



# **Surrender notice with introductory note**

## **The Environmental Permitting (England & Wales) Regulations 2016**

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SmithKline Beecham Limited

Worthing Pharmaceutical Manufacturing Facility  
Worthing  
West Sussex  
BN14 8QH

### **Surrender application number**

EPR/QP3935LE/S007

### **Permit number**

EPR/QP3935LE

# **Worthing Pharmaceutical Manufacturing Facility**

## **Permit number EPR/QP3935LE**

### **Introductory note**

#### **This introductory note does not form a part of the notice.**

The following notice gives notice of the surrender in part of an environmental permit.

This partial surrender removes parcels of land at the southern boundary of the site, that have been decommissioned and sold to a third party. The installation boundary for Site Plan B is amended to reflect the partial surrender. Building 21 remains outside of the permitted area as per condition 2.2.1 and schedule 2 of permit QP3935LE and as per the condition 2.2.1 amendment and Site Plan B of variation EPR/QP3935LE/V005.

There is no change to site plan A detailing the pipeline route from Effluent Treatment Plant (ETP) to English Channel. However, this has been included in this permit to clarify that it is still part of the permit.

Overall, the surrendered land is deemed to be in a satisfactory condition with respect to the permit surrender application.

In addition to this surrender, due to the changes on site, the permit is varied. The permit is updated to reflect the current activities and operations taking place on site.

The variation removes all the pharmaceutical activities listed in the permit as these activities are no longer undertaken at the site. All chemical activities, directly associated activities, associated monitoring and reporting, have been removed from the permit leaving only the effluent treatment plant 5.4 activity.

Emissions monitoring requirements associated with the pharmaceutical wastewater effluent stream have been removed or amended.

There are four boilers which are currently included in the permit as Directly Associated Activities (DAA's) that have been decommissioned. Two of these boilers have been removed and replaced with new steam generators (2 Clayton Model SSEOG-404-2 Steam Generators each with a thermal input of 4.22 MWth), these are to be separately regulated under a standalone Medium Combustion Plant (MCP) permit.

Surface water drains located on the surrendered land were capped/sealed off at the culvert.

The effluent treatment plant remains as an activity as the capacity is greater than 50 tonnes/day and the plant continues to treat surface water runoff from the remaining site as well as non-permitted pharmaceutical and non-pharmaceutical manufacturing process effluent.

The operating techniques have been amended due to the removal of chemical activities and updated to reflect onsite activity.

Any changes made as a result of the part surrender/variation are set out in the schedules.

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

| <b>Status log of the permit</b>                  |                       |   |
|--|-----------------------|---|
| <b>Description</b>                               | <b>Date</b>           | <b>Comments</b>   |
| Application QP3935LE                             | 17/03/06              | Duly made   |
| Additional Information Received                  | 25/07/06              |   |
| Permit determined                                | 15/11/06              |   |
| Variation notice LP3636UE issued                 | 24/8/07               |   |
| Variation application DP3133GB received          | 17/07/08              |   |
| Variation notice DP3133GB issued                 | 11/08/08              |   |
| Agency variation determined<br>EPR/QP3935LE/V004 | 29/05/13              | Agency variation to implement the changes introduced by IED   |
| Application QP3935LE/V005 received (Variation)   | Duly Made<br>26/01/18 | Application to increase to the permitted boundary and to add a new point source to air for VOC emissions to the currently permitted list. |
| Schedule 5 request for further information       | 14/02/18              | Responses dated 12/03/18  |
| Variation determined<br>EPR/QP3935LE/V005        | 11/05/18              | Varied Permit Issued.   |
| Part surrender application<br>EPR/QP3935LE/S006  | 20/08/19              | Application for surrender of area of site used for warehousing.   |
| Part surrender determined<br>EPR/QP3935LE/S006   | 12/11/19              | Part surrender complete.  |
| Variation application<br>EPR/QP3935LE/V007       | Returned<br>21/07/21  | Application returned  |
| Part surrender application<br>EPR/QP3935LE/S007  | Duly Made<br>10/08/22 | Application to surrender parcels of land and remove pharmaceutical activities from the permit.  |
| Additional information received                  | 31/03/2023            | Clarification on building/activity cessations, effluent composition and removal of ETP emissions points.                                  |
| Additional information received                  | 19/05/2023            | Revised site plan B confirming site boundary.   |
| Part surrender determined                        | 30/05/2023            | Part surrender complete.  |

|  |  |  |
|--|--|--|
| EPR/QP3935LE/S007<br>Billing reference<br>(JP3344QP) |  |  |
|--|--|--|

