



Headquarters,
Johnstown Castle Estate,
County Wexford, Ireland

GREENHOUSE GAS EMISSIONS PERMIT

Permit Register Number: IE-GHG012-06

Operator: MSD International GmbH (trading as MSD Ireland (Ballydine))
Ballydine, Kilsheelan, Clonmel, Tipperary,
E91V091

Installation Name: MSD International GmbH (trading as MSD Ireland (Ballydine))

Location: Ballydine, Kilsheelan, Clonmel, Tipperary,
Ireland, E91V091

Introductory Note

This introductory note does not form a part of the Greenhouse Gas Emissions Permit and does not purport to be a legal interpretation of the 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 N^o IE-GHG012-06.

All correspondence in relation to this permit, unless otherwise specified by the Agency, should be addressed to:

Email: ghgpermit@epa.ie

By Post: Emissions Trading,
Environmental Protection Agency
P.O. Box 3000, Johnstown Castle Estate,
Co. Wexford
EIRCODE Y35 W821

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 to any interested party on the Agency's website at www.epa.ie and for operators only via www.edenireland.ie.

Monitoring Plan

The associated Monitoring Plan approved in accordance with Condition 3.1 of this permit will be made available to operators and verifiers on the European Commission portal EU ETS Reporting <https://ets-reporting.ec.europa.eu>.

Surrender of the permit:

Before this Greenhouse Gas Emissions Permit can be wholly or partially surrendered, a written application must be made to the Agency, and written permission received from, the Agency through www.edenireland.ie.

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 www.edenireland.ie.

Integrated Pollution Control or Industrial Emissions Licence held pursuant to the Environmental Protection Agency Act 1992, as amended. (as of the date of this permit): 13 June 2023

IPC/IE Licence Register Number
MSD International GmbH - P0011

Status Log of this GHG Permit

Current Permit

Permit number	Date application received	Date Permit issued	Comment
IE-GHG012-06	07-April-2023	13-Jun-2023	Inclusion of the following 2 emission sources: S15 'Emergency Generator at Local Computer Room' (0.5 MW) from 15 March 2023, S16 'Emergency Generator at BCON API Plant' (0.3 MW). Removal of the existing source S4 'Vapour (Fume) Incinerator' (1.33 MW) from 22 July 2022.

Previous Permits

Permit number	Change Type	Date application received	Date Permit issued	Comment
IE-GHG012-10342-1	GHG Permit Application	25 June 2013	27 June 2013	
IE-GHG012-10342-2	GHG Variation	11 September 2014	22 April 2015	Inclusion of the source stream AC-1, Acetylene and associated emission source S11.
IE-GHG012-10342-3	GHG Variation	10 February 2016	11 March 2016	Inclusion of the source stream VOC 1. Removal of reference to the Electric Thermal Oxidiser.
IE-GHG012-10342-4	GHG Variation	08 July 2016	22 August 2016	Addition of a new emission source S12 (boiler no 4) emission point A1-2A. Removal of emission source S1 (boiler no. 1).
IE-GHG012-10342-5	GHG Variation	07 July 2018	07 September 2018	Addition of two new emission sources S13 Emergency Generator at Potable Water Plant (0.3MW, emission Point EFP 05) and S14 Utilities & Maintenance Equipment (0.45MW, emission Point EFP 06). Update of emission source S6 from North Firewater pump house - 3 pumps (0.7 MW) to S6 North Firewater pump house - 2 pumps (0.5 MW).

