

## Form IPPC Part B – application for a permit



For MEPA use only

Application Reference

Use this part of the form if you are applying for a new permit  
Please read carefully Annex 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 2 Operator** write the name of the operator for each activity (if you are the operator yourself, write "Applicant").

In **column 1 Activities in "the stationary technical unit"** please identify all activities listed in Schedule 1 to the IPPC Regulations that are proposed to be carried out in the "stationary technical unit" of the installation.

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.

#### B1.1 Installation table for new permit application

##### COLUMN 1

Activities in the "stationary technical unit"

##### COLUMN 2

Schedule 1 refs

##### COLUMN 2

Operator

Installations using a chemical or Biological process for the Production of basic pharmaceutical Products.	4.5	Applicant

Directly associated activities

Reverse Osmosis System which Provides water for all the plant.		Applicant
Recovery of Organic Solvents from Wastes produced from processes		Applicant

## B1 About the installation *continued*

### B1.2 Why is the application being made?

- ☐ the installation is new,
- ☐ it is an existing installation and you are applying in accordance with the timetable in the IPPC Regulations,
- ☐ it is an existing installation and you have the agreement of the MEPA to make this application now. Please attach proof of this agreement, such as a letter from the MEPA.

Document reference number for proof

- ☒ it is an existing installation for which a 'substantial change' is proposed,
- ☐ it is for a mobile plant being moved to a new location.

### B1.3 Site maps and reports

Please provide:

- a site report 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.

Document reference number for the report

Refer to IPPC Application 2.2 & 2.4 & Plan 1

- suitable maps or plans showing the location of the site of the installation, the location and nature of the various activities on that site and the area of the site covered by the site report

Document reference number for the maps or plans

Refer to IPPC Application Attach 1 & 2 & Sec 7.1

## B2 Your proposed techniques

Please provide written information about the aspects of your installation listed below. We need this information, and that which you give in response to B3 and B4, to determine whether you will operate the installation in a way which meets all the environmental requirements of the IPPC Regulations.

In each case you should:

- address all of the issues set out in the section of the relevant technical guidance identified in brackets,
- justify your proposals against any indicative requirements contained in the guidance and,
- provide any other information about the installation which you think is relevant to that issue.

Information required:

## B2 Your proposed techniques *cont.*

**B2.1** Provide details of your proposed management techniques.

Document reference number:

IPPC Applic. Sec.3

**B2.2** Identify the raw and auxiliary materials, other substances and water that you propose to use.

Document reference number:

IPPC Applic. Sec. 5.2.1

**B2.3** Describe the proposed installation activities and the proposed techniques and measures to prevent and reduce waste arisings and emissions of substances and heat (including during periods of start-up or shut-down, momentary stoppage, leak or malfunction).

Document reference number:

IPPC Applic. Sec. 4. 5. 6 & 7

**B2.4** Characterise and quantify each waste stream from the installation and describe the proposed measures for waste management, storage and handling.

Document reference number:

IPPC Applic. Sec. 5.3.8

**B2.4.1** Identify if there may be a discharge of any List I or List II substance and if any are identified, explain how the requirements of the Groundwater Regulations (LN203 of 2002) have been addressed.

Document reference number:

IPPC Applic. Sec. 5.2.3

**B2.5** Could the installation involve the release of any Schedule A or Schedule B substance into the sewers and if any are identified explain how the requirements of LN139 of 2002 have been addressed

No ☒ Yes ☐

IPPC Application Section 5.2.2 & 6.3.2 & 5.3.6

**B2.5.1** Identify if there may be a direct discharge of any List I or List II substance to coastal (up to 1 nautical mile from the coast line) or territorial waters; and if any are identified, explain how the requirements of the Discharge of Dangerous Substances Regulations (LN212 of 2001) have been addressed?

No ☒ Yes ☐

N/A

**B2.6** Describe how each waste stream is proposed to be recovered or disposed of and, 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.

IPPC Applic. Sec. 5

Document reference number:  
IPPC Application 5.3.

**B2.7.1** Provide a breakdown of the proposed energy consumption and generation by source and end-use

Document reference number: IPPC Applic. Sec. 8

Information required: N/A

**B2.7.2** Describe the proposed basic measures for improvement of energy efficiency

Document reference number: IPPC Applic. Sec. 8.3

**B3.1** Describe the nature, quantities and sources of foreseeable emissions into each environmental medium.

**B2.8** Describe the documented system proposed to be used to identify, assess and minimise the environmental risks and hazards of accidents and their consequences.

