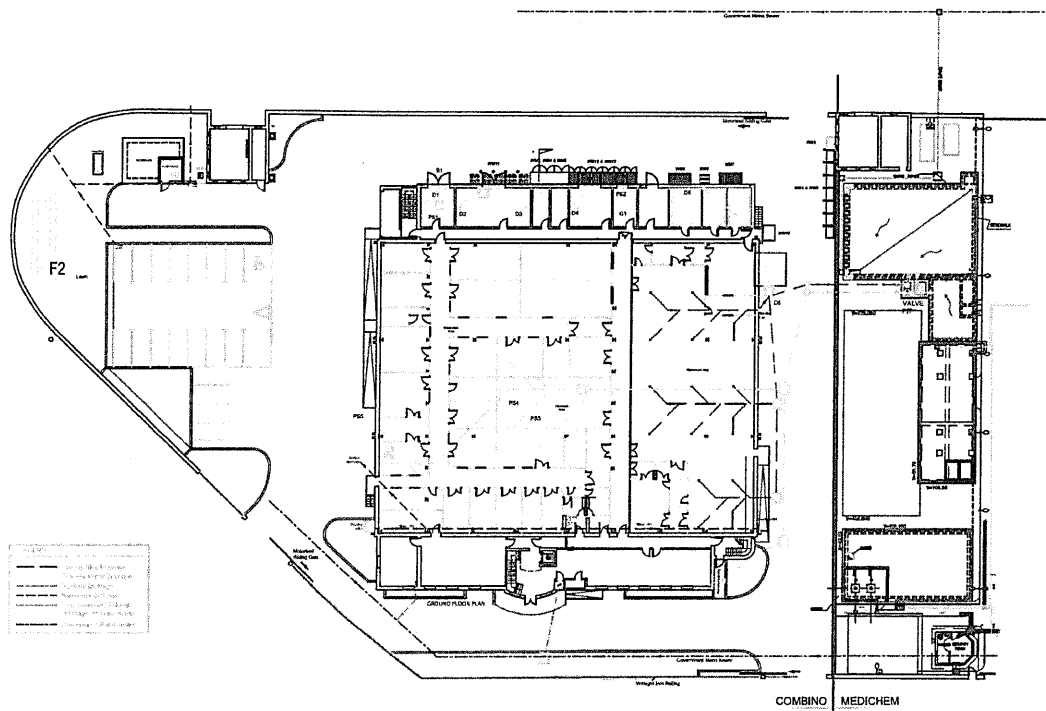


Fig. S2.1: Site of installation, showing extent of area authorised for activity (outlined in bold blue).

Schedule 3
Site Layout Plan



Schedule 4

Submission of certificates/monitoring

Kindly provide status update for the requirements tabled below. Where relevant supporting documentation is to be attached-

Monitoring results as per section 2.2 and 2.3 on an annual basis	<input type="checkbox"/>
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Applicant's declaration		
<i>I declare that, to the best of my knowledge, all the above information is correct and substantiated.</i>		
.....
Name name <i>(in block letters)</i>	ID Card Number	on behalf of / in my own <i>(in block letters)</i>
.....		
Signature		Date

END OF PERMIT