

Notice of variation and consolidation with introductory note

The Environmental Permitting (England & Wales) Regulations 2016

Avara Avlon Pharma Services Ltd

Avlon Site
Severn Road
Hallen
Bristol
BS10 7ZE

Variation application number

EPR/BP3736DN/V002

Permit number

EPR/BP3736DN

Avlon Site

Permit number EPR/BP3736DN

Introductory note

This introductory note does not form a part of the notice

Under the Environmental Permitting (England & Wales) Regulations 2016 (schedule 5, part 1, paragraph 19) a variation may comprise a consolidated permit reflecting the variations and a notice specifying the variations included in that consolidated permit.

Schedule 1 of the notice specifies the conditions that have been varied and schedule 2 comprises a consolidated permit which reflects the variations being made. Only the variations specified in schedule 1 are subject to a right of appeal.

Following the change of ownership to Avara Avlon Pharma Services Ltd, the site is now set up as a contract manufacturing facility that will need the flexibility to carry out short manufacturing campaigns for a number of new products. To enable accommodation of these new products within short timescales, a number of the manufacturing plants and the Kilo Scale Facility (KSF) are to be included within the existing Multi-Product Protocol.

Although the KSF is an existing facility that sits within the existing site boundary, its previous use was outside the scope of EPR. As it will be now be used for commercial manufacture, it will be included as a new Stationary Technical Unit (STU) within the updated EPR installation boundary.

Site background:

The facility comprises a 70 hectare plot located at Severn Road, Hallen, Bristol, (NGR: ST5450 8345).

Activities at the installation comprise the manufacture of bulk and pure pharmaceutical products on a batch process operation basis, in a range of vessels up to a maximum volume of 10,000 litres, within several production modules. The production processes use a range of materials including a number of organic chemical compounds, acids/bases and organic solvents in bulk and packaged quantities. The inventory is such that the site qualifies as a top-tier COMAH site.

Raw materials are received by road tanker, intermediate bulk containers (IBCs) or drums, and are stored on-site in bulk tanks, drums or IBCs. The raw materials are conveyed to one of seven manufacturing units where they are processed via various reaction, crystallising, filtering and drying processes before being packaged for distribution.

The installation includes Directly Associated Activities which are detailed in table S1.1 in schedule 1 to the permit.

There are a number of emissions to air and water through the routine production processes; these are detailed in tables S3.1 and S3.2 in schedule 4 of this permit.

The emissions to air are composed typically of volatile organic compounds (VOCs), combustion gases, particulates and acid gases. The emissions are minimised through the use of a range of abatement techniques including condensers, filters, scrubbers and/or cryogenic abatement and carbon adsorption prior to release to the environment.

The emissions to water are treated in the effluent treatment plant before being discharged to the Severn Estuary. Severn Estuary SPA/Ramsar/SAC/SSSI lie within 5km of the installation. There are 5 local wildlife sites within 2km of the installation boundary.

The schedules specify the changes made to the permit.

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

Status log of the permit		
Description	Date	Comments
Application EPR/RP3331SL/A001	Duly made 29/03/06	
Additional Information received	27/07/06; 04/08/06; 07/09/06	
Permit determined EPR/RP3331SL	22/12/06	
Application EPR/RP3331SL/V002	31/07/07	
Additional Information received	02/11/07	
Variation notice EPR/RP3331SL/V002 issued	01/01/08	
Variation application EPR/RP3331SL/V003	15/09/08	
Additional information received	17/09/08	Installation site drawing showing installation boundary supplied by e-mail
Variation determined EPR/RP3331SL/V003	14/10/08	
Variation application EPR/RP3331SL/V004	Duly made 26/07/10	
Additional information received (i) Multi-product protocol (ii) Change of registered office address (iii) Confirmation of emission point	17/08/10 18/08/10 18/08/10	
Schedule 5 notice dated 05/08/10	10/09/10	
Variation determined EPR/RP3331SL/V004	29/09/10	
Application EPR/RP3331SL/V005	Duly made 12/09/12	Application to add a new Solvent Recovery Unit.
Additional information received	26/10/12	
Variation determined EPR/RP3331SL/V005	20/11/12	
Application EPR/RP3331SL/V006 (variation and consolidation)	Duly made 11/12/13	Application to vary the permit, moving location of part of the process and adding 1 new emission point.
Additional information received	06/02/14	Minor updates to tables S4.1 and S4.4

Status log of the permit		
Description	Date	Comments
Variation determined EPR/RP3331SL/V007	07/03/14	
Notified of Change of company registered office address	17/05/16	Address Changed to 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, CB2 0AA
Variation issued EPR/RP3331SL/V007	23/06/16	
Application EPR/BP3736DN/V002 (full transfer of permit EPR/RP3331SL)	Duly made 19/09/16	Application to transfer the permit in full to Avara Avlon Pharma Services Ltd.
Transfer determined EPR/BP3736DN	16/11/16	Full transfer of permit complete.
Variation application EPR/BP3736DN/V002	Duly made 08/08/18	
Variation determined EPR/BP3736DN/V002 Billing reference RP3533QT	21/12/2018	

End of introductory note

Notice of variation and consolidation

The Environmental Permitting (England and Wales) Regulations 2016

The Environment Agency in exercise of its powers under regulation 20 of the Environmental Permitting (England and Wales) Regulations 2016 varies

Permit number

EPR/BP3736DN

Issued to

Avara Avlon Pharma Services Ltd (“the operator”)

whose registered office is

**9a Burroughs Gardens
London
NW4 4AU**

company registration number 10257441

to operate a regulated facility at

**Avlon Site
Severn Road
Hallen
Bristol
BS10 7ZE**

to the extent set out in the schedules.

