Permit with introductory note

The Environmental Permitting (England & Wales) Regulations 2016

MSD Animal Health UK Limited

MSD Animal Health (Milton Keynes)
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Permit number

EPR/UP3801PH

MSD Animal Health (Milton Keynes)
Permit number EPR/UP3801PH

Introductory note

This introductory note does not form a part of the permit

The main features of the permit are as follows.

This permit authorises the operator to perform the following listed activities and directly associated activities at the MSD Animal Health (Milton Keynes):

- Listed activities:
    - Section 4.5 A(1)(a) Producing pharmaceutical products;
    - Section 5.4 A(1)(a)(ii) Disposal of non-hazardous waste with a capacity exceeding 50 tonnes per day involving - physico-chemical treatment.
- Directly associated activities (DAA):
    - Hot water supply;
    - Steam generation;
    - Back-up power supply;
    - Surface water management.

The permit allows the operator to produce animal active pharmaceutical ingredient (API) (such as antigens and vaccines) for commercial purposes. The maximum capacity of the facility is 377 fermentation batches of API per annum.

The vaccines are manufactured from approximately thirty strains of micro-organism and are for use in animals. The vaccines are manufactured using inactivated sterile antigens produced on the site, formulated with proprietary adjuvant and buffered saline.

The current antigen production facility operates the following production processes:

- Whole cell antigen, with inactive Downstream Processing (DSP) – Salmonella, Pasteurella & Mannheimia;
- Whole cell antigen with inactive DSP – Mycoplasma; and
- Inactivated toxins and cells from a range of Clostridium.

Growth media and solutions for antigen preparation are prepared in the general services area and transferred by fixed pipework to the fermenters. The media can be sterilised by filtration or by heat, using steam within the fermenter vessels themselves. Cell cultures are produced in negative pressure isolators typically up to volumes of 10 litres. These cultures are transferred either by fixed pipework or single use tubing to 250 litre capacity seed fermenters, which in turn are used to inoculate either 2,000 or 3,000 litre production fermenters.

The cell cultures are produced by batch fermentation and the product of the fermentation is clarified and concentrated either by continuous centrifugation or Ultra-filtration.

All antigens are stored inactivated. Chemical inactivation, using formalin (formaldehyde solution) or Binary Ethyleneimine (BEI), takes place in either the bulk antigen or the final concentrated antigen stages.

The antigens are stored in 50 litre containers at +2°C to +8°C. Antigens such as Mycoplasma and Erysipelothrix rhusiopathiae M2 are shipped to other MSD sites in single use bag systems. The remaining antigens are formulated into vaccines at the Milton Keynes facility.

Vaccine formulation begins with the preparation of a vaccine base. Containers of aluminium hydroxide gel are transferred from the warehouse to the production facility. The gel is pumped from the containers into a preparation vessel and diluted with buffered saline. The prepared base is then transferred through pipework to either a holding or blending vessel for sterilisation. Antigens are added to the sterile vaccine base following formulations specific for each vaccine.

Following successful testing the vaccines are filled into LDPE (low density polyethylene) bottles through an aseptic semi-automated filling line.

Emissions from the permitted activities include emissions of substances to air and noise. Uncontaminated surface water from rainwater run-off is discharged to the River Ouzel and process waters treated by the effluent treatment plant (ETP) are discharged to the sewer.

Point source emissions to air include the combustion operations for raising steam and hot water for use in the process and production facility heating. Significant point source emissions to air include oxides of nitrogen (NOx). The primary combustion units, the boilers, are fired on natural gas and use low NOx burners.

Minor emissions of formaldehyde, methanol and hydrogen peroxide used in isolator fumigation between production cycles, are emitted via the HVAC systems for buildings 71 and 73 and also of formaldehyde, methanol and BEI from Building 72.

All combustion, isolator plant and HVAC equipment are subject to regular planned maintenance to ensure efficient operation, as part of the installation's planned preventative maintenance (PPM) programme.

Noise emissions have been assessed and do not present a risk of significant impacts at sensitive receptors.

Wastes arising from the permitted activities and general site activities are segregated and stored on-site pending collection for off-site recovery/disposal. Storage is in defined areas with containment designed to minimise the risk of spills. Drummed process waste is sent off-site for disposal.

Fugitive emissions of Volatile Organic Compounds (VOCs) are generated from the use of methanol and Isopropyl Alcohol (IPA) / cleaning wipes and sprays used internally in laboratory and production areas.

There are no fugitive emissions of dust from the installation.

All raw materials and products are kept in closed containers to protect the product and prevent fugitive dust emissions.

Heat for hot water and steam is provided by four boilers and back-up plant if necessary. Power for the facility is provide by mains natural gas and electricity.

The installation has been involved in the research, development and manufacture of animal health vaccines since the 1970's and MSD acquired the installation in 2009. The installation consulted with the Environment Agency in 2010, at such time the activities were assessed as not being subject to the Regulations, however revised legislation as a result of the requirements of the EU Industrial Emissions Directive (IED) mean an environment permit is required.

The installation is located in Walton, approximately 4.5km south east of Milton Keynes (National Grid Reference: SP 89010 36550). The installation is underlain by undifferentiated superficial deposits predominantly consisting of clay over unproductive bedrock (rock layers or drift deposits with low permeability.

The site is boarded by main roads to the north and east. The nearest residential receptor is on the southern boundary (approx. 60 m). There are no designated sites within 10 km of the installation and no site of special scientific interest within 2 km. There are seven non-statutory sites (Local Wildlife Sites) and an ancient woodland located within 2 km of the installation. These are:

- Caldecote Lake (approx. 350 m form the site)
- Mount Farm Lake (approx. 1758 m from the site)
- River Ouzel, Simpson Bridge (approx. 514 m from the site)
- Walton Hall Campus pond (approx. 654 m from the site)
- Walton Lake (approx. 816 m from the site)
- Pond, Kents Hill Spinney (approx. 1020 m from the site)

- Pond in Ouzel Valley Park (approx. 1612 m from the site)
- Ancient Woodland - England Woodland name: Unknown (approx. 1019 m from the site)

The operator has an environmental management system which has been developed to meet the requirements of ISO 14001:2015 and BSI certified Energy Management System ISO50001:2011.