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 (including electronic modes of representing or reproducing words in visible form).
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 Implementing Regulation (EU) 2018/2067 of 19 December 2018 on the verification of data and on 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 as amended.
Emissions	The release of greenhouse gases into the atmosphere from sources in an installation.
EPA	Environmental Protection Agency.
EU ETS Reporting	EU Commission on-line tool for Operators, Verifiers and Competent Authorities to perform their tasks under the M&R Regulation. EU ETS Reporting is accessible via the following URL. https://ets-reporting.ec.europa.eu/
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 Implementing Regulation (EU) 2018/2066 of 19 December 2018 on the monitoring and reporting of greenhouse gas emissions pursuant to Directive 2003/87/EC of the European Parliament and of the Council and amending Commission Regulation (EU) No 601/2012 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 the M&R Regulations.
N/A	Not applicable.
Monitoring Plan	The Plan submitted and approved by the Agency in accordance with Condition 3.1 of this permit.
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)	MSD International GmbH (trading as MSD Ireland (Ballydine))
“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 carrying out verification activities pursuant to the A & V Regulation and accredited by a national accreditation body pursuant to Regulation (EC) No 765/2008 and the A & V Regulation 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
Schedule 1

The Registry as provided for under Article 19 of Directive 2003/87/EC.
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:

MSD International GmbH (trading as MSD Ireland (Ballydine))
Ballydine, Kilsheelan, Clonmel, Tipperary, E91V091

Company Registration Number: 906390
from

The Former Operator:

Merck Sharp & Dohme (Ireland) Ltd. Ballydine Kilsheelan Clonmel Tipperary

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):

MSD International GmbH (trading as MSD Ireland (Ballydine))

Installation number: 10

located at:
Ballydine, Kilsheelan, Clonmel, Tipperary, E91V091

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 14 December 2010, *MSD International GmbH(trading as MSD Ireland (Ballydine))* 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 2005-2010, 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 GHG permit granted to the Operator on 07 September 2018 and bearing Permit Register No.: IE-GHG012-10342-5. The previous GHG permit (Permit Reg. No. IE-GHG012-10342-5) is superseded by this permit from 13 June 2023.
- 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.: 10

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
(S9) Wastewater Treatment

- 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
S2	Boiler No 2	14.45	MW
S3	Boiler No 3	20.7	MW
S5	South Firewater Pump House - 2 pumps	0.45	MW
S6	North Firewater Pump House - 2 pumps	0.5	MW
S7	Emergency Absorber Pump House	0.1	MW

Emission Source Reference	Emission Source Description	Capacity	Capacity Units
S8	Emergency Generator at surface water diversion facility	0.12	MW
S10	Regenerative Thermal Oxidiser	1.26	MW
S11	Acetylene for oxy acetylene cutting	0	MW
S12	Boiler No 4	10.75	MW
S13	Emergency Generator at Potable Water Plant	0.3	MW
S14	Utilities & Maintenance Equipment	0.45	MW
S15	Emergency Generator at Local Computer Room	0.5	MW
S16	Emergency Generator at BCON API Plant	0.3	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 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 All notifications required under Condition 2 above shall be made to the address given in the Introductory Note included with this permit, unless otherwise specified by the Agency.
- 2.7 The Operator shall submit to the Agency by 31 March of each year an activity level report and a verification report on the activity level report in accordance with Commission Implementing Regulation (EU) 2019/1842 of 31 October 2019. 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 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 a change in the availability of data, due to the use of new types of measurement instrument, 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 monitoring plan as approved by the Agency, the Operator shall apply the highest achievable tier, or a conservative no-tier approach if application of the tier is not achievable, 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 monitoring plan as approved by the Agency;
- (ii) in detail, the interim monitoring methodology applied by the Operator to determine the emissions until the conditions for the application of the monitoring plan as approved by the Agency have been restored;
- (iii) the measures the Operator is taking to restore the conditions for the application of the monitoring plan as approved by the Agency;
- (iv) the anticipated point in time when application of the monitoring plan as approved by the Agency 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, or the Agency approved extension to the deadlines in accordance with Article 69(1) of the M&R Regulation:
- (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 or the EU Commission'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.

- 4.2 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, unless such an account is already open on the Union Registry. The necessary information and the timeframe for submission shall be specified by the National Administrator.

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.

Signed by the authorised person on this the 13 June 2023

Annette Prendergast