The notice shall take effect from 21/12/2018

Name	Date
Anne Lloyd	21/12/2018

Authorised on behalf of the Environment Agency

Schedule 1

The following conditions were varied as a result of the application made by the operator:

- Condition 1.5 for amendments to multi product protocol
- Table S3.1; Point source emissions to air - emission limits and monitoring requirements
- Table S3.1A; Point source emissions to air - emission limits and monitoring requirements subject to agreed Multi Product Protocol (MPP)
- Table S3.4; Process monitoring requirements
- Table S4.1; Reporting of monitoring data

Schedule 2 – consolidated permit

Consolidated permit issued as a separate document.

Permit

The Environmental Permitting (England and Wales) Regulations 2016

Permit number

EPR/BP3736DN

This is the consolidated permit referred to in the variation and consolidation notice for application EPR/BP3736DN/V002 authorising,

Avara Avlon Pharma Services Ltd (“the operator”),

whose registered office is

9a Burroughs Gardens

London

NW4 4AU

company registration number 10257441

to operate an installation at

Avlon Site

Severn Road

Hallen

Bristol

BS10 7ZE

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

Name	Date
Anne Lloyd	21/12/2018

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.

1.5 Multi product protocol

- 1.5.1 Where the operator proposes to make a change under a multi product protocol that is not otherwise the subject of an application for approval under the Regulations or this permit:
- (a) the Environment Agency shall be notified of the proposed change;
 - (b) the notification shall contain a description of the change including: an assessment of its environmental impact; any relevant supporting assessments and drawings; and the proposed implementation date;
 - (c) the change shall not be implemented unless approved in writing by the Environment Agency;
 - (d) as from any approved implementation date, the operator shall operate in accordance with the changed multi product protocol in place of the previously approved version.

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.

3 Emissions and monitoring

3.1 Emissions to water, air and 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, S3.1A, S3.2 and S3.3.
- 3.1.2 The limits given in schedule 3 shall not be exceeded.
- 3.1.3 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, S3.1A, S3.2 and S3.3
- (b) process monitoring specified in table S3.4;

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, S3.1A, 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.
- 4.2.5 The operator shall submit an annual solvent management plan in order to demonstrate compliance with the requirements of the Industrial Emissions Directive, by 31 January each year in respect of the previous year.

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 (a)(i) or 4.3.1 (b)(i) where the information relates to the breach of a limit specified in the permit, 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.

- 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 listed in Schedule 1 of the EP Regulations	Description of specified activity	Limits of specified activity
S4.1 A1 (a) (i)	Production of hydrocarbons (linear or cyclic, saturated or unsaturated, aliphatic or aromatic).	From receipt of raw materials to storage of finished product.
S4.1 A1 (a) (ii)	Production of organic compounds containing oxygen, such as alcohols, aldehydes, ketones, carboxylic acids, esters, ethers, peroxides, phenols, epoxy resins.	From receipt of raw materials to storage of finished product.
S4.1 A1 (a) (iii)	Production of organic compounds containing sulphur, such as sulphides, mercaptans, sulphonic acids, sulphonates, sulphates and sulphones and sulphur heterocyclics.	From receipt of raw materials to storage of finished product.
S4.1 A1 (a) (iv)	Production of organic compounds containing nitrogen, such as amines, amides, nitrous-, nitro- or azo- compounds, nitrates, nitriles, nitrogen heterocyclics, cyanates, isocyanates, di-isocyanates and di-isocyanate prepolymer.	From receipt of raw materials to storage of finished product.
S4.1 A1 (a) (v)	Production of organic compounds containing phosphorous, such as substituted phosphines and phosphate esters.	From receipt of raw materials to storage of finished product.
S4.1 A1 (a) (vi)	Production of organic compounds containing halogens, such as halocarbons, halogenated aromatic compounds and acid halides.	From receipt of raw materials to storage of finished product.
S4.1 A1 (a) (vii)	Production of organometallic compounds, such as lead alkyls, Grignard reagents and lithium alkyls.	From receipt of raw materials to storage of finished product.
S4.5 A1 (a)	Production of pharmaceutical products.	From receipt of raw materials to storage of finished product.
S5.4 A1 (a) (i)	Disposal of non-hazardous waste involving biological treatment of waste waters.	From receipt of strong and high strength effluents to discharge of treated effluent.
Directly Associated Activity		
Rosuvastatin milling	Milling of pharmaceutical products	From receipt of Rosuvastatin calcium to transfer of milled product
Boiler plant	Production of steam	Operation of four gas fired boilers (back-up fuel gas oil), each boiler with a net thermal rating of 7.2 MW and a back-up fuel oil fired boiler with a net thermal rating of 7.2 MW
Services and utilities	Nitrogen supply, air compression, operation of chillers, operation of cooling towers	Nitrogen supply, air compression, operation of

Table S1.1 activities		
		chillers, operation of cooling towers.
Storage of materials	Storage of raw materials and products in bulk storage areas, warehouse and drum storage areas.	From receipt of materials in the storage area to removal from the storage area.
Telescoped Mother Liquor Recovery	Recovery of active pharmaceutical ingredients (API) and treatment of residual API at the installation effluent treatment plant	From recovery of API to treatment of residual waste streams at the ETP.
Combined heat and power plant (CHP)	Production of approximately 2.8 MW of electricity and approximately 1.4 Te/hr steam for on-site use by means of two identical package CHP of 3.3 MW thermal input each.	From supply of natural gas and pre-treated water to export of electricity, steam and hot water produced. Including waste heat boiler for steam production (high grade heat) and pre-heater of boiler feed water (residual low grade heat).
Quetiapine Milling	Milling of Pharmaceutical products	From receipt of Quetiapine Hydrogen Fumarate to transfer of milled product.
Solvent Recovery Unit	Recovery of ethanol IDA in the Quetiapine Fumarate production stage.	From receipt of spent ethanol IDA from E4 plant to either, purification and re-use in the Quetiapine Fumarate Process, or removal from site.