The status log of the permit sets out the permitting history, including any changes to the permit reference number.

Status log of the permit		
Description	**Date**	**Comments**
Application EPR/UP3801PH/A001	Duly made 17/07/2019	Application for animal vaccine production plant.
Response to Schedule 5 Notice dated 11/11/19.	28/11/2019	Response to question detailing: • containment process control and locations • refrigerants • back-up generators use and testing • revised air dispersion modelling
Additional information received	08/07/2020	Report detailing: • change of name, • additional information on emergency fire pumps and Building 72 HVAC system, • clarification regarding emissions, and • use of cleaning materials
Additional information received	09/09/2020	Confirming the VOC emission from fumigation with formaldehyde will only be from one stack at any one time.
Permit determined EPR/UP3801PH (Billing ref. UP3801PH)	14/10/2020	Permit issued to MSD Animal Health UK Limited.

End of introductory note

Permit

The Environmental Permitting (England and Wales) Regulations 2016

Permit number

EPR/UP3801PH

The Environment Agency hereby authorises, under regulation 13 of the Environmental Permitting (England and Wales) Regulations 2016

MSD Animal Health UK Limited ("the operator"),

whose registered office is/whose principal office is

Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

company registration number 00946942

to operate an installation at

MSD Animal Health (Milton Keynes)
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

to the extent authorised by and subject to the conditions of this permit.

Name	Date
Claire Roberts	**14/10/2020**

Authorised on behalf of the Environment Agency

Conditions

1 Management

1.1 General management

1.1.1 The operator shall manage and operate the activities:

(a) in accordance with a written management system that identifies and minimises risks of pollution, including those arising from operations, maintenance, accidents, incidents, non-conformances, closure and those drawn to the attention of the operator as a result of complaints; and

(b) using sufficient competent persons and resources.

1.1.2 Records demonstrating compliance with condition 1.1.1 shall be maintained.

1.1.3 Any person having duties that are or may be affected by the matters set out in this permit shall have convenient access to a copy of it kept at or near the place where those duties are carried out.

1.2 Energy efficiency

1.2.1 The operator shall:

(a) take appropriate measures to ensure that energy is used efficiently in the activities;

(b) review and record at least every four years whether there are suitable opportunities to improve the energy efficiency of the activities; and

(c) take any further appropriate measures identified by a review.

1.3 Efficient use of raw materials

1.3.1 The operator shall:

(a) take appropriate measures to ensure that raw materials and water are used efficiently in the activities;

(b) maintain records of raw materials and water used in the activities;

(c) review and record at least every four years whether there are suitable alternative materials that could reduce environmental impact or opportunities to improve the efficiency of raw material and water use; and

(d) take any further appropriate measures identified by a review.

1.4 Avoidance, recovery and disposal of wastes produced by the activities

1.4.1 The operator shall take appropriate measures to ensure that:

(a) the waste hierarchy referred to in Article 4 of the Waste Framework Directive is applied to the generation of waste by the activities; and

(b) any waste generated by the activities is treated in accordance with the waste hierarchy referred to in Article 4 of the Waste Framework Directive; and

(c) where disposal is necessary, this is undertaken in a manner which minimises its impact on the environment.

1.4.2 The operator shall review and record at least every four years whether changes to those measures should be made and take any further appropriate measures identified by a review.

2 Operations

2.1 Permitted activities

2.1.1 The operator is only authorised to carry out the activities specified in schedule 1 table S1.1 (the "activities").

2.2 The site

2.2.1 The activities shall not extend beyond the site, being the land shown edged in green on the site plan at schedule 7 to this permit.

2.3 Operating techniques

2.3.1 The activities shall, subject to the conditions of this permit, be operated using the techniques and in the manner described in the documentation specified in schedule 1, table S1.2, unless otherwise agreed in writing by the Environment Agency.

2.3.2 If notified by the Environment Agency that the activities are giving rise to pollution, the operator shall submit to the Environment Agency for approval within the period specified, a revision of any plan or other documentation ("plan") specified in schedule 1, table S1.2 or otherwise required under this permit which identifies and minimises the risks of pollution relevant to that plan , and shall implement the approved revised plan in place of the original from the date of approval, unless otherwise agreed in writing by the Environment Agency.

2.3.3 Any raw materials or fuels listed in schedule 2 table S2.1 shall conform to the specifications set out in that table.

2.3.4 The operator shall ensure that where waste produced by the activities is sent to a relevant waste operation, that operation is provided with the following information, prior to the receipt of the waste:

(a) the nature of the process producing the waste;

(b) the composition of the waste;

(c) the handling requirements of the waste;

(d) the hazardous property associated with the waste, if applicable; and

(e) the waste code of the waste.

2.3.5 The operator shall ensure that where waste produced by the activities is sent to a landfill site, it meets the waste acceptance criteria for that landfill.

2.4 Improvement programme

2.4.1 The operator shall complete the improvements specified in schedule 1 table S1.3 by the date specified in that table unless otherwise agreed in writing by the Environment Agency.

2.4.2 Except in the case of an improvement which consists only of a submission to the Environment Agency, the operator shall notify the Environment Agency within 14 days of completion of each improvement.

3 Emissions and monitoring

3.1 Emissions to water, air or land

3.1.1 There shall be no point source emissions to water, air or land except from the sources and emission points listed in schedule 3 tables S3.1, S3.2 and S3.3.

3.1.2 The limits given in schedule 3 shall not be exceeded.

3.1.3 Total annual emissions from the emission point(s) set out in schedule 3 tables S3.1, S3.2 and S3.3 of a substance listed in schedule 3 table S3.4 shall not exceed the relevant limit in table S3.4.

3.1.4 Periodic monitoring shall be carried out at least once every 5 years for groundwater and 10 years for soil, unless such monitoring is based on a systematic appraisal of the risk of contamination.

3.2 Emissions of substances not controlled by emission limits

3.2.1 Emissions of substances not controlled by emission limits (excluding odour) shall not cause pollution. The operator shall not be taken to have breached this condition if appropriate measures, including, but not limited to, those specified in any approved emissions management plan, have been taken to prevent or where that is not practicable, to minimise, those emissions.

