Headquarters,
Johnstown Castle Estate,
County Wexford, Ireland

GREENHOUSE GAS EMISSIONS PERMIT

Permit Register Number: IE-GHG079-10387-3

Operator: Hovione Limited
Loughbeg
Ringaskiddy
Cork

Installation Name: Hovione Limited

Site Name: Hovione Limited

Location: Loughbeg
Ringaskiddy
Cork
Ireland

Introductory Note

This introductory note does not form a part of the Greenhouse Gas Emissions Permit.

This Greenhouse Gas Emissions Permit authorises the holder to undertake named activities resulting in emissions of Carbon Dioxide from the listed emission sources. It also contains requirements that must be met in respect of such emissions, including monitoring and reporting requirements. This Greenhouse Gas Emissions Permit places an obligation on the Operator to surrender allowances to the Agency equal to the annual reportable emissions of carbon dioxide equivalent from the installation in each calendar year, no later than four months after the end of each such year.

Contact with Agency:

If you contact the Agency about this Greenhouse Gas Emissions Permit please quote the following reference: Greenhouse Gas Emissions Permit Nº IE-GHG079-10387.

All correspondence in relation to this permit should be addressed to:

Email: help.ets@epa.ie

By Post: Climate Change Unit, Environmental Protection Agency
P.O. Box 3000, Johnstown Castle Estate,
Co. Wexford

Updating of the permit:

This Greenhouse Gas Emissions Permit may be updated by the Agency, subject to compliance with Condition 2. The current Greenhouse Gas Emissions Permit will normally be available on the Agency's website at www.epa.ie and ETSWAP.

Surrender of the permit:

Before this Greenhouse Gas Emissions Permit can be wholly or partially surrendered, a written application must be made to the on-line ETS portal, and written permission received from, the Agency through ETSWAP.

Transfer of the permit or part of the permit:

Before this Greenhouse Gas Emissions Permit can be wholly or partially transferred to another Operator a joint written application to transfer this Greenhouse Gas Emissions Permit must be made (by both the existing and proposed Operators) to, and written permission received from, the Agency through the on-line ETS portal ETSWAP.

Licence held pursuant to the Environmental Protection Agency Act 1992, as amended. (as of the date of this permit)**:**

IPC/IE Licence Register Number
P0010-04

Status Log

Current Permit

Permit number	Date application received	Date Permit issued	Comment
IE-GHG079-10387-3	21 September 2015	05 February 2016	1. Removal of redundant Thermal Oxidisers (S14 & S15) and corresponding reduction in total capacity. 2. Update for new gas meter and serial number (SN 80112125/2014) Update to uncertainty and measurement range for the new meter. 3. Clarification on measurement of forklift truck gas oil usage.

Previous Permits

Permit number	Change Type	Date application received	Date Permit issued	Comment
IE-GHG079-10387-1	GHG Permit Application	30 October 2013	29 November 2013	
IE-GHG079-10387-2	GHG Variation	04 December 2014	11 December 2014	Removal of 5267541 TP lab meter and 5267542 TP Canteen meter used for deduction of natural gas off site and update of relevant management procedures.

End of Introductory Note

Glossary of Terms

For the purposes of this permit the terms listed in the left hand column shall have the meaning given in the right hand column below:

The Agency	Environmental Protection Agency.
Agreement	Agreement in writing.
Allowance	Permission to emit to the atmosphere one tonne of carbon dioxide equivalent during a specified period issued for the purposes of Directive 2003/87/EC by the Agency or by a designated national competent authority of a Member State of the European Union.
Annual Reportable Emissions	Reportable Emissions of carbon dioxide made in any calendar year commencing from 1 January 2005 or the year of commencement of the activity, whichever is the later.
A & V Regulation	Commission Regulation (EU) No 600/2012 of 21 June 2012 on the verification of greenhouse gas emission reports and tonne-kilometre reports and the accreditation of verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council and any amendments or revisions thereto.
Category A Installation	As defined in Article 19.2 (a) of the M&R Regulation.
Category B Installation	As defined in Article 19.2 (b) of the M&R Regulation.
Category C Installation	As defined in Article 19.2 (c) of the M&R Regulation.
The Directive	Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC.
Emissions	The release of greenhouse gases into the atmosphere from sources in an installation.
EPA	Environmental Protection Agency.
Fall-Back Methodology	As defined in Article 22 of the M&R Regulation.
GHG	Greenhouse gas.
GHG Permit	Greenhouse gas emissions permit.
Greenhouse Gas	Any of the gases in Schedule 2 of the Regulations.
IPC/IE	Integrated Pollution Control/Industrial Emissions.
Installation	Any stationary technical unit where one or more activities listed in Schedule 1 to the Regulations are carried out. Also any other directly associated activities which have a technical connection with the activities carried out on that site and which could have an effect on emissions and pollution. References to an installation include references to part of an installation.

Installation with low emissions	As defined in Article 47 of the M&R Regulation.
Major Source Streams	As defined in Article 19.3 (c) of the M&R Regulation.
M&R Regulation	Commission Regulation (EU) No 601/2012 of 21 June 2012 on the monitoring and reporting of greenhouse gas emissions pursuant to Directive 2003/87/EC of the European Parliament and of the Council and any amendments or revisions thereto.
Mis-statement	An omission, misrepresentation or error in the Operators reported data, not considering the uncertainty permissible pursuant to Article 12(1)(a) of Regulation (EU) no 601/2012.
N/A	Not applicable.
Monitoring Plan	The Plan submitted and approved in accordance with Condition 3.1 of this permit and attached at Appendix 1.
Non-conformity	Any act or omission by the Operator, either intentional or unintentional, that is contrary to the greenhouse gas emissions permit and the requirements of the Monitoring Plan.
The National Administrator	The person so designated in accordance with the requirements of any Regulations adopted as provided for under Article 19.3 of Directive 2003/87/EC.
The Operator (for the purposes of this permit)	Hovione Limited
"operator"	Any person who operates or controls an installation or to whom decisive economic power over the functioning of the installation has been delegated.
Person	Any natural or legal person.
Reportable emissions	The total releases to the atmosphere of carbon dioxide (expressed in tonnes of carbon dioxide equivalent) from the emission sources specified in Table 2 and arising from the Schedule 1 activities which are specified in Table 1.
The Regulations	European Communities (Greenhouse Gas Emissions Trading) Regulations 2012 (S.I. No 490 of 2012) and any amendments or revisions thereto.
The Verifier	A legal person or another legal entity carrying out verification activities pursuant to Regulation (EU) No 600/2012 and accredited by a national accreditation body pursuant to Regulation (EC) No 765/2008 and Regulation (EU) No 600/2012 or a natural person otherwise authorised, without prejudice to Article 5(2) of Regulation (EC) No 765/2008, at the time a verification report is issued.
The Registry	The Registry as provided for under Article 19 of Directive 2003/87/EC.

Schedule 1	Schedule 1 to the Regulations.

Reasons for the Decision

The Agency is satisfied, on the basis of the information available, that subject to compliance with the conditions of this permit, the Operator is capable of monitoring and reporting emissions in accordance with the requirements of the Regulations.

Activities Permitted

Pursuant to the Regulations the Agency transfers this Greenhouse Gas Emissions Permit, subject to any subsequent revisions, corrections or modifications it deems appropriate, to:

The Operator:

Hovione Limited
Loughbeg
Ringaskiddy
Cork

Company Registration Number: 463979

from

The Former Operator:

Pfizer Ireland Pharmaceuticals
Pottery Road

Dun Laoghaire
Dublin

to carry out the following

Categories of activity:

Annex 1 Activity
Combustion of fuels in installations with a total rated thermal input exceeding 20 MW (except in installations for the incineration of hazardous or municipal waste)

at the following installation(s):

Hovione Limited **Installation number:** 61

located at

Loughbeg
Ringaskiddy
Cork
Ireland

subject to the five conditions contained herein, with the reasons therefor and associated tables attached thereto.

In accordance with Joint Declaration made to the Agency on 19 March 2009, *Hovione Limited* is deemed to have assumed and accepted all liabilities, requirements and obligations provided for in or arising under the permit, regardless of how and in respect of what period, including the period 2005-2008, prior to the transfer of the permit, that may arise.

Conditions

Condition 1. The Permitted Installation

1.1 This permit is being granted in substitution for the previous GHG permit granted to the Operator as listed in the Status Log of this GHG permit.