Table S1.2 Operating techniques		
Description	Parts	Date Received
Application	The response to section B2.1, excluding 2.1.3 and 2.1.5, B2.2, Appendices F4.B2.1A, F4.B2.1B, F4.B2.1C, F4.B2.1D, F4.B2.1E, F4.B2.1F, F4.B2.1G, F4.B2.1H, F4.B2.1I, F4.B2.1J, F4.B2.1K, F4.B2.1L, F4.B2.1M, F4.B2.1N, F4.B2.1O, F4.B2.1S, F4.B2.1U, F4.B2.1V, F4.B2.1W, F4.B2.1X and F4.B2.1Y – Multi Product Protocol, as identified in the Application.	29/03/06
Request for further information dated 17/07/06	Additional information supplied in support / revision of Appendices F4.B2.1H	07/09/06
Application for variation EA/EPR/RP3331SL/V003	The responses to section C2 as identified in the Application.	15/09/08
Application for variation EA/EPR/RP3331SL/V004	(i) Document F4.B2.1N Supporting information for Avlon works PPC application, DAA5 – Boilerhouse and Combined Heat and Power (CHP) plant; sections 1 (all subsections), section 2, sub-sections 2.2.1, 2.2.2 and 2.2.3. (ii) Documents F4.B2.1A, F4.B2.1B, F4.B2.1W, F4.B2.1H, F4.B2.1E, F4.B2.1G, F4.B2.1X, F4.B2.1K, F4.B2.1Y - Section 2.3, Details of surrogate monitoring	29/06/10
Application for variation EPR/RP3331SL/V005	Updated documents - F4.B2.1B, F4.B2.1W, F4.B2.1L	12/09/12

Table S1.2 Operating techniques		
Description	Parts	Date Received
Response to request for further information dated 16/10/12	<ul style="list-style-type: none"> ▪ Updated document F4.B2.1Z – Supporting information for Avlon Works PPC Application – DAA9 – Solvent Recovery Unit (SRU) ▪ Location plan showing the emission points Response no.3 clarifying the carbon beds usage	26/10/12
Application for variation EPR/RP3331SL/V006	<ul style="list-style-type: none"> ▪ Part C3, section 3 of application form; updated documents F4.B2.1AA	11/12/13
Application for variation EPR/BP3736DN	<ul style="list-style-type: none"> ▪ Appendix I – Multi Product Protocol (F4.B2.1S) ▪ Appendix II – Installation Boundary Diagram (AVW354605) ▪ Appendix III – STU DAA supporting information documents for all MPP areas ▪ Appendix IV – Example of completed STU document (F4.B2.1W) for existing product ▪ Appendix V – Avlon SHE Management System (SMS04) 	03/05/18
Response to request for further information dated 24/07/18	Revised Documents <ul style="list-style-type: none"> ▪ Appendix I – F4.B2.1S Avlon Works Multi Product Protocol ▪ Appendix III STU DAA – MPP documents ▪ Appendix IV – Example completed STU supporting information document F4.B2.1W Additional Information <ul style="list-style-type: none"> • MPP 1 – Supporting information • Site Condition Report – KSF Aug 18 • Site Plan with MPP STU DAA locations 	08/08/18

Schedule 2 – Waste types, raw materials and fuels

Table S2.1 Raw materials and fuels	
Raw materials and fuel description	Specification
Gas oil (standby fuel)	<0.1 % sulphur by weight (w/w)

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
A4 [V011 on Drawing no. 354600 within the Application]	Bulk storage tank F111				No monitoring required	
A5 [V012 on Drawing no. 354600 within the Application]	Bulk storage tank F112				No monitoring required	
A6 [V019 on Drawing no. 354600 within the Application]	Bulk storage tank F119				No monitoring required	
A7 [V006 on Drawing no. 354600 within the Application]	Bulk storage tank F106				No monitoring required	
A8 [V009 on Drawing no. 354600 within the Application]	Bulk storage tank F109				No monitoring required	
A10 [V018 on Drawing no. 354600 within the Application]	Bulk storage tanks F116 & F118 via carbon bed (G138)				No monitoring required	
A11 [V101 on Drawing no. 354597 within the Application]	Reactor D721 POCl ₃ addition	Hydrogen chloride	10 mg/m ³	Hourly average	Annually	BS EN 1911:1998 Parts 1,2 &3
	E1 Reactors (D721, D722, D702, D703); Receivers (D701, D723, F724, F726); Pressure filter (G721); Bulk storage (F285)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A12 [V102 on Drawing no. 354597 within the Application]	F752 pressure venting prior to discharge	Total Class B Volatile Organic compounds (expressed as	2 kg/hr	Hourly average	6-monthly	BS EN 13649:2002

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
		carbon)				
	F752 Solids discharging				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A13 [V103 on Drawing no. 354597 within the Application]	Solids (sodium iodide/ sodium carbonate) charging (T702)	Particulates	20 mg/m ³	Hourly average	Quarterly	BS EN 13284-1:2002
	T702 Solids charging				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A14 [V104 on Drawing no. 354597 within the Application]	Fumaric acid charging (T703)	Particulates	20 mg/m ³	Hourly average	Quarterly	BS EN 13284-1:2002
	T703 Solids charging				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A15 [V105 on Drawing no. 354597 within the Application]	Lactam charging (T721)	Particulates	20 mg/m ³	Hourly average	Quarterly	BS EN 13284-1:2002
	T721 Solids charging				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A16 [V106 on Drawing no. 354597 within the Application]	Piperazine charging (T722)	Particulates	20 mg/m ³	Hourly average	Quarterly	BS EN 13284-1:2002
	T722 Solids charging				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	