Document reference number: IPPC Applic. Sec. 6

Document reference number: IPPC Applic. Sec. 5.3

**B2.9** Describe the main sources of noise and vibration (including infrequent sources); the nearest noise sensitive locations and relevant environmental noise measurement surveys which have been undertaken; and the proposed techniques and measures for control of noise

Document reference number: IPPC Applic. Sec. 5.3.7

**B2.10** Describe the proposed measures for monitoring emissions including any environmental monitoring, and the frequency, measurement methodology and evaluation procedure proposed.

Document reference number: Attachment 30

**B2.11** Describe the 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).

Document reference number: IPPC Applic. Sec. 10

**B2.12** 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: N/A

## B4 Impact on the environment

Please provide written information about the impact your emissions may have on the environment.

You should:

- address all of the issues set out in the section;
- justify your proposals;
- provide any other information about the installation which you think is relevant to that issue.

Information required:

**B4.1** Provide an assessment of the potential significant environmental effects (including transboundary effects) of the foreseeable emissions.

Document reference number: IPPC Applic. Sec. 5.3 & 5.4

## B3 Your proposed emissions

Please provide written information about the emissions which will result from the techniques you described in response to the questions in section B2.

You should:

- provide any other information about the installation which you think is relevant to that issue...

**B4.2** 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
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## B5 Environmental statements

**B5.1** Has the development of the installation (or any subsequent change or extension of the development) required an environmental statement under LN204/2001 on the assessment of the effects of certain public and private projects on the environment?

No ☒

Yes ☐ please supply a copy of the environmental statement submitted and details of any decision made.

Document reference number: 

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## B6 Statutory consultees

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

**B6.1** In which area is the installation located?  
If premises are on a boundary please give names of all relevant authorities.

Local Council

**Bulebel Industrial Estate:**

**This area is managed by Malta Industrial Parks. The area falls under the Local Council of Zejtun.**

**B6.2** Are there any other sites which may be affected by emissions from the installation?

No ☒

Yes ☐ please give names of the sites

N/A

**B6.3** Could the installation involve the release of any substance into a harbour managed by a port authority?

No ☒

Yes ☐ please name the port authority

N/A

## B7 Specified waste management activities

**B7.1** Are you applying to operate any 'specified waste management activities'?

No ☒ go to 'B8 What to do next'

Yes ☐ please give details

N/A

## Planning status

**B7.2** Which of the following applies to the specified waste management activities identified in B7.1?

We cannot issue a permit unless one of the following applies. We will need to see a copy of the relevant documents.

☐ You have planning permission.  
Document reference number

☐ 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

## B7 Specified waste management activities *continued*

### Technically competent person

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

### Relevant offences

**B7.3** 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.*

No ☒

Yes ☐ *please give full information*

*Document reference number for this information*

N/A

*The details we need are listed below.*

- Full name of company or individual convicted
- If an individual has been convicted please state their position at time of offence
- Name of court
- Date of conviction
- Offence and penalty imposed
- Date of any outstanding appeal lodged against conviction
- Any additional information which the operator would like us to take into account in determining whether they are a 'technically competent person'. For example, why the offence happened, and what has been done to prevent a similar event occurring.

**B7.4** Who will provide the technically competent management of the specified waste management activities?

*Please give details for each person and provide written evidence*

Responsible person

Document reference number for copy of certificate

Responsible person

Date:

Document reference number for copy of certificate

Responsible person

Full name: N/A

Position: N/A

Date: N/A

Document reference number for copy of certificate

N/A

Responsible person

Full name: N/A

Position: N/A

Date: N/A

Document reference number for copy of certificate

N/A

*Now go to question B7.6.*

## B7 Specified waste management activities *continued*

### Management of other installations

B7.6 Are any of these 'Responsible people' already providing the technically competent management at other IPPC installations or at sites licensed under the Environmental Protection Act 2001?

No ☒ go to question B7.7.

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.

### Financial provision

B7.7 If known, how does the operator intend to make financial provision for the specified waste management activities?

- ☐ Renewable bonds
- ☐ Bonds
- ☐ Bank guarantee
- ☐ Parent company guarantee please include one copy of the parent company's audited trading accounts for the last three years (or for the period of trading if less than three years). These should be no more than 18 months out of date.

Document reference number for accounts

- ☐ Escrow account
- ☐ Trust fund
- ☐ Insurance captive
- ☐ Lump sum
- ☐ Other please specify

### Expenditure plan

B7.8 Please provide a plan of the estimated expenditure for each phase of the specified waste management activities

The plan should include the likely costs of:

- monitoring (emission/discharge and ambient monitoring).,
- restoration – landfill only,
- aftercare – landfill only,
- clearing the installation (including drainage systems) of all wastes – non-landfill,
- 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

## B8 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.