1.2 The Operator is authorised to undertake the activities and/or the directly associated activities specified in Table 1 below resulting in the emission of carbon dioxide:

Table 1 - Activities which are listed in Schedule 1 of the Regulations and other directly associated activities carried out on the site:

Installation No.: 61

Activity Description
Combustion of fuels in installations with a total rated thermal input exceeding 20 MW (except in installations for the incineration of hazardous or municipal waste)

Directly Associated Activity Description
(Forklift Trucks - Diesel) Forklift Trucks
(WWTP) Waste Water Treatment Plant

1.3 Carbon dioxide from Schedule 1 activities shall be emitted to atmosphere only from the emission sources as listed in Table 2 below:

Table 2 Emission Sources and Capacities:

Emission Source Reference	Emission Source Description	Capacity	Capacity Units
S1-PU-34-01-1100	Old Diesel Fire Pump	0.16	MW
S2-PU-34-01-1200	Old Diesel Fire Pump	0.16	MW
S3-BLR-3202-1000	Hot Water Boiler	0.44	MW
S4-BLR-32-02-2000	Hot Water Boiler	0.16	MW
S5-BLR-37-01-2000	Hot Water Boiler	0.08	MW
S6-BLR-31-11-1000	Hot Water Boiler	0.94	MW
S7-BLR-31-11-2000	Hot Water Boiler	0.94	MW

Emission Source Reference	Emission Source Description	Capacity	Capacity Units
S8-GEN-11-09-4000	Emergency Diesel Generator	1.5	MW
S9-PU-11-23-1100	Diesel Foam System Pump	0.15	MW
S10-BLR-11-01-3000	Steam Boiler	10	MW
S11-BLR-11-11-2000	Steam Boiler	10	MW
S12-BLR-11-11-3000	Steam Boiler	10	MW
S13-BLR-11-11-1000	Steam Boiler	10	MW
S16	Canteen	0.1	MW

1.4 The activity shall be controlled, operated and maintained so that emissions of carbon dioxide shall take place only as set out in this GHG Emissions Permit. The permit does not control emissions of gases other than carbon dioxide. All agreed plans, programmes and methodologies required to be carried out under the terms of this permit, become part of this permit.

1.5 This GHG Permit is for the purposes of GHG emissions permitting under the European Communities (Greenhouse Gas Emissions Trading) Regulations 2012 and any amendments to the same only and nothing in this permit shall be construed as negating the Operator's statutory obligations or requirements under any other enactments or regulations unless specifically amended by the Regulations.

1.6 Any reference in this permit to 'installation' shall mean the installation as described in the Greenhouse Gas Emissions Permit application and any amendments approved by the Agency.

Reason: To describe the installation and clarify the scope of this permit.

Condition 2. Notification

2.1 No alteration to, or reconstruction in respect of, the activity or any part thereof which would, or is likely to, result in a change in:

2.1.1 the nature or functioning of the installation;

2.1.2 the capacity of the installation as detailed in this permit;

2.1.3 the fuels used at the installation;

2.1.4 the range of activities to be carried out at the installation

that may require updating of the GHG permit shall be carried out or commenced without prior notice to and without the prior written agreement of the Agency.

2.2 The Operator shall notify the Agency in writing of the cessation of all or part of any activity listed in Table 1 of this permit no later than one month from the date of cessation or by 31 December of the year of cessation, whichever is sooner.

2.3 The Operator shall apply for an update of this GHG Permit where there is a change to the Operator name and/or registered address of the Operator, within seven days of the change.

2.4 For installations or parts of installations which have not come into operation when the application for this permit was made the Operator shall notify the Agency of the date of commencement of the activity within seven days of commencement.

2.5 The Operator shall notify the Agency in writing within three days of becoming aware of any factors which may prevent compliance with the conditions of this permit.

2.6 The Operator shall submit to the Agency by 21 January of each year a declaration of operability. The declaration submitted shall be in the format required by the Agency.

2.7 All notifications required under Condition 2 above shall be made to the address given in the Explanatory Note included with this permit.

2.8 The Operator shall submit to the Agency by 31 December of each year all relevant information about any planned or effective changes to the capacity, activity level and operation of an installation. The information submitted shall be in the format required by the Agency.

Reason: To provide for the notification of updated information on the activity.

Condition 3. Monitoring and Reporting

3.1 The Operator shall monitor and record greenhouse gas emissions on site in accordance with the M&R Regulation and the approved Monitoring Plan attached at Appendix 1 to this GHG permit and in compliance with any other guidance approved by the Agency for the purposes of implementing the Directive and/or the Regulations.

3.2 The Operator shall modify the monitoring plan in any of the following situations:

3.2.1 new emissions occur due to new activities carried out or due to the use of new fuels or materials not yet contained in the monitoring plan;

3.2.2 the change of availability of data, due to the use of new measurement instrument types, sampling methods or analysis methods, or for other reasons, leads to higher accuracy in the determination of emissions;

3.2.3 data resulting from the previously applied monitoring methodology has been found incorrect;

3.2.4 changing the monitoring plan improves the accuracy of the reported data, unless this is technically not feasible or incurs unreasonable costs;

3.2.5 the monitoring plan is not in conformity with the requirements of the M&R Regulation and the Agency requests a change;

3.2.6 it is necessary to respond to the suggestions for improvement of the monitoring plan contained in the verification report.

The Operator shall notify any proposals for modification of the monitoring plan to the Agency without undue delay. Any significant modifications of the monitoring plan, as defined in Article 15

of the M&R Regulation, shall be subject to approval by the Agency. Where approved these changes shall be implemented within a timeframe agreed by the Agency.

3.3 Temporary changes to the monitoring methodology:

3.3.1 Where it is for technical reasons temporarily not feasible to apply the tier in the monitoring plan for the activity data or each calculation factor of a fuel or material stream as approved by the Agency, the Operator shall apply the highest achievable tier until the conditions for application of the tier approved in the monitoring plan have been restored. The Operator shall take all necessary measures to allow the prompt restoration of the tier in the approved monitoring plan. The Operator shall notify the temporary change to the monitoring methodology without undue delay to the Agency specifying:

(i) The reasons for the deviation from the tier;

(ii) in detail, the interim monitoring methodology applied by the Operator to determine the emissions until the conditions for the application of the tier in the monitoring plan have been restored;

(iii) the measures the Operator is taking to restore the conditions for the application of the tier in the approved monitoring plan;

(iv) the anticipated point in time when application of the approved tier will be resumed.

3.3.2 A record of all non-compliances with the approved monitoring plan shall be maintained on-site and shall be available on-site for inspection by authorised persons of the Agency and/or by the Verifier at all reasonable times.

3.4 The Operator shall appoint a Verifier to ensure that, before their submission, the reports required by Condition 3.5 below are verified in accordance with the criteria set out in Schedule 5 of the Regulations, the A&V Regulation and any more detailed requirements of the Agency.

3.5 The written report of the verified annual reportable emissions and the verification report in respect of each calendar year shall be submitted to the Agency by the Operator no later than 31 March of the following year. The reports shall be in the format required by the Agency and meet the criteria set out in the M&R and A&V Regulations.

3.6 The Operator shall enter the verified annual reportable emissions figure for the preceding year into the Registry no later than 31 March of the following year. This figure shall be electronically approved by the Verifier in the registry no later than 31 March of each year.

3.7 Where an Operator is applying the Fall-Back methodology, the Operator shall assess and quantify each year the uncertainties of all parameters used for the determination of the annual emissions in accordance with the ISO Guide to the Expression of Uncertainty in Measurement or another equivalent internationally accepted standard and include the verified results in the written report of the verified annual reportable emissions to be submitted to the Agency by 31 March each year.

3.8 An Operator shall submit to the Agency for approval a report containing the information detailed in (i) or (ii) below, where appropriate, by the following deadlines:

(a) for a category A installation, by 30 June every four years;

(b) for a category B installation, by 30 June every two years;

(c) for a category C installation, by 30 June every year.

(i) Where the Operator does not apply at least the tiers required pursuant to the first subparagraph of Article 26(1) and to Article 41(1) of the M&R Regulation, the Operator shall provide a justification as to why it is technically not feasible or would incur unreasonable costs to apply the required tiers. Where evidence is found that measures needed for

reaching those tiers have become technically feasible and do not incur unreasonable costs, the Operator shall notify the Agency of appropriate modifications to the monitoring plan and submit proposals for implementing appropriate measures and its timing.

(ii) Where the Operator applies a fall-back monitoring methodology, the Operator shall provide a justification as to why it is technically not feasible or would incur unreasonable costs to apply at least tier 1 for one or more major or minor source streams. Where evidence is found that measures needed for reaching at least tier 1 for those source streams have become technically feasible and do not incur unreasonable costs, the Operator shall notify the Agency of appropriate modifications to the monitoring plan, submit proposals and a timeframe for implementing appropriate measures.