3.2.2 The operator shall:

(a) if notified by the Environment Agency that the activities are giving rise to pollution, submit to the Environment Agency for approval within the period specified, an emissions management plan which identifies and minimises the risks of pollution from emissions of substances not controlled by emission limits;

(b) implement the approved emissions management plan, from the date of approval, unless otherwise agreed in writing by the Environment Agency.

3.2.3 All liquids in containers, whose emission to water or land could cause pollution, shall be provided with secondary containment, unless the operator has used other appropriate measures to prevent or where that is not practicable, to minimise, leakage and spillage from the primary container.

3.3 Odour

3.3.1 Emissions from the activities shall be free from odour at levels likely to cause pollution outside the site, as perceived by an authorised officer of the Environment Agency, unless the operator has used appropriate measures, including, but not limited to, those specified in any approved odour management plan, to prevent or where that is not practicable to minimise the odour.

3.3.2 The operator shall:

(a) if notified by the Environment Agency that the activities are giving rise to pollution outside the site due to odour, submit to the Environment Agency for approval within the period specified, an odour management plan which identifies and minimises the risks of pollution from odour;

(b) implement the approved odour management plan, from the date of approval, unless otherwise agreed in writing by the Environment Agency.

3.4 Noise and vibration

3.4.1 Emissions from the activities shall be free from noise and vibration at levels likely to cause pollution outside the site, as perceived by an authorised officer of the Environment Agency, unless the operator has used appropriate measures, including, but not limited to, those specified in any approved noise and vibration management plan to prevent or where that is not practicable to minimise the noise and vibration.

3.4.2 The operator shall:

(a) if notified by the Environment Agency that the activities are giving rise to pollution outside the site due to noise and vibration, submit to the Environment Agency for approval within the period specified, a noise and vibration management plan which identifies and minimises the risks of pollution from noise and vibration;

(b) implement the approved noise and vibration management plan, from the date of approval, unless otherwise agreed in writing by the Environment Agency.

3.5 Monitoring

3.5.1 The operator shall, unless otherwise agreed in writing by the Environment Agency, undertake the monitoring specified in the following tables in schedule 3 to this permit:

(a) point source emissions specified in tables S3.1, S3.2 and S3.3;

(b) process monitoring specified in table S3.5;

3.5.2 The operator shall maintain records of all monitoring required by this permit including records of the taking and analysis of samples, instrument measurements (periodic and continual), calibrations, examinations, tests and surveys and any assessment or evaluation made on the basis of such data.

3.5.3 Monitoring equipment, techniques, personnel and organisations employed for the emissions monitoring programme and the environmental or other monitoring specified in condition 3.5.1 shall have either MCERTS certification or MCERTS accreditation (as appropriate), where available, unless otherwise agreed in writing by the Environment Agency.

3.5.4 Permanent means of access shall be provided to enable sampling/monitoring to be carried out in relation to the emission points specified in schedule 3 tables S3.1, S3.2 ,and S3.3 unless otherwise agreed in writing by the Environment Agency.

4 Information

4.1 Records

4.1.1 All records required to be made by this permit shall:

(a) be legible;

(b) be made as soon as reasonably practicable;

(c) if amended, be amended in such a way that the original and any subsequent amendments remain legible, or are capable of retrieval; and

(d) be retained, unless otherwise agreed in writing by the Environment Agency, for at least 6 years from the date when the records were made, or in the case of the following records until permit surrender:

(i) off-site environmental effects; and

(ii) matters which affect the condition of the land and groundwater.

4.1.2 The operator shall keep on site all records, plans and the management system required to be maintained by this permit, unless otherwise agreed in writing by the Environment Agency.

4.2 Reporting

4.2.1 The operator shall send all reports and notifications required by the permit to the Environment Agency using the contact details supplied in writing by the Environment Agency.

4.2.2 A report or reports on the performance of the activities over the previous year shall be submitted to the Environment Agency by 31 January (or other date agreed in writing by the Environment Agency) each year. The report(s) shall include as a minimum:

(a) a review of the results of the monitoring and assessment carried out in accordance with the permit including an interpretive review of that data;

(b) the annual production /treatment data set out in schedule 4 table S4.2; and

(c) the performance parameters set out in schedule 4 table S4.3 using the forms specified in table S4.4 of that schedule.

4.2.3 Within 28 days of the end of the reporting period the operator shall, unless otherwise agreed in writing by the Environment Agency, submit reports of the monitoring and assessment carried out in accordance with the conditions of this permit, as follows:

(a) in respect of the parameters and emission points specified in schedule 4 table S4.1;

(b) for the reporting periods specified in schedule 4 table S4.1 and using the forms specified in schedule 4 table S4.4 ; and

(c) giving the information from such results and assessments as may be required by the forms specified in those tables.

4.2.4 The operator shall, unless notice under this condition has been served within the preceding four years, submit to the Environment Agency, within six months of receipt of a written notice, a report assessing whether there are other appropriate measures that could be taken to prevent, or where that is not practicable, to minimise pollution.

4.3 Notifications

4.3.1 In the event:

(a) that the operation of the activities gives rise to an incident or accident which significantly affects or may significantly affect the environment, the operator must immediately—

(i) inform the Environment Agency,

(ii) take the measures necessary to limit the environmental consequences of such an incident or accident, and

(iii) take the measures necessary to prevent further possible incidents or accidents;

(b) of a breach of any permit condition the operator must immediately—

(i) inform the Environment Agency, and

(ii) take the measures necessary to ensure that compliance is restored within the shortest possible time;

(c) of a breach of permit condition which poses an immediate danger to human health or threatens to cause an immediate significant adverse effect on the environment, the operator must immediately suspend the operation of the activities or the relevant part of it until compliance with the permit conditions has been restored.

4.3.2 Any information provided under condition 4.3.1 shall be confirmed by sending the information listed in schedule 5 to this permit within the time period specified in that schedule.