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
A17 [V107 on Drawing no. 354597 within the Application]	HF discharging (T723)	Particulates	10 mg/m ³	Hourly average	Quarterly	BS EN 13284-1:2002
	T723 Solids charging				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A18 [V108 on Drawing no. 354597 within the Application]	Raw material drum charging (T728)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A19 [V109 on Drawing no. 354600 within the Application]	Bulk effluent storage (D805)				No monitoring required	
A20 [V110 on Drawing no. 354600 within the Application]	Bulk effluent storage (D900)				No monitoring required	
A22 [V201 on Drawing no. 354596 within the Application]	E2 reactors (D741, D742, D743) receivers (D744, F745, F749) & pressure filter (G741).				No monitoring required	
	E2 reactors (D741, D742, D743) receivers (D744, F745, F749) & pressure filter (G741).				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A23 [V202 on Drawing no. 354596 within the application]	T741 (A1 charge) E2 Urethane charge	Particulates	20 mg/m ³	Hourly average	Quarterly	BS EN 13284-1:2002
	T760 (A1 charge) E2 Lactam discharge)	Particulates	20 mg/m ³	Hourly average	Quarterly	BS EN 13284-1:2002
	T741 (A1 charge) E2				Monitoring as required	

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
	solids charging				by agreed Multi Product Protocol, in line with Table S3.1A	
	T760 (A1 charge) E2 solids discharging					
A24 [V203 on Drawing no. 354596 within the application]	D804 Bulk effluent storage				No monitoring required	
A25 [V407 on Drawing no. 354595 within the application]	D1210 Reactor; F1240 Receiver; F1250 Measure vessel via an acid gas scrubber (E970)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
	PCF addition to Reactor D1210 via acid gas scrubber (E970)	Hydrogen chloride	10 mg/m ³	Hourly average	Annually	BS EN 1911:1998, Parts 1, 2 & 3
A26 [V408 on drawing no. 354595 within the application]	Specialized gas scrubber (E973)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A27 [V401 on Drawing no. 354595 within the application]	Heat exchanger C2325. Reactors D940, D943, D946, D950, D956, D2206, F954. Receivers F2371/2372 Bulk Storage F113, F115.	Total Class A Volatile Organic Compounds (as individual VOCs)	100 g/hr	Hourly average	Annually	BS EN 13649:2002
		Total Class B Volatile Organic Compounds (expressed as Carbon)	2 kg/hr	Hourly average	Annually	BS EN 13649:2002
		Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A				

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
	Centrifuge E6-0730 SRU reflux tank (F2398, 2400) SRU bulk storage (F102, F103, F105, F117, F108) Via condenser (C959)					
A30 [V413 on Drawing no. 354595 within the application]	D1220 Reactor; G1230 pressure filter; D2205 Receiver; F1241 knock-out pot. - via carbon absorber (G1281 and G1282)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A31 [V421 on Drawing no. 354595 within the application]	F987 plant sump				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A32 [V403 on Drawing no. 354595 within the application]	T941/T944 solids charge via HEPA filters (G941, G944)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A34 [V410 on Drawing no. 354595 within the application]	T980 Liquid charge booth J988 Plant vent fan				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A35 [V411 on Drawing no. 354595 within the application]	T983 Liquids charge booth				Monitoring as required by agreed Multi Product Protocol, in	

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
					line with Table S3.1A	
A36 [V414 on Drawing no. 354595 within the application]	T1215 Glove box via HEPA filter (G1215)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A37 [V415 on Drawing no. 354595 within the application]	T1230 product discharge via particulate filters (G1235 & G1239)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
	T1230 Urethane discharge via particulate filters (G1235/G1239)	Particulates	10 mg/m ³	Hourly average	Quarterly	BS EN13284-1:2002
		Total Class B Volatile Organic compounds (expressed as carbon)	2 kg/hr	Hourly average	Annually	BS EN 13649:2002
A38 [V416 on Drawing no. 354595 within the application]	T1260 screening booth				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A39 [V417 on Drawing no. 354595 within the application]	T1264 Liquid charge booth				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A40 [V451 on Drawing no. 354595 within the application]	T1300 E9 Mill product discharge via particulate filters (G1301 & G1302)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A41 [V412 on Drawing no. 354595 within the application]	Isotanker bay				Monitoring as required by agreed Multi Product Protocol, in	

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
					line with Table S3.1A	
A42 [V405 on Drawing no. 354595 within the application]	Special liquids and gases annexe via carbon absorber (G560)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A43 [V409 on Drawing no. 354595 within the application]	Special liquids and gases annexe via carbon absorber (G977)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A45 [V432 on Drawing no. 354600 within the application]	F120 bulk storage tank				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A47 [V007 on Drawing no. 354600 within the application]	F107 bulk solvent storage				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A48 [V501 on Drawing no. 354594 within the application]	E5 Ros: Reactors (MF0100, MF0300, MF1100, MF1200). Receivers (MF1300, MF1400, MF1500, MF1600) BEM charge (MF 0303) Bulk storage (MF3003) E6-Ros TMLR: Reactors E6-0200, E6-0400, E6-500, E6-0700, E6-0800,	Ammonia	15mg/m ³	Hourly average	Quarterly	BS EN 14791: 2005
		Carbon monoxide	100mg/m ³	Hourly average	Continuous	FID
		Oxides of nitrogen (as NO ₂)	200mg/m ³	Hourly average	Quarterly	NDUV
		Particulates	20mg/m ³	Hourly average	Continuous	BS EN 13284-1 :2002
		Total Organic Carbon	10 mg/m ³	Daily average	Continuous	FID
			20 mg/m ³	Half-hourly average	Continuous	FID

