

Form IPPC Part B: Application for a New Permit



For ERA use only

Application reference:

Use this part of the form if you are applying for a new permit. Please read carefully Appendix I attached with this application.

B1 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 Schedule 1 of the Industrial Emissions (IPPC) Regulations 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: Annex I references**, write the category the installation falls under in Schedule 1 of the IPPC permit under 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”).

B1.1 The installation and its activities

COLUMN 1 Activities in the “stationary technical unit”

Manufacture of pharmaceutical preparations

COLUMN 2 Schedule 1 references

COLUMN 3 Operator

Applicant

Directly associated activities

Utilities (LPG boiler, diesel generator, Reverse Osmosis system)
Storage, treatment and disposal/recycling of hazardous waste
The Manufacture of finished dosage form

Applicant
Applicant

B1.2 Non-technical summary

Please provide a non-technical summary of the proposed installation activities.

Document reference number:

[Annex B-1](#)

B1 About the installation *continued*

B1.3 Why is the application being made?

- ☐ the installation is new;
- ☒ it is an existing installation for which a 'substantial change' is proposed which would necessitate an IPPC permit;
- ☐ the installation is existing (in operation before 7 January 2013) and did not require a permit under the Integrated Pollution Prevention and Control (IPPC) Regulations, (S.L.435.49) but requires an IPPC permit under the Industrial Emissions (IPPC) Regulations (S.L. 549.77)

Document reference number for plans:

[Annex B-4](#)

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

B1.4 Site maps and reports

Please provide:

B.1.4.1

A site report, providing a history of the site (including current and past uses) and describing the condition of the site of that part of the installation in respect of which you are applying for a permit, 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:

[Annex B-2](#)

B1.4.2

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

Document reference number for map(s):

[Annex B-3](#)

B1.4.3

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

B2 Your proposed techniques *

B2.1 Environmental Management System

Provide details of your proposed management techniques and environmental management system (EMS). An EMS can take the form of a standardised system (e.g. EN ISO 14001:2015; EMAS) or a non-standardised (“customised”) system, provided that is properly designed and implemented.

Document reference number:

Annex B-5

B2.2 Proposed activities

B2.2.1 Describe the proposed installation activities.

Document reference number:

Annex B-1

B2.2.2 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).

Document reference number:

Annex B-6

B2.2.3 Submit a flow diagram summarising the proposed installation activities.

Document reference number:

Annex B-7

B2.2.4 Include a comparison of the proposed activities with relevant BAT conclusions published by the European Commission, where these have been published.¹

Document reference number:

Annex B-8

B2.2.5 Include an outline of the main alternatives considered to the proposed technology, techniques and measures.

Document reference number:

Annex B-8

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

B2 Your proposed techniques *continued*

B2.3 Raw materials

Identify the raw and auxiliary materials, and any other substances that you propose to use, including fuels.

Give details of quantities proposed to be used annually and submit respective MSDS sheets.

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:

[Annex B-9 a to c \(confidential\)](#)

B2.4 Ozone depleting substances and fluorinated greenhouse gases

Provide a list of equipment using ozone depleting substances and fluorinated greenhouse gases, with a fluid charge of 3 kg or more.

For each 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:

[Annex B-10](#)

B2.5 Maintenance

Provide a proposed maintenance programme for the installation, and a template for keeping records of maintenance.

Document reference number:

[Annex B-20 \(confidential\)](#)

B2.6 Energy

B2.6.1: Provide a breakdown of the proposed 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).

Document reference number:

[Annex B-11 and B-21](#)

B2.6.2: Describe the proposed basic measures for improvement of energy efficiency.

Document reference number:

[Annex B-11](#)

B2.7 Water

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

Document reference number:

[Annex B-11](#)

B2.8 Risk assessment

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

Include:

- (a) emergency plans in case of fire and other emergencies (e.g. explosions);
- (b) plans for actions to be taken in case of failure of abatement equipment;
- (c) plans for actions to be taken in case of other environmentally relevant incidents (e.g. spillages, gas leakage).

Provide certification from a competent company or engineer that the relevant fire safety procedures and equipment are in place.

Certification and fire plans shall include the presence of emergency firefighting water supplies for use by the Civil Protection Department.

Document reference number:

[Annex B-12, B-22a and B22b \(confidential\)](#)

B2.9 Training

Please submit a proposal for a training programme and a proposed template for keeping training records. Please submit the name of the technically competent person on site who will be responsible for such training.

Document reference number:

[Annex B-5 and B-23 \(confidential\)](#)

B2 Your proposed techniques *cont.*

B2.10 Cessation

Submit an 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 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.
- A draft waste management strategy including:
 - The identification and characterisation of sources, types of wastes (including equipment, tanks, fuels and by-products);
 - Criteria for segregation of wastes;
 - Proposed treatment, conditioning, transport, storage and disposal/recovery methods;
 - Potential reuse/recycling of such wastes.

Document reference number:

[Annex B-13](#)

B2.11 Multi-operator installations

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

Document reference number:

[Annexes B26, B27a, B27b, B28](#)

B3 Your proposed emissions

B3.1 Waste²

B3.1.1: Characterise (using the European Waste Catalogue code, in accordance with LN 184 of 2011 as amended³) and quantify each waste stream from the installation.

Document reference number:

[Annex B-14a](#)

² For installations carrying out waste management activities (activities listed in "Section 5: Waste management" of Annex I of the Industrial Emissions Directive), please use this section to document both incoming and outgoing waste.

³ <http://www.era.org.mt/file.aspx?f=6289>.