3.9 Where the verification report states outstanding non conformities, misstatements or recommendations for improvements the Operator shall submit a report to the Agency for approval by 30 June of the year in which the verification report is issued. This requirement does not apply to the Operator of an installation with low emissions where the verification report contains recommendations for improvements only. The report shall describe how and when the Operator has rectified or plans to rectify the non-conformities identified and to implement recommended improvements. Where recommended improvements would not lead to an improvement of the monitoring methodology this must be justified by the Operator. Where the recommended improvements would incur unreasonable costs the Operator shall provide evidence of the unreasonable nature of the costs. The Operator shall implement the improvements specified by the Agency in response to the report submitted in accordance with this Condition in accordance with a timeframe set by the Agency.

3.10 The Operator shall make available to the Verifier and to the Agency any information and data relating to emissions of carbon dioxide which are required in order to verify the reports referred to in Condition 3.5 above or as required by the Agency to facilitate it in establishing benchmarks and/or best practice guidance.

3.11 Provision shall also be made for the transfer of environmental information, in relation to this permit, to the Agency's computer system, as may be requested by the Agency.

3.12 The Operator shall retain all information as specified in the M&R Regulation for a period of at least 10 years after the submission of the relevant annual report. This shall include all annual emissions reports submitted by the Former Operator(s) in respect of the installation.

3.13 A record of independent confirmation of capacities listed in this permit shall be available on-site for inspection by authorised persons of the Agency at all reasonable times.

3.14 The Operator shall keep records of all modifications of the monitoring plan. The records shall include the information specified in Article 16.3 of the M&R Regulation.

3.15 The Operator shall ensure that members of the public can view a copy of this permit and any reports submitted to the Agency in accordance with this permit at all reasonable times. This requirement shall be integrated with the requirements of any public information programme approved by the Agency in relation to any other permit or licence held by the Operator for the site.

3.16 Any discrepancies with regard to reports submitted by the Former Operator(s) in respect of this installation become the liability of the Operator.

Reason: To provide for monitoring and reporting in accordance with the Regulations.

Condition 4. Allowances

4.1 Surrender of Allowances

4.1.1 The Operator shall, by 30 April in each year, surrender to the Agency, or other appropriate body specified by the Agency, allowances equal to the annual reportable emissions in the preceding calendar year.

4.1.2 The number of allowances to be surrendered shall be the annual reportable emissions for the preceding calendar year plus such allowances as may be necessary to cover any earlier calendar year in respect of which allowances remain outstanding and due, including any liabilities arising from the period before the permit was transferred. This includes allowances to cover the amount of any annual reportable emissions in respect of which allowances were not surrendered in accordance with Condition 4.1.1 in the previous year, and the amount of any reportable emissions which were discovered during the previous year to have been unreported in reports submitted under Condition 3 in that or in earlier years.

4.1.3 In relation to activities or parts of activities which have ceased to take place and have been notified to the Agency in accordance with Condition 2.2 above, the Operator shall surrender to the Agency allowances equal to the annual reportable emissions from such activities in the preceding calendar year or part thereof, together with such allowances as may be necessary to cover any earlier calendar year in respect of which allowances remain outstanding and due as described in Condition 4.1.2 above.

4.1.4 The Operator may, from 2008 onwards, subject to the provisions of the Regulations and the relevant National Allocation Plan for that compliance year, surrender emission reduction units (ERUs) and certified emission reduction units (CERs) in place of allowances.

4.2 The holding, transfer, surrender and cancellation of allowances shall be in accordance with the requirements of any Regulations adopted as provided for under Article 19.3 of Directive 2003/87/EC, any amendment or revision to the same and any guidance issued by the Agency or the National Administrator.

4.3 The Operator shall provide the National Administrator with all the necessary information for the opening of an Operator holding account for the installation described in Condition 1 of this permit within twenty working days of the issue of this permit, unless such an account is already open.

Reason: *To provide for the surrendering, holding, transfer and cancellation of allowances in respect of reported emissions.*

Condition 5. Penalties

5.1 Any Operator who fails to comply with Condition 4.1 above shall be subject to the provisions of the Regulations, including, but not limited to the payment of penalties.

Reason: To provide for the payment of excess emissions penalties as required under the Regulations.

Sealed by the seal of the Agency on this the 05 February 2016:

PRESENT when the seal of the Agency was affixed hereto:

_____

Ms. Annette Prendergast
Inspector/ Authorised Person

Appendix 1 to Greenhouse Gas Emissions Permit Number IE-GHG079-10387

Monitoring Plan

1. Guidelines & Conditions

1. Directive 2003/87/EC as amended by Directive 2009/29/EC (hereinafter "the (revised) EU ETS Directive") requires operators of installations which are included in the European Greenhouse Gas Emission Trading Scheme (the EU ETS) to hold a valid GHG emission permit issued by the relevant Competent Authority and to monitor and report their emissions and have the reports verified by an independent and accredited verifier.

The Directive can be downloaded from:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2003L0087:20090625:EN:PDF

2. The Monitoring and Reporting Regulation (Commission Regulation (EU) No 601/2012) (hereinafter the "MRR") defines further requirements for monitoring and reporting.

The MRR can be downloaded from:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:181:0030:0104:EN:PDF

Article 12 of the MRR sets out specific requirements for the content and submission of the monitoring plan and its updates. Article 12 outlines the importance of the Monitoring plan as follows:

The monitoring plan shall consist of a detailed complete and transparent documentation of the monitoring methodology of a specific installation [or aircraft operator] and shall contain at least the elements laid down in Annex I.

Furthermore Article 74(1) states:

Member States may require the operator and aircraft operator to use electronic templates or specific file formats for submission of monitoring plans and changes to the monitoring plan as well as for submission of annual emissions reports tonne-kilometre data reports verification reports and improvement reports. Those templates or file format specifications established by the Member States shall at least contain the information contained in electronic templates or file format specifications published by the Commission

3. All Commission guidance documents on the Monitoring and Reporting Regulation will be published at the link below as they become available:

http://ec.europa.eu/clima/policies/ets/monitoring/index_en.htm

(a) Information sources:

EU Websites:

EU-Legislation: http://eur-lex.europa.eu/en/index.htm
EU ETS general: http://ec.europa.eu/clima/policies/ets/index_en.htm

Monitoring and Reporting in the EU ETS: http://ec.europa.eu/clima/policies/ets/monitoring/index_en.htm

Environmental Protection Agency Website:

http://www.epa.ie

Environmental Protection Agency Contact:

GHGpermit@epa.ie

2. Application Details

The Installation Name, Site Name and the address of the site of the installation are detailed below. The Site Name and address can be updated from the Organisation Details Page on the ETSWAP website. The Installation Name can only be updated by your Competent Authority.

Installation name	Hovione Limited
Site name	Hovione Limited
Address	Loughbeg Ringaskiddy Cork Ireland
Grid reference of site main entrance	E 178928, N 63252
Licence held pursuant to the Environmental Protection Agency Act 1992, as amended.	Yes

IPC/IE Licence Register Number	Licence holder	Competent body
P0010-04	Hovione Limited	Environmental Protection Agency

Has the regulated activity commenced at the Installation?	Yes
Date of Regulated Activity commencement	01 January 2008

This information is only required to identify the first relevant reporting year of an installation. If the installation was in operation from the beginning of 2008 and held a Greenhouse Gas Emissions Permit from this point, 1 January 2008 will be used where the actual date of commencement is not readily known.

3. About the Operator

The information about the "Operator" is listed below. The "Operator" is defined as the person who it is proposed will have control over the relevant Regulated Activities in the installation in respect of which this application is being made.

(b) Operator Details

The name of the operator and where applicable the company registration number are detailed below. These details can only be updated by the Environmental Protection Agency.

Operator name	Hovione Limited
Company Registration Number	463979

Operator Legal status

The legal status of the operator is:	Company / Corporate Body

(c) Company / Corporate Body

Is the trading / business name different to the operator name?	No

Details of the individual authorised to submit this application on behalf of the company / corporate body.

Title	[redacted]
Forename	[redacted]
Surname	[redacted]
Position	HSE Director

Registered office address

Address Line 1	Loughbeg
Address Line 2	N/A
City/Town	Ringaskiddy
County	Cork
Postcode	N/A

Principal office address

Is the principal office address different to the registered office address?	No

Holding company

Does the company belong to a holding company?	Yes
Holding company name	Hovione Holding Limited

Holding company address

Address Line 1	Aubin House, 11th floor
Address Line 2	171-172 Gloucester Road
City/Town	Wanchai
County	N/A
Postcode	Hong Kong SAR
Company registration number	N/A
Is the holding company principal address different to the	No

holding company address?

