



Site Condition Report

Substantial Permit Variation

31st March 2026

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Site Condition Report

Substantial Permit Variation



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Figure 3-8 – Central Zone (2), circa 197218

Acronyms and Abbreviations

Name	Description
BAT	Best Available Technology
BGS	British Geological Society
BPNs	Building Preservation Notices
CIA	Chemical Industries Association
Col	Certificates of Immunity
DAA	Directly Associated Activities
EA	Environment Agency
EPR	Environmental Permitting
ERM	Environmental Resources Management
FDA	Food and Drug Administration
GIA	Gross Internal Area
GMP	Good Manufacturing Practice
kV	Kilovolt
IBC	Intermediate Bulk Container
ICI	Imperial Chemical Industries
IED	Industrial Emissions Directive
LCPA	Fractionated (S)-2-chloropropionic Acid
LNR	Local Nature Reserve
LPG	Liquefied Petroleum Gas
LWS	Local Wildlife Site
MCC	Mammalian Cell Culture
MMA	Mixed Martial Arts
MWth	Megawatt Thermal
NHLE	National Heritage List for England
NGR	National Grid Reference
NNR	National Nature Reserve
NWL	Northumbrian Water Limited
PHB	Polyhydroxybutyrate
PO	Post Office

PTA	Purified Terephthalic Acid
PUFA	Polyunsaturated Fatty Acids
QMS	Quality Management System
RoFMS	Risk of Flooding from Multiple Sources
RoFRS	Risk of Flooding from Rivers and the Sea
SAC	Special Area of Conservation
SINC	Sites of Importance for Nature Conservation
SCR	Site Condition Report
SMCA	Sodium Mono Chloroacetate
SPA	Special Protection Area
SPZ	Source Protection Zone
SSSI	Site of Special Scientific Interest
STU	Stationary Technical Unit
TX	Texas
UK	United Kingdom
UNESCO	United Nations Educational, Scientific and Cultural Organization
UKAS	United Kingdom Accreditation Service
URS	United Research Services
UXO	Unexploded Ordnance

1. INTRODUCTION

1.1 Background

This document has been prepared by Fujifilm Diosynth Biotechnologies UK Limited (“Fujifilm”) and its environmental consultant Sol Environment (“Sol”) in support of a bespoke permit variation application as required by the *Environmental Permitting (England and Wales) Regulations 2016* concerning current and proposed activities to be undertaken at Fujifilm Diosynth Biotechnologies UK Limited, PO Box 2, Chilton Lifesciences EA/EPR/BJ89871Q (Issued on 29/03/2010), Belasis Avenue, Cleveland, TS23 1LH (the “Site”).

This document has been prepared in line with the current Environment Agency (EA) Guidance i.e. Environmental permitting: H5 Site condition report (Environment Agency, 2013) As this is considered an application Sections 1 to 3, as outlined in the Site Condition Report (SCR) Template, are provided below.

1.2 Current Permitted Activities

Fujifilm Diosynth Biotechnologies UK Limited operates a manufacturing site at the northern boundary of the Billingham site. The Billingham site comprises several installations within a site boundary, each operated by a different company.

The site comprises manufacturing, office and laboratory areas (not included within the installation) and is within a predominantly industrial area on the north bank of the River Tees.

The existing Installation undertakes the manufacture of a range of pharmaceutical products based on chemical and biological manufacture. These products are sold for further onward processing by third parties to form finished pharmaceutical products or are included in third party pharmaceutical products and medicines.

Processing involves fermentation and biotransformation using a range of raw materials and varying process conditions. Manufacturing takes place in closed vessels, which are supplied with nutrients and air. Processing conditions such as pH, temperature and oxygen availability are kept under strict control. The main emissions from the process are water vapour and carbon dioxide.

Following completion of the fermentation process, the product may be pre-conditioned by adjusting the temperature or pH. This stage can be followed by purification by filtration or chromatography. The product is harvested using centrifugation and other filtration techniques. The product will be bottled and then held in chilled storage before dispatch. Due to the unique and commercially confident nature of the products and associated production processes, detailed manufacturing descriptions are not provided within this application document.

All processes are carried out under Good Manufacturing Practice (GMP) and are approved by the Food and Drug Administration (FDA) and the Medicines and Healthcare Products Regulatory Agency (MHRA).

There are eight permitted emission points to air, four of which originate from fermenters. The remaining four are from the boilers, the spray drier and an emergency purification vent. The spray drier has abatement equipment. There is a discharge to the River Tees, which runs to the south of the Billingham site and is used by other installations. Emissions to water from the Site are monitored at the discharge point into the Billingham drain. The Teesmouth and Cleveland Coast Special Protection Area (SPA) habitat site is located within 10 km of the installation.

The installation operates an Environmental Management System that is not certified to ISO 14001. The installation is a member of a Climate Change Agreement (Agreement Dated: 1st day of April 2013, Agreement Identifier: CIA/T00088 v1, TU Identifier: CIA/T00088).

1.3 Proposed Variation Application

The application variation includes the following key elements associated with Schedule 1 activities listed within the *Environmental Permitting (England and Wales) Regulations 2016*:

- Borealis – The operation of a new 26,800m² (GIA) biotech manufacturing facility, comprising an array of production suites, warehouse and storage, buffer preparation and hold facilities, laboratories, and offices. Borealis includes a new liquid waste treatment plant, solid waste management building, and standby generator. This project introduces new process release points to air including an emission point from an emergency generator, new discharges to foul sewer and potential noise emissions (from a roof-mounted plant room). All foul discharges will be to the Northumbrian Water Limited (NWL) combined sewer. This will be regulated as a new Stationary Technical Unit Section 4.5 Part A(1)(a).
- BIC-UK – Development and construction of offices and laboratories purely for R&D purposes. Discharges from this facility are all discharged to foul sewer via the Cowpen Road combined sewer. Although BIC-UK is for R&D purposes only, as per the Environment Agency Note 4.3 of Regulatory Guidance Note No. 2 Understanding the meaning of regulated facility - Appendices 1 and 2, the facility cannot be defined as pure R&D. It is therefore understood that the facility will be required to be permitted as a separate Section 4.5 Part A(1)(a) Activity.
- Minor operational changes – The inclusion of existing emission points previously missed or not included within previous permit variation applications.

The application includes the following changes to the Directly Associated Activities (DAA):

- Boiler plant upgrades – Upgrade of boiler plant from current >20 MWth to circa 10 MWth.
- Dewar Store and Nitrogen Tank – Installation of a bulk nitrogen storage tank, and small external store building for storing small dewars (nitrogen storage bottles). This is considered a Directly Associated Activity.

The proposed variation application requires additional land and therefore changes the permitted installation boundary i.e. needs to be extended to include Borealis and BIC-UK (**Figure 1-1**).