End of introductory note

# Notice of surrender

## The Environmental Permitting (England and Wales) Regulations 2016

The Environment Agency in exercise of its powers under regulation 25 of the Environmental Permitting (England and Wales) Regulations 2016 accepts the surrender in part of

### Permit number

**EPR/QP3935LE**

### Issued to

**SmithKline Beecham Limited** (“the operator”)

whose registered office is

**980 Great West Road**

**Brentford**

**Middlesex**

**TW8 9GS**

company registration number 02337959

to operate a regulated facility at

**Worthing Pharmaceutical Manufacturing Facility**

**Dominion Way**

**Worthing**

**West Sussex**

**BN14 8PB**

to the extent set out in the schedules.

The notice shall take effect from 30/05/2023.

| Name           | Date       |
|----------------|------------|
| Vicky Patchett | 30/05/2023 |

Authorised on behalf of the Environment Agency

## Schedule 1 – conditions to be deleted

The following conditions are deleted as a result of the application made by the operator.

Table S4.1 as referenced by conditions 3.1.1, 3.6.1 and 3.6.4 is deleted to remove emission points A1(a) & A1(b), A2, A3-A20, A21-23 from the effluent treatment plant, A24, A26, Pressure relief valves and vents from tanks.

| <b>Table S4.1 Point source emissions to air – emission limits and monitoring requirements</b> |  |                   |                               |                         |                             |  |
|---|--|-------------------|-------------------------------|-------------------------|-----------------------------|--|
| <b>Emission point ref. &amp; location</b>   | <b>Source</b>                              | <b>Parameter</b>  | <b>Limit (including unit)</b> | <b>Reference period</b> | <b>Monitoring frequency</b> | <b>Monitoring standard or method</b>   |
| A1(a) & A1(b) on site plan in schedule 4  | Solvent Recovery Unit                      | No parameters set | --                            | --                      | --                          | Permanent sampling access not required |
| A2 on site plan in schedule 4   | Boiler house                               | No parameters set | --                            | --                      | --                          | Permanent sampling access not required |
| A3 on site plan in schedule 4   | Mupirocin Free Acid manufacturing unit     | No parameters set | --                            | --                      | --                          | Permanent sampling access not required |
| A4 on site plan in schedule 4   | Calcium Mupirocin process                  | No parameters set | --                            | --                      | --                          | Permanent sampling access not required |
| A5 on site plan in schedule 4   | Mupirocin Free Acid recrystallisation unit | No parameters set | --                            | --                      | --                          | Permanent sampling access not required |
| A6 on site plan in schedule 4   | Mupirocin Free Acid recrystallisation unit | No parameters set | --                            | --                      | --                          | Permanent sampling access not required |
| A7 on site plan in schedule 4   | Mupirocin Free Acid recrystallisation unit | No parameters set | --                            | --                      | --                          | Permanent sampling access not required |
| A8 on site plan in schedule 4   | Mupirocin Free Acid recrystallisation unit | No parameters set | --                            | --                      | --                          | Permanent sampling access not required |

|                                  |  |                   |    |    |    |  |
|----------------------------------|--|-------------------|----|----|----|--|
| A9 on site plan in schedule 4    | HAF vessels (emergency) and general plant scrubber (emergency) | No parameters set | -- | -- | -- | Permanent sampling access not required |
| A10 on site plan in schedule 4   | HAF vessels and scrubber E1114A/B                              | No parameters set | -- | -- | -- | Permanent sampling access not required |
| A11 on site plan in schedule 4   | Calcium Mupirocin process                                      | No parameters set | -- | -- | -- | Permanent sampling access not required |
| A12 on site plan in schedule 4   | Calcium Mupirocin process                                      | No parameters set | -- | -- | -- | Permanent sampling access not required |
| A13 on site plan in schedule 4   | Potassium Clavulanate filter dryer                             | No parameters set | -- | -- | -- | Permanent sampling access not required |
| A14 on site plan in schedule 4   | HVAC system in manufacturing area                              | No parameters set | -- | -- | -- | Permanent sampling access not required |
| A15 on site plan in schedule 4   | HVAC system in manufacturing area                              | No parameters set | -- | -- | -- | Permanent sampling access not required |
| A16 on site plan B in schedule 4 | F1027 Foul Solvent Tank  | No parameters set | -- | -- | -- | Permanent sampling access not required |
| A17 on site plan B in schedule 4 | J1015 Vacuum pump vent   | No parameters set | -- | -- | -- | Permanent sampling access not required |
| A18 on site plan B in schedule 4 | F1044 Solvent storage vessel                                   | No parameters set | -- | -- | -- | Permanent sampling access not required |