(d) Operator Authority

Does the operator named above have the authority and ability to:

a.	manage site operations through having day-to-day control of plant operation including the manner and rate of operation	Yes
b.	ensure that permit conditions are effectively complied with	Yes
c.	control monitor and report specified emissions	Yes
d.	be responsible for trading in Allowances so that at the end of a reporting period allowances can be balanced against reported emissions.	Yes

4. Service Contact

e. Service Contact

Name	[redacted]
Address / Email Address	Loughbeg Ringaskiddy Cork Ireland

5. Installation Activities

f. Installation Description

Below is a description of the installation and its activities, a brief outline description of the site and the installation and the location of the installation on the site. The description also includes a non-technical summary of the activities carried out at the installation briefly describing each activity performed and the technical units used within each activity.

Hovione Limited is a multi purpose organic chemical synthesis plant capable of the custom manufacture of chemical products for the pharmaceutical industry. The plant can accommodate a wide range of complete chemical reactions and processes.

Synthesis of the various products takes place by batch processing under detailed and comprehensive cGMP (current Good Manufacturing Practice) disciplines.

The production capacity resides in Production Building B-01, B-02 and B-10, the spray dryer building .

The following equipment is used in the production processes: reactor vessels, isolation filters, dryers and crystallisers together with ancillary piping, pumps, control equipment and services.

The combustion installation main components consists of 4 steam boilers (10 MW each) all fuelled on natural gas and which are run as required. There are a number of smaller diesel powered generators and pumps and a number of smaller natural gas users.

There is one incoming main gas connection to the site.

g. Annex 1 Activities

The table below lists the technical details for each Annex 1 activity carried out at the installation.

Note that 'capacity' in this context means:

- Rated thermal input (for combustion installations) which is defined as the rate at which fuel can be burned at the maximum continuous rating of the installation multiplied by the calorific value of the fuel and expressed as megawatts thermal.
- Production capacity for those specified Annex I activities for which production capacity determines ETS eligibility.

Annex 1 Activity	Total Capacity	Capacity units	Specified Emissions
Combustion of fuels in installations with a total rated thermal input exceeding 20 MW (except in installations for the incineration of hazardous or municipal waste)	44.63	MW	Carbon Dioxide

h. Site Diagram

The table below lists attachments (if available) that provide a simple diagram showing emissions sources source streams sampling points and metering/measurement equipment.

Attachment	Description
100-G-136 GHG Source streams.pdf	Source Streams
100-G-137 Gas Meters.pdf	Gas Meters
100-G-134 Rev 01TOs removed.pdf	100-G-134 GHG Emission Sources
100-G-135 Rev 01 TOs removed.pdf	100-G 135 GHG Emission Points

i. Estimated Annual Emissions

Detail of the estimated annual emission of CO_2 equivalent. This information enables categorisation of the installation in accordance with Article 19 of the MRR and is based on the average verified annual emissions of the previous trading period data OR if this data is not available or is inappropriate a conservative estimate of annual average emissions including transferred CO_2 excluding CO_2 from biomass.

Estimated Annual Emissions (tonnes $CO_{2(e)}$) 3454.6

Installation Category: A

6. Emissions Details

j. About your emissions

Annex I of the Monitoring and Reporting Regulations (MRR) requires that monitoring plans include a description of "the installation" and activities to be carried out and monitored including a list of emission sources and source streams. The information provided in this template relates to the Annex I activity(ies) comprised in the installation in question and should relate to a single installation. It includes any activities carried out by the operator and does not include related activities carried out by other operators.

k. Emission Sources

The table below lists all the emission sources at the installation, which may include directly associated activities/excluded activities.

Emission Source Reference	Emission Source Description
S1-PU-34-01-1100	Old Diesel Fire Pump
S2-PU-34-01-1200	Old Diesel Fire Pump
S3-BLR-3202-1000	Hot Water Boiler

Emission Source Reference	**Emission Source Description**
S4-BLR-32-02-2000	Hot Water Boiler
S5-BLR-37-01-2000	Hot Water Boiler
S6-BLR-31-11-1000	Hot Water Boiler
S7-BLR-31-11-2000	Hot Water Boiler
S8-GEN-11-09-4000	Emergency Diesel Generator
S9-PU-11-23-1100	Diesel Foam System Pump
S10-BLR-11-01-3000	Steam Boiler
S11-BLR-11-11-2000	Steam Boiler
S12-BLR-11-11-3000	Steam Boiler
S13-BLR-11-11-1000	Steam Boiler
S16	Canteen
Forklift Trucks - Diesel	Forklift Trucks
WWTP	Waste Water Treatment Plant

The table below lists the emission sources which are linked to the Regulated Activities at the installation.

Emission Source Reference	**Emission Source Description**
S1-PU-34-01-1100	Old Diesel Fire Pump
S2-PU-34-01-1200	Old Diesel Fire Pump
S3-BLR-3202-1000	Hot Water Boiler
S4-BLR-32-02-2000	Hot Water Boiler
S5-BLR-37-01-2000	Hot Water Boiler
S6-BLR-31-11-1000	Hot Water Boiler
S7-BLR-31-11-2000	Hot Water Boiler
S8-GEN-11-09-4000	Emergency Diesel Generator
S9-PU-11-23-1100	Diesel Foam System Pump
S10-BLR-11-01-3000	Steam Boiler
S11-BLR-11-11-2000	Steam Boiler
S12-BLR-11-11-3000	Steam Boiler
S13-BLR-11-11-1000	Steam Boiler
S16	Canteen

I. Emission Points

The table below lists all the emission points at the installation, which may include directly associated activities/excluded activities.

Emission Point Reference	Emission Point Description
LB-08	Old Diesel Fire Pump Exhaust
LB-09	Old Diesel Fire Pump Exhaust
LB-01	Hot Water Boiler Flue
LB-02	Hot Water Boiler Flue
LB-10	Hot Water Boiler Flue
LB-04	Hot Water Boiler Flue
LB-05	Hot Water Boiler Flue
LB-03	Emergency Diesel Generator Exhaust
LB-11	Diesel Foam System Pump Exhaust
UT1-06	Steam Boiler Stack
UT1-07	Steam Boiler Stack
UT1-08	Steam Boiler Stack
UT1-09	Steam Boiler Stack
LB-012	Canteen Various
FLT Diesel EP	Forklift Truck Exhausts
WWTP EP	Waste Water Treatment Plant

m. Source Streams (fuels and/or materials)

The table below lists the source streams which are used in Schedule 1 Activities at the installation.

Source Stream Reference	Source Stream Type	Source Stream Description
NG-001	Combustion: Other gaseous & liquid fuels	Natural Gas
DSL-001	Combustion: Commercial standard fuels	Gas/Diesel Oil
PG-001	Combustion: Other gaseous & liquid fuels	Liquefied Petroleum Gases

n. Emissions Summary

The table below provides a summary of the emission source and source stream details in the installation.

Source streams (Fuel / Material)	Emission Source Refs.	Emission Point Refs.	Annex 1 Activity
NG-001	S10-BLR-11-01-3000,S11-BLR-11-11-2000,S12-BLR-11-11-3000,S13-BLR-11-11-1000,S16,S3-BLR-3202-	LB-01,LB-012,LB-02,LB-04,LB-05,LB-10,UT1-06,UT1-07,UT1-08,UT1-09	Combustion of fuels in installations with a total rated thermal input exceeding 20 MW (except

Source streams (Fuel / Material)	Emission Source Refs.	Emission Point Refs.	Annex 1 Activity
	1000,S4-BLR-32-02-2000,S5-BLR-37-01-2000,S6-BLR-31-11-1000,S7-BLR-31-11-2000		in installations for the incineration of hazardous or municipal waste)
DSL-001	Forklift Trucks - Diesel,S10-BLR-11-01-3000,S11-BLR-11-11-2000,S12-BLR-11-11-3000,S13-BLR-11-11-1000,S1-PU-34-01-1100,S2-PU-34-01-1200,S8-GEN-11-09-4000,S9-PU-11-23-1100	LB-08,LB-09,LB-03,LB-11,UT1-06,UT1-07,UT1-08,UT1-09,FLT Diesel EP	Combustion of fuels in installations with a total rated thermal input exceeding 20 MW (except in installations for the incineration of hazardous or municipal waste)
PG-001	S10-BLR-11-01-3000,S11-BLR-11-11-2000,S12-BLR-11-11-3000,S13-BLR-11-11-1000	UT1-06,UT1-07,UT1-08,UT1-09	Combustion of fuels in installations with a total rated thermal input exceeding 20 MW (except in installations for the incineration of hazardous or municipal waste)

o. Excluded Activities

Certain activities that result in greenhouse gas emissions may be excluded under the EU ETS Directive for example truly mobile sources such as vehicle emissions.