4.3.3 Where the Environment Agency has requested in writing that it shall be notified when the operator is to undertake monitoring and/or spot sampling, the operator shall inform the Environment Agency when the relevant monitoring and/or spot sampling is to take place. The operator shall provide this information to the Environment Agency at least 14 days before the date the monitoring is to be undertaken.

4.3.4 The Environment Agency shall be notified within 14 days of the occurrence of the following matters, except where such disclosure is prohibited by Stock Exchange rules:

Where the operator is a registered company:

(a) any change in the operator's trading name, registered name or registered office address; and

(b) any steps taken with a view to the operator going into administration, entering into a company voluntary arrangement or being wound up.

Where the operator is a corporate body other than a registered company:

(a) any change in the operator's name or address; and

(b) any steps taken with a view to the dissolution of the operator.

In any other case:

(a) the death of any of the named operators (where the operator consists of more than one named individual);

(b) any change in the operator's name(s) or address(es); and

(c) any steps taken with a view to the operator, or any one of them, going into bankruptcy, entering into a composition or arrangement with creditors, or, in the case of them being in a partnership, dissolving the partnership.

4.3.5 Where the operator proposes to make a change in the nature or functioning, or an extension of the activities, which may have consequences for the environment and the change is not otherwise the subject of an application for approval under the Regulations or this permit:

(a) the Environment Agency shall be notified at least 14 days before making the change; and

(b) the notification shall contain a description of the proposed change in operation.

4.3.6 The Environment Agency shall be given at least 14 days' notice before implementation of any part of the site closure plan.

4.3.7 Where the operator has entered into a climate change agreement with the Government, the Environment Agency shall be notified within one month of:

(a) a decision by the Secretary of State not to re-certify the agreement;

(b) a decision by either the operator or the Secretary of State to terminate the agreement; and

(c) any subsequent decision by the Secretary of State to re-certify such an agreement.

4.4 Interpretation

4.4.1 In this permit the expressions listed in schedule 6 shall have the meaning given in that schedule.

4.4.2 In this permit references to reports and notifications mean written reports and notifications, except where reference is made to notification being made "immediately, in which case it may be provided by telephone.

Schedule 1 – Operations

Table S1.1 activities			
Activity reference	**Activity listed in Schedule 1 of the EP Regulations**	**Description of specified activity**	**Limits of specified activity**
AR1	Section S4.5 A(1)(a) Producing pharmaceutical products	Production of active pharmaceutical product (veterinary vaccines and antigens) for commercial purposes using batch production techniques.	Receipt of raw materials to despatch of finished product. Maximum production capacity shall be 377 fermentation batches per annum of product. Storage of process related wastes generated pending removal from site for recovery. Maximum storage of raw materials and waste on site at any one time as per Appendix A of response (dated 28 November 2019) to Schedule 5 notice (dated 11 November 2019).
AR2	Section 5.4 A(1)(a)(ii) Disposal of non-hazardous waste with a capacity exceeding 50 tonnes per day involving - physico-chemical treatment.	Non-hazardous effluent treatment plant	Receipt of aqueous effluent from production activities into treatment facilities to discharge into sewer.
	Directly Associated Activity		
AR3	Hot water supply	2 x 4.22 MWth gas-fired hot water boilers	From receipt of gas to Boilers discharge of exhaust gases and the generation of hot water.
AR4	Steam generation	2 x 4 MWth Steam boilers	From receipt of gas to Boilers discharge of exhaust gases and the generation of steam.
AR5	Back-up power supply	1 x 320 KWth diesel generator emergency back-up generator. 1 x 800KWth diesel generator emergency back-up generator 1 x 456KWth diesel generator emergency back-up generator	Back-up generators operated for the purpose of testing for no more than 50 hours per year
AR6	Surface water management	Clean surface water only.	From collection of surface waters to discharge points to River Ouzel.

Table S1.1 activities			
Activity reference	**Activity listed in Schedule 1 of the EP Regulations**	**Description of specified activity**	**Limits of specified activity**
AR7	Pre-treatment of raw material - water	Treatment of mains water for use in heat and steam production.	--

Table S1.2 Operating techniques		
Description	**Parts**	**Date Received**
Application	Sections 1, 2, 6, 7, 8, 9.2 – 9.4, 10, 13, 14 and 16 of the application document "Environmental Permit Application report" (dated 18/06/19) provided in response to section 3a – technical standard, Part B3 of the application form.	Duly Made 17/07/2019
Response to Schedule 5 Notice dated 11/11/19.	Response to questions 1, 2 and 3 detailing containment process control and locations. Response to question 5 detailing refrigerants. Response to questions 6 and 7 detailing back-up generators use and testing.	28/11/19
Air Quality Report provided with Response to Schedule 5 Notice dated 11/11/19.	Air Quality parameters as detailed in Appendix D.	28/11/19
Additional information	Addendum 1 Report detailing: • change of name, • additional information on emergency fire pumps and Building 72 HVAC system, • clarification regarding emissions, and • use of cleaning materials	08/07/20
Air Quality Report provided with Addendum 1 Report	Air Quality parameters as detailed in Section 4, flow rates stated and control measures employed in Table 9-1.	08/07/20

Table S1.3 Improvement programme requirements		
Reference	**Requirement**	**Date**
IC 1	The operator shall submit a report to the Environment Agency for technical assessment and approval. The report shall justify changing the monitoring specified in table S3.1 for VOCs in the discharge to air (A8, A9 and A15) to be undertaken by calculation once one round of monitoring has been completed and verification of the calculations in Addendum 1 report have been verified. Justification for any change to calculation rather than monitoring for a specific parameter shall be based on: • evidence of the effectiveness of the techniques used to minimise and abate emissions to such a level as to present no risk of exceedance of the emission limit values (ELVs) or mass emission limits set in the permit; and/or, • evidence that the emissions levels are sufficiently stable; and/or,	14/05/21