|   |  |                   |    |    |    |  |
|---|--|-------------------|----|----|----|--|
| A19 on site plan B in schedule 4            | CSA Nutrex process equipment                             | No parameters set | -- | -- | -- | Permanent sampling access not required |
| A20 on site plan B in schedule 4            | CSA Nutrex process equipment                             | No parameters set | -- | -- | -- | Permanent sampling access not required |
| A21 on site plan B in schedule 4            | Effluent Plant vessels                                   | No parameters set | -- | -- | -- | Permanent sampling access not required |
| A22 on site plan B in schedule 4            | Effluent Plant vessels (backup)                          | No parameters set | -- | -- | -- | Permanent sampling access not required |
| A23 on site plan B in schedule 4            | Effluent Plant building extraction                       | No parameters set | -- | -- | -- | Permanent sampling access not required |
| A24 on site plan B in schedule 4            | All fermentation vessels                                 | No parameters set | -- | -- | -- | Permanent sampling access not required |
| A26 (ABS Vent) on site plan B in schedule 4 | Augmentin Bulk Sterile (ABS) Process vent, via abatement | Propan-2-ol       | -- | -- | -- | Permanent sampling access not required |
|   |  | Acetone           |    |    |    |  |
| Pressure Relief Valves                      | All Process Reactors                                     | No parameters set | -- | -- | -- | Permanent sampling access not required |
| Vents from Tanks                            | All storage tanks  | No parameters set | -- | -- | -- | Permanent sampling access not required |



Table S5.2 as referenced by condition 4.2.1 is deleted to acknowledge that the permitted pharmaceutical activities have ceased operation.

| <b>Table S5.2: Annual production/treatment</b> |              |
|--|--------------|
| <b>Parameter</b>                               | <b>Units</b> |
| Total pharmaceuticals produced                 | tonnes       |

### **Schedule 2 – conditions to be amended**

The following conditions are amended as detailed, as a result of the application made by the operator.

Condition 3.1.1 shall be amended to remove table S4.1

There shall be no point source emissions to water, air or land except from the sources and emission points listed in schedule 4 tables S4.2 and S4.3.

Condition 3.6.1 shall be amended to remove table S4.1

The operator shall, unless otherwise agreed in writing by the Agency, undertake monitoring for the parameters, at the locations and at not less than the frequencies specified in the following tables in schedule 4 to this permit:

- (a) point source emissions specified in tables S4.2 and S4.3

Condition 3.6.4 shall be amended to remove table S4.1

Permanent means of access shall be provided to enable sampling/monitoring to be carried out in relation to the emission points specified in schedule 4 tables S4.2 and S4.3 unless otherwise specified in that schedule.

Table S1.1 as referenced by condition 2.1.1 is amended to acknowledge that the permitted activities (aside from an Effluent Treatment Plant) have ceased operation. Table S1.1 is amended to:

**Table S1.1 activities**

| <b>Activity listed in Schedule 1 of the EP Regulations</b> | <b>Description of specified activity and WFD Annex I and II operations</b>                           | <b>Limits of specified activity and waste types</b>   |
|--|--|---|
| S5.4 Part A(1)(a)(ii)                                      | Treating effluent in an Effluent Treatment Plant   | From the treatment of non-permitted pharmaceutical, non-pharmaceutical process effluent and site surface water in the effluent treatment plant to the discharge of treated effluent into the English Channel via a multi-port diffuser. |
| <b>Directly Associated Activity</b>                        |  |   |
| Surface water collection and storage                       | Collection and storage of uncontaminated or contaminated site surface water in drainage channel sump | From the collection of site surface waters (other than from roads and roofs) to transfer for treatment in the on-site Effluent Treatment System and discharge to the English Channel by way of emission point W2                        |

Table S1.2 as referenced by condition 2.3.1 is amended to remove 'Multi Product Protocol', information describing ABS Plant, the abatement equipment and monitoring for VOC emissions in the operating techniques associated with the removed chemical activities. Site operating techniques updated to reflect current activities onsite.