Do you have any excluded activities which need to be identified in your monitoring plan? Yes

Detail of these activities:

Source Stream Refs	Emission Source Ref	Emission Point Ref
DSL-001	Forklift Trucks - Diesel	FLT Diesel EP
n/a	WWTP	WWTP EP

7. Low Emissions Eligibility

p. Low Emissions Eligibility

The operator may submit a simplified monitoring plan for an installation where no nitrous oxide activities are carried out and it can be demonstrated that:

(a) the average verified annual emissions of the installation during the previous trading period was less than 25 000 tonnes $CO_{2(e)}$ per year or;

(b) where this data is not available or inappropriate a conservative estimate shows that emissions for the next 5 years will be less than 25 000 tonnes $CO_{2(e)}$ per year.

Note: the above data shall include transferred CO_2 but exclude CO_2 stemming from biomass.

Does the installation satisfy the criteria for installations with low emissions (as defined by Article 47 of the MRR)?	Yes

If the installation is an installation with low emissions as defined above there are a number of special provisions which may be applied to provide a simplified monitoring plan. These provisions are set out in Article 47 of the MRR.

8. Monitoring Approaches

q. Monitoring Approaches

Emissions may be determined using either a calculation based methodology ("calculation") or measurement based methodology ("measurement") except where the use of a specific methodology is mandatory according to the provisions of the MRR. [MRR Article 21].

Note: the operator may subject to competent authority approval combine measurement and calculation for different sources. The operator is required to ensure and demonstrate that neither gaps nor double counting of reportable emissions occurs.

Please specify whether or not you propose to apply the following monitoring approaches. Select all monitoring approaches that are applicable to you. The consecutive sections will become mandatory based on the selected approaches.

Calculation	Yes
Measurement	No
Fall-back approach	No
Monitoring of N_2O	No
Monitoring of PFC	No
Monitoring of transferred / inherent CO_2	No

9. Calculation

r. Approach Description

The calculation approach including formulae used to determine annual CO_2 emissions:

The data collection and calculation of Installation CO2 emissions is governed by site procedure HE.HSE.IOP082 " Site Energy, Water and CO2 Emission Management".

Natural gas:

Supplier bills are collected and the gas consumption in gross kWh is used as the initial basis for activity data. There are two main gas meters in parallel in the gas compound along with temperature and pressure correctors, altogether give an uncertainty of 1.41% for each meter. For nett calorific value conversion of natural gas, we use the volume to gross energy conversion by gas supplier on energy bills and gross to net gas calorific value conversion method specified by the Agency. Emission factor and oxidation factor are taken from the annual "Country Specific Net Calorific Values and CO2 Emission Factors for use in the Annual Installation Emissions Report" document issued by the Agency.

Gas oil:

For Diesel data collection, total projected diesel emissions are in the order of 11 tonnes and approx 0.31% of total site emissions (2014 verified report information). This qualifies as a 'de minimis' source. It is proposed to account for diesel by systematically capturing and checking all diesel delivery dockets in conjunction with the opening and closing stock inventory for diesel and using these as a basis for quantifying diesel fuel coming on to site. Diesel oil is used for forklift trucks on site. It is excluded from the scope of the EUETS scheme and as such is deducted from the total volume of fuel delivered to the site. The fuel source for the forklift trucks is the central diesel oil storage tank. A flow meter is now installed on the line into the fork truck diesel tank . A PM routine will record the volume dispensed to the forktruck diesel tank on a monthly basis. Diesel oil usage for forklift trucks will be deducted from the total diesel imported as per site procedure HE.HSE.IOP082 " Site Energy, Water and CO2 Emission Management". Density for diesel is taken from the supplier data sheet,data sheets will be obtained twice a year. Net calorific value, emission factor and oxidation factor are taken from the annual 'Country Specific Net calorific Values and CO2 Emission factors for use in the Annual Installation Emission report 'document issued by the EPA.

LPG:

The total projected LPG annual usage is in the order of 100 kg which equates to less than 1 ton CO2 and between 0-1% of total site emissions. It is used for pre ignition of diesel fuel oil under emergency circumstances on the steam boilers. It is proposed to account for LPG by reference to LPG delivery dockets and using these as the basis for specifically quantifying LPG fuel coming on to site.

s. Measurement Devices

Below is a description of the specification and location of the measurement systems used for each source stream where emissions are determined by calculation

Also a description of all measurement devices including sub-meters and meters used to deduct non-Annex I activities to be used for each source and source stream.

Source Stream Refs.	Emission Source Refs.	Measurement Device Ref.	Type of Measurement Device	Measurement Range	Metering Range Units	Specified Uncertainty (+/- %)	Location
NG-001	S3-BLR-3202-1000,S4-BLR-32-02-2000,S5-BLR-37-01-2000,S6-BLR-31-11-1000,S7-BLR-31-11-2000,S10-BLR-11-01-3000,S11-BLR-11-11-2000,S12-BLR-11-11-3000,S13-BLR-11-11-1000,S16	SN 80112125/2014 Duty standby	Turbine meter	32-650	m3/hr	1.41	Bord Gais Compound (Main Entrance)
NG-001	S10-BLR-11-01-3000,S11-BLR-11-11-2000,S12-BLR-11-11-3000,S13-BLR-11-11-1000,S16,S3-BLR-3202-1000,S4-BLR-32-02-2000,S5-BLR-37-01-2000,S6-BLR-31-11-1000,S7-BLR-31-11-2000	SN 80042149/1998 Duty standby	Turbine meter	50-650	m3/hr	1.41	Bord Gais Compound (Main Entrance)
DSL-001	S1-PU-34-01-1100,S2-PU-34-01-1200	Deliveries To Old Fire Pump Building	Delivery receipts in conjunction with opening & closing	N/A	N/A	N/A	Tank at Old Fire Pump Building

Source Stream Refs.	Emission Source Refs.	Measurement Device Ref.	Type of Measurement Device	Measurement Range	Metering Range Units	Specified Uncertainty (+/- %)	Location
			stocks				
DSL-001	S10-BLR-11-01-3000,S11-BLR-11-11-2000,S12-BLR-11-11-3000,S13-BLR-11-11-1000,S8-GEN-11-09-4000,S9-PU-11-23-1100	Deliveries to Eng Building Location	Delivery receipts in conjunction with opening & closing stocks	N/A	N/A	N/A	At Engineering Building
DSL-001	Forklift Trucks - Diesel,S10-BLR-11-01-3000,S11-BLR-11-11-2000,S12-BLR-11-11-3000,S13-BLR-11-11-1000,S8-GEN-11-09-4000,S9-PU-11-23-1100	Deduction For Fork lift Truck	flow meter in conjunction with opening & closing stocks	N/A	N/A	N/A	FLT - Diesel Tank
PG-001	S10-BLR-11-01-3000,S11-BLR-11-11-2000,S12-BLR-11-11-3000,S13-BLR-11-11-1000	Boiler House	Delivery Receipts	N/A	N/A	N/A	Boiler House

Source Stream Refs.	Measurement Device Ref.	Determination Method	Instrument Under Control Of	Conditions Of Article 29(1) Satisfied	Invoices Used To Determine Amount Of Fuel Or Material	Trade Partner And Operator Independent
NG-001	SN 80112125/2014	Continual	Trade partner	Yes	Yes	Yes

Source Stream Refs.	Measurement Device Ref.	Determination Method	Instrument Under Control Of	Conditions Of Article 29(1) Satisfied	Invoices Used To Determine Amount Of Fuel Or Material	Trade Partner And Operator Independent
	Duty standby					
NG-001	SN 80042149/1998 Duty standby	Continual	Trade partner	Yes	Yes	Yes
DSL-001	Deliveries To Old Fire Pump Building	Batch	Trade partner	Yes	Yes	Yes
DSL-001	Deliveries to Eng Building Location	Batch	Trade partner	Yes	Yes	Yes
DSL-001	Deduction For Fork lift Truck	Batch	Operator	N/A	N/A	N/A
PG-001	Boiler House	Batch	Trade partner	Yes	Yes	Yes

t. Applied Tiers

The table below identifies the tiers applied against the relevant input data for each source stream and confirms whether a standard (MRR Article 24) or mass balance (MRR Article 25) approach is applied.

(i) The highest tiers as defined in Annex II of the MRR should be used by Category B and C installations to determine the activity data and each calculation factor (except the oxidation factor and conversion factor) for each major source stream. Category A installations should apply as a minimum the tiers listed in Annex V.