Table S1.3 Improvement programme requirements		
Reference	**Requirement**	**Date**
	• evidence that monitoring of a process control parameter may be used to reliably replace monitoring of that parameter in the emission to air. Any such justifications shall be made with reference to the standards for BAT set out in the sector guidance note EPR 4.02 and /or any other relevant guidance notified to the operator and confirmed in writing by the Environment Agency. If appropriate, the report shall include proposals for the revised monitoring frequencies for specific parameters. The notification requirements of condition 2.4.2 will be deemed to have been complied with on submission of the report. Once approved in writing and from the date stipulated by the Environment Agency, the operator shall adopt the revised monitoring technique and frequencies, if applicable, subject to such amendments or additions as notified by the Environment Agency.	
IC 2	The operator shall submit a report to the Environment Agency for technical assessment and approval. The report shall review the substances used on site as defined by Article 58 of IED. The report shall review viability and where appropriate submit plans for the replacement of these substances, any additional measures (e.g. abatement) and timescales (in the shortest possible time as per Article 58) for doing so. Once approved in writing and from the date stipulated by the Environment Agency, the plan shall be delivered in accordance with the agreed timescales, subject to such amendments or additions as notified by the Environment Agency.	14/11/20
IC3	The operator shall submit a revised drainage plan to the Environment Agency. The plan shall show the waste storage areas, drainage controls, containment and bunded areas, and collision protection of any tanks on site.	14/11/20

Schedule 2 – Waste types, raw materials and fuels

Table S2.1 Raw materials and fuels	
Raw materials and fuel description	**Specification**
Diesel	Less than 0.001% sulphur content

Schedule 3 – Emissions and monitoring

Table S3.1 Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location	**Source**	**Parameter**	**Limit (including unit)**	**Reference period**	**Monitoring frequency**	**Monitoring standard or method**
A1 [Point A1 on site plan referenced as FIGURE 4 – Rev 1* (dated 07/05/20)]	Boiler House Hot Water Boiler Stack	Oxides of Nitrogen (NO and NO_2 expressed as NO_2)	250 mg/m^3	Periodic	Every 3 years	EN 14792:2017
		Carbon Monoxide	--	Periodic	Every 3 years	EN 15058:2017
A2 [Point A2 on site plan referenced as FIGURE 4 – Rev 1* (dated 07/05/20)]	Boiler House Hot Water Boiler Stack	Oxides of Nitrogen (NO and NO_2 expressed as NO_2)	250 mg/m^3	Periodic	Every 3 years	EN 14792:2017
		Carbon Monoxide	--	Periodic	Every 3 years	EN 15058:2017
A3 [Point A3 on site plan referenced as FIGURE 4 – Rev 1* (dated 07/05/20)]	Steam Boiler Stack	Oxides of Nitrogen (NO and NO_2 expressed as NO_2)	250 mg/m^3	Periodic	Every 3 years	EN 14792:2017
		Carbon Monoxide	--	Periodic	Every 3 years	EN 15058:2017
A4 [Point A4 on site plan referenced as FIGURE 4 – Rev 1* (dated 07/05/20)]	Steam Boiler Stack	Oxides of Nitrogen (NO and NO_2 expressed as NO_2)	250 mg/m^3	Periodic	Every 3 years	EN 14792:2017
		Carbon Monoxide	--	Periodic	Every 3 years	EN 15058:2017
A5 [Point A5 on site plan referenced as FIGURE 4 – Rev 1* (dated 07/05/20)]	Boiler House Generator Stack	Oxides of Nitrogen (NO and NO_2 expressed as NO_2)	No limit set	Periodic	Every 3 years	[Note 3]
		Carbon monoxide	No limit set	Periodic	Every 3 years	[Note 3]

Table S3.1 Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location	**Source**	**Parameter**	**Limit (including unit)**	**Reference period**	**Monitoring frequency**	**Monitoring standard or method**
		Sulphur dioxide	No limit set	Periodic	Every 3 years	[Note 3]
		Particulates	No limit set	Periodic	Every 3 years	[Note 3]
A6 [Point A6 on site plan referenced as FIGURE 4 – Rev 1* (dated 07/05/20)]	Buildings 74 & 84 Generator Stack	Oxides of Nitrogen (NO and NO_2 expressed as NO_2)	No limit set	Periodic	Every 3 years	[Note 3]
		Carbon monoxide	No limit set	Periodic	Every 3 years	[Note 3]
		Sulphur dioxide	No limit set	Periodic	Every 3 years	[Note 3]
		Particulates	No limit set	Periodic	Every 3 years	[Note 3]
A7 [Point A7 on site plan referenced as FIGURE 4 – Rev 1* (dated 07/05/20)]	Buildings 71 & 73 Diesel Generator Stack	Oxides of Nitrogen (NO and NO_2 expressed as NO_2)	No limit set	Periodic	Every 3 years	[Note 3]
		Carbon monoxide	No limit set	Periodic	Every 3 years	[Note 3]
		Sulphur dioxide	No limit set	Periodic	Every 3 years	[Note 3]
		Particulates	No limit set	Periodic	Every 3 years	[Note 3]
A8 [Point A8 on site plan referenced as FIGURE 4 – Rev 1* (dated 07/05/20)]	HVAC Systems on Building 71	VOC [Note 6]	[Note 1]	Hourly average	Six monthly	[Note 4] [Note 5]
		Class B VOC - Methanol	[Note 2]	Hourly average	Six monthly	[Note 4] [Note 5]
		Hydrogen peroxide	No limit set	--	--	--
A9 [Point A9 on site plan referenced as	HVAC Systems on Building 73	VOC [Note 6]	[Note 1]	Hourly average	Six monthly	[Note 4] [Note 5]