Table S1.2 is amended to:

| <b>Table S1.2 Operating techniques</b> |   |                      |
|--|---|----------------------|
| <b>Description</b>                     | <b>Parts</b>  | <b>Date Received</b> |
| Application EPR/QP3935LE/S007          | Sections 2.3, 2.4, 3.1, 3.2, Appendix F of Partial Permit Surrender and Variation (EPR/QP3935LE): Supporting Information Document, GSK Worthing, 20 July 2022<br>Project No.: 0623807 | 10/08/22             |

Table S4.2 as referenced by conditions 3.1.1, 3.6.1 and 3.6.4, is amended to remove parameters associated with previous chemical activities, leaving only non-pharmaceutical process effluent and site surface run-off treated in the effluent treatment plant remaining in the permit.

Table S4.2 is amended to:

| <b>Table S4.2 Point Source emissions to water (other than sewer) and land – emission limits and monitoring requirements</b> |                              |  |                           |                         |                                       |  |
|---|------------------------------|--|---------------------------|-------------------------|---------------------------------------|--|
| <b>Emission point ref. &amp; location</b>   | <b>Parameter</b>             | <b>Source</b>  | <b>Limit (incl. unit)</b> | <b>Reference Period</b> | <b>Monitoring frequency</b>           | <b>Monitoring standard or method</b>   |
| W1 on site plan in schedule 2 emission to Teville stream  | No parameters set            | Site surface run-off from roads and roofs  | -                         | -                       | -                                     | Permanent sampling access not required |
| W2 between TQ 181023 and TQ 181024 emission to English Channel  | Daily flow rate              | Process effluent and Site surface run-off treated in the site effluent treatment plant | 5000 m <sup>3</sup> /day  | 24 hours                | Every discharge                       | Calculated from flow                   |
| W2 between TQ 181023 and TQ 181024 emission to English Channel  | Instantaneous discharge rate | Process effluent and Site surface run-off treated in the site effluent treatment plant | 0.18 m <sup>3</sup> /sec  | Instantaneous           | Continuous throughout every discharge | Krohne Mag Flow                        |

**Table S4.2 Point Source emissions to water (other than sewer) and land – emission limits and monitoring requirements**

| <b>Emission point ref. &amp; location</b>                      | <b>Parameter</b>   | <b>Source</b>  | <b>Limit (incl. unit)</b> | <b>Reference Period</b>                 | <b>Monitoring frequency</b> | <b>Monitoring standard or method</b> |
|--|--|--|---------------------------|---|-----------------------------|--------------------------------------|
| W2 between TQ 181023 and TQ 181024 emission to English Channel | Suspended solids   | Process effluent and Site surface run-off treated in the site effluent treatment plant | 1900 mg/l                 | 24hr flow proportional composite sample | Weekly                      | BS EN 872:1996 or BS 6068-2.54:1996  |
| W2 between TQ 181023 and TQ 181024 emission to English Channel | COD  | Process effluent and Site surface run-off treated in the site effluent treatment plant | 6000 mg/l                 | 24hr flow proportional composite sample | Weekly                      | BS EN 1899-2 (1998)                  |
| W2 between TQ 181023 and TQ 181024 emission to English Channel | Mercury and its compounds, expressed as mercury (Total Hg) | Process Effluent and Site surface run-off treated in the site effluent treatment plant | 5 µg/l                    | 24hr flow proportional composite sample | Monthly                     | BS EN 1233:1997 or BS 6268-2.38:1997 |
| W2 between TQ 181023 and TQ 181024 emission to English Channel | Zinc   | Process Effluent and Site surface run-off treated in the site effluent treatment plant | 500 µg/l                  | 24hr flow proportional composite sample | Weekly                      | BS6068-2.29:1987 or ISO 8288-986     |