(ii) Operators may apply a tier one level lower than those referred to in sub paragraph (i) above for Category C installations and up to two levels lower for Category A and B installations with a minimum of tier 1 if the operator can demonstrate to the satisfaction of the competent authority that this is not technically feasible or would lead to unreasonable cost to apply the higher tier. The justification for not applying the higher tier should be recorded when completing the tier table.

(iii) The competent authority may allow an operator to apply even lower tiers than those referred to in the sub paragraph (ii) with a minimum of tier 1 for a transition period of up to three years if the operator can demonstrate to the satisfaction of the competent authority that this is not technically feasible or would lead to unreasonable cost to apply the higher tier and provides an improvement plan detailing how and by when at least the tier referred to in sub paragraph (ii) will be achieved. The improvement plan should be referenced in subsequent table and provided to the competent authority at the time of submission of this plan.

(iv) For minor source streams operators shall apply the highest tier which is technically feasible and will not lead to unreasonable costs with a minimum of tier 1 for activity data and each calculation factor. For de-minimis source streams operators may use conservative estimations rather than tiers unless a defined tier can be achieved without additional effort (MRR Article 26(2)).

(v) Installations with low emissions as identified in section 6(d) may apply as a minimum tier 1 for determining activity data and calculation factors for all source streams unless higher accuracy is achievable without additional effort.

* Note 1: For commercial standard fuels the minimum tiers listed in Annex V of the MRR may be applied for all activities in all installations.

* Note 2: If you are intending to apply a fall-back approach please complete the table below and select "n/a" for the tiers to be applied for each source stream where a fall-back approach is used. Section 10 "Fall-back" must also be completed for these source streams.

* Note 3: For biomass or mixed fuels the emission factor is the preliminary emission factor as defined in Definition 35 Article 3 of the MRR.

Source Stream Refs.	Emission Source Refs.	Measurement Device Refs.	Overall Metering Uncertainty (less than +/- %)	Applied Monitoring Approach	Activity Data Tier Applied	Net Calorific Value Tier Applied	Emission Factor Tier Applied	Carbon Content Tier Applied	Oxidation Factor Tier Applied	Conversion Factor Tier Applied	Biomass Fraction Tier Applied	Estimated Emissions $tCO_{2(e)}$	% of Total Estimated Emissions	Source Category	Highest Tiers Applied	Justification for not applying the highest tiers	Improvement Plan Reference (where applicable)
NG-001	S3-BLR-3202-1000,S4-BLR-32-02-2000,S5-BLR-37-01-2000,S6-BLR-31-11-1000,S	SN 80112 125/2014 Duty standby,SN 80042 149/1998 Duty standby	<1.5%	Standard	4	2b	2a	N/A	1	N/A	N/A	3443.78	99.69	Major	Yes	n/a	n/a

Source Stream Refs.	Emission Source Refs.	Measurement Device Refs.	Overall Metering Uncertainty (less than +/- %)	Applied Monitoring Approach	Activity Data Tier Applied	Net Calorific Value Tier Applied	Emission Factor Tier Applied	Carbon Content Tier Applied	Oxidation Factor Tier Applied	Conversion Factor Tier Applied	Biomass Fraction Tier Applied	Estimated Emissions $tCO_{2(e)}$	% of Total Estimated Emissions	Source Category	Highest Tiers Applied	Justification for not applying the highest tiers	Improvement Plan Reference (where applicable)
	7-BLR-31-11-2000,S10-BLR-11-01-3000,S11-BLR-11-11-2000,S12-BLR-11-11-3000,S13-BLR-11-11-1000,S16																
DSL-001	S10-BLR-11-01-3000,S11-BLR-11-11-	Deliveries To Old Fire Pump Building,Deliv	N/A	Standard	No tier	2a	2a	N/A	1	N/A	N/A	10.77	0.31	De-minimis	N/A	n/a	n/a

Source Stream Refs.	Emission Source Refs.	Measurement Device Refs.	Overall Metering Uncertainty (less than +/- %)	Applied Monitoring Approach	Activity Data Tier Applied	Net Calorific Value Tier Applied	Emission Factor Tier Applied	Carbon Content Tier Applied	Oxidation Factor Tier Applied	Conversion Factor Tier Applied	Biomass Fraction Tier Applied	Estimated Emissions $tCO_{2(e)}$	% of Total Estimated Emissions	Source Category	Highest Tiers Applied	Justification for not applying the highest tiers	Improvement Plan Reference (where applicable)
	2000,S12-BLR-11-11-3000,S13-BLR-11-11-1000,S1-PU-34-01-1100,S2-PU-34-01-1200,S8-GEN-11-09-4000,S9-PU-11-23-1100	eries to Eng Building Location,Deduction For Fork lift Truck															
PG-001	S10-BLR-11-01-3000,S11-BLR-	Boiler House	N/A	Standard	No tier	2a	2a	N/A	1	N/A	N/A	0	0	De-minimis	N/A	n/a	n/a

Source Stream Refs.	Emission Source Refs.	Measurement Device Refs.	Overall Metering Uncertainty (less than +/- %)	Applied Monitoring Approach	Activity Data Tier Applied	Net Calorific Value Tier Applied	Emission Factor Tier Applied	Carbon Content Tier Applied	Oxidation Factor Tier Applied	Conversion Factor Tier Applied	Biomass Fraction Tier Applied	Estimated Emissions $tCO_{2(e)}$	% of Total Estimated Emissions	Source Category	Highest Tiers Applied	Justification for not applying the highest tiers	Improvement Plan Reference (where applicable)
	11-11-2000,S12-BLR-11-11-3000,S13-BLR-11-11-1000																

Total Estimated Emissions for Calculation (tonnes $CO_{2(e)}$) 3454.55

u. Applied tiers

Applied tiers for each source stream

Source Stream Ref.	Emission Source Refs.	Activity Data Tier Applied	Net Calorific Value Tier Applied	Emission Factor Tier Applied	Carbon Content Tier Applied	Oxidation Factor Tier Applied	Conversion Factor Tier Applied	Biomass Fraction Tier Applied
NG-001	S3-BLR-3202-1000,S4-BLR-32-02-2000,S5-BLR-37-01-2000,S6-BLR-31-11-1000,S7-BLR-31-11-2000,S10-BLR-11-01-3000,S11-BLR-11-11-2000,S12-BLR-11-11-3000,S13-BLR-11-11-1000,S16	4	2b	2a	N/A	1	N/A	N/A
DSL-001	S10-BLR-11-01-3000,S11-BLR-11-11-2000,S12-BLR-11-11-3000,S13-BLR-11-11-1000,S1-PU-34-01-1100,S2-PU-34-01-1200,S8-GEN-11-09-4000,S9-PU-11-23-1100	No tier	2a	2a	N/A	1	N/A	N/A
PG-001	S10-BLR-11-01-3000,S11-BLR-11-11-2000,S12-	No tier	2a	2a	N/A	1	N/A	N/A

Source Stream Ref.	Emission Source Refs.	Activity Data Tier Applied	Net Calorific Value Tier Applied	Emission Factor Tier Applied	Carbon Content Tier Applied	Oxidation Factor Tier Applied	Conversion Factor Tier Applied	Biomass Fraction Tier Applied
	BLR-11-11-3000,S13-BLR-11-11-1000							

v. Justification for Applied tiers

Justifications for the applied tiers for each major source stream where highest tiers are not currently achieved.

Source Stream Ref.	**Emission Source Refs.**	**Justification for the applied tier**	**Improvement Plan Reference (where applicable)**
N/A	N/A	N/A	N/A

10. Calculation Factors

w. Default Values

The table below lists, for each parameter, where default values are to be used for calculation factors.

Source Stream Refs.	Emission Source Refs.	Parameter	Reference Source	Default Value applied (where appropriate)
NG-001	S10-BLR-11-01-3000,S11-BLR-11-11-2000,S12-BLR-11-11-3000,S13-BLR-11-11-1000,S16,S3-BLR-3202-1000,S4-BLR-32-02-2000,S5-BLR-37-01-2000,S6-BLR-31-11-1000,S7-BLR-31-11-2000	EF & OxF	Country Specific Net Calorific Values & CO2 emission factors for use in the Annual Installation Emission Report - Updated annually by the EPA	n/a
DSL-001,PG-001	S10-BLR-11-01-3000,S11-BLR-11-11-2000,S12-BLR-11-11-3000,S13-BLR-11-11-1000,S1-PU-34-01-1100,S2-PU-34-01-1200,S8-GEN-11-09-4000,S9-PU-11-23-1100	NCV, EF & OxF	Country Specific Net Calorific values & CO2 emission factors for use in the Annual Installation Emission Report-updated annually by the EPA	n/a

Sampling and Analysis

Do you undertake sampling and analysis of any of the parameters used in the calculation of your CO_2 emissions? No

11. Management

x. Monitoring and Reporting Responsibilities

Responsibilities for monitoring and reporting emissions from the installation are listed below:

Relevant job titles/posts and provide a succinct summary of their role relevant to monitoring and reporting are listed below.