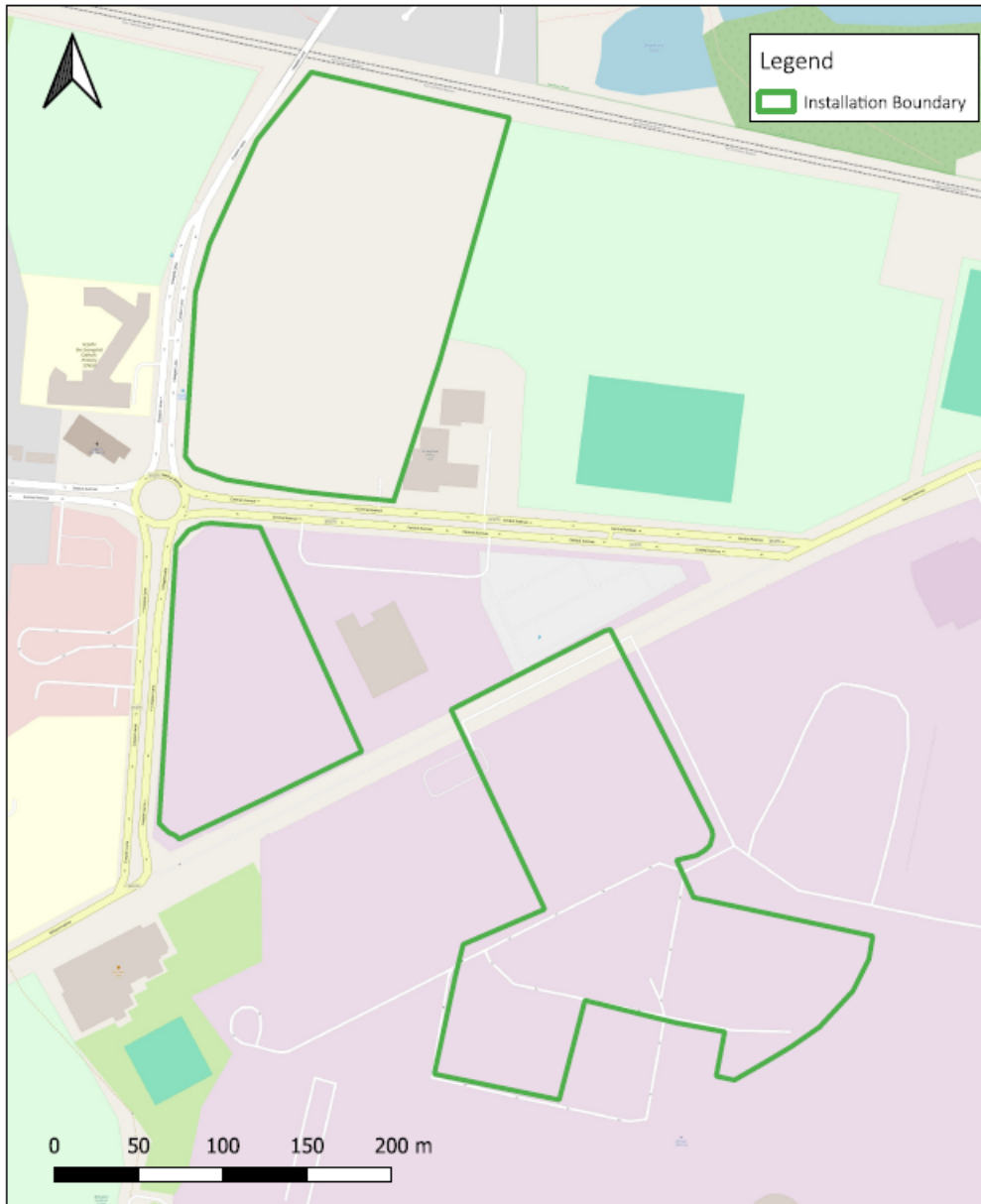


Figure 1-1 –Proposed Permit Boundary

2. SITE DETAILS

The Site details are outlined in **Table 2-1**.

Table 2-1 – Site Details

Required Information	
Name of Applicant	Fujifilm Diosynth Biotechnologies UK Limited
Activity Address	Fujifilm Diosynth Biotechnologies UK Limited, PO Box 2, Chilton Lifesciences, Belasis Avenue, Cleveland, TS23 1LH
National Grid Reference (NGR)	Centre of the main permitted area - NZ 46607 22612
Document reference and dates for Site Condition Report at permit application and surrender	<p>Application Avecia Biologics Ltd Application Site Report (copy not available)</p> <p>Variation 024-1987 Fujifilm SCR REV00 (this report)</p> <p>Surrender N/A</p>
Document references for site plans (including location and boundaries)	<p>Annex A: Site Plans</p> <p>Annex B: Site Investigation Reports</p>

3. CONDITIONS OF LAND AT PERMIT ISSUE

3.1 Environmental Setting

Desk-based research of the local geology, hydrogeology, hydrology, and ecology was carried out to establish the potential for migration of contamination onto or away from the Site, and to assess the surface water and groundwater sensitivity of the surrounding area.

This section should be read in conjunction with the original permit application site report. Where required this section includes the original permit application information but updates have been applied where appropriate.

3.1.1 Location

The installation is in Billingham, Cleveland, which is part of the Tees Valley region and is located 560 metres south of Billingham railway station and 790 metres from the centre of Billingham.

The permitted installation is composed of four distinct parcels of land as outlined in **Table 3-1**.

Table 3-1 – Installation Details

Area	Description
Area 1 – Existing permitted area (including the chemical storage area extension)	North – The B1275 (Central Avenue) beyond which Borealis and the Synthonia Sports Ground. East – Other commercial activities within the Billingham Chemicals Complex. South – Other commercial activities within the Billingham Chemicals Complex. West – Other commercial activities within the Billingham Chemicals Complex.
Area 2 – BIC-UK (Laboratory)	North – The B1275 (Central Avenue) beyond which Borealis, the Synthonia Sports Ground, St John the Evangelist Catholic Primary School and residential properties. East – BIC-UK (Offices) located outside the permitted boundary but still part of the Fujifilm Diosynth Biotechnologies UK Limited operations. South – Other commercial activities within the Billingham Chemicals Complex. West – Cowpen Lane beyond which is Billingham South Community Primary School and residential properties.
Area 3 – Borealis	North – The Stockton and Darlington railway line (Durham Coast Line) beyond which is residential housing and Charlton’s Pond (Nature Reserve). East – Synthonia Sports Ground. South – The B1275 (Central Avenue) beyond which is the existing permitted area. West – Cowpen Lane beyond which is St John the Evangelist Catholic Primary School and residential properties.

3.1.2 Geology

The British Geological Survey (BGS) Geoindex outlines that the entire permitted area is underlain by Glaciolacustrine Deposits (Devensian) composed of clay and silt (**Figure 3-1**) which in turn is underlain by Sherwood Sandstone (**Figure 3-2**).

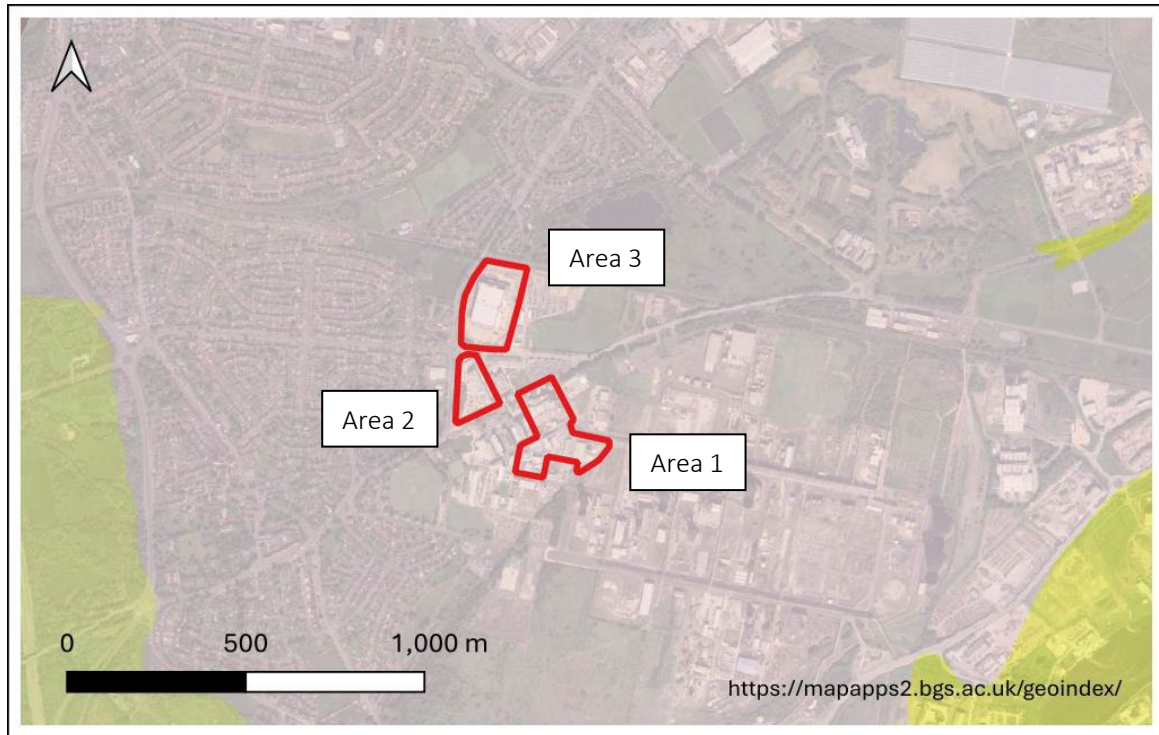


Figure 3-1 – Superficial Geology (1:50,000)