**Table S4.2 Point Source emissions to water (other than sewer) and land – emission limits and monitoring requirements**

| <b>Emission point ref. &amp; location</b>                      | <b>Parameter</b>                   | <b>Source</b>  | <b>Limit (incl. unit)</b>                       | <b>Reference Period</b> | <b>Monitoring frequency</b> | <b>Monitoring standard or method</b> |
|--|------------------------------------|--|---|-------------------------|-----------------------------|--------------------------------------|
| W2 between TQ 181023 and TQ 181024 emission to English Channel | Period when discharge is permitted | Process effluent and site surface run-off treated in the site effluent treatment plant | From 3 hours before to 3 hours after high water |                         |                             |                                      |

Table S5.3 as referenced by condition 4.2.1 is amended to remove all reporting requirements associated with pharmaceuticals activities which are no longer taking place at the site. Table S5.3 is amended to:

**Table S5.3 Performance parameters**

| <b>Parameter</b> | <b>Frequency of assessment</b> | <b>Units</b>          |
|------------------|--------------------------------|-----------------------|
| Water usage      | Annually                       | m <sup>3</sup> /tonne |

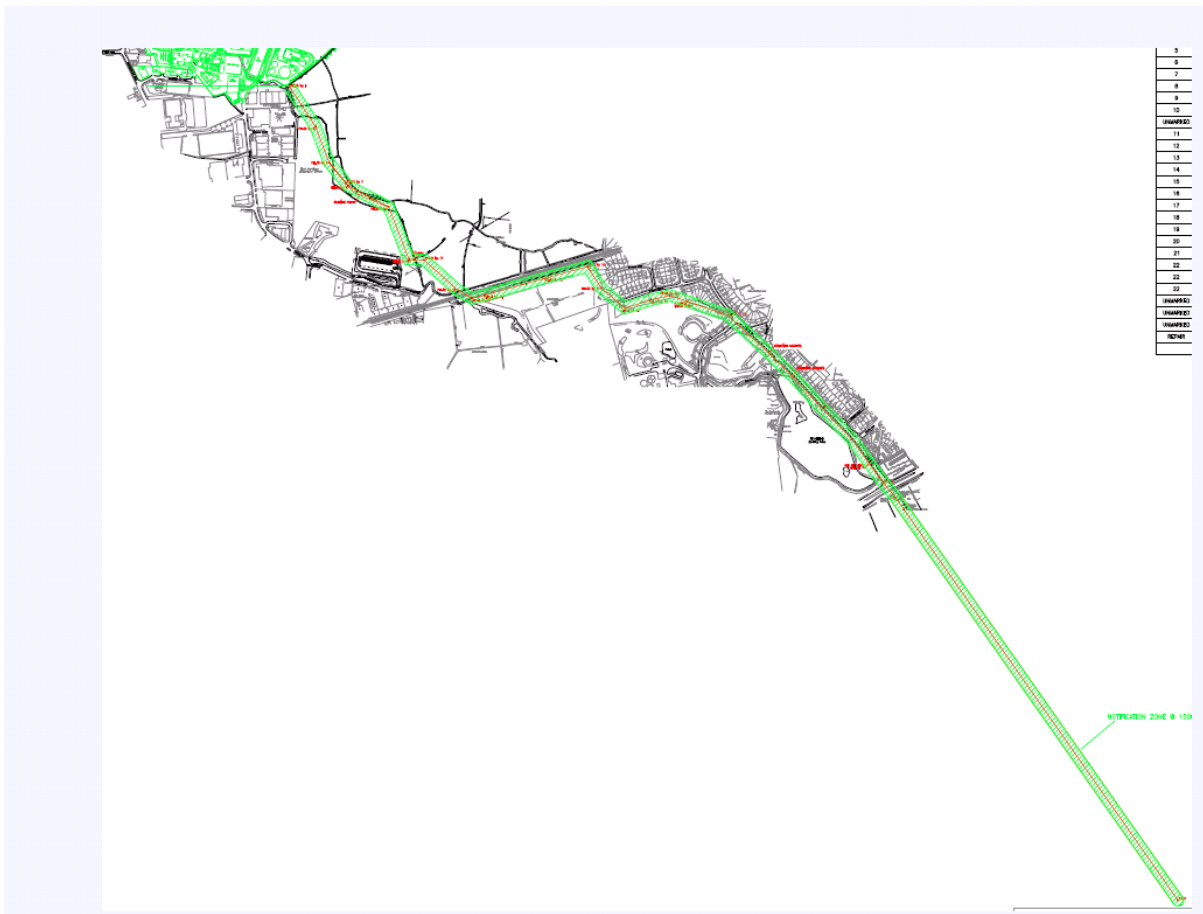
**Schedule 3 – conditions to be added**

None.