Job Title / Post	**Responsibilities**
Environmental Technical Specialist	- Timely preparation and submission of the verified Greenhouse Gas (GHG) Emissions AIER to the EPA. - Ensure that all other aspects of the site's GHG permit are addressed in a timely manner and to the satisfaction of the Agency. - Preparation, submission and where required revision of the M & R plan. - Ensure internal reviews are completed as per permit and site procedure HE.HSE.IOP082 " Site Energy, Water and CO2 Emission Management" requirements - Ensure any changes to the operation are reviewed and submitted to the agency before 31st December each year.
HSE Director	- Responsible for confirming all relevant information and is not involved in the determination or recording of that same data. - Ensure that balancing of allowances with the additional financial stipulations stated in the GHG permit are dealt with in a manner which is in accordance with the conditions in the GHG permit - Changes to the monitoring methodology shall be proposed without undue delay - Ensure that by 30th April each year, allowances equal to the annual reportable emissions of the relevant greenhouse gases in the preceding year, are surrendered to the Agency.
Utilities & Site Services Engineer	- Monitor energy and water usage. - Maintain invoices for electricity, gas, water, diesel and LPG. - Maintain the gas meter calibration records - Ensure internal reviews are completed as per permit

Job Title / Post	**Responsibilities**
	and site procedure HE.HSE.IOP082 " Site Energy, Water and CO2 Emission Management" requirements

Attachment	**Description**
N/A	N/A

y. Assignment of Responsibilities

Details of the procedure used for managing the assignment of responsibilities for monitoring and reporting within the installation and for managing the competencies of responsible personnel in accordance with Article 58(3)(c) of the MRR:

This procedure identifies how the monitoring and reporting responsibilities for the roles identified above are assigned and how training and reviews are undertaken.

Title of procedure	Site Energy, Water and CO2 Management
Reference for procedure	HE.HSE.IOP082
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	Section 4 in HE.HSEIOP082 details the subject topic and responsibilities of each person. All relevant personnel are made aware of their responsibilities when they acknowledge the procedure on Docstream, the Hovione internal on-line document control system. All IOP's are reviewed on a three year basis in accordance with corporate procedure HQ.CCO.COP001 to manage the assignment of responsibilities for monitoring and reporting within the installation and for managing the competencies of responsible personnel in accordance with Article 58(3)(c) of the MRR.
Post or department responsible for the procedure and for any data generated	HSE department
Location where records are kept	Docstream-Hovione online document control system
Name of IT system used	Docstream
List of EN or other standards applied	N/A

z. Monitoring Plan Appropriateness

Details of the procedure used for regular evaluation of the monitoring plan's appropriateness covering in particular any potential measures for the improvement of the monitoring methodology:

Title of procedure	Site Energy, Water and CO2 Management
Reference for procedure	HE.HSE.IOP082
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	Section 5.1.5 in HE.HSEIOP082 details the procedure for the internal reviews /checks of the data and monitoring plan before the verification process regarding the

	appropriateness of the monitoring plan to ensure regular evaluation of the monitoring plan's appropriateness, covering in particular any potential measures for the improvement of the monitoring methodology.
Post or department responsible for the procedure and for any data generated	HSE department
Location where records are kept	Docstream-Hovione online document control system
Name of IT system used	Docstream
List of EN or other standards applied	N/A

aa. Data Flow Activities

Details of the procedures used to manage data flow activities in accordance with Article 57 of the MRR:

Title of procedure	Site Energy, Water and CO2 Management
Reference for procedure	HE.HSE.IOP082
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	Section 5.1.3 in HE.HSEIOP082 details the sequence and interaction of data acquisition and handling activities, including methods of calculations and measurements, to manage data flow activities in accordance with Article 57 of the MRR.
Post or department responsible for the procedure and for any data generated	HSE department
Location where records are kept	Docstream-Hovione online document control system
Name of IT system used	Docstream
List of EN or other standards applied	N/A
List of primary data sources	- Gas and LPG Invoices - Diesel Invoices & opening and closing stocks - Fork truck diesel usage - flow meter - Country specific net calorific values & CO2 emission factors for use in the Annual Installation Emission Report - updated by the Agency annually

Description of the relevant processing steps for each specific data flow activity. Identify each step in the data flow and include the formulas and data used to determine emissions from the primary data. Include details of any relevant electronic data processing and storage systems and other inputs (including manual inputs) and confirm how outputs of data flow activities are recorded	Natural gas data collection: - Supplier bills are collected and the gas consumption in gross kWh is used as the initial basis for activity data. For nett calorific value conversion of natural gas, we use the volume to gross energy conversion by gas supplier on energy bills and gross to nett gas calorific value conversion method specified by the Agency. Emission factor and oxidation factor are taken from the annual "Country Specific Net Calorific Values and CO2 Emission Factors for use in the Annual Installation Emissions Report" document issued by the Agency. Gas oil: - • For Diesel data collection,total projected diesel emissions are in the order of 11 tonnes and approx 0.31% of total site emissions (2014 verified report information). This qualifies as a 'de minimis' source. It is proposed to account for diesel by systematically capturing and checking all diesel delivery dockets in conjunction with the opening and closing stock inventory for diesel and using these as a basis for quantifying diesel fuel coming on to site. Diesel oil usage for forklift trucks will be deducted from the total diesel imported as per section 5.1.11 in HE.HSEIOP082. Density for diesel is taken from the supplier data sheet, data sheets will be obtained twice a year. Net calorific value, emission factor and oxidation factor are taken from the annual 'Country Specific Net calorific Values and CO2 Emission factors for use in the Annual Installation Emission report 'document issued by the EPA. LPG: The total projected LPG annual usage is in the order of 100 kg which equates to 0 tonnes and between 0-1% of total site emissions. It is used for pre ignition of diesel fuel oil under emergency circumstances on the steam boilers. It is proposed to account for LPG by reference to LPG delivery dockets and using these as the basis for specifically quantifying LPG fuel coming on to site. All of this data is then in putted into an excel spreadsheet which is then used to carry out the required calculations. This spreadsheet is reviewed by our verifier before entry

into the AIER.

Submit relevant documents to record data flow activities

Attachment	Description
N/A	N/A

bb. Assessing and Controlling Risks

Details of the procedures used to assess inherent risks and control risks in accordance with Article 58 of the MRR:

Title of procedure	Internal Environmental Audit Procedure
Reference for procedure	HE.HSE.IOP060
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	Assessing and controlling risks is part of the environmental management system on site, to assess inherent risks and control risks in accordance with Article 58 of the MRR. A risk assessment has been carried out and is located in the greenhouse gas folder in the Hovione O drive.
Post or department responsible for the procedure and for any data generated	HSE department
Location where records are kept	Docstream for procedures. O drive for Risk assessment and audits
Name of IT system used	Hovione Intranet, Docstream
List of EN or other standards applied	N/A

cc. Quality Assurance of Metering / Measuring Equipment

Details of the procedures used to ensure quality assurance of measuring equipment in accordance with Article 58 and 59 of the MRR.

Title of procedure	Site Energy, Water and CO2 Management
Reference for procedure	HE.HSE.IOP082
Diagram reference	N/A

Brief description of procedure. The description should cover the essential parameters and operations performed	Section 5.1.12 in HE.HSE.IOP082 details that the records of calibration from Bord Gais for the gas meters is obtained annually by the Utilities & Site Services Engineer and stored in the Hovione O drive, to ensure quality assurance of measuring equipment in accordance with Article 58 and 59 of the MRR. The on site measuring equipment is calibrated and maintained in accordance with the specifications on SAP.
Post or department responsible for the procedure and for any data generated	HSE dept
Location where records are kept	Docstream-Hovione online document control system
Name of IT system used	Docstream
List of EN or other standards applied	N/A

dd. Quality Assurance of Information Technology used for Data Flow Activities

Details of the procedures used to ensure quality assurance of information technology used for data flow activities in accordance with Article 58 and 60 of the MRR:

Title of procedure	There are 5 procedures to cover this topic: a)Computerized systems validation b)Electronic records and electronic signatures c)User access to Hovione software applications d)system backup and restore procedure e)security of installations and servers
Reference for procedure	a)CCO.COP039 b)CCO.COP011 c)IT.IOP025 d)CCO.COP048 e)IT.IOP018
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	a)Description: Computerized systems are validated using the life cycle approach according to system criticality and the activities are performed/ documented, to ensure quality assurance of information technology used for data flow activities in accordance with Article 58 and 60 of the MRR. b)Backups are performed daily and recorded in IT operations. Each backup is review and verified to confirm that all anomalies that occurred have been clearly resolved and duly noted in the application. Monthly backups are stored in a safe location away from the plant. Weekly backup is stored away from the building in which the server room is located. c)Access to the servers areas is restricted to authorized

	personnel only. This access is performed through a codified door. All servers, hard disc sub-systems and the main sub-systems communications are protected with UPS. All computers at Hovione are installed with an anti-virus software. Hardware is responsible to verify the network regularly.
Post or department responsible for the procedure and for any data generated	IT
Location where records are kept	Docstream/ACCESS/IT operations
Name of IT system used	Docstream/ACCESS/IT operations
List of EN or other standards applied	N/A

ee. Review and Validation of Data

Details of the procedures used to ensure regular internal reviews and validation of data in accordance with Articles 58 and 62 of the MRR.