Table S3.1 Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location	**Source**	**Parameter**	**Limit (including unit)**	**Reference period**	**Monitoring frequency**	**Monitoring standard or method**
FIGURE 4 – Rev 1* (dated 07/05/20)]		Class B VOC - Methanol	[Note 2]	Hourly average	Six monthly	[Note 4] [Note 5]
		Hydrogen peroxide	No limit set	--	--	--
A10 – A12 [Points A10-A12 on site plan referenced as FIGURE 4 – Rev 1* (dated 07/05/20)]	QC Lab Fume Hoods	No parameters set	No limit set	--	--	--
A13 [Point A13 on site plan referenced as FIGURE 4 – Rev 1* (dated 07/05/20)]	QC Lab Vapour Hydrogen Peroxide (VHP) Isolator	Hydrogen peroxide	No limit set	--	--	--
A14 [Point A14 on site plan referenced as FIGURE 4 – Rev 1* (dated 07/05/20)]	QC Sampling Fume Hood	No parameters set	No limit set	--	--	--
A15 [Point A15 on site plan referenced as FIGURE 4 – Rev 1* (dated 07/05/20)]	Building 72 Ventilation System	VOC [Note 6]	[Note 1]	Hourly average	Six monthly	[Note 4] [Note 5]
		Class B VOC - Methanol	[Note 2]	Hourly average	Six monthly	[Note 4] [Note 5]
A16- A17 [Points A16 – A17 on site plan referenced as FIGURE 4 – Rev 1* (dated 07/05/20)]	Emergency Firewater Pumps	Oxides of Nitrogen (NO and NO_2 expressed as NO_2)	No limit set	Periodic	Every 3 years	[Note 3]
		Carbon monoxide	No limit set	Periodic	Every 3 years	[Note 3]
		Sulphur dioxide	No limit set	Periodic	Every 3 years	[Note 3]
		Particulates	No limit set	Periodic	Every 3 years	[Note 3]

Table S3.1 Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location	**Source**	**Parameter**	**Limit (including unit)**	**Reference period**	**Monitoring frequency**	**Monitoring standard or method**

* - FIGURE 4 – Rev 1* (dated 07/05/20)] in Appendix B of Addendum Report received 08/07/20.

Note 1: The following Industrial Emissions Directive (IED) Annex VII limit for VOCs specified in Article 58 of the IED:

- 10 g/h for the mass flow of the sum of the compounds from all release points for emissions of VOCs with the following hazard statements H340, H350, H350i, H360D or H360F. In the case where the combined mass flows do not exceed the thresholds of 10 g/h the operator may agree in writing with the Environment Agency a higher ELV provided the operator can justify that exceedance of this limit, does not threaten to breach significance thresholds for long or short term impacts.

Note 2: Total emission limit for Class B VOC across all point source emissions is 2 kg/hr or 5 TPA (expressed as carbon) whichever is lower.

Note 3: To be agree in writing with the Environment Agency

Note 4: In accordance with our online guidance on 'Monitoring stack emissions: techniques and standards for periodic monitoring' 18 December 2019, available from this link (active October 2020).

Note 5: Unless otherwise agreed in writing with the Environment Agency in line with IC1.

Note 6: Emissions of this parameter are restricted to a single source from fumigation with formaldehyde emitting at any one time unless otherwise agreed in writing with the Environment Agency.

Table S3.2 Point Source emissions to water (other than sewer) and land – emission limits and monitoring requirements						
Emission point ref. & location	**Source**	**Parameter**	**Limit (incl. unit)**	**Reference Period**	**Monitoring frequency**	**Monitoring standard or method**
W1 on FIGURE 5 – Rev 1* (dated 08/11/2018) emission to River Ouzel	Clean Surface water only	No parameters set	No limit set	--	--	--
W2 on FIGURE 5 – Rev 1* (dated 08/11/2018) emission to River Ouzel	Clean Surface water only	No parameters set	No limit set	--	--	--

* - in Appendix A of Environmental Permit Application Report received 04/07/19.

Table S3.3 Point source emissions to sewer, effluent treatment plant or other transfers off-site– emission limits and monitoring requirements						
Emission point ref. & location	**Source**	**Parameter**	**Limit (incl. Unit)**	**Reference period**	**Monitoring frequency**	**Monitoring standard or method**
S1 on FIGURE 5 – Rev 1* (dated 08/11/2018) emission to Cotton Valley Sewage Treatment Works	Site effluent treatment plant	Formaldehyde	0.97 mg/l	Spot sample	Monthly	[Note 1]
* - in Appendix A of Environmental Permit Application Report received 04/07/19. Note 1: To be agree in writing with the Environment Agency						

Table S3.4 Annual limits		
Substance	**Medium**	**Limit (including unit)**
--	--	--

Table S3.5 Process monitoring requirements				
Emission point reference or source or description of point of measurement	**Parameter**	**Monitoring frequency**	**Monitoring standard or method**	**Other specifications**
ETP outlet	pH	Continuous	Not applicable	--
ETP outlet	Chemical oxygen demand (COD)	One spot sample every 60 minutes or as otherwise agreed in writing with the Environment Agency.	Not applicable	--

Schedule 4 – Reporting

Parameters, for which reports shall be made, in accordance with conditions of this permit, are listed below.

Table S4.1 Reporting of monitoring data			
Parameter	**Emission or monitoring point/reference**	**Reporting period**	**Period begins**
Emissions to air Parameters as required by condition 3.5.1.	A8, A9, A15 A1 – A7	Every 12 months Every 36 months	1 January
Emissions to water Parameters as required by condition 3.5.1	S1	Every 6 months	1 January, 1 July

Table S4.2: Annual production/treatment	
Parameter	**Units**
Active pharmaceutical ingredient production	Kilogrammes

Table S4.3 Performance parameters		
Parameter	**Frequency of assessment**	**Units**
Water usage	Annually	tonnes
Energy usage	Annually	MWh
Total raw material used	Annually	tonnes

Table S4.4 Reporting forms		
Media/parameter	**Reporting format**	**Date of form**
Air	Form air 1 or other form as agreed in writing by the Environment Agency	14/10/2020
Sewer	Form sewer 1 or other form as agreed in writing by the Environment Agency	14/10/2020
Water usage	Form water usage 1 or other form as agreed in writing by the Environment Agency	14/10/2020
Energy usage	Form energy 1 or other form as agreed in writing by the Environment Agency	14/10/2020
Other performance indicators	Form performance 1 or other form as agreed in writing by the Environment Agency	14/10/2020

Schedule 5 – Notification

These pages outline the information that the operator must provide.

Units of measurement used in information supplied under Part A and B requirements shall be appropriate to the circumstances of the emission. Where appropriate, a comparison should be made of actual emissions and authorised emission limits.

If any information is considered commercially confidential, it should be separated from non-confidential information, supplied on a separate sheet and accompanied by an application for commercial confidentiality under the provisions of the EP Regulations.