# Schedule 4 – amended plan

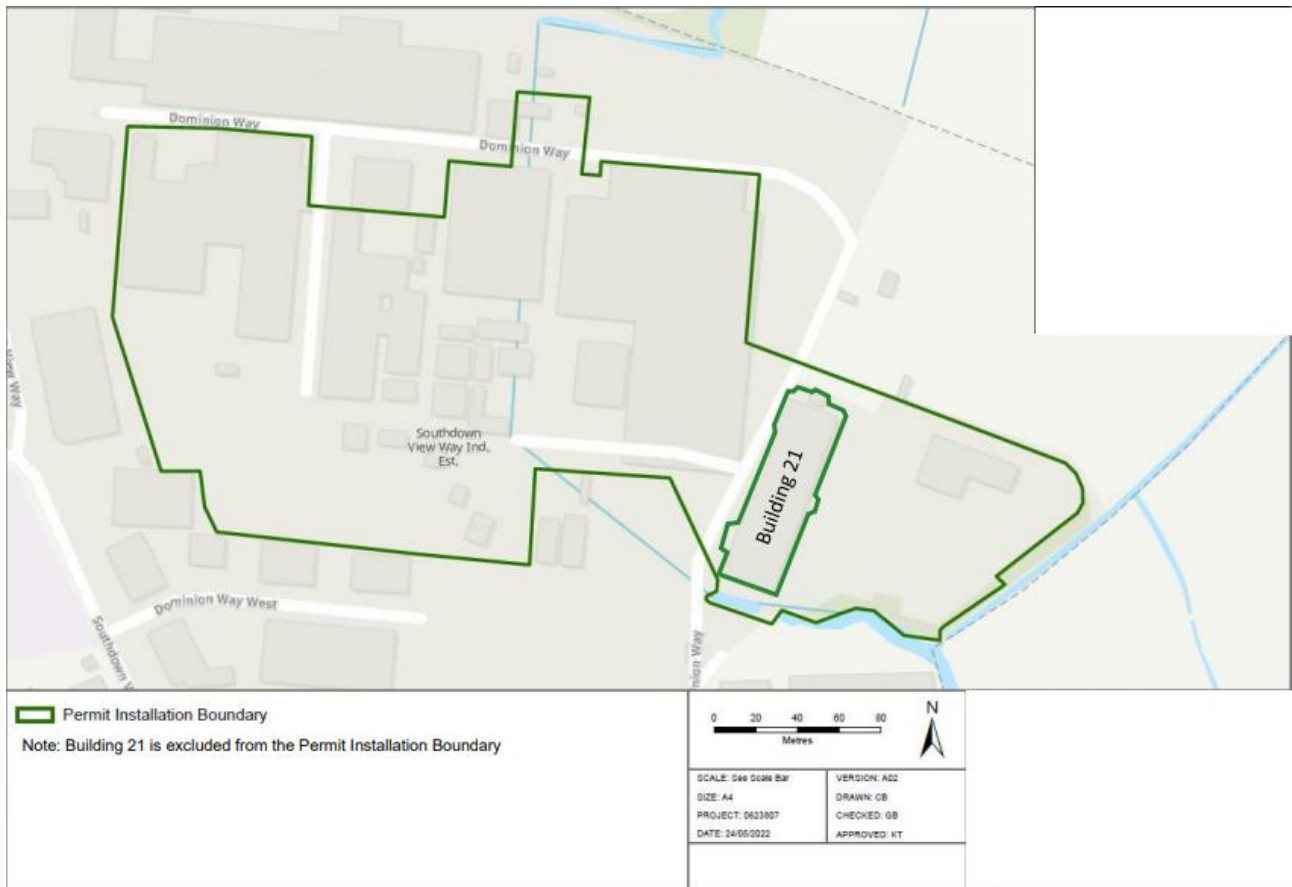
No amendments to Site Plan A

Site Plan A- Pipeline route from Effluent Treatment Plant (ETP) to English Channel



The area of the site is reduced to that shown in the attached amended plan.

**Site Plan B - Installation boundary excluding pipeline route from ETP to English Channel**



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