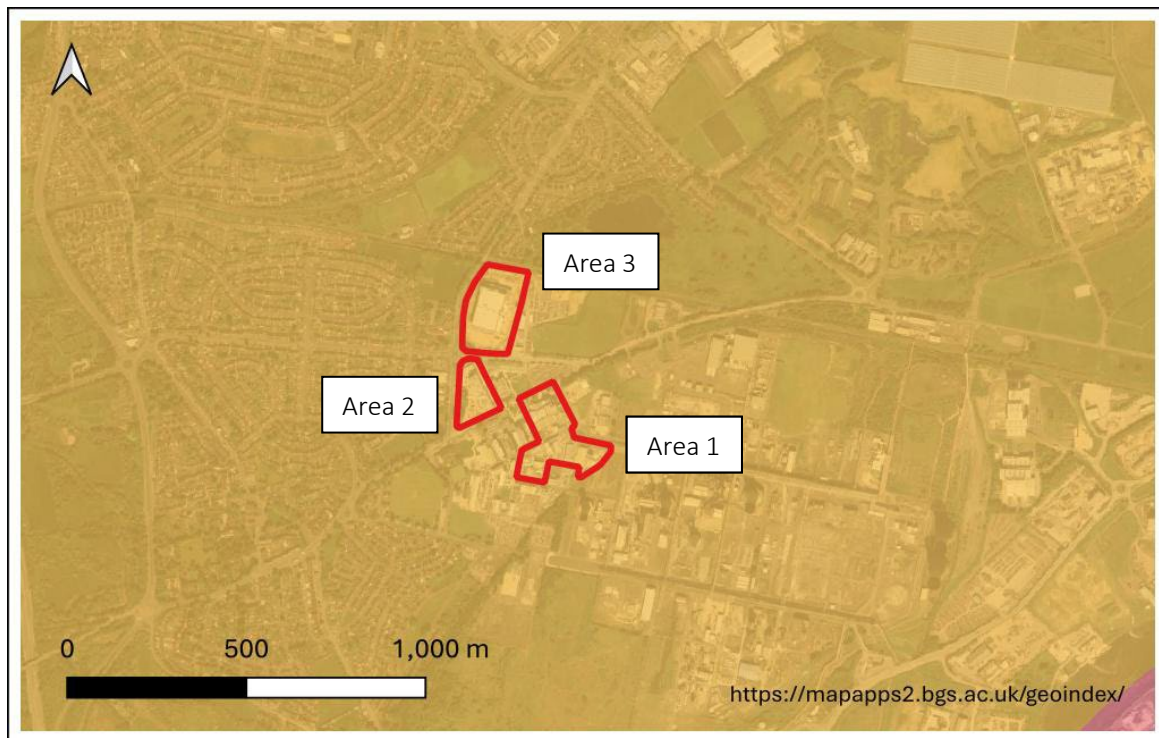


Figure 3-2 – Solid Geology (1:50,000)

The BGS reports no artificial ground, but investigations have identified a thin, discontinuous, layer of ash fill across the site. Sand has not been found in any of the boreholes drilled on the Chilton Site or in the car park but was intersected in boreholes drilled to the north of Belasis Avenue and close to the north gate. The sand contains limited amounts of water, which seeps into excavations and maintains the moisture content of the underlying clay. The sand changes into the underlying laminated clay by gradation over between 0.6 and 1.4 metres. This sandy clay is found all over the Chilton Site (including the permitted installation).

Below the sandy clay is a layer of laminated clay. The laminated clay is relatively stiff and dry except during exceptionally wet spells. Within the clay are abundant thin partings of pale grey very fine-grained sand and mica flakes. These partings ooze water for short periods when they are excavated through. The base of this formation is abrupt.

The laminated clay lies directly on top of a layer of stiff brown boulder clay. Most of the boreholes drilled terminate in this clay but the few, which pass through, have intersected a relatively thin, discontinuous, bed of sand and gravel. The sand overlies a second bed of boulder clay, which lies directly on top of the Sherwood sandstone.

The superficial deposits are directly underlain by soft red Sherwood Sandstone, which becomes thicker towards the south. The Sherwood Sandstone has only been intersected in a few of the boreholes drilled on the Billingham Main Site. Rockhead elevations are generally about twelve metres below the Ordnance Datum, but below Chilton Site there appears to be a buried valley, running from north northwest to south southeast, which depresses the rockhead to about sixteen metres below the Ordnance Datum.

The change in lithology to the underlying dry Roxby Formation (darker red mudstones and siltstones with subordinate sandstones) is gradational by alteration and is therefore difficult to locate.

The anhydrite forms an impermeable barrier between the base of the Roxby Formation and the top of the Magnesian Limestone. The Chilton Site is located over the southwest portion of the Billingham Anhydrite Mine. At Chilton, the base of the anhydrite is at an elevation of about two hundred metres below the Ordnance datum.

The Magnesian Limestone consists of beds of hard compact yellowish or grey limestone. Despite its massive compact nature, there are many cavities and fissures, which act as flow paths for groundwater.

A series of east-west trending faults cut the solid geology in the Billingham area. Because of the superficial cover, there is no surface indication of these faults, and they have only been located during mining or drilling brine wells. The nearest fault to the site is the Saltholme Fault, a series of parallel faults, which runs some two kilometres to the north of the site and has been proven to cause a fifty-metre downward displacement of the formations. This fault forms the northern boundary of the Billingham Anhydrite Mine. Other faults further to the north include the Hartlepool Fault, which forms the southern boundary of the Durham coalfield.

3.1.3 Hydrogeology

The hydrogeology of the Billingham region is complex and not fully understood despite considerable study. The complexity is compounded by the fact that there are no major aquifers, and a great depth of superficial deposits cover the rockhead. Groundwater flows are controlled by the topography, the dip of the more hydraulically conductive strata and the alignment of the faults. There are three water-bearing horizons of

interest in the region. These are the superficial deposits, the Sherwood Sandstone Group and the Magnesian Limestone:

- **Glacial Superficial Deposits (Unconsolidated Formations)** – The natural hydraulic gradient in the superficial deposits in the Tees Valley is very shallow and groundwater flows are almost static. The tidal range of up to 6.1 metres causes groundwater levels close to the river to rise and fall. However, compared with the tidal range, groundwater variation is small (e.g. at Seal Sands, 1 km from the river, a tidal variation of 4.7 metres generates a groundwater range of 38 mm). The superficial deposits are either unclassified or designated as Secondary A. Secondary A are permeable layers capable of supporting water supplies at a local rather than strategic scale, and in some cases forming an important source of base flow to rivers. These are generally aquifers formerly classified as minor aquifers.
- **Sherwood Sandstone** – The Sherwood Sandstone aquifer is of limited plan area and appears to have a complete covering of superficial deposits. Recharge locations are not obvious, and it is thought that most of the water enters the aquifer by percolating through the alluvium. However, due to the relatively impermeable nature of the superficial deposits, the rate of recharge will be low except where deposits of sand occur. Large quantities of water have, however, been abstracted from the Sherwood Sandstone aquifer in the past. The bedrock is classified as a Principal Aquifer. Principal Aquifers are layers of rock or drift deposits that have high intergranular and/or fracture permeability - meaning they usually provide a high level of water storage. They may support water supply and/or river base flow on a strategic scale. In most cases, principal aquifers are aquifers previously designated as major aquifer.
- **Magnesian Limestone** – The Magnesian Limestone is the only formation through which there is a major flow of groundwater across the region. Recharge occurs where the limestone outcrops in the Pennines. Water flows east and discharges into the River Skerne. High land to the east of the Skerne and groundwater abstraction around Darlington and Newton Aycliffe prevents any significant easterly flow beyond the Skerne. The bedrock is classified as a Principal Aquifer.

The BGS classifies the groundwater vulnerability as between Low and Medium. The permitted installation is not within a Source Protection Zone (SPZ). The edge of a Zone III (total catchment) SPZ is located 5.4 km north of the Site.

According to the EA River Basin Management Plan, the Tees Sherwood Sandstone has a “Good quantitative status” that is “Probably Not at Risk”.

3.1.4 Hydrology

The River Tees, at Bamlet’s Bight (adjacent to Bamett’s Wharf), lies one and a half kilometres to the southeast.

The River Tees rises in the Pennines and flows one hundred and sixty kilometres to Tees Bay where it enters the North Sea. Below Darlington, the Tees was tidal up to the weir at Low Worsall, due to the very low gradient, until the completion of the Tees Barrage.

The EA maintains a river gauging station on the Tees at Low Moor, some thirty kilometres above the barrage and four kilometres above Low Worsall. This is the lowest gauging station in the Tees network. The average

annual mean flow at that point based on 2007 -2021 data is 24.9 m³/sec. The only significant flow into the Tees, above the barrage, below that point is from the Leven, on which there is a gauging station Leven Bridge, which has an average annual mean flow of 2.1 m³/sec. The average annual mean flow to the barrage is therefore 27 m³/sec.