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
	MF0500, MF0600). Receivers (E6-0600, E6-0980). Bulk storage (E6-3101, E6-1750, E6-3001, E6-3003) Measure vessels (E6-0420, E6-0520) Via MF0880 Catox					
	E5: Reactors (MF0100, MF0103, MF0300, MF0303, MF0400, MF0500, MF0600, MF1100, MF1200, MF1600); Receivers (MF1300, MF1400, MF1500, MF1600). Pressure filters (MF1823, MF1839, MF1881); Bulk storage (MF3001, MF3003, MF3101) E6: Reactors E6-0200, E6-0400, E6-500, E6-0700, E6-0800). Receivers (E6-0600, E6-0980). Bulk storage (E6-3101, E6-1750, E6-3001, E6-3003) Measure vessels				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	

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
	(E6-0420, E6-0520) Bulk storage (E63001, E6-3003) Via MF0880 Catox.					
A49 [V502 on Drawing no. 354594 within the application]	MF0701, MF0903, MF0953 Vacuum pump; MF1300, MF1500, MF1600 Receivers; MF1823, MF1839, MF1881 pressure filters via carbon absorbers (MF0707)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A50 [V503 on Drawing no. 354594 within the application]	MF0804/0869 solids discharge via particulate filter (MF0857/0879) MF1816 screening booth				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
	E5 MF0869 solids discharge via filters (MF0879)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A51 [V509 on Drawing no. 354594 within the application]	MF1103 solids charge MF1804 solids discharge				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A52 [V512 on Drawing no. 354594 within the application]	MF1830/1875 solids discharge via particulate filters (MF1950/1889)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	

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
A54 [V602 on Drawing no. 354593 within the application]	E6-1360 TMLR E6 Pures discharge; E6-0700 TMLR E6 glove-bag pures charge (re-treat). Ros discharge E6-1360, E6-1560, E6-1660, E6-2060 via filter (E6-1362)	API – Particulate	0.15 mg/m ³	Hourly average	Annually	BS EN 13824-1:2002
	E6-1360, E6-1560, E6-1660, E6-2060 solids discharge via filter (E6-1362) E6-0700 glove-bag solids charge.				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A55 [V603 on Drawing no. 354593 within the application]	E6-1882: Ros/Ros TMLR clean out via carbon bed (E6-1880) E6-3005 bulk storage				No monitoring required	
	E6-1200 Reactor E6-1300, E6-1500, E6-1600, E6-2000 Receivers E6-3005 bulk storage.				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	

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
A56 [V604 on Drawing no. 354593 within the application]	E6-0660/0760 E6 Quetiapine pures conical dryer discharge via pre/HEPA filters (E6-0662)	API-Particulates	0.15 mg/m ³	Hourly average	Annually	BS EN 13284-1:2002
	E6-0660/0760 E6 solids discharge via pre/HEPA filters (E6-0662)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A57 [V605 on Drawing no. 354593 within the application]	E6-0303, E6 BEM charge via filters (E6-0314/0312)	Particulates	10 mg/m ³	Hourly average	Quarterly	BS EN 13284-1:2002
	E6-0303 solids charge via filters (E6-0314/0312)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A59 [V607 on Drawing no. 354593 within the application]	Ros: Reactors (E6-100, E6-0300, E6-1100) Receivers (E6-1400) Measure vessels (E6-0828, E6-0829); Bulk storage (E6-1750, E6-3003, E6-3101) via VOC unit (E6-0880)	Total Organic Carbon	75 mg/m ³ (If >75mg/m ³ then the limit reverts to a mass release of 2kg/hr)	Hourly average	Continuous	FID
	Reactors (E6-100, E6-0300, E6-1100); Receivers (E6-1400); Measure vessels (E6-0828,					Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A

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
	E6-0829); Bulk storage (E6-1750, E6-3003, E6-3101)					
A60 [V950 on Drawing no. 354592 within the application]	Effluent Treatment Plant main vent				No monitoring required	
A61 [V951 on Drawing no. 354592 within the application]	F1503, F1504, F1505, F1506 ETP bulk effluent storage				No monitoring required	
A62 [V971 on Drawing no. 354592 within the application]	F801 solvent interceptor				No monitoring required	
A63 [V972 on Drawing no. 354592 within the application]	D801, D802, D803 strong effluent collection vessel				No monitoring required	
A64 [V599 on Drawing no. 354591 within the application]	MF2200 Nitrogen purge vent				No monitoring required	
A65 [V598 on Drawing no. 354591 within the application]	MF2100 (MF2101) mill discharge via pre/HEPA filter (XF53A/B)	API – Particulate	0.15 mg/m ³	Hourly average	Quarterly	BS EN 13284-1:2002
	MF2100 solids discharge via pre/HEPA filter (XF53A/B)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A66 [V597 on Drawing no. 354591 within the application]	E5 Mill Charge MF2000 via pre/HEPA filter MF2701 (MF2304)	API – Particulate	0.15 mg/m ³	Hourly average	Annually	BS EN 13284-1:2002
	MF2000 Solids charge via pre/HEPA filter				Monitoring as required by agreed Multi Product Protocol, in	