Part A

Permit Number	
Name of operator	
Location of Facility	
Time and date of the detection	

(a) Notification requirements for any malfunction, breakdown or failure of equipment or techniques, accident, or emission of a substance not controlled by an emission limit which has caused, is causing or may cause significant pollution	
To be notified within 24 hours of detection	
Date and time of the event	
Reference or description of the location of the event	
Description of where any release into the environment took place	
Substances(s) potentially released	
Best estimate of the quantity or rate of release of substances	
Measures taken, or intended to be taken, to stop any emission	
Description of the failure or accident.	

(b) Notification requirements for the breach of a limit	
To be notified within 24 hours of detection unless otherwise specified below	
Emission point reference/ source	
Parameter(s)	
Limit	
Measured value and uncertainty	
Date and time of monitoring	

(b) Notification requirements for the breach of a limit	
To be notified within 24 hours of detection unless otherwise specified below	
Measures taken, or intended to be taken, to stop the emission	

Time periods for notification following detection of a breach of a limit	
Parameter	**Notification period**

(c) Notification requirements for the breach of permit conditions not related to limits	
To be notified within 24 hours of detection	
Condition breached	
Date, time and duration of breach	
Details of the permit breach i.e. what happened including impacts observed.	
Measures taken, or intended to be taken, to restore permit compliance.	

(d) Notification requirements for the detection of any significant adverse environmental effect	
To be notified within 24 hours of detection	
Description of where the effect on the environment was detected	
Substances(s) detected	
Concentrations of substances detected	
Date of monitoring/sampling	

Part B – to be submitted as soon as practicable

Any more accurate information on the matters for notification under Part A.	
Measures taken, or intended to be taken, to prevent a recurrence of the incident	

Measures taken, or intended to be taken, to rectify, limit or prevent any pollution of the environment which has been or may be caused by the emission	
The dates of any unauthorised emissions from the facility in the preceding 24 months.	

Name*	
Post	
Signature	
Date	

* authorised to sign on behalf of the operator

Schedule 6 – Interpretation

“accident” means an accident that may result in pollution.

“application” means the application for this permit, together with any additional information supplied by the operator as part of the application and any response to a notice served under Schedule 5 to the EP Regulations.

“authorised officer” means any person authorised by the Environment Agency under section 108(1) of The Environment Act 1995 to exercise, in accordance with the terms of any such authorisation, any power specified in section 108(4) of that Act.

“background concentration” means such concentration of that substance as is present in:

- for emissions to surface water, the surface water quality up-gradient of the site; or
- for emissions to sewer, the surface water quality up-gradient of the sewage treatment works discharge.

“EP Regulations” means The Environmental Permitting (England and Wales) Regulations SI 2016 No.1154 and words and expressions used in this permit which are also used in the Regulations have the same meanings as in those Regulations.

“emissions of substances not controlled by emission limits” means emissions of substances to air, water or land from the activities, either from the emission points specified in schedule 3 or from other localised or diffuse sources, which are not controlled by an emission or background concentration limit.

“groundwater” means all water, which is below the surface of the ground in the saturation zone and in direct contact with the ground or subsoil.

“Industrial Emissions Directive” or “IED” means DIRECTIVE 2010/75/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 November 2010 on industrial emissions

“MCERTS” means the Environment Agency’s Monitoring Certification Scheme.

“Medium Combustion Plant” or ”MCP” means a combustion plant with a rated thermal input equal to or greater than 1 MW but less than 50 MW.

“Medium Combustion Plant Directive” or “MCPD” means Directive 2015/2193/EU of the European Parliament and of the Council on the limitation of emissions of certain pollutants into the air from medium combustion plants.

“quarter” means a calendar year quarter commencing on 1 January, 1 April, 1 July or 1 October.

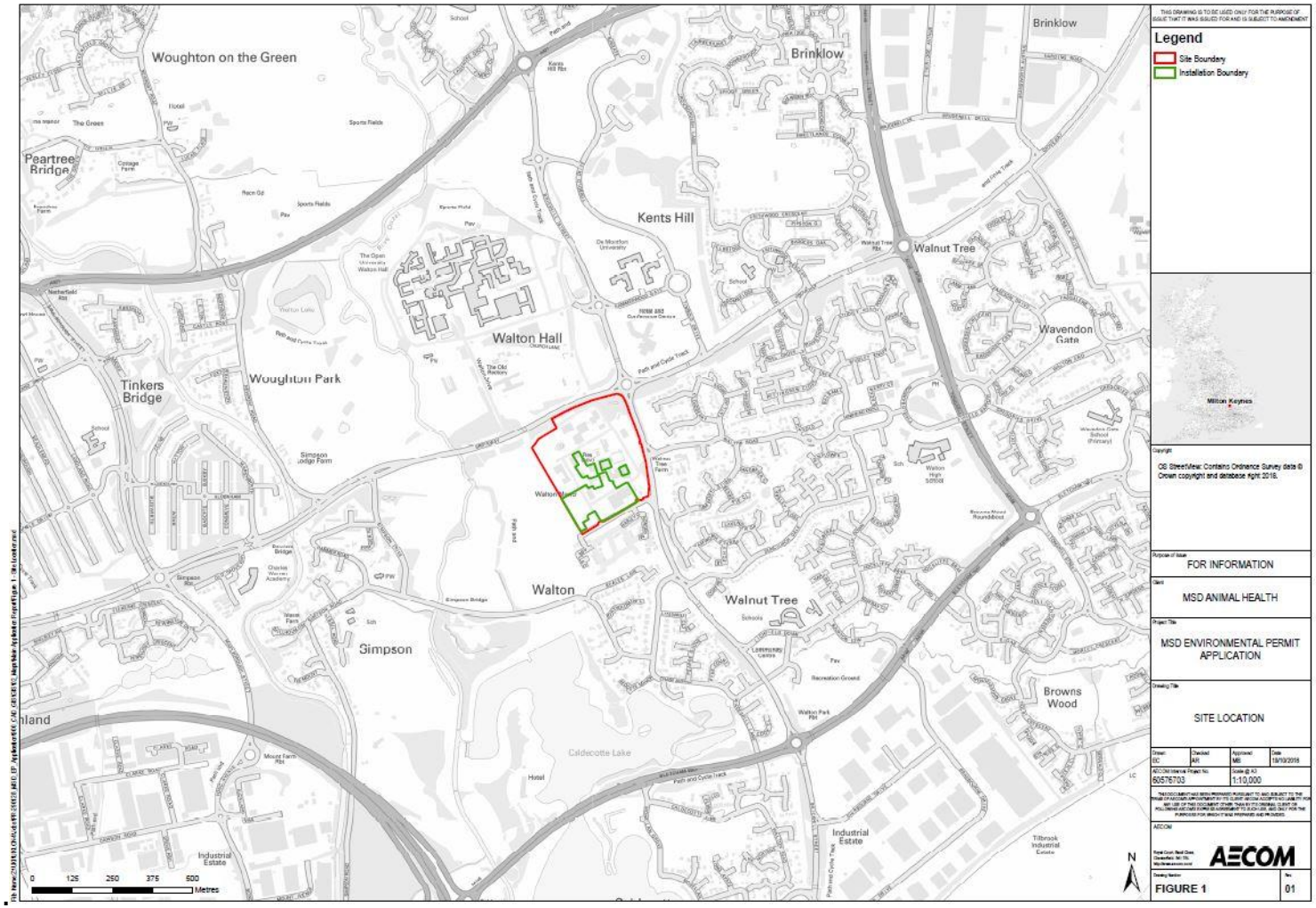
Where a minimum limit is set for any emission parameter, for example pH, reference to exceeding the limit shall mean that the parameter shall not be less than that limit.