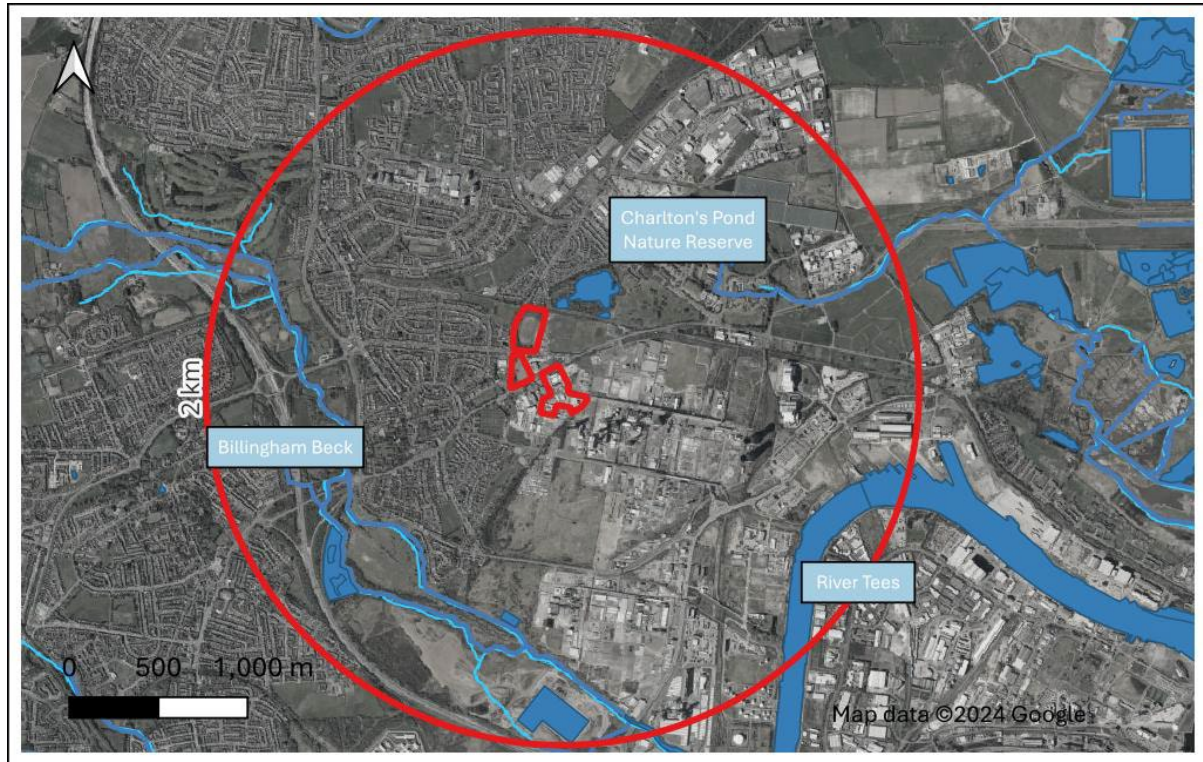


Figure 3-3 – Hydrology within 2km of the Permitted Installation

According to the EA Catchment Explorer, the Tees Waterbody (water body ID: GB510302509900) is heavily modified and in 2019 was classified as:

- Ecological quality – Moderate;
- Physico-chemical quality – Moderate;
- Hydromorphological Supporting Elements – Supports Good; and
- Chemical (Priority hazardous substances and priority substances) – Fail.

3.1.5 Flood Risk

The Risk of Flooding from Multiple Sources (RoFMS) is a EA produced map showing the risk of flooding from multiple sources produced using the EA’s national scale products i.e. Risk of Flooding from Surface Water (RoFSW) and Risk of Flooding from Rivers and the Sea (RoFRS), as inputs and created by adding together risk from individual sources (i.e. it attempts to present the combined flood risk). The flood risk bands relate to the overall chance of flooding from any of the potential sources of flooding included in RoFMS. The chance of flooding is:

- 1 - greater than 3.3% chance of flooding in any year;
- 2 - between 3.3% and 1% chance of flooding in any year;

- 3 - between 1% and 0.1% chance of flooding in any year; and
- 4 - below 0.1% chance of flooding in any year.

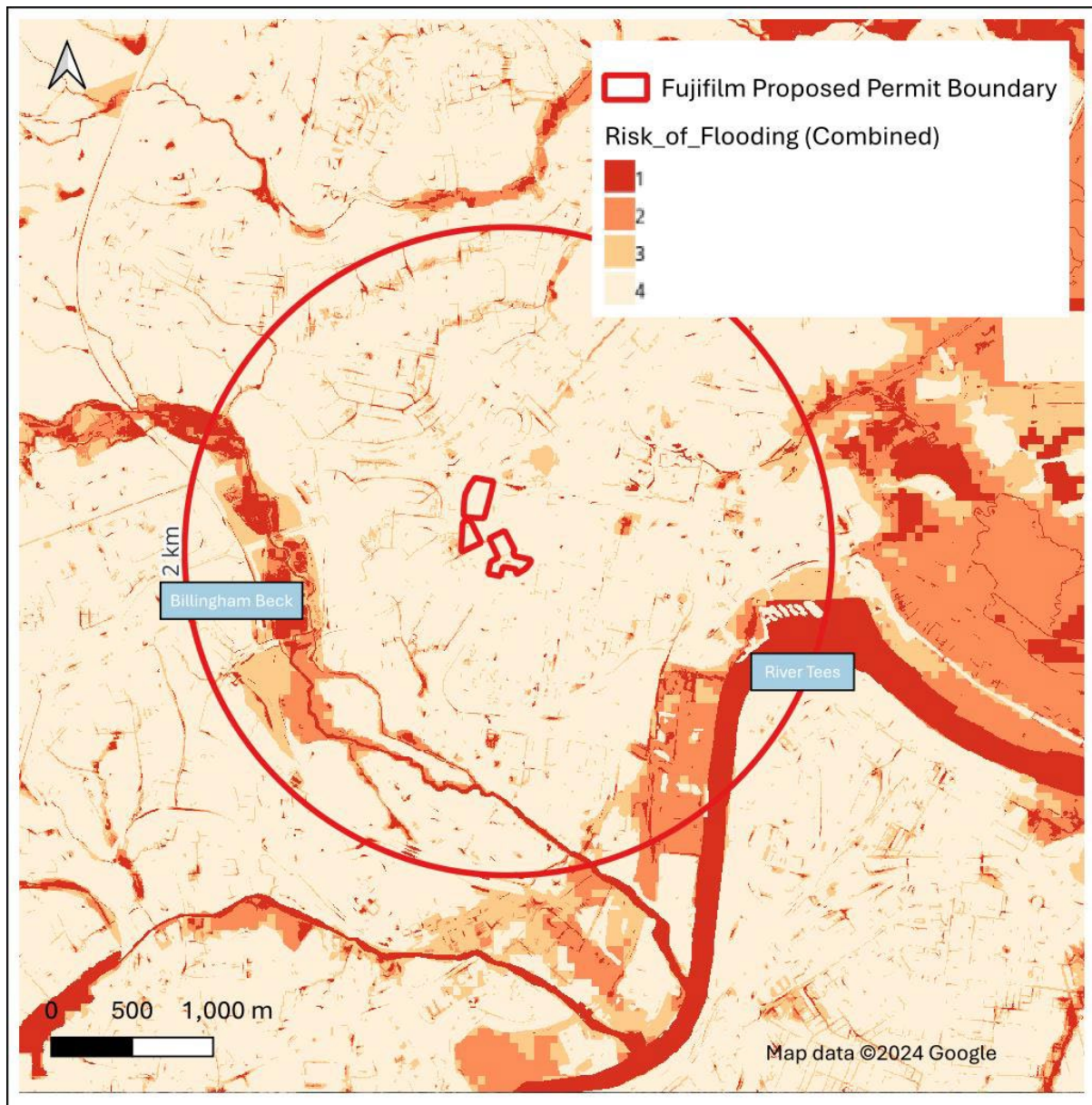


Figure 3-4 – Flood Risk (combined sources)

3.1.6 Ecology

The EA and Local Council websites were queried to locate Sites of Special Scientific Interest (SSSI), Special Protection Areas (SPAs), Special Areas of Conservation (SACs), Ramsar sites, National Nature Reserves (NNR), Ancient Woodland, Local Nature Reserves (LNR) and Local Wildlife Sites (LWS) also known as Sites of Interest for Nature Conservation (SINCs) within 1 km to 10 km (depending on the site designation) of the Site. The identified designated areas (within the screening distance) are outlined in **Table 3-2** and **Figure 3-5**.