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
	(MF2701) MF2120 solids discharge via pre/HEPA filter (MF2787)				line with Table S3.1A	
A68 [V004 on Drawing no. 354600 within the application]	F104 Bulk solvent storage				No monitoring required	
A69 [V010 on Drawing no. 354600 within the application]	F110 Bulk solvent storage				No monitoring required	
A70 [V014 on Drawing no. 354600 within the application]	F114 Bulk solvent storage				No monitoring required	
A72 [V902 on Drawing no. 354599 within the application]	F815 gas oil storage				No monitoring required	
A73 [V903 on Drawing no. 354599 within the application]	F816 gas oil storage				No monitoring required	
A74 [V904 on Drawing no. 354599 within the application]	F817 gas oil storage				No monitoring required	
A75 [V905 Drawing no. 354599 within the application]	F818 gas oil storage				No monitoring required	
A76 [V906 on Drawing no. 354599 within the application]	Boilers 1, 2, 3 and 4				No monitoring required	
A77 [V907 on Drawing no. 354599 within the application]	Boiler 5 (stand-by boiler)				No monitoring required	
A78 [V440 on Drawing No. 354600 within the application]	Effluent tanker loading via Carbon bed (G2318)				No monitoring required	
A79 [V460 on Drawing No. 354711 within the application]	T1355 Quetiapine Pure charge via Matcon bin. T1355 Quetiapine pure				No monitoring required	

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
	discharge.					
	T1355 Solids charge				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
	T1351 Solids discharge via pre/HEPA filter (G2360A/B)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A81 [V462 on Drawing No. 354711 within the application]	Quetiapine Pure Mill via HEPA filter (G2302)				No monitoring required	
	J2855 Screw feeder; J2859 Mill; G2304 Reverse jet filter; C2344 Cooler; G2298 solids filter – via HEPA filter (G2302)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A82 [V610 on Drawing No. 354593 within the application]	E6-3600/3610 Quetiapine Pures conical dryer charge via pre/HEPA filters (E6-2653)	API-Particulates	0.15 mg/m ³	Hourly average	Annually	BS EN 13284-1:2002
	E6-3600/3610 discharge station via pre/HEPA filters (E6-2653)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A83 [V630 on Drawing No. 354593 within the application]	E6- 0640/0740 conical driers; E6-0925 receiver (Quetiapine Pures)				No monitoring required	

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
	E6- 0640/0740 conical driers; E6-0925 receiver				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A85 [V908 on Drawing no. F4.B1P within the application for variation V004]	CHP Engine 1 – natural gas fired combined heat and power plant	Oxides of nitrogen (as NO ₂)	No limit set	Hourly average	Annually	ISO 10849
		Carbon monoxide	No limit set	Hourly average	Annually	ISO 12039
A86 [V909 on Drawing no. F4.B1P within the application for variation V004]	CHP Engine 2 – natural gas fired combined heat and power plant	Oxides of nitrogen (as NO ₂)	No limit set	Hourly average	Annually	ISO 10849
A88 [V472 on Figure 1 within the response to request for further information for variation V005]	F251 Bulk storage tank				No monitoring required	
A89 [V464 on drawing 354595 v2 within application for variation V006]	Solids Charge via pre/HEPA filters (G1417/G2402)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A90 [V465] E4 Annexe see AVW354605	ADPS charge via HEPA filter (G1250)	Particulates	20 mg/m ³	Hourly average	Quarterly	BS EN 13284-1:2002
A91 [V701] Kilo scale Facility see AVW354605	Reactor (D2101, D2102, D2103, D2201, D2202 and D2203), Vacuum Oven (B2000 & B2010) via condenser and gas/particulate scrubber.				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	

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
A92 [V702] Kilo scale Facility see AVW354605	Heat transfer fluid storage Tank F2601				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A93 [V703] Kilo scale Facility see AVW354605	SLE0100 (Smart Lab 1)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A94 [V704] Kilo scale Facility see AVW354605	SLE0200 (Smart Lab 2)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A95 [V705] Kilo scale Facility see AVW354605	Fume cupboards; Vacuum oven booth extract.				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A96 [V609] E6 Plant see AVW354605	E6-0640, E6-0740 charge chute purging via pre/HEPA filters (E6-2652)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A97 [V031] Bulk Storage tanks see AVW354605	Bulk storage (F201)				No monitoring required.	
A98 [V435] E4 Plant see AVW354605	Bin and discharge chute inerting (G2323) via pre and HEPA filters (G2328A/B)				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A99 [V436] E4 Plant see AVW354605	Bin and discharge chute inerting (G2324) via pre and				Monitoring as required by agreed Multi Product Protocol, in	

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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
	HEPA filters (G2329A/B)				line with Table S3.1A	
A100 [V504] E5 Plant see AVW354605	MF1815 liquids charging booth.				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A101 [V519] E5 Plant see AVW354605	MF0815 liquids charging booth.				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A102 [V466] Bulk Storage tanks see AVW354605	Bulk storage (F252)				No monitoring required.	
A103 [V433] Bulk Storage tanks see AVW354605	Bulk storage (F253)				No monitoring required.	
A104 [V208] Bulk Storage tanks see AVW354605	Bulk storage (F254)				No monitoring required.	
A105[V021] Bulk Storage tanks see AVW354605	Bulk storage F121				No monitoring required.	
A106[V601] E6 Plant see AVW354605	E6-1111 solids charge				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A107[V608] E6 Plant see AVW354605	E6-0812 liquids charge				Monitoring as required by agreed Multi	

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
					Product Protocol, in line with Table S3.1A	
A108[V612] E6 Plant see AVW354605	E6-1812 liquids charge				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	
A109[V614] E6 Plant see AVW354605	E6-2744 Matcon IBC drying.				Monitoring as required by agreed Multi Product Protocol, in line with Table S3.1A	

Table S3.1A Point source emissions to air – emission limits and monitoring requirements subject to agreed Multi Product Protocol (MPP)