B3 Your proposed emissions *cont.*

B3.1.2: Describe the proposed measures for waste management, storage and handling. 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:

[Annexes B-14a and B-14b](#)

B3.1.3: Describe how each waste stream is, in order of priority and in accordance with Directive 2008/98/EC, 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.

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 waste, give details on off-site transportation, including registered waste carriers/brokers to be used.

Document reference number:

[Annexes B-14a and B-14b](#)

B3.2 Emissions to Groundwater

Could there be a discharge to groundwater 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:

[n/a](#)

B3 Your proposed emissions *continued*

B3.3 Emissions to Sewer

B3.3.1: Does the installation have (or is proposing to have) a sewer connection?

Yes ☐ No ☒

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:

[Annex B-28](#)

B3.3.2: Does the installation have (or is proposing to have) a cesspit?

Yes ☐ No ☒

Please provide certification by an independent, warranted engineer showing that the 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:

[n/a](#)

B3.3.3: 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:

[Annex A-2 of IPPC Form A](#)

B3.3.4: Could the installation involve the release of any Schedule A or Schedule B substance into the sewers?

Yes ☐ No ☒

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

Document reference number:

[n/a](#)

B3.4 Emissions to the Sea

Identify if there may be a direct discharge to coastal (up to 1 nautical mile from the coast line) or territorial waters.

Yes ☐ No ☒

If any 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:

[n/a](#)

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:

[n/a](#)

B3.5 Rainwater

Describe how rainwater is handled on site. Attach a site drainage map indicating rainwater capture and harvesting/discharge.

Document reference number:

[n/a](#)

B3.6 Emissions to Air

Identify if there may be 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 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:

[Annexes B-15a and B-15b](#)

B3 Your proposed emissions *continued*

B3.7 Odour emissions

Identify if there may be 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:

n/a

B3.8 Emissions to Land

Identify if there may be 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:

n/a

B3.9 Noise

Describe:

B3.9.1: The main sources of noise and vibration (including infrequent sources) of the proposed installation;

B3.9.2: The proposed techniques and measures for control of noise;

B3.9.3: The nearest noise sensitive locations and distance away from the site (a site map shall also be submitted for this purpose); and

B3.9.4: 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:

Annex B-16 (confidential)

B3.10 Monitoring

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

B3.10.1: The location of each proposed monitoring point (plotted on a suitably-labelled block plan of the site);

B3.10.2: The substances (in each environmental medium) which are proposed to be monitored;

B3.10.3: The frequency with which monitoring is proposed to take place;

B3.10.4: The proposed measurement methodology, which should be a standard methodology, such as EN or ISO standard, or equivalent;

B3.10.5: The proposed procedure for evaluation of the results.

Document reference number:

Annex B-15a

B3.11 Emissions & waste summary

By means of a mass flow diagram, summarise the emissions and waste described in sections B3.1, B3.2, B3.3, B3.4, B3.6, and B3.8 of this application.

Document reference number:

Annex B-24

B4 Impact on the environment

B4.1 Environmental effects

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

Document reference number:

n/a

B4.2 Effects on other sites

Provide an assessment of whether the installation 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:

n/a

B5 Environmental statements

B5.1 Environmental statement

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

Yes ☐ No ☒

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

Document reference number:

n/a

B6 Statutory consultees

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

B6.1 Local council

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

Hal Far
B'Bugia Local Council

B6.2 Other sites

Are there any other sites which may be affected by emissions from the installation? (Refer also to your answer to B4.2).

Yes ☒ No ☐

If yes, please give the names of the sites:

Medichem Malta
Manufacturing Ltd

B6.3 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:

n/a

B7 Planning status

B7.1 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:

- PA/04695/04 : Internal and external alterations to existing factory in Hal Far Industrial Area

- PA/01825/05: Internal and External alterations to existing factory as approved by PA 4695/04, and addition of sub-station on property

-PA/0217/06: Addition of workshop to existing factory

-PA/06006/06: Additional storey onto office block- Factory HF60

PA/2174/06 – Construction of workshop

-PA/04360/15 - Renewal of PA/06006/06

☐ 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 Directorate.

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:

B8 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.

B8.1 Relevant offences

Has the operator, or any other 'relevant person' been convicted of any relevant offence?

A 'relevant person' includes each partner, director, manager, company secretary or any similar officer or can be an employee, such as a proposed technically competent person.

Yes ☐ No ☒

Please provide a recent police conduct certificate for the nominated technically competent person/s.

Document reference number:

Annex B-17 (confidential)

B8.2 Technically competent management

Who will provide the technically competent management for the installation?

Please give details for each person and provide written evidence.

Responsible person 1:

Full Name: Selina Zerafa
Position: EPHS Manager
Date of employment: 21/01/2019
Mobile number: /

Document reference number for copies of CV and relevant qualifications:

Annex B-18 (confidential)

Responsible person 2:

Full Name: n/a
Position: n/a
Date of employment: n/a
Mobile number: n/a

Document reference number for copies of CV and relevant qualifications:

n/a

B8 Technically competent person *cont.*

Responsible person 3:

Full Name: n/a
Position: n/a
Date of employment: n/a
Mobile number: n/a

Document reference number for copies of CV and relevant qualifications:

n/a

Responsible person 4:

Full Name: n/a
Position: n/a
Date of employment: n/a
Mobile number: n/a

Document reference number for copies of CV and relevant qualifications:

n/a

B8.3 Management of other installations

Are any of these 'Responsible people' already providing the technically competent management at other IPPC installations or at sites licensed under the environmental provisions of the Environment and Development Planning Act, 2010?

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:

Annex B-19

B9 Expenditure plan

B9.1 Expenditure plan

Please provide a plan of the estimated expenditure for each phase of the following specified activities.

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:

Annex B-25

B10 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 440 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.