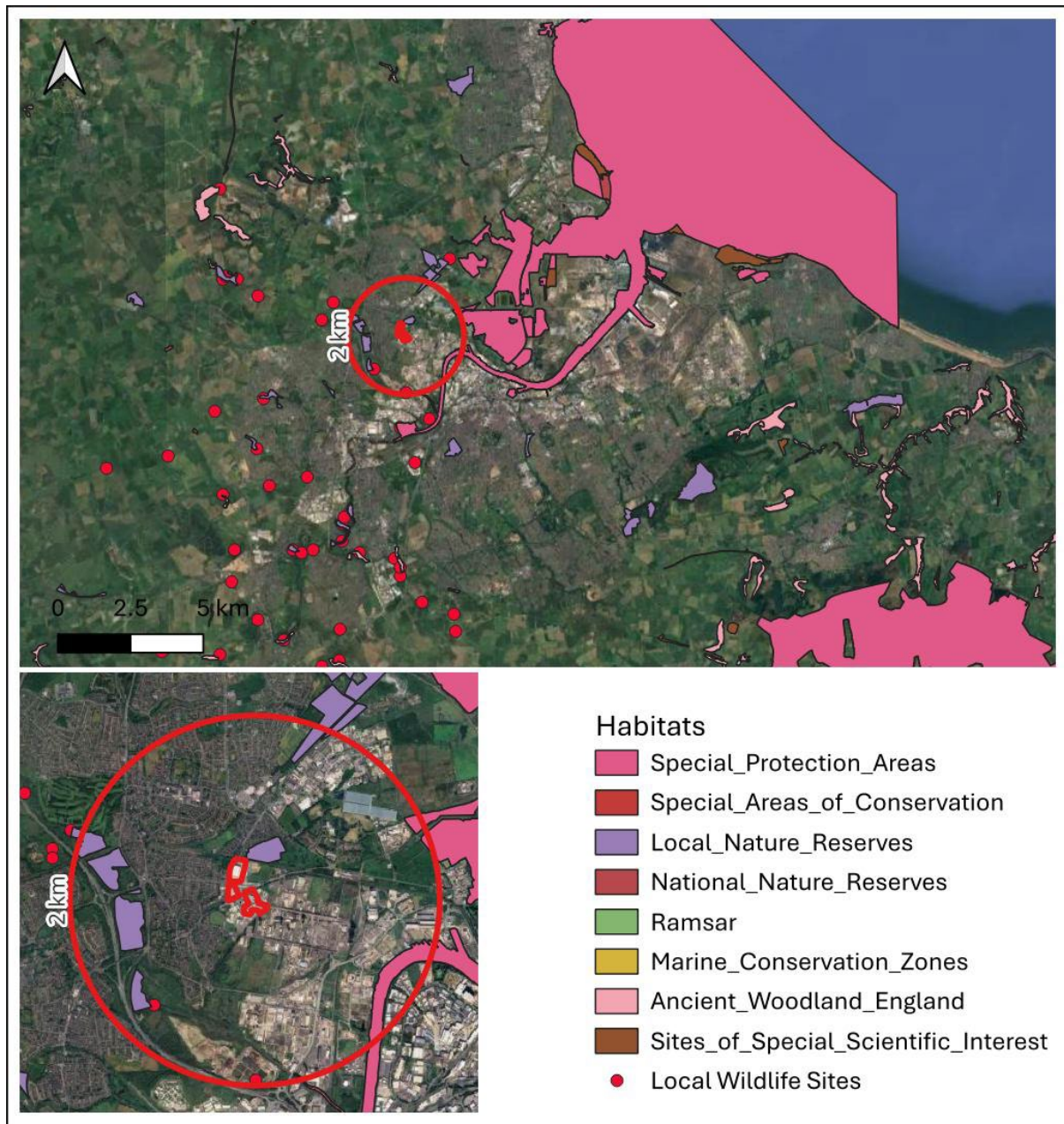


Figure 3-5 – Ecological and Statutory Designated Sites

Table 3-2 – Designated Areas

Designation	Screening Distance	Description and Status
Ramsar	10 km	Teemouth And Cleveland Coast (ID: UK11068)
SPA	10 km	Teemouth And Cleveland Coast (ID: UK9006061)
SAC	10 km	None
Marine Conservation Zone	10 km	None

Designation	Screening Distance	Description and Status
SSSI	2 km	Teesmouth And Cleveland Coast (ID:
NNR	2 km	None
LNR	2 km	<p>Charlton's Pond – Charlton's Pond is largely made up of two waterbodies as well as woodland and open-cut grassland. The lake at the site is the largest waterbody in the Borough and includes a restricted area that was designated as a conservation area for birds in 1968. The lake and the smaller pond were originally brick clay extraction pits from the late 1800s.</p> <p>Cowpen Bewley Woodland Country Park – Once a waste disposal site and before that, clay was quarried here and used locally for brick making. It was transformed into a woodland park in the 1990s with the planting of around a quarter of a million trees.</p> <p>Billingham Beck Valley – The low-lying land frequently floods which, in combination with traditional summer hay cutting or grazing, has resulted in a whole host of wildflowers such as meadowsweet, flag iris and valerian. These areas also attract butterflies in the summer, including the meadow brown, common blue and dingy skipper.</p>
Ancient Woodlands	2 km	None
LWS/SINCs	2 km	Air Products Reedbeds (E2 Reedbed) and Norton Bottoms (E2 Reedbed and U1 Urban Grassland).

3.1.7 Other Sensitive Receptors

There are five schools and multiple residential receptors located within 2 km of the installation. No nursing homes or hospitals are located within 2 km of the installation boundary.

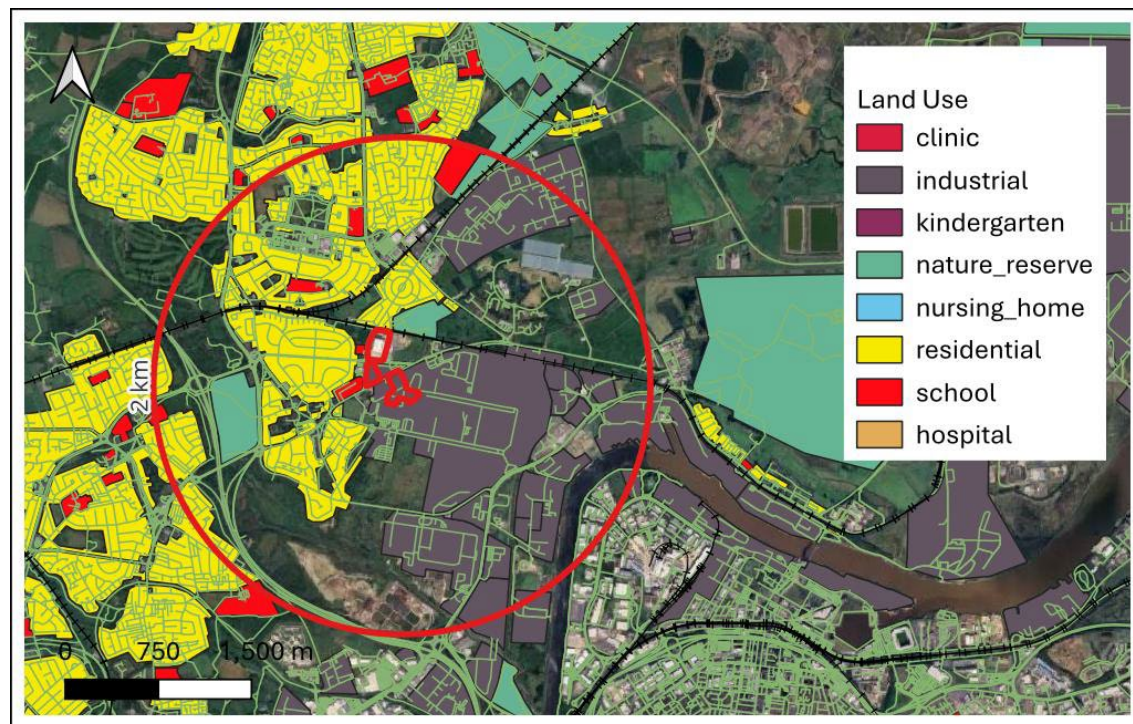


Figure 3-6 – Sensitive Receptors

3.1.8 Protected Buildings

The National Heritage List for England (NHLE) is the only official and up-to-date database of all nationally designated heritage assets, including listed buildings, scheduled monuments, protected wreck sites, registered parks and gardens, registered battlefields, World Heritage Sites, applications for Certificates of Immunity (COIs) and current Building Preservation Notices (BPNs) in England.

The NHLE is maintained by Historic England, the public body responsible for all heritage designations in England except World Heritage Sites, which are designated by UNESCO.

There are no on-site heritage assets and none are identified within 250 metres of the installation boundary.