Unless otherwise stated, any references in this permit to concentrations of substances in emissions into air means:

- in relation to emissions from combustion processes, the concentration in dry air at a temperature of 273K, at a pressure of 101.3 kPa and with an oxygen content of 3% dry for liquid and gaseous fuels, 6% dry for solid fuels; and/or
- in relation to emissions from non-combustion sources, the concentration at a temperature of 273K and at a pressure of 101.3 kPa, with no correction for water vapour content.

“year” means calendar year ending 31 December.

Schedule 7 – Site plan



END OF PERMIT

Reporting Forms

Permit Number:	**UP3801PH**	**Operator:**	**MSD Animal Health UK Limited**
Facility:	**MSD Animal Health (Milton Keynes)**	**Form Number:**	**Air1 / 14/10/20**

Reporting of emissions to air for the period from DD/MM/YYYY to DD/MM/YYYY

Emission Point	Substance / Parameter	Emission Limit Value	Reference Period	Result [1]	Test Method [2]	Sample Date and Times [3]	Uncertainty [4]

1. The result given is the maximum value (or the minimum value in the case of a limit that is expressed as a minimum) obtained during the reporting period, expressed in the same terms as the emission limit value. Where the emission limit value is expressed as a range, the result is given as the 'minimum – maximum' measured values.
2. Where an internationally recognised standard test method is used the reference number is given. Where another method that has been formally agreed with the Environment Agency is used, then the appropriate identifier is given. In other cases the principal technique is stated, for example gas chromatography.
3. For non-continuous measurements the date and time of the sample that produced the result is given. For continuous measurements the percentage of the process operating time covered by the result is given.
4. The uncertainty associated with the quoted result at the 95% confidence interval, unless otherwise stated.

Signed …… Date……..

(Authorised to sign as representative of Operator)

Permit Number:	**UP3801PH**	**Operator:**	**MSD Animal Health UK Limited**
Facility:	**MSD Animal Health (Milton Keynes)**	**Form Number:**	**Sewer 1 / 14/10/20**

Reporting of emissions to sewer for the period from DD/MM/YYYY to DD/MM/YYYY

Emission Point	Substance / Parameter	Emission Limit Value	Reference Period	Result [1]	Test Method [2]	Sample Date and Times [3]	Uncertainty [4]

1. The result given is the maximum value (or the minimum value in the case of a limit that is expressed as a minimum) obtained during the reporting period, expressed in the same terms as the emission limit value. Where the emission limit value is expressed as a range, the result is given as the 'minimum – maximum' measured values.
2. Where an internationally recognised standard test method is used the reference number is given. Where another method that has been formally agreed with the Environment Agency is used, then the appropriate identifier is given. In other cases the principal technique is stated, for example gas chromatography.
3. For non-continuous measurements the date and time of the sample that produced the result is given. For continuous measurements the percentage of the process operating time covered by the result is given.
4. The uncertainty associated with the quoted result at the 95% confidence interval, unless otherwise stated.

Signed ……. Date……..

(Authorised to sign as representative of Operator)

Permit Number:	**UP3801PH**	**Operator:**	**MSD Animal Health UK Limited**
Facility:	**MSD Animal Health (Milton Keynes)**	**Form Number:**	**Water usage1 / 14/10/20**

Reporting of Water Usage for the year YYYY

Water Source	**Usage (m^3/year)**	**Specific Usage (m^3/unit output)**
Mains water		
TOTAL WATER USAGE		

Operator's comments:

Signed ……. Date……..

(Authorised to sign as representative of Operator)

Permit Number:	**UP3801PH**	**Operator:**	**MSD Animal Health UK Limited**
Facility:	**MSD Animal Health (Milton Keynes)**	**Form Number:**	**Energy1 / 14/10/20**

Reporting of Energy Usage for the year YYYY

Energy Source	**Energy Usage**		**Specific Usage (MWh/unit output)**
	Quantity	**Primary Energy (MWh)**	
Electricity *	MWh		
Natural Gas	MWh		
Steam	MWh equivalent		
TOTAL	**-**		

* Conversion factor for delivered electricity to primary energy = 2.4

Operator's comments:

Signed ……. Date……..

(Authorised to sign as representative of Operator)

Permit Number:	**UP3801PH**	**Operator:**	**MSD Animal Health UK Limited**
Facility:	**MSD Animal Health (Milton Keynes)**	**Form Number:**	**Performance 1 / 14/10/20**

Reporting of other performance indicators for the period DD/MM/YYYY to DD/MM/YYYY

	Units

Operator's comments:

Signed ……. Date……..

(Authorised to sign as representative of Operator)