Title of procedure	Site Energy, Water and CO2 Management
Reference for procedure	HE.HSE.IOP082
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	Section 5.1.5 HE.HSE.IOP082 details the internal reviews which take place on site.
	Quarterly reviews of collected data are carried out as per Flowchart 11: Input and Output Flows. Environmental Technical Specialist & Utilities & Site Services Engineer)
	The HSE Director is responsible for confirming all relevant information and data and is not involved in the determination or recording of that same data.

	An annual review of the GHG monitoring plan is carried out (Environmental Technical Specialist & Utilities & Site Services Engineer) to evaluate the appropriateness of the plan and includes any potential measures for the improvement of the monitoring methodology. The review includes: • Checking the list of emission sources and source streams, ensuring completeness of the emissions and source streams and that all relevant changes in the nature and functioning of the installation are included in the monitoring plan, • Assessing compliance with the uncertainty thresholds for activity data and other parameters (where applicable) for the applied tiers for each source stream and emission source; • Assessment of potential measures for improvement of the monitoring methodology applied any changes required will be completed in ETSWAP.
Post or department responsible for the procedure and for any data generated	HSE department
Location where records are kept	Docstream/O drive for audits
Name of IT system used	Docstream/O drive for audits
List of EN or other standards applied	N/A

ff. Corrections and Corrective Actions

Details of the procedures used to handle corrections and corrective actions in accordance with Articles 58 and 63 of the MRR:

Title of procedure	EMS non conformity, corrective and preventative action procedure
Reference for procedure	HE.HSE.IOP064
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	Section 5.1.14 details : Corrective and preventive actions identified in the course of an internal audit are addressed as per HE.HSE.IOP064 – EMS Non Conformity, Corrective and Preventive Action

	Procedure. In the event of a breakdown or malfunction of the equipment used to monitor or record the emissions of greenhouse gases, the Agency must be notified and alternative sampling and monitoring facilities should be installed where possible to the satisfaction of the Agency. Notifications to the Agency are completed using the IN Notification on the ETSWAP website .This is outlined in HE.HSE.IOP020 – HSE Incident Investigation and Reporting and HE.HSE.IOP056 Environmental Incidents – Documentation and Reporting. Changes to the monitoring methodology shall be proposed without undue delay by the Operator, in association with the HSE Director, when: • Data availability has changed, allowing for higher accuracy in the determination of emissions. • A previously non existent emission has started. • Errors are detected in data resulting from monitoring methodology. • The Agency has requested a change. Where approved, these changes shall be implemented within a timeframe agreed by the Agency. The monitoring plan will be updated when • the monitoring plan has been found not to be in conformity with the requirements of the M & R regulation or the Agency requests a change • to meet recommendations for improvement of the monitoring plan contained in the verification report.
Post or department responsible for the procedure and for any data generated	HSE Department

Location where records are kept	Docstream-Hovione online document system
Name of IT system used	Docstream
List of EN or other standards applied	N/A

gg. Control of Outsourced Activities

Details of the procedures used to control outsourced processes in accordance with Articles 59 and 64 of the MRR.

Title of procedure	Site Energy, Water and CO2 Management
Reference for procedure	HE.HSE.IOP082
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	The only outsourced process is the third party verifier. Details regarding the verifiers appointment is present in section 5.1.13 of this procedure and is used to control outsourced processes in accordance with Articles 59 and 64 of the MRR.
Post or department responsible for the procedure and for any data generated	HSE Department
Location where records are kept	Docstream-Hovione online document control system
Name of IT system used	Docstream
List of EN or other standards applied	N/A

hh. Record Keeping and Documentation

Details of the procedures used to manage record keeping and documentation:

Title of procedure	Site Energy, Water and CO2 Management
Reference for procedure	HE.HSE.IOP082
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	HE.HSE.IOP082 briefly details records storage regarding the AIER, verified reports,invoices, risk assessments,calibration certs and invoices. Section 6 "records" details the retention period of documents and general greenhouse gas documents. This is to manage record keeping and documentation as stipulated in Annex IX of the MRR, records shall be held on site for a period of at least 10 years after filing.
Post or department responsible for the procedure and for	HSE department

any data generated	
Location where records are kept	Docstream-Hovione online document control system
Name of IT system used	Docstream-Hovione online document control system
List of EN or other standards applied	N/A

ii. Risk Assessment

The results of a risk assessment that demonstrates that the control activities and procedures are commensurate with the risks identified:

Attachment	Description
N/A	N/A

jj. Environmental Management System

Does your organisation have a documented Environmental Management System?	Yes
Is the Environmental Management System certified by an accredited organisation?	No

12. Changes in Operation

kk. Changes in Operation

Article 24(1) of Commission Decision 2011/278/EC requires that Member States must ensure that all relevant information about any planned or effective changes to the capacity activity level and operation of an installation is submitted by the operator to the competent authority by 31 December each year. Article 12(3) of the MRR further provides that Member States may require information to be included in the monitoring plan of an installation for the purposes of meeting these requirements.

Details of the procedure used to ensure regular reviews are carried out to identify any planned or effective changes to the capacity activity level and operation of the installation that have an impact on the installation's allocation:

The procedure specified below cover the following:

- planning and carrying out regular checks to determine whether any planned or effective changes to the capacity activity level and operation of an installation are relevant under Commission Decision 2011/278/EC; and

- Procedures to ensure such information is submitted to the competent authority by 31 December of each year.

Title of procedure	Site Energy,Water and CO2 Management
Reference for procedure	He.HSE.IOP082
Diagram reference	N/A
Brief description of procedure. The description should cover the essential parameters and operations performed	This procedure outlines the responsibility of the operator to carry out an annual check regarding its operations and to report any changes to the agency by the 31st December each year.
Post or department responsible for the procedure and for any data generated	HSE Department
Location where records are kept	Docstream-Hovione online document control system
Name of IT system used	N/A

13. Abbreviations

II. Abbreviations Acronyms or definitions

Abbreviations acronyms or definitions that have been used in this monitoring plan:

Abbreviation	**Definition**
N/A	N/A

14. Additional Information

Any other information:

Attachment	**Description**
Pfizer Loughbeg St 1 23-10-2014 80112125.2014.pdf	2014 Gas Meter 80112125/2014 calibration information
Pfizer Loughbeg St 2 21-07-2014 80042149.1998.pdf	2014 Gas Meter 80042149/1998 calibration information
Pfizer Loughbeg Meter 80112125 uncertainty calcs.pdf	Gas meter SN 80112125 uncertainty calcs
2014 gas calibration certs all.pdf	2014 Gas Calibration certs
SN80042149 1998 Metering Uncertainty Calculations	SN80042149 -1998 Metering Uncertainty Calculations

Attachment	Description
Hovione Oct 201 3.pdf	

15. Confidentiality

mm. Confidentiality Statement

It is the Environmental Protection Agency's policy to make information received by it in the course of its work open to inspection by any person on request. This is in accordance with the provisions of the European Communities (Access to Information on the Environment) Regulations 2007 to 2011.

In the event that you considered that some of the information being submitted of a confidential nature, then the nature of this information and the reasons why it should be considered confidential, with reference to the European Communities (Access to Information on the Environment) Regulations 2007 to 2011 and any amendments must be explicitly requested using the facility below. The Board of the Environmental Protection Agency will consider the requests and if the information can be deemed as confidential and necessary.

Notwithstanding any request for confidentiality, the Environmental Protection Agency explicitly reserves the right to release data to the Commission, including emissions and allocations to the public, on the basis that the data will be used for the purposes foreseen in Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a scheme for greenhouse gas emission allowance trading within the Community and amending Council Directive 96/61/EC.

Please tick this box if you consider that any part of your form should be treated as commercially confidential/sensitive: false

END of Appendix I.