Emission point ref. & location	Source	Parameter	Limit (incl. unit)	Reference Period	Monitoring frequency	Monitoring standard or method
A11, A25, to A27 (inclusive), A30 to A32 (inclusive), A34 to A43 (inclusive), A45, A47 to A52 (inclusive), A85, A86	Various as detailed in Table S3.1	Ammonia	10 mg/m ³ (Note 3)	Hourly average	As defined within the agreed Multi Product Protocol (MPP).	US EPA Method 320
		Benzene	5 mg/m ³	Hourly average		BS EN 13649:2002
		Bromine	10 mg/m ³	Hourly average		US EPA Method 26
		Carbon monoxide	100 mg/m ³	Hourly average		ISO 12039
		Chlorine	10 mg/m ³	Hourly average		BS EN 13649:2002
		Formaldehyde	2 mg/m ³	Hourly average		US EPA 316

		Hydrogen bromide	5 mg/m ³	Hourly average		BS EN 1911:1998
		Hydrogen chloride	10 mg/m ³	Hourly average		BS En 1911:1998
		Hydrogen sulphide	5 mg/m ³	Hourly average		US EPA Method 15
		Oxides of nitrogen (as NO ₂)	200 mg/m ³	Hourly average		ISO 10849
		Sulphides & Mercaptans (as methyl mercaptan)	0.1 mg/m ³	Hourly average		ISC Method 43901-01070T
		Oxides of sulphur (as SO ₂)	100 mg/m ³	Hourly average		BS EN 6069:1993I
		Total amines (as dimethylamine)	10 mg/m ³	Hourly average		BS EN 13649:2002
A12, A25, to A27 (inclusive), A30 to A32 (inclusive),, A34 to A43 (inclusive),, A45, A47 to A52 (inclusive), A59	Various as detailed in Table S3.1	Total Class A Volatile Organic Compounds (as individual VOCs)	20 mg/m ³ (Note 1)	Hourly average	As defined within the agreed Multi Product Protocol (MPP).	BS EN 13649:2002
		Total Class B Volatile Organic Compounds (expressed as Carbon)	75 mg/m ³ (Note 2)	Hourly average		BS EN 13526 2001
		Total phenols, cresols and xylols (as phenol)	10 mg/m ³	Hourly average		BS EN 13649:2002
		Trimethylamine	2 mg/m ³	Hourly average		BS EN 13649:2002
A13, A14, A15, A16, A17, A23, A32, ,A36,A38, A40, A48, A90	Various as detailed in Table S3.1	Particulate	20mg/m ³	Hourly average		BS EN 13284-1:2002
A37, A38, A40, A48, A50, A51, A52, A54, A56, A65, A66, A81, A82	Various as detailed in Table S3.1	API Particulate	0.15mg/m ³	Hourly average		BS EN 13824-1:2002
A11, to A18 (inclusive), A22, A23, A25, A26, A27,	Various as detailed in Table S3.1	As defined within the agreed Multi Product Protocol (MPP) and agreed in writing by the Environment Agency				

A30, A31, A32, A34 to A43 (inclusive), A45, A47, A48, A50, A51, A52, A54, A55, A56, A57, A59. A65, A66, A79, A81, A82, A83, A89, A91, A92 to A96 (inclusive), A98 to A101 (inclusive), A106 to A109 (inclusive)		
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Note 1 - concentration limit shall apply when mass release exceeds 100g/hr

Note 2 - concentration limit shall apply when mass release exceeds 2 Kg/hr

Note 3 - Emission point A48 ammonia limit 15 mg/m³ as an hourly average

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 site plan in AVW354605 emission to River Severn	Effluent Treatment Plant	Flow	3000 m ³ /day	Daily	Continuous	Magnetic flow meter
			14000 m ³ /week	Weekly	Continuous	Magnetic flow meter
		Chemical Oxygen Demand	500 kg/day	Flow Weighted Composite Sample	Daily	BS ISO 15705:2002
			1400 kg/week	Flow Weighted Composite Sample	Weekly	BS ISO 15705:2002
		pH	6 – 9.5	Flow Weighted Composite Sample	Daily	ISO 10523:1994
		Suspended solids	1000 kg/week	Flow Weighted Composite Sample	Weekly	BS EN ISO 872:2005
		Ammonia	600 kg/week	Flow Weighted Composite Sample	Weekly	BS6068:2003 & ISO 7150-1:1984
		Orthophosphate	10 kg/week	Flow Weighted Composite Sample	Weekly	BS EN ISO 6878:2004
		Quetiapine Urethane	6 kg/week	Flow Weighted Composite Sample	Weekly	In-house method HPLC with UV detection
		Rosuvastatin	1 kg/week	Flow Weighted Composite Sample	Weekly	
		Chlorinated hydrocarbons (as Cl)	0.2 kg/week	Flow Weighted Composite Sample	Weekly	BS EN ISO 10301:1997
		Iron (as Fe)	400 kg/week	Flow Weighted Composite Sample	Weekly	ISO/IEC 17025:2005
W2 on site plan in AVW25845 emission to River Severn	Uncontaminated surface water run-off			No monitoring required		

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
	-	-	-	-		

Table S3.4 Process monitoring requirements

Emission point reference or source or description of point of measurement	Parameter	Monitoring frequency	Other specifications
A11	Caustic strength of scrubber	Every batch	Minimum strength – 2% w/w
	Circulation flow of scrubbing liquor	Continuous	Minimum flow - 1.1 m ³ /hr
	Level in scrubber sump	Continuous	Minimum level – 868 litres
A12	Filter pressure prior to venting	Every batch	Maximum pressure – 3 barg
	Temperature of exhaust condenser vapour outlet just prior to venting	Every batch	Maximum temperature – 30°C
A23	Caustic strength of scrubber	Weekly	Minimum strength – 2% w/w
	Circulation flow of scrubbing liquor	Continuous	Minimum flow – 7 m ³ /hr
	Level of scrubber sump	Continuous	Minimum level – 2300 litres
A27	Syltherm temperature to pre-condenser C959	Every batch	Maximum temperature – minus 20°C
	Syltherm flow-rate to pre-condenser C959	Every batch	Minimum flow rate – 10 m ³ /hr
A48	Ammonia cylinder weight decrease	Daily	Maximum weight difference – 10kg/day
A59	Carbon bed time on-line	Daily	Max 96 hours
W1	Turbidity	Continuous	In line with agreed response to IP17 of Table S1.3 of permit EPR/ RP3331SL/V005