3.2 Pollution History

3.2.1 Pollution Incidents That May Have Affected Land / Water

Records have been maintained since 1995 of all losses of containment, which have occurred on the Chilton Site. Incidents that have been reported to the Environment Agency are listed below. It should be noted that all these losses of containment were direct to drain and are therefore unlikely to have caused contamination of soil or groundwater.

- 15th September 1998. Part A notification was submitted following the inadvertent release of about four tonnes of glycerol to the Tees.
- 28th February 2000. Precautionary Part A notification was submitted following the dropping of a drum containing about 150 l of Sodium mono chloroacetate (SMCA), which ran off into the Roscoe Road drain system. Part A was subsequently withdrawn, as all material was contained in a sump on site.
- 5th September 2003. Precautionary Part A notification was submitted following the inadvertent release of about 200 kg of hydroxy sulphone to the Tees. Part A was subsequently withdrawn, as no harm was done to the receiving water.
- 19th May 2022. An incident occurred at Fujifilm involving the accidental deposit of 8 litres of phosphoric acid into the site drainage system which was able to leave the site at emission point W1. The Environment Agency were satisfied that sufficient improvement was made in order to prevent a repeat of the incident

3.2.2 Historical Land Uses and Associated Contaminants

The permitted installation is composed of four distinct parcels of land as outlined in **Table 3-3**.

Table 3-3 – Installation details – Historical Baseline

Required Information	Phase I Desk Study	Phase II Site Investigation
Area 1 – Existing permitted area (including the chemical storage area extension)	Not available – Historical summary provided below	Yes – Multiple investigations, refer to Table 3-5. (Annex B)
Area 2 – BIC-UK (Laboratory)	Yes – Solmek Ltd (2019), Full site history (Annex B)	Yes – Solmek Ltd (2019) (Annex B)
Area 3 –Borealis	Yes – Solmek Ltd (2022), Full site history (Annex B)	Yes – Solmek Ltd (2022) (Annex B)

3.2.2.1 Chilton (Formerly Research) Site to the 1970s

The ordnance survey plan of 1895 shows the village of Billingham with an inn and a smithy. Also marked are a water mill on the Billingham Beck (near modern Mill Lane), Tibbertley, Brook House and Grange farms and the NER Hartlepool and Port Clarence Branches.

The 1915 plan shows that remarkably little change had occurred over the intervening twenty years. Changes of note are the development of the Haverton Hill Road and the Billingham Beck Branch of the NER. The mill is marked as disused.

Operations commenced at Billingham in 1917 when the Ministry of Munitions selected the Billingham Site as a location to manufacture nitrogen, for explosives, in the face of increasing action by U Boats against Chilean nitrate supply ships.

Chilton Site (originally known as the Research Site) was commissioned in about 1925 to support the manufacture of ammonia and nitro chalk on the Main Site - which at that time was primarily a munitions factory. Aspects of research carried out included catalyst and fertiliser development and engineering research. In 1932, research commenced into the production of petrol from coal.

In 1937 work on the “Tube Alloys Project” commenced in “B” & “C” Buildings (not Avecia assets) on the Research Site. All work associated with this project, which subsequently became the “Manhattan Project”, was transferred to Los Alamos in New Mexico in 1941. All other aspects of research continued during the war years with continuing work on oil refining and steam reforming of petrochemicals.

Starting in 1946 considerable work was conducted on the production of downstream chemicals from hydrocarbons in preparation of the commissioning of the new Wilton Site. Research into a new process for the production of methanol commenced in the 1950s.

Hydrocarbon research continued until the early 1970s when it was transferred to the Wilton Centre. Engineering research work was also terminated at Billingham at that time, except for metallurgy and control electrical research, which continued on-site until the late 1980s. However, these areas were replaced by research into biotechnology.

3.2.2.2 Recent History (Post-1970s)

For this report, the recent history of the Chilton Site has been divided into five zones (Figure 3-7).



Figure 3-7 – Historical Site Zoning

North Zone

The North Zone was, until 1998, occupied by the engineering department huts and then the staff car park (closest to the road) and “S” and “T” Buildings.

“S” Building was a laboratory, built in the early 1950s. In the 1970s it contained small fermenters and downstream processing equipment used for technology trials. The building was demolished to slab level in the winter of 1998.

“T” Building, built in the 1930s, was originally a petroleum development facility for the Heavy Organics Division of ICI, which had contained several semi-tech distillation columns. More recently, it was used as the Biopol (BHP) biodegradable plastics applications laboratory. Between 1984 and 1987 a large quantity of, drummed chloroform, and methylene chloride, was used in this building. At that time, the drums were stored to the east of “O9” Building and on the site of the “T2” Boiler House. The process was changed in 1987, and the use of solvents was discontinued. The building was demolished to slab level in the winter of 1998.

ABC5000 (now referred to as MF1/2) construction commenced in 2002 with the commissioning of the plant for biological pharmaceutical production in 2003.

An S5 office building was also in this zone from 2018 to 2020, but this is excluded from the EPR permit as is not a permitted activity.

Central Zone (1)

The Central Zone (1) used to be the site of the Pruteen/Quorn Pilot Plant, the "S2" Spray Dryer, the "T2" Boiler House and "V" Building. Of these, only the "T2" Boiler house remains. S1 and S3 office buildings are also in this zone, but these are excluded from the EPR Permit.

The Pruteen Pilot Plant was constructed in 1972. It was converted, in 1986, to produce Quorn ("Q1") and was closed in 1994. Pruteen operated off methanol while Quorn used conventional fermentation media. The plant was demolished to slab level in the winter of 1998.

The "S2" spray dryer was originally the Pruteen harvesting and flash drying facility. The spray dryer was commissioned in 1987 and was used to dry PHB and LCPA. The spray dryer was gas-fired and no raw materials have been used on this site. The plant was demolished to slab level in the summer of 2009.

The "T2" Boiler House was commissioned in 1989. Steam is raised in two gas-fired boilers. The boiler house was built on the site of a facility, which incorporated two tanks used to store propylene or ethylene.

"V" Building, built partly on the site of a shed (V2) in which Pearl (composite insulation) Boarding manufacturing trials were carried out, was designed to produce Glucose Isomerase. Production commenced in 1976, stopped in 1980 and then restarted in 1984 for a year. Quorn was produced in "V" Building in 1985. Ecosyl and other inoculants have been produced in this building since 1986. Raw materials used in "V" Building comprise conventional fermentation media. Two Cycleclear production runs were carried out in this building in the late 1980's. For each run, a small quantity of cyanide was stored for two or three days in a bunded tank located to the south of the building. The bunded area was then the site of the caustic storage tank. Production in V building ceased at the end of March 2010. V Building was demolished to slab level in Q1 of 2011. When the demolition work started, there was a slight movement of the concrete and ground when heavy machinery drove over it and water was noted on the surface where V building had once stood. Similar issues had been observed during the construction of L6 Warehouse and the cause was attributed to a water leak in 2008 and the clay layer, under the course backfill material, acting as a sponge. The water was effectively being squeezed from the ground when the heavy demolition machinery was being used in the area. The level was monitored and the water reduced over a four-week period. Since the completion of the work, there has been no further occurrence of water pooling within the proximity of V building slab.

Site Water Supply – A new water main was installed to ABC5000 when the facility was built 2003 and is separate from the supply to the rest of the site. The main water supply was via an underground pipe which had been in place since the site was built. In May 2011, the water main feed to R building burst and the pipe trench filled with water. The repair was completed and a new overground pipeline was installed from ABC5000 and commissioned during Q1 of 2012.

Central Zone (2)

The Central Zone (2) contains "O7" (now known as "MF3 and MF4") and "O9" (now "MCC") and storage facilities for effluent, and oxygen.

"O7" Building, was originally used for the trial production of Pruteen, from natural gas, in a small (1 m³) fermenter. The facility was then used for trial conversion of Pruteen to nucleic acid and trial production of an agrichemical (Bt) using spore-forming organisms. It was subsequently used for harvesting and testing Biopol until 1990. The building was gutted and converted to a GMP manufacturing facility (ABC1000) in 1998.

This facility has been subsequently expanded to the east (beyond the pipe bridge) and to the south. The building is now known as MF3 and MF4 and has the capability of manufacturing two separate streams.