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	A11-A17 (inclusive), A23, A25, A27, A37, A48, A54, A56, A57, A59, A65, A66, A82, A85, A86, A90	Annually	01/01/07
Emissions to water Parameters as required by Condition 3.5.1	W1	Quarterly	01/01/07
Process monitoring	A11, A12, A27, A48, , A59, W1	Quarterly	01/10/10

Table S4.2: Annual production/treatment	
Parameter	Units
Total product produced	tonnes
Telescope mother recovery system operated	% of available time

Table S4.3 Performance parameters		
Parameter	Frequency of assessment	Units
Water usage	Annually	Tonnes
Energy usage	Annually	Tonnes
Total Raw Material usage	Annually	Tonnes

Table S4.4 Reporting forms		
Media/parameter	Reporting format	Date of form
Air	Form Air1 or other form as agreed in writing by the Environment Agency	December 2018
Water	Form Water1 or other form as agreed in writing by the Environment Agency	December 2018
Water usage	Form Water usage1 or other form as agreed in writing by the Environment Agency	December 2018
Energy usage	Form Energy 1 or other form as agreed in writing by the Environment Agency	December 2018
Other performance indicators	Form Performance1 or other form as agreed in writing by the Environment Agency	December 2018

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	

(b) Notification requirements for the breach of a limit	
To be notified within 24 hours of detection unless otherwise specified below	
Date and time of monitoring	
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 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.

“emissions to land” includes emissions to groundwater.

“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” 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.

“Multi-Product Protocol” (MPP) - means a procedure written by an operator and approved by the Environment Agency, which is referenced in the operational techniques table of this permit. It describes the operators management process which can be used to request changes, within the limits in that document only, to the original permit without the need for a formal permit variation application.

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

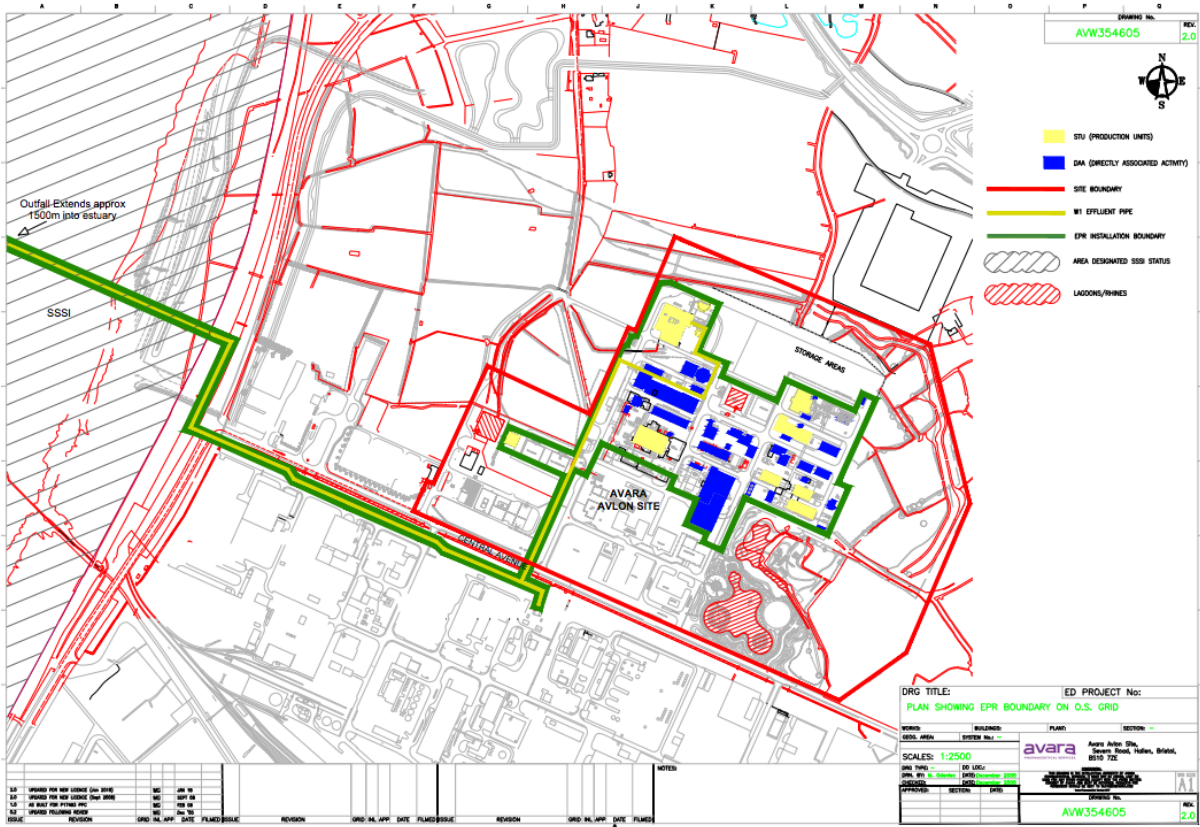
Where a minimum limit is set for any emission parameter, for example pH, reference to exceeding the limit shall mean that the parameter shall not be less than that limit.

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 gas engines or gas turbines, the concentration in dry air at a temperature of 273K, at a pressure of 101.3 kPa and with an oxygen content of 15% dry for liquid and gaseous 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