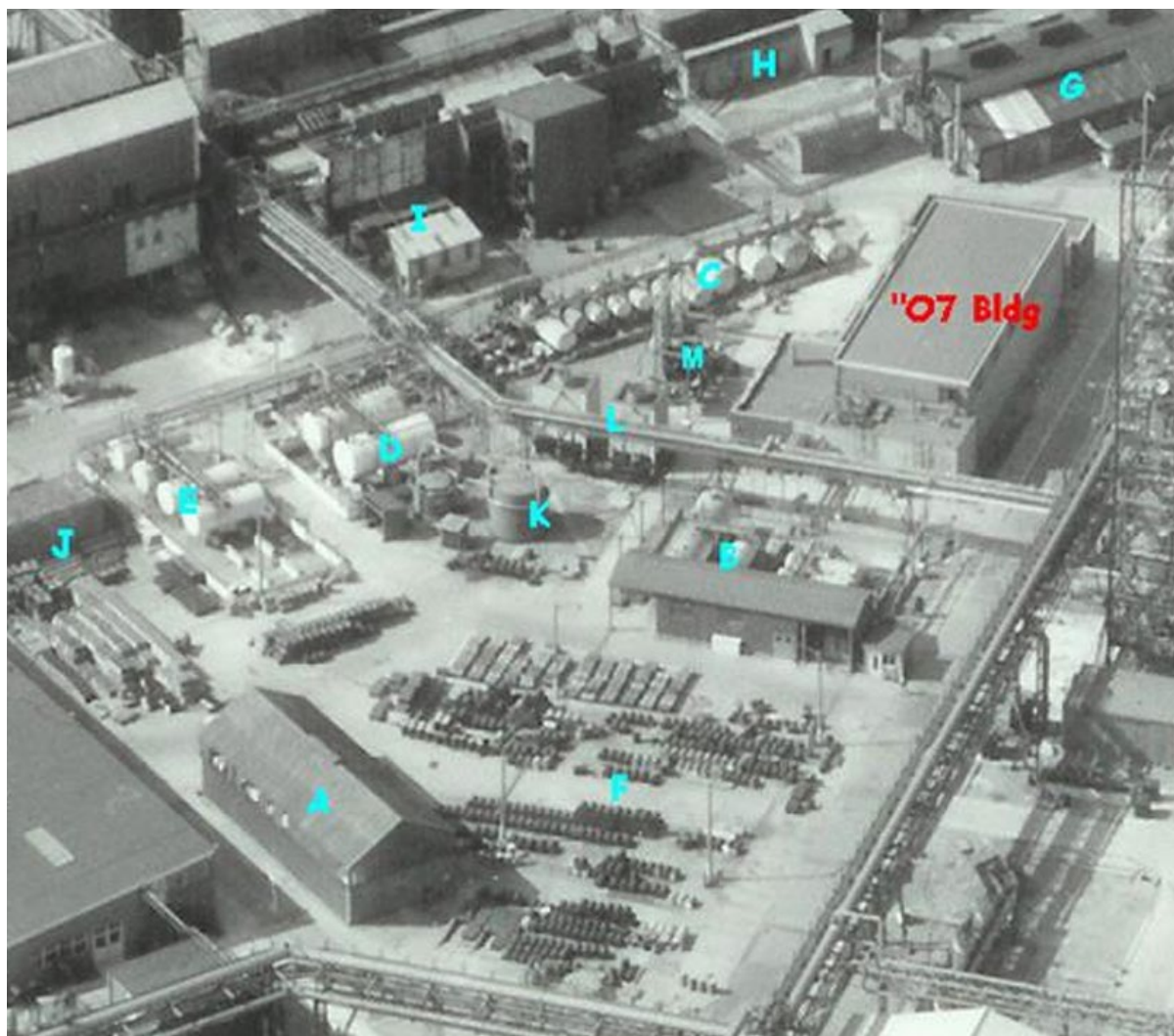


Figure 3-8 – Central Zone (2), circa 1972

The buildings and areas identified in **Figure 3-8** are summarised in **Table 3-4**.

Table 3-4 – Central Zone (2) Historical Uses

Area Ref	Description
A	“Blue” Store, which was used to store bagged “Pruteen”.
B	Tanks marked “B” were used to store methanol (up to 2,000 per annum), the feedstock for “Pruteen” production. These tanks were subsequently used to store caustic and glucose syrup. The tank compound was demolished to slab level during the winter of 1998.
C	Tanks marked “C” were used to store various substances including heptane (for use in the original “O4 N&S” sheds for catalyst manufacture), xylene, caustic, methanol, waste oil and waste solvents. These tanks were decontaminated and the whole compound demolished in 1997.
D	Tanks marked “D” was used to store methanol. Tanks marked “E” were for storage of naptha, vinyl acetate and ethylene oxide. These tanks were removed in the late 1970s. The methanol tanks were demolished

Area Ref	Description
	in around 1985. The concrete plinths to the north of the tanks marked "D" were bases for LPG tanks. These were decommissioned in the late 1960s.
F	Area "F" was a drum park for drums containing organic solvents, methanol and light distillates. "O9" Building was constructed on this area in 1973. This was originally a development facility, which contained a 250 l computer controlled fermenter and associated equipment. After this, the building was used as a store for dry materials and engineering spares and offices. O9 was converted into a Mammalian Cell Culture (MCC) manufacturing facility in 2013. The MCC facility is an additional GMP manufacturing facility. This building also houses the Cell Bank, and Stability facilities.
G	The shed marked "G" was the original "O1" Building. This building was constructed in the 1930s and was first used for analytical research. Later it was used for testing catalysts in small HP reactor vessels. Buildings "H" and "I" are referred to in the section on the South Zone.
J	The building marked as "J", known as the "bomb bays" was a brick built structure used for trial production of ethylene oxide from naphtha and oxygen. Later it was used to store drums of solvents, solvent wastes and soil samples taken after the accident at Chernobyl. This building was demolished in 1998.
K	Structure "K" was a gasholder. This structure was used to store coke oven gas and, later, Syngas, which had been generated elsewhere on the Billingham Site and was brought to Chilton Site in a pipe which ran along the adjacent bridge.
L	Wooden cooling towers, marked "L" on the photograph, were demolished in 1997. The structure marked "M" is believed to be a heavy oil distillate plant. It is understood that some of the tanks marked "C" were used to store product from this plant.

South Zone

The South Zone contains "O1", "O3", "O4", and "O6" Buildings.

The "O1" Building was originally the Quorn harvesting plant. This was shut down early in 1994. The filter belts were then used for the separation of FC4010 from cake.

FC4010 production stopped in 2007, the filter belts were removed. The building was used as a -70°C store for the final product as well as a holding area for MF3&4s consumables and downstream production equipment when not in use between 2007 and 2017. Since 2017 (after refurbishment) the facility has been used solely for -70°C storage of product stability samples in dedicated freezer units. The MF3/4 equipment store has been transferred to O3 building.

The "O3" Building was constructed in 1987 on the site of a shed which was originally used to evaluate catalysts and then for the development of biotechnology processes. Fermentation trials conducted in this shed included Pruteen, GI, griseofulvin and citric acid. The facility contained a 15m³ fermenter and associated plant. This facility has been used to produce Polyhydroxybutyrate (PHB), Fractionated (S)-2-chloropropionic acid (LCPA) and to carry out biotransformations of FC4010. FC4010 production stopped in 2007 and LCPA production stopped in 2008. O3 Fermenter Building and cooling tower were demolished to slab level in Q1-2011 and the main building was converted into a storage facility for MF1/2's downstream production equipment, which was commissioned in Q4-2011.

The "O6" Building was designed to be a multi-purpose facility for conducting the extraction of product from fermenter broth. The building was commissioned in 1985. It was originally used for about eighteen months as the development facility for Gibberilic Acid. This process entailed the use of small quantities of pentanone. More recently the building has been used over a brief period for the development of the polyunsaturated fatty acids (PUFA) extraction process using hexane. This facility was shut down in 1999 and was used as a

store for downstream equipment used in ABC5000 processes. The building was previously used as an offline qualification training room and part of the facility was used by R&D to carry out trials on CSA1 centrifuge on varying products from February 2009 to December 2010. In early 2011, the area was used to store downstream equipment and had a high-pressure refold unit installed for one of the processes manufactured on-site. Following a substantial internal refurbishment O6 building is currently used as an engineering workshop for equipment maintenance and repairs, but also for the validation of new equipment.

The “O4” compressor house is a modern facility built on the site of “O4 N&S” Building. This building manufactured catalysts for the ICI olefins plant at Corpus Christi, TX. The building was demolished before the O7 tank farm one tank of which was used to store heptane. The area used to house three air compressors. J401 water-cooled air compressor was taken out of service in 2009 when the O3-cooling tower was decommissioned. J402 and J403 air compressors (air-cooled) were decommissioned in 2015/6. The O4 building is now used as equipment storage for the MCC facility.

East Zone

The east zone contains the “L4” final product store, in which product is stored in freezers at temperatures down to –80° C., the “L5” R&D facility (which is not regulated by EPR), the “L6” warehouse, a drum park, L8 Raw materials lab, and L9 Effluent monitoring facility. “L4”, “L6” and the IBC/drum storage area are modern facilities built to serve MF3 & 4 and MF1/2.

The L8 Raw Materials Laboratory was transferred to R4 in 2018, and the old portacabin-type buildings were decommissioned and removed from the site.

This area had been the location of the Petrochemical research and development and semi-tech facility. This facility comprised the original “L4” Building and adjacent blast bays to the west of the site and the naphtha reforming plant to the southwest of the site. Construction of this facility commenced in 1958, with the blast bays built in 1962. The facility operated until 1970 when research and development work moved to Wilton. The site remained derelict until 1975 when it was demolished.

Work carried out in “L4” Building and the adjacent blast bays was on ethylene derivatives using naphtha and oxygen as feedstock chemicals and on Nylon and Purified Terephthalic Acid (PTA). There is, therefore, the potential to find a range of aromatics in the soil and groundwater as well as phenol and cumene, which were byproducts from this process, adipic acid, and a range of metallic catalysts (e.g. Cu, Zn, Cr, V and alumina). Chlorinated or nitrated hydrocarbons are not expected to be present. Work carried out to the south of the LDR was on the reforming of naphtha using steam and the synthesis of methanol.

3.2.2.3 Operations (Post-mid-1980s)

Since the 1980s operations on Chilton Site have been based on biotechnology. A summary of products made on the Chilton Site is outlined in **Table 3-5**.

Table 3-5 – Site Operations Since the 1980s

Date	Product	Fermentation and Processing
1981 - 2010	Ecosyl	Bacterial in “V” Frozen and sent off-site
1987 - 2008	L-CPA	Bacterial (two types) in “O3” Spray-dried in “S2”

Date	Product	Fermentation and Processing
1987 - 1998	Biopol	Carried out at Belasis Spray-dried in "S2"
1996 - 2007	FC4010	Fungal in "O3". Biotransformation using an acetone carrier Filtered in "O1" and then taken to Belasis for further processing
1997 - 1999	ARA	Carried out on Belasis Site "O6" (hexane)
1998 - 2002	Lactoferrin	Fungal in "O3" "V" and later ABC1000
2002 - 2004	FC1461	Bacterial in "V" Sent to Avecia Grangemouth for processing
1998 -	Various small batches of Active Pharmaceutical Ingredients/Proteins	Bacteria & Yeast in ABC1000 Centrifugation, Filtration and chromatography operations in ABC1000
2004 -	Various larger batches of Active Pharmaceutical Ingredients/Proteins	Bacteria & Yeast in ABC5000 Centrifugation, Filtration and chromatography operations in ABC5000
2013 -	Batches of Active Pharmaceutical Ingredients/Proteins	CHO – Mammalian Cell Culture Filtration, and Chromatography operations in MCC
2020 -	Vaccine production	Insect cell & Baculovirus culture Filtration, and Chromatography operations in MCC

3.2.3 Any Visual / Olfactory Evidence of Existing Contamination

The permitted installation has been subject to various phases of investigation (as outlined in **Table 3-5**) where historic contamination has been identified, assessed and recorded.

There is no visual or olfactory evidence of contamination associated with the current permitted activities.

3.2.4 Evidence of Damage to Pollution Prevention Measures

The pollution prevention measures operated within the installation comprise primary, secondary and tertiary containment systems. The systems are described within the main installation report and have been selected and maintained to comply with the prevailing BAT requirements.

No damage of current pollution prevention measures has been identified.

3.2.5 Evidence of Historic Contamination, for example, Historical Site Investigation, Assessment, Remediation and Verification Reports (where available)

The geoenvironmental site investigations that have been conducted on-site (within the permitted area) are outlined in **Table 3-6**.

Table 3-6 – Permitted Area Site Investigation History

Year	Report	Available
2001	Chilton Site – Multiplex Development J T Hymas Site Investigation, Report 15275, Avecia Ltd, August 2001.	Yes

2009	Site-wide (baseline assessment) URS (2009) Phase II Baseline Assessment of the Avecia Biologics Ltd Chilton Site. Project: 49309303, Report number-LERP003.	Not Available
-	V Building No further details are available.	Not Available
2018	L6 Extension Solmek Ltd (2018). Contamination Sampling and Testing, Proposed Cold Store Extension, 6 th April 2018, Ref. S180324, Project No. P510-039.	Yes
2019	BIC-UK Solmek Ltd (2019). Phase 2 Site Investigation, Project Meridian, Fujifilm, Billingham, Turner and Townsend, Report S190632, August 2019.	Yes
2021	Borealis ERM (2021). Phase II Environmental Site Assessment, Document subtitle Former Synthonia Football Club, Central Avenue, Billingham, TS23 1LF, Project No. 0578628, Date 11 February 2021	Yes
2022	Borealis Solmek Ltd (2022). Phase 2 Site Investigation, Fujifilm Synthonia Site, Billingham, Fujifilm, Report S220408, May 2022.	Yes

No remediation and associated verification reports have been produced.

3.2.6 Stage 1 to 3 Assessment

In line with the requirements of the European Commission Guidance concerning baseline reports under Article 22(2) of Directive 2010/75/EU on industrial emissions (2014/C 136/03), a three-stage assessment is required to determine whether there is a risk from hazardous substances to soil and/or groundwater.

3.2.6.1 Stage 1 - Identify hazardous substances

Hazardous substances for the purpose of a site condition report are defined in Article 3 of the Classification, Labelling and Packaging of Substances and Mixtures Regulations 2008 (CLPR). The CLPR define a 'hazardous substance or mixture' which meets the criteria given in Parts 2 to 4 of Annex I. They are:

- Part 2 – physical hazards (H2**)
- Part 3 – health hazards (H3**)
- Part 4 – environmental hazards (H4**)

All substances that are identified as hazardous (under the definition above) shall be subject to the Stage 2 assessment.

3.2.6.2 Stage 2 - Identify relevant hazardous substances

If the hazardous substances (identified in Stage 1) are capable of contaminating soil and/or groundwater, they are called relevant hazardous substances.

All substances that are identified as relevant hazardous substances (under the definition above) shall be subject to the Stage 3 assessment.

3.2.6.3 Stage 3 - Assess the potential pollution risk

An applicant must assess the potential pollution risk for each relevant hazardous substance. This includes the probability of releases and their consequences using the standard source-pathway-receptor approach.

The residual risk, including consideration of all control measures, is assessed using a standard contaminated land risk matrix ¹.

Table 3-7 – Risk Assessment (residual risk)

Consequence		Severe	Medium	Mild	Minor
Likelihood	High	Very High	High	Moderate	Moderate/Low
	Likely	High	Moderate	Moderate/Low	Low
	Low	Moderate	Moderate/Low	Low	Very Low
	Unlikely	Moderate/Low	Low	Very Low	Very Low

Where there is an identified risk from a relevant hazardous substance, an applicant must establish baseline reference data for each one.

The Stage 1 to Stage 3 assessment is outlined within **Annex C**.

¹ Rudland, D J, Lancefield, R M and Mayell, P N (2001). Construction Industry Research and Information Association (CIRIA), Contaminated land risk assessment. A guide to good practice (C552), ISBN: 978-0-86017-552-0

4. PERMITTED ACTIVITIES

4.1 Current and Proposed Activities

The permitted activities associated with the installation are outlined in **Table 4-1**.

Table 4-1 – Permitted and Directly Associated Activities

Sch 1 Ref	Description	Limits
Section 4.5 Part A(1)(a)	Producing pharmaceutical products using a chemical or biological process	From receipt of raw materials to despatch of finished products including the handling and storage of waste
DAA	Boiler Plant Combustion of gas to generate heat for processing via hot oil systems	Combustion of gas in a combustion plant with a total thermal input of 21.8 MW originating from 2 natural gas-fired boilers.

4.2 Non-permitted Activities Undertaken

The site has various ancillary operations that are not directly connected to the stationary technical units (STUs), they are located:

- Within the permitted boundary – Although these areas/activities are not considered part of the permitted installation (direct technical connection) the area within which they are located has been included within the permit boundary.
- Outside the permitted boundary – Other areas, outside the permitted boundary, but within the Fujifilm ownership, are located adjacent to the permitted installation. These activities (e.g. offices associated with BIC-UK) have no direct technical connection to the STUs and/or could not have an effect on emissions or pollution.

4.3 Other Requirements

Plans showing activity location and layout are provided in Annex A. The environmental risk assessment is outlined within the